AbbVie's outlook depends heavily on a well-positioned Humira and late-stage pipeline drugs.

by Damien Conover

Sector Director

Authors can be reached at Analyst Feedback

Morningstar's Editorial Policies

Analyst Note 04/28/2016

In conjunction with first-quarter results that largely matched our expectations, AbbVie announced the $5.8 billion acquisition of Stemcentrx, but we don't expect any material change in our fair value based on the earnings or the acquisition, and we continue to view the stock as slightly undervalued. Despite our below-consensus view of Humira sales in 2019 ($12 billion versus $17 billion), we believe the stock has already factored in a rapid decline of Humira following the entry of biosimilars likely in 2018. Further, we believe the market is underappreciating AbbVie's growing pipeline. The acquisition of Stemcentrx doesn't alter our valuation much, but the increasing presence in oncology should bode well for AbbVie's moat, as cancer drugs tend to carry lower hurdles for approval and strong pricing power.

The Stemcentrx acquisition positions AbbVie well in solid tumors, but the price paid seems to account for the majority of the value. Beyond the upfront $5.8 billion price, Stemcentrx can earn payouts up to $4 billion for good clinical data. While limited data is available for Stemcentrx's lead drug Rova-T, phase 1/2 small cell lung cancer data (27 patients) showed a strong 44% response rate in second and third line DLL3 expressing patients, where limited treatment options exist. We assume AbbVie has seen updated data that will be presented at the Best of ASCO (American Society of Oncology) in early June. With over 60,000 small cell cancer patients expressing DLL3, the drug's market potential is over $2 billion in this indication, if follow up data is supportive.

Morningstar's

Analyst

Price 05-20-2016
59.69 USD

Consider Buy
45.5 USD

Stewardship Rating
Standard

Bulls Say

- AbbVie supports a should act as valu the dividend are v
- We believe Humir drugs for RA, Croh the drug will conti
- The new competit antibodies will not initially as safety a the drugs requires

Bears Say

- Several of AbbVie other drug compa new drugs.
- The side effects e weigh on the com market.
- AbbVie's pipeline the eventual sales patent loss.

In the quarter, strong Humira sales helped offset disappointing hepatitis C sales, a dynamic that will likely continue through the year. Humira continues to gain in both volume and price. However, the competitive entry from Merck's hepatitis C drug Zepatier will likely put further pressure on AbbVie's hepatitis C franchise until the next-generation drug ABT-493/ABT-530 reaches the market in late 2017.

Competitors ABBV

Name
AbbVie Inc
Johnson & Johnson
Pfizer Inc
Novartis AG ADR
Novartis AG
Merck & Co Inc

Investment Thesis 10/22/2015

Armed with a 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. 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 three years. With approvals in rheumatoid arthritis, psoriasis, and Crohn's disease, Humira should continue to grow in these markets as penetration rates are below 25% on average. 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, new JAK inhibitors and IL-17 antibodies represent major drug advancements in rheumatoid arthritis and psoriasis, which will likely lead to some market share losses for Humira. Also, while 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, we model above 20% annual revenue declines for Humira by 2019.

Beyond Humira, cancer drug Imbruvica is poised to become the next biggest sales contributor. Imbruvica's strong clinical data in several forms of blood cancer should lead to peak sales above $6 billion. AbbVie's remaining drugs are largely mature with patent expirations long past, but have manufacturing or specific dosing complexities which make generic competition less likely.

Looking ahead, AbbVie's pipeline is weighted heavily toward new cancer drugs. In particular, AbbVie's pipeline should lead to an increasingly strong position in blood cancer. The company should be able to leverage its solid entrenchment with Imbruvica to launch the new drugs.

Economic Moat 10/22/2015

We believe AbbVie supports a narrow moat based on patent-protected drugs, 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 AbbVie's Big Pharma peers, which tend to carry wide moats, one drug (Humira) represents the majority of AbbVie's sales (more than 50%) and profits (greater than 70%). As a result of both emerging branded competition to

Humira in the immediate term and a potential generic biosimilar threat in the 2017-18 time frame, we believe excess returns are likely to persist for 10 years, but we cannot be as certain of this for our 20-year 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 and cancer markets. 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 R&D has created a database of intellectual insights that should help increase the odds of successful drug development. Finally, AbbVie's 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 the company a leading candidate for smaller drug firms needing help to develop and commercialize innovative new drugs.

Valuation 10/30/2015

We are increasing our AbbVie fair value estimate to $65 from $58. Primarily based on the management’s improving margin outlook, we are increasing our operating margin assumptions, an area where AbbVie likely has considerable flexibility given the high-margin nature of its product portfolio. Also, we are increasing our projections for neurology drug Duodopa and immunology drug ABT-494 based on increased prioritization from AbbVie. However, our $25 billion 2020 total sales projection remains well below management’s guidance of $37 billion, with the primary difference regarding immunology drug Humira. While management is projecting 2020 Humira sales at over $18 billion, we project Humira sales at $8 billion. We anticipate quicker launches of biosimilar versions of Humira after the December 2016 patent loss in the U.S. However, AbbVie believes other less-powerful patents will keep biosimilars off the market much longer. Helping offset the likely eventual Humira sales declines, cancer drug Imbruvica holds strong blockbuster potential in blood cancers. Also, the company has several other late-stage cancer drugs that should further help mitigate the eventual Humira sales declines. On the bottom line, over the next five years we expect improving margins, largely driven by the higher contribution to total sales by Humira and new cancer drugs, which carry very high margins. For the weighted average cost of capital, we use a 7.5% cost of equity and market rates for the cost of debt.

Risk 10/22/2015

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 significantly exposed to any new competitive threats to Humira.

Management 10/22/2015

We believe AbbVie's management team has demonstrated Standard stewardship, as the key leaders haven't had much of a track record yet. While the failed acquisition attempt for Shire is concerning, we believe the new abrupt U.S. Treasury laws largely caused the acquisition to collapse, somewhat giving management a pass. Nevertheless, the $1.6 billion breakup fee related to the failed Shire deal does show that management didn't gauge the political landscape correctly. Further, the $21 billion Pharmacyclics acquisition appears to be a fair use of capital if Imbruvica reaches our $6 billion peak sales projection.

Turning to management specifically, 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, but execution has been going well under his leadership. 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 the company's light pipeline.

Overview

Profile:

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