

# Organon

Q1 2022 Earnings





### Disclaimer statement

This text should be viewed in conjunction with Organon's Q1 2022 earnings call

#### Safe Harbor for Forward-Looking Statements

Except for historical information herein, this presentation includes "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, including, but not limited to, statements about management's expectations about Organon's future financial performance and prospects. Forward-looking statements may be identified by words such as "expects," "intends," "anticipates," "plans," "believes," "seeks," "estimates," "will" or words of similar meaning. These statements are based upon the current beliefs and expectations of the company's management and are subject to significant risks and uncertainties. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements. Risks and uncertainties include, but are not limited to, an inability to execute on our business development strategy or realize the benefits of our planned acquisitions; general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of the ongoing COVID-19 pandemic and emergence of variant strains; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances; new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company's ability to accurately predict its future financial results and performance; the company's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; difficulties developing and sustaining relationships with commercial counterparties; dependence on the effectiveness of the company's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions. The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company's filings with the Securities and Exchange Commission (SEC), including the company's Annual Report on Form 10-K for the year ended December 31, 2021 and subsequent periodic filings, available at the SEC's Internet site (www.sec.gov).



## Disclaimer statement, cont.

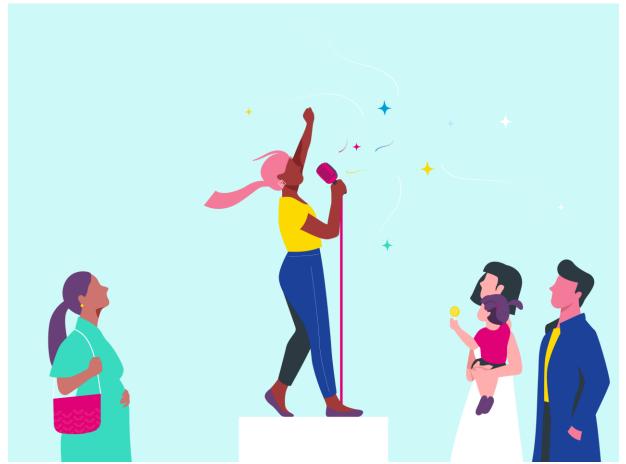
#### **Non-GAAP Information**

This presentation contains "non-GAAP financial measures," which are financial measures that either exclude or include amounts that are not excluded or included in the most directly comparable measures calculated and presented in accordance with U.S. generally accepted accounting principles ("GAAP"). Specifically, the company makes use of the non-GAAP financial measures Adjusted EBITDA, Adjusted Net Income, and Adjusted Diluted EPS, which are not recognized terms under GAAP and are presented only as a supplement to the company's GAAP financial statements. The company believes that these non-GAAP financial measures help to enhance an understanding of the company's financial performance. However, the presentation of these measures has limitations as an analytical tool and should not be considered in isolation, or as a substitute for the company's results as reported under GAAP. Because not all companies use identical calculations, the presentations of these non-GAAP measures may not be comparable to other similarly titled measures of other companies. You should refer to the appendix of this presentation relevant definitions and reconciliations of non-GAAP financial measures contained herein to the most directly comparable GAAP measures. In addition, the company's full-year 2022 guidance measures (other than revenue) are provided on a non-GAAP basis because the company is unable to reasonably predict certain items contained in the GAAP measures. Such items include, but are not limited to, acquisition related expenses, restructuring and related expenses, stock-based compensation and other items not reflective of the company's ongoing operations. The company uses non-GAAP financial measures in its operational and financial decision making, and believes that it is useful to exclude certain items in order to focus on what it regards to be a more meaningful representation of the underlying operating performance of the business.



# First quarter 2022 highlights





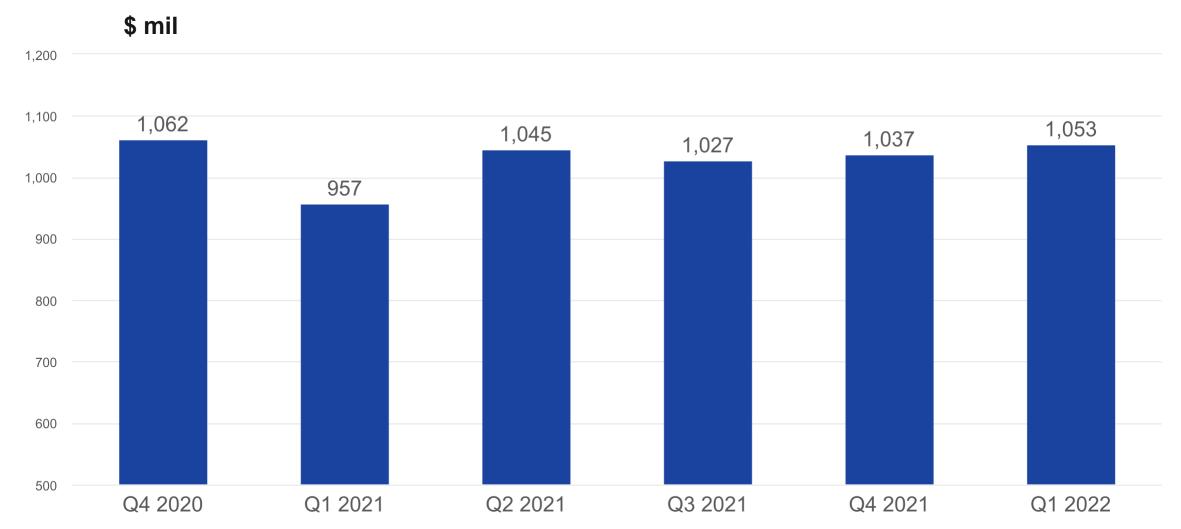
- Double digit growth in Biosimilars and Fertility
- Capitalizing on opportunities in Established Brands
- Continued business development with license for Xaciato<sup>™</sup>
- \$1,567 million Revenue
- \$647 million Adjusted EBITDA
- \$1.65 Adjusted EPS from continuing operations



## Established Brands sizeable and stable base of revenue









# Building a Women's Health portfolio



Entered into licensing agreement for <i>Xaciato</i> ™ March 2022	Bacterial Vaginosis FDA-approved for BV in females 12 and over, the most common cause of vaginitis worldwide estimated to affect approximately 21 million women in the U.S. <sup>(1)</sup>
<i>Marvelon</i> ™ and <i>Mercilon</i> ™ February 2022	Contraception Expanding contraception portfolio by recapturing commercial rights to certain currently marketed products in Asia
Acquisition of Forendo Pharma December 2021	Endometriosis Affects up to 170 million patients, or up to 10% of women of reproductive age
Licensing of investigational ebopiprant, being studied in pre-term labor July 2021	Pre-term labor 15 million babies (11.1% of all live births) born pre-term every year (2)
Acquisition of Alydia Health/JADA® System June 2021	Postpartum hemorrhage One of the most common complications of birth, requiring pharmacologic treatment in up to 10% of mothers (3)

<sup>(1)</sup> Centers for Disease Control and Prevention Bacterial Vaginosis CDC Fact Sheet; https://www.cdc.gov/std/bv/stdfact-bacterial-vaginosis.htm



<sup>(2)</sup> WHO Key Facts, 2018: https://www.who.int/news-room/fact-sheets/detail/preterm-birth

<sup>(3)</sup> Widmer M et al. "Heat-Stable Carbetocin versus Oxytocin to Prevent Hemorrhage after Vaginal Birth." N Engl J Med 2018; 379:743-752

Q1 revenue: volume growth more than offset LOE, price +4% reported +8% ex-FX \$ mil ~30 1,567 ~210 ~60 1,506 ~30 ~30

Q1 2021

LOE (1)

Price

VBP (2)



Q1 2022

Volume

Supply/Other (3)

FX

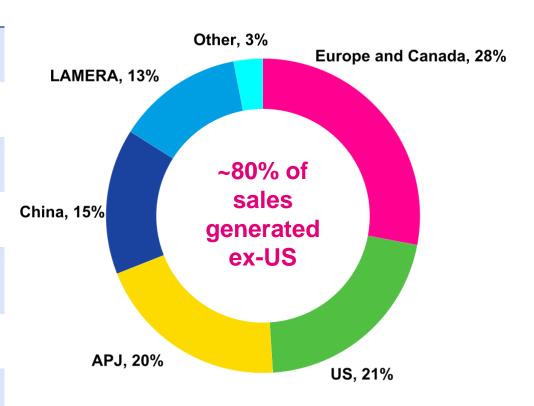
<sup>(1)</sup> LOE = Loss of Exclusivity

<sup>(2)</sup> VBP = Volume-Based Procurement

<sup>(3)</sup> Other includes manufacturing sales to Merck & Co., Inc., Rahway, NJ, USA and other third parties, and allocated amounts from pre-spin revenue hedging activities.

# **Strong ex-US performance**

\$ mil	Q1-22	Q1-21 (pre-spin)	Actual VPY	Ex FX VPY
Europe and Canada	436	434	_	8%
United States	329	351	(6)%	(6)%
Asia Pacific and Japan	314	278	13%	22%
China	236	206	15%	13%
Latin America, Middle East, Russia and Africa	209	167	25%	34%
Other (1)	43	70	(39)%	(39)%
Total Revenue	1,567	1,506	4%	8%





<sup>(1)</sup> Other includes manufacturing sales to Merck & Co., Inc., Rahway, NJ, USA and other third parties, and allocated amounts from pre-spin revenue hedging activities.

## Women's Health





- Double digit fertility growth in Q1
- Q1 Nexplanon sales were impacted by customer buying patterns
- Positive demand trends for Nexplanon; expect double digit growth for full year 2022

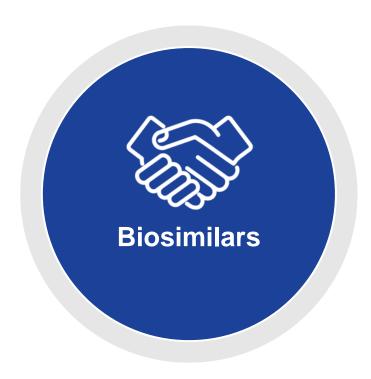
399	378
Q1 2021	Q1 2022

Revenues \$ mil	Q1-2022	Q1-2021	Act VPY	Ex FX VPY
<b>Top Contraception Products</b>				
Nexplanon®	171	183	(7)%	(5)%
NuvaRing®	41	45	(10)%	(6)%
Cerazette™	18	17	5%	11%
Top Fertility Products				
Follistim®	61	52	17%	20%
Ganirelix Acetate Injection	30	29	2%	6%
Other Women's Health products	57	73	(21)%	(18)%
Total Women's Health	378	399	(5)%	(3)%



## **Biosimilars**





- Double digit growth for Renflexis
- Ontruzant growth in US tempered by EU competition; approved in Canada
- US demand for biosimilars continues to grow



Revenues \$ mil	Q1-2022	Q1-2021	Act VPY	Ex FX VPY
Renflexis®	46	38	21%	21%
Ontruzant®	22	22	_	5%
Brenzys™	14	10	40%	44%
Aybintio™	10	8	26%	37%
Hadlima™	6	2	NM	NM
Biosimilars	99	81	22%	25%



## **Established brands**





- Limited LOE impact in Q1; no VBP impact
- Benefits from one-time items
- Improved outlook for 2022



Revenues \$ mil	Q1-2022	Q1-2021	Act VPY	Ex FX VPY
Cardiovascular	410	389	5%	11%
Respiratory	305	236	29%	35%
Non-Opioid Pain, Bone & Dermatology	201	181	11%	18%
Other	136	152	(10)%	(6)%
Total Est. Brands	1,053	957	10%	15%

Totals may not foot due to rounding.



# Timing of spend benefits Q1 Adj. EBITDA margin



\$ mil	Q1-22	Q1-21 (pre-spin)	Actual VPY
Revenue	1,567	1,506	4%
Cost of sales	561	591	(5)%
Gross profit	1,006	915	10%
Non-GAAP Adjusted Gross profit (1)	1,042	937	11%
Selling, general, and administrative	371	382	(3)%
Research and development	96	67	43%
Adjusted EBITDA (2)	647	566	14%
Net income, continuing operations (3)	348	395	(12)%
Diluted EPS	1.36	1.56	(13)%
Non-GAAP Adjusted net income, continuing operations (3)	420	451	(7)%
Non-GAAP Adjusted diluted EPS	1.65	1.78	(7)%
Gross margin	64.2%	60.8%	
Non-GAAP Adjusted Gross margin (1)	66.5%	62.2%	
Adjusted EBITDA margin (2)	41.3%	37.6%	

<sup>(1)</sup> See Slide 19 of this presentation for a reconciliation of Gross Profit to Adjusted Gross Profit.



<sup>(2)</sup> See Slides 20 of this presentation for a reconciliation of EBITDA and Adjusted EBITDA measures.

<sup>(3)</sup> See Slides 21 of this presentation for a reconciliation of Net Income from continuing operations to Adjusted net income from continuing operations.

# Debt capitalization as of March 31, 2022

Net leverage ratio ~3.6x

\$ mil

	June 30, 2021	September 30, 2021	<b>December 31,2021</b>	March 31, 2022
Reported cash and cash equivalents	730	1,008	737	694
Cash for IOM-exit inventory (1)	<u>(400)</u>	<u>(320)</u>	<u>(O)</u>	<u>(0)</u>
Cash available to Organon	330	688	737	694
Gross Debt (2)	9,348	9,298	9,134	9,094
Net Debt (2)	9,018	8,610	8,397	8,400

<sup>(1)</sup> Organon's starting cash balance at spin included \$400 million from Merck & Co., Inc., Rahway, NJ, USA which was used for the purchase of inventory upon exit of certain Interim Operating Model arrangements.

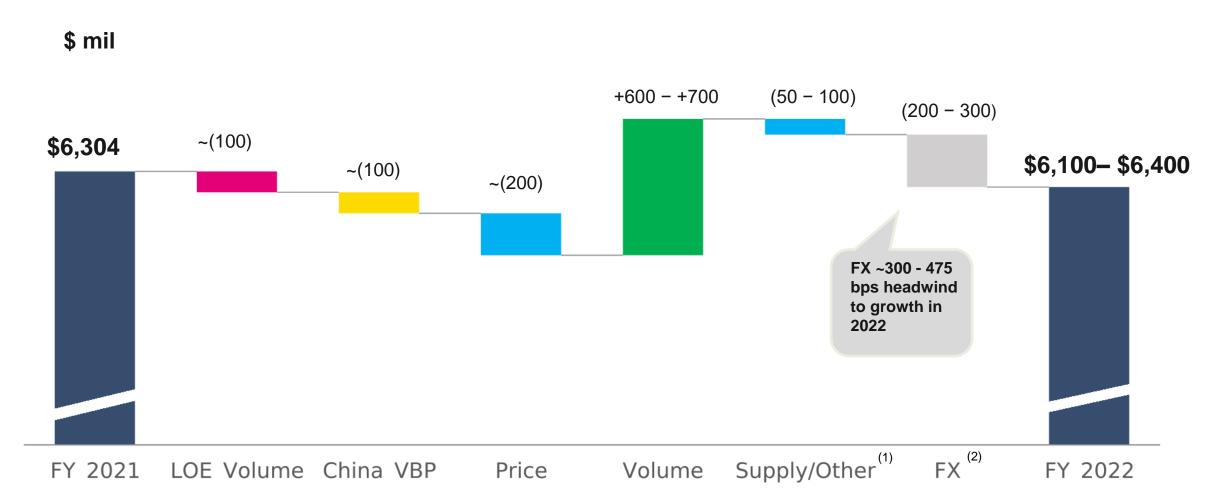
<sup>(2)</sup> Debt figures are net of discounts and unamortized fees of \$135 million, \$130 million, \$124 million, and \$119 million as of June 30, 2021, September 30, 2021, December 31, 2021, and March 31, 2022, respectively.



# Revenue drivers consistent with previous guidance







<sup>(1)</sup> Other includes manufacturing sales to Merck & Co., Inc., Rahway, NJ, USA and other third parties, and allocated amounts from pre-spin revenue hedging activities.



<sup>(2)</sup> Based on 2021 performance and April month end spot rates for 2022.

# Affirming full year 2022 financial guidance

\$M, provided on a Non- GAAP basis, except Revenue	Guidance provided February 17, 2022	Guidance provided as of May 5, 2022
Revenue	\$6,100 - \$6,400	Unchanged
Adjusted gross margin	Mid-60% range	Unchanged
SG&A (as % of revenue)	Mid-20% range	Unchanged
R&D (as % of revenue)	Mid-upper single-digit	Unchanged
Adjusted EBITDA margin	34% - 36%	Unchanged
Interest expense	~\$400	Unchanged
Depreciation	\$100 - \$115	Unchanged
Effective non-GAAP tax rate	17.5% - 19.5%	Unchanged
Fully diluted weighted avg. shares outstanding	~255M	Unchanged



# Q&A



# **Appendix**



# **Established Brands exceptional Q1 performance**



\$ mil	Q1-2022	Q1-2021 (pre-spin)	Actual VPY	Ex FX VPY
Women's Health	378	399	(5)%	(3)%
Biosimilars	99	81	22%	25%
Est. Brands	1,053	957	10%	15%
Other (1)	37	69	(45)%	(46)%
Total Revenue	1,567	1,506	4%	8%

<sup>(1)</sup> Other includes manufacturing sales to Merck & Co., Inc., Rahway, NJ, USA and other third parties, and allocated amounts from pre-spin revenue hedging activities.



# **Gross margin reconciliation**

\$ mil	Q1-2022	Q1-2021 (pre-spin)
Revenue	1,567	1,506
Cost of sales	561	591
Gross Profit	1,006	915
Gross Margin	64.2%	60.8%
Amortization	28	20
One-time costs (1)	5	_
Stock-based compensation	3	2
Non-GAAP Adjusted Gross Profit (2)	1,042	937
Non-GAAP Adjusted Gross Margin	66.5%	62.2%

<sup>(1)</sup> One-time costs for the three months ended March 31, 2022 primarily include costs to stand up the Company.



<sup>(2)</sup> Non-GAAP Adjusted Gross Profit is calculated by excluding amortization, one-time costs, and the portion of stock-based compensation expense allocated to Cost of sales.

# Income from continuing operations before tax to Adjusted EBITDA

\$ mil	Q1-2022	Q1-2021 (pre-spin)
Income from continuing operations before income taxes	442	467
Depreciation	25	18
Amortization (1)	28	20
Interest expense	97	<del></del>
EBITDA	592	505
Restructuring costs	<del></del>	1
One-time costs (2)	40	49
Acquired in-process research and development	<del></del>	
Stock-based compensation	15	11
Adjusted EBITDA	647	566
Adjusted EBITDA margin	41.3%	37.6%

<sup>(1)</sup> Amortization in all periods is included in Cost of sales.

<sup>(2)</sup> One-time costs primarily include costs incurred in connection with the spin-off of Organon. For the three months ended March 31, 2022, approximately \$25 million of the one-time costs are recorded in Selling, general and administrative expenses, \$6 million are recorded in Other (income) expense, \$5 million are recorded in Cost of sales, and \$4 million are recorded in Research and development. For the three months ended March 31, 2021, \$49 million of the one-time costs are classified in Selling, general and administrative expenses.



# Income from continuing operations before tax to Adjusted Net Income

\$ mil (except EPS)	Q1-2022	Q1-2021(pre-spin)
Income from continuing operations before income taxes	442	467
Amortization (1)	28	20
Restructuring costs	_	1
One-time costs (2)	40	49
Acquired in-process research and development	<del>-</del>	_
Stock-based compensation	15	11
Total Adjustments	83	81
Non-GAAP pre-tax income from continuing operations	525	548
Taxes on income as reported in accordance with GAAP	94	72
Tax benefit on adjustments	14	15
Tax (deduction)/benefit on GAAP-only discrete items	(3)	10
Non-GAAP adjusted taxes on income	105	97
Non-GAAP adjusted net income, continuing operations	420	451
Non-GAAP adjusted net income, continuing operations per diluted share	1.65	1.78

<sup>(1)</sup> Amortization in all periods is included in Cost of sales.



<sup>(2)</sup> One-time costs primarily include costs incurred in connection with the spin-off of Organon. For the three months ended March 31, 2022, approximately \$25 million of the one-time costs are recorded in Selling, general and administrative expenses, \$6 million are recorded in Other (income) expense, \$5 million are recorded in Cost of sales, and \$4 million are recorded in Research and development. For the three months ended March 31, 2021, \$49 million of the one-time costs are classified in Selling, general and administrative expenses.

# In-process R&D recast – Income from continuing operations before tax to Adjusted EBITDA



Organon & Co.

Reconciliation of GAAP Income from Continuing Operations Before Income Taxes to Adjusted EBITDA

(\$ in millions)

	Q	1 2021	Q2 2021				Q3 2021				2021		FY 2021								
\$ mil		As eported and ecast <sup>(4)</sup>	As Reported and Recast <sup>(4)</sup>		As Reported		Impact of Non-GAAP Reporting Changes		Recast		Non-GA As Report		pact of n-GAAP porting nanges		Recast		As Reported		Impact of Non-GAAP Reporting Changes		lecast
Income from continuing operations before income taxes	\$	467	\$ 43	37	\$ 38	9	\$	\$	389	$\ _{\$}$	236	\$	_	\$	236	\$	1,529	\$	_	\$	1,529
Depreciation		18	2	21	2	5	_		25		28		_		28		92				92
Amortization (1)		20	2	22	2	7	_		27		34		_		34		103		_		103
Interest expense		_	$\epsilon$	52	9	8			98		98				98		258				258
EBITDA	\$	505	\$ 54	2	\$ 53	9	\$	\$	539	\$	396	\$		\$	396	\$	1,982	\$		\$	1,982
Restructuring costs		1		1		1			1		_		_		_		3		_		3
One-time costs (2)		49	$\epsilon$	66	5	6	_		56		59		_		59		231		_		231
Acquired in-process research and development (3)			_	_	2	5	(25	)	_		79		(79)				104		(104)		
Stock-based compensation		11	1	8	1.	5_	_		15		15				15		59				59
Adjusted EBITDA	\$	566	\$ 62	27	\$ 63	6	\$ (25	) \$	611	\$	549	\$	(79)	\$	470	\$	2,379	\$	(104)	\$	2,275

<sup>&</sup>lt;sup>(1)</sup> Amortization in all periods is included in Cost of sales.

<sup>(4)</sup> The change does not affect the previously reported Adjusted EBITDA results for the first and second quarter of 2021 as there were no adjustments which affected either of the periods.



<sup>(2)</sup> One-time costs primarily include costs incurred in connection with the spin-off of Organon as well as acquisition related costs. Refer to the Company's previously filed Current Reports on Form 8-Ks for a further description of these costs for each reported period.

<sup>(3)</sup> Costs represent upfront licensing payment associated with ObsEva of \$25 million during the third quarter of 2021 and Forendo of \$79 million in the fourth quarter of 2021, which were recorded in Research and development expense.

# In-process R&D recast – Income from continuing operations before income tax to Non-GAAP Adjusted net income



Organon & Co.

Reconciliation of GAAP Income from Continuing Operations Before Income Taxes to Non-GAAP Adjusted Net Income

(\$ in millions, except per share amounts)

\$ mil	Q1	2021	Q2 2021		Q3 2021		1		Q4 2021		FY 2021					
Ψ 11111			Impact of Non-GAAP  Non-GAAP  Reporting  and Recast (5)									Impact of Non-GAAP Reporting As Reported Changes				
Income from continuing operations before income taxes	\$	467	\$ 437	\$ 389	\$ —	\$ 389	\$	236	\$ —	\$ 236	\$ 1,52	9 \$ -	- \$	1,529		
Adjustments:																
Amortization (1)		20	22	27	_	27		34	_	34	10	-	_	103		
Restructuring costs		1	1	1	_	1		_	_	_			_	3		
One-time costs (2)		49	66	56	_	56		59	_	59	23	<u> </u>	_	231		
Acquired in-process research and development (3)			_	25	(25)	_		79	(79)	_	10	(10	4)	_		
Stock-based compensation		11	18	15		15	JL	15		15	5			59		
Total Adjustments		81	107	124	(25)	99	╙	187	(79)	108	50	(10	4)	396		
Non-GAAP pre-tax income from continuing operations	\$	548	\$ 544	\$ 513	\$ (25)	\$ 488	\$	423	\$ (79)	\$ 344	\$ 2,02	\$ (10	4) \$	1,925		
Taxes on income as reported in accordance with GAAP		72	6	66	_	66		34	_	34	17	3 –	_	178		
Tax benefit on adjustments		15	20	23	(2)	21		35	(17)	18	9.	3 (1	9)	74		
Tax benefit on GAAP-only discrete items (4)		10	81	_				5		5	9	<u> </u>	_	96		
Non-GAAP adjusted taxes on income	\$	97	\$ 107	\$ 89	\$ (2)	\$ 87	\$	74	\$ (17)	\$ 57	\$ 36	7 \$ (1	9) \$	348		
Non-GAAP adjusted net income, continuing operations	\$	451	\$ 437	\$ 424	\$ (23)	\$ 401	\$	349	\$ (62)	\$ 287	\$ 1,66	2 \$ (8	5) \$	1,577		
Non-GAAP adjusted net income from continuing operations per diluted share	\$	1.78	\$ 1.72	\$ 1.67	\$ (0.09)	\$ 1.58	\$	1.37	\$ (0.24)	\$ 1.13	\$ 6.5	1 \$ (0.3	3) \$	6.20		

<sup>(1)</sup> Amortization in all periods is included in Cost of sales.

<sup>(2)</sup> One-time costs primarily include costs incurred in connection with the spin-off of Organon as well as acquisition related costs. Refer to the Company's previously filed Current Reports on Form 8-Ks for a further description of these costs for each reported period.

<sup>(3)</sup> Costs represent upfront licensing payment associated with ObsEva of \$25 million during the third quarter of 2021 and Forendo of \$79 million in the fourth quarter of 2021, which were recorded in Research and development expense.

<sup>(4)</sup> Amounts include a tax benefit of approximately \$70 million recorded in the second quarter of 2021 and a tax benefit of \$5 million recorded in the fourth quarter of 2021 related to a portion of non-US step up in tax basis as a result of its separation from Merck & Co., Inc., Rahway, NJ, USA.

<sup>(5)</sup> The change does not affect the previously reported Non-GAAP results for the first and second quarter of 2021 as there were no adjustments which affected either of the periods.

# **Broad and diverse portfolio**



### Women's Health



(etonogestrel/ethinyl estradiol vaginal ring)

delivers 0.120 mg/0.015 mg per day



Follistim® AQ Cartridge
(follitropin beta injection)

For use only with
Follistim Pen® Jada

### **Biosimilars**

# **BRENZYS**<sup>TM</sup>

etanercept

## RENFLEXIS

(infliximab-abda) for injection, for intravenous use 100 mg







#### **Established Brands**











Number of products

11

5

49

