

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **October 23, 2018**

BIOGEN INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

0-19311

(Commission File Number)

33-0112644

(IRS Employer Identification No.)

225 Binney Street, Cambridge, Massachusetts 02142

(Address of principal executive offices; Zip Code)

Registrant's telephone number, including area code: **(617) 679-2000**

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On October 23, 2018, Biogen Inc. issued a press release announcing its results of operations and financial condition for the third quarter ended September 30, 2018. A copy of the press release is furnished as Exhibit 99.1 and is incorporated herein by reference.

The press release is being furnished pursuant to Item 2.02 of this Current Report on Form 8-K and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that Section, nor shall such document be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act.

Item 9.01 Financial Statements and Exhibits.

The exhibit listed below is furnished as part of this Current Report on Form 8-K.

| <u>Exhibit Number</u> | <u>Description</u> |
|-----------------------|--|
| 99.1 | Biogen's press release dated October 23, 2018. |

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

BIOGEN INC.

By: /s/James Basta
James Basta
Chief Corporation Counsel and Assistant Secretary

Date: October 23, 2018



BIOGEN Q3 2018 REVENUES INCREASED 12% TO \$3.4 BILLION

GAAP diluted EPS increased 24%; Non-GAAP diluted EPS increased 17%

Updated data from NURTURE study showed many presymptomatic infants treated with SPINRAZA[®] were developing within normal bounds

Biogen launches IMRALDI[™], a biosimilar referencing HUMIRA[®], in Europe

First patient dosed in Phase 3 study of BIIB093 for stroke

Company completes enrollment in Phase 2 studies of opicinumab in multiple sclerosis and BIIB092 in progressive supranuclear palsy

Cambridge, Mass., October 23, 2018 -- Biogen Inc. (Nasdaq: BIIB) today reported third quarter 2018 financial results, including:

- Total revenues of \$3.4 billion, a 12% increase versus the prior year.
 - Multiple sclerosis (MS) revenues were \$2.3 billion, including approximately \$137 million in royalties on the sales of OCREVUS[®], relatively stable versus the third quarter of 2017.
 - Revenue growth was driven in part by SPINRAZA, which contributed \$468 million in global revenues.
- GAAP net income and diluted earnings per share (EPS) attributable to Biogen Inc. of \$1.4 billion and \$7.15, respectively, compared to \$1.2 billion and \$5.79 in the third quarter of 2017, respectively.
- Non-GAAP net income and diluted EPS attributable to Biogen Inc. of \$1.5 billion and \$7.40, respectively, compared to \$1.3 billion and \$6.31 in the third quarter of 2017, respectively.

| (In millions, except per share amounts) | Q3 '18 | Q3 '17 | Q2 '18 | Q3 '18 v. Q3 '17 | Q3 '18 v. Q2 '18 |
|--|---------------|---------------|---------------|-------------------------|-------------------------|
| Total revenues | \$ 3,439 | \$ 3,078 | \$ 3,357 | 12% | 2% |
| GAAP net income# | \$ 1,444 | \$ 1,226 | \$ 867 | 18% | 67% |
| GAAP diluted EPS | \$ 7.15 | \$ 5.79 | \$ 4.18 | 24% | 71% |
| Non-GAAP net income# | \$ 1,494 | \$ 1,337 | \$ 1,202 | 12% | 24% |
| Non-GAAP diluted EPS | \$ 7.40 | \$ 6.31 | \$ 5.80 | 17% | 28% |

Net income attributable to Biogen Inc.

Note: Percent changes represented as favorable/(unfavorable)

A reconciliation of GAAP to Non-GAAP quarterly financial results can be found in Table 3 at the end of this press release.

“Biogen performed well against our strategic and operational priorities in the most recent quarter,” said Michel Vounatsos, Biogen’s chief executive officer. “Reported revenues grew at a double-digit rate boosted by strong gains from SPINRAZA, our biosimilars business, and OCREVUS royalties versus a year ago. Net income and earnings per share both increased at double-digit rates supported by a lower tax rate and a lower share count. Our core MS business was relatively resilient during the quarter. For SPINRAZA, in the U.S. we saw increased new patient demand among adults. Outside of the U.S., SPINRAZA revenues benefitted from strong patient uptake across a number of geographies, as well as broadening approvals and solid reimbursement patterns.”

“Biogen continued to advance our pipeline beyond our industry leading portfolios in MS and Alzheimer’s,” Mr. Vounatsos continued. “In the third quarter, we made notable progress in stroke, progressive supranuclear palsy, and ALS. As ever, we remain focused on allocating our capital properly and efficiently with the goal of maximizing returns on behalf of our shareholders over the long-term.”

Revenue Highlights

| (In millions) | Q3 '18 | Q3 '17 | Q2 '18 | Q3 '18 v. Q3 '17 | Q3 '18 v. Q2 '18 |
|--|-----------------|-----------------|-----------------|------------------|------------------|
| Multiple Sclerosis: | | | | | |
| TECFIDERA® | \$ 1,090 | \$ 1,070 | \$ 1,087 | 2% | 0% |
| Total Interferon | \$ 590 | \$ 662 | \$ 626 | (11%) | (6%) |
| AVONEX® | \$ 482 | \$ 538 | \$ 502 | (10%) | (4%) |
| PLEGRIDY® | \$ 108 | \$ 124 | \$ 124 | (13%) | (13%) |
| TYSABRI® | \$ 470 | \$ 469 | \$ 467 | 0% | 1% |
| FAMPYRA™ | \$ 23 | \$ 24 | \$ 23 | (7%) | (2%) |
| ZINBRYTA® | \$ 0 | \$ 14 | \$ 0 | (100%) | NMF |
| Spinal Muscular Atrophy: | | | | | |
| SPINRAZA | \$ 468 | \$ 271 | \$ 423 | 73% | 11% |
| Other Product Revenues: | | | | | |
| Biosimilars | \$ 135 | \$ 101 | \$ 127 | 33% | 6% |
| FUMADERM™ | \$ 5 | \$ 11 | \$ 6 | (55%) | (13%) |
| Total Product Revenues: | \$ 2,780 | \$ 2,623 | \$ 2,758 | 6% | 1% |
| OCREVUS Royalties | \$ 137 | \$ 65 | \$ 113 | 112% | 21% |
| RITUXAN®/GAZYVA® Revenues | \$ 375 | \$ 342 | \$ 377 | 10% | (1%) |
| Other Revenues | \$ 147 | \$ 49 | \$ 109 | 202% | 36% |
| Total Revenues | \$ 3,439 | \$ 3,078 | \$ 3,357 | 12% | 2% |
| MS Product Revenues + OCREVUS Royalties | \$ 2,310 | \$ 2,304 | \$ 2,316 | 0% | (0%) |

Note: Numbers may not foot due to rounding; percent changes represented as favorable/(unfavorable)

- In the third quarter of 2018 channel inventory levels in the U.S. were relatively stable for TECFIDERA, AVONEX, and PLEGRIDY combined. This compares to a decrease of approximately \$45 million in the second quarter of 2018 and relatively stable inventory levels in the third quarter of 2017.
- In the third quarter of 2018 SPINRAZA revenues comprised \$224 million in sales in the U.S. and \$244 million in sales outside the U.S. The number of commercial patients receiving SPINRAZA grew approximately 11% in the U.S. and approximately 29% outside the U.S. versus the second quarter of 2018. In the third quarter of 2018 Biogen recorded SPINRAZA revenues in over 30 countries.

Expense Highlights

| (In millions) | Q3 '18 | Q3 '17 | Q2 '18 | Q3 '18 v. Q3 '17 | Q3 '18 v. Q2 '18 |
|------------------------|--------|--------|--------|------------------|------------------|
| GAAP cost of sales | \$ 461 | \$ 370 | \$ 421 | (25%) | (9%) |
| Non-GAAP cost of sales | \$ 461 | \$ 370 | \$ 421 | (25%) | (9%) |
| GAAP R&D | \$ 508 | \$ 446 | \$ 981 | (14%) | 48% |
| Non-GAAP R&D | \$ 508 | \$ 446 | \$ 819 | (14%) | 38% |
| GAAP SG&A | \$ 498 | \$ 433 | \$ 516 | (15%) | 4% |
| Non-GAAP SG&A | \$ 495 | \$ 433 | \$ 512 | (14%) | 3% |

Note: Percent changes represented as favorable/(unfavorable)

Other Financial Highlights

- In the third quarter of 2018 GAAP amortization of acquired intangibles was \$282 million, including impairment charges totaling \$189 million related to updates in the development status of vixotrigine (BIIB074), which are discussed below. The effects of these impairments were partially offset by a \$90 million reduction in our contingent consideration liability.
- In the third quarter of 2018 GAAP other net income was \$115 million. This includes a gain of approximately \$141 million related to changes in the fair value of certain equity investments, including shares of Ionis Pharmaceuticals, Inc., as of September 30, 2018. Non-GAAP other net expense was \$26 million.
- For the third quarter of 2018 the Company's effective GAAP tax rate was 20%, and the Company's effective non-GAAP tax rate was 21%.
- In the third quarter of 2018 Biogen's board of directors authorized a program to repurchase up to \$3.5 billion of the Company's common stock.
- As of September 30, 2018, Biogen had cash, cash equivalents, and marketable securities totaling approximately \$5.7 billion, and approximately \$5.9 billion in notes payable.
- In the third quarter of 2018 the Company generated \$1.7 billion in net cash flows from operations.
- For the third quarter of 2018 the Company's weighted average diluted shares were 202 million.

Recent Events

- This week Biogen will present data from its Alzheimer's disease (AD) clinical development portfolio at the Clinical Trials on Alzheimer's Disease (CTAD) annual meeting in Barcelona, Spain (October 24-27). Biogen will share a late-breaking oral presentation and a late-breaking poster on the efficacy of aducanumab, Biogen's anti-amyloid beta antibody candidate for early AD, as well as cumulative safety data from the Phase 1b PRIME long-term extension study of patients with mild cognitive impairment (MCI) due to Alzheimer's disease and mild AD dementia. These results are generally consistent with previous interim analyses, and there were no changes to the risk-benefit profile of aducanumab. In addition, Samantha Budd Haerberlein, vice president, Alzheimer's disease, dementia, and movement disorders, late stage clinical development at Biogen, will deliver a keynote address focused on lessons learned from clinical research into AD. The oral presentation, keynote address, and an investor Q&A call, will be webcast on Biogen's website at investors.biogen.com. The poster presentations will also be available on Biogen's website.
 - Wednesday, October 24, 7:15 a.m. ET / 1:15 p.m. CEST - *Poster Presentations: Cumulative Aducanumab Safety Data from PRIME: A Randomized, Double-blind, Placebo-controlled, Phase 1b Study and Aducanumab 48-Month Analyses from PRIME, a Phase 1b Study in Patients with Early Alzheimer's Disease*
 - Thursday, October 25, 7:30-8:00 a.m. ET / 1:30-2:00 p.m. CEST - *Keynote: What Have We Learned from Aducanumab?*
 - Thursday, October 25, 4:15 p.m. ET / 10:15 p.m. CEST - *Investor Q&A call with Alfred Sandrock, Jr., M.D., Ph.D., executive vice president and chief medical officer at Biogen, and Samantha Budd Haerberlein, Ph.D., vice president, Alzheimer's disease, dementia and movement disorders, late stage clinical development at Biogen*
 - Friday, October 26, 9:15-9:30 a.m. ET / 3:15-3:30 p.m. CEST - *Oral Presentation: Aducanumab Titration Dosing Regimen: 36-Month Analyses from PRIME, a Phase 1b Study in Patients with Early Alzheimer's Disease*
- At CTAD, Biogen's collaborator Eisai Co., Ltd. (Eisai) will also present clinical and biomarker updates from the Phase 2 study of BAN2401, an anti-amyloid beta antibody, along with safety and efficacy data for elenbecestat (development code: E2609), an investigational oral beta-amyloid cleaving enzyme (BACE) inhibitor, from the Phase 2 study in MCI to moderate AD. The BAN2401 presentation will be webcast live on Eisai's website on Thursday, October 25, 8:30-9:30 a.m. ET / 2:30-3:30 p.m. CEST.
- Today Biogen and UCB announced top-line results from a Phase 2b study evaluating the safety and efficacy of dapirolizumab pegol (DZP), an anti-CD40L pegylated Fab, in adults with moderately-to-severely active systemic lupus erythematosus (SLE) despite receiving standard-of-care treatment such as corticosteroids, anti-malarials and non-biological immunosuppressants. The primary endpoint of the study to demonstrate a dose response at 24 weeks on the British Isles Lupus Assessment Group (BILAG)-based Composite Lupus Assessment (BICLA) was not met ($p=0.06$). The study did demonstrate consistent and potentially meaningful improvements for the majority of clinical endpoints in patients treated with DZP compared with placebo. In addition, biomarker data demonstrated evidence of proof of biology. DZP was well tolerated and demonstrated an acceptable safety profile. Biogen and UCB continue to further evaluate these data while assessing potential next steps. The companies expect to present this data at a future scientific forum.

- In October 2018 Biogen and Samsung Bioepis Co. Ltd. announced the European launch of IMRALDI, an adalimumab biosimilar referencing Humira. IMRALDI is approved in Europe for the treatment of rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, adult and adolescent hidradenitis suppurativa, Crohn's disease, paediatric Crohn's disease, ulcerative colitis, and uveitis.
- In October 2018 Biogen presented data in more than 70 oral and poster presentations at the 34th Congress of the European Committee for Treatment and Research in MS (ECTRIMS) in Berlin, Germany. Key updates included clinical data and real-world evidence that further support the long-term efficacy and well-characterized safety of Biogen's leading MS therapies, including data supporting the use of TECFIDERA and TYSABRI early within the disease course. Additional data highlighted the potential utility of serum neurofilament light (sNfL) as a biomarker of MS disease activity and updates on Biogen's efforts to improve monitoring of cognition and other key MS outcomes through MS PATHS (Multiple Sclerosis Partners Advancing Technology and Health Solutions).
- In October 2018 Biogen presented new interim results from NURTURE, an ongoing open-label, single-arm efficacy and safety study of SPINRAZA in 25 presymptomatic infants with spinal muscular atrophy (SMA) at the Annual Congress of the World Muscle Society (WMS) held in Mendoza, Argentina. As of May 2018 all NURTURE study participants were alive and none required permanent ventilation, in contrast to the natural history of SMA. In addition, 100% of study participants achieved the motor milestone of sitting independently, 88% were able to walk with assistance, and 77% were able to walk independently. All NURTURE study participants were older than 15 months at the time of the analysis.
- In October 2018 Biogen presented data from its movement disorders portfolio at the International Congress of Parkinson's Disease and Movement Disorders (MDS) in Hong Kong. Data presented included safety data from the Phase 1 long-term extension study of BIIB092, an anti-tau antibody, in progressive supranuclear palsy (PSP), baseline demographics from the BIIB092 Phase 2 PASSPORT study in PSP, and the design of the BIIB054 Phase 2 SPARK study in Parkinson's disease.
- In September 2018 Biogen received results from the Phase 2b study of vixotrigine (BIIB074) in painful lumbosacral radiculopathy (PLSR). The study did not meet its primary or secondary efficacy endpoints, and the Company will discontinue development in this indication. The safety data were consistent with the profile reported in previous studies. In addition, the Company has delayed the initiation of the Phase 3 studies of vixotrigine in trigeminal neuralgia as it awaits the outcome of ongoing interactions with the U.S. Food and Drug Administration regarding the design of the Phase 3 studies, a more detailed review of the Phase 2b PLSR data, and insights from the ongoing Phase 2 study in small fiber neuropathy.
- In September 2018 Biogen completed enrollment in the Phase 2b AFFINITY study, evaluating opicinumab as an add-on therapy in MS patients who are adequately controlled on their anti-inflammatory disease-modifying therapy (DMT), versus the DMT alone. Opicinumab is a first-in-class human monoclonal antibody directed against LINGO-1 and is being evaluated to determine its potential for improving pre-existing disability in relapsing MS patients through remyelination.
- In September 2018 Biogen enrolled the first patient in the Phase 2b study evaluating BG00011 (STX-100) in idiopathic pulmonary fibrosis.
- In September 2018 Biogen completed enrollment in the Phase 2 study of BIIB092 in PSP.

- In September 2018 Biogen enrolled the first patient in the Phase 1 study evaluating BIIB078 (IONIS-C9_{Rx}), an antisense oligonucleotide drug candidate, in adults with C9ORF72-associated amyotrophic lateral sclerosis.
- In August 2018 Biogen enrolled the first patient in the global Phase 3 CHARM study, designed to evaluate BIIB093 (intravenous (IV) glibenclamide) for the prevention and treatment of severe cerebral edema in large hemispheric infarction, one of the most severe types of ischemic stroke.
- In July 2018 Eisai presented detailed results from the Phase 2 study (Study 201) of BAN2401, as well as detailed results from the Phase 2 study (Study 202) of elenbecestat, at the 2018 Alzheimer's Association International Conference (AAIC) in Chicago.

Conference Call and Webcast

The Company's earnings conference call for the third quarter will be broadcast via the internet at 8:00 a.m. ET on October 23, 2018, and will be accessible through the Investors section of Biogen's website, www.biogen.com. Supplemental information in the form of a slide presentation is also accessible at the same location on the internet and will be subsequently available on the website for at least one month.

Note about Earnings Releases and Calls

Starting with the second quarter 2018 earnings release, Biogen has ceased publishing press releases relating to future earnings calls, earnings releases, and investor events via newswire services. The Company will post these materials on the Investors section of Biogen's website, www.biogen.com, and issue a statement on [Twitter](https://twitter.com/biogen) (@biogen) when they become available.

About Biogen

At Biogen, our mission is clear: we are pioneers in neuroscience. Biogen discovers, develops, and delivers worldwide innovative therapies for people living with serious neurological and neurodegenerative diseases. One of the world's first global biotechnology companies, Biogen was founded in 1978 by Charles Weissmann, Heinz Schaller, Kenneth Murray, and Nobel Prize winners Walter Gilbert and Phillip Sharp, and today has the leading portfolio of medicines to treat multiple sclerosis, has introduced the first and only approved treatment for spinal muscular atrophy, and is focused on advancing neuroscience research programs in Alzheimer's disease and dementia, MS and neuroimmunology, movement disorders, neuromuscular disorders, pain, ophthalmology, neuropsychiatry, and acute neurology. Biogen also manufactures and commercializes biosimilars of advanced biologics.

We routinely post information that may be important to investors on our website at www.biogen.com. Follow us on social media - [Twitter](https://twitter.com/biogen), [LinkedIn](https://www.linkedin.com/company/biogen), [Facebook](https://www.facebook.com/biogen), [YouTube](https://www.youtube.com/biogen).

Safe Harbor

This press release contains forward-looking statements, including statements relating to: our strategy and plans; potential of our commercial business and pipeline programs; capital allocation and investment strategy; clinical trials and data readouts and presentations; regulatory filings and the timing thereof; risks and uncertainties associated with drug development and commercialization; and anticipated benefits and potential of investments, collaborations and business development activities. These forward-looking statements may be accompanied by such words as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "potential," "possible," "will," and other words and terms of similar meaning. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early stage clinical trials may not be indicative of full results or results from later stage or larger

scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements or the scientific data presented.

These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including: our dependence on revenues from our principal products; failure to compete effectively due to significant product competition in the markets for our products; difficulties in obtaining and maintaining adequate coverage, pricing, and reimbursement for our products; the occurrence of adverse safety events, restrictions on use with our products or product liability claims; failure to protect and enforce our data, intellectual property, and other proprietary rights and the risks and uncertainties relating to intellectual property claims and challenges; uncertainty of long-term success in developing, licensing, or acquiring other product candidates or additional indications for existing products; the risk that positive results in a clinical trial may not be replicated in subsequent or confirmatory trials or success in early stage clinical trials may not be predictive of results in later stage or large scale clinical trials or trials in other potential indications; risks associated with clinical trials, including our ability to adequately manage clinical activities, unexpected concerns that may arise from additional data or analysis obtained during clinical trials, regulatory authorities may require additional information or further studies or may fail to approve or may delay approval of our drug candidates; risks associated with current and potential future healthcare reforms; problems with our manufacturing processes; risks relating to technology failures or breaches; our dependence on collaborators and other third parties for the development, regulatory approval, and commercialization of products and other aspects of our business, which are outside of our full control; failure to successfully execute on our growth initiatives; risks relating to management and key personnel changes, including attracting and retaining key personnel; risks relating to investment in and expansion of manufacturing capacity for future clinical and commercial requirements; failure to comply with legal and regulatory requirements; fluctuations in our effective tax rate; the risks of doing business internationally, including currency exchange rate fluctuations; risks related to commercialization of biosimilars; risks related to investment in properties; the market, interest, and credit risks associated with our portfolio of marketable securities; risks relating to stock repurchases; risks relating to access to capital and credit markets; risks related to indebtedness; environmental risks; risks relating to the sale and distribution by third parties of counterfeit versions of our products; risks relating to the use of social media for our business; change in control provisions in certain of our collaboration agreements; risks relating to the spin-off of our hemophilia business, including risks of operational difficulties and exposure to claims and liabilities; and the other risks and uncertainties that are described in the Risk Factors section of our most recent annual or quarterly report and in other reports we have filed with the Securities and Exchange Commission.

These statements are based on our current beliefs and expectations and speak only as of the date of this press release. We do not undertake any obligation to publicly update any forward-looking statements.

| | |
|------------------------------|---------------------------------|
| Biogen Media Contact: | Biogen Investor Contact: |
| David Caouette | Matt Calistri |
| Biogen Inc. | Biogen Inc. |
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TABLE 1

BIOPEN INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENT OF INCOME
(unaudited, in millions, except per share amounts)

| | For the Three Months Ended September 30, | | For the Nine Months Ended September 30, | |
|---|---|------------|--|------------|
| | 2018 | 2017 | 2018 | 2017 |
| Revenues: | | | | |
| Product, net | \$ 2,780.1 | \$ 2,622.5 | \$ 8,061.1 | \$ 7,642.3 |
| Revenues from anti-CD20 therapeutic programs | 511.7 | 406.5 | 1,445.3 | 1,144.2 |
| Other | 147.2 | 48.8 | 420.2 | 180.4 |
| Total revenues | 3,439.0 | 3,077.8 | 9,926.6 | 8,966.9 |
| Cost and expenses: | | | | |
| Cost of sales, excluding amortization of acquired intangible assets | 460.8 | 370.0 | 1,327.8 | 1,120.8 |
| Research and development | 507.9 | 446.4 | 1,985.6 | 1,666.0 |
| Selling, general and administrative | 497.7 | 433.4 | 1,515.2 | 1,361.9 |
| Amortization of acquired intangible assets | 281.9 | 108.9 | 493.2 | 674.9 |
| Collaboration profit (loss) sharing | 47.5 | 35.2 | 129.2 | 82.5 |
| Acquired in-process research and development | 27.5 | — | 112.5 | 120.0 |
| Restructuring charges | 6.0 | — | 9.2 | — |
| (Gain) loss on fair value remeasurement of contingent consideration | (87.9) | 30.0 | (91.6) | 61.2 |
| Total cost and expenses | 1,741.4 | 1,423.9 | 5,481.1 | 5,087.3 |
| Income from operations | 1,697.6 | 1,653.9 | 4,445.5 | 3,879.6 |
| Other income (expense), net | 115.1 | (44.0) | 39.6 | (150.6) |
| Income before income tax expense and equity in loss of investee, net of tax | 1,812.7 | 1,609.9 | 4,485.1 | 3,729.0 |
| Income tax expense | 369.8 | 383.8 | 956.0 | 892.6 |
| Equity in loss of investee, net of tax | — | — | — | — |
| Net income | 1,442.9 | 1,226.1 | 3,529.1 | 2,836.4 |
| Net income (loss) attributable to noncontrolling interests, net of tax | (1.5) | — | 45.2 | (0.1) |
| Net income attributable to Biogen Inc. | \$ 1,444.4 | \$ 1,226.1 | \$ 3,483.9 | \$ 2,836.5 |
| Net income per share: | | | | |
| Basic earnings per share attributable to Biogen Inc. | \$ 7.17 | \$ 5.80 | \$ 16.86 | \$ 13.32 |
| Diluted earnings per share attributable to Biogen Inc. | \$ 7.15 | \$ 5.79 | \$ 16.83 | \$ 13.30 |
| Weighted-average shares used in calculating: | | | | |
| Basic earnings per share attributable to Biogen Inc. | 201.4 | 211.4 | 206.6 | 213.0 |
| Diluted earnings per share attributable to Biogen Inc. | 201.9 | 211.8 | 207.0 | 213.3 |

TABLE 2

BIOGEN INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited, in millions)

| | As of September 30, 2018 | As of December 31, 2017 |
|--|-----------------------------|----------------------------|
| ASSETS | | |
| Cash, cash equivalents and marketable securities | \$ 4,428.4 | \$ 3,689.0 |
| Accounts receivable, net | 2,017.3 | 1,787.0 |
| Inventory | 916.6 | 902.7 |
| Other current assets | 1,356.7 | 1,494.6 |
| Total current assets | 8,719.0 | 7,873.3 |
| Marketable securities | 1,244.5 | 3,057.3 |
| Property, plant and equipment, net | 3,538.9 | 3,182.4 |
| Intangible assets, net | 3,379.0 | 3,879.6 |
| Goodwill | 5,440.1 | 4,632.5 |
| Investments and other assets | 3,170.7 | 1,027.5 |
| TOTAL ASSETS | \$ 25,492.2 | \$ 23,652.6 |
| LIABILITIES AND EQUITY | | |
| Current liabilities | \$ 3,174.9 | \$ 3,368.2 |
| Notes payable | 5,931.1 | 5,935.0 |
| Other long-term liabilities | 2,626.4 | 1,751.3 |
| Equity | 13,759.8 | 12,598.1 |
| TOTAL LIABILITIES AND EQUITY | \$ 25,492.2 | \$ 23,652.6 |

TABLE 3

BIOGEN INC. AND SUBSIDIARIES
GAAP TO NON-GAAP RECONCILIATION:
NET INCOME ATTRIBUTABLE TO BIOGEN INC. AND DILUTED EARNINGS PER SHARE
(unaudited, in millions, except per share amounts)

An itemized reconciliation between diluted earnings per share on a GAAP and Non-GAAP basis is as follows:

| | For the Three Months Ended | | |
|--|----------------------------|--------------------|----------------|
| | September 30, 2018 | September 30, 2017 | June 30, 2018 |
| GAAP earnings per share - Diluted | \$ 7.15 | \$ 5.79 | \$ 4.18 |
| Adjustments to GAAP net income attributable to Biogen Inc. (as detailed below) | 0.25 | 0.52 | 1.62 |
| Non-GAAP earnings per share - Diluted | <u>\$ 7.40</u> | <u>\$ 6.31</u> | <u>\$ 5.80</u> |

| | For the Nine Months Ended | |
|--|---------------------------|--------------------|
| | September 30, 2018 | September 30, 2017 |
| GAAP earnings per share - Diluted | \$ 16.83 | \$ 13.30 |
| Adjustments to GAAP net income attributable to Biogen Inc. (as detailed below) | 2.39 | 3.25 |
| Non-GAAP earnings per share - Diluted | <u>\$ 19.22</u> | <u>\$ 16.55</u> |

An itemized reconciliation between net income attributable to Biogen Inc. on a GAAP and Non-GAAP basis is as follows:

| | For the Three Months Ended | | |
|--|----------------------------|--------------------|-------------------|
| | September 30, 2018 | September 30, 2017 | June 30, 2018 |
| GAAP net income attributable to Biogen Inc. | \$ 1,444.4 | \$ 1,226.1 | \$ 866.6 |
| Adjustments: | | | |
| Amortization of acquired intangible assets ^{A, B} | 281.9 | 108.9 | 107.4 |
| Acquired in-process research and development | 27.5 | — | 75.0 |
| (Gain) loss on fair value remeasurement of contingent consideration ^A | (87.9) | 30.0 | 1.9 |
| Premium paid on purchase of Ionis common stock ^C | — | — | 162.1 |
| (Gain) loss on equity security investments | (141.2) | — | (5.4) |
| Net distribution to noncontrolling interests ^D | (1.5) | — | 48.5 |
| Restructuring, business transformation and other cost saving initiatives: | | | |
| 2017 corporate strategy implementation ^E | 3.1 | — | 4.0 |
| Restructuring charges ^E | 6.0 | — | 1.6 |
| Income tax effect related to reconciling items | (19.3) | (27.7) | (63.7) |
| Tax reform ^F | (18.5) | — | 3.5 |
| Non-GAAP net income attributable to Biogen Inc. | <u>\$ 1,494.5</u> | <u>\$ 1,337.3</u> | <u>\$ 1,201.5</u> |

| | For the Nine Months Ended | |
|--|---------------------------|--------------------|
| | September 30, 2018 | September 30, 2017 |
| GAAP net income attributable to Biogen Inc. | \$ 3,483.9 | \$ 2,836.5 |
| Adjustments: | | |
| Amortization of acquired intangible assets ^{A, B} | 493.2 | 674.9 |
| Acquired in-process research and development | 112.5 | 120.0 |
| (Gain) loss on fair value remeasurement of contingent consideration ^A | (91.6) | 61.2 |
| Premium paid on purchase of Ionis common stock ^C | 162.1 | — |
| (Gain) loss on equity security investments | (140.2) | — |
| Net distribution to noncontrolling interests ^D | 45.3 | — |
| Restructuring, business transformation and other cost saving initiatives: | | |
| 2017 corporate strategy implementation ^E | 10.9 | — |
| Restructuring charges ^E | 9.2 | — |
| Hemophilia business separation costs | — | 19.2 |
| Income tax effect related to reconciling items | (96.7) | (182.5) |
| Tax reform ^F | (10.9) | — |
| Non-GAAP net income attributable to Biogen Inc. | \$ 3,977.7 | \$ 3,529.3 |

^A Amortization of acquired intangible assets for the three and nine months ended September 30, 2018, includes the impact of impairment charges related to certain in-process research and development (IPR&D) assets associated with our vixotrigine (BII074) program totaling \$189.3 million.

During the third quarter of 2018 we completed a Phase 2b study for vixotrigine in painful lumbosacral radiculopathy (PLSR). The study did not meet its primary or secondary efficacy endpoints and we will discontinue development in PLSR. As a result, we recognized an impairment charge of approximately \$60.0 million during the third quarter of 2018 to reduce the fair value of the IPR&D intangible asset to zero.

In addition, we have delayed the initiation of the Phase 3 studies of vixotrigine in trigeminal neuralgia (TGN) as we await the outcome of ongoing interactions with the U.S. Food and Drug Administration regarding the design of the Phase 3 studies, a more detailed review of the data from the Phase 2b study of vixotrigine in PLSR and insights from the Phase 2 study of vixotrigine in small fiber neuropathy. We have reassessed the fair value of the TGN program using reduced expected lifetime revenues, higher expected clinical development costs and a lower cumulative probability of success. As a result, we recognized an impairment charge of \$129.3 million during the third quarter of 2018 to reduce the fair value of the TGN IPR&D intangible asset to \$41.8 million. We also adjusted the value of our contingent consideration obligations related to this program to reflect the lower cumulative probabilities of success resulting in a gain of \$89.6 million in the third quarter of 2018.

We may recognize additional impairment charges in the future depending upon our ability to advance vixotrigine for the treatment of TGN or other indications.

^B Amortization of acquired intangible assets also includes impairment and amortization charges related to the intangible asset associated with our U.S. and rest of world licenses to Forward Pharma AVS' (Forward Pharma) intellectual property, including Forward Pharma's intellectual property related to TECFIDERA. In exchange for these licenses, we paid Forward Pharma \$1.25 billion in cash, of which \$795.2 million was recognized as an intangible asset in the first quarter of 2017.

We have two intellectual property disputes with Forward Pharma, one in the U.S. and one in the European Union, concerning intellectual property related to TECFIDERA. In March 2017 the U.S. intellectual property dispute was decided in our favor. We evaluated the recoverability of the U.S. asset acquired from Forward Pharma and recorded a \$328.2 million impairment charge in the first quarter of 2017 to adjust the carrying value of the acquired U.S. asset to fair value reflecting the impact of the developments in the U.S. legal dispute. In March 2018 the European Patent Office revoked Forward Pharma's European Patent No. 2 801 355. Based upon our assessment of these rulings, we continue to amortize the remaining net book value of the U.S. and rest of world intangible assets in our condensed consolidated statements of income utilizing an economic consumption model.

^C In June 2018 we closed a new ten-year exclusive agreement with Ionis Pharmaceuticals, Inc. (Ionis) to develop novel antisense oligonucleotide drug candidates for a broad range of neurological diseases for a total payment of \$1.0 billion consisting of an upfront payment of \$375.0 million and the purchase of approximately 11.5 million shares of Ionis' common stock at a cost of \$625.0 million.

The 11.5 million shares of Ionis' common stock were purchased at a premium to their fair value at the transaction closing date. The premium consisted of acquiring the shares at a price above the fair value based on the trailing 10-day weighted-average close price prior to entering into the agreement in April 2018 and the effect of certain holding period restrictions. We recorded an asset of \$462.9 million in investments and other assets in our condensed consolidated balance sheets reflecting the fair value of the common stock and a charge of \$162.1 million to research and development expense in our condensed consolidated statements of income during the second quarter of 2018, reflecting the premium paid for the common stock.

^D Net distribution to noncontrolling interests reflects the \$50.0 million payment to Neurimmune SubOne AG (Neurimmune), net of Neurimmune's tax, to further reduce the previously negotiated royalty rates payable on products developed under our amended collaboration and license agreement, including on potential commercial sales of aducanumab, by an additional 5%.

^E 2017 corporate strategy and restructuring charges are related to our efforts to create a leaner and simpler operating model.

^F The Tax Cuts and Jobs Act of 2017 (2017 Tax Act), which was signed into law in December 2017, has resulted in significant changes to the U.S. corporate income tax system. During the fourth quarter of 2017 we recognized within our provision for income taxes a \$1.2 billion provisional estimate under the U.S. Securities and Exchange Commission Staff Accounting Bulletin No. 118. Our provisional estimate included an amount

resulting from a one-time mandatory deemed repatriation tax on accumulated foreign subsidiaries' previously untaxed foreign earnings (the Transition Toll Tax) and amounts related to the impact of remeasuring our deferred tax balances to reflect other aspects of the 2017 Tax Act.

The final determination of the Transition Toll Tax and remeasurement of our deferred assets and liabilities will be completed as additional information becomes available, but no later than one year from the enactment of the 2017 Tax Act. Our preliminary estimate of the Transition Toll Tax and the remeasurement of our deferred tax assets and liabilities is subject to the finalization of management's analysis related to certain matters, such as developing interpretations of the provisions of the 2017 Tax Act and changes to certain estimates and amounts related to the earnings and profits of certain subsidiaries.

During the three months ended September 30, 2018, we recognized a net reduction of \$34.6 million in our estimated Transition Toll Tax, an expense of \$5.1 million to remeasure our deferred tax balances and an \$11.0 million expense to reflect other aspects of the 2017 Tax Act. During the nine months ended September 30, 2018, the remeasurement of our deferred tax balances resulted in an expense totaling \$12.7 million.

Use of Non-GAAP Financial Measures

We supplement our consolidated financial statements presented on a GAAP basis by providing additional measures which may be considered "Non-GAAP" financial measures under applicable SEC rules. We believe that the disclosure of these Non-GAAP financial measures provides additional insight into the ongoing economics of our business and reflects how we manage our business internally, set operational goals and form the basis of our management incentive programs. These Non-GAAP financial measures are not in accordance with generally accepted accounting principles in the United States and should not be viewed in isolation or as a substitute for reported, or GAAP, net income attributable to Biogen Inc. and diluted earnings per share.

Our "Non-GAAP net income attributable to Biogen Inc." and "Non-GAAP earnings per share - Diluted" financial measures exclude the following items from "GAAP net income attributable to Biogen Inc." and "GAAP earnings per share - Diluted":

1. Purchase accounting, merger-related and other adjustments

We exclude certain purchase accounting related items associated with the acquisition of businesses, assets and amounts in relation to the consolidation or deconsolidation of variable interest entities for which we are the primary beneficiary. These adjustments include, but are not limited to, charges for in-process research and development and certain milestones, the amortization of intangible assets, and charges or credits from the fair value remeasurement of our contingent consideration obligations.

2. Hemophilia business separation costs

We have excluded costs that are directly associated with the set up and spin-off of our hemophilia business into an independent, publicly-traded company on February 1, 2017. These costs represent incremental third party costs attributable solely to hemophilia separation and set up activities.

3. Restructuring, business transformation and other cost saving initiatives

We exclude costs associated with the company's execution of certain strategies and initiatives to streamline operations, achieve targeted cost reductions, rationalize manufacturing facilities or refocus R&D activities. These costs may include employee separation costs, retention bonuses, facility closing and exit costs, asset impairment charges or additional depreciation when the expected useful life of certain assets have been shortened due to changes in anticipated usage and other costs or credits that management believes do not have a direct correlation to our on-going or future business operations.

4. (Gain) loss on equity security investments

Effective January 2018 we exclude unrealized and realized gains and losses and discounts or premiums on our equity security investments as we do not believe that these components of income or expense have a direct correlation to our on-going or future business operations.

5. Other items

We evaluate other items of income and expense on an individual basis, and consider both the quantitative and qualitative aspects of the item, including (i) its size and nature, (ii) whether or not it relates to our ongoing business operations and (iii) whether or not we expect it to occur as part of our normal business on a regular basis. We also include an adjustment to reflect the related tax effect of all reconciling items within our reconciliation of our GAAP to Non-GAAP net income attributable to Biogen Inc. and diluted earnings per share.

