

29 April 2016

## Q1 2016 Results

## Financial Summary

	\$m	% change	
		CER <sup>1</sup>	Actual
Total Revenue <sup>2</sup>	6,115	5	1
Core <sup>3</sup> Op. Profit	1,593	(8)	(12)
Core EPS	\$0.95	(7)	(12)
Reported Op. Profit	1,038	17	11
Reported EPS	\$0.51	26	17

- Total Revenue grew by 5%, driven by a significant increase in Externalisation Revenue
- Core R&D costs increased by 15%, reflecting recent acquisitions; Core R&D costs declined versus Q4 2015
- Core SG&A costs fell by 6% and represented 35% of Total Revenue (Q1 2015: 39%)
- Core EPS declined by 7%, reflecting a significant reduction in Other Operating Income
- Reported Operating Profit grew by 17% to \$1,038m. Reported EPS grew by 26% to \$0.51
- FY 2016 CER guidance unchanged

## Commercial Highlights

The Growth Platforms grew by 6%, representing 56% of Total Revenue:

1. Respiratory: +2%. Growth of *Pulmicort* and newly-acquired medicines offset by a decline in sales of *Symbicort*
2. *Brilinta/Brilique*: +46%. Continued encouraging progress; post-MI approval in the EU
3. Diabetes: +23%. Strong sales growth included an increase of +65% in Emerging Markets. Global *Farxiga/Forxiga* growth of 128%
4. Emerging Markets: +6%. Good China sales growth of +11%; slowdowns in other regions
5. Japan: -7%, reflecting destocking ahead of mandated biennial price reductions from April 2016
6. New Oncology: Contributed \$99m. Launch of *Tagrisso* in key markets progressing well

## Achieving Scientific Leadership: Progress since the last results announcement

Regulatory Approvals	<i>Bevespi Aerosphere</i> (previously PT003) - COPD (US) <i>Zurampic</i> - gout (EU) <i>Brilique</i> - post-myocardial infarction (post-MI) (EU) <i>Tagrisso</i> - lung cancer (JP)
Other Key Developments	Breakthrough Therapy Designation: durvalumab - bladder cancer (US) Orphan Drug Designation: acalabrutinib - blood cancers (EU); MEDI-551 - neuromyelitis optica (US) Fast Track Designation: MEDI8852 - hospitalised influenza (US)

## Advancing The Strategy

- A sharper focus on main therapy areas; additional investment to Oncology
- Collaborations in opportunistic areas to be accelerated
- Streamlining operations, supporting the sharper focus and the reduction in SG&A costs
- Strengthening ability to deliver strategic ambitions

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

"We delivered a first-quarter performance in line with expectations, with the growth in Total Revenue underpinned by the performance of the Growth Platforms. I was particularly pleased with the results in China, where we continued to deliver double-digit sales growth, and with the progress of our New Oncology launches.

"Strong advances were made in our late-stage pipeline, with regulatory approvals for *Bevespi Aerosphere* in the US for COPD, *Brilique* in the EU for post-myocardial infarction and *Tagrisso* in Japan for lung cancer. Looking ahead, we anticipate increased newsflow across the pipeline, including a number of regulatory decisions and data readouts, particularly in Oncology.

"As we continue to make encouraging progress with our priorities and our pipeline grows faster than anticipated, we are further sharpening our strategic focus on our main therapy areas, intensifying our efforts in Oncology and accelerating collaborations in opportunistic areas. We are also driving greater efficiency across the organisation to support the advancement of our strategy."



**Advancing The Strategy Through Sharper Focus**

AstraZeneca continues to make significant progress towards the Total Revenue target of \$45bn\* by 2023. The Company has increased pipeline productivity, built therapy-area leadership, developed the Growth Platforms and transformed AstraZeneca's culture. The shape of the business is evolving rapidly, with a growing number of specialty-care medicines, in particular in Oncology.

In line with the strategy designed to deliver benefits to patients and value for shareholders, the Company today announces further focus on the main therapy areas to drive greater productivity across the organisation. The prioritisation of investments will be sharpened, enabling the allocation of additional investment to Oncology. Alongside this, the Company will continue to work with others in the opportunity-led parts of the portfolio, such as Infection, Neuroscience and inflammatory diseases outside Respiratory.

This focus will streamline further AstraZeneca's operations, primarily in commercial and manufacturing. This, together with the drive for greater efficiency, will deliver a material decline in Core SG&A costs in FY 2016 and FY 2017.

These changes will enhance operational effectiveness and, once implemented by the end of FY 2017, are expected to generate net annualised benefits of \$1.1bn<sup>1</sup> that will be reflected primarily within Core SG&A costs. Associated with the changes, the Company expects to incur \$1.5bn<sup>1</sup> in one-time restructuring charges, the majority of which will be cash costs. Final estimates for programme costs, benefits and colleague impacts will be subject to consultation.

**FY 2016 Guidance**

All 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 Earnings Per Share	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. The guidance also assumes the loss of exclusivity for *Crestor* in the US from May 2016.

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

Externalisation activities, a result of increasing R&D productivity and the focus on three main therapy areas, relate to specific risk and reward-sharing strategic collaborations. They broaden, accelerate and maximise the development and commercialisation potential for a number of the Company's medicines. Initial and milestone revenue, together with sales-related revenue arising from externalisation activities, are included in the Company's financial statements as Externalisation Revenue.

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

**FY 2016 Currency Impact**

Based on average exchange rates in the quarter and the Company's published currency sensitivities, an adverse full-year impact of around 2% from currency movements on Total Revenue would be anticipated. A similar impact is anticipated in respect of Core EPS in the full year. Further details on currency sensitivities are contained within the Operating and Financial Review.

<sup>1</sup> At FY2013 exchange rates



**Pipeline: Forthcoming Major Newsflow**

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

Q2 2016	<p>benralizumab - severe asthma: Data readout</p> <p>saxagliptin/dapagliflozin - type-2 diabetes: Regulatory submission (US)</p> <p>ZS-9 - hyperkalaemia: Regulatory decision (US)</p> <p><i>Lynparza</i> - gastric cancer: Data readout</p>
H2 2016	<p><i>Bevespi Aerosphere</i> - COPD (EU): Regulatory submission (EU)</p> <p>benralizumab - severe asthma: Regulatory submission (US, EU)</p> <p><i>Brilinta/Brilique</i> - peripheral arterial disease (PAD): Data readout</p> <p>saxagliptin/dapagliflozin: Regulatory decision (EU)</p> <p>roxadustat - anaemia: Rolling regulatory submission (CN)</p> <p><i>Lynparza</i> - breast cancer: Data readout</p> <p><i>Lynparza</i> - ovarian cancer (2nd line): Data readout</p> <p>cediranib - ovarian cancer: Regulatory decision (EU)</p> <p>selumetinib - lung cancer: Data readout</p> <p>durvalumab - head and neck cancer (HAWK): Data readout</p> <p>acalabrutinib - blood cancer: Data readout, regulatory submission (US)</p> <p>CAZ AVI - serious infections: Regulatory decision (EU)</p>
H1 2017	<p>brodalumab - psoriasis: Regulatory decision</p> <p><i>Brilinta/Brilique</i> - PAD: Regulatory submission</p> <p>ZS-9: Regulatory decision (EU)</p> <p><i>Lynparza</i> - gastric cancer: Regulatory submission</p> <p><i>Lynparza</i> - breast cancer: Regulatory submission</p> <p><i>Lynparza</i> - ovarian cancer (2nd line): Regulatory submission</p> <p><i>Lynparza</i> - ovarian cancer (1st line): Data readout</p> <p>selumetinib - lung cancer: Regulatory submission</p> <p>durvalumab - head and neck cancer (HAWK): Regulatory submission</p> <p>durvalumab - lung cancer (PACIFIC): Data readout</p> <p>durva + treme - lung cancer (MYSTIC, ARCTIC): Data readout</p> <p>durva + treme - head and neck cancer (CONDOR): Data readout</p>



**Notes**

1. All growth rates and guidance are shown at constant exchange rates (CER) unless otherwise specified.
2. Total Revenue is defined as Product Sales and Externalisation Revenue.
3. See the Operating and Financial Review for a definition of Core financial measures and a reconciliation of Core to Reported financial measures.

The performance shown in this announcement covers the three-month period to 31 March 2016 (the quarter) compared to the three-month period to 31 March 2015 (the comparative quarter).

**Results Presentation**

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

**Reporting Calendar**

The Company intends to publish its first-half financial results on 28 July 2016.

**About AstraZeneca**

AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three main therapy areas - Respiratory, Inflammation and Autoimmunity, Cardiovascular and Metabolic Disease and Oncology - as well as in Infection and Neuroscience. 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).

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*Key: RIA - Respiratory, Inflammation & Autoimmunity, CVMD - Cardiovascular & Metabolic Disease, ING - Infection, Neuroscience & Gastrointestinal*

## Operating and Financial Review

All narrative on growth and results in this section relates to Core performance, based on constant exchange rates (CER) unless stated otherwise. Financial figures are in US\$ millions (\$m). The performance shown in this announcement covers the three-month period to 31 March 2016 (the quarter) compared to the three-month period to 31 March 2015 (the comparative quarter). 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 intangibles, including impairment reversals but excluding any charges relating to IT assets
- charges and provisions related to our global restructuring programmes (this will include such charges that relate to the impact of our global restructuring programmes on our 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

More detail on the nature of these measures is given on page 64 of the [Annual Report](#) and Form 20-F Information 2015.

### Total Revenue

Total Revenue increased by 5% to \$6,115m, comprising Product Sales of \$5,565m (up by 1%) and Externalisation Revenue of \$550m (up by 78%). Based on actual exchange rates, Total Revenue increased by 1%, reflecting the particular weakness of key trading currencies against the US dollar.

### Product Sales

The level of growth in Product Sales reflected the US market entry of *Nexium* generic products in 2015, as well as the level of competition impacting sales of *Symbicort*. Overall US sales grew by 4% in the quarter, with sales in Europe down by 4%.

Within Product Sales, the Growth Platforms grew by 6%, representing 56% of Total Revenue:

Growth Platform	Product Sales (\$m)	% CER change
Respiratory	1,207	2
<i>Brilinta/Brilique</i>	181	46
Diabetes	578	23
Emerging Markets	1,465	6
Japan	429	(7)
New Oncology <sup>1</sup>	99	n/m
<b>TOTAL<sup>2</sup></b>	<b>3,435</b>	<b>6</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 product and regional basis





Externalisation Revenue

Externalisation Revenue recognised in the quarter amounted to \$550m and primarily comprised the following:

Medicine	Partner	Region	\$m
<i>Plendil</i>	China Medical System Holdings Ltd (CMS) - commercialisation rights - initial revenue	China	298
<i>Nexium</i> OTC 20mg	Pfizer Inc. - milestone revenue	Global Rights	93
<i>Moventig</i>	ProStrakan Group plc (ProStrakan) - commercialisation rights - initial revenue	EU	70
Authorised <i>Crestor</i> generic	Daiichi Sankyo Company (Daiichi Sankyo) - distribution rights - initial revenue	Japan	42

Examples of sustainable future Externalisation Revenue are shown below:

Announcement Date	Medicine / NME*	Partner	Region	Externalisation Revenue
29 October 2010	<i>Nexium</i>	Daiichi Sankyo	Japan	<ul style="list-style-type: none"> <li>Initial \$100m milestone</li> <li>Sales-related revenue (undisclosed)</li> </ul>
19 March 2015	<i>Movantik</i>	Daiichi Sankyo	US	<ul style="list-style-type: none"> <li>Initial \$200m milestone</li> <li>Up to \$625m in sales-related revenue</li> </ul>
1 September 2015	brodalumab	Valeant Pharmaceuticals Inc.	Global (excl. Japan and other Asian markets)	<ul style="list-style-type: none"> <li>Initial \$100m milestone</li> <li>\$170m pre-launch</li> <li>\$175m upon launch</li> <li>Ongoing profit share</li> </ul>
2 September 2015	<i>FluMist</i>	Daiichi Sankyo	Japan	<ul style="list-style-type: none"> <li>Initial (undisclosed) milestone</li> <li>Sales-related revenue (undisclosed)</li> </ul>

\*NME = New Molecular Entity

**Product Sales**

The performance of a selection of key medicines is shown below. A geographical split of the performance is shown in Note 7.

	\$m	% Change	
		CER	Actual
<b>Respiratory, Inflammation &amp; Autoimmunity</b>			
<i>Symbicort</i>	749	(7)	(11)
<i>Pulmicort</i>	310	14	8
<i>Tudorza/Eklira</i>	39	33	30
<i>Daliresp</i>	31	n/m	n/m
<i>Duaklir</i>	13	n/m	n/m
Others	65	(4)	(11)
<b>TOTAL</b>	<b>1,207</b>	<b>2</b>	<b>(3)</b>
<b>Cardiovascular &amp; Metabolic Disease</b>			
<i>Brilinta/Brilique</i>	181	46	38
<i>Onglyza</i>	211	20	15
<i>Farxiga/Forxiga</i>	165	128	117
<i>Bydureon</i>	135	11	10
<i>Byetta</i>	62	(30)	(31)
Legacy:			
<i>Crestor</i>	1,156	2	(1)
<i>Seloken/Toprol-XL</i>	185	5	(5)
<i>Atacand</i>	71	(17)	(25)
Others	126	(21)	(26)

<b>TOTAL</b>	<b>2,292</b>	<b>7</b>	<b>3</b>
<b>Oncology</b>			
<i>Iressa</i>	135	(1)	(6)
<i>Tagrisso</i>	51	n/m	n/m
<i>Lynparza</i>	44	n/m	n/m
Legacy:			
<i>Faslodex</i>	190	24	18
<i>Zoladex</i>	178	(1)	(8)
<i>Casodex</i>	62	(9)	(11)
<i>Arimidex</i>	57	(3)	(8)
Others	21	(37)	(40)
<b>TOTAL</b>	<b>738</b>	<b>15</b>	<b>9</b>
<b>Infection, Neuroscience &amp; Gastrointestinal</b>			
<i>Nexium</i>	463	(24)	(28)
<i>Synagis</i>	244	20	20
<i>Seroquel XR</i>	202	(21)	(23)
<i>Losec/ Prilosec</i>	75	(18)	(22)
<i>FluMist/ Fluenz</i>	5	(29)	(29)
<i>Movantik/ Moventig</i>	17	n/m	n/m
Others	322	(9)	(16)
<b>TOTAL</b>	<b>1,328</b>	<b>(13)</b>	<b>(17)</b>
<b>TOTAL PRODUCT SALES</b>	<b>5,565</b>	<b>1</b>	<b>(3)</b>



## Product Sales Summary

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### Respiratory, Inflammation & Autoimmunity

#### Symbicort

*Symbicort* sales declined during the quarter by 7% to \$749m. The decline was driven primarily by continuing price pressures, partly offset by volume growth.

In the US, sales of \$322m represented a decline of 6%. This reflected the impact of the level of competition in the quarter, partly offset by encouraging volume growth that was driven by sustained total and new-to-brand prescription share gains.

In Europe, sales declined by 19% to \$231m, a result of declining market demand in the class, as well as increased competition from analogue medicines. In contrast, Emerging Markets sales grew by 18% to \$105m; China sales grew by 48% to \$41m.

#### Pulmicort

*Pulmicort* sales were \$310m in the quarter, an increase of 14%. Growth reflected the performance of *Pulmicort Respules* in Emerging Markets, where *Pulmicort* sales grew by 24% to \$207m. China sales increased by 34% to \$182m partly reflecting the increasing prevalence of acute chronic obstructive pulmonary disease (COPD) and paediatric asthma. To address this growing prevalence, AstraZeneca continued its expansion of treatment centres, as well as provided increased access to home-based patient care systems.

#### Tudorza/Eklira

Sales in the quarter of \$39m were driven by the strong volume performance in Rest of World markets, where *Eklira* continued to outperform the long-acting muscarinic antagonist (LAMA) market.

#### Daliresp

Rights were acquired in March 2015 from Actavis for *Daliresp* in the US and Canada. During the quarter sales were \$31m; new-to-brand prescriptions increased by 10% versus Q4 2015.

#### Duaklir

*Duaklir* has launched successfully in more than 25 countries, with sales of \$13m during the quarter reflecting the encouraging levels of share achieved in major European markets. Further launches will follow in due course.

### Cardiovascular & Metabolic Disease

#### Brilinta/Brilique

During the quarter, sales of *Brilinta/Brilique* increased by 46% to \$181m.

US sales for the quarter were \$70m, an increase of 52%. The expanded indication launched in the second half of 2015 and was underpinned by new-to-brand prescription market share of 12%. *Brilinta* remains the branded oral anti-platelet market leader in the US.

Sales of *Brilique* in Europe delivered growth of 19% to \$60m, which reflected the indication-leadership position attained across a number of markets.

Emerging Markets sales grew by 109% to \$41m, with China representing the largest single market in the region for *Brilinta*, where sales were up by 229% to \$22m, despite the medicine not being included in the National Drug Reimbursement List.

#### Onglyza

Sales were up by 20% in the quarter to \$211m as the DPP-4 class continued to demonstrate volume growth.

Sales in the US increased by 27% to \$124m following the impact of changes in the level of access support. Continued competitive pressures in the DPP-4 class, however, drove further market share erosion, which was partially offset by a higher net price.

Sales in Europe declined by 6% to \$33m, a lower rate of decline compared to the overall DPP-4 class. Emerging Markets sales increased by 20% to \$36m.

#### Farxiga/Forxiga

Sales of *Farxiga/Forxiga* were \$165m, up 128%; sales in the US of \$94m represented growth of 154%. Encouraging levels of patient access and greater promotional activity drove volume and total prescription share growth during the period.

Sales in Europe for *Forxiga* were up 72% to \$41m in the quarter. The medicine continued to lead the SGLT2 class. Emerging Markets sales increased by 145% to \$21m, reflecting launch activity.

#### Bydureon/Byetta

GLP-1 class volumes grew by 25% during the quarter and continues to be the fastest-growing class for patients with type-2 diabetes. Combined sales for *Bydureon/Byetta* were \$197m, with *Bydureon* sales, up 11%, representing approximately 69% of total *Bydureon/Byetta* sales. *Byetta* sales declined by 30% to \$62m with the Company's focus switching to *Bydureon*.

In the US, *Bydureon* sales were \$108m, an increase of 2% despite increased competition from new market entrants. Sales in Europe increased by 44% to \$23m, reflecting the Company's ongoing effort to expand its Diabetes presence.

#### Legacy: Crestor

Sales of *Crestor* increased in the quarter by 2% to \$1,156m.

In the US, *Crestor* sales increased by 4% to \$636m, driven by a higher net price that was partially offset by the impact of destocking. *Crestor* continued to maintain both total and new-to-brand prescription levels of market share.

In Europe, sales declined by 7% to \$212m, reflecting the increasing prevalence of generic-medicine competition. *Crestor* consolidated its position as the leading statin in Japan, with sales growth in the quarter of 2% to \$108m. Sales in China grew by 24% to \$89m.

### Oncology

#### Iressa

Sales of *Iressa* in the quarter declined by 1% to \$135m, driven by the competitive environment in Japan where sales were down by 7% to \$26m. In Emerging Markets sales decreased by 6% to \$67m, with China sales decreasing by 11% to \$37m, again a result of strong levels of competition.

Following the US launch in July 2015, *Iressa* saw an encouraging number of new-patient starts as demand volume grew. In Europe, sales increased by 3% to \$34m; volume share was maintained.

#### Tagrisso

Sales of *Tagrisso* were \$51m, with the US representing 88% of the total, with increasing testing rates driving the number of new-patient starts. During the period, *Tagrisso* also received regulatory approvals in the EU and Japan.

#### Lynparza

Sales of *Lynparza* reached \$44m in the quarter; US sales of \$28m were driven primarily by higher demand and net price. Sales in Europe were \$14m, following successful launches in France and Germany. Further launches included Spain, Australia, Israel and Switzerland, and the medicine is now available in 21 countries.

#### Legacy: Faslodex

*Faslodex* sales increased by 24% to \$190m. US sales grew by 19% to \$99m, reflecting higher levels of demand. Europe sales were up 18% to \$56m in the quarter, with Emerging Market sales of \$21m representing growth of 69%. Supported by the 2015 launch of 500mg *Faslodex*, China sales accelerated to \$5m, up 150%.

#### Legacy: Zoladex

Sales declined by 1% to \$178m, primarily driven by a decline in Europe of 9% to \$39m. China sales were \$32m, reflecting growth of 10%.

### Infection, Neuroscience & Gastrointestinal

#### Nexium

Sales of *Nexium* declined by 24% in the quarter to \$463m due primarily to the impact of generic-medicine competition in the US and Europe.

US sales declined by 42% to \$131m following the loss of exclusivity and changes in managed-care contracts. Sales in Europe declined by 16% to \$60m with Emerging Markets sales declining by 9% to \$177m. Japan sales decreased by 24% to \$69m.

#### Synagis

Sales of *Synagis* increased by 20% to \$244m. A 1% decline in US sales in the quarter to \$160m reflected the ongoing reduction in demand due to the results of the American Academy of Pediatrics Committee on Infectious Disease guidelines issued in 2014. These guidelines were more restrictive than the approved label, which further reduced patients eligible for preventative therapy with *Synagis*.

#### Seroquel XR

Sales declined by 21% to \$202m. In the US sales were \$144m, representing a decline of 15%. Sales in Europe fell by 41% to \$35m, due primarily to the impact of generic-medicine competition.

#### FluMist/Fluenz

Sales in the quarter declined to \$5m, a decrease of 29%, reflecting primarily in lower volumes.

#### Movantik/Moventiq

Sales for the quarter totalled \$17m, with all of the sales coming from the US where patients switched from over-the-counter laxative medicines or prescription laxative medicines to *Movantik*. The medicine is the leading branded gastrointestinal medicine amongst opioid-induced constipation prescribing specialists.

### Regional Product Sales

	Q1 2016		
	\$m	% Change	
		CER	Actual
US	2,246	4	4
Europe	1,218	(4)	(9)
Established ROW	636	(7)	(10)
<i>Japan</i>	429	(7)	(6)
<i>Canada</i>	116	(1)	(14)
<i>Other Established ROW</i>	91	(12)	(22)
Emerging Markets	1,465	6	(4)
<i>China</i>	774	11	7
<i>Ex. China</i>	691	-	(14)
<b>Total</b>	<b>5,565</b>	<b>1</b>	<b>(3)</b>

#### US

US sales increased in the quarter by 4% to \$2,246m, driven primarily by the performance of several of the Company's Growth Platforms. The growth was underpinned by favourable performances for *Farxiga* (up by 154% to \$94m), *Brilinta* (up by 52% to \$70m) and *Onglyza* (increasing by 27% to \$124m). *Crestor* sales were \$636m, a 4% increase versus the comparative quarter; destocking continued, ahead of the loss of exclusivity in May 2016.

#### Europe

Sales in Europe declined by 4% to \$1,218m, driven primarily by ongoing price erosion. The strong growth of *Farxiga* (up by 72% to \$41m) and *Brilique* (increasing by 19% to \$60m) was offset by a 19% decline in *Symbicort* sales to \$231m, which reflected adverse pricing and lower volumes driven by competition from analogue medicines. *Duaklir* sales increased to \$12m, representing strong market-share growth in Germany and UK.

#### Established ROW

Sales in the Established Rest Of World (ROW) declined by 7% to \$636m. Japan sales declined by 7% to \$429m, reflecting impact of destocking ahead of the biennial price cut in April 2016. Sales of *Crestor* increased by 2% to \$108m. *Nexium* sales declined by 24% to \$69m; the medicine however retained the position as the number one brand by market share volume and new-to-brand prescription share. Canada sales declined by 1% to \$116m.

Emerging Markets

Emerging Markets sales increased by 6% to \$1,465m, despite downward pressure from macro-economic conditions in Latin America and government price initiatives in the Middle East. China, with sales up by 11% to \$774m, represented 53% of Emerging Markets sales. Brazil sales grew by 19% to \$83m. Sales in CVMD (\$37m) and Oncology (\$17m) contributed 65% to the overall sales achieved in Brazil, reflecting the number of innovative products available to physicians and patients. Russia sales were up by 5% to \$48m.

## Financial Performance

	Reported	Restructuring	Intangible Amortisation & Impairments	Diabetes Alliance	Other	Core		% Change	
						Q1 2016	Q1 2015	CER	Actual
Product Sales	5,565	-	-	-	-	5,565	5,748	1	(3)
Externalisation Revenue	550	-	-	-	-	550	309	78	78
<b>Total Revenue</b>	<b>6,115</b>	-	-	-	-	<b>6,115</b>	<b>6,057</b>	<b>5</b>	<b>1</b>
Cost of Sales	(1,004)	9	29	-	-	(966)	(953)	6	1
<b>Gross Profit</b>	<b>5,111</b>	<b>9</b>	<b>29</b>	-	-	<b>5,149</b>	<b>5,104</b>	<b>5</b>	<b>1</b>
Gross Margin <sup>1</sup>	82.5%					83.1%	83.4%	-0.7	-0.3
Distribution	(76)	-	-	-	-	(76)	(77)	6	(1)
% Total Revenue	1.2%					1.2%	1.3%	-	-0.1
R&D	(1,480)	38	13	-	-	(1,429)	(1,280)	15	12
% Total Revenue	24.2%					23.4%	21.1%	-2.0	-2.3
SG&A	(2,572)	108	229	108	-	(2,127)	(2,368)	(6)	(10)
% Total Revenue	42.1%					34.8%	39.1%	+4.2	+4.3
Other Operating Income	55	-	21	-	-	76	426	(81)	(82)
% Total Revenue	0.9%					1.2%	7.0%	-5.7	-5.8
<b>Operating Profit</b>	<b>1,038</b>	<b>155</b>	<b>292</b>	<b>108</b>	-	<b>1,593</b>	<b>1,805</b>	<b>(8)</b>	<b>(12)</b>
% Total Revenue	17.0%					26.1%	29.8%	-3.6	-3.7
Net Finance Expense	(311)	-	-	97	57	(157)	(118)		
Joint Ventures	(4)	-	-	-	-	(4)	(5)		
<b>Profit Before Tax</b>	<b>723</b>	<b>155</b>	<b>292</b>	<b>205</b>	<b>57</b>	<b>1,432</b>	<b>1,682</b>	<b>(10)</b>	<b>(15)</b>
Taxation	(98)	(33)	(66)	(47)	(5)	(249)	(312)		
Tax Rate	14%					17%	19%		
<b>Profit After Tax</b>	<b>625</b>	<b>122</b>	<b>226</b>	<b>158</b>	<b>52</b>	<b>1,183</b>	<b>1,370</b>	<b>(9)</b>	<b>(14)</b>
Non- controlling Interests	21	(5)	-	-	-	16	(2)		
<b>Net Profit</b>	<b>646</b>	<b>117</b>	<b>226</b>	<b>158</b>	<b>52</b>	<b>1,199</b>	<b>1,368</b>	<b>(7)</b>	<b>(12)</b>
Weighted Average Shares	1,264	1,264	1,264	1,264	1,264	1,264	1,263		
<b>Earnings Per Share</b>	<b>0.51</b>	<b>0.09</b>	<b>0.18</b>	<b>0.13</b>	<b>0.04</b>	<b>0.95</b>	<b>1.08</b>	<b>(7)</b>	<b>(12)</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.





**Profit and Loss**Gross Profit

Core Gross Profit increased by 5% in the quarter to \$5,149m. Excluding the impact of externalisation, the Core Gross-Profit margin decreased by one percentage point, reflecting a 6% increase in the Cost of Sales.

Operating Expenses

Core R&D costs were up 15% in the quarter to \$1,429m as the Company continued to focus on its pipeline. The increase 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. Excluding the impact of these two investments, Core R&D costs would have increased by 9%. Full-year total Core R&D costs are expected to be at a similar level to FY 2015.

In line with prior commitments to materially reduce Core SG&A costs over the full year, Core SG&A costs declined by 6% in the quarter to \$2,127m. Core SG&A costs declined by four percentage points as a proportion of Total Revenue.

Other Operating Income

Core Other Operating Income of \$76m primarily reflected royalty income arising from a number of prior agreements, including those relating to HPV vaccines and ertapenem. The level of income decreased by 81% versus the comparative quarter.

Core Operating Profit

Core Operating Profit declined by 8% to \$1,593m in the quarter. The Core Operating Margin declined by four percentage points to 26% of Total Revenue. The declines primarily reflected the level of Core Other Operating Income versus the comparative quarter, while the Company continued to invest in the pipeline and the Growth Platforms.

Reported Operating Profit

Reported Operating Profit increased by 17% to \$1,038m, principally due to lower amortisation charges versus the comparative quarter.

Finance Expense

The Core Net Finance Expense was \$157m in the quarter, compared to \$118m in the comparative quarter. The increase reflected the increase in net debt, driven itself by the acquisition of ZS Pharma and the investment in Acerta Pharma.

The Reported Net Finance Expense of \$311m included a charge of \$154m relating to the discount unwind on acquisition-related liabilities recognised on business combinations.

Taxation

The Core and Reported tax rates for the quarter were 17% and 14% respectively. These tax rates were lower than the UK Corporation Tax Rate of 20%, mainly due to the impact of the geographical mix of profits. The cash tax paid for the quarter was \$205m, representing 14% of Core Profit Before Tax and 28% of Reported Profit Before Tax. Both the Core and Reported tax rates for the comparative quarter were around 19%.

Earnings Per Share (EPS)

Core EPS in the quarter declined by 7% to \$0.95. Reported EPS increased by 26% to \$0.51, again, principally relating to the lower amortisation charge.

Productivity

AstraZeneca continues to make significant progress towards the Total Revenue target of \$45bn\* by 2023. The Company has increased pipeline productivity, built therapy-area leadership, developed the Growth Platforms and transformed AstraZeneca's culture. The shape of the business is evolving rapidly, with a growing number of specialty-care medicines, in particular in Oncology.

In line with the strategy designed to deliver benefits to patients and value for shareholders, the Company today announces further focus on the main therapy areas to drive greater productivity across the organisation. The prioritisation of investments will be sharpened, enabling the allocation of additional investment to Oncology. Alongside this, the Company will continue to work with others in the opportunity-led parts of the portfolio, such as Infection, Neuroscience and inflammatory diseases outside Respiratory.

This focus will streamline further AstraZeneca's operations, primarily in commercial and manufacturing. This, together with the drive for greater efficiency, will deliver a material decline in Core SG&A costs in FY 2016 and FY 2017.

These changes will enhance operational effectiveness and, once implemented by the end of FY 2017, are expected to generate net annualised benefits of \$1.1bn that will be reflected primarily within Core SG&A costs. Associated with the changes, the Company expects to incur up to \$1.5bn in one-time restructuring charges, the majority of which will be cash costs. Final estimates for programme costs, benefits and colleague impacts will be subject to consultation.

These new initiatives are in addition to the ongoing restructuring programmes described in the Annual Report and Form 20-F Information 2015. The restructuring charges over the period from April 2016 through to the end of FY 2017 for all programmes are anticipated to be \$2.4bn in aggregate, with approximately \$1.5bn of these restructuring costs expected to be taken in the remainder of FY 2016, with the balance in FY 2017.

\* At FY2013 exchange rates

**Cash Flow and Balance Sheet**Cash Flow

The Company generated a cash inflow from operations of \$1,583m, compared with \$415m in the comparative quarter. Cash generated from operations reflected a decrease in working capital and short-term provisions of \$64m compared to an increase of \$664m.

Net cash outflows from investing activities were \$2,887m compared with \$556m in the comparative quarter. The increase reflected the net cash outflow of \$2,383m on the investment in Acerta Pharma.

Net cash outflows from financing activities were \$1,361m. This compared to an outflow of \$2,569m in the comparative quarter. The reduction reflected the impact of a loan repayment in the comparative quarter.

The cash payment of contingent consideration on business considerations in respect of the Bristol-Myers Squibb Company share of the global Diabetes alliance amounted to \$26m in the quarter.

Debt and Capital Structure

At 31 March 2016, outstanding gross debt (interest-bearing loans and borrowings) was \$16,312m (31 March 2015: \$10,569m). Of the gross debt outstanding at 31 March 2016, \$2,168m was due within one year (31 March 2015: \$2,299m). The Company's net debt position at 31 March 2016 was \$11,751m (31 December 2015: \$7,762m).

Shares in Issue

During the quarter, 0.4 million shares were issued in respect of share option exercises for a consideration of \$18m. The total number of shares in issue as at 31 March 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 opportunities.



**Sensitivity: Foreign-Exchange Rates**

The Company provides the following currency sensitivity information:

Currency	Primary Relevance	Average Exchange Rates Versus USD		Impact Of 5% Weakening In Exchange Rate Versus USD (\$m) <sup>2</sup>		
		FY 2015	YTD 2016 <sup>1</sup>	Change %	Total Revenue	Core Operating Profit
EUR	Product Sales	0.90	0.91	(1)	(178)	(103)
JPY	Product Sales	121.04	115.35	5	(102)	(66)
CNY	Product Sales	6.28	6.54	(4)	(133)	(62)
SEK	Costs	8.43	8.45	-	(8)	71
GBP	Costs	0.65	0.70	(6)	(34)	96
Other <sup>3</sup>					(201)	(122)

<sup>1</sup>Based on average daily spot rates YTD to the end of March 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 31 March 2016, AstraZeneca had hedged around 91% of forecast short-term currency exposure that arises between the booking and settlement dates on non-local currency purchases and Product Sales.

## Corporate and Business Development Update

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The highlights of the Company's corporate and business development activities since the prior results announcement on 4 February 2016 are shown below.

### a) Agreement with CMS - *Plendil* in China

On 29 February 2016, AstraZeneca announced that it had entered into a licensing agreement with CMS for the commercialisation rights in China to its calcium channel blocker, *Plendil* (felodipine). *Plendil* was first approved in China in 1995 for the treatment of hypertension, or high blood pressure, and in FY 2015 achieved Product Sales of \$189m. AstraZeneca recognised income of \$298m in the quarter.

AstraZeneca will maintain a significant, long-term interest in the future value derived from *Plendil* sales in China. As such, the aforementioned income has been presented as Externalisation Revenue within the Company's financial statements. AstraZeneca will manufacture and supply the medicine to CMS and will retain the global rights to *Plendil* outside China.

### b) Agreement with CMS - *Imdur* outside the US

On 29 February 2016, AstraZeneca announced that it had entered into an agreement with CMS and its associated company, Tibet Rhodiola Pharmaceutical Holding Co., for the divestment of the global rights to *Imdur* outside the US. *Imdur* is a mature medicine for the prevention of angina in patients with heart disease; its global sales outside the US were \$57m in FY 2015. Under the terms of this agreement, AstraZeneca will receive \$190m for the rights to *Imdur* in all markets outside the US. The divestment is expected to close in the second quarter of 2016 and income from the agreement will be reported as Core Other Operating Income.

### c) Agreement with ProStrakan - *Movantik* in Europe

On 1 March 2016, AstraZeneca announced that it had entered into an agreement with ProStrakan for the rights to *Movantik* (naloxegol) in the EU, Iceland, Norway, Switzerland and Liechtenstein. *Movantik* is the first once-daily, oral peripherally-acting mu-opioid receptor antagonist approved in Europe for the treatment of opioid-induced constipation in adult patients who have had an inadequate response to laxatives.

Under the terms of the agreement, ProStrakan made an initial payment to AstraZeneca of \$70m in the quarter to acquire the rights to sell and develop *Movantik* in the aforementioned geographies. AstraZeneca will maintain a significant, long-term interest in the future of *Movantik*. As such, the income described has been presented as Externalisation Revenue within the Company's financial statements.

### d) Agreement with Eli Lilly and Company (Lilly) - AZD3293

On 8 April 2016 Lilly announced that AMARANTH, a Phase II trial of AZD3293, an oral beta secretase cleaving enzyme (BACE) inhibitor currently in development as a potential treatment for early Alzheimer's disease, will move fully into Phase III of the programme.

Under the terms of the agreement, the decision to move AZD3293 into Phase III testing triggered a further milestone payment from Lilly to AstraZeneca of \$100m, which will be reported as Externalisation Revenue within the Company's financial statements in the second quarter.

### e) Agreement with Ironwood Pharmaceuticals, Inc. (Ironwood) - *Zurampic* in US

On 26 April 2016, AstraZeneca announced that it had entered into a licensing agreement with Ironwood Pharmaceuticals, Inc. (Ironwood) for the exclusive US rights to *Zurampic* (lesinurad). *Zurampic* was approved by the FDA in December 2015, in combination with a xanthine oxidase inhibitor (XOI), for the treatment of hyperuricemia associated with uncontrolled gout.

Under the terms of the agreement, Ironwood will acquire exclusive US rights to *Zurampic*. In addition, Ironwood will gain the exclusive US rights to the fixed-dose combination of lesinurad and allopurinol. AstraZeneca plans to submit the fixed-dose combination programme for regulatory review in the second half of 2016. Ironwood will pay AstraZeneca sales-related and other milestone payments of up to \$265m and tiered single-digit royalties on Product Sales. AstraZeneca will manufacture and supply *Zurampic*, provide certain support and services to Ironwood and undertake the FDA post-approval commitment on their behalf.

## 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 4 February 2016 (the period):

Regulatory Approvals	4	<ul style="list-style-type: none"> <li>- <i>Bevespi Aerosphere</i> - COPD (US)</li> <li>- <i>Zurampic</i> - gout (EU)</li> <li>- <i>Brilique</i> - post-MI (EU)</li> <li>- <i>Tagrisso</i> - lung cancer (JP)</li> </ul>
Other Key Developments	4	<ul style="list-style-type: none"> <li>- Breakthrough Therapy Designation:               <ul style="list-style-type: none"> <li>- durvalumab - bladder cancer (US)</li> </ul> </li> <li>- Orphan Drug Designation:               <ul style="list-style-type: none"> <li>- acalabrutinib - blood cancers (EU)</li> <li>- MEDI-551 - neuromyelitis optica (US)</li> </ul> </li> <li>- Fast Track Designation:               <ul style="list-style-type: none"> <li>- MEDI8852 - hospitalised influenza (US)</li> </ul> </li> </ul>
New Molecular Entities (NMEs) in Pivotal Trials or under Regulatory Review*	13	<p><b>RIA</b></p> <ul style="list-style-type: none"> <li>- brodalumab - psoriasis*</li> <li>- benralizumab - severe asthma</li> <li>- tralokinumab - severe asthma</li> <li>- PT010 - COPD</li> <li>- anifrolumab - lupus (SLE)</li> </ul> <p><b>CVMD</b></p> <ul style="list-style-type: none"> <li>- roxadustat - anaemia</li> <li>- ZS-9* - hyperkalaemia</li> </ul> <p><b>Oncology</b></p> <ul style="list-style-type: none"> <li>- cediranib* - ovarian cancer</li> <li>- durvalumab - multiple cancers</li> <li>- acalabrutinib - blood cancers</li> <li>- moxetumomab pasudotox - leukaemia</li> <li>- selumetinib - lung cancer</li> </ul> <p><b>ING</b></p> <ul style="list-style-type: none"> <li>- CAZ AVI* - serious infections</li> </ul>
Projects in clinical pipeline	124	

Key: RIA - Respiratory, Inflammation & Autoimmunity, CVMD - Cardiovascular & Metabolic Disease, ING - Infection, Neuroscience & Gastrointestinal





## 1. Respiratory, Inflammation & Autoimmunity (RIA)

Five potential medicines in RIA remain in pivotal trials or under registration. AstraZeneca's Respiratory portfolio includes a range of differentiated potential medicines such as novel combinations, biologics and devices for the treatment of asthma and COPD. The pipeline also includes a number of potential medicines in inflammatory and autoimmune diseases within areas such as psoriasis, systemic lupus and rheumatoid arthritis.

### a) *Symbicort* (COPD)

During the period, AstraZeneca obtained approval for *Symbicort* pMDI (pressurised metered dose inhaler device) in the EU. *Symbicort* pMDI is now indicated for use in adults, aged 18 and older, for the symptomatic treatment of COPD in patients with a forced expiratory volume in one second (FEV1) below 70% of the predicted normal (post-bronchodilator) level and an exacerbation history, despite regular bronchodilator therapy. This development further augments *Symbicort's* prevailing approvals in the EU.

### b) *Bevespi Aerosphere* (COPD)

During the period the FDA approved *Bevespi Aerosphere* (glycopyrrolate and formoterol fumarate) inhalation for the long-term, maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema. *Bevespi Aerosphere* is the first LAMA/LABA medicine to be delivered in a pMDI and the first medicine using AstraZeneca's unique Co-Suspension technology.

### c) *Zurampic* (gout)

On 19 February 2016, *Zurampic* (lesinurad) 200mg tablets received marketing authorisation in the EU in combination with a XOI for the adjunctive treatment of hyperuricemia in adult gout patients who have not achieved target serum uric-acid levels with an XOI alone. The EU approval of *Zurampic* was based on data from three pivotal Phase III trials, CLEAR1, CLEAR2 and CRYSTAL, which represented the largest clinical-trial data set of gout patients (n=1,537 total) treated with combination urate-lowering therapy.

### d) Tralokinumab (atopic dermatitis)

A Phase II trial of tralokinumab in atopic dermatitis was completed in the period. Top-line results from the trial showed that at week 12, a statistically-significant improvement from baseline in EASI score (Eczema Area and Severity Index) was observed in the two highest tralokinumab dosage arms tested compared to the placebo arm. Significant improvements in DLQI (dermatology life quality index) were also observed. No safety issues were detected. Full trial results will be disclosed at a future medical congress.

### e) MEDI-551 (neuromyelitis optica)

In the period AstraZeneca's global biologics research and development arm, MedImmune, obtained Orphan Drug Designation from the FDA for MEDI-551, a CD19 monoclonal antibody, for the treatment of patients with neuromyelitis optica (NMO), as well as NMO spectrum disorders. NMO is a rare, life-threatening autoimmune disease of the central nervous system, in which the body's immune system attacks healthy cells most commonly present in the optic nerves and spinal cord, resulting in severe damage. MEDI-551 is currently in Phase IIb clinical development.

## 2. Cardiovascular & Metabolic Disease (CVMD)

AstraZeneca's CVMD therapy area focuses on ways to reduce morbidity, mortality and organ damage by addressing multiple risk factors across cardiovascular (CV) disease, diabetes and chronic kidney disease (CKD) indications. This patient-centric approach is reinforced by science-led life-cycle management programmes and technologies, including early research into regenerative methods.

### a) *Brilinta/Brilique* (CV disease)

On 19 February 2016, the European Commission granted marketing authorisation for *Brilique* for long-term prevention of cardiovascular death, heart attack and stroke for patients with a history of heart attack. The EU approval was based on the results from the PEGASUS TIMI-54 trial, a large-scale outcomes trial involving more than 21,000 patients. PEGASUS TIMI-54 investigated *Brilinta/Brilique* tablets plus low-dose aspirin, compared to placebo plus low dose aspirin, for the long-term prevention of death from CV disease, heart attack and stroke in patients who had experienced a heart attack one to three years prior to trial enrollment.

On 23 March 2016, the SOCRATES trial top-line results read out. The trial assessed the efficacy of *Brilinta/Brilique* 90mg tablets twice daily when compared to aspirin 100mg once daily in patients with acute ischaemic stroke or transient ischaemic attack. Fewer events were observed on *Brilinta/Brilique* versus the comparator in the overall trial population; the trend however did not reach statistical significance and the primary efficacy endpoint of time to first occurrence of any event from the composite of stroke (ischaemic or haemorrhagic), myocardial infarction (MI) and death was not met. AstraZeneca does not anticipate that the results will support a regulatory submission for the stroke indication.

On 29 March 2016, the American College of Cardiology (ACC) and American Heart Association (AHA) updated their treatment-guidelines for Acute Coronary Syndrome (ACS) and the duration of dual antiplatelet therapy. *Brilinta* is now preferred over clopidogrel for the management of patients with ACS who have received a coronary stent and in non-ST Elevation ACS patients treated with medical therapy alone. This update was also the first time that the ACC and AHA have recommended *Brilinta* over clopidogrel for patients who have experienced an ST-elevation myocardial infarction (STEMI). The update was also the first US guideline to provide the medical community with insights drawn from the PEGASUS-TIMI 54 trial. The guideline supported continuation of P2Y12 therapy beyond 12 months in prior MI patients who are not at high bleeding risk.

### b) *Onglyza* and *Kombiglyze XR* (type-2 diabetes)

In early April 2016, the Company received a communication from the FDA on proposed label changes related to a potential risk for an increase in heart failure in the SAVOR outcomes trial for *Onglyza* (saxagliptin). The Company initially submitted the trial findings to the FDA in February 2014. The SAVOR trial met the primary safety endpoint, demonstrating that *Onglyza* did not increase the composite risk for CV death, non-fatal MI and non-fatal ischaemic stroke when added to a patient's current standard of care (with or without other anti-diabetic therapies), as compared to placebo. To reflect the recent communication from the FDA, the *Onglyza* label was updated accordingly and the FDA's review of the data is now complete.

### c) Type-2 diabetes outcomes trials

Two significant type-2 diabetes outcomes trials are underway and fully recruited. Details and updates on those two trials are listed below:

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

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

### 3. Oncology

AstraZeneca has a deep-rooted heritage in Oncology and offers a quickly-growing portfolio of new medicines that has the potential to transform patients' lives and the Company's future. With at least six new medicines to be launched between 2014 and 2020 and a broad pipeline of small molecules and biologics in development, the Company is committed to advancing New Oncology as one of AstraZeneca's six Growth Platforms focused on lung, ovarian, breast and blood cancers. In addition to core capabilities, the Company is actively pursuing innovative collaborations and investments that accelerate the delivery of AstraZeneca's strategy, as illustrated by the Company's investment in Acerta Pharma in haematology.

By harnessing the power of four scientific platforms - immuno-oncology (IO), the genetic drivers of cancer and resistance, DNA damage response and antibody drug conjugates - and by championing the development of personalised combinations, AstraZeneca has the vision to redefine cancer treatment and, one day, eliminate cancer as a cause of death.

#### a) *Faslodex* (breast cancer)

AstraZeneca announced on 2 March 2016 that the FDA had approved a new indication expanding the use of *Faslodex*, to include use in combination with palbociclib. The combination use is for the treatment of women with hormone receptor-positive, human epidermal growth factor receptor 2 negative advanced or metastatic breast cancer whose cancer has progressed after endocrine therapy. The approval was based on data from the Phase III PALOMA-3 trial, which met the primary endpoint of progression-free survival.

#### b) *Tagrisso* (lung cancer)

On 14 April 2016 AstraZeneca reported new Phase I extended follow-up data on *Tagrisso* in both 1st- and 2nd-line treatment of patients with non-small cell lung cancer (NSCLC) at the European Lung Cancer Conference. Late-breaker presentations reinforced the efficacy and safety profile for *Tagrisso* previously seen in the AURA clinical-trials programme.

The FLAURA Phase III trial for 1st-line use of *Tagrisso* in epidermal growth factor receptor (EGFR)-mutated NSCLC randomised its last patient during the period. Data is expected in 2017 for potential regulatory submission in the earlier metastatic setting, compared to the prevailing 2nd-line use of the medicine.

On 29 March 2016 the Japanese Ministry of Health, Labour and Welfare approved *Tagrisso* 80mg once-daily tablets for the treatment of patients with EGFR T790M mutation-positive inoperable or recurrent NSCLC that is resistant to EGFR tyrosine kinase inhibitor therapy. The approval follows the EU and US approvals in late 2015. Given the high prevalence of EGFR mutations (30-40% of lung cancer patients) and, subsequently, T790M mutations in Asia, Japan is anticipated to be a proportionally significant market for *Tagrisso*.

During the period, the Company decided not to restart enrolment of patients into CAURAL, a Phase III trial assessing *Tagrisso* in combination with durvalumab as a potential second and later-line treatment for patients with EGFRm T790M NSCLC. The decision not to restart enrolment reflects the view that the trial design no longer offers the best setting to assess this combination. There has been no change in the safety or data findings following the suspension of enrolment into the trial in October 2015.

On 2 March 2016, the National Comprehensive Cancer Network, a US guideline-setting organisation, included *Tagrisso* in its guidelines for the treatment of patients with brain metastases who have progressed on 1st-line therapies. This important recommendation will expand the utilisation of *Tagrisso* to patients with limited treatment options.

#### c) *Tremelimumab* (mesothelioma)

On 29 February 2016, the Company announced that DETERMINE, a Phase IIb clinical trial of 10mg/kg tremelimumab monotherapy in 2nd or 3rd-line treatment of unresectable malignant mesothelioma, did not meet its primary endpoint of overall survival. It was encouraging however that the safety profile of this potential medicine was consistent with expectations.

The results did not have an impact on ongoing combination trials with tremelimumab at the ten-fold lower dose of 1mg/kg every four weeks. Mesothelioma remains a difficult-to-treat disease with no approved medicine beyond 1st-line treatment.

#### d) *Durvalumab* (multiple cancers)

##### *Monotherapy*

Durvalumab continues to be the cornerstone in the IO pipeline and is currently being tested in monotherapy, combination therapy and through numerous collaborations. Current combination trials include both large and small molecules, as well as chemotherapy. Through a broad and diverse development programme, the Company is committed to finding the patients who benefit most from unique combinations and targeted approaches using multiple biomarkers.

In the period, Breakthrough Therapy Designation was granted for durvalumab for the treatment of patients with programmed death-ligand 1 (PD-L1) positive inoperable or metastatic urothelial bladder cancer, whose tumour has progressed during or after the current standard of care. This designation was based on early clinical data from a large cohort Phase I/II trial (Study 1108), which has now enrolled more than 1,000 patients with various cancers.

##### *Combination therapy*

Pre-clinical data have suggested that targeting both PD-L1 and cytotoxic T-lymphocyte-associated protein 4 (CTLA-4) may have additive or synergistic effects and, to date, data from the combination treatment with durvalumab and tremelimumab have demonstrated anti-tumour activity in patients with locally advanced or metastatic NSCLC, irrespective of PD-L1 status. New data from the Phase Ib durvalumab + tremelimumab (durva + treme) combination trial in NSCLC (Study 006) were published on 5 February 2016 in *The Lancet Oncology*. The data cut-off of 1 June 2015 was the same date as per the Society for Immunotherapy of Cancer publication on 6 November 2015. This was, however, a more mature and robust data set of confirmed responses, with a longer follow-up period.

In patients receiving the combination at the dose chosen for Phase III (durvalumab 20mg/kg Q4W equivalent + tremelimumab 1mg/kg Q4W), the overall response rate was 29% in patients with PD-L1 negative tumours (<25% tumour staining) and 40% in

patients with zero tumour staining. Disease control was 43% and 50% respectively, with a manageable safety profile, given the advanced disease setting.

An update on key AstraZeneca-sponsored ongoing trials with durvalumab is provided below:

#### LUNG CANCER

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

<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> PD-L1 negativity cut-off measured at <25% of tumour-cell staining

<sup>5</sup> SoC = Standard of Care

<sup>6</sup> SCLC = Small Cell Lung Cancer

#### METASTATIC OR RECURRENT HEAD AND NECK CANCER

Name	Phase	Line of treatment	Population	Design	Timelines	Status
<i>Monotherapy</i>						
HAWK	II	2nd line	PD-L1 pos. SCCHN <sup>1</sup>	durvalumab (single arm)	FPD Q1 2015	Recruitment completed

					LPCD Q2 2016 Data expected H2 2016	Indication granted FDA Fast Track Designation
Combination therapy						
CONDOR	II	2nd line	PD-L1 neg. SCCHN	durvalumab vs tremelimumab vs durva + treme	FPD Q2 2015 LPCD Q2 2016 Data expected H1 2017	Recruitment completed
EAGLE	III	2nd line	SCCHN	durvalumab vs durva + treme vs SoC	FPD Q4 2015 Data expected 2018	Recruiting
KESTREL	III	1st line	SCCHN	durvalumab vs durva + treme vs SoC	FPD Q4 2015 Data expected 2018	Recruiting

<sup>†</sup>SCCHN = Squamous Cell Carcinoma of the Head and Neck

#### OTHER METASTATIC CANCERS

Name	Phase	Line of treatment	Population	Design	Timelines	Status
Combination therapy						
DANUBE	III	1st line	Cisplatin chemo-therapy-eligible/ineligible bladder cancer	durvalumab vs durva + treme vs SoC	FPD Q4 2015 Data expected 2018	Recruiting
ALPS	II	2nd line	Pancreatic ductal carcinoma	durva + treme (single arm)	FPD Q4 2015 Data expected 2017	Recruiting
-	II	2nd line	Unresectable liver cancer	durvalumab vs tremelimumab vs durva + treme	FPD Q1 2016	Recruiting
-	II	2nd/3rd line	Metastatic gastric cancer	durvalumab vs tremelimumab vs durva + treme	-	In preparation

e) Acalabrutinib (blood cancers)

On 25 February 2016, the European Medicines Agency adopted and approved three positive opinions recommending acalabrutinib for Orphan Drug Designation in chronic lymphocytic leukaemia (CLL)/small lymphocytic lymphoma (SLL), mantle cell lymphoma (MCL) and lymphoplasmacytic lymphoma (Waldenström's macroglobulinaemia, WM).

Acalabrutinib has the potential for regulatory submission in the second half of the year in one type of blood cancer, for which it is currently being assessed in Phase II/III trials.

f) Early-stage pipeline

During the period, the Company initiated a Phase I trial for monalizumab, a humanised, monoclonal antibody targeting natural-killer cell NKG2A. This potential medicine is being developed with Innate Pharma SA under a co-development and commercialisation agreement. The trial is a combination with durvalumab and will explore the medicine's safety, tolerability and anti-tumour activity in solid tumours.

**4. Infection, Neuroscience and Gastrointestinal**

a) MEDI8852 (hospitalised influenza)

On 7 March 2016, AstraZeneca's global biologics research and development arm, MedImmune, received Fast Track Designation from the FDA for its potential new medicine MEDI8852, a human, monoclonal antibody for the treatment of patients hospitalised with type-A strain influenza. MEDI8852 is currently being evaluated in a Phase Ib/IIa clinical trial to assess the safety and efficacy of a single intravenous dose in combination with oseltamivir and as a monotherapy in adult patients with confirmed acute, uncomplicated influenza caused by type-A strains.

b) AZD3293 (Alzheimer's disease)

On 8 April 2016, AstraZeneca announced that AMARANTH, a Phase II/III trial of AZD3293, an oral BACE inhibitor in development as a potential treatment for early Alzheimer's disease, will move into the Phase III portion of the trial.

The transition into Phase III will also trigger the start of an additional Phase III trial with AZD3293. DAYBREAK will focus on patients with mild Alzheimer's disease and is scheduled to begin enrolling patients in the second half of the year. Emerging evidence suggests that cognitive decline precedes and predicts a functional decline in Alzheimer's disease, particularly during earlier stages of the disease. Accordingly, AMARANTH will be amended and DAYBREAK will use a single, cognitive endpoint, ADAS-cog13.

## ASTRAZENECA DEVELOPMENT PIPELINE 31 MARCH 2016

Includes AstraZeneca-sponsored or -directed studies only

### Phase III / Pivotal Phase II / Registration

#### NMEs and significant additional indications

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

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

# Collaboration.

Compound	Mechanism	Area Under Investigation	Date Commenced Phase	Estimated Regulatory Submission / Submission Acceptance†			
				US	EU	Japan	China
<b>Respiratory, Inflammation and Autoimmunity</b>							
Zurampic <sup>®</sup> (lesinurad) CLEAR 1,2 CRYSTAL	selective uric acid reabsorption inhibitor (URAT-1)	chronic treatment of hyperuricemia in patients with gout	Q4 2011	Approved	Approved <sup>1</sup>	N/A	N/A
Bevespi <sup>®</sup> Aerosphere (PT003)	LABA/LAMA	COPD	Q2 2013	Approved	H2 2016	2017	2017
brodalumab <sup>#</sup> AMAGINE-1,2,3	IL-17R mAb	psoriasis	Q3 2012	Accepted	Accepted	N/A	N/A
benralizumab <sup>#</sup> CALIMA SIROCCO ZONDA BISE BORA GREGALE	IL-5R mAb	severe asthma	Q4 2013	H2 2016	H2 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	2017	2019
tralokinumab STRATOS 1,2 TROPOS MESOS	IL-13 mAb	severe asthma	Q3 2014	2018	2018	2018	
anifrolumab <sup>#</sup> TULIP	IFN-alphaR mAb	systemic lupus erythematosus	Q3 2015	2019 (Fast Track)	2019	2019	
<b>Cardiovascular and Metabolic Diseases</b>							
Brilinta/Brilique <sup>2</sup>	P2Y12 receptor antagonist	arterial thrombosis		Launched	Launched	Accepted	Launched
Farxiga/Forxiga <sup>3</sup>	SGLT2 inhibitor	type-2 diabetes		Launched	Launched	Launched	Accepted
Epanova <sup>#</sup>	omega-3 carboxylic acids	severe hypertrigly-ceridemia		Approved		2018	
ZS-9 (sodium zirconium cyclosilicate)	potassium binder	hyperkalaemia		Accepted	Accepted		
roxadustat <sup>#</sup> OLYMPUS ROCKIES	hypoxia-inducible factor prolyl hydroxylase inhibitor	anaemia in CKD/ESRD	Q3 2014	2018	N/A	N/A	H2 2016 <sup>4</sup>
<b>Oncology</b>							
Tagrisso AURA, AURA 2, (AURA17 Asia regional)	EGFR tyrosine kinase inhibitor	≥2nd-line advanced EGFRm T790M NSCLC	Q2 2014	Launched (Breakthrough designation, Priority Review, Orphan Drug)	Launched <sup>5</sup> (Accelerated assessment)	Approved <sup>6</sup>	2017
Tagrisso AURA 3	EGFR tyrosine kinase inhibitor	≥2nd-line advanced EGFRm T790M NSCLC	Q3 2014	2017	2017	2017	2018
cediranib ICON 6	VEGFR tyrosine kinase inhibitor	PSR ovarian cancer	Q2 2007		Accepted (Orphan Drug)		
acalabrutinib <sup>#</sup> (ACP-196)	Bruton's tyrosine kinase (BTK) inhibitor	B-cell blood cancers	Q1 2015	H2 2016 (Orphan Drug)	(Orphan Drug)		
selumetinib <sup>#</sup> SELECT-1	MEK inhibitor	2nd-line KRASm NSCLC	Q4 2013	2017	2017		
selumetinib <sup>#</sup> ASTRA	MEK inhibitor	differentiated thyroid cancer	Q3 2013	2018	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	2020	2020	
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	PD-L1 mAb + CTLA-4 mAb	1st-line NSCLC	Q4 2015	2019	2019	2019	

NEPTUNE							
durvalumab <sup>#</sup> HAWK <sup>1</sup>	PD-L1 mAb	2nd-line SCCHN (PD-L1 positive)	Q1 2015	2017 (Fast Track)	2019	2019	
durvalumab <sup>#</sup> + tremelimumab CONDOR <sup>1</sup>	PD-L1 mAb + CTLA-4 mAb	2nd-line SCCHN (PD-L1 negative)	Q2 2015	2017	2019	2019	
durvalumab <sup>#</sup> + tremelimumab KESTREL	PD-L1 mAb + CTLA-4 mAb	1st-line SCCHN	Q4 2015	2018	2018	2018	
durvalumab <sup>#</sup> + tremelimumab EAGLE	PD-L1 mAb + CTLA-4 mAb	2nd-line SCCHN	Q4 2015	2019	2019	2019	
durvalumab <sup>#</sup> + tremelimumab ALPS <sup>1</sup>	PD-L1 mAb + CTLA-4 mAb	metastatic pancreatic ductal carcinoma	Q4 2015	2017	2017	2017	
durvalumab <sup>#</sup> + tremelimumab DANUBE	PD-L1 mAb + CTLA-4 mAb	1st-line bladder	Q4 2015	2018	2018	2018	
Infection, Neuroscience and Gastrointestinal							
Zinforo <sup>2</sup>	extended spectrum cephalosporin with affinity to penicillin-binding proteins	pneumonia/skin infections		N/A	Launched	N/A	Submitted
CAZ AVI <sup>#</sup>	cephalosporin/ beta lactamase inhibitor	hospital-acquired pneumonia/ ventilator-associated pneumonia	Q2 2013	N/A	Accepted		2017
CAZ AVI <sup>#</sup>	cephalosporin/ beta lactamase inhibitor	serious infections, complicated intra-abdominal infection, complicated urinary tract infection	Q1 2012	N/A	Accepted		2017
MEDI-550	pandemic influenza virus vaccine	pandemic influenza prophylaxis		N/A	Q2 2016 <sup>6</sup>	N/A	N/A
AZD3293 <sup>3</sup> AMARANTH	beta-secretase inhibitor	Early Alzheimer's disease	Q2 2016 <sup>7</sup>	2020	2020	2020	

<sup>1</sup> Registrational Phase II/III trial

<sup>2</sup> Approval received February 2016

<sup>3</sup> Brilinta in the US; Brikique in rest of world

<sup>4</sup> Farxiga in the US; Forxiga in rest of world

<sup>5</sup> Rolling NDA submission to be initiated in H2 2016

<sup>6</sup> EU Approval received 3 February 2016; JP approval received 28 March 2016

<sup>7</sup> CHMP Positive Opinion received April 2016

<sup>8</sup> First patient dosed April 2016

## Phases I and II

### NMEs and significant additional indications

Compound	Mechanism	Area Under Investigation	Phase	Date Commenced Phase
Respiratory, Inflammation and Autoimmunity				
PT010	LABA/LAMA/ICS	asthma	II	Q2 2014
tralokinumab	IL-13 mAb	atopic dermatitis	II	Q1 2015
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 (RDEA3170)	selective uric acid reabsorption inhibitor (URAT-1)	chronic treatment of hyperuricemia in patients with gout	II	Q3 2013
abediterol (AZD0548)	LABA	asthma/COPD	II	Q4 2007
AZD7594	inhaled SGRM	asthma/COPD	II	Q3 2015
AZD7624	inhaled P38 inhibitor	COPD	II	Q4 2014
AZD9412 <sup>#</sup>	inhaled interferon beta	asthma/COPD	II	Q3 2015
mavrilimumab <sup>#</sup>	GM-CSFR mAb	rheumatoid arthritis	II	Q1 2010
inebilizumab <sup>#</sup> (MEDI-551) <sup>#</sup>	CD19 mAb	neuromyelitis optica	II	Q1 2015 (Orphan Drug)
MEDI2070 <sup>#</sup>	IL-23 mAb	Crohn's disease	II	Q1 2013
tezepelumab <sup>#</sup> (MEDI9929) <sup>#</sup>	TSLP mAb	asthma / atopic dermatitis	II	Q2 2014
lesinurad + allopurinol FDC	selective uric acid reabsorption inhibitor (URAT-1) +xanthine oxidase inhibitor FDC	chronic treatment of hyperuricemia in patients with gout	I	Q4 2015
AZD1419 <sup>#</sup>	TLR9 agonist	Asthma	I	Q3 2013
AZD5634	inhaled ENaC	cystic fibrosis	I	Q1 2016
AZD7986	DPP1	COPD	I	Q4 2014
AZD8871	MABA	COPD	I	Q4 2015
AZD9567	oral SGRM	rheumatoid arthritis	I	Q4 2015

MEDI0700#	BAFF/B7RP1 bispecific mAb	systemic lupus erythematosus	I	Q1 2016
MEDI4920	anti-CD40L-Tn3 fusion protein	primary Sjögren's syndrome	I	Q2 2014
MEDI5872#	B7RP1 mAb	systemic lupus erythematosus	I	Q4 2008
MEDI7836	IL-13 mAb-YTE	asthma	I	Q1 2015
MEDI9314	IL-4R mAb	atopic dermatitis	I	Q1 2016
<b>Cardiovascular and Metabolic Diseases</b>				
MEDI4166	PCSK9/GLP-1 mAb + peptide fusion	diabetes / cardiovascular	II	Q1 2016
MEDI6012	LCAT	ACS	II	Q4 2015
AZD4076	anti-miR103/107 oligonucleotide	non-alcoholic fatty liver disease/non-alcoholic steatohepatitis (NASH)	I	Q4 2015
AZD5718	FLAP	CAD	I	Q1 2016
MEDI0382	GLP-1/ glucagon dual agonist	diabetes / obesity	I	Q1 2015
MEDI8111	Rh-factor II	trauma / bleeding	I	Q1 2014
<b>Oncology</b>				
durvalumab#	PD-L1 mAb	bladder cancer	II	Q1 2016 (Breakthrough Therapy Designation)
durvalumab#	PD-L1 mAb	solid tumours	II	Q3 2014
durvalumab# + tremelimumab	PD-L1 mAb + CTLA-4 mAb	gastric cancer	II	Q2 2015
durvalumab# + AZD5069	PD-L1 mAb + CXCR2	SCCHN	II	Q3 2015
durvalumab# + AZD9150#	PD-L1 mAb + STAT3 inhibitor			
durvalumab#	PD-L1 mAb	solid tumours	I	Q3 2014
durvalumab# + monalizumab <sup>1</sup>	PD-L1 mAb + NKG2a mAb	solid tumours	I	Q1 2016
durvalumab# + MEDI9447	PD-L1 mAb + CD73 mAb	solid tumours	I	Q1 2016
durvalumab# + MEDI6383#	PD-L1 mAb + OX40 agonist	solid tumours	I	Q2 2015
durvalumab# + Jressa	PD-L1 mAb+ EGFR tyrosine kinase inhibitor	NSCLC	I	Q2 2014
durvalumab# + MEDI0680	PD-L1 mAb + PD-1 mAb	solid tumours	I	Q2 2014
durvalumab# + dabrafenib + trametinib <sup>2</sup>	PD-L1 mAb+ BRAF inhibitor + MEK inhibitor	melanoma	I	Q1 2014
durvalumab# + tremelimumab	PD-L1 mAb + CTLA-4 mAb	solid tumours	I	Q4 2013
Tagrisso + (durvalumab# or selumetinib# or savolitinib#) TATTON	EGFR tyrosine kinase inhibitor + (PD-L1 mAb or MEK inhibitor or MET tyrosine kinase inhibitor)	advanced EGFRm NSCLC	I	Q3 2014
selumetinib#	MEK inhibitor	2nd-line KRAS wt NSCLC	II	Q1 2013
savolitinib/volitinib#	MET tyrosine kinase inhibitor	papillary renal cell carcinoma	II	Q2 2014
AZD1775#	WEE-1 inhibitor	ovarian cancer	II	Q4 2012
vistusertib (AZD2014)	mTOR serine/ threonine kinase inhibitor	solid tumours	II	Q1 2013
AZD3759 BLOOM	EGFR tyrosine kinase inhibitor	brain metastases in advanced EGFRm NSCLC	II	Q4 2015
Tagrisso (AZD9291) BLOOM	EGFR tyrosine kinase inhibitor			
AZD5363#	AKT kinase inhibitor	breast cancer	II	Q1 2014
AZD4547	FGFR tyrosine kinase inhibitor	solid tumours	II	Q4 2011
inebilizumab# (MEDI-551)	CD19 mAb	diffuse B-cell lymphoma	II	Q1 2012



MEDI-573#	IGF mAb	metastatic breast cancer	II	Q2 2012
AZD0156	ATM serine/threonine kinase inhibitor	solid tumours	I	Q4 2015
AZD2811#	Aurora B kinase inhibitor	solid tumours	I	Q4 2015
AZD6738	ATR serine/threonine kinase inhibitor	solid tumours	I	Q4 2013
AZD8186	PI3 kinase beta inhibitor	solid tumours	I	Q2 2013
AZD9150#	STAT3 inhibitor	haematological malignancies	I	Q1 2012
AZD9496	selective oestrogen receptor downregulator (SERD)	ER+ breast cancer	I	Q4 2014
MEDI0562#	humanised OX40 agonist	solid tumours	I	Q1 2015
MEDI-565#	CEA BiTE mAb	solid tumours	I	Q1 2011
MEDI0639#	DLL-4 mAb	solid tumours	I	Q2 2012
MEDI0680	PD-1 mAb	solid tumours	I	Q4 2013
MEDI1873	GITR agonist fusion protein	solid tumours	I	Q4 2015
MEDI3617#	ANG-2 mAb	solid tumours	I	Q4 2010
MEDI4276	HER2 bispecific ADC mAb	solid tumours	I	Q4 2015
MEDI6383#	OX40 agonist	solid tumours	I	Q3 2014
MEDI9197#	TLR 7/8 agonist	solid tumours	I	Q4 2015
MEDI9447	CD73 mAb	solid tumours	I	Q3 2015
<b>Infection, Neuroscience and Gastrointestinal</b>				
CXL#	beta lactamase inhibitor / cephalosporin	methicillin-resistant <i>S. aureus</i>	II	Q4 2010
AZD3241	myeloperoxidase inhibitor	multiple system atrophy	II	Q2 2015 (Orphan Drug)
MEDI3902	PsI/PcrV bispecific mAb	prevention of nosocomial pseudomonas pneumonia	II	Q2 2016 (FDA Fast Track)
MEDI4893	mAb binding to <i>S. aureus</i> toxin	hospital-acquired pneumonia / serious <i>S. aureus</i> infection	II	Q4 2014 (FDA Fast Track)
MEDI7510	RSV sF+GLA-SE	prevention of RSV disease in older adults	II	Q3 2015
MEDI8852	influenza A mAb	influenza A treatment	II	Q4 2015 (FDA Fast Track)
MEDI8897#	RSV mAb-YTE	passive RSV prophylaxis	II	Q1 2015 (FDA Fast Track)
ATM AVI#	monobactam/ beta lactamase inhibitor	targeted serious bacterial infections	I	Q4 2012
AZD8108	NMDA antagonist	suicidal ideation	I	Q4 2014
MEDI1814	amyloid beta mAb	Alzheimer's disease	I	Q2 2014
MEDI7352	NGF/TNF bispecific mAb	osteoarthritis pain	I	Q1 2016

1 MedImmune-sponsored trial in collaboration with Innate Pharma

2 MedImmune-sponsored trial in collaboration with Novartis AG



## Significant Life-Cycle Management

Compound	Mechanism	Area Under Investigation	Date Commenced Phase	Estimated Regulatory Submission Acceptance <sup>1</sup>			
				US	EU	Japan	China
<b>Respiratory, Inflammation and Autoimmunity</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		2018	Launched	2018	2018
<b>Cardiovascular and Metabolic Diseases</b>							
<i>Brinta/Brilique</i> <sup>5</sup> PEGASUS- TIMI 54	P2Y12 receptor antagonist	outcomes trial in patients with prior myocardial infarction	Q4 2010	Launched (Priority Review)	Launched	Accepted	Accepted <sup>6</sup>
<i>Brinta/Brilique</i> <sup>5</sup> EUCLID	P2Y12 receptor antagonist	outcomes trial in patients with peripheral artery disease	Q4 2012	2017	2017	2017	2018
<i>Brinta/Brilique</i> <sup>5</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
<i>Brinta/Brilique</i> <sup>5</sup> HESTIA	P2Y12 receptor antagonist	prevention of vaso-occlusive crises in paediatric patients with sickle cell disease	Q1 2014	2020	2020		
<i>Onglyza</i> SAVOR-TIMI 53	DPP-4 inhibitor	type-2 diabetes outcomes trial	Q2 2010	Launched	Launched		H2 2016 <sup>1</sup>
<i>Kombiglyze XR/Komboglyze</i> <sup>2</sup>	DPP-4 inhibitor/ metformin FDC	type-2 diabetes		Launched	Launched		Submitted
<i>Farxiga/Forxiga</i> <sup>4</sup> DECLARE- TIMI 58	SGLT2 inhibitor	type-2 diabetes outcomes trial	Q2 2013	2020	2020		
<i>Farxiga/Forxiga</i> <sup>4</sup>	SGLT2 inhibitor	type-1 diabetes	Q4 2014	2018	2017	2018	
<i>Xigduo XR/</i> <i>Xigduo</i> <sup>3</sup>	SGLT2 inhibitor/ metformin FDC	type-2 diabetes		Launched	Launched		
saxagliptin/ dapagliflozin FDC	DPP-4 inhibitor/ SGLT2 inhibitor FDC	type-2 diabetes	Q2 2012	Accepted	Accepted		
<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
<i>Epanova/</i> <i>Farxiga/Forxiga</i> <sup>4</sup>	omega-3 carboxylic acids/ SGLT2 inhibitor	non-alcoholic fatty liver disease/non-alcoholic steatohepatitis (NASH)	Q1 2015				
<b>Oncology</b>							
<i>Faslodex</i> FALCON	oestrogen receptor antagonist	1st-line hormone receptor +ve advanced breast cancer	Q4 2012	H2 2016	H2 2016	H2 2016	2020
<i>Lynparza</i> (olaparib) GOLD	PARP inhibitor	2nd-line gastric cancer	Q3 2013			2017	2017
<i>Lynparza</i> (olaparib) OlympiAD	PARP inhibitor	gBRCA metastatic breast cancer	Q2 2014	2017	2017	2017	
<i>Lynparza</i> (olaparib) SOLO-2	PARP inhibitor	2nd-line or greater BRCAm PSR ovarian cancer, maintenance monotherapy	Q3 2013	2017	2017	2017	
<i>Lynparza</i> (olaparib) SOLO-1	PARP inhibitor	1st-line BRCAm ovarian cancer	Q3 2013	2017	2017	2017	
<i>Lynparza</i> (olaparib) SOLO-3	PARP inhibitor	gBRCA PSR ovarian cancer	Q1 2015	2018			
<i>Lynparza</i> (olaparib) POLO	PARP inhibitor	pancreatic cancer	Q1 2015	2018	2018	2018	
<i>Lynparza</i> (olaparib)	PARP inhibitor	prostate cancer	Q3 2014	(Breakthrough Therapy Designation) 7			
<i>Lynparza</i> (olaparib) OlympiA	PARP inhibitor	gBRCA adjuvant breast cancer	Q2 2014	2020	2020	2020	
<i>Tagrisso</i> FLAURA	EGFR tyrosine kinase inhibitor	1st-line advanced EGFRm NSCLC	Q1 2015	2017	2017	2017	2017
<i>Tagrisso</i> ADAURA	EGFR tyrosine kinase inhibitor	adjuvant EGFRm NSCLC	Q4 2015	2022	2022	2022	2022
<b>Infection, Neuroscience and Gastrointestinal</b>							
<i>Nexium</i>	proton pump inhibitor	stress ulcer prophylaxis					H2 2016
<i>Nexium</i>	proton pump inhibitor	paediatrics		Launched	Launched	H2 2016	Accepted
<i>Diprivan</i> <sup>#</sup>	sedative and anaesthetic	conscious sedation		N/A	Launched	Accepted	Launched
<i>linaclotide</i> <sup>#</sup>	GC-C receptor peptide agonist	irritable bowel syndrome with constipation (IBS-C)		N/A	N/A	N/A	Accepted

<sup>1</sup> Timing of China submission dependent on US regulatory approval

<sup>2</sup> *Kombiglyze XR* in the US; *Komboglyze* in the EU

<sup>3</sup> *Xigduo XR* in the US; *Xigduo* in the EU

<sup>4</sup> *Farxiga* in the US; *Forxiga* in rest of world

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

6 *Submission accepted 11 April 2016*

7 *Breakthrough Therapy designation granted for prostate cancer patients with BRCA1/2 or ATM gene mutated mCRPC who have received previous taxane-based chemotherapy and one newer hormonal agent (abiraterone or enzalutamide).*

#### Terminations (discontinued projects between 1 January and 31 March 2016)

NME / Line Extension	Compound	Reason for Discontinuation	Area Under Investigation
LCM	inebilizumab <sup>#</sup> (MEDI-551) + rituximab	Safety/efficacy	haematological malignancies
NME	AZD5312 <sup>#</sup>	Safety/efficacy	solid tumours
NME	AZD8835	Safety/efficacy	solid tumour
NME	tremelimumab <sup>#</sup> DETERMINE	Safety/efficacy	mesothelioma 2nd/3rd line
LCM	<i>Tagrisso</i> + durvalumab CAURAL	Safety/efficacy	≥2nd-line advanced EGFRm T790M NSCLC
NME	abrilumab <sup>#</sup>	Strategic	Crohn's disease / ulcerative colitis
NME	AZD8999	Strategic	COPD
LCM	<i>Brilinta/Brilique</i> <sup>6</sup> SOCRATES	Safety/efficacy	outcomes trial in patients with stroke or TIA

### Condensed Consolidated Statement of Comprehensive Income

For the quarter ended 31 March	2016 \$m	2015 \$m
Product sales	5,565	5,748
Externalisation revenue	550	309
<b>Total revenue</b>	<b>6,115</b>	<b>6,057</b>
Cost of sales	(1,004)	(1,269)
<b>Gross profit</b>	<b>5,111</b>	<b>4,788</b>
Distribution costs	(76)	(77)
Research and development expense	(1,480)	(1,356)
Selling, general and administrative costs	(2,572)	(2,799)
Other operating income and expense	55	377
<b>Operating profit</b>	<b>1,038</b>	<b>933</b>
Finance income	14	11
Finance expense	(325)	(261)
Share of after tax losses in associates and joint ventures	(4)	(5)
<b>Profit before tax</b>	<b>723</b>	<b>678</b>
Taxation	(98)	(126)
<b>Profit for the period</b>	<b>625</b>	<b>552</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	(191)	(17)
Tax on items that will not be reclassified to profit or loss	41	4
	(150)	(13)
<i>Items that may be reclassified subsequently to profit or loss</i>		
Foreign exchange arising on consolidation	(167)	(449)
Foreign exchange arising on designating borrowings in net investment hedges	207	(408)
Fair value movements on derivatives designated in net investment hedges	(32)	21
Net available for sale (losses)/gains taken to equity	(29)	19
Tax on items that may be reclassified subsequently to profit or loss	10	100
	(11)	(717)
<b>Other comprehensive income for the period, net of tax</b>	<b>(161)</b>	<b>(730)</b>
<b>Total comprehensive income for the period</b>	<b>464</b>	<b>(178)</b>
<b>Profit attributable to:</b>		
Owners of the Parent	646	550
Non-controlling interests	(21)	2
	625	552
<b>Total comprehensive income attributable to:</b>		
Owners of the Parent	485	(179)
Non-controlling interests	(21)	1
	464	(178)
Basic earnings per \$0.25 Ordinary Share	\$0.51	\$0.44
Diluted earnings per \$0.25 Ordinary Share	\$0.51	\$0.44
Weighted average number of Ordinary Shares in issue (millions)	1,264	1,263
Diluted weighted average number of Ordinary Shares in issue (millions)	1,265	1,265



## Condensed Consolidated Statement of Financial Position

	At 31 Mar 2016 \$m	At 31 Dec 2015 \$m	At 31 Mar 2015 \$m
<b>ASSETS</b>			
<b>Non-current assets</b>			
Property, plant and equipment	6,560	6,413	5,913
Goodwill	11,988	11,868	11,387
Intangible assets	29,627	22,646	20,319
Derivative financial instruments	419	446	491
Investments in associates and joint ventures	104	85	52
Other investments	500	458	490
Other receivables	874	907	977
Deferred tax assets	1,482	1,294	1,381
	<u>51,554</u>	<u>44,117</u>	<u>41,010</u>
<b>Current assets</b>			
Inventories	2,344	2,143	1,968
Trade and other receivables	5,866	6,622	6,704
Other investments	671	613	493
Derivative financial instruments	8	2	37
Income tax receivable	452	387	297
Cash and cash equivalents	3,428	6,240	3,192
	<u>12,769</u>	<u>16,007</u>	<u>12,691</u>
<b>Total assets</b>	<u>64,323</u>	<u>60,124</u>	<u>53,701</u>
<b>LIABILITIES</b>			
<b>Current liabilities</b>			
Interest-bearing loans and borrowings	(2,168)	(916)	(2,299)
Trade and other payables	(11,174)	(11,663)	(10,510)
Derivative financial instruments	(4)	(9)	(17)
Provisions	(790)	(798)	(602)
Income tax payable	(1,796)	(1,483)	(2,330)
	<u>(15,932)</u>	<u>(14,869)</u>	<u>(15,758)</u>
<b>Non-current liabilities</b>			
Interest-bearing loans and borrowings	(14,144)	(14,137)	(8,270)
Derivative financial instruments	-	(1)	-
Deferred tax liabilities	(4,420)	(2,733)	(1,611)
Retirement benefit obligations	(2,099)	(1,974)	(2,506)
Provisions	(461)	(444)	(424)
Other payables	(10,625)	(7,457)	(8,176)
	<u>(31,749)</u>	<u>(26,746)</u>	<u>(20,987)</u>
<b>Total liabilities</b>	<u>(47,681)</u>	<u>(41,615)</u>	<u>(36,745)</u>
<b>Net assets</b>	<u>16,642</u>	<u>18,509</u>	<u>16,956</u>
<b>EQUITY</b>			
<b>Capital and reserves attributable to equity holders of the Company</b>			
Share capital	316	316	316
Share premium account	4,322	4,304	4,276
Other reserves	2,028	2,036	2,039
Retained earnings	8,075	11,834	10,305
	<u>14,741</u>	<u>18,490</u>	<u>16,936</u>
<b>Non-controlling interests</b>	<u>1,901</u>	<u>19</u>	<u>20</u>
<b>Total equity</b>	<u>16,642</u>	<u>18,509</u>	<u>16,956</u>





## Condensed Consolidated Statement of Cash Flows

	2016 \$m	2015 \$m
For the quarter ended 31 March		
<b>Cash flows from operating activities</b>		
Profit before tax	723	678
Finance income and expense	311	250
Share of after tax losses in associates and joint ventures	4	5
Depreciation, amortisation and impairment	569	849
Decrease/(increase) in working capital and short-term provisions	64	(664)
Non-cash and other movements	(88)	(703)
<b>Cash generated from operations</b>	1,583	415
Interest paid	(185)	(242)
Tax paid	(205)	(245)
<b>Net cash inflow/(outflow) from operating activities</b>	1,193	(72)
<b>Cash flows from investing activities</b>		
Movement in short-term investments and fixed deposits	33	276
Purchase of property, plant and equipment	(267)	(227)
Disposal of property, plant and equipment	2	8
Purchase of intangible assets	(39)	(848)
Disposal of intangible assets	-	325
Purchase of non-current asset investments	(68)	(23)
Disposal of non-current asset investments	-	37
Upfront payments on business acquisitions	(2,564)	-
Payment of contingent consideration on business acquisitions	(26)	(144)
Interest received	42	40
<b>Net cash outflow from investing activities</b>	(2,887)	(556)
<b>Net cash outflow before financing activities</b>	(1,694)	(628)
<b>Cash flows from financing activities</b>		
Proceeds from issue of share capital	18	15
Repayment of loans	-	(884)
Dividends paid	(2,409)	(2,357)
Hedge contracts relating to dividend payments	5	(43)
Repayment of obligations under finance leases	(3)	(10)
Movement in short-term borrowings	1,028	710
<b>Net cash outflow from financing activities</b>	(1,361)	(2,569)
Net decrease in cash and cash equivalents in the period	(3,055)	(3,197)
Cash and cash equivalents at the beginning of the period	6,051	6,164
Exchange rate effects	43	(19)
<b>Cash and cash equivalents at the end of the period</b>	3,039	2,948
<b>Cash and cash equivalents consists of:</b>		
Cash and cash equivalents	3,428	3,192
Overdrafts	(389)	(244)
	3,039	2,948



## 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	-	-	-	550	550	2	552
Other comprehensive income	-	-	-	(729)	(729)	(1)	(730)
Transfer to other reserves	-	-	18	(18)	-	-	-
<b>Transactions with owners:</b>							
Dividends	-	-	-	(2,400)	(2,400)	-	(2,400)
Issue of Ordinary Shares	-	15	-	-	15	-	15
Share-based payments	-	-	-	(127)	(127)	-	(127)
Net movement	-	15	18	(2,724)	(2,691)	1	(2,690)
<b>At 31 Mar 2015</b>	<b>316</b>	<b>4,276</b>	<b>2,039</b>	<b>10,305</b>	<b>16,936</b>	<b>20</b>	<b>16,956</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	-	-	-	646	646	(21)	625
Other comprehensive income	-	-	-	(161)	(161)	-	(161)
Transfer to other reserves	-	-	(8)	8	-	-	-
<b>Transactions with owners:</b>							
Dividends	-	-	-	(2,402)	(2,402)	-	(2,402)
Acerta put option	-	-	-	(1,825)	(1,825)	-	(1,825)
Changes in non-controlling interest	-	-	-	-	-	1,903	1,903
Issue of Ordinary Shares	-	18	-	-	18	-	18
Share-based payments	-	-	-	(25)	(25)	-	(25)
Net movement	-	18	(8)	(3,759)	(3,749)	1,882	(1,867)
<b>At 31 Mar 2016</b>	<b>316</b>	<b>4,322</b>	<b>2,028</b>	<b>8,075</b>	<b>14,741</b>	<b>1,901</b>	<b>16,642</b>

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

### 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 quarter ended 31 March 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.

Legal proceedings

The information contained in Note 6 updates the disclosures concerning legal proceedings and contingent liabilities in the Group's Annual Report and Form 20-F Information 2015.

Going concern

The Group has considerable financial resources available. As at 31 March 2016 the Group has \$4.2bn in financial resources (cash balances of \$3.4bn and undrawn committed bank facilities of \$3bn which are available until April 2021, with only \$2.2bn of debt due within one year). The Group's revenues are largely derived from sales of products which are covered by patents which provide a relatively high level of resilience and predictability to cash inflows, although our revenue is expected to continue to be significantly impacted by the expiry of patents over the medium term. In addition, government price interventions in response to budgetary constraints are expected to continue to adversely affect revenues in many of our mature markets. However, we anticipate new revenue streams from both recently launched medicines and products in development, and the Group has a wide diversity of customers and suppliers across different geographic areas. Consequently, the Directors believe that, overall, the Group is well placed to manage its business risks successfully.

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

Financial information

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

## 2 RESTRUCTURING COSTS

Profit before tax for the quarter ended 31 March 2016 is stated after charging restructuring costs of \$155m (\$213m for the first quarter of 2015). These have been charged to profit as follows:

	Q1 2016 \$m	Q1 2015 \$m
Cost of sales	9	43
Research and development expense	38	62
Selling, general and administrative costs	108	108
<b>Total</b>	<b>155</b>	<b>213</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 31 Mar 2016 \$m
Loans due after one year	(14,109)	-	-	(6)	(15)	(14,130)
Finance leases due after one year	(28)	-	-	14	-	(14)
<b>Total long-term debt</b>	<b>(14,137)</b>	<b>-</b>	<b>-</b>	<b>8</b>	<b>(15)</b>	<b>(14,144)</b>
Current instalments of finance leases	(67)	3	-	(26)	(1)	(91)
<b>Total current debt</b>	<b>(67)</b>	<b>3</b>	<b>-</b>	<b>(26)</b>	<b>(1)</b>	<b>(91)</b>
Other investments	613	(29)	140	(1)	(13)	710
Net derivative financial instruments	438	30	-	(45)	-	423
Cash and cash equivalents	6,240	(2,852)	-	-	40	3,428
Overdrafts	(189)	(203)	-	-	3	(389)
Short-term borrowings	(660)	(1,028)	-	-	-	(1,688)
	6,442	(4,082)	140	(46)	30	2,484
<b>Net debt</b>	<b>(7,762)</b>	<b>(4,079)</b>	<b>140</b>	<b>(64)</b>	<b>14</b>	<b>(11,751)</b>

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



#### 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 31 March 2016, Acerta Pharma had no revenues and its loss after tax was \$49 million.

Given the proximity of the completion of the transaction to the date of the Interim Financial Statements, the finalisation of the accounting entries for this transaction has yet to be completed. Our provisional assessment of the fair values of the assets and liabilities acquired is detailed below. Our assessment will be completed in 2016.

	<b>Fair value \$m</b>
Intangible assets	7,307
Other assets including cash and cash equivalents	238
Deferred tax liabilities	(1,827)
Other liabilities	(90)
<b>Total net assets acquired</b>	<b>5,628</b>
Non-controlling interests	(1,903)
Goodwill	84
<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 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 \$1,171m of other investments, \$1,756m of loans, and \$423m of derivatives as at 31 March 2016. The total fair value of interest-bearing loans and borrowings at 31 March 2016, which have a carrying value of \$16,312m in the Condensed Consolidated Statement of Financial Position, was \$17,724m. 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	(26)	-	(26)	(144)
Revaluations	-	-	-	(9)
Discount unwind	97	27	124	132
Foreign exchange	-	-	-	(3)
<b>At 31 March</b>	<b>5,163</b>	<b>1,346</b>	<b>6,509</b>	<b>6,875</b>



## 6 LEGAL PROCEEDINGS AND CONTINGENT LIABILITIES

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

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

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

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

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

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

#### Patent litigation

##### ***Crestor (rosuvastatin)***

##### *US patent proceedings*

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

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

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

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

##### ***Faslodex (fulvestrant)***

##### *US patent proceedings*

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



**Patent proceedings outside the US**

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

**Movantik/Moventig (naloxegol)****US patent proceedings**

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

**Patent proceedings outside the US**

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

**Onglyza (saxagliptin) and Kombiglyze (saxagliptin and metformin)****US patent proceedings**

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

**Nexium (esomeprazole magnesium)****US patent proceedings**

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

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

**Patent Proceedings outside the US**

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

**Product liability litigation****Onglyza (saxagliptin)**

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

**Commercial litigation****Nexium/Prilosec trademark litigation**

As previously disclosed, AstraZeneca filed separate complaints in the US District Court for the District of Delaware against Camber Pharmaceuticals, Inc. (Camber) and Dr. Reddy's Laboratories, Inc. (Dr. Reddy's) to enforce certain AstraZeneca trademark rights related to *Nexium* and *Prilosec*. The Delaware District Court issued preliminary injunctions against Camber's and Dr. Reddy's sales of generic esomeprazole magnesium in purple capsules. The Camber action has been settled through negotiation and as part of the settlement, the Delaware District Court entered a Consented Judgment of Permanent Injunction and Other Relief on 31 March 2016 in favour of AstraZeneca. Dr. Reddy's filed its own separate claims against AstraZeneca in both the Delaware District Court and the US District Court for the District of New Jersey. Dr. Reddy's also appealed the preliminary injunction decision of the Delaware District Court to the US Court of Appeals for the Third Circuit and in April 2016, voluntarily withdrew its appeal. All District Court cases involving Dr. Reddy's related to this matter had been stayed pending the appeal, and have now resumed.

**Nexium Consumer litigation**

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

**Toprol-XL (metoprolol succinate)**

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

## 7 PRODUCT ANALYSIS - Q1 2016

	World		US		Europe		Established ROW		Emerging Markets	
	Q1 2016 \$m	CER %	Q1 2016 \$m	CER %	Q1 2016 \$m	CER %	Q1 2016 \$m	CER %	Q1 2016 \$m	CER %
<b>Respiratory, Inflammation &amp; Autoimmunity:</b>										
<i>Symbicort</i>	749	(7)	322	(6)	231	(19)	91	(2)	105	18
<i>Pulmicort</i>	310	14	56	8	29	(19)	18	(5)	207	24
<i>Tudorza/Eklira</i>	39	33	17	89	21	17	1	(50)	-	-
<i>Daliresp</i>	31	n/m	31	n/m	-	-	-	-	-	-
<i>Duaklir</i>	13	n/m	-	-	12	n/m	-	-	1	n/m
Others	65	(4)	4	(20)	19	(10)	3	(40)	39	5
<b>Total Respiratory, Inflammation &amp; Autoimmunity</b>	<b>1,207</b>	<b>2</b>	<b>430</b>	<b>4</b>	<b>312</b>	<b>(14)</b>	<b>113</b>	<b>(9)</b>	<b>352</b>	<b>20</b>
<b>Cardiovascular &amp; Metabolic disease:</b>										
<i>Brilinta/Brilique</i>	181	46	70	52	60	19	10	22	41	109
<i>Onglyza</i>	211	20	124	27	33	(6)	18	43	36	20
<i>Farxiga/Forxiga</i>	165	128	94	154	41	72	9	200	21	145
<i>Bydureon</i>	135	11	108	2	23	44	2	100	2	100
<i>Byetta</i>	62	(30)	42	(38)	10	(38)	5	25	5	200
<b>Legacy:</b>										
<i>Crestor</i>	1,156	2	636	4	212	(7)	125	(5)	183	12
<i>Seloken/Toprol-XL</i>	185	5	21	(22)	22	(8)	2	(33)	140	14
<i>Atacand</i>	71	(17)	9	(18)	24	(17)	4	(43)	34	(13)
Others	126	(21)	5	(75)	30	(21)	9	(40)	82	(7)
<b>Total Cardiovascular &amp; Metabolic Disease</b>	<b>2,292</b>	<b>7</b>	<b>1,109</b>	<b>8</b>	<b>455</b>	<b>(1)</b>	<b>184</b>	<b>(1)</b>	<b>544</b>	<b>16</b>
<b>Oncology:</b>										
<i>Iressa</i>	135	(1)	4	n/m	34	3	30	(6)	67	(6)
<i>Tagrisso</i>	51	n/m	45	n/m	6	n/m	-	-	-	-
<i>Lynparza</i>	44	n/m	28	n/m	14	n/m	-	-	2	n/m
<b>Legacy:</b>										
<i>Faslodex</i>	190	24	99	19	56	18	14	17	21	69
<i>Zoladex</i>	178	(1)	10	67	39	(9)	62	-	67	(3)
<i>Casodex</i>	62	(9)	-	-	7	(13)	26	(22)	29	7
<i>Arimidex</i>	57	(3)	4	33	8	(38)	16	(16)	29	19
Others	21	(37)	-	n/m	2	(88)	13	-	6	-
<b>Total Oncology</b>	<b>738</b>	<b>15</b>	<b>190</b>	<b>79</b>	<b>166</b>	<b>8</b>	<b>161</b>	<b>(6)</b>	<b>221</b>	<b>5</b>
<b>Infection, Neuroscience &amp; Gastrointestinal:</b>										
<i>Nexium</i>	463	(24)	131	(42)	60	(16)	95	(23)	177	(9)
<i>Synagis</i>	244	20	160	(1)	84	102	-	-	-	-
<i>Seroquel XR</i>	202	(21)	144	(15)	35	(41)	5	(29)	18	(4)
<i>LOSEC/Prilosec</i>	75	(18)	2	(71)	21	(15)	13	(32)	39	(5)
<i>Movantik/Moventig</i>	17	n/m	17	n/m	-	-	-	-	-	-
<i>FluMist/Fluenz</i>	5	(29)	5	(29)	-	-	-	-	-	-
Others	322	(9)	58	21	85	-	65	9	114	(32)
<b>Total Infection, Neuroscience &amp; Gastrointestinal</b>	<b>1,328</b>	<b>(13)</b>	<b>517</b>	<b>(17)</b>	<b>285</b>	<b>1</b>	<b>178</b>	<b>(14)</b>	<b>348</b>	<b>(17)</b>
<b>TOTAL PRODUCT SALES</b>	<b>5,565</b>	<b>1</b>	<b>2,246</b>	<b>4</b>	<b>1,218</b>	<b>(4)</b>	<b>636</b>	<b>(7)</b>	<b>1,465</b>	<b>6</b>

## Shareholder Information

### Announcements and Meetings

Announcement of half year and second quarter 2016 results	28 July 2016
Announcement of nine months and third quarter 2016 results	10 November 2016

### Dividends

Future dividends will normally be paid as follows:

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

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

### Trademarks

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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 media 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.