Healthcare Biotechnology – Pharmaceuticals

Investment Thesis

We recommend an overweight position for the Healthcare Biotechnology industry. The unique nature of prescription drug treatments limits both supplier and buyer power from all but the largest players (government and insurance companies). Revenues from major companies are seeing double digit growth and profit margins. Additionally the structure of patents allows a maintained competitive advantage and future profitability.

Drivers of Thesis

- **Very attractive profit prospects.** The current biotech industry presents many attractive traits for investment. Operating margins of successful companies are between 40 – 60% and revenues continue to climb. Major patents do not face expiration in the near future.

- **Current drops in prices create value opportunities.** Recent drops in major biotech firm prices are mainly in response to market volatility and correction from industry over valuation from peak in July, not drops in revenue or core firm value. It is possible that 2016 may bring the P/E of even the most profitable companies into the single digits.

- **Forecast friendly industry.** The length of time requires for FDA approval, which can take over a decade, prevents surprise product entrances into the market, which gives a long view of potential threats and competitions before they enter the market. This can make forecasting easier.

Risks to Thesis

- **Government regulation.** The government’s ability to impose price caps, reduce patent lives and deny companies preferred status poses the single greatest threat the ongoing profitability of the industry.

- **Star Drugs.** Many successful companies owe their profitability to a single or handful of “star drugs”. Expiration of patents or introduction of a competitive or superior drugs have the potential to significantly harm the value prospects of a firm.

### 12 Month Performance

![12 Month Performance Chart](image)

Data Source: Factset

## Stock Rating

**Overweight**

### Biotech Pharmaceutical Industry

<table>
<thead>
<tr>
<th>Market Cap</th>
<th>(in billions)</th>
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<tr>
<td>Gilead Sciences</td>
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<tr>
<td>Amgen</td>
<td>$109.36</td>
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<tr>
<td>Abbvie</td>
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<tr>
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<td>$40.20</td>
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<td>Alexion</td>
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### P/E

- Celgene: 50.46
- Regeneron: 49.66
- Biogen: 17.20
- Abbvie: 17.09
- Amgen: 16.01
- Gilead Sciences: 7.15

### Operating Margin

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<td>Celgene</td>
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### Industry Description

The Biotech pharmaceuticals industry includes companies who develop and market large molecule drugs typically geared towards targeting diseases with no known cure such as HIV/AIDS and Hepatitis C. The industry had revenues of over $90 Billion in 2013, much of it concentrated among major firms with highly lucrative patents. Companies compete through superior R&D and successful patents. Government regulation has the potential of limiting future profits through healthcare legislation.

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**Important disclosures appear on the last page of this report.**
EXECUTIVE SUMMARY

Our overweight recommendation is based on remaining patent lives, forecasts of sustained revenues and industry growth paired with a fairly long view to potential threats due to government regulations and public disclosure of R&D pipelines as major players continue to pump tens of millions of dollars into the R&D programs yearly.

Major (top 10) firms within the Biotech industry represent the best investment opportunities due to their sizable Research and Development budgets.

The greatest threats to the industry are the expiration of patents and government healthcare regulation leading to the shortening of patents or pricing power.

INDUSTRY DESCRIPTION

A relatively new entrant to the healthcare sector, the Biotech industry began in the 1970’s. It has since grown from a handful of companies to over 1,200 in the US alone. Companies in the Biotech space are focused on developing, patenting and marketing new drugs. The United States leads the world in Biotech, with revenues exceeding US$60 billion and an industry market value in 2014 of $360 billion.¹

Biotech pharmaceuticals is a sub-division of the larger biotech category. Biotechnology is the process of genetic manipulation of microorganisms for practical use and as such has many non-pharmaceutical applications such as livestock feed, chemicals and medical devices. For the duration of this report the term “biotech” will refer specifically to the pharmaceutical applications of biotechnology.

Biotech is a high risk, high reward industry inside the fairly stable defensive sector of health care. Every year hundreds of companies race to develop “star drugs” that will devour market share while sitting safely behind an FDA approved patent. Many compete and few succeed. Those firms that do succeed tend to continue succeeding as tens of millions of dollars of revenue are channeled into R&D annually. Some estimates state that only 1 out of every 5,000 – 10,000 potential drug candidates will make it to market. Beyond that only 20% of marketed drugs are profitable. Most firms make the majority of their profits from a handful of drugs.²

Biotech shares an ambiguous border with the broader industry of “pharmaceuticals”. The two share many of the same drivers, with many companies having both pharmaceutical and biotechnology divisions. Due to these blurred lines and the fact that the technical distinction between the two is the molecular composition and size of their ingredients they are often merged into the broader (and unofficial) title of Biopharmaceuticals. It is expected in coming years the category will become an official industry within healthcare.

Patents & FDA Approval

Patents are king in the Biotech industry. A company with a successful patent can enjoy near monopolistic profit levels until the patent expires or a competing drug is produced that does not violate the existing patent. Patents have traditionally lasted for 20 years from the time of patent issuance. While this may seem like a lengthy window of profit opportunity it is deceptive. Patents are filed in the earliest stages of a drug’s engineering. The subsequent R&D paired with arduous FDA approval process can last up to 10 years.

Before a drug can be marketed to the public it must first pass 3 phases of FDA approval.³

Phase I: 30 healthy volunteers test the safety profile of the drug to ensure it is not harmful to humans.

Phase II: A few hundred patients are used to test the drug dosing and efficacy in treating the illness. These patients are tested against a control group given a placebo drug.

Phase III: In the longest (and most expensive) phase several thousand participants are used to test the drug’s efficacy, safety and fine tune the proper dosing.

Once the drug has successfully passed all 3 phases (which typically costs millions of dollars) the firm presents a New Drug Application to the FDA. These documents can be over 50,000 pages long. It is worth noting that at any phase in the process the FDA can decline to approve the drug even after years of testing and millions in expenses.

Once the patent expires other companies are free to use the chemical recipe to produce generics (referred to as “biosimilars” in the biotech industry). The US government recently passed legislation shortening biotech patents to 12 years. This is because biosimilars (unlike generics) must
go through their own FDA approval process, making them much harder to replicate in a generic format. 

**Buyer Power**

Biotech industry has a unique structure that adds to the complexity of its economics. A number of significant factors result in significant competitive advantage for biotech companies.

Most significant is the fact that in biotechnology the end users are typically purchasing the product to treat life-threatening illnesses with no known cure. In light of this there are very few substitutions to biotech products and end users have very little buyer power over how much they will pay for the drugs. Additionally the majority of the value in the industry is in intellectual capital (patented drug formulas). The actual ingredients of the formulas tend to be commoditized, leading to low supplier power.

This weak buyer power is balanced by another uniqueness of the healthcare industry. While millions of people may be taking a particular drug there are a very small (a few dozen) number of payers. The vast majority of money that exchanges hands in the biotech industry happens between the firm and two groups: Insuranse companies and the U.S. government. It is from these two giants that the majority of patient advocacy and cost negotiations come from. Insurance companies frequently bargain for lower costs and the U.S. Government has the power to use regulation to limit company pricing or at least lessen the duration of its patents.

Recent high profile pharmaceutical controversies such as Martin Shkreli and his company Turing Pharmaceuticals’ hyperinflation of an AIDS related drug Daraprim have raised public cries for increased regulation of healthcare costs.

**Research and Development**

Biotech is one of the most research-intensive industries in the United States. According to a 2014 report by PR Newswire, biotech companies in the US have invested more than $600 billion in R&D since the year 2000. It is not uncommon for a firm to spend 15-30% of revenues on R&D. Biotech is a constant race to stay ahead of the pack and develop the next big drug, as such R&D dollars spent is one of the most telling items on an income statement with regards to future prospects of a firm.

**US Healthcare Reform**

The Affordable Care Act of 2010 has the potential to cause the most significant shifts to the industry landscape. Among other sweeping changes the act mandates every American have health insurance (or pay an annual fine), tightens employer restrictions on providing healthcare to employees and looks to increasingly infuse government control into the healthcare sector.

The act is still in its early stages. It has come under criticism from some lawmakers with potential presidential candidates threatening to repeal it. Because of this the specifics of what it will do to the healthcare industry are not clearly known, but speculations can be made.

If healthcare reform takes a similar path as European and Canadian healthcare industries (which are most similar the US) firms will most likely face cost controls and increased competition pressure from generics. One of the easiest ways for the government to punish drug companies who refuse to lower prices is to shorten the length of patent lives. This has already happened as a part of the ACA, shortening Biotech drug patent lives to 10 years. Additionally companies that refuse to lower prices may find themselves removed from the “approved drug list” of government sponsored health insurance.

If the pricing premium were to be removed from the biotech industry it would lose a significant amount of its profitability. Healthcare reform has the highest potential to do this and as such should be monitored carefully by
analysts. It is worth noting that as legislation is typically
drawn out and regulations often to not go immediately
into effect these are changes that would most likely have
a long horizon and would be seen coming industry-wide.

**Breakthroughs in HIV/AIDS and Hepatitis Medication.**

The last several years have seen significant medical
breakthroughs through biotechnology. Experts are
expressing hope that science is on the verge of winning the
fight against diseases once thought of as incurable.
Notably are medical advances in the treatment of
HIV/AIDS and Hepatitis C.

According to the World Health Organization more than 35
million people are living with HIV/AIDS (almost 1% of
adults aged 15 – 49). Over 2 million people are infected
every year and it is estimated that $15 Billion is spent
annually on HIV treatment and care.7

Today a 20-year-old who is newly diagnosed and treated
with anti-HIV drugs can expect to live 50 more
years compared to only a few years or even
months in the 1980’s.8 In 2012 the FDA approved
Gilead Science’s biotech drug Truvada as a
 preventative measure for HIV prevention.
Although the drug is able to significantly reduce
risk of infection its title of “AIDS Vaccine” is a
dangerous misnomer.9

Hepatitis C is an infective disease that primarily affects the
liver, causing cirrhosis, liver failure and liver cancer. An
estimated 130-200 million people worldwide are infected.
A recent breakthrough drug called Sovaldi has shown to
have a higher cure rate than any treatment previously
offered. Sovaldi’s maker has come under fire for pricing
the drug at $1,000 per pill.

**INDUSTRY TRENDS**

**Mergers and Acquisitions**

2015 was the year of M&A for Biotech companies. The
first 6 months saw $59.3 billion in deals (a 94% increase
over the same period in 2014). This has led some experts
to speculate that some major players are beginning to rely
more on M&A than R&D, which has traditionally been
done in house, allowing smaller companies to develop high
potential drugs and then purchasing them and implementing them into their product line.10 Immuno-
oncology was one of the key drivers to mergers in 2015,
which also saw a high value on diabetes treatment drugs.11

**AbbVie-Pharmacyclic**

Abbvie-Pharmacyclic: Abbvie, one of the largest players in
the Biotech industry purchased cancer treatment
company Pharmacyclics for $21 billion. This move gives
Abbvie a scientific and commercial present in the oncology
research space as well as gaining the patent to Imbruvica
a first-in-class treatment for hematological cancers (a $24
billion global market).12

**Pfizer-allergen**

One of the most notable M&A’s of 2015 the merger of
Pfizer and Allergen forms the world’s biggest drug
company by sales. While the major incentive for the
merger is taxes (Pfizer will move from US to Irish tax rates)
the newly merged company could have annual sales of
over $65 Billion and will no doubt impact the biotech
landscape. It is worth mentioning that while neither
company is exclusively biotech they have biotech divisions
and the blurred lines between pharma and biotech will
lead them to carry many biotech patents.13

**Impact of M & A**

Mergers and acquisitions have the potential of upsetting
some of the balance in the industry by making long-term
strategic forecasting more difficult. Traditionally if a
company were developing a new drug it would spend
years in the approval process, during which other firms
would be able to monitor the progress and brace for any
competitive threat. Under an M & A model a larger
company could scoop up a smaller company at the point
of patent granting and proceed to market and produce the
drug using their economies of scale and infrastructure,
leading it to be a much greater competitive threat than if
it were a smaller company with fewer resources.

Mergers and Acquisitions also further consolidate the
power of a few top firms in an industry that tends to be
dominated by a few powerhouse firms.
MARKETS AND COMPETITION

While there are over 1,000 existing firms that would classify themselves as biotech, the majority of profitability and market share in the industry is consolidated amongst a smaller number of large firms. A study of the competitive landscape gives a picture of potential future profitability. Several large firms may be in the same space but offering different treatments for different diseases. This could allow major companies to excel in the biotech industry without direct rivalry. Rivalry happens when two companies market similar drugs against each other. Profit margins can run anywhere from 20 – 50% so a price war can significantly limit profitability. In the absence of government regulation a look at the future pipeline for any potential competing drugs are on their way can be an indicator of trouble on the horizon.

Gilead Sciences

Gilead Sciences is a biopharmaceutical company focused on research and the development of innovative medicines. Gilead has had a stellar 4 year run seeing triple digit revenue growth in 2014. Much of the success is due to one of Gilead’s star drugs: Sovaldi, which is billed as the most effective cure for Hepatitis C on the market. Sovaldi made up about 50% of Gilead’s 2014 sales. Gilead has come under fire recently for pricing the pill at $1,000 per pill. Companies like Gilead are a case study for the vulnerability of a successful business to government regulation as a price cap on this single drug would have reaching implications for future profitability.

Gilead was chosen by CVS Health as their main option for patients on its commercial drug list. This softens the blow felt from Express Scripts Holding Co, the largest pharmacy benefit manager to choose Gilead’s competitor AbbVie’s Hep C drug as the exclusive treatment option for patients on its main commercial plan.14

Amgen Inc.

Amgen Inc., based in California has grown to become one of the world’s largest independent biotech companies. Its total revenues in the first quarter of 2015 were $5.03 Billion, (up 11% from 2014). It owns the patent to Enbrel, Prolia, EpoGen, Sensipar, and Xgeva. In spite of a strong year changing foreign exchange rates negatively influenced their product sales growth15. Amgen leads the industry in sales but their revenue growth was some of the lowest among the top 8 (7.5%, explained in part but not completely by their high revenue numbers from previous years). They are also greatly slowed their R&D investment growth (a 5% increase in 2014 vs. 21% in 2013). We feel this could be a sign of problems down the line as Amgen could be riding the tide of their star drugs while not assigning an appropriate amount to R&D.

Abbvie Inc.

Abbvie Inc. formed in 2013 after separating from Abbot Laboratories. AbbVie specializes in forming advance therapies for complex and serious illnesses.16 AbbVie, one of the largest firms in the industry became even larger in 2015 when it acquired pharmacyclic for $21 billion, giving it further reach into developing and marketing therapies for blood cancer. Being one of the largest players in the
industry means AbbVie is more likely to experience heightened rivalries over competing drugs. Notable skirmishes were AbbVie beating out Gilead for preferred status from Express Scripts and the introduction of a competing Hep C drug in 2016 that will directly compete with Gilead’s Sovaldi, likely leading to a lowered price on Gilead’s biggest money maker.

**Celgene Corporation**

Celgene specializes in manufacturing cancer and inflammatory disorder therapies. Significant drugs in their product line include Revlimid, Pomalyst/Imnovid and Abraxane which has found broad use in breast, lung and pancreatic cancers in the United States. Celgene is another leader that has slowed their investment in R&D, seeing their R&D growth slow from 29.1% in 2013 down to 9.2%, although this should not be viewed as a sign that they are not investing in their future pipeline. In April of 2015 Celgene made news when they announced they would begin a collaboration with AstraZeneca to study their Phase III cancer drug candidate, MEDI4736. Later that same month Celgene acquired Quanticel for about $485 million. Celgene is using mergers and acquisitions to position themselves as a leader in cancer drug development.

**Biogen Inc**

Biogen develops therapies for neurological autoimmune and hematological disorders. One of Biogen’s star drugs is Tecfidera, a treatment for multiple sclerosis. Tecfidera’s revenues totaled $825 million, part of Biogen’s total MS product line sales of $2.1 Billion. Although one of the smaller players in the top 8 in terms of market cap Biogen has seen strong revenue growth, seeing revenues increase by 32% in 2013 and 46% in 2014.

<table>
<thead>
<tr>
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<th>Revenue</th>
<th>R&amp;D</th>
<th>R&amp;D/ Rev</th>
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<td>GILD</td>
<td>24,890,000</td>
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Data Source: Factset (figures are in thousands)
CATALYSTS FOR GROWTH

There are a number of catalysts for growth in the Biotech industry.

Population change.

More people in a given market logically increases the need for medicine. According to the United Nation’s world Population Prospects report the world population is growing by approximately 74 million people per year. By these estimates the world population will reach 9.0 Billion by 2020 and 11 Billion by 2050.

It should be noted that while the bulk of this growth will be in less developed regions, a notable exception is the United States, with an expected increase of 95 million people in the next 30 years (31% growth).

Increasing Wealth

The wealthier people are the more health care they tend to consume. The economic development of emerging economies is of specific interest in this area as it will yield an increase in healthcare consumption in markets that may not currently be pursued.

Demographic Shifts

Aging populations consume more medication. The US census department forecasts that by 2050 the number of Americans over the age of 65 will increase from 43.1 Million to 83.7 million.

An additional demographic is the increase in obesity. The CDC reports that 34.9% of US adults are obese, leading to conditions like heart disease, type 2 diabetes and certain types of cancer. The market for diabetes related biotech presents significant opportunities.

Cures for Untreatable / Incurable Diseases

Biotech offers the potential to treat and cure diseases that currently offer no effective treatment options. The exciting advances in biotech offer the potential to introduced wholly unique offerings to this market facing no competition. For example, if an effective HIV/AIDS vaccination were developed every major government in the world would purchase hundreds of millions of copies. These speculations may seem to border on science fiction but in light of the direction medical science is taking claims for “miracle” drugs coming down major company pipelines should be investigated and considered (although with more than a grain of salt).

INVESTMENT POSITIVES

- In the absence of unforeseen substitute treatment breakthrough, government intervention or patent legislation the biotech industry will continue to benefit from premium prices and high revenues into the future. The lengthy nature of the patent pipeline will identify competitive or industry threats while they are still far enough out to form a reaction plan.
- The economies of developing nations paired with advanced technology allowing for new disease treatments and cures creates many opportunities for industry growth into new markets.
- It is hard to imagine a future in which people do not need medication. As biotech is currently at the forefront of medical research it does not face the risk of becoming an obsolete or out-of-demand industry in the near future.

INVESTMENT NEGATIVES

- Healthcare reform continues to hold the potential to significant impact profitability in this industry. The 2016 election could hold significant sway over the ACA Act. A republican president may work to minimize the impacts while a democrat would likely work to uphold the act.
- Recent market volatility has quickly reduced the significant returns in comparison to the S&P 500 as well as the S&P healthcare index. At its peak in July 2015 S&P’s 5 year average return (3.36) was more than double the S&P healthcare sector (1.6). Biotech seems to be on a steeper downward trend, which could indicate underperformance in a bear market to match its superior performance in a bull market.
- The nature of the biotech industry, in which a select number of “star drugs” tend to be the major value drivers for each company, can quickly pull an analyst out of their element, making it potentially difficult to forecast future values. An analyst would be remiss to overlook a poorly run company for the sake of investing in a potential star drug that ends up fizzling. An analyst would do well to...
remember that conservatively 1 out of 5,000 proposed drugs makes it through the FDA process and only 1 out of 5 of certified drugs are profitable. Betting on the next big thing could prove dangerous.

**VALUATION**

The biotech industry in in a strong position for the coming future.

**Strong Revenue Growth:**

The last 2 years have shown significant growth for major players in the biotech industry. The top 8 companies by market cap size saw an average revenue growth of 21% in 2013 and 36% in 2014. 2015 numbers have not been reported fully yet but reporting companies are on pace to report revenue growth of about 24% (2014 averages come to about 24% as well when Gilead Science’s astounding 122% growth is removed as an outlier).

**Data Source:** GILD, AMGN, ABBV, CELG, BIIB 10k’s

**Long remaining Patent Lives:**

The biotech/pharma industry went over a significant patent cliff (a period of multiple patent’s ending and the significant sales drop that follows) with a number of major patents expiring in recent years including: Plavix, Singulair, Diovan and Lipitor. We are entering a period of fairly smooth sailing with regards to major drug expiration (noted exceptions is Pfizer’s Lyrica [2018], which is not biotech).

In light of patent lives we can expect prices to remain at a premium which means a high profit margin. In 2015 the top 8 companies by market cap saw an average profit margin of 23.8%.

**Limited impact by government regulation:**

Largely the impact of the Affordable Care Act have been fairly benign with regard to price caps. The most significant impact is felt in reducing the patent safety period from 20 years to 12 before competitors can seek approval from the FDA for biosimilar generics. Even in the wake of the ACA some biotech firms are reporting record revenues: Gilead Sciences saw $2.8 Billion in revenues in 2014, Abbvie saw $3.3 Billion and Amgen saw $4.3 Billion.

**High Potential for Selective Investment:**

It bears repeating that Biotech is a high risk high reward sector. The companies that do well do exceedingly well but many (the vast majority) fail to make the grade. In light of this the smart analyst will select for investment based on the valuation of the company on the basis of future cash streams, not by trying to guess what the next major drug is going to be which borders on outright speculation.

**KEYS TO MONITOR**

Future success for the biotech industry hinges on three areas:

**Existing drug patent remaining lives & Sales:**

Historic sales paired with the remaining lives of drug patents give important insight into future cash flows for the company. An all-star drug on its last year of patent life speaks clearly as to the sales future of a firm, especially if another all-star hasn’t risen up through the ranks yet.

**Future drug pipelines:**

Biotech companies must constantly keep moving forward. Expiring patents must be replaced by new drugs. New drugs must pass through the long and arduous FDA approval process. New patents must be engineered almost a decade in advance of expected sales. The progress and content of industry pipelines (especially stage III) should be carefully monitored for a picture of future industry value.
Impact of healthcare legislation and Insurance negotiating power:

As it assumes a greater role in health care finance the government has a vested interest in keeping costs down. The government (and to a lesser extent insurance companies) pose the single largest threat to the profitability of the biotech industry. Changes in legislation, particularly those impacting patent lives and pricing should be carefully factored into forecasted future value.

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