

AstraZeneca PLC  
10 November 2016 07:00

**Year-To-Date and Q3 2016 Results**  
**Performance in line with our expectations**

**Financial Summary**

	YTD 2016			Q3 2016		
	\$m	% change		\$m	% change	
		CER <sup>1</sup>	Actual		CER	Actual
Total Revenue	17,417	(3)	(5)	5,699	(4)	(4)
<i>Product Sales</i>	16,059	(6)	(8)	5,025	(14)	(14)
<i>Externalisation Revenue</i>	1,358	56	55	674	n/m	n/m
Reported Operating Profit	2,369	(26)	(22)	1,028	(29)	(12)
Core Operating Profit <sup>2</sup>	4,695	(13)	(12)	1,696	(13)	(2)
Reported Earnings Per Share (EPS)	\$1.31	(26)	(18)	\$0.80	4	32
Core EPS	\$3.10	(10)	(7)	\$1.32	12	28

**The Reported and Core EPS performance in Q3 2016 included a non-recurring tax benefit of \$0.36, resulting from agreements on transfer pricing arrangements between various tax authorities.**

- Total Revenue declined by 3% in the year to date to \$17,417m, reflecting a decline in Product Sales that was driven by the entry in the US of multiple *Crestor* generic medicines
- Continued good progress on cost control:
  - Reported and Core R&D expenses grew by 4% to \$1,402m and were stable at \$1,337m in the third quarter, respectively
  - Reported and Core SG&A expenses reduced by 8% to \$2,403m and by 12% to \$1,892m in the third quarter, respectively
- Reported EPS declined by 26% in the year to date, reflecting the fall in Product Sales. Core EPS declined by 10%, reflecting the phasing of Other Operating Income towards the final quarter of the year
- Full-year financial guidance remains unchanged

**Commercial Highlights**

The Growth Platforms grew by 6% in the year to date (Q3 2016: Up by 3%):

- Emerging Markets: 6% growth supported by China (up by 10%); Latin America sales declined by 11%, impacted by the reduction of activities in Venezuela
- Diabetes: Growth of 13%. *Farxiga* became the Company's largest-selling Diabetes medicine. Slower Diabetes growth of 6% in the third quarter, reflecting an expected decline in the sales of *Onglyza*
- Respiratory: A decline of 2%, with marked declines in the sale of *Symbicort* in the US and Europe, reflecting the competitive environment and a Q3 rebate true-up in the US
- *Brilinta*: Growth of 39%. Deceleration in the third quarter, a function of wholesaler stocking in the comparative period
- New Oncology: Strong sales of \$197m in Q3 2016 (H1: \$251m), driven by *Tagrisso* and *Lynparza*

**Achieving Scientific Leadership: Progress Since The Last Results Announcement**

Regulatory Approvals	- <i>Brilinta</i> - cardiovascular (CV) disease (JP)
Regulatory Submissions* /Acceptances	- <i>Faslodex</i> - breast cancer (1st line) (JP)* - <i>Tagrisso</i> - lung cancer (CN)* - ZS-9 - hyperkalaemia (US)
Positive Phase III Data Readouts	- <i>Lynparza</i> - ovarian cancer (2nd line) - <i>Farxiga</i> + <i>Bydureon</i> - type-2 diabetes - benralizumab - severe, uncontrolled asthma
Other Key Developments	- Priority Review Designation: <i>Tagrisso</i> (CN) - Fast Track Designation: AZD3293 - Alzheimer's disease (US)

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

“The performance in the third quarter was in line with our expectations, reflecting the transitional impact from the first full quarter of generic competition to *Crestor* in the US. We sharpened significantly our focus on our three therapy areas, by prioritising our portfolio through externalisation and divestments. This focus, underpinned by our productivity initiatives, supported the rapid reduction in SG&A costs. This enabled our increased investment in Oncology, as well as in China and launched new medicines in key markets.

Our late-stage pipeline continued to advance at a pace we could not have anticipated three years ago, as we saw with recent positive results for *Tagrisso* in lung cancer, *Lynparza* in ovarian cancer and our first respiratory biologic medicine, benralizumab, in severe, uncontrolled asthma.

Importantly, we are entering an intensive period of news flow over the next twelve months, in particular revealing the potential of our Immuno-Oncology and targeted medicines. Our focus on scientific excellence keeps us on track with our goals, as we approach an inflection point of a pipeline designed to transform our company and the lives of patients.”

**FY 2016 Guidance**

Guidance for FY 2016 is unchanged and is shown at CER<sup>1</sup>:

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.

Core R&D costs are now expected to be ahead of those in FY 2015. The Company will materially reduce 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 year to date and the Company’s published currency sensitivities, there is expected to be an immaterial impact from currency movements on Total Revenue in FY 2016. Core EPS is 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.

**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.

### Pipeline: Forthcoming Major News Flow

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 from the pipeline.

Q4 2016	<p><i>Tagrisso</i> - lung cancer: Regulatory submission (US, EU) (AURA3)</p> <p>roxadustat - anaemia: Rolling regulatory submission (CN)</p> <p>benralizumab - severe, uncontrolled asthma: Regulatory submission (US, EU)</p>
H1 2017	<p><i>Faslodex</i> - breast cancer (1st line): Regulatory decision (JP); regulatory submission (US, EU)</p> <p><i>Lynparza</i> - breast cancer: Data readout</p> <p><i>Lynparza</i> - ovarian cancer (2nd line): Regulatory submission</p> <p>durva + treme - lung cancer (MYSTIC): Data readout</p> <p>durva + treme - lung cancer (ARCTIC): Data readout</p> <p>durva + treme - HNSCC* (CONDOR): Data readout, regulatory submission (US) (Phase II)*</p> <p>acalabrutinib - blood cancer: Data readout, regulatory submission (US) (Phase II)*</p> <p>saxagliptin/dapagliflozin - type-2 diabetes: Regulatory decision (US)</p> <p><i>Bydureon</i> - autoinjector: Regulatory submission (US)</p> <p>ZS-9 - hyperkalaemia: Regulatory decision (US, EU)</p> <p>benralizumab - severe, uncontrolled asthma: Regulatory submission (JP)</p> <p>brodalumab - psoriasis: Regulatory decision (US, EU)</p>
H2 2017	<p><i>Lynparza</i> - ovarian cancer (1st line): Data readout</p> <p><i>Lynparza</i> - breast cancer: Regulatory submission</p> <p><i>Tagrisso</i> - lung cancer: Regulatory decision (CN)</p> <p><i>Tagrisso</i> - lung cancer (1st line): Data readout</p> <p>durvalumab - lung cancer (PACIFIC): Data readout, regulatory submission (US)</p> <p>durva + treme - lung cancer (MYSTIC): Regulatory submission</p> <p>durva + treme - lung cancer (ARCTIC): Regulatory submission</p> <p>durva + treme - HNSCC# (KESTREL): Data readout</p> <p>moxetumomab - leukaemia: Data readout</p> <p>roxadustat - anaemia: Data readout (AstraZeneca-sponsored trial)</p> <p>tralokinumab - severe, uncontrolled asthma: 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.*

*#Head and Neck Squamous Cell Carcinoma*

## Results Presentation

A conference call and webcast for investors and analysts, hosted by management, will begin at midday UK time today. [Click here](#) to register for the webcast, with further details available via [astrazeneca.com/investors](http://astrazeneca.com/investors).

## Reporting Calendar

The Company intends to publish its full-year and fourth-quarter financial results on 2 February 2017.

## 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 main therapy areas - Oncology, Cardiovascular & Metabolic Diseases and Respiratory. The Company also is selectively active in the areas of autoimmunity, neuroscience and infection. 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](http://www.astrazeneca.com) and follow us on Twitter @AstraZeneca.

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## 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 nine and three-month periods to 30 September 2016 (the year to date (YTD) and the third quarter, respectively) compared to the nine and three-month periods to 30 September 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

	YTD 2016		Q3 2016	
	\$m	% CER change	\$m	% CER change
Product Sales	16,059	(6)	5,025	(14)
Externalisation Revenue	1,358	56	674	n/m
<b>Total Revenue</b>	<b>17,417</b>	<b>(3)</b>	<b>5,699</b>	<b>(4)</b>

Based on actual exchange rates, Total Revenue declined by 5% in the year to date, reflecting the strength of the US dollar.

### Product Sales

The level of decline in Product Sales was driven by the US market entry of multiple *Crestor* generic medicines in the third quarter, as well as the ongoing impact of *Nexium* generic medicines in the US. Q3 2016 sales of *Crestor* and *Nexium* in the US declined by 82% and 50%, respectively. Overall US Product Sales declined by 17% in the year to date (Q3 2016: Down by 35%), with Product Sales in Europe declining by 2% (Q3 2016: Down by 1%).

Within Product Sales, the Growth Platforms grew by 6% in the year to date, representing 62% of Total Revenue:

Growth Platforms	YTD 2016		Q3 2016	
	Product Sales (\$m)	% CER change	Product Sales (\$m)	% CER change
Emerging Markets	4,308	6	1,395	3
Respiratory	3,543	(2)	1,110	(8)
Diabetes	1,829	13	606	6
Japan	1,593	(2)	595	-
<i>Brilinta</i>	603	39	208	25
New Oncology <sup>1</sup>	448	n/m	197	n/m
<b>Total<sup>2</sup></b>	<b>10,763</b>	<b>6</b>	<b>3,584</b>	<b>3</b>

<sup>1</sup>New Oncology comprises Lynparza, Iressa (US) and Tagrisso

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

## Externalisation Revenue

Externalisation Revenue recognised in the year to date amounted to \$1,358m. Highlights included:

Medicine	Partner	Region	\$m
Anaesthetics	Aspen Global Incorporated (Aspen) - initial revenue	Global (excl. US)	520
<i>Plendil</i>	China Medical System Holdings Ltd - commercialisation rights - initial revenue	China	298
Tralokinumab - atopic dermatitis	LEO Pharma A/S (LEO Pharma) - initial revenue	Global	115
AZD3293	Eli Lilly and Company (Lilly) - milestone revenue	Global	100
<i>Nexium</i> OTC 20mg	Pfizer Inc. (Pfizer) - milestone revenue	Global	93
<i>Moventig</i>	ProStrakan Group plc (ProStrakan) - commercialisation rights - initial and milestone revenue	EU	78

Examples of sustainable future Externalisation Revenue streams are shown below:

Announcement Date	Medicine	Partner	Region	Externalisation Revenue
<a href="#">1 July 2016</a>	Tralokinumab - atopic dermatitis	LEO Pharma	Global	<ul style="list-style-type: none"> <li>Initial \$115m milestone</li> <li>Up to \$1bn in commercially-related milestones</li> <li>Up to mid-teen tiered percentage royalties on sales</li> </ul>
<a href="#">9 June 2016</a>	Anaesthetics	Aspen	Global (excl. US)	<ul style="list-style-type: none"> <li>Initial \$520m milestone</li> <li>Up to \$250m in sales-related revenue</li> <li>Double-digit percentage trademark royalties on sales</li> </ul>
<a href="#">2 September 2015</a>	<i>FluMist</i>	Daiichi Sankyo Company, Ltd. (Daiichi Sankyo)	Japan	<ul style="list-style-type: none"> <li>Initial (undisclosed) milestone</li> <li>Sales-related revenue (undisclosed)</li> </ul>
<a href="#">1 September 2015</a>	Brodalumab	Valeant Pharmaceuticals International, Inc. (Valeant)	Global, later amended to US	<ul style="list-style-type: none"> <li>Initial \$100m milestone</li> <li>Pre-launch milestone up to \$170m</li> <li>Sales-related royalties up to \$175m</li> </ul>
<a href="#">19 March 2015</a>	<i>Movantik</i>	Daiichi Sankyo	US	<ul style="list-style-type: none"> <li>Initial \$200m milestone</li> <li>Up to \$625m in Product Sales-related revenue</li> </ul>

## Product Sales

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

	YTD 2016				Q3 2016		
	\$m	% of Total	% Change CER Actual		\$m	% Change CER Actual	
<b>Oncology</b>							
<i>Iressa</i>	395	2	(3)	(5)	125	(13)	(11)
<i>Tagrisso</i>	276	2	n/m	n/m	133	n/m	n/m
<i>Lynparza</i>	156	1	n/m	n/m	58	111	107
Legacy:							
<i>Faslodex</i>	608	4	19	17	207	11	11
<i>Zoladex</i>	581	4	(4)	(6)	199	(5)	(5)
<i>Casodex</i>	187	1	(9)	(8)	62	(8)	(5)
<i>Arimidex</i>	175	1	(6)	(8)	56	(14)	(13)
Others	75	-	(32)	(29)	27	(29)	(21)
<b>Total Oncology</b>	<b>2,453</b>	<b>15</b>	<b>17</b>	<b>16</b>	<b>867</b>	<b>17</b>	<b>19</b>
<b>Cardiovascular &amp; Metabolic Diseases</b>							
<i>Brilinta</i>	603	4	39	36	208	25	22
<i>Farxiga</i>	596	4	79	75	220	64	63
<i>Onglyza</i>	571	4	(2)	(4)	169	(16)	(17)
<i>Bydureon</i>	436	3	3	3	145	(10)	(10)
<i>Byetta</i>	199	1	(18)	(18)	61	(15)	(15)
Legacy:							
<i>Crestor</i>	2,770	17	(24)	(25)	688	(44)	(44)
<i>Seloken/Toprol-XL</i>	559	3	8	2	185	12	8
<i>Atacand</i>	234	1	(9)	(15)	74	(3)	(6)
Others	337	2	(24)	(27)	95	(28)	(29)
<b>Total Cardiovascular &amp; Metabolic Diseases</b>	<b>6,305</b>	<b>39</b>	<b>(8)</b>	<b>(10)</b>	<b>1,845</b>	<b>(21)</b>	<b>(21)</b>
<b>Respiratory</b>							
<i>Symbicort</i>	2,249	14	(10)	(11)	697	(17)	(18)
<i>Pulmicort</i>	773	5	8	4	224	4	1
<i>Tudorza/Eklira</i>	134	1	(5)	(6)	47	(17)	(19)
<i>Dalirespl/Daxas</i>	113	1	57	57	42	27	27
<i>Duaklir</i>	44	-	n/m	n/m	14	88	75
Others	230	1	23	19	86	46	41
<b>Total Respiratory</b>	<b>3,543</b>	<b>22</b>	<b>(2)</b>	<b>(4)</b>	<b>1,110</b>	<b>(8)</b>	<b>(10)</b>
<b>Other</b>							
<i>Nexium</i>	1,541	10	(19)	(20)	516	(21)	(20)
<i>Seroquel XR</i>	617	4	(20)	(21)	190	(26)	(26)
<i>Synagis</i>	375	2	(3)	(3)	104	(11)	(11)
<i>Losec/Prilosec</i>	217	1	(15)	(17)	72	(11)	(12)
<i>Movantik/Moventig</i>	65	-	n/m	n/m	25	n/m	n/m
<i>FluMist/Fluenz</i>	37	-	(58)	(62)	26	(61)	(66)
Others	906	6	(15)	(19)	270	(25)	(25)
<b>Total Other</b>	<b>3,758</b>	<b>23</b>	<b>(16)</b>	<b>(18)</b>	<b>1,203</b>	<b>(22)</b>	<b>(22)</b>
<b>Total Product Sales</b>	<b>16,059</b>	<b>100</b>	<b>(6)</b>	<b>(8)</b>	<b>5,025</b>	<b>(14)</b>	<b>(14)</b>

Operating &amp; Financial Review

Corporate &amp; Business Development

Research &amp; Development

Development Pipeline

Interim Financial Statements

## Product Sales Summary

### ONCOLOGY

YTD sales of \$2,453m; up by 17%. Oncology sales represented 15% of Total Product Sales.

#### Iressa (YTD sales of \$395m; down by 3%)

Sales in the US were \$16m as the Company prioritised the launch of *Tagrisso*.

In Europe, sales declined by 5% to \$91m, reflected primarily in lower market shares.

Emerging Markets sales declined by 6% to \$187m. China sales declined by 13% to \$98m, as a result of the price re-set following national reimbursement listing in China that was obtained in June. The price adjustment was partially offset by an expected increase in volume demand.

#### Tagrisso (YTD sales of \$276m)

In the third quarter, sales of *Tagrisso* were higher than *Iressa* sales for the first time. *Tagrisso* became the leading AstraZeneca medicine for the treatment of lung cancer. Regulatory approvals were granted in a number of additional markets, including Korea, Switzerland and Canada; the Company anticipates additional regulatory approvals and reimbursement decisions in due course. To date, *Tagrisso* has received regulatory approval in 41 markets worldwide.

Sales in the US increased by 33% in the third quarter as compared to the second quarter, taking year-to-date sales to \$180m. Sales growth in the third quarter was driven by new patient starts and treatment duration.

On 29 September 2016, a third-party, blood-based companion-diagnostic test for *Tagrisso* was approved in the US, to confirm the presence of a T790M mutation in patients with locally-advanced or metastatic EGFR T790M mutation-positive non-small cell lung cancer (NSCLC), who have been previously treated with EGFR tyrosine kinase inhibitor (TKI) therapy.

After regulatory approval in the EU and Japan earlier in the year, sales in the year to date were \$49m in Europe and \$43m in Japan.

#### Lynparza (YTD sales of \$156m)

*Lynparza* is now available to patients in 30 countries, with regulatory reviews underway in seven additional countries including Singapore, Brazil, and Russia. Almost 4,800 patients have been prescribed *Lynparza* since the US launch in December 2014.

Sales in the US increased by 109% in the year to date to \$96m, primarily driven by longer duration of therapy, as patients stayed on treatment for longer due to efficacy benefits.

Sales in Europe increased to \$56m, following several successful launches.

#### Legacy: Faslodex (YTD sales of \$608m; up by 19%)

Sales in the US in the year to date increased by 23% to \$321m, mainly driven by an expanded label in March 2016 for 2nd-line advanced or metastatic breast cancer, in combination with another recently-approved medicine.

Europe year-to-date sales increased by 11% to \$169m.

An increase in demand in Brazil (sales up by 4% to \$20m) and China (sales up by 114% to \$14m) drove Emerging Markets sales to \$70m, representing an increase of 26%.

#### Legacy: Zoladex (YTD sales of \$581m; down by 4%)

The decline in global sales was attributed to Europe sales (down 5% to \$117m) and Established Rest Of World (ROW) sales (down by 6% to \$199m). This decline in demand was partially offset by favourable sales performances in the US (up by 23% to \$27m) and China (up by 22% to \$105m). Latin America sales, outside of Brazil, declined by 40% in the year to date, reflecting the reduction of AstraZeneca's activities in Venezuela.



## **CARDIOVASCULAR & METABOLIC DISEASES**

YTD sales of \$6,305m; down by 8%. Cardiovascular & Metabolic Diseases sales represented 39% of Total Product Sales.

### **Brilinta (YTD sales of \$603m; up by 39%)**

A slowdown in third-quarter sales growth of 25% to \$208m reflected inventory built by US wholesalers in Q3 2015, during the launch of the 60mg dose; underlying growth remained strong in the period.

Sales in the US in the year to date were \$243m, representing an increase of 43%. The overall performance reflected updated preferred guidelines from the American College of Cardiology and the American Heart Association in the first half of the year; *Brilinta* remained the branded oral anti-platelet market leader in the US. *Brilinta*'s new-to-brand prescription market share was 12.8% at the end of the third quarter, representing an increase of four basis points.

Year-to-date sales of *Brilique* in Europe increased by 15% to \$192m, reflecting indication leadership across a number of markets. In the first half of the year, 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), reflecting the PEGASUS trial.

Emerging Markets year-to-date sales grew by 88% to \$136m, with China representing 48% of Emerging Markets sales at \$65m, despite the medicine not being included on the National Reimbursement Drug List yet. The Company anticipates inclusion in due course. Growth in China was underpinned by strong levels of hospital-listing expansion. Year-to-date sales in the overall Asia-Pacific region increased by 52% to \$30m.

### **Farxiga (YTD sales of \$596m; up by 79%)**

In the year to date, sales of *Farxiga* surpassed those of *Onglyza* and became the leading AstraZeneca medicine for type-2 diabetes.

Sales of *Farxiga* in the US increased by 78% to \$327m in the year to date, primarily reflecting overall market growth and increased market share. Greater emphasis on promotional activity and improved levels of patient access resulted in higher market share. As a consequence, total prescription share grew against the backdrop of a US slowdown in SGLT2 market growth.

Year-to-date sales of *Forxiga* in Europe increased by 58% to \$136m, as the medicine continued to lead the SGLT2 class.

Emerging Markets sales increased by 120% to \$92m, driven by ongoing launches and improved access across all regions. In particular, strong performances were seen in the Asia-Pacific region (up by 124% to \$36m), Brazil (up by 53% to \$19m), and Middle East, Africa & Others (up to \$22m).

### **Onglyza (YTD sales of \$571m; down by 2%)**

Year-to-date sales in the US declined by 6% to \$304m, as the Company prioritised sales and marketing resources towards *Farxiga*. Continued competitive pressures in the DPP-4 class were partially offset by favourable restocking activity, encouraging federal-business sales and lower utilisation of patient-access programmes.

Year-to-date sales in Europe declined by 5% to \$102m. In contrast, sales in Canada (up by 8% to \$39m) and Emerging Markets sales (up by 3% to \$110m) reflected encouraging volume demand.

Sales in Japan to Kyowa Hakko Kirin Co., Ltd (Kyowa), who are responsible for the sale and marketing of *Onglyza*, increased to \$11m.

### **Bydureon/Byetta (YTD sales of \$635m; down by 4%)**

Combined year-to-date US sales for *Bydureon/Byetta* were \$476m. *Bydureon* sales in the US declined by 3% to \$349m, representing 73% of total *Bydureon/Byetta* US sales. Around 75% of sales came from the new dual-chamber pen compared to the previous tray presentation. The decline in *Byetta* sales of 23% to \$127m was attributed to the Company's promotional focus on *Bydureon*. The decline in both *Bydureon* and *Byetta* US sales was attributed to lower market growth, increased competition from new market entrants and the lack of a competitive delivery device. A regulatory submission for the new *Bydureon* autoinjector is anticipated in the US in the first half of 2017.

Year-to-date sales in Europe increased by 12% to \$112m, reflecting the Company's ongoing effort to expand its Diabetes presence. Year-to-date sales of *Byetta* and *Bydureon* in Emerging Markets increased by 31% to \$19m and by 50% to \$4m, respectively. On 10 October 2016, AstraZeneca entered into a strategic collaboration with 3SBio Inc. (3SBio), a leading Chinese biotechnology business, for the rights to commercialise *Byetta* and *Bydureon* in the Chinese market and drive greater access for patients.

Legacy: Crestor (YTD sales of \$2,770m; down by 24%)

In the US, *Crestor* year-to-date sales declined by 45% to \$1,128m, reflecting generic *Crestor* (rosuvastatin) penetration since May 2016. Third-quarter sales declined by 82% to \$124m and reflected the multiple generic *Crestor* medicines that entered the US market from July 2016.

In Europe, year-to-date sales declined by 3% to \$657m, reflecting the increasing prevalence of generic-medicine competition. *Crestor* consolidated its position as the leading statin in Japan, with year-to-date sales growth of 6% to \$392m. Year-to-date sales in China grew by 24% to \$238m, while Russia sales grew by 33% to \$20m.

**RESPIRATORY**

YTD sales of \$3,543m; down by 2%. Respiratory sales represented 22% of Total Product Sales.

Symbicort (YTD sales of \$2,249m; down by 10%)

Year-to-date sales in the US declined by 14% to \$958m. This reflected a Q3 rebate true-up in the US and the competitive environment. These influences were partially offset by volume and market-share growth.

In Europe, year-to-date sales declined by 15% to \$679m, a result of reducing market demand in the class, as well as increased competition from analogue medicines.

In contrast to western markets, year-to-date Emerging Markets sales grew by 11% to \$302m, reflecting sales growth in China of 33% to \$120m, Latin America sales growth of 10% to \$26m and Russia sales growth of 3% to \$25m. Emerging Markets sales in the third quarter, down by 13% to \$93m, were adversely impacted by significant healthcare spending cuts in Saudi Arabia.

Pulmicort (YTD sales of \$773m; up by 8%)

Strong underlying growth in Emerging Markets drove a 20% sales increase to \$501m in the year to date.

Emerging Markets represented 65% of *Pulmicort* sales, which more than offset sales declines in the US, Europe and Established ROW. China sales increased by 21% to \$408m and represented 53% of sales of *Pulmicort*. Volume demand in China reflected the increasing prevalence of acute chronic obstructive pulmonary disease (COPD) and paediatric asthma. AstraZeneca continued its expansion of treatment centres and provided increased access to home-based patient-care systems.

Tudorza/Eklira (YTD sales of \$134m; down by 5%)

Sales in the US declined by 22% to \$61m in the year to date, reflecting adverse market demand and limited Medicare Part D access in the first half of the year. Sales in Europe increased by 14% to \$65m.

Daliresp/Daxas (YTD sales of \$113m; up by 57%)

Sales in the US increased by 40% to \$101m in the year to date, driven primarily by favourable market penetration. US rights were acquired in March 2015 and US sales represented 89% of total global sales in the year to date; European rights were added in May 2016. Since completion, *Daxas* year-to-date sales in Europe amounted to \$10m.

Duaklir (YTD sales of \$44m)

*Duaklir* has been launched successfully in more than 25 countries and sales grew to \$44m in the year to date.

## **OTHER**

YTD sales of \$3,758m; down by 16%. Other sales represented 23% of Total Product Sales.

### Nexium (YTD sales of \$1,541m; down by 19%)

Sales in the US declined by 42% to \$419m in the year to date, reflecting lower demand and inventory destocking, which followed the loss of exclusivity in 2015.

Year-to-date sales in Europe declined by 7% to \$190m, with Emerging Markets sales stable at \$543m. Japan sales declined by 5% to \$312m, reflecting a mandated biennial price reduction, effective from April 2016.

### Seroquel XR (YTD sales of \$617m; down by 20%)

Year-to-date sales of *Seroquel XR* in the US declined by 18% to \$444m. Since 1 November 2016, two generic medicines have had the ability to launch in the US.

Year-to-date sales of *Seroquel XR* in Europe declined by 33% to \$106m as a number of European markets continued to face generic competition.

### Synagis (YTD sales of \$375m; down by 3%)

Sales in the US increased by 9% to \$171m in the year to date, despite more-restrictive guidelines from the American Academy of Pediatrics Committee on Infectious Disease which has reduced the number of patients eligible for preventative therapy with *Synagis*.

Sales in Europe to AbbVie Inc., who are responsible for the sale and marketing, declined by 11% to \$204m.

### FluMist/Fluenz (YTD sales of \$37m; down by 58%)

The Company confirmed on 23 June 2016 that the Advisory Committee on Immunization Practices (ACIP) of the US 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 this influenza season.

The Company consequently wrote down the value of its inventory of *FluMist* by \$47m in the first half of the year, which was reflected within the Cost of Sales. Year-to-date sales of *FluMist* in the US declined by 85% to \$13m.

## Regional Product Sales

	YTD 2016				Q3 2016		
	\$m	% of Total	% Change		\$m	% Change	
			CER	Actual		CER	Actual
US	5,747	36	(17)	(17)	1,538	(35)	(35)
Europe	3,732	23	(2)	(4)	1,265	(1)	(3)
Established ROW <sup>1</sup>	2,272	14	(3)	2	827	(1)	11
<i>Japan</i>	1,593	10	(2)	8	595	-	19
<i>Canada</i>	371	2	(1)	(7)	126	1	-
<i>Other Established ROW</i>	308	2	(10)	(14)	106	(11)	(10)
Emerging Markets <sup>2</sup>	4,308	27	6	(2)	1,395	3	(2)
<i>China</i>	2,027	13	10	5	643	10	3
<i>Ex. China</i>	2,281	14	2	(7)	752	(1)	(6)
<b>Total</b>	<b>16,059</b>	<b>100</b>	<b>(6)</b>	<b>(8)</b>	<b>5,025</b>	<b>(14)</b>	<b>(14)</b>

<sup>1</sup> Established ROW comprises Japan, Canada, Australia and New Zealand.

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

### US (YTD sales of \$5,747m; down by 17%)

The year-to-date decline in US sales reflected generic *Crestor* (rosuvastatin) competition since May 2016, and in particular, multiple generic *Crestor* medicines that entered the US market from July 2016. Unfavourable managed-care pricing and continued competitive intensity also impacted sales of *Symbicort*.

### Europe (YTD sales of \$3,732m; down by 2%)

Strong growth in sales of *Forxiga* (up by 58% to \$136m) and *Brilique* (up by 15% to \$192m) was more than offset by a 15% decline in *Symbicort* sales to \$679m in the year to date. However, *Symbicort* maintained its position as the number one ICS/LABA medicine by volume despite competition from analogue medicines. *Lynparza* and *Tagrisso* sales increased to \$56m and \$49m respectively, following encouraging launches.

### Established ROW (YTD sales of \$2,272m; down by 3%)

Year-to-date sales of *Forxiga* in Established ROW increased by 82% to \$41m. *Nexium* sales declined by 12% to \$389m.

Japan sales declined by 2% to \$1,593m, reflecting the biennial price reduction effective from April 2016 of around 6%. The decline was partly offset by sales of *Crestor*, up by 6% to \$392m in the year to date. Since the launch of *Tagrisso* in Japan in May 2016, sales amounted to \$43m.

### Emerging Markets (YTD sales of \$4,308m; up by 6%)

Sales growth in the year to date in Emerging Markets was impacted by challenging macro-economic conditions in Latin America, where year-to-date sales declined by 11% to \$364m. The effects of significant reductions in Saudi Arabian governmental healthcare spending, as well as the reduction of AstraZeneca's activities in Venezuela, also adversely impacted sales. China sales, however, grew by 10% to \$2,027m, representing 47% of Emerging Markets sales in the year to date.

Sales in Brazil increased by 5% to \$265m, reflecting the strong performances of *Forxiga* (up by 53% to \$19m), Oncology medicines (up by 3% to \$59m) and *Seloken* (up by 9% to \$47m). Russia sales increased by 13% to \$155m, led by strong performances in Cardiovascular & Metabolic Diseases medicine sales (up by 35% to \$54m).

## Financial Performance

Year To Date	Reported		% Change		Core		% Change	
	YTD 2016	YTD 2015	CER	Actual	YTD 2016	YTD 2015	CER	Actual
Product Sales	16,059	17,434	(6)	(8)	16,059	17,434	(6)	(8)
Externalisation Revenue	1,358	875	56	55	1,358	875	56	55
<b>Total Revenue</b>	<b>17,417</b>	<b>18,309</b>	<b>(3)</b>	<b>(5)</b>	<b>17,417</b>	<b>18,309</b>	<b>(3)</b>	<b>(5)</b>
Cost of Sales	(2,966)	(3,377)	(9)	(12)	(2,785)	(2,910)	(1)	(4)
<b>Gross Profit</b>	<b>14,451</b>	<b>14,932</b>	<b>(2)</b>	<b>(3)</b>	<b>14,632</b>	<b>15,399</b>	<b>(3)</b>	<b>(5)</b>
<i>Gross Margin<sup>1</sup></i>	<i>81.7%</i>	<i>80.6%</i>	<i>+0.6</i>	<i>+0.9</i>	<i>82.9%</i>	<i>83.3%</i>	<i>-0.9</i>	<i>-0.4</i>
Distribution Expense	(243)	(240)	7	2	(243)	(240)	7	2
<i>% Total Revenue</i>	<i>1.4%</i>	<i>1.3%</i>	<i>-0.1</i>	<i>-0.1</i>	<i>1.4%</i>	<i>1.3%</i>	<i>-0.1</i>	<i>-0.1</i>
R&D Expense	(4,347)	(4,251)	5	2	(4,150)	(4,036)	6	3
<i>% Total Revenue</i>	<i>25.0%</i>	<i>23.2%</i>	<i>-2.1</i>	<i>-1.8</i>	<i>23.8%</i>	<i>22.0%</i>	<i>-2.0</i>	<i>-1.8</i>
SG&A Expense	(8,027)	(8,444)	(2)	(5)	(6,119)	(6,804)	(7)	(10)
<i>% Total Revenue</i>	<i>46.1%</i>	<i>46.1%</i>	<i>-0.4</i>	<i>-</i>	<i>35.1%</i>	<i>37.2%</i>	<i>+1.7</i>	<i>+2.1</i>
Other Operating Income	535	1,029	(47)	(48)	575	1,027	(43)	(44)
<i>% Total Revenue</i>	<i>3.1%</i>	<i>5.6%</i>	<i>-2.5</i>	<i>-2.5</i>	<i>3.3%</i>	<i>5.6%</i>	<i>-2.3</i>	<i>-2.3</i>
<b>Operating Profit</b>	<b>2,369</b>	<b>3,026</b>	<b>(26)</b>	<b>(22)</b>	<b>4,695</b>	<b>5,346</b>	<b>(13)</b>	<b>(12)</b>
<i>% Total Revenue</i>	<i>13.6%</i>	<i>16.5%</i>	<i>-4.0</i>	<i>-2.9</i>	<i>27.0%</i>	<i>29.2%</i>	<i>-3.2</i>	<i>-2.2</i>
Net Finance Expense	(978)	(750)	37	30	(489)	(355)	50	38
Joint Ventures	(22)	(9)			(22)	(9)		
<b>Profit Before Tax</b>	<b>1,369</b>	<b>2,267</b>	<b>(46)</b>	<b>(40)</b>	<b>4,184</b>	<b>4,982</b>	<b>(18)</b>	<b>(16)</b>
Taxation	220	(249)			(325)	(790)		
Tax Rate %	(16)%	11%			8%	16%		
<b>Profit After Tax</b>	<b>1,589</b>	<b>2,018</b>	<b>(30)</b>	<b>(21)</b>	<b>3,859</b>	<b>4,192</b>	<b>(11)</b>	<b>(8)</b>
Non-controlling Interests	68	(1)			63	(1)		
<b>Net Profit</b>	<b>1,657</b>	<b>2,017</b>	<b>(26)</b>	<b>(18)</b>	<b>3,922</b>	<b>4,191</b>	<b>(10)</b>	<b>(6)</b>
Weighted Average Shares	1,265	1,264			1,265	1,264		
<b>Earnings Per Share (\$)</b>	<b>1.31</b>	<b>1.60</b>	<b>(26)</b>	<b>(18)</b>	<b>3.10</b>	<b>3.32</b>	<b>(10)</b>	<b>(7)</b>

<sup>1</sup> Gross Margin reflects Gross Profit derived from Product Sales, divided by Product Sales

<sup>2</sup> All financial figures, except Earnings Per Share, are in \$ millions (\$m). Weighted Average Shares are in millions.

Quarter	Reported		% Change		Core		% Change	
	Q3 2016	Q3 2015	CER	Actual	Q3 2016	Q3 2015	CER	Actual
Product Sales	5,025	5,850	(14)	(14)	5,025	5,850	(14)	(14)
Externalisation Revenue	674	95	n/m	n/m	674	95	n/m	n/m
<b>Total Revenue</b>	<b>5,699</b>	<b>5,945</b>	<b>(4)</b>	<b>(4)</b>	<b>5,699</b>	<b>5,945</b>	<b>(4)</b>	<b>(4)</b>
Cost of Sales	(900)	(1,041)	(6)	(14)	(805)	(992)	(11)	(19)
<b>Gross Profit</b>	<b>4,799</b>	<b>4,904</b>	<b>(4)</b>	<b>(2)</b>	<b>4,894</b>	<b>4,953</b>	<b>(2)</b>	<b>(1)</b>
<i>Gross Margin<sup>1</sup></i>	82.2%	82.2%	-1.6	-0.1	84.1%	83.0%	-0.5	+1.1
Distribution Expense	(76)	(79)	2	(3)	(76)	(79)	2	(3)
<i>% Total Revenue</i>	1.3%	1.3%	-0.1	-	1.3%	1.3%	-0.1	-
R&D Expense	(1,402)	(1,429)	4	(2)	(1,337)	(1,400)	-	(5)
<i>% Total Revenue</i>	24.6%	24.0%	-1.9	-0.6	23.5%	23.5%	-1.1	-
SG&A Expense	(2,403)	(2,679)	(8)	(10)	(1,892)	(2,220)	(12)	(15)
<i>% Total Revenue</i>	42.2%	45.1%	+1.9	+2.9	33.2%	37.3%	+3.1	+4.1
Other Operating Income	110	453	(75)	(76)	107	474	(76)	(77)
<i>% Total Revenue</i>	1.9%	7.6%	-5.6	-5.7	1.9%	8.0%	-6.0	-6.1
<b>Operating Profit</b>	<b>1,028</b>	<b>1,170</b>	<b>(29)</b>	<b>(12)</b>	<b>1,696</b>	<b>1,728</b>	<b>(13)</b>	<b>(2)</b>
<i>% Total Revenue</i>	18.0%	19.7%	-5.3	-1.7	29.8%	29.1%	-2.8	+0.7
Net Finance Expense	(342)	(237)	45	44	(174)	(105)	62	64
Joint Ventures	(10)	(2)			(10)	(2)		
<b>Profit Before Tax</b>	<b>676</b>	<b>931</b>	<b>(49)</b>	<b>(27)</b>	<b>1,512</b>	<b>1,621</b>	<b>(18)</b>	<b>(7)</b>
Taxation	319	(161)			136	(318)		
Tax Rate %	(47)%	17%			(9)%	20%		
<b>Profit After Tax</b>	<b>995</b>	<b>770</b>	<b>1</b>	<b>29</b>	<b>1,648</b>	<b>1,303</b>	<b>11</b>	<b>26</b>
Non-controlling Interests	19	-			19	-		
<b>Net Profit</b>	<b>1,014</b>	<b>770</b>	<b>4</b>	<b>32</b>	<b>1,667</b>	<b>1,303</b>	<b>12</b>	<b>28</b>
Weighted Average Shares	1,265	1,264			1,265	1,264		
<b>Earnings Per Share (\$)</b>	<b>0.80</b>	<b>0.61</b>	<b>4</b>	<b>32</b>	<b>1.32</b>	<b>1.03</b>	<b>12</b>	<b>28</b>

<sup>1</sup> Gross Margin reflects Gross Profit derived from Product Sales, divided by Product Sales

<sup>2</sup> All financial figures, except Earnings Per Share, are in \$ millions (\$m). Weighted Average Shares are in millions.

## Reconciliation of Reported to Core Performance

YTD 2016	Reported	Restructuring	Intangible Asset Amortisation & Impairments	Diabetes Alliance	Other <sup>1</sup>	Core
	\$m	\$m	\$m	\$m	\$m	\$m
Cost of Sales	(2,966)	87	94	-	-	(2,785)
R&D Expense	(4,347)	146	51	-	-	(4,150)
SG&A Expense	(8,027)	504	754	311	339	(6,119)
Other Operating Income	535	(24)	64	-	-	575
Net Finance Expense	(978)	-	-	292	197	(489)
Taxation	220	(150)	(221)	(139)	(35)	(325)
Non-controlling Interests	68	(5)	-	-	-	63
<b>Total</b>		<b>558</b>	<b>742</b>	<b>464</b>	<b>501</b>	

Q3 2016	Reported	Restructuring	Intangible Asset Amortisation & Impairments	Diabetes Alliance	Other <sup>1</sup>	Core
	\$m	\$m	\$m	\$m	\$m	\$m
Cost of Sales	(900)	59	36	-	-	(805)
R&D Expense	(1,402)	39	26	-	-	(1,337)
SG&A Expense	(2,403)	176	250	93	(8)	(1,892)
Other Operating Income	110	(24)	21	-	-	107
Net Finance Expense	(342)	-	-	97	71	(174)
Taxation	319	(53)	(81)	(44)	(5)	136
Non-controlling Interests	19	-	-	-	-	19
<b>Total</b>		<b>197</b>	<b>252</b>	<b>146</b>	<b>58</b>	

<sup>1</sup> 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).

## Profit and Loss Commentary

### Gross Profit

Reported Gross Profit declined by 2% in the year to date to \$14,451m reflecting the market entry of multiple *Crestor* generic medicines in the US. Excluding the impact of externalisation revenue, the Reported Gross Profit Margin was 81.7%, representing an increase of one percentage point driven by lower restructuring and amortisation charges, partially offset by an adverse impact from the mix of sales and a write-down of *FluMist* inventory in the US. Excluding these lower restructuring and amortisation charges, Core Gross Profit declined by 3% in the year to date to \$14,632m and, excluding the impact of externalisation, the Core Gross Profit margin declined by one percentage point to 82.9%.

In the third quarter, Reported Gross Profit declined by 4% to \$4,799m and Reported Gross Margin declined by two percentage points to 82.2%. Excluding restructuring and amortisation charges, Core Gross Profit declined by 2% to \$4,894m and Core Gross Margin was stable, including the favourable impact of the growth in the sale of specialty-care medicines.

#### Operating Expenses: R&D

Reported R&D costs increased by 5% in the year to date to \$4,347m (Q3 2016: \$1,402m, growth of 4%). These increases 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 in the year to date would have increased by 1%.

Excluding the impact of lower restructuring and impairment charges, Core R&D costs increased by 6% in the year to date to \$4,150m (Q3 2016: \$1,337m, stable). Without the impact of the aforementioned investments in ZS Pharma and Acerta Pharma, Core R&D costs in the year to date would have increased by 1%.

#### Operating Expenses: SG&A

Reported SG&A costs declined by 2% in the year to date to \$8,027m, with efficiency savings in sales and marketing operations and further reductions in IT costs partly offset by higher restructuring costs, amortisation charges and other adjustments, which are excluded from the Core measurement. Reported SG&A costs declined by 8% in the third quarter to \$2,403m.

Core SG&A costs declined by 7% in the year to date to \$6,119m, in line with full-year expectations of a material reduction. Core SG&A costs declined by 12% in the quarter to \$1,892m.

#### Other Operating Income

Reported Other Operating Income of \$535m in the year to date included:

Agreement	\$m
Sale of ex-US rights to <i>Imdur</i>	183
<i>Crestor</i> royalties	165
HPV royalties	94
Ertapenem royalties	36

A number of transactions have closed or are expected to close in the fourth quarter of 2016, favourably impacting Other Operating Income. These include:

Agreement	\$m
Sale of the small-molecule antibiotics business to Pfizer. The total payment is to be recognised net of the carrying values disposed and other costs to sell	c.335 net
Sale of the ex-US rights to <i>Rhinocort Aqua</i> to Cilag GmbH International (Cilag)	330
Out-licensing of a potential medicine (MEDI2070) for inflammatory diseases to Allergan plc (Allergan)	167 net, reflecting an agreement with Amgen Inc. (Amgen)
Licensing agreement with Insmid Inc. for global exclusive rights to AZD7986, a novel oral inhibitor of dipeptidyl peptidase	30



### Operating Profit

Reported Operating Profit declined by 26% in the year to date to \$2,369m. The Reported Operating Margin declined by four percentage points to 14% of Total Revenue.

Core Operating Profit declined by 13% to \$4,695m in the year to date. The Core Operating Margin declined by three percentage points to 27% of Total Revenue.

### Net Finance Expense

Reported Net Finance Expense increased by 37% in the year to date to \$978m reflecting an increase in Net Debt that was driven by the acquisition of ZS Pharma and the majority investment in Acerta Pharma. Excluding the discount unwind on acquisition-related liabilities, Core Net Finance Expense increased by 50% in the year to date to \$489m.

### Taxation

Excluding a one-off benefit of \$453m following agreements between the Canadian tax authority and the UK and Swedish tax authorities in respect of transfer pricing arrangements for the 13-year period from 2004-2016, the Reported and Core tax rates for the year to date were 17% and 19% respectively. Including the impact of this benefit, the Reported and Core tax rates for the year to date were (16)% and 8% respectively. The cash tax paid for the year to date was \$445m, which was 33% of Reported Profit Before Tax and 11% of Core Profit Before Tax.

The Reported and Core tax rates for the first nine months of 2015 were 24% and 22% respectively when excluding a one-off tax benefit of \$186m following agreement of US federal tax liabilities of open years up to 2008, other provision releases and the benefit of the UK patent box. Including the impact of these benefits, the Reported and Core tax rates were 11% and 16% respectively.

### Earnings Per Share (EPS)

Reported EPS of \$1.31 in the year to date represented a 26% decline, with Core EPS in the year to date declining by 10% to \$3.10. Both Reported and Core EPS in the year to date included a non-recurring benefit of \$0.36 in the third quarter, resulting from the aforementioned agreement on transfer pricing.

The declines were driven by the market entry of multiple *Crestor* generic medicines in the US, as well as the ongoing impact of US *Nexium* generic medicines. The reductions reflected higher Other Operating Income in 2015. The anticipated phasing of Other Operating Income in 2016 is towards the final quarter of 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 \$713m were incurred in the year to date. The Company remains on track to realise benefits and incur costs in line with prior announcements.

To continue the focus on cost discipline, the Company disposed of its R&D facility in Bangalore, India in the period and announced plans to bring together five of its San Francisco Bay Area, US sites into one location. More than 350 employees in existing AstraZeneca, Acerta Pharma, MedImmune and Pearl facilities will move to the new location in 2017.

## **Cash Flow and Balance Sheet**

### Cash Flow

The Company generated a net cash inflow from operating activities of \$2,185m, compared with \$2,753m in the comparative period. This primarily reflected the material decline in Profit Before Tax in the year to date.

Net cash outflows from investing activities were \$4,572m compared with \$1,654m in the comparative period. The increase primarily reflected the net cash outflow of \$2,383m in relation to the majority investment in Acerta Pharma. On 10 August 2016, the Company also announced that it had increased its equity interest in Moderna Therapeutics (Moderna) with a \$140m investment, as part of Moderna's preferred-stock financing.

Net cash outflows from financing activities were \$1,020m, incorporating \$2,483m of new long-term loans, net of dividend payments in the year to date of \$3,561m. This compared to an outflow of \$3,406m 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 \$197m in the year to date. 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. From 2017 a single annual rate will be applied.

#### Debt and Capital Structure

At 30 September 2016, outstanding gross debt (interest-bearing loans and borrowings) was \$17,683m (30 September 2015: \$10,947m). Of the gross debt outstanding at 30 September 2016, \$2,939m was due within one year (30 September 2015: \$2,671m). The Company's net debt position at 30 September 2016 was \$13,399m (30 September 2015: \$5,886m).

#### Shares in Issue

During the year to date, 0.9 million shares were issued in respect of share option exercises for a consideration of \$40m. The total number of shares in issue as at 30 September 2016 was 1,265 million.

#### 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) <sup>2</sup>	
		FY 2015	YTD 2016 <sup>1</sup>		Total Revenue	Core Operating Profit
EUR	Product Sales	0.90	0.90	1	(178)	(103)
JPY	Product Sales	121.04	108.64	11	(102)	(66)
CNY	Product Sales	6.28	6.59	(5)	(133)	(62)
SEK	Costs	8.43	8.40	-	(8)	71
GBP	Costs	0.65	0.72	(9)	(34)	96
Other <sup>3</sup>					(201)	(122)

<sup>1</sup>Based on average daily spot rates in the nine months to the end of September 2016.

<sup>2</sup>Based on 2015 actual results at 2015 actual exchange rates.

<sup>3</sup>Other 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 September 2016, AstraZeneca had hedged 86% of forecast short-term currency exposure that arises between the booking and settlement dates on Product Sales and non-local currency purchases.

## 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) Sale Of Small-Molecule Antibiotics Business

On 24 August 2016, the Company announced that it had entered into an agreement with Pfizer to sell the commercialisation and development rights to its small-molecule antibiotics business and late-stage pipeline in most markets outside the US. The agreement with Pfizer is expected to close in the fourth quarter of 2016, subject to customary closing conditions.

As AstraZeneca will de-recognise an intangible product asset and will not maintain a significant ongoing interest in the late-stage, small-molecule antibiotics business, all payments will be reported as Other Operating Income in the Company's financial statements. This includes the upfront payment of \$550m and an unconditional payment of \$175m in 2019 (both to be recognised net of the carrying value of assets disposed and other costs to sell in 2016), the milestones of up to \$250m, sales-related payments of up to \$600m and recurring double-digit royalties on sales of *Zavicefta* and ATM AVI.

### b) Sale Of *Rhinocort Aqua*

On 7 October 2016, the Company announced that it had entered into an agreement with Cilag, an affiliate of Johnson & Johnson, for the divestment of the rights to *Rhinocort Aqua* outside the US. *Rhinocort Aqua* is a nasal spray indicated for allergic and non-allergic rhinitis (inflammation of the inside of the nose), and for the treatment of nasal polyps (swelling of the nasal lining). The active ingredient is the anti-inflammatory medicine budesonide.

The agreement is subject to customary closing conditions and is expected to complete in the fourth quarter of 2016. As AstraZeneca will not maintain a significant ongoing interest in *Rhinocort Aqua*, the \$330m payment received from Cilag upon completion of the transaction will be recognised as Other Operating Income in the Company's financial statements.

### c) Externalisation Of Beta-Blocker Medicine *Toprol-XL*

On 31 October 2016, the Company completed an agreement with Aralez Pharmaceuticals Trading DAC, a subsidiary of Aralez Pharmaceuticals Inc., for the rights to branded and authorised generic *Toprol-XL* (metoprolol succinate) in the US. *Toprol-XL* is a beta-blocker medicine for the control of hypertension (high blood pressure), angina (chest pain) and heart failure. It was first approved in the US in 1992.

AstraZeneca will retain a significant ongoing interest in *Toprol-XL* through retained ownership of the brand in Rest of World (ROW) markets and product supply to Aralez. Therefore the upfront payment of \$175m, milestones and sales-related payments of up to \$48m and mid-teen percentage royalties will be reported as Externalisation Revenue in the Company's financial statements.

### d) Licensing Agreement: Monoclonal Antibody MEDI2070

On 3 October 2016, the Company announced that MedImmune, its global biologics research and development arm, had entered into a licensing agreement with Allergan for the global rights to MEDI2070. MEDI2070 is an IL-23 monoclonal antibody currently in a Phase IIb clinical trial for moderate-to-severe Crohn's disease (a chronic inflammatory disease of the intestines) and is ready for Phase II for ulcerative colitis (a chronic inflammatory condition of the colon and rectum). MedImmune will continue the ongoing Phase II trials until a mutually-agreed transition date.

The transaction is expected to close in the fourth quarter of 2016, subject to customary closing conditions, including the expiration or early termination of the waiting period under the Hart Scott Rodino Act. AstraZeneca is expected to retain approximately \$167m of the upfront payment and up to approximately \$847m in future potential milestones, as well as the tiered royalty payments of up to low double-digit percent, following payment to Amgen under the provisions of the original agreement. As AstraZeneca will not retain a significant ongoing interest in MEDI2070, all income will be reported as Other Operating Income in the Company's financial statements.

e) Benralizumab in Japan

On 28 October 2016, AstraZeneca exercised its exclusive option to commercialise benralizumab for the treatment of severe, uncontrolled asthma and COPD in Japan. This follows the option agreement entered into with Kyowa in July 2015. Previously, Kyowa held the exclusive development and commercialisation rights for benralizumab in Japan, as well as certain other countries in Asia, while AstraZeneca has exclusive rights in all other countries, including the US and Europe. On exercising the option, AstraZeneca is responsible for all sales and marketing activity for benralizumab in asthma and COPD in Japan.

f) Externalisation of *Bydureon* and *Byetta* in China

On 10 October 2016, AstraZeneca entered into a strategic collaboration with 3SBio for the rights to commercialise *Bydureon* and *Byetta* in the Chinese market. The agreement allows the Company to benefit from 3SBio's established expertise in injectable medicines and also focus resources on AstraZeneca's oral diabetes franchise, including *Onglyza*, which is already marketed in China, as well as *Forxiga* and *Kombiglyze*, which are anticipated to launch in China in 2017.

Under the terms of the collaboration agreement, 3SBio will make an upfront payment of \$50m and will pay development milestones of up to a further \$50m for the exclusive rights to commercialise *Bydureon* and *Byetta* in the Chinese market (excluding Hong Kong) for an initial period of 20 years. AstraZeneca will retain a significant ongoing interest in *Bydureon* and *Byetta* through retained ownership of the brands in other markets and will manufacture and supply these medicines to 3SBio for an agreed purchase price. Therefore the upfront payment and development milestones will be reported as Externalisation Revenue in the Company's financial statements.

## 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 July 2016 (the period):

Regulatory Approvals	1	- <i>Brilinta</i> - CV disease (JP)
Regulatory Submissions* /Acceptances	3	- <i>Faslodex</i> - breast cancer (1st line) (JP)* - <i>Tagrisso</i> - lung cancer (CN)* - ZS-9 - hyperkalaemia (US)
Positive Phase III Data Readouts	3	- <i>Lynparza</i> - ovarian cancer (2nd line) - <i>Farxiga</i> + <i>Bydureon</i> - type-2 diabetes - benralizumab - severe, uncontrolled asthma
Other Key Developments	2	- Priority Review Designation: <i>Tagrisso</i> (CN) - Fast Track Designation: AZD3293 - Alzheimer's disease (US)
New Molecular Entities (NMEs) in Pivotal Trials or under Regulatory Review**#	13	<p><b>Oncology</b></p> <ul style="list-style-type: none"> <li>- durvalumab - multiple cancers</li> <li>- durva + treme - multiple cancers</li> <li>- acalabrutinib - blood cancers</li> <li>- moxetumomab pasudotox - leukaemia</li> <li>- selumetinib - thyroid cancer</li> </ul> <p><b>Cardiovascular &amp; Metabolic Diseases</b></p> <ul style="list-style-type: none"> <li>- ZS-9** - hyperkalaemia</li> <li>- roxadustat - anaemia</li> </ul> <p><b>Respiratory</b></p> <ul style="list-style-type: none"> <li>- benralizumab - severe, uncontrolled asthma</li> <li>- tralokinumab - severe, uncontrolled asthma</li> <li>- PT010 - COPD</li> </ul> <p><b>Other</b></p> <ul style="list-style-type: none"> <li>- brodalumab - psoriasis**</li> <li>- anifrolumab - lupus</li> <li>- AZD3293 - Alzheimer's disease</li> </ul>
Projects in clinical pipeline#	138	

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## ONCOLOGY

AstraZeneca has a deep-rooted heritage in Oncology and offers a 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 recent investment in Acerta Pharma in haematology.

At the recent European Society for Medical Oncology meeting, AstraZeneca highlighted its progress in Oncology with 46 scientific presentations, including new 1st-line data that demonstrated the superiority of *Faslodex* over the current standard of care in postmenopausal women with HR-positive, locally-advanced or metastatic breast cancer. The Company also presented updated safety and efficacy data from two cohorts from Study 1108; durvalumab monotherapy in NSCLC and HNSCC, in addition to a comparative analysis of PD-L1 diagnostic assays in c.500 HNSCC-tumour samples.

### a) Lynparza (ovarian and other cancers)

*Lynparza* continues to be the cornerstone of the AstraZeneca DNA Damage Response (DDR) line of medicines. An extensive lifecycle programme is underway, including in earlier lines of treatment in metastatic ovarian, breast and prostate cancers. For the potential treatment in metastatic BRCA-mutated breast cancer, the OLYMPIAD trial has seen fewer events than originally expected and, as a consequence, the data readout is now anticipated to be in the first half of 2017.

During the period, the Company reported positive results from the Phase III SOLO-2 trial designed to determine the efficacy of *Lynparza* tablets (300mg, twice daily) as a monotherapy for the maintenance treatment of platinum-sensitive relapsed, BRCA-mutated ovarian cancer. Results from the trial demonstrated a clinically-meaningful and statistically-significant improvement of progression-free survival (PFS) among patients treated with *Lynparza*, compared to placebo and provided additional evidence to support the use of *Lynparza* in this patient population.

### b) Tagrisso (lung cancer)

During the period, *Tagrisso* was accepted for submission and granted Priority Review status by the China Food and Drug Administration agency as a potential treatment for patients with locally-advanced, or metastatic EGFR T790M mutation-positive NSCLC, who have been previously treated with EGFR TKI therapy. The designation has the potential to expedite more rapid access to *Tagrisso* for patients in China. The Chinese application was supported by three key trials - a China-led Asian regional trial (AURA17), a pharmacokinetic trial in the local population (AURA18) and the global AURA3 trial, which included Chinese patients.

### c) Cediranib (ovarian cancer)

On 21 September 2016, AstraZeneca announced the decision to voluntarily withdraw the marketing authorisation application (MAA) submitted to the EMA's Committee for Medicinal Products for Human Use for cediranib in combination with platinum-based chemotherapy, followed by maintenance monotherapy for the treatment of adult patients with platinum-sensitive relapsed ovarian cancer (including fallopian tube or primary peritoneal). The decision to withdraw the MAA was based on questions raised by the EMA at the late stage of the review process. The MAA for cediranib was supported by data from ICON6, a Phase III trial led by investigators from University College, London and the Medical Research Council. The Company has not made additional regulatory submissions for cediranib in this indication in any other markets.

Cediranib remains an important part of AstraZeneca's ovarian cancer pipeline, and a number of Phase III trials are ongoing to test cediranib as a potential combination partner with *Lynparza* and other pipeline medicines; these trials are not affected by the aforementioned withdrawal.

### d) Selumetinib (multiple cancers)

On 9 August 2016, the Company announced the high-level results from the Phase III SELECT-1 trial for selumetinib in patients with 2nd-line KRAS mutant (KRAS<sup>m</sup>) NSCLC. The results showed that the trial did not meet its primary endpoint of PFS, and selumetinib did not have a significant effect on overall survival (OS). The adverse event profiles for selumetinib and docetaxel were consistent with those seen previously. This outcome did not impact the on-going selumetinib programme in differentiated thyroid cancer, in paediatric

neurofibromatosis Type 1 (in collaboration with the US National Cancer Institute), and in combination with other potential medicines in a range of tumour types.

e) Savolitinib (multiple cancers)

Based on data from multiple Phase I/II trials, savolitinib has shown early clinical benefit as a highly selective c-Met inhibitor in a number of cancers. As a result, Chi-Med (part of CK Hutchison Holdings Limited) and AstraZeneca have expanded the joint development plan for savolitinib to cover multiple c-Met-driven, solid tumour indications including NSCLC, kidney, gastric and colorectal cancers.

f) Durvalumab (multiple cancers)

The Company continues to advance multiple monotherapy trials of durvalumab and combination trials of durvalumab with tremelimumab and other potential medicines in Immuno-Oncology (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>						
Monotherapy						
ADJUVANT <sup>1</sup>	III	N/A	Stage Ib-IIIa NSCLC	durvalumab vs placebo	FPD <sup>2</sup> Q1 2015  Data expected 2020	Ongoing
PACIFIC	III	N/A	Stage III unresectable NSCLC	durvalumab vs placebo	FPD Q2 2014  LPCD <sup>3</sup> Q2 2016  Data expected H2 2017	Recruitment completed
<i>Advanced/metastatic disease</i>						
Combination therapy						
MYSTIC	III	1st line	NSCLC	durvalumab vs durva + treme vs SoC <sup>4</sup>	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	Ongoing
-	III	1st line	NSCLC	durvalumab + chemotherapy +/- tremelimumab	-	Ongoing in safety lead-in Phase I/II trial
ARCTIC	III	3rd line	PD-L1 neg. NSCLC	durvalumab vs tremelimumab vs durva + treme vs SoC	FPD Q2 2015  LPCD Q3 2016  Data expected H1 2017	Recruitment completed

<sup>1</sup> Conducted by the National Cancer Institute of Canada <sup>2</sup> FPD = First Patient Dosed <sup>3</sup> LPCD = Last Patient Commenced Dosing  
<sup>4</sup> SoC = Standard of Care <sup>5</sup> SCLC = Small Cell Lung Cancer



## METASTATIC OR RECURRENT HEAD AND NECK CANCER

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

With recent changes in the HNSCC competitive landscape, including the approval in the US for PD-1 monotherapy for recurrent or metastatic HNSCC with disease progression on or after platinum-containing chemotherapy, the Company is unlikely to make a regulatory submission for this single-arm Phase II trial. This trial in PD-L1+ patients was originally designed as a potential fast-to-market opportunity in 2nd-line HNSCC. The HAWK trial results are anticipated to be available internally in due course, following trial conclusion and data analysis.

On 27 October 2016, AstraZeneca confirmed that the FDA had placed a partial clinical hold on the enrolment of new patients with HNSCC in clinical trials of durvalumab as monotherapy and in combination with tremelimumab or other potential medicines. All trials are continuing with existing patients. The partial clinical hold on new patient enrolment relates only to HNSCC. Trials for durvalumab in different cancer types, as monotherapy, or in combination with tremelimumab or other potential medicines, are progressing as planned with pivotal data in lung cancer anticipated in the first half of 2017.

## 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 + trema vs SoC	FPD Q4 2015  Data expected 2018	Ongoing

### g) Acalabrutinib (blood cancers)

Based on maturity of clinical data in an intended fast-to-market indication of unmet need in B-cell blood cancers, the Company rolled the potential data readout and regulatory submission for one blood cancer to the first half of 2017.

Acalabrutinib is a cornerstone of the AstraZeneca strategy in haematology and the Company continues to see important progress in the clinical-development programme for the potential medicine. With more than 2,000 patients now having been treated with acalabrutinib in clinical trials, the safety profile supports the potential for acalabrutinib to become a best-in-class BTK inhibitor for patients intolerant to a currently-approved BTK inhibitor with B-cell cancers.

## 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 CV disease, diabetes and chronic kidney disease (CKD) indications.

### a) Brilinta (CV disease)

During the period, the EUCLID Phase III trial in Peripheral Artery Disease (PAD) readout, with the data demonstrating that the primary endpoint of superiority over clopidogrel was not met. Safety findings from the trial were in line with the known safety profile of *Brilinta*. Based on the current expectations, it is unlikely that the Company will seek regulatory submission of an indication in PAD.

During the period, the Japanese Ministry of Health, Labour and Welfare approved *Brilinta* 90mg for patients with acute coronary syndrome (ACS) for whom the use of other antiplatelet medicines in combination with aspirin is difficult. *Brilinta* 60mg was also approved for patients who have suffered a heart attack at least one year prior and are at high risk of developing a further atherothrombotic event.

### b) Farxiga + Bydureon (type-2 diabetes)

With the increasing evidence suggesting the beneficial effect of SGLT2 inhibitors, such as *Farxiga*, on renal and CV outcomes in patients with type-2 diabetes, the decision was made to design two large Phase IIIb outcome trials to further investigate the potential role of *Farxiga* in the management of CKD and chronic heart failure (CHF), in patients with or without type-2 diabetes. This marked the first time that a major outcome trial will be conducted to evaluate an SGLT2 inhibitor in CKD, for which there are currently few treatment options and a significant unmet medical need.

During the period, the DURATION-8 combination trial of *Farxiga* and *Bydureon* showed reduced blood sugar, weight and systolic blood pressure. The Phase III trial demonstrated that the combination of these medicines provides benefits to patients above and beyond what is seen with the individual medicines. The Company is currently assessing the potential for a regulatory submission based on these data.

### c) Type-2 diabetes medicines in CV outcomes trials

As the field of type-2 diabetes medicines consistently evolves, with multiple outcomes trials producing data, AstraZeneca continues to assess both *Farxiga* and *Bydureon* for potential long-term CV benefits. Two significant type-2 diabetes outcomes trials are underway and are ongoing:

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	Latest 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	Latest 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)

In the beginning of the fourth quarter, the FDA accepted AstraZeneca's resubmission of the new drug application (NDA) for ZS-9 (sodium zirconium cyclosilicate), the medicine in development for the treatment of hyperkalaemia (high potassium level in blood serum) by ZS Pharma, a wholly owned subsidiary of AstraZeneca. The FDA indicated that this was a complete Class 2 response; the Agency is anticipated to act on the resubmission within 6 months of the date of receipt.

#### e) Roxadustat (anaemia)

Roxadustat is a potential first-in-class oral HIF-PH inhibitor in Phase III development for the treatment of anaemia in CKD patients, including those on dialysis and not on dialysis. AstraZeneca, FibroGen, Inc. (Fibrogen) and Astellas Pharma Inc. are jointly undertaking an extensive worldwide Phase III programme consisting of 15 trials enrolling more than 8,000 patients.

FibroGen, responsible for regulatory activities in China, recently announced that enrolment had completed in both Phase III clinical trials, intended for regulatory submission. These trials include both CKD patients on and not on dialysis. Further, FibroGen has confirmed that roxadustat is on track to initiate the rolling regulatory-submission process in 2016.

### RESPIRATORY

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.

#### Benralizumab (severe, uncontrolled asthma)

AstraZeneca shared positive benralizumab Phase III data from the SIROCCO and CALIMA trials at the recent European Respiratory Society meeting. These data were also published in *The Lancet* on 5 September 2016. These results demonstrated that adding benralizumab to the standard of care significantly reduced exacerbations and improved lung function and asthma symptoms in severe, uncontrolled asthma. The outcomes were demonstrated for the 8-week dosing regimen, with no additional benefit observed with 4-week dosing.

During the period, the Phase III ZONDA trial also met its primary endpoint. ZONDA is an efficacy and safety trial of benralizumab to reduce oral corticosteroid use in patients with uncontrolled asthma on high-dose, inhaled corticosteroid plus long-acting Beta2 agonist and chronic oral corticosteroid therapy. Full results will be presented at a forthcoming medical meeting. ZONDA is the fourth positive efficacy trial supporting benralizumab's unique efficacy and safety profile in severe, uncontrolled asthma.

## OTHER

### a) Anifrolumab (lupus)

During the period, the first patient completed the anifrolumab systemic lupus erythematosus (SLE) Phase III trial and rolled over to the long-term extension trial for another three years of treatment/follow-up. The Phase III programme consists of two double-blind placebo controlled trials (TULIP SLE1 and TULIP SLE2) as well as the long-term extension; the Company continues to anticipate regulatory submission in 2019.

Anifrolumab is a monoclonal antibody that blocks the type I interferon (IFN) receptor, thereby inhibiting the activity of all type I IFNs, which play a central role in lupus pathophysiology. Anifrolumab is currently in Phase III development for SLE and Phase II for Lupus Nephritis; a Phase I trial for expansion from current intravenous to subcutaneous administration was recently completed.

### b) AZD3293 (Alzheimer's Disease)

On 22 August 2016, AstraZeneca and Lilly announced the receipt of the FDA's Fast Track Designation for the development programme in Alzheimer's disease for AZD3293, an oral beta secretase cleaving enzyme (BACE) inhibitor currently in Phase III clinical trial. The FDA's Fast Track programme is designed to expedite the development and review of new therapies to treat serious conditions and tackle key unmet medical needs. Lilly leads clinical development, in collaboration with scientists from AstraZeneca who will be responsible for manufacturing.

AZD3293 has been shown in trials to reduce levels of amyloid beta in the cerebrospinal fluid of people with Alzheimer's and healthy volunteers. The progression of Alzheimer's disease is characterised by the accumulation of amyloid plaque in the brain. BACE is an enzyme associated with the development of amyloid beta. Inhibiting BACE is expected to prevent the formation of amyloid plaque and eventually slow the progression of the disease. In addition to the AMARANTH Phase III trial for AZD3293, AstraZeneca and Lilly have dosed patients in a second Phase III trial, DAYBREAK-ALZ, which studies the safety and efficacy of AZD3293 in patients with mild Alzheimer's disease.

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## ASTRAZENECA DEVELOPMENT PIPELINE 30 SEPTEMBER 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.

Compound	Mechanism	Area Under Investigation	Date Commenced Phase	Estimated Regulatory Acceptance Date / Submission Status			
				US	EU	Japan	China
<b>Oncology</b>							
<i>Tagrisso</i> AURA, AURA2, (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	Accepted <sup>1</sup>
<i>Tagrisso</i> AURA3	EGFR tyrosine kinase inhibitor	≥2nd-line advanced EGFRm T790M NSCLC	Q3 2014	Q4 2016	Q4 2016	N/A <sup>2</sup>	N/A
acalabrutinib <sup>#</sup>	BTK inhibitor	B-cell malignancy	Q1 2015	2017 (Orphan drug)			
acalabrutinib <sup>#</sup>	BTK inhibitor	1st-line CLL	Q3 2015	2020 (Orphan drug)	2020 (Orphan drug)		
acalabrutinib <sup>#</sup>	BTK inhibitor	r/r CLL, high risk	Q4 2015	2020 (Orphan drug)	2020 (Orphan drug)		
selumetinib <sup>#</sup> ASTRA	MEK inhibitor	differentiated thyroid cancer	Q3 2013	2018 (Orphan drug)	2018		
moxetumomab pasudotox <sup>#</sup> PLAIT	anti-CD22 recombinant immunotoxin	hairy cell leukaemia	Q2 2013	2017 (Orphan drug)	2018		
durvalumab <sup>#</sup> PACIFIC	PD-L1 mAb	stage III NSCLC	Q2 2014	2017	2017	2017	
durvalumab <sup>#</sup> HAWK <sup>†</sup>	PD-L1 mAb	2nd-line HNSCC (PD-L1 positive)	Q1 2015	2017 (Fast Track)	2017		
durvalumab <sup>#</sup> + tremelimumab ARCTIC	PD-L1 mAb + CTLA-4 mAb	3rd-line NSCLC	Q2 2015	2017	2017	2017	
durvalumab <sup>#</sup> + tremelimumab MYSTIC	PD-L1 mAb + CTLA-4 mAb	1st-line NSCLC	Q3 2015	2017	2017	2017	2020
durvalumab <sup>#</sup> + tremelimumab NEPTUNE	PD-L1 mAb + CTLA-4 mAb	1st-line NSCLC	Q4 2015	2019	2019	2019	
durvalumab <sup>#</sup> + tremelimumab CONDOR <sup>†</sup>	PD-L1 mAb + CTLA-4 mAb	2nd-line HNSCC (PD-L1 negative)	Q2 2015	2017	2017		
durvalumab <sup>#</sup> + tremelimumab KESTREL	PD-L1 mAb + CTLA-4 mAb	1st-line HNSCC	Q4 2015	2018	2018	2018	
durvalumab <sup>#</sup> + tremelimumab EAGLE	PD-L1 mAb + CTLA-4 mAb	2nd-line HNSCC	Q4 2015	2018	2018	2018	
durvalumab <sup>#</sup> + tremelimumab ALPS <sup>†</sup>	PD-L1 mAb + CTLA-4 mAb	metastatic pancreatic ductal carcinoma	Q4 2015	2017	2017	2017	

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Compound	Mechanism	Area Under Investigation	Date Commenced Phase	Estimated Regulatory Acceptance Date / Submission Status			
				US	EU	Japan	China
durvalumab <sup>#</sup> + tremelimumab DANUBE	PD-L1 mAb + CTLA-4 mAb	1st-line bladder cancer	Q4 2015	2018	2018	2018	
<b>Cardiovascular &amp; Metabolic Diseases</b>							
<i>Brilinta</i> <sup>3</sup>	P2Y12 receptor antagonist	arterial thrombosis		Launched	Launched	Approved <sup>3</sup>	Launched
<i>Farxiga</i> <sup>4</sup>	SGLT2 inhibitor	type-2 diabetes		Launched	Launched	Launched	Accepted
<i>Epanova</i> <sup>#</sup>	omega-3 carboxylic acids	severe hypertriglyceridemia		Approved		2018	
ZS-9 (sodium zirconium cyclosilicate)	potassium binder	hyperkalaemia		Accepted <sup>5</sup>	Accepted		
roxadustat <sup>#</sup> OLYMPUS (US) ROCKIES (US)	hypoxia-inducible factor prolyl hydroxylase inhibitor	anaemia in CKD/ESRD	Q3 2014	2018	N/A	N/A	Q4 2016 <sup>6</sup>
<b>Respiratory</b>							
<i>Bevespi Aerosphere</i> (PT003)	LABA/LAMA	COPD	Q2 2013	Approved	2017	2018	2018
benralizumab <sup>#</sup> CALIMA SIROCCO ZONDA BISE BORA GREGALE	IL-5R mAb	severe asthma	Q4 2013	Q4 2016	Q4 2016	N/A	N/A
benralizumab <sup>#</sup> 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	
<b>Other</b>							
anifrolumab <sup>#</sup> TULIP	IFN-alphaR mAb	systemic lupus erythematosus	Q3 2015	2019 (Fast Track)	2019	2019	
<i>Zinforo</i> <sup>#7</sup>	extended spectrum cephalosporin with affinity to penicillin-binding proteins	pneumonia/skin infections		N/A	Launched	N/A	Submitted
<i>Zavicefta</i> <sup>#7</sup> (CAZ AVI <sup>#</sup> )	cephalosporin/beta lactamase inhibitor	hospital-acquired pneumonia/ventilator-associated pneumonia	Q2 2013	N/A	Approved	N/A	2017
<i>Zavicefta</i> <sup>#7</sup>	cephalosporin/beta lactamase inhibitor	serious infections, complicated intra-abdominal infection, complicated urinary tract infection	Q1 2012	N/A	Approved	N/A	2017

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Compound	Mechanism	Area Under Investigation	Date Commenced Phase	Estimated Regulatory Acceptance Date / Submission Status			
				US	EU	Japan	China
AZD3293 <sup>#</sup> AMARANTH DAYBREAK-ALZ	beta-secretase inhibitor	Alzheimer's disease	Q2 2016	2020 <sup>8</sup> (Fast Track)	2020	2020	

† Registrational Phase II trial

# Collaboration

1 CN submission accepted 1 September 2016

2 Tagrisso has full approval in Japan. A Japanese Patient Information update will include AURA3 data

3 Brilinta in the US; Brilique in rest of world. JP approval received 28 Sept 2016

4 Farxiga in the US; Forxiga in rest of world

5 US resubmission accepted on 13 October 2016

6 Rolling NDA submission to be initiated in Q4 2016

7 AstraZeneca announced on 24 August 2016 that it had entered into an agreement with Pfizer to sell the commercialisation and development rights to its late-stage, small-molecule antibiotics business in most markets globally outside the US. The transaction is expected to close during Q4 2016

8 Fast Track Designation, 22 August 2016

## Phases I and II

### NMEs and significant additional indications

Compound	Mechanism	Area Under Investigation	Phase	Date Commenced Phase
<b>Oncology</b>				
durvalumab <sup>#</sup>	PD-L1 mAb	bladder cancer	II	Q1 2016 (Breakthrough Therapy)
durvalumab <sup>#</sup>	PD-L1 mAb	solid tumours	II	Q3 2014
durvalumab <sup>#</sup> + tremelimumab	PD-L1 mAb + CTLA-4 mAb	gastric cancer	II	Q2 2015
durvalumab <sup>#</sup> + AZD5069	PD-L1 mAb + CXCR2	HNSCC	II	Q3 2015
durvalumab <sup>#</sup> + AZD9150 <sup>#</sup>	PD-L1 mAb + STAT3 inhibitor			
durvalumab <sup>#</sup> + MEDI0680	PD-L1 mAb + PD-1 mAb	solid tumours	II	Q3 2016
durvalumab <sup>#</sup>	PD-L1 mAb	solid tumours	I	Q3 2014
durvalumab <sup>#</sup> + monalizumab	PD-L1 mAb + NKG2a mAb	solid tumours	I	Q1 2016
durvalumab <sup>#</sup> + MEDI9447	PD-L1 mAb + CD73 mAb	solid tumours	I	Q1 2016
durvalumab <sup>#</sup> + Iressa	PD-L1 mAb+ EGFR tyrosine kinase inhibitor	NSCLC	I	Q2 2014
durvalumab <sup>#</sup> + dabrafenib + trametinib	PD-L1 mAb+ BRAF inhibitor + MEK inhibitor	melanoma	I	Q1 2014
durvalumab <sup>#</sup> + tremelimumab	PD-L1 mAb + CTLA-4 mAb	solid tumours	I	Q4 2013
Tagrisso + (durvalumab <sup>#</sup> or selumetinib <sup>#</sup> or savolitinib <sup>#</sup> ) TATTON	EGFR tyrosine kinase inhibitor + (PD-L1 mAb or MEK inhibitor or MET tyrosine kinase inhibitor)	advanced EGFRm NSCLC	II	Q2 2016
Tagrisso	EGFRm	leptomeningeal disease	II	Q3 2016
selumetinib + durvalumab <sup>#</sup>	MEK inhibitor + PD-L1 mAb	solid tumours	I	Q4 2015
savolitinib/volitinib <sup>#</sup>	MET tyrosine kinase inhibitor	papillary renal cell carcinoma	II	Q2 2014

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Compound	Mechanism	Area Under Investigation	Phase	Date Commenced Phase
AZD1775 <sup>#</sup> + chemotherapy	Wee1 inhibitor + chemotherapy	ovarian cancer	II	Q4 2012
AZD1775 <sup>#</sup>	Wee1 inhibitor	solid tumours	I	Q3 2015
AZD1775 <sup>#</sup> + Lynparza	Wee1 inhibitor + PARP inhibitor	solid tumours	I	Q3 2015
AZD1775 <sup>#</sup> + durvalumab <sup>#</sup>	Wee1 inhibitor + PD-L1 mAb	solid tumours	I	Q4 2015
AZD6738 + Lynparza	ATR inhibitor	gastric cancer	II	Q3 2016
vistusertib (AZD2014)	mTOR serine/threonine kinase inhibitor	solid tumours	II	Q1 2013
AZD3759 BLOOM <sup>#</sup>	EGFR tyrosine kinase inhibitor	CNS metastases in advanced EGFRm NSCLC	II	Q4 2015
Tagrisso BLOOM	EGFR tyrosine kinase inhibitor			
AZD5363 <sup>#</sup>	AKT kinase inhibitor	breast cancer	II	Q1 2014
AZD4547	FGFR tyrosine kinase inhibitor	solid tumours	II	Q4 2011
MEDI-573 <sup>#</sup>	IGF mAb	metastatic breast cancer	II	Q2 2012
AZD0156	ATM serine/threonine kinase inhibitor	solid tumours	I	Q4 2015
AZD2811 <sup>#</sup>	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 <sup>#</sup>	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 <sup>#</sup>	humanised OX40 agonist	solid tumours	I	Q1 2015
MEDI0562 <sup>#</sup> + tremelimumab	humanised OX40 agonist + CTLA-4 mAb	solid tumours	I	Q2 2016
MEDI0562 <sup>#</sup> + durvalumab <sup>#</sup>	humanised OX40 agonist + PD-L1 mAb	solid tumours	I	Q2 2016
MEDI-565 <sup>#</sup>	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
MEDI4276	HER2 bispecific ADC mAb	solid tumours	I	Q4 2015
MEDI9197 <sup>#</sup>	TLR 7/8 agonist	solid tumours	I	Q4 2015
MEDI9447	CD73 mAb	solid tumours	I	Q3 2015
<b>Cardiovascular &amp; Metabolic Diseases</b>				
MEDI0382	GLP-1/ glucagon dual agonist	diabetes / obesity	II	Q3 2016
MEDI4166	PCSK9/GLP-1 mAb + peptide fusion	diabetes / cardiovascular	II	Q1 2016
MEDI6012	LCAT	ACS	II	Q4 2015

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Compound	Mechanism	Area Under Investigation	Phase	Date Commenced Phase
AZD4076	anti-miR103/107 oligonucleotide	non-alcoholic fatty liver disease/non-alcoholic steatohepatitis (NASH)	I	Q4 2015
AZD4831	Myeloperoxidase	Heart failure with a preserved ejection fraction	I	Q3 2016
AZD5718	FLAP	CAD	I	Q1 2016
MEDI8111	Rh-factor II	trauma / bleeding	I	Q1 2014
<b>Respiratory</b>				
PT010	LABA/LAMA/ICS	asthma	II	Q2 2014
abediterol <sup>#</sup>	LABA	asthma/COPD	II	Q4 2007
AZD7594	inhaled SGRM	asthma/COPD	II	Q3 2015
AZD9412 <sup>#</sup>	inhaled interferon beta	asthma/COPD	II	Q3 2015
tezepelumab <sup>#</sup>	TSLP mAb	asthma / atopic dermatitis	II	Q2 2014
AZD1419 <sup>#</sup>	TLR9 agonist	asthma	II	Q3 2013
AZD5634	inhaled ENaC	cystic fibrosis	I	Q1 2016
AZD7986 <sup>#</sup>	DPP1	COPD	I	Q4 2014
AZD8871 <sup>#</sup>	MABA	COPD	I	Q4 2015
AZD9567	oral SGRM	rheumatoid arthritis	I	Q4 2015
MEDI9314	IL-4R mAb	atopic dermatitis	I	Q1 2016
<b>Other</b>				
anifrolumab <sup>#</sup>	IFN-alphaR mAb	lupus nephritis	II	Q4 2015
anifrolumab <sup>#</sup>	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
mavrilimumab <sup>#</sup>	GM-CSFR mAb	rheumatoid arthritis	II	Q1 2010
inebilizumab <sup>#</sup>	CD19 mAb	neuromyelitis optica	II	Q1 2015 (Orphan drug)
MEDI2070 <sup>#1</sup>	IL-23 mAb	Crohn's disease	II	Q1 2013
MEDI7734	ILT7 mAb	myositis	I	Q3 2016
MEDI0700 <sup>#</sup>	BAFF/B7RP1 bispecific mAb	systemic lupus erythematosus	I	Q1 2016
MEDI4920	anti-CD40L-Tn3 fusion protein	primary Sjögren's syndrome	I	Q2 2014
MEDI5872 <sup>#</sup>	B7RP1 mAb	primary Sjögren's syndrome	II	Q3 2016
CXL <sup>#2</sup>	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	Respiratory syncytial virus (RSV) sF+GLA-SE	Prevention of RSV disease in older patients	II	Q3 2015
MEDI8852	influenza A mAb	influenza A treatment	II	Q4 2015 (Fast Track, US)
MEDI8897 <sup>#</sup>	RSV mAb-YTE	passive RSV prophylaxis	II	Q1 2015 (Fast Track, US)
ATM AVI <sup>#2</sup>	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

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- 1 AstraZeneca entered into a licensing agreement with Allergan (3 October 2016)
- 2 AstraZeneca announced on 24 August 2016 that it had entered into an agreement with Pfizer to sell the commercialisation and development rights to its late-stage, small-molecule antibiotics business in most markets globally outside the US. The transaction is expected to close during Q4 2016

## Significant Lifecycle Management (LCM)

Compound	Mechanism	Area Under Investigation	Date Commenced Phase	Estimated Regulatory Acceptance Date / Submission Status			
				US	EU	Japan	China
<b>Oncology</b>							
Faslodex FALCON	oestrogen receptor antagonist	1st-line hormone receptor +ve advanced breast cancer	Q4 2012	H1 2017	H1 2017	Accepted <sup>1</sup>	2017
Lynparza OlympiAD	PARP inhibitor	gBRCA metastatic breast cancer	Q2 2014	2017	2017	2017	
Lynparza SOLO-2	PARP inhibitor	2nd-line or greater BRCAm PSR ovarian cancer, maintenance monotherapy	Q3 2013	2017 (Fast Track)	2017	2017	
Lynparza SOLO-1	PARP inhibitor	1st-line BRCAm ovarian cancer	Q3 2013	2018	2018	2018	
Lynparza SOLO-3	PARP inhibitor	gBRCA PSR ovarian cancer	Q1 2015	2018			
Lynparza POLO	PARP inhibitor	pancreatic cancer	Q1 2015	2018	2018	N/A	
Lynparza	PARP inhibitor	prostate cancer	Q3 2014	(Breakthrough Therapy)			
Lynparza OlympiA	PARP inhibitor	gBRCA adjuvant breast cancer	Q2 2014	2020	2020	2020	
Tagrisso FLAURA	EGFR tyrosine kinase inhibitor	1st-line advanced EGFRm NSCLC	Q1 2015	2017	2017	2017	2017
Tagrisso ADAURA	EGFR tyrosine kinase inhibitor	adjuvant EGFRm NSCLC	Q4 2015	2022	2022	2022	2022
<b>Cardiovascular &amp; Metabolic Diseases</b>							
Brilinta <sup>2</sup> PEGASUS-TIMI 54	P2Y12 receptor antagonist	outcomes trial in patients with prior myocardial infarction	Q4 2010	Launched (Priority Review)	Launched	Approved <sup>2</sup>	Accepted
Brilinta <sup>2</sup> 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
Brilinta <sup>2</sup> HESTIA	P2Y12 receptor antagonist	prevention of vaso-occlusive crises in paediatric patients with sickle cell disease	Q1 2014	2020	2020		
Onglyza SAVOR-TIMI 53	DPP-4 inhibitor	type-2 diabetes outcomes trial	Q2 2010	Launched	Launched		Accepted

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Compound	Mechanism	Area Under Investigation	Date Commenced Phase	Estimated Regulatory Acceptance Date / Submission Status			
				US	EU	Japan	China
<i>Kombiglyze XR/Komboglyze</i> <sup>3</sup>	DPP-4 inhibitor/ metformin FDC	type-2 diabetes		Launched	Launched		Submitted
<i>Farxiga</i> <sup>4</sup> DECLARE-TIMI 58	SGLT2 inhibitor	type-2 diabetes outcomes trial	Q2 2013	2020	2020		
<i>Farxiga</i> <sup>3</sup>	SGLT2 inhibitor	type-1 diabetes	Q4 2014	2018	2018	2018	
<i>Xigduo XR/Xigduo</i> <sup>5</sup>	SGLT2 inhibitor/ metformin FDC	type-2 diabetes		Launched	Launched		
<i>Qtern</i> (saxagliptin/ dapagliflozin FDC)	DPP-4 inhibitor/ SGLT2 inhibitor FDC	type-2 diabetes	Q2 2012	Accepted	Approved		
<i>Bydureon</i> weekly suspension	GLP-1 receptor agonist	type-2 diabetes	Q1 2013	2017	2017		
<i>Bydureon</i> EXSCEL	GLP-1 receptor agonist	type-2 diabetes outcomes trial	Q2 2010	2018	2018	2018	
<i>Epanova</i> STRENGTH	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
<b>Respiratory</b>							
<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> <sup>#</sup>	LAMA/LABA	COPD	Q3 2016	2018	Launched		2019
<b>Other</b>							
<i>Nexium</i>	proton pump inhibitor	stress ulcer prophylaxis		N/A	N/A	N/A	Q4 2016
<i>Nexium</i>	proton pump inhibitor	paediatrics		Launched	Launched	Q4 2016	Accepted
<i>linaclotide</i> <sup>#</sup>	GC-C receptor peptide agonist	irritable bowel syndrome with constipation (IBS-C)		N/A	N/A	N/A	Accepted

# Collaboration

- 1 JP submission accepted 19 August 016
- 2 *Brilinta* in the US; *Brilique* in rest of world. JP approval received 28 Sept 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

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## Terminations (discontinued projects between 1 July 2016 and 30 September 2016)

NME / Line Extension	Compound	Reason for Discontinuation	Area Under Investigation
NME	AZD7624	Safety/Efficacy	COPD
LCM	<i>Brilinta</i> EUCLID	Safety/Efficacy	Peripheral artery disease
NME	inebilizumab	Safety/Efficacy	Diffuse large B-cell lymphoma
NME	MEDI3617 <sup>#</sup>	Safety/Efficacy	solid tumours
NME	cediranib ICON 6	Regulatory	PSR ovarian cancer
NME	selumetinib <sup>#</sup> SELECT-1	Safety/Efficacy	2nd-line KRAS <sup>m</sup> NSCLC

## Completed Projects / Divestitures

Compound	Mechanism	Area Under Investigation	Completed/ Divested	Estimated Regulatory Submission Acceptance <sup>†</sup>			
				US	EU	Japan	China
<i>Zurampic</i> <sup>1</sup>	selective uric acid reabsorption inhibitor (URAT-1)	chronic treatment of hyperuricemia in patients with gout	Completed / Divested	Launched	Approved	n/a	n/a
<i>Zurampic</i> + allopurinol FDC <sup>1</sup>	selective uric acid reabsorption inhibitor (URAT-1)+xanthine oxidase inhibitor FDC	chronic treatment of hyperuricemia in patients with gout	Divested				
MEDI-550	pandemic influenza virus vaccine	pandemic influenza prophylaxis	Completed	n/a	Approved	n/a	n/a
tralokinumab <sup>2</sup>	IL-13 mAb	atopic dermatitis	Divested				
brodalumab <sup>3</sup> AMAGINE-1,2,3	IL-17R mAb	psoriasis	Divested				

- <sup>1</sup> AstraZeneca has granted Ironwood Pharmaceuticals, Inc. exclusive US rights (26 April 2016) and Grünenthal GmbH exclusive rights in Europe and Latin America (2 June 2016). *Zurampic* launched in US on 3 Oct 2016
- <sup>2</sup> AstraZeneca entered licensing agreement with LEO Pharma (1 July 2016, completed on 16 August 2016)
- <sup>3</sup> 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)

## Condensed Consolidated Statement of Comprehensive Income

For the <b>nine months</b> ended 30 September	2016 \$m	2015 \$m
Product sales	16,059	17,434
Externalisation revenue	1,358	875
<b>Total revenue</b>	17,417	18,309
Cost of sales	(2,966)	(3,377)
<b>Gross profit</b>	14,451	14,932
Distribution costs	(243)	(240)
Research and development expense	(4,347)	(4,251)
Selling, general and administrative costs	(8,027)	(8,444)
Other operating income and expense	535	1,029
<b>Operating profit</b>	2,369	3,026
Finance income	44	33
Finance expense	(1,022)	(783)
Share of after tax losses in associates and joint ventures	(22)	(9)
<b>Profit before tax</b>	1,369	2,267
Taxation	220	(249)
<b>Profit for the period</b>	1,589	2,018
<b>Other comprehensive income</b>		
<i>Items that will not be reclassified to profit or loss</i>		
Remeasurement of the defined benefit pension liability	(1,127)	34
Tax on items that will not be reclassified to profit or loss	256	(12)
	(871)	22
<i>Items that may be reclassified subsequently to profit or loss</i>		
Foreign exchange arising on consolidation	(690)	(359)
Foreign exchange arising on designating borrowings in net investment hedges	(194)	(322)
Fair value movements on cash flow hedges	(26)	-
Fair value movements on cash flow hedges transferred to profit or loss	41	-
Fair value movements on derivatives designated in net investment hedges	(96)	24
Amortisation of loss on cash flow hedge	1	1
Net available for sale gains/(losses) taken to equity	126	(63)
Tax on items that may be reclassified subsequently to profit or loss	63	84
	(775)	(635)
<b>Other comprehensive income for the period, net of tax</b>	(1,646)	(613)
<b>Total comprehensive income for the period</b>	(57)	1,405
<b>Profit attributable to:</b>		
Owners of the Parent	1,657	2,017
Non-controlling interests	(68)	1
	1,589	2,018
<b>Total comprehensive income attributable to:</b>		
Owners of the Parent	12	1,405
Non-controlling interests	(69)	-
	(57)	1,405
Basic earnings per \$0.25 Ordinary Share	\$1.31	\$1.60
Diluted earnings per \$0.25 Ordinary Share	\$1.31	\$1.59
Weighted average number of Ordinary Shares in issue (millions)	1,265	1,264
Diluted weighted average number of Ordinary Shares in issue (millions)	1,266	1,265

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## Condensed Consolidated Statement of Comprehensive Income

For the <b>quarter</b> ended 30 September	2016 \$m	2015 \$m
Product sales	5,025	5,850
Externalisation revenue	674	95
<b>Total revenue</b>	<b>5,699</b>	<b>5,945</b>
Cost of sales	(900)	(1,041)
<b>Gross profit</b>	<b>4,799</b>	<b>4,904</b>
Distribution costs	(76)	(79)
Research and development expense	(1,402)	(1,429)
Selling, general and administrative costs	(2,403)	(2,679)
Other operating income and expense	110	453
<b>Operating profit</b>	<b>1,028</b>	<b>1,170</b>
Finance income	13	9
Finance expense	(355)	(246)
Share of after tax losses in associates and joint ventures	(10)	(2)
<b>Profit before tax</b>	<b>676</b>	<b>931</b>
Taxation	319	(161)
<b>Profit for the period</b>	<b>995</b>	<b>770</b>
<b>Other comprehensive income</b>		
<i>Items that will not be reclassified to profit or loss</i>		
Remeasurement of the defined benefit pension liability	(285)	(208)
Tax on items that will not be reclassified to profit or loss	21	45
	(264)	(163)
<i>Items that may be reclassified subsequently to profit or loss</i>		
Foreign exchange arising on consolidation	(167)	(348)
Foreign exchange arising on designating borrowings in net investment hedges	(127)	(105)
Fair value movements on cash flow hedges	77	-
Fair value movements on cash flow hedges transferred to profit or loss	(19)	-
Fair value movements on derivatives designated in net investment hedges	(17)	4
Net available for sale gains/(losses) taken to equity	162	(34)
Tax on items that may be reclassified subsequently to profit or loss	(12)	41
	(103)	(442)
<b>Other comprehensive income for the period, net of tax</b>	<b>(367)</b>	<b>(605)</b>
<b>Total comprehensive income for the period</b>	<b>628</b>	<b>165</b>
<b>Profit attributable to:</b>		
Owners of the Parent	1,014	770
Non-controlling interests	(19)	-
	995	770
<b>Total comprehensive income attributable to:</b>		
Owners of the Parent	648	166
Non-controlling interests	(20)	(1)
	628	165
Basic earnings per \$0.25 Ordinary Share	\$0.80	\$0.61
Diluted earnings per \$0.25 Ordinary Share	\$0.80	\$0.60
Weighted average number of Ordinary Shares in issue (millions)	1,265	1,264
Diluted weighted average number of Ordinary Shares in issue (millions)	1,266	1,265

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## Condensed Consolidated Statement of Financial Position

	At 30 Sep 2016 \$m	At 31 Dec 2015 \$m	At 30 Sep 2015 \$m
<b>ASSETS</b>			
<b>Non-current assets</b>			
Property, plant and equipment	6,690	6,413	6,205
Goodwill	11,806	11,868	11,430
Intangible assets	28,507	22,646	19,997
Derivative financial instruments	278	446	479
Investments in associates and joint ventures	95	85	48
Other investments	715	458	444
Other receivables	681	907	925
Deferred tax assets	1,584	1,294	1,391
	<u>50,356</u>	<u>44,117</u>	<u>40,919</u>
<b>Current assets</b>			
Inventories	2,420	2,143	2,193
Assets held for sale	332	-	-
Trade and other receivables	5,449	6,622	5,876
Other investments	909	613	496
Derivative financial instruments	26	2	30
Income tax receivable	640	387	523
Cash and cash equivalents	3,090	6,240	4,081
	<u>12,866</u>	<u>16,007</u>	<u>13,199</u>
<b>Total assets</b>	<u>63,222</u>	<u>60,124</u>	<u>54,118</u>
<b>LIABILITIES</b>			
<b>Current liabilities</b>			
Interest-bearing loans and borrowings	(2,939)	(916)	(2,671)
Trade and other payables	(9,961)	(11,663)	(10,593)
Derivative financial instruments	(12)	(9)	(25)
Provisions	(936)	(798)	(682)
Income tax payable	(1,534)	(1,483)	(2,065)
	<u>(15,382)</u>	<u>(14,869)</u>	<u>(16,036)</u>
<b>Non-current liabilities</b>			
Interest-bearing loans and borrowings	(14,744)	(14,137)	(8,276)
Derivative financial instruments	(25)	(1)	-
Deferred tax liabilities	(4,051)	(2,733)	(1,559)
Retirement benefit obligations	(2,870)	(1,974)	(2,542)
Provisions	(396)	(444)	(381)
Other payables	(10,842)	(7,457)	(7,956)
	<u>(32,928)</u>	<u>(26,746)</u>	<u>(20,714)</u>
<b>Total liabilities</b>	<u>(48,310)</u>	<u>(41,615)</u>	<u>(36,750)</u>
<b>Net assets</b>	<u>14,912</u>	<u>18,509</u>	<u>17,368</u>
<b>EQUITY</b>			
<b>Capital and reserves attributable to equity holders of the Company</b>			
Share capital	316	316	316
Share premium account	4,344	4,304	4,291
Other reserves	2,031	2,036	2,035
Retained earnings	6,381	11,834	10,707
	<u>13,072</u>	<u>18,490</u>	<u>17,349</u>
<b>Non-controlling interests</b>	<u>1,840</u>	<u>19</u>	<u>19</u>
<b>Total equity</b>	<u>14,912</u>	<u>18,509</u>	<u>17,368</u>

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## Condensed Consolidated Statement of Cash Flows

For the nine months ended 30 September	2016 \$m	2015 \$m
<b>Cash flows from operating activities</b>		
Profit before tax	1,369	2,267
Finance income and expense	978	750
Share of after tax losses in associates and joint ventures	22	9
Depreciation, amortisation and impairment	1,767	2,136
Increase in working capital and short-term provisions	(472)	(35)
Non-cash and other movements	(545)	(987)
<b>Cash generated from operations</b>	3,119	4,140
Interest paid	(489)	(433)
Tax paid	(445)	(954)
<b>Net cash inflow from operating activities</b>	2,185	2,753
<b>Cash flows from investing activities</b>		
Movement in short-term investments and fixed deposits	(165)	285
Purchase of property, plant and equipment	(912)	(874)
Disposal of property, plant and equipment	47	16
Purchase of intangible assets	(761)	(1,379)
Disposal of intangible assets	117	737
Purchase of non-current asset investments	(210)	(47)
Disposal of non-current asset investments	-	59
Payments to joint ventures	(19)	-
Upfront payments on business acquisitions	(2,564)	-
Payment of contingent consideration on business acquisitions	(197)	(553)
Interest received	105	102
Payments made by subsidiaries to non-controlling interests	(13)	-
<b>Net cash outflow from investing activities</b>	(4,572)	(1,654)
<b>Net cash (outflow)/inflow before financing activities</b>	(2,387)	1,099
<b>Cash flows from financing activities</b>		
Proceeds from issue of share capital	40	30
New long-term loans	2,483	-
Repayment of loans	-	(884)
Dividends paid	(3,561)	(3,486)
Hedge contracts relating to dividend payments	18	(51)
Repayment of obligations under finance leases	(12)	(40)
Movement in short-term borrowings	12	1,025
<b>Net cash outflow from financing activities</b>	(1,020)	(3,406)
Net decrease in cash and cash equivalents in the period	(3,407)	(2,307)
Cash and cash equivalents at the beginning of the period	6,051	6,164
Exchange rate effects	43	(70)
<b>Cash and cash equivalents at the end of the period</b>	2,687	3,787
<b>Cash and cash equivalents consists of:</b>		
Cash and cash equivalents	3,090	4,081
Overdrafts	(403)	(294)
	2,687	3,787

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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
<b>At 1 Jan 2015</b>	316	4,261	2,021	13,029	19,627	19	19,646
Profit for the period	-	-	-	2,017	2,017	1	2,018
Other comprehensive income	-	-	-	(612)	(612)	(1)	(613)
Transfer to other reserves	-	-	14	(14)	-	-	-
<b>Transactions with owners:</b>							
Dividends	-	-	-	(3,537)	(3,537)	-	(3,537)
Issue of Ordinary Shares	-	30	-	-	30	-	30
Share-based payments	-	-	-	(176)	(176)	-	(176)
Net movement	-	30	14	(2,322)	(2,278)	-	(2,278)
<b>At 30 Sep 2015</b>	<b>316</b>	<b>4,291</b>	<b>2,035</b>	<b>10,707</b>	<b>17,349</b>	<b>19</b>	<b>17,368</b>
	Share capital \$m	Share premium account \$m	Other reserves* \$m	Retained earnings \$m	Total \$m	Non-controlling interests \$m	Total equity \$m
<b>At 1 Jan 2016</b>	316	4,304	2,036	11,834	18,490	19	18,509
Profit for the period	-	-	-	1,657	1,657	(68)	1,589
Other comprehensive income	-	-	-	(1,645)	(1,645)	(1)	(1,646)
Transfer to other reserves	-	-	(5)	5	-	-	-
<b>Transactions with owners:</b>							
Dividends	-	-	-	(3,540)	(3,540)	-	(3,540)
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	-	40	-	-	40	-	40
Share-based payments	-	-	-	(105)	(105)	-	(105)
Net movement	-	40	(5)	(5,453)	(5,418)	1,821	(3,597)
<b>At 30 Sep 2016</b>	<b>316</b>	<b>4,344</b>	<b>2,031</b>	<b>6,381</b>	<b>13,072</b>	<b>1,840</b>	<b>14,912</b>

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

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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 nine months ended 30 September 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 nine months ended 30 September 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 and Interim Financial Statements for the six months ended 30 June 2016.

#### Going concern

The Group has considerable financial resources available. As at 30 September 2016 the Group has \$3.2bn in financial resources (cash balances of \$3.1bn and undrawn committed bank facilities of \$3bn which are available until April 2021, with only \$2.9bn 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 shown 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 year ended 30 September 2016 is stated after charging restructuring costs of \$713m (\$250m for the third quarter of 2016). These have been charged to profit as follows:

	YTD 2016 \$m	YTD 2015 \$m	Q3 2016 \$m	Q3 2015 \$m
Cost of sales	87	124	59	23
Research and development expense	146	180	39	56
Selling, general and administrative costs	504	358	176	135
Other operating income and expense	(24)	-	(24)	-
<b>Total</b>	<b>713</b>	<b>662</b>	<b>250</b>	<b>214</b>

### 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 Sep 2016 \$m
Loans due after one year	(14,109)	(2,483)	-	1,772	84	(14,736)
Finance leases due after one year	(28)	-	-	20	-	(8)
<b>Total long-term debt</b>	<b>(14,137)</b>	<b>(2,483)</b>	<b>-</b>	<b>1,792</b>	<b>84</b>	<b>(14,744)</b>
Current instalments of loans	-	-	-	(1,775)	-	(1,775)
Current instalments of finance leases	(67)	12	-	(34)	-	(89)
<b>Total current debt</b>	<b>(67)</b>	<b>12</b>	<b>-</b>	<b>(1,809)</b>	<b>-</b>	<b>(1,864)</b>
Other Investments	613	167	140	59	(52)	927
Net derivative financial instruments	438	(2)	-	(169)	-	267
Cash and cash equivalents	6,240	(3,183)	-	-	33	3,090
Overdrafts	(189)	(224)	-	-	10	(403)
Short-term borrowings	(660)	(12)	-	(1)	1	(672)
	6,442	(3,254)	140	(111)	(8)	3,209
<b>Net debt</b>	<b>(7,762)</b>	<b>(5,725)</b>	<b>140</b>	<b>(128)</b>	<b>76</b>	<b>(13,399)</b>

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 September 2016, Acerta Pharma had no revenues and its loss after tax was \$157m.

In the period since 2 February 2016, the acquisition accounting has been adjusted to reflect new information regarding the value of net assets acquired with Acerta. This has resulted in an increase in other assets and a decrease in goodwill of \$15m.

	<b>Fair value \$m</b>
Intangible assets	7,307
Other assets including cash and cash equivalents	253
Deferred tax liabilities	(1,827)
Other liabilities	(90)
<b>Total net assets acquired</b>	<b>5,643</b>
Non-controlling interests	(1,903)
Goodwill	69
<b>Fair value of total consideration</b>	<b>3,809</b>
Less: fair value of deferred consideration	(1,332)
<b>Total upfront consideration</b>	<b>2,477</b>
Less: cash and cash equivalents acquired	(94)
<b>Net cash outflow</b>	<b>2,383</b>

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

## 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 \$1,624m of other investments, \$1,749m of loans, and \$267m of derivatives as at 30 September 2016. The total fair value of interest-bearing loans and borrowings at 30 September 2016 which have a carrying value of \$17,683m in the Condensed Consolidated Statement of Financial Position, was \$19,559m. 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
<b>At 1 January</b>	5,092	1,319	6,411	6,899
Settlements	(197)	-	(197)	(553)
Revaluations	32	100	132	58
Discount unwind	292	80	372	395
Foreign exchange	-	2	2	2
<b>At 30 September</b>	<b>5,219</b>	<b>1,501</b>	<b>6,720</b>	<b>6,801</b>

## 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 and as part of the Company's Half-Yearly Financial Report for the six-month period to 30 June 2016 (the Disclosures). Unless noted otherwise below or in the Disclosures, no provisions have been established in respect of the claims discussed below.

As discussed in the 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 Disclosures and herein.

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

### Matters disclosed in respect of the third quarter of 2016 and to 10 November 2016.

#### Patent litigation

##### **Tagrisso (osimertinib)**

###### *Patent proceedings outside the US*

In Europe, in October 2016, Stada Arzneimittel AG filed an opposition to the grant of European Patent No. 2,736,895.

##### **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*. A trial against two of the defendants commenced on 11 July 2016 and was scheduled to reconvene on 1 August 2016. AstraZeneca settled the lawsuits against both of these defendants prior to trial reconvening and consequently those cases have since been dismissed. AstraZeneca continues to litigate against several additional defendants with trial anticipated in 2017.

###### *Patent proceedings outside the US*

As previously disclosed, in Spain, in January 2016 the Barcelona Commercial Court ordered a preliminary injunction preventing Sandoz Farmacéutica, S. A. from launching its generic version of *Faslodex*. The preliminary injunction was maintained following an oral hearing in July 2016.

In Germany, in September 2016, a provisional injunction request based on European Patent No. 1,250,138 (the '138 Patent) was granted by the Regional Court of Düsseldorf against ratiopharm GmbH (ratiopharm). As previously disclosed, in July 2015, AstraZeneca was served with complaints filed by Hexal AG (Hexal) and ratiopharm requesting the revocation of the '138 patent. The German Federal Patent Court has scheduled a hearing on this matter for 22 November 2016.

Also in Germany, as previously disclosed, in December 2015 AstraZeneca filed a patent infringement suit relating to European Patent No. 2,255,573 against Hexal in the Regional Court of Mannheim referring to Hexal's threatened launch of a generic *Faslodex* product. These proceedings were stayed at an oral hearing in August 2016.

##### **Onglyza (saxagliptin) and Kombiglyze (saxagliptin and metformin)**

###### *US patent proceedings*

As previously disclosed, AstraZeneca initiated patent infringement proceedings against Wockhardt Bio AG and Wockhardt USA LLC, Sun Pharma Global FZE, Sun Pharmaceutical Industries Ltd. and Amneal Pharmaceuticals LLC (Wockhardt, Sun and Amneal) in the US District Court for the District of Delaware (the District Court) after those entities had submitted ANDAs 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

their ANDAs. In August and September 2016, AstraZeneca was informed that Wockhardt, Sun and Amneal had changed their Paragraph IV Certifications to Paragraph III Certifications, seeking approval to market the products described in their ANDAs following expiration of the '186 Patent. The patent infringement proceedings against these entities continues.

A trial was held in September 2016 against Wockhardt, Sun and Amneal, Mylan Pharmaceuticals Inc. (Mylan), Aurobindo Pharma Ltd., Aurobindo Pharma U.S.A., Inc., Actavis Laboratories FL, Inc. and Watson Laboratories, Inc. in the District Court. A decision on the validity of the '186 Patent is awaited. In September 2016, Apotex Corp. and Apotex, Inc. agreed to be bound by the District Court's judgment.

As previously disclosed, in June 2016, the US Court of Appeals for the Federal Circuit denied Mylan's petition for rehearing *en banc* of the decision affirming the denial of Mylan's motion to dismiss for lack of jurisdiction. In September 2016, Mylan filed a petition for writ of *certiorari* with the Supreme Court of the United States seeking an appeal of that decision.

As previously disclosed, in May 2016, the US Patent and Trademark Office (USPTO) instituted an *inter partes* review brought by Mylan challenging the validity of the '186 Patent (the Mylan IPR) and a number of generics companies also filed petitions for *inter partes* review challenging the validity of the '186 Patent and sought to join the Mylan IPR. In August and September 2016 respectively, Wockhardt Bio AG and Teva Pharmaceuticals USA, Inc. were joined with the Mylan IPR. A decision as to whether the others will be permitted to join the Mylan IPR is awaited.

### **Crestor (rosuvastatin)**

#### *Patent proceedings outside the US*

As previously disclosed, 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 appealed; however, the parties settled the preliminary proceedings before the appeal hearing. AstraZeneca and Shionogi have commenced patent infringement proceedings against Biogaran.

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. The individual has appealed to the Intellectual Property High Court of Japan with the intervention of Nippon Chemiphar Co. Ltd (Nippon). In addition, Nippon has commenced a separate patent invalidation request with the JPO in relation to the *Crestor* substance patent. A hearing was held on 30 September 2016.

As previously disclosed, in the UK, in October 2015, Resolution Chemicals Ltd. commenced an action in the UK Patent Court alleging partial invalidity and non-infringement of the supplementary protection certificate related to the *Crestor* substance patent. The case has been stayed.

In Switzerland, in May 2016, Mepha Pharma AG challenged the validity of the supplementary protection certificate related to the *Crestor* substance patent. In September 2016, AstraZeneca responded.

### **Product liability litigation**

#### **Farxiga (dapagliflozin)**

As previously disclosed, AstraZeneca has been named as a defendant in lawsuits filed in four jurisdictions involving plaintiffs claiming physical injury, including diabetic ketoacidosis and kidney failure, from treatment with *Farxiga*. Since then, additional cases with similar allegations have been filed in other jurisdictions. On 25 October 2016, one of these cases was dismissed with prejudice in favour of AstraZeneca. Motions to dismiss are pending in other jurisdictions. In October 2016, counsel for plaintiffs in a product liability action pertaining to *Invokana* (a product in the same class as *Farxiga*) filed a motion with the Judicial Panel on Multidistrict Litigation seeking transfer of any currently pending cases as well as any similar, subsequently filed cases to a coordinated and consolidated pre-trial Multidistrict Litigation proceeding on a class-wide basis.

#### **Onglyza/Kombiglyze (saxagliptin)**

As previously disclosed, AstraZeneca is defending various lawsuits filed in state and federal courts in the US involving multiple plaintiffs claiming heart failure, cardiac failure and/or death injuries from treatment with either *Onglyza* or *Kombiglyze*. In October 2016, 14 of these claims were dismissed in response to motions filed by AstraZeneca. Approximately 80 plaintiffs claims currently remain in active litigation.

#### **Synagis (palivizumab)**

As previously disclosed, AstraZeneca and MedImmune were 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*. In July 2016, the plaintiffs dismissed their claims voluntarily.

### **Nexium and Prilosec (esomeprazole and omeprazole)**

As previously disclosed, all claims alleging that *Nexium* caused osteoporotic injuries, such as bone deterioration, loss of bone density and/or bone fractures, have now been dismissed with judgment entered in AstraZeneca's favour. Approximately 270 plaintiffs have appealed the dismissal of their claims to the US Court of Appeals for the Ninth Circuit, and fewer than 40 plaintiffs have appealed the dismissal of their claims to the California Second Appellate Division. On 27 October 2016, the US Court of Appeals for the Ninth Circuit affirmed the dismissal of the approximately 270 claims that were pending in federal court.

AstraZeneca is defending various lawsuits in federal courts in the US involving multiple plaintiffs claiming that they have been diagnosed with kidney injuries following treatment with proton pump inhibitors, including *Nexium* and *Prilosec*. In October 2016, counsel for these plaintiffs filed a motion with the Judicial Panel on Multidistrict Litigation seeking transfer of any currently pending cases as well as any similar, subsequently filed cases to a coordinated and consolidated pre-trial Multidistrict Litigation proceeding.

### **Commercial litigation**

#### **Pearl Therapeutics**

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

#### **Crestor Citizen's Petition**

As previously disclosed, in May 2016, AstraZeneca filed a Citizen's Petition with the FDA requesting that the FDA does not approve any pending generic ANDAs for rosuvastatin until the expiration of the paediatric orphan exclusivity for *Crestor*. In 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. The filings requested 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. In July 2016, the Court denied AstraZeneca's application for a TRO. On 19 August 2016, the Court entered an order dismissing the case without prejudice.

#### **Nexium settlement anti-trust litigation**

As previously disclosed, AstraZeneca is a defendant in a multidistrict litigation class action and individual lawsuit alleging that AstraZeneca's settlements of certain patent litigation in the US relating to *Nexium* violated US anti-trust law and various state laws. A trial in the US District Court for the District of Massachusetts commenced in October 2014 and, in December 2014, a jury returned a verdict in favour of AstraZeneca. Following the Court's denial of the plaintiffs' motion for a new trial and preliminary injunction, the Court entered judgment in favour of AstraZeneca in September 2015. The plaintiffs have appealed that judgment and oral argument on the appeal was heard on 5 October 2016.

#### **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. and Dr. Reddy's Laboratories, Inc. to enforce certain AstraZeneca trademark rights related to *Nexium* and *Prilosec*. This matter is now resolved.

### **Government investigations/proceedings**

#### **Foreign Corrupt Practices Act**

As previously disclosed, in connection with investigations into anti-bribery and corruption issues in the pharmaceutical industry, AstraZeneca received inquiries from enforcement agencies, including the Department of Justice (DOJ) and the Securities Exchange Commission (SEC), regarding, among other things, sales practices, internal controls, certain distributors and interactions with healthcare providers and other government officials in several countries. In August 2016, AstraZeneca entered into a civil settlement with the SEC to resolve these inquiries. The DOJ has informed AstraZeneca that it has closed its inquiry into this matter.

#### **Seroquel IR (quetiapine fumarate) and Seroquel XR (quetiapine fumarate)**

As previously disclosed, AstraZeneca was in litigation with the Attorney General of Mississippi in relation to the state law claims brought by state Attorneys General which alleged that AstraZeneca had made false and/or misleading statements in marketing and promoting *Seroquel*. This litigation has been resolved and the matter has been dismissed.



## 8 PRODUCT ANALYSIS – YTD 2016

	World		US		Europe		Established ROW		Emerging Markets	
	YTD 2016 \$m	CER %	YTD 2016 \$m	CER %	YTD 2016 \$m	CER %	YTD 2016 \$m	CER %	YTD 2016 \$m	CER %
<b>Oncology:</b>										
<i>Iressa</i>	395	(3)	16	n/m	91	(5)	101	(9)	187	(6)
<i>Tagrisso</i>	276	n/m	180	n/m	49	n/m	43	n/m	4	n/m
<i>Lynparza</i>	156	n/m	96	109	56	n/m	-	-	4	n/m
Legacy:										
<i>Faslodex</i>	608	19	321	23	169	11	48	13	70	26
<i>Zoladex</i>	581	(4)	27	23	117	(5)	199	(6)	238	(3)
<i>Casodex</i>	187	(9)	2	n/m	19	(14)	84	(21)	82	6
<i>Arimidex</i>	175	(6)	12	(20)	27	(27)	53	(16)	83	13
Others	75	(32)	-	n/m	4	(80)	51	7	20	(9)
<b>Total Oncology</b>	<b>2,453</b>	<b>17</b>	<b>654</b>	<b>79</b>	<b>532</b>	<b>14</b>	<b>579</b>	<b>(1)</b>	<b>688</b>	<b>3</b>
<b>Cardiovascular &amp; Metabolic Diseases:</b>										
<i>Brilinta</i>	603	39	243	43	192	15	32	26	136	88
<i>Farxiga</i>	596	79	327	78	136	58	41	82	92	120
<i>Onglyza</i>	571	(2)	304	(6)	102	(5)	55	21	110	3
<i>Bydureon</i>	436	3	349	(3)	75	38	8	17	4	50
<i>Byetta</i>	199	(18)	127	(23)	37	(19)	16	-	19	31
Legacy:										
<i>Crestor</i>	2,770	(24)	1,128	(45)	657	(3)	445	(1)	540	12
<i>Seloken/Toprol-XL</i>	559	8	81	16	67	(6)	10	11	401	9
<i>Atacand</i>	234	(9)	28	4	74	(6)	15	(29)	117	(10)
Others	337	(24)	27	(34)	89	(16)	38	(18)	183	(27)
<b>Total Cardiovascular &amp; Metabolic Diseases</b>	<b>6,305</b>	<b>(8)</b>	<b>2,614</b>	<b>(23)</b>	<b>1,429</b>	<b>3</b>	<b>660</b>	<b>3</b>	<b>1,602</b>	<b>9</b>
<b>Respiratory:</b>										
<i>Symbicort</i>	2,249	(10)	958	(14)	679	(15)	310	1	302	11
<i>Pulmicort</i>	773	8	138	(7)	73	(15)	61	(5)	501	20
<i>Tudorza/Eklira</i>	134	(5)	61	(22)	65	14	7	-	1	n/m
<i>Daliresp/Daxas</i>	113	57	101	40	10	n/m	1	n/m	1	n/m
<i>Duaklir</i>	44	n/m	-	-	42	n/m	1	n/m	1	n/m
Others	230	23	7	(42)	83	24	33	94	107	18
<b>Total Respiratory</b>	<b>3,543</b>	<b>(2)</b>	<b>1,265</b>	<b>(11)</b>	<b>952</b>	<b>(7)</b>	<b>413</b>	<b>5</b>	<b>913</b>	<b>17</b>
<b>Other:</b>										
<i>Nexium</i>	1,541	(19)	419	(42)	190	(7)	389	(12)	543	-
<i>Seroquel XR</i>	617	(20)	444	(18)	106	(33)	14	(30)	53	(5)
<i>Synagis</i>	375	(3)	171	9	204	(11)	-	-	-	-
<i>Losec/Prilosec</i>	217	(15)	7	(61)	63	(11)	42	(30)	105	(3)
<i>Movantik/Moventig</i>	65	n/m	64	n/m	-	-	-	-	1	n/m
<i>FluMist/Fluenz</i>	37	(58)	13	(85)	21	n/m	2	n/m	1	n/m
Others	906	(15)	96	(43)	235	(11)	173	(14)	402	(9)
<b>Total Other</b>	<b>3,758</b>	<b>(16)</b>	<b>1,214</b>	<b>(29)</b>	<b>819</b>	<b>(12)</b>	<b>620</b>	<b>(14)</b>	<b>1,105</b>	<b>(4)</b>
<b>Total Product Sales</b>	<b>16,059</b>	<b>(6)</b>	<b>5,747</b>	<b>(17)</b>	<b>3,732</b>	<b>(2)</b>	<b>2,272</b>	<b>(3)</b>	<b>4,308</b>	<b>6</b>

9 PRODUCT ANALYSIS – Q3 2016

	World		US		Europe		Established ROW		Emerging Markets	
	Q3 2016 \$m	CER %	Q3 2016 \$m	CER %	Q3 2016 \$m	CER %	Q3 2016 \$m	CER %	Q3 2016 \$m	CER %
<b>Oncology:</b>										
<i>Iressa</i>	125	(13)	6	n/m	30	-	36	(14)	53	(23)
<i>Tagrisso</i>	133	n/m	77	n/m	24	n/m	28	n/m	4	n/m
<i>Lynparza</i>	58	111	34	70	24	n/m	-	-	-	-
Legacy:										
<i>Faslodex</i>	207	11	110	15	56	8	18	7	23	9
<i>Zoladex</i>	199	(5)	8	-	37	(9)	69	(12)	85	1
<i>Casodex</i>	62	(8)	-	-	6	(14)	28	(25)	28	15
<i>Arimidex</i>	56	(14)	2	(75)	9	(25)	18	(11)	27	8
Others	27	(29)	-	n/m	1	(86)	19	13	7	-
<b>Total Oncology</b>	<b>867</b>	<b>17</b>	<b>237</b>	<b>69</b>	<b>187</b>	<b>19</b>	<b>216</b>	<b>2</b>	<b>227</b>	<b>(1)</b>
<b>Cardiovascular &amp; Metabolic Diseases:</b>										
<i>Brilinta</i>	208	25	84	22	67	11	12	20	45	60
<i>Farxiga</i>	220	64	118	71	47	37	16	36	39	100
<i>Onglyza</i>	169	(16)	92	(17)	29	(22)	18	19	30	(21)
<i>Bydureon</i>	145	(10)	115	(17)	25	30	3	(33)	2	n/m
<i>Byetta</i>	61	(15)	38	(16)	12	(24)	6	-	5	-
Legacy:										
<i>Crestor</i>	688	(44)	124	(82)	219	-	159	1	186	17
<i>Seloken/Toprol-XL</i>	185	12	28	27	23	(4)	5	150	129	10
<i>Atacand</i>	74	(3)	7	(22)	25	(7)	5	(29)	37	11
Others	95	(28)	11	83	25	(26)	13	(14)	46	(39)
<b>Total Cardiovascular &amp; Metabolic Disease</b>	<b>1,845</b>	<b>(21)</b>	<b>617</b>	<b>(47)</b>	<b>472</b>	<b>-</b>	<b>237</b>	<b>4</b>	<b>519</b>	<b>9</b>
<b>Respiratory:</b>										
<i>Symbicort</i>	697	(17)	277	(30)	213	(8)	114	4	93	(13)
<i>Pulmicort</i>	224	4	32	(20)	19	(5)	21	(10)	152	13
<i>Tudorza/Eklira</i>	47	(17)	20	(39)	24	9	3	-	-	n/m
<i>Daliresp/Daxas</i>	42	27	35	6	6	n/m	1	n/m	-	-
<i>Duaklir</i>	14	88	-	-	14	88	-	-	-	-
Others	86	46	-	n/m	32	48	16	n/m	38	31
<b>Total Respiratory</b>	<b>1,110</b>	<b>(8)</b>	<b>364</b>	<b>(27)</b>	<b>308</b>	<b>2</b>	<b>155</b>	<b>10</b>	<b>283</b>	<b>5</b>
<b>Other:</b>										
<i>Nexium</i>	516	(21)	125	(50)	63	(2)	152	(5)	176	(2)
<i>Seroquel XR</i>	190	(26)	138	(26)	30	(34)	4	(33)	18	6
<i>Synagis</i>	104	(11)	8	n/m	96	(20)	-	-	-	-
<i>Losec/Prilosec</i>	72	(11)	2	(67)	22	-	15	(28)	33	-
<i>Movantik/Moventig</i>	25	n/m	24	n/m	-	-	-	-	1	n/m
<i>FluMist/Fluenz</i>	26	(61)	2	(97)	21	n/m	2	n/m	1	n/m
Others	270	(25)	21	(66)	66	(24)	46	(37)	137	(4)
<b>Total Other</b>	<b>1,203</b>	<b>(22)</b>	<b>320</b>	<b>(44)</b>	<b>298</b>	<b>(13)</b>	<b>219</b>	<b>(16)</b>	<b>366</b>	<b>(2)</b>
<b>Total Product Sales</b>	<b>5,025</b>	<b>(14)</b>	<b>1,538</b>	<b>(35)</b>	<b>1,265</b>	<b>(1)</b>	<b>827</b>	<b>(1)</b>	<b>1,395</b>	<b>3</b>

## Shareholder Information

Announcement of full year and fourth quarter 2016 results	2 February 2017
Announcement of first quarter 2017 results	27 April 2017
Annual General Meeting	27 April 2017
Announcement of half year and second quarter 2017 results	27 July 2017
Announcement of nine months and third quarter 2017 results	9 November 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 second interim dividend for 2016, payable on 20 March 2017, will be 17 February 2017. Ordinary Shares listed in London and Stockholm will trade ex-dividend from 16 February 2017. American Depositary Shares listed in New York will trade ex-dividend from 15 February 2017.

The record date for the first interim dividend for 2017, payable on 11 September 2017, will be 11 August 2017. Ordinary Shares listed in London and Stockholm will trade ex-dividend from 10 August 2017. American Depositary Shares listed in New York will trade ex-dividend from 9 August 2017.

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## Addresses for Correspondence

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## Cautionary Statements Regarding Forward-Looking Statements

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.