# PFIZER REPORTS THIRD-QUARTER 2018 RESULTS Tuesday, October 30, 2018 10:45:00 AM (GMT)

- Third-Quarter 2018 Revenues of \$13.3 Billion, Reflecting 2% Operational Growth
- Third-Quarter 2018 Reported Diluted EPS<sup>(1)</sup> of \$0.69, Adjusted Diluted EPS<sup>(2)</sup> of \$0.78
- Narrowed Certain 2018 Financial Guidance Ranges; Midpoint of Updated Adjusted Diluted EPS<sup>(2)</sup> Guidance Range of \$2.98 to \$3.02 is Unchanged from July 2018
- Repurchased \$1.1 Billion of Common Stock in Third-Quarter 2018 and \$9.0 Billion to Date in 2018; Now Expect to Repurchase Approximately \$12 Billion of Shares in 2018

Pfizer Inc. (NYSE:PFE) reported financial results for third-quarter 2018 and narrowed certain 2018 financial guidance ranges.

Results for the third quarter and first nine months of 2018 and 2017<sup>(3)</sup> are summarized below.

#### **OVERALL RESULTS**

O VERWIEL RESOLUTE										
(\$ in millions, except										
per share amounts)	Th	ird-Quarte	er	Nine Months						
	2018	2017	Change	2018	2017	Change				
Revenues	\$ 13,298	\$ 13,168	1%	\$ 39,670	\$ 38,843	2%				
Reported Net Income <sup>(1)</sup>	4,114	2,840	45%	11,546	9,034	28%				
Reported Diluted EPS <sup>(1)</sup>	0.69	0.47	46%	1.92	1.49	29%				
Adjusted Income <sup>(2)</sup>	4,661	4,059	15%	14,156	12,313	15%				
Adjusted Diluted EPS <sup>(2)</sup>	0.78	0.67	16%	2.36	2.03	16%				

#### REVENUES

(\$ in millions)			Т	hird-Qua	arter		Nine Months						
	2018		8 2017		% Change			2018		2017	% Ch	nange	
		2016		2017	Total	Oper.		2010		2017	Total	Oper.	
Innovative Health	\$	8,471	\$	8,118	4%	5%	\$	24,573	\$	23,204	6%	4%	
Essential Health		4,826		5,050	(4%)	(4%)		15,097		15,639	(3%)	(6%)	
<b>Total Company</b>	\$	13,298	\$	13,168	1%	2%	\$	39,670	\$	38,843	2%		
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On February 3, 2017, Pfizer completed the sale of its global infusion therapy net assets, Hospira Infusion Systems (HIS). Therefore, financial results for the first nine months of 2018 do not reflect any contribution from legacy HIS operations, while the first nine months of 2017 reflect approximately one month of legacy HIS domestic operations and approximately two months of legacy HIS international operations<sup>(3)</sup>.

Some amounts in this press release may not add due to rounding. All percentages have been calculated using unrounded amounts. References to operational variances pertain to period-over-period growth rates that exclude the impact of foreign exchange<sup>(4)</sup>.

## 2018 FINANCIAL GUIDANCE<sup>(5)</sup>

Pfizer's updated 2018 financial guidance is presented below.

The guidance range for Revenues was narrowed from a range of \$53.0 to \$55.0 billion to a range of \$53.0 to \$53.7 billion, primarily reflecting:

- lower-than-anticipated Essential Health revenues, primarily due to continued legacy Hospira Sterile Injectable Pharmaceuticals (SIP) product shortages in the U.S.; and
- recent unfavorable changes in foreign exchange rates in relation to the U.S. dollar from mid-July 2018 to mid-October 2018, primarily the weakening of certain emerging markets currencies and the euro.

Revenues	\$53.0 to \$53.7 billion						
Revenues	(previously \$53.0 to \$55.0 billion)						
	20.8% to 21.3%						
Adjusted Cost of Sales <sup>(2)</sup> as a Percentage of Revenues	(previously 20.5% to 21.5%)						
Additional Cload Francisco (2)	\$14.0 to \$14.5 billion						
Adjusted SI&A Expenses <sup>(2)</sup>	(previously \$14.0 to \$15.0 billion)						
Adjusted R&D Expenses <sup>(2)</sup>	\$7.7 to \$8.1 billion						
Adicated Other (Incorporation (2)	Approximately \$1.3 billion of income						
Adjusted Other (Income)/Deductions <sup>(2)</sup>	(previously approximately \$1.0 billion of income)						
Effective Tax Rate on Adjusted Income <sup>(2),(6)</sup>	Approximately 16.0%						
Adiabated Bilitard EDG(2)	\$2.98 to \$3.02						
Adjusted Diluted EPS <sup>(2)</sup>	(previously \$2.95 to \$3.05)						

Financial guidance for Adjusted diluted EPS<sup>(2)</sup> reflects anticipated share repurchases totaling approximately \$12 billion in 2018, including \$9.0 billion of share repurchases already completed to date in 2018. Dilution related to share-based employee compensation programs is expected to offset the reduction in shares associated with these share repurchases by approximately half.

#### CAPITAL ALLOCATION

- During the first nine months of 2018, Pfizer returned \$13.2 billion directly to shareholders, through a combination of:
  - \$6.0 billion of dividends, composed of \$0.34 per share of common stock in each of the first, second and third quarters of 2018; and
  - \$7.2 billion of share repurchases, composed of \$3.2 billion of open-market share repurchases and a \$4.0 billion accelerated share repurchase agreement executed in March 2018 and completed in September 2018.
- As of October 30, 2018, Pfizer's remaining share repurchase authorization was \$7.4 billion.

#### **EXECUTIVE COMMENTARY**

Ian Read, Chairman and Chief Executive Officer, stated, "We reported solid third-quarter 2018 financial results, with total company revenues up 2% operationally, driven by the continued growth of key brands such as Eliquis, Ibrance, Prevnar 13, Xeljanz and Xtandi, as well as biosimilars and emerging markets. The performance of these growth drivers was partially offset by product losses of exclusivity, a decline in Legacy Established Products in developed markets and ongoing legacy Hospira sterile injectable supply shortages.

"We believe we are well-positioned to develop and commercialize differentiated new medicines, creating sustainable value for shareholders and patients. Our new organizational structure allows us to focus on maximizing the opportunity of our in-market products, advancing key pipeline programs and accelerating growth in emerging markets.

"Earlier this month, we announced that Albert Bourla will succeed me as CEO starting in January 2019. Albert's extensive knowledge of our business, firm grasp of the issues, and deep caring for patients will help Pfizer continue to build on the outstanding foundation we have put in place. I am confident that he is implementing a structure and building a leadership team that will maximize the company's growth opportunities," Mr. Read concluded.

Frank D'Amelio, Executive Vice President, Business Operations and Chief Financial Officer, stated, "I am pleased with our results over the first nine months of 2018, which keep us on track to deliver a solid

financial performance this year. We updated our 2018 financial guidance to reflect our performance to date as well as our outlook for the remainder of the year. Importantly, the midpoint of our guidance range for Adjusted diluted EPS<sup>(2)</sup>, which implies 13% growth compared to last year, is unchanged from our July 2018 guidance update. Additionally, to date in 2018, we returned \$15.0 billion directly to shareholders through dividends and share repurchases, demonstrating our continued commitment to returning capital to our shareholders."

# QUARTERLY FINANCIAL HIGHLIGHTS (Third-Quarter 2018 vs. Third-Quarter 2017)

Third-quarter 2018 revenues totaled \$13.3 billion, an increase of \$130 million, or 1%, compared to the prior-year quarter, reflecting operational growth of \$243 million, or 2%, partially offset by the unfavorable impact of foreign exchange of \$113 million, or 1%.

#### Innovative Health (IH) Highlights

- IH revenues increased 5% operationally, primarily driven by continued growth from key brands including:
  - Eliquis globally, up 36% operationally, primarily driven by continued increased adoption in non-valvular atrial fibrillation as well as oral anti-coagulant market share gains:
  - Ibrance outside the U.S., up 98% operationally, primarily driven by continued uptake in developed Europe and the December 2017 launch in Japan;
  - Prevnar 13 in the U.S., up 12%, primarily due to higher government purchases for the pediatric indication;
  - Xeljanz globally, up 26% operationally, primarily driven by continued uptake in the rheumatoid arthritis indication; and
  - Xtandi in the U.S., up 20%, primarily due to continued uptake in the metastatic castrateresistant prostate cancer (CRPC) indication,

## partially offset primarily by:

- the loss of exclusivity of Viagra in the U.S. in December 2017 and the resulting shift in the reporting of Viagra revenues in the U.S. and Canada to the Essential Health business at the beginning of 2018<sup>(3)</sup>; and
- lower revenues for Enbrel in most developed Europe markets primarily due to continued biosimilar competition.

#### **Essential Health (EH) Highlights**

- EH revenues declined 4% operationally, negatively impacted primarily by:
  - a 14% operational decline in the Legacy Established Products (LEP) portfolio in developed markets, primarily driven by industry-wide pricing challenges in the U.S. and generic competition;
  - a 17% operational decline in the Peri-LOE Products portfolio in developed markets, primarily due to expected declines in Lyrica in developed Europe, partially offset by the addition of Viagra revenues from the U.S. and Canada that were previously recorded in the IH business; and
  - a 9% operational decline in the SIP portfolio in developed markets, primarily due to continued legacy Hospira product shortages in the U.S.,

# partially offset primarily by:

- 11% operational growth in emerging markets, primarily reflecting growth across the LEP and SIP portfolios in China; and
- 46% operational growth from Biosimilars in developed markets, primarily from Inflectra in certain channels in the U.S. as well as in developed Europe.

# GAAP Reported<sup>(1)</sup> Income Statement Highlights

## SELECTED TOTAL COMPANY REPORTED COSTS AND EXPENSES (1)

(\$ in millions)											
(Favorable)/Unfavorable		Т	hird-Qua	ter			ne Months	Months			
	2018		2017	% Cł	nange	2018		2017	% Change		
	2016		2017	Total	Oper.	 2010		2017	Total	Oper.	
Cost of Sales <sup>(1)</sup>	\$ 2,694	\$	2,844	(5%)	2%	\$ 8,173	\$	7,972	3%	1%	
Percent of Revenues	20.3	%	21.6%	N/A	N/A	20.6%	1	20.5%	N/A	N/A	
SI&A Expenses <sup>(1)</sup>	3,494		3,504	_	_	10,448		10,249	2%	_	
R&D Expenses <sup>(1)</sup>	2,008		1,865	8%	8%	5,549		5,367	3%	3%	
Total	\$ 8,197	\$	8,213	_	3%	\$ 24,170	\$	23,588	2%	1%	
Other (Income)/Deductions—net <sup>(1)</sup>	(\$414	) \$	5 79	*	*	(\$1,143)	\$	65	*	*	
Effective Tax Rate on Reported Income <sup>(1),(6)</sup>	1.6	%	20.3%			9.9%	١	20.1%			

<sup>\*</sup> Indicates calculation not meaningful or result is equal to or greater than 100%.

Pfizer recorded other income— $net^{(1)}$  in third-quarter 2018 compared with other deductions— $net^{(1)}$  in the prior-year quarter, primarily due to:

- a non-cash gain associated with a transaction with Bain Capital Private Equity and Bain Capital Life Sciences to create a new biopharmaceutical company, Cerevel Therapeutics, LLC, to continue development of a portfolio of clinical and preclinical stage neuroscience assets primarily targeting disorders of the central nervous system;
- lower charges for certain legal matters; and
- lower asset impairment charges.

Pfizer's effective tax rate on Reported income<sup>(1)</sup> for third-quarter 2018 was favorably impacted by:

- the adoption of a territorial tax system and the lower U.S. tax rate as a result of the December 2017 enactment of the TCJA<sup>(6)</sup>, as well as favorable adjustments to the provisional estimate of the legislation;
- the favorable change in the jurisdictional mix of earnings as a result of operating fluctuations in the normal course of business; and
- an increase in benefits associated with the resolution of certain tax positions pertaining to prior years primarily with various foreign tax authorities, and the expiration of certain statutes of limitations.

# Adjusted<sup>(2)</sup> Income Statement Highlights

# SELECTED TOTAL COMPANY ADJUSTED COSTS AND EXPENSES (2)

(\$ in millions)													
(Favorable)/Unfavorable			Т	hird-Qua	rter			Nine Months					
		2010		2017	% Cl	Change		2018		2017	% C	hange	
		2018		2017	Total	Oper.		2018		2017	Total	Oper.	
Adjusted Cost of Sales <sup>(2)</sup>	\$	2,673	\$	2,696	(1%)	7%	\$	8,086	\$	7,720	5%	3%	
Percent of Revenues		20.1%		20.5%	N/A	N/A		20.4%		19.9%	N/A	N/A	
Adjusted SI&A Expenses <sup>(2)</sup>		3,471		3,482	_			10,264		10,167	1%	(1%)	
Adjusted R&D Expenses <sup>(2)</sup>		1,998		1,857	8%	8%		5,526		5,348	3%	3%	
Total	\$	8,143	\$	8,036	1%	4%	\$	23,876	\$	23,235	3%	1%	
Adjusted Other (Income)/Deductions—net <sup>(2)</sup>		(\$302)		(\$268)	13%	34%		(\$1,143)		(\$547)	*	*	
Effective Tax Rate on Adjusted Income <sup>(2),(6)</sup>		13.3%		23.7%				15.2%		22.9%			

\* Indicates calculation not meaningful or result is equal to or greater than 100%.

Pfizer's effective tax rate on Adjusted income<sup>(2)</sup> for third-quarter 2018 was favorably impacted by the aforementioned December 2017 enactment of the TCJA<sup>(6)</sup>.

Third-quarter 2018 diluted weighted-average shares outstanding used to calculate Reported<sup>(1)</sup> and Adjusted<sup>(2)</sup> diluted EPS declined by 54 million shares compared to the prior-year quarter primarily due to Pfizer's ongoing share repurchase program, reflecting the impact of share repurchases during 2018, partially offset by dilution related to share-based employee compensation programs.

A full reconciliation of Reported<sup>(1)</sup> to Adjusted<sup>(2)</sup> financial measures and associated footnotes can be found starting on page 22 of the press release located at the hyperlink below.

# RECENT NOTABLE DEVELOPMENTS (Since July 31, 2018)

# **Product Developments**

- Ibrance (palbociclib) -- In October 2018, Pfizer announced detailed overall survival (OS) data from the PALOMA-3 trial, which evaluated Ibrance in combination with fulvestrant compared to placebo plus fulvestrant in women with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) metastatic breast cancer whose disease progressed on or after prior endocrine therapy. In the study, there was a numerical improvement in OS of nearly seven months with Ibrance plus fulvestrant compared to placebo plus fulvestrant (median OS: 34.9 months [95% CI: 28.8, 40.0] versus 28.0 months [95% CI: 23.6, 34.6]), although this difference did not reach the prespecified threshold for statistical significance (HR=0.814; 95% CI: 0.644, 1.029; 1-sided p=0.0429). These data were presented as a late-breaking oral abstract during the Presidential Symposium at the 2018 Congress of the European Society for Medical Oncology and simultaneously published in The New England Journal of Medicine (NEJM). The difference in OS demonstrated in this analysis (6.9 months) is consistent with the improvement previously demonstrated for the primary endpoint of progression-free survival (PFS) in PALOMA-3. In the updated, non-pre-specified PFS analysis. the combination of Ibrance plus fulvestrant showed a statistically significant and clinically meaningful 6.6month PFS improvement compared to placebo plus fulvestrant (11.2 vs. 4.6 months; HR=0.50 [95% CI, 0.40-0.62]; P<0.0001).
- Lyrica (pregabalin) -- In August 2018, Pfizer completed its submission to the U.S. Food and Drug Administration (FDA) seeking pediatric exclusivity for Lyrica. Pfizer anticipates a decision from the FDA by December 30, 2018, the current anticipated loss of market exclusivity date. If granted, pediatric exclusivity would extend the period of U.S. market exclusivity for Lyrica by an additional six months, to June 30, 2019.
- Talzenna (talazoparib) -- In October 2018, Pfizer announced that the FDA approved Talzenna, a once-daily, oral poly ADP ribose polymerase inhibitor for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated, HER2- locally advanced or metastatic breast cancer. Patients are selected for therapy based on an FDA-approved companion diagnostic.
- Vizimpro (dacomitinib) -- In September 2018, Pfizer announced that the FDA approved Vizimpro, a kinase inhibitor for the first-line treatment of patients with metastatic non-small cell lung cancer with epidermal growth factor receptor exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test.

## • Vyndagel (tafamidis)

• In September 2018, Pfizer announced that additional sensitivity and post-hoc analyses from the Phase 3 Transthyretin Amyloid Cardiomyopathy (ATTR-ACT) study provide further detail on the effect of tafamidis across wild-type, hereditary, and New York Heart Association (NYHA) class sub-groups of patients with transthyretin amyloid cardiomyopathy (ATTR-CM). Tafamidis reduced the risk of all-cause mortality across all sub-groups (wild-type, hereditary and NYHA I, II and III functional class) versus placebo. This included a 29% and 31% reduction in the risk of death observed in wild-type (HR 0.71; 95% CI [0.474, 1.052]) and hereditary (HR 0.69; 95% CI [0.408,1.167]) sub-groups, respectively. The findings were presented during the Heart Failure Society of America Annual Scientific Meeting.

- In August 2018, Pfizer announced the primary results from the ATTR-ACT study, which showed tafamidis significantly reduced the hierarchical combination of both all-cause mortality and frequency of cardiovascular-related hospitalizations compared to placebo over a 30-month period (P=0.0006) in patients with wild-type or variant (hereditary) ATTR-CM. The ATTR-ACT study showed tafamidis significantly reduced all-cause mortality (29.5% vs. 42.9%; hazard ratio = 0.70, 95% confidence interval [CI] 0.51-0.96, P=0.0259) and cardiovascular-related hospitalizations (0.48 vs 0.70 annualized rate; relative risk ratio = 0.68, 95% CI 0.56-0.81, P<0.0001), compared to placebo. This represents a 30% reduction in the risk of mortality and 32% reduction in the rate of cardiovascular-related hospitalization. The late-breaking findings were presented during the European Society of Cardiology Congress 2018 and simultaneously published online in NEJM. The NEJM manuscript, titled "Tafamidis Treatment for Patients with Transthyretin Amyloid Cardiomyopathy," was also published in the September 13 printed issue of NEJM.</p>
- Xeljanz (tofacitinib) -- In August 2018, Pfizer announced that the European Commission (EC) approved Xeljanz 10 mg twice-daily (BID) for at least eight weeks, followed by Xeljanz 5 mg BID or 10 mg BID, for the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic agent. Xeljanz is the first and only oral therapy and Janus kinase (JAK) inhibitor to be approved for this patient population. In approving Xeljanz for UC, the European Medicines Agency's Committee for Human Medicinal Products has, as part of its assessment, determined Xeljanz to be of significant clinical benefit for patients with UC in comparison with existing therapies.

## • Xtandi (enzalutamide)

- In October 2018, the EC approved Xtandi for the treatment of adult men with high-risk nonmetastatic CRPC. Xtandi was previously approved by the EC for the treatment of adult men with metastatic CRPC.
- In August 2018, Pfizer and Astellas announced amendments to the protocols for two registrational Phase 3 trials, ARCHES and EMBARK, designed to evaluate the safety and efficacy of Xtandi in men with hormone-sensitive prostate cancer. These amendments accelerate timelines for the anticipated primary completion dates of both trials. Changes to the ARCHES protocol include revision of the planned analyses of the primary and secondary endpoints. Enrollment was completed earlier this year. The companies now anticipate the primary completion date for the ARCHES clinical trial to be in late 2018. The previously expected primary completion date was April 2020. The main purpose of the amendment to the EMBARK protocol is to revise the planned analyses of the primary and several secondary endpoints, which reduced the target sample size. Enrollment was completed earlier this year. With these changes, the estimated primary completion date for the EMBARK clinical trial is mid-2020. Previously, the expected primary completion date for EMBARK was March 2021.

#### **Pipeline Developments**

A comprehensive update of Pfizer's development pipeline was published today and is now available at <a href="https://www.pfizer.com/science/drug-product-pipeline">www.pfizer.com/science/drug-product-pipeline</a>. It includes an overview of Pfizer's research and a list of compounds in development with targeted indication and phase of development, as well as mechanism of action for some candidates in Phase 1 and all candidates from Phase 2 through registration.

• Domagrozumab (PF-06252616) -- In August 2018, Pfizer announced that it is terminating two ongoing clinical studies evaluating domagrozumab for the treatment of Duchenne muscular dystrophy (DMD): a Phase 2 safety and efficacy study (B5161002) and an open-label extension study (B5161004). The Phase 2 study (B5161002) did not meet its primary efficacy endpoint, which was to demonstrate a difference in the mean change from baseline in 4 Stair Climb (in seconds) following one year of treatment with domagrozumab as compared to placebo in patients with DMD. Further evaluation of the totality of evidence including secondary endpoints did not support a significant treatment effect. The decision comes after a thorough review of data available at the time of the primary analysis, which evaluated all study participants after one year of treatment, as well as those participants who were in the trial beyond one year. The studies were not terminated for safety reasons. Pfizer will continue to review the data to better understand any insights they may provide, and will share results with the scientific and patient community.

- **PF-05280014 (proposed biosimilar trastuzumab)** -- In October 2018, the FDA acknowledged for review a Biologics License Application (BLA) resubmission for PF-05280014, a proposed biosimilar to Herceptin<sup>(7)</sup>. This resubmission addressed information requested by the FDA in an April 2018 Complete Response Letter. The expected Biosimilar User Fee Act (BsUFA) goal date for a decision by the FDA is in first-quarter 2019. In July 2018, Pfizer announced that the EC approved Trazimera, the brand name for PF-05280014 in Europe.
- **PF-05280586 (proposed biosimilar rituximab)** -- In September 2018, the FDA accepted for review a BLA for PF-05280586, a proposed biosimilar to Rituxan/MabThera<sup>(8)</sup>. The BsUFA goal date for a decision by the FDA is in third-quarter 2019.
- **PF-06439535 (proposed biosimilar bevacizumab)** -- In August 2018, the FDA accepted for review a BLA for PF-06439535, a proposed biosimilar to Avastin<sup>(9)</sup>. The BsUFA goal date for a decision by the FDA is in second-quarter 2019.
- **PF-06482077** -- In September 2018, Pfizer announced that its 20-Valent Pneumococcal Conjugate Vaccine (20vPnC) candidate, PF-06482077, received Breakthrough Therapy designation from the FDA for the prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae* serotypes in the vaccine in adults aged 18 years and older. Pfizer expects to start Phase 3 trials in a few months.

#### • PF-06651600

- In September 2018, Pfizer announced results from its Phase 2a study of PF-06651600, an oral JAK3 inhibitor, and PF-06700841, a tyrosine kinase (TYK) 2/JAK1 inhibitor, compared to placebo, in patients with moderate to severe alopecia areata (AA), an autoimmune disease characterized by hair loss and often associated with profound psychological consequences. Both JAK inhibitors met the primary efficacy endpoint in improving hair regrowth on the scalp relative to baseline at week 24 (33.6 points and 49.5 points for JAK3 and TYK2/JAK1, respectively) as measured by the Severity of Alopecia Tool score (100 point scale). The findings were presented during a Late-Breaking News session at the European Academy of Dermatology and Venereology Congress. Based on the totality of the data and the emerging clinical profiles, Pfizer decided to advance PF-06651600 to the next phase of development for moderate to severe AA and will continue to be evaluated for rheumatoid arthritis, Crohn's disease (CD) and UC. PF-06700841 will continue to be evaluated for psoriasis, CD and UC.
- In September 2018, Pfizer announced PF-06651600 received Breakthrough Therapy designation from the FDA for the treatment of patients with AA.
- Tanezumab (PF-4383119, RN624) -- In October 2018, Pfizer and Eli Lilly and Company (Lilly) presented results from a Phase 3 study evaluating the efficacy and safety of subcutaneous administration of tanezumab, an investigational humanized monoclonal antibody, in patients with osteoarthritis (OA) pain treated for 16 weeks. The study met all three co-primary efficacy endpoints, demonstrating that among patients with moderate-to-severe OA pain of the knee or hip, both dosing regimens of tanezumab were associated with a statistically significant improvement in pain, physical function and patient's global assessment of their OA, compared to placebo.

The Phase 3 OA study evaluated changes from baseline to 16 weeks for three co-primary efficacy endpoints of pain intensity and physical function, assessed using the Western Ontario and McMaster Universities Osteoarthritis Index subscale and patient's overall assessment of their OA. At 16 weeks of treatment, patients receiving tanezumab reported significantly greater pain relief compared to those taking placebo, with more than half of patients reporting a reduction in their pain of 50% or more, and approximately 35% reporting a 70% or greater improvement.

Tanezumab was generally well tolerated, with 0.4% and 1.3% of patients in the tanezumab 2.5 mg and 2.5/5 mg arms, respectively, discontinuing treatment due to adverse events (AEs); 1.3% of patients in the placebo arm discontinued treatment due to AEs. No cases of osteonecrosis were observed in the study. Rapidly progressive osteoarthritis (RPOA) was observed with tanezumab-treated patients at a frequency of 1.3% and was not observed in the placebo arm. The incidence of RPOA Type 1 (accelerated joint space narrowing) in the tanezumab 2.5 mg and 2.5/5 mg arms was 1.3% and 0.4%, respectively, and the incidence of RPOA Type 2 (damage or deterioration of the joint) was 0.9% and 0%, respectively. In the study, 3.5% and 6.9% of patients receiving tanezumab 2.5 mg

and 2.5/5 mg, respectively, had total joint replacement surgery, compared to 1.7% receiving placebo. The majority of surgeries (68%) took place after treatment was completed, during or shortly after the 24-week safety follow up period of the study. All surgeries in this study took place among patients with more severe OA at screening (Kellgren-Lawrence grade 3-4). These data were presented during a late-breaking oral session at the 2018 American College of Rheumatology Annual Meeting.

## **Corporate Developments**

- In October 2018, Pfizer announced that it entered into a non-exclusive clinical development agreement with Novartis to investigate one or more combination therapies for the treatment of non-alcoholic steatohepatitis (NASH). The companies will conduct both non-clinical and Phase 1 clinical studies of Pfizer's investigational therapies, including an Acetyl CoA-Carboxylase inhibitor (PF-05221304, currently in Phase 2), a Diacylglycerol O-Acyltransferase 2 inhibitor (PF-06865571, Phase 1) and a Ketohexokinase inhibitor (PF-06835919, Phase 2), together with Novartis's tropifexor, a non-bile acid, Farnesoid X receptor agonist. With three assets in development and several first-in-class pre-clinical candidates under investigation, Pfizer is building a robust NASH program, which was entirely developed in-house and targets NASH through multiple, diverse pathways of the disease. The collaboration with Novartis helps Pfizer to explore combination approaches at an early stage.
- In October 2018, Bain Capital, LP and Pfizer announced the creation of Cerevel Therapeutics, LLC (Cerevel), a new biopharmaceutical company focused on developing drug candidates to treat disorders of the central nervous system (CNS). Pfizer is contributing a portfolio of pre-commercial neuroscience assets to Cerevel, which include three clinical-stage compounds and several pre-clinical compounds designed to target a broad range of CNS disorders including Parkinson's, Alzheimer's, epilepsy, schizophrenia and addiction. Funds affiliated with Bain Capital Private Equity and Bain Capital Life Sciences have committed \$350 million with the ability to provide additional capital should it be needed in the future. Bain Capital and Pfizer will support Cerevel in building a dedicated team of CNS scientists and life sciences executives with extensive experience in clinical development of potential therapies for patients who have neurological and neuropsychological diseases. The most advanced assets in the portfolio are a D1 partial agonist which will likely enter Phase 3 in 2019 to treat the symptoms of Parkinson's disease, and a Phase 2 ready selective GABA 2/3 agonist which will initially be studied for epilepsy. The company also has active programs in early development, discovery and a research program in neuroinflammation. Pfizer felt that placing this set of neuroscience assets, after its decision to curtail research within the area, in a company with dedicated focus and expertise in CNS was the optimal next step. Pfizer will retain a 25% equity position in Cerevel. Two senior Pfizer executives, Morris Birnbaum, MD, PhD, Senior Vice President, Chief Scientific Officer of Internal Medicine, and Doug Giordano, Senior Vice President of Worldwide Business Development will serve on the Cerevel Board of Directors, along with Adam Koppel and Chris Gordon, Managing Directors of Bain Capital. The company will be based in the Greater Boston area.
- In October 2018, Pfizer announced its Board of Directors unanimously elected Dr. Albert Bourla, Pfizer Chief Operating Officer, to succeed Ian Read as CEO effective January 1, 2019. Ian Read will transition from his current role as Chairman and CEO to Executive Chairman of Pfizer's Board of Directors.

The executive team that will report to Dr. Bourla, coincident with the commencement of his new role, will be as follows:

- Frank D'Amelio Chief Financial Officer and Executive Vice President, Global Supply and Business Operations, will also assume the leadership for our manufacturing operations, Pfizer Global Supply.
- Mikael Dolsten Global President, Worldwide Research and Development and Medical, will also assume oversight of the Chief Medical Officer's role.
- Michael Goettler Global President, Established Medicines. As previously announced, Michael will lead the Established Medicines business that will operate as an autonomous, stand-alone unit within Pfizer.
- Angela Hwang Group President, Pfizer Innovative Medicines, will become the Group President of Pfizer's science-based Innovative business responsible for the entire portfolio of innovative medicines.

- Rady Johnson Executive Vice President, Chief Compliance, Quality and Risk Officer, will continue in his role as the company's Chief Compliance Officer.
- Doug Lankler Executive Vice President, General Counsel, will continue in his role as the company's General Counsel.
- Freda Lewis-Hall Executive Vice President, Chief Patient Officer, will assume a new role as Pfizer's Chief Patient Officer, deploying the resources of the company to advocate on behalf of all patients who rely on Pfizer to deliver new therapies and vaccines.
- Rod MacKenzie Executive Vice President, Chief Development Officer, will expand his
  responsibilities to include Pfizer's regulatory affairs function in addition to all late stage
  development activities.
- Dawn Rogers Executive Vice President, Chief Human Resources Officer, will continue to lead the Human Resources team.
- Sally Susman Executive Vice President, Chief Corporate Affairs Officer, will continue to lead the Corporate Affairs function.
- John Young Group President, Chief Business Officer, will assume a new role, responsible for strategy, business development, portfolio management and valuation activities; business analytics; global commercial operations; and Patient and Health Impact, among others.
   Pfizer's Consumer Healthcare business will also report to John.

Additionally, given the growing strategic importance of deploying digital technologies in research, discovery and business processes, Pfizer is appointing a Chief Digital Officer responsible for creating and implementing a strategy that accelerates and improves our digital capabilities so we can deliver more value to patients. Lidia Fonseca will join Pfizer's Executive Leadership Team in January 2019, as Executive Vice President, Chief Digital and Technology Officer.

Please find Pfizer's press release and associated financial tables, including reconciliations of certain GAAP reported to non-GAAP adjusted information, at the following hyperlink:

https://investors.pfizer.com/files/doc financials/Quarterly/2018/q3/Q3-2018-PFE-Earnings-Release.pdf

(Note: If clicking on the above link does not open up a new web page, you may need to cut and paste the above URL into your browser's address bar.)

For additional details, see the associated financial schedules and product revenue tables attached to the press release located at the hyperlink referred to above and the attached disclosure notice.

- 1. Revenues is defined as revenues in accordance with U.S. generally accepted accounting principles (GAAP). Reported net income is defined as net income attributable to Pfizer Inc. in accordance with U.S. GAAP. Reported diluted earnings per share (EPS) is defined as diluted EPS attributable to Pfizer Inc. common shareholders in accordance with U.S. GAAP.
- 2. Adjusted income and its components and Adjusted diluted EPS are defined as reported U.S. GAAP net income<sup>(1)</sup> and its components and reported diluted EPS<sup>(1)</sup> excluding purchase accounting adjustments, acquisition-related costs, discontinued operations and certain significant items (some of which may recur, such as restructuring or legal charges, but which management does not believe are reflective of ongoing core operations). Adjusted cost of sales, Adjusted selling, informational and administrative (SI&A) expenses, Adjusted research and development (R&D) expenses and Adjusted other (income)/deductions are income statement line items prepared on the same basis as, and therefore components of, the overall Adjusted income measure. As described in the *Financial Review—Non-GAAP Financial Measure (Adjusted Income)* section of Pfizer's 2017 Financial Report, which was filed as Exhibit 13 to Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2017, management uses Adjusted income, among other factors, to set performance goals and to measure the performance of the overall company. Because Adjusted income is an important internal measurement for Pfizer, management believes that investors' understanding of our performance is enhanced by disclosing this performance measure. Pfizer reports Adjusted income, certain components of Adjusted income, and Adjusted diluted EPS in order to portray the results of

the company's major operations—the discovery, development, manufacture, marketing and sale of prescription medicines, vaccines and consumer healthcare (OTC) products—prior to considering certain income statement elements. See the accompanying reconciliations of certain GAAP Reported to Non-GAAP Adjusted information for the third quarter and first nine months of 2018 and 2017. The Adjusted income and its components and Adjusted diluted EPS measures are not, and should not be viewed as, substitutes for U.S. GAAP net income and its components and diluted EPS.

- 3. Pfizer's fiscal year-end for international subsidiaries is November 30 while Pfizer's fiscal year-end for U.S. subsidiaries is December 31. Therefore, Pfizer's third quarter and first nine months for U.S. subsidiaries reflect the three and nine months ending on September 30, 2018 and October 1, 2017 while Pfizer's third quarter and first nine months for subsidiaries operating outside the U.S. reflect the three and nine months ending on August 26, 2018 and August 27, 2017.
- 4. References to operational variances in this press release pertain to period-over-period growth rates that exclude the impact of foreign exchange. The operational variances are determined by multiplying or dividing, as appropriate, the current period U.S. dollar results by the current period average foreign exchange rates and then multiplying or dividing, as appropriate, those amounts by the prior-year period average foreign exchange rates. Although exchange rate changes are part of Pfizer's business, they are not within Pfizer's control. Exchange rate changes, however, can mask positive or negative trends in the business; therefore, Pfizer believes presenting operational variances provides useful information in evaluating the results of its business.
- 5. The 2018 financial guidance reflects the following:
  - Pfizer does not provide guidance for GAAP Reported financial measures (other than revenues) or a reconciliation of forward-looking non-GAAP financial measures to the most directly comparable GAAP Reported financial measures on a forward-looking basis because it is unable to predict with reasonable certainty the ultimate outcome of pending litigation, unusual gains and losses, acquisition-related expenses and potential future asset impairments 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.
  - Does not assume the completion of any business development transactions not completed as of September 30, 2018, including any one-time upfront payments associated with such transactions.
  - Guidance for Adjusted other (income)/deductions<sup>(2)</sup> does not attempt to forecast unrealized net gains or losses on equity securities. Pfizer is unable to predict with reasonable certainty unrealized gains or losses on equity securities in a given period. Net unrealized gains and losses on equity securities are now recorded in Adjusted other (income)/deductions<sup>(2)</sup> during each quarter, reflecting the adoption of a new accounting standard in the first quarter of 2018. Prior to the adoption of the new standard, net unrealized gains and losses on virtually all equity securities with readily determinable fair values were reported in Accumulated other comprehensive income.
  - Exchange rates assumed are a blend of the actual exchange rates in effect through thirdquarter 2018 and mid-October 2018 exchange rates for the remainder of the year.
  - Reflects an anticipated negative revenue impact of \$1.8 billion due to recent and expected generic and biosimilar competition for certain products that have recently lost or are anticipated to soon lose patent protection. Assumes no generic competition for Lyrica in the U.S. until June 2019, which is contingent upon a six-month patent-term extension granted by the FDA for pediatric exclusivity, which the company is currently pursuing.
  - Reflects a full year contribution from Consumer Healthcare. Pfizer continues to expect that any decision regarding strategic alternatives for Consumer Healthcare will be made during 2018.
  - Reflects the anticipated favorable impact of approximately \$350 million on revenues and approximately \$0.02 on Adjusted diluted EPS<sup>(2)</sup> as a result of favorable changes in foreign exchange rates relative to the U.S. dollar compared to foreign exchange rates from 2017.
  - Guidance for Adjusted diluted EPS<sup>(2)</sup> assumes diluted weighted-average shares outstanding of

approximately 6.0 billion shares, which reflects anticipated share repurchases totaling approximately \$12 billion in 2018, including \$9.0 billion of share repurchases already completed to date in 2018. Dilution related to share-based employee compensation programs is expected to offset the reduction in shares associated with these share repurchases by approximately half.

- 6. Given the significant changes resulting from and complexities associated with the Tax Cuts and Jobs Act (TCJA), the estimated financial impacts associated with the TCJA that were recorded in fourth-quarter 2017 are provisional and subject to further analysis, interpretation and clarification of the TCJA, which could result in further changes to these estimates during the fourth quarter of 2018.
- 7. Herceptin<sup>®</sup> is a registered U.S. trademark of Genentech, Inc.
- 8. Rituximab is marketed in the U.S. under the brand name Rituxan<sup>®</sup> and marketed in the E.U. and other regions under the brand name MabThera<sup>®</sup>. Rituxan<sup>®</sup> is a registered trademark of Biogen MA Inc. MabThera<sup>®</sup> is a registered trademark of F. Hoffman-La Roche AG.
- 9. Avastin<sup>®</sup> is a registered U.S. trademark of Genentech, Inc.

DISCLOSURE NOTICE: Except where otherwise noted, the information contained in this earnings release and the related attachments is as of October 30, 2018. We assume no obligation to update any forward-looking statements contained in this earnings release and the related attachments as a result of new information or future events or developments.

This earnings release and the related attachments contain forward-looking statements about our anticipated future operating and financial performance, business plans and prospects, in-line products and product candidates, including anticipated regulatory submissions, data read-outs, study starts, approvals, performance, timing of exclusivity and potential benefits of Pfizer's products and product candidates, strategic reviews, capital allocation, business-development plans, the benefits expected from our plans to organize our commercial operations into three businesses effective at the beginning of the company's 2019 fiscal year, our acquisitions and other business development activities, our ability to successfully capitalize on growth opportunities, manufacturing and product supply and plans relating to share repurchases and dividends, among other things, that involve substantial risks and uncertainties. You can identify these statements by the fact that they use future dates or use words such as "will," "may," "could," "likely," "ongoing," "anticipate," "estimate," "expect," "project," "intend," "plan," "believe," "assume," "target," "forecast," "guidance," "goal," "objective," "aim" and other words and terms of similar meaning. Among the factors that could cause actual results to differ materially from past results and future plans and projected future results are the following:

- the outcome of research and development activities, including, without limitation, the ability to meet
  anticipated pre-clinical and clinical trial commencement and completion dates, regulatory submission
  and approval dates, and launch dates for product candidates, as well as the possibility of unfavorable
  pre-clinical and clinical trial results, including unfavorable new clinical data and additional analyses of
  existing clinical data;
- decisions by regulatory authorities regarding whether and when to approve our drug applications, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted; decisions by regulatory authorities regarding labeling, ingredients and other matters that could affect the availability or commercial potential of our products; uncertainties regarding our ability to address the comments received by us from regulatory authorities such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency with respect to certain of our drug applications to the satisfaction of those authorities; and recommendations by technical or advisory committees, such as the Advisory Committee on Immunization Practices, that may impact the use of our vaccines;
- the speed with which regulatory authorizations, pricing approvals and product launches may be achieved:
- the outcome of post-approval clinical trials, which could result in the loss of marketing approval for a product or changes in the labeling for, and/or increased or new concerns about the safety or efficacy of, a product that could affect its availability or commercial potential;

- risks associated with preliminary, early stage or interim data, including the risk that final results of studies for which preliminary, early stage or interim data have been provided and/or additional clinical trials may be different from (including less favorable than) the preliminary, early stage or interim data results and may not support further clinical development of the applicable product candidate or indication:
- the success of external business-development activities, including the ability to identify and execute
  on potential business development opportunities, the ability to satisfy the conditions to closing of
  announced transactions in the anticipated time frame or at all, the ability to realize the anticipated
  benefits of any such transactions, and the potential need to obtain additional equity or debt financing
  to pursue these opportunities which could result in increased leverage and impact our credit ratings;
- competitive developments, including the impact on our competitive position of new product entrants, in-line branded products, generic products, private label products, biosimilars and product candidates that treat diseases and conditions similar to those treated by our in-line drugs and drug candidates;
- the implementation by the FDA and regulatory authorities in certain other countries of an abbreviated legal pathway to approve biosimilar products, which could subject our biologic products to competition from biosimilar products, with attendant competitive pressures, after the expiration of any applicable exclusivity period and patent rights;
- risks related to our ability to develop and launch biosimilars, including risks associated with "at risk" launches, defined as the marketing of a product by Pfizer before the final resolution of litigation (including any appeals) brought by a third party alleging that such marketing would infringe one or more patents owned or controlled by the third party, and access challenges for our biosimilar products where our product may not receive appropriate formulary access or remains in a disadvantaged position relative to the innovator product;
- the ability to meet competition from generic, branded and biosimilar products after the loss or expiration of patent protection for our products or competitor products;
- the ability to successfully market both new and existing products domestically and internationally;
- difficulties or delays in manufacturing, including delays caused by natural events, such as hurricanes; supply shortages at our facilities; and legal or regulatory actions, such as warning letters, suspension of manufacturing, seizure of product, debarment, injunctions or voluntary recall of a product;
- trade buying patterns;
- the impact of existing and future legislation and regulatory provisions on product exclusivity;
- trends toward managed care and healthcare cost containment, and our ability to obtain or maintain timely or adequate pricing or formulary placement for our products;
- the impact of any significant spending reductions or cost controls affecting Medicare, Medicaid or other publicly funded or subsidized health programs or changes in the tax treatment of employersponsored health insurance that may be implemented;
- the impact of any U.S. healthcare reform or legislation, including any replacement, repeal, modification or invalidation of some or all of the provisions of the U.S. Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act;
- U.S. federal or state legislation or regulatory action and/or policy efforts affecting, among other things, pharmaceutical product pricing, reimbursement or access, including under Medicaid, Medicare and other publicly funded or subsidized health programs; patient out-of-pocket costs for medicines, manufacturer prices and/or price increases that could result in new mandatory rebates and discounts or other pricing restrictions; the importation of prescription drugs from outside the U.S. at prices that are regulated by governments of various foreign countries; restrictions on direct-to-consumer advertising; limitations on interactions with healthcare professionals; or the use of comparative effectiveness methodologies that could be implemented in a manner that focuses primarily on the cost differences and minimizes the therapeutic differences among pharmaceutical products and restricts access to innovative medicines; as well as pricing pressures for our products as a result of highly competitive insurance markets;

- legislation or regulatory action in markets outside the U.S. affecting pharmaceutical product pricing, reimbursement or access, including, in particular, continued government-mandated reductions in prices and access restrictions for certain biopharmaceutical products to control costs in those markets;
- the exposure of our operations outside the U.S. to possible capital and exchange controls, expropriation and other restrictive government actions, changes in intellectual property legal protections and remedies, as well as political unrest, unstable governments and legal systems and inter-governmental disputes;
- contingencies related to actual or alleged environmental contamination;
- claims and concerns that may arise regarding the safety or efficacy of in-line products and product candidates;
- any significant breakdown, infiltration or interruption of our information technology systems and infrastructure;
- legal defense costs, insurance expenses and settlement costs;
- the risk of an adverse decision or settlement and the adequacy of reserves related to legal proceedings, including patent litigation, such as claims that our patents are invalid and/or do not cover the product of the generic drug manufacturer or where one or more third parties seeks damages and/or injunctive relief to compensate for alleged infringement of its patents by our commercial or other activities, product liability and other product-related litigation, including personal injury, consumer, off-label promotion, securities, antitrust and breach of contract claims, commercial, environmental, government investigations, employment and other legal proceedings, including various means for resolving asbestos litigation, as well as tax issues;
- the risk that our currently pending or future patent applications may not result in issued patents, or be granted on a timely basis, or any patent-term extensions that we seek may not be granted on a timely basis, if at all:
- our ability to protect our patents and other intellectual property, both domestically and internationally;
- interest rate and foreign currency exchange rate fluctuations, including the impact of possible currency devaluations in countries experiencing high inflation rates;
- governmental laws and regulations affecting domestic and foreign operations, including, without limitation, tax obligations and changes affecting the tax treatment by the U.S. of income earned outside the U.S. that may result from pending and possible future proposals, including further clarifications and/or interpretations of the recently passed Tax Cuts and Jobs Act;
- any significant issues involving our largest wholesale distributors, which account for a substantial portion of our revenues;
- the possible impact of the increased presence of counterfeit medicines in the pharmaceutical supply chain on our revenues and on patient confidence in the integrity of our medicines;
- the end result of any negotiations between the U.K. government and the EU regarding the terms of the U.K.'s exit from the EU, which could have implications on our research, commercial and general business operations in the U.K. and the EU, including the approval and supply of our products;
- any significant issues that may arise related to the outsourcing of certain operational and staff functions to third parties, including with regard to quality, timeliness and compliance with applicable legal requirements and industry standards;
- any significant issues that may arise related to our joint ventures and other third-party business arrangements;
- changes in U.S. generally accepted accounting principles;
- further clarifications and/or changes in interpretations of existing laws and regulations, or changes in laws and regulations, in the U.S. and other countries;
- uncertainties related to general economic, political, business, industry, regulatory and market

conditions including, without limitation, uncertainties related to the impact on Pfizer, our customers, suppliers and lenders and counterparties to our foreign-exchange and interest-rate agreements of challenging global economic conditions and recent and possible future changes in global financial markets; the related risk that our allowance for doubtful accounts may not be adequate; and the risks related to volatility of our income due to changes in the market value of equity investments;

- any changes in business, political and economic conditions due to actual or threatened terrorist activity in the U.S. and other parts of the world, and related U.S. military action overseas;
- growth in costs and expenses;
- changes in our product, segment and geographic mix;
- the impact of purchase accounting adjustments, acquisition-related costs, discontinued operations and certain significant items;
- the impact of acquisitions, divestitures, restructurings, internal reorganizations, including our plans to
  organize our commercial operations into three businesses effective at the beginning of the company's
  2019 fiscal year, and cost-reduction and productivity initiatives, each of which requires upfront costs
  but may fail to yield anticipated benefits and may result in unexpected costs or organizational
  disruption;
- the impact of product recalls, withdrawals and other unusual items;
- the risk of an impairment charge related to our intangible assets, goodwill or equity-method investments;
- risks related to internal control over financial reporting;
- risks and uncertainties related to our acquisitions of Hospira, Inc. (Hospira), Anacor Pharmaceuticals, Inc. (Anacor), Medivation, Inc. (Medivation) and AstraZeneca's small molecule anti-infectives business, including, among other things, the ability to realize the anticipated benefits of those acquisitions, including the possibility that expected cost savings related to the acquisition of Hospira and accretion related to the acquisitions of Hospira, Anacor and Medivation will not be realized or will not be realized within the expected time frame; the risk that the businesses will not be integrated successfully; disruption from the transactions making it more difficult to maintain business and operational relationships; risks related to our ability to grow revenues for Xtandi; significant transaction costs; and unknown liabilities; and
- risks and uncertainties related to our evaluation of strategic alternatives for our Consumer Healthcare
  business, including, among other things, the ability to realize the anticipated benefits of any strategic
  alternatives we may pursue for our Consumer Healthcare business, the potential for disruption to our
  business and diversion of management's attention from other aspects of our business, the possibility
  that such strategic alternatives will not be completed on terms that are advantageous to Pfizer, the
  possibility that we may be unable to realize a higher value for Pfizer Consumer Healthcare through
  strategic alternatives, and unknown liabilities.

We cannot guarantee that any forward-looking statement will be realized. Achievement of anticipated results is subject to substantial risks, uncertainties and inaccurate assumptions. Should known or unknown risks or uncertainties materialize or should underlying assumptions prove inaccurate, actual results could vary materially from past results and those anticipated, estimated or projected. Investors should bear this in mind as they consider forward-looking statements, and are cautioned not to put undue reliance on forward-looking statements. A further list and description of risks, uncertainties and other matters can be found in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 and in our subsequent reports on Form 10-Q, in each case including in the sections thereof captioned "Forward-Looking Information and Factors That May Affect Future Results" and "Item 1A. Risk Factors", and in our subsequent reports on Form 8-K.

The operating segment information provided in this earnings release and the related attachments does not purport to represent the revenues, costs and income from continuing operations before provision for taxes on income that each of our operating segments would have recorded had each segment operated as a standalone company during the periods presented.

This earnings release may include discussion of certain clinical studies relating to various in-line products

and/or product candidates. These studies typically are part of a larger body of clinical data relating to such products or product candidates, and the discussion herein should be considered in the context of the larger body of data. In addition, clinical trial data are subject to differing interpretations, and, even when we view data as sufficient to support the safety and/or effectiveness of a product candidate or a new indication for an in-line product, regulatory authorities may not share our views and may require additional data or may deny approval altogether.

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