

News Release

Regulatory News Service

AstraZeneca PLC
28 July 2016 07:00

This announcement contains inside information.

H1 2016 Results

Financial Summary

	H1 2016			Q2 2016		
	\$m	% change		\$m	% change	
		CER ¹	Actual		CER ¹	Actual
Total Revenue	11,718	(3)	(5)	5,603	(10)	(11)
<i>Product Sales</i>	11,034	(2)	(5)	5,469	(5)	(6)
<i>Externalisation Revenue</i>	684	(12)	(12)	134	(72)	(72)
Reported Operating Profit	1,341	(24)	(28)	303	(64)	(67)
Core Operating Profit ²	2,999	(14)	(17)	1,406	(21)	(22)
Reported Earnings Per Share (EPS)	\$0.51	(45)	(48)	\$0.00	(99)	(100)
Core EPS	\$1.78	(20)	(22)	\$0.83	(31)	(31)

- Total Revenue down by 3% as expected, reflecting a 2% decline in Product Sales that was driven by patent expiries, in particular *Crestor* in the US. The phasing of Externalisation Revenue is towards H2 2016
- Reported and Core R&D costs increased by 6% and 9% respectively; Reported SG&A costs were stable, with Core SG&A costs declining by 5%, supporting full-year commitments
- Reported EPS declined 45%, negatively impacted by restructuring charges related to the recently-announced cost reduction programme. Core EPS declined 20%, reflecting the phasing of Externalisation Revenue to the second half of the year
- An unchanged first interim dividend per share of \$0.90
- FY 2016 guidance unchanged

Commercial Highlights

The Growth Platforms grew by 7% in the half. Of the six platforms, the performance included:

- Emerging Markets: +7%. Encouraging China growth of 11%
- Diabetes: +18%. A good performance underpinned by the success of *Farxiga*
- Respiratory: +1%. Strong Emerging Markets sales of *Symbicort*, pricing compression in the US and Europe
- New Oncology: Sales of \$251m reflected the successful ongoing launch of *Tagrisso*

Achieving Scientific Leadership: Progress since the last results announcement

Regulatory Approvals / Conditional Marketing Authorisation*	- <i>Qtern</i> (saxagliptin/dapagliflozin) - type-2 diabetes (EU) - <i>Zavicefta</i> (previously CAZ AVI) - serious infections (EU) - Pandemic Live Attenuated Influenza Vaccine - pandemic influenza (EU)*
Regulatory Submission Acceptances	- saxagliptin/dapagliflozin, resubmission (US)
Positive Phase III Data Readouts	- benralizumab - severe asthma - <i>Faslodex</i> - breast cancer (1st line) - <i>Tagrisso</i> - lung cancer (2nd line)
Other Key Developments	- Orphan Drug Designation: selumetinib - thyroid cancer (US) - Fast Track Designation: <i>Lynparza</i> - ovarian cancer (2nd line) (US)

Pascal Soriot, Chief Executive Officer, commenting on the results said:

“Our performance in the first half was in line with expectations, reflecting the anticipated near-term patent expiry challenges and the phasing of Externalisation Revenue in 2016. Our Growth Platforms continued to advance and made up over 60% of Total Revenue. Importantly, our transformed pipeline is advancing quickly and delivering a rich flow of differentiated medicines, boding well for our return to growth.

Alongside positive results for our first potential Respiratory biologic medicine, benralizumab, and for *Tagrisso* in second-line lung cancer, we are encouraged by the rapid patient recruitment in our Immuno-Oncology durva/treme combination programmes. This strong scientific momentum is set to continue, in particular where we anticipate key Immuno-Oncology data.”

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FY 2016 Guidance

Guidance for FY 2016 is unchanged and is shown at CER¹.

Total Revenue	A low to mid single-digit percentage decline
Core EPS	A low to mid single-digit percentage decline

The above guidance incorporates the dilutive effects arising from the Acerta Pharma B.V. (Acerta Pharma) and ZS Pharma, Inc. (ZS Pharma) transactions announced in FY 2015.

Externalisation Revenue is expected to be ahead of that in FY 2015, including an element of recurring income arising from prior agreements. This is in line with the Company's long-term business model, which includes externalisation as part of the portfolio-management strategy.

Externalisation activities, a result of increasing R&D productivity and the focus on three therapy areas, relate to specific risk and reward-sharing strategic collaborations. They broaden, accelerate and maximise the development and commercialisation potential for a number of the Company's medicines. Initial and milestone revenue, together with sales-related revenue, is included in the Company's financial statements as Externalisation Revenue. Receipts will be defined as Externalisation Revenue where AstraZeneca retains a significant ongoing interest in the potential or on-market medicine.

Core R&D costs are expected to be at a similar level to FY 2015. The Company is committed to materially reducing Core SG&A costs in FY 2016 versus the prior year. These measures are based on constant exchange rates.

The Company presents Core EPS guidance. It is unable to provide guidance on a Reported/GAAP basis because the Company cannot reliably forecast material elements of the Reported/GAAP result, including the fair value adjustments arising on acquisition-related liabilities, intangible asset impairment charges and legal settlement provisions.

FY 2016 Currency Impact

Based on average exchange rates in the first half and the Company's published currency sensitivities, there is now expected to be only a minimal adverse impact from currency movements on Total Revenue in FY 2016. Core EPS is now expected to benefit from currency movements by a low to mid single-digit percentage versus the prior year. Further details on currency sensitivities are contained within the Operating and Financial Review.

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Pipeline: Forthcoming Major Newsflow

Innovation is critical to addressing unmet patient needs and is at the heart of the Company's growth strategy. The focus on research and development is designed to yield strong results for the pipeline.

H2 2016	<p>benralizumab - severe asthma: Regulatory submission (US, EU) brodalumab - psoriasis: Regulatory decision (US)</p> <p><i>Brilinta</i> - peripheral arterial disease (PAD): Data readout ZS-9 - hyperkalaemia: Regulatory re-submission (US) roxadustat - anaemia: Rolling regulatory submission (CN)</p> <p><i>Lynparza</i> - breast cancer: Data readout <i>Lynparza</i> - ovarian cancer (2nd line): Data readout <i>Tagrisso</i> - lung cancer: Regulatory submission (CN) cediranib - ovarian cancer: Regulatory decision (EU) selumetinib - lung cancer: Data readout durvalumab - head and neck cancer (HAWK): Data readout (Phase II)* acalabrutinib - blood cancer: Data readout, regulatory submission (US) (Phase II)*</p>
H1 2017	<p>brodalumab: Regulatory decision (EU)</p> <p><i>Brilinta</i> - PAD: Regulatory submission saxagliptin/dapagliflozin - type-2 diabetes: Regulatory decision (US) ZS-9 - hyperkalaemia: Regulatory decision (EU)</p> <p><i>Lynparza</i> - breast cancer: Regulatory submission <i>Lynparza</i> - ovarian cancer (2nd line): Regulatory submission selumetinib - lung cancer: Regulatory submission durvalumab - head and neck cancer (HAWK): Regulatory submission (US) (Phase II)* durva + treme - head and neck cancer (CONDOR): Data readout, regulatory submission (US) (Phase II)* durva + treme - lung cancer (MYSTIC): Data readout durva + treme - lung cancer (ARCTIC): Data readout</p>
H2 2017	<p>tralokinumab - severe asthma: Data readout</p> <p>roxadustat - anaemia: Data readout (AstraZeneca-sponsored trial)</p> <p><i>Lynparza</i> - ovarian cancer (1st line): Data readout, regulatory submission <i>Tagrisso</i> - lung cancer (1st line): Data readout durvalumab - lung cancer (PACIFIC): Data readout, regulatory submission (US) durva + treme - lung cancer (MYSTIC): Regulatory submission durva + treme - lung cancer (ARCTIC): Regulatory submission durva + treme - head and neck cancer (KESTREL): Data readout moxetumumab - leukaemia: Data readout</p>

The term 'data readout' in this section refers to Phase III data readouts, unless specified otherwise.

*Potential fast-to-market opportunity ahead of randomised, controlled trials.

Notes

1. All growth rates and guidance are shown at constant exchange rates (CER) unless otherwise specified.
2. See the Operating and Financial Review for a definition of Core financial measures and a reconciliation of Core to Reported financial measures.

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Results Presentation

A conference call for investors and analysts, hosted by management, will begin at midday UK time today. Details can be accessed via www.astrazeneca.com/investors.

Reporting Calendar

The Company intends to publish its nine-month financial results on 10 November 2016.

About AstraZeneca

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three therapy areas – Respiratory & Autoimmunity, Cardiovascular & Metabolic Diseases and Oncology. The Company is also active in inflammation, infection and neuroscience through numerous collaborations. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: www.astrazeneca.com.

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Adrian Kemp
Company Secretary
AstraZeneca PLC

Operating and Financial Review

All narrative on growth and results in this section is based on CER unless stated otherwise. Financial figures are in US\$ millions (\$m). The performance shown in this announcement covers the six and three-month periods to 30 June 2016 (the half and the quarter, respectively) compared to the six and three-month periods to 30 June 2015.

Core measures, which are presented in addition to Reported financial information, are non-GAAP measures provided to enhance understanding of the Company's underlying financial performance. Core financial measures are adjusted to exclude certain significant items, such as:

- amortisation and impairment of intangible assets, including impairment reversals but excluding any charges relating to IT assets
- charges and provisions related to global restructuring programmes (this will include such charges that relate to the impact of global restructuring programmes on capitalised IT assets)
- other specified items, principally comprising legal settlements and acquisition-related costs, which include fair value adjustments and the imputed finance charge relating to contingent consideration on business combinations

Details on the nature of these measures are provided on page 64 of the [Annual Report](#) and Form 20-F Information 2015.

Total Revenue

	H1 2016		Q2 2016	
	\$m	% CER change	\$m	% CER change
Product Sales	11,034	(2)	5,469	(5)
Externalisation Revenue	684	(12)	134	(72)
Total Revenue	11,718	(3)	5,603	(10)

Based on actual exchange rates, Total Revenue fell by 5% in the half, reflecting the strength of the US dollar.

Product Sales

The level of decline in Product Sales was driven by the US market entry of a *Crestor* generic medicine in the second quarter, as well as the ongoing impact of *Nexium* generic medicines in the US. Overall US Product Sales declined by 7% in the half, with Product Sales in Europe down by 3%.

Within Product Sales, Growth Platform sales grew by 7% in the half and represented 61% of Total Revenue:

Growth Platforms	H1 2016		Q2 2016	
	Product Sales (\$m)	% CER change	Product Sales (\$m)	% CER change
Emerging Markets	2,913	7	1,448	9
Respiratory	2,433	1	1,226	1
Diabetes	1,223	18	645	13
Japan	998	(3)	569	1
<i>Brilinta</i>	395	48	214	51
New Oncology ¹	251	n/m	152	n/m
Total²	7,179	7	3,744	8

¹New Oncology comprises Lynparza, Iressa (US) and Tagrisso

²Total Product Sales for Growth Platforms adjusted to remove duplication on a medicine and regional basis

Externalisation Revenue

Externalisation Revenue recognised in the half amounted to \$684m. Highlights included:

Medicine	Partner	Region	\$m
<i>Plendil</i>	China Medical System Holdings Ltd (CMS) - commercialisation rights - initial revenue	China	298
AZD3293	Eli Lilly and Company (Lilly) - milestone revenue	Global	100
<i>Nexium</i> OTC 20mg	Pfizer Inc. - milestone revenue	Global	93
<i>Moventig</i>	ProStrakan Group plc (ProStrakan) - commercialisation rights - initial revenue	EU	70

Examples of sustainable future Externalisation Revenue are shown below:

Announcement Date	Medicine	Partner	Region	Externalisation Revenue
1 July 2016	Tralokinumab - atopic dermatitis	LEO Pharma*	Global	<ul style="list-style-type: none"> Initial \$115m milestone \$1bn in commercially-related milestones Up to mid-teen tiered percentage royalties on Product Sales
9 June 2016	Anaesthetics	Aspen*	Global (excl. US)	<ul style="list-style-type: none"> Initial \$520m milestone \$250m in sales-related revenue Double-digit percentage trademark royalties on Product Sales
2 September 2015	<i>FluMist</i>	Daiichi Sankyo	Japan	<ul style="list-style-type: none"> Initial (undisclosed) milestone Sales-related revenue (undisclosed)
19 March 2015	<i>Movantik</i>	Daiichi Sankyo	US	<ul style="list-style-type: none"> Initial \$200m milestone Up to \$625m in sales-related payments
29 October 2010	<i>Nexium</i>	Daiichi Sankyo	Japan	<ul style="list-style-type: none"> Initial \$100m milestone Sales-related revenue (undisclosed)

*For further details, please see the Corporate & Business Development section

Product Sales

The performance of key medicines is shown below, with a geographical split shown in Notes 8 and 9.

	H1 2016			Q2 2016		
	\$m	% Change		\$m	% Change	
		CER	Actual		CER	Actual
Respiratory & Autoimmunity						
<i>Symbicort</i>	1,552	(6)	(8)	803	(4)	(5)
<i>Pulmicort</i>	549	10	6	239	6	3
<i>Tudorza/Eklira</i>	87	4	2	48	(13)	(13)
<i>Dalirespl/Daxas</i>	71	n/m	n/m	40	25	25
<i>Duaklir</i>	30	n/m	n/m	17	n/m	n/m
Others	144	13	9	79	34	34
Total	2,433	1	(1)	1,226	1	-

	H1 2016			Q2 2016		
	\$m	% Change		\$m	% Change	
		CER	Actual		CER	Actual
Cardiovascular & Metabolic Diseases						
<i>Onglyza</i>	402	6	3	191	(7)	(8)
<i>Brilinta</i>	395	48	44	214	51	49
<i>Farxiga</i>	376	88	83	211	65	64
<i>Bydureon</i>	291	11	11	156	11	11
<i>Byetta</i>	138	(19)	(20)	76	(6)	(7)
Legacy:						
<i>Crestor</i>	2,082	(15)	(16)	926	(29)	(29)
<i>Seloken/Toprol-XL</i>	374	7	(3)	189	8	2
<i>Atacand</i>	160	(11)	(18)	89	(5)	(10)
Others	242	(23)	(23)	116	(25)	(26)
Total	4,460	(2)	(5)	2,168	(11)	(12)
Oncology						
<i>Iressa</i>	270	2	(1)	135	5	5
<i>Tagrisso</i>	143	n/m	n/m	92	n/m	n/m
<i>Lynparza</i>	98	n/m	n/m	54	n/m	n/m
Legacy:						
<i>Faslodex</i>	401	23	20	211	23	23
<i>Zoladex</i>	382	(3)	(7)	204	(4)	(5)
<i>Casodex</i>	125	(9)	(10)	63	(10)	(9)
<i>Arimidex</i>	119	(2)	(6)	62	(2)	(3)
Others	48	(33)	(33)	27	(30)	(27)
Total	1,586	18	15	848	20	20
Infection & Neuroscience						
<i>Nexium</i>	1,025	(18)	(21)	562	(13)	(13)
<i>Seroquel XR</i>	427	(17)	(19)	225	(14)	(15)
<i>Synagis</i>	271	-	-	27	(59)	(59)
<i>Losec/Prilosec</i>	145	(17)	(20)	70	(16)	(18)
<i>Movantik/Moventig</i>	40	n/m	n/m	23	n/m	n/m
<i>FluMist/Fluenz</i>	11	(48)	(48)	6	(57)	(57)
Others	636	(11)	(16)	314	(12)	(17)
Total	2,555	(13)	(16)	1,227	(14)	(16)
Total Product Sales	11,034	(2)	(5)	5,469	(5)	(6)

Product Sales Summary

Respiratory & Autoimmunity

Symbicort

Symbicort sales declined by 6% to \$1,552m in the half. The decline was driven primarily by continuing price erosion, partially offset by volume growth. *Symbicort* became, however, the global market leader by volume in the period.

In the US, sales of \$681m represented a decline of 5%. This reflected the impact of competitive intensity in the half that was partly offset by encouraging volume growth and market-share gains.

In Europe, sales declined by 18% to \$466m, a result of declining market demand in the class, as well as increased competition from analogue medicines. In contrast, Emerging Markets sales grew by 25% to \$209m; China sales grew by 33% to \$80m.

Pulmicort

Pulmicort sales were \$549m in the half, an increase of 10%. Growth reflected the performance of *Pulmicort Respules* in Emerging Markets, where *Pulmicort* sales grew by 23% to \$349m. China sales increased by 26% to \$288m, partly reflecting the increasing prevalence of acute chronic obstructive pulmonary disease (COPD) and paediatric asthma. To address this growing prevalence, AstraZeneca continued its expansion of treatment centres, as well as provided increased access to home-based patient care systems.

Tudorza/Eklira

Sales in the half were up by 4% to \$87m, driven by Europe sales growth of 17% to \$41m. US sales declined by 9% to \$41m, partly reflecting lower market demand and a loss of Medicare Part D access, which was partially mitigated by the effect of inventory stocking.

Daliresp/Daxas

Rights were acquired in March 2015 from Actavis plc (Actavis) for *Daliresp* in the US and Canada. Sales in the half were \$71m, driven by higher volume demand and inventory stocking. In the US, sales grew to \$66m and represented 93% of global sales.

On 3 May 2016, AstraZeneca announced that it had completed the acquisition of the core respiratory business of Takeda Pharmaceutical Company Limited (Takeda). The agreement, initially announced in December 2015, included the expansion of rights to *Daliresp* in the US (marketed as *Daxas* in other countries). Since completion, *Daxas* sales in Europe amounted to \$4m.

Duaklir

Duaklir has been launched successfully in more than 25 countries, with sales of \$30m during the half reflecting encouraging levels of market share achieved in major European markets. Further launches are anticipated in due course.

Cardiovascular & Metabolic Diseases

Onglyza

Sales increased by 6% to \$402m as DPP-4 class volumes continued to grow.

Sales in the US were stable at \$212m. A higher net price, restocking levels and good federal-business sales offset the continued competitive pressures in the DPP-4 class.

Sales in Europe increased by 4% to \$73m, a comparable rate to the overall DPP-4 class. Emerging Markets sales increased by 16% to \$80m, with strong performance in Brazil (up by 67% to \$8m) and Latin America ex-Brazil (up by 27% to \$11m).

Brilinta

Sales in the half increased by 48% to \$395m.

US sales of *Brilinta* were \$159m, an increase of 57%. Updated preferred guidelines regarding acute coronary syndrome treatment from the American College of Cardiology and the American Heart Association in March 2016 helped to expand the use of *Brilinta*, illustrated by a new-to-brand prescription market share of 12%. *Brilinta* became the branded oral anti-platelet market leader in the US in the half.

Sales of *Brilique* in Europe grew by 17% to \$125m, reflecting indication leadership across a number of markets. In the second quarter, the German Institute for Quality and Efficiency in Healthcare gave its assessment of the additional benefit from *Brilique* at the 60mg dose. This assessment referred to the new indication (high-risk, post-myocardial infarction) which emanated from the PEGASUS trial.

Emerging Markets sales grew by 106% to \$91m, with China representing 47% of Emerging Markets sales at \$43m, despite the medicine not being included on the National Drug Reimbursement List.

Farxiga

During the half, sales increased by 88% to \$376m.

Sales of *Farxiga* in the US increased by 82% to \$209m, reflecting higher market volumes, extended market share and net pricing. Encouraging levels of patient access and greater promotional activity drove volumes and total prescription share growth during the period.

Sales of *Forxiga* in Europe were up 72% to \$89m in the half as the medicine continued to lead the SGLT2 class. Emerging Markets sales increased by 135% to \$53m, with strong performances in Asia Pacific (up by 167% to \$22m), Brazil (up by 78% to \$12m), and Latin America ex-Brazil (up by 80% to \$8m).

Bydureon/Byetta

Combined sales for *Bydureon/Byetta* were \$429m with *Bydureon* sales up by 11%, representing around 68% of total *Bydureon/Byetta* sales. With the Company's focus on *Bydureon*, *Byetta* sales declined by 19% to \$138m.

In the US, *Bydureon* sales were \$234m, an increase of 5%, despite increased competition from new market entrants. Sales in Europe increased by 43% to \$50m, reflecting the Company's ongoing effort to expand its Diabetes presence.

Legacy: Crestor

Sales of *Crestor* declined in the half by 15% to \$2,082m.

In the US, *Crestor* sales declined by 27% to \$1,004m as the first *Crestor* generic competitor entered the market on 2 May 2016. The impact of destocking offset the favourable effects from a higher net price. *Crestor* continued to maintain both total and new-to-brand prescription levels of market share; multiple generic *Crestor* medicines, however, entered the US market in July 2016.

In Europe, sales declined by 4% to \$438m, reflecting the increasing prevalence of generic-medicine competition. *Crestor* consolidated its position as the leading statin in Japan, with sales growth in the half of 5% to \$250m. Sales in China grew by 16% to \$156m.

Oncology

Iressa

Sales of *Iressa* in the half increased by 2% to \$270m.

Following the US launch in July 2015, first-half sales were \$10m as the Company prioritised the launch of *Tagrisso*.

In Europe, sales declined by 8% to \$61m, reflected in falling market-volume share in France and Italy. Emerging Markets sales increased by 3% to \$134m. The growth was limited by a decline in China sales of 3% to \$71m, reflecting the competitive environment. In June 2016, however, *Iressa* received national reimbursement listing in China.

Tagrisso

Sales of *Tagrisso* were \$143m, with the US representing 72% of global sales; the first regulatory approval for *Tagrisso* was in the US in November 2015.

After regulatory approval in the EU and Japan in the first quarter, *Tagrisso* sales amounted to \$25m in Europe and \$15m in Japan. Regulatory approvals have been granted in a number of further markets, including Korea, Switzerland and Canada; the Company anticipates additional regulatory approvals in due course.

Lynparza

Sales of *Lynparza* reached \$98m in the half. Sales in the US increased to \$62m, primarily driven by higher demand, an increased net price and changes in inventory-stocking levels. Sales in Europe were \$32m following several successful launches. *Lynparza* is now available for patients in 29 countries, with regulatory reviews underway in nine additional countries including Singapore, Brazil, and Russia.

Legacy: Faslodex

Faslodex sales increased by 23% to \$401m. US sales grew by 28% to \$211m, driven by higher levels of demand following an expanded label for 2nd-line treatment for advanced or metastatic breast cancer.

Europe sales increased by 13% to \$113m. Emerging Markets sales were up in the half by 36% to \$47m, with China sales growth of 125% to \$9m.

Legacy: Zoladex

Sales declined by 3% to \$382m, primarily driven by a decline in Europe sales of 3% to \$80m and an Emerging Market sales decline of 5% to \$153m. China sales grew by 5% to \$60m. US sales increased by 36% to \$19m, reflecting higher volume demand and a higher net price.

Infection & Neuroscience

Nexium

Sales of Nexium declined by 18% to \$1,025m in the half, due primarily to the impact of generic-medicine competition in the US and Europe.

Sales in the US declined by 39% to \$294m following the loss of exclusivity in 2015 and changes in managed-care contracts. Sales in Europe declined by 10% to \$127m, with Emerging Markets sales increasing by 1% to \$367m. Japan sales decreased by 11% to \$184m, reflecting the competitive environment.

Seroquel XR

Sales declined by 17% to \$427m. Sales in the US were \$306m, representing a decline of 13%. Sales in Europe declined by 32% to \$76m, due primarily to the impact of generic-medicine competition.

Synagis

Sales of Synagis remained stable at \$271m. Sales in US increased by 2% to \$163m, driven primarily by higher net pricing, which was partly mitigated by lower demand. This was a consequence of the more-restrictive guidelines from the American Academy of Pediatrics Committee on Infectious Disease, which reduced the number of patients eligible for preventative therapy with Synagis.

FluMist/Fluenz

Sales in the half declined by 48% to \$11m, reflecting lower volumes. The Company confirmed on 23 June 2016 that the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention had provided its interim recommendation not to use *FluMist Quadrivalent Live Attenuated Influenza Vaccine (FluMist Quadrivalent)* in the US for the 2016-2017 influenza season. The ACIP's updated recommendation is expected to result in very limited US demand in the second half of the year. The Company consequently wrote down the value of its inventory of *FluMist* by \$47m in the second quarter, which was reflected within the Cost of Sales.

Regional Product Sales

	H1 2016			Q2 2016		
	\$m	% Change		\$m	% Change	
		CER	Actual		CER	Actual
US	4,209	(7)	(7)	1,963	(17)	(17)
Europe	2,467	(3)	(5)	1,249	(2)	(1)
Established ROW ¹	1,445	(4)	(3)	809	(1)	3
Japan	998	(3)	2	569	1	9
Canada	245	(1)	(10)	129	(1)	(7)
Other Established	202	(9)	(16)	111	(6)	(10)
Emerging Markets ²	2,913	7	(2)	1,448	9	1
China	1,384	11	6	610	10	5
Ex. China	1,529	4	(8)	838	8	(2)
Total	11,034	(2)	(5)	5,469	(5)	(6)

¹ Established ROW comprises Japan, Canada, Australia and New Zealand.

² Emerging Markets comprises all remaining Rest of World markets, including Brazil, China, India, Mexico, Russia and Turkey.

US

US sales declined by 7% in the half to \$4,209m, driven primarily by the loss of exclusivity of *Crestor* on 2 May 2016. *Crestor* sales were \$1,004m, a 27% decrease versus the comparative period. The decline was partially offset by favourable performances from Growth-Platform medicines *Farxiga* (up by 82% to \$209m), *Brilinta* (up by 57% to \$159m) and *Lynparza* (up to \$62m).

Europe

Sales in Europe declined by 3% to \$2,467m, driven primarily by ongoing price pressures. The strong growth of *Forxiga* sales (up by 72% to \$89m) and *Brilique* sales (increasing by 17% to \$125m) was more than offset by an 18% decline in *Symbicort* sales to \$466m, which reflected adverse pricing and lower volumes, driven by competition from analogue medicines. *Lynparza* sales increased to \$32m following its launch in 2015, reflecting a strong performance in Germany.

Established ROW

Sales in the Established Rest Of World (ROW) declined by 4% to \$1,445m. Japan sales for the half declined by 3% to \$998m, reflecting the biennial price cut in April 2016. Sales of *Forxiga* increased by 127% to \$25m. *Nexium* sales declined by 15% to \$237m, despite retaining position as the number one medicine in the class by market-share volume and new-to-brand prescription share.

Emerging Markets

Emerging Markets sales increased by 7% to \$2,913m, despite continued downward pressure from macro-economic conditions in Latin America. China sales grew by 11% to \$1,384m; China represented 48% of Emerging Markets sales in the half.

Sales in Brazil grew by 13% to \$177m due to the strong performances of *Forxiga* (up by 78% to \$12m), Oncology (up by 13% to \$40m) and *Seloken* (up by 16% to \$32m). Russia sales were up by 12% to \$104m, led by strong performances in Cardiovascular & Metabolic Diseases medicine sales (up by 32% to \$32m).

Financial Performance

H1 2016	Reported	Intangible Asset Amortisation & Impairments				Core		% Change	
		Restructuring	Diabetes Alliance	Other ¹	H1 2016	H1 2015	CER	Actual	
Product Sales	11,034	-	-	-	-	11,034	11,584	(2)	(5)
Externalisation Revenue	684	-	-	-	-	684	780	(12)	(12)
Total Revenue	11,718	-	-	-	-	11,718	12,364	(3)	(5)
Cost of Sales	(2,066)	28	58	-	-	(1,980)	(1,918)	5	3
Gross Profit	9,652	28	58	-	-	9,738	10,446	(4)	(7)
<i>Gross Margin²</i>	<i>81.5%</i>					<i>82.3%</i>	<i>83.4%</i>	<i>-1.1</i>	<i>-1.1</i>
Distribution Expense	(167)	-	-	-	-	(167)	(161)	9	4
<i>% Total Revenue</i>	<i>1.4%</i>					<i>1.4%</i>	<i>1.3%</i>	<i>-0.2</i>	<i>-0.1</i>
R&D Expense	(2,945)	107	25	-	-	(2,813)	(2,636)	9	7
<i>% Total Revenue</i>	<i>25.1%</i>					<i>24.0%</i>	<i>21.3%</i>	<i>-2.5</i>	<i>-2.7</i>
SG&A Expense	(5,624)	328	504	218	347	(4,227)	(4,584)	(5)	(8)
<i>% Total Revenue</i>	<i>48.0%</i>					<i>36.1%</i>	<i>37.1%</i>	<i>+0.8</i>	<i>+1.0</i>
Other Operating Income	425	-	43	-	-	468	553	(14)	(15)
<i>% Total Revenue</i>	<i>3.6%</i>					<i>4.0%</i>	<i>4.5%</i>	<i>-0.5</i>	<i>-0.5</i>
Operating Profit	1,341	463	630	218	347	2,999	3,618	(14)	(17)
<i>% Total Revenue</i>	<i>11.4%</i>					<i>25.6%</i>	<i>29.3%</i>	<i>-3.5</i>	<i>-3.7</i>
Net Finance Expense	(636)	-	-	195	126	(315)	(250)		
Joint Ventures	(12)	-	-	-	-	(12)	(7)		
Profit Before Tax	693	463	630	413	473	2,672	3,361	(18)	(21)
Taxation	(99)	(97)	(140)	(95)	(30)	(461)	(472)		
Tax Rate	14%					17%	14%		
Profit After Tax	594	366	490	318	443	2,211	2,889	(21)	(23)
Non-controlling Interests	49	(5)	-	-	-	44	(1)		
Net Profit	643	361	490	318	443	2,255	2,888	(20)	(22)
Weighted Average Shares	1,264	1,264	1,264	1,264	1,264	1,264	1,263		
Earnings Per Share (\$)	0.51	0.29	0.39	0.25	0.34	1.78	2.29	(20)	(22)

¹ Other adjustments include provision charges related to certain legal matters (see Note 7) and fair value adjustments arising on acquisition-related liabilities (see Note 6).

² Gross Margin reflects Gross Profit derived from Product Sales, divided by Product Sales

³ All financial figures, except Earnings Per Share, are in \$ millions (\$m). Weighted Average Shares are in millions.

Q2 2016	Reported	Intangible Asset				Core		% Change	
		Restructuring	Amortisation & Impairments	Diabetes Alliance	Other ¹	Q2 2016	Q2 2015	CER	Actual
Product Sales	5,469	-	-	-	-	5,469	5,836	(5)	(6)
Externalisation Revenue	134	-	-	-	-	134	471	(72)	(72)
Total Revenue	5,603	-	-	-	-	5,603	6,307	(10)	(11)
Cost of Sales	(1,062)	19	29	-	-	(1,014)	(965)	3	5
Gross Profit	4,541	19	29	-	-	4,589	5,342	(13)	(14)
<i>Gross Margin²</i>	<i>80.6%</i>					<i>81.5%</i>	<i>83.5%</i>	<i>-1.5</i>	<i>-2.0</i>
Distribution Expense	(91)	-	-	-	-	(91)	(84)	11	8
<i>% Total Revenue</i>	<i>1.6%</i>					<i>1.6%</i>	<i>1.3%</i>	<i>-0.3</i>	<i>-0.3</i>
R&D Expense	(1,465)	69	12	-	-	(1,384)	(1,356)	3	2
<i>% Total Revenue</i>	<i>26.1%</i>					<i>24.7%</i>	<i>21.5%</i>	<i>-3.2</i>	<i>-3.2</i>
SG&A Expense	(3,052)	220	275	110	347	(2,100)	(2,216)	(3)	(5)
<i>% Total Revenue</i>	<i>54.5%</i>					<i>37.5%</i>	<i>35.1%</i>	<i>-2.7</i>	<i>-2.4</i>
Other Operating Income	370	-	22	-	-	392	127	n/m	n/m
<i>% Total Revenue</i>	<i>6.6%</i>					<i>7.0%</i>	<i>2.0%</i>	<i>+4.9</i>	<i>+5.0</i>
Operating Profit	303	308	338	110	347	1,406	1,813	(21)	(22)
<i>% Total Revenue</i>	<i>5.4%</i>					<i>25.1%</i>	<i>28.7%</i>	<i>-3.5</i>	<i>-3.6</i>
Net Finance Expense	(325)	-	-	98	69	(158)	(132)		
Joint Ventures	(8)	-	-	-	-	(8)	(2)		
(Loss)/Profit Before Tax	(30)	308	338	208	416	1,240	1,679	(27)	(26)
Taxation	(1)	(64)	(74)	(48)	(25)	(212)	(160)		
Tax Rate	(3)%					17%	10%		
(Loss)/Profit After Tax	(31)	244	264	160	391	1,028	1,519	(33)	(32)
Non-controlling Interests	28	-	-	-	-	28	1		
Net (Loss)/Profit	(3)	244	264	160	391	1,056	1,520	(31)	(31)
Weighted Average Shares	1,265	1,265	1,265	1,265	1,265	1,265	1,264		
Earnings Per Share (\$)	0.00	0.20	0.21	0.12	0.30	0.83	1.21	(31)	(31)

¹ Other adjustments include provision charges related to certain legal matters (see Note 7) and fair value adjustments arising on acquisition-related liabilities (see Note 6).

² Gross Margin reflects Gross Profit derived from Product Sales, divided by Product Sales

³ All financial figures, except Earnings Per Share, are in \$ millions (\$m). Weighted Average Shares are in millions.

Profit and Loss

Gross Profit

Reported Gross Profit declined by 1% in the half to \$9,652m and, excluding the impact of externalisation, the Reported Gross Profit Margin was 81.5%, an increase of two percentage points. An adverse impact from the mix of sales, the market entry of a *Crestor* generic medicine in the US, as well as a write-down of inventory levels of *FluMist* in the US were more than offset by lower restructuring and amortisation charges. Excluding these charges, Core Gross Profit declined by 4% to \$9,738m and, excluding the impact of externalisation, the Core Gross Profit margin declined by one percentage point to 82.3%.

Operating Expenses: R&D

Reported R&D costs increased by 6% in the half to \$2,945m. This reflected the number of potential medicines in pivotal trials as well as the absorption of the R&D costs of ZS Pharma and Acerta Pharma. These costs were partially offset by lower restructuring costs and impairment charges. Without the impact of ZS Pharma and Acerta Pharma, Reported R&D costs would have increased by 1%.

Excluding the impact of lower restructuring and impairment charges, Core R&D costs increased by 9% to \$2,813m (Q2 2016: Growth of 3%). Without the impact of the aforementioned investments in ZS Pharma and Acerta Pharma, Core R&D costs in the half would have increased by 3%.

Operating Expenses: SG&A

Reported SG&A costs were stable in the half at \$5,624m, with efficiency savings in sales and marketing operations and further reductions in IT costs offset by higher restructuring costs, amortisation charges and fair value adjustments, which are excluded from the Core measurement. Core SG&A costs declined by 5% in the half to \$4,227m, in line with full-year expectations of a material reduction.

Other Operating Income

Reported Other Operating Income of \$425m included:

- \$183m of income related to the disposal of the ex-US rights to *Imdur*
- \$89m of royalty income related to the entry of the first US *Crestor* generic medicine from the period between 2 May 2016 and 8 July 2016
- Other royalty income of \$117m, including that related to HPV and the antibiotic medicine, ertapenem

Operating Profit

Reported Operating Profit declined by 24% to \$1,341m. The Reported Operating Margin declined by three percentage points to 11% of Total Revenue.

Core Operating Profit declined by 14% to \$2,999m in the half. The Core Operating Margin declined by three percentage points to 26% of Total Revenue.

Net Finance Expense

Reported Net Finance Expense of \$636m compared to \$513m in the prior half, and included \$321m for the discount unwind on acquisition-related liabilities. The Core Net Finance Expense, which excludes the aforementioned discount unwind, was \$315m in the half, compared to \$250m in the comparative period. The increase reflected higher loan interest arising from an increase in net debt, driven by the acquisition of ZS Pharma and the investment in Acerta Pharma.

Taxation

The Reported and Core tax rates for the half were 14% and 17% respectively. These tax rates were lower than the UK Corporation Tax Rate of 20%, mainly due to the impact of the geographical mix of profits, tax settlements and the UK patent box. The cash tax paid for the half was \$262m, which was 38% of Reported Profit Before Tax and 10% of Core Profit Before Tax. The Reported and Core tax rates for H1 2015 were 7% and 14% respectively.

Earnings Per Share (EPS)

Reported EPS of \$0.51 in the half represented a 45% decline, with Core EPS in the half declining by 20% to \$1.78. The declines were driven by the first market entry of a *Crestor* generic medicine in the US, as well as the ongoing impact of US *Nexium* generic medicines. The reduction also reflected the phasing of Externalisation Revenue over the year.

Productivity

AstraZeneca continues to enhance productivity through the implementation of its restructuring initiatives, including those announced on 29 April 2016. Restructuring charges of \$463m were incurred in the half. The Company remains on track to realise savings and incur expenses in line with prior announcements.

Cash Flow and Balance Sheet

Cash Flow

The Company generated a net cash inflow from operations of \$1,374m, compared with \$1,008m in the comparative period. Improved working capital and lower net tax payments more than offset the lower profit.

Net cash outflows from investing activities were \$3,948m compared with \$1,234m in the comparative period. The increase primarily reflected the net cash outflow of \$2,383m on the investment in Acerta Pharma.

Net cash outflows from financing activities were \$6m, incorporating \$2,483m of new long-term loans, net of a dividend payment in the period of \$2,409m. This compared to an outflow of \$2,388m in the comparative period.

The cash payment of contingent consideration in respect of the Bristol-Myers Squibb Company share of the global Diabetes alliance amounted to \$141m in the half. The consideration is based on a tiered structure, whereby a higher royalty rate is applied until a specified level of sales is achieved in the year; thereafter a lower rate is applied to the remaining sales in the year and settled in the quarter following the application of the charge.

Debt and Capital Structure

At 30 June 2016, outstanding gross debt (interest-bearing loans and borrowings) was \$17,579m (30 June 2015: \$11,008m). Of the gross debt outstanding at 30 June 2016, \$1,060m was due within one year (30 June 2015: \$2,705m). The Company's net debt position at 30 June 2016 was \$12,734m (30 June 2015: \$5,994m).

On 9 May 2016, the Company announced the successful pricing of euro medium-term notes in an aggregate principal amount of €2.2bn, consisting of three tranches:

- €500m of five-year, fixed-rate notes with a coupon of 0.25%
- €900m of eight-year, fixed-rate notes with a coupon of 0.75%
- €800m of 12-year, fixed-rate notes with a coupon of 1.25%

Shares in Issue

During the half, 0.5 million shares were issued in respect of share option exercises for a consideration of \$22m. The total number of shares in issue as at 30 June 2016 was 1,265 million.

Dividends

The Board has recommended an unchanged first interim dividend of \$0.90 (68.7 pence, 7.81 SEK) per Ordinary Share.

Capital Allocation

The Board's aim is to continue to strike a balance between the interests of the business, financial creditors and the Company's shareholders. After providing for investment in the business, supporting the progressive dividend policy and maintaining a strong, investment-grade credit rating, the Board will keep under review potential investment in immediately earnings-accretive, value-enhancing opportunities.

Sensitivity: Foreign-Exchange Rates

The Company provides the following currency sensitivity information:

Currency	Primary Relevance	Average Exchange Rates Versus USD		Change %	Impact Of 5% Weakening In Exchange Rate Versus USD (\$m) ²	
		FY 2015	H1 2016 ¹		Total Revenue	Core Operating Profit
EUR	Product Sales	0.90	0.90	1	(178)	(103)
JPY	Product Sales	121.04	111.74	8	(102)	(66)
CNY	Product Sales	6.28	6.54	(4)	(133)	(62)
SEK	Costs	8.43	8.33	1	(8)	71
GBP	Costs	0.65	0.70	(6)	(34)	96
Other ³					(201)	(122)

¹Based on average daily spot rates in the six months to the end of June 2016

²Based on 2015 actual results at 2015 actual exchange rates

³Other important currencies include AUD, BRL, CAD, KRW and RUB

Currency Hedging

AstraZeneca monitors the impact of adverse currency movements on a portfolio basis, recognising correlation effects. The Company may hedge to protect against adverse impacts on cash flow over the short to medium term. As at 30 June 2016, AstraZeneca had hedged 90% of forecast short-term currency exposure that arises between the booking and settlement dates on non-local currency purchases and Product Sales.

Related-Party Transactions

There have been no significant related-party transactions in the period.

Principal Risks and Uncertainties

It is not anticipated that the nature of the principal risks and uncertainties that affect the business, and which are set out on pages 212 to 226 of the Annual Report and Form 20-F Information 2015, will change in respect of the second six months of the financial year.

In summary, the principal risks and uncertainties listed in the Annual Report and 20-F Information 2015 are:

a) Medicine pipeline and intellectual property risks

Failure to meet development targets; delay to new product launches; acquisitions and strategic alliances, including licensing and collaborations, may be unsuccessful; difficulties obtaining and maintaining regulatory approvals for new products; failure to obtain and enforce effective intellectual property (IP) protection.

b) Commercialisation risks

Expiry or loss of, or limitations to, IP rights and consequential pressure from generic competition; abbreviated approval processes for biosimilars; political and socio-economic conditions; developing our business in Emerging Markets; challenges to achieving commercial success of new products; effects of patent litigation in respect of IP rights; price controls and reductions; economic, regulatory and political pressures; illegal trade in medicines; increasing implementation and enforcement of more stringent anti-bribery and anti-corruption legislation; failure to adhere to applicable laws, rules and regulations; failure of information technology and cybercrime; any expected gains from productivity initiatives are uncertain; failure of outsourcing; failure to attract and retain key personnel and failure to successfully engage with employees.

c) Supply chain and business execution risks

Difficulties and delays in the manufacturing, distribution and sale of products; reliance on third-party goods and services; manufacturing biologic products.

d) Legal, regulatory and compliance risks

Adverse outcome of litigation and/or governmental investigations; failure to adhere to applicable laws, rules and regulations relating to anti-competitive behaviour; substantial product-liability claims; failure to adhere to applicable laws, rules and regulations relating to environment, health and safety; environmental and occupational health and safety liabilities; misuse of social media platforms and new technology.

e) Economic and financial risks

Failure to achieve strategic priorities or to meet targets or expectations; adverse impact from sustained economic downturn; fluctuations in exchange rates; limited third-party insurance coverage; taxation; pensions.

Corporate and Business Development Update

The highlights of the Company's corporate and business development activities since the prior results announcement are shown below.

a) Licensing Agreements In Skin Diseases

On 1 July 2016, the Company announced that it had entered into an agreement with LEO Pharma A/S (LEO Pharma), a specialist in dermatological care, for the global licence to tralokinumab in skin diseases. Tralokinumab is a potential new medicine (an IL-13 monoclonal antibody) that has completed a Phase IIb trial for the treatment of patients with atopic dermatitis, an inflammatory skin disease resulting in itchy, red, swollen and cracked skin.

Under the terms of the agreement, LEO Pharma will make an upfront payment to AstraZeneca of \$115m, up to \$1bn in commercially-related milestones and up to mid-teen tiered percentage royalties on Product Sales. AstraZeneca will manufacture and supply tralokinumab to LEO Pharma. AstraZeneca will retain all rights to tralokinumab in respiratory disease and any other indications outside of dermatology. The Company anticipates completion of the transaction in the third quarter.

On the same date, AstraZeneca and an affiliate of Valeant Pharmaceuticals International, Inc. (Valeant) agreed to terminate the licence for Valeant's right to develop and commercialise brodalumab in Europe. Simultaneously, AstraZeneca has entered into an agreement with LEO Pharma for the exclusive licence to brodalumab in Europe. Brodalumab is an IL-17 receptor monoclonal antibody under regulatory review for patients with moderate-to-severe plaque psoriasis (a skin disease that causes red patches of skin covered with silvery scales) and in development for psoriatic arthritis (inflammation of the joints associated with psoriasis).

In September 2015, AstraZeneca and Valeant entered an agreement granting Valeant an exclusive licence to develop and commercialise brodalumab globally, outside Japan and certain other Asian countries where the rights are held by Kyowa Hakko Kirin Co., Ltd. Valeant will continue to lead development and commercialisation of brodalumab in the US and all other markets included in the original agreement.

LEO Pharma will gain the European rights to brodalumab under similar terms to those agreed with Valeant. Additionally, Amgen Inc. will continue to receive a low single-digit percentage inventor royalty.

b) Rights To Global Anaesthetics Portfolio

On 9 June 2016, the Company announced that it had entered into a commercialisation agreement with Aspen Global Incorporated (AGI), part of Aspen Pharmacare Holdings Limited, for rights to its global anaesthetics portfolio outside the US.

Under the terms of the agreement, AGI will acquire the commercialisation rights for an upfront consideration of \$520m. Additionally, AGI will pay AstraZeneca up to \$250m in a Product Sales-related payment, as well as double-digit percentage trademark royalties on Product Sales. AstraZeneca will manufacture and supply the medicines on a cost-plus basis to AGI for an initial period of 10 years. Upon completion, anticipated in the third quarter of 2016, AGI will assume responsibility for all activities relating to the sale of the portfolio in all relevant markets.

AstraZeneca will retain a significant ongoing interest in the anaesthetics portfolio, including a long-term manufacturing and supply agreement and participation in commercial strategy. The upfront and milestone payments, as well as royalty receipts, which are open-ended, will therefore be reported as Externalisation Revenue in the Company's financial statements.

c) Zurampic In Europe And Latin America

On 2 June 2016, AstraZeneca announced that it had entered into a licensing agreement with Grünenthal GmbH (Grünenthal) for the exclusive rights to *Zurampic* (lesinurad) in Europe and Latin America. *Zurampic* was approved by the European Medicines Agency (EMA) in February 2016, in combination with a xanthine oxidase inhibitor, for the adjunctive treatment of hyperuricemia (excess of uric acid in the blood) in adult patients with uncontrolled gout.

Under the terms of the agreement, Grünenthal will submit a fixed-dose combination programme for regulatory review and will pay AstraZeneca up to \$230m in sales and other related milestones over the lifetime of the

contract. Grünenthal will also pay tiered, low double-digit percentage royalties on annual Product Sales. Revenue from the licensing agreement will provide AstraZeneca with future recurring Externalisation Revenue from expected milestone payments and tiered, low double-digit percent royalty payments on Product Sales. The Company anticipates completion of the transaction in the third quarter.

d) Acquisition Of Takeda's Respiratory Business

On 3 May 2016 AstraZeneca announced that it had completed the acquisition of the main respiratory business of Takeda. The agreement, announced in December 2015, included the expansion of rights to roflumilast (marketed as *Daliresp* in the US and *Daxas* in other countries), the only approved oral phosphodiesterase 4 (PDE4) inhibitor for the treatment of COPD. PDE4 is an enzyme involved in modulating production of inflammatory mediators by immune cells. AstraZeneca has marketed *Daliresp* in the US since the acquisition of the rights from Actavis in the first quarter of 2015.

e) Agreement with China Medical System Holdings (CMS) - *Imdur* outside the US

On 29 February 2016, AstraZeneca announced that it had entered into an agreement with CMS and its associated company, Tibet Rhodiola Pharmaceutical Holding Co., for the divestment of the global rights to *Imdur* outside the US. *Imdur* is a mature medicine for the prevention of angina in patients with heart disease; its global sales outside the US were \$57m in FY 2015. The transaction completed in the second quarter.

Under the terms of this agreement, AstraZeneca recognised income of \$183m for the rights to *Imdur* in all markets outside the US. Income from the agreement was reported within Other Operating Income.

Research and Development Update

A comprehensive table with AstraZeneca's pipeline of medicines in human trials can be found later in this document.

Since the results announcement on 28 April 2016 (the period):

Regulatory Approvals	3	<ul style="list-style-type: none"> - <i>Qtern</i> (saxagliptin/dapagliflozin) - type-2 diabetes (EU) - <i>Zavicefta</i> (previously CAZ AVI) - serious infections (EU) - Pandemic Live Attenuated Influenza Vaccine - pandemic influenza (EU)¹
Regulatory Submission Acceptances	1	<ul style="list-style-type: none"> - saxagliptin/dapagliflozin, resubmission (US)
Positive Phase III Data Readouts	3	<ul style="list-style-type: none"> - benralizumab - severe asthma - <i>Faslodex</i> - breast cancer (1st line) - <i>Tagrisso</i> - lung cancer (2nd line)
Other Key Developments	2	<ul style="list-style-type: none"> - Orphan Drug Designation: selumetinib - thyroid cancer (US) - Fast Track Designation: <i>Lynparza</i> - ovarian cancer (2nd line) (US)
New Molecular Entities (NMEs) in Pivotal Trials or under Regulatory Review*	14	<p>Respiratory & Autoimmunity</p> <ul style="list-style-type: none"> - brodalumab - psoriasis* - benralizumab - severe asthma - tralokinumab - severe asthma - PT010 - COPD - anifrolumab - lupus <p>Cardiovascular & Metabolic Diseases</p> <ul style="list-style-type: none"> - ZS-9* - hyperkalaemia - roxadustat - anaemia <p>Oncology</p> <ul style="list-style-type: none"> - cediranib* - ovarian cancer - selumetinib - lung cancer - durvalumab - multiple cancers - durva + treme - multiple cancers - acalabrutinib - blood cancers - moxetumomab pasudotox - leukaemia <p>Neuroscience</p> <ul style="list-style-type: none"> - AZD3293 - early Alzheimers' disease
Projects in clinical pipeline	145	

¹Conditional Marketing Authorisation

1. Respiratory & Autoimmunity

AstraZeneca's Respiratory portfolio includes a range of differentiated potential medicines such as novel combinations, biologics and devices for the treatment of asthma and COPD. The pipeline also includes a number of potential medicines designed to treat autoimmune diseases, with a lead programme in systemic lupus erythematosus.

AstraZeneca highlighted the breadth of its Respiratory portfolio at the American Thoracic Society international conference in May 2016, involving more than 60 posters and abstracts that illustrated progress in asthma and COPD medicines.

The following shows the progress in the Respiratory & Autoimmunity portfolio since the last results announcement:

a) Benralizumab (severe asthma)

On 17 May 2016, the Company announced positive top-line results from the benralizumab Phase III programme, an encouraging milestone for AstraZeneca and for millions of patients suffering from severe asthma. Two pivotal Phase III trials (SIROCCO and CALIMA) achieved statistical significance in reducing exacerbations among patients with severe uncontrolled asthma with eosinophilic inflammation. These trials evaluated treatment with benralizumab versus placebo added to high-dose inhaled corticosteroid (ICS) plus long-acting beta agonist (LABA) for the prevention of asthma exacerbations in patients with uncontrolled severe asthma.

Benralizumab is an eosinophil-depleting monoclonal antibody and AstraZeneca's first respiratory biologic medicine. Upon anticipated regulatory approval, benralizumab will potentially be used in addition to inhaled combination medicines. Benralizumab has the potential to deliver rapid and sustained improvement in lung function, symptoms and quality of life, together with significant reductions in exacerbations, hospitalisations and oral corticosteroids use; and simple, convenient dosing and administration.

b) Brodalumab (psoriasis)

On 19 July 2016, the Dermatologic and Ophthalmic Drugs Advisory Committee appointed by the US FDA voted unanimously to recommend approval for brodalumab for adult patients with moderate-to-severe plaque psoriasis. 14 of the panelists voted for approval with conditions related to product labelling and post-marketing obligations based on observations related to suicidal ideation and behaviour. Patient safety is the highest priority and as such the Company is committed to supporting the partner Valeant in addressing any concerns raised by the Committee as the FDA continues its review of brodalumab. Valeant is the Biologics License Application (BLA) holder for brodalumab and is responsible for all development and commercialisation activities in the US. Valeant has communicated that the FDA assigned a Prescription Drug User Fee Act (PDUFA) date of 16 November 2016 for the BLA.

2. Cardiovascular & Metabolic Diseases

This therapy area includes a broad type-2 diabetes portfolio, differentiated devices and unique small and large-molecule programmes to reduce morbidity, mortality and organ damage across cardiovascular (CV) disease, diabetes and chronic kidney disease (CKD) indications.

a) *Brilinta* (CV disease)

In May 2016, the *Brilinta* THEMIS trial completed its recruitment, with more than 19,000 patients now randomised within the trial. THEMIS is part of PARTHENON, AstraZeneca's largest clinical-trial programme, evaluating *Brilinta* in more than 80,000 high-risk CV patients. THEMIS is an event-driven, randomised, double-blind, placebo-controlled trial, designed to evaluate the effect of *Brilinta* versus placebo for prevention of major CV events in patients with established coronary artery disease and type-2 diabetes, but without a previous myocardial infarction (MI) or stroke. Results are expected in 2018.

The Ministry of Health, Labour and Welfare Drug Committee assessment of *Brilinta*'s application for approval is ongoing in Japan and a regulatory decision is now anticipated in the second half of 2016.

There were three new treatment guidelines updated in China in the first half of the year. The ACS Emergency Room Rapid Guideline, Chinese PCI Guideline and the Coronary Artery Bypass Graft Consensus (2016) guideline. These recommended *Brilinta* as 'first-choice treatment' over any other platelet inhibitor.

b) *Qtern* (saxagliptin/dapagliflozin) (type-2 diabetes)

On 19 July 2016 AstraZeneca announced that the European Commission had approved *Qtern* tablets for the treatment of type-2 diabetes in the European Union (EU) plus Iceland, Liechtenstein and Norway. The fixed-dose combination of saxagliptin and dapagliflozin was the first DPP-4/SGLT2 combination medicine to be approved.

After receiving a Complete Response Letter (CRL) from the US FDA in October 2015, the Company submitted a regulatory filing with new clinical data, which was accepted by the FDA. The submission was based on discussions with regulators and was a first step towards regulatory approval in the US. The PDUFA date is scheduled for the first quarter of 2017.

c) Type-2 diabetes CV outcomes trials

As the field of type-2 diabetes medicines continues to evolve, with multiple outcomes trials producing data, AstraZeneca continues to assess both the SGLT2 and GLP-1 classes for potential long-term benefits. Two significant type-2 diabetes outcomes trials are underway and are fully recruited. Details and updates on those two trials are listed below:

Medicine	Trial	Mode of Action	Number of Patients	Primary Endpoint	Timeline
<i>Bydureon</i>	EXSCEL	GLP-1 agonist	~15,000	Time to first occurrence of CV death, non-fatal MI or non-fatal stroke	2018 (final analysis)
<i>Farxiga</i>	DECLARE	SGLT2 inhibitor	~17,000*	Time to first occurrence of CV death, non-fatal MI or non-fatal stroke	2019 (final analysis) 2017 (anticipated interim analysis)

*Includes ~10,000 patients who have had no prior index event (primary prevention) and ~7,000 patients who have suffered an index event (secondary prevention).

d) ZS-9 (hyperkalaemia)

On 27 May 2016, AstraZeneca announced that the US FDA had issued a CRL regarding the new drug application (NDA) for ZS-9 (sodium zirconium cyclosilicate), the potential new medicine being developed for the treatment of hyperkalaemia (a high potassium level in the blood serum) by ZS Pharma, a wholly-owned subsidiary of AstraZeneca. The CRL referred to observations arising from a pre-approval manufacturing inspection. The FDA also acknowledged receipt of recently-submitted data which it had yet to review. The CRL did not require the generation of new clinical data. AstraZeneca and ZS Pharma have made important progress in addressing the findings of the CRL and are in dialogue with the FDA regarding the timing of the resubmission of the NDA. From the time of the resubmission, anticipated to be in the second half of the year, the Company assumes a maximum of a six-month period for the FDA review.

In the EU, the EMA has accepted a request to extend the submission timeline in order for the Company to provide a comprehensive and complete package. The Company continues to anticipate EU approval in the first half of 2017.

e) Roxadustat (anaemia)

In the period, the Company approved Phase III investment for roxadustat in an additional type of anaemia, Myelodysplastic Syndrome (MDS), with AstraZeneca's partner, Fibrogen, Inc. MDS is a condition in which the bone marrow produces insufficient levels of healthy blood cells and there are abnormal (blast) cells in the blood and/or bone marrow. Anaemia is observed in approximately 60-80% of MDS patients, producing symptoms of fatigue, angina, dizziness, cognitive impairment or altered sense of well-being and all too often requiring transfusions. Transfused patients with MDS experience higher rates of cardiac events, diabetes, infections, and transformation to acute myeloid leukaemia and have a decreased overall survival rate when compared with non-transfused patients.

The Phase III trial will seek to demonstrate the efficacy and safety of roxadustat, which acts on both the production of red blood cells and management of iron, in achieving transfusion independence in patients with lower-risk MDS and a low transfusion burden.

Roxadustat is already in late Phase III development against anaemia arising from CKD, with a rolling regulatory submission expected to initiate in China before the end of the year. The first Phase III data from an AstraZeneca-sponsored registrational trial are expected to be available during the second half of 2017, with a potential regulatory submission in the US anticipated in 2018.

3. Oncology

AstraZeneca has a deep-rooted heritage in Oncology and offers a rapidly-growing portfolio of new medicines that has the potential to transform patients' lives and the Company's future. With at least six new medicines to be launched between 2014 and 2020 and a broad pipeline of small molecules and biologics in development, the Company is committed to advancing New Oncology as one of AstraZeneca's six Growth Platforms focused on lung, ovarian, breast and blood cancers.

In addition to core capabilities, the Company is actively pursuing innovative collaborations and investments that accelerate the delivery of AstraZeneca's strategy, as illustrated by the Company's investment in Acerta Pharma in haematology.

AstraZeneca highlighted its pipeline of Oncology medicines at the American Society of Clinical Oncology meeting on 6 June 2016. At the meeting, AstraZeneca's Oncology management team presented both pipeline programmes and lifecycle management trials in Immuno-Oncology (IO), DNA Damage Response (DDR), tumour drivers & resistance and haematology. The Company presented 73 abstracts and oral presentations, including updates on the *Lynparza* Study 19, *Tagrisso* in leptomeningeal disease and durvalumab in 2nd-line, PDL1-positive urothelial bladder cancer. In addition to the breadth and depth of the data shared at the meeting, AstraZeneca announced a number of encouraging updates in the period.

a) *Faslodex* (breast cancer)

On 27 May 2016, the Company announced that *Faslodex* had met its primary endpoint in the FALCON trial. Top-line data showed that 1st-line treatment with *Faslodex* extends progression-free survival (PFS) in postmenopausal women with locally-advanced or metastatic hormone receptor-positive breast cancer, compared to the current standard of care. Full evaluation of the data is ongoing and results are expected to be presented at a forthcoming medical meeting.

b) *Lynparza* (ovarian and other cancers)

The Phase III SOLO-2 trial for *Lynparza* was granted Fast Track Designation by the FDA in the period. SOLO-2 is designed to evaluate *Lynparza* as a potential maintenance treatment for platinum-sensitive, relapsed germline BRCA-mutated, ovarian-cancer patients who are in complete or partial response following platinum-based chemotherapy. The FDA's Fast Track programme is designed to expedite the development and review of medicines to treat serious conditions and fill an unmet medical need. SOLO-2 high-level results are expected to be available later this year.

On 18 May 2016, the top-line results from the Phase III *Lynparza* GOLD trial in advanced gastric-cancer patients were announced. *Lynparza*, in combination with paclitaxel chemotherapy and compared with paclitaxel chemotherapy alone, did not meet the primary endpoint of overall survival (OS) in either the overall population or patients whose tumour tested negative for Ataxia-Telangectasia Mutated (ATM) protein. While there was a numerical survival trend in the *Lynparza* plus paclitaxel arm, it did not meet statistical significance. The particular regimen in the GOLD trial, at a low dose and in combination with chemotherapy, differed from other Phase III trials in the *Lynparza* programme. The *Lynparza* GOLD data will be analysed and submitted for presentation at a forthcoming medical meeting.

c) *Tagrisso* (lung cancer)

On 18 July 2016 the Company announced that *Tagrisso*'s confirmatory Phase III AURA3 trial had met its primary endpoint, demonstrating superior PFS data compared to standard platinum-based doublet chemotherapy in 2nd-line patients with EGFR T790M mutation-positive, locally-advanced or metastatic non-small cell lung cancer (NSCLC) whose disease had progressed following 1st-line EGFR tyrosine kinase inhibitor therapy.

Tagrisso also demonstrated a safety profile consistent with previous trials and, in addition to PFS, the objective response rate, disease control rate and duration of response also achieved clinically-meaningful improvements versus chemotherapy. A full evaluation of the AURA3 data, including an analysis of OS data is ongoing and the results will be presented at a forthcoming medical meeting.

d) Selumetinib (lung and other cancers)

On 12 May 2016, selumetinib was granted Orphan Drug Designation by the FDA for the treatment of patients with differentiated thyroid cancer (DTC). DTC, diagnosed in approximately 60,000 patients in the US each year, is usually treated with surgery. High-risk patients, however, need additional radioactive iodine (RAI) to kill cancer cells. Up to one in seven patients do not respond to RAI because they lack a key substance, sodium/iodine importer, that is needed to move RAI into cancer cells.

Selumetinib is a MEK 1/2 inhibitor that has already demonstrated clinically-meaningful increases in iodine uptake and retention in patients with thyroid cancer who did not previously respond to RAI. A MEK inhibitor inhibits the mitogen-activated protein kinase enzymes (MEK1 and/or MEK2).

e) Durvalumab (multiple cancers)

The Company continues to advance multiple monotherapy trials of durvalumab and combination trials of durvalumab with tremelimumab in IO. An update on key AstraZeneca-sponsored ongoing trials with durvalumab is provided over the page:

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LUNG CANCER

Name	Phase	Line of treatment	Population	Design	Timelines	Status
<i>Early disease</i>						
<i>Monotherapy</i>						
ADJUVANT ¹	III	N/A	Stage Ib-IIIa NSCLC	durvalumab vs placebo	FPD ² Q1 2015 Data expected 2020	Recruiting
PACIFIC	III	N/A	Stage III unresectable NSCLC	durvalumab vs placebo	FPD Q2 2014 LPCD ³ Q2 2016 Data expected H2 2017	Recruitment completed
<i>Advanced/metastatic disease</i>						
<i>Combination therapy</i>						
MYSTIC	III	1st line	NSCLC	durvalumab vs durva + treme vs SoC ⁴	FPD Q3 2015 LPCD Q3 2016 Data expected H1 2017	Recruitment completed
NEPTUNE	III	1st line	NSCLC	durva + treme vs SoC	FPD Q4 2015 Data expected 2018	Recruiting
-	III	1st line	NSCLC	durvalumab + chemotherapy +/- tremelimumab	-	Recruiting in safety lead-in Phase I/II trial
ARCTIC	III	3rd line	PD-L1 neg. ⁵ NSCLC	durvalumab vs tremelimumab vs durva + treme vs SoC	FPD Q2 2015 LPCD Q3 2016 Data expected H1 2017	Recruitment completed
-	III	1st line	SCLC ⁶	durva + treme + chemotherapy vs SoC	-	Awaiting first patient dosed

¹ Conducted by the National Cancer Institute of Canada ² FPD = First Patient Dosed ³ LPCD = Last Patient Commenced Dosing

⁴ SoC = Standard of Care ⁵ PD-L1 negativity cut-off measured at <25% of tumour-cell staining ⁶ SCLC = Small Cell Lung Cancer

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METASTATIC OR RECURRENT HEAD AND NECK CANCER

Name	Phase	Line of treatment	Population	Design	Timelines	Status
Monotherapy						
HAWK	II	2nd line	PD-L1 pos. SCCHN ¹	durvalumab (single arm)	FPD Q1 2015 LPCD Q2 2016 Data expected H2 2016	Recruitment completed
Combination therapy						
CONDOR	II	2nd line	PD-L1 neg. SCCHN	durvalumab vs tremelimumab vs durva + treme	FPD Q2 2015 LPCD Q2 2016 Data expected H1 2017	Recruitment completed
KESTREL	III	1st line	SCCHN	durvalumab vs durva + treme vs SoC	FPD Q4 2015 Data expected H2 2017	Recruiting
EAGLE	III	2nd line	SCCHN	durvalumab vs durva + treme vs SoC	FPD Q4 2015 Data expected 2018	Recruiting

¹SCCHN = Squamous Cell Carcinoma of the Head and Neck

METASTATIC UROTHELIAL BLADDER CANCER

Name	Phase	Line of treatment	Population	Design	Timelines	Status
Combination therapy						
DANUBE	III	1st line	Cisplatin chemotherapy-eligible/ineligible bladder cancer	durvalumab vs durva + treme vs SoC	FPD Q4 2015 Data expected 2018	Recruiting

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OTHER METASTATIC CANCERS/EARLY TRIALS

Name	Phase	Line of treatment	Population	Design	Timelines	Status
Combination therapy						
ALPS	II	2nd line	Pancreatic ductal carcinoma	durva + treme (single arm)	FPD Q4 2015 Data expected H2 2017	Recruiting
-	II	2nd line	Unresectable liver cancer	durvalumab vs tremelimumab vs durva + treme	FPD Q1 2016 Data expected 2017	Recruiting
-	II	2nd/3rd line	Metastatic gastric cancer	durvalumab vs tremelimumab vs durva + treme	FPD Q2 2016 Data expected 2017	Recruiting

f) MEDI0562 (cancer)

During the period, AstraZeneca made a final selection of the OX40 agonist to take forward to mid- and late-stage development. The fully-humanised OX40 monoclonal antibody, MEDI562 is advancing in Phase I as a monotherapy and in combination with durvalumab or tremelimumab. Data compiled from the murine OX40 (MEDI6469) and fusion-protein OX40 (MEDI6383) programmes have informed and directed the ongoing development of MEDI0562.

Infection & Neuroscience

a) *Zavicefta* (serious infections)

On 28 June 2016, the EMA granted marketing authorisation to *Zavicefta* (ceftazidime and avibactam, previously known as CAZ AVI) for a broad label of indications covering complicated intra-abdominal infections, complicated urinary tract infections including pyelonephritis (infection of the kidney), and hospital-acquired pneumonia, including ventilator-associated pneumonia. The approval also included using *Zavicefta* to treat infections caused by aerobic Gram-negative organisms in adult patients who have limited treatment options, an indication which, to date, has not been awarded to any other novel antibiotic medicine.

On 21 July 2016, the Company announced positive results from the Phase III REPROVE trial, which assessed the efficacy of *Zavicefta* compared with meropenem in the treatment of adult patients with hospital-acquired pneumonia, including ventilator-associated pneumonia. *Zavicefta* met the primary objective of statistical non-inferiority compared to meropenem at the test of cure visit (day 21 from randomisation). The trial showed an adverse event profile consistent with current knowledge of the safety profile of the medicines.

b) Pandemic Live Attenuated Influenza Vaccine (P/LAIV) (pandemic influenza)

On 1 April 2016, the Committee for Medicinal Products for Human Use of the EMA issued a positive opinion recommending the conditional approval of P/LAIV. P/LAIV is indicated for the prevention of influenza in a pandemic setting in children and adolescents. In the event that the World Health Organization declares a pandemic, a dossier can be submitted for conversion to full approval, providing an expedient public-health tool to protect European children.

ASTRAZENECA DEVELOPMENT PIPELINE 30 JUNE 2016

AstraZeneca-sponsored or -directed studies

Phase III / Pivotal Phase II / Registration

New Molecular Entities (NMEs) and significant additional indications

Regulatory submission dates shown for assets in Phase III and beyond. As disclosure of compound information is balanced by the business need to maintain confidentiality, information in relation to some compounds listed here has not been disclosed at this time.

† US and EU dates correspond to anticipated acceptance of the regulatory submission.

Collaboration.

Compound	Mechanism	Area Under Investigation	Date Commenced Phase	Estimated Regulatory Submission / Submission Acceptance†			
				US	EU	Japan	China
Respiratory & Autoimmunity							
Zurampic ^{#1} (lesinurad) CLEAR 1,2 CRYSTAL	selective uric acid reabsorption inhibitor (URAT-1)	chronic treatment of hyperuricemia in patients with gout	Q4 2011	Approved	Approved	N/A	N/A
Bevespi Aerosphere (PT003)	LABA/LAMA	COPD	Q2 2013	Approved	2017	2017	2017
brodalumab ^{#2} AMAGINE-1,2,3	IL-17R mAb	psoriasis	Q3 2012	Accepted	Accepted	N/A	N/A
benralizumab [#] CALIMA SIROCCO ZONDA BISE BORA GREGALE	IL-5R mAb	severe asthma	Q4 2013	H2 2016	H2 2016	N/A	N/A
benralizumab [#] TERRANOVA GALATHEA	IL-5R mAb	COPD	Q3 2014	2018	2018	N/A	N/A
PT010	LABA/LAMA/ICS	COPD	Q3 2015	2018	2018	2018	2019
tralokinumab STRATOS 1,2 TROPOS MESOS	IL-13 mAb	severe asthma	Q3 2014	2018	2018	2018	
anifrolumab [#] TULIP	IFN-alphaR mAb	systemic lupus erythematosus	Q3 2015	2019 (Fast Track)	2019	2019	
Cardiovascular & Metabolic Diseases							
Brilinta ³	P2Y12 receptor antagonist	arterial thrombosis		Launched	Launched	Accepted	Launched
Farxiga ⁴	SGLT2 inhibitor	type-2 diabetes		Launched	Launched	Launched	Accepted
Epanova [#]	omega-3 carboxylic acids	severe hypertriglyceridemia		Approved		2018	
ZS-9 (sodium zirconium cyclosilicate)	potassium binder	hyperkalaemia		H2 2016	Accepted		
roxadustat [#] OLYMPUS (US) ROCKIES (US)	hypoxia-inducible factor prolyl hydroxylase inhibitor	anaemia in CKD/ESRD	Q3 2014	2018	N/A	N/A	H2 2016 ⁵
Oncology							
Tagrisso AURA, AURA 2, (AURA17 Asia regional)	EGFR tyrosine kinase inhibitor	≥2nd-line advanced EGFRm T790M NSCLC	Q2 2014	Launched (Breakthrough Therapy, Priority Review, Orphan drug)	Launched (Accelerated assessment)	Approved	H2 2016

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Compound	Mechanism	Area Under Investigation	Date Commenced Phase	Estimated Regulatory Submission / Submission Acceptance†			
				US	EU	Japan	China
Tagrisso AURA 3	EGFR tyrosine kinase inhibitor	≥2nd-line advanced EGFRm T790M NSCLC	Q3 2014	2017	2017	2017	2018
cediranib ICON 6	VEGFR tyrosine kinase inhibitor	PSR ovarian cancer	Q2 2007		Accepted (Orphan drug)		
acalabrutinib [#] (ACP-196)	Bruton's tyrosine kinase (BTK) inhibitor	B-cell blood cancers	Q1 2015	H2 2016 (Orphan drug)			
selumetinib [#] SELECT-1	MEK inhibitor	2nd-line KRASm NSCLC	Q4 2013	2017	2017		
selumetinib [#] ASTRA	MEK inhibitor	differentiated thyroid cancer	Q3 2013	2018 (Orphan drug) ⁶	2018		
moxetumomab pasudotox [#] PLAIT	anti-CD22 recombinant immunotoxin	hairy cell leukaemia	Q2 2013	2017 (Orphan drug)	2018		
durvalumab [#] PACIFIC	PD-L1 mAb	stage III NSCLC	Q2 2014	2017	2020	2020	
durvalumab [#] + tremelimumab ARCTIC	PD-L1 mAb + CTLA-4 mAb	3rd-line NSCLC	Q2 2015	2017	2017	2017	
durvalumab [#] + tremelimumab MYSTIC	PD-L1 mAb + CTLA-4 mAb	1st-line NSCLC	Q3 2015	2017	2017	2017	2020
durvalumab [#] + tremelimumab NEPTUNE	PD-L1 mAb + CTLA-4 mAb	1st-line NSCLC	Q4 2015	2019	2019	2019	
durvalumab [#] HAWK ^{††}	PD-L1 mAb	2nd-line SCCHN (PD-L1 positive)	Q1 2015	2017 (Fast Track)	2019	2019	
durvalumab [#] + tremelimumab CONDOR ^{††}	PD-L1 mAb + CTLA-4 mAb	2nd-line SCCHN (PD-L1 negative)	Q2 2015	2017	2019	2019	
durvalumab [#] + tremelimumab KESTREL	PD-L1 mAb + CTLA-4 mAb	1st-line SCCHN	Q4 2015	2018	2018	2018	
durvalumab [#] + tremelimumab EAGLE	PD-L1 mAb + CTLA-4 mAb	2nd-line SCCHN	Q4 2015	2019	2019	2019	
durvalumab [#] + tremelimumab ALPS ^{††}	PD-L1 mAb + CTLA-4 mAb	metastatic pancreatic ductal carcinoma	Q4 2015	2017	2017	2017	
durvalumab [#] + tremelimumab DANUBE	PD-L1 mAb + CTLA-4 mAb	1st-line bladder cancer	Q4 2015	2018	2018	2018	
Infection & Neuroscience							
Zinforo [#]	extended spectrum cephalosporin with affinity to penicillin-binding proteins	pneumonia/skin infections		N/A	Launched	N/A	Submitted
Zavicefta [#] (CAZ AVI [#])	cephalosporin/ beta lactamase inhibitor	hospital-acquired pneumonia/ ventilator-associated pneumonia	Q2 2013	N/A	Approved ⁷	N/A	2017

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Compound	Mechanism	Area Under Investigation	Date Commenced Phase	Estimated Regulatory Submission / Submission Acceptance†			
				US	EU	Japan	China
Zavicefta [#]	cephalosporin/ beta lactamase inhibitor	serious infections, complicated intra-abdominal infection, complicated urinary tract infection	Q1 2012	N/A	Approved ⁷	N/A	2017
MEDI-550	pandemic influenza virus vaccine	pandemic influenza prophylaxis		N/A	Approved ⁸	N/A	N/A
AZD3293 [#] AMARANTH	beta-secretase inhibitor	Early Alzheimer's disease	Q2 2016	2020	2020	2020	

† Registrational Phase II trial

- AstraZeneca announced it has granted Ironwood exclusive US rights (26 April 2016) and Grünenthal exclusive rights in Europe and Latin America (2 June 2016)
- AstraZeneca and Valeant agreed to terminate the licence for Valeant's right to develop and commercialise brodalumab in Europe. AstraZeneca entered into an agreement with LEO Pharma for the exclusive licence to brodalumab in Europe (1 July 2016)
- Brilinta in the US; Brilique in rest of world
- Farxiga in the US; Forxiga in rest of world
- Rolling NDA submission to be initiated in H2 2016
- FDA granted Orphan Drug Designation 10 May 2016
- EU approval received 24 June 2016
- EU approval received 20 May 2016

Phases I and II

NMEs and significant additional indications

Compound	Mechanism	Area Under Investigation	Phase	Date Commenced Phase
Respiratory & Autoimmunity				
PT010	LABA/LAMA/ICS	asthma	II	Q2 2014
tralokinumab ^{#1}	IL-13 mAb	atopic dermatitis	II	Q1 2015
anifrolumab [#]	IFN-alphaR mAb	lupus nephritis	II	Q4 2015
anifrolumab [#]	IFN-alphaR mAb	systemic lupus erythematosus (subcutaneous)	I	Q4 2015
verinurad	selective uric acid reabsorption inhibitor (URAT-1)	chronic treatment of hyperuricemia in patients with gout	II	Q3 2013
abediterol	LABA	asthma/COPD	II	Q4 2007
AZD7594	inhaled SGRM	asthma/COPD	II	Q3 2015
AZD7624	inhaled P38 inhibitor	COPD	II	Q4 2014
AZD9412 [#]	inhaled interferon beta	asthma/COPD	II	Q3 2015
mavrilimumab [#]	GM-CSFR mAb	rheumatoid arthritis	II	Q1 2010
inebilizumab [#]	CD19 mAb	neuromyelitis optica	II	Q1 2015 (Orphan drug)
MEDI2070 [#]	IL-23 mAb	Crohn's disease	II	Q1 2013
tezepelumab [#]	TSLP mAb	asthma / atopic dermatitis	II	Q2 2014
lesinurad + allopurinol FDC ^{#2}	selective uric acid reabsorption inhibitor (URAT-1)+xanthine oxidase inhibitor FDC	chronic treatment of hyperuricemia in patients with gout	I	Q4 2015
AZD1419 [#]	TLR9 agonist	Asthma	I	Q3 2013
AZD5634	inhaled ENaC	cystic fibrosis	I	Q1 2016
AZD7986	DPP1	COPD	I	Q4 2014
AZD8871	MABA	COPD	I	Q4 2015
AZD9567	oral SGRM	rheumatoid arthritis	I	Q4 2015

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MEDI0700 [#]	BAFF/B7RP1 bispecific mAb	systemic lupus erythematosus	I	Q1 2016
MEDI4920	anti-CD40L-Tn3 fusion protein	primary Sjögren's syndrome	I	Q2 2014
MEDI5872 [#]	B7RP1 mAb	systemic lupus erythematosus	I	Q4 2008
MEDI9314	IL-4R mAb	atopic dermatitis	I	Q1 2016
Cardiovascular & Metabolic Diseases				
MEDI4166	PCSK9/GLP-1 mAb + peptide fusion	diabetes / cardiovascular	II	Q1 2016
MEDI6012	LCAT	ACS	II	Q4 2015
AZD4076	anti-miR103/107 oligonucleotide	non-alcoholic fatty liver disease/non-alcoholic steatohepatitis (NASH)	I	Q4 2015
AZD5718	FLAP	CAD	I	Q1 2016
MEDI0382	GLP-1/ glucagon dual agonist	diabetes / obesity	I	Q1 2015
MEDI8111	Rh-factor II	trauma / bleeding	I	Q1 2014
Oncology				
durvalumab [#]	PD-L1 mAb	bladder cancer	II	Q1 2016 (Breakthrough Therapy)
durvalumab [#]	PD-L1 mAb	solid tumours	II	Q3 2014
durvalumab [#] + tremelimumab	PD-L1 mAb + CTLA-4 mAb	gastric cancer	II	Q2 2015
durvalumab [#] + AZD5069	PD-L1 mAb + CXCR2	SCCHN	II	Q3 2015
durvalumab [#] + AZD9150 [#]	PD-L1 mAb + STAT3 inhibitor			
durvalumab [#]	PD-L1 mAb	solid tumours	I	Q3 2014
durvalumab [#] + monalizumab	PD-L1 mAb + NKG2a mAb	solid tumours	I	Q1 2016
durvalumab [#] + MEDI9447	PD-L1 mAb + CD73 mAb	solid tumours	I	Q1 2016
durvalumab [#] + <i>Iressa</i>	PD-L1 mAb+ EGFR tyrosine kinase inhibitor	NSCLC	I	Q2 2014
durvalumab [#] + MEDI0680	PD-L1 mAb + PD-1 mAb	solid tumours	I	Q2 2014
durvalumab [#] + dabrafenib + trametinib	PD-L1 mAb+ BRAF inhibitor + MEK inhibitor	melanoma	I	Q1 2014
durvalumab [#] + tremelimumab	PD-L1 mAb + CTLA-4 mAb	solid tumours	I	Q4 2013
<i>Tagrisso</i> + (durvalumab [#] or selumetinib [#] or savolitinib [#]) TATTON	EGFR tyrosine kinase inhibitor + (PD-L1 mAb or MEK inhibitor or MET tyrosine kinase inhibitor)	advanced EGFRm NSCLC	II	Q2 2016
selumetinib + durvalumab [#]	MEK inhibitor + PD-L1 mAb	solid tumours	I	Q4 2015
savolitinib/volitinib [#]	MET tyrosine kinase inhibitor	papillary renal cell carcinoma	II	Q2 2014
AZD1775 [#] + chemotherapy	Wee1 inhibitor + chemotherapy	ovarian cancer	II	Q4 2012
AZD1775 [#]	Wee1 inhibitor	solid tumours	I	Q3 2015
AZD1775 [#] + <i>Lynparza</i>	Wee1 inhibitor + PARP inhibitor	solid tumours	I	Q3 2015
AZD1775 [#] + durvalumab [#]	Wee1 inhibitor + PD-L1 mAb	solid tumours	I	Q4 2015

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vistusertib (AZD2014)	mTOR serine/threonine kinase inhibitor	solid tumours	II	Q1 2013
AZD3759 BLOOM	EGFR tyrosine kinase inhibitor	brain metastases in advanced EGFRm NSCLC	II	Q4 2015
Tagrisso BLOOM	EGFR tyrosine kinase inhibitor			
AZD5363 [#]	AKT kinase inhibitor	breast cancer	II	Q1 2014
AZD4547	FGFR tyrosine kinase inhibitor	solid tumours	II	Q4 2011
inebilizumab [#]	CD19 mAb	diffuse B-cell lymphoma	II	Q1 2012
MEDI-573 [#]	IGF mAb	metastatic breast cancer	II	Q2 2012
AZD0156	ATM serine/threonine kinase inhibitor	solid tumours	I	Q4 2015
AZD2811 [#]	Aurora B kinase inhibitor	solid tumours	I	Q4 2015
AZD6738	ATR serine/threonine kinase inhibitor	solid tumours	I	Q4 2013
AZD8186	PI3 kinase beta inhibitor	solid tumours	I	Q2 2013
AZD9150 [#]	STAT3 inhibitor	haematological malignancies	I	Q1 2012
AZD9496	selective oestrogen receptor downregulator (SERD)	ER+ breast cancer	I	Q4 2014
AZD4635	A2aR inhibitor	solid tumours	I	Q2 2016
MEDI0562 [#]	humanised OX40 agonist	solid tumours	I	Q1 2015
MEDI0562 [#] + tremelimumab	humanised OX40 agonist + CTLA-4 mAb	solid tumours	I	Q2 2016
MEDI0562 [#] + durvalumab [#]	humanised OX40 agonist + PD-L1 mAb	solid tumours	I	Q2 2016
MEDI-565 [#]	CEA BiTE mAb	solid tumours	I	Q1 2011
MEDI0680	PD-1 mAb	solid tumours	I	Q4 2013
MEDI1873	GITR agonist fusion protein	solid tumours	I	Q4 2015
MEDI3617 [#]	ANG-2 mAb	solid tumours	I	Q4 2010
MEDI4276	HER2 bispecific ADC mAb	solid tumours	I	Q4 2015
MEDI9197 [#]	TLR 7/8 agonist	solid tumours	I	Q4 2015
MEDI9447	CD73 mAb	solid tumours	I	Q3 2015
Infection & Neuroscience				
CXL [#]	beta lactamase inhibitor / cephalosporin	methicillin-resistant <i>S. aureus</i>	II	Q4 2010
AZD3241	myeloperoxidase inhibitor	multiple system atrophy	II	Q2 2015 (Orphan drug)
MEDI3902	Psi/PcrV bispecific mAb	prevention of nosocomial pseudomonas pneumonia	II	Q2 2016 (Fast Track, US)
MEDI4893	mAb binding to <i>S. aureus</i> toxin	hospital-acquired pneumonia / serious <i>S. aureus</i> infection	II	Q4 2014 (Fast Track, US)
MEDI7510	RSV sF+GLA-SE	prevention of RSV disease in older adults	II	Q3 2015

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MEDI8852	influenza A mAb	influenza A treatment	II	Q4 2015 (Fast Track, US)
MEDI8897 [#]	RSV mAb-YTE	passive RSV prophylaxis	II	Q1 2015 (Fast Track, US)
ATM AVI [#]	monobactam/ beta lactamase inhibitor	targeted serious bacterial infections	II	Q2 2016
AZD8108	NMDA antagonist	suicidal ideation	I	Q4 2014
MEDI1814	amyloid beta mAb	Alzheimer's disease	I	Q2 2014
MEDI7352	NGF/TNF bispecific mAb	osteoarthritis pain	I	Q1 2016

1 AstraZeneca entered licensing agreement with LEO Pharma (1 July 2016)

2 AstraZeneca announced it granted Ironwood exclusive US rights (26 April 2016) and Grünenthal exclusive rights in Europe and Latin America (2 June 2016)

Significant Lifecycle Management (LCM)

Compound	Mechanism	Area Under Investigation	Date Commenced Phase	Estimated Regulatory Submission Acceptance [†]			
				US	EU	Japan	China
Respiratory & Autoimmunity							
<i>Symbicort</i> SYGMA	ICS/LABA	as-needed use in mild asthma	Q4 2014	N/A	2018		2019
<i>Symbicort</i>	ICS/LABA	breath actuated Inhaler asthma/COPD		2018			
<i>Duaklir Genuair</i> [#]	LAMA/LABA	COPD		2018	Launched	2018	2018
Cardiovascular & Metabolic Diseases							
<i>Brilinta</i> ¹ PEGASUS-TIMI 54	P2Y12 receptor antagonist	outcomes trial in patients with prior myocardial infarction	Q4 2010	Launched (Priority Review)	Launched	Accepted	Accepted
<i>Brilinta</i> ¹ EUCLID	P2Y12 receptor antagonist	outcomes trial in patients with peripheral artery disease	Q4 2012	2017	2017	2017	2018
<i>Brilinta</i> ¹ THEMIS	P2Y12 receptor antagonist	outcomes trial in patients with type-2 diabetes and CAD, but without a previous history of MI or stroke	Q1 2014	2018	2018	2018	2019
<i>Brilinta</i> ¹ HESTIA	P2Y12 receptor antagonist	prevention of vaso-occlusive crises in paediatric patients with sickle cell disease	Q1 2014	2020	2020		
<i>Onglyza</i> SAVOR-TIMI 53	DPP-4 inhibitor	type-2 diabetes outcomes trial	Q2 2010	Launched	Launched		Accepted ²
<i>Kombiglyze XR/Komboglyze</i> ³	DPP-4 inhibitor/ metformin FDC	type-2 diabetes		Launched	Launched		Submitted
<i>Farxiga</i> ⁴ DECLARE-TIMI 58	SGLT2 inhibitor	type-2 diabetes outcomes trial	Q2 2013	2020	2020		
<i>Farxiga</i> ⁴	SGLT2 inhibitor	type-1 diabetes	Q4 2014	2018	2017	2018	

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Compound	Mechanism	Area Under Investigation	Date Commenced Phase	Estimated Regulatory Submission Acceptance [†]			
				US	EU	Japan	China
<i>Xigduo XR/ Xigduo</i> ⁵	SGLT2 inhibitor/ metformin FDC	type-2 diabetes		Launched	Launched		
<i>Qtern (saxagliptin/ dapagliflozin FDC)</i>	DPP-4 inhibitor/ SGLT2 inhibitor FDC	type-2 diabetes	Q2 2012	Accepted	Approved ⁶		
<i>Bydureon weekly suspension</i>	GLP-1 receptor agonist	type-2 diabetes	Q1 2013	2017	2017		
<i>Bydureon EXSCEL</i>	GLP-1 receptor agonist	type-2 diabetes outcomes trial	Q2 2010	2018	2018	2018	
<i>Epanova STRENGTH</i>	omega-3 carboxylic acids	outcomes trial in statin-treated patients at high CV risk, with persistent hypertriglyceridemia plus low HDL-cholesterol	Q4 2014	2020	2020	2020	2020
Oncology							
<i>Faslodex FALCON</i>	oestrogen receptor antagonist	1st-line hormone receptor +ve advanced breast cancer	Q4 2012	H2 2016	H2 2016	H2 2016	2020
<i>Lynparza OlympiAD</i>	PARP inhibitor	gBRCA metastatic breast cancer	Q2 2014	2017	2017	2017	
<i>Lynparza SOLO-2</i>	PARP inhibitor	2nd-line or greater BRCAm PSR ovarian cancer, maintenance monotherapy	Q3 2013	2017 (Fast Track)	2017	2017	
<i>Lynparza SOLO-1</i>	PARP inhibitor	1st-line BRCAm ovarian cancer	Q3 2013	2018	2018	2018	
<i>Lynparza SOLO-3</i>	PARP inhibitor	gBRCA PSR ovarian cancer	Q1 2015	2018			
<i>Lynparza POLO</i>	PARP inhibitor	pancreatic cancer	Q1 2015	2018	2018	2018	
<i>Lynparza</i>	PARP inhibitor	prostate cancer	Q3 2014	(Breakthrough Therapy)			
<i>Lynparza OlympiA</i>	PARP inhibitor	gBRCA adjuvant breast cancer	Q2 2014	2020	2020	2020	
<i>Tagrisso FLAURA</i>	EGFR tyrosine kinase inhibitor	1st-line advanced EGFRm NSCLC	Q1 2015	2017	2017	2017	2017
<i>Tagrisso ADAURA</i>	EGFR tyrosine kinase inhibitor	adjuvant EGFRm NSCLC	Q4 2015	2022	2022	2022	2022
Infection & Neuroscience							
<i>Nexium</i>	proton pump inhibitor	stress ulcer prophylaxis					H2 2016
<i>Nexium</i>	proton pump inhibitor	paediatrics		Launched	Launched	H2 2016	Accepted

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Compound	Mechanism	Area Under Investigation	Date Commenced Phase	Estimated Regulatory Submission Acceptance [†]			
				US	EU	Japan	China
<i>linaclotide</i> [#]	GC-C receptor peptide agonist	irritable bowel syndrome with constipation (IBS-C)		N/A	N/A	N/A	Accepted

1 *Brilinta* in the US; *Brilique* in rest of world

2 Submission filed and accepted July 2016

3 *Kombiglyze XR* in the US; *Komboglyze* in the EU

4 *Farxiga* in the US; *Forxiga* in rest of world

5 *Xigduo XR* in the US; *Xigduo* in the EU

6 EU approval 19 July 2016

Terminations (discontinued projects between 1 April and 30 June 2016)

NME / Line Extension	Compound	Reason for Discontinuation	Area Under Investigation
NME	MEDI7836	Safety/Efficacy	asthma
NME	MEDI6383 [#]	Strategic	solid tumours
NME	durvalumab [#] + MEDI6383 [#]	Strategic	solid tumours
NME	MEDI0639	Safety/Efficacy	solid tumours
LCM	<i>Epanova/Farxiga</i>	Safety/Efficacy	non-alcoholic fatty liver disease/non-alcoholic steatohepatitis (NASH)
LCM	<i>Lynparza GOLD</i>	Safety/Efficacy	2nd-line gastric cancer

Completed Projects / Divestitures

Compound	Mechanism	Area Under Investigation	Completed/ Divested	Estimated Regulatory Submission Acceptance [†]			
				US	EU	Japan	China
<i>Diprivan</i> ^{#1}	sedative and anaesthetic	conscious sedation	Divested	N/A	Launched	Accepted	Launched

1 AstraZeneca announced it entered into a commercialisation agreement with Aspen Global Incorporated (AGI), part of the Aspen Group, for its global anaesthetics portfolio outside of the US on 9 June 2016.

Condensed Consolidated Statement of Comprehensive Income

For the half year ended 30 June	2016 \$m	2015 \$m
Product sales	11,034	11,584
Externalisation revenue	684	780
Total revenue	11,718	12,364
Cost of sales	(2,066)	(2,336)
Gross profit	9,652	10,028
Distribution costs	(167)	(161)
Research and development expense	(2,945)	(2,822)
Selling, general and administrative costs	(5,624)	(5,765)
Other operating income and expense	425	576
Operating profit	1,341	1,856
Finance income	31	24
Finance expense	(667)	(537)
Share of after tax losses in associates and joint ventures	(12)	(7)
Profit before tax	693	1,336
Taxation	(99)	(88)
Profit for the period	594	1,248
Other comprehensive income		
<i>Items that will not be reclassified to profit or loss</i>		
Remeasurement of the defined benefit pension liability	(842)	242
Tax on items that will not be reclassified to profit or loss	235	(57)
	(607)	185
<i>Items that may be reclassified subsequently to profit or loss</i>		
Foreign exchange arising on consolidation	(523)	(11)
Foreign exchange arising on designating borrowings in net investment hedges	(67)	(217)
Cash flow hedge losses	(103)	-
Cash flow hedge gains transferred to the income statement	60	-
Fair value movements on derivatives designated in net investment hedges	(79)	20
Amortisation of loss on cash flow hedge	1	1
Net available for sale losses taken to equity	(36)	(29)
Tax on items that may be reclassified subsequently to profit or loss	75	43
	(672)	(193)
Other comprehensive income for the period, net of tax	(1,279)	(8)
Total comprehensive income for the period	(685)	1,240
Profit attributable to:		
Owners of the Parent	643	1,247
Non-controlling interests	(49)	1
	594	1,248
Total comprehensive income attributable to:		
Owners of the Parent	(636)	1,239
Non-controlling interests	(49)	1
	(685)	1,240
Basic earnings per \$0.25 Ordinary Share	\$0.51	\$0.99
Diluted earnings per \$0.25 Ordinary Share	\$0.51	\$0.99
Weighted average number of Ordinary Shares in issue (millions)	1,264	1,263
Diluted weighted average number of Ordinary Shares in issue (millions)	1,265	1,265

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Condensed Consolidated Statement of Comprehensive Income

For the quarter ended 30 June	2016 \$m	2015 \$m
Product sales	5,469	5,836
Externalisation revenue	134	471
Total revenue	5,603	6,307
Cost of sales	(1,062)	(1,067)
Gross profit	4,541	5,240
Distribution costs	(91)	(84)
Research and development expense	(1,465)	(1,466)
Selling, general and administrative costs	(3,052)	(2,966)
Other operating income and expense	370	199
Operating profit	303	923
Finance income	17	13
Finance expense	(342)	(276)
Share of after tax losses in associates and joint ventures	(8)	(2)
(Loss)/Profit before tax	(30)	658
Taxation	(1)	38
(Loss)/Profit for the period	(31)	696
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Remeasurement of the defined benefit pension liability	(651)	259
Tax on items that will not be reclassified to profit or loss	194	(61)
	(457)	198
Items that may be reclassified subsequently to profit or loss		
Foreign exchange arising on consolidation	(356)	438
Foreign exchange arising on designating borrowings in net investment hedges	(274)	191
Cash flow hedge losses	(103)	-
Cash flow hedge gains transferred to the income statement	60	-
Fair value movements on derivatives designated in net investment hedges	(47)	(1)
Amortisation of loss on cash flow hedge	1	1
Net available for sale losses taken to equity	(7)	(48)
Tax on items that may be reclassified subsequently to profit or loss	65	(57)
	(661)	524
Other comprehensive income for the period, net of tax	(1,118)	722
Total comprehensive income for the period	(1,149)	1,418
(Loss)/Profit attributable to:		
Owners of the Parent	(3)	697
Non-controlling interests	(28)	(1)
	(31)	696
Total comprehensive income attributable to:		
Owners of the Parent	(1,121)	1,418
Non-controlling interests	(28)	-
	(1,149)	1,418
Basic earnings per \$0.25 Ordinary Share	\$0.00	\$0.55
Diluted earnings per \$0.25 Ordinary Share	\$0.00	\$0.55
Weighted average number of Ordinary Shares in issue (millions)	1,265	1,264
Diluted weighted average number of Ordinary Shares in issue (millions)	1,265	1,265

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Condensed Consolidated Statement of Financial Position

	At 30 Jun 2016 \$m	At 31 Dec 2015 \$m	At 30 Jun 2015 \$m
ASSETS			
Non-current assets			
Property, plant and equipment	6,613	6,413	6,134
Goodwill	11,848	11,868	11,467
Intangible assets	29,438	22,646	20,486
Derivative financial instruments	337	446	471
Investments in associates and joint ventures	105	85	52
Other investments	470	458	448
Other receivables	764	907	957
Deferred tax assets	1,524	1,294	1,342
	<u>51,099</u>	<u>44,117</u>	<u>41,357</u>
Current assets			
Inventories	2,422	2,143	2,198
Trade and other receivables	5,619	6,622	6,615
Other investments	731	613	531
Derivative financial instruments	5	2	51
Income tax receivable	628	387	450
Cash and cash equivalents	3,915	6,240	3,967
	<u>13,320</u>	<u>16,007</u>	<u>13,812</u>
Total assets	<u>64,419</u>	<u>60,124</u>	<u>55,169</u>
LIABILITIES			
Current liabilities			
Interest-bearing loans and borrowings	(1,060)	(916)	(2,705)
Trade and other payables	(10,259)	(11,663)	(10,659)
Derivative financial instruments	(57)	(9)	(6)
Provisions	(999)	(798)	(731)
Income tax payable	(1,960)	(1,483)	(2,049)
	<u>(14,335)</u>	<u>(14,869)</u>	<u>(16,150)</u>
Non-current liabilities			
Interest-bearing loans and borrowings	(16,519)	(14,137)	(8,303)
Derivative financial instruments	(103)	(1)	-
Deferred tax liabilities	(4,076)	(2,733)	(1,582)
Retirement benefit obligations	(2,628)	(1,974)	(2,377)
Provisions	(426)	(444)	(479)
Other payables	(10,942)	(7,457)	(7,979)
	<u>(34,694)</u>	<u>(26,746)</u>	<u>(20,720)</u>
Total liabilities	<u>(49,029)</u>	<u>(41,615)</u>	<u>(36,870)</u>
Net assets	<u>15,390</u>	<u>18,509</u>	<u>18,299</u>
EQUITY			
Capital and reserves attributable to equity holders of the Company			
Share capital	316	316	316
Share premium account	4,326	4,304	4,281
Other reserves	2,030	2,036	2,033
Retained earnings	6,858	11,834	11,649
	<u>13,530</u>	<u>18,490</u>	<u>18,279</u>
Non-controlling interests	<u>1,860</u>	<u>19</u>	<u>20</u>
Total equity	<u>15,390</u>	<u>18,509</u>	<u>18,299</u>

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Condensed Consolidated Statement of Cash Flows

For the half year ended 30 June	2016 \$m	2015 \$m
Cash flows from operating activities		
Profit before tax	693	1,336
Finance income and expense	636	513
Share of after tax losses in associates and joint ventures	12	7
Depreciation, amortisation and impairment	1,156	1,565
Increase in working capital and short-term provisions	(183)	(767)
Non-cash and other movements	(380)	(612)
Cash generated from operations	1,934	2,042
Interest paid	(298)	(252)
Tax paid	(262)	(782)
Net cash inflow from operating activities	1,374	1,008
Cash flows from investing activities		
Movement in short-term investments and fixed deposits	(15)	273
Purchase of property, plant and equipment	(584)	(497)
Disposal of property, plant and equipment	8	16
Purchase of intangible assets	(723)	(1,222)
Disposal of intangible assets	102	350
Purchase of non-current asset investments	(66)	(30)
Disposal of non-current asset investments	-	56
Payments to joint ventures	(15)	-
Upfront payments on business acquisitions	(2,564)	-
Payment of contingent consideration on business acquisitions	(141)	(239)
Interest received	63	59
Payments made by subsidiaries to non-controlling interests	(13)	-
Net cash outflow from investing activities	(3,948)	(1,234)
Net cash outflow before financing activities	(2,574)	(226)
Cash flows from financing activities		
Proceeds from issue of share capital	22	20
New long-term loans	2,483	-
Repayment of loans	-	(884)
Dividends paid	(2,409)	(2,357)
Hedge contracts relating to dividend payments	5	(43)
Repayment of obligations under finance leases	(8)	(34)
Movement in short-term borrowings	(99)	910
Net cash outflow from financing activities	(6)	(2,388)
Net decrease in cash and cash equivalents in the period	(2,580)	(2,614)
Cash and cash equivalents at the beginning of the period	6,051	6,164
Exchange rate effects	34	(29)
Cash and cash equivalents at the end of the period	3,505	3,521
Cash and cash equivalents consists of:		
Cash and cash equivalents	3,915	3,967
Overdrafts	(410)	(446)
	3,505	3,521

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Condensed Consolidated Statement of Changes in Equity

	Share capital \$m	Share premium account \$m	Other reserves* \$m	Retained earnings \$m	Total \$m	Non- controlling interests \$m	Total equity \$m
At 1 Jan 2015	316	4,261	2,021	13,029	19,627	19	19,646
Profit for the period	-	-	-	1,247	1,247	1	1,248
Other comprehensive income	-	-	-	(8)	(8)	-	(8)
Transfer to other reserves	-	-	12	(12)	-	-	-
Transactions with owners:							
Dividends	-	-	-	(2,400)	(2,400)	-	(2,400)
Issue of Ordinary Shares	-	20	-	-	20	-	20
Share-based payments	-	-	-	(207)	(207)	-	(207)
Net movement	-	20	12	(1,380)	(1,348)	1	(1,347)
At 30 Jun 2015	316	4,281	2,033	11,649	18,279	20	18,299
	Share capital \$m	Share premium account \$m	Other reserves* \$m	Retained earnings \$m	Total \$m	Non- controlling interests \$m	Total equity \$m
At 1 Jan 2016	316	4,304	2,036	11,834	18,490	19	18,509
Profit for the period	-	-	-	643	643	(49)	594
Other comprehensive income	-	-	-	(1,279)	(1,279)	-	(1,279)
Transfer to other reserves	-	-	(6)	6	-	-	-
Transactions with owners:							
Dividends	-	-	-	(2,402)	(2,402)	-	(2,402)
Dividend paid by subsidiary to non-controlling interest	-	-	-	-	-	(13)	(13)
Acerta put option	-	-	-	(1,825)	(1,825)	-	(1,825)
Changes in non-controlling interest	-	-	-	-	-	1,903	1,903
Issue of Ordinary Shares	-	22	-	-	22	-	22
Share-based payments	-	-	-	(119)	(119)	-	(119)
Net movement	-	22	(6)	(4,976)	(4,960)	1,841	(3,119)
At 30 Jun 2016	316	4,326	2,030	6,858	13,530	1,860	15,390

* Other reserves include the capital redemption reserve and the merger reserve.

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Responsibility Statement of the Directors in Respect of the Half-Yearly Financial Report

We confirm that to the best of our knowledge:

- the condensed set of financial statements has been prepared in accordance with IAS 34 *Interim Financial Reporting* as adopted by the European Union and as issued by the International Accounting Standards Board;
- the half-yearly management report includes a fair review of the information required by:
 - (a) DTR 4.2.7R of the Disclosure and Transparency Rules, being an indication of important events that have occurred during the first six months of the financial year and their impact on the condensed set of financial statements; and a description of the principal risks and uncertainties for the remaining six months of the year; and
 - (b) DTR 4.2.8R of the Disclosure and Transparency Rules, being related party transactions that have taken place in the first six months of the current financial year and that have materially affected the financial position or performance of the enterprise during that period; and any changes in the related party transactions described in the last annual report that could do so.

The Board

The Board of Directors that served during all or part of the six-month period to 30 June 2016 and their respective responsibilities can be found on pages 86 and 87 of the AstraZeneca Annual Report and Form 20-F Information 2015.

Approved by the Board and signed on its behalf by

Pascal Soriot
Chief Executive Officer

28 July 2016

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Independent Review Report to AstraZeneca PLC

Introduction

We have been engaged by the Company to review the condensed set of Financial Statements in the half-yearly financial report for the six months ended 30 June 2016 (but not for the quarter ended 30 June 2016 as presented in the Condensed Consolidated Statement of Comprehensive Income for the quarter ended 30 June 2016) which comprises Condensed Consolidated Statement of Comprehensive Income, Condensed Consolidated Statement of Financial Position, Condensed Consolidated Statement of Cash Flows, Condensed Consolidated Statement of Changes in Equity and Notes 1 to 8. We have read the other information contained in the half-yearly financial report and considered whether it contains any apparent misstatements or material inconsistencies with the information in the condensed set of financial statements.

This report is made solely to the Company in accordance with the terms of our engagement to assist the Company in meeting the requirements of the Disclosure and Transparency Rules (the DTR) of the UK's Financial Conduct Authority (the UK FCA). Our review has been undertaken so that we might state to the Company those matters we are required to state to it in this report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the Company for our review work, for this report, or for the conclusions we have reached.

Directors' responsibilities

The half-yearly financial report is the responsibility of, and has been approved by, the Directors. The Directors are responsible for preparing the half-yearly financial report in accordance with the DTR of the UK FCA.

As disclosed in Note 1, the annual financial statements of the Group are prepared in accordance with IFRSs as adopted by the EU. The condensed set of financial statements included in this half-yearly financial report has been prepared in accordance with IAS 34 *Interim Financial Reporting* as adopted by the EU.

Our responsibility

Our responsibility is to express to the Company a conclusion on the condensed set of financial statements in the half-yearly financial report based on our review.

Scope of review

We conducted our review in accordance with International Standard on Review Engagements (UK and Ireland) 2410 *Review of Interim Financial Information Performed by the Independent Auditor of the Entity* issued by the Auditing Practices Board for use in the UK. A review of interim financial information consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing (UK and Ireland) and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the condensed set of financial statements in the half-yearly financial report for the six months ended 30 June 2016 is not prepared, in all material respects, in accordance with IAS 34 as adopted by the EU and the DTR of the UK FCA.

Antony Cates

for and on behalf of KPMG LLP
Chartered Accountants
15 Canada Square
London E14 5GL

28 July 2016

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Notes to the Interim Financial Statements

1 BASIS OF PREPARATION AND ACCOUNTING POLICIES

These unaudited condensed consolidated interim financial statements (interim financial statements) for the six months ended 30 June 2016 have been prepared in accordance with IAS 34 Interim Financial Reporting as adopted by the European Union (EU) and as issued by the International Accounting Standards Board (IASB).

The annual financial statements of the Group are prepared in accordance with International Financial Reporting Standards (IFRSs) as adopted by the EU and as issued by the IASB. The interim financial statements have been prepared applying the accounting policies and presentation that were applied in the preparation of the Group's published consolidated financial statements for the year ended 31 December 2015. There have been no significant new or revised accounting standards applied in the six months ended 30 June 2016.

Legal proceedings

The information contained in Note 7 updates the disclosures concerning legal proceedings and contingent liabilities in the Group's Annual Report and Form 20-F Information 2015.

Going concern

The Group has considerable financial resources available. As at 30 June 2016 the Group has \$5.8bn in financial resources (cash balances of \$3.9bn and undrawn committed bank facilities of \$3bn which are available until April 2021, with only \$1.1bn of debt due within one year). The Group's revenues are largely derived from sales of products which are covered by patents which provide a relatively high level of resilience and predictability to cash inflows, although our revenue is expected to continue to be significantly impacted by the expiry of patents over the medium term. In addition, government price interventions in response to budgetary constraints are expected to continue to adversely affect revenues in many of our mature markets. However, we anticipate new revenue streams from both recently launched medicines and products in development, and the Group has a wide diversity of customers and suppliers across different geographic areas. Consequently, the Directors believe that, overall, the Group is well placed to manage its business risks successfully.

On the basis of the above paragraph and after making enquiries, the Directors have a reasonable expectation that the Company and the Group have adequate resources to continue in operational existence for the foreseeable future. Accordingly, the interim financial statements have been prepared on a going concern basis.

Financial information

The comparative figures for the financial year ended 31 December 2015 are not the Company's statutory accounts for that financial year. Those accounts have been reported on by the Group's auditors and have been delivered to the registrar of companies. The report of the auditors was (i) unqualified, (ii) did not include a reference to any matters to which the auditors drew attention by way of emphasis without qualifying their report, and (iii) did not contain a statement under section 498(2) or (3) of the Companies Act 2006.

2 RESTRUCTURING COSTS

Profit before tax for the quarter ended 30 June 2016 is stated after charging restructuring costs of \$463m (\$308m for the second quarter of 2016). These have been charged to profit as follows:

	H1 2016 \$m	H1 2015 \$m	Q2 2016 \$m	Q2 2015 \$m
Cost of sales	28	101	19	58
Research and development expense	107	124	69	62
Selling, general and administrative costs	328	223	220	115
Total	463	448	308	235

3 NET DEBT

The table below provides an analysis of net debt and a reconciliation of net cash flow to the movement in net debt.

	At 1 Jan 2016 \$m	Cash Flow \$m	Acquisitions \$m	Non-cash & Other \$m	Exchange Movements \$m	At 30 Jun 2016 \$m
Loans due after one year	(14,109)	(2,483)	-	(12)	94	(16,510)
Finance leases due after one year	(28)	-	-	19	-	(9)
Total long-term debt	(14,137)	(2,483)	-	7	94	(16,519)
Current instalments of finance leases	(67)	8	-	(31)	-	(90)
Total current debt	(67)	8	-	(31)	-	(90)
Other Investments	613	17	140	15	(37)	748
Net derivative financial instruments	438	10	-	(266)	-	182
Cash and cash equivalents	6,240	(2,355)	-	-	30	3,915
Overdrafts	(189)	(225)	-	-	4	(410)
Short-term borrowings	(660)	99	-	1	-	(560)
	6,442	(2,454)	140	(250)	(3)	3,875
Net debt	(7,762)	(4,929)	140	(274)	91	(12,734)

Non-cash movements in the period include fair value adjustments under IAS 39.

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4 MAJORITY EQUITY INVESTMENT IN ACERTA PHARMA

On 2 February 2016, AstraZeneca completed an agreement to invest in a majority equity stake in Acerta Pharma, a privately-owned biopharmaceutical company based in the Netherlands and US. The transaction provides AstraZeneca with a potential best-in-class irreversible oral Bruton's tyrosine kinase (BTK) inhibitor, acalabrutinib (ACP-196), currently in Phase III development for B-cell blood cancers and in Phase I/II clinical trials in multiple solid tumours.

Under the terms of the agreement, AstraZeneca has acquired 55% of the issued share capital of Acerta for an upfront payment of \$2.5bn. A further payment of \$1.5bn will be paid either on receipt of the first regulatory approval for acalabrutinib for any indication in the US, or the end of 2018, depending on which is first. The agreement also includes options which, if exercised, provide the opportunity for Acerta shareholders to sell, and AstraZeneca to buy, the remaining 45% of shares in Acerta. The options can be exercised at various points in time, conditional on the first approval of acalabrutinib in both the US and Europe and when the extent of the commercial opportunity has been fully established, at a price of approximately \$3bn net of certain costs and payments incurred by AstraZeneca and net of agreed future adjusting items, using a pre-agreed pricing mechanism. Acerta has approximately 150 employees.

AstraZeneca's 55% holding is a controlling interest and Acerta's combination of intangible product rights with an established workforce and their operating processes requires that the transaction is accounted for as a business combination in accordance with IFRS 3.

Goodwill is principally attributable to the value of the specialist knowhow inherent in the acquired workforce and the accounting for deferred taxes. Goodwill is not expected to be deductible for tax purposes. Acerta Pharma's results have been consolidated into the Group's results from 2 February 2016. From the period from acquisition to 30 June 2016, Acerta Pharma had no revenues and its loss after tax was \$112 million.

	Fair value \$m
Intangible assets	7,307
Other assets including cash and cash equivalents	238
Deferred tax liabilities	(1,827)
Other liabilities	(90)
Total net assets acquired	5,628
Non-controlling interests	(1,903)
Goodwill	84
Fair value of total consideration	3,809
Less: fair value of deferred consideration	(1,332)
Total upfront consideration	2,477
Less: cash and cash equivalents acquired	(94)
Net cash outflow	2,383

5 ACQUISITION OF ZS PHARMA

On 17 December 2015, AstraZeneca completed the acquisition of ZS Pharma, a biopharmaceutical company based in San Mateo, California. ZS Pharma uses its proprietary ion-trap technology to develop novel treatments for hyperkalaemia, a serious condition of elevated potassium in the bloodstream, typically associated with CKD and Chronic Heart Failure.

During 2016, we have revised our assessment of the fair values of the assets and liabilities acquired as a result of new information obtained about facts and circumstances that existed at the date of acquisition that impact the value of deferred tax. This has resulted in a reduction to both deferred tax liabilities and goodwill of \$68m.

	Fair value \$m
Non-current assets	
Intangible assets	3,162
Property, plant and equipment	21
	3,183
Current assets	169
Current liabilities	(50)
Non-current liabilities	
Deferred tax liabilities	(977)
Other liabilities	(13)
	(990)
Total net assets acquired	2,312
Goodwill	388
Total upfront consideration	2,700
Less: cash and cash equivalents acquired	(73)
Less: deferred upfront consideration	(181)
Net cash outflow	2,446

6 FINANCIAL INSTRUMENTS

As detailed in the Group's most recent annual financial statements, our principal financial instruments consist of derivative financial instruments, other investments, trade and other receivables, cash and cash equivalents, trade and other payables, and interest-bearing loans and borrowings. As indicated in Note 1, there have been no changes to the accounting policies for financial instruments, including fair value measurement, from those disclosed on pages 146 and 147 of the Company's Annual Report and Form 20-F Information 2015. In addition, there have been no changes of significance to the categorisation or fair value hierarchy of our financial instruments. Financial instruments measured at fair value include \$1,201m of other investments, \$1,760m of loans, and \$182m of derivatives as at 30 June 2016. The total fair value of interest-bearing loans and borrowings at 30 June 2016, which have a carrying value of \$17,579m in the Condensed Consolidated Statement of Financial Position, was \$19,385m. Contingent consideration liabilities arising on business combinations have been classified under Level 3 in the fair value hierarchy and movements in fair value are shown below:

	Diabetes Alliance 2016 \$m	Other 2016 \$m	Total 2016 \$m	Total 2015 \$m
At 1 January	5,092	1,319	6,411	6,899
Settlements	(141)	-	(141)	(239)
Revaluations	32	128	160	82
Discount unwind	195	53	248	263
At 30 June	5,178	1,500	6,678	7,005

7 LEGAL PROCEEDINGS AND CONTINGENT LIABILITIES

AstraZeneca is involved in various legal proceedings considered typical to its business, including litigation and investigations relating to product liability, commercial disputes, infringement of intellectual property rights, the validity of certain patents, anti-trust law and sales and marketing practices. The matters discussed below constitute the more significant developments since publication of the disclosures concerning legal proceedings in the Company's Annual Report and Form 20-F Information 2015 (the 2015 Disclosures). Unless noted otherwise below or in the 2015 Disclosures, no provisions have been established in respect of the claims discussed below.

As discussed in the 2015 Disclosures, for the majority of claims in which AstraZeneca is involved it is not possible to make a reasonable estimate of the expected financial effect, if any, that will result from ultimate resolution of the proceedings. In these cases, AstraZeneca discloses information with respect only to the nature and facts of the cases but no provision is made.

In cases that have been settled or adjudicated, or where quantifiable fines and penalties have been assessed and which are not subject to appeal, or where a loss is probable and we are able to make a reasonable estimate of the loss, we record the loss absorbed or make a provision for our best estimate of the expected loss.

The position could change over time and the estimates that we have made and upon which we have relied in calculating these provisions are inherently imprecise. There can, therefore, be no assurance that any losses that result from the outcome of any legal proceedings will not exceed the amount of the provisions that have been booked in the accounts. The major factors causing this uncertainty are described more fully in the 2015 Disclosures and herein.

AstraZeneca has full confidence in, and will vigorously defend and enforce, its intellectual property.

Matters disclosed in respect of the first quarter of 2016 and to 29 April 2016.

Patent litigation

Crestor (rosuvastatin)

US patent proceedings

As previously disclosed, AstraZeneca is defending three patent infringement lawsuits in the US District Court for the District of South Carolina (the District Court) which, among other things, claim that AstraZeneca's *Crestor* sales induce infringement of the plaintiffs' patents. In December 2015, the District Court issued an order dismissing the first of these cases, filed by Palmetto Pharmaceuticals, LLC (Palmetto), and entered judgment in AstraZeneca's favour, which Palmetto is appealing. In February 2016, the District Court granted AstraZeneca's motions for summary judgment and dismissed the remaining two, consolidated cases filed by co-plaintiffs Medical University of South Carolina Foundation for Research Development and Charleston Medical Therapeutics (together CMT) and entered judgment in AstraZeneca's favour, which CMT has appealed.

Patent proceedings outside the US

As previously disclosed, in Australia, AstraZeneca was unsuccessful in defending the validity of certain *Crestor* patents, at trial and on appeal. This patent litigation concluded in September 2015. A provision has been taken in respect of claims from generic entities which were prevented by court order from launching their products in Australia before AstraZeneca's patents were subsequently found invalid. In April 2016, AstraZeneca was notified that the Commonwealth of Australia also intends to pursue a claim against AstraZeneca in relation to alleged losses it suffered in connection with this patent litigation. AstraZeneca will respond appropriately in due course.

As previously disclosed, in the Netherlands, in April 2014, AstraZeneca received a writ of summons from Resolution Chemicals Ltd. (Resolution) alleging partial invalidity and non-infringement of the supplementary protection certificate (SPC) related to the *Crestor* substance patent. In July 2015, the District Court of the Hague determined that the SPC does not extend to zinc salts of rosuvastatin and that Resolution's rosuvastatin zinc product does not infringe the SPC. AstraZeneca appealed. In February 2016, the Court of Appeal of the Hague overturned the decision and found that Resolution's product does infringe the SPC. Resolution may seek to appeal.

Faslodex (fulvestrant)

US patent proceedings

As previously disclosed, AstraZeneca has filed patent infringement lawsuits in the US District Court in New Jersey relating to four patents listed in the FDA Orange Book with reference to *Faslodex*, after AstraZeneca received seven Paragraph IV notices relating to six Abbreviated New Drug Applications (ANDAs) seeking FDA approval to market generic versions of *Faslodex* prior to the expiration of AstraZeneca's patents. The first trial, against the first three ANDA filers, is scheduled to commence on 27 June 2016.

Patent proceedings outside the US

As previously disclosed, in September 2015, AstraZeneca filed a request for a provisional injunction against Hexal AG (Hexal) in the Regional Court of Düsseldorf after Hexal threatened to launch a generic *Faslodex* product in Germany. The request was denied in November 2015 and AstraZeneca appealed. In February 2016, the Higher Regional Court of Düsseldorf ruled in AstraZeneca's favour and ordered the provisional injunction against Hexal.

Movantik/Moventig (naloxegol)

US patent proceedings

As previously disclosed, in 2015, Neptune Generics LLC, filed a petition seeking inter partes review (IPR) with the US Patent Office challenging the validity of an FDA Orange Book listed patent relating to *Movantik* (US Patent No. 7,786,133). In April 2016, the US Patent Trial and Appeal Board denied the petition.

Patent proceedings outside the US

As previously disclosed, in Europe, Generics UK Ltd. (trading as Mylan) filed an opposition to the grant of European Patent No. 1,694,363 with the European Patent Office (EPO). In February 2016, the Opposition Division of the EPO upheld the patent as granted and dismissed the opposition.

Onglyza (saxagliptin) and Kombiglyze (saxagliptin and metformin)

US patent proceedings

As previously disclosed, following the denial of Mylan Pharmaceuticals, Inc.'s (Mylan) motion to dismiss for lack of jurisdiction by the US District Court for the District of Delaware (the District Court), Mylan appealed that decision. In March 2016, the US Court of Appeals for the Federal Circuit affirmed the District Court's decision (the March Decision). In April 2016, Mylan filed a petition for rehearing *en banc* of the March Decision.

Nexium (esomeprazole magnesium)

US patent proceedings

In February 2016, AstraZeneca received a Paragraph IV notice from MacLeods Pharmaceuticals Ltd. (MacLeods) challenging certain patents listed in the FDA Orange Book with reference to *Nexium*. MacLeods submitted an ANDA seeking to market esomeprazole magnesium. In March 2016, in response to MacLeods' notice, AstraZeneca filed a patent infringement lawsuit against MacLeods in the US District Court for the District of New Jersey. The litigation is at an early stage and no trial date has been set.

In March 2016, AstraZeneca received a Paragraph IV notice from Hetero USA Inc. (Hetero) challenging certain patents listed in the FDA Orange Book with reference to *Nexium 24HR* (OTC). Hetero submitted an ANDA seeking to market OTC esomeprazole magnesium. AstraZeneca is reviewing Hetero's notice.

Patent Proceedings outside the US

As previously disclosed, in Canada, in July 2014, the Federal Court found Canadian Patent No. 2,139,653 invalid and not infringed by Apotex Inc. In July 2015, AstraZeneca's appeal was dismissed. On 10 March 2016, the Supreme Court of Canada granted AstraZeneca leave to appeal. A tentative hearing date is set for 8 November 2016.

Product liability litigation

Onglyza (saxagliptin)

As previously disclosed, Amylin Pharmaceuticals, LLC, a wholly owned subsidiary of AstraZeneca, and/or AstraZeneca are among multiple defendants in various lawsuits filed in state and federal courts in the US involving multiple plaintiffs claiming physical injury from treatment with *Onglyza*. The lawsuits allege injuries including pancreatic cancer. AstraZeneca has been served with lawsuits filed in California state court on behalf of approximately 35 plaintiffs alleging heart failure, congestive heart failure, cardiac failure and/or death resulting from treatment with *Onglyza/Kombiglyze*.

Commercial litigation

Nexium/Prilosec trademark litigation

As previously disclosed, AstraZeneca filed separate complaints in the US District Court for the District of Delaware against Camber Pharmaceuticals, Inc. (Camber) and Dr. Reddy's Laboratories, Inc. (Dr. Reddy's) to enforce certain AstraZeneca trademark rights related to *Nexium* and *Prilosec*. The Delaware District Court issued preliminary injunctions against Camber's and Dr. Reddy's sales of generic esomeprazole magnesium in purple capsules. The Camber action has been settled through negotiation and as part of the settlement, the Delaware District Court entered a Consented Judgment of Permanent Injunction and Other Relief on 31 March 2016 in favour of AstraZeneca. Dr. Reddy's filed its own separate claims against AstraZeneca in both the Delaware District Court and the US District Court for the District of New Jersey. Dr. Reddy's

also appealed the preliminary injunction decision of the Delaware District Court to the US Court of Appeals for the Third Circuit and in April 2016, voluntarily withdrew its appeal. All District Court cases involving Dr. Reddy's related to this matter had been stayed pending the appeal, and have now resumed.

Nexium Consumer litigation

As previously disclosed, in July 2015, the Delaware Superior Court granted AstraZeneca's motion to dismiss and entered judgment in a putative class action alleging that AstraZeneca's promotion, advertising and pricing of *Nexium* to physicians, consumers and third party payers was unfair, unlawful and deceptive. In April 2016, the Delaware Supreme Court affirmed the dismissal.

Toprol-XL (metoprolol succinate)

As previously disclosed, in March 2015, AstraZeneca was served with a state court complaint filed by the Attorney General for the State of Louisiana alleging that, in connection with enforcement of its patents for *Toprol-XL*, it had engaged in unlawful monopolisation and unfair trade practices, causing the state government to pay increased prices for *Toprol-XL*. In February 2016, the Louisiana state court heard oral argument on AstraZeneca's motion to dismiss and ordered the dismissal of the complaint with prejudice and judgment in AstraZeneca's favour.

Matters disclosed in respect of the second quarter of 2016 and to 28 July 2016.

Patent litigation

Byetta (exenatide)

US patent proceedings

As previously disclosed, AstraZeneca filed a patent infringement lawsuit against Teva Pharmaceuticals USA, Inc. (Teva) in the US District Court for the District of Delaware (the District Court) relating to patents listed in the FDA Orange Book with reference to *Byetta*. In June 2016, AstraZeneca settled the patent litigation against Teva. The District Court entered a consent judgment which will enjoin Teva from launching its proposed exenatide product until 15 October 2017, subject to regulatory approval. Patent infringement proceedings against Amneal Pharmaceuticals LLC are ongoing, with trial scheduled for December 2017.

Crestor (rosuvastatin)

US patent proceedings

As previously disclosed, in February 2016, the US District Court for the District of South Carolina granted AstraZeneca's motions for summary judgment and dismissed two consolidated patent infringement lawsuits filed by co-plaintiffs Medical University of South Carolina Foundation for Research Development and Charleston Medical Therapeutics (together, CMT) relating to the sale of *Crestor*, which CMT appealed. In July 2016, AstraZeneca and CMT jointly filed a stipulation requesting the appellate court to dismiss CMT's appeal.

Patent proceedings outside the US

As previously disclosed, in Australia, AstraZeneca was unsuccessful in defending the validity of certain *Crestor* patents, at trial and on appeal. The patent litigation concluded in September 2015. A provision was taken in Q4 2015 in respect of claims from generic entities which were prevented by court order from launching their products in Australia before AstraZeneca's patents were subsequently found to be invalid. In April 2016, AstraZeneca was notified that the Commonwealth of Australia also intends to pursue a claim against AstraZeneca in relation to alleged losses it suffered in connection with the same patent litigation and AstraZeneca has updated its provisions accordingly.

As previously disclosed, in the Netherlands, in April 2014, AstraZeneca received a writ of summons from Resolution Chemicals Ltd. (Resolution) alleging partial invalidity and non-infringement of the supplementary protection certificate (SPC) related to the *Crestor* substance patent. In July 2015, the District Court of the Hague determined that the SPC does not extend to zinc salts of rosuvastatin and that Resolution's rosuvastatin zinc product does not infringe the SPC. In February 2016, the Court of Appeal of the Hague overturned the decision and found that Resolution's product does infringe the SPC. Resolution has appealed. The hearing has been scheduled for 16 December 2016.

In France, in February 2016, Biogaran S.A.S. (Biogaran) obtained a marketing authorisation for its rosuvastatin zinc product. In April 2016, AstraZeneca and Shionogi Seiyaku Kabushiki Kaisha (Shionogi) sought a preliminary injunction to prevent Biogaran from launching its product. On 4 July 2016, the Paris Court of First Instance declined to issue a preliminary injunction. AstraZeneca and Shionogi have appealed.

As previously disclosed, in Japan, in March 2015, an individual filed a patent invalidation request with the Japanese Patent Office (JPO) in relation to the *Crestor* substance patent. On 13 July 2016, the JPO dismissed the request.

Faslodex (fulvestrant)

US patent proceedings

As previously disclosed, AstraZeneca has filed patent infringement lawsuits in the US District Court in New Jersey (the District Court) relating to four patents listed in the FDA Orange Book with reference to *Faslodex* after AstraZeneca received seven Paragraph IV notices relating to six ANDAs seeking FDA approval to market generic versions of *Faslodex* prior to the expiration of AstraZeneca's patents. In July 2016, AstraZeneca settled one of these, the lawsuit brought against Sandoz, Inc (Sandoz), and the District Court entered a consent judgment, which includes an injunction preventing Sandoz from launching a generic fulvestrant product until 25 March 2019, or earlier in some circumstances. Trial against two other defendants commenced on 11 July 2016 and is scheduled to reconvene on 1 August 2016.

In July 2016, AstraZeneca was served with four petitions for inter parties review by the Patent Trial and Appeal Board relating to each of the four Orange Book-listed patents.

Onglyza (saxagliptin) and Kombiglyze (saxagliptin and metformin)

US patent proceedings

In May 2016, Apotex Inc. and Apotex Corp. (collectively Apotex) sent a notice that it had submitted an ANDA for saxagliptin hydrochloride 2.5mg and 5mg tablets containing a Paragraph IV Certification alleging that US Patent No. RE44,186 (the '186 Patent), listed in the FDA Orange Book with reference to *Onglyza* and *Kombiglyze XR*, is invalid and/or will not be infringed by the products as described in its ANDA. In July 2016, AstraZeneca initiated patent infringement proceedings asserting the '186 Patent in the US District Court for the District of Delaware against Apotex.

In June 2016, Teva Pharmaceuticals USA, Inc., Amneal Pharmaceuticals, LLC, Actavis Laboratories FL, Inc., and Sun Pharma Global FZE each sent notices that they had submitted ANDAs for saxagliptin hydrochloride and metformin hydrochloride 2.5mg/1000mg, 5mg/1000mg, and 5mg/500mg tablets containing a Paragraph IV Certification alleging that US Patent No. 9,339,472 (the '472 Patent) listed in the FDA Orange Book with reference to *Kombiglyze XR*, is invalid, unenforceable and/or will not be infringed by the products as described in their ANDAs.

As previously disclosed, in April 2016, Mylan Pharmaceuticals, Inc. (Mylan) filed a petition for rehearing *en banc* (the Petition) of a March 2016 decision by the US Court of Appeals for the Federal Circuit (the Federal Circuit) affirming a decision by the US District Court for the District of Delaware that denied Mylan's motion to dismiss for lack of jurisdiction. In June 2016, the Federal Circuit denied the Petition.

As previously disclosed, in January 2016, Mylan filed a Request for Rehearing with the US Patent and Trademark Office (USPTO) seeking reconsideration of a December 2015 decision by the USPTO denying institution of an *inter partes* review challenging the validity of the '186 Patent (the Mylan IPR). In May 2016, the USPTO instituted the Mylan IPR. Following institution of the Mylan IPR, Wockhardt Bio AG, Amneal Pharmaceuticals LLC, Sun Pharmaceuticals Industries Ltd., Sun Pharma Global FZE, Teva Pharmaceuticals USA, Inc., and Aurobindo Pharma Ltd. also filed petitions for *inter partes* review challenging the validity of the '186 Patent and have sought to join the Mylan IPR.

Seroquel XR (quetiapine fumarate)

Patent proceedings outside the US

In Spain, in May 2016, the Supreme Court affirmed a decision from October 2013 which found the *Seroquel XR* formulation patent invalid. The generic challengers were Accord Healthcare S.L.U. and Sandoz Farmaceutica S.A.

In Sweden, in May 2016, following a challenge to the validity of the formulation patent covering *Seroquel XR* by Sandoz A/S, the Stockholm District Court found the *Seroquel XR* formulation patent invalid.

In Denmark, in June 2016, following a challenge to the validity of the formulation patent covering *Seroquel XR* by Teva Denmark A/S and Accord Healthcare Ltd., the Danish Maritime and Commercial High Court found the *Seroquel XR* formulation patent invalid.

As previously disclosed, in France, in April 2015, Mylan SAS (Mylan) brought a patent invalidation action against AstraZeneca's French designation of the *Seroquel XR* formulation patent. In July 2016, the tribunal de grande instance de Paris found the *Seroquel XR* formulation patent invalid.

In various countries in Europe generic entities have claimed, or could claim, damages relating to preliminary injunctions issued in those countries that prevented generic *Seroquel XR* sales by those entities. A provision has been taken.

Product liability litigation

Byetta/Bydureon (exenatide)

As previously disclosed, Amylin Pharmaceuticals, LLC, a wholly owned subsidiary of AstraZeneca, and/or AstraZeneca are among multiple defendants in various lawsuits filed in federal and state courts in the US involving claims of physical injury from treatment with *Byetta* and/or *Bydureon*. The lawsuits allege several types of injuries including pancreatitis, pancreatic cancer, thyroid cancer, and kidney cancer. A multi-district litigation has been established in the US District Court for the Southern District of California (the District Court) in regard to the alleged pancreatic cancer cases in federal courts. Further, a co-ordinated proceeding has been established in Los Angeles, California in regard to the various lawsuits in California state courts.

In November 2015, the District Court granted the defendants' motion for summary judgment and dismissed all claims alleging pancreatic cancer that accrued prior to 11 September 2015. A similar motion was granted in favour of the defendants in the California state co-ordinated proceeding, and judgment was entered in May 2016. The plaintiffs have appealed both rulings.

As previously disclosed, a single case was pending in Alabama state court and is now resolved.

Crestor (rosuvastatin calcium)

AstraZeneca is defending a number of lawsuits alleging multiple types of injuries caused by the use of *Crestor*, including diabetes mellitus, various cardiac injuries, rhabdomyolysis, and/or liver and kidney injuries. The claims of approximately 600 plaintiffs, comprising approximately 100 California residents and approximately 500 non-California residents, were aggregated in one co-ordinated proceeding in Los Angeles, California. The claims of approximately 600 additional non-California plaintiffs were also pending in California state court. In October 2014, the co-ordination judge dismissed the claims of the non-California plaintiffs whose claims were in the co-ordinated proceeding. The plaintiffs appealed the October 2014 order dismissing the non-California plaintiffs from the proceeding. In July 2016, the Court of Appeal in California dismissed the plaintiffs' appeal, effectively dismissing the claims of all of the non-California residents from California state court, leaving the option of re-filing in the plaintiffs' home states. The claims of approximately 80 plaintiffs remain pending in California state court.

Farxiga (dapagliflozin)

As previously disclosed, AstraZeneca has been named as one of multiple defendants in a lawsuit filed in the US District Court for the Western District of Kentucky involving one plaintiff claiming physical injury, including diabetic ketoacidosis and kidney failure, from treatment with *Farxiga*. Since then, cases with similar allegations have been filed in three additional jurisdictions. Motions to dismiss are pending in the Western District of Kentucky and one other jurisdiction.

Onglyza/Kombiglyze (saxagliptin)

AstraZeneca is defending various lawsuits filed in state and federal courts in the US involving multiple plaintiffs claiming injury from the treatment with either *Onglyza* or *Kombiglyze*. In May 2016, a federal judge in California granted AstraZeneca's motion for summary judgment and dismissed the claims of 14 of these plaintiffs who alleged injuries including pancreatic cancer. The previously disclosed lawsuit, filed on behalf of approximately 50 plaintiffs alleging heart failure, cardiac failure and/or death resulting from treatment with *Onglyza/Kombiglyze* remains pending.

Synagis (palivizumab)

AstraZeneca and MedImmune have been named as defendants in a lawsuit filed in the US District Court for the Middle District of Louisiana involving two plaintiffs alleging wrongful death from treatment with *Synagis*. A motion to dismiss is pending.

Commercial litigation

Nexium/Prilosec trademark litigation

As previously disclosed, AstraZeneca filed separate complaints in the US District Court for the District of Delaware against Camber Pharmaceuticals, Inc. (Camber) and Dr. Reddy's Laboratories, Inc. (Dr. Reddy's) to enforce certain AstraZeneca trademark rights related to *Nexium* and *Prilosec*. The Delaware District Court issued preliminary injunctions against Camber's and Dr. Reddy's sales of generic esomeprazole magnesium in purple capsules. The Camber action has been settled through negotiation and, as part of the settlement, the Delaware District Court entered a Consented Judgment of Permanent Injunction and Other Relief on 31 March 2016 in favour of AstraZeneca. Dr. Reddy's filed its own separate claims against AstraZeneca in both the Delaware District Court and the US District Court for the District of New Jersey. The New Jersey District Court has determined that the Delaware action should proceed first.

Toprol-XL (metoprolol succinate)

As previously disclosed, in March 2015, AstraZeneca was served with a state court complaint filed by the Attorney General for the State of Louisiana alleging that, in connection with enforcement of its patents for *Toprol-XL*, it had engaged in unlawful

monopolisation and unfair trade practices, causing the state government to pay increased prices for *Toprol-XL*. In February 2016, the Louisiana state court granted AstraZeneca's motion to dismiss the complaint with prejudice and judgment in AstraZeneca's favour. The State of Louisiana has appealed this decision.

Pearl Therapeutics

AstraZeneca has been served with a complaint filed in Delaware State court by the former shareholders of Pearl Therapeutics, Inc. (Pearl) that alleges, among other things, breaches of contractual obligations relating to a 2013 merger agreement between AstraZeneca and Pearl.

Crestor Citizen's Petition

On 31 May 2016, AstraZeneca filed a Citizen's Petition with the FDA requesting that the Agency not approve any pending generic ANDAs for rosuvastatin until the expiration of paediatric orphan exclusivity for *Crestor*. On 27 June 2016, AstraZeneca filed its Complaint for Declaratory and Injunctive Relief and an Application for a Temporary Restraining Order (TRO) with the US District Court for the District of Columbia requesting that the Court prohibit the FDA from granting final approval to any pending ANDAs for generic versions of *Crestor* until the expiration of paediatric orphan exclusivity. On 19 July 2016, the Court denied AstraZeneca's application for a TRO, but provided for FDA to produce to AstraZeneca a copy of the administrative record.

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8 PRODUCT ANALYSIS - H1 2016

	World		US		Europe		Established ROW		Emerging Markets	
	H1 2016 \$m	CER %	H1 2016 \$m	CER %	H1 2016 \$m	CER %	H1 2016 \$m	CER %	H1 2016 \$m	CER %
Respiratory & Autoimmunity:										
<i>Symbicort</i>	1,552	(6)	681	(5)	466	(18)	196	-	209	25
<i>Pulmicort</i>	549	10	106	(2)	54	(18)	40	(2)	349	23
<i>Tudorza/Eklira</i>	87	4	41	(9)	41	17	4	n/m	1	n/m
<i>Dalirespl/Daxas</i>	71	n/m	66	n/m	4	n/m	-	-	1	n/m
<i>Duaklir</i>	30	n/m	-	-	28	n/m	1	n/m	1	n/m
Others	144	13	7	(30)	51	13	17	55	69	12
Total Respiratory & Autoimmunity	2,433	1	901	(2)	644	(11)	258	2	630	23
Cardiovascular & Metabolic Diseases:										
<i>Onglyza</i>	402	6	212	-	73	4	37	22	80	16
<i>Brilinta</i>	395	48	159	57	125	17	20	29	91	106
<i>Farxiga</i>	376	88	209	82	89	72	25	127	53	135
<i>Bydureon</i>	291	11	234	5	50	43	5	67	2	-
<i>Byetta</i>	138	(19)	89	(26)	25	(17)	10	-	14	45
Legacy:										
<i>Crestor</i>	2,082	(15)	1,004	(27)	438	(4)	286	(2)	354	9
<i>Seloken/Toprol-XL</i>	374	7	53	10	44	(6)	5	(29)	272	9
<i>Atacand</i>	160	(11)	21	17	49	(6)	10	(29)	80	(16)
Others	242	(23)	16	(54)	64	(11)	25	(20)	137	(22)
Total Cardiovascular & Metabolic Diseases	4,460	(2)	1,997	(11)	957	4	423	2	1,083	9
Oncology:										
<i>Iressa</i>	270	2	10	n/m	61	(8)	65	(6)	134	3
<i>Tagrisso</i>	143	n/m	103	n/m	25	n/m	15	n/m	-	-
<i>Lynparza</i>	98	n/m	62	n/m	32	n/m	-	-	4	n/m
Legacy:										
<i>Faslodex</i>	401	23	211	28	113	13	30	16	47	36
<i>Zoladex</i>	382	(3)	19	36	80	(3)	130	(3)	153	(5)
<i>Casodex</i>	125	(9)	2	n/m	13	(13)	56	(20)	54	2
<i>Arimidex</i>	119	(2)	10	43	18	(28)	35	(18)	56	15
Others	48	(33)	-	-	3	(77)	32	3	13	(12)
Total Oncology	1,586	18	417	85	345	12	363	(3)	461	5
Infection & Neuroscience:										
<i>Nexium</i>	1,025	(18)	294	(39)	127	(10)	237	(15)	367	1
<i>Seroquel XR</i>	427	(17)	306	(13)	76	(32)	10	(29)	35	(9)
<i>Synagis</i>	271	-	163	2	108	(2)	-	-	-	-
<i>Losec/Prilosec</i>	145	(17)	5	(58)	41	(16)	27	(32)	72	(5)
<i>Movantik/Moventig</i>	40	n/m	40	n/m	-	-	-	-	-	-
<i>FluMist/Fluenz</i>	11	(48)	11	(48)	-	-	-	-	-	-
Others	636	(11)	75	(29)	169	(6)	127	(3)	265	(11)
Total Infection & Neuroscience	2,555	(13)	894	(21)	521	(12)	401	(13)	739	(5)
Total Product Sales	11,034	(2)	4,209	(7)	2,467	(3)	1,445	(4)	2,913	7

9 PRODUCT ANALYSIS – Q2 2016

	World		US		Europe		Established ROW		Emerging Markets	
	Q2 2016 \$m	CER %	Q2 2016 \$m	CER %	Q2 2016 \$m	CER %	Q2 2016 \$m	CER %	Q2 2016 \$m	CER %
Respiratory & Autoimmunity:										
<i>Symbicort</i>	803	(4)	359	(4)	235	(17)	105	2	104	33
<i>Pulmicort</i>	239	6	50	(11)	25	(17)	22	-	142	21
<i>Tudorza/Eklira</i>	48	(13)	24	(33)	20	18	3	50	1	n/m
<i>Dalirespl/Daxas</i>	40	25	35	9	4	n/m	-	-	1	n/m
<i>Duaklir</i>	17	n/m	-	-	16	n/m	1	-	-	-
Others	79	34	3	40	32	33	14	n/m	30	25
Total Respiratory & Autoimmunity	1,226	1	471	(7)	332	(7)	145	8	278	26
Cardiovascular & Metabolic Diseases:										
<i>Onglyza</i>	191	(7)	88	(22)	40	14	19	6	44	12
<i>Brilinta</i>	214	51	89	62	65	16	10	38	50	104
<i>Farxiga</i>	211	65	115	47	48	71	16	100	32	127
<i>Bydureon</i>	156	11	126	9	27	42	3	50	-	(133)
<i>Byetta</i>	76	(6)	47	(11)	15	7	5	(17)	9	11
Legacy:										
<i>Crestor</i>	926	(29)	368	(52)	226	(1)	161	1	171	5
<i>Seloken/Toprol-XL</i>	189	8	32	52	22	(4)	3	(25)	132	4
<i>Atacand</i>	89	(5)	12	71	25	9	6	(14)	46	(18)
Others	116	(25)	11	(27)	34	-	16	-	55	(38)
Total Cardiovascular & Metabolic Disease	2,168	(11)	888	(27)	502	9	239	5	539	3
Oncology:										
<i>Iressa</i>	135	5	6	n/m	27	(19)	35	(6)	67	15
<i>Tagrisso</i>	92	n/m	58	n/m	19	n/m	15	n/m	-	-
<i>Lynparza</i>	54	n/m	34	89	18	n/m	-	-	2	n/m
Legacy:										
<i>Faslodex</i>	211	23	112	37	57	8	16	15	26	15
<i>Zoladex</i>	204	(4)	9	13	41	2	68	(6)	86	(7)
<i>Casodex</i>	63	(10)	2	100	6	(14)	30	(18)	25	(4)
<i>Arimidex</i>	62	(2)	6	50	10	(17)	19	(19)	27	11
Others	27	(30)	-	n/m	1	(60)	19	6	7	(22)
Total Oncology	848	20	227	89	179	16	202	1	240	4
Infection & Neuroscience:										
<i>Nexium</i>	562	(13)	163	(36)	67	(3)	142	(8)	190	13
<i>Seroquel XR</i>	225	(14)	162	(12)	41	(20)	5	(29)	17	(13)
<i>Synagis</i>	27	(59)	3	n/m	24	(66)	-	-	-	-
<i>Losec/Prilosec</i>	70	(16)	3	(40)	20	(17)	14	(32)	33	(5)
<i>Movantik/Moventig</i>	23	n/m	23	n/m	-	-	-	-	-	-
<i>FluMist/Fluenz</i>	6	(57)	6	(57)	-	-	-	-	-	-
Others	314	(12)	17	(71)	84	(13)	62	(13)	151	12
Total Infection & Neuroscience	1,227	(14)	377	(27)	236	(24)	223	(12)	391	9
Total Product Sales	5,469	(5)	1,963	(17)	1,249	(2)	809	(1)	1,448	9

Shareholder Information

Announcements

Announcement of nine months and third quarter 2016 results	10 November 2016
Announcement of full year and fourth quarter 2016 results	2 February 2017

Future dividends will normally be paid as follows:

First interim	Announced with half year and second quarter results and paid in September
Second interim	Announced with full year and fourth quarter results and paid in March

The record date for the first interim dividend for 2016, payable on 12 September 2016, will be 12 August 2016. Ordinary Shares listed in London and Stockholm will trade ex-dividend from 11 August 2016. American Depositary Shares listed in New York will trade ex-dividend from 10 August 2016.

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In order, among other things, to utilise the 'safe harbour' provisions of the US Private Securities Litigation Reform Act 1995, we are providing the following cautionary statement: This document contains certain forward-looking statements with respect to the operations, performance and financial condition of the Group, including, among other things, statements about expected revenues, margins, earnings per share or other financial or other measures. Although we believe our expectations are based on reasonable assumptions, any forward-looking statements, by their very nature, involve risks and uncertainties and may be influenced by factors that could cause actual outcomes and results to be materially different from those predicted. The forward-looking statements reflect knowledge and information available at the date of preparation of this document and AstraZeneca undertakes no obligation to update these forward-looking statements. We identify the forward-looking statements by using the words 'anticipates', 'believes', 'expects', 'intends' and similar expressions in such statements. Important factors that could cause actual results to differ materially from those contained in forward-looking statements, certain of which are beyond our control, include, among other things: the loss or expiration of, or limitations to, patents, marketing exclusivity or trademarks, or the risk of failure to obtain and enforce patent protection; the risk of substantial adverse litigation/government investigation claims and insufficient insurance coverage; effects of patent litigation in respect of IP rights; exchange rate fluctuations; the risk that R&D will not yield new products that achieve commercial success; the risk that strategic alliances and acquisitions, including licensing and collaborations, will be unsuccessful; the impact of competition, price controls and price reductions; taxation risks; the risk of substantial product liability claims; the impact of any delays in the manufacturing, distribution and sale of any of our products; the impact of any failure by third parties to supply materials or services; the risk of failure of outsourcing; the risks associated with manufacturing biologics; the risk of delay to new product launches; the difficulties of obtaining and maintaining regulatory approvals for products; the risk of failure to adhere to applicable laws, rules and regulations; the risk of failure to adhere to applicable laws, rules and regulations relating to anti-competitive behaviour; the risk that new products do not perform as we expect; failure to achieve strategic priorities or to meet targets or expectations; the risk of an adverse impact of a sustained economic downturn; political and socio-economic conditions; the risk of environmental liabilities; the risk of occupational health and safety liabilities; the risk associated with pensions liabilities; the risk of misuse of social medial platforms and new technology; the risks associated with developing our business in emerging markets; the risk of illegal trade in our products; the risks from pressures resulting from generic competition; the risk of failure to successfully implement planned cost reduction measures through productivity initiatives and restructuring programmes; economic, regulatory and political pressures to limit or reduce the cost of our products; the risk that regulatory approval processes for biosimilars could have an adverse effect on future commercial prospects; the impact of failing to attract and retain key personnel and to successfully engage with our employees; the impact of increasing implementation and enforcement of more stringent anti-bribery and anti-corruption legislation; and the risk of failure of information technology and cybercrime. Nothing in this document/presentation/webcast should be construed as a profit forecast.