Biogen Annual Report 2019

Form 10-K (NASDAQ:BIIB)

Published: February 6th, 2019

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2018

or

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission file number: 0-19311

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BIOGEN INC.

(Exact name of registrant as specified in its charter)

Delaware	**33-0112644**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*

225 Binney Street, Cambridge, Massachusetts 02142

(617) 679-2000

(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, $0.0005 par value	**The Nasdaq Global Select Market**

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes x No o

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files): Yes x No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer x	Accelerated filer o
Non-accelerated filer o	Smaller reporting company o
	Emerging growth company o

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. o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes o No x

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) computed by reference to the price at which the common stock was last sold as of the last business day of the registrant's most recently completed second fiscal quarter was $58,267,511,287.

As of February 1, 2019, the registrant had 196,708,784 shares of common stock, $0.0005 par value, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement for our 2019 Annual Meeting of Stockholders are incorporated by reference into Part III of this report.

BIOGEN INC.
ANNUAL REPORT ON FORM 10-K
For the Year Ended December 31, 2018
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NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements that are being made pursuant to the provisions of the Private Securities Litigation Reform Act of 1995 (the Act) with the intention of obtaining the benefits of the “Safe Harbor” provisions of the Act. 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,” “would” and other words and terms of similar meaning. Reference is made in particular to forward-looking statements regarding:

- the anticipated amount, timing and accounting of revenues; contingent, milestone, royalty and other payments under licensing, collaboration or acquisition agreements; tax positions and contingencies; collectability of receivables; pre-approval inventory; cost of sales; research and development costs; compensation and other selling, general and administrative expenses; amortization of intangible assets; foreign currency exchange risk; estimated fair value of assets and liabilities; and impairment assessments;
- expectations, plans and prospects relating to sales, pricing, growth and launch of our marketed and pipeline products;
- the timing, outcome and impact of administrative, regulatory, legal and other proceedings related to our patents and other proprietary and intellectual property rights, tax audits, assessments and settlements, pricing matters, sales and promotional practices, product liability and other matters;
- patent terms, patent term extensions, patent office actions and expected availability and period of regulatory exclusivity;
- the potential impact of increased product competition in the markets in which we compete, including increased competition from generics, biosimilars, prodrugs and other products approved under alternative regulatory pathways;
- our plans and investments in our core and emerging growth areas, as well as implementation of our 2017 corporate strategy;
- the drivers for growing our business, including our plans and intent to commit resources relating to research and development programs and business development opportunities;
- our ability to finance our operations and business initiatives and obtain funding for such activities;
- the costs and timing of potential clinical trials, filings and approvals, and the potential therapeutic scope of the development and commercialization of our and our collaborators’ pipeline products;
- adverse safety events involving our marketed products or generic or biosimilar products marketed by others;
- the potential impact of healthcare reform in the United States (U.S.) and measures being taken worldwide designed to reduce healthcare costs and limit the overall level of government expenditures, including the impact of pricing actions and reduced reimbursement for our products;
- our manufacturing capacity, use of third-party contract manufacturing organizations and plans and timing relating to the expansion of our manufacturing capabilities, including anticipated investments and activities in new manufacturing facilities;
- the anticipated benefits and the potential costs and expenses related to our current or future initiatives to streamline our operations and reallocate resources;
- the impact of the continued uncertainty of the credit and economic conditions in certain countries in Europe and our collection of accounts receivable in such countries;
- the potential impact on our results of operations and liquidity of the United Kingdom's (U.K.) intent to voluntarily depart from the European Union (E.U.);
- lease commitments, purchase obligations and the timing and satisfaction of other contractual obligations;
- the impact of new laws, regulatory requirements, judicial decisions and accounting standards; and
- the anticipated costs and tax treatment of the spin-off of our hemophilia business as well as the timeline for selling substantially all remaining hemophilia related inventory.

These forward-looking statements involve risks and uncertainties, including those that are described in Item 1A. *Risk Factors* included in this report and elsewhere in this report that could cause actual results to differ materially from those reflected in such statements. You should not place undue reliance on these statements. Forward-looking statements speak only as of the date of this report. Except as required by law, we do not undertake any obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

NOTE REGARDING COMPANY AND PRODUCT REFERENCES

References in this report to:

- “Biogen,” the “company,” “we,” “us” and “our” refer to Biogen Inc. and its consolidated subsidiaries;
- “RITUXAN” refers to both RITUXAN (the trade name for rituximab in the U.S., Canada and Japan) and MabThera (the trade name for rituximab outside the U.S., Canada and Japan); and
- "ELOCTATE" refers to both ELOCTATE (the trade name for Antihemophilic Factor (recombinant), Fc Fusion Protein in the U.S., Canada and Japan) and ELOCTA (the trade name for Antihemophilic Factor (recombinant), Fc Fusion Protein in the E.U.).

NOTE REGARDING TRADEMARKS

PART I

Item 1. Business

Overview

Biogen is a global biopharmaceutical company focused on discovering, developing and delivering worldwide innovative therapies for people living with serious neurological and neurodegenerative diseases, including in our core growth areas of multiple sclerosis (MS) and neuroimmunology, Alzheimer's disease (AD) and dementia, movement disorders, including Parkinson's disease, and neuromuscular disorders, including spinal muscular atrophy (SMA) and amyotrophic lateral sclerosis (ALS). We are also focused on discovering, developing and delivering worldwide innovative therapies in our emerging growth areas of acute neurology, neurocognitive disorders, pain and ophthalmology. In addition, we are employing innovative technologies to discover potential treatments for rare and genetic disorders, including new ways of treating diseases through gene therapy in our core and emerging growth areas. We also manufacture and commercialize biosimilars of advanced biologics.

biogenbubbles.jpg

Our marketed products include TECFIDERA, AVONEX, PLEGRIDY, TYSABRI and FAMPYRA for the treatment of MS, SPINRAZA for the treatment of SMA and FUMADERM for the treatment of severe plaque psoriasis. We also have certain business and financial rights with respect to RITUXAN for the treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukemia (CLL) and other conditions, RITUXAN HYCELA for the treatment of non-Hodgkin's lymphoma and CLL, GAZYVA for the treatment of CLL and follicular lymphoma, OCREVUS for the treatment of primary progressive MS (PPMS) and relapsing MS (RMS) and other potential anti-CD20 therapies pursuant to our collaboration arrangements with Genentech, Inc. (Genentech), a wholly-owned member of the Roche Group. For additional information on our collaboration arrangements with Genentech, please read Note 19, *Collaborative and Other Relationships*, to our consolidated financial statements included in this report.

We support our drug discovery and development efforts through the commitment of significant resources to discovery, research and development programs and business development opportunities. For over two decades we have led in the research and development of new therapies to treat MS, resulting in our leading portfolio of MS treatments. Now our research is focused on additional improvements in the treatment of MS, such as the development of next generation therapies for MS, with a goal to reverse or possibly repair damage caused by the disease. We are also applying our scientific expertise to solve some of the most challenging and complex diseases, including AD, progressive supranuclear palsy (PSP), Parkinson's disease, ALS, stroke, epilepsy, cognitive impairment associated with schizophrenia (CIAS) and pain.

Our innovative drug development and commercialization activities are complemented by our biosimilar products that expand access to medicines and reduce the cost burden for healthcare systems. We are leveraging our manufacturing capabilities and know-how to develop, manufacture and market biosimilar products through Samsung Bioepis Co., Ltd. (Samsung Bioepis), our joint venture with Samsung BioLogics Co., Ltd. (Samsung BioLogics). Under our commercial agreement, we market and sell BENEPALI, an etanercept biosimilar referencing ENBREL, FLIXABI, an infliximab biosimilar referencing REMICADE, and IMRALDI, an adalimumab biosimilar referencing HUMIRA, in the E.U. For additional information on our collaboration arrangement with Samsung Bioepis, please read Note 19, *Collaborative and Other Relationships*, to our consolidated financial statements included in this report.

Key Business Developments

The following is a summary of key developments affecting our business since the beginning of 2018.

For additional information on our acquisitions, collaborative and other relationships discussed below, please read Note 2, *Acquisitions,* Note 19, *Collaborative and Other Relationships*, Note 20, *Investments in Variable Interest Entities*, and Note 27, *Subsequent Events*, to our consolidated financial statements included in this report.

Acquisitions, Collaborative and Other Relationships

BIIB100 Acquisition

In January 2018 we acquired BIIB100 (formerly known as KPT-350) from Karyopharm Therapeutics Inc. (Karyopharm). BIIB100 is a Phase 1 ready investigational oral compound for the treatment of certain neurological and neurodegenerative diseases, primarily in ALS. BIIB100 is a novel therapeutic candidate that works by inhibiting a protein known as XP01, with the goal of reducing inflammation and neurotoxicity, along with increasing neuroprotective responses.

BIIB104 Acquisition

In April 2018 we acquired BIIB104 (formerly known as PF-04958242) from Pfizer Inc. (Pfizer). BIIB104 is a first-in-class, Phase 2b ready AMPA receptor potentiator for CIAS, representing our first program in neurocognitive disorders. AMPA receptors mediate fast excitatory synaptic transmission in the central nervous system, a process which can be disrupted in a number of neurological and psychiatric diseases, including schizophrenia.

Neurimmune SubOne AG

In May 2018 we made a $50.0 million payment to Neurimmune SubOne AG (Neurimmune) under the terms of our amended collaboration and license agreement with Neurimmune (as amended, the Neurimmune Agreement) to reduce the previously negotiated royalty rates payable on products developed under the Neurimmune Agreement, including royalties payable on potential commercial sales of aducanumab, our anti-amyloid beta antibody candidate for the treatment of AD, by 5%. Our royalty rates payable on products developed under the Neurimmune Agreement, including royalties payable on potential commercial sales of aducanumab, will now range from the high single digits to sub-teens.

Ionis Pharmaceuticals, Inc.

In June 2018 we closed a 10-year exclusive agreement with Ionis Pharmaceuticals, Inc. (Ionis) to develop novel antisense oligonucleotide (ASO) drug candidates for a broad range of neurological diseases (the 2018 Ionis Agreement). We have the option to license therapies arising out of the 2018 Ionis Agreement and will be responsible for the development and potential commercialization of such therapies.

TMS Co., Ltd. Option Agreement

In June 2018 we entered into an exclusive option agreement with TMS Co., Ltd. (TMS) granting us the option to acquire TMS-007, a plasminogen activator with a novel mechanism of action (MOA) associated with breaking down blood clots, which is in Phase 2 development in Japan, and backup compounds for the treatment of stroke.

Samsung Bioepis

In June 2018 we exercised our option under our joint venture agreement with Samsung BioLogics to increase our ownership percentage in Samsung Bioepis from approximately 5% to approximately 49.9%. The share purchase transaction was completed in November 2018.

BIIB110 Acquisition

In July 2018 we acquired BIIB110 (formerly known as ALG-801) (Phase 1a) and ALG-802 (preclinical) from AliveGen Inc. (AliveGen). BIIB110 and ALG-802 represent novel ways of targeting the myostatin pathway. We initially plan to study BIIB110 in multiple neuromuscular indications, including SMA and ALS.

BIIB067 Option Exercise

In December 2018 we exercised our option with Ionis and obtained a worldwide, exclusive, royalty-bearing license to develop and commercialize BIIB067 (IONIS-SOD1$_{Rx}$), an investigational treatment for ALS with superoxide dismutase 1 (SOD1) mutations.

C4 Therapeutics

In December 2018 we entered into a collaborative research and license agreement with C4 Therapeutics (C4T) to investigate the use of C4T's novel protein degradation platform to discover and develop potential new treatments

for neurological diseases, such as AD and Parkinson's disease. We will be responsible for the development and potential commercialization of any therapies resulting from this collaboration.

Skyhawk Therapeutics, Inc.

In January 2019 we entered into a collaboration and research and development services agreement with Skyhawk Therapeutics, Inc. (Skyhawk) pursuant to which the companies will leverage Skyhawk's SkySTAR technology platform with the goal of discovering innovative small molecule treatments for patients with neurological diseases, including MS and SMA. We will be responsible for the development and potential commercialization of any therapies resulting from this collaboration.

Other Key Developments

ZINBRYTA Withdrawal

In March 2018 we and AbbVie Inc. (AbbVie) announced the voluntary worldwide withdrawal of ZINBRYTA for RMS.

IMRALDI

In October 2018 we began to recognize revenues on sales of IMRALDI, an adalimumab biosimilar referencing HUMIRA, to third parties in the E.U. We and Samsung Bioepis previously entered into an agreement with AbbVie for the commercialization of IMRALDI. Under the terms of the agreement, AbbVie granted us and Samsung Bioepis patent licenses for the use and sale of IMRALDI in Europe, on a country-by-country basis, and we make royalty payments to AbbVie on behalf of Samsung Bioepis.

2018 Share Repurchase Program

In August 2018 our Board of Directors authorized a program to repurchase up to $3.5 billion of our common stock (2018 Share Repurchase Program). Our 2018 Share Repurchase Program does not have an expiration date. All share repurchases under our 2018 Share Repurchase Program will be retired.

Product and Pipeline Developments

Core Growth Areas

Multiple Sclerosis and Neuroimmunology

TECFIDERA (dimethyl fumarate)

- In April 2018 we presented new real-world data that demonstrated that people with RMS treated with TECFIDERA early in the course of their disease may experience better long-term outcomes. These data were presented at the 70th annual meeting of the American Academy of Neurology (AAN) in Los Angeles, CA.
- In October 2018 we presented clinical and real-world evidence that further support the long-term efficacy and well characterized safety of TECFIDERA early within the disease course. These data were presented at the 34th Congress of the European Committee for Treatment and Research in MS (ECTRIMS) in Berlin, Germany.

TYSABRI (natalizumab)

- In April 2018, at the 70th annual meeting of the AAN in Los Angeles, CA, we presented new real-world data that demonstrated that people with RMS treated with TYSABRI early in the course of their disease may experience better long-term outcomes.
- In April 2018 we presented observational data that demonstrated that extended interval dosing with TYSABRI is associated with a significant reduction in the risk of progressive multifocal leukoencephalopathy (PML), a serious brain injury, compared with standard interval dosing in the TOUCH prescribing program. These data were presented at the 70th annual meeting of the AAN in Los Angeles, CA. In November 2018 we initiated the Phase 3b NOVA study evaluating the efficacy and safety of extended interval dosing (every six weeks) for natalizumab compared to standard interval dosing in patients with RMS and enrolled the first patient in December 2018.
- In October 2018 we presented clinical and real-world evidence that further support the long-term efficacy and well characterized safety of TYSABRI early within the disease course. These data were presented at the 34th Congress of ECTRIMS in Berlin, Germany.

PLEGRIDY (peginterferon beta-1a)

- In December 2018 we dosed the first patient in a bioequivalence study to test whether exposure levels of PLEGRIDY are maintained with intramuscular administration.

ZINBRYTA (daclizumab)

- In March 2018 we and AbbVie announced the voluntary worldwide withdrawal of ZINBRYTA for RMS.

BIIB098 (formerly known as ALKS 8700) (diroximel fumarate; DRF)

- In April 2018 MRI and relapse results from the Phase 3 EVOLVE-MS-1 study for diroximel fumarate in patients with relapsing remitting MS (RRMS) were presented at the 70th annual meeting of the AAN in Los Angeles, CA.
- In December 2018 Alkermes Pharma Ireland Limited, a subsidiary of Alkermes plc (Alkermes), submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for diroximel fumarate. Alkermes is seeking approval of diroximel fumarate under the 505(b)(2) regulatory pathway. If approved, we intend to market diroximel fumarate under the brand name VUMERITY. This name has been conditionally accepted by the FDA and will be confirmed upon approval.

Opicinumab (anti-LINGO)

- In September 2018 we completed enrollment of 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.

Neuromuscular Disorders

SPINRAZA (nusinersen)

- 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 March 2018 we presented 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. We also presented a case series demonstrating SPINRAZA's effectiveness among teens and young adults. These data were presented at the Muscular Dystrophy Association Clinical Conference in Arlington, VA.

- In April 2018 we presented data from the CS2/CS12 studies that demonstrated that with SPINRAZA treatment, older patients were able to walk longer distances while experiencing stable or less fatigue at the same time, in contrast to natural history. The study participants have Type 2 or Type 3 SMA and were ages 12 to 15 years at study enrollment.

  We also presented data on part one of the Phase 2 EMBRACE study as well as an interim analysis of the SHINE open-label extension study, which examined the longer-term safety and efficacy of SPINRAZA in infantile-onset SMA patients.

  These data were presented at the 70th annual meeting of the AAN in Los Angeles, CA.

- In June 2018 we presented data from our SPINRAZA clinical development program for SMA at the Cure SMA 2018 Annual SMA Conference in Dallas, TX. Platform and poster presentations highlighted interim analyses from the SHINE and NURTURE studies, which assess SPINRAZA's safety and efficacy among those with infantile-onset SMA, and data on the utility of plasma phosphorylated neurofilament heavy chain (pNF-H) as a potential biomarker for SMA.

- In October 2018 we presented new interim results from NURTURE, an ongoing open-label, single-arm efficacy and safety study of SPINRAZA in 25 presymptomatic infants with SMA at the Annual Congress of the World Muscle Society 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 November 2018 we were awarded the 2018 International Prix Galien as Best Biotechnology Product for SPINRAZA. The prestigious honor marks the seventh Prix Galien for SPINRAZA, following country recognitions in the U.S., Germany, Italy, Belgium-Luxembourg, the Netherlands, and the U.K. The International Prix Galien is given every two years by Prix Galien International Committee members in recognition of excellence in scientific innovation to improve human health.

BIIB089 - SMA

- In May 2018 we submitted an Investigational New Drug Application for BIIB089 in SMA.

- In October 2018 we announced that the FDA had placed BIIB089 on a clinical hold.

BIIB078 (IONIS-C9$_{Rx}$) - ALS

- In September 2018 we enrolled the first patient in the Phase 1 study evaluating BIIB078, an ASO drug candidate, in adults with C9ORF72-associated ALS.

BIIB067 (IONIS-SOD1$_{Rx}$) - ALS

- In December 2018 we and Ionis announced results from a positive interim analysis of the ongoing Phase 1 study of BIIB067 in ALS with SOD1 mutations. The interim analysis showed that, over a three month period,