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AbbVie's Outlook Highly Dependent on Well-Positioned Humira

MORNINGSTAR By Damien Conover, CFA | Morningstar – Fri, Dec 14, 2012 7:00 AM EST

Abbott Laboratories' (ABT) split, planned for early January, will result in a diversified medical product company, which will keep the Abbott name, and a research-based pharmaceutical company, AbbVie. We value AbbVie at $38 per share, suggesting a market capitalization of $60 billion. Accounting for more than 50% of sales and more than 70% of profits, immunology drug Humira represents a key determinant for our narrow economic moat rating and fair value estimate for the pharma firm. The drug's strong efficacy and safe side effect profile should continue to support our 11% five-year projected compound annual growth rate. However, unlike the wide moats of AbbVie's Big Pharma peers, which are supported by diverse and robust product portfolios, one drug precariously represents the majority of AbbVie's profits. Even with new competition to Humira and the generic biosimilar threat starting in 2017, we still believe AbbVie's excess returns are likely to persist for 10 years, but lack the certainty needed for a wide moat rating. AbbVie's other patent-protected drugs, economies of scale, intellectual intangibles, and a powerful salesforce support a narrow moat rating.

Near-Term Humira Growth Positions AbbVie Well Until 2017

We expect Humira will remain a leading drug in immunology disease over the next five years, and we project it will have an 11% five-year compound annual growth rate (slightly above consensus expectations because of our high conviction in the drug's strong efficacy and safety). However, patent losses on several less prominent drugs reduce our five-year total sales CAGR to 5%. We believe earnings should outpace total sales growth thanks to the increasing contribution from Humira, which carries higher margins than the company average. Longer term, the company needs to build a better pipeline to prepare for increased Humira competition after 2016.

Armed with best-in-class Humira, AbbVie is well positioned to drive strong cash flows to support its next generation of pipeline drugs. With AbbVie's next generation of drugs not likely to reach the market until 2015 and several midsize drugs losing patent protection, Humira's cash flows are particularly important. The company also holds a portfolio of hard-to-make drugs that will help supplement Humira's growth.

At more than 50% of total sales and a higher portion of earnings (due to higher-margin revenue), Humira is set to drive the majority of AbbVie's performance over the next five years. With approvals in rheumatoid arthritis, 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 multi-billion-dollar opportunities. Furthermore, with leading efficacy and a favorable side effect profile, Humira should continue to post double-digit growth over the next couple of years, in our view.

Despite a strong near-term outlook for Humira, uncertainty around encroaching competition is likely to weigh on investor sentiment toward the company. In particular, Pfizer's new RA drug Xeljanz represents a key new competitor, as it offers patients efficacy potentially as good as Humira in an oral form (in contrast to the twice-monthly Humira injections). However, Xeljanz'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 are likely to reach the market over the next three years.

Humira's biologic composition may deter generic competition following the late 2016 patent loss in the United States 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 constitute sales outside 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 because of manufacturing complexities have been able to retain a significant portion of sales.

AbbVie's pipeline is weighted heavily toward 2015 launches, with its hepatitis C drugs the crown jewel in the pipeline. While AbbVie holds other pipeline drugs, its 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.

Humira's Strength Drives AbbVie's Narrow Moat

We believe AbbVie has a narrow moat based on patent-protected drugs, economies of scale, intellectual intangibles, and a powerful salesforce. As is the case for most drug firms, the core of AbbVie's moat lies in its portfolio of patent-protected drugs. However, unlike Big Pharma peers, which tend to carry wide moats, one drug represents the majority of AbbVie's sales (50%) and profits (greater than 70%). As a result of emerging branded competition to Humira in the immediate term and a potential generic biosimilar threat in 2017-18, we believe excess returns are likely to persist for 10 years, but we cannot be highly certain of this outlook, which would be needed for a wide moat rating. Further supporting our narrow moat rating, AbbVie holds a relatively weak pipeline with a high concentration of new drugs in the very competitive hepatitis C market. A stronger pipeline and a more diverse product lineup would be needed for a wide moat rating.

Nevertheless, AbbVie derives enormous cash flows from its current product portfolio to fund ongoing discovery and development of the next generation of drugs. The large cash flows create an economy of scale that enables AbbVie to fund the average $800 million required for a new drug. While not as strong as other Big Pharma firms, AbbVie's research and development has created a database of intellectual insights that should help increase the odds of successful drug development. Finally, an entrenched salesforce in one of the most sought-after therapeutic areas of immunology should help the firm launch its next generation of drugs and make AbbVie a leading candidate for smaller drug firms needing help to develop and commercialize innovative new drugs.

Several competitive threats are targeting Humira. New branded drugs are launching in all of Humira key therapeutic areas, including RA, psoriasis, and Crohn's disease. We don't expect Humira will lose a high degree of market share to these new drugs; slow market erosion over the longer term is more likely. Also, while the 2017-18 Humira patent losses are likely to bring new competitive threats from generic manufacturers, the damage should be partly mitigated by the biologic complexity of manufacturing and marketing a generic version of the drug. AbbVie also faces several near-term minor patent losses from its cardiovascular product line, which should weigh on returns through 2014. Exacerbating its exposure to patent losses, without a strong late-stage pipeline, AbbVie lacks the products needed to replace increasing branded and generic competition. Additionally, major industry headwinds have created roadblocks to creating the next generation of drugs. In particular, the Food and Drug Administration has grown increasingly risk-sensitive, approving only very safe drugs or drugs in highly needed areas like cancer. Insurance companies are reducing coverage for follow-on drugs, forcing pharma firms to push for true innovation and reducing the power of their distribution networks. Lastly, governments around the world are evaluating comparative effectiveness programs and more aggressive price negotiations, raising the bar for future innovation.

Humira Drives Our Fair Value Estimate

Accounting for more than half of AbbVie's projected 2012 sales, Humira is the key driver of our valuation and outlook for the firm. We believe its 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. 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 negative 4%. 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. We use an 8% weighted average cost of capital that combines a 10% cost of equity and market rates for the cost of debt.

Scenario Analysis Shows Wide Swings in Valuation

We believe Humira's sales trajectory following the drug patent losses in 2017-18 represents the biggest unknown facing AbbVie. In our base case, we estimate approximately 20% annual Humira declines due to increasing generic competition and new branded competition emerging and gaining traction.

In our bear case, we assume 50% annual Humira declines starting in 2018, based on strong generic and branded competition. In this scenario, our fair value estimate drops to $16 as Humira's high margins have an amplified impact on the bottom line. Conversely, in our best case, we assume generic and branded competition fail to materially take market share from Humira. Under this case, we project 2% annual Humira growth in 2018, which results in a $49 fair value estimate.

Relatively Green Management Team Needs to Build a Better Pipeline

We believe AbbVie's management team has standard stewardship, as the key leaders haven't had much of a 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 high degree of exposure the company has on Humira. Under Abbott's umbrella, AbbVie didn't create enough pipeline products internally or through acquisitions to create the wide moat that many of AbbVie's 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 more than 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 its light pipeline.

Strong Financial Position Supports Robust Dividend

Following the split from Abbott, AbbVie will carry approximately $16 billion in debt and $7 billion in cash. With cash flows from operations close to $6 billion annually, AbbVie shouldn't have any problem servicing its interest expenses. However, we also don't expect AbbVie will pay down debt rapidly, as it needs to bulk up its pipeline through acquisitions and partnerships. In addition, we expect AbbVie will probably pay out close to $2.5 billion annually in dividends.

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