# A STRATEGIC ANALYSIS OF DRUG LICENSING OPPORTUNITIES

by

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Bachelor of Business Administration, Simon Fraser University, 2004

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# ABSTRACT

This is an analysis of a biotech company's license partnering opportunities. The company (referred to as Company X) has a product candidate in Phase II clinical trials but does not have the resources or expertise needed to take this candidate through to commercial production and sales. As a result, Company X is seeking to enter into a license agreement with a large pharmaceutical company.

This analysis provides an overview of the biotech and target disease markets, as well as an overview of the typical components of biotech license deals. The analysis then considers the elements that are included in forecasts and valuation models when determining the value of a biotech product candidate, and specifically examines the assumptions in Company X's valuation model and its outputs. It also considers multiple criteria against which to evaluate potential license partners.

**Keywords**

Biotech; licence; product candidate; valuation

# DEDICATION

For my Husband, Ryan Wildman, and my Parents, John and Barbara Cowperthwaite;

Thank you for your support in everything I do.

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I would like to thank the management team at Company X, especially their CBO, for allowing me to be a part of this project, as well as for their assistance throughout it. I have learned an immeasurable amount from the experience.

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# GLOSSARY

| | |
|---|---|
| **Biogeneric** | Biogeneric drugs are copies of innovative biotech or drug products sold by multiple manufacturers once any limited market exclusivity period (i.e. patent protection) has expired. |
| **Blockbuster Drug** | A blockbuster drug is a drug generating more than $1 billion of revenue for its owner each year. |
| **DCF** | Discounted Cash Flow |
| **Efficacy** | Refers to the ability of a drug to induce a certain action at a certain concentration, or that the therapeutic effect of a given intervention is acceptable. |
| **Genotype** | The genetic constitution (the genome) of a cell, an individual or an organism. For the purpose of this analysis refers to different forms of the target disease. |
| **NPV** | Net Present Value |
| **ROW** | Rest of World |

# 1 PURPOSE OF THIS ANALYSIS

Company X is a public Canadian biotech company that currently has a product candidate in Phase II clinical trials. A pharmaceutical company is acting as a partner in the Phase II trials. In return for product contribution, testing and consulting services, Company X granted the partner a period of exclusive access to the trial data and an option to first negotiation in pursuing a licence for the product candidate.

Company X specializes in drug research and development, and does not have the resources or expertise required to commercialize a product candidate. Therefore, for their product candidate to reach the target drug market, Company X will have to form a strategic licensing partnership with a pharmaceutical company.

Company X must prepare for negotiations in the event that the Phase II trial partner elects to exercise their option to pursue a license for the product candidate. This will involve having an understanding of the value of the product candidate to the partner. Should the partner not choose to negotiate, or terms are not agreeable, Company X also needs to be prepared to negotiate with alternate potential strategic partners. A partner's current market reach, drug development pipeline, and drug portfolio in the target disease area will influence the value that Company X's product candidate provides to them. If a partner is able to bundle Company X's product candidate with existing drugs in their portfolio for sale, the drug will be of significantly more value to them.

The purpose of this report is to provide Company X with an evaluation of the value of their product candidate to three potential license partners, an analysis as to which potential license partner would be the best fit for Company X, and suggest negotiating terms.

The structure of this report begins with an introduction to Company X, followed by an overview of the biotech market, target disease market and the drug development process. After this, the report identifies three potential license partners, in conjunction with Company X's strategic negotiating alternatives. Company X is limited in its strategic alternatives due to existing agreements. The report examines how biotech license deals are traditionally constructed, then details how I worked with Company X to construct forecasts and a valuation model, and the results.

Based on the outputs of the model and additional evaluation of the potential partners, the report recommends that Company X pursue license negotiations with Company A for a total licensing deal valued at approximately $600 million.

# 2 INTRODUCTION TO COMPANY X

## 2.1 Purpose of this Section

The purpose of this section is to familiarize the reader with Company X and its current situation. In order to accomplish this, the section has three sub-sections. The first sub-section briefly covers the history of Company X and discusses its area of focus. The second sub-section includes a description of Company X's current products and development pipeline. The final sub-section comments on Company X's position within the biotech industry.

## 2.2 The Background of Company X

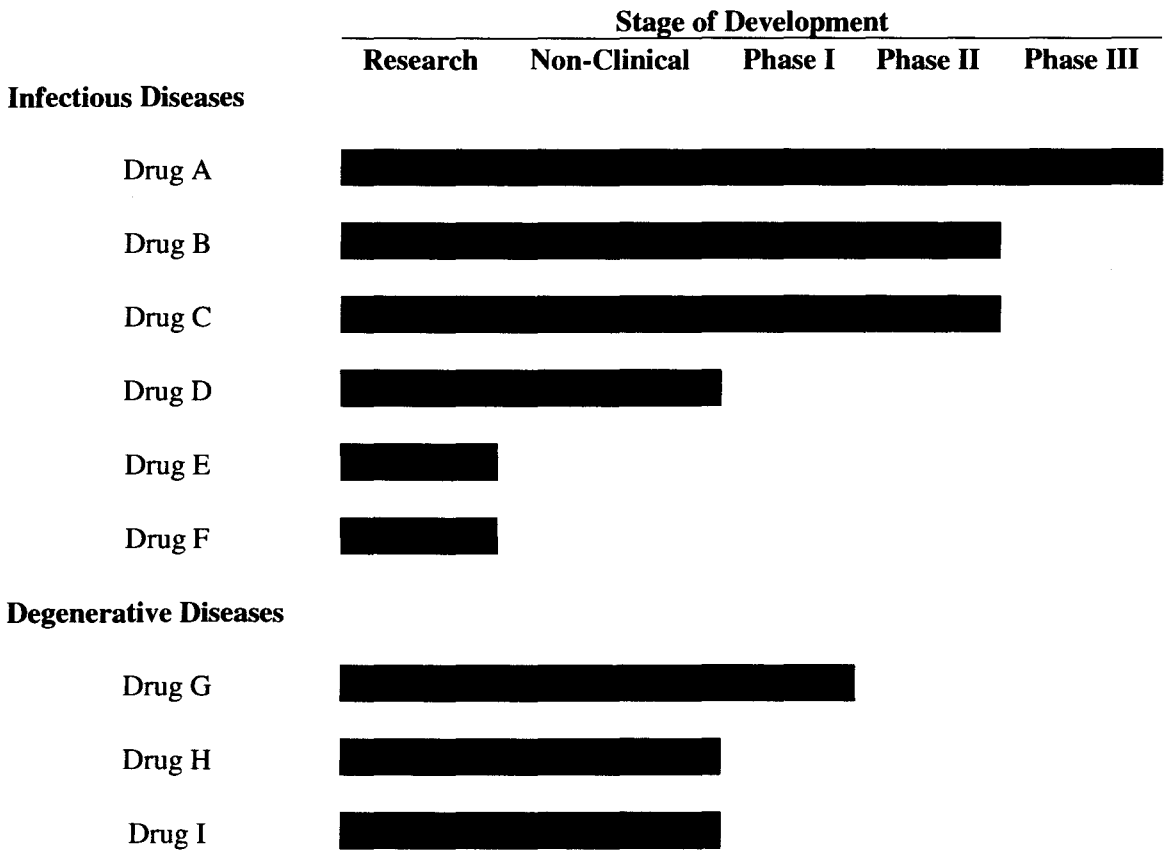
Founded in the early 1990's, Company X is a biotech company based on technology licensed from a Canadian University. In 1998, Company X entered a product candidate into a Phase I clinical trial for the first time. During 2001 and 2002, the company underwent a corporate restructuring, which resulted in the appointment of a new senior management team. This new team has significant experience and expertise in both the biotech and pharmaceutical industries.

The business model of Company X focuses on developing products from the post-discovery stage through to mid-stage clinical development. After obtaining preliminary efficacy, Company X intends to license product candidates. This is typically in late Phase II clinical trials. In addition, Company X is actively pursuing earlier stage corporate research collaborations with companies where the combination of technologies, resources, and expertise can advance product candidates more effectively. Company X, which has a market cap of approximately $60 million, focuses primarily on drug development in the areas of infectious and degenerative diseases.

## 2.3 Company X's Current Products and Pipeline

Company X has nine products, as shown in Figure 1. Two of these products are currently in a research phase and three are in the non-clinical phase of development. Of the remaining four products, one is in Phase I clinical trials, two are in Phase II clinical trials, and one is in Phase III clinical trials. Two of the products that are currently in clinical trials are licensed. The final product in clinical trials is the product candidate that is the focus of this analysis. This product is being testing in partnership with a pharmaceutical company.

**Figure 1: Company X's Product Pipeline**




*Source: Based on information from Company X's website (2007).*

## 2.4 Company X's Position in the Biotech Industry

There are more than 1,500 biotech companies in North America. The global biotech market is worth more than $114.1 billion (Datamonitor, 2006). Company X is part of the medical segment of the biotech industry. The majority of biotech companies, including Company X, are small and unprofitable. Company X is below industry average for revenues, gross profit, operating income, and net income.

## 2.5 Summary: Company X Needs to Find a Partner

This section presented the reader with an overview of Company X and their current situation. Company X's primary focus is on developing products from the post-discovery stage through to mid-stage clinical development. Company X then licenses these products to a partner with the resources and expertise to get the product to the commercial marketplace.

Company X is currently in a situation where it has a strong product candidate in Phase II clinical trails and needs to identify its best potential license partner, and then proceed with the negotiation process. This is a common situation faced by companies within the biotech industry. The following section includes an analysis and overview of the biotech industry.

# 3 THE BIOTECH INDUSTRY: A CHANGING MARKET

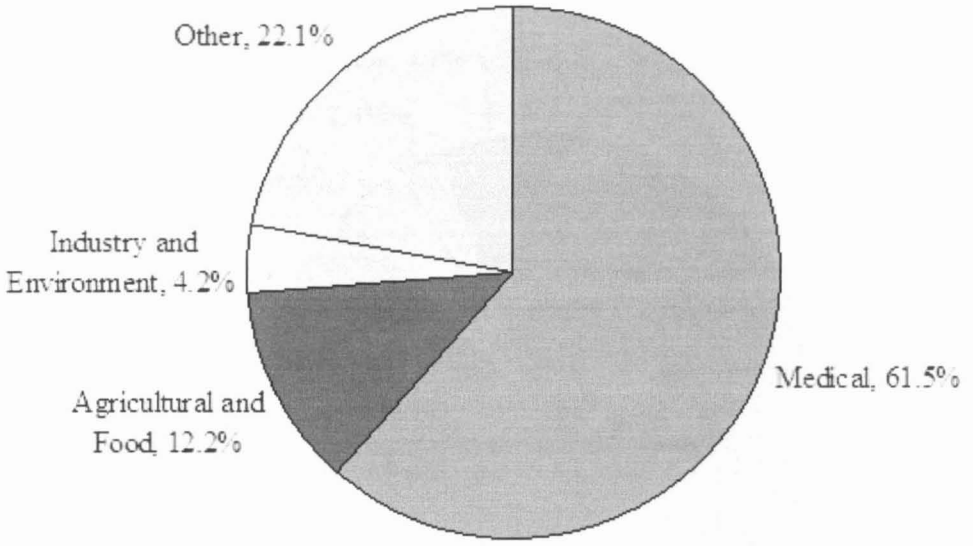
## 3.1 Purpose of this Section

The purpose of this section is to define the biotech market for the purpose of this report in order to provide the reader with a clear understanding of the industry. This section will also include an analysis of the biotech industry, an examination of the value chain present in the industry, and describe how this value chain drives the business models of the industry. Porter's Five Forces model, developed in 1980, is the basis for the industry analysis sub-section (Porter, 1980). Finally, this section will also provide an overview of the trend of biotech companies entering into license agreements with large pharmaceutical companies.

## 3.2 Industry Definition

At 30 years old, the biotech industry is still an immature industry and it continues to grow and change (*Biotechnology Statistics*, n.d.). The development of new products through the manipulation of living things characterizes the industry. The industry has three principle segments: industrial, agricultural, and medical. There is little to no overlap between the types of products produced within each segment (Figure 2). For the purpose of this paper, the "biotech industry" will be referring strictly to the biotech medical segment.

**Figure 2: Percentage Breakdown of Biotech Industry Segments**

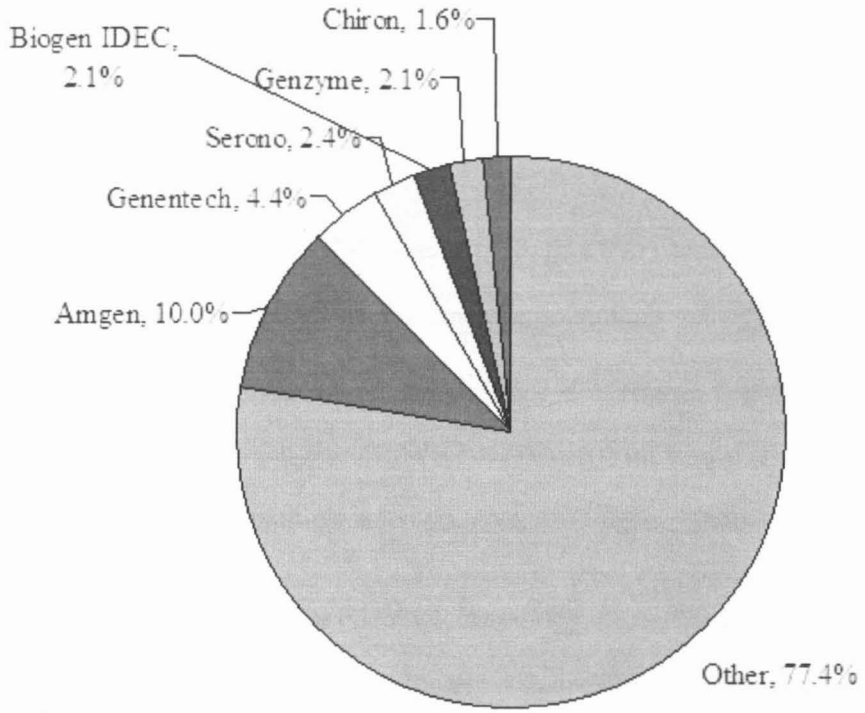



*Source: Based on information in Global Biotechnology Industry Profile (2006).*

## 3.3 The Current State of the Biotech Industry

In 2004, the global biotech industry generated revenues of $114.1 billion. US companies dominated the market, controlling a total market share of 56.8% (Datamonitor, 2006). In 2010, the US market will have a value of $131.8 billion, and the global market a value of $226.1 billion. This represents increases of 92% and 79% since 2004 respectively (Datamonitor, 2006). North America alone has 1,500 biotech companies (Datamonitor, 2005); however globally there are only six key competitors within in the industry that have a significant portion (>1%) of the market share, as shown in Figure 3:

**Figure 3: Key Competitors in the Biotech Industry**




*Source: Based on information in Global Biotechnology Industry Profile (2006).*

### 3.3.1 Amgen

Amgen was founded in 1980 to develop biotech products for human diseases using recombinant DNA. This technology made it possible for Amgen to create the biotech industry's first two blockbuster drugs, Epogen and Neupogen. These two drugs have made Amgen one of the few firms within the industry to generate continuous profits. Amgen's early success made them a first-mover within the emerging biotech industry, which is further evidenced by the number of firms that have since tried to imitate Amgen's success.

In the past 27 years, Amgen has grown rapidly to employ over 19,400 people in 43 facilities world-wide (Amgen, 2006). Today, Amgen is headquartered in Thousand Oaks, California, and is actively involved in developing, manufacturing, marketing and distributing

products in five primary areas of therapeutic treatment: hematology, oncology, inflammatory diseases, metabolic and neurodegenerative disorders. Amgen is the largest independent biotech company in the industry, with a market share of approximately 10.0% (Datamonitor, 2006).

### 3.3.2 Biogen

A group of biologists founded Biogen in 1978. Based in Cambridge, Massachusetts, Biogen focuses on developing treatments for cancer, autoimmune and inflammatory diseases. The company's portfolio of approved drugs includes Rituxan and Zevalin, both of which treat B-cell non-Hodgkin's lymphoma. Biogen also markets Amevive, a drug to treat psoriasis, and the best-selling treatment for relapsing multiple sclerosis, Avonex (Biogen, 2006).

Biogen develops products for oncology, neurology, dermatology and rheumatology (AIID). A major competitive advantage for Biogen is their full vertical integration. However, their over-reliance on two major products (Avonex and Ritxan) and a limited number of diseases currently addressed in their R&D pipeline are causing industry analysts to question the viability of Biogen's future. While Biogen has posted negative or very low net income, they represent approximately 2.1% of the biotech industry (Datamonitor, 2006).

### 3.3.3 Genentech

Robert Swanson, a venture capitalist, and biochemist Dr. Herbert Boyer founded Genentech in 1976: Genentech founded the biotechnology industry. As one of the world's most successful biotechs, Genentech has three billion dollar blockbuster drugs: Rituxan, which fights non-Hodgkin's lymphoma; Avastin, a treatment for colon and pancreatic cancers; and Herceptin, for breast cancer. Lung cancer drug Tarceva rounds out the company's oncology portfolio. Genentech's other marketed drugs include cardiovascular therapies Activase and TNKase, human

growth hormone Nutropin, cystic fibrosis drug Pulmozyme, and asthma drug Xolair, developed with Novartis and Tanox (Genentech, 2006).

In total, Genentech has 13 profitable drugs currently in the market (Genentech, 2006). The company's integration extends from R&D through manufacturing and marketing. They are currently attempting to imitate Amgen's market position. A competitive disadvantage currently facing Genentech is having a limited number of diseases in phase I of their R&D pipeline. Roche, a major pharmaceutical company, owns 56% of the company. Genentech accounts for approximately 4.4% of the biotech industry (Datamonitor, 2006).

### 3.3.4 Genzyme

Founded in 1981 and based in Cambridge, Massachusetts, Genzyme specializes in developing and commercializing orphan drugs. Many of its drugs are replacement enzymes, which treat lysosomal storage disorders. Genzyme is notorious for charging extraordinary prices in order to recoup expenses from small patient populations. However, the company is also renowned for its ethics and corporate responsibility. For example, they provide drugs free of charge to patients not covered by insurance or government health plans outside the US (Genzyme, 2006).

Genzyme is the world's third largest biotechnology company, employing over 8,000 people around the world. Its competitive advantages include its diversification beyond drug development into diagnostic product services, having a fully integrated operation, and focusing research in areas outside those focused on by their rivals. Genzyme has only become profitable since 2004, and may have limited their growth potential by focusing on less profitable research areas. Genzyme represents approximately 2.1% of the industry (Datamonitor, 2006).

### 3.3.5 Serono

Incorporated in 1987, and headquartered in Switzerland, Serono develops and markets drugs in the fields of reproductive health, multiple sclerosis and growth & metabolism. It is a world-leader in the infertility market. Serono operates in four core therapeutic areas: neurology for the treatment of relapsing forms of multiple sclerosis, reproductive health for treatments of infertility, dermatology, where Serono has launched biologics in Europe for moderate-to-severe psoriasis, and growth and metabolism for treatments for HIV-associated wasting and growth deficiencies. Serono also conducts research in oncology and autoimmune diseases (Serono, 2006).

Serono's competitive advantages include corporate presence in 44 countries with products sold in 94 countries (Serono, 2006). In addition, their strong R&D focus in central nervous system drugs is significantly different that most of their direct biotech competitors. Disadvantages include not having marketing, sales and service abilities. Serono also has few products in the second stage of clinical trials. Serono represents approximately 2.4% of the biotech industry (Datamonitor, 2006).

### 3.3.6 Chiron

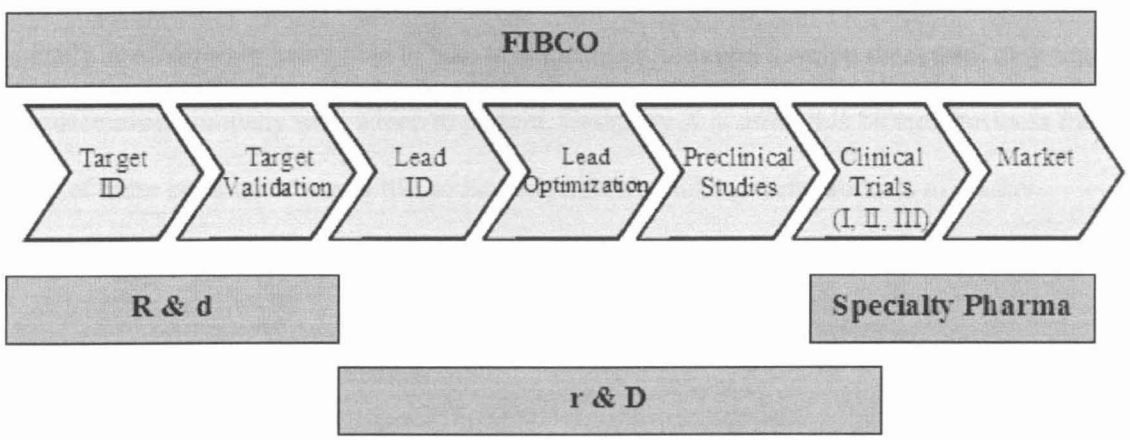
Dr. William Rutter, a biotechnology researcher at the University of California in San Francisco, founded Chiron in 1981. Chiron's therapeutic drugs include Proleukin, used to treat metastatic kidney cancer and metastatic melanoma, and Betaseron, a treatment for a specific form of multiple sclerosis. Chiron is a leading provider of blood testing products used by the blood banking industry to screen donated blood, including widely used tests for hepatitis and HIV. Chiron has a strong presence as well, particularly in Europe, in the vaccines market, making and marketing a wide range of paediatric and adult vaccines (Chiron, 2006).

Among Chiron's innovations in the pharmaceutical industry are the first genetically engineered vaccine, the first blood-screening test for hepatitis C, the first drugs to treat multiple sclerosis and metastatic kidney cancer, and the first cloning and sequencing of the HIV genome. Chiron was also one of the first biotechnology companies to post a profit, making $6.8 million in 1990 (Chiron, 2006). Novartis, a major pharmaceutical company, acquired Chiron in late 2006. While Novartis has decided to retain the Chiron brand, its operating results will now be part of the pharmaceutical industry on a prospective basis. Prior to the acquisition, Chiron represented 1.6% of the biotech industry (Datamonitor, 2006).

## 3.4 The Biotech Value Chain and Business Models

The business model that a biotech company uses is a function of its position on the industry's value chain. Companies will tend to start at one point on the chain then continue to expand into other areas, building their capabilities over time. It is more common to see a company move forwards on the chain than backwards (Grey, 2002). Figure 4 depicts both a typical biotech industry value chain and most common business models:

**Figure 4: Typical Biotech Industry Value Chain and Business Models**




*Source: Based on information in Value Chain of the Biotech Industry (2004), and the Pharmaceutical Industry (2006).*

### 3.4.1 FIBCO Model

Biotech companies that are fully integrated, and operate within all aspects of the industry's value chain are FIBCOs (Fully Integrated Biotech Company) (Grey, 2002). These FIBCOs operate much like a large pharmaceutical company, and it is becoming increasingly common to see FIBCOs enter into license agreements with smaller biotech companies to maintain a sufficient number of products in their development pipeline. There are few FIBCOs, and they are generally the largest in the industry. For example, market leader Amgen is a FIBCO.

### 3.4.2 R & d Model

Companies focusing on discovery research follow the "Big R, Little d" business model (Grey, 2002). These companies are typically involved at the start of the value chain, performing target identification and target validation. This is a very common model for new biotech start-ups to follow, and will tend to evolve into a "Little r, Big D" model over time.

### 3.4.3 r & D Model

Companies focusing on developing drugs and taking them into the initial phases of clinical trials follow the "Little r, Big D" business model (Grey, 2002). These companies are typically specialized in being able to take lead identifications and develop them until they find a pharmaceutical company with which to partner. Company X is using this biotech business model. Many of these companies would like to become FIBCOs, taking their products to market themselves, but lack the resources and expertise to do so.

### 3.4.4 Specialty Pharma Model

Specialty pharma companies license drug technology that is in mid- to late-stage clinical trials in order to finish the remaining trials and complete the drug approval process (Grey, 2002).

These companies will typically have significant experience in running clinical trials. There are very few specialty pharma companies. It is more common to see a late stage clinical drug licensed to a FIBCO or pharmaceutical company.

## 3.5 Industry Analysis

Within the biotech industry, the threat of new start-up companies and the threat of insurers negotiating power are the most significant forces. Threats of substitutes and supplier negotiating power are both low. Currently, competition is not intense; however, with the introduction of biogeneric drugs, competition will become intense.

### 3.5.1 Intensity of Competition Among Biotechs

Competition is a particularly interesting area of the biotech industry. Impressive profits exist for companies that are able to achieve success; however, few companies will ever achieve this success, and most are fortunate to recoup the funds they have sunk into extensive research and testing. Competition is not currently intense in the industry due to the high degree of differentiation between drug products, a high level of market share concentration between a few firms, and the overall lack of price competition within the industry.

This is set to change in the near future due to the increasing pressure to allow biogeneric drugs into the US market, coinciding with the expiry of several major drug patents. Biogenerics are copies of innovative biotech or drug products sold by multiple manufacturers once any limited market exclusivity period has expired (Peters, 2006). Biogenerics are set to affect the industry's profit margins negatively by increasing price competition between drug brands. Currently, very few biotech drugs have generic versions, but the pharmaceutical industry's history shows that the introduction of generics results in strong price competition. This shift in competition could ultimately change the face of the entire biotech industry. Consequently, all the major biotechs are

doing everything within their power, such as lobbying the government and increasing patent protection, to prevent biogenerics from entering the market.

Currently, within the target disease market for Company X's product candidate, there are several major pharmaceutical's drugs whose patent protection is set to expire. Profitability of these drugs will decrease as a result. Pharmaceutical companies are seeking new drugs that offer patent protection to replace the unprotected drugs in their portfolios and in their bundles for combination therapies. This presents an important opportunity for Company X and its product candidate to fill this need for a large pharmaceutical company.

Table 1 provides a summary of criteria evaluated to reach an assessment on the degree of competition in the biotech industry. Porter's methodology is the basis for the criteria (Porter, 1980):

**Table 1: Analysis of Competition Threat**

| Intensity of Competition (Low) | | |
|---|---|---|
| **Industry Characterization** | **Influence [Strong (+) or Weak (-)]** | **Rationale** |
| Degree of seller concentration | + | There is often only one company per drug; however, when patents expire the concentration will decrease as generics enter the market. |
| Extent of price competition | - | Currently there is almost no price competition. |
| Rate of industry growth | - | Grew by 12.2% in 2005 and is projected to increase by 79% by 2010. Demand for products is somewhat predicable based on demographics. |
| Significant cost of differences among firms | - | This industry currently has fully integrated firms and small R&D firms so costs vary depending on size and scope. |
| Excess capacity | - | Unlike a commodity or traditional manufacturing industry, capacity isn't a significant threat to profitability. If demand increases, capacity can be met by increasing production (it only takes a few days for cells to multiply exponentially). |
| Cost structure of firms | - | Disease has a constant and predictable demand. Therefore capacity can be predicted as well as production runs. |
| Ability to differentiate | - | There is always differentiation between biological drugs that target a common disease due to patents. The differentiation will diminish with generics. In the future there will be more generics but also second generation drugs that will be unique, along with new drugs. Brand loyalty depends on efficacy and marketing. Drug insurance companies will always choose generics if efficacy is not an issue. |
| Switching costs | - | There are low switching costs if a generic drug with similar efficacy exists. Efficacy determines the choice of drugs. |
| Strength of exit barriers? | -/+ | For small R&D companies, there is not much cost. For the large companies there are higher barriers due to manufacturing facilities, distribution channels, and sale teams. |

*Source: Based on information in Competitive strategy: techniques for analyzing industries and competitors (1980).*

### 3.5.2 Threat of New Start-Up Biotechs

The threat of new start-up companies is high in the biotech industry. The industry consists primarily of small to medium size enterprises, the majority of which are not profitable (Datamonitor, 2005). Most of these start-up companies entered the market to develop a single product. Their hope is to have their product licensed or acquired by a larger biotech or pharmaceutical company that is capable of developing, marketing, and distributing it. As a result, few start-ups show any net income as they primarily conduct R&D activities.

Adding to the threat of new start-ups are the low barriers to entry in the biotech industry. Although the probability of creating a drug that will gain final approval is highly unlikely for a new start-up biotech, all it takes is one successful new product to seize another company's market share (*The Drug Development Process*, n.d.). This can be disastrous for existing biotech firms who tend to rely on one or two products to generate more than 90% of their revenues.

While there may be hundreds of new entrants to the biotech industry on a yearly basis, the real threat for existing biotech are from the new start-ups that plan to concentrate their research in similar therapeutic areas. It is important to note, however, that drugs developed for one therapeutic area may prove to be more useful in a completely different area. Therefore, existing biotechs need to be somewhat wary of all new entrants to the market.

Table 2 provides a summary of criteria evaluated to reach an assessment of the threat of new start-ups in the biotech industry. Porter's methodology is the basis for the criteria (Porter, 1980):

**Table 2: Analysis of New Start-Ups Threat**

| Threat of New Start-Ups (Strong) | | |
|---|---|---|
| **Characterization of New Start-Ups** | **Influence [Strong (+) or Weak (-)]** | **Rationale** |
| Economies of scale | - | Small companies that simply license the results of their R&D will not need to invest in manufacturing. But if the firm wants to be vertically integrated they need significant investment in specialized manufacturing facilities |
| Importance of reputation | + | For small start-ups, emphasis is on ideas and innovative research rather than company reputation. |
| Entrant's access to technology | + | Knowledge is required for entry; however, there are many people who work at Universities or companies with this knowledge. |
| Government protection of incumbents | + | Governments encourage new entrants. This will continue to be the case for the foreseeable future. |
| Entrant's access to distribution channel | + | Through partnerships and licensing, companies can gain access to the distribution channel (as long as their product is safe and effective). |
| Perception of entrants about expected retaliation by incumbents | + | Small biotechs are considered to be the innovation engines of both the biotech and pharmaceutical industries. Incumbents encourage their entrance so that they may have opportunities to form alliances or partnerships with the successful ones. |
| Capital requirements | +/- | New companies need capital to start up; however, most governments offer significant grants in biotech to encourage entry into the industry. |

*Source: Based on information in Competitive strategy: techniques for analyzing industries and competitors (1980).*

### 3.5.3 Insurer Buyer Power

The biotech industry is heavily reliant on insurers, including insurance companies and government drug programs, to authorize their products for reimbursement. Doctors are unlikely to prescribe drugs that are not eligible for reimbursement. Pharmacies are also unlikely to stock them. It can be difficult for new drugs to gain reimbursement status, particularly if the new drug is only marginally more effective than a less expensive drug already available on the market.

Canada illustrates the strength of insurer power on the industry by negotiating significantly lower prices than those in the more fragmented US market for the same drug. Within the US, Medicare forces drug manufacturers to sell them their products at a lower price than that paid by independent insurance companies.

Table 3 provides a summary of criteria evaluated to reach an assessment of the threat of insurers in the biotech industry. Porter's methodology is the basis for the criteria (Porter, 1980):

**Table 3: Analysis of Insurers Threat**

| **Threat of Insurers (Strong)** | | |
|---|---|---|
| **Characterization of Insurers** | **Influence [Strong (+) or Weak (-)]** | **Rationale** |
| Is buyer's industry more concentrated than the industry it purchases from? | + | Yes (i.e. public healthcare programs). |
| Price Sensitivity | + | There is some negotiating between large purchasers (i.e. Canada has lower drug prices than the US) and the companies |
| Do buyers purchase in large volumes? | +/- | Depending on the biological drug product and its shelf-life. In general, drugs will be sold in large volume to wholesale distributors (i.e. hospitals and pharmacies). |
| Do buyers pose a credible threat of backwards integration? | - | No. Hospitals will not become or buy biotech firms. |
| Does product represent significant fraction of cost in buyer's business? | + | Yes. |
| Availability of information on price and quantity | +/- | Quality information is widely available through published research papers. Price information is typically not available. |

*Source: Based on information in Competitive strategy: techniques for analyzing industries and competitors (1980).*

### 3.5.4 Supplier Bargaining Power

Suppliers currently exert weak forces on the biotech industry as they generally provide commoditized materials, or service multiple industries. Supplies in the biotech industry include lab equipment, lab supplies, chemicals, and necessary testing services.

Table 4 provides a summary of criteria evaluated to reach an assessment of the threat of suppliers in the biotech industry. Porter's methodology is the basis for the criteria (Porter, 1980):

**Table 4: Analysis of Suppliers Threat**

| Threat of Suppliers (Weak) | | |
|---|---|---|
| **Characterization of Suppliers** | **Influence [Strong (+) or Weak (-)]** | **Rationale** |
| Is supplier industry more concentrated than the industry it sells to? | - | No. There are thousands of small biotech companies. Overall, they outnumber the suppliers. |
| Switching costs | - | Typically low. |
| Ability to forward integrate | - | No. Supply companies lack biotech knowledge and the risks are too high. Many suppliers provide products to several different industries. |
| Are suppliers able to price discriminate among prospective customers? | - | Due to the mix of specialized and non-specialized products needed in this industry, only specialized suppliers can price discriminate. |

*Source: Based on information in Competitive strategy: techniques for analyzing industries and competitors (1980).*

### 3.5.5 Threat of Substitute Treatments

Currently substitutes are weak because biotech drugs target specific disease areas and therefore rarely have an effective alternative. Substitute treatments may include holistic medicine, chemical-based compounds, surgical procedures, or natural disease progression.

Table 5 provides a summary of criteria evaluated to reach an assessment of the threat of substitution in the biotech industry. Porter's methodology is the basis for the criteria (Porter, 1980):

**Table 5: Analysis of Substitution Threat**

| Threat of Substitutions (Weak) | | |
|---|---|---|
| **Characterization of Substitutes** | **Influence [Strong (+) or Weak (-)]** | **Rationale** |
| Availability of close substitutes? | +/- | There is a large differentiation gap that exists between biological drugs and chemical based compounds. |
| Price-value characteristics of substitutes? | + | Chemical drugs are sometimes cheaper, but efficacy and toxicity are more important than price. |
| Availability of close compliments? | - | Chemical drug cocktails are available for some diseases. This will increase as more drugs are discovered and personalized medicine is realized. Other options such as "do nothing" are not reasonable options to consider for a person wanting to fight a disease. |
| Price-value characteristics of close compliments? | +/- | Depends on the disease and the needs of the patient. |

*Source: Based on information in Competitive strategy: techniques for analyzing industries and competitors (1980).*

## 3.6 Biotech Partnerships with Pharmaceutical Companies

Many biotech companies will form partnerships with large pharmaceutical companies when they have a product candidate that has reached Phase I or II clinical trials, as they do not have the resources or expertise required to complete the drug approval process and get their drug to the commercial marketplace. This may take the form of a license agreement, strategic alliance, or buy-out (*Royalty Essential Reports for Deal Making and Licensing*, 2006). Pharmaceutical companies have a significant amount of capital and expertise in manufacturing and marketing; however, many are struggling with depleted product pipelines. Biotech companies are highly innovative enterprises, and well placed to fill the R&D needs of the large pharmaceutical firms. For many biotechs, it would be impossible to have their drug candidates reach the commercial market without partnering with a pharmaceutical company. This report will further explore the various components of license agreements between biotech and pharmaceutical companies in Chapter 7.

## 3.7 Summary: the Biotech Industry is Changing

This section has reviewed the impact that different forces are currently having on the biotech industry. With the introduction of biogeneric drugs, the intensity of competition within the industry is likely to escalate significantly. The threat of biogenerics is also pushing large pharmaceutical companies to stock their product pipelines with new, innovative drugs. These are primarily sourced through entering into license agreements with biotech companies, most likely those following a "Little r, Big D" business model.

Company X is following a "Little r, Big D" business model and the target disease market for its current product candidate has several major drugs set to come off patent. Company X anticipates that this will make its product candidate more attractive to the pharmaceutical companies with products already in the target disease market. While it is important to have a

general understanding of the biotech industry, it is also crucial to understand the target disease market in which a company's product candidate will compete. The next section of this report will examine more details of the target disease marketplace for Company X's product candidate.

# 4 THE GROWING TARGET DISEASE MARKET

## 4.1 Purpose of this Section

The purpose of this section is to provide the reader with an understanding of the target disease market in which Company X's product candidate will compete. This section will include information on the current size of the target disease market, how the disease is currently treated, and unmet medial needs that arise from the current treatment strategy. This section will also identify anticipated future treatments of the target disease, and explain where Company X's product candidate will fit into this market.

## 4.2 Size of the Target Disease Market

The target disease affects approximately 10 million patients in seven major markets. These markets are the US, Japan, UK, Germany, France, Spain and Italy. Patients affected worldwide are estimated near 200 million. On average, only 2.15% of patients affected by the target disease are treated annually (Datamonitor, 2006). About 85% of individuals acutely infected with the target disease become chronically infected (Worman, 2005). An estimated 8,000 – 10,000 Americans die annually of complications related to the target disease, and this figure is expected to triple in the next 10 – 20 years (Franciscus, 2006).

Since the formal identification of this disease in the late 1980's, a number of treatments have become available. The current standard of care is a combination therapy (i.e. treatment involves the use of more than one drug). Because the target disease is treated using combination therapy, pharmaceutical companies will often create a bundle of their own drugs to act as a complete treatment alternative.

The target disease market will likely grow from $2.2 billion in 2005 to $4.4 billion in 2010 and $8.8 billion by 2015 (Datamonitor, 2006). The rapid adoption of more effective drugs released into the market will drive this substantial growth. As these drugs will be new to market, they will be protected by patents and able to command a premium price.

While patients are the ultimate end users of the drugs under development, Company X will be looking to partner with a large pharmaceutical company that has the manufacturing and marketing expertise to bring the product candidate into the end user marketplace. A pharmaceutical company would not market directly to patients either; rather they market to primary care physicians and target disease leading experts. Ideally, world-renowned physicians will endorse and recommend Company X's product candidate, resulting in it becoming part of the new standard of care treatment for the target disease.

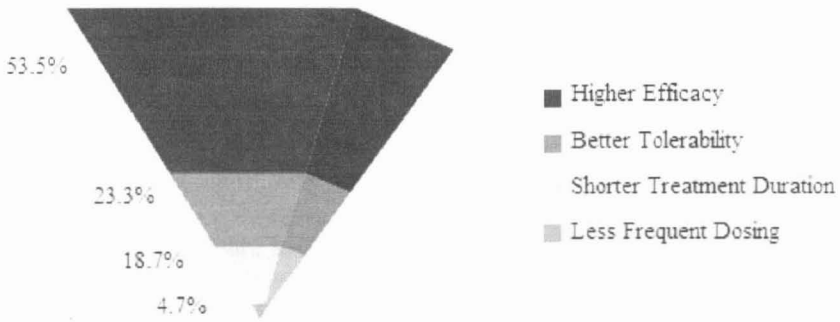
## 4.3 How the Disease is Treated Currently

A combination of two drugs is the current treatment for the target disease. This is the standard of care in 2007. Of the two drugs used in this combination (Drug A, and Drug B), there are two pharmaceutical companies with FDA approved versions of Drug A. Drug B is no longer patent protected, and is manufactured by numerous pharmaceutical companies. Patients typically take a combination of Drug A and Drug B for 48 weeks (Worman, 2005). Depending on the specific genotype of the disease that a patient has, treatment success rates (referred to as attaining a sustained response) can range from 30 to 89% (Worman, 2005). The decision to discontinue treatment occurs if after 12 weeks if a patient does not appear to be responding to the standard of care (Worman, 2005). Side effects from the standard of care treatment can range from moderate (nausea, chills, joint pain, anaemia) to severe (endocrine disorders, colitis, neuropsychiatry disorders) (Franciscus, 2006).

## 4.4 Needs Not Met with Current Treatments

For the target disease, the most important unmet medial need is efficacy: achieving a sustained response in the patient for a significant period from treatment. Second is tolerability: the ability of a patient to take the treatments without severe adverse side effects. Figure 5 shows the relative degree of these unmet needs in the opinion of leading target disease experts:

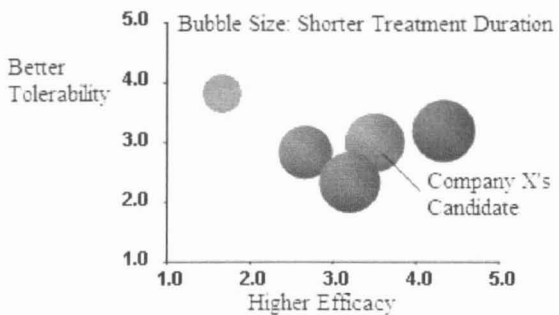
**Figure 5: Percentage Breakdown of Unmet Medical Needs**




*Source: Adapted from information in Target Disease: Industry Profile (2006).*

In clinical trials, Company X's product candidate appears to address both of these unmet medical needs when used in combination therapies, as shown in Figure 6:

**Figure 6: Strategic Positioning in Efficacy and Tolerability**




*Source: Adapted from information in Target Disease: Industry Profile (2006).*

## 4.5 How the Disease is Expected to be Treated in the Future

Many of the drugs in development that target this disease area have different approaches to treatment from the current standard of care. Expectations based on clinical trail data are that these new drugs, used in combination, will vastly improve the sustained response rates achieved through treatment. None of the drugs in development is a monotherapy treatment, meaning they are for use in combination with at least one other drug. It is anticipated that the new standard of care will consist of three drugs, and that patients with difficult to treat genotypes will benefit from four drug therapy (Franciscus, 2006).

There is also evidence that some of the new drugs in development, including Company X's product candidate, will have successful treatment results in patients who did not respond to the current standard of care and had their treatments discontinued after 12 weeks. Therefore, when these drugs initially enter the market, there will be an additional surge of patients seeking treatment.

## 4.6 Where Company X's Drug Fits

Company X's product candidate is an add-on drug. It does not show any efficacy when tested as a monotherapy; however, clinical trials have shown synergies with other drugs. Company X's product candidate has a novel approach to treatment of the target disease, and is the only drug of its kind in development. A key advantage that Company X's product candidate has is that due to its mechanism of treating the disease, the patient will not develop a resistance to the drug. Expectations are that Company X's product candidate will form part of both three and four drug combination therapies.

## 4.7 Summary: There is a Large Market with Unmet Medical Needs

This section has demonstrated that the disease target market is large, and continues to grow. Current treatment options lack in both efficacy and tolerability, resulting in a high degree of unmet medical needs in the market. Company X's product candidate, when used in combination with other drugs, appears to address both unmet needs. The product candidate also has an advantage in that its mechanism of disease treatment will be unique in the marketplace, and will prevent patients from becoming resistant to the drug. The next section will address the complications associated with taking the drugs that are currently under development, such as Company X's product candidate, through the clinical trial and approval process.

# 5 THE DRUG DEVELOPMENT PROCESS: GETTING A DRUG FROM THE LAB TO THE MARKETPLACE

## 5.1 Purpose of this Section

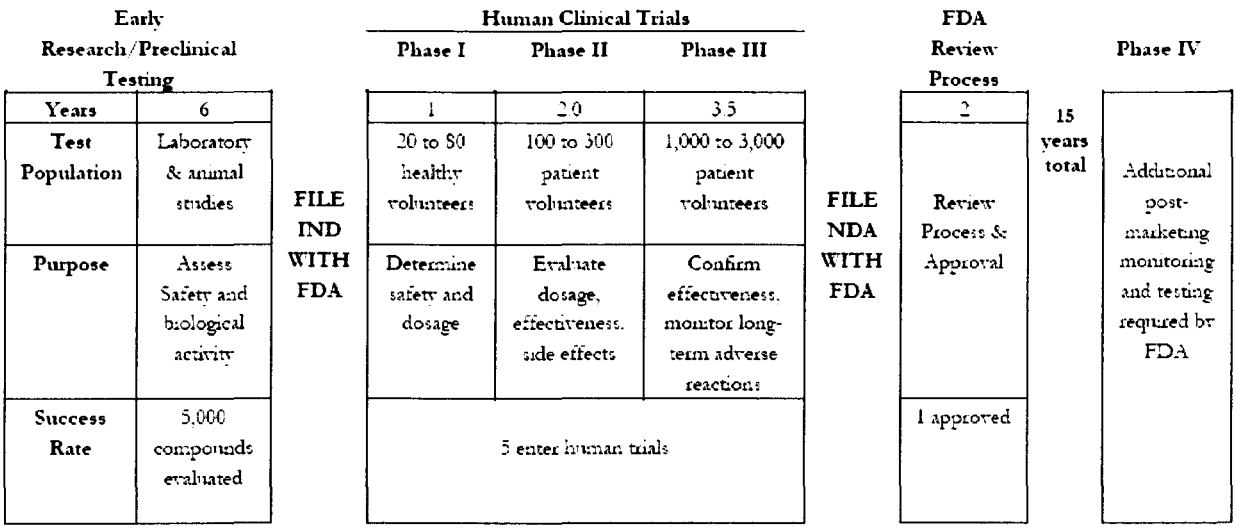
The purpose of this section is to provide the reader with an overview of the steps and risks involved in brining a new drug to the commercial marketplace. This will include describing the major regulatory authorities, and highlighting what happens at each step of the approval process.

## 5.2 The Food and Drug Administration

The major regulatory authorities are the Food and Drug Administration (FDA) in the US, the European Commission in Europe, and the Health and Food Protection Board in Canada. These agencies are responsible for assessing new drug products and for approving or rejecting them for marketing and use in humans. Because the US is the largest market for drugs, this report will focus on the development process in the US and the FDA requirements for approval.

The FDA regulates the development of novel drugs. The Centre for Drug Evaluation and Research (CDER) regulates both prescription and over-the-counter drugs. CDER ensures that drug products are safe and effective. All new drug products must undergo a rigorous process of pre-clinical and clinical evaluation. According to a report from the Pharmaceutical Research and Manufacturers of America, it takes 15 years and over $800 million for an experimental drug to travel from the lab bench to the patient (Kelly, 2006). For every 5,000 compounds that enter pre-clinical testing, only five will continue on to clinical trials in humans, and only one approved for marketing in the US (Kelly, 2006). Figure 7 shows a summary of the approval process:

**Figure 7: Summary of FDA New Drug Approval Process**




*Source: Based on information in the Drug Approval Application Process (2006), and An Introduction to Clinical Trails (2006).*

After each stage of development, the company that is testing the new product meets with the FDA to determine the appropriate next steps and establish end-points for future trials. Similar processes are required in other countries.

## 5.3 Preclinical Testing

In preclinical testing a biotech or pharmaceutical company conducts laboratory and animal studies to demonstrate biological activity of the compound against the targeted disease, and evaluate the compound for safety in animals. Not all drugs that a company investigates will reach even preclinical testing. For the 5,000 compounds that reach this phase, there may be as many as 5,000 to 25,000 which do not (*The Drug Development Process*, n.d.).

## 5.4 Investigational New Drug Application

After completing preclinical testing, the company files an Investigational New Drug application (IND) with the FDA to begin testing the drug in humans. The IND comes into effect if the FDA does not disapprove it within 30 days (Kelly, 2006). Included in the IND are results of

previous experiments and studies. The IND must also include how, where and whom will conduct the next studies, the chemical structure of the compound, how it is thought to work in the body, any toxic effects found in the animal studies, and how the compound is manufactured (Kelly, 2006). The Institutional Review Board where the studies are being conducted must review and approve the IND. Progress reports on clinical trials must be submitted to the FDA at least once annually (Kelly, 2006).

## 5.5 Phase I: Human Clinical Trials

Phase I clinical trials involve approximately 20 to 80 healthy volunteers (*The Drug Development Process*, n.d.). These tests study a drug's safety profile, including the safe dosage range. The studies also analyze how a drug is absorbed, distributed, metabolized and excreted from the body, and the duration of its action (Kelly, 2006).

## 5.6 Phase II: Human Clinical Trials

Phase II clinical trials are controlled studies of approximately 100 to 300 volunteer patients with disease being targeted (*The Drug Development Process*, n.d.). The aim of these studies is to assess the drug's effectiveness against the disease and further analyze its safety. Phase II studies may also include analyzing dose ranges. It may be required to conduct more than one Phase II study (Kelly, 2006).

## 5.7 Phase III: Human Clinical Trials

Phase III clinical trials are much larger than Phases I and II and will include approximately 1,000 to 3,000 patients in clinics and hospitals (*The Drug Development Process*, n.d.). This phase determines whether the drug's effectiveness is statistically significant. Continuously monitoring patients for safety or adverse reactions to the drug is crucial in this phase. It is typical to conduct more than one Phase III study (Kelly, 2006).

## 5.8 New Drug Application

Following successful completion of all three phases of human clinical trials, the company analyzes all of the data. If the data demonstrates that the drug is both safe and effective, the company then files a New Drug Application (NDA) with the FDA. The NDA must contain all of the scientific information that the company has gathered relating to the compound. NDAs can exceed 100,000 pages (Kelly, 2006). In 2006, the average review time for approved products was 16 months (*The Drug Development Process*, n.d.).

## 5.9 FDA Panel Review

Once CDER has reviewed the NDA, the company testing the drug presents the data to a panel of experts. The members of the panel may ask for clarification of specific data points, request explanations for certain outcomes or events observed in the trial, or pose questions on potential issues that may occur if the product is approved for marketing (Kelly, 2006). The members of the panel then vote in favour of or against recommending marketing approval. While the FDA does not have to take the recommendation of the panel, it usually does (Kelly, 2006).

## 5.10 FDA Approval

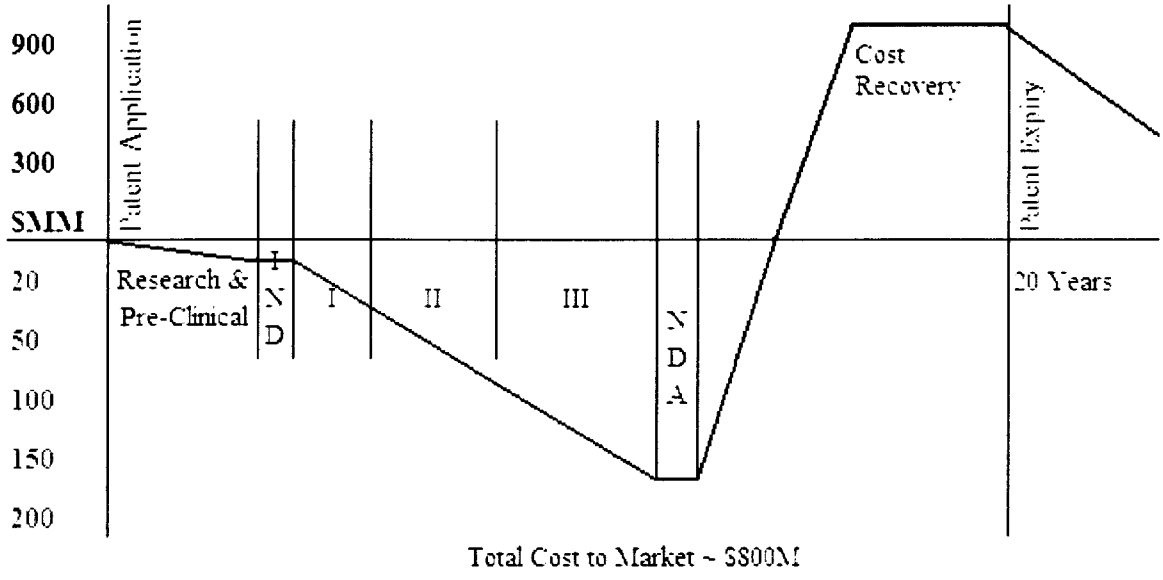
Once the Review Panel has issued its recommendation, the FDA makes the final decision on product approval. If FDA grants final approval, the company may commence marketing the new drug.

## 5.11 Commercialization

Commercial launch of a product is possible once a product receives final FDA approval. Because of the segmentation of the health care market into different therapeutic areas, specialized sales forces are necessary to market a new product successfully. Hiring, training, and maintaining

these sales forces across large geographical areas can be very costly. As Figure 8 shows, the company must focus on recovering the capital that is has invested in reaching this point.

**Figure 8: Summary of Capital Expenditure and Recovery in Drug Approval Process**




*Source: Based on information in The Drug Development Process (n.d.).*

The length of time from approval to patent expiry will have an impact on the price that the company will try to set for the new drug in order to ensure that it not only recovers its investment but will also generate additional income from the drug prior to patent expiry.

## 5.12 Summary: Drug Development is a Time and Capital-Intensive Process

This section has introduced the reader to the rigorous process through which the FDA approves new drugs. The odds against a new drug achieving final FDA approval are substantial, and the costs undertaken in the process immense. By the time that a drug has reached Phase II clinical trials, the risk of the drug not making it to commercialization is lower, but still present. Most licensing deals occur after Phase II trials, as the costs associated with the much larger Phase

III clinical trials are often prohibitive to smaller biotech companies. This is the case for Company X. The next section will discuss the strategic licensing alternatives that Company X must consider.

# 6 LICENSING PARTNER AND STRATEGIC ALTERNATIVES FOR COMPANY X

## 6.1 Purpose of this Section

The purpose of this section is to identify strategic licensing partner alternatives for Company X to consider, enabling their product candidate to complete the drug approval process as outlined in Chapter 5. This section will take into account limitations on Company X due to an existing partnership agreement, and negotiating strategies. Then, the section introduces three potential license partners. Finally, there is an outline of the potential strategies for Company X to employ while performing the license agreement negotiations.

## 6.2 Limitations on Company X Due to Existing Agreements

As previously described, Company X's product candidate is currently in Phase II clinical trials. Company X needed to have access to existing drugs for the target disease with which it could test its product candidate as a combination therapy since it is not a monotherapy drug. In order to save the costs of having to purchase these drugs, and to alleviate some of the costs associated with running a Phase II clinical trial, Company X entered into a partnership agreement with Company A. In return for product contribution, testing and consulting services for the Phase II clinical trials, Company X granted Company A a period of exclusive access to the trial data with an option to first negotiation in pursuing a licence to the product candidate.

Strategically for Company X, this means that they are obligated to negotiate with only Company A after the Phase II clinical trial is initially complete. Once the period of exclusive access has expired, or should Company X and Company A not reach agreeable terms for a license, Company X will be free to negotiate with other potential license partners.

## 6.3 Why Pharmaceutical Companies Need Deals Too

While biotech companies like Company X need to enter into licensing deals with large pharmaceutical companies to ensure that their drugs will have an opportunity to reach the commercial marketplace, pharmaceutical companies also have incentives for creating these deals. Pharmaceutical companies expend vast quantities of capital and labour to commercialize their current drug portfolios. In many cases, this has resulted in a less significant focus on R&D within these companies. Therefore, to ensure their continued success, these pharmaceutical companies need to stock their depleted pipelines with new and innovative products (Besley, 2004).

Licensing new drug candidates from biotech companies, such as Company X, are very important strategic moves for large pharmaceutical companies. Some of the key elements that a pharmaceutical company will consider before entering into an agreement with a biotech include whether there is a strategic fit of the opportunity within their current pipeline or drug portfolio, whether the opportunity will be competitive, and if it appears to be a feasible product to bring to commercial markets (Fischette, 2004).

## 6.4 Strategic Negotiations: Competition is a Useful Tool

When a biotech company is considering a negotiating strategy for dealing with pharmaceutical companies, it is important to remember that there are some key differences in these businesses. Biotechs are smaller and more flexible than pharmaceutical companies are. To achieve a successful agreement, each party must understand the other's business, the value proposition each brings to the table, and, importantly, the subtle nuances that can ultimately make or break a deal (Deepak, 2007). The components of a licensing deal, described in Chapter 7, can be complex. For pharmaceutical companies, choosing the wrong license partner could lead to a drop in stock price. For biotechs, the consequences may be much graver. Therefore, negotiating biotech-pharmaceutical license deals can be a very high-stress process for a biotech company.

Often times, the biotech company entering into negotiations with a large pharmaceutical company will have little, if any, experience in such a situation. This is in stark contrast to the pharmaceutical companies, which have significant experience in these types of negotiations. This may put the biotech at a disadvantage. To address this, many biotech firms will initiate negotiations with more than one pharmaceutical company. The resulting effect of having multiple pharmaceutical companies in negotiations is that they will be less likely to under-bid the value of the license agreement. Because these pharmaceutical companies are in such need to replenish their pipelines with products that are likely to be successful, they are more apt to act in a competitive manner with other pharmaceutical companies negotiating for the same license (Lawrence, 2005).

Due to the highly confidential nature of these agreements and the process surrounding them, the biotech company will not explicitly inform the pharmaceutical companies as to whom they are competing against (Fischette, 2004). For the pharmaceutical companies, having to negotiate in such a scenario is a disadvantage, as they may become preoccupied with which of their competitors is also interested in the license and their reasons behind it. In the past, pharmaceutical companies have paid large sums to license a drug from a biotech company simply to prevent a competing pharmaceutical company from gaining access to it (Fischette, 2004). Competitive negotiation situations help to ensure that the biotech will receive the highest possible price for their license agreement, as each potential license partner will tend to make their best offer to guarantee their ownership of the drug rather than risk coming in with a low price and losing out to a competitor (Hal, 2007). Therefore, if possible, it is to a biotech's advantage to negotiate with multiple pharmaceutical companies when constructing a license deal.

## 6.5 Overview of Potential Strategic Partners for Company X

There are three potential strategic partners identified for Company X to consider. These companies all have existing drugs in the target disease market, or have drugs in late-stage clinical trials for the target disease market. Any of these companies could license Product X's candidate to sell as part of a product bundle. Selling a bundle that would act as a complete combination therapy for the target disease may be a lucrative competitive advantage for the license partner.

### 6.5.1 Company A

Company A is Company X's partner in completing Phase II clinical trials, and has a period of exclusive access to the trial data with an option to first negotiation in pursuing a licence to the product candidate. Company A is a US-based pharmaceutical company that has a market cap of $37 billion (Company A, 2006). It currently has one drug in the target disease market, representing a forecasted 28% of the market's US sales in 2007 (Datamonitor, 2006). This disease area currently represents as estimated 11% of Company A's total sales (Company A, 2006).

### 6.5.2 Company B

Company B is a European-based pharmaceutical company that has a market cap of $153 billion (Company B, 2006). It currently has two drugs in target disease market, representing a forecasted 52% of the market's US sales in 2007 (Datamonitor, 2006). This disease area currently represents as estimated 7% of Company B's total sales (Company B, 2006).

### 6.5.3 Company C

Company C is a European-based pharmaceutical company that has a market cap of $132 billion (Company C, 2006). It currently has two drugs in development for the target disease, expected to launch in 2009 and 2010. This disease area represents $nil of Company C's current sales, and is forecasted to represent approximately 2% of total sales by 2011 (Datamonitor, 2006).

## 6.6 Company X's Strategic Negotiating Alternatives

The following is an outline of the strategic negotiating alternatives, which Company X has to consider:

### 6.6.1 Negotiate Only with Company A

Company X could choose to enter into negotiations with only Company A, its current partner in Phase II clinical trials for the product candidate. This alternative would mean that Company X would not pursue other potential license partners.

### 6.6.2 Negotiate with Company A Followed by Company B

This alternative would involve Company X entering into negotiations with Company A, its current partner in Phase II clinical trials for the product candidate, and then also entering into negotiations with Company B. Company X could not initiate the process with Company B until the period of exclusivity has expired with Company A. This would allow Company X to leverage the benefits of competitive negotiations.

### 6.6.3 Negotiate with Company A Followed by Company C

This alternative would involve Company X entering into negotiations with Company A, its current partner in Phase II clinical trials for the product candidate, and then also entering into negotiations with Company C. Company X could not initiate the process with Company C until the period of exclusivity has expired with Company A. This would allow Company X to leverage the benefits of competitive negotiations.

### 6.6.4 Negotiate with Company A Followed by Companies B and C

This alternative would involve Company X entering into negotiations with Company A, its current partner in Phase II clinical trials for the product candidate, then also entering into negotiations with Company B, and Company C. Company X could not initiate the process with

Company B or Company C until the period of exclusivity has expired with Company A. This would allow Company X to leverage the benefits of competitive negotiations to the fullest extent possible.

## 6.7 Summary: Company X Has Four Strategic Alternatives

Company X has four strategic alternatives to consider for negotiating a license agreement for its product candidate. These alternatives range from entering into negotiations only with its current clinical trial partner, to negotiating with all three potential partners. This analysis considers these strategic alternatives, along with the evaluation of each of the potential partners in Chapter 9. The following section will examine how a license deal between Company X and any of these potential partners may be constructed.

# 7 HOW COMPANIES CONSTRUCT BIOTECH-PHARMACEUTICAL LICENSE DEALS

## 7.1 Purpose of this Section

The purpose of this section is to examine the typical structure of license agreements between biotech and pharmaceutical companies. This will include a discussion of the various inputs that are used in determining a value for a product candidate, including market size, penetration rate, pricing, and growth rates. The next sub-section provides an overview of typical license terms, including factors that may influence the royalty rate that is included in the agreement. Finally, this section includes a summary of recent license deals completed for drugs in the same target disease market as Company X's product candidate.

## 7.2 Biotech Valuation Models

Valuation models provide a base figure upon which license negotiations start. As outlined in Chapter 5, biotech companies face daunting odds in order to get a product candidate to market. This high level of uncertainty, in part, leads to the reality that valuing biotech companies or product candidates can prove extremely difficult. The valuation may appear to rely heavily on assumptions rather than a specific process; however, there are generally accepted methods used to value biotech companies and product candidates (Bogdan, 2006).

Primarily used are discounted cash flow (DCF) analyses in which revenues and costs are forecasted, then discounted to reflect the time and risk associated with them (Bogdan, 2006). As this analysis focuses on the valuation of a drug candidate, the following discussion relates to a DCF model.

### 7.2.1 Structure

Valuation models incorporate various forecasts to determine the Net Present Value (NPV) of a product candidate over approximately ten years. Biotech patents typically last for twenty years; however, some of this patent life will have lapsed during the development phase. It is essential that the valuation model account for the remaining years of patent protection for the product candidate, as well as several years past patent protection expiry (Bogdan, 2006). Having a valuation model that considers ten years is a common practice when considering the value of a product candidate. In order to arrive at a NPV, the model must use a discount rate. This rate will reflect the passage of time and the amount of risk involved with uncertain cashflows. Valuation models should include both the expected revenues and costs of sales associated with the product candidate (McClure, 2006).

### 7.2.2 Assumptions

In order to create industry forecasts, assumptions are a necessary tool. Industry research using specialist reports, benchmark industry deals, and industry experience and expertise of the company's executive management team form the basis of the assumptions. Crucial assumptions made in the creation of a valuation model include:

**Potential Market Size**: This represents the total patient population that would benefit from the product candidate (Bogdan, 2006). Division of this potential market may be by major drug territories, which include the US, Europe, Japan, and the Rest of World (ROW).

**Market Penetration Rate**: This represents the expected market share captured by the product candidate. If there is a competitive drug market, and there is limited advantage offered by the product candidate in terms of increased effectiveness or reduced side effects, the drug is not likely to win substantial market share. Alternately, if no other drug currently available addresses

the same needs, the product candidate will likely enjoy a high market penetration rate (McClure, 2006).

**Estimated Sales Price**: Product candidates that address unmet medical needs involve more uncertainty when determining a sales price than do drug candidates entering a competitive market, which should be able to determine a reasonable price based on the currently available competitors.

**Estimated Sales Growth Rate and Peak**: An estimate is required to determine how long it will take the product candidate to reach its expected peak market penetration level. Similarly, there must be consideration given to the effects of patent expiry on the sales levels of the product candidate, especially if it is susceptible to competition from biogenerics (Bogdan 2006).

**Discount Rate**: Selecting an appropriate discount rate for the valuation model will account for the inherent risk involved in the product candidate, as well as the passage of time. As the product candidate moves through the development process, the risk decreases with each major milestone. It is estimated that product candidates in Phase I clinical trials have a 15% probability of becoming a marketable product. The odds in Phase II increase to 30%, Phase III to 90% (McClure, 2006). These increased odds result in a lower required discount rate, reflecting the lower risk levels.

## 7.3 License Terms

Biotech-pharmaceutical license deals are typically comprised of three elements: upfront payments, milestone payments, and royalty payments. When these deals take place, often the total value of the deal is publicly available, but little detail of the transaction is. Ultimately, the company that has developed the drug (licensor) is looking to get the highest possible value for

their product, whereas the partner (licensee) is looking to keep the value of the deal as low as possible (Bogdan, 2006).

### 7.3.1 Upfront Payments

Upfront payments are the only guaranteed payments involved in a license agreement. Therefore, they are extremely important to the licensor. The licensor will need to attempt to recover their costs incurred to develop the product candidate through this initial sum (Mudhar, 2006).

### 7.3.2 Milestone Payments

Milestone payments may include payments for events such as successful completion of trials, initiation of, or successful registrations, FDA approval, initiation of, or successful bridging studies, product launch, and certain sales thresholds, among others. Milestones may also vary depending on the region under consideration. For example, bridging studies would most often apply to non-US markets, whereas FDA approval would apply only to the US market. Milestone payments represent the diminishing risk associated with the product candidate as it nears reaching market (Medius Associates, 2001).

### 7.3.3 Royalty Payments

Royalty rates determine what percentage of the total sales of the product candidate the licensee will remit to the licensor. There are wide ranges of factors that affect the royalty rate applied, including (Medius Associates, 2001):

**Strength and Scope of Intellectual Property Rights:** If patents or other intellectual property rights protect the drug it is a much more attractive candidate and will demand a higher royalty rate.

**Extent of Territorial Rights:** If the license agreement is for significant territorial rights (i.e. World rights, as opposed to only the ROW and Japan), there will be a higher royalty rate.

**Exclusivity of Rights:** If the license agreement provides an exclusive right to the licensee to manufacture and market the product, the royalty rate will be higher.

**Inherent Risk:** The risk level of a drug correlates to its stage in development. Typically, deals for which product candidates are somewhere between discovery and Phase I trials have royalty rates in the 5 - 10% range whereas earlier stage agreements have rates below 5%. Products which have reached Phase II trials (or beyond) result in royalty rates over 10% (Medius Associates, 2001).

**Strategic Need / Portfolio Fit:** If the potential licensee already has a complimentary drug in their portfolio with which the licensed drug can be bundled, royalty rates are higher. Similarly, if the licensed drug could act as a replacement for a current portfolio drug which is about to run out of patent protection, the royalty rate in the agreement will be higher to reflect on the better fit.

**Therapeutic Field**: If the potential licensee already has a presence or expertise in a certain therapeutic field and the drug is not substantially different from its existing portfolio, it may be of limited value. However, if the licensed drug addresses a therapeutic area into which the licensees would like to establish themselves, the royalty rate in the agreement will be higher to reflect on the better fit.

## 7.4 Industry Benchmarks for Deals in the Target Disease Market

Between 2004 and 2006, there were seven significant deals made with drug candidates for the target disease, summarized in Table 6. Due to confidentiality agreements between companies, some detailed information on deal specifics are not included:

**Table 6: Drug Licensing Deals Between 2004 and 2006**

| Clinical Phase | Total Value ($M) | Upfront Payment ($M) | Royalty Rate |
|---|---|---|---|
| Phase II b | $545 | $165 | Mid-20% |
| Preclinical | $530 | $60 | 50/50 profit share in US |
| Phase I | $570 | $20 | N/A |
| Phase II b | $525 | $25 | Co-promote |
| Preclinical | $102 | N/A | N/A |
| Preclinical | $300 | $57 | Double-digit |
| Phase II b | $507 | $45 | Co-promote |

*Source: Based on information in Target Disease: Industry Profile (2006).*

## 7.5 Summary: License Deal Values are Complex to Determine

This section has provided a summary of the various assumptions and forecasts that are required to create a comprehensive biotech valuation model. It has also introduced the most common elements of license deals, along with factors that can affect them. Constructing a valuation model to determine a starting point for negotiations is a complex and time-intensive task that involves many uncertainties. Recent license agreements within the target disease market of Company X's product candidate have ranged from $100 to over $500 million. The following section will detail the construction of Company X's forecasts and valuation model, applying the information as outlined in this section.

# 8 CONSTRUCTION OF COMPANY X'S FORECASTS

## 8.1 Purpose of this Section

The purpose of this section is to describe the process undertaken to construct relevant forecasts for use in Company X's valuation model. This section will take into account the components of biotech-pharmaceutical license deals as described in Chapter 7, and apply them to Company X's product candidate and information relating to the target disease market as described in Chapter 4. This section includes an overview of Company X's strategy in creating the forecasts, as well as the assumptions used. I have assisted Company X to construct forecasts for product demand, patient population, treatment duration range, market penetration, and pricing.

## 8.2 Company X's Corporate Strategy

Over 50 product candidates, in various stages of R&D, are under development by over 30 different pharmaceutical and biotech companies to treat this disease (Datamonitor, 2006). Over the next five years, a number of new drugs will launch and form parts of combination therapies. The new therapies will stimulate demand, increase the average cost of treatment, and drive market growth. Per Datamonitor estimates, the target disease market will almost quadruple to an annual sales level of $8.8 billion by 2015. Company X expects that its product candidate will achieve market approvals in the US market by 2014, Europe by 2014, and Japan by 2015.

In order to establish an understanding of the relative value of their product candidate to potential partners, I have assisted Company X to create forecasts for use in a valuation model. This model will determine the NPV of the product candidate when licensed to each potential partner. These forecasts include industry research, experience, and assumptions. The forecasts

will provide support when negotiating license terms for the product candidate. All forecasts are in nominal dollars (i.e. current dollar values).

## 8.3 Target Disease Patient Population Forecast

Estimates of patient populations for treatment in major markets including the US, Japan, UK, Germany, France, Spain, and Italy are included in the model. These estimates rely on industry reports, analyst coverage, as well as the significant industry experience and expertise held by Company X's executive management and clinical teams.

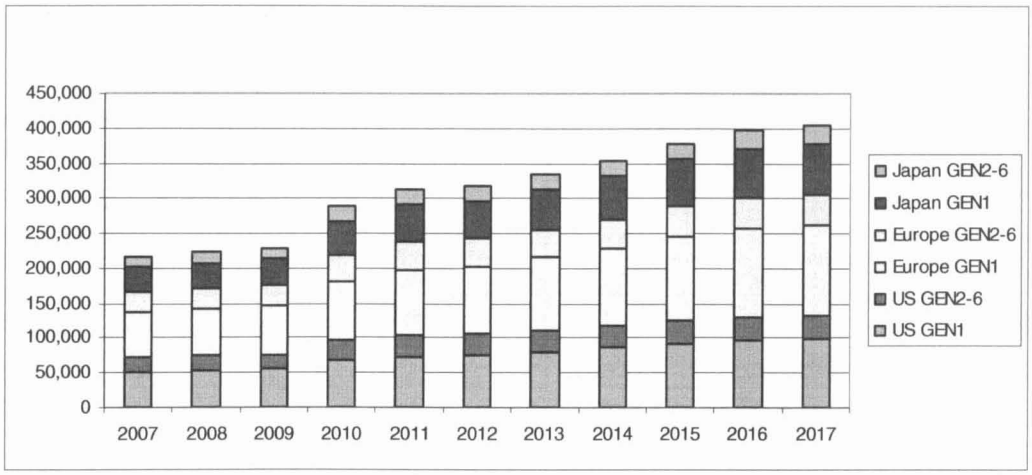
As shown in Table 7, a sample of what the forecast data looks like, the patient population forecast segments patients by whether they fall into one of two genotype categories. Genotypes are often treated differently, with some genotypes being more likely to receive triple or four drug combination therapies. Also built into the patient population forecast are the potential outcomes of treatment. These outcomes are that a patient will be cured, a non-responder, relapsed, or a partial responder. These outcomes of treatment vary for each genotype of the disease. Patients not cured are included in the following years' patient population.

**Table 7: Sample Patient Population Forecast Data**

| | Year W | Year X | Year Y | Year Z |
|---|---|---|---|---|
| **Naïve & Relapsing Patients** | | | | |
| | **230,428** | **258,810** | **279,072** | **287,960** |
| | | | | |
| US GEN1 | 53,326 | 59,924 | 64,641 | 66,723 |
| US GEN2-6 | 22,715 | 25,483 | 27,453 | 28,304 |
| Europe GEN1 | 69,486 | 78,083 | 84,230 | 86,942 |
| Europe GEN2-6 | 29,598 | 33,206 | 35,771 | 36,881 |
| Japan GEN1 | 38,783 | 43,581 | 47,012 | 48,526 |
| Japan GEN2-6 | 16,520 | 18,533 | 19,965 | 20,585 |
| | | | | |
| | | | | |
| **Non and Partial Responders** | | | | |
| | **124,317** | **120,061** | **117,250** | **115,433** |
| | | | | |
| US GEN1 | 32,634 | 32,216 | 31,832 | 31,644 |
| US GEN2-6 | 8,391 | 7,404 | 6,860 | 6,449 |
| Europe GEN1 | 42,523 | 41,978 | 41,479 | 41,233 |
| Europe GEN2-6 | 10,934 | 9,648 | 8,939 | 8,404 |
| Japan GEN1 | 23,734 | 23,430 | 23,151 | 23,014 |
| Japan GEN2-6 | 6,102 | 5,385 | 4,989 | 4,690 |

The patient population for the target disease will continue to grow over the next ten years. Figure 9, a graphical representation of the expected patient population produced by Company X's forecasts, demonstrates this trend:

**Figure 9: Patient Populations by Region**




## 8.4 Target Disease Treatment Demand Forecast

The treatment demand forecast links back to the patient population forecast as discussed above. As shown in Table 8, a sample of the forecast data, demand for treatment of the target disease is broken down into three areas: double combinations, triple combinations, and four drug combinations. Each has an assigned expected treatment rate, depending on which of the genotype categories a patient is included in.

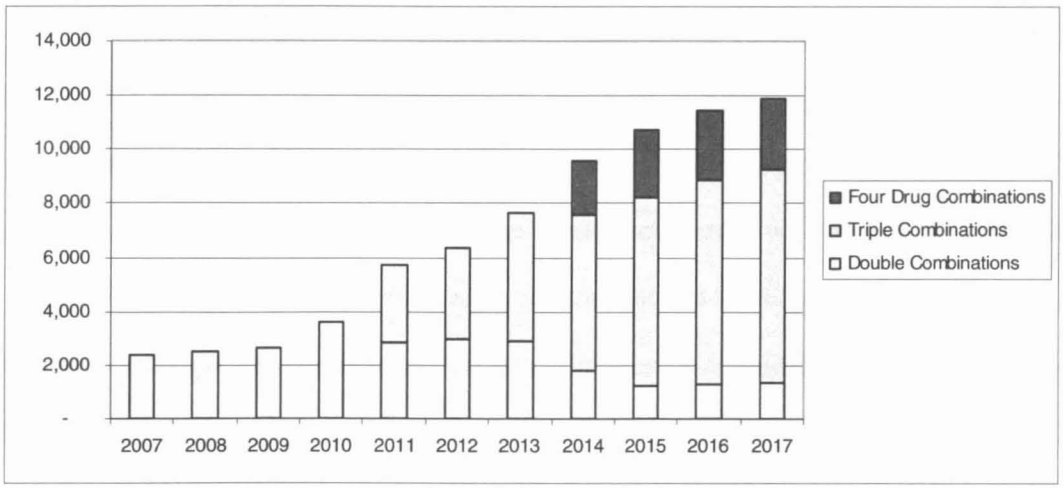
**Table 8: Sample Treatment Demand Forecast Data**

| | Therapy Type | Year W | Year X | Year Y | Year Z |
|---|---|---|---|---|---|
| GEN1 Naïve & Relapsing | double | 40% | 25% | 15% | 15% |
| | triple | 60% | 70% | 80% | 80% |
| | quad | 0% | 5% | 5% | 5% |
| | | | | | |
| GEN1 Non & Partial Responding | double | 50% | 10% | 0% | 0% |
| | triple | 50% | 50% | 50% | 50% |
| | quad | 0% | 40% | 50% | 50% |
| | | | | | |
| GEN 2-6 Naïve & Relapsing | double | 70% | 58% | 50% | 50% |
| | triple | 30% | 40% | 47% | 47% |
| | quad | 0% | 2% | 3% | 3% |
| | | | | | |
| GEN 2-6 Non & Partial Responding | double | 30% | 10% | 0% | 0% |
| | triple | 70% | 50% | 50% | 50% |
| | quad | 0% | 40% | 50% | 50% |

The trend of increasing toward three and four drug therapy over time is due to the fact that there will be a large number of new drugs introduced into the target disease market. These drugs will likely act synergistically and form larger combinations. As shown above, four drug therapies will used primarily in non- and partial-responders. Note that "naïve" refers to a patient undergoing first-time treatment.

Expectations are for three drug combinations to become the standard of care, and represent the majority of treatment demand, as shown in Figure 10:

**Figure 10: Demand for Combination Therapies (in $M)**




## 8.5 Pricing Forecast for Target Disease Market

Current market prices, together with forecast prices supplied by Datamonitor reports, form the basis for pricing estimates. Typically, new drugs to market demand a peak selling price. However, after patents expire, prices may decrease dramatically. This consideration has been included in the model, as demonstrated in Table 9:

**Table 9: Sample Pricing Forecast Data**

| | Year W | Year X | Year Y | Year Z |
|---|---|---|---|---|
| Drug X | 40.31 | 40.31 | 40.31 | 40.31 |
| Inflator | 0% | 0% | 0% | 0% |
| Drug Y | 24.00 | 24.00 | 21.12 | 19.01 |
| Inflator | 0% | 0% | -12% | -10% |
| Drug Z | 43.20 | 43.20 | 43.20 | 43.20 |
| Inflator | 0% | 0% | 0% | 0% |

## 8.6 Target Disease Treatment Range Forecast

Company X's forecast assumes, based on Phase II clinical trial results, use of the product candidate in triple and four drug combination regiments. It is also assumed that there will be a range of treatment duration from 12 weeks to 48 weeks, depending on which genotype of the disease is present in the patient. The average duration of therapy will increase as better-tolerated regiments are more effective, and therefore government and insurance reimbursement programs will support longer average treatment courses. The average completed treatment course for the target disease will increase from 25 weeks in 2006 to 30 weeks in 2015 (Datamonitor, 2006).

## 8.7 Market Share Forecast

Company X created a base case of how much market share each drug will likely capture in the marketplace. For this base case, Company X has assumed development of their drug without the help of a partner. Additional market share forecasts determine the incremental value that their product candidate could offer to potential license partners. For example, a market share forecast was constructed assuming that Company X licensed the product candidate to Company A. Higher market shares were then allocated to all drugs included in Company A's portfolio as they would now have the capability to market a complete treatment bundle which is expected to be more attractive.

Tables 10 and 11 provide examples of data for each of these scenarios. The incremental sales provided to Company A is therefore the difference in their total market share between the base case scenario and the scenario where they are the assumed license partner.

**Table 10: Sample Market Share Forecast Data, Base Case**

| Drug | Year W | Year X | Year Y | Year Z |
|---|---|---|---|---|
| | | | | |
| Drug 1 | 12% | 10% | 11% | 10% |
| Drug 2 | 9% | 8% | 8% | 8% |
| Drug 3 | 9% | 7% | 7% | 7% |
| Drug 4 | 6% | 7% | 6% | 6% |
| Drug 5 | 2% | 5% | 6% | 6% |
| Drug 6 | 26% | 26% | 27% | 27% |
| Drug 7 | 10% | 11% | 11% | 11% |
| Drug 8 | 5% | 6% | 6% | 6% |
| All Others | 19% | 20% | 19% | 18% |

**Table 11: Sample Market Share Forecast Data, Assuming Company A Partnership**

| Drug | Year W | Year X | Year Y | Year Z |
|---|---|---|---|---|
| | | | | |
| Drug 1 | 11% | 10% | 10% | 9% |
| Drug 2 | 10% | 10% | 10% | 10% |
| Drug 3 | 9% | 7% | 7% | 7% |
| Drug 4 | 6% | 6% | 6% | 6% |
| Drug 5 | 3% | 5% | 6% | 6% |
| Drug 6 | 26% | 26% | 25% | 25% |
| Drug 7 | 11% | 12% | 12% | 13% |
| Drug 8 | 6% | 7% | 7% | 7% |
| All Others | 18% | 18% | 17% | 18% |

Market share forecasts were created for the base case, and assuming that each of the three potential license partners were the assumed partner. This results in four market share forecasts.

The market share forecasts account for estimates of the market penetration that achieved by the significant competitive drugs and possible combinational therapies (including double, triple, and four drug combinations). The forecast includes a four-year build up to peak market penetration after product launch for all new products entering the market.

## 8.8 Summary: Forecasts Anticipate Continued Target Disease Market Growth

This section has provided a summary of the various forecasts that Company X has created to for use as part of its valuation model. These forecasts demonstrate that the target disease market will grow over the next ten years. Company X has also created multiple market share forecasts in order to determine the relative value of their product candidate to their potential license partners. The following section will discuss the inclusion of these forecasts in Company X's valuation model.

# 9 CONSTRUCTION OF COMPANY X'S VALUATION MODEL

## 9.1 Purpose of this Section

The purpose of this section is to describe the process undertaken to construct Company X's valuation model. The forecasts developed as discussed in Chapter 8 form the basis of the valuation model. This section includes an overview of Company X's strategy in creating the model, the discount rate selection process, and various outputs from the model.

## 9.2 Company X's Corporate Strategy

In order to establish an understanding of the relative value of the product candidate to potential partners, I assisted Company X with taking the forecasts created as described in Chapter 8 and incorporating them together to achieve a comprehensive look at the target disease market. Creating multiple market share forecasts will allow the model to be run using different partnership scenarios. This will allow Company X to see how much value their product candidate would have to potential license partners individually.

## 9.3 Discount Rate Selected by Company X

Company X has selected a nominal discount rate of 10% (i.e. unadjusted for inflation) to use in their valuation model. The senior management team of Company X feels that this rate accurately reflects the degree of risk that is associated with drug development and licensing, and takes into account the numerous assumptions made in the forecasting process. This rate is consistent with rates used in past valuation models by Company X, and the rate has been applied consistently when considering each potential license partner.

## 9.4 Determining Incremental Value to Potential Partners

As discussed in Chapter 8, Company X created a base market share forecast, in which no partnership was assumed. This base case allows Company X to determine how much market share each drug in the market will likely capture. In order to determine the incremental value to a partner, three additional market share forecasts were made assuming a different license partner in each that would benefit from being able to bundle Company X's product candidate with their own. The incremental value provided to the license partner is the difference in their total market share between the base case scenario and the scenario where they are the assumed license partner, multiplied by the expected sales prices of the relevant drugs.

The model also accounts for costs that the potential license partners would have to incur. These include incremental marketing expenses and remaining development costs. These costs will amount to an estimated value of approximately $600 million over a number of years.

## 9.5 Valuation Model Outputs: Incremental Value and NPV

### 9.5.1 Incremental Value

As shown in Table 12, the incremental value provided to the potential partners ranges from $2.7 to $4.2 billion. This is the total expected increase in sales over their entire portfolio of drugs in the target disease market over the ten years covered by the model. Note that this is not a discounted figure.

**Table 12: Incremental Value to Potential Partners**

| | Product Candidate Sales ($M) | Total Increased Sales ($M) |
|---|---|---|
| **Company A** | $2,884 | $4,232 |
| **Company B** | $2,912 | $2,769 |
| **Company C** | $2,754 | $3,735 |

These figures demonstrate that each of the potential partners would benefit significantly from having Company X's product candidate included in their portfolio. As there is evidence of a benefit to each potential partner, it is appropriate to determine a NPV of the investment into Company X's product candidate for each.

### 9.5.2 NPV

As shown in Table 13, the calculated NPV of acquiring Company X's product candidate for the potential partners ranges from $169 to $324 million. This number takes into account the total increase in sales, as shown in Table 12, as well as incremental marketing expenses and remaining development costs, estimated to be approximately $600 million. A discount rate of 10% appropriately discounts the incremental revenues and expenses on a year-by-year basis.

**Table 13: Net Present Value to Potential Partners**

| | NPV ($M) |
|---|---|
| Company A | $324 |
| Company B | $169 |
| Company C | $311 |

Similar to Table 12, the figures in Table 13 demonstrate that there is a positive value to the investment in Company X's product candidate for each of the three potential license partners. These NPV numbers are of critical importance, as they will assist Company X in determining what the appropriate values of terms for the license negotiating process are. Typically, a biotech will aim to have the NPV of the license agreement equal approximately 50% of the NPV of the investment to its partner: somewhere between $80 and $160 million for Company X (Fischette, 2004).

## 9.6 Summary: Significant Value to Potential Partners

This section has summarized the output of Company X's valuation model, including the incremental value and overall NPV of acquiring the product candidate to each potential license partner. It is clear that for each of the potential partners, Company X's product candidate represents a significant increase in sales values, and would be an attractive investment. The following section will evaluate the potential license partners on additional criteria in order to make a final recommendation to Company X on their licensing partner strategy.

# 10 EVALUATION OF POTENTIAL LICENSE PARTNERS

## 10.1 Purpose of this Section

The purpose of this section is to evaluate Company X's three potential license partners to determine which would make the best strategic partner. This is important information to consider, along with the outputs of the valuation model from Chapter 9. This section will detail criteria chosen to evaluate, including market reach, current drug franchises and current needs. Evaluation criteria also include the incremental value provided and NPV of the investment. The next sub-section will describe the method used to apply these criteria to each of the potential partners, along with the results of the evaluation.

## 10.2 Criteria for Evaluation

Company X's management evaluated each potential partner based on the following criteria:

### 10.2.1 Market Reach and Market Share

This represents the ability of the potential partner to manufacture and market the product candidate, including the number of major markets in which they have a presence, their relative expertise in the target disease area, and past performance of achieving a high level of market penetration.

### 10.2.2 Current Drug Franchises

Consideration as to whether or not the potential partner currently has any drugs in their portfolio, development pipeline for the target disease. This may offer bundling opportunities that can add a significant amount of value.

### 10.2.3 Current Needs/Fit

Consideration is given to whether the potential partner currently has drugs that are similar to Company X's product candidate that are about to lose patent protection.

### 10.2.4 Incremental Value Provided

This is the amount of sales in addition to sales forecasted for the potential partner attributable to their licensing of Company X's product candidate. This increase in sales is primarily due to the increase of bundle sales.

### 10.2.5 Value per Valuation Model

This represents the output of the overall valuation model, which suggests a NPV of the product candidate. The NPV will differ for each potential partner because of changes made in the various forecast assumptions for each potential partner individually.

## 10.3 Method of Evaluation

A weighted value assigned to each evaluation criteria described above represents its importance in determining the appropriateness of the partnership. Each criterion is ranked on a scale of 1 through 5, with 1 representing a low score, and 5 the highest score possible. The weighted scores result in a final score for each of the three potential partners. The potential partner with the highest score is the strongest candidate for Company X to pursue.

## 10.4 Results of Evaluation

Each criterion has been rated on a scale of 1 through 5, with 1 representing a low score, and 5 the highest score possible. Based on the evaluation criteria and weighting, Table 14 presents the results of the evaluation:

**Table 14: Results of Comparative Evaluation**

| Criteria | Weighting | Company A | | Company B | | Company C | |
|---|---|---|---|---|---|---|---|
| | | Score | Weighted Score | Score | Weighted Score | Score | Weighted Score |
| Market Reach and Market Share | *10%* | 3 | 0.3 | 4 | 0.4 | 2 | 0.2 |
| Current Drug Franchises | *10%* | 3 | 0.3 | 5 | 0.5 | 2 | 0.2 |
| Current Needs/Fit | *20%* | 4 | 0.8 | 3 | 0.6 | 5 | 1.0 |
| Incremental Value Provided | *10%* | 4 | 0.4 | 2 | 0.2 | 4 | 0.4 |
| Value Per Valuation Model | *50%* | 5 | 2.5 | 2 | 1.0 | 4 | 2.0 |
| **Overall Assessment** | ***100%*** | | **4.3** | | **2.7** | | **3.8** |

### 10.4.1 Market Reach and Market Share

Rating of this criterion is on a scale of 1 (small market reach and market share) to 5 (total market reach and market share). This criterion is of equal importance as the potential partner's current drug franchise, and the incremental value provided by the product candidate.

**Company A**

Company A has the ability to manufacture and market the product candidate, with access to all major markets in which they are currently marketing a drug in the same disease area. The product candidate and Company A's current drug can form a combination treatment. Company A has achieved a moderate degree of market penetration with its current drug franchise in the target disease area. Company A has the weakest marketing abilities of the three potential partners. Company A's market reach and market share attains a rating of "3".

**Company B**

Company B has the ability to manufacture and market the product candidate, with access to all major markets in which they are currently marketing a drug in the same disease. The product candidate and Company B's current drug can form a combination treatment. Company B has achieved a high degree of market penetration with its current drug franchise in the disease area, and has powerful marketing abilities for which it is well know. Company B's market reach and market share attains a rating of "4".

**Company C**

Company C has the ability to manufacture and market the product candidate, with access to all major markets. However, they are not currently in these markets with drugs in the disease area, and do not have past experience in it. Company C also has strong marketing abilities. Company C's market reach and market share attains a rating of "2".

### 10.4.2 Current Drug Franchises

Rating of this criterion is on a scale of 1 (no current drug franchise in the disease area) to 5 (comprehensive current drug franchise in the disease area). This criterion is weighted as twice as important as the potential partner's market reach/share, the incremental value provided by the product candidate.

**Company A**

Company A currently has one drug in the area of the disease, representing a forecasted 28% of the market's US sales in 2007 (Datamonitor, 2006). It also has a drug that slated to reach the market in this disease area in 2012. Company A's current drug franchise in the disease area attains a rating of "3".

**Company B**

Company B currently has two drugs in the area of the disease, representing a forecasted 52% of the market's US sales in 2007 (Datamonitor, 2006). However, the company does not have any drugs expected to reach the market in the disease area in the near future, and has only one drug in the disease area in preclinical stages of development. Company B's current drug franchise in the disease area attains a rating of "5".

**Company C**

Company C currently has no drugs on the market in the disease area; however, it has two drugs expected to reach the market in this disease area in 2009 and 2013, one of which will likely become part of the standard of care in treatment of the disease. Company C also has three additional drugs in the disease area in preclinical stages of development. Company C's current drug franchise in the disease area attains a rating of "2".

### 10.4.3 Current Needs/Fit

Rating of this criterion is on a scale of 1 (no current need to add/poor fit to its drug franchise in the disease area) to 5 (absolute need to add/excellent fit to its drug franchise in the disease area). This criterion is of equal importance as the potential partner's market reach/share, the potential partner's current drug franchise, and the incremental value provided by the product candidate.

**Company A**

Company A would be able to bundle the product candidate with the drug that it currently markets in the disease area. This may allow them to boost their market share. Company A's current need to add/good fit to its drug franchise in the disease area attains a rating of "4".

**Company B**

Company B would be able to bundle the product candidate with the drugs that it currently markets in the disease area, however; because of their current drugs nearing the end of their patent protection, Company B may not pursue an active involvement in the disease area in the future. Company B's current need to add/good fit to its drug franchise in the disease area attains a rating of "3".

**Company C**

Company C is poised to have a drug that will likely become part of the standard of care treatment for the target disease. Company C could bundle the product candidate with its other drugs in order to market a total treatment package, rather than insurers having to buy drugs for combination therapy form multiple pharmaceutical companies. This could prove to be a significant competitive advantage. Company C's current need to add/good fit to its drug franchise in the disease area attains a rating of "5".

### 10.4.4 Incremental Value Provided

Rating of this criterion is on a scale of 1 (no additional value provided by adding the product candidate to the current drug franchise) to 5 (extensive value provided by adding the product candidate to the current drug franchise). This criterion is of equally importance as the potential partner's market reach/share, and the potential partner's current drug franchise.

**Company**

As per Table 12 in Chapter 9, Company A may have a total sales increase of $4.2 billion by adding Company X's product candidate to their franchise. Company A's value provided by adding the product candidate to the current drug franchise attains a rating of "4".

**Company B**

As per Table 12 in Chapter 9, Company B may have a total sales increase of $2.8 billion by adding Company X's product candidate to their franchise. Company A's value provided by adding the product candidate to the current drug franchise attains a rating of "2".

**Company C**

As per Table 12 in Chapter 9, Company B may have a total sales increase of $3.7 billion by adding Company X's product candidate to their franchise. Company A's value provided by adding the product candidate to the current drug franchise attains a rating of "3".

### 10.4.5 Value per Valuation Model

Rating of this criterion is on a scale of 1 (no NPV provided by adding the product candidate to the current drug franchise) to 5 (extensive NPV by adding the product candidate to the current drug franchise). This criterion is the most relevant factor in making a decision, and is therefore most heavily weighted. It represents approximately 50% the top total NPV of the license agreement that Company X would seek to negotiate with the potential partner.

**Company A**

As per Table 13 in Chapter 9, calculations show that Company A may have a NPV of $324 million on their investment by adding Company X's product candidate to their franchise. Company A's total NPV provided by adding the product candidate to the current drug franchise attains a rating of "5".

**Company B**

As per Table 13 in Chapter 9, calculations show that Company A may have a NPV of $169 million on their investment by adding Company X's product candidate to their franchise. Company B's total NPV provided by adding the product candidate to the current drug franchise attains a rating of "2".

**Company C**

As per Table 13 in Chapter 9, calculations show that Company A may have a NPV of $311 million on their investment by adding Company X's product candidate to their franchise. Company B's total NPV provided by adding the product candidate to the current drug franchise attains a rating of "4".

## 10.5 Summary: Company A is the Strongest Potential Partner for Company X's Product Candidate

This section has summarized the evaluation of all three potential license partners against criteria as selected by Company X's management team. These criteria were weighed to signify their importance when considering which partner would be best suited to partner with Company X, and included the financial benefits that the potential partners may receive from licensing the product candidate, as outlined in Chapter 9. The final section of this analysis will provide Company X with a recommendation on its partnering strategy and terms for negotiations.

# 11 RECOMMENDED LICENSE PARTNER STRATEGY AND CONCLUSION

## 11.1 Purpose of this Section

The purpose of this section is to tie together the evaluation of the potential license partners with the outputs of Company X's valuation model, and to assess with which potential partner Company X should focus its efforts on negotiating. This section will also recommend one of the strategies as outlined in Chapter 6.

## 11.2 Strongest Potential License Partner

Based on the criteria for evaluation and the results of the evaluation in Chapter 10, I recommend that Company X focus on pursuing a licensing agreement with Company A. Company A has the ability to manufacture and market the product candidate, with access to all major markets in which they are currently marketing a drug in the target disease area. Company A's current drugs could be used in combination with the product candidate. Company A has achieved a moderate degree of market penetration with its current drug franchise in the target disease area.

Company A would be able to bundle the product candidate with the drug that it currently markets in the target disease market. This may allow them to boost their market share. Company A is expected to benefit the most from the potential partnership, as per Table 12 in Chapter 9, it is expected that Company A would have a total sales increase of $4.2 billion by adding Company X's product candidate to their franchise. In addition, as per Table 13 in Chapter 9, calculations show that Company A may have a NPV of $324 million on their investment by adding Company X's product candidate to their franchise. Finally, Company A already has some knowledge and

experience with the product candidate, as they have been Company X's partner in completing Phase II clinical trials.

## 11.3 Recommended Negotiation Strategy

As outlined in Chapter 6, Company X has four potential strategic negotiating alternatives. I recommend that Company X follow the strategy outlined in 6.4.4. This involves entering into negotiations with Company A, its current partner in Phase II clinical trials for the product candidate, and then also entering into negotiations with Company B, and Company C. Company X could not initiate the process with Company B or Company C until the period of exclusivity has expired with Company A.

This is the recommended strategy because while Company A appears to be the strongest potential licensing partner, each of the three companies would benefit from the addition of Company X's product candidate to their target disease drug franchises. Having multiple negotiations ongoing will increase Company X's chances of successfully negotiating a license deal for the product candidate. It will also allow Company X to leverage the benefits of competitive negotiations to the fullest extent possible.

## 11.4 Proposed License Terms for Negotiation with Recommended License Partner

License agreements typically involve upfront payments, as well as milestone and royalty payments. Company X will use the NPV generated by the valuation model to create an expectation for the total value of the license deal, negotiated with their potential partner. As Company A is the strongest potential partner, these terms will focus on what Company X should propose to Company A. Terms for negotiations with Company B and Company C would have to be more conservative to reflect the fact that the NPV of the model is lower for them.

Based on the expected NPV of $324 million associated with the recommended license partner, Company A, Company X should prepare for negotiations by determining what a fair and appropriate upfront license payment, milestone payments, and a reasonable royalty rate would be.

### 11.4.1 Upfront License Payment

Upfront payments are the only guaranteed payments in a license agreement. Therefore, Company X should ensure that its upfront license payment would cover the costs that it has incurred to date to bring the product candidate to Phase II clinical trials. I recommend that the starting point for negotiations with Company A involve an upfront payment of $20 million.

### 11.4.2 Milestone Payments

Milestone payments may include payments for events such as successful completion of trials, initiation of, or successful registrations, FDA approval, and sales thresholds, among others. For Company X, I recommend that milestone payments include FDA approval, and sales thresholds of $300, $900, and >$1,200 million in sales. Total potential milestone payments should be approximately $150 million.

### 11.4.3 Royalty Rate

Company X's product candidate will still have patent protection when it reaches the target disease market for several years. The extent of the license agreement will be for exclusive whole world rights, as opposed to rights for limited markets. There is reduced inherent risk for Company A, as the product candidate is already in Phase II clinical trials. Because Company A already has a presence in the target disease market, Company X's product candidate will increase its ability to create a total treatment bundle, which represents a strong strategic fit for Company A's needs. There are all-important factors to consider when determining what royalty rate Company X should seek in its negotiations with Company A.

Taking into consideration the strong factors above, and the fact that the only comparable deal as shown in Table 6 had a royalty rate in the mid-20%'s, I recommend that Company X start its royalty rate negotiations at 22%. This reflects that Company A would receive intellectual property protection, total market rights, and that the product candidate is a strong strategic fit for its current drug franchise.

## 11.5 Summary: Recommended Deal Terms for Company A

Company X should begin its negotiations with Company X by asking for an upfront license payment of $20 million, potential milestone payments of $150 million, and a royalty rate of 22%. This represents a total license deal of approximately $600 million. This is a higher total value deal than seen in the past two years; however, it is expected that these deals will continue to increase in value to reflect the growing target disease market and influx of novel drugs.

With these proposed license terms and payments factored into Company X's valuation model over the course of the agreement, the revised NPV of the investment for Company A is approximately $200 million. Therefore, these appear to be reasonable terms that will provide Company X with a strong return on their product candidate, while providing Company A with a good return on its investment.

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