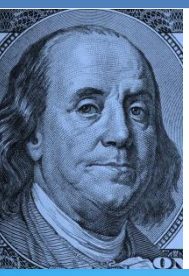
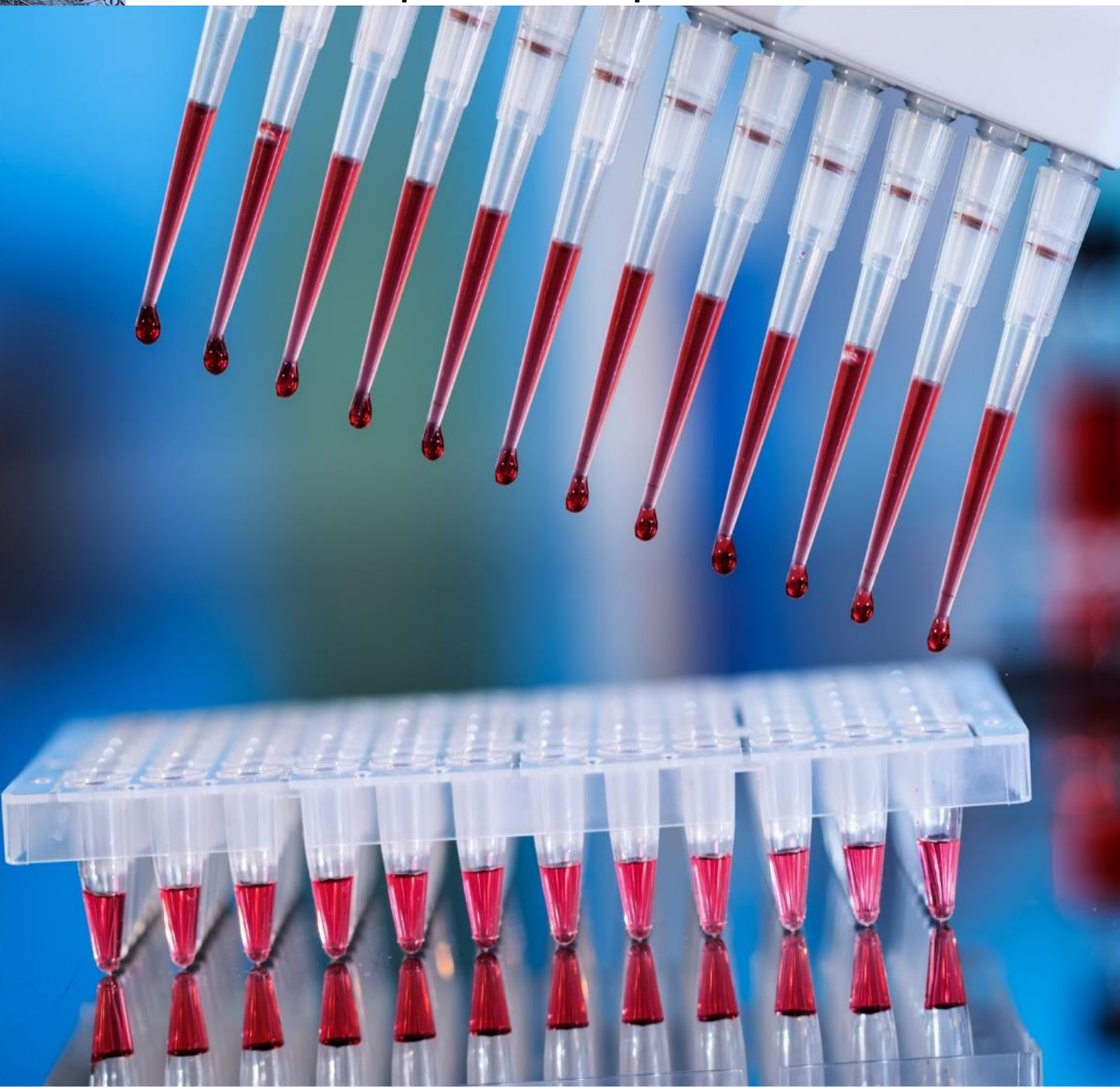


3 Essential Stocks for Biotech Profits

A Special Research Report from Bret Jensen's *Biotech Gems*



Investors Alley

Fellow Investor,

I created this report for you because it may be time to gravitate to the more stable large cap names with solid growth prospects and still reasonable valuations. Small biotech stocks have dominated the best performers list in the first half of 2015. However, with many issues within the space doubling, tripling or quadrupling in the first half of the year, the risk of a correction is increasing. Here are three large cap equities that should be the foundation of any good well-diversified biotech portfolio, and are great long-term holdings that will grow your wealth.

Thank you and Happy Hunting.

Bret Jensen
Editor
Biotech Gems

Celgene Corporation (NASDAQ:CELG)

A biopharmaceutical firm with multiple revenue generating products and a rich pipeline of drug candidates. The company markets to over 70 countries, owns manufacturing facilities in both the U.S. and Europe, and focuses on the development of therapies for unmet medical needs in cancer and inflammatory diseases. Celgene has increased EPS year-over-year since 2010, and its core products generated slightly over $7 billion in sales in 2015. The firm's patent protection on most of its drugs extends into the next decade, and many of its commercialized products are poised to expand thanks to new treatment indications.

Core Products

Celgene's best performing product is Revlimid for the treatment of Multiple myeloma, a type of cancer that results from blood disease. The drug also treats a condition called Myelodysplastic syndromes, which causes low blood cell counts, as well as Mantle cell lymphoma. Sales in the first quarter of 2015 increased 17% to over one billion dollars despite a foreign exchange headwind. In February, the FDA expanded the approved indication for Revlimid to include patients with newly diagnosed Multiple myeloma, and the EU approved it for untreated patients not eligible for transplant. The approvals should help strengthen the drug's position as a crucial component in the treatment of myeloma.

The patent for Revlimid is set to expire in 2027 for the U.S. market. The lengthy time until expiration enables Celgene to take advantage of potential growth opportunities like the new market share made available by the U.S. and European regulatory approvals mentioned previously. The drug is also being investigated as a

part of a combination therapy in which it would serve as the backbone compound for the treatment of myeloma. Revlimid is enrolled in five Phase III trials centered on the treatment of lymphoma with data expected in early 2017. Celgene is doing everything it can to leverage its most successful commercial product and expects Revlimid to generate sales of over five billion dollars in 2015.

Celgene also markets a chemotherapy product called Abraxane that helps stop cancer cells from dividing and growing so that they eventually die. In combination with one other drug, Abraxane has become the standard of care for metastatic pancreatic cancer in the United States and is in the early stages of its European launch for this particular type of cancer. The firm is launching the product for the treatment of non-small cell lung cancer in Germany and Austria after it received European Union approval in February, and will progress to other countries once reimbursement details are ironed out. Abraxane brought in just over $220 million in the first quarter, which represents a 21% increase year-over-year.

The drug is also enrolled in multiple clinical trials, including a Phase II trial for breast cancer and a Phase III trial in which the therapy is an adjuvant for pancreatic cancer. Celgene expects to yield revenues of about one billion dollars from this product in 2015, although it forecasts those sales to grow to around two billion dollars by 2020. Abraxane is also being studied as a core component in over two dozen ongoing trials with immunotherapy agents, none of which were included in the firm's revenue forecast. Celgene's patent doesn't expire until 2026 in the U.S. and 2022 in Europe, so the company has ample time to continue growing Abraxane into a blockbuster product.

The company's other myeloma drug is called Pomalyst ("Imnovid" in Europe). Similar to Revlimid but more potent, Pomalyst is approved for use by patients with myeloma who have received at least two prior therapies. Sales of the drug for the first quarter were about $200 million, a 46% increase year-over-year, and it received regulatory approval in Japan this February about 18 months ahead of schedule.

Rounding out Celgene's growth driving core products is Otezla, which treats psoriasis and psoriatic arthritis. So far the drug has the leading share of new patients ahead of all other products, either branded or unbranded, for both conditions. The company has initiated a global Phase III trial to study Otezla's effectiveness in treating Behcet's disease, a chronic inflammatory disorder, and is undertaking a host of trials to pinpoint other potential treatment areas.

Pomalyst, Abraxane and Otezla combined for net sales of just over $480 million in the first quarter, a 50% increase compared to the first quarter of last year. I think it's important to note that these products are still in the relatively early stages of their global launches, and they are all being studying in clinical trials that could boost their growth prospects over the long run.

Pipeline Candidates:

Celgene is developing a number of candidates in Phases I and II that are not derived from its core products but have the potential to be commercialized down the line. GED-0301 for Crohn's disease is one such candidate and is moving forward into Phase III trials in mid-2015. Many Crohn's disease patients don't reach remission with current medications, so any success GED-0301 finds in improving the condition will be welcomed by an underserved market. The treatment will also be studied in a Phase II trial in the second half of 2015 with its focus on ulcerative colitis.

The company is also developing CC-486, which is enrolled in Phase II clinical trials for breast cancer, nasopharyngeal carcinoma, and non-small cell lung cancer. The firm announced in April that it would purchase Quanticel Pharmaceuticals, a biotech firm that focuses on cancer therapies. Celgene will have full access to Quanticel's lead programs, including its drug candidates that are expected to enter the clinic in early 2016. The acquisition is a smart strategic move because it expands the portfolio of opportunities available and increases the likelihood of Celgene commercializing another product.

Celgene is also partnered with Acceleron Pharma, and the two companies are moving forward with a Phase III program focused around their candidate luspatercept, which targets lower-risk Myelodysplastic syndromes. One other recently announced partnership, with AstraZeneca (NYSE: AZN), hopes to develop and commercialize MEDI4736 for hematologic malignancies like non-Hodgkin's lymphoma.

Celgene's 2015 milestone calendar is particularly full of late stage clinical trials. Over the long run, likely one to two years down the line, these studies could act as positive catalysts if their results are promising and help lead to the commercialization of new products.

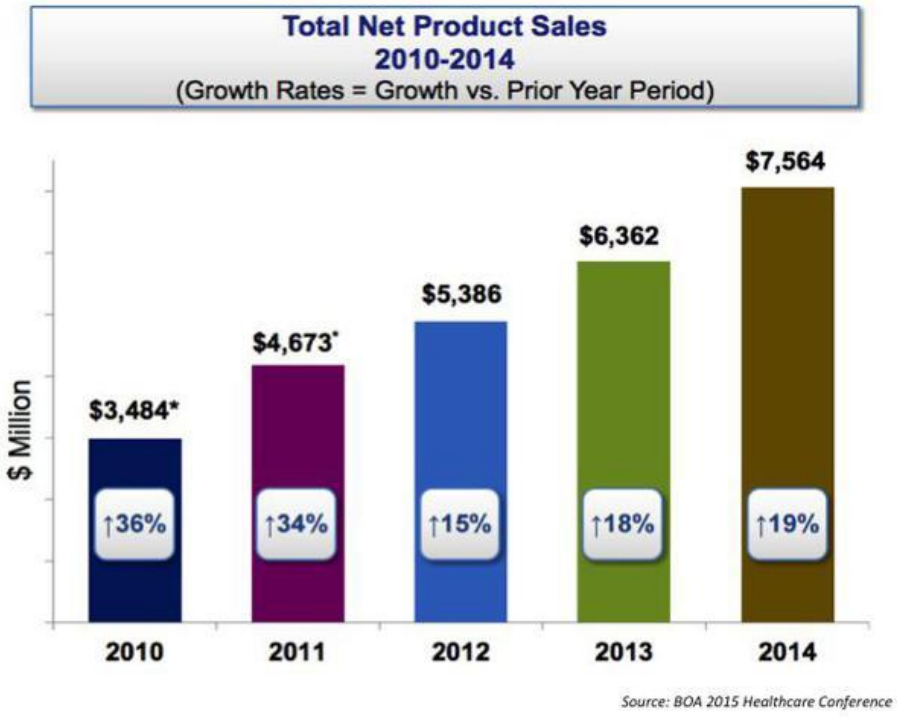
Franchise	Milestone	Expected Timing
Hematology & Oncology	• Regulatory decisions on REVLIMID® for NDMM in the U.S. and EU	Feb 2015
	• Regulatory decision on REVLIMID® for NDMM in Japan	H2
	• Submit REVLIMID® for non-del5q MDS in U.S. and Japan	2015
	• Presentation of FLASH meta-analysis on durable CR in follicular NHL	Q2
	• Initiate enrollment in REVLIMID® Ph III ROBUST™ trial in DLBCL	Jan 2015
	• EU regulatory decision on ABRAXANE® in NSCLC	Mar 2015
	• Regulatory decision on POMALYST® for RRMM in Japan	Mar 2015
	• Complete enrollment in REVLIMID® Ph III CONTINUUM® trial in CLL	H2
	• CHMP opinion on VIDAZA® for elderly AML	H2
	• Advance CC-122 in Ph I/II trials in DLBCL	H2
	• Initiate luspatercept in Ph III trial in beta-thalassemia	H2
	• Initiate Ph III trial with AG-221 in AML with IDH-2 mutation	H2
I & I	• EU regulatory decision on OTEZLA® in PSOR and PsA	Jan 2015
	• Complete enrollment in GED-0301 registration-enabling endoscopy trial	H2
	• Initiate enrollment in GED-0301 Ph III trials in Crohn's disease	H2
	• Initiate GED-0301 clinical program in ulcerative colitis	H2
	• Complete enrollment in CC-220 Ph II trial in SLE	H2

Source: BOA 2015 Healthcare Conference

As well, Celgene has made a couple of strategic deals in July that enhances its long term growth prospects. The company recently announced a $1 billion partnership deal with **Juno Therapeutics (NASDAQ: JUNO)** which significantly deepened its exposure to the emerging field of immunotherapy and was also well-received by investors. More importantly, last week the company picked up **Receptos (NASDAQ:RCPT)** for just over $7 billion. Receptos has a late stage trial compound that has a high chance of being approved. Celgene believes the drug could eventually produce $4 billion to $6 billion in peak sales. If this turns out to be an accurate forecast, this acquisition will greatly enhance revenue and earnings growth in coming years.

Financial Footing:

Celgene has delivered revenue and earnings growth year after year since 2010. Product sales improved by 19% to over $7 billion in 2014 compared to the previous year, and the firm delivered earnings of slightly under $4.00 per share. The company is on track to achieve its net sales guidance of about $9 billion dollars this year, which represents a 20% increase from 2014. Full year adjusted earnings are expected to be just under $5.00 per share and about 25% higher than last year. Sales of its core products are driving Celgene's growth, and analysts estimate that EPS should jump to above $6.00 per share in 2016.



The company is committed to returning capital to its shareholders, Celgene repurchased over $1 billion in shares during the first quarter of 2015. Since implementing its repurchase program six years ago, the company has bought back over $10 billion of its common stock, which represents about 11% of its current float. The firm ended the first quarter with just over $7 billion in cash and marketable securities. This money can be put to use through the buyback program or as funding for the Celgene's many clinical trials.

In 2014, Celgene managed to grow its free cash flow by $500 million to slightly under $3 billion. The long lives of Celgene's core product patents should protect its most important revenue streams while it develops other commercial opportunities. As the firm's less mature branded products fill out their global market share opportunities I think they will help contribute to even greater free cash flow growth.

Summary:

Most analysts hold bullish outlooks on shares of Celgene, and the eight who cover the company have an average price target of $146 per share. Deutsche Bank reiterated its Buy rating on Celgene in March with a price target of $160 per share, and analysts at the Bank of Montreal have set a target of $163. Shares currently trade at approximately $135, so the average price target on Celgene represents a potential upside of about 18%. Celgene is currently priced at 22 times next year's projected profits. This is pretty much in line with the overall market multiple despite clearly superior growth prospects. The stock deserves to trade at a solid premium to the market and is a classic growth at a reasonable price pick, also known as G.A.R.P.

Celgene is an excellent core holding to any diversified biotech portfolio because it has a stable of unique products, all of which hold potential applications in markets not yet factored into earnings estimates. Management has a proven track record of progressing drugs through clinical trials and eventually onto the global market. The firm has multiple product candidates in late stage trials, the financial footing to commercialize those products, and a proven worldwide distribution platform.

Recommendation: Buy Celgene up to $140.

Position: Long CELG

Gilead Sciences (NASDAQ: GILD)

The stock is the cheapest large cap growth stock in the market that I am aware of at the current moment. Long term investors can look forward to years of significant capital appreciation as well as some income as the company just initiated its first dividend payout as free cash flow is exploding. The stock is currently the biggest position within my own portfolio.

Gilead offers myriad attractive traits for both value and growth investors. The company has two market leading franchises, a deep pipeline and incredibly cheap valuations. Let’s take a detailed look at Gilead’s product portfolio, pipeline, increasing free cash flow and valuations.

Hepatitis C Stranglehold:

Approximately 185 million people worldwide are infected with Hepatitis C, with about four million of those cases occurring in the United States. Of those four million, it is estimated that only 1.6 million are diagnosed. Gilead possesses two extremely effective Hepatitis C products, Sovaldi and Harvoni.

Despite restrictive prior authorizations requiring final approval by insurance companies, Sovaldi experienced phenomenal uptake in 2014. Sales of the drug reached $10.3 billion for the year, with 109,000 patients treated in the U.S. and roughly 33,000 treated in Europe (primarily France and Germany). Sovaldi was the biggest launch of a new drug by first year revenues in history. In addition, during the fourth quarter alone about 31,000 patients initiated treatment with Harvoni, which launched just 10 months after Sovaldi, and sales of the drug totaled $2.1 billion.

The good news for Gilead's shareholders is that Sovaldi and Harvoni sales are really just getting started in Europe and the U.K. The company also just received approval for some types of hepatitis C in Japan which has more than one million citizens carrying the hepatitis C virus. In its just completed quarter (which we will discuss in a later section of this article), 70,000 out of the approximately 90,000 people that began a hepatitis C treatment course with Gilead's drugs were in the United States. As we go forward, a larger percentage of overall sales will come from overseas, thus providing an additional channel for long term growth as well as diversification.

HIV Market Leader:

In the HIV treatment space, Gilead is the market leader in single tablet regimens and offers a plethora of distinct products. Stribild, Complera and Atripla are all standalone, complete single tablet treatments that require a daily dosage of just one pill. They are popular with patients, but more importantly they increase adherence to the regimen and as a result improve outcomes overall. Gilead has made impressive gains in terms of enabling access to its HIV medicines.

Despite its lead position in the HIV treatment market, Gilead continues to innovate. One of its newest developments, tenofovir alafenamide (TAF), is a component of the single tablet regimen that would improve the treatment's safety profile. In a 48-week clinical study, the new component proved to be non-inferior to Stribild and efficient. More importantly, the study showed that TAF lowered negative impacts to the renal systems and lowered decreases in bone mineral density when compared to Viread, another product offered by Gilead. Considering the fact that people who begin receiving treatment in their twenties may continue on that regiment for the rest of their lives, a reduction in negative side effect is an extremely positive step forward.

Robust Pipeline and Impressive Cardiovascular Franchise

Gilead possesses a strong pair of cardiovascular drugs aimed at treating pulmonary arterial hypertension and chronic angina. Letairis and Ranexa delivered over $1 billion in revenue during 2014, with Letairis capturing around 44% of the U.S. market. The firm also possesses an incredibly deep pipeline, with potential products for HIV/AIDS, liver diseases, hematology and oncology, inflammatory and respiratory diseases, and cardiovascular conditions. It also has about 400 ongoing and planned clinical studies, with a solid number of those studies in Phase Three.

John Milligan, COO and President of Gilead, spoke about some of the most interesting pipeline products at the Barclays Capital Health Care Conference on March 11th. One drug, Simtuzumab, works to knock out an enzyme highly associated with Nonalcoholic steatohepatitis (liver inflammation caused by the buildup of fat). He also mentioned the MMP9 inhibitor, an antibody which the company saw as having very strong activity in gastric cancer and ulcerative colitis.

The drug is fairly benign and could have implications for a broad range of diseases. With so many drugs targeting a wide range of diseases in its pipeline, I believe Gilead has set itself up well for the future. I expect it to made significant strides as it develops treatments for oncology and hepatitis B over the next few years.

1st Quarter Results & Free Cash Flow:

Once again Gilead left analysts' expectations in the dust when it reported in early May. Earnings per share came in at $2.94, more than 60 cents a share over the consensus. To put that into perspective, the company made just over $2.00 a share in profits for all of 2013! Quarterly revenues came in just under $700 million over expectations and for good measure the company raised its revenue forecast by a cool $2 billion.

JP Morgan expects Gilead to generate $30 billion in cash over the next three years and $60 billion over the next five years, giving the firm supreme strategic flexibility in the biotech industry. The company's total market capitalization is just over $150 billion. Gilead is executing a $15 billion buyback of shares over the next few years. The company just initiated its first dividend program, paying out $1.72 per share annually, a 1.6% yield. This program should broaden Gilead's investor base and open it up to those looking for an income return on their investment.

Valuation & Summary:

Rarely have I seen a large cap stock as cheap or misunderstood by analysts than Gilead and it reminds me of **Apple (NASDAQ: AAPL)** in the early summer of 2013 when the shares could get no love and the company supposedly had lost its

"mojo"… we all know how that turned out. At the start of 2014, analysts in general had the company producing between $3 billion to $5 billion in sales from its new hepatitis C drugs with S&P projecting $2.8 billion. Gilead delivered approximately $12 billion in sales for Sovaldi and Harvoni in FY2014. In its just reported quarter these drugs produced sales of over $4.5 billion, $1 billion over the consensus for the quarter. Analysts have also been wrong about the impact of **AbbVie's (NYSE: ABBV)** Viekera Pak on the hepatitis C space. Most had that hepatitis C package taking 15% to 25% market share by now. In reality that is running closer to 10%.

Earnings estimates have popped up nicely since the company reported quarterly numbers. The current consensus stands at nearly $11.00 a share in earnings for Gilead in FY2015 and this might prove once again to be conservative.

At the start of 2014, the consensus had the company earning just over $4.00 a share in profit for FY2014. When all was said and done Gilead delivered over $8.00 a share in earnings per share. OOPS!

With the recent guidance bump from management, revenues should be up 15% to 20% in FY2015. Earnings should increase 30% to 40% above the levels of 2014. Despite these growth prospects, Gilead goes for approximately 9.5 times forward earnings along with a 1.6% dividend yield making it one of the cheapest large cap growth stocks I have encountered in quite some time.

Recommendation: Buy up to $125.00 a share.

Position: Long GILD

Amgen (NASDAQ: AMGN)

Amgen is one of the pioneers of the entire biotech sector in fact. This California based grandfather of biotech has been a public company for more than three decades and produces over $20 billion annually in top line revenue.

Although not as sexy or potentially lucrative as some small cap that can double or triple your money in a couple months, the company still has years of growth and upside ahead of it. More importantly, it is not nearly as volatile a stock as the small cap picks; this is important as we enter the third quarter looking like the markets are set for a rockier ride than we have seen in a while as Greece, China and Puerto Rico dominate the financial headlines.

Amgen has everything one could ask for from a stable large cap selection within the biotech indusy. This includes established products, a deep pipeline, a strong balance sheet and the shares are reasonably valued as well. Although no longer producing blockbuster growth, Amgen is still delivering solid mid-single digit sales increases translating into better earnings growth. It even pays a two percent dividend yield and I expect dividend payouts will continue to go up in line with earnings growth in the future. The stock is offering a solid entry point after declining some $20 a share from a 52 week high earlier in the year. Let's take a deeper look at this icon of the industry.

Main Products:

Amgen's main products include Neupogen which stimulates neutrophils (white blood cells that defend against bacterial infection) production in cancer patients whose natural neutrophils were destroyed by chemotherapy. Combined with Neulasta, a long-acting white blood cell stimulant this franchise produces almost $6 billion in annual global sales. Next up is Enbrel which is approved to treat rheumatoid arthritis (RA), psoriatic arthritis, and chronic plaque psoriasis. In late 2011, Enbrel was issued a new patent, which extends to 2028. Enbrel was acquired through the 2002 purchase of Immunex and has global sales approaching $5 billion annually.

Rounding out the company's core product portfolio is Epogen which is a genetically engineered version of human erythropoietin (EPO) with annual sales of over $2 billion even if it has been hampered by Medicare pricing for dialysis patients. The company also owns Aranesp, a recombinant protein that stimulates the production of red blood cells in predialysis and dialysis patients and does just under $2 billion in global sales.

AMGN launched denosumab "Prolia" a few years ago for treatment of post-menopausal osteoporosis and for prostate cancer patients with bone loss due to

hormone ablation in both the U.S. and Europe. This compound is already over $1 billion in annual sales and is growing over 30% year-over-year as of the last reported quarter. The company has several other drugs that do up to $1 billion a year in revenues as well constituting a very well balanced portfolio of products.

Pipeline:

Amgen has a robust pipeline with 16 compounds in Phase III trials that could accelerate growth and support a resilient, but largely mature, drug portfolio. There are some exciting milestones on the horizon. Amgen is one of the few companies that is almost ready to launch their PCSK9 inhibitor "Repatha" into this market, subject to regulatory approvals. PCSK9 inhibitors are a new, more effective class of cholesterol drugs. This could easily be a niche that produces $10 billion to $15 billion in annual sales in a few years with several products competing for market share. Corlanor was approved in April to reduce the risk of hospitalization for worsening heart failure in patients with chronic heart failure. This is the first new heart failure medicine to the market in the U.S. in almost a decade. The company believes up to one million patients are candidates for this treatment.

Remaining 2015 Milestones

Clinical Program	Indication	Milestone
Repatha™ (evolocumab)*	Dyslipidemia	Global regulatory reviews
Kyprolis® (carfilzomib)	Relapsed multiple myeloma	Global regulatory reviews
Talimogene laherparepvec	Metastatic melanoma	Global regulatory reviews
Brodalumab†	Moderate-to-severe plaque psoriasis	Global submissions
AMG 416	Secondary hyperparathyroidism	Global submissions
AMG 334	Episodic migraine	Phase 3 initiation
Omecamtiv mecarbil‡	Chronic heart failure	Phase 2 data

Kyprolis recently delivered impressive results showing a doubling of progression free survival versus bortezomib in relapsed multiple myeloma patients. The compound is currently under accelerated review in both the United States and Europe for multiple myeloma patients who have relapsed. The drug is already approved for some conditions of multiple myeloma and showing strong growth.

Amgen received approval for BLINCYTO targeting acute lymphoblastic leukemia earlier this year and is rolling out the product. The launch of its new the on-body injector for Neulasta is going very well with positive feedback from healthcare providers. These are some of the key products within the company's pipeline or just launched. The rest of 2015 has several key milestones upcoming for Amgen.

Biosimilars:

As can be seen from the chart below, Amgen has several late stage biosimilar products that will come to market over the next few years. Both the company and S&P believe this line of business can generate upwards of $3 billion annually in approximately five years. This would represent almost 15% of the company's current overall revenue and is an important and developing part of Amgen's growth story.

Amgen Biosimilars Have the Potential to Deliver $3B+ in Annual Revenue

	Status	Originator Worldwide 2014 Sales*
ABP 501	Phase 3 complete (RA and PsO)	HUMIRA® ~ $13B
ABP 980	Phase 3 breast cancer	Herceptin® ~ $7B
ABP 215	Phase 3 NSCLC	Avastin® ~ $7B
ABP 710	Phase 1	REMICADE® ~ $9B
ABP 798	Clinical ready	RITUXAN® ~ $8B
ABP 494	Process development	ERBITUX® ~ $2B
Molecules #7–#9	Process development	~ $7B
Total		~ $52B

Balance Sheet & Analyst Commentary:

The company has a solid balance sheet and recently added another $2 billion to its stock buyback authorization. Amgen also just increased its dividend payout by 30% earlier this year and I expect the company will continue to use its increasing cash flow to reward shareholders both by stock buybacks and increased dividends. Amgen is also in the middle of a significant restructuring to streamline operations and maintain and improve margins.

Analyst support has been quite positive of late. Five analyst firms have chimed on Amgen since June 8th including Jefferies, Piper Jaffray and Deutsche Bank. All have reiterated Buy ratings and have price targets ranging from $182.00 to $195.00 a share on Amgen.

This is approximately 18% to 27% upside from the current price of the stock. Most analysts cite Amgen's upcoming launches and approvals and pipeline as key factors in their Buy ratings and price targets.

Valuation & Conclusion:

As can be seen from the analysis above, Amgen is an established player in the biotech space. It has a healthy combination of established products, just launched compounds, an impressive pipeline and soon to be growing presence in biosimilars. Revenues should continue to increase in the low to middle single digits year-over-year for years to come. The company raised full year 2015 revenue and earnings guidance during its last earnings report in late April.

The company earned $8.70 a share in FY2014 and is on track to post approximately $9.60 a share in profit in FY2015. The current consensus calls for $10.50 to $10.60 a share in the black in FY2016. At its current stock price of around $153.00 a share, AMGN sells for 14.5 times those forward earnings. This is a slight discount to the overall market multiple and a discount that is not warranted given the consistency of Amgen's growth, its pipeline, strong balance sheet and two percent dividend yield. This is not a "home run" stock. However, Amgen should be a core contributor to the overall Biotech Gems portfolio for quarters and years to come.

Recommendation: Buy AMGN up to $170.00 a share.

Position: Long AMGN

The importance of these stocks is not to deliver the high returns that the small biotech names have in the past. These three stocks are meant to be the bedrock of your portfolio. Because, when and if a change in sentiment does wash over the biotech space; they will hold up well and allow investors sleep at night. In what

looks to be an increasingly overbought market, I am taking the necessary steps to mitigate risk by investing in these three core stocks that will make up the majority of my portfolio.