

# Forward looking statements

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# Q1 2019 earnings call agenda

Introduction

**Matt Calistri** 

VP, Investor Relations

Overview

**Michel Vounatsos** 

Chief Executive Officer

**R&D Update** 

Michael Ehlers, M.D., Ph.D.

EVP, Research & Development

**Financial Update** 

**Jeffrey Capello** 

EVP, Chief Financial Officer

**Closing Remarks** 

**Michel Vounatsos** 

Chief Executive Officer

Available for Q&A

Al Sandrock, M.D., Ph.D.

EVP, Chief Medical Officer



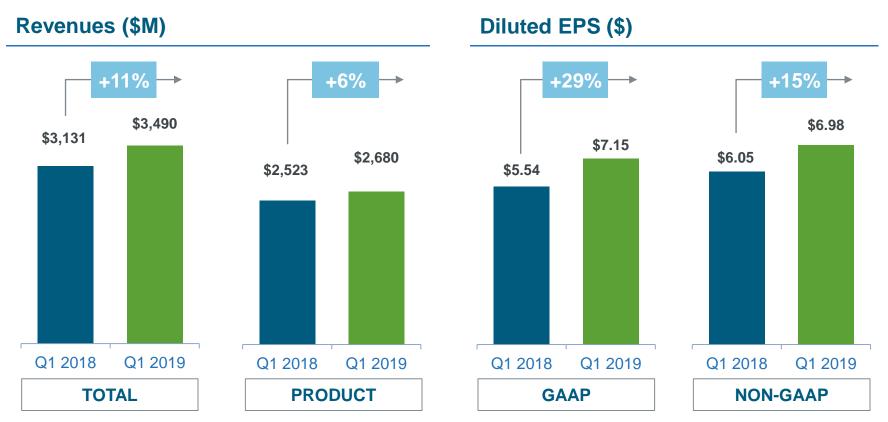
# **Overview**

Michel Vounatsos
Chief Executive Officer





# Strong performance in Q1 2019





# Diligent focus on capital allocation

# Maximizing the value of our investments

Organic pipeline

Collaborations

Acquired programs

Samsung Bioepis JV

Solothurn Facility\*

# Capital allocation aiming for highest potential return

- Repurchased ~ 4.5 million shares to-date in 2019 for ~ \$1.1 billion
- \$1.0 billion remaining under 2018 share repurchase program and \$5.0 billion under newly authorized 2019 share repurchase program
- Agreement to sell our Hillerød facility to FUJIFILM for up to \$890 million#; potential to deploy capital for higher return
- Agreement to acquire Nightstar Therapeutics<sup>^</sup>
- Investing in our pipeline



<sup>\*</sup> Expected to be operational by end of 2020.

<sup>#</sup> The purchase price is subject to certain working capital adjustments and other contractual terms. The proposed transaction remains subject to customary closing conditions, including filings and clearances under the Danish Competition Act.

<sup>^</sup> The closing of the proposed acquisition of Nightstar Therapeutics plc remains subject to customary closing conditions, including the approval by Nightstar Therapeutics shareholders and the issuance of an order by the U.K. Court.

# Progress diversifying our pipeline



	Additions Since Jan. 2017	Current Programs
MS / Neuroimmunology	+1	3
AD / Dementia	+3	5
PD / Movement Disorders	+1	2
Neuromuscular Disorders	+2	3
Acute Neurology	+3	3
Pain	+2	3
<b>Neurocognitive Disorders</b>	+1	1
Therapeutic Adjacencies		3
Total	+13	23

# Results for aducanumab

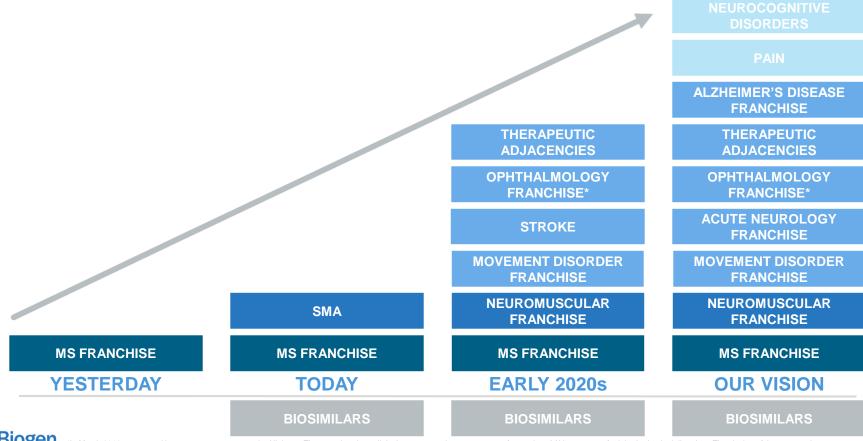
# Discontinuation of aducanumab is a disappointment for patients, families, and the scientific community

- We followed the science and will leverage learnings from aducanumab to inform future studies
- Remaining programs targeting betaamyloid will be informed by analysis of the Phase 3 studies of aducanumab and the Phase 2 study of BAN2401
- Plan to continue to advance programs targeting tau, including BIIB092, BIIB076, and BIIB080





# Continuing to build a multi-franchise portfolio



## Core focus remains neuroscience



#### **Key Priorities**

Short-term focus on execution, financial discipline, and capital allocation

Opportunities to improve business performance

**Indication expansions** 

**Accelerating time to market** 

Optimizing clinical resources and manufacturing capacity



Deep scientific and clinical development expertise in neuroscience

Global commercial expertise, including market access: leading MS, SMA, and European anti-TNF biosimilars portfolio

World-class biologics manufacturing capabilities

Highly talented and energized team



# Maximizing resilience in MS



- '514 patent has been scrutinized multiple times
- Previously prevailed in an IPR and interference proceeding
- Continue to believe we have valid patents
- Preparing for all possible outcomes



- Opportunity to launch ahead of the outcome of TECFIDERA IPR and district court litigation
- Novel oral fumarate
- Potential to be another important choice for MS patients
- NDA filing accepted by FDA; decision expected in Q4 2019
- Composition of matter patent with base expiration in 2033



## SPINRAZA: the standard of care in SMA



> 300

Number of patients on whom data has been reported

**Up to 6 Years** 

Duration of follow-up period

> 7,000\*

Number of patients with real-world experience

Expect SPINRAZA to continue to grow; global epidemiology larger than initially estimated

\*Data as of March 31, 2019



Study of SPINRAZA in presymptomatic infants#

100%

Alive

NONE

Required tracheostomy or permanent ventilation

100%

Able to sit without support

88%

Able to walk either with assistance or independently

#Data as of May 2018 (n=25)



# **R&D Update**

Michael Ehlers, M.D., Ph.D. EVP, Research & Development





## **Results for aducanumab**

- Decision to discontinue ENGAGE and EMERGE was based on a futility analysis
  - Futility criteria: < 20% conditional power to meet primary endpoint in both studies
- Aducanumab treatment resulted in a dose- and time-dependent reduction in cerebral amyloid deposition, as assessed by amyloid-PET imaging
- Will not initiate Phase 3 secondary prevention study of aducanumab to prevent or delay the clinical onset of Alzheimer's disease at this time
- Data will be presented at future medical meetings
- Remaining programs targeting beta-amyloid will be informed by further analysis of the Phase 3 studies of aducanumab and the Phase 2 study of BAN2401
- Plan to continue to advance programs targeting tau, including BIIB092, BIIB076, and BIIB080





# Added 13 clinical programs since beginning of 2017

BIIB098 (diroximel fumarate)\* - MS Filed MS and Neuroimmunology Opicinumab (anti-LINGO) - MS Ph2 BIIB061 (oral remvelination) - MS Elenbecestat (E2609)\* - Alzheimer's Ph<sub>3</sub> BAN2401 (Aß mAb)\* - Alzheimer's Ph2 Advancing to Ph3 Alzheimer's Disease BIIB092 (gosuranemab) - Alzheimer's Core Ph2 and Dementia Growth BIIB076 (anti-tau mAb) - Alzheimer's New Ph<sub>1</sub> **Areas** BIIB080 (IONIS-MAPT<sub>Ry</sub>)# - Alzheimer's Ph1 New BIIB092 (gosuranemab) - PSP New Parkinson's Disease and Ph<sub>2</sub> **Movement Disorders** BIIB054 (a-synuclein mAb) - Parkinson's Ph<sub>2</sub> BIIB067 (tofersen) - ALS Ph3^ Neuromuscular Disorders BIIB078 (IONIS-C9py)# - ALS Ph1 New Including SMA and ALS Ph<sub>1</sub> BIIB110 (ActRIIA/B ligand trap) - SMA BIIB093 (glibenclamide IV) - LHI Stroke Ph<sub>3</sub> New Ph2 New **Acute Neurology** TMS-007# - Acute Ischemic Stroke Ph<sub>2</sub> New Natalizumab - Epilepsy **Emerging Neurocognitive Disorders** New Growth BIIB104 (AMPA) - CIAS Advancing to Ph3 **Areas** Ph<sub>2</sub> BIIB074 (vixotrigine) - Trigeminal Neuralgia Pain BIIB074 (vixotrigine) - Small Fiber Neuropathy Ph2 New BIIB095 (Nav 1.7) - Neuropathic Pain Dapirolizumab pegol (anti-CD40L)\* - SLE Ph2 Advancing to Ph3 Therapeutic Adjacencies BIIB059 (anti-BDCA2) - CLE/SLE Ph<sub>2</sub> BG00011 (STX-100) - IPF Ph2

Biogen. \* Collaboration programs; # Option agreement; ^ Biogen is collaborating with regulators to further define the scope of the clinical data package required to support the registration of BIB067

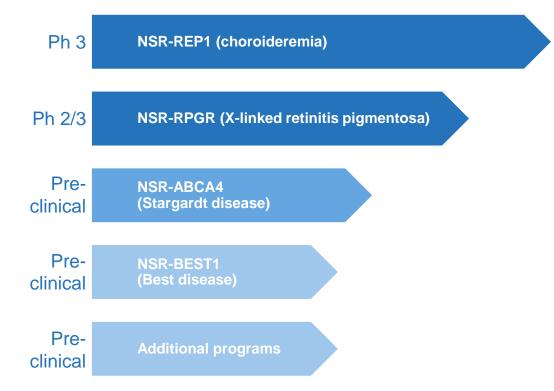
MS = multiple sclerosis; PSP = progressive supranuclear palsy; ALS = amyotrophic lateral sclerosis; SMA = spinal muscular atrophy; LHI = large hemispheric infarction; CIAS = cognitive impairment

15 associated with schizophrenia: SLE = systemic lupus erythematosus: CLE = cutaneous lupus erythematosus; IPF = idiopathic pulmonary fibrosis

## Nightstar Therapeutics: broad pipeline for inherited retinal disorders



- Retinal degeneration shares many characteristics with degenerative CNS diseases
- Inherited retinal diseases afflict up to ~200,000 patients in the U.S. alone
- Look forward to joining forces with the remarkable team at Nightstar with the goal of bringing breakthrough therapies to patients to slow or halt blindness across a range of inherited retinal diseases

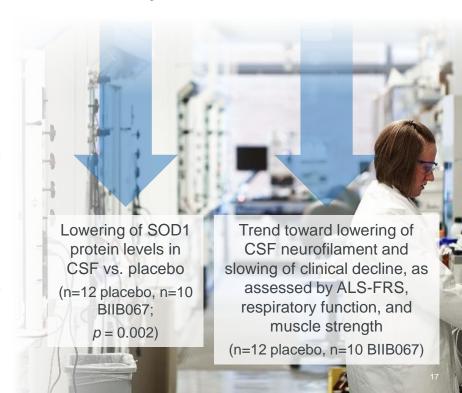




# Dosed first patient in phase 3 VALOR study of BIIB067

- BIIB067 selectively targets SOD1 mRNA to reduce the levels of toxic mutant SOD1 protein
- VALOR is a continuation of the Phase 1/2 study in which BIIB067 demonstrated both proof-of-biology and proof-of-concept
- Primary endpoint is an analysis based on the ALS Functional Rating Scale-Revised Score
- Collaborating with regulators to further define scope of clinical data package required to support registration
- Positive implications for additional ASOs in our pipeline in collaboration with Ionis Pharmaceuticals that utilize RNase H-mediated mRNA degradation
- Plan to present data from the Phase 1/2 study of BIIB067 at AAN 2019

# Summary of Phase 1/2 Study of BIIB067 in SOD1 ALS





## SPINRAZA: the standard of care in SMA

Encore presentation of data from the NURTURE study of SPINRAZA presented at the 2019 Muscular Dystrophy Association Clinical and Scientific Conference

**NURTURE data demonstrate the unprecedented efficacy profile of SPINRAZA** in presymptomatic infants with SMA



Study of SPINRAZA in presymptomatic infants#

100% Alive NONE

Required tracheostomy or permanent ventilation

100%

Able to sit without support

88%

Able to walk either with assistance or independently

#Data as of May 2018 (n=25)



# **Progress in movement disorders**

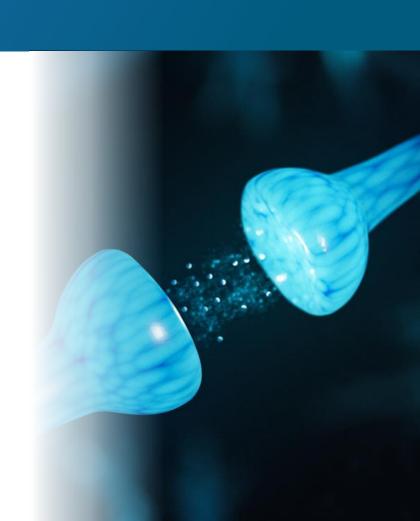
#### **Progressive supranuclear palsy (PSP)**

- BIIB092 is a monoclonal antibody targeting tau
- Final readout for the Phase 2 study of BIIB092 in PSP expected in 2H 2019

#### Parkinson's disease

- **BIIB054** is a monoclonal antibody targeting α-synuclein
- Data on the primary outcome measure from Phase
   2 study of BIIB054 in Parkinson's disease expected in
   2H 2020





# Progressing two assets in lupus

# BIIB059 (anti-BDCA2 mAb)

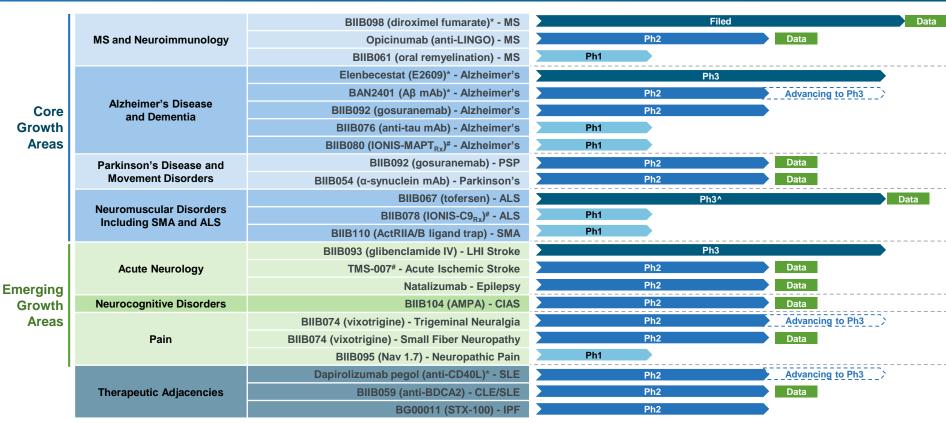
- Currently evaluating BIIB059 in a Phase
   2 study in cutaneous lupus
   erythematosus (CLE) and systemic lupus
   erythematosus (SLE)
- Data expected by the end of 2019

# Dapirolizumab pegol\* (anti-CD40 ligand pegylated Fab)

- Although primary endpoint was not met, we believe totality of the Phase 2b data supported proof-ofconcept
- Phase 2b study in SLE demonstrated consistent and potentially meaningful improvements for the majority of clinical endpoints
  - Biomarker data demonstrated evidence of proof-of-biology
  - Well-tolerated and demonstrated an acceptable safety profile
- Post-hoc analysis indicated notable response in a refined population
- Expect to work with UCB to agree on details of a potential global phase 3 program



## Ten mid- to late-stage readouts expected by end of 2020



: data readout expected by end of 2020

Collaboration programs; # Option agreement; ^ Biogen is collaborating with regulators to further define the scope of the clinical data package required to support the registration of BIIB067 MS = multiple sclerosis; PSP = progressive supranuclear palsy; ALS = amyotrophic lateral sclerosis; SMA = spinal muscular atrophy; LHI = large hemispheric infarction; CIAS = cognitive impairment associated with schizophrenia; SLE = systemic lupus erythematosus; CLE = cutaneous lupus erythematosus; IPF = idiopathic pulmonary fibrosis

# Biogen's R&D priorities moving forward

- Focus on clinical trial execution and resource optimization
  - 10 mid- to late-stage readouts expected by end of 2020
- Diversification, including potential indication expansions
- Continued progress advancing pipeline, including ways to accelerate time to market
- Balancing pipeline risk, including continued pursuit of late stage opportunities





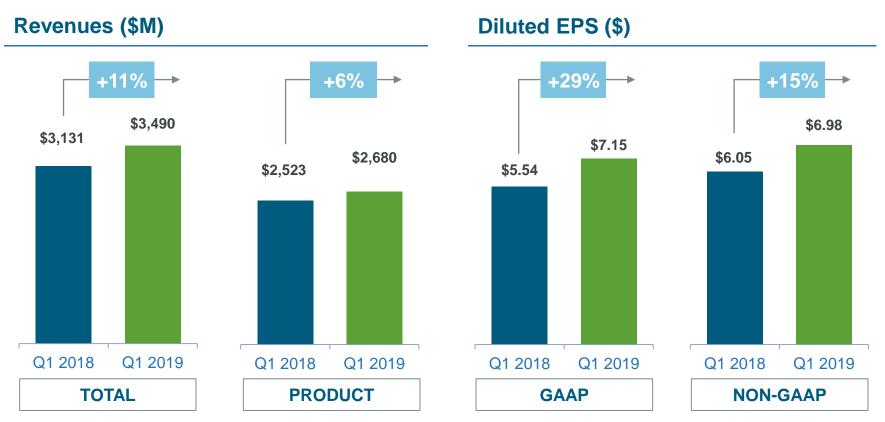
# Financial Update

Jeffrey Capello EVP, Chief Financial Officer





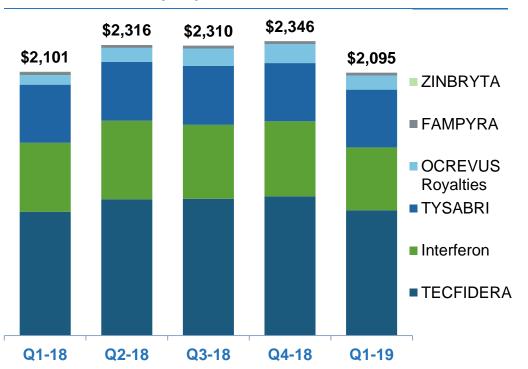
# Strong performance in Q1 2019





# Global multiple sclerosis performance

#### MS Revenues (\$M)



#### **Highlights**

Revenues vs. Q1 2018 and Q4 2018

	$\Delta Y/Y$		∆Q/Q
Total	- 0%	and	- 11%
U.S. Product	- 4%	and	- 16%
ROW Product	+ 3%	and	+ 7%
OCREVUS Royalties	+ 46%	and	- 26%

 Decrease in channel inventory in the U.S. of ~\$170 million in Q1 2019 compared to decrease of ~\$140 million in Q1 2018 and increase of ~\$105 million in Q4 2018

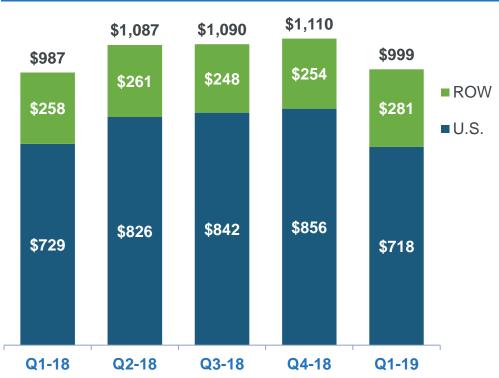


Numbers may not foot due to rounding.

# **Global TECFIDERA performance**



#### **TECFIDERA Revenues (\$M)**



#### **Highlights**

Revenues vs. Q1 2018 and Q4 2018

	$\Delta Y/Y$		$\Delta Q/Q$
WW	+ 1%	and	- 10%
U.S.	- 2%	and	- 16%
ROW	+ 9%	and	+ 11%

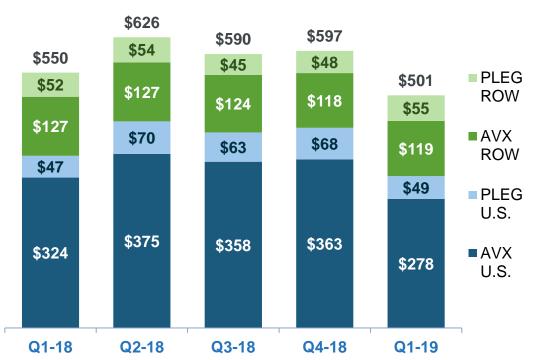
 Decrease in channel inventory in the U.S. of ~\$110 million in Q1 2019 compared to decrease of ~\$80 million in Q1 2018 and increase of ~\$60 million in Q4 2018

## Global interferon performance





#### Interferon Revenues (\$M)



#### Highlights

Revenues vs. Q1 2018 and Q4 2018

	$\Delta Y/Y$	$\Delta Q/Q$
WW	- 9%	and - 16%
U.S.	- 12%	and - 24%
ROW	- 3%	and + 4%

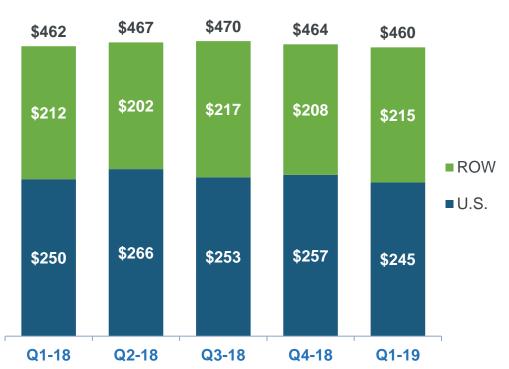
 Decrease in channel inventory in the U.S. of ~\$45 million in Q1 2019 compared to decrease of ~\$60 million in Q1 2018 and increase of ~\$35 million in Q4 2018



# **Global TYSABRI performance**



#### TYSABRI Revenues (\$M)



#### **Highlights**

Revenues vs. Q1 2018 and Q4 2018

	$\Delta Y/Y$		∆Q/Q
WW	- 0%	and	- 1%
U.S.	- 2%	and	- 5%
ROW	+ 1%	and	+ 4%

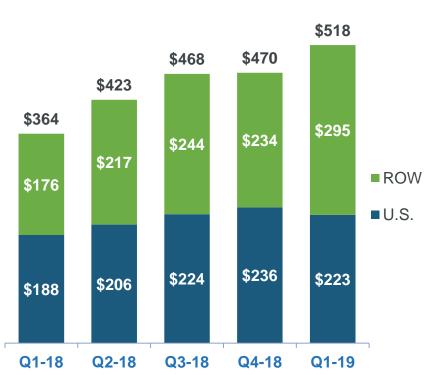
 Decrease in channel inventory in the U.S. of ~\$15 million in Q1 2019 compared to relatively stable inventory in Q1 2018 and increase of ~\$10 million in Q4 2018

# **Global SPINRAZA performance**





#### SPINRAZA Revenues (\$M)



#### **Dosing Schedule**



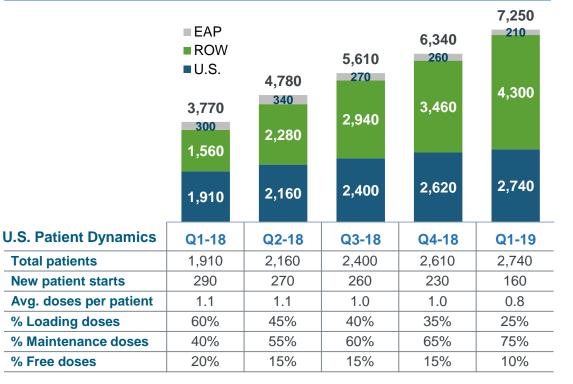
#### **Highlights**

- Approved in over 40 countries\*
- Formal reimbursement in over 30 countries\*
- Recorded revenues from over 40 markets in Q1 2019

# **SPINRAZA** patient dynamics



#### **SPINRAZA Patients**



#### **Highlights**

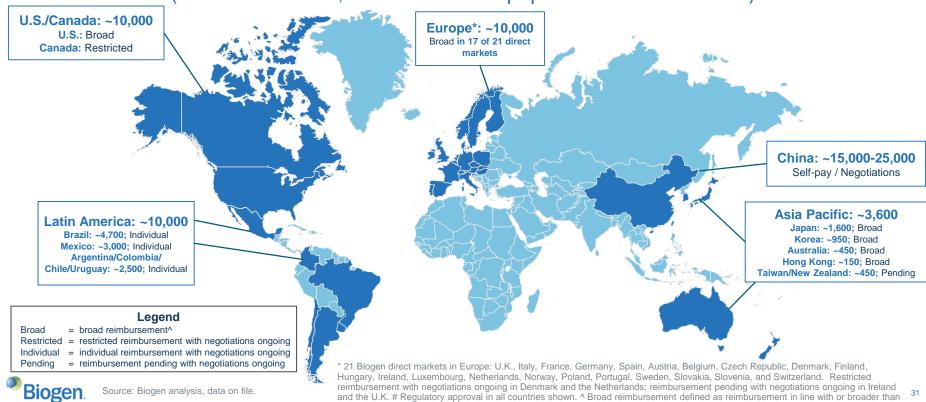
- As of March 31, 2019, over 7,500
   patients on therapy across the postmarketing setting, the EAP, and clinical
  trials
- Low discontinuations
- Over 1,000 adults on therapy in the U.S., an increase of ~ 8% versus Q4 2018
  - ~ 50% of new patient starts in Q1 2019 were adults
- Approved in Argentina, Colombia, Taiwan, and China (self-pay in China)
- Secured broad reimbursement in France and South Korea
- Named patient sales program in Turkey expanded to cover Type 1, 2, and 3 patients



# Global opportunity: over 45,000 individuals with SMA

## Estimated Prevalence of SMA in Biogen Direct Markets#

(Total market size, not addressable population for SPINRAZA)



and the U.K. # Regulatory approval in all countries shown. A Broad reimbursement defined as reimbursement in line with or broader than

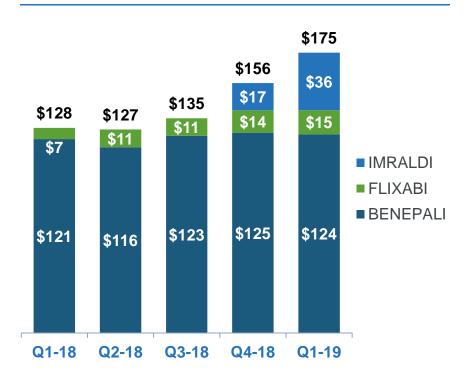
clinical trial data; coverage of all ages up to 18 years and in certain countries also coverage for adults.

Source: Biogen analysis, data on file.

## **Biosimilars business**



#### **Biosimilars Revenues (\$M)**



#### **Commercialization in Europe**

- ~ 145,000 patients currently on Biogen biosimilars\*
- IMRALDI launched in Europe on October 17, 2018
- Expect uptake of Biogen biosimilars to contribute estimated healthcare savings of up to €1.8 billion in 2019 across Europe\*

#### **Samsung Bioepis Joint Venture**

- Increased equity stake to ~49.9%
- Leveraging expertise in protein engineering and biologics manufacturing
- Advancing biosimilars of trastuzumab and bevacizumab



# Q1 2019 financial results summary: revenues

\$ in Millions	Q1 2019	Q1 2018	Q4 2018	Δ Υ/Υ	∆ <b>Q/Q</b>
Total MS Product Revenues <sup>1</sup>	\$1,983	\$2,025	\$2,195	(2%)	(10%)
SPINRAZA U.S.	\$223	\$188	\$236	19%	(5%)
SPINRAZA ROW <sup>1</sup>	\$295	\$176	\$234	68%	26%
Total SPINRAZA Revenues <sup>1</sup>	\$518	\$364	\$470	42%	10%
Biosimilars Revenues	\$175	\$128	\$156	37%	12%
FUMADERM Revenues	\$4	\$7	\$5	(41%)	(18%)
Total Product Revenues <sup>1</sup>	\$2,680	\$2,523	\$2,826	6%	(5%)
RITUXAN/GAZYVA Revenues	\$405	\$366	\$383	11%	6%
OCREVUS Royalties	\$112	\$77	\$152	46%	(26%)
Revenues from Anti-CD20 Therapeutic Programs	\$517	\$443	\$535	17%	(3%)
Other Revenues	\$292	\$164	\$166	78%	76%
Total Revenues <sup>1</sup>	\$3,490	\$3,131	\$3,526	11%	(1%)



Numbers may not foot due to rounding. Percent changes represented as favorable & (unfavorable). For all periods, there were no adjustments between GAAP and Non-GAAP revenues.

<sup>1</sup> Net of Hedge

# Q1 2019 financial results summary

\$ in Millions	Q1 2019	Q1 2018	Q4 2018	ΔΥ/Υ	∆Q/Q
GAAP Cost of Sales	\$602	\$446	\$489	(35%)	(23%)
% of Total Revenues	17%	14%	14%	 	 
Non-GAAP Cost of Sales	\$602	\$446	\$489	(35%)	(23%)
% of Total Revenues	17%	14%	14%	 	 
GAAP R&D Expenses	\$564	\$497	\$612	(13%)	8%
% of Total Revenues	16%	16%	17%	 	 
Non-GAAP R&D Expenses	\$564	\$497	\$602	(13%)	6%
% of Total Revenues	16%	16%	17%		
GAAP SG&A Expenses	\$568	\$501	\$591	(13%)	4%
% of Total Revenues	16%	16%	17%	 	 
Non-GAAP SG&A Expenses	\$563	\$497	\$591	(13%)	5%
% of Total Revenues	16%	16%	17%	 	 
GAAP Loss on Assets & Liabilities Held for Sale	\$116	\$0	\$0	NMF	NMF
GAAP Amortization of Acquired Intangibles	\$68	\$104	\$254	34%	73%
Collaboration Profit Sharing	\$58	\$43	\$56	(37%)	(4%)



Numbers may not foot due to rounding. Percent changes represented as favorable & (unfavorable). A reconciliation of our GAAP to Non-GAAP financial results is at the end of this presentation.

# **Q1 2019 financial results summary**

\$ in Millions except EPS, Shares in Millions	Q1 2019	Q1 2018	Q4 2018	Δ <b>Y/Y</b>	∆ <b>Q/Q</b>
GAAP Other Income (Expense)	\$357	(\$41)	(\$29)	NMF	NMF
Non-GAAP Other Income (Expense)	(\$19)	(\$35)	(\$16)	46%	(15%)
GAAP Tax Rate	23%	22%	33%		 
Non-GAAP Tax Rate	18%	21%	21%		 
GAAP JV Equity Income (Loss)	(\$29)	\$0	\$0	NMF	NMF
Non-GAAP JV Equity Income (Loss)	(\$14)	\$0	\$0	NMF	NMF
GAAP Net Income (Loss) Attributable to Noncontrolling Interests	(\$0)	(\$2)	(\$2)	NMF	NMF
Non-GAAP Net Income (Loss) Attributable to Noncontrolling Interests	(\$0)	(\$0)	(\$0)	NMF	NMF
Weighted average diluted shares used in calculating diluted EPS	197	212	200	7%	2%
GAAP Net Income Attributable to Biogen Inc.	\$1,409	\$1,173	\$947	20%	49%
GAAP Diluted EPS	\$7.15	\$5.54	\$4.73	29%	51%
Non-GAAP Net Income Attributable to Biogen Inc.	\$1,374	\$1,282	\$1,400	7%	(2%)
Non-GAAP Diluted EPS	\$6.98	\$6.05	\$6.99	15%	(0%)



Numbers may not foot due to rounding. Percent changes represented as favorable & (unfavorable). A reconciliation of our GAAP to Non-GAAP financial results is at the end of this presentation.

# **Closing Remarks**

Michel Vounatsos
Chief Executive Officer





# Ten mid- to late-stage readouts expected by end of 2020

	<b>Expected Data Readout</b>	Timing	G7 Prevalence <sup>^</sup>
Multiple sclerosis	Head-to-head data for BIIB098	Mid 2019	~ 1.4 million
PSP	Phase 2 data for BIIB092	2H 2019	~ 70 thousand
CLE/SLE	Phase 2 data for BIIB059	Late 2019	~ 800 thousand
Epilepsy*	Phase 2 data for natalizumab	1H 2020	~ 1.1 million*
Multiple sclerosis	Phase 2b data for opicinumab	Mid 2020	~ 1.4 million
Parkinson's disease	Phase 2 data for BIIB054	2H 2020	~ 3.1 million
SOD1 ALS‡	Phase 3 data for BIIB067	2H 2020	~ 1,200‡
Small fiber neuropathy	Phase 2 data for BIIB074	Late 2020	~ 12.4 million
CIAS	Phase 2b data for BIIB104	Late 2020	~ 16.3 million
Stroke#	Phase 2 data for TMS-007	Late 2020	~ 700 thousand#



# **Questions** & Answers





# **Appendix**





# Q1 2019 financial results summary: MS revenues

\$ in Millions	Q1 2019	Q1 2018	Q4 2018	Δ Υ/Υ	∆ <b>Q/Q</b>
TECFIDERA U.S.	\$718	\$729	\$856	(2%)	(16%)
TECFIDERA ROW <sup>1</sup>	\$281	\$258	\$254	9%	11%
Total TECFIDERA Revenues <sup>1</sup>	\$999	\$987	\$1,110	1%	(10%)
AVONEX U.S.	\$278	\$324	\$363	(14%)	(23%)
AVONEX ROW <sup>1</sup>	\$119	\$127	\$118	(6%)	1%
Total AVONEX Revenues <sup>1</sup>	\$397	\$451	\$481	(12%)	(17%)
PLEGRIDY U.S.	\$49	\$47	\$68	4%	(28%)
PLEGRIDY ROW <sup>1</sup>	\$55	\$52	\$48	5%	13%
Total PLEGRIDY Revenues <sup>1</sup>	\$104	\$100	\$116	4%	(11%)
Total Interferon Revenues <sup>1</sup>	\$501	\$550	\$597	(9%)	(16%)
TYSABRI U.S.	\$245	\$250	\$257	(2%)	(5%)
TYSABRI ROW <sup>1</sup>	\$215	\$212	\$208	1%	4%
Total TYSABRI Revenues <sup>1</sup>	\$460	\$462	\$464	(0%)	(1%)
FAMPYRA <sup>1</sup>	\$23	\$24	\$23	(6%)	1%
ZINBRYTA ROW	\$0	\$1	\$0	(100%)	NMF
Total MS Product Revenues <sup>1</sup>	\$1,983	\$2,025	\$2,195	(2%)	(10%)
	I I	I I	1		
OCREVUS Royalties	\$112	\$77	\$152	46%	(26%)
MS Product Revenues <sup>1</sup> + OCREVUS Royalties	\$2,095	\$2,101	\$2,346	(0%)	(11%)



Numbers may not foot due to rounding. Percent changes represented as favorable & (unfavorable). For all periods, there were no adjustments between GAAP and Non-GAAP revenues.

<sup>1</sup> Net of Hedge

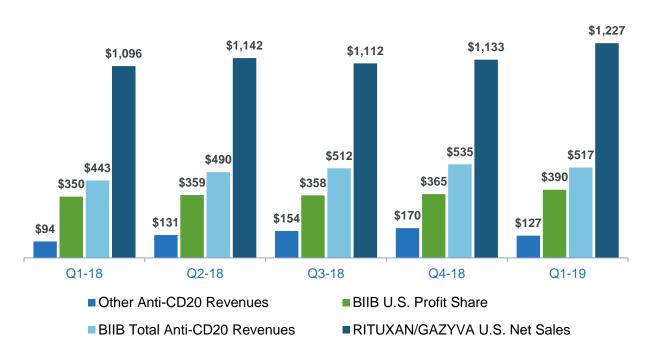
# Q1 2019 impact of foreign exchange and hedging

	Actuals	ctuals in the Quarter Hedge Favorable/ Favorable/		• • • • • • • • • • • • • • • • • • • •		Favo	Hedge Impact Favorable/ (Unfavorable)		Total Impact Favorable/ (Unfavorable)	
	Q1'19	Q1'19	Q1'18	Q4'18	Vs. Q1'18	Vs. Q4'18	Vs. Q1'18	Vs. Q4'18	Vs. Q1'18	Vs. Q4'18
Total Revenues	\$3,490	\$18	(\$33)	<b>\$13</b>	(\$77)	(\$1)	\$52	<b>\$6</b>	(\$25)	\$4
TECFIDERA	\$999	\$8	(\$13)	\$5	(\$19)	(\$0)	\$21	\$3	\$2	\$2
Interferon	\$501	\$4	(\$9)	\$3	(\$14)	(\$0)	\$13	\$1	(\$1)	\$1
TYSABRI	\$460	\$6	(\$11)	\$4	(\$17)	(\$1)	\$17	\$2	(\$0)	\$1
SPINRAZA	\$518	\$0	N/A	N/A	(\$13)	\$0	\$0	\$0	(\$13)	\$0
Biosimilars	\$175	N/A	N/A	N/A	(\$10)	(\$0)	-	-    - 	(\$10)	(\$0)



# **Anti-CD20 performance**

#### Revenues from Anti-CD20 Therapeutic Programs (\$M)



#### **Highlights**

Revenues

- Revenues vs. Q1 2018 and Q4 2018  $\Delta Y/Y$  $\Delta Q/Q$ U.S. Net Sales + 12% and +8% U.S. Profit + 12% and + 7% Share<sup>1</sup> Other Anti-+ 35% and - 25% **CD20 BIIB Total** Anti-CD20 + 17% and - 3%
- Other revenues from anti-CD20 therapeutic programs consist of royalty revenues on sales of OCREVUS and our share of pre-tax copromotion profits on RITUXAN in Canada.



#### **GAAP** to Non-GAAP Reconciliation Net Income Attributable to Biogen Inc. and Diluted Earnings Per Share (unaudited, in millions, except per share amounts)

An itemized reconciliation between diluted earnings per share on a GAAP and Non-GAAP basis is as follows:

For the Three	Months Ended
---------------	--------------

GAAP earnings per share - Diluted
Adjustments to GAAP net income attributable to Biogen
Inc. (as detailed below)
Non-GAAP earnings per share - Diluted

March 31, 2019		March 31, 2018		December 31, 2018	
\$	7.15	\$	5.54	\$	4.73
	(0.17)		0.51		2.26
\$	6.98	\$	6.05	\$	6.99

An itemized reconciliation between net income attributable to Biogen Inc. on a GAAP and Non-GAAP basis is as follows:

	For the Three Months Ended			
	March 31, 2019	March 31, 2018	December 31, 2018	
AP net income attributable to Biogen Inc.	\$ 1,408.8	\$ 1,172.9	\$ 946.8	
ljustments:				
Acquisition and divestiture related costs:				
Amortization and impairment of acquired intangible assets A	68.2	103.9	254.1	
Acquired in-process research and development	_	10.0	_	
Research and development <sup>B</sup>	_	_	10.0	
Loss (gain) on fair value remeasurement of contingent consideration <sup>C</sup>	11.5	(5.6)	79.3	
Loss on assets and liabilities held for sale D	115.5	_	_	
Net distribution to noncontrolling interests	_	_	(1.6)	
Acquisition-related transaction and integration costs	4.3	_	_	
Subtotal: Acquisition and divestiture related costs	199.5	108.3	341.8	
Restructuring, business transformation and other cost saving initiatives:				
2017 corporate strategy implementation <sup>E</sup>	1.0	3.8	_	
Restructuring charges <sup>E</sup>	0.4	1.6	2.8	
Subtotal: Restructuring, business transformation and other cost saving initiatives	1.4	5.4	2.8	
Gain) loss on equity security investments	(376.1)	6.4	12.2	
ncome tax effect related to reconciling items	126.1	(11.3)	(49.8)	
Amortization included in Equity in loss of investee, net of tax <sup>F</sup>	14.7	_	_	
Elimination of deferred tax asset <sup>G</sup>	_	_	10.6	
Tax reform H	_	_	135.8	
n-GAAP net income attributable to Biogen Inc.	\$ 1,374.4	\$ 1,281.7	\$ 1,400.2	

#### Use of Non-GAAP Financial Measures

We supplement our consolidated financial statements presented on a GAAP basis by providing additional measures which may be considered "Non-GAAP" financial measures under applicable SEC rules. We believe that the disclosure of these Non-GAAP financial measures provides additional insight into the ongoing economics of our business and reflects how we manage our business internally. set operational goals and form the basis of our management incentive programs. These Non-GAAP financial measures are not in accordance with generally accepted accounting principles in the United States and should not be viewed in isolation or as a substitute for reported, or GAAP, net income attributable to Biogen Inc. and diluted earnings per share.

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. Acquisition and divestiture related costs

We exclude transaction, integration and certain other costs related to the acquisition and divestiture of businesses. We exclude certain purchase accounting related items associated with the acquisition of assets and amounts in relation to the 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 R&D 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.



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#### Notes to GAAP to Non-GAAP Reconciliation

Aln January 2017 we entered into a settlement and license agreement among Biogen Swiss Manufacturing GmbH, Biogen International Holding Ltd., Forward Pharma A/S (Forward Pharma) and certain related parties, which was effective February 1, 2017. Pursuant to this agreement, we obtained U.S. and rest of world licenses to Forward Pharma's intellectual property, including Forward Pharma's intellectual property related to TECFIDERA. In exchange, we paid Forward Pharma \$1.25 billion in cash, of which \$795.2 million was recognized as an intangible asset in the first quarter of 2017.

We have two intellectual property disputes with Forward Pharma, one in the U.S. and one in the European Union, concerning intellectual property related to TECFIDERA.

In March 2017 the U.S. intellectual property dispute was decided in our favor. Forward Pharma appealed to the U.S. Court of Appeals for the Federal Circuit. We evaluated the recoverability of the U.S. asset acquired from Forward Pharma and recorded a \$328.2 million impairment charge in the first quarter of 2017 to adjust the carrying value of the acquired U.S. asset to fair value reflecting the impact of the developments in the U.S. legal dispute and continued to amortize the remaining net book value of the U.S. intangible asset in our consolidated statements of income utilizing an economic consumption model. The U.S. Court of Appeals for the Federal Circuit upheld the U.S. Patent and Trademark Office's March 2017 ruling and in January 2019 denied Forward Pharma's petition for rehearing. We evaluated the recoverability of the U.S. asset based upon these most recent developments and recorded a \$176.8 million impairment charge in the fourth quarter of 2018 to reduce the remaining net book value of the U.S. asset to zero.

In March 2018 the European Patent Office (EPO) revoked Forward Pharma's European Patent No. 2 801 355. Forward Pharma has filed an appeal to the Technical Boards of Appeal of the EPO and the appeal is pending. Based upon our assessment of this ruling, we continue to amortize the remaining net book value of the rest of world intangible asset in our consolidated statements of income utilizing an economic consumption model.

<sup>B</sup> GAAP research and development expense for the three months ended December 31, 2018, includes a \$10.0 million contingent consideration payment accrued in relation to the acquisition of an asset.

<sup>c</sup> During the third quarter of 2018 we adjusted the fair value of our contingent consideration obligations related to our BIIBO74 (vixotrigine) program for the treatment of trigeminal neuralgia (TGN) to reflect the lower cumulative probabilities of success, which resulted in a gain of \$89.6 million.

In late December 2018 we received feedback from the U.S. Food and Drug Administration regarding the design of the Phase 3 studies of vixotrigine for the treatment of TGN. Following this feedback, we are now planning to initiate the Phase 3 studies for our vixotrigine program for the treatment of TGN and, as a result, we adjusted the fair value of our contingent consideration obligations related to our vixotrigine program for the treatment of TGN to reflect the increased probabilities of success and recognized a loss of \$80.6 million in the fourth quarter of 2018.



#### **Notes to GAAP to Non-GAAP Reconciliation (Continued)**

In March 2019 we entered into a share purchase agreement with FUJIFILM Corporation (FUJIFILM) under which FUJIFILM will acquire all of the outstanding shares of our subsidiary that owns our biologics manufacturing operations in Hillerød, Denmark.

Upon closing of the proposed transaction, we expect to receive up to \$890.0 million in cash, subject to certain working capital adjustments and other contractual terms.

As part of the proposed transaction, we have provided FUJIFILM with certain minimum batch production commitment guarantees. There is a risk that the minimum contractual batch production commitments will not be met. Based upon current estimates we expect to incur an adverse commitment obligation of approximately \$120.0 million associated with such guarantees. We may adjust this estimate based upon changes in business conditions, which may result in the recognition of additional losses. We are also obligated to indemnify FUJIFILM for liabilities that may exist relating to certain business activities incurred prior to the closing of the proposed transaction.

We determined that the operations to be disposed of in the proposed transaction did not meet the criteria to be classified as discontinued operations under the applicable guidance.

In February 2019 the assets and liabilities related to our Hillerød, Denmark manufacturing operations met the criteria to be classified as held for sale and were reclassified as assets held for sale and liabilities held for sale, respectively, in our condensed consolidated balance sheets.

In the first quarter of 2019 we recorded a loss of approximately \$174.6 million in our condensed consolidated statements of income. This estimated loss includes a pre-tax loss of \$115.5 million reflecting our current estimated fair value of the assets and liabilities held for sale, adjusting for our expected costs to sell our Hillerød, Denmark manufacturing operations of approximately \$10.0 million and our estimate of the fair value of an adverse commitment of approximately \$120.0 million associated with the guarantee of future minimum batch production at the Hillerød facility. The value of this adverse commitment was determined using a probability-weighted estimate of future manufacturing activity. In addition, we recorded a tax expense of \$59.1 million related to the proposed transaction. Our total estimated loss is based on current exchange rates and business conditions, and any changes to these factors through the closing date of the transaction will result in adjustments to the carrying values of the related assets and liabilities as well as a corresponding adjustment to the loss amount recognized on the sale.

Following the closing of the proposed transaction, the final purchase price will be adjusted by an amount equal to the difference between our current estimates of working capital and inventory balances that will be transferred to FUJIFILM and the amounts that are ultimately transferred.

The proposed transaction remains subject to customary closing conditions, including filings and clearances under the Danish Competition Act. We expect to complete the proposed transaction in the second half of 2019.

E 2017 corporate strategy implementation and restructuring charges are related to our efforts to create a leaner and simpler operating model.

FAmortization included in Equity in loss of investee, net of tax represents the amortization of the differences between the fair value of our investment in Samsung Bioepis Co., Ltd. (Samsung Bioepis) and the carrying value of our interest in the underlying net assets of the investee. These basis differences are amortized over their economic life.

<sup>G</sup> Elimination of deferred tax asset due to Samsung Bioepis qualifying as a corporate joint venture for accounting purposes.

<sup>H</sup> The Tax Cuts and Jobs Act of 2017 (2017 Tax Act) resulted in significant changes to the U.S. corporate income tax system. These changes include a federal statutory rate reduction from 35% to 21%, the elimination or reduction of certain domestic deductions and credits and limitations on the deductibility of interest expense and executive compensation. The 2017 Tax Act also transitions international taxation from a worldwide system to a modified territorial system and includes base erosion prevention measures on non-U.S. earnings, which has the effect of subjecting certain earnings of our foreign subsidiaries to U.S. taxation as global intangible low-taxed income (GILTI). During the fourth quarter of 2018 we elected to recognize deferred taxes for the basis differences expected to reverse as GILTI is incurred and have established initial deferred tax balances, as of the enactment date of the 2017 Tax Act.

During the fourth quarter of 2017 we recognized within our provision for income taxes a \$1.2 billion provisional estimate pursuant to the U.S. Securities and Exchange Commission Staff Accounting Bulletin No. 118. Our provisional estimate included an amount of \$989.6 million associated with a one-time mandatory deemed repatriation tax on accumulated foreign subsidiaries' previously untaxed foreign earnings (the Transition Toll Tax) and \$184.0 million related to the impact of remeasuring our deferred tax balances to reflect the new federal statutory rate and other changes to U.S. tax law.

Tax reform amounts for the three months ended December 31, 2018, reflects the effect of an expense of \$135.8 million related to the establishment of GILTI deferred taxes.

The final determination of the Transition Toll Tax and remeasurement of our deferred assets and liabilities was completed in the fourth quarter of 2018.

