BIOGEN INC. Form 10-Q October 24, 2017

UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549 Form 10-Q

# QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF $^{\rm x}$ 1934

For the quarterly period ended September 30, 2017

OR

# TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF $^{\rm 0}$ 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 (I.R.S. Employer incorporation or organization) 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)

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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 o

Non-accelerated filer o Smaller reporting company o (Do not check if a smaller reporting company) 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 Exchange

Act): Yes o No x

The number of shares of the issuer's Common Stock, \$0.0005 par value, outstanding as of October 20, 2017 was 211,476,936 shares.

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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," "intend," "may," "plan," "potential," "possible," "will" and other words as similar meaning. Reference is made in particular to forward-looking statements regarding:

the anticipated amount, timing and accounting of revenues, contingent payments, 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 potential impact of increased product competition in the markets in which we compete;

patent terms, patent term extensions, patent office actions and expected availability and period of regulatory exclusivity;

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;

the drivers for growing our business, including our plans and intent to commit resources relating to business development opportunities and research and development programs;

the anticipated benefits and the potential costs and expenses related to our corporate restructurings or other initiatives to streamline our operations and reallocate resources;

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 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.);

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 of healthcare reform in the United States (U.S.) and measures being taken worldwide designed to reduce healthcare costs to limit the overall level of government expenditures, including the impact of pricing actions and reduced reimbursement for our 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;

the anticipated benefits, costs and tax treatment of the spin-off of our hemophilia business;

lease commitments, purchase obligations and the timing and satisfaction of other contractual obligations;

our ability to finance our operations and business initiatives and obtain funding for such activities; and the impact of new laws and accounting standards.

These forward-looking statements involve risks and uncertainties, including those that are described in the "Risk Factors" section of 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.

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#### 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

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## PART I FINANCIAL INFORMATION

# BIOGEN INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED STATEMENTS OF INCOME

(unaudited, in millions, except per share amounts)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenues:				
Product, net	\$2,622.5	\$2,539.6	\$7,642.3	\$7,315.0
Revenues from anti-CD20 therapeutic programs	406.5	317.6	1,144.2	996.3
Other	48.8	98.6	180.4	265.5
Total revenues	3,077.8	2,955.8	8,966.9	8,576.8
Cost and expenses:				
Cost of sales, excluding amortization of acquired intangible assets	370.0	416.9	1,120.8	1,100.2
Research and development	446.4	529.0	1,666.0	1,439.4
Selling, general and administrative	433.8	462.7	1,363.1	1,452.4
Amortization of acquired intangible assets	108.9	99.7	674.9	281.4
Acquired in-process research and development	_	_	120.0	
Collaboration profit (loss) sharing	35.2	4.7	82.5	(0.9)
(Gain) loss on fair value remeasurement of contingent consideration	30.0	5.9	61.2	18.8
Restructuring charges		11.6	_	21.3
Total cost and expenses	1,424.3	1,530.5	5,088.5	4,312.6
Income from operations	1,653.5	1,425.3	3,878.4	4,264.2
Other income (expense), net	(43.6)	(58.1)	(149.4)	(169.4)
Income before income tax expense and equity in loss of investee, net of	1,609.9	1,367.2	3,729.0	4,094.8
tax	•	•	•	•
Income tax expense	383.8	337.0	892.6	1,047.0
Equity in loss of investee, net of tax				
Net income	1,226.1	1,030.2	2,836.4	3,047.8
Net income (loss) attributable to noncontrolling interests, net of tax		. ,	. ,	(5.8)
Net income attributable to Biogen Inc.	\$1,226.1	\$1,032.9	\$2,836.5	\$3,053.6
Net income per share:				
Basic earnings per share attributable to Biogen Inc.	\$5.80 \$5.79	\$4.72	\$13.32	\$13.95
Diluted earnings per share attributable to Biogen Inc.		\$4.71	\$13.30	\$13.92
Weighted-average shares used in calculating:				
Basic earnings per share attributable to Biogen Inc.	211.4	218.9	213.0	219.0
Diluted earnings per share attributable to Biogen Inc.	211.8	219.4	213.3	219.4

See accompanying notes to these unaudited condensed consolidated financial statements.

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## BIOGEN INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (unaudited, in millions)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2017	2016	2017	2016
Net income attributable to Biogen Inc.	\$1,226.1	\$1,032.9	\$2,836.5	\$3,053.6
Other comprehensive income:				
Unrealized gains (losses) on securities available for sale, net of tax	1.0	(5.4)	6.6	1.6
Unrealized gains (losses) on cash flow hedges, net of tax	(35.5)	1.3	(162.3)	(17.0)
Unrealized gains (losses) on pension benefit obligation, net of tax		0.4	(0.5)	1.3
Currency translation adjustment	43.9	(14.4)	146.7	(62.8)
Total other comprehensive income (loss), net of tax	9.4	(18.1)	(9.5)	(76.9)
Comprehensive income attributable to Biogen Inc.	1,235.5	1,014.8	2,827.0	2,976.7
Comprehensive income (loss) attributable to noncontrolling interests, net of tax	_	(2.6)	(0.1)	(5.7)
Comprehensive income	\$1,235.5	\$1,012.2	\$2,826.9	\$2,971.0

See accompanying notes to these unaudited condensed consolidated financial statements.

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# BIOGEN INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED BALANCE SHEETS

(unaudited, in millions, except per share amounts)

	As of September 30, 2017	As of December 31, 2016
ASSETS	2017	2010
Current assets:		
Cash and cash equivalents	\$1,548.1	\$2,326.5
Marketable securities	1,960.2	2,568.6
Accounts receivable, net	1,567.5	1,441.6
Due from anti-CD20 therapeutic programs	518.0	300.6
Inventory	1,007.2	1,001.6
Other current assets	967.0	1,093.3
Total current assets	7,568.0	8,732.2
Marketable securities	3,062.0	2,829.4
Property, plant and equipment, net	2,995.9	2,501.8
Intangible assets, net	4,019.4	3,808.3
Goodwill	4,127.5	3,669.3
Investments and other assets	1,300.4	1,335.8
Total assets	\$23,073.2	\$22,876.8
LIABILITIES AND EQUITY		
Current liabilities:		
Current portion of notes payable and other financing arrangements	\$573.2	\$4.7
Taxes payable	121.3	231.9
Accounts payable	298.7	279.8
Accrued expenses and other	2,455.2	2,903.5
Total current liabilities	3,448.4	3,419.9
Notes payable and other financing arrangements	5,938.3	6,512.7
Deferred tax liability	120.7	93.1
Other long-term liabilities	716.9	722.5
Total liabilities	10,224.3	10,748.2
Commitments and contingencies		
Equity:		
Biogen Inc. shareholders' equity:		
Preferred stock, par value \$0.001 per share	_	_
Common stock, par value \$0.0005 per share	0.1	0.1
Additional paid-in capital	59.2	_
Accumulated other comprehensive loss		(319.9)
Retained earnings	16,107.7	15,071.6
Treasury stock, at cost		(2,611.7)
Total Biogen Inc. shareholders' equity	12,860.5	12,140.1
Noncontrolling interests		(11.5)
Total equity	12,848.9	12,128.6
Total liabilities and equity	\$23,073.2	\$22,876.8

See accompanying notes to these unaudited condensed consolidated financial statements.

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BIOGEN INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (unaudited, in millions)

For the Nine Months

**Ended September** 

30,

2017 2016

Cash flows from operating activities:

Net income \$2,836.4 \$3,047.8

Adjustments to reconcile net income to net cash flows from operating activities:

Depreciation, amortization and acquired in-process research and development 992.0