

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): **February 3, 2022**

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))

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, \$0.0005 par value	BIIB	The Nasdaq Global Select Market

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 February 3, 2022, Biogen Inc. issued a press release announcing its results of operations and financial condition for the fourth quarter and year ended December 31, 2021. 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.

(d) Exhibits

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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Biogen's press release dated February 3, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)



BIOGEN REPORTS FOURTH QUARTER AND FULL YEAR 2021 RESULTS

Revenue: Fourth quarter \$2,734 million; Full Year \$10,982 million

GAAP diluted EPS: Fourth quarter \$2.50; Full Year \$10.40

Non-GAAP diluted EPS: Fourth quarter \$3.39; Full Year \$19.22

Engaging with Centers for Medicare and Medicaid Services on ADUHELM reimbursement

Biogen to sell its equity in its biosimilar joint venture to Samsung Biologics for up to \$2.3 billion

Biogen exercises option with Genentech to share profits for a late-stage bispecific antibody

Progressing the pipeline with 5 key data readouts and 3 regulatory filings expected in 2022

Cambridge, Mass., February 3, 2022 -- Biogen Inc. (Nasdaq: BIIB) today reported fourth quarter and full year 2021 financial results.

“Biogen continued to execute well in the fourth quarter despite the challenges we have faced,” said Michel Vounatsos, Biogen's Chief Executive Officer. “We have introduced the first FDA approved treatment for Alzheimer’s disease in nearly 20 years, and we are engaging with the Centers for Medicare and Medicaid Services with the hope of finding a path for immediate patient access.”

Fourth Quarter 2021 Operating Results

- Fourth quarter total revenue of \$2,734 million decreased 4% versus the prior year at both actual currency and constant currency*.
 - Multiple sclerosis (MS) revenue, including royalties on sales of OCREVUS[®], of \$1,789 million decreased 1% versus the prior year at both actual currency and constant currency.
 - SPINRAZA[®] revenue of \$441 million decreased 12% versus the prior year at actual currency and 10% at constant currency.
 - ADUHELM[®] revenue was \$1 million.
 - Biosimilars revenue of \$221 million increased 12% versus the prior year at actual currency and 13% at constant currency.
- Fourth quarter GAAP net income and diluted earnings per share (EPS) attributable to Biogen Inc. were \$368 million and \$2.50, respectively.
- Fourth quarter Non-GAAP net income and diluted EPS attributable to Biogen Inc. were \$500 million and \$3.39, respectively.

A reconciliation of GAAP to Non-GAAP financial measures can be found in Table 4 at the end of this news release.

* Percentage changes in revenue growth at constant currency are presented excluding the impact of changes in foreign currency exchange rates and hedging gains or losses. The current period's foreign currency revenue values are converted into U.S. dollars using the average exchange rates from the prior period.

- Fourth quarter GAAP and Non-GAAP cost of sales was \$660 million as compared to \$491 million in the fourth quarter of 2020.
 - Fourth quarter 2021 GAAP and Non-GAAP cost of sales includes approximately \$164 million in charges associated with inventory and purchase commitments in excess of forecasted demand related to ADUHELM. Eisai Co., Ltd.'s (Eisai's) share of these charges (approximately 45%) is reflected in collaboration profit sharing.
- Fourth quarter GAAP and Non-GAAP R&D expense was \$700 million as compared to \$1,726 million in the fourth quarter of 2020.
 - Fourth quarter 2020 GAAP and Non-GAAP R&D expense includes a \$1,084 million charge related to the collaboration with Sage Therapeutics Inc. (Sage).
 - Fourth quarter 2021 GAAP and Non-GAAP R&D expense includes a \$60 million opt-in payment to Ionis Pharmaceuticals, Inc. (Ionis) to obtain exclusive rights to develop and commercialize BIIB115, a preclinical investigational antisense oligonucleotide (ASO) for the treatment of spinal muscular atrophy (SMA), and approximately \$50 million related to the exercise of our option to participate in a profit-sharing arrangement with Genentech, Inc. for the development and commercialization of mosunetuzumab, a late-stage bispecific antibody in development for B-cell non-Hodgkin's lymphoma and other therapeutic areas.
- Fourth quarter GAAP SG&A expense was \$788 million as compared to \$806 million in the fourth quarter of 2020. Fourth quarter Non-GAAP SG&A expense was \$785 million as compared to \$803 million in the fourth quarter of 2020.
 - Beginning in the second quarter of 2021, upon FDA approval, the reimbursement from Eisai for its share of U.S. ADUHELM SG&A expense is reflected in collaboration profit sharing rather than SG&A.
 - Fourth quarter 2021 GAAP and Non-GAAP SG&A expense includes approximately \$155 million related to ADUHELM commercialization. Eisai's reimbursement of U.S. ADUHELM SG&A expense of approximately \$45 million is reflected in collaboration profit sharing.
- Fourth quarter GAAP and Non-GAAP amortization and impairment of acquired intangible assets was \$68 million and \$8 million, respectively.
- Fourth quarter GAAP and Non-GAAP collaboration profit sharing reduced our net operating expense by \$67 million, which includes reimbursement of approximately \$140 million from Eisai related to the commercialization of ADUHELM in the U.S. partially offset by \$75 million of net profit sharing expense related to our collaboration with Samsung Bioepis.
- Fourth quarter GAAP other expense was \$182 million, primarily driven by net unrealized losses on our strategic equity investments of \$116 million. Fourth quarter Non-GAAP other expense was \$67 million, primarily driven by interest expense.
- Fourth quarter effective GAAP and Non-GAAP tax rates were 109.5% and 17.2%, respectively. The fourth quarter 2021 effective GAAP tax rate was impacted by a deferred tax valuation allowance expense of approximately \$390 million on Neurimmune SubOne AG's (Neurimmune) tax basis in ADUHELM. An equal and offsetting amount was attributed to noncontrolling interest, resulting in zero net impact to net income attributable to Biogen Inc.

- Fourth quarter 2021 GAAP loss attributable to noncontrolling interest was \$389 million, which includes the recognition of a deferred tax valuation allowance expense related to Neurimmune's tax basis in ADUHELM of approximately \$390 million. Fourth quarter 2021 Non-GAAP income attributable to noncontrolling interest was \$7 million.

Full Year 2021 Operating Results

- Full year total revenue of \$10,982 million decreased 18% versus the prior year at actual currency and 19% at constant currency*.
 - Multiple sclerosis (MS) revenue, including royalties on sales of OCREVUS, of \$7,088 million decreased 18% versus the prior year at actual currency and 19% at constant currency.
 - SPINRAZA revenue of \$1,905 million decreased 7% versus the prior year at actual currency and 9% at constant currency.
 - ADUHELM revenue was \$3 million.
 - Biosimilars revenue of \$831 million increased 4% versus the prior year at actual currency and 1% at constant currency.
- Full year GAAP net income and diluted EPS attributable to Biogen Inc. were \$1,556 million and \$10.40, respectively.
- Full year Non-GAAP net income and diluted EPS attributable to Biogen Inc. were \$2,875 million and \$19.22, respectively.

A reconciliation of GAAP to Non-GAAP financial measures can be found in Table 4 at the end of this news release.

* Percentage changes in revenue growth at constant currency are presented excluding the impact of changes in foreign currency exchange rates and hedging gains or losses. The current period's foreign currency revenue values are converted into U.S. dollars using the average exchange rates from the prior period.

- Full year GAAP and Non-GAAP cost of sales was \$2,110 million as compared to \$1,805 million for the full year 2020.
- Full year GAAP and Non-GAAP R&D expense was \$2,501 million as compared to \$3,991 million for the full year 2020.
 - Beginning in 2021, material upfront payments and premiums paid on the acquisition of common stock associated with significant collaboration and licensing arrangements along with the related transaction costs incurred are no longer excluded from Non-GAAP R&D and SG&A expenses. The 2020 Non-GAAP financial results have been updated to reflect payments totaling \$1,894 million related to collaborations with Sangamo Therapeutics, Inc., Denali Therapeutics Inc., and Sage.
 - Full year 2020 GAAP and Non-GAAP R&D expense also includes a total of \$68 million in upfront payments related to collaboration agreements with Scribe Therapeutics Inc., Atalanta Therapeutics, and ViGeneron GmbH.
 - Full year 2021 GAAP and Non-GAAP R&D expense includes a total of \$285 million in payments related to our collaborations with InnoCare Pharma Limited, Ionis, Bio-Thera Solutions, Ltd., Genentech, Capsigen Inc., and Ginkgo Bioworks.

- Full year GAAP SG&A expense was \$2,674 million as compared to \$2,505 million for the full year 2020. Full year Non-GAAP SG&A expense was \$2,666 million as compared to \$2,502 million for the full year 2020.
 - Full year 2021 GAAP and Non-GAAP SG&A expense includes approximately \$480 million related to ADUHELM. Eisai's reimbursement of U.S. ADUHELM SG&A expense of approximately \$135 million is reflected in collaboration profit sharing.
- Full year GAAP and Non-GAAP amortization and impairment of acquired intangible assets was \$881 million and \$15 million, respectively.
- Full year GAAP and Non-GAAP collaboration profit sharing was a net expense of \$7 million, which includes \$285 million of net profit sharing expense related to our collaboration with Samsung Bioepis partially offset by reimbursement of approximately \$275 million from Eisai related to the commercialization of ADUHELM in the U.S.
- Full year 2021 GAAP other expense was \$1,096 million, primarily driven by net unrealized losses on our strategic equity investments of \$821 million. Non-GAAP other expense was \$265 million, primarily driven by interest expense.
- Full year effective GAAP and Non-GAAP tax rates were 3.0% and 15.7%, respectively. Full year 2021 GAAP effective tax rate included a \$100 million net deferred tax benefit associated with the accelerated approval of ADUHELM by the FDA. This deferred tax benefit has an equal and offsetting amount assigned to noncontrolling interest, resulting in zero net impact to net income attributable to Biogen Inc. This net tax benefit included the initial recognition of a \$490 million deferred tax benefit in Q2 2021, offset by a \$390 million expense related to a valuation allowance established in Q4 2021.
- Full year 2021 GAAP and Non-GAAP income attributable to noncontrolling interest was \$172 million and \$79 million, respectively, which includes a milestone payment of \$100 million to Neurimmune related to the approval of ADUHELM in the U.S. recognized in Q2 2021. GAAP income attributable to noncontrolling interest also includes a net deferred tax benefit related to Neurimmune's tax basis in ADUHELM of approximately \$100 million.

Financial Position

- As of December 31, 2021, Biogen had cash, cash equivalents, and marketable securities totaling \$4,695 million and \$7,273 million in total debt. This resulted in net debt of \$2,578 million.
- Throughout 2021 Biogen repurchased approximately 6.0 million shares of the Company's common stock for a total value of \$1,800 million. No shares were repurchased in the fourth quarter of 2021. As of December 31, 2021, there was \$2,800 million remaining under the share repurchase program authorized in October 2020.
- For the fourth quarter of 2021 the Company's weighted average diluted shares were 147 million. For 2021 the Company's full year weighted average diluted shares were 150 million.
- Fourth quarter 2021 cash from operations was \$838 million. Capital expenditures were \$52 million, and free cash flow, defined as cash flow from operations less capital expenditures, was \$787 million.
- Full year 2021 cash flow from operations was \$3,640 million. Capital expenditures were \$258 million, and free cash flow, defined as net cash flow from operations less capital expenditures, was \$3,382 million.

Full Year 2021 Financial Guidance

Biogen expects full year 2022 revenue to be between \$9.7 billion and \$10.0 billion.

This financial guidance assumes minimal ADUHELM revenue in 2022. This guidance also assumes continued declines in RITUXAN revenue due to biosimilar competition, as well as continued erosion of TECFIDERA revenue in the U.S. due to generic entry. Further, this guidance assumes the potential entry of TECFIDERA generics in the E.U. as early as the first half of 2022 as the outcome of the ongoing challenges to TECFIDERA market protection is difficult to predict. Biogen expects the decreased revenue from these high margin products to reduce its gross margin percentage compared to 2021.

Biogen expects full year 2022 Non-GAAP diluted EPS to be between \$14.25 and \$16.00.

Our guidance assumptions are highly dependent on the final National Coverage Determination (NCD) for monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease, which is currently uncertain. If the final NCD is not broader than the proposed NCD, our anticipated results and guidance may be impacted.

This guidance assumes we will not have any write-offs of ADUHELM inventory in 2022, which is valued at approximately \$225 million as of December 31, 2021. This guidance also assumes reasonable levels of utilization of our manufacturing capacity dedicated to our Alzheimer's disease programs. If our manufacturing capacity is underutilized, we will incur incremental period costs which are not reflected in our guidance.

Non-GAAP R&D expense is expected to be between \$2.2 billion and \$2.3 billion, and Non-GAAP SG&A expense is expected to be between \$2.5 billion and \$2.6 billion. This Non-GAAP SG&A expense estimate includes approximately \$400 million in support of the launch of ADUHELM, of which approximately \$145 million would be reimbursable by Eisai and reflected in the collaboration profit sharing line.

These R&D and SG&A expense estimates reflect the implementation of previously disclosed cost-reduction measures, which are estimated to yield approximately \$500 million in annualized savings, of which approximately \$350 million is expected to be realized in 2022. These savings are expected to be achieved through various initiatives which may include downsizing of our global Alzheimer's infrastructure, the savings from which would be shared with Eisai, and operating efficiency gains across SG&A and R&D. These savings are expected to be offset by approximately \$200 million in additional investments in Biogen's pipeline and strategic initiatives such as new product launches. In the event of a final NCD that is not broader than the proposed NCD, we anticipate taking further cost-reduction measures, which are not reflected in our guidance, to align our cost base with our revenue base. Some of the savings from these further cost-reduction measures would be shared with Eisai.

The Non-GAAP tax rate for 2022 is expected to be between 15.5% and 16.5%.

We expect that we will utilize a portion of the remaining share repurchase authorization of \$2,800 million through the end of 2022.

This guidance assumes that foreign exchange rates as of December 31, 2021, will remain in effect for the remainder of the year, net of hedging activities.

This financial guidance does not include any impact from potential acquisitions or large business development transactions, as both are hard to predict, or any impact of potential tax or healthcare reform.

Biogen may incur charges, realize gains or losses, or experience other events or circumstances in 2022 that could cause any of these assumptions to change and/or actual results to vary from this financial guidance.

Biogen does not provide guidance for GAAP reported financial measures (other than revenue) or a reconciliation of forward-looking Non-GAAP financial measures to the most directly comparable GAAP reported financial measures because the Company is unable to predict with reasonable certainty the financial impact of items such as the transaction, integration, and certain other costs related to acquisitions or large business development transactions; unusual gains and losses; potential future asset impairments; gains and losses from our equity security investments; and the ultimate outcome of pending significant litigation without unreasonable effort. These items are uncertain, depend on various factors, and could have a material impact on GAAP reported results for the guidance period. For the same reasons, the Company is unable to address the significance of the unavailable information, which could be material to future results.

Business Development Updates

- In January 2022 Biogen and Samsung Biologics entered into an agreement whereby Biogen will sell its equity stake in the Samsung Bioepis joint venture to Samsung Biologics for an aggregate consideration of up to \$2.3 billion. Biogen will continue to commercialize certain Samsung Bioepis biosimilars pursuant to the terms of the companies' existing agreements. Biogen will continue to record revenue and costs associated with the commercialization of its anti-TNF biosimilars in Europe, the economics of which will be substantially unchanged. Closing of the transaction is currently anticipated in mid-2022, contingent on the effectiveness of a securities registration statement filed by Samsung Biologics and satisfaction of certain regulatory and other customary closing conditions.
- In January 2022 Biogen exercised its option with Genentech to participate in the development and commercialization of mosunetuzumab, a CD20xCD3 T-cell engaging bispecific antibody in development for B-cell non-Hodgkin's lymphoma and other therapeutic areas. Biogen will pay a \$30 million one-time option fee to Genentech and will pay approximately \$20 million for a portion of the mosunetuzumab development expenses incurred during 2021. Biogen will have joint decision-making rights related to development and commercialization, and Genentech will continue to lead the strategy and implementation of the program. Biogen will share in the operating profits and losses of mosunetuzumab in the United States in the low to mid 30% range and is eligible to receive low single-digit royalties on sales outside the United States.

ADUHELM Updates

- In January 2022 Biogen and Eisai provided an update on ENVISION, the Phase 4 post-marketing confirmatory study of ADUHELM. The companies anticipate submitting the final protocol for review to the FDA in March 2022, with the initiation of patient screening in May 2022.
 - The study is a post-marketing requirement of the FDA's accelerated approval and will be a global, placebo-controlled trial, aiming to enroll 1,500 early Alzheimer's disease patients. The companies aim to enroll 18 percent of U.S. participants in ENVISION from black/African American and Hispanic/Latino populations.
 - Based on enrollment rates from the previous Phase 3 trials with ADUHELM, the primary completion date is expected to be approximately four years after the study begins.
 - The primary endpoint will be measured by the Clinical Dementia Rating–Sum of Boxes at 18 months after treatment initiation with ADUHELM.
 - Secondary endpoints include Alzheimer's Disease Assessment Scale-Cognitive Subscale, Alzheimer's Disease Cooperative Study - Activities of Daily Living Inventory - Mild Cognitive Impairment Version, Integrated Alzheimer's Disease Rating Scale, Mini-Mental State Examination and Neuropsychiatric Inventory-10.

- The trial will also include a planned long-term extension to collect longer-term treatment data for up to 48 months.
- In January 2022 the Centers for Medicare and Medicaid Services (CMS) released a proposed National Coverage Determination (NCD) decision memorandum proposing Medicare coverage of FDA approved monoclonal antibodies that target amyloid for the treatment of Alzheimer's disease only for patients enrolled in qualifying clinical trials. The final NCD is expected to be issued in April 2022.
- In the fourth quarter of 2021 Biogen announced that, effective January 1, 2022, the wholesale acquisition cost of ADUHELM in the United States has been reduced by approximately 50%. For a patient of average weight (74 kg), the yearly cost at the maintenance dose (10 mg/kg) is now \$28,200.
- In the fourth quarter of 2021 Biogen and Eisai announced that the First Committee on New Drugs (NDC) of the Pharmaceutical Affairs and Food Sanitation Council that advises the Ministry of Health, Labour and Welfare in Japan has decided to continue deliberations on the application for the manufacturing and marketing approval of aducanumab for the treatment of Alzheimer's disease. The NDC is seeking additional data to be submitted as part of this process. The companies will continue to actively engage with the Pharmaceuticals and Medical Devices Agency in Japan to agree on additional data requirements.
- In the fourth quarter of 2021 Biogen and Eisai announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency has adopted a negative opinion on the Marketing Authorization Application for aducanumab for the treatment of the early stages of Alzheimer's disease. This decision is aligned to the negative trend vote of the committee in November 2021. Biogen is seeking a re-examination of the opinion by the CHMP.
- In the fourth quarter of 2021 Biogen and Eisai presented data at the annual CTAD conference from approximately 7,000 plasma samples from more than 1,800 patients in the ADUHELM Phase 3 clinical trials showed a statistically significant correlation between plasma p-tau reduction and less cognitive and functional decline in Alzheimer's disease. Reductions in plasma p-tau181 were also correlated with a lowering of amyloid beta plaque. The analysis of plasma samples was conducted by an independent lab, drawing from the two pivotal ADUHELM Phase 3 EMERGE and ENGAGE trials.

Lecanemab (BAN2401) Updates

- In the fourth quarter of 2021 Eisai and Biogen announced that lecanemab, an investigational anti-amyloid beta (A β) antibody for the treatment of early Alzheimer's disease (AD), was granted Fast Track designation by the FDA. FDA granted Breakthrough Therapy designation for lecanemab in June of 2021.
- In the fourth quarter of 2021 Eisai and Biogen presented data at the annual CTAD conference on:
 - Exploring the use of plasma-based biomarkers in the Phase 3 AHEAD 3-45 study of lecanemab. AHEAD 3-45 is the first preclinical AD trial to use these biomarkers to detect AD pathology and potentially accelerate the screening process.
 - Sensitivity analyses evaluating the consistency of lecanemab efficacy results across multiple statistical models in patients with MCI due to AD and mild AD (collectively known as early AD).

Zuranolone Updates

- In the fourth quarter of 2021 Sage announced that the CORAL Study primary endpoint (HAMD-17 change from baseline) will be measured at Day 3. This update is in line with the goal of the study to

demonstrate a rapid reduction in depressive symptoms and benefits throughout treatment period when zuranolone is co-initiated with standard antidepressants in patients with major depressive disorder.

- In the fourth quarter of 2021 Sage and Biogen announced 12-month data for the cohort of patients (n=199), who received zuranolone 50 mg once nightly for 14-days as their initial dose in the ongoing Phase 3 open-label SHORELINE study in major depressive disorder and had the opportunity to be followed for 12-months. For the primary endpoint of safety and tolerability, the data analyzed to date show zuranolone was generally well-tolerated, with no new safety findings or trends identified in the long-term safety data available regardless of the number of courses of zuranolone a patient received. Additionally, nearly 75% of patients responded to the initial 2-week treatment course as assessed on the 17-item Hamilton Rating Scale for Depression. Of those who responded to the initial course and continued in the study, approximately 80% of those patients received at most one additional zuranolone treatment during their time in the study.

Other Pipeline Updates

- In January 2022, Biogen announced the first patient was dosed in the Phase 1 study evaluating BIIB121 in Angelman syndrome, a rare genetic neurodevelopmental disorder.
- In the fourth quarter of 2021 Biogen exercised its option to obtain from Ionis a worldwide, exclusive, royalty-bearing license to develop and commercialize BIIB115, an investigational antisense oligonucleotide in development for SMA that may have the potential for extended dosing intervals as compared to SPINRAZA. As part of the option exercise, Biogen paid Ionis a \$60 million one-time upfront payment in the fourth quarter of 2021.
- In the fourth quarter of 2021 Biogen and TheraPanacea announced that they have entered into a collaboration focused on multiple therapeutic areas in neuroscience, to further build on the companies' existing relationship. The collaboration aims to develop innovative machine learning and artificial intelligence solutions for personalized and earlier treatment in neurology. Under the terms of the agreement, Biogen will invest up to \$15 million in exchange for TheraPanacea convertible debt. Biogen gains exclusive rights to TheraPanacea's technology in neuroscience.

TECFIDERA and VUMERITY Events

- In 2020 U.S. federal courts in West Virginia and Delaware entered judgments in favor of the defendants in patent infringement proceedings relating to TECFIDERA Orange-Book listed patents. In late 2021, the U.S. Court of Appeals for the Federal Circuit affirmed the judgment of the West Virginia federal court.
- In the fourth quarter of 2021 Biogen announced that the European Commission granted marketing authorization for VUMERITY® (diroximel fumarate) to treat adults with relapsing-remitting multiple sclerosis.

Management Updates

- In the fourth quarter of 2021 Alfred W. Sandroock, Jr., M.D., Ph.D., Head of Research & Development, retired from the Company effective December 31, 2021. Priya Singhal, M.D., M.P.H., Head of Global Safety and Regulatory Sciences, also with oversight responsibility for Japan and China R&D, has assumed Dr. Sandroock's duties as Head of Research & Development on an interim basis until a permanent successor is identified.

Other Recent Events

- In the fourth quarter of 2021 Biogen announced that it has set an industry record as the most frequently recognized biotechnology company on the Dow Jones Sustainability World Index, earning recognition

for the ninth consecutive year, more than any other biotechnology company. The acknowledgment highlights the company's longstanding leadership actions and transparency on environmental, social and governance issues.

Conference Call and Webcast

The Company's earnings conference call for the fourth quarter will be broadcast via the internet at 8:00 a.m. ET on February 3, 2022, 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.

About Biogen

As pioneers in neuroscience, Biogen discovers, develops, and delivers worldwide innovative therapies for people living with serious neurological diseases as well as related therapeutic adjacencies. One of the world's first global biotechnology companies, Biogen was founded in 1978 by Charles Weissmann, Heinz Schaller, Sir Kenneth Murray, and Nobel Prize winners Walter Gilbert and Phillip Sharp. Today, Biogen has a leading portfolio of medicines to treat multiple sclerosis, has introduced the first approved treatment for spinal muscular atrophy, and is providing the first and only approved treatment to address a defining pathology of Alzheimer's disease. Biogen is also commercializing biosimilars and focusing on advancing the industry's most diversified pipeline in neuroscience that will transform the standard of care for patients in several areas of high unmet need.

In 2020, Biogen launched a bold 20-year, \$250 million initiative to address the deeply interrelated issues of climate, health, and equity. Healthy Climate, Healthy Lives™ aims to eliminate fossil fuels across the company's operations, build collaborations with renowned institutions to advance the science to improve human health outcomes, and support underserved communities.

The company routinely posts information that may be important to investors on its website at www.biogen.com. To learn more, please visit www.biogen.com and follow Biogen on social media — [Twitter](#), [LinkedIn](#), [Facebook](#), [YouTube](#).

Safe Harbor

This news release contains forward-looking statements, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, relating to: our strategy and plans; potential of, and expectations for, our commercial business and pipeline programs; capital allocation and investment strategy; clinical development programs, clinical trials, and data readouts and presentations; risks and uncertainties associated with drug development and commercialization; regulatory discussions, submissions, filings, and approvals and the timing thereof; the potential benefits, safety, and efficacy of our and our collaboration partners' products and investigational therapies; the anticipated benefits and potential of investments, collaborations, and business development activities; our future financial and operating results; 2022 financial guidance; plans relating to share repurchases. These forward-looking statements may be accompanied by such words as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "potential," "possible," "prospect," "will," "would," 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 products; the impact of the final NCD; uncertainty of long-term success in developing, licensing, or acquiring other product

candidates or additional indications for existing products; risks that the proposed transaction with Samsung Biologics will not be completed in a timely manner or at all; the possibility that certain closing conditions to the proposed transaction will not be satisfied; uncertainty as to whether the anticipated benefits of the proposed transaction can be achieved; failure to compete effectively due to significant product competition in the markets for our products; failure to successfully execute or realize the anticipated benefits of our strategic and growth initiatives; difficulties in obtaining and maintaining adequate coverage, pricing, and reimbursement for our products; our dependence on collaborators, joint venture partners, 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; risks associated with current and potential future healthcare reforms; risks related to commercialization of biosimilars; failure to obtain, protect, and enforce our data, intellectual property, and other proprietary rights and the risks and uncertainties relating to intellectual property claims and challenges; 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; the occurrence of adverse safety events, restrictions on use with our products, or product liability claims; risks relating to the distribution and sale by third parties of counterfeit or unfit versions of our products; risks relating to the use of social media for our business; risks relating to technology failures or breaches; risks relating to management and key personnel changes, including attracting and retaining key personnel; failure to comply with legal and regulatory requirements; the risks of doing business internationally, including currency exchange rate fluctuations; risks relating to investment in our manufacturing capacity; problems with our manufacturing processes; fluctuations in our effective tax rate; the direct and indirect impacts of the ongoing COVID-19 pandemic on our business, results of operations, and financial condition; fluctuations in our operating results; risks related to investment in properties; the market, interest, and credit risks associated with our investment portfolio; risks relating to share repurchase programs; risks relating to access to capital and credit markets; risks related to indebtedness; change in control provisions in certain of our collaboration agreements; environmental risks; and any other risks and uncertainties that are described in other reports we have filed with the U.S. Securities and Exchange Commission.

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

Biogen Investor Contact: Biogen Media Contact:

Mike Hencke Allison Parks
Biogen Inc. Biogen Inc.
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TABLE 1

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

	For the Three Months Ended December 31,		For the Twelve Months Ended December 31,	
	2021	2020	2021	2020
Revenue:				
Product, net	\$ 2,193.5	\$ 2,301.6	\$ 8,846.9	\$ 10,692.2
Revenue from anti-CD20 therapeutic programs	414.1	419.0	1,658.5	1,977.8
Other	126.2	132.0	476.3	774.6
Total revenue	<u>2,733.8</u>	<u>2,852.6</u>	<u>10,981.7</u>	<u>13,444.6</u>
Cost and expense:				
Cost of sales, excluding amortization and impairment of acquired intangible assets	660.1	490.6	2,109.7	1,805.2
Research and development	699.5	1,726.0	2,501.2	3,990.9
Selling, general and administrative	787.9	806.3	2,674.3	2,504.5
Amortization and impairment of acquired intangible assets	68.1	249.2	881.3	464.8
Collaboration profit sharing	(67.3)	66.4	7.2	232.9
(Gain) loss on divestiture of Hillerød, Denmark manufacturing operations	—	(92.5)	—	(92.5)
(Gain) loss on fair value remeasurement of contingent consideration	(1.6)	(62.8)	(50.7)	(86.3)
Acquired in-process research and development	—	—	18.0	75.0
Total cost and expense	<u>2,146.7</u>	<u>3,183.2</u>	<u>8,141.0</u>	<u>8,894.5</u>
Income from operations	587.1	(330.6)	2,840.7	4,550.1
Other income (expense), net	(182.1)	683.5	(1,095.5)	497.4
Income before income tax expense and equity in loss of investee, net of tax	405.0	352.9	1,745.2	5,047.5
Income tax (benefit) expense	443.2	13.3	52.5	992.3
Equity in (income) loss of investee, net of tax	(17.7)	(18.0)	(34.9)	(5.3)
Net income	(20.5)	357.6	1,727.6	4,060.5
Net income (loss) attributable to noncontrolling interests, net of tax	(388.7)	(0.3)	171.5	59.9
Net income attributable to Biogen Inc.	<u>\$ 368.2</u>	<u>\$ 357.9</u>	<u>\$ 1,556.1</u>	<u>\$ 4,000.6</u>
Net income per share:				
Basic earnings per share attributable to Biogen Inc.	\$ 2.51	\$ 2.33	\$ 10.44	\$ 24.86
Diluted earnings per share attributable to Biogen Inc.	\$ 2.50	\$ 2.32	\$ 10.40	\$ 24.80
Weighted-average shares used in calculating:				
Basic earnings per share attributable to Biogen Inc.	146.9	153.7	149.1	160.9
Diluted earnings per share attributable to Biogen Inc.	147.5	154.0	149.6	161.3

TABLE 2

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

	As of December 31, 2021	As of December 31, 2020
ASSETS		
Cash, cash equivalents and marketable securities	\$ 3,802.5	\$ 2,610.1
Accounts receivable, net	1,549.4	1,913.8
Inventory	1,351.5	1,068.6
Other current assets	1,153.1	1,294.6
Total current assets	7,856.5	6,887.1
Marketable securities	892.0	772.1
Property, plant and equipment, net	3,416.4	3,411.5
Operating lease assets	375.4	433.3
Intangible assets, net	2,221.3	3,084.3
Goodwill	5,761.1	5,762.1
Deferred tax asset	1,415.1	1,369.5
Investments and other assets	1,939.5	2,899.0
TOTAL ASSETS	\$ 23,877.3	\$ 24,618.9
LIABILITIES AND EQUITY		
Current portion of notes payable	\$ 999.1	\$ —
Other current liabilities	3,299.1	3,742.2
Total current liabilities	4,298.2	3,742.2
Notes payable	6,274.0	7,426.2
Deferred tax liability	694.5	1,032.8
Long-term operating lease liabilities	330.4	402.0
Other long-term liabilities	1,320.5	1,329.6
Equity	10,959.7	10,686.1
TOTAL LIABILITIES AND EQUITY	\$ 23,877.3	\$ 24,618.9

TABLE 3

BIOGEN INC. AND SUBSIDIARIES
PRODUCT REVENUE & TOTAL REVENUE
(unaudited, in millions)

	For the Three Months Ended December 31,					
	2021			2020		
	United States	Rest of World	Total	United States	Rest of World	Total
Multiple Sclerosis (MS):						
TECFIDERA	\$ 160.5	\$ 326.0	\$ 486.5	\$ 319.7	\$ 288.2	\$ 607.9
VUMERITY®*	123.9	1.0	124.9	38.9	—	38.9
Total Fumarate	284.4	327.0	611.4	358.6	288.2	646.8
AVONEX®	193.8	91.6	285.4	259.9	96.5	356.4
PLEGRIDY®	37.7	54.6	92.3	48.1	51.5	99.6
Total Interferon	231.5	146.2	377.7	308.0	148.0	456.0
TYSABRI	288.0	224.7	512.7	270.7	204.5	475.2
FAMPYRA®	—	26.4	26.4	—	25.1	25.1
Spinal Muscular Atrophy:						
SPINRAZA	150.1	290.6	440.7	159.5	338.5	498.0
Alzheimer's disease:						
ADUHELM**	1.0	—	1.0	—	—	—
Biosimilars:						
BENEPALI™	—	134.4	134.4	—	117.6	117.6
IMRALDI™	—	62.5	62.5	—	53.7	53.7
FLIXABI™	—	24.0	24.0	—	26.1	26.1
Other:						
FUMADERM™	—	2.7	2.7	—	3.1	3.1
Total product revenue, net	\$ 955.0	\$ 1,238.5	\$ 2,193.5	\$ 1,096.8	\$ 1,204.8	\$ 2,301.6

*VUMERITY became commercially available in the E.U. in November 2021.

** In June 2021 the U.S. Food and Drug Administration (FDA) granted accelerated approval of ADUHELM, which became commercially available in the United States (U.S.) during the second quarter of 2021.

TABLE 3 (continued)

BIOGEN INC. AND SUBSIDIARIES
PRODUCT REVENUE & TOTAL REVENUE
(unaudited, in millions)

(In millions)	For the Twelve Months Ended December 31,					
	2021			2020		
	United States	Rest of World	Total	United States	Rest of World	Total
Multiple Sclerosis (MS):						
TECFIDERA	\$ 680.6	\$ 1,271.3	\$ 1,951.9	\$ 2,677.7	\$ 1,163.4	\$ 3,841.1
VUMERITY®*	408.9	1.5	410.4	64.3	—	64.3
Total Fumarate	1,089.5	1,272.8	2,362.3	2,742.0	1,163.4	3,905.4
AVONEX®	830.2	378.5	1,208.7	1,083.4	408.5	1,491.9
PLEGRIDY®	152.9	204.5	357.4	190.1	195.5	385.6
Total Interferon	983.1	583.0	1,566.1	1,273.5	604.0	1,877.5
TYSABRI	1,142.2	920.9	2,063.1	1,096.8	849.3	1,946.1
FAMPYRA®	—	105.2	105.2	—	103.1	103.1
Spinal Muscular Atrophy:						
SPINRAZA	587.9	1,317.2	1,905.1	787.8	1,264.3	2,052.1
Alzheimer's disease:						
ADUHELM**	3.0	—	3.0	—	—	—
Biosimilars:						
BENEPALI™	—	498.3	498.3	—	481.6	481.6
IMRALDI™	—	233.4	233.4	—	216.3	216.3
FLIXABI™	—	99.4	99.4	—	97.9	97.9
Other:						
FUMADERM™	—	11.0	11.0	—	12.2	12.2
Total product revenue, net	\$ 3,805.7	\$ 5,041.2	\$ 8,846.9	\$ 5,900.1	\$ 4,792.1	\$ 10,692.2

*VUMERITY became commercially available in the E.U. in November 2021.

** In June 2021 the U.S. Food and Drug Administration (FDA) granted accelerated approval of ADUHELM, which became commercially available in the United States (U.S.) during the second quarter of 2021.

(In millions)	For the Three Months Ended December 31,		For the Twelve Months Ended December 31,	
	2021	2020	2021	2020
Product revenue	\$ 2,193.5	\$ 2,301.6	\$ 8,846.9	\$ 10,692.2
OCREVUS royalties	261.2	202.4	991.7	845.4
RITUXAN/GAZYVA® revenue	152.9	216.6	666.8	1,132.4
Other revenue	126.2	132.0	476.3	774.6
Total revenue	\$ 2,733.8	\$ 2,852.6	\$ 10,981.7	\$ 13,444.6

TABLE 4

BIOGEN INC. AND SUBSIDIARIES
GAAP TO NON-GAAP RECONCILIATION
OPERATING EXPENSE & OTHER INCOME (EXPENSE), NET
(unaudited, in millions, except per share amounts)

We supplement our GAAP consolidated financial statements and GAAP financial measures with other financial measures, such as adjusted net income, adjusted diluted earnings per share, revenue growth at constant currency, which excludes the impact of changes in foreign exchange rates and hedging gains or losses, and free cash flow, which is defined as net flow from operations less capital expenditures. We believe that these and other Non-GAAP financial measures provide additional insight into the ongoing economics of our business and reflect how we manage our business internally, set operational goals and form the basis of our management incentive programs. Non-GAAP financial measures are in addition to, not a substitute for, or superior to, measures of financial performance prepared in accordance with GAAP.

(In millions, except per share amounts)	For the Three Months Ended December 31,		For the Twelve Months Ended December 31,	
	2021 ⁽¹⁾	2020 ⁽²⁾	2021 ⁽¹⁾	2020 ⁽²⁾
Selling, General and Administrative Expense:				
Total selling, general and administrative, GAAP	\$ 787.9	\$ 806.3	\$ 2,674.3	\$ 2,504.5
Less: other	2.7	2.8	7.9	2.8
Total selling, general and administrative, Non-GAAP	\$ 785.2	\$ 803.5	\$ 2,666.4	\$ 2,501.7
Amortization and Impairment of Acquired Intangible Assets:				
Total amortization and impairment of acquired intangible assets, GAAP	\$ 68.1	\$ 249.2	\$ 881.3	\$ 464.8
Less: impairment charges ^A	—	190.4	629.3	209.7
Less: amortization of acquired intangible assets	60.5	58.8	237.1	255.1
Total amortization and impairment of acquired intangible assets, Non-GAAP	\$ 7.6	\$ —	\$ 14.9	\$ —
(Gain) Loss on Fair Value Remeasurement of Contingent Consideration:				
Total (gain) loss on fair value remeasurement of contingent consideration, GAAP	\$ (1.6)	\$ (62.8)	\$ (50.7)	\$ (86.3)
Less: (gain) loss on fair value remeasurement of contingent consideration	(1.6)	(62.8)	(50.7)	(86.3)
Total (gain) loss on fair value remeasurement of contingent consideration, Non-GAAP	\$ —	\$ —	\$ —	\$ —
Other Income (Expense), net:				
Total other income (expense), net, GAAP	\$ (182.1)	\$ 683.5	\$ (1,095.5)	\$ 497.4
Less: gain (loss) on equity security investments	(115.4)	734.2	(821.3)	693.9
Plus: premium paid on debt exchange or early debt redemption	—	—	9.5	9.4
Total other income (expense), net, Non-GAAP	\$ (66.7)	\$ (50.7)	\$ (264.7)	\$ (187.1)
Income Tax (Benefit) Expense:				
Total income tax (benefit) expense, GAAP	\$ 443.2	\$ 13.3	\$ 52.5	\$ 992.3
Less: Neurimmune step-up tax basis ^B	395.6	—	(96.4)	—
Less: valuation allowance associated with TECFIDERA IP court decision	—	1.0	—	90.3
Less: income tax effect related to Non-GAAP reconciling items	(52.7)	110.7	(388.0)	81.1
Total income tax expense, Non-GAAP	\$ 100.3	\$ (98.4)	\$ 536.9	\$ 820.9
Effective Tax Rate:				
Total effective tax rate, GAAP	109.5 %	3.8 %	3.0 %	19.7 %
Less: Neurimmune step-up tax basis ^B	97.7	—	(5.5)	—
Less: valuation allowance associated with TECFIDERA IP court decision	—	0.3	—	1.8
Less: impact of GAAP to Non-GAAP adjustments	(5.4)	(31.1)	(7.2)	0.5
Total effective tax rate, Non-GAAP	17.2 %	34.6 %	15.7 %	17.4 %

TABLE 4 (continued)

BIOGEN INC. AND SUBSIDIARIES
GAAP TO NON-GAAP RECONCILIATION
INCOME TAX, NET INCOME ATTRIBUTABLE TO BIOGEN INC. & DILUTED EPS
(unaudited, in millions, except per share amounts)

(In millions, except per share amounts)	For the Three Months Ended December 31,		For the Twelve Months Ended December 31,	
	2021 ⁽¹⁾	2020 ⁽²⁾	2021 ⁽¹⁾	2020 ⁽²⁾
Equity in (Income) Loss of Investee, Net of Tax:				
Total equity in (income) loss of investee, GAAP	\$ (17.7)	\$ (18.0)	\$ (34.9)	\$ (5.3)
Less: amortization of equity in (income) loss of investee	7.4	6.8	38.4	40.0
Total equity in (income) loss of investee, Non-GAAP	<u>\$ (25.1)</u>	<u>\$ (24.8)</u>	<u>\$ (73.3)</u>	<u>\$ (45.3)</u>
Net Income (Loss) Attributable to Noncontrolling Interests, Net of Tax:				
Total net income (loss) attributable to noncontrolling interests, GAAP	\$ (388.7)	\$ (0.3)	\$ 171.5	\$ 59.9
Less: Neurimmune step-up tax basis ^B	(395.6)	—	96.4	—
Less: net distribution to noncontrolling interests and other	0.1	—	(4.3)	0.3
Total net income (loss) attributable to noncontrolling interests, Non-GAAP	<u>\$ 6.8</u>	<u>\$ (0.3)</u>	<u>\$ 79.4</u>	<u>\$ 59.6</u>
Net Income Attributable to Biogen Inc.:				
Total net income attributable to Biogen Inc., GAAP	\$ 368.2	\$ 357.9	\$ 1,556.1	\$ 4,000.6
Plus: impairment charges ^A	—	190.4	629.3	209.7
Plus: amortization of acquired intangible assets	60.5	58.8	237.1	255.1
Plus: acquired in-process research and development	—	—	18.0	75.0
Plus: (gain) loss on fair value remeasurement of contingent consideration	(1.6)	(62.8)	(50.7)	(86.3)
Less: (gain) loss on divestiture of Hillerød, Denmark manufacturing operations	—	(92.5)	—	(92.5)
Plus: (gain) loss on equity security investments	115.4	(734.2)	821.3	(693.9)
Plus: net distribution to noncontrolling interests & amortization of equity in (income) loss of investee	7.5	6.8	34.1	40.3
Plus: premium paid on debt exchange or early debt redemption	—	—	9.5	9.4
Plus: valuation allowance associated with TECFIDERA IP court decision	—	1.0	—	90.3
Plus: income tax effect related to Non-GAAP reconciling items	(52.7)	110.7	(388.0)	81.1
Plus: other	3.1	2.8	8.3	2.8
Total net income attributable to Biogen Inc., Non-GAAP	<u>\$ 500.4</u>	<u>\$ (161.1)</u>	<u>\$ 2,875.0</u>	<u>\$ 3,891.6</u>
Diluted Earnings Per Share				
Total diluted earnings per share, GAAP	\$ 2.50	\$ 2.32	\$ 10.40	\$ 24.80
Plus: adjustments to GAAP net income attributable to Biogen Inc. (as detailed above)	0.89	(3.37)	8.82	(0.67)
Total diluted earnings per share, Non-GAAP	<u>\$ 3.39</u>	<u>\$ (1.05)</u>	<u>\$ 19.22</u>	<u>\$ 24.13</u>

⁽¹⁾ Beginning in the third quarter of 2021 amortization expense recorded in intangible assets that arose from collaboration and licensing arrangements is no longer excluded from our Non-GAAP results on a prospective basis. Non-GAAP financial results for 2020 have not been updated to reflect this change.

⁽²⁾ Beginning in the second quarter of 2021 material upfront payments and premiums paid on the acquisition of common stock associated with significant collaboration and licensing arrangements along with the related transaction costs incurred are no longer excluded from Non-GAAP research and development expense and selling, general and administrative expense. Non-GAAP financial results for 2020 have been updated to include the \$1,084.0 million payment related to our collaboration with Sage Therapeutics, Inc. recorded in the fourth quarter of 2020, the \$601.3 million payment related to our collaboration with Denali Therapeutics, Inc. recorded in the third quarter of 2020 and the \$208.0 million payment related to our collaboration with Sangamo Therapeutics, Inc. recorded in the second quarter of 2020 along with the associated transaction costs and income tax effect.

TABLE 4 (continued)

**BIOGEN INC. AND SUBSIDIARIES
GAAP TO NON-GAAP RECONCILIATION
REVENUE GROWTH AT CONSTANT CURRENCY
(unaudited)**

Percentage changes in revenue growth at constant currency are presented excluding the impact of changes in foreign currency exchange rates and hedging gains or losses. The current period's foreign currency revenue values are converted into U.S. dollars using the average exchange rates from the prior period.

	For the Three Months Ended December 31, 2021		For the Twelve Months Ended December 31, 2021	
Total Revenue				
Revenue change, as reported	(4.2)	%	(18.3)	
Less: impact of foreign currency translation and hedging (gains) losses	(0.2)		0.7	
Revenue change at constant currency	(4.0)	%	(19.0)	
Total MS Revenue (including OCREVUS royalties)				
Revenue change, as reported	(0.9)	%	(18.3)	
Less: impact of foreign currency translation and hedging (gains) losses	0.4		0.3	
Revenue change at constant currency	(1.3)	%	(18.6)	
Total SPINRAZA Revenue				
Revenue change, as reported	(11.5)	%	(7.2)	
Less: impact of foreign currency translation and hedging (gains) losses	(1.2)		1.7	
Revenue change at constant currency	(10.3)	%	(8.9)	
Total Biosimilars Revenue				
Revenue change, as reported	11.9	%	4.5	
Less: impact of foreign currency translation and hedging (gains) losses	(1.6)		3.6	
Revenue change at constant currency	13.5	%	0.9	
Total Other Revenue				
Revenue change, as reported	(4.5)	%	(38.5)	
Less: impact of foreign currency translation and hedging (gains) losses	—		0.1	
Revenue change at constant currency	(4.5)	%	(38.6)	

TABLE 4 (continued)

BIOGEN INC. AND SUBSIDIARIES
GAAP TO NON-GAAP RECONCILIATION
FREE CASH FLOW
(unaudited, in millions)

We define free cash flow as net cash provided by (used in) operating activities in the period less capital expenditures made in the period. The following table reconciles net cash provided by (used in) operating activities, a GAAP measure, to free cash flow, a Non-GAAP measure.

	For the Three Months Ended December		For the Twelve Months Ended December	
	2021	2020	2021	2020
Cash Flow:				
Net cash provided by (used in) operating activities	\$ 838.3	\$ (367.1)	\$ 3,639.9	\$ 4,229.8
Net cash provided by (used in) investing activities	(112.7)	(166.4)	(563.7)	(608.6)
Net cash provided by (used in) financing activities	9.8	(401.1)	(2,086.2)	(5,272.7)
Net increase (decrease) in cash and cash equivalents	<u>\$ 735.4</u>	<u>\$ (934.6)</u>	<u>\$ 990.0</u>	<u>\$ (1,651.5)</u>
Net cash provided by (used in) operating activities	\$ 838.3	\$ (367.1)	\$ 3,639.9	\$ 4,229.8
Less: Purchases of property, plant and equipment	51.6	86.0	258.1	424.8
Free cash flow	<u>\$ 786.7</u>	<u>\$ (453.1)</u>	<u>\$ 3,381.8</u>	<u>\$ 3,805.0</u>

Notes to GAAP to Non-GAAP Reconciliation

[^] For the years ended December 31, 2021 and 2020, amortization and impairment of acquired intangible assets totaled \$881.3 million and \$464.8 million, respectively.

During the fourth quarter of 2020 we recognized an impairment charge of \$115.0 million related to BIIB111 as a result of third-party manufacturing delays that impacted the timing and increased the costs associated with advancing BIIB111 through Phase 3 development.

In February 2021 we announced that we discontinued development of BIIB054 (cinpanemab) for the potential treatment of Parkinson's disease as our Phase 2 SPARK study did not meet its primary or secondary endpoints. Although we made this determination in February 2021, it was based on conditions that existed as of December 31, 2020. As a result, we recognized an impairment charge of approximately \$75.4 million during the fourth quarter of 2020 to reduce the fair value of the related in-process research and development (IPR&D) intangible asset to zero.

During the year ended December 31, 2020, amortization and impairment of acquired intangible assets reflects the impact of the BIIB111 and BIIB054 impairment charges as well as a \$19.3 million impairment charge related to one of our IPR&D intangible assets.

During the second quarter of 2021 we announced that our Phase 3 STAR study of BIIB111 and our Phase 2/3 XIRIUS study of BIIB112 did not meet their primary endpoints. In the third quarter of 2021 we suspended further development on these programs based on the decision by management as part of its strategic review process. For the year ended December 31, 2021, we recognized an impairment charge of \$365.0 million related to BIIB111 and an impairment charge of \$220.0 million related to BIIB112, reducing the remaining book values of these IPR&D intangible assets to zero.

[^] For the year ended December 31, 2021, compared to the same period in 2020, we recorded a current year deferred tax benefit associated with the accelerated approval of ADUHELM by the FDA. During the second quarter of 2021, we recorded approximately \$490.0 million in a deferred tax asset related to Neurimmune SubOne AG's tax basis in ADUHELM. The net deferred tax asset is comprised of approximately \$945.0 million of gross deferred tax asset, reduced by approximately \$455.0 million of unrecognized tax benefit. During the fourth quarter of 2021 we recorded a valuation allowance of approximately \$390.0 million related to this deferred tax asset. The realization of which is dependent on future sales of ADUHELM and approval of the Swiss cantonal tax authorities, with an equal and offsetting amount assigned to noncontrolling interest, resulting in zero net impact to net income attributable to Biogen Inc.

Use of Non-GAAP Financial Measures

We supplement our GAAP consolidated financial statements and GAAP financial measures with other financial measures, such as adjusted net income, adjusted diluted earnings per share, revenue growth at constant currency, which excludes the impact of changes in foreign exchange rates and hedging gains or losses, and free cash flow, which is defined as net flow from operations less capital expenditures. We believe that these and other Non-GAAP financial measures provide additional insight into the ongoing economics of our business and reflect how we manage our business internally, set operational goals and form the basis of our management incentive programs. Non-GAAP financial measures are in addition to, not a substitute for, or superior to, measures of financial performance prepared in accordance with GAAP.

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. Acquisitions and divestitures

We exclude transaction, integration and certain other costs related to the acquisition and divestiture of businesses, the acquisitions of assets and items associated with the initial consolidation or deconsolidation of variable interest entities. These adjustments include, but are not limited to, charges for in-process research and development and certain milestones, the amortization and impairment of intangible assets, charges or credits from the fair value remeasurement of our contingent consideration obligations and losses on assets and liabilities held for sale.

2. Restructuring, business transformation and other cost saving initiatives

We exclude costs associated with our execution of certain strategies and initiatives to streamline operations, achieve targeted cost reductions, rationalize manufacturing facilities or refocus research and development 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 ongoing or future business operations.

3. (Gain) loss on equity security investments

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 ongoing or future business operations.

4. 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 earnings per share - diluted.