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# AbbVie's outlook is highly dependent on a well-positioned Humira.



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### **Thesis** 01/04/13

Armed with the best-in-class immunology drug Humira, AbbVie is well positioned to drive strong cash flows to support the company's next generation of pipeline drugs. However, with AbbVie's next generation of drugs not likely to reach the market until 2015 and several midsized drugs losing patent protection, Humira's cash flows are particularly important. Furthermore, the company also holds a portfolio of hard-to-make drugs

that will help supplement Humira's growth.

At over 50% of total sales and a higher portion of earnings (due to higher margin revenue), Humira is well positioned to drive the majority of AbbVie's performance over the next five years. With approvals in rheumatoid arthritis (RA), psoriasis, and Crohn's disease, Humira is well positioned for growth in these markets as penetration rates are below 20% on average. Despite the low penetration, these markets already represent multibillion-dollar opportunities. Furthermore, with leading efficacy and a favorable side-effect profile, we expect Humira to continue to post double-digit growth over the next couple of years.

Despite a strong near-term outlook for Humira, uncertainty around encroaching competition will likely weigh on investor sentiment toward the company. In particular, Pfizer's <u>PFE</u> new RA drug, tofacitinib, represents a key new competitor, as it offers patients efficacy potentially as good as Humira in an oral form (in contrast to twice-monthly Humira injections). However, tofacitinib's side-effect profile is still not fully clear and represents some risks, which may delay physician acceptance unless patients fail an anti-TNF-alpha drug like Humira. Additionally, many Phase III RA drugs will likely reach the market over the next three years.

Humira's biologic composition may deter generic completion following the late-2016 patent loss in the U.S. and the 2018 patent loss in Europe. With the high degree of complexity in developing generic biologics, we anticipate a much smaller degree of generic erosion following Humira's patent loss. We model in 20% annual revenue declines for Humira following the loss of exclusivity.

Turning to the remainder of the company, a combination of products losing patent protection and mature drugs largely represent sales outside of Humira. The company's lipid-lowering franchises--Tricor, Trilipix, and Niaspan--will all face generic competition in 2013-14. In addition, many of the other remaining products have already lost patent protection, but due to manufacturing complexities have been able to retain a significant portion of sales.

Looking toward the future, AbbVie's pipeline is weighted heavily toward 2015

## Morningstar's Take ABBV

Price 01-04-2013 Fair Value Estimate Uncertainty
34.39 USD 38.00 USD -
Consider Buy Consider Sell Economic Moat
26.60 USD 51.30 USD Narrow

#### Stewardship Rating

Standard

#### **Bulls Say**

- AbbVie will pay \$1.60 per share in dividends, which should act as valuation support, as the cash flows to support the dividend are very secure over the next five years.
- We believe Humira represents one of the best immunology drugs for RA, Crohn's disease, and psoriasis, and we expect it will continue to penetrate these markets.
- The new competitive RA threat from Pfizer's Xeljanz will not likely take much share from Humira initially as Xeljanz's safety and efficacy profile is still uncertain and the drug requires heavy monitoring during usage.
- The company's hepatitis C pipeline drugs could take a meaningful piece of a market that should grow to over \$20 billion by 2020.

#### **Bears Say**

- We expect AbbVie to lose close to \$2 billion in sales over the 2013-14 time period as patents expire on cardiovascular drugs Niaspan, Trilipix and Tricor.
- The poor competitive position of HIV drug Kaletra will likely mean a slow sales decline over the next four years, creating a drag on overall company growth.
- Besides the hepatitis C drugs, AbbVie's pipeline prospects are as strong as the company needs to help ensure long-term growth following the Humira patent loss.
- New product launches and successful acquisitions are needed to support the company's dividend following the Humira patent loss.

AbbVie Inc	\$35.42	2.37	18,038
Name	Price	% Chg	TTM Sales \$ mil
Competitors ABBV			More

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launches, with its hepatitis C drugs representing the crown jewel in the pipeline. While AbbVie holds other pipeline drugs, the company's next-generation hepatitis C drugs offer the potential to replace Humira sales if successful in Phase III development. Additionally, we expect AbbVie will redeploy capital through bolt-on acquisitions to strengthen its internal pipeline.

#### **Valuation**

Our fair value estimate for AbbVie is \$38 per share. Accounting for more than half of AbbVie's projected 2012 sales, Humira is the key driver of its valuation and outlook. We believe Humira's leading efficacy and relatively clean side-effect profile in underpenetrated treatment areas, including RA, psoriasis, and inflammatory bowel disease, will drive an 11% five-year CAGR for the drug. (In the analysis of the therapeutic areas below, we highlight Humira's competitive positioning.) However, we expect Humira sales will begin to decline approximately 20% beginning in 2018 as generic biologics increase and greater branded competition intensifies, which lowers our 10-year CAGR for the drug to -4%.

Aside from Humira, AbbVie holds several drugs that are losing patent protection over the next five years, which offsets the near-term Humira growth and results in a total sales five-year CAGR of 5%. Over the longer term, we expect pipeline products will help mitigate the heavy Humira declines in 2018. On the bottom line, over the next five years we expect slightly improving margins, largely driven by the higher contribution to total sales by Humira, which carries very high margins. However, we expect margins will fall toward the back half of our 10-year explicit forecast period as sales from Humira decline. For the weighted average cost of capital, we use an 8% rate that combines a 10% cost of equity and market rates for the cost of debt.

# <u>Risk</u>

Similar to other drug companies, AbbVie faces the risks of new product failures, reimbursement challenges for new drugs, and drug pricing cuts by large payer groups that are growing increasingly price-sensitive. Further, AbbVie's high concentration of Humira sales makes the company very exposed to any new competitive threats to Humira.

#### **Management & Stewardship**

We believe AbbVie's management team has demonstrated standard stewardship, as the key leaders haven't had much of a track record yet and many decisions were overseen by Abbott's leadership, which had to balance a more diversified company. However, AbbVie's departure from Abbott highlights the company's high degree of exposure to Humira. Under Abbott's umbrella, AbbVie didn't create enough pipeline products both internally and through acquisitions to create the wide moat that many of its more diversified peers hold. The company's relatively poor positioning is a concern, but holding AbbVie management accountable is difficult given that AbbVie wasn't calling all the shots as part of Abbott.

AbbVie is led by Rick Gonzalez, who joined Abbott in 1977 and held many managerial posts throughout his career there. However, he only recently led the drug group starting in July 2010 after a brief retirement. His relatively short tenure in the key field of drug commercialization and development is a concern. Backing up Gonzalez, CFO Bill Chase has been with Abbott for over 20 years. Chase's background in licensing and acquisitions will be helpful, as AbbVie will need to redeploy the strong cash flows from Humira into acquisitions and partnering to augment the company's light pipeline.

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#### Overview

#### **Financial Health:**

Over the next five years, AbbVie should generate very strong cash flows driven by Humira sales. After the Humira patent losses in the 2017-2018 time frame, we expect cash flow will fall significantly. However, successful pipeline development should help mitigate the loss of Humira.

#### **Profile:**

AbbVie is a pharmacuetical company with a strong exposure to immunology and cardiovascular disease. The company's top drug, Humira, represents over half of the firm's profits. The company was spun off from Abbott in early 2013.

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