

## Biogen Inc. (BIIB)

**\$289.94** (As of 08/11/20)

Price Target (6-12 Months): **\$304.00**

Long Term: 6-12 Months

**Zacks Recommendation:**

**Neutral**

(Since: 01/02/19)

Prior Recommendation: Underperform

Short Term: 1-3 Months

**Zacks Rank: (1-5)**

**3-Hold**

Zacks Style Scores:

VGM:A

Value: A

Growth: A

Momentum: C

## Summary

Biogen beat Q2 estimates for earnings and sales. Biogen's efforts to diversify beyond MS to other areas like Alzheimer's are commendable. Biogen regularly in-licenses assets to build its pipeline. Several important data readouts are expected in 2020-2021. Meanwhile, its biosimilars business is expected to drive long-term growth. The approvability of Alzheimer's drug, aducanumab, has improved after FDA granted priority tag to its BLA. However, sales of Tysabri and Spinraza are being hurt due to COVID-19. Tecfidera and Spinraza's competitive environment is getting increasingly challenging. The initial rollout of Vumerity has been slow due to COVID-19 and this coupled with a potential Tecfidera generic entrant in 2020/2021 makes the future of Biogen's MS franchise uncertain. The stock has underperformed its industry this year so

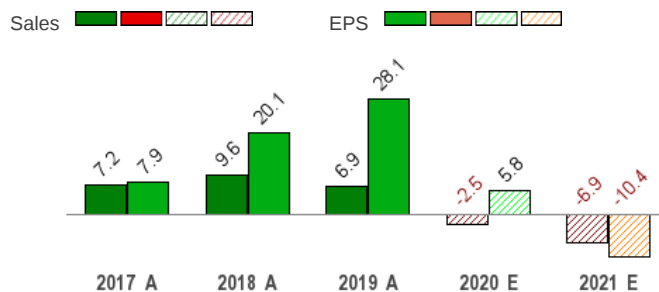
## Price, Consensus & Surprise



## Data Overview

|                            |                                                   |
|----------------------------|---------------------------------------------------|
| 52 Week High-Low           | \$374.99 - \$215.78                               |
| 20 Day Average Volume (sh) | 1,246,647                                         |
| Market Cap                 | \$45.9 B                                          |
| YTD Price Change           | -2.3%                                             |
| Beta                       | 0.56                                              |
| Dividend / Div Yld         | \$0.00 / 0.0%                                     |
| Industry                   | <a href="#">Medical - Biomedical and Genetics</a> |
| Zacks Industry Rank        | Bottom 36% (163 out of 253)                       |

## Sales and EPS Growth Rates (Y/Y %)



|                           |            |
|---------------------------|------------|
| Last EPS Surprise         | 27.8%      |
| Last Sales Surprise       | 7.2%       |
| EPS F1 Est- 4 week change | 7.0%       |
| Expected Report Date      | 10/27/2020 |
| Earnings ESP              | 0.0%       |
| P/E TTM                   | 7.9        |
| P/E F1                    | 8.2        |
| PEG F1                    | 0.6        |
| P/S TTM                   | 3.2        |

## Sales Estimates (millions of \$)

|      | Q1      | Q2      | Q3      | Q4      | Annual*  |
|------|---------|---------|---------|---------|----------|
| 2021 | 3,156 E | 3,125 E | 3,074 E | 3,085 E | 13,059 E |
| 2020 | 3,534 A | 3,682 A | 3,412 E | 3,412 E | 14,022 E |
| 2019 | 3,490 A | 3,617 A | 3,600 A | 3,671 A | 14,378 A |

## EPS Estimates

|      | Q1       | Q2        | Q3       | Q4       | Annual*   |
|------|----------|-----------|----------|----------|-----------|
| 2021 | \$8.01 E | \$7.92 E  | \$7.75 E | \$7.63 E | \$31.83 E |
| 2020 | \$9.14 A | \$10.26 A | \$8.28 E | \$7.76 E | \$35.51 E |
| 2019 | \$6.98 A | \$9.15 A  | \$9.17 A | \$8.34 A | \$33.57 A |

\*Quarterly figures may not add up to annual.

The data in the charts and tables, including the Zacks Consensus EPS and Sales estimates, is as of 08/11/2020. The reports text is as of 08/12/2020.

## Overview

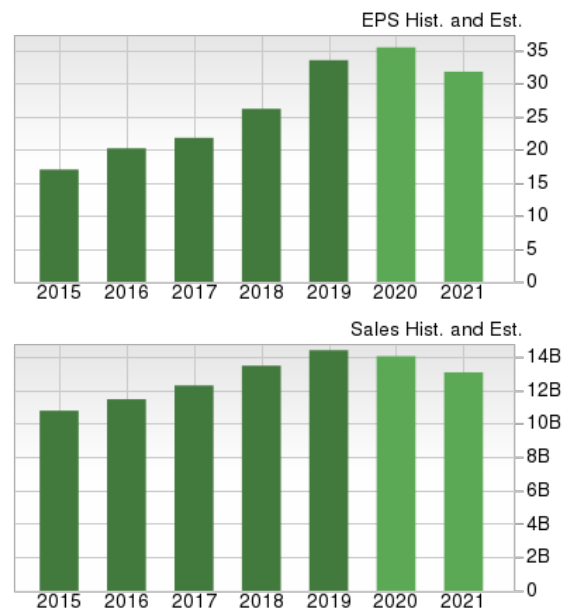
Based in Cambridge, MA, Biogen Inc. is one of the world's leading biotechnology companies, which focuses on developing innovative therapies for treating serious neurological and neurodegenerative diseases, including its core growth areas of multiple sclerosis (MS) and neuroimmunology, Alzheimer's disease (AD) and dementia, movement disorders including Parkinson's disease, neuromuscular disorders, including spinal muscular atrophy (SMA) and amyotrophic lateral sclerosis (ALS) and ophthalmology.

Key multiple sclerosis/MS drugs in its portfolio are Tecfidera, Vumerity, Avonex, Plegridy, Fampyra and Tysabri. Other approved/ marketed products include Fumaderm (severe psoriasis) and Spinraza (spinal muscular atrophy (SMA)). Key MS drugs Tecfidera and Tysabri accounted for around 39% and 16%, respectively, of the company's 2019 product revenues. Spinraza accounted for 18% of Biogen's total product revenues in 2019.

On Feb 1, 2017, Biogen completed the spin-off of its hemophilia business into a new company called Bioverativ. Bioverativ began trading under the ticker symbol "BIVV" on the NASDAQ stock market from Feb 2.

Biogen also generates significant royalties from partnership agreements with other pharmaceutical and biotechnology companies. It has collaborations with companies like Roche (Rituxan and Gazyva – cancer and Ocrevus – PPMS and RMS), Eisai (aducanumab and BAN2401– Alzheimer's disease), Acorda (Fampyra), Alkermes (Vumerity) and Ionis (Spinraza).

Biogen garnered total sales of \$14.4 billion in 2019, up 7% year over year.



## Reasons To Buy:

- ▲ **MS – Key Focus Area:** Biogen holds a strong position in the MS market with a wide range of products including Avonex, Tysabri, Tecfidera and Plegridy. Biogen's MS revenues (including royalties) were \$9.2 billion in 2019, up 2% year over year, almost half of which came from Tecfidera. Tecfidera recorded revenues of \$4.4 billion in 2019 driven by strong global patient growth. Meanwhile, Tysabri, the company's second MS product, continues to contribute significantly to the top line despite carrying a "black box" warning for the risk of progressive multifocal leukoencephalopathy (PML) and other cautionary messages. Biogen recorded Tysabri revenues of around \$1.9 billion in 2019.

Biogen's efforts to diversify beyond MS to other areas like Alzheimer's are commendable. Biogen regularly in-licenses assets to build its pipeline.

Avonex posted sales of \$1.7 billion in 2019. Another MS treatment, Plegridy, launched in 2014, raked in sales of \$436 million in 2019.

Meanwhile, Roche's Ocrevus (ocrelizumab) was approved for the treatment of relapsing MS (RMS) and primary progressive MS (PPMS) in Mar 2017. Though Ocrevus poses strong competition for Biogen's MS drugs, Biogen is receiving royalties on U.S. sales of Ocrevus.

Meanwhile Biogen is working on consolidating its position in the MS market by bringing new treatments to market. In November 2017, Biogen in-licensed worldwide commercialization rights to Alkermes' Vumerity (BIIB098), which the company claims has a potentially differentiated profile to Tecfidera. Vumerity gained FDA's approval for relapsing forms of MS in October 2019 and was launched in the fourth quarter of 2019.

- ▲ **Growth Opportunities beyond MS:** As competition in the MS market intensifies, Biogen is trying to diversify its pipeline and aims to be a leader in neuroscience and the adjacent therapeutic area. In the three years from 2017-2019, Biogen executed 15 business development transactions, which significantly boosted its pipeline.

Biogen is looking to strengthen its Alzheimer's disease (AD) and other neurodegenerative disorders pipeline. The December 2016 FDA approval of Biogen's spinal muscular atrophy (SMA) treatment, Spinraza (nusinersen), consolidated its position in the neurological disease market with the drug being the first and only treatment to be approved in the U.S. for SMA. The market potential of the disease is huge. The drug has performed beyond expectations witnessing strong patient uptake in the United States and internationally and has now become the standard of care in SMA. Biogen has also expanded its collaboration with Ionis to identify new gene therapies for the treatment of SMA as well as a broad range of neurological diseases. In July 2018, Biogen acquired two programs from AliveGen, targeting the myostatin pathway for potential muscle enhancement across a range of neuromuscular diseases including SMA. In early 2019, Biogen signed new collaboration with Skyhawk Therapeutics to develop an oral splicing modulator for multiple diseases, including MS and SMA.

Biogen is also building a portfolio of best-in-class treatments for stroke and acute neurology. In May 2018, Biogen purchased a phase III candidate, BIIB093/Cirara from Remedy Pharmaceuticals, which is being studied for the treatment of large hemispheric infarction (LHI), a severe form of stroke with no available therapy.

The June 2019 acquisition of gene therapy maker Nightstar Therapeutics provided Biogen with two potentially mid-to late-stage clinical assets (BIIB111 and BIIB112) in inherited retinal disease. Meanwhile, Biogen signed a collaboration with Sangamo Therapeutics in 2020 to make gene regulation therapies for a range of neurological indication including Alzheimer's disease.

We believe the company will continue pursuing deals to add late-stage and commercial assets to its portfolio.

- ▲ **Pipeline Diversification:** Biogen plans to strengthen existing efforts in multiple sclerosis and spinal muscular atrophy while continuing to focus R&D efforts in the field of neuroscience. The company also spun off its hemophilia business in February 2017, which allows it to focus on neurology, its key area of expertise.

Promising pipeline candidates include opicinumab (a potential remyelination therapy in MS - phase II), BIIB054 (Parkinson's – phase II), BIIB092/gosuranemab (monoclonal antibody for Alzheimer's – phase II), BIIB104 (cognitive impairment associated with schizophrenia (CIAS)- phase IIb), dapirolizumab pegol (active systemic lupus erythematosus [SLE] - phase IIb; phase III to start in third quarter of 2020), BIIB111 (choroideremia – phase III), BIIB093 (LHI – phase III, brain contusion – phase II), BIIB059 (lupus - phase II), tofersen/BIIB067 (ALS with SOD1 mutations – phase III) and BAN2401 (early Alzheimer's – phase III). By the end of 2021, seven mid- to late-stage data readouts are expected across clinical programs in MS, ALS, ophthalmology, Parkinson's disease, stroke and Alzheimer's disease and others. A regulatory application seeking approval of aducanumab in patients with early-stage Alzheimer's disease was granted priority review by the FDA in August 2020 with a decision expected on March 7, 2021. If aducanumab is approved by the FDA, it will become the first medicine to be approved to reduce the clinical decline associated with Alzheimer's disease, thus opening up a huge market opportunity for Biogen.

- ▲ **Exploring Biosimilar Opportunity:** Biogen is also working with Samsung BioLogics to bring new biosimilars to market. Samsung Bioepis, the joint venture between the two companies, markets three anti-TNF biosimilars in the EU – Flixabi (a biosimilar referencing Remicade), Benepali (a biosimilar referencing Enbrel) and Imraldi (a biosimilar referencing Humira). Biosimilars revenues rose 43% in 2018 and 35% in 2019. Biogen has a 49.9% stake in Samsung Bioepis. In December 2019, Biogen acquired exclusive rights from Samsung Bioepis to commercialize two new potential ophthalmology biosimilars – SB11, a biosimilar of Roche's Lucentis and SB15, a biosimilar to Regeneron's Eylea. Biogen is optimistic that its biosimilars business has the opportunity to potentially double over the next couple of years.

- ▲ **Restructuring Initiative to Drive Cost Savings:** With its focus on streamlining operations and increasing efficiencies, in October 2015, Biogen announced a restructuring program. Under the program, it discontinued several pipeline programs and executed an 11% reduction in its workforce. The restructuring program generated annual cost savings of about \$250 million which were invested in pipeline development and commercial activities. In 2016, Biogen initiated additional cost saving measures that included the realignment of its organizational structure and achieve further targeted cost reductions.

- ▲ **Favorable Debt Profile:** As at the end of Jun 30, 2020, Biogen had approximately \$7.8 billion in long-term debt (senior notes payable + long

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term operating lease liabilities) on its balance sheet. Cash, cash equivalents, and marketable securities totaled approximately \$4.32 billion. Though its cash is lower than its total debt, none of its debt is payable in the next 12 months. Though, its debt to capital ratio of 41 is higher than 28 at the end of March 2020, it is because it issued senior notes worth \$3.0 billion in April 2020. Its debt to capital ratio has improved consistently over a few quarters before 2020.

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## Reasons To Sell:

- ▼ **Shares Underperforming Industry:** Biogen's shares have 2.3% this year so far, comparing unfavorably with an increase of 4.5% for the industry.
- ▼ **Rising Competitive Pressure on MS Drugs:** The competitive landscape remains challenging for Biogen's MS products with newer, competitive entrants. The Ocrevus launch by Roche is adversely impacting MS franchise sales, mainly Tysabri. Moreover, treatments like Novartis' Gilenya and Sanofi's Aubagio pose competitive threat to Tysabri.

Sales of Tysabri and Spinraza are being hurt by COVID-19 in 2020. Competitive pressure is also expected to rise in 2020 in both MS and SMA markets.

Biogen's U.S. Interferon revenues are also experiencing declining trends with patients transitioning to other oral or high efficacy MS therapies with the trend expected to continue in 2020. Global MS revenues, excluding Ocrevus royalties, declined 4% in 2018 and almost 1% in 2019. Volumes of Tecfidera and Tysabri are expected to decline in the United States in 2020.

In February 2020, PTAB ruled in Biogen's favor in its IPR litigation against Mylan on the '514 patent, which covers the treatment of multiple sclerosis with 480mg dose of dimethyl fumarate (DMF), the active ingredient of Tecfidera. While PTAB's February ruling in favor of Biogen removed a short-term overhang, the company still needs to deal with the ongoing district court litigations with generic makers for the '514 patent. In June, a district court of West Virginia invalidated the 514 patent in a lawsuit filed by Mylan. The patent has also been challenged in a Delaware district court. Though Biogen plans to appeal the West Virginia court's decision, if the Delaware court gives a decision similar to the West Virginia court ruling, then a Tecfidera generic could be introduced as early as 2021, much earlier than 2028 when the patent expires.

- ▼ **Competition to Spinraza may Rise in 2020:** Novartis' new SMA treatment, Zolgensma was approved in May 2019 to treat children under two years old, representing about 5% of the prevalent market. Biogen acknowledged that it has begun to see some negative impact of Zolgensma's launch on Spinraza's U.S. sales within the infant population.

Meanwhile, Roche and PTC Therapeutics' regulatory application seeking approval for risdiplam in a broad range of patients with SMA is under priority review with the FDA, which may be approved in mid-2020, and raise competitive pressure on Spinraza.

- ▼ **Safety Concerns of MS Drugs:** We remain concerned that an increase in the number of PML cases associated with the use of Tysabri could lead to a slowdown in Tysabri sales going forward. Additional instances of PML cases could hamper the product's acceptance in the medical community thereby limiting its sales growth.

Since the emergence of the first PML case in a patient on Tecfidera, increased caution is being exercised by physicians and patients. These issues are being faced in the more mature markets of Europe like Germany as well. Additional PML cases would have a negative impact on Tecfidera sales.

In March 2018, Biogen announced the decision to withdraw Zinbryta from the markets, less than two years of its approval, due to growing safety concerns and limited commercial adoption of the drug due to its restrictive label. The company decided to discontinue marketing of the drug on grounds of its complex and evolving benefit/risk profile.

- ▼ **Development and Regulatory Setbacks:** Although Biogen has an impressive pipeline, we remind investors that product development involves a high degree of risk. Among some recent setbacks, in 2016, Biogen discontinued the development of amiselimod, which was being evaluated for the treatment of autoimmune diseases.

In early 2018, Pfizer halted development of Tysabri for acute ischemic stroke (AIS) as Tysabri did not demonstrate improvement in clinical outcomes compared to placebo in a phase IIb study in AIS patients.

In March 2019, Biogen/Eisai announced the discontinuation of ENGAGE and EMERGE phase III studies on aducanumab in early AD as a futility analysis showed that the studies were unlikely to meet their primary endpoints. In October, Biogen revealed plans to pursue U.S. regulatory approval of aducanumab based on positive results of a new analysis of larger dataset, which became available after the discontinuation of the studies. However, the FDA may not approve aducanumab particularly with mixed outcome results across the two studies. Also, the FDA may require additional studies to be conducted.

In September 2019, Biogen and Eisai discontinued two late-stage studies on elenbecestat. The decision was taken following a safety review conducted by the Data Safety Monitoring Board. The board's recommendation to discontinue the studies was due to unfavorable risk-benefit ratio.

## Last Earnings Report

### Biogen Beats on Q2 Earnings & Sales

Biogen reported second-quarter 2020 earnings per share of \$10.26, which comprehensively beat the Zacks Consensus Estimate of \$7.99. Earnings rose 12% year over year driven by higher sales and lower share count.

Sales came in at \$3.68 billion, up 2% from the year-ago quarter. Sales also beat the Zacks Consensus Estimate of \$3.43 billion. Total revenues rose 4% on a sequential basis.

Higher sales of Tecfidera and one-time licensing revenues in the quarter offset lower sales of Tysabri and Spinraza as well as biosimilar products.

Quarter Ending 06/2020

| Report Date      | Jul 22, 2020 |
|------------------|--------------|
| Sales Surprise   | 7.17%        |
| EPS Surprise     | 27.77%       |
| Quarterly EPS    | 10.26        |
| Annual EPS (TTM) | 36.91        |

### Product Sales Rise

Product sales in the quarter were \$2.8 billion, down 3% year over year. Royalties on sales of Roche's Ocrevus were \$208 million in the quarter, up 14% year over year. Revenues from Biogen's share of Rituxan and Gazyva operating profits declined 31% from the year-ago period to \$270 million. Other revenues surged 155% in the quarter to \$408 million due to one-time licensing revenues of \$330 million in the quarter.

Biogen's first-quarter product sales benefited by approximately \$100 million due to accelerated sales as people stocked medicines amid coronavirus-led lockdown, primarily in Europe. Out of this \$75 million was utilized by customers in the second quarter, which hurt sales in the quarter.

### Multiple Sclerosis Revenues

Biogen's MS revenues were \$2.34 billion in the reporter quarter, including Ocrevus royalties, which declined 2% year over year but rose 2% sequentially. MS revenues, excluding Ocrevus royalties, declined 4% year over year.

An increase in channel inventory benefited U.S. MS product revenues by approximately \$10 million in the second quarter against a decrease of approximately \$115 million in the first quarter.

Meanwhile, the number of patients on Biogen's MS products globally increased to 3% versus the prior year. In the quarter, Biogen witnessed increased share of new prescriptions in the United States and stabilized market share in Europe.

Tecfidera sales rose 3% year over year to \$1.18 billion driven by patient growth. Tecfidera global sales were up 8% sequentially. We believe that COVID-19 did not have a significant impact on Tecfidera sales in the second quarter as the majority of Tecfidera prescriptions in the United States are delivered via mail.

Outside U.S. Tecfidera sales declined 4% as demand growth was offset by price declines and currency headwinds.

Vumerity, launched in the United States late in 2019, recorded \$9 million in sales, higher than \$2 million in the previous quarter. The launch uptake of the drug has been slow due to lower new patient starts and switches due to COVID-19 and reduced physician interaction.

Total Fumarates (Tecfidera + Vumerity) revenues were \$1.19 billion in the quarter, up 3% year over year. U.S. Fumarates sales in the quarter were \$921.7 million, up 6% year over year. Ex-U.S. sales were \$268.6 million, up 4.2% year over year.

Tysabri sales declined 9% year over year and 17% sequentially to \$432 million. Tysabri U.S. sales declined 7.6% to \$244.1 million in the quarter due to the impact of COVID-19 given delays in dosing at infusion sites. Tysabri is administered in a hospital setting. This means that hospitals may have delayed Tysabri infusions as they prioritized treatment of COVID-19 patients or patients may have chosen to delay treatment. These factors may continue to hurt Tysabri's sales in the remaining quarters of 2020.

International Tysabri revenues declined 10.9% to \$187.9 million due to currency headwinds and unfavorable channel dynamics.

Combined interferon revenues (Avonex and Plegridy) in the quarter were \$481 million, down 13% year over year. Avonex revenues declined 11% from the year-ago quarter to \$389 million. Plegridy contributed \$93 million to revenues, down 20% year over year.

### Other Products

Sales of Spinraza increased 1% year over year to \$495 million as higher sales in ex-U.S. markets offset lower sales in the United States. Spinraza sales declined 12% sequentially.

Spinraza U.S. sales were \$210.3 million in the quarter, down 8.8% year over year due to dosing delays resulting from COVID-19. In ex-U.S. markets, Spinraza sales rose 23.3% year over year to \$284.3 million.

On the call, the company said that the dosing delays peaked in April and began to normalize in May and June.

The number of patients on Spinraza declined slightly in the United States compared to the first quarter as COVID-19 impacted new patient starts in the quarter. Spinraza's new patient starts and regimen compliance declined in the United States in the second quarter as it is administered in a physician's office. Amid the pandemic situation and government lockdowns, people may have postponed their visits to doctor's office.

Also, in 2020, Spinraza's sales growth rate is expected to moderate from 2019 levels, primarily due to a lower rate of new patient starts as well as the impact of loading dose dynamics as patients transition to dosing once every four months. Lower prices in some international markets may

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also hurt sales.

In the quarter, biosimilars revenues decreased 7% year over year to \$172 million due to the negative impact of COVID-19. Imraldi generated sales of \$45 million in the quarter, down 5% year over year. Benepali recorded sales of \$106 million in the quarter, down 12% year over year. Flixabi sales of \$21 million rose 23% year over.

Research and development (R&D) expenses rose 18% year over year to \$564 million due to \$125 million license fee related to Biogen's collaboration with Sangamo. Selling, general and administrative (SG&A) expenses were flat year over year at \$555 million.

In the quarter, Biogen repurchased approximately 9.0 million shares worth \$2.8 billion. As of Jun 30, approximately \$1.25 billion remained for share buyback under the new \$5 billion plan approved by the board in December 2019.

## 2020 Guidance

Biogen raised its earnings guidance for the year. However, the company slightly lowered its sales expectations due to the impact of COVID-19. Revenues in 2020 are now expected in the range of \$13.8-\$14.2 billion versus \$14-\$14.3 billion expected previously. Earnings per share are now expected between \$34.00 and \$36.00 per share versus \$31.50 and \$33.50 previously.

Adjusted R&D costs are expected to be 16% to 17% of total revenues versus 15% to 16% expected previously. Adjusted SG&A costs are expected in the range of 17.5% to 18.5% of total revenues versus 19.5% to 20.5% guided previously. Adjusted tax rate guidance is 18% to 19%. SG&A costs are expected to increase in the second half of the year as the company prepares for commercial launch of aducanumab.

However, the guidance does not include the impact from the potential entry of generic versions of Tecfidera in the United States in 2020.

## Pipeline Update

Regarding the impact of COVID-19 on pipeline progress, Biogen said that the majority of clinical studies are currently on track or only slightly delayed. Seven mid-to-late stage readouts are expected by the end of 2021.

On the call, the company faced questions about using a priority review voucher (which it received at the time of Spinraza's approval) for aducanumab. However, management declined to comment.

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## Recent News

### FDA Grants Priority Review to Aducanumab BLA – August 7

Biogen and Eisai announced that the FDA has granted priority review to its biologics license application (BLA) seeking approval of aducanumab for Alzheimer's disease.

The priority review status accelerated FDA's review timeline to six months from acceptance of the BLA instead of the standard 10 months. With the FDA granting priority review to the BLA, a decision is expected on Mar 7, 2021. Biogen did not use its priority review voucher (PRV), which was granted at the time of approval of Spinraza. However, the FDA plans to hold an Advisory Committee meeting for the BLA.

The BLA filing includes data from the ENGAGE and EMERGE phase III studies as well as the phase Ib PRIME study in patients with early-stage Alzheimer's disease.

In March 2019, Biogen and Eisai announced the discontinuation of ENGAGE and EMERGE studies as a futility analysis showed that these were unlikely to meet their primary endpoints. In October 2019, surprisingly, Biogen revealed plans to pursue U.S. regulatory approval of aducanumab based on positive results of a new analysis of larger dataset, which became available after the discontinuation of the studies.

The new analysis of the larger dataset showed a different outcome than the one predicted at the time of the futility analysis. The EMERGE study met the primary endpoint, showing that patients treated with a high dose (10mg/kg) of aducanumab experienced a statistically significant reduction in clinical decline of Alzheimer's disease. The ENGAGE study, however, did not meet the primary endpoint. However, Biogen said that data from a subset of patients in the ENGAGE study who received higher dose of aducanumab supported the findings from the EMERGE study. Biogen completed the BLA filing in July.

Biogen has left no stone unturned to resurrect aducanumab because if it is approved by the FDA, it will become the first medicine to be approved to reduce the clinical decline associated with this devastating disease. It will also be the first medicine to show that removing amyloid beta (plaque in the brain) results in better clinical outcomes in Alzheimer's patients. It will bring in huge revenues for Biogen by meaningfully changing the course of Alzheimer's treatment.

### Binding Agreement with Denali to Co-Develop Parkinson's Candidate – August 6

Biogen announced a binding agreement with Denali to co-develop and co-commercialize its small molecule LRRK2 inhibitor program, DNL151, for Parkinson's disease for an upfront payment of \$560 million. DNL151 will enter late-stage clinical studies in 2021. For the LRRK2 inhibitor program, Biogen and Denali will share global development costs on a 60/40 basis. However, in the United States, the profits/losses will be split on a 50/50 basis, if the drug is approved and launched.

Biogen will also receive exclusive option rights to two pre-clinical programs for neurodegenerative diseases leveraging Denali's blood-brain barrier crossing TV technology platform. It will also get a right of first negotiation for two additional TV platform programs.

In addition to the upfront payment Biogen will also make a \$465 million equity investment in Denali. In addition, Denali can earn up to \$1.25 billion in potential milestone payments if the LRRK2 program achieves certain development and commercial milestone

### New CFO – July 21

Biogen announced the appointment of Michael McDonnell as executive vice president and chief financial officer, effective from Aug 15. Prior to joining Biogen, McDonnell served in the same position at IQVIA. He will replace Jeffrey D. Capello who will step down as EVP and CFO.

### To Begin Phase IV Study to Compare Spinraza Versus Zolgensma – July 21

Biogen announced that it plans to initiate a global phase IV study, RESPOND, to evaluate the clinical benefit and safety of Spinraza for treating SMA in infants and children who still have unmet clinical needs following treatment with Novartis' Zolgensma.

Per Biogen's press release, some patients in a long-term study of Zolgensma shifted to treatment with Spinraza. The efficacy will be assessed by change from baseline on motor function measures, additional clinical outcomes and caregiver burden.

Biogen plans to submit the study protocol to regulatory authorities in the coming months and aims to enroll the first patient in the first quarter of 2021.

The two-year, open-label RESPOND study will analyze whether the proven efficacy of Spinraza and its continuous production of SMN protein might also benefit those who were previously on gene therapy.

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## Valuation

Biogen's shares have declined 2.3% in the year-to-date period but up 24.4% over the trailing 12-month period. Stocks in the Zacks sub-industry

are up 4.5%, while those in the sector are up 0.6% in the year-to-date period. Over the past year, stocks in the Zacks sub-industry are up 16.2%, while those in the sector are up 7.3%.

The S&P 500 Index is up 4.2% in the year-to-date period and 15.0% in the past year.

The stock is currently trading at 3.2X trailing 12-month sales per share which compares to 3.43X for the Zacks sub-industry, 3.09 X for the Zacks sector and 3.46X for the S&P 500 Index.

Over the past five years, the stock has traded as high as 7.45X and as low as 2.85X, with a 5-year median of 5.07X. Our Neutral recommendation indicates that the stock will perform in-line with the market. Our \$304.0 price target reflects 3.4X trailing 12-month sales per share.

The table below shows summary valuation data for BIIB

| Valuation Multiples - BIIB |               |       |              |        |         |
|----------------------------|---------------|-------|--------------|--------|---------|
|                            |               | Stock | Sub-Industry | Sector | S&P 500 |
| P/S TTM                    | Current       | 3.2   | 3.43         | 3.09   | 3.46    |
|                            | 5-Year High   | 7.45  | 4.98         | 3.99   | 3.68    |
|                            | 5-Year Low    | 2.85  | 2.24         | 2.29   | 2.43    |
|                            | 5-Year Median | 5.07  | 3.21         | 3.18   | 3.21    |
| P/E F12M                   | Current       | 8.72  | 50.31        | 22.11  | 22.8    |
|                            | 5-Year High   | 18.77 | 66.15        | 23.17  | 22.8    |
|                            | 5-Year Low    | 6.74  | 21.12        | 15.89  | 15.25   |
|                            | 5-Year Median | 12.6  | 37.67        | 18.97  | 17.58   |
| P/B TTM                    | Current       | 4.07  | 2.89         | 4.39   | 4.68    |
|                            | 5-Year High   | 7.28  | 6.01         | 5.07   | 4.68    |
|                            | 5-Year Low    | 2.84  | 2.06         | 2.94   | 2.83    |
|                            | 5-Year Median | 5.04  | 3.87         | 4.3    | 3.74    |

As of 8/10/2020

## Industry Analysis Zacks Industry Rank: Bottom 36% (163 out of 253)



## Top Peers

| Company (Ticker)                           | Rec          | Rank |
|--------------------------------------------|--------------|------|
| Alexion Pharmaceuticals, Inc. (ALXN)       | Neutral      | 3    |
| Amgen Inc. (AMGN)                          | Neutral      | 3    |
| CSL Limited Sponsored ADR (CSLLY)          | Neutral      | 3    |
| Gilead Sciences, Inc. (GILD)               | Neutral      | 3    |
| Regeneron Pharmaceuticals, Inc. (REGN)     | Neutral      | 2    |
| SINO PHARMACEUT (SBMFF)                    | Neutral      | NA   |
| Vertex Pharmaceuticals Incorporated (VRTX) | Neutral      | 3    |
| Illumina, Inc. (ILMN)                      | Underperform | 5    |

| Industry Comparison Industry: Medical - Biomedical And Genetics |           |            |           | Industry Peers |           |         |
|-----------------------------------------------------------------|-----------|------------|-----------|----------------|-----------|---------|
|                                                                 | BIIB      | X Industry | S&P 500   | CSLLY          | GILD      | REGN    |
| Zacks Recommendation (Long Term)                                | Neutral   | -          | -         | Neutral        | Neutral   | Neutral |
| Zacks Rank (Short Term)                                         | 3         | -          | -         | 3              | 3         | 2       |
| VGM Score                                                       | A         | -          | -         | B              | A         | B       |
| Market Cap                                                      | 45.90 B   | 264.55 M   | 23.61 B   | 91.24 B        | 85.38 B   | 65.89 B |
| # of Analysts                                                   | 27        | 3          | 14        | 2              | 13        | 10      |
| Dividend Yield                                                  | 0.00%     | 0.00%      | 1.69%     | 0.82%          | 3.99%     | 0.00%   |
| Value Score                                                     | A         | -          | -         | D              | A         | B       |
| Cash/Price                                                      | 0.09      | 0.22       | 0.07      | NA             | 0.22      | 0.05    |
| EV/EBITDA                                                       | 6.33      | -3.87      | 13.32     | NA             | 11.72     | 23.77   |
| PEG Ratio                                                       | 0.58      | 1.90       | 2.95      | NA             | 2.22      | 1.57    |
| Price/Book (P/B)                                                | 4.07      | 4.09       | 3.22      | 17.33          | 4.71      | 7.27    |
| Price/Cash Flow (P/CF)                                          | 7.50      | 17.42      | 12.79     | 39.67          | 9.33      | 24.73   |
| P/E (F1)                                                        | 8.17      | 26.96      | 22.02     | 40.59          | 9.97      | 21.14   |
| Price/Sales (P/S)                                               | 3.17      | 16.41      | 2.57      | NA             | 3.85      | 8.24    |
| Earnings Yield                                                  | 12.25%    | -13.79%    | 4.29%     | 2.46%          | 10.03%    | 4.73%   |
| Debt/Equity                                                     | 0.69      | 0.01       | 0.77      | NA             | 1.22      | 0.08    |
| Cash Flow (\$/share)                                            | 38.63     | -1.07      | 6.94      | 2.53           | 7.30      | 24.22   |
| Growth Score                                                    | A         | -          | -         | A              | B         | B       |
| Hist. EPS Growth (3-5 yrs)                                      | 17.80%    | 17.80%     | 10.41%    | NA             | -17.61%   | 32.23%  |
| Proj. EPS Growth (F1/F0)                                        | 5.78%     | 14.89%     | -6.51%    | 3.56%          | 2.99%     | 14.86%  |
| Curr. Cash Flow Growth                                          | 9.02%     | 14.86%     | 5.22%     | 13.26%         | -2.57%    | 10.30%  |
| Hist. Cash Flow Growth (3-5 yrs)                                | 11.97%    | 7.73%      | 8.55%     | NA             | -8.08%    | 23.75%  |
| Current Ratio                                                   | 2.46      | 5.68       | 1.34      | NA             | 2.33      | 2.12    |
| Debt/Capital                                                    | 40.98%    | 3.40%      | 44.59%    | NA             | 54.94%    | 7.33%   |
| Net Margin                                                      | 40.91%    | -201.60%   | 10.13%    | NA             | -1.16%    | 37.30%  |
| Return on Equity                                                | 50.10%    | -60.32%    | 14.59%    | NA             | 33.59%    | 26.71%  |
| Sales/Assets                                                    | 0.54      | 0.18       | 0.51      | NA             | 0.38      | 0.54    |
| Proj. Sales Growth (F1/F0)                                      | -2.52%    | 4.64%      | -1.45%    | 7.60%          | 7.90%     | 7.48%   |
| Momentum Score                                                  | C         | -          | -         | D              | A         | A       |
| Daily Price Chg                                                 | -3.44%    | -2.04%     | -0.17%    | 0.55%          | -0.60%    | -1.54%  |
| 1 Week Price Chg                                                | 11.29%    | 3.55%      | 2.30%     | 2.78%          | -0.26%    | -1.88%  |
| 4 Week Price Chg                                                | 3.08%     | 0.00%      | 6.41%     | 2.93%          | -11.78%   | -6.61%  |
| 12 Week Price Chg                                               | -6.50%    | 5.39%      | 15.42%    | 2.66%          | -5.86%    | 7.40%   |
| 52 Week Price Chg                                               | 24.32%    | 11.31%     | 2.88%     | 34.08%         | 5.91%     | 96.44%  |
| 20 Day Average Volume                                           | 1,246,647 | 338,755    | 2,007,486 | 34,034         | 8,457,803 | 651,242 |
| (F1) EPS Est 1 week change                                      | 0.00%     | 0.00%      | 0.00%     | 0.00%          | 0.00%     | 19.93%  |
| (F1) EPS Est 4 week change                                      | 7.01%     | 0.00%      | 1.84%     | 0.20%          | 4.78%     | 19.93%  |
| (F1) EPS Est 12 week change                                     | 7.18%     | 1.10%      | 2.40%     | -0.60%         | 9.88%     | 18.12%  |
| (Q1) EPS Est Mthly Chg                                          | 1.19%     | 0.00%      | 0.72%     | NA             | 15.52%    | 55.81%  |

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## Zacks Stock Rating System

We offer two rating systems that take into account investors' holding horizons: Zacks Rank and Zacks Recommendation. Each provides valuable insights into the future profitability of the stock and can be used separately or in combination with each other depending on your investment style.

### Zacks Recommendation

The Zacks Recommendation aims to predict performance over the next 6 to 12 months. The foundation for the quantitatively determined Zacks Recommendation is trends in the company's estimate revisions and earnings outlook. The Zacks Recommendation is broken down into 3 Levels; Outperform, Neutral and Underperform. Unlike many Wall Street firms, we have an excellent balance between the number of Outperform and Neutral recommendations. Our team of 70 analysts are fully versed in the benefits of earnings estimate revisions and how that is harnessed through the Zacks quantitative rating system. But we have given our analysts the ability to override the Zacks Recommendation for the 1200 stocks that they follow. The reason for the analyst over-rides is that there are often factors such as valuation, industry conditions and management effectiveness that a trained investment professional can spot better than a quantitative model.

### Zacks Rank

The Zacks Rank is our short-term rating system that is most effective over the one- to three-month holding horizon. The underlying driver for the quantitatively-determined Zacks Rank is the same as the Zacks Recommendation, and reflects trends in earnings estimate revisions.

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### Zacks Style Scores

The Zacks Style Score is as a complementary indicator to the Zacks rating system, giving investors a way to focus on the highest rated stocks that best fit their own stock picking preferences.

Academic research has proven that stocks with the best Value, Growth and Momentum characteristics outperform the market. The Zacks Style Scores rate stocks on each of these individual styles and assigns a rating of A, B, C, D and F. We also produce the VGM Score (V for Value, G for Growth and M for Momentum), which combines the weighted average of the individual Style Scores into one score. This is perfectly suited for those who want their stocks to have the best scores across the board.

|                |   |
|----------------|---|
| Value Score    | A |
| Growth Score   | A |
| Momentum Score | C |
| VGM Score      | A |

As an investor, you want to buy stocks with the highest probability of success. That means buying stocks with a Zacks Recommendation of Outperform, which also has a Style Score of an A or a B.

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