Studies in Applied Finance

INVESTMENT THESIS FOR BIOGEN, INC. (NASDAQ: BIIB)

Alex Serafini

Johns Hopkins Institute for Applied Economics, Global Health, and the Study of Business Enterprise
Investment Thesis for Biogen Inc. (NASDAQ: BIIB) by Alex Serafini

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About the Series

The Studies in Applied Finance series is under the direction of Professor Steve H. Hanke (hanke@jhu.edu), Co-director of The Johns Hopkins Institute for Applied Economics, Global Health, and the Study for Business Enterprise, and Dr. Hesam Motlagh (hesammotlagh@gmail.com), a Fellow at the Johns Hopkins Institute for Applied Economics, Global Health, and the Study of Business Enterprise.

This working paper is one in a series on Applied Financial Economics that focuses on company valuations. The authors are mainly students at The Johns Hopkins University and The Johns Hopkins School of Medicine in Baltimore, MD who have conducted their work at the institute as undergraduate and graduate researchers.

About the Author

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Keywords: Financial Modeling, Biogen Inc., Biotech Model, Net Present Value, Monte Carlo Simulation, Investment Thesis, and Management Compensation
Investment Thesis for Biogen Inc. (NASDAQ: BIIB) by Alex Serafini

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<td>$13.83</td>
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*Based on consensus estimates as of market close on 5/4/2017 (Source: Bloomberg Terminal)
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Executive Summary

Biogen Inc. (NASDAQ: BIIB), based out of Cambridge, MA, is a pharmaceutical company focused on neurodegenerative diseases, with its primary portfolio consisting of treatments for multiple sclerosis (this portfolio retains 38% of the world’s multiple sclerosis treatment market share). Over the recent years, Biogen has narrowed its focus to neurodegenerative diseases by spinning off its hemophilia business and investing heavily in Alzheimer’s disease Research and Development (R&D), for which it currently holds the most promising early Alzheimer’s disease phase three clinical trial prospects on the market (ADUCANUMAB and E2609). The company has also taken several measures to cut costs and prepare for future increases in product demand including but not limited to selling unnecessary plants and purchasing new facilities that are fit for manufacturing its pipeline drugs. Lastly, Biogen holds a group of executive officers who have had extensive experience in the medical field and are paid via the “Say on Pay” compensation plan, which is mainly performance based and therefore beneficial to investors.

In order to estimate Biogen’s fundamental value, we analyzed its historical financials and recent SEC filings, including its 2016 10-K and DEF 14A. By utilizing a Probabilistic Discount Cash Flow Model (P-DCF, a model that combines financial statement projections with Monte Carlo simulations), we projected a probability distribution of estimated cash flow per share to determine the fundamental value of Biogen. Our analysis arrived at a share price of $282.09, a 5.02% upside from the current share price, after the use of conservative assumptions. For these reasons, we rate BIIB as a HOLD.

Catalysts and Risks

Research Catalysts

- **ADUCANUMAB**, BiIBs monoclonal antibody against beta amyloid (Aβ) plaques in early-onset Alzheimer’s Disease (eAD), was given the European Medicines Agency’s (EMA) Priority Medicine (PRIME) designation, as well as the U.S. Food and Drug Administration’s (FDA) Fast Track designation, both of which expedite the clinical trial and approval process for this drug (which is currently under the Phase 3 Trials ENGAGE and EMERGE).
- **E2609**, a β-secretase (BACE) inhibitor created in collaboration with Eisai Co. Ltd. entered Phase 3 (in the United States), after promising Phase 2 results demonstrating the prevention of Aβ plaque formation.
- **ADALIMUMAB (SB5)**, a biosimilar referencing HUMIRA in the treatment of various forms of psoriasis (made in collaboration with Samsung Bioepis) had its Market Authorization Application (MAA) submitted to the European Commission (EC) in late 2016. HUMIRA was the highest selling drug in the world in 2016, thus approval of the MAA has significant revenue implications for BIIB.1

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• Multiple drugs currently being tested by Genentech under its anti-CD20 collaboration with BIIB have shown promising clinical results compared to gold standard treatments.

**Operational Catalysts**
- In an effort to centralize BIIB's product focus, it has spun off its hemophilia business as Bioverativ (NASDAQ: BIVV), from which BIIB shareholders have received 1 BIVV share for every 2 BIIB shares. This allows more efficient capital allocation to R&D in BIIB's promising MS and eAD pipelines.
- BIIB has subleased its rights to Brammer Bio MA, LLC, a manufacturing facility in Cambridge, MA, while also letting go of several workers in its restructuring effort (a transaction that resulted in $7.4 million in severance costs). This has allowed for increased capital allocation to plant purchases for its more promising drugs including biosimilars and its eAD drugs.

**Risks**
- Although BIIB's Phase 3 and filed drugs have high promise with regards to commercialization, there is the risk that the final round of clinical trials will result in below-end point results or that adverse effects could be encountered after commercialization, both of which would result in harm to revenues and share price.
- BIIB relies heavily on collaborations and single active ingredient suppliers for most of its drug portfolio, which means BIIB's performance is at risk of third party underperformance.
- BIIB has been subjected to patent infringement litigations, which may lead to large settlement fees and/or large royalty payments. For instance, in 2016 BIIB entered litigation with Forward Pharma which resulted in a $1.25 billion settlement payment to Forward Pharma.
- BIIB's global exposure means that drug regulation, pricing, and distribution vary widely, leading to risks such as fines and product revenue loss.

**Company Description**

**Overview**
Biogen was founded in 1979 by a group of scientists, including Nobel Prize winners Walter Gilbert and Phillip Sharp. The Company was listed on NASDAQ in 1983 after developing leukemia and hepatitis B treatments. In 1996, Biogen began its world-renowned Multiple Sclerosis drug portfolio with AVONEX, an interferon-based treatment for relapsing MS (rMS). In 2003, Biogen and IDEC Pharmaceuticals merged to create Biogen Idec, which listed on NASDAQ as BIIB (although its name returned to Biogen Inc. in 2015). In 2016, Biogen became the first company to treat spinal muscular atrophy (SMA) and spun off its hemophilia assets through a publicly traded company, Bioverativ (NASDAQ: BIVV). The company’s current primary focus is
its MS and SMA portfolio, though it has extended its focus to diseases including psoriasis, eAD, and biosimilars.²

Biogen’s largest competitors by disease-specific drug revenues are:

1. **Multiple Sclerosis**: Novartis (GILENYA & EXTAVIA), Bayer (BETASERON), Teva/Sanofi (COPAXONE), Merck (REBIF)
2. **Biosimilars**:
   a. **Reference Drugs**: AbbVie Inc. (HUMIRA), Amgen (ENBREL), Johnson & Johnson/Merck (REMICADE)
   b. **Other Biosimilars**: Amgen (AMJEVITA – ref. HUMIRA), Pfizer (INFLECTRA – ref. REMICADE), Sandoz (ERELZI – ref. ENBREL)

Biogen is sold on the NASDAQ with a market cap of $56.97 billion and is specifically in the biotech segment. Primary competitors in this segment include Amgen, Gilead, and Celgene. Biogen controls 40.42% of the MS Immunomodulator industry (worth a cumulative $9.8 billion, mostly through their drug TECFIDERA). Furthermore, Biogen has introduced a series of generic/biosimilar drugs that reference Remicade, Enbrel, and Humira. These three drugs cumulatively make up 89.35% of the anti-Tumor Necrosis Factor (a key player in inflammatory responses) industry, a $37.1 billion segment that takes up the majority of the immunosuppressant market (thus, giving Biogen a large target population for its new biosimilars portfolio). Biogen’s strong MS and biosimilars portfolios are further underpinned by its penetration into new disease markets, such as eAD and SMA, for which Biogen’s pipeline/recently approved drugs are the first of their treatment type for the disease or the only treatment for the disease. Ultimately, Biogen’s portfolio and R&D direction make it a strong competitor within the biotech industry.

*Current Business Segments*³

1. **Multiple Sclerosis**

Multiple Sclerosis is a neurological disease in which oligodendrocytes (cells that allow for high speed conduction of electrical impulses in the central nervous system, leading to actions such as movement) are targeted and lesioned due to autoimmunity. This can result in loss of muscle control, paralysis, slowing of cognitive function, and possibly death. The disease presents with progressive or relapse/relapsing-remitting symptoms (refer to Figure 1). BIIB has a wide range of MS-targeting drugs that are sold globally.

**Tecfidera**: *small organic* oral therapy that reduces relapses and brain lesion development, as well as progression of MS.

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**Avonex:** *biologic interferon beta-1a* that reduces relapses and slows disease progression.

**Plegridy:** *biologic peginterferon beta-1a* (pegylation extends the half-life of the drug, reducing the necessary dosing frequency) that reduces relapses.

**Tysabri:** *biologic monoclonal antibody* that reduces relapses and is particularly effective for highly frequent relapse-remitting conditions.

**Zinbryta:** *biologic monoclonal antibody* used for relapsing conditions if two or more MS therapies have failed due to increased risks associated with the drug (made in collaboration with AbbVie Inc.).

**Fampyra:** *small organic* oral therapy that improves walking abilities in MS patients and can be used in conjunction with immunotherapeutic MS drugs (made in collaboration with Acorda Therapeutics, Inc.).

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**Figure 1. The various classifications of MS.** Biogen focuses on the PRMS and RRMS classifications, with the potential to extend drug use to the remaining classifications. Genentech recently gained approval on its MS drug, OCREVUS, which will be used to treat relapsing and primary progressive forms of MS. Although Biogen will receive royalties on OCREVUS revenues, the drug will compete with several of Biogen’s MS portfolio drugs.

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2. **Spinal Muscular Atrophy**

SMA results from motor neuron death in the spinal cord and lower brain stem, leading to progressive muscular degeneration and weakness. The severity of this disease is directly linked to the level of survival motor neuron protein (SMN) a patient has, which can decrease significantly with genetic mutations or loss of the SMN1 gene. The disease presents as three different tiers, with progressively fewer symptoms: Type 1 (little to no SMN and most severe), Type 2, and Type 3 (less severe due to greater amounts of SMN). BiIB currently has the only commercially available SMA treatment, SPINRAZA, which has been designated as an orphan drug and was recently recommended by the European Medicines Agency for broad indication, suggesting future sales outside of the United States.\(^5\)

2017 Q1 Spinraza revenues reached $47 million, which far exceeded analyst expectations, aligning with management’s goal to anchor a large portion of future revenues to this SMA drug.\(^6\) This, along with the company’s efforts to expand health plan coverage and administration sites, present data from its CHERISH, NUUTURE, and ENDEAR trials, and reach out to the community through newborn screening partnerships and free drug administration reflects positively on Biogen’s abilities to increase market penetration and improve prospects for future sales. Biogen has also begun the process of applying for drug approval on the international scene (including Canada, Europe, Japan, and Australia).

**Spinraza**: *anti-sense oligonucleotide therapy* intended to reduce the severity of early- and late-onset spinal muscular atrophy by targeting SMN gene mutations on chromosome 5q, with the goal of increasing the amount of SMN protein within patients (made in collaboration with Ionis).

3. **Biosimilars**

BIIBs biosimilar portfolio is focused on referencing biologic therapies focused on diseases such as psoriasis (various forms, as well as arthritis stemming from this condition), Crohn’s disease, ulcerative colitis, spondylitis, and spondyloarthritis. BENEPALI references ENBREL, while FLIXABI references REMICADE. Biogen’s biosimilar revenue growth of 25% from 2016 Q4 to 2017 Q1 suggests strong future earnings in this branch of the drug portfolio.\(^7\)

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\(^7\) Ibid.
**Benepali**: biosimilar referencing ENBREL that treats diseases including rheumatoid arthritis, psoriatic arthritis, axial spondyloarthritis, and plaque psoriasis, specifically after failed treatment with disease-specific drugs.

**Flixabi**: monoclonal antibody biosimilar referencing REMICADE that treats diseases including rheumatoid arthritis, various forms of Crohn’s disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis, and plaque psoriasis, specifically after failed treatment with disease-specific drugs.

4. **Plaque Psoriasis**

Plaque psoriasis is an inflammatory skin disorder that leads to scaling patches of skin that can be itchy or painful. BIIB currently holds one drug, FUMADERM, in its portfolio for the treatment of this disease.

**Fumaderm**: small organic oral therapy that reduces psoriatic symptoms, specifically after failure of topical treatments.

The revenues from these drugs (net of hemophilia segment and Genentech collaboration revenues) are summarized in Table 1 below, and have shown growth year-over-year for the past five years.
Table 1. BIIB total drug sales (net of hemophilia products and royalty-yielding collaborations). This demonstrates Biogen’s ability to consistently grow its overall, in-house drug sales YOY.


As mentioned before, BIIB is involved in collaborations with other companies, resulting in shared profits and royalties. These revenues are presented in Figure 2 below.
Management has suggested BIIB will rely primarily on its MS portfolio and SMA treatment. However, the diversification of its overall portfolio, along with a strong pipeline for treating eAD suggests that the company is prepared for heightening competition in the MS and SMA markets. Biogen further expanded its Alzheimer’s portfolio by deciding to license a Phase 1 anti-tau antibody from Bristol-Myers Squibb for $300 million in April.¹⁸ BIIBs primary Alzheimer’s disease competitor, Eli Lilly, recently saw its late stage SOLANEZUMAB (a monoclonal antibody targeting soluble Aβ monomers) fail to reach its endpoint in late 2016.⁹ Because ADUCANUMAB targets insoluble plaques and has demonstrated dose-dependent decreases in Aβ plaque concentrations (which SOLANEZUMAB was not able to accomplish), it has the potential to be one of the most effective Alzheimer’s treatments in history.

Historical Performance

In 2016, BIIB totaled $9.82 billion in product revenues, an increase of 6.85% from 2015 (primarily due to its MS portfolio drugs, TECFIDERA and TYSABRI), which resulted in over $4.52 billion in net, operational cash flows per Biogen’s 10-K. BIIB has consistently grown its sales over the last five years, achieving an average a year-over-year (YOY) growth rate of 24.98%. What is most impressive is BIIB’s operational efficiency; the company has an average EBITDA margin on net sales of 46.57%. This high EBITDA margin is largely a result of low and stable cost of sales gross margin (averaging 9.28% of net sales over the last five years).

On the balance sheet, there is a 37.75% increase in goodwill between 2015 and 2016 which can be partially attributed to payments to Fumapharm AG shareholders after its acquisition in 2006 (and its products, FUMADERM and TECFIDERA). Biogen must pay contingent fees to Fumapharm shareholders based on the revenues yielded from these two drugs, the sum of which are directed to the goodwill account on the asset side of Biogen’s balance sheet (based on the accounting standards for business combinations at the time of acquisition). Upon reaching $11.0 billion in cumulative sales from these two drugs by 2016 Q4, Biogen owes $300 million in contingent payments (with $300 million in additional payments for every $1.0 billion in sales if the prior 12 months of sales exceeds $3.0 billion; this contingent contract ends upon reaching $20.0 billion in sales from the Fumapharm AG acquired drugs). Besides the significant leveraging activities of 2015 (discussed in the debt analysis), BIIB has maintained stable financials over the last five years.

Regarding invested capital (working capital and long-term assets), BIIB has a large average yearly growth in working capital of 4.38% (margin on net sales) and a capital expenditures growth averaging 25.83% (margin on net sales). Although this would normally be of concern as it could require high leveraging by the company, management has indicated a preference towards using free cash over direct leveraging for invested capital, which is reflected by its low average interest expense margin on total debt of 0.33% and net debt over enterprise value of 1.40% (although this trend might change soon due to their 2015 $6.0 billion senior unsecured note issuance). The high capital expenditures are a result of restructuring activities that include the recent purchasing of Eisai Co. Ltd.’s RTP, North Carolina factory and the acquisition of land for a new plant in Solothurn, Switzerland.

BIIB had an average long-term asset turnover (Net Sales/Long-term Assets) of 0.85 between 2012 and 2016. Although this is low (and reflects poorly on either the company’s ability to sell products or properly allocate capital) by overall standards, it is important to consider that the abovementioned purchases of property, plant, and equipment will benefit expected increases in future product demand. Furthermore, drug production equipment must abide by the FDA’s current Good Manufacturing Practices (cGMPs), which requires pharmaceutical companies to

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pay a premium for equipment that meets these standards (as well as for maintenance of such facilities).

Regarding debt, BIIB had been able to adequately cover its debt with operation income up until 2014. In 2015, BIIB issued $6.0 billion in senior unsecured notes, leading to a Total Debt:EBITDA ratio that surpassed 1.0x. However, the ratio has since decreased slowly as EBITDA continues to creep upwards while the company’s current maturities and notes payable remain constant (refer to Figure 3).

![Figure 3. Biogen's ability to operationally cover its debt. BIIB has consistently shown an ability to leverage itself in a managable manner, even after a heavy unsecured senior note issuance in 2015. Furthermore, its steadily increasing EBITDA suggests solid operational activities.](image)


A look at Biogen's debt schedule reveals that debt is spread out well over time (refer to Capture 1), suggesting it can be easily refinanced or paid-off by excess cash flows if necessary, with the company reporting over $4.52 billion in net, operational cash flows in 2016 (more than any
principal payment due over the next 30 years). Furthermore, cash and cash equivalents have been increasing steadily over the last 5 years at an average rate of 47.99% YOY. BIIB also entered a five-year, $1.0 billion revolver agreement in 2015, with a consolidated leverage ratio covenant that prevents BIIB from exceeding a debt ratio of 3.5 to 1.

Based on the aforementioned leveraging activities, BIIB has been given the following credit ratings: Moody’s long-term (Baa1) and senior unsecured debt (Baa1) with a negative outlook, and S&P long-term foreign issuer credit (A-) and long-term local issuer credit (A-) with a stable outlook. The negative outlook is most likely attributed with the recent $6.0 billion issuance of senior unsecured notes. However, these ratings indicate that BIIB is still investment grade.

BIIBs current bond yields in both the short- and long-term are slightly below the USD US Health Care BBB+, BBB, BBB- yield curve, suggesting that BIIB bonds are selling at high prices and the public is confident in the company’s ability to pay back debt (refer to Capture 2). This coincides
with positive analyst recommendations regarding the purchase of Biogen’s common stock (refer to Capture 3), which has trended similarly to its peers’ stocks (refer to Capture 4).

Bloomberg Terminal Capture 2. Biogen’s current bond yields. Biogen current bond yields with respect to its peer group (measured through the US Health Care BBB+, BBB. BBB- index, a collection of bonds from biotechnology and pharmaceutical companies of similar credit rating as Biogen). The lower yield suggests investors are confident in Biogen’s ability to pay back debt in the short-term, as the bonds are selling at a premium to the comparison index. In the long-term, investors expect Biogen to pay off its debt as well as its peers.

Source: Bloomberg Terminal (accessed 4/3/17); Command <GC>
Bloomberg Terminal Capture 3. Analyst recommendations and forecasts. Analyst recommendations for BIIB stock appear positive or neutral, with our model’s estimated free cash flows per share being within the analysts’ target price projection range.

Source: Bloomberg Terminal (accessed 4/11/17); Command <ANR>
Comparison to peer stock trends. Biogen’s share price trends very similarly with the NASDAQ Biotech Index (NBI), as well as the iShares NASDAQ Biotechnology ETF (that shadows the performance of several NASDAQ biotech companies as well). This suggests that many factors affecting Biogen’s share price will also affect those of its peers.

Source: Bloomberg Terminal (Accessed 5/4/17); Command <GP>

Model Assumptions
The values used for our P-DCF and Monte Carlo simulations differed based on the current status of individual drugs in order to be as company-specific and as accurate as possible. There are three drug status variations discussed in further detail below: 1) historical drugs, 2) first-year drugs, and 3) pipeline drugs. Regarding values associated with expenses and capital allocation, some values were adjusted to reflect company trends more accurately, such as the removal of certain major, non-recurring expenses. These adjustments were kept in-line by historical model tuning parameters, which comprise of 1) free cash flow return on invested

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capital (FROIC = Free Cash Flow/Invested Capital), 2) potential free cash flow yield (PFCFY = Free Cash Flow/Total Revenues), 3) long term asset turnover (LTAT = Total Revenues/Long-term Assets), and 4) Long-term Assets/Invested Capital. By anchoring our adjustments to the historical maxima, minima, and averages of these metrics, we were able to maintain a more realistic projection of the company’s future.

In accordance with these “guiderails”, the following adjustments were made to the historical values available in the ‘Value Drivers’ tab of the accompanying spreadsheet. Considering PLEGRIDY has only been available on the market for three years, we disregarded the growth from year one to year two (660.67%) and chose the year two to year three growth rate of 42.30% for our historical projections (this approach was taken for TECFIDERA revenues as well). The remaining historical drug revenue growth adjustments comprised of choosing the CAGR instead of the average value over the previous two to five years, as the CAGR values tended to be more conservative. Lastly, our invested capital metrics were adjusted to remain close to the historical model tuning parameters (annual growth in working capital: 0.00%; annual capital expenditures: 15.00% of total revenues).

**Historical Drug Projections**

Within the historical revenue projections, individual drug growth rates (which are based on two- to five-year historical growth, as a percentage of total drug sales) were depreciated in two manners: 1) bi-annually (except for PLEGRIDY, which was depreciated annually to conservatively attenuate its high, early growth) to attain a negative YOY growth rate by the tenth projected year (unless current drug growth is already negative, which resulted in no artificial depreciation) and 2) deduction of a drug’s assumed growth rate by 10% upon expiration of U.S. or E.U. government exclusivity (except for Tysabri, which demonstrated growth despite 2016 expirations in both European and US exclusivity – thus we only reduced growth by 5% for each of these expirations) – refer to Diagram 1. These assumptions reflect the highly competitive pharmaceutical environment, especially after regulatory exclusivity periods end.

![Diagram 1. Historical drug projection approach.](image)
First-Year Drug Projections

Diagram 2. First-year drug projection approach.

This approach is used for drugs in BIIB’s portfolio went on sale in 2016. As there is no historical growth rate in these situations, one can choose to project based on the prevalence or incidence of the disease. The advantage of using incidence rates, as well as first-year patient recruitment data, is that projections are more company-specific and provide a more realistic annual growth rate for the diseased population. Prevalence, on the other hand, gives an estimate of the existing patient population, which assumes that the growth of the disease coincides with the growth of the population and does not provide information regarding new cases per year. First-year patient counts are added back every projected year to reflect the impact of Biogen’s marketing strategies – refer to Diagram 2.
Pipeline Drug Projections

For the sake of simplicity, only pipeline drugs currently in Phase 3 clinical trials or those whose final approval application has been filed were projected. Prevalence was used over incidence in this projection as there is no first-year, company-specific data, requiring an estimate of recruitment from the entire diseased population. Furthermore, a weighted average of the yearly revenues from each pipeline drug was taken based on the drug’s probability of success for the sake of conservative projections. The revenue projections for each drug are multiplied by 0 or 1 within the Monte Carlo simulation based on the probability of successful launch of the drug – refer to Diagram 3. This contributes to an octa-modal distribution (share price when individual drugs fail [three scenarios], when two of three drugs fail [three scenarios], or when all drugs succeed/fail [two scenarios]). However, because BIIB currently relies most heavily on its historical drug portfolio, the price of the company’s stock should not fall below zero unless its core portfolio fails (as opposed to a pre-profit biotechnology company, whose share price relies solely on its pipeline). A sensitivity analysis resulted in the floating of 2026E change in working capital and capital expenditure margins, tightening the final probability distribution.

Furthermore, these drugs are modeled on a beta distribution to demonstrate how the likelihood of successful market launch increases as the drug gets further through the clinical trial process (refer to Figure 4).
The more skewed left this distribution is, the greater the chance of the drug successfully completing all clinical trials and final approval for marketing.

The equations used to obtain the $\alpha$ and $\beta$ values for the beta distributions are as follows (with the equation outputs for SB5 serving as an example):

$$\alpha = \left(\frac{1 - \mu}{\sigma^2} - \frac{1}{\mu}\right)\mu^2 = 13.6583$$

$$\beta = \alpha \left(\frac{1}{\mu} - 1\right) = 5.0517$$

Due to the properties of a beta distribution, the higher the probability of success, the farther to the right the distribution is pushed. According to Keegan, drugs in Phase 3 clinical trials have a 60% chance of reaching market approval. Thus, 0.6 was the value used for $\mu$ when determining the beta distributions for ADUCANUMAB and E2609. According to Hartmann et al., drugs that seek market approval in the E.U. through a Market Authorization Application (MAA) have a 73% probability of approval (n=183). Thus, 0.73 was used as a mean for SB5, giving it the highest leftward skew of the three modeled pipeline drugs. The assumed variance used for the three drugs was 0.01.

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Assumed Prices and Penetration Values
Considering prices for pharmaceutical drugs vary widely based on location and disease, the assumed cost-to-patient for each first-year drug was estimated via data from prescription websites, whereas costs for pipeline drugs were estimated based on drugs of similar nature (refer to Table 2).

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<th>Annual Price (estimate)</th>
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<td>ZINBRYTA</td>
<td>$92,337.36 ($7,694.78/month)</td>
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<tr>
<td>SPINRAZA</td>
<td>$750,000.00 (first year)</td>
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<tr>
<td></td>
<td>$350,000.00 (every following year)</td>
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<tr>
<td>BENEPALI</td>
<td>$6,462.96 (£656 for 4x 50mg; one-month’s worth)</td>
</tr>
<tr>
<td>FLIXABI</td>
<td>$2,011.88 (£377.00/unit; eight-weeks worth)</td>
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<tr>
<td>ADUCANUMAB</td>
<td>$46,000 (based on Campath; monoclonal antibody cancer treatment)</td>
</tr>
<tr>
<td>E2609</td>
<td>$6,000 (based on Donepezil; cholinesterase inhibitor for Alzheimer’s)</td>
</tr>
<tr>
<td>ADALIMUMAB (SB5)</td>
<td>$13,960.80 (70% of $1,662/month for reference drug, Humira)</td>
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</tbody>
</table>

Table 2. Assumed annual prices for first-year and pipeline drugs. For ADUCANUMAB and E2609, the prices were determined based on drugs that utilize similar molecular mechanisms and are currently sold on the market. Because SB5 is a biosimilar that references Humira, we chose to take 70% of the annual Humira price as our assumed value per a study performed by Blackstone and Joseph in 2013. Prices vary based on location and insurer.

Of special interest in Biogen’s pipeline is its two eAD-treating drugs: ADUCANUMAB and E2609. Besides its acceptance into the EMAs PRIME program and the FDAs Fast Track program, ADUCANUMABs (a monoclonal antibody that targets the N-terminal of beta-amyloid peptides) recently published Phase 1b study showed a significant reduction in beta-amyloid plaque in

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Alzheimer’s patients that was dose- and time-dependent. Whereas ADUCANUMAB has started its Phase 3 EMERGE and ENGAGE, other companies pursuing similar monoclonal antibody-based treatments have recently seen Phase 3 failures, such as Eli Lilly’s SOLANEZUMAB, putting the spotlight on Biogen.

E2609 is a BACE1-inhibitor-based (BACE1 is a beta secretase cleaving enzyme that creates beta-amyloid through its site-specific amyloid precursor protein (APP) slicing) drug that prevents the formation of beta-amyloid plaques and was recently cleared to commence its Phase 3 MISSION AD trial. In its Phase 1 trial, the plasma beta-amyloid concentrations in patients were reduced in a dose-dependent manner. As with ADUCANUMAB, similar Phase 3 BACE-inhibitor drug failures have recently occurred, such as Merck’s VERUBECESTAT. All of the aforementioned factors were taken into account when determining reasonable market penetration rates for these Alzheimer’s drugs (refer to Table 3).

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Table 3. Assumed market penetrations for first-year and pipeline drugs. Market Penetration for SPINRAZA, ADUCANUMAB, E2609, AND SB5 were assumed based on expected strengths and weaknesses of the drugs. Currently, SPINRAZA is priced at $750,000 for the first year of treatment, with an annual price of $375,000 for every following year. Considering this is unsustainable, we started projected sales at a low penetration rate, but increased this rate for the drug every two years after 50% bi-annual price cuts. Both ADUCANUMAB AND E2609 are unique Alzheimer’s Disease treatments, which is reflected by their high initial market penetration rates. E2609 is twice that of ADUCANUMAB for two reasons: 1) it theoretically treats those who are in both the early and late stages of the disease, which means there is theoretically a larger target population, and 2) it will likely be significantly cheaper than ADUCANUMAB, making it more accessible.

SB5, the only phase 3 biosimilar, was given a very low penetration rate because the immunosuppressant industry is highly competitive and Humira (the drug SB5 references) has a strong brand reputation, which might make patients more resistant to changing their prescription (this strong reputation is reflected by the $16.078 billion in 2016 FY revenues that AbbVie secured). However, there is a large target population in this sector, as 955,717 patients were treated with Humira alone in 2015, suggesting strong revenues can still be yielded regardless of the low penetration rate. ZINBRYTA, BENEPALI, AND FLIXABI penetration rates are based on available data.

Model Results

Conservative projections using the abovementioned model structure, along with certain growth adjustments, yielded a probable free cash flow of $282.09 per share (refer to Figure 5). Compared to the historical model tuning parameters, our model created reasonable ranges and average values for LTAT and LTA/IC, whereas the free cash flow measures were lower than historical values (see ‘Monte Carlo (All Drugs)’ tab of accompanying spreadsheet for specific values). This makes sense regarding the current outlook for the pharmaceutical industry, as increasingly strict government price regulations can decrease the revenue a company makes on certain drugs, reducing free cash flows available to that company. Lastly, our model appeared


to weigh performance of future drugs (first-year and pipeline) the most, again coinciding with a competitive pharmaceutical market where drugs are replaced rather rapidly (refer to Figure 6).

**Figure 5. Monte Carlo simulation estimated free cash flow/share probability distribution.** Due to the varying possibilities of failure and success regarding Biogen’s pipeline drugs, the probability distribution has relatively high breadth and kurtosis. However, the model shows very little downside in the case that all three pipeline drugs do fail, showing a decent outlook for the company even in the worst case scenario, with a high upside in the best case scenario (a mean of $472.01, although our model’s assumptions suggest $282.09 is more realistic/fundamental value).
Figure 6. Model reliance on separate drug classifications. By running the probabilistic discount cash flow model with only historical, historical & first-year, and all drugs including relevant pipeline drugs, we arrived at the “makeup” of our projected FCF/share. This suggests our model is heavily weighted on the potential of new drugs, which makes sense in a highly competitive pharmaceutical industry that constantly takes market shares away from existing drugs.

Proxy Statement Analysis

Based on analysis of Biogen’s financials and 10-K, the company appears to have a significant upside to its share price as a result of a strong pipeline and managerial decisions that should benefit the company in the long term, such as spinning off non-central aspects of its business (with the Bioverativ launch) and leasing its unnecessary plant in Cambridge. To further understand the motivations behind these executive actions, we analyzed the company’s most recent DEF 14A.

Michel Vounatsos, Biogen’s CEO, took over the position in January 2017, but served as CCO and Executive Vice President for Biogen before this transition. Prior to joining Biogen, he served as President of Merck’s Global Primary Care segment, giving him experience in the global medical setting. A majority of the Executive Vice Presidents have been with Biogen for at least four years, with new recruits including Paul McKenzie (Pharmaceutical Operations and Technology) and Michael Ehlers (R&D). The recruitment of Mr. Ehlers to lead the management of Biogen’s pipeline is very promising, as he is one of the most influential neuroscience researchers in the U.S. (refer to BIIB SEC 2017 10-K for a full description of his accomplishments). Biogen’s Chief

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Medical Officer, Alfred Sandrock, Jr., has been with the company for almost 20 years. All of the executives, except Adriana Karaboutis (Technology, Business Solutions and Corporate Affairs), had experience with a medical/biotechnological company prior to joining Biogen.

When analyzing Biogen’s DEF 14A, the two main factors we consider were: 1) how much of each executive’s compensation is “at risk” (paid in the form of short- or long-term performance-based bonuses) and 2) the metrics for determining how much above base salary an executive makes. Generally, the more “at risk” an executive’s compensation is, the better, as improvements made in the company result in improvements in salary (refer to Figure 7).

![Figure 7. Executive compensation “at-risk” breakdown. The fact that a large majority of all executives’ compensations are highly performance based reflects positively on Biogen. This reinforces executive efforts to improve the company both on a short-term and long-term basis, depending on the metrics by which the final compensations are determined. Source: BIIB SEC DEF-14A (2017)](image)

It is important to consider the members of the peer groups used to determine the appropriate threshold, target, and maximum bonus values, as selection of peers with poor ethics or non-comparable finances suggests a poor compensation plan. Biogen, however, has established a peer group composed of only Biotechnology and Pharmaceutical companies, suggesting that its compensation plan is based on comparable companies that abide by stringent regulations (refer to Table 4).
Table 4. Biogen peer comparison list. The chosen competitors are all in a comparable industry, with somewhat similar capital structures.

Source: BIIB SEC DEF 14A (2017)

The three aspects of BIIB’s “Say on Pay” executive compensation plan are as follows: 1) base salary, 2) annual (short-term) bonus plan, and 3) long-term incentives (as well as health, death, tax, and retirement benefit plans). “Say on Pay” utilizes several multipliers determined based on the metrics of each aspect of the compensation plan, which is ultimately multiplied by the executive’s base salary (refer to Tables 5, 6, and 7; Figure 8).

Diagram 4. “Say on Pay” multipliers for determining level of executive compensation.

Source: BIIB SEC DEF 14A (2017)

For 2016, the company multiplier and individual multipliers were considered the same (110%). Thus, every company performance multiplier is essentially squared (121%) before being multiplied by the target bonus and base salary (both determined via peer group comparisons).
Table 5. Biogen executive short-term compensation plan and results for 2016 FY. Because the company and individual multipliers were deemed equal by the board of directors, the overall multiplier is 121% (up from 56.25% in 2015). The financial metrics used in determining this multiplier are highly adjustable/subjective and are generally not preferred (although they are commonly used). Revenues were adjusted to neutralize effects of foreign exchange fluctuations – although this may seem reasonable, we disagree with this accounting approach as these fluctuations are recurring in a globally operating company. The final short-term bonus awards for each executive are listed in the lower table.

*Source: BIIB SEC DEF 14A (2017)*
Table 6/Figure 8. Biogen executive long-term incentive plan and results for 2016 FY. We believe that measurement of free cash flows benefits shareholders most in the long run, as it focuses on the operational strength of the company (as well as strategic capital allocation).

Long-term incentives are distributed in two manners: 1) cash-settled performance units (CSPUs – measured in the top table) and 2) market stock units (MSUs – measured in the middle and lower tables). Both of these awards vest over a three year period, beginning when the actual units earned are determined based on performance metrics. While CSPU payouts are based on the financial performance of the company in the long-term, MSU payouts are directly linked to growth of Biogen’s stock price.

Source: BIIB SEC DEF 14A (2017)

Biogen also enforces “Share Ownership Guidelines”, which require the CEO and Executive Vice Presidents to own a number of shares equal in value to 6x and 3x their basic salaries, respectively. These executive officers have five years from their initial appointment to achieve this level of share ownership, and if these values are not met in time, 100% of vested shares are
required to be held (and not settled in cash) until the requirements are met. This aligns the interests of executives with those of Biogen’s shareholders.

Table 7. Overall executive compensation breakdowns for 2014 FY, 2015 FY, and 2016 FY. It is interesting to note the impact of performance-based compensation, as several executives’ wages decreased in 2015.

Source: BIIB SEC DEF 14A (2017)

Performance highlights (between 2015 and 2016) listed in the DEF 14A include the return of $1.0 billion in 2016 (and $5.0 billion in 2015) to shareholders through stock repurchases (refer to Figure 9), extending R&D to new therapeutic areas that are focused on treating neuropathic pain, various autoimmune diseases, and ophthalmic diseases, and investing in new manufacturing facilities (Solothurn, Switzerland and Research Triangle Park, North Carolina).

The company was also able to achieve carbon neutrality in 2015, leading to prestigious acknowledgements that could further improve public image (specifically, leader on the Corporate Knights 2015 Global 100 sustainability index and Biotechnology Industry Leader on the Dow Jones Sustainability World Index).
Investment Thesis for Biogen Inc. (NASDAQ: BIIB) by Alex Serafini

Figure 9. Shareholder return breakdown. Biogen historically has never paid a dividend to its shareholders. With this in mind, it is very interesting to find that it has remained about even with its peer group median over the last three years in terms of total shareholder return, and has outperformed the peer group over the last five years, considering Biogen only provides shareholders with returns through share buyback programs (with 2016 buybacks listed above – publicly announced programs include the 2011, 2015, and 2016 Share Repurchas Programs). The graph on the top right shows shareholder returns via common stock value appreciation compared to the NASDAQ Pharmaceutical Index, the NASDAQ Biotechnology Index, and the S&P 500 (assuming a $100 investment in 2011).


The final factor we considered when analyzing Biogen’s management was their share repurchasing habits (refer to Capture 5). The most recent buyback program approved by the Board of Directors was the $5.0 billion 2016 Share Repurchase Program, through which management repurchased 2,193,864 shares at an average of $296.80/share in 2016 Q4. We cross-referenced the number of shares repurchased to the relative share price to determine whether these buybacks are in the interest of the company (repurchases would occur at lower stock prices) or in the interest of executives (repurchases would be made at higher prices so executives can sell vested shares for a larger return).
Biogen’s share repurchasing strategy. Management appears to approve large share repurchases when the company’s stock price is either low or declining. This suggests their decisions are made with the investors’ well-being in mind.

Source: Bloomberg Terminal (Accessed 4/23/17); Command <GP>

Multiples Analysis

In order to get a better sense of short-term measures of performance for Biogen, we analyzed the historical values and projected values (received from both our models and 2017/2018 analyst consenses) of three commonly used multiples: P/E, EPS, and EV/EBITDA (refer to Capture 6 for historical analysis; Figure 10 for projection analysis). P/E and EV/EBITDA will give us a sense of how the market is currently viewing the value of Biogen’s shares compared to how the company is actually performing. EPS will simply serve as a measure of performance.

In our analysis we found that historical EV/EBITDA and P/E have decreased over the last three years even though the company has consistently grown its revenue and net earnings over this period of time. This suggests an artificial, market-based decrease in the company’s value due to factors such as impending and stringent government regulation on the pharmaceutical industry and a currently unstable market climate. Besides the large drop in diluted EPS in early 2017, the
company has been able to maintain steady growth in this metric, suggesting good short-term growth potential. Our projections conclude that these trends will continue in the long-run, suggesting that the stock will progressively become “cheaper” with decreases in P/E over time at approximately the same rate as analyst consensus projections, with an appreciating EPS value over the same period (again, at the same rate as analyst consensus projections). Thus, these ratios support our investment thesis of BUY when considering the stock based on short-term metrics.

Bloomberg Terminal Capture 6. Historical multiples analysis. Over the past two years, Biogen saw a relatively steady decline in its EV/EBITDA and P/E ratios. Considering Biogen has created steadily increasing revenues and net earnings over the same period, this suggests the price of shares have not been growing as quickly as the company itself, further supporting the hypothesis that the company has been undervalued. Biogen has steadily grown its diluted EPS over the same time period (with the exceptional drop in late 2016 that can be attributed to a one-time litigation with Forward Pharma).

Source: Bloomberg Terminal (Accessed 4/26/17); Command <GP>
Historical Insider Trades
The final stage of our Biogen analysis involves determining whether there is an outstanding trend regarding insider share selling, which generally suggests that there is a concerning business factor behind the scenes (refer to Capture 7). We also took a look at the largest share holders to determine the institutional investors currently backing the company (refer to Capture 8).

In our analysis of insider transactions, we found a balance between executive sales and purchases of BIIB stock over the past two years. This suggests that there is nothing “behind the scenes” at Biogen that should be of concern to potential investors, as more selling than buying by executives can hint at a lack of confidence in the company or fear of stock price crashes in the near future.
Historical insider transactions. Insider transactions over the past year appear relatively balanced, suggesting that there is nothing particularly concerning about the company at the time being from the management’s perspective.

Institutional funding of Biogen. Several major institutional investors, including Blackrock, Vanguard Group, and T. Rowe Price Group Inc. appear at the top of Biogen’s holders list, suggesting that there is a large amount of confidence in the company’s future prospects.


Additional Factors to Consider

Area-Specific Price Regulations

Within the U.S., there are several government price restrictions placed upon pharmaceutical companies, specifically through programs such as Medicaid (rebate based on Average Manufacture Price relation to inflation), Medicare (rebate based on Average Sales Price), Medicare Part D (50% discount on brand name prescriptions when beneficiaries reach coverage cap), Federal Agency Discounted Pricing (76% pricing cap based on Average Manufacture Price), and 340B Discounted Pricing through the Public Health Service (rebate based on Average Manufacture Price).

In areas outside of the U.S., Biogen risks encountering strict government enforcement of reimbursement caps and must often negotiate with foreign governments over acceptable
prices to sell its drugs at, which can not only decrease revenues, but also delay the marketing process for certain drugs. Some countries also utilize “reference pricing”, which is essentially quoting Biogen on acceptable drug prices based on those agreed upon in other countries, which reinforces the need for careful negotiation on Biogen’s part in every country.

The Future of the Affordable Care Act (ACA) – Repeal versus Remain

It is estimated that approximately 20 million Americans will lose coverage through a plausible ACA repeal (another attempt at repealing the health plan is definitely within the realm of possibilities, considering the recent reform’s approval by the House of Representatives), with 52 million at risk of rejection by insurance companies if the pre-existing conditions coverage clause is removed with the repeal. Considering that approximately 32.5% of MS patients in the United States are covered by Medicare (with 6% covered by Medicaid), a repeal could significantly reduce Biogen’s MS portfolio revenues through the removal of the ACA’s Medicaid expansion and Part D coverage for Medicare patients (decreasing the number of patients that can afford their treatments).

According to Bloomberg, it is likely that pharmaceutical companies such as Eli Lilly and Mylan (which are comparable to Biogen) will see the largest operating margin strains if Part B and D of government-sponsored health insurance are revised towards increased price constraints and legal government price negotiations. Reimbursement reductions involved in such changes include suggested reductions in allowable Medicare Part B markups (over Average Sales Price) from 6% to 2.5%, as well as the use of a flat fee. Lastly, Democrats are pushing the movement of all government-sponsored health care towards the Veterans Administration model, which apparently has the capability to pay 40% less for drugs than Medicare Part D plans. All of the abovementioned policy changes would not only directly reduce pharmaceutical revenues, but also carry the risk of reducing the demand for certain drugs.

Conclusion

Between Biogen’s strong core MS portfolio, promising drug pipeline, and managerial decisions to cut off peripheral or unnecessary assets (the Hemophilia segment and Cambridge plant in particular), we are confident about Biogen’s operational activities and potential. This, when paired with a strong executive team working under a company-focused “Say on Pay” incentives plan reflects well on Biogen’s overall future prospects. For these reasons, we recommend Biogen as a HOLD at a target price of $282.09, a 5.02% upside.