Biogen Annual Report 2020

Form 10-K (NASDAQ:BIIB)

Published: February 6th, 2020

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

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

For the fiscal year ended December 31, 2019

or

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

Commission file number: 0-19311

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, MA 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	Trading Symbol(s)	Name of Each Exchange Where Registered
Common Stock, $0.0005 par value	**BIIB**	**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 (§ 232.405 of this chapter) 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 whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		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. o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ 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 $43,010,112,437.

As of February 4, 2020, the registrant had 174,064,011 shares of common stock, $0.0005 par value, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement for our 2020 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, 2019
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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, acquisition or divestiture 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 products approved under abbreviated regulatory pathways;
- our plans and investments in our core and emerging growth areas, as well as implementation of our corporate strategy;
- the drivers for growing our business, including our plans and intention to commit resources relating to research and development programs and business development opportunities, as well as the potential benefits and results of, and the anticipated timing to complete, certain business development transactions;
- 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, generic or biosimilar versions of our marketed products or any other products from the same class as one of our products;
- 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, plans and timing relating to changes in our manufacturing capabilities and activities in new or existing manufacturing facilities;
- 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.) departure from the European Union (E.U.);
- lease commitments, purchase obligations and the timing and satisfaction of other contractual obligations; and
- the impact of new laws, including the Swiss Federal Act on Tax Reform and AHV Financing, regulatory requirements, judicial decisions and accounting standards.

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 as well as related therapeutic adjacencies. Our core growth areas include multiple sclerosis (MS) and neuroimmunology; Alzheimer's disease (AD) and dementia; neuromuscular disorders, including spinal muscular atrophy (SMA) and amyotrophic lateral sclerosis (ALS); movement disorders, including Parkinson's disease; and ophthalmology. We are also focused on discovering, developing and delivering worldwide innovative therapies in our emerging growth areas of immunology; neurocognitive disorders; acute neurology; and pain. In addition, we commercialize biosimilars of advanced biologics. We support our drug discovery and development efforts through the commitment of significant resources to discovery, research and development programs and business development opportunities.

Our marketed products include TECFIDERA, AVONEX, PLEGRIDY, TYSABRI, VUMERITY 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 18, *Collaborative and Other Relationships*, to our consolidated financial statements included in this report.

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 also introduced the first approved treatment for SMA and are continuing to pursue research and development for potential advancements in the treatment of SMA, including a muscle enhancement program, novel antisense oligonucleotide (ASO) drug candidates and an oral splicing modulator. We are also applying our scientific expertise to solve some of the most challenging and complex diseases, including AD, ALS, Parkinson's disease, choroideremia (CHM), X-linked retinitis pigmentosa (XLRP), systemic lupus erythematosus (SLE), cutaneous lupus erythematosus (CLE), cognitive impairment associated with schizophrenia (CIAS), stroke, epilepsy and pain.

Our innovative drug development and commercialization activities are complemented by our biosimilar business that expands access to medicines and reduce the cost burden for healthcare systems. Through Samsung Bioepis Co., Ltd. (Samsung Bioepis), our joint venture with Samsung BioLogics Co., Ltd. (Samsung BioLogics), we market and sell BENEPALI, an etanercept biosimilar referencing ENBREL, IMRALDI, an adalimumab biosimilar referencing HUMIRA, and FLIXABI, an infliximab biosimilar referencing REMICADE, in certain countries in Europe and have exclusive rights to commercialize these products in China. Additionally, we have exclusive rights to commercialize two potential ophthalmology biosimilar products, SB11 referencing LUCENTIS and SB15 referencing EYLEA, in major markets worldwide, including the U.S., Canada, Europe, Japan and Australia. For additional information on our collaboration arrangements with Samsung Bioepis, please read Note 18, *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 2019.

For additional information on our acquisitions, collaborative and other relationships discussed below, please read Note 2, *Acquisitions*, Note 3, *Divestitures,* Note 18, *Collaborative and Other Relationships,* and Note 19, *Investments in Variable Interest Entities,* to our consolidated financial statements included in this report.

Acquisitions, Collaborative and Other Relationships

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 are leveraging Skyhawk's SkySTAR technology platform with the goal of discovering innovative small molecule treatments for patients with neurological diseases, including MS and SMA. We are responsible for the development and potential commercialization of any therapies resulting from this collaboration. In October 2019 we amended this agreement to add an additional discovery program.

Nightstar Therapeutics plc

In June 2019 we completed our acquisition of all of the outstanding shares of Nightstar Therapeutics plc (NST), a clinical-stage gene therapy company focused on adeno-associated virus (AAV) treatments for inherited retinal disorders. As a result of this acquisition, we added two mid- to late-stage clinical assets, as well as preclinical programs, in ophthalmology.

Divestiture of Hillerød, Denmark Manufacturing Operations

In August 2019 we completed the sale of all of the outstanding shares of our subsidiary that owned our biologics manufacturing operations in Hillerød, Denmark to FUJIFILM Corporation (FUJIFILM).

Samsung Bioepis

In December 2019 we completed a transaction with Samsung Bioepis and secured the exclusive rights to commercialize two potential ophthalmology biosimilar products, SB11 referencing LUCENTIS and SB15 referencing EYLEA, in major markets worldwide, including the U.S., Canada, Europe, Japan and Australia. We also acquired an option to extend our existing commercial agreement with Samsung Bioepis for BENEPALI, IMRALDI and FLIXABI in Europe and obtained exclusive rights to commercialize these products in China.

BIIB080 Option Exercise

In December 2019 we exercised our option with Ionis Pharmaceuticals, Inc. (Ionis) and obtained a worldwide, exclusive, royalty-bearing license to develop and commercialize BIIB080 (tau ASO), an investigational treatment for AD.

Pfizer Inc.

In January 2020 we entered into an agreement to acquire PF-05251749, a novel CNS-penetrant small molecule inhibitor of casein kinase 1 (CK1), for the potential treatment of patients with behavioral and neurological symptoms across various psychiatric and neurological diseases from Pfizer Inc. (Pfizer). In particular, we plan to develop the Phase 1 asset for the treatment of sundowning in AD and irregular sleep wake rhythm disorder (ISWRD) in Parkinson's disease. This 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 U.S. We expect this transaction to close in the first quarter of 2020.

Other Key Developments

VUMERITY

In October 2019 the U.S. Food and Drug Administration (FDA) approved VUMERITY for the treatment of RMS. The FDA approval of VUMERITY was based on a New Drug Application (NDA) submitted under the 505(b)(2) filing pathway. It included interim exposure and safety findings from EVOLVE-MS-1, an ongoing, Phase 3, single-arm, open label, two-year safety study evaluating VUMERITY in patients with relapsing remitting MS (RRMS), and data from pharmacokinetic bridging studies comparing VUMERITY and TECFIDERA to establish bioequivalence, and relied, in part, on the FDA's findings of safety and efficacy for TECFIDERA. In November 2019 VUMERITY became available in the U.S.

Aducanumab (Aβ mAb)

In October 2019 we and our collaboration partner Eisai Co., Ltd. (Eisai) announced that we plan to pursue regulatory approval for aducanumab, our anti-amyloid beta antibody candidate for the potential treatment of AD, in the U.S.

2019 Share Repurchase Programs

In March 2019 our Board of Directors authorized a program to repurchase up to $5.0 billion of our common stock (March 2019 Share Repurchase Program). Our March 2019 Share Repurchase Program does not have an expiration date. All share repurchases under our March 2019 Share Repurchase Program will be retired.

In December 2019 our Board of Directors authorized a program to repurchase up to $5.0 billion of our common stock (December 2019 Share Repurchase Program). Our December 2019 Share Repurchase Program does not have an expiration date. All share repurchases under our December 2019 Share Repurchase Program will be retired.

Board of Directors Update

In June 2019 stockholders elected two new independent directors, William A. Hawkins and Jesus B. Mantas, to Biogen's Board of Directors, who are each serving for a one-year term until the 2020 annual meeting of stockholders and their successors are duly elected and qualified.

Management Changes

During 2019 we announced the following management changes:

- The appointment of Alfred Sandrock, Jr., M.D., Ph.D. as Executive Vice President, Research and Development; and
- The appointment of Alphonse Galdes, Ph.D., as Executive Vice President, Pharmaceutical Operations and Technology.

For additional information on these and our other executive officers, please read the subsection entitled "Information about our Executive Officers" included in this report.

Product and Pipeline Developments

Core Growth Areas

Multiple Sclerosis and Neuroimmunology

TECFIDERA (dimethyl fumarate)

- In May 2019, at the 71st annual meeting of the American Academy of Neurology (AAN) in Philadelphia, PA, we presented re-analyzed pooled images from the Phase 3 DEFINE and CONFIRM studies that showed that treatment with TECFIDERA significantly slowed the rate of whole brain volume loss by 35.9% during the second year of treatment compared to placebo.
- In September 2019, at the 35th Congress of the European Committee for Treatment and Research in MS (ECTRIMS) and 24th Annual Conference of Rehabilitation in MS in Stockholm, Sweden, we presented new 10-year results from the ongoing Phase 3 ENDORSE extension study and comparative effectiveness analyses of TECFIDERA that support the consistent, long-term benefits of treatment with TECFIDERA.

TYSABRI (natalizumab)

- In January 2019 the first patient was enrolled in the global Phase 3b NOVA study evaluating the efficacy and safety of extended interval dosing (EID; every six weeks) for natalizumab compared to standard interval dosing in patients with RMS.
- In May 2019, at the 71st annual meeting of the AAN in Philadelphia, PA, we presented updated safety analyses from the TOUCH database safety analysis evaluating EID of natalizumab (of approximately every six weeks) compared to every four-week dosing based on the TOUCH prescribing program database.
- In September 2019, at the 35th Congress of ECTRIMS and 24th Annual Conference of Rehabilitation in MS in Stockholm, Sweden, we presented new data from the observational, open-label, single-arm STRIVE study that support the real-world long-term effectiveness of TYSABRI in patients with early RMS, who are within three years from diagnosis and are anti-JC virus antibody negative.

AVONEX (interferon beta-1a) and PLEGRIDY (peginterferon beta-1a)

- In September 2019, at the 35th Congress of ECTRIMS and 24th Annual Conference of Rehabilitation in MS in Stockholm, Sweden, we presented new data from two real-world observational studies that provide further support that exposure to interferon beta treatment, including AVONEX and PLEGRIDY, before conception and/or during pregnancy is not expected to have an adverse effect on pregnancy or infant growth outcomes.
- In October 2019 the European Medicines Agency (EMA) updated the summaries of product characteristics for AVONEX and PLEGRIDY to remove pregnancy contraindications and, where clinically needed, to allow use during pregnancy and breastfeeding in women with RMS.

VUMERITY (diroximel fumarate; DRF)

- In May 2019, at the 71st annual meeting of the AAN in Philadelphia, PA, we presented updated safety and exploratory efficacy results from the ongoing open-label EVOLVE-MS-1 study of VUMERITY in RMS.
- In May 2019 we presented new interim data from the EVOLVE-MS-1 study at the annual meeting of the Consortium of Multiple Sclerosis Centers in Seattle, WA. These data indicated that VUMERITY was generally well tolerated and significantly reduced disease activity in newly diagnosed RMS patients and those previously treated with interferons or glatiramer acetate. Treatment discontinuations due to gastrointestinal events occurred at a low rate over one year.
- In July 2019 we and Alkermes plc announced positive topline results from EVOLVE-MS-2, a large, randomized, double-blind, five-week, Phase 3 study of VUMERITY for RMS, compared to TECFIDERA. VUMERITY was statistically superior to TECFIDERA on the study's pre-specified primary endpoint, with patients treated with VUMERITY self-reporting significantly fewer days of key gastrointestinal symptoms with intensity scores ≥ 2 on the Individual Gastrointestinal Symptom and Impact Scale, as compared to TECFIDERA (p=0.0003).
- In September 2019, at the 35th Congress of ECTRIMS and 24th Annual Conference of Rehabilitation in MS in Stockholm, Sweden, we presented interim data from the Phase 3 EVOLVE-MS-1 study that support the potential of VUMERITY as a novel oral fumarate.
- In November 2019, at the 27th Annual Meeting of the European Charcot Foundation in Italy, we presented results from the Phase 3 EVOLVE-MS-2 study demonstrating the improved patient-assessed gastrointestinal tolerability of VUMERITY compared to TECFIDERA.

BIIB091 (BTK inhibitor)

- In May 2019 the first participant was dosed in the Phase 1 study of BIIB091 in MS.
- In December 2019 dosing began for the final multiple ascending dose cohort in the Phase 1 study of BIIB091 in MS.

Alzheimer's Disease and Dementia

Aducanumab (Aβ mAb)

- In March 2019 we and our collaboration partner Eisai announced the decision to discontinue the global Phase 3 trials, ENGAGE and EMERGE, designed to evaluate the efficacy and safety of aducanumab in patients with mild cognitive impairment due to AD and mild AD dementia.
- In October 2019 we and our collaboration partner Eisai announced that we plan to pursue regulatory approval for aducanumab in the U.S. and that the Phase 3 EMERGE study met its primary endpoint showing a significant reduction in clinical decline. We believe that results from a subset of patients in the Phase 3 ENGAGE study who received sufficient exposure to high dose aducanumab support the findings from EMERGE. The decision to file is based on a new analysis, conducted in consultation with the FDA, of a larger dataset from the Phase 3 EMERGE and ENGAGE trials that were discontinued in March 2019 following a futility analysis.
- In December 2019, at the 12th Clinical Trials on Alzheimer's Disease annual meeting in San Diego, CA, we presented topline results from the Phase 3 EMERGE and ENGAGE trials of aducanumab.

BAN2401 (Aβ mAb)

- In May 2019 our collaboration partner Eisai dosed the first patient in the global Phase 3 study (Clarity AD) of BAN2401 in early AD.

BIIB092 (gosuranemab)

- In September 2019 we completed enrollment of the Phase 2 study of gosuranemab for early AD.

Neuromuscular Disorders

SPINRAZA (nusinersen)

- In February 2019 SPINRAZA was approved by the China National Medical Products Association for the treatment of 5q SMA.
- In April 2019 we presented new data illustrating the rapidly progressive nature of SMA in adults, adolescents and older children. We also presented data from the NURTURE study, highlighting the benefits of pre-symptomatic treatment and findings on the role of neurofilament as a potential biomarker for predicting motor function in SMA. These data were presented at the Muscular Dystrophy Association Clinical and Scientific Conference in Orlando, FL.
- In April 2019 data from CS2/CS12, an open-label study of the safety and tolerability of SPINRAZA in individuals with later-onset SMA, were published in the peer-reviewed journal *Neurology*, the medical journal of the AAN. The data showed that individuals with later-onset SMA, treated with SPINRAZA, regained motor function that had been previously lost and that treatment stabilized their disease activity leading to improvements in activities of daily living.
- In May 2019, at the 71st annual meeting of the AAN in Philadelphia, PA, we presented data from the NURTURE study that demonstrated that pre-symptomatic infants with SMA treated with SPINRAZA over three years achieved motor milestones that are more consistent with normal childhood development, as well as interim results from the ENDEAR/CHERISH/SHINE open-label extension study that showed that treatment with SPINRAZA, particularly when initiated earlier, leads to progressive motor milestone improvements and increased survival rates for individuals with infantile-onset SMA.
- In May 2019 The National Institute for Health and Care Excellence (NICE) in the U.K. recommended funding for SPINRAZA on the National Health Service. The positive recommendation is for the treatment of infants, children and adults with 5q SMA, including pre-symptomatic and symptomatic SMA Types 1, 2 and 3.
- In June and July 2019 we presented new results from the NURTURE study, adding data to the longest study of SMA in pre-symptomatic infants (n=25). The data reported, after up to 45.1 months of analysis, continued to demonstrate efficacy and safety in patients treated pre-symptomatically with SPINRAZA in comparison to the natural history of SMA. These new data also showed that patients treated with SPINRAZA had continuous improvement, with the majority of patients achieving motor milestones within timeframes consistent with normal development. These data were presented at the Cure SMA Annual SMA Conference in Anaheim, CA and the 5th Congress of the European Academy of Neurology in Oslo, Norway.
- In September 2019 we announced that we plan to initiate DEVOTE, a new Phase 2/3 study evaluating whether a higher dose of SPINRAZA can offer even greater efficacy in treating SMA, as well as the safety and tolerability of SPINRAZA, when administered at a higher dose.
- In September 2019 we presented new data further demonstrating the safety and efficacy of treatment with SPINRAZA in individuals with later-onset SMA at the 13th Congress of the European Paediatric Neurology Society in Athens, Greece. An integrated analysis from SHINE, an open-label extension study for patients with SMA who participated in prior SPINRAZA studies, found that children with later-onset SMA (Type 2 or Type 3) experienced improvements or stabilization in one or more measures of motor function for up to nearly six years, in contrast to the expected decline observed in natural history cohorts.
- In October 2019 the journal *Neuromuscular Disorders* published data from NURTURE, the first study investigating a treatment targeting the underlying cause of SMA in infants treated pre-symptomatically. Data from the NURTURE study demonstrated that infants who initiated treatment with SPINRAZA prior to the onset of clinical symptoms attained unparalleled results compared to the natural history of the disease. These published results from the NURTURE study were previously presented at the 2019 Cure SMA Annual