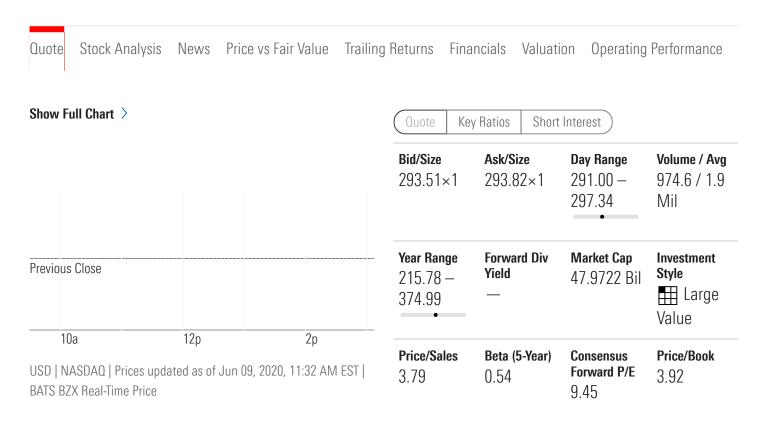
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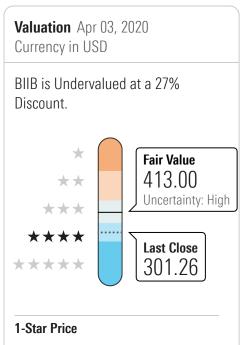
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# Biogen Inc BIIB ★★★★

Rating as of Jun 8, 2020







Maintaining Our Biogen Fair Value Estimate and Assumed 40% Probability of 2021 Aducanumab Launch

## Karen Andersen

Sector Strategist

Analyst Note | by Karen Andersen Updated Apr 22, 2020

We're maintaining our \$413 fair value estimate for Biogen following strong first-quarter results, despite our expectation for sales pressure later in the year as well as delays in the FDA filing for Alzheimer's disease drug candidate aducanumab (pushed back from early 2020 to third-quarter 2020). Biogen saw 1% top-line growth to more than \$3.5 billion in the first quarter, but excluding a headwind from other revenue (weak comparisons due to a large hemophilia inventory sale in the first

> 640.15

Economic Moat
Wide
Trend: Stable

5-Star Price
< 247.80

Stewardship
Standard

guarter of 2019), Biogen saw 8% product sales growth driven by 9% growth in the firm's multiple sclerosis (MS) franchise (3% patient growth), 9% sales growth of spinal muscular atrophy drug Spinraza, and 25% growth in biosimilar sales in Europe. The pandemic appears to have accelerated some sales into the first quarter, benefiting sales of some MS therapies (particularly in Europe) and slightly benefiting Spinraza. We continue to model sales declines for the full year as a result of delayed use of MS treatments like Tysabri and Ocrevus, some delays in treatment with Spinraza, and biosimilar competition for oncology therapy Rituxan. Unlike Biogen's interferon therapies and Tecfidera for MS, all of these therapic or hospital to receive treatment, although trying to facilitate home infusions of Analyst Note eventually be infused at home, in the Business Strategy and Outlook trial delays (including stroke drug BIII **Economic Moat** administration), Biogen expects to se remaining near-term readouts by the Fair Value and Profit Drivers prior guidance. Overall, despite coror Risk and Uncertainty and a delay for aducanumab, we con Stewardship portfolio supporting a wide economic Close Full Analysis undervalued.

Business Strategy and Outlook | by Karen Andersen Updated Feb 05, 2020

We think Biogen's specialty-market-focused drug portfolio and novel, neurology-focused pipeline create a wide economic moat.

Biogen's strategy has its roots in the 2003 merger of Biogen (multiple sclerosis drug Avonex) and Idec (cancer drug Rituxan). Rituxan's market penetration is high, and patents in the United States (where Biogen derives its profit share from Roche) expired in 2018, leading to biosimilar approvals in the U.S. in late 2019. While this pressures Biogen's profit share, subcutaneous Rituxan as well as novel antibody Gazyva will allow for extended oncology revenue.

In MS, Avonex and longer-acting Plegridy generate \$2 billion in annual sales and remain the leading MS interferon drugs. Biogen also acquired full rights to MS antibody Tysabri (more than \$1.5 billion in annual sales) from partner Elan. Oral MS drug Tecfidera (\$4 billion annually) had a strong launch and continues to show solid safety and efficacy

data. While a recent patent ruling validates formulation patents through 2028 in the U.S., the ability of Biogen's new oral drug Vumerity to improve GI tolerability should only partly offset headwinds from increased competition in the MS market. While pricing power and demand for Biogen's injectable MS portfolio are eroding in the face of new competition, Biogen receives substantial royalties on the biggest new competitor, Roche's Ocrevus, which helps offset pressure on older MS drugs.

Outside of MS, Biogen has strong human genetic validation for its neurology pipeline. Spinal muscular atrophy drug Spinraza (partnered with Ionis) is a \$2 billion franchise, although competition from Novartis (gene therapy Zolgensma approved in May 2019) and Roche (oral drug risdiplam) could begin to erode Spinraza sales. Aducanumab has the largest potential, and could launch as the first disease-modifying Alzheimer's therapy by late 2020. While there is significant uncertainty surrounding the potential approval of aducanumab, we think the market also underestimates Biogen's remaining pipeline, which includes a continuing partnership with Ionis and drug candidates to treat conditions including stroke, Parkinson's, pain, and ALS.

## Economic Moat | by Karen Andersen Updated Feb 05, 2020

Biogen has achieved strong profitability based on its Roche collaboration in oncology and Biogen's diversified MS franchise. We think barriers to entry are high for potential biosimilars to Biogen's products, and Biogen has a strong R&D strategy for maintaining its leadership in MS and neurodegenerative diseases, where pricing power is strong, patient need for novel therapies is high, and Biogen has been building a solid pipeline. These factors contribute to the firm's wide moat. Returns on invested capital, which we think will average in the high teens during our 10-year explicit forecast period, easily exceed our 7.3% estimate of Biogen's cost of capital.

Biogen's profit share with Roche is poised to see growth, boosting Biogen's margins, despite biosimilar pressure. Rituxan remains the standard of care in several forms of hematological cancer. While the profit share on Rituxan should erode with U.S. biosimilar competition in 2020, Gazyva's superior data in leukemia and certain forms of lymphoma, as well as potential in lupus, should help counter this threat

to the profit share. In addition, Biogen receives substantial (more than 20%) royalties on Roche's MS therapy Ocrevus in the U.S., and we now model peak sales of roughly \$9 billion (\$7 billion in the U.S.) for this dominant therapy.

Turning to Biogen's own MS franchise, Avonex is the leading interferon therapy in MS because of its long-term safety record and relatively convenient once-weekly injections, and Plegridy improves convenience to twice-monthly injections. Biogen's Tysabri continues to achieve blockbuster sales based on outstanding efficacy despite rare but serious side effects, and we think efforts to target the drug to patients least likely to experience side effects will allow the firm to see continued sales despite novel products with cleaner safety profiles. Oral MS drug Tecfidera had a strong launch and continues to show solid safety and efficacy data, and the drug appears to have emerged from patent litigation risks with protection through 2028 in the U.S. The ability of Biogen's new oral drug Vumerity to improve GI tolerability should partly offset headwinds from competition, but we still assume Biogen's total oral MS drug sales will decline by 20% by 2024.

With the exception of Tecfidera, all of Biogen's current blockbusters are biologics. Biosimilar competition is a looming threat, but we think the significant manufacturing and development costs that biosimilar makers are expected to incur would slow any erosion of sales of these products, limiting the number of contenders and their ability to compete on price. Data quality may also be an issue with biosimilars; the first application for an Avonex biosimilar was rejected based on insufficient efficacy, and we don't have any MS biosimilars on our radar. In oncology, delays and discontinuations with Rituxan biosimilars pushed the European launch to 2017, and U.S. launches began in late 2019. Tysabri is likely to be a lower-priority target for biosimilar entrants, given the risk monitoring and potentially serious side effects in certain patients.

Fair Value and Profit Drivers | by Karen Andersen Updated Apr 03, 2020 We're lowering our Biogen fair value estimate to \$413 from \$421 affect taking into account coronavirus-related treatment delays for hospital administered therapies (Spinraza) as well as delays to clinical trials for its novel neurology-focused pipeline. While several studies expected to read out in 2020 could still be on track (Parkinson's, MS, and

ophthalmology gene therapy among them), ALS and stroke trials that were expected to have data in 2021 could be delayed by several months. Overall, this lowers our 2020 sales estimate by \$400 million (3% of sales). However, with aducanumab FDA filing expected any day now, we don't think a potential aducanumab launch in late 2020 or early 2021 is at risk for a significant delay at this point. Also, most of Biogen's MS therapies, like oral Tecfidera or injectable Avonex/Plegridy, are delivered to the home and should not see disruptions. We also think delays for neurology infusion center therapies could be less pronounced (Tysabri and Ocrevus are both infused).

We think combined global sales of Avonex and Plegridy will continue to fall, with high-single-digit declines annually because of new competition. We expect Tysabri to stay relatively flat around \$1.9 billion annually. We include Ocrevus sales hitting nearly \$7 billion by 2023. We assume generic Tecfidera in the U.S. in 2028, with some offset to total fumarate revenue from the launch of Vumerity in 2019.

In Alzheimer's, we assume a 40% probability of approval for aducanumab in late 2020. This amounts to nearly \$3 billion in probability-adjusted sales by 2028 for aducanumab. We do not include Alzheimer's related sales for Biogen's tau pipeline.

For Spinraza (nusinersen), we assume sales begin to decline in 2020 as new patients and treated Spinraza patients could opt for either competing gene therapy (Novartis' Zolgensma) or small-molecule therapy (Roche/PTC's risdiplam), and as fewer patients initiate therapy (the first year of therapy is twice as expensive).

Overall, we think Biogen's top line will growing 2% annually through 2024, with 1% bottom-line growth. We include a placeholder for future litigation risk at roughly 1% of non-GAAP net income going forward (medium level relative to the rest of the branded drug industry).

We still rate the systematic risk surrounding Biogen shares as below average, and we use a 7.5% cost of equity assumption to align our capital cost assumptions with the returns that equity investors are likely to demand over the long run.

Risk and Uncertainty | by Karen Andersen Updated Feb 05, 2020

Biogen's profitability depends on four key blockbusters and a high-risk but potentially high-reward pipeline. If physicians and payers fail to support Gazyva use over Rituxan despite strong superiority data in leukemia and a large lymphoma setting, Biogen and Roche could be vulnerable to competition from cheaper, biosimilar Rituxan in 2020 in the U.S., and revenue from the Roche collaboration feeds directly to the bottom line and boosts Biogen's margins. While Plegridy is likely to help Biogen maintain its lead in the interferon market, we expect generic Copaxone to weigh on sales of injectable MS therapies. Biogen's MS portfolio has enjoyed tremendous pricing power in the United States, and insurers could begin to find ways to put pressure on future price increases as more competitors reach the market (Avonex and Plegridy were excluded from the CVS national formulary in 2016-17). Tecfidera's U.S. sales are seeing slower growth, partly due to concerns about cases of PML and gastrointestinal issues, and other oral drugs (Celgene's ozanimod) are poised to enter the market. Mixed results for Alzheimer's therapy aducanumab in phase 3 trials also demonstrates the high-risk nature of some of Biogen's chosen areas of focus within neurology.

### Stewardship | by Karen Andersen Updated Oct 22, 2019

We award Biogen a Standard stewardship rating. George Scangos took over as CEO in July 2010 from longtime Biogen executive James C. Mullen, after serving as CEO of development-stage biotech Exelixis for 14 years and previously spending 10 years at Bayer. Scangos helped refocus the pipeline on neurodegenerative diseases and neurologyrelated indications, building a strong team in neurology drug discovery and emphasizing small, tuck-in acquisitions. Significant recent management turnover (chief commercial officer Tony Kingsley and R&D chief Doug Williams both left in 2015, and Scangos departed at the beginning of 2017) and the decision to spin off the firm's hemophilia franchise led to speculation that the firm was for sale. Despite the turnover, chief medical officer Alfred Sandrock has decades of experience to support Biogen's pipeline, and his recently added title of executive vice president of R&D (with the departure of Michael Ehlers) is well deserved. Current CEO Michael Vounatsos (previously Biogen's chief commercial officer) had a 20-year career at Merck.

Longtime director William Young stepped down from his role as independent chairman and was replaced by Stelios Papadopoulos

(chairman at Exelixis and Regulus) at Biogen's annual meeting in May 2014. Overall, we see the board as well qualified, diverse, and independent, despite the long tenures of several directors. We applaud Biogen's efforts to emphasize restricted stock and options in compensation packages for top executives, which we believe aligns their interests with shareholders'. However, takeover defenses, such as authorized preferred stock, may work against the interests of shareholders. Complex rights agreements between Biogen and partner Roche are triggered if Biogen is acquired, which could damp the enthusiasm of potential acquirers.

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# **Company Profile**

#### **Business Description**

Biogen and Idec merged in 2003, combining forces to market Biogen's multiple sclerosis drug Avonex and Idec's cancer drug Rituxan. Today, Rituxan and next-generation antibody Gazyva are marketed via a collaboration with Roche. Biogen also markets novel MS drugs Plegridy, Tysabri, Tecfidera, and Vumerity. In Japan, Biogen's MS portfolio is co-promoted by Eisai. Hemophilia therapies Eloctate and Alprolix (partnered with SOBI) were spun off as part of Bioverativ in 2017. Biogen has several drug candidates in phase 3 trials in neurology and neurodegenerative diseases and has launched Spinraza with partner lonis.

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