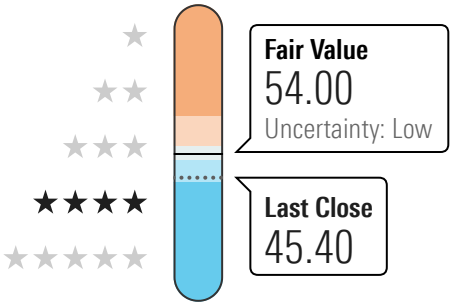
Roche Holding AG ADR RHHBY ★★★★

Rating as of Jul 20, 2020

Morningstar's Analysis

Valuation Jun 01, 2020
Currency in USD

RHHBY is Undervalued at a 16% Discount.



1-Star Price
> 67.50

Economic Moat
Wide
Trend: Stable

5-Star Price
< 43.20

Stewardship
Standard

Annual Pipeline Review of Leading Big Pharma and Biotech Supports Moats

Damien Conover
Sector Director

Analyst Note | by Damien Conover Updated Jul 10, 2020

Most Big Pharma and Big Biotech stocks in our coverage support wide economic moats as a result of their ability to generate new drugs to replace mature ones losing patent protection. Innovation is the central building block for the strong economic moats in the drug and biotechnology industry, supporting drug pricing power and launch trajectories. However, following patent expirations, drug sales fall significantly, making the continuous cycle of new drugs essential to the moats in the industry. In looking at the leading large-cap U.S. and European drug and biotech industries, we expect steady innovation to drive 5% annual sales growth over the next five years, similar to consensus expectations. Overlaying our growth analysis with valuation, we see underappreciated areas: Roche's Tecentriq in several cancer niches; Bristol-Myers Squibb's steady position in immuno-oncology and massive pipeline and cash flow support from Celgene; Merck's oncology portfolio and vaccine and animal health cash flows; and Pfizer's new immunology drugs and strong vaccine positioning.

Business Strategy and Outlook | by Karen Andersen Updated Dec 17, 2019

We think Roche's drug portfolio and industry-leading diagnostics conspire to create sustainable competitive advantages. As the market

leader in both biotech and diagnostics, this Swiss healthcare giant is in a unique position to guide global health care into a safer, more personalized, and more cost-effective endeavor. Strong information sharing continues between Genentech and Roche researchers, boosting research and development productivity and personalized medicine offerings that take advantage of Roche's diagnostic arm.

Roche's biologics focus and innovative pipeline are key to the firm's ability to maintain its wide moat and continue to achieve growth as current blockbusters face competition. More than 80% of Roche's pharmaceutical sales are from biologics, which provides a buffer against traditional generic competition. Blockbuster cancer biologics Avastin, Rituxan, and Herceptin accounted for 36% of Roche's revenue in 2018, but all three are under threat from biosimilars in the U.S. and Europe (although growth in China remains strong). However, with the launch of Perjeta in 2012 and Kadcyla in 2013, Roche is in a strong position to continue expanding its breast cancer franchise beyond Herceptin, regardless of biosimilars. Gazyva, now approved in CLL and NHL and in testing in lupus, will also extend the longevity of the Rituxan franchise. Avastin's lung cancer sales are vulnerable to biosimilars and competition from new therapies Opdivo and Keytruda, but Roche's own immuno-oncology drug Tecentriq launched in 2016. Roche is also expanding outside of oncology with MS drug Ocrevus ($9 billion peak sales) and hemophilia drug Hemlibra ($6 billion peak sales) launching strongly.

Roche's diagnostics business is also strong. With a 20% share of the global in vitro diagnostics market, Roche holds the number-one rank in this industry over competitors Siemens, Abbott, and Ortho. Pricing pressure has been intense in the diabetes-care market, but new instruments and immunoassays have buoyed the core professional diagnostics segment.

Economic Moat | by Karen Andersen Updated Dec 17, 2019

Roche's wide moat arises from its status as the leader in oncology therapeutics (30% market share) as well as in vitro diagnostics (20% share), and the firm has a promising strategy of combining its expertise in both areas to generate a growing personalized medicine pipeline, making use of companion diagnostics. Much of Roche's moat in

pharmaceuticals is derived from its long relationship with Genentech. Roche first acquired a controlling interest in Genentech in 1990 and owned almost 56% of the firm before Genentech's board accepted its $95 per share offer to acquire a full interest in 2009. Genentech's portfolio of blockbuster cancer biologics--which includes Avastin, Rituxan, and Herceptin--continues to grow. Genentech's commercial structure in the United States complemented Roche's international operations, and Roche also secured rights to Genentech's pipeline in the process, as its option to in-license drug candidates from Genentech was set to expire in 2015.

Roche's Herceptin was one of the original personalized therapies, and breast and gastric cancer patients who are HER2+ continue to see strong survival benefits from this antibody therapy. Since then, Roche has established a record of developing and launching personalized medicine therapies and companion diagnostics in oncology, including Tarceva in EGFR-mutant patients, Kadcyla and Perjeta for HER2+ patients, and melanoma drug Zelboraf for BRAF mutation patients. Zelboraf was the first product developed using a companion diagnostic from the start of clinical trials, and pairing drugs with diagnostics early in development shortens development timelines, reduces up-front investment, and boosts the likelihood of a meaningful benefit to patients. We think this will allow Roche to justify high price tags globally for future personalized therapies despite global pricing pressure and budget constraints.

Roughly 80% of Roche's pharmaceutical sales are from biologics, which we believe insulates the firm from rapid erosion of blockbuster drugs, even after patents expire. Biosimilars (follow-on versions of branded biologics) are associated with significantly higher costs of manufacturing, clinical trials, and marketing than traditional small-molecule generics, and therefore we do not expect them to have as dramatic an impact on markets after patents expire. That said, biosimilars have been available for several drugs in Europe for years, and recent Rituxan and Herceptin biosimilar launches initially hit Roche's branded sales by more than 40% in 2018-19. While biosimilars should erode U.S. sales of Avastin, Herceptin, and Rituxan in 2020, we assume more modest declines of roughly 30% initially, given Roche's strong hospital channel presence and only a portion of formularies directing patients to biosimilars. Overall, we expect Roche's oncology

sales could prove difficult to erode, given the firm's multiple blockbuster therapies and strategies to improve its drugs incrementally (more convenient subcutaneous versions) and more meaningfully (Perjeta and Gazyva's superior efficacy).

Fair Value and Profit Drivers | by Karen Andersen Updated Jun 02, 2020

We're raising our fair value estimate to $54 per share from $52 following details surrounding strong combination treatment data for Tecentrig and tiragolumab in PDL1-high non-small cell lung cancer and Tecentriq's approval in liver cancer. We now see Tecentriq sales surpassing CHF 11 billion in 2024 (up from CHF 9 billion), although our assumed sales for tiragolumab remain at more than CHF 3 billion, if approved, by 2029.

In terms of pandemic effects, Actemra and molecular diagnostics sales are benefiting, but Ocrevus treatment delays could weigh on results in the second quarter. We're maintaining estimates for drugs that could see relative benefits to competitors due to coronavirus, like Polivy (versus CAR-T) and Hemlibra (versus infused drugs). However, we still assume headwinds on 2020 sales for most of Roche's cancer drugs and ophthalmology drug Lucentis, as older patients delay treatment to avoid exposure to the virus. We also expect the second-half launches of new neurology medicines satralizumab and risdiplam to be delayed into 2021. In diagnostics, Roche can supply 15 million coronavirus tests per month, which should counter some of the pressure on centralized and point-of-care diagnostics (less routine screening) and molecular diagnostics (fewer blood donations).

We think Roche's pharmaceutical division will see a 5% top-line compound annual growth rate through 2024 (at constant currencies). Rituxan biosimilars and new oral competitors in the blood cancer space should be partly countered by Gazyva's superiority to Rituxan in CLL and indolent/maintenance NHL indications. We expect sales of Herceptin, Rituxan, and Avastin to decline from roughly CHF 20 billion in 2019 to CHF 10 billion in 2024 due to biosimilar competition. We expect the core pharmaceutical operating margin to hover in the mid-40s for the remainder of our explicit forecast period. In diagnostics, we see operating margins remaining in the high teens on product mix and efficiency gains.

We assume a 7.4% cost of capital for Roche. We still rate the systematic risk surrounding Roche shares as below average and assume a cost of equity of 7.5%, which we believe aligns our capital cost assumptions with the returns that equity investors are likely to demand over the long run. We assume a 5.5% pretax cost of debt to reflect a more normalized long-term rate environment. We currently use an exchange rate of CHF 0.96/$1.

Risk and Uncertainty | by Karen Andersen Updated Dec 17, 2019

Roche will continue to rely on innovation and key acquisitions to maintain growth. If monoclonal antibody biosimilars are quickly approved and accepted by insurers, physicians, and patients, Roche could experience top-line pressure as key products Rituxan, Avastin, and Herceptin succumb to competition. Blockbuster eye disease drug Lucentis is witnessing competition from Regeneron's Eylea, and Novartis' Beovu. Roche has had several high-profile pipeline failures in recent years--including Alzheimer's drug crenezumab, eye disease drug lampalizumab, diabetes candidates taspoglutide and aleglitazar, cholesterol drug dalcetrapib, and schizophrenia drug bitopertin--and it may continue to struggle to diversify outside its strong foundation in cancer biologics. Slightly more than 50% of Roche's U.S. sales are government paid, as its oncology antibodies are most often paid for through Medicare Part B. We have seen recent proposals for lowering reimbursement further for Part B drugs (lower reimbursement for 340B sales went into effect in 2018), and we think some of Roche's high-priced cancer therapies could be vulnerable to pricing pressure in the U.S. in the long run through private payers as well, as competition increases.

Stewardship | by Karen Andersen Updated Jun 02, 2020

Although we think Roche's governance has been good, vague compensation standards and a separate class of voting shares prevent the firm from surpassing a Standard stewardship rating. Franz Humer stepped down from his position as CEO in 2008 after 10 years in the top spot; Lufthansa CEO and Roche board member Christoph Franz replaced Humer as board chairman in 2014. Current CEO Severin Schwan--former head of the firm's diagnostics unit--has been instrumental in the acquisitions of Ventana and Genentech. We think Schwan has done an

excellent job of juggling the often competing demands of investing in the pipeline, paying down debt, and increasing the dividend.

We're pleased to see that Genentech's management continued in leadership roles after the acquisition, but we've seen more attrition since. For example, Genentech CEO and chairman Arthur Levinson was chairman of Genentech's board during the integration process and joined Roche's board of directors in 2010; he stepped down in 2014 due to conflicts of interest with his new age-related disease venture, Calico (former Roche chief medical officer Hal Barron also moved to Calico in 2013). Genentech research and early development remains an autonomous unit within Roche; we think this separation of Genentech's research engine from Roche will continue to help the firm retain top talent. We also think Roche's own discovery and development efforts are beginning to improve, although we note some disruption here as John Reed's five-year tenure leading this group ended in April 2018, and William Pao (head of oncology discovery and translation) took his place. However, Roche's nonvoting shares--the vast majority of shares available on the market--don't offer investors a say in how the firm is run. A shareholder group with pooled voting rights owns 45% of voting shares, and Novartis owns 33% of voting shares.

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