Biogen Reports Quarterly Revenues of $3.1 Billion

Total revenues grew 11% or 15% excluding hemophilia revenues*
GAAP diluted EPS increased 60%; Non-GAAP EPS increased 16%
Company adds new Phase 2 program in neuropsychiatry
Company invests in industry leading central nervous system antisense oligonucleotide platform with Ionis Pharmaceuticals

April 24, 2018 06:59 AM Eastern Daylight Time

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Biogen Inc. (Nasdaq: BIIB) today reported first quarter 2018 financial results, including:

- Total revenues of $3.1 billion, an 11% increase versus the prior year or a 15% increase excluding hemophilia revenues*.
  - Multiple sclerosis (MS) revenues were $2.1 billion, including approximately $77 million in royalties on the sales of OCREVUS®.
  - Revenue growth was principally driven by SPINRAZA®, which contributed $364 million in global revenues, biosimilars, which contributed $128 million, and Other Revenues of $164 million.
- GAAP net income and diluted earnings per share (EPS) attributable to Biogen Inc. of $1.2 billion and $5.54, respectively, compared to $748 million and $3.46 in the first quarter of 2017, respectively.
  - In the first quarter of last year GAAP net income and diluted EPS were negatively impacted by $243 million and $1.14, net of tax, respectively, related to the U.S. Patent and Trademark Office ruling in favor of Biogen in the Company's interference proceeding with Forward Pharma A/S.
- Non-GAAP net income and diluted EPS attributable to Biogen Inc. of $1.3 billion and $6.05, respectively, compared to $1.1 billion and $5.20 in the first quarter of 2017, respectively.

* In Q1 2017 Biogen completed the spin-off of its global hemophilia business. The 15% increase in total revenues excludes all hemophilia revenues in January 2017. Hemophilia revenues include ELOCTATE® and ALPROLIX® product revenues as well as royalty and contract manufacturing revenue related to Sobi.

(In millions, except per share amounts)	Q1 '18	Q1 '17	Q4 '17	Q1 '18 v. Q1 '17	Q1 '18 v. Q4 '17
Total revenues*	$3,131	$2,811	$3,307	11%*	(5%)
GAAP net income#	$1,173	$ 748	$ (297)	57%	NMF
GAAP diluted EPS	$ 5.54	$ 3.46	$ (1.40)	60%	NMF
Non-GAAP net income#	$1,282	$1,123	$1,116	14%	15%
Non-GAAP diluted EPS	$ 6.05	$ 5.20	$ 5.26	16%	15%

Net income attributable to Biogen Inc.

Note: Percent changes represented as favorable/(unfavorable)

- In the fourth quarter of 2017 GAAP net income and EPS were negatively impacted by $1.2 billion and $5.51, respectively, due to the transition toll tax and re-measurement of the Company's net deferred tax assets related to the Tax Cuts and Jobs Act of 2017.

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

"We started 2018 well with our first quarter revenues growing 11% versus the prior year, or 15% excluding hemophilia revenues. This is in line with our expectations," said Michel Vounatsos, Biogen's Chief Executive Officer. "The fundamentals and resilience of our multiple sclerosis business remained strong, while we experienced anticipated seasonality at the beginning of the year. I believe there is significant opportunity for the future growth of SPINRAZA worldwide as we position Biogen for long-term leadership in spinal muscular atrophy."

"As pioneers in neuroscience, we continued to advance and expand our portfolio of potential breakthrough treatments for areas of high unmet need. We have added a new Phase 2 asset in our emerging growth area of neuropsychiatry, and we meaningfully enhanced our collaboration with Ionis to develop a new pipeline of gene-based therapies for neurological diseases."

Revenue Highlights

(In millions)	Q1 '18	Q1 '17	Q4 '17	Q1 '18 v. Q1 '17	Q1 '18 v. Q4 '17
Multiple Sclerosis:					
TECFIDERA®	$ 987	$ 958	$1,076	3%	(8%)
Total Interferon	$ 550	$ 648	$ 645	(15%)	(15%)
AVONEX®	*$ 451*	*$ 537*	*$ 520*	*(16%)*	*(13%)*
PLEGRIDY®	*$ 100*	*$ 112*	*$ 125*	*(11%)*	*(20%)*
TYSABRI®	$ 462	$ 545	$ 463	(15%)	(0%)
FAMPYRA™	$ 24	$ 20	$ 24	19%	1%
ZINBRYTA®	$ 1	$ 11	$ 12	(87%)	(88%)
Spinal Muscular Atrophy					
SPINRAZA	$ 364	$ 47	$ 363	NMF	0%
Hemophilia*:					
ELOCTATE	$ —	$ 48	$ —	NMF	NMF
ALPROLIX	$ —	$ 26	$ —	NMF	NMF
Other Product Revenues:					
Biosimilars	$ 128	$ 66	$ 122	93%	5%
FUMADERM™	$ 7	$ 10	$ 9	(28%)	(21%)
Total Product Revenues:	**$2,523**	**$2,380**	**$2,712**	**6%**	**(7%)**
OCREVUS Royalties	$ 77	$ —	$ 77	NMF	(0%)
RITUXAN®/GAZYVA® Revenues	$ 366	$ 341	$ 338	7%	8%
Other Revenues	$ 164	$ 90	$ 180	83%	(8%)
Total Revenues*	**$3,131**	**$2,811**	**$3,307**	**11%***	**(5%)**
MS Product Revenues + OCREVUS Royalties	**$2,101**	**$2,183**	**$2,296**	**(4%)**	**(8%)**

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

- U.S. MS revenues in the first quarter of 2018 were negatively impacted by approximately $180 million due to the difference between the channel inventory level changes during the first quarter of 2018 and the fourth quarter of 2017 for TECFIDERA, AVONEX and PLEGRIDY.

- In the first quarter of 2017 TYSABRI revenues outside the U.S. benefitted by approximately $45 million due to reaching an agreement with the Price and Reimbursement Committee of the Italian National Medicines Agency (AIFA) related to TYSABRI sales in prior periods.
- In the first quarter of 2018 SPINRAZA revenues comprised $188 million in sales in the U.S. and $176 million in sales outside the U.S. The number of patients receiving SPINRAZA grew 16% in the U.S. and 56% outside the U.S. versus the fourth quarter of 2017. Outside the U.S., SPINRAZA revenues were primarily from Germany, Japan, Italy and France.
- Total revenues benefitted by approximately $54 million versus the prior year due to changes in foreign exchange rates, offset by hedging losses.

Expense Highlights

(In millions)	Q1 '18	Q1 '17	Q4 '17	Q1 '18 v. Q1 '17	Q1 '18 v. Q4 '17
GAAP cost of sales	$ 446	$ 385	$ 509	(16%)	12%
Non-GAAP cost of sales	$ 446	$ 385	$ 509	(16%)	12%
GAAP R&D	$ 497	$ 423	$ 588	(17%)	15%
Non-GAAP R&D	$ 497	$ 421	$ 588	(18%)	15%
GAAP SG&A	$ 501	$ 499	$ 572	(1%)	12%
Non-GAAP SG&A	$ 497	$ 482	$ 554	(3%)	10%

Other Financial Highlights

- For the first quarter of 2018 the Company's effective GAAP tax rate was 22%, and the Company's effective non-GAAP tax rate was 21%.
- In the first quarter of 2018 Biogen repurchased approximately 0.9 million shares of the Company's common stock for a total value of $250 million.
- As of March 31, 2018, Biogen had cash, cash equivalents and marketable securities totaling approximately $7.1 billion, and approximately $5.9 billion in notes payable. During the first quarter of 2018 Biogen repatriated $3.5 billion of cash, resulting in 85% of cash, cash equivalents and marketable securities being held in the U.S. at the end of the quarter.
- For the first quarter of 2018 the Company's weighted average diluted shares were 212 million.

Business Development Updates

- In April 2018 Biogen and Ionis Pharmaceuticals Inc. (Ionis) announced a new ten-year exclusive collaboration agreement that leverages Biogen's leadership in neuroscience research and drug development with Ionis' leadership in antisense oligonucleotide (ASO) drug discovery to develop novel gene-based drug candidates for a broad range of neurological diseases. Under the terms of the collaboration, Biogen will make an upfront payment of $375 million and purchase $500 million of Ionis equity at a 25% cash premium, for a total expected payment of $1 billion. Biogen will have the option to license therapies arising out of this collaboration and will be responsible for their development and commercialization. Biogen may pay development milestones to Ionis of up to $125 million or $270 million, depending on the indication, and royalties on net sales. The transaction is subject to customary closing conditions, including the expiration of the applicable waiting period under the Hart Scott Rodino Antitrust Improvements Act of 1976 in the United States and is expected to close in the second quarter of 2018.
- In March 2018 Biogen announced an agreement to acquire from Pfizer Inc. BIIB104 (formerly known as PF-04958242), and the transaction closed today. BIIB104 is a first-in-class, Phase 2b ready AMPA receptor potentiator for cognitive impairment associated with schizophrenia (CIAS), representing the Company's first program in neuropsychiatry. AMPA receptors mediate fast excitatory synaptic transmission in the central nervous system. BIIB104 has previously demonstrated an acceptable safety profile and treatment effect trends across key

cognitive domains in Phase 1b clinical studies. The purchase included an upfront payment of $75 million with up to $515 million in additional development and commercialization milestone payments, as well as tiered royalties in the low to mid-teen percentages.

Recent Events

- This week, Biogen is presenting data from its portfolio of marketed treatments and clinical development programs for neurodegenerative diseases at the 70th annual meeting of the American Academy of Neurology (AAN) in Los Angeles, California. Platform and poster presentations are highlighting the benefits SPINRAZA provides for individuals with spinal muscular atrophy (SMA) across the age and disease spectrum, the Company's MS therapies and non-therapeutic research collaborations designed to elevate the care of MS and the Company's investigational therapies for Alzheimer's disease, Parkinson's disease and progressive supranuclear palsy.
- In April 2018 Biogen's collaboration partner Applied Genetic Technologies Corporation announced that it has dosed the first patient in the Phase 1/2 clinical trial evaluating the safety and efficacy of an investigational AAV-based gene therapy for the treatment of x-linked retinitis pigmentosa.
- In April 2018 Biogen and Samsung Bioepis announced an agreement with AbbVie Inc. for the commercialization of IMRALDI™, a biosimilar referencing HUMIRA® (adalimumab). Under terms of the agreement, AbbVie will grant patent licenses for the use and sale of IMRALDI in Europe, on a country-by-country basis. The companies have agreed to dismiss all pending patent litigation. Biogen expects to launch IMRALDI in Europe in October 2018.
- In March 2018 Biogen initiated a Phase 1 study of BIIB095, a Nav 1.7 inhibitor for neuropathic pain.
- In March 2018 Biogen presented data from its portfolio of investigational therapies for people with neurodegenerative diseases at the Advances in Alzheimer's and Parkinson's Therapies (AAT-AD/PD) Focus Meeting in Torino, Italy. Data presented included an analysis from the Phase 1b PRIME study of aducanumab for early Alzheimer's disease demonstrating a 69% reduction from baseline in amyloid plaque as observed on the Centiloid Conversion scale for the 10 mg/kg treatment group at 54 weeks ($P<0.001$ versus placebo).
- In March 2018 Biogen presented new data for SPINRAZA for the treatment of SMA at the Muscular Dystrophy Association (MDA) Clinical Conference in Arlington, Virginia. Data included new interim Phase 2 results from NURTURE, the ongoing open-label, single-arm study evaluating the efficacy and safety of SPINRAZA among pre-symptomatic infants with SMA. In NURTURE, all infants treated with SPINRAZA were alive, did not require permanent ventilation and showed improvement in motor function and motor milestone achievements as of July 5, 2017, compared to the disease's natural history. Biogen also presented a case series demonstrating SPINRAZA's effectiveness among teens and young adults.
- In March 2018 Biogen and AbbVie announced the voluntary worldwide withdrawal of ZINBRYTA for relapsing MS. The companies believe that characterizing the complex and evolving benefit/risk profile of ZINBRYTA will not be possible going forward given the limited number of patients being treated.
- In February 2018 the end of study results from CHERISH, the Phase 3 study evaluating SPINRAZA for the treatment of individuals with later-onset SMA, were published in The *New England Journal of Medicine*. Results from CHERISH demonstrated meaningful motor function and upper limb improvements in individuals with later-onset SMA rarely seen in the natural course of the disease, which is typically a continued decline in motor function over time.
- In February 2018 Biogen announced that in the Phase 2b dose-ranging ACTION 2 study in individuals with acute ischemic stroke (AIS), natalizumab did not demonstrate improvement in clinical outcomes compared to placebo. Both doses of natalizumab were generally well-tolerated and no new or important safety signals were observed. The results of the Phase 2b ACTION 2 study do not impact the benefit-risk profile of natalizumab in approved indications, including MS. Further development of natalizumab in AIS will not be pursued.

Conference Call and Webcast

The Company's earnings conference call for the first quarter will be broadcast via the internet at 8:30 a.m. ET on April 24, 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 Future Earnings Releases and Calls

Starting with the second quarter 2018 earnings release, Biogen intends to cease 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 (@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, LinkedIn, Facebook, YouTube.

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; anticipated benefits and potential of investments, collaborations and business development activities; and the anticipated timing to complete certain transactions. These forward-looking statements may be accompanied by such words as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "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 sales 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 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 repurchase programs; 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.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.