

AstraZeneca PLC
27 April 2017 07:00

Q1 2017 Results

An encouraging start as the pipeline newsflow continued in a potentially defining year

Financial Summary

	\$m	% change	
		Actual ¹	CER ²
Total Revenue	5,405	(12)	(10)
<i>Product Sales</i>	4,843	(13)	(12)
<i>Externalisation Revenue</i>	562	2	3
Reported Operating Profit	917	(12)	(23)
Core ³ Operating Profit	1,667	5	(2)
Reported Earnings Per Share (EPS)	\$0.42	(17)	(35)
Core EPS	\$0.99	4	(4)

- The Product Sales performance mainly reflected the residual impact of the US *Crestor* patent expiry
- One third of Externalisation Revenue was represented by sustainable and ongoing income⁴
- Continued good progress on cost control, reflecting the evolving shape of the business:
 - Reported R&D costs declined by 2% (up by 2% at CER) to \$1,453m; Core R&D costs declined by 6% (3% at CER) to \$1,338m
 - Reported SG&A costs declined by 11% (8% at CER) to \$2,300m; Core SG&A costs declined by 14% (12% at CER) to \$1,829m
- Reported EPS declined by 17% (35% at CER); Core EPS increased by 4% (down by 4% at CER)
- Financial guidance for 2017 confirmed

Commercial Highlights

The Growth Platforms grew by 4% (5% at CER) and represented 66% of Total Revenue:

- Emerging Markets: 7% growth (9% at CER), becoming AstraZeneca's largest sales region
- Respiratory: A decline of 2% (stable at CER), with growth offset by the performance of *Symbicort* in the US
- New CVMD⁵: Growth of 5% (6% at CER), with competitive pressures in the US continuing
- Japan: Growth of 5% (3% at CER), partly reflecting the ongoing successful launch of *Tagrisso* and the performance of *Symbicort*
- New Oncology⁶: Sales of \$236m (Q1 2016: \$99m), accompanied by regulatory approval for *Tagrisso* in China

Achieving Scientific Leadership

The table below highlights the number of successes in the late-stage pipeline since the last results announcement:

Regulatory Approvals	<i>Tagrisso</i> - lung cancer (US, EU; full approval) <i>Tagrisso</i> - lung cancer (CN) <i>Forxiga</i> - type-2 diabetes (CN) <i>Qtern</i> - type-2 diabetes (US) <i>Siliq</i> - psoriasis (US; by partner)
Regulatory Submission Acceptances	<i>Lynparza</i> - ovarian cancer (2nd line) (US) (Priority Review) <i>Bydureon</i> - type-2 diabetes (autoinjector) (US) <i>Symbicort</i> - COPD exacerbations (US) benralizumab - severe, uncontrolled asthma (JP)
Phase III or Major Data Readouts	<i>Lynparza</i> - breast cancer <i>Farxiga</i> - type-2 diabetes (CVD-REAL real-world study)
Other Key Developments	Orphan Drug Designation: <i>Lynparza</i> - ovarian cancer (JP) Complete Response Letter: ZS-9 (sodium zirconium cyclosilicate) - hyperkalaemia (US) Orphan designation: inebilizumab - neuromyelitis optica spectrum disorder (EU)

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

“Our good start to the year supported our guidance for 2017. Notably, Emerging Markets became our largest region, representing 32% of sales. The pipeline continued to deliver in what we expect will be a pivotal year for AstraZeneca as we announced important developments, in particular in Oncology. In addition to the availability of positive data for *Lynparza* in ovarian and breast cancer, we also received full approvals in the US and Europe for *Tagrisso* in lung cancer and launched this important medicine in record time in China. While we were disappointed to receive the Complete Response Letter for ZS-9, we remain confident in this treatment for hyperkalaemia.

“The Total Revenue performance reflected the transitional impact of recent patent expiries, which is expected to recede in the second half of the year. Importantly, we anticipate the significant progress of the pipeline to continue, including our Immuno-Oncology and targeted treatments. We will also maintain our commitment to drive efficiency across the company to support our efforts to bring new medicines to patients.”

FY 2017 Guidance: Confirmed

The Company provides guidance on Total Revenue and Core EPS only. All commentary in this section is at CER and is unchanged from the prior results announcement:

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

*The Core EPS guidance anticipates a normalised effective Core tax rate in FY 2017 of 16-20% (FY 2016: 11%)

Guidance is subject to base-case assumptions of the progression of the pipeline and the extensive level of news flow listed on the following page. Variations in performance between quarters can be expected to continue, with year-on-year comparisons expected to ease in H2 2017, when the impact of the entry in July 2016 of multiple *Crestor* generic medicines in the US will annualise.

The Company presents Core EPS guidance only at CER. It is unable to provide guidance on a Reported/GAAP basis because the Company cannot reliably forecast material elements of the Reported/GAAP result, including the fair value adjustments arising on acquisition-related liabilities, intangible asset impairment charges and legal settlement provisions. Please refer to the section ‘Cautionary Statements Regarding Forward-Looking Statements’ at the end of this announcement.

In addition to the unchanged guidance above, the Company also provides indications in other areas of the Income Statement. The sum of Externalisation Revenue and Other Operating Income in FY 2017 is anticipated to be ahead of that in FY 2016. Sustainable and ongoing income is expected to increase further as a proportion of total Externalisation Revenue in FY 2017. Core R&D costs are expected to be broadly in line with those in FY 2016 and the Company anticipates a further reduction in Core SG&A costs in FY 2017, reflecting the evolving shape of the business. A full explanation of these items is listed in the Operating & Financial Review.

FY 2017 Currency Impact

Based only on average exchange rates in Q1 2017 and the Company’s published currency sensitivities, the Company expects a low single-digit percentage adverse impact from currency movements on Total Revenue and a minimal impact on Core EPS. Further details on currency sensitivities are contained within the Operating and Financial Review.

Notes

1. All growth rates are shown at actual exchange rates, unless stated otherwise.
2. Constant exchange rates. These are non-GAAP measures because they remove the effects of currency movements from Reported results.
3. Core financial measures. These are non-GAAP measures because, unlike Reported performance, they cannot be derived directly from the information in the Group Financial Statements. See the Operating and Financial Review for a definition of Core financial measures and a reconciliation of Core to Reported financial measures.
4. Sustainable and ongoing income is defined as Externalisation Revenue, excluding upfront receipts.
5. New Cardiovascular and Metabolic Diseases, incorporating *Brilinta* and Diabetes.
6. New Oncology comprises *Tagrisso*, *Lynparza* and *Iressa* (US).

Pipeline: Forthcoming Major News Flow

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

Q2 2017	<p><i>Faslodex</i> - breast cancer (1st line): Regulatory decision (JP) <i>Lynparza</i> - ovarian cancer (2nd line): Regulatory submission (EU) durvalumab (durva) - bladder cancer: Regulatory decision (US) acalabrutinib - blood cancer: Data readout, regulatory submission (US) (Phase II)# <i>Bevespi</i> - COPD: Regulatory submission (EU)</p>
Mid-2017	<p>durva +/- tremelimumab (treme) - lung cancer (MYSTIC): Data readout</p>
H2 2017	<p><i>Faslodex</i> - breast cancer (1st line): Regulatory decision (US, EU) <i>Lynparza</i> - ovarian cancer (2nd line): Regulatory decision (US) <i>Lynparza</i> - breast cancer: Regulatory submission <i>Lynparza</i> - ovarian cancer (1st line): Data readout <i>Tagrisso</i> - lung cancer (1st line): Data readout durvalumab - lung cancer (PACIFIC): Data readout, regulatory submission (US) durva +/- treme - lung cancer (ARCTIC): Data readout, regulatory submission durva +/- treme - lung cancer (MYSTIC): Regulatory submission durva +/- treme - head & neck cancer (KESTREL): Data readout moxetumomab - leukaemia: Data readout <i>Bydureon</i> - cardiovascular (CV) outcomes trial: Data readout, regulatory submission benralizumab - severe, uncontrolled asthma: Regulatory decision (US) tralokinumab - severe, uncontrolled asthma: Data readout</p>
2018	<p><i>Lynparza</i> - ovarian cancer (1st line): Regulatory submission <i>Tagrisso</i> - lung cancer (1st line): Regulatory submission durva + treme - lung cancer (NEPTUNE): Data readout durva +/- treme - head & neck cancer (KESTREL): Regulatory submission durva +/- treme - head & neck cancer (EAGLE): Data readout, regulatory submission durva +/- treme - bladder cancer (DANUBE): Data readout, regulatory submission moxetumomab - leukaemia: Regulatory submission selumetinib - thyroid cancer: Data readout, regulatory submission <i>Bydureon</i> - autoinjector: Regulatory decision (US) roxadustat - anaemia: Data readout (AstraZeneca-sponsored trials), regulatory submission <i>Duaklir</i> - COPD: Regulatory submission (US) benralizumab - severe, uncontrolled asthma: Regulatory decision (EU, JP) benralizumab - COPD: Data readout, regulatory submission tralokinumab - severe, uncontrolled asthma: Regulatory submission PT010 - COPD: Data readout, regulatory submission anifrolumab - lupus: Data readout</p>

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

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

Conference Call

A conference call and accompanying webcast for investors and analysts, hosted by management, will begin at 12pm UK time today. Details can be accessed via astrazeneca.com/investors.

Reporting Calendar

The Company intends to publish its first-half and second-quarter financial results on 27 July 2017.

About AstraZeneca

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

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Operating And Financial Review

All narrative on growth and results in this section is based on actual exchange rates, unless stated otherwise. Financial figures are in US\$ millions (\$m). The performance shown in this announcement covers the three-month period to 31 March 2017 (the quarter) compared to the three-month period to 31 March 2016.

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. These non-GAAP measures are not a substitute for, or superior to, measures of financial performance prepared in accordance with GAAP. Core financial measures are adjusted to exclude certain significant items, such as:

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

Details on the nature of these measures are provided on page 64 of the [Annual Report](#) and Form 20-F Information 2016. Reference should be made to the reconciliation of Core to Reported financial information included therein and in the Reconciliation of Reported to Core Performance table listed later in this announcement. The Company strongly encourages readers not to rely on any single financial measure, but to review AstraZeneca's financial statements, including the notes thereto, and other publicly-filed Company reports, carefully and in their entirety.

Total Revenue

	\$m	% change	
		Actual	CER
Product Sales	4,843	(13)	(12)
Externalisation Revenue	562	2	3
Total Revenue	5,405	(12)	(10)

Product Sales

The Product Sales performance was primarily driven by the impact of the entry in July 2016 of multiple *Crestor* generic medicines in the US. Emerging Markets became the largest sales region for the Company in the quarter, with sales growth of 7% (9% at CER) to \$1,562m. US Product Sales declined by 34% to \$1,485m, also impacted by the performances of *Symbicort* and *Seroquel XR*. Product Sales in Europe declined by 7% (3% at CER) to \$1,129m.

Within Product Sales, the Growth Platforms grew by 4% (5% at CER), representing 66% of Total Revenue:

Growth Platform	\$m	% change	
		Actual	CER
Emerging Markets	1,562	7	9
Respiratory	1,181	(2)	-
New CVMD	798	5	6
Japan	450	5	3
New Oncology	236	n/m	n/m
Total*	3,572	4	5

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

Externalisation Revenue

Where AstraZeneca retains a significant ongoing interest in medicines or potential new medicines, income arising from externalisation agreements is reported as Externalisation Revenue in the Company's financial statements.

The table below illustrates the level of sustainable and ongoing income within the total of Externalisation Revenue. The Company anticipates that sustainable and ongoing income will grow as a proportion of Externalisation Revenue over time.

	\$m	% of Total	% change	
			Actual	CER
Royalties	45	8	18	24
Milestones	136	24	44	50
Total Sustainable and Ongoing Externalisation Revenue	181	32	37	42
Upfront Receipts	381	68	(9)	(9)
Total Externalisation Revenue	562	100	2	3

A breakdown of Externalisation Revenue in the quarter is shown below:

Medicine	Partner	Region	\$m
Zoladex	TerSera Therapeutics LLC (TerSera) - initial revenue	US and Canada	250
Siliq (brodalumab)	Valeant Pharmaceuticals International, Inc. (Valeant) - milestone revenue	US	130
MEDI8897	Sanofi Pasteur Inc. (Sanofi Pasteur) - initial revenue	Global	127
Other			55
Total			562

Examples of sustainable and ongoing income, as part of Externalisation Revenue, are shown below:

Announcement Date	Medicine	Partner	Region	Externalisation Revenue
3 March 2017	MEDI8897	Sanofi Pasteur	Global	<ul style="list-style-type: none"> Initial €120m milestone Up to €495m in sales and development-related milestones
20 February 2017	Zoladex	TerSera	US and Canada	<ul style="list-style-type: none"> Initial \$250m milestone Up to \$70m in sales-related milestones Mid-teen percentage royalties on sales
4 October 2016	Toprol-XL	Aralez Pharmaceuticals Inc.	US	<ul style="list-style-type: none"> Initial \$175m milestone Up to \$48m milestone and sales-related revenue Mid-teen percentage royalties on sales
1 July 2016	Tralokinumab - atopic dermatitis	LEO Pharma A/S (LEO Pharma)	Global	<ul style="list-style-type: none"> Initial \$115m milestone Up to \$1bn in commercially-related milestones Up to mid-teen tiered percentage royalties on sales
9 June 2016	Anaesthetics	Aspen Global Inc.	Global (excl. US)	<ul style="list-style-type: none"> Initial \$520m milestone Up to \$250m in sales-related revenue Double-digit percentage trademark royalties on sales
1 September 2015	Siliq (brodalumab) - psoriasis	Valeant	Global, later amended to US	<ul style="list-style-type: none"> Initial \$100m milestone Pre-launch milestone of \$130m Sales-related royalties up to \$175m Profit sharing
19 March 2015	Movantik	Daiichi Sankyo Company, Ltd (Daiichi Sankyo)	US	<ul style="list-style-type: none"> Initial \$200m milestone Up to \$625m in sales-related revenue

A number of AstraZeneca medicines were externalised or disposed after Q1 2016, adversely impacting the overall Product Sales performance in the quarter:

Medicine	Region	Agreement Completion Date	Q1 2016 Impacted Region Product Sales (\$m)
Anaesthetics	Global (excl. US)	1 September 2016	134
Toprol-XL	US	31 October 2016	21
Bydureon and Byetta	China	11 October 2016	3
Total			158

Product Sales

The performance of key medicines is shown below, with a geographical split shown in Note 6.

	\$m	% of total*	% change	
			Actual	CER
Oncology				
<i>Tagrisso</i>	171	4	n/m	n/m
<i>Iressa</i>	124	3	(8)	(7)
<i>Lynparza</i>	57	1	30	32
Legacy:				
<i>Faslodex</i>	214	4	13	13
<i>Zoladex</i>	185	4	4	5
<i>Casodex</i>	56	1	(10)	(8)
<i>Arimidex</i>	52	1	(9)	(7)
Others	26	1	24	24
Total Oncology	885	18	20	21
CVMD				
<i>Brilinta</i>	224	5	24	27
<i>Farxiga</i>	207	4	25	25
<i>Onglyza</i>	154	3	(27)	(27)
<i>Bydureon</i>	153	3	13	14
<i>Byetta</i>	46	1	(26)	(24)
Legacy:				
<i>Crestor</i>	631	13	(45)	(44)
<i>Seloken/Toprol-XL</i>	186	4	1	3
<i>Atacand</i>	75	2	4	7
Others	103	2	(18)	(16)
Total CVMD	1,779	37	(22)	(21)
Respiratory				
<i>Symbicort</i>	677	14	(10)	(8)
<i>Pulmicort</i>	337	7	9	14
<i>Daliresp/Daxas</i>	44	1	42	42
<i>Tudorza/Eklira</i>	37	1	(5)	(3)
<i>Duaklir</i>	19	0	46	54
Others	67	1	3	6
Total Respiratory	1,181	24	(2)	-
Other				
<i>Nexium</i>	461	10	-	1
<i>Synagis</i>	230	5	(6)	(6)
<i>Losec/Prilosec</i>	68	1	(9)	(7)
<i>Seroquel XR</i>	67	1	(67)	(66)
<i>Movantik/Moventig</i>	30	1	76	76
<i>FluMist/Fluenz</i>	0	0	(100)	(100)
Others	142	3	(56)	(56)
Total Other	998	21	(25)	(24)
Total Product Sales	4,843	100	(13)	(12)

*Due to rounding, the sum of individual brand percentages may not agree to totals.

Product Sales Summary

ONCOLOGY

Product Sales of \$885m; an increase of 20% (21% at CER).

Oncology Product Sales represented 18% of total Product Sales, up from 13% in Q1 2016.

Tagrisso

Product Sales of \$171m (Q1 2016: \$51m).

Tagrisso was the leading AstraZeneca medicine for the treatment of lung cancer by sales in the quarter. Regulatory approvals were granted in a number of new markets in the period, including Brazil, Hong Kong and Taiwan; the Company anticipates additional regulatory approvals and reimbursement decisions in due course. To date, *Tagrisso* has received regulatory approval in 48 countries.

In March 2017, the China Food and Drug Administration (China FDA) granted marketing authorisation for *Tagrisso* 40mg and 80mg once-daily oral tablets. *Tagrisso* was the first AstraZeneca medicine approved under the China FDA's Priority Review pathway, using an accelerated timeline for an innovative medicine. *Tagrisso* was launched in China in April 2017.

Sales in the US and Europe were \$90m and \$35m, respectively. The doubling of sales in the US primarily reflected patient demand. Sequential Japan sales, at \$39m, were stable. However, in local currency, sequential quarterly growth was 7%, underpinned by encouraging testing rates.

Iressa

Product Sales of \$124m; a decline of 8% (7% at CER).

Emerging Markets sales declined by 9% (7% at CER) to \$61m. China Product Sales declined by 8% (3% at CER) to \$34m, a result of new pricing following the inclusion on the National Reimbursement Drug List (NRDL) in February 2017; this was the first update to the NRDL in China in many years. Strong competition from branded and generic medicines in South Korea also contributed to the overall sales decline.

Sales in the US increased to \$8m (Q1 2016: \$4m), with sales in Europe declining by 24% (24% at CER) to \$26m. Given the extensive benefit to patients and the significant future potential of *Tagrisso*, the Company continues to prioritise the ongoing launch of *Tagrisso*.

Lynparza

Product Sales of \$57m; an increase of 30% (32% at CER).

Lynparza was available to patients in 31 countries by the end of the quarter, with regulatory reviews underway in seven additional countries, including Russia, Brazil and Singapore. Almost 5,000 patients globally have been prescribed *Lynparza* since the first launch in December 2014. In the US, *Lynparza* is approved in later line, germline-BRCA, advanced ovarian cancer. Sales in the US declined by 4% to \$27m, reflecting changes in the competitive landscape. Sales in Europe increased by 79% (79% at CER) to \$25m, following a number of successful launches.

Legacy: Faslodex

Product Sales of \$214m; an increase of 13% (13% at CER).

China sales grew by 20% (20% at CER) to \$6m, supporting Emerging Markets sales of \$27m which represented growth of 29% (24% at CER). US sales increased by 19% to \$118m, mainly driven by an expansion of the label in March 2016 for 2nd-line advanced or metastatic breast cancer, in combination with palbociclib. Europe sales declined by 4% (2% at CER) to \$54m. An increase in demand led to Japan sales growth of 8% (8% at CER) to \$14m.

Legacy: Zoladex

Product Sales of \$185m; an increase of 4% (5% at CER).

Emerging Markets sales growth of 30% (31% at CER) to \$87m was particularly reflected in volume demand in China, where sales increased by 34% (44% at CER) to \$43m. Sales in Europe declined by 18% (13% at CER) to \$32m.

Sales in Established Rest Of World (ROW), declined by 6% (8% at CER) to \$58m, driven by lower volume demand. Sales in the US, falling by 20% to \$8m, declined as a result of unfavourable pricing, despite an increase in volume demand. On 31 March 2017, the Company completed an agreement with TerSera for the commercial rights to *Zoladex* in the US and Canada.

CVMD

Product Sales of \$1,779m; a decline of 22% (21% at CER).

CVMD Product Sales represented 37% of total Product Sales, down from 41% in Q1 2016.

Brilinta

Product Sales of \$224m; an increase of 24% (27% at CER).

Emerging Markets sales grew by 46% (54% at CER) to \$60m, with China Product Sales increasing by 59% (68% at CER) to \$35m. China represented 58% of Emerging Markets sales of *Brilinta*, despite not being included on the China NRDL. *Brilinta* was recently added to the price-negotiation list in China and the Company continues to aim towards favourable levels of reimbursement. Growth in Emerging Markets was underpinned by an improvement in market share, beyond geographic expansion and breadth of hospital listings. Strong sales growth was delivered in many markets outside China, including Russia, Turkey and India.

US sales of *Brilinta*, at \$87m, represented an increase of 24%. The performance reflected updated preferred guidelines from the American College of Cardiology and the American Heart Association in 2016, as well as the narrowing of a competitor's label; *Brilinta* remained the branded oral anti-platelet (OAP) market leader in the US. Sales of *Brilique* in Europe increased by 8% (12% at CER) to \$65m, reflecting indication leadership across a number of markets. *Brilique* continued to outperform the overall OAP market in Europe.

Farxiga

Product Sales of \$207m; an increase of 25% (25% at CER).

Farxiga continued to be the best-selling AstraZeneca medicine for the treatment of type-2 diabetes, as well as the global leader in the sodium-glucose co-transporter 2 (SGLT2) class, despite increasing levels of intra-class competition.

Emerging Markets sales increased by 100% (90% at CER) to \$42m, driven by ongoing launches and improved access. In March 2017, *Forxiga* received approval from the China FDA. *Forxiga* was the first SGLT2 medicine to be approved in China.

US sales increased by 2% to \$96m. Sales growth was subdued by the impact of affordability programmes and managed-care access, together with a modest change in levels of inventory. The SGLT2 class gained market share from other types of type-2 diabetes medicines; it also has the potential to take further share, based on presentations at medical meetings of real-world evidence provided by the CVD-REAL study (see the Research and Development Update).

Sales in Europe increased by 22% (24% at CER) to \$50m, as the medicine continued to lead the growing class. In Japan, where Ono Pharmaceutical Co., Ltd is a partner, sales amounted to \$7m.

Onglyza

Product Sales of \$154m; a decline of 27% (27% at CER).

The performance reflected adverse pressures on the dipeptidyl peptidase-4 (DPP-4) class and an acceleration of the aforementioned Diabetes market dynamics. Sales in Emerging Markets declined by 17% (17% at CER) to \$30m as the Company focused on *Forxiga*. However, *Onglyza* entered the NRDL in China in the period.

US sales declined by 35% to \$81m. Continued competitive pressures in the DPP-4 class led to lower market share and were only partially offset by reduced levels of utilisation of patient-access programmes. Sales in Europe declined by 18% (18% at CER) to \$27m.

Bydureon/Byetta

Product Sales of \$199m; an increase of 1% (2% at CER).

Sales of *Bydureon* and *Byetta* in Emerging Markets were \$1m and \$5m, respectively. In 2016, AstraZeneca entered a strategic collaboration with 3SBio Inc. (3SBio) for the rights to commercialise *Bydureon* and *Byetta* in the Chinese market. The agreement allows the Company to benefit from 3SBio's established local expertise in injectable medicines, as well as focus on its oral type-2 diabetes medicines. Thus, sales in China are recorded by 3SBio.

Combined US sales for *Bydureon* and *Byetta* were \$157m. *Bydureon* US sales increased by 18% to \$127m, representing 81% of total *Bydureon/Byetta* sales. The decline in US *Byetta* sales continued in the period; the fall of 29% to \$30m reflected the Company's promotional focus on once-weekly *Bydureon* over twice-daily *Byetta*. The new *Bydureon* autoinjector device was accepted for US regulatory review in the quarter. Combined sales in Europe declined by 9% (9% at CER) to \$30m, reflecting the level of competitive pressures in the glucagon-like peptide-1 (GLP-1) class.

Legacy: Crestor

Product Sales of \$631m; a decline of 45% (44% at CER).

Sales in China grew by 13% (20% at CER) to \$101m, while Russia sales grew to \$6m. In the US, sales declined by 82% to \$112m, reflecting the market entry in July 2016 of multiple *Crestor* generic medicines. In Europe, sales declined by 8% (4% at CER) to \$195m, reflecting the increasing use of generic medicines. In Japan, where Shionogi Inc. is a partner, *Crestor* maintained its position as the leading statin, with growth of 1% (down by 1% at CER) to \$109m.

RESPIRATORY

Product Sales of \$1,181m; a decline of 2% (stable at CER).

Respiratory Product Sales represented 24% of total Product Sales, up from 22% in Q1 2016.

Symbicort

Product Sales of \$677m; a decline of 10% (8% at CER).

Symbicort continued to lead the global market by volume within the inhaled corticosteroids (ICS) / Long-Acting Beta Agonist (LABA) class. Emerging Markets sales grew by 7% (10% at CER) to \$112m, partly reflecting growth in China of 17% (24% at CER) to \$48m and in Latin America (ex-Brazil), where sales grew by 63% (63% at CER) to \$13m.

In contrast, US sales declined by 21% to \$255m, in line with expectations of a competitive start to 2017. These expectations reflected the impact of the continued effects of pricing pressure from managed-care access within the class. Competition also remained intense from other classes, such as Long-Acting Muscarinic (LAMA)/LABA combination medicines. In Europe, sales declined by 13% (9% at CER) to \$200m, primarily driven by competition from other branded and *Symbicort*-analogue medicines. In Japan, where Astellas Pharma Inc. is a partner, sales increased by 21% (19% at CER) to \$51m.

Pulmicort

Product Sales of \$337m; an increase of 9% (14% at CER).

Emerging Markets sales increased by 21% (28% at CER) to \$250m, reflecting strong underlying volume growth. Emerging Markets represented 74% of total *Pulmicort* sales. China sales increased by 15% (22% at CER) to \$210m and represented 62% of global sales. Volume demand in China continued to increase, due to the prevalence of acute chronic obstructive pulmonary disease (COPD) and paediatric asthma. Sales in the US and Europe declined by 27% to \$41m and by 10% (7% at CER) to \$26m, respectively.

Daliresp/Daxas

Product Sales of \$44m; an increase of 42% (42% at CER).

US sales increased by 23% to \$38m, driven primarily by favourable levels of market penetration. The US represented 86% of total sales.

Tudorza/Eklira

Product Sales of \$37m; a decline of 5% (3% at CER).

Sales in the US declined by 12% to \$15m, reflecting adverse market demand, limited Medicare Part-D access and the Company's focus on the launch of *Bevespi Aerosphere*. Sales in Europe declined by 5% (stable at CER) to \$20m.

Duaklir

Product Sales of \$19m; an increase of 46% (54% at CER).

Duaklir is now helping to treat patients in over 25 countries. The growth in sales in the quarter was favourably impacted by the performance in Germany, where sales increased by 50% (50% at CER) to \$9m.

Bevespi Aerosphere

Product Sales of \$1m; launched in 2017.

The *Bevespi Aerosphere* inhalation aerosol was launched commercially in the US during the quarter and performed in line with similar launches.

OTHER

Product Sales of \$998m; a decline of 25% (24% at CER).

Other Product Sales represented 21% of total Product Sales, down from 24% in Q1 2016.

Nexium

Product Sales of \$461m; stable (up by 1% at CER).

Emerging Markets sales declined by 1% (up by 3% at CER) to \$175m and increased by 4% to \$136m in the US. The latter reflected favourable pricing, which offset a decline in volume demand and inventory destocking that followed the loss of exclusivity in 2015. Sales in Europe increased by 2% (3% at CER) to \$61m. In Japan, where Daiichi Sankyo is a partner, sales declined by 1% (4% at CER) to \$68m, reflecting the annualisation of the mandated biennial price reduction, effective from April 2016.

Synagis

Product Sales of \$230m; a decline of 6% (6% at CER).

US sales declined by 2% to \$157m for the quarter due to lower market demand. Product Sales to AbbVie Inc., which is responsible for the commercialisation of *Synagis* in over 80 countries outside the US, declined by 13% (13% at CER) to \$73m.

Seroquel XR

Product Sales of \$67m; a decline of 67% (66% at CER).

Sales of *Seroquel XR* in the US declined by 83% to \$24m. Since November 2016, two competitors have launched generic medicines in the US. Sales of *Seroquel XR* in Europe declined by 37% (37% at CER) to \$22m, reflecting the impact of generic-medicine competition.

FluMist/Fluenz

The Company confirmed in 2016 that the Advisory Committee on Immunization Practices of the US Centers for Disease Control and Prevention had provided its interim recommendation not to use *FluMist Quadrivalent Live Attenuated Influenza Vaccine (FluMist Quadrivalent)* in the US for the 2016-2017 influenza season.

Regional Product Sales

	\$m	% of Total	% change	
			Actual	CER
Emerging Markets ¹	1,562	32	7	9
<i>China</i>	782	16	1	7
<i>Ex. China</i>	780	16	13	12
US	1,485	31	(34)	(34)
Europe	1,129	23	(7)	(3)
Established ROW ²	667	14	5	2
<i>Japan</i>	450	9	5	3
<i>Canada</i>	125	3	8	3
<i>Other Established ROW</i>	92	2	1	(3)
Total	4,843	100	(13)	(12)

¹Emerging Markets comprises all remaining Rest of World markets, including Brazil, China, India, Mexico, Russia and Turkey.

²Established ROW comprises Japan, Canada, Australia and New Zealand.

Emerging Markets

Product Sales of \$1,562m; an increase of 7% (9% at CER).

Emerging Markets, representing 32% of total Product Sales, was the largest sales region for AstraZeneca in the quarter. China sales grew by 1% (7% at CER) to \$782m, representing half of Emerging Markets sales. Alongside the aforementioned additions of *Onglyza* and *Iressa* on the NRD in China, *Brilinta*, *Faslodex* and *Seroquel XR* entered the negotiation list in the quarter, with discussions on their potential reimbursement in progress. *Crestor* also had its 2nd-line usage restriction removed and *Zoladex* was reclassified from the hormone and endocrine classification to oncology, which is expected to continue to support growth.

Sales in Brazil and Russia continued to be adversely impacted by challenging macro-economic conditions, leading to a subdued sales increase of 2% (down by 19% at CER) to \$85m in Brazil; Russia sales grew by 15% (down by 10% at CER) to \$55m. Sales in Middle East, Africa & Others increased by 21% (33% at CER) to \$247m.

US

Product Sales of \$1,485m; a decline of 34%.

The decline in sales reflected generic-medicine launches that impacted sales of *Crestor* and *Seroquel XR*. Unfavourable managed-care pricing and continued competitive intensity adversely impacted sales of *Symbicort*. However, the New Oncology Growth Platform in the US grew by 62% to \$125m, driven primarily by encouraging *Tagrisso* volume demand, where sales grew by 22% to \$90m in Q1 2017 from \$74m in Q4 2016. The New CVMD Growth Platform in the US declined by 2% to \$435m, impacted by the competitive environment in Diabetes.

Europe

Product Sales of \$1,129m; a decline of 7% (3% at CER).

The New Oncology Growth Platform in Europe grew by 186% (186% at CER) to \$60m, partly driven by *Tagrisso* sales of \$35m; *Tagrisso* was launched in Europe in Q1 2016. *Lynparza* sales of \$25m represented growth of 79% (79% at CER). *Forxiga* sales growth of 22% (24% at CER) to \$50m was accompanied by *Brilique* growth of 8% (12% at CER) to \$65m. This growth was more than offset by a 13% decline (9% at CER) in *Symbicort* sales to \$200m. However, *Symbicort* maintained its position as the number one ICS/LABA medicine by volume, despite competition from branded and analogue medicines.

Established ROW

Product Sales of \$667m; an increase of 5% (2% at CER).

Japan sales increased by 5% (3% at CER) to \$450m, partly reflecting the ongoing successful launch of *Tagrisso* and the performance of *Symbicort*, which offset the biennial price reduction, effective from April 2016. *Symbicort* sales in Japan increased by 21% (19% at CER) to \$51m and, following the launch in Japan in May 2016, *Tagrisso* sales for the quarter amounted to \$39m.

Nexium sales declined by 6% (9% at CER) to \$89m and sales of *Forxiga* increased by 111% (111% at CER) to \$19m.

Financial Performance

	Reported		% change		Core ¹		% change	
	Q1 2017 (\$m)	Q1 2016 (\$m)	Actual	CER	Q1 2017 (\$m)	Q1 2016 (\$m)	Actual	CER
Gross Profit	4,511	5,111	(12)	(12)	4,578	5,149	(11)	(11)
<i>Gross Margin</i> ²	82.3%	82.5%	-	-2	83.6%	83.1%	+1	-1
Distribution Expense	(77)	(76)	1	6	(77)	(76)	1	6
% Total Revenue	1.4%	1.2%	-	-	1.4%	1.2%	-	-
R&D Expense	(1,453)	(1,480)	(2)	2	(1,338)	(1,429)	(6)	(3)
% Total Revenue	26.9%	24.2%	-3	-3	24.8%	23.4%	-1	-2
SG&A Expense	(2,300)	(2,572)	(11)	(8)	(1,829)	(2,127)	(14)	(12)
% Total Revenue	42.6%	42.1%	-	-1	33.8%	34.8%	+1	+1
Other Operating Income	236	55	n/m	n/m	333	76	n/m	n/m
% Total Revenue	4.4%	0.9%	+3	+4	6.2%	1.2%	+5	+5
Operating Profit	917	1,038	(12)	(23)	1,667	1,593	5	(2)
% Total Revenue	17.0%	17.0%	-	-3	30.8%	26.1%	+5	+3
Net Finance Expense	(322)	(311)	3	9	(174)	(157)	11	15
Taxation	(70)	(98)			(258)	(249)		
Tax Rate	12%	14%			17%	17%		
Earnings Per Share (\$)	0.42	0.51	(17)	(35)	0.99	0.95	4	(4)

¹ Each of the measures in the Core column in the above table are non-GAAP measures.

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

Reconciliation Of Reported To Core Performance

	Reported	Restructuring	Intangible Asset Amortisation & Impairments	Diabetes Alliance	Other ¹	Core ²
	\$m	\$m	\$m	\$m	\$m	\$m
Gross Profit	4,511	38	29	-	-	4,578
R&D Expense	(1,453)	104	11	-	-	(1,338)
SG&A Expense	(2,300)	94	252	102	23	(1,829)
Other Operating Income	236	76	21	-	-	333
Operating Profit	917	312	313	102	23	1,667
Net Finance Expense	(322)	-	-	82	66	(174)
Profit Before Tax	582	312	313	184	89	1,480
Taxation	(70)	(66)	(78)	(37)	(7)	(258)
Earnings Per Share (\$)	0.42	0.19	0.19	0.12	0.07	0.99

¹ Other adjustments include provision charges related to certain legal matters (see Note 5) and discount unwind on acquisition-related liabilities (see Note 4).

² Each of the measures in the Core column in the above table are non-GAAP measures.

Profit And Loss Commentary

Gross Profit

Reported Gross Profit declined by 12% (12% at CER) to \$4,511m, partly reflecting the entry in July 2016 of multiple *Crestor* generic medicines in the US and the resulting impact on Product Sales. Excluding the impact of Externalisation Revenue, the Reported Gross Profit Margin was stable (down by two percentage points at CER) at 82.3%.

Core Gross Profit declined by 11% (11% at CER) to \$4,578m and, excluding the impact of Externalisation Revenue, the Core Gross Profit margin increased by one percentage point (down by one percentage point at CER) to 83.6%, reflecting a changing mix of sales, including the impact of patent expiries, partly offset by the resilience of some legacy medicines in established markets and the growing influence of specialty-care medicines.

Operating Expenses: R&D

Reported R&D costs declined by 2% (up by 2% at CER) to \$1,453m. Core R&D costs declined by 6% (3% at CER) to \$1,338m, supported by resource prioritisation and cost control.

Operating Expenses: SG&A

Reported SG&A costs declined by 11% (8% at CER) to \$2,300m, reflecting the evolving shape of the business. Core SG&A costs declined by 14% (12% at CER) to \$1,829m.

The Company has continued to consolidate its operations used by multiple parts of the business. It is committed to driving simplification and standardisation through centralisation in shared services of back-office and some middle-office activities that are currently performed in various enabling units, including Finance, HR, Procurement and IT. Instead of operating numerous shared-service centres and managing outsourced vendors independently,

the recently-launched Global Business Services organisation will, over time, provide integration of governance, locations and business practices to all shared services and outsourcing activities across AstraZeneca.

Other Operating Income

Where AstraZeneca does not retain a significant ongoing interest in medicines or potential new medicines, income from disposal transactions is reported as Other Operating Income in the Company's financial statements.

Reported Other Operating Income of \$236m included:

- \$161m of gains recognised on the sale of short-term investments
- A milestone receipt of \$50m in relation to the disposal of *Zavicefta* (ceftazidime and avibactam) to Pfizer Inc.

Core Other Operating Income was \$333m, with the difference to Reported Other Operating Income primarily driven by a restructuring charge taken against land and buildings.

Operating Profit

Reported Operating Profit declined by 12% (23% at CER) to \$917m. The Reported Operating Margin was stable (down by three percentage points at CER) at 17% of Total Revenue. Core Operating Profit increased by 5% (down by 2% at CER) to \$1,667m. The Core Operating Margin increased by five percentage points (three percentage points at CER) to 31% of Total Revenue.

Net Finance Expense

Reported Net Finance Expense increased by 3% (9% at CER) to \$322m, reflecting an increase in Net Debt that was driven by the majority investment in Acerta Pharma in February 2016. Excluding the discount unwind on acquisition-related liabilities, Core Net Finance Expense increased by 11% (15% at CER) to \$174m.

Taxation

The Reported and Core tax rates for the quarter were 12% and 17% respectively. These tax rates were lower than the 2017 UK Corporation Tax Rate of 19.25%, mainly due to the impact of the geographical mix of profits. The net cash tax paid for the quarter was \$62m, representing 11% of Reported Profit Before Tax and 4% of Core Profit Before Tax. Reduced net tax cash payments primarily reflected refunds following a previously disclosed agreement of inter-government transfer pricing arrangements. The Reported and Core tax rates for the comparative quarter were 14% and 17% respectively.

Earnings Per Share (EPS)

Reported EPS of \$0.42 represented a decline of 17% (35% at CER). Core EPS grew by 4% (down by 4% at CER) to \$0.99. The Core performance was driven by a decline in Total Revenue that was partly offset by good progress on cost control.

Cash Flow And Balance Sheet

Cash Flow

The Company generated a net cash inflow from operating activities of \$88m, compared with \$1,193m in the comparative period. The decline reflected partly the fall in Profit Before Tax, as well as an increase in working capital and short-term provisions of \$887m, compared to a decrease of \$64m in the comparative Q1 2016 period reflecting a different phasing of receipts in 2016.

Net cash outflows from investing activities were \$146m compared with \$2,887m in the comparative period. The prior-period outflow primarily reflected the upfront payment as part of the majority investment in Acerta Pharma.

Net cash outflows from financing activities were \$2,042m, driven by dividend payments of \$2,368m, partly offset by higher short-term borrowings.

The cash payment of contingent consideration in respect of the Bristol-Myers Squibb Company share of the global Diabetes alliance amounted to \$138m, comprising a \$100m milestone payment, in respect of *Qtern* and royalty payments.

Debt and Capital Structure

At 31 March 2017, outstanding gross debt (interest-bearing loans and borrowings) was \$17,402m (31 March 2016: \$16,312m). Of the gross debt outstanding at 31 March 2017, \$2,839m was due within one year (31 March

2016: \$2,168m). The Company's net debt position at 31 March 2017 was \$13,510m (31 March 2016: \$11,751m).

Capital Expenditure

Capital expenditure in the period amounted to \$286m.

Shares in Issue

During the quarter, 0.4 million shares were issued in respect of share option exercises for consideration of \$17m. The total number of shares in issue as at 31 March 2017 was 1,266 million.

Capital Allocation

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

Sensitivity: Foreign-Exchange Rates

The Company provides the following currency sensitivity information:

Currency	Primary Relevance	Average Exchange Rates Versus USD			Impact Of 5% Strengthening In Exchange Rate Versus USD (\$m) ¹	
		FY 2016	Q1 2017 ²	change %	Total Revenue	Core Operating Profit
EUR	Product Sales	0.90	0.94	-4%	+179	+123
JPY	Product Sales	108.84	113.74	-4%	+104	+71
CNY	Product Sales	6.65	6.87	-3%	+131	+74
SEK	Costs	8.56	8.93	-4%	+7	-98
GBP	Costs	0.74	0.81	-9%	+29	-131
Other ³					+194	+124

¹Based on 2016 results at 2016 actual exchange rates.

²Based on average daily spot rates between 1 January and 31 March 2017.

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

Currency Hedging

AstraZeneca monitors the impact of adverse currency movements on a portfolio basis, recognising correlation effects. The Company may hedge to protect against adverse impacts on cash flow over the short to medium term. As at 31 March 2017, AstraZeneca had hedged 96% of forecast short-term currency exposure that arises between the booking and settlement dates on Product Sales and non-local currency purchases.

Corporate And Business Development Update

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

a) Commercial Rights To Zoladex In The US And Canada

On 31 March 2017, AstraZeneca announced that it had completed an agreement with TerSera for the sale of commercial rights to *Zoladex* (goserelin acetate implant) in the US and Canada. *Zoladex* is an injectable luteinising hormone-releasing medicine, used to treat prostate cancer, breast cancer and certain benign gynaecological disorders. It was first approved in the US and Canada in 1989.

Under the terms of the agreement, AstraZeneca received a payment of \$250m from TerSera in the quarter. As AstraZeneca will maintain a significant ongoing interest in *Zoladex* in the US and Canada, the payment was reported as Externalisation Revenue in the Company's financial statements.

b) MedImmune And Sanofi Pasteur Form Alliance

On 3 March 2017, the Company announced that MedImmune, the global biologics research and development arm of AstraZeneca, and Sanofi Pasteur, the vaccines division of Sanofi, had agreed to develop and commercialise MEDI8897 jointly. MEDI8897 is a monoclonal antibody (mAb) for the prevention of lower respiratory tract illness (LRTI) caused by respiratory syncytial virus (RSV), the most prevalent cause of LRTI among infants and young children. MEDI8897 is currently in a Phase IIb clinical trial.

Under the global agreement that closed in March 2017, Sanofi Pasteur made an upfront payment of €120m and will pay up to €495m upon achievement of certain development and sales-related milestones. The two companies will share all costs and profits equally. MedImmune and AstraZeneca will continue to lead all development activity through initial approvals and AstraZeneca will retain MEDI8897 manufacturing activities. Sanofi Pasteur will lead commercialisation activities for MEDI8897. As AstraZeneca will maintain a significant ongoing interest in MEDI8897, the payment was reported as Externalisation Revenue in the Company's financial statements.

c) Tudorza And Duaklir In The US

On 17 March 2017, AstraZeneca announced that it had entered a strategic collaboration with Circassia Pharmaceuticals plc (Circassia) for the development and commercialisation of *Tudorza* and *Duaklir* in the US. *Tudorza* was approved and launched in the US in 2012. *Duaklir* is expected to be submitted for US regulatory review in 2018. The transaction closed on 12 April 2017.

Under the terms of the agreement, AstraZeneca received \$50m in Ordinary Shares in Circassia on completion and will receive \$100m at the earlier of approval of *Duaklir* in the US or 30 June 2019. Should Circassia decide to exercise an option to sub-license the commercial rights to *Tudorza* in the US, it will pay up to a further \$80m.

The two companies will share US profits from *Tudorza* equally. AstraZeneca will continue to book US Product Sales of *Tudorza* until Circassia's potential exercise of the option. Circassia will pay AstraZeneca tiered percentage royalties on potential future US sales of *Duaklir*. In addition, Circassia will contribute up to \$62.5m towards the development activities for the medicines. As AstraZeneca will retain a significant, ongoing interest in the medicines, income will be reported as Externalisation Revenue. This includes approximately \$60m at closing, as well as any potential future royalties, deferred income and any future payment for the option to gain the US commercial rights to *Tudorza*. Any potential future supply of the medicines to Circassia will be reported as Product Sales.

d) Benralizumab Rights In Asia

On 24 March 2017, it was announced that AstraZeneca had entered an agreement with Kyowa Hakko Kirin Co., Ltd. (Kyowa) for the exclusive rights to benralizumab for the treatment of severe, uncontrolled asthma and COPD in Asia.

Under the terms of the agreement, AstraZeneca will pay Kyowa \$15m upfront and subsequent payments for regulatory and commercial milestones, as well as low double-digit percentage sales royalties. As a result of the agreement, AstraZeneca will be responsible for the development, sales and marketing of benralizumab in 13 Asian countries and regions, except Japan, where AstraZeneca already holds the commercialisation rights to benralizumab.

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 2 February 2017 (the period):

Regulatory Approvals	6	<ul style="list-style-type: none"> - <i>Tagrisso</i> - lung cancer (US, EU; full approval) - <i>Tagrisso</i> - lung cancer (CN) - <i>Forxiga</i> - type-2 diabetes (CN) - <i>Qtern</i> - type-2 diabetes (US) - <i>Siliq</i> - psoriasis (US; by partner)
Regulatory Submission Acceptances	4	<ul style="list-style-type: none"> - <i>Lynparza</i> - ovarian cancer (2nd line) (US) (Priority Review) - <i>Bydureon</i> - type-2 diabetes (autoinjector) (US) - <i>Symbicort</i> - COPD exacerbations (US) - benralizumab - severe, uncontrolled asthma (JP)
Phase III or Major Data Readouts	2	<ul style="list-style-type: none"> - <i>Lynparza</i> - breast cancer - <i>Farxiga</i> - type-2 diabetes (CVD-REAL real-world study)
Other Key Developments	3	<ul style="list-style-type: none"> - Orphan Designation: <i>Lynparza</i> - ovarian cancer (JP) - Complete Response Letter: ZS-9 (sodium zirconium cyclosilicate) - hyperkalaemia (US) - Orphan designation: inebilizumab - neuromyelitis optica spectrum disorder (EU)
New Molecular Entities (NMEs) In Phase III Trials Or Under Regulatory Review	12	<p>Oncology</p> <ul style="list-style-type: none"> - durvalumab* - multiple cancers - durva + treme - multiple cancers - acalabrutinib - blood cancers - moxetumomab pasudotox - leukaemia - selumetinib - thyroid cancer <p>Cardiovascular & Metabolic Diseases</p> <ul style="list-style-type: none"> - ZS-9 (sodium zirconium cyclosilicate)* - hyperkalaemia - roxadustat* - anaemia <p>Respiratory</p> <ul style="list-style-type: none"> - benralizumab* - severe, uncontrolled asthma, COPD - tralokinumab - severe, uncontrolled asthma - PT010 - COPD <p>Other</p> <ul style="list-style-type: none"> - anifrolumab - lupus - lanabecestat (formerly AZD3293) - Alzheimer's disease
Projects in clinical pipeline	124	

*Under Regulatory Review
The table as at 27 April 2017

Operating & Financial Review

Corporate & Business Development

Research & Development

Development Pipeline

Interim Financial Statements

ONCOLOGY

AstraZeneca has a deep-rooted heritage in Oncology and offers a growing portfolio of new medicines that has the potential to transform patients' lives and the Company's future. At least six new Oncology medicines are expected to be launched between 2014 and 2020, of which *Lynparza* and *Tagrisso* are already benefitting patients. An extensive pipeline of small-molecule and biologic medicines is in development and the Company is committed to advancing Oncology, primarily focused on lung, ovarian, breast and blood cancers, as one of AstraZeneca's Growth Platforms.

At the 2017 American Association for Cancer Research meeting in Washington D.C., 60 abstracts, including seven oral presentations, were published. These covered, *inter alia*, tumour drivers and resistance, immuno-oncology (IO), antibody-drug conjugates and DNA damage response.

a) Lynparza (multiple cancers)

During the period, the Company presented data from the Phase III SOLO-2 trial, in which women with germline BRCA-mutated, platinum-sensitive, relapsed ovarian cancer were treated with *Lynparza* tablets (300mg twice daily) or placebo, in the maintenance setting. The trial met its primary endpoint of investigator-assessed progression-free survival (PFS) with a hazard ratio of 0.30 (equal to a 70% reduction in the risk of disease progression) and a median survival of 19.1 months vs 5.5 months with placebo. PFS, as measured by Blinded Independent Central Review, demonstrated a hazard ratio of 0.25 (75% risk reduction), with a median PFS of 30.2 months vs 5.5 months for placebo, representing an improvement of over two years. *Lynparza* tablets demonstrated a safety profile generally consistent with previous trials, including a low incidence of haematological adverse events. The 300mg twice daily tablet dose used in SOLO-2 reduces the pill burden for patients from 16 capsules to 4 tablets per day.

During the period, the Company achieved regulatory submission acceptance for a New Drug Application (NDA) for *Lynparza* tablets for use in platinum-sensitive, relapsed ovarian cancer patients in the maintenance setting. Priority Review status was granted, with an anticipated Prescription Drug User Fee Act (PDUFA) date during Q3 2017. The regulatory submission included data from the aforementioned SOLO-2 trial, as well as a prior *Lynparza* trial in ovarian cancer, Study 19.

In the period, the Company received an Orphan Drug Designation for *Lynparza* in Japan. Presently, there are no approved medicines in Japan to treat BRCA-mutated ovarian cancer, which affects an estimated 3,500 women every year.

In breast cancer, *Lynparza* met the primary endpoint in the Phase III OlympiAD trial, comparing *Lynparza* tablets to standard of care (SoC) chemotherapy in the treatment of patients with HER2-negative metastatic breast cancer harbouring germline BRCA1 or BRCA2 mutations. Patients treated with *Lynparza* showed a statistically-significant and clinically-meaningful improvement in PFS, compared with those who received SoC chemotherapy. This was the first positive randomised Phase III trial to demonstrate the efficacy and safety of a poly ADP ribose polymerase (PARP) inhibitor beyond ovarian cancer. The Company anticipates presenting the data at the forthcoming American Society of Clinical Oncology Annual Meeting in Chicago, US in June 2017.

PROfound, a Phase III trial in metastatic, castrate-resistant prostate cancer patients, who have previously received a new hormonal agent, actively started recruitment in the period. This trial is based on early clinical data published in *The New England Journal of Medicine*. The prostate cancer indication received US Breakthrough Therapy Designation in 2016 and PROfound is the first pivotal trial for *Lynparza* in prostate cancer and the first to utilise a new 15-gene homologous recombination repair panel.

b) Tagrisso (lung cancer)

On 27 March 2017, the Company announced that it had received marketing authorisation by the China FDA for *Tagrisso* 40mg and 80mg once-daily oral tablets. These tablets are a treatment for adult patients with locally-advanced or metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC), whose disease has progressed on or after EGFR tyrosine kinase inhibitor (TKI) therapy.

This early approval followed the China FDA's Priority Review in recognition of the submitted data from the AURA17 and AURA18 trials. *Tagrisso* is the first AstraZeneca medicine approved under the China FDA's Priority Review pathway, using an accelerated timeline for an innovative medicine. Presently, lung cancer is the most common form of cancer and the leading cause of cancer-related deaths in China. Approximately 30-40% of Chinese patients with NSCLC have the EGFR mutation at diagnosis and around half of patients with NSCLC, whose disease progresses after treatment with an EGFR-TKI-based medicine, develop the T790M mutation.

On 31 March 2017, the Company announced that the US FDA had granted full approval for *Tagrisso* 80mg once-daily tablets. These tablets are for the aforementioned treatment of patients with metastatic EGFR T790M mutation-positive NSCLC, as detected by an US FDA-approved test, whose disease has progressed on or after an EGFR-TKI therapy. The approval was based on the Phase III AURA3 trial data that demonstrated a significant improvement in PFS with *Tagrisso*, as compared to SoC chemotherapy. The trial also demonstrated a hazard ratio of 0.30 (equal to a 70% reduction in the risk of disease progression) and a median PFS of 10.1 months, compared to 4.4 months from chemotherapy. The full approval was converted from the prior accelerated approval.

On 25 April 2017, AstraZeneca announced that the European Medicines Agency (EMA) had granted full marketing authorisation for *Tagrisso* on a similar basis to the aforementioned approval in the US. The full approval was based on the results of the Phase III AURA3 trial, which were presented in 2016.

c) Durvalumab (multiple cancers)

The Company continues to advance multiple monotherapy trials of durvalumab and combination trials of durvalumab with tremelimumab and other potential new medicines in IO. The combination of durvalumab and tremelimumab is being assessed in Phase III trials in metastatic urothelial cancer, NSCLC, small cell lung cancer and head and neck squamous cell carcinoma (HNSCC) and in Phase I/II trials in gastric cancer, pancreatic cancer, hepatocellular carcinoma and haematological malignancies.

• BLADDER CANCER

In December 2016, AstraZeneca received US FDA acceptance of the Biologics License Application for durvalumab in patients with locally-advanced or metastatic urothelial carcinoma, whose disease has progressed during or after one standard platinum-based regimen. The application was granted Priority Review status. The PDUFA date is anticipated to be in Q2 2017.

In Canada, the New Drug Submission (NDS) for durvalumab was filed with Health Canada, seeking conditional approval in patients with locally-advanced or metastatic urothelial carcinoma, whose disease has progressed during or after platinum-based chemotherapy. This NDS was granted advance consideration under Health Canada's Notice of Compliance with Conditions policy, allowing the submission based on encouraging results from the Phase I/II Study 1108. In Australia, the Therapeutic Goods Administration accepted a similar submission in the period.

During the period, AstraZeneca announced updated efficacy and safety data for durvalumab in patients with locally-advanced or metastatic urothelial cancer from the Phase I/II 1108 trial. These data, presented at the 2017 American Society of Clinical Oncology Genitourinary Cancers Symposium, showed an objective response rate of 20.4% in all evaluable patients (n=103) and 31.1%, in patients whose tumours express PD-L1. At the time of data cut-off, median overall survival (OS) was 14.1 months. Durvalumab, dosed at a rate of 10mg/kg, was administered intravenously every two weeks for up to 12 months in this trial and demonstrated a manageable safety profile.

The following table details the ongoing Phase III trial in metastatic urothelial cancer:

Name	Phase	Line of Treatment	Population	Design	Timelines	Status
DANUBE	III	1st line	Cisplatin chemotherapy-eligible/ineligible bladder cancer	durvalumab, durva + treme vs SoC chemotherapy	FPCD ¹ Q4 2015 LPCD ² Q1 2017 ³ First data anticipated 2018	Recruitment completed ³

¹ First Patient Commenced Dosing

² Last Patient Commenced Dosing

³ Global trial, excluding China

• LUNG CANCER

During the period, the Company maintained strong momentum in its immunotherapy efforts in lung cancer, including the decision to initiate a new trial, POSEIDON, testing the durva + trema combination with chemotherapy. This followed successful Phase I testing of the Company's triple combination of two immunotherapies combined with chemotherapy.

The Company now expects the first data from the Phase III ARCTIC trial in 3rd-line PDL1-low/negative NSCLC to be available in H2 2017. The trial results are event-driven; events for the primary endpoints of PFS and OS have occurred more slowly than originally anticipated in the advanced patient population that the trial is assessing.

As previously communicated, the ongoing Phase III NEPTUNE trial was expanded to include local Chinese patients to support regulatory submission of the 1st-line NSCLC durva + trema combination data in China. During the period, the first patient was dosed in the China expansion cohort. This expansion is not expected to impact the anticipated OS data readout in 2018 from the global cohort, which is fast approaching full recruitment. Further, during the period, the NEPTUNE trial was refined to include a primary OS endpoint for patients with PDL1-expressing tumours.

An overview of key AstraZeneca-sponsored ongoing Phase III trials in lung cancer is provided below:

Name	Phase	Line of Treatment	Population	Design	Timelines	Status
Monotherapy						
ADJUVANT [†]	III	N/A	Stage Ib-IIIa NSCLC	durvalumab vs placebo	FPCD Q1 2015 First data anticipated 2020	Recruitment ongoing
PACIFIC	III	N/A	Stage III unresectable NSCLC	durvalumab vs placebo	FPCD Q2 2014 LPCD Q2 2016 First data anticipated H2 2017	Recruitment completed
PEARL	III	1st line	NSCLC (Asia)	durvalumab vs SoC chemotherapy	FPCD Q1 2017 First data anticipated 2020	Recruitment ongoing
Combination therapy						
MYSTIC	III	1st line	NSCLC	durvalumab, durva + trema vs SoC chemotherapy	FPCD Q3 2015 LPCD Q3 2016 First data anticipated mid-2017	Recruitment completed

Name	Phase	Line of Treatment	Population	Design	Timelines	Status
NEPTUNE	III	1st line	NSCLC	durva + treme vs SoC chemotherapy	FPCD Q4 2015 First data anticipated 2018	Recruitment ongoing
POSEIDON	III	1st line	NSCLC	durvalumab + SoC, durva + treme + SoC vs SoC chemotherapy	-	Recruitment initiating
ARCTIC	III	3rd line	PDL1-low/neg. NSCLC	durvalumab, tremelimumab, durva + treme vs SoC chemotherapy	FPCD Q2 2015 LPCD Q3 2016 First data anticipated H2 2017	Recruitment completed
CASPIAN	III	1st line	Small-cell lung cancer (SCLC)	durvalumab + SoC, durva + treme + SoC vs SoC chemotherapy	FPCD Q1 2017 First data anticipated 2020	Recruitment ongoing

Conducted by the National Cancer Institute of Canada

• HEAD AND NECK CANCER

During the period, the Phase III KESTREL trial completed patient recruitment ahead of schedule, despite a delay from a partial clinical hold on recruitment in 2016. Additionally, the trial was refined to include a primary OS endpoint for patients with PDL1-expressing tumours. At this stage, the Company continues to anticipate data availability in H2 2017.

An overview of key AstraZeneca-sponsored ongoing Phase III trials in head and neck cancer is provided below:

Name	Phase	Line of Treatment	Population	Design	Timelines	Status
Combination therapy						
KESTREL	III	1st line	HNSCC	durvalumab, durva + treme vs SoC	FPCD Q4 2015 LPCD Q1 2017 First data anticipated H2 2017	Recruitment completed
EAGLE	III	2nd line	HNSCC	durvalumab, durva + treme vs SoC	FPCD Q4 2015 First data anticipated 2018	Recruitment ongoing

CARDIOVASCULAR & METABOLIC DISEASES

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

a) *Forxiga* (type-2 diabetes)

In March 2017, the Company received marketing authorisation from the China FDA for *Forxiga* 5mg and 10mg once-daily oral tablets. These tablets are indicated as an adjunct to diet and exercise to improve glycaemic control (blood sugar level) in adults with type-2 diabetes. *Forxiga* was the first SGLT2 inhibitor to be approved in China and belongs to a newer class of oral diabetes medicines that works independently from insulin to help remove excess glucose from the body. The prevalence of diabetes is escalating rapidly in China, now impacting 114 million patients, representing almost one-third of diabetes cases worldwide.

b) *Qtern* (type-2 diabetes)

On 28 February 2017, AstraZeneca announced that once-daily *Qtern* tablets (*Farxiga* 10mg and *Onglyza* 5mg fixed-dose combination) had been approved by the US FDA as an adjunct to diet and exercise to improve glycaemic control in adults with type-2 diabetes who have inadequate control with *Farxiga* (10mg) or who are already treated with *Farxiga* and *Onglyza*.

c) *Bydureon* (type-2 diabetes)

During the period, the new *Bydureon* autoinjector regulatory submission was accepted for review by the US FDA. The autoinjector is designed to provide patients with a convenient, easy-to-use device for administration of *Bydureon* as a once-weekly treatment for type-2 diabetes patients.

In addition to the autoinjector, the regulatory submission of the DURATION-8 combination trial results (*Farxiga* plus *Bydureon*) was also accepted by the US FDA in the period. In parallel, an EU regulatory submission was accepted by the EMA. The DURATION-8 Phase III trial demonstrated that the addition of *Bydureon* to *Farxiga* provides benefits to patients above and beyond what is observed with the individual medicines, including reduced blood sugar, weight and systolic blood pressure. The Company anticipates a response from the regulatory agencies on the potential label additions for *Bydureon* and *Farxiga* in 2018 at the earliest.

d) Type-2 diabetes medicines in CV outcomes trials

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

At the 2017 American College of Cardiology Session and Expo, AstraZeneca shared results of the CVD-REAL real-world evidence study. The study showed that treatment with SGLT2 inhibitors, versus other type-2 diabetes medicines, significantly reduced rates of hospitalisation due to heart failure (HF) and all-cause mortality.

The study assessed more than 300,000 patients across Europe and the US, approximately 87% of whom did not have existing CV disease. It demonstrated that treatment with SGLT2 inhibitor medicines, including *Farxiga* (dapagliflozin), canagliflozin, and empagliflozin reduced the rate of hospitalisation for HF by 39% and death from any cause by 51%. For the composite endpoint of hospitalisation for HF and death from any cause, the reduction was 46%.

Patients with type-2 diabetes have a two to three times greater risk of HF and are at an increased risk of having a heart attack or stroke, when compared to the overall population. Around half of deaths of patients with type-2 diabetes are caused by CV disease. Two significant type-2 diabetes outcomes trials are highlighted below:

Medicine	Trial	Mode of Action	Number of Patients	Primary Endpoint	Timeline
<i>Bydureon</i>	EXSCEL	GLP-1 agonist	~14,000	Time to first occurrence of CV death, non-fatal myocardial infarction or non-fatal stroke	H2 2017

Medicine	Trial	Mode of Action	Number of Patients	Primary Endpoint	Timeline
<i>Farxiga</i>	DECLARE	SGLT2 inhibitor	~17,000*	Time to first occurrence of CV death, non-fatal myocardial infarction or non-fatal stroke	2019 at the latest (final 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)

During the period, the first patients were dosed in the *Farxiga* HF and CKD Phase III trials. These two extensive outcomes trials are designed to help define the potential role of *Farxiga* in the management of HF and CKD respectively, in patients with and without type-2 diabetes. HF and CKD are common, disabling, costly and deadly conditions that continue to increase in prevalence and for which new and effective medicines are needed.

c) ZS-9 (sodium zirconium cyclosilicate) (hyperkalaemia)

On 17 March 2017, the Company announced that the US FDA had issued a second Complete Response Letter (CRL) regarding the NDA for ZS-9, which is being developed for the treatment of hyperkalaemia by ZS Pharma, a wholly-owned subsidiary of AstraZeneca. Hyperkalaemia is a serious condition characterised by high potassium levels in the blood serum caused by CV, renal and metabolic diseases.

The second CRL followed an inspection by the US FDA of the dedicated manufacturing facility. The second CRL did not require the generation of any new clinical data. AstraZeneca and ZS Pharma are actively working with the US FDA to resolve the remaining matters as soon as possible.

In the EU, the Company announced on 24 February 2017 that the Committee for Medicinal Products for Human Use (CHMP) of the EMA had issued a positive opinion recommending the approval of ZS-9 for the treatment of hyperkalaemia. Following the second CRL in the US, the CHMP will consider the potential impact of this new information on the adopted opinion.

RESPIRATORY

AstraZeneca's Respiratory portfolio is aimed at transforming the treatment of asthma and COPD through combination inhaled therapies, biologics for the unmet medical needs of specific patient populations and an early pipeline focused on disease modification.

The growing range of medicines includes up to four anticipated launches between 2017 and 2020. The capability in inhalation technology spans both pressurised metered dose inhalers and dry-powder inhalers to serve patient needs, as well as the innovative *Aerosphere* CO-SUSPENSION™ Delivery Technology, a focus of AstraZeneca's future-platform development for respiratory-disease combination therapies.

a) Symbicort (COPD)

During the period, the US FDA accepted for review a supplemental NDA proposing an additional indication for *Symbicort* to reduce exacerbations in patients with COPD and a history of exacerbations. The PDUFA date for this additional indication is anticipated to be in Q3 2017.

b) Benralizumab (asthma)

During the period, the Pharmaceuticals and Medical Devices Agency in Japan accepted a regulatory submission for benralizumab. The submission, for the treatment of patients with severe, uncontrolled asthma with an eosinophilic phenotype, was based on the results of the Phase III trials, CALIMA, SIROCCO and ZONDA.

c) Tezepelumab (asthma)

In February 2017, tezepelumab, a first-in-class monoclonal antibody that targets thymic stromal lymphopoietin (TSLP) met its primary endpoint in a Phase IIb trial (PATHWAY) in patients with severe asthma. Tezepelumab, which is being developed in collaboration with Amgen Inc. (Amgen), demonstrated a significant reduction in the rate of asthma exacerbations, compared to placebo, over the 52-week treatment period.

TSLP is thought to play a critical role in the activation of the immune system in response to allergens, viruses and other pathogens in the lung, all of which are known triggers for asthma exacerbations. Blocking TSLP

with tezepelumab may uniquely prevent exacerbations across a broad population of patients with severe asthma. The Phase IIb data will be presented at a forthcoming medical meeting.

OTHER

a) Brodalumab (psoriasis)

On 16 February 2017, the Company announced that the US FDA had approved brodalumab (*Siliq* in the US) for the treatment of adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy and have failed to respond or no longer respond to other systemic therapies.

Through a collaboration agreement, AstraZeneca granted Valeant, an expert in dermatology, the exclusive license to develop and commercialise brodalumab globally, except in Japan and certain other Asian countries where rights are held by Kyowa Hakko Kirin Co., Ltd through an agreement with Amgen and in Europe, where LEO Pharma holds exclusive rights to develop and commercialise brodalumab.

b) Inebilizumab (neuromyelitis optica spectrum disorder)

On 29 March 2017, the EMA granted Orphan designation to inebilizumab (formerly MEDI-551) for the treatment of neuromyelitis optica spectrum disorder (NMOSD). NMOSD is a rare and life-threatening autoimmune disease of the central nervous system in which the body's immune system attacks healthy cells, most commonly in the optic nerve and spinal cord. NMOSD may cause severe muscle weakness and paralysis, loss of vision, respiratory failure, problems with bowel and bladder function and neuropathic pain. There is currently no cure or approved medicine for this rare disease.

Developed by MedImmune, inebilizumab is currently in Phase IIb clinical development for NMOSD and received Orphan Drug Designation by the US FDA in early 2016.

ASTRAZENECA DEVELOPMENT PIPELINE 31 March 2017

AstraZeneca-sponsored or -directed trials

Phase III / Pivotal Phase II / Registration

New Molecular Entities (NMEs) and significant additional indications

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

Compound	Mechanism	Area Under Investigation	Date Commenced Phase	Estimated Regulatory Acceptance Date / Submission Status			
				US	EU	Japan	China
Oncology							
durvalumab [#]	PD-L1 mAb	≥2nd-line advanced bladder cancer		Accepted (Breakthrough Therapy & Priority Review)			
acalabrutinib [#]	BTK inhibitor	B-cell malignancy	Q1 2015	H1 2017 (Orphan drug)			
acalabrutinib [#]	BTK inhibitor	1st-line CLL	Q3 2015	2020 (Orphan drug)	2020 (Orphan drug)		
acalabrutinib [#]	BTK inhibitor	r/r CLL, high risk	Q4 2015	2020 (Orphan drug)	2020 (Orphan drug)		
selumetinib ASTRA	MEK inhibitor	differentiated thyroid cancer	Q3 2013	2018 (Orphan drug)	2018		
moxetumomab pasudotox [#] PLAIT	anti-CD22 recombinant immunotoxin	hairy cell leukaemia	Q2 2013	2018 (Orphan drug)			
durvalumab [#] PACIFIC	PD-L1 mAb	stage III NSCLC	Q2 2014	H2 2017	H2 2017	H2 2017	
durvalumab [#] PEARL	PD-L1 mAb	1st-line NSCLC	Q1 2017				2019
durvalumab [#] + tremelimumab ARCTIC	PD-L1 mAb + CTLA-4 mAb	3rd-line NSCLC	Q2 2015	H2 2017	H2 2017	H2 2017	
durvalumab [#] + tremelimumab MYSTIC	PD-L1 mAb + CTLA-4 mAb	1st-line NSCLC	Q3 2015	H2 2017	H2 2017	H2 2017	
durvalumab [#] + tremelimumab NEPTUNE	PD-L1 mAb + CTLA-4 mAb	1st-line NSCLC	Q4 2015	2019	2019	2019	2020
durvalumab [#] + tremelimumab + SoC CASPIAN	PD-L1 mAb + CTLA-4 mAb + SoC	1st-line SCLC	Q1 2017				
durvalumab [#] + tremelimumab KESTREL	PD-L1 mAb + CTLA-4 mAb	1st-line HNSCC	Q4 2015	2018	2018	2018	
durvalumab [#] + tremelimumab EAGLE	PD-L1 mAb + CTLA-4 mAb	2nd-line HNSCC	Q4 2015	2018	2018	2018	
durvalumab [#] + tremelimumab DANUBE	PD-L1 mAb + CTLA-4 mAb	1st-line bladder cancer	Q4 2015	2018	2018	2018	
Lynparza [¶] + cediranib CONCERTO	PARP inhibitor + VEGF inhibitor	recurrent platinum-resistant ovarian cancer	Q1 2017	2020			

Operating & Financial Review

Corporate & Business Development

Research & Development

Development Pipeline

Interim Financial Statements

Cardiovascular & Metabolic Diseases							
Farxiga ²	SGLT2 inhibitor	type-2 diabetes		Launched	Launched	Launched	Approved
Epanova	omega-3 carboxylic acids	severe hypertriglyceridemia		Approved		2018	
ZS-9 (sodium zirconium cyclosilicate)	potassium binder	hyperkalaemia		-	Accepted	2019	
roxadustat [#] OLYMPUS (US) ROCKIES (US)	hypoxia-inducible factor prolyl hydroxylase inhibitor	anaemia in CKD/ESRD	Q3 2014	2018			Initiated ³
Respiratory							
Bevespi Aerosphere (PT003)	LABA/LAMA	COPD		Launched	H1 2017	2018	2018
benralizumab [#] CALIMA SIROCCO ZONDA BISE BORA GREGALE	IL-5R mAb	severe asthma		Accepted	Accepted	Accepted	2020
benralizumab [#] TERRANOVA GALATHEA	IL-5R mAb	COPD	Q3 2014	2018	2018	2019	
PT010	LABA/LAMA/ICS	COPD	Q3 2015	2019	2019	2018	2019
tralokinumab STRATOS 1,2 TROPOS MESOS	IL-13 mAb	severe asthma	Q3 2014	2018	2018	2018	
Other							
anifrolumab [#] TULIP	IFN-alphaR mAb	systemic lupus erythematosus	Q3 2015	2019 (Fast Track)	2019	2019	
lanabecestat [#] (AZD3293) AMARANTH + extension, DAYBREAK-ALZ	beta-secretase inhibitor	Alzheimer's disease	Q2 2016	2020 (Fast Track)	2020	2020	

¶ Registrational Phase II trial

Collaboration

1 Brilinta in the US and Japan; Brilique in ROW

2 Farxiga in the US; Forxiga in ROW

3 Rolling New Drug Application (NDA) regulatory submission initiated in Q4 2016

Operating & Financial Review

Corporate & Business Development

Research & Development

Development Pipeline

Interim Financial Statements

Phases I and II

NMEs and significant additional indications

Compound	Mechanism	Area Under Investigation	Phase	Date Commenced Phase
Oncology				
durvalumab [#]	PD-L1 mAb	solid tumours	II	Q3 2014
durvalumab [#] + tremelimumab	PD-L1 mAb + CTLA-4 mAb	hepatocellular carcinoma (liver cancer)	II	Q4 2016
durvalumab [#] + tremelimumab	PD-L1 mAb + CTLA-4 mAb	gastric cancer	II	Q2 2015
durvalumab [#] + AZD5069	PD-L1 mAb + CXCR2	HNSCC	II	Q3 2015
durvalumab [#] + AZD9150 [#]	PD-L1 mAb + STAT3 inhibitor			
durvalumab [#] + dabrafenib + trametinib	PD-L1 mAb+ BRAF inhibitor + MEK inhibitor	melanoma	I	Q1 2014
durvalumab [#] + AZD1775 [#]	PD-L1 mAb + Wee1 inhibitor	solid tumours	I	Q4 2015
durvalumab [#] + MEDI0680	PD-L1 mAb + PD-1 mAb	solid tumours	II	Q3 2016
durvalumab [#] or durvalumab [#] + (tremelimumab or AZD9150 [#])	PD-L1 mAb or PD-L1 mAb + (CTLA-4 mAb or STAT3 inhibitor)	diffuse large B-cell lymphoma	I	Q3 2016
durvalumab [#] + <i>Iressa</i>	PD-L1 mAb+ EGFR inhibitor	NSCLC	I	Q2 2014
durvalumab [#] + MEDI0562 [#]	PD-L1 mAb + humanised OX40 agonist	solid tumours	I	Q2 2016
durvalumab [#] + MEDI9447	PD-L1 mAb + CD73 mAb	solid tumours	I	Q1 2016
durvalumab [#] + monalizumab	PD-L1 mAb + NKG2a mAb	solid tumours	I	Q1 2016
durvalumab [#] + selumetinib	PD-L1 mAb + MEK inhibitor	solid tumours	I	Q4 2015
durvalumab [#] + tremelimumab	PD-L1 mAb + CTLA-4 mAb	solid tumours	I	Q4 2013
tremelimumab + MEDI0562 [#]	CTLA-4 mAb + humanised OX40 agonist	solid tumours	I	Q2 2016
<i>Lynparza</i> + AZD6738	PARP inhibitor + ATR inhibitor	gastric cancer	II	Q3 2016
<i>Lynparza</i> + AZD1775 [#]	PARP inhibitor + Wee1 inhibitor	solid tumours	I	Q3 2015
savolitinib [#]	MET inhibitor	papillary renal cell carcinoma	II	Q2 2014
<i>Tagrisso</i> + (selumetinib [#] or savolitinib [#]) TATTON	EGFR inhibitor + (MEK inhibitor or MET inhibitor)	advanced EGFRm NSCLC	II	Q2 2016
<i>Tagrisso</i> BLOOM	EGFR inhibitor	CNS metastases in advanced EGFRm NSCLC	II	Q4 2015
AZD1775 [#] + chemotherapy	Wee1 inhibitor + chemotherapy	ovarian cancer	II	Q4 2012
AZD1775 [#]	Wee1 inhibitor	solid tumours	II	Q1 2016
vistusertib (AZD2014)	mTOR inhibitor	solid tumours	II	Q1 2013
AZD5363 [#]	AKT inhibitor	breast cancer	II	Q1 2014
AZD4547	FGFR inhibitor	solid tumours	II	Q4 2011
MEDI-573 [#]	IGF mAb	metastatic breast cancer	II	Q2 2012
AZD0156	ATM inhibitor	solid tumours	I	Q4 2015
AZD2811 [#]	Aurora B inhibitor	solid tumours	I	Q4 2015
AZD4635	A2aR inhibitor	solid tumours	I	Q2 2016
AZD6738	ATR inhibitor	solid tumours	I	Q4 2013
AZD8186	PI3k 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
MEDI-565 [#]	CEA BiTE mAb	solid tumours	I	Q1 2011
MEDI0562 [#]	humanised OX40 agonist	solid tumours	I	Q1 2015
MEDI0680	PD-1 mAb	solid tumours	I	Q4 2013

Operating & Financial Review

Corporate & Business Development

Research & Development

Development Pipeline

Interim Financial Statements

Compound	Mechanism	Area Under Investigation	Phase	Date Commenced Phase
MEDI1873	GITR agonist fusion protein	solid tumours	I	Q4 2015
MEDI3726 [#]	PSMA antibody drug conjugate	prostate cancer	I	Q1 2017
MEDI4276	HER2 bi-specific antibody drug conjugate	solid tumours	I	Q4 2015
MEDI5083	immune activator	solid tumours	I	Q1 2017
MEDI9197 [#]	TLR 7/8 agonist	solid tumours	I	Q4 2015
MEDI9447	CD73 mAb	solid tumours	I	Q3 2015
Cardiovascular & Metabolic Diseases				
MEDI0382	GLP-1/ glucagon dual agonist	diabetes / obesity	II	Q3 2016
MEDI4166	PCSK9/GLP-1 mAb + peptide fusion	diabetes / cardiovascular	II	Q1 2016
MEDI6012	LCAT	ACS	II	Q4 2015
AZD4076	anti-miR103/107 oligonucleotide	non-alcoholic fatty liver disease/non-alcoholic steatohepatitis (NASH)	II	Q4 2016
AZD4831	myeloperoxidase	HF with a preserved ejection fraction	I	Q3 2016
MEDI5884 [#]	cholesterol modulation	cardiovascular	I	Q1 2017
AZD5718	FLAP	CAD	I	Q1 2016
AZD8601 [#]	VEGF-A	cardiovascular	I	Q1 2017
MEDI8111	Rh-factor II	trauma / bleeding	I	Q1 2014
Respiratory				
tezepelumab [#]	TSLP mAb	asthma / atopic dermatitis	II	Q2 2014
abediterol [#]	LABA	asthma/COPD	II	Q4 2007
AZD7594	inhaled SGRM	asthma/COPD	II	Q3 2015
PT010	LABA/LAMA/ICS	asthma	II	Q2 2014
AZD1419 [#]	inhaled TLR9 agonist	asthma	II	Q4 2016
AZD8871 [#]	MABA	COPD	II	Q1 2017
AZD0284	RORg	psoriasis/respiratory	I	Q4 2016
AZD5634	inhaled ENaC	cystic fibrosis	I	Q1 2016
AZD7594+abediterol [#]	inhaled SGRM+LABA	asthma/COPD	I	Q4 2016
AZD7986 [#]	DPP1	COPD	I	Q4 2014
AZD9567	oral SGRM	rheumatoid arthritis/respiratory	I	Q4 2015
Other				
anifrolumab [#]	IFN-alphaR mAb	lupus nephritis	II	Q4 2015
anifrolumab [#]	IFN-alphaR mAb	systemic lupus erythematosus (subcutaneous)	II	Q1 2017
inebilizumab [#]	CD19 mAb	neuromyelitis optica	II (Orphan drug US, EU)	Q1 2015
mavrilimumab [#]	GM-CSFR mAb	rheumatoid arthritis	II	Q1 2010
verinurad	selective uric acid reabsorption inhibitor (URAT-1)	chronic treatment of hyperuricemia in patients with gout	II	Q3 2013
MEDI5872 [#]	B7RP1 mAb	primary Sjögren's syndrome	II	Q3 2016
MEDI3902	Psl/PcrV bispecific mAb	prevention of nosocomial <i>Pseudomonas aeruginosa</i> pneumonia	II (Fast Track, US)	Q2 2016
MEDI4893	mAb binding to <i>S. aureus</i> toxin	prevention of nosocomial <i>Staphylococcus aureus</i> pneumonia	II (Fast Track, US)	Q4 2014
MEDI8852	influenza A mAb	influenza A treatment	II (Fast Track, US)	Q4 2015

Operating & Financial
Review

Corporate & Business
Development

Research & Development

Development Pipeline

Interim Financial
Statements

Compound	Mechanism	Area Under Investigation	Phase	Date Commenced Phase
MEDI8897 [#]	RSV mAb-YTE	passive RSV prophylaxis	II (Fast Track, US)	Q1 2015
MEDI0700 [#]	BAFF/B7RP1 bispecific mAb	systemic lupus erythematosus	I	Q1 2016
MEDI1814 [#]	amyloid beta mAb	Alzheimer's disease	I	Q2 2014
MEDI4920	anti-CD40L-Tn3 fusion protein	primary Sjögren's syndrome	I	Q2 2014
MEDI7352	NGF/TNF bispecific mAb	osteoarthritis pain	I	Q1 2016
MEDI7734	ILT7 mAb	myositis	I	Q3 2016
MEDI9314	IL-4R mAb	atopic dermatitis	I	Q1 2016

Collaboration

Significant Lifecycle Management

Compound	Mechanism	Area Under Investigation	Date Commenced Phase	Estimated Regulatory Acceptance Date / Submission Status			
				US	EU	Japan	China
Oncology							
Faslodex FALCON	oestrogen receptor antagonist	1st-line hormone receptor +ve advanced breast cancer		Accepted	Accepted	Accepted	H2 2017
Lynparza OlympiAD	PARP inhibitor	gBRCA metastatic breast cancer	Q2 2014	H2 2017	2018	H2 2017	
Lynparza SOLO-2	PARP inhibitor	2nd-line or greater BRCAm PSR ovarian cancer, maintenance monotherapy	Q3 2013	Accepted (Priority Review)	H1 2017	H2 2017	
Lynparza SOLO-1	PARP inhibitor	1st-line BRCAm ovarian cancer	Q3 2013	2018	2018	2018	
Lynparza SOLO-3	PARP inhibitor	gBRCA PSR ovarian cancer	Q1 2015	2018			
Lynparza POLO	PARP inhibitor	pancreatic cancer	Q1 2015	2018	2018		
Lynparza PROfound	PARP inhibitor	prostate cancer	Q1 2017	(Breakthrough Therapy)			
Lynparza OlympiA	PARP inhibitor	gBRCA adjuvant breast cancer	Q2 2014	2020	2020	2020	
Tagrisso FLAURA	EGFR inhibitor	1st-line advanced EGFRm NSCLC	Q1 2015	H2 2017	H2 2017	H2 2017	H2 2017
Tagrisso ADAURA	EGFR inhibitor	adjuvant EGFRm NSCLC	Q4 2015	2022	2022	2022	2022
Cardiovascular & Metabolic Diseases							
Brilinta ¹ THEMIS	P2Y12 receptor antagonist	outcomes trial in patients with type-2 diabetes and CAD, but without a previous history of myocardial infarction or stroke	Q1 2014	2019	2019	2019	2020
Brilinta ¹ HESTIA	P2Y12 receptor antagonist	prevention of vaso-occlusive crises in paediatric patients with sickle cell disease	Q1 2014	2020	2020		

Operating & Financial Review

Corporate & Business Development

Research & Development

Development Pipeline

Interim Financial Statements

Compound	Mechanism	Area Under Investigation	Date Commenced Phase	Estimated Regulatory Acceptance Date / Submission Status			
				US	EU	Japan	China
<i>Kombiglyze XR/Komboglyze</i> ²	DPP-4 inhibitor/ metformin FDC	type-2 diabetes		Launched	Launched		Accepted
<i>Farxiga</i> ³ DECLARE-TIMI 58	SGLT2 inhibitor	type-2 diabetes outcomes trial	Q2 2013	2020	2020		
<i>Farxiga</i> ³	SGLT2 inhibitor	type-1 diabetes	Q4 2014	2018	2018	2018	
<i>Farxiga</i> ³	SGLT2 inhibitor	effect of dapagliflozin on the incidence of worsening HF or cardiovascular death in patients with chronic HF	Q1 2017	2020	2020	2020	2020
<i>Farxiga</i> ³	SGLT2 inhibitor	renal outcomes and cardiovascular mortality in patients with CKD	Q1 2017	2021	2021	N/A	2021
<i>Xigduo XR/Xigduo</i> ⁴	SGLT2 inhibitor/ metformin FDC	type-2 diabetes		Launched	Launched		
<i>Qtern</i> (saxagliptin/ dapagliflozin FDC)	DPP-4 inhibitor/ SGLT2 inhibitor FDC	type-2 diabetes		Approved	Launched		
<i>Bydureon</i> weekly autoinjector	GLP-1 receptor agonist	type-2 diabetes	Q1 2013	Accepted	H2 2017		
<i>Bydureon</i> EXSCEL	GLP-1 receptor agonist	type-2 diabetes outcomes trial	Q2 2010	H2 2017	H2 2017		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
Respiratory							
<i>Symbicort</i> SYGMA	ICS/LABA	as-needed use in mild asthma	Q4 2014		2018		2019
<i>Duaklir Genuair</i> [#]	LAMA/LABA	COPD		2018	Launched		2019
Other							
<i>Nexium</i>	proton pump inhibitor	stress ulcer prophylaxis					Submitted
<i>Nexium</i>	proton pump inhibitor	paediatrics		Launched	Launched	Accepted	
linaclotide [#]	GC-C receptor peptide agonist	irritable bowel syndrome with constipation (IBS-C)					Accepted

Collaboration

1 *Brilinta* in the US and Japan; *Brilique* in ROW

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

3 *Farxiga* in the US; *Forxiga* in ROW

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

Operating & Financial Review

Corporate & Business Development

Research & Development

Development Pipeline

Interim Financial Statements

Terminations (discontinued projects: 1 January 2017 to 31 March 2017)

NME / Line Extension	Compound	Reason for Discontinuation	Area Under Investigation
<i>Symbicort</i> - breath actuated inhaler	ICS/LABA	Strategic	asthma/COPD
AZD3241	myeloperoxidase inhibitor	Safety/Efficacy	multiple system atrophy
AZD9412#	inhaled interferon beta	Strategic	asthma/COPD

Completed Projects / Divestitures (1 January 2017 to 31 March 2017)

Compound	Mechanism	Area Under Investigation	Completed/ Divested	Estimated Regulatory Submission Acceptance [†]			
				US	EU	Japan	China
<i>Tagrisso</i> AURA, AURA2, (AURA17 Asia regional)	EGFR inhibitor	≥2nd-line advanced EGFRm T790M NSCLC	Completed	Launched (Breakthrough Therapy, Priority Review, Orphan drug)	Launched (Accelerated assessment)	Launched	Launched
<i>Tagrisso</i> AURA3	EGFR inhibitor	≥2nd-line advanced EGFRm T790M NSCLC	Completed	Launched	Launched		
<i>Brilinta</i> ¹	P2Y12 receptor antagonist	arterial thrombosis	Completed	Launched	Launched	Launched	Launched
<i>Onglyza</i> SAVOR-TIMI 53	DPP-4 inhibitor	type-2 diabetes outcomes trial	Completed	Launched	Launched		Launched

Operating & Financial Review

Corporate & Business Development

Research & Development

Development Pipeline

Interim Financial Statements

Condensed Consolidated Statement of Comprehensive Income

For the quarter ended 31 March	2017 \$m	2016 \$m
Product sales	4,843	5,565
Externalisation revenue	562	550
Total revenue	5,405	6,115
Cost of sales	(894)	(1,004)
Gross profit	4,511	5,111
Distribution costs	(77)	(76)
Research and development expense	(1,453)	(1,480)
Selling, general and administrative costs	(2,300)	(2,572)
Other operating income and expense	236	55
Operating profit	917	1,038
Finance income	18	14
Finance expense	(340)	(325)
Share of after tax losses in associates and joint ventures	(13)	(4)
Profit before tax	582	723
Taxation	(70)	(98)
Profit for the period	512	625
Other comprehensive income		
<i>Items that will not be reclassified to profit or loss</i>		
Remeasurement of the defined benefit pension liability	1	(191)
Tax on items that will not be reclassified to profit or loss	(1)	41
	-	(150)
<i>Items that may be reclassified subsequently to profit or loss</i>		
Foreign exchange arising on consolidation	154	(167)
Foreign exchange arising on designating borrowings in net investment hedges	100	207
Fair value movements on cash flow hedges	7	-
Fair value movements on cash flow hedges transferred to profit or loss	(39)	-
Fair value movements on derivatives designated in net investment hedges	(30)	(32)
Net available for sale losses taken to equity	(150)	(29)
Tax on items that may be reclassified subsequently to profit or loss	24	10
	66	(11)
Other comprehensive income for the period, net of tax	66	(161)
Total comprehensive income for the period	578	464
Profit attributable to:		
Owners of the Parent	537	646
Non-controlling interests	(25)	(21)
	512	625
Total comprehensive income attributable to:		
Owners of the Parent	603	485
Non-controlling interests	(25)	(21)
	578	464
Basic earnings per \$0.25 Ordinary Share	\$0.42	\$0.51
Diluted earnings per \$0.25 Ordinary Share	\$0.42	\$0.51
Weighted average number of Ordinary Shares in issue (millions)	1,265	1,264
Diluted weighted average number of Ordinary Shares in issue (millions)	1,266	1,265

Operating & Financial Review

Corporate & Business Development

Research & Development

Development Pipeline

Interim Financial Statements

Condensed Consolidated Statement of Financial Position

	At 31 Mar 2017 \$m	At 31 Dec 2016 \$m	Restated* At 31 Mar 2016 \$m
ASSETS			
Non-current assets			
Property, plant and equipment	6,954	6,848	6,560
Goodwill	11,688	11,658	11,855
Intangible assets	27,386	27,586	29,627
Derivative financial instruments	310	343	419
Investments in associates and joint ventures	88	99	104
Other investments	739	727	500
Other receivables	891	901	874
Deferred tax assets	1,266	1,102	1,482
	<u>49,322</u>	<u>49,264</u>	<u>51,421</u>
Current assets			
Inventories	2,652	2,334	2,344
Trade and other receivables	4,686	4,573	5,881
Other investments	530	884	671
Derivative financial instruments	13	27	8
Income tax receivable	627	426	452
Cash and cash equivalents	3,129	5,018	3,428
	<u>11,637</u>	<u>13,262</u>	<u>12,784</u>
Total assets	<u>60,959</u>	<u>62,526</u>	<u>64,205</u>
LIABILITIES			
Current liabilities			
Interest-bearing loans and borrowings	(2,839)	(2,307)	(2,168)
Trade and other payables	(9,899)	(10,486)	(11,174)
Derivative financial instruments	(1)	(18)	(4)
Provisions	(1,044)	(1,065)	(790)
Income tax payable	(1,646)	(1,380)	(1,796)
	<u>(15,429)</u>	<u>(15,256)</u>	<u>(15,932)</u>
Non-current liabilities			
Interest-bearing loans and borrowings	(14,563)	(14,501)	(14,144)
Derivative financial instruments	(107)	(117)	-
Deferred tax liabilities	(4,036)	(3,956)	(4,302)
Retirement benefit obligations	(2,171)	(2,186)	(2,099)
Provisions	(378)	(353)	(461)
Other payables	(9,496)	(9,488)	(10,625)
	<u>(30,751)</u>	<u>(30,601)</u>	<u>(31,631)</u>
Total liabilities	<u>(46,180)</u>	<u>(45,857)</u>	<u>(47,563)</u>
Net assets	<u>14,779</u>	<u>16,669</u>	<u>16,642</u>
EQUITY			
Capital and reserves attributable to equity holders of the Company			
Share capital	316	316	316
Share premium account	4,368	4,351	4,322
Other reserves	2,042	2,047	2,028
Retained earnings	6,263	8,140	8,075
	<u>12,989</u>	<u>14,854</u>	<u>14,741</u>
Non-controlling interests	1,790	1,815	1,901
Total equity	<u>14,779</u>	<u>16,669</u>	<u>16,642</u>

*31 March comparatives have been restated to reflect an adjustment to the acquisition-accounting for ZS Pharma (as detailed in Note 25 of the AstraZeneca Annual Report and Form 20-F Information 2016, page 174) and an adjustment to the acquisition-accounting for Acerta Pharma (as detailed in Note 4 of the Full Year and Fourth Quarter 2016 Results Announcement).

 Operating & Financial
Review

 Corporate & Business
Development

Research & Development

Development Pipeline

 Interim Financial
Statements

Condensed Consolidated Statement of Cash Flows

For the quarter ended 31 March	2017 \$m	2016 \$m
Cash flows from operating activities		
Profit before tax	582	723
Finance income and expense	322	311
Share of after tax losses in associates and joint ventures	13	4
Depreciation, amortisation and impairment	658	569
(Increase)/decrease in working capital and short-term provisions	(887)	64
Non-cash and other movements	(349)	(88)
Cash generated from operations	339	1,583
Interest paid	(189)	(185)
Tax paid	(62)	(205)
Net cash inflow from operating activities	88	1,193
Cash flows from investing activities		
Movement in short-term investments and fixed deposits	357	33
Purchase of property, plant and equipment	(286)	(267)
Disposal of property, plant and equipment	9	2
Purchase of intangible assets	(99)	(39)
Disposal of intangible assets	51	-
Purchase of non-current asset investments	(18)	(68)
Disposal of non-current asset investments	8	-
Upfront payments on business combinations	-	(2,564)
Payment of contingent consideration on business combinations	(213)	(26)
Interest received	45	42
Net cash outflow from investing activities	(146)	(2,887)
Net cash outflow before financing activities	(58)	(1,694)
Cash flows from financing activities		
Proceeds from issue of share capital	17	18
New long term loans	3	-
Dividends paid	(2,368)	(2,409)
Hedge contracts relating to dividend payments	(32)	5
Repayment of obligations under finance leases	(14)	(3)
Movement in short-term borrowings	352	1,028
Net cash outflow from financing activities	(2,042)	(1,361)
Net decrease in cash and cash equivalents in the period	(2,100)	(3,055)
Cash and cash equivalents at the beginning of the period	4,924	6,051
Exchange rate effects	14	43
Cash and cash equivalents at the end of the period	2,838	3,039
Cash and cash equivalents consists of:		
Cash and cash equivalents	3,129	3,428
Overdrafts	(291)	(389)
	2,838	3,039

Operating & Financial Review

Corporate & Business Development

Research & Development

Development Pipeline

Interim Financial Statements

Condensed Consolidated Statement of Changes in Equity

	Share capital \$m	Share premium account \$m	Other reserves* \$m	Retained earnings \$m	Total \$m	Non-controlling interests \$m	Total equity \$m
At 1 Jan 2016	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	-	-	-
Transactions with owners:							
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)
At 31 Mar 2016	316	4,322	2,028	8,075	14,741	1,901	16,642
	Share capital \$m	Share premium account \$m	Other reserves* \$m	Retained earnings \$m	Total \$m	Non-controlling interests \$m	Total equity \$m
At 1 Jan 2017	316	4,351	2,047	8,140	14,854	1,815	16,669
Profit for the period	-	-	-	537	537	(25)	512
Other comprehensive income	-	-	-	66	66	-	66
Transfer to other reserves	-	-	(5)	5	-	-	-
Transactions with owners:							
Dividends	-	-	-	(2,404)	(2,404)	-	(2,404)
Issue of Ordinary Shares	-	17	-	-	17	-	17
Share-based payments	-	-	-	(81)	(81)	-	(81)
Net movement	-	17	(5)	(1,877)	(1,865)	(25)	(1,890)
At 31 Mar 2017	316	4,368	2,042	6,263	12,989	1,790	14,779

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

Operating & Financial Review

Corporate & Business Development

Research & Development

Development Pipeline

Interim Financial Statements

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 three months ended 31 March 2017 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 2016. There have been no significant new or revised accounting standards applied in the three months ended 31 March 2017.

Legal proceedings

The information contained in Note 5 updates the disclosures concerning legal proceedings and contingent liabilities in the Group's Annual Report and Form 20-F Information 2016.

Going concern

The Group has considerable financial resources available. As at 31 March 2017, the Group has \$3.3bn in financial resources (cash balances of \$3.1bn and undrawn committed bank facilities of \$3.0bn which are available until April 2022, with only \$2.8bn 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 2016 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 2017 is stated after charging restructuring costs of \$312m (\$155m for the first quarter of 2016). These have been charged to profit as follows:

	Q1 2017 \$m	Q1 2016 \$m
Cost of sales	38	9
Research and development expense	104	38
Selling, general and administrative costs	94	108
Other operating income and expense	76	-
Total	312	155

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 2017 \$m	Cash Flow \$m	Non-cash & Other \$m	Exchange Movements \$m	At 31 Mar 2017 \$m
Loans due after one year	(14,495)	(3)	(2)	(60)	(14,560)
Finance leases due after one year	(6)	-	3	-	(3)
Total long-term debt	(14,501)	(3)	1	(60)	(14,563)
Current instalments of loans	(1,769)	-	7	-	(1,762)
Current instalments of finance leases	(87)	14	(4)	-	(77)
Total current debt	(1,856)	14	3	-	(1,839)
Other investments	898	(353)	-	3	548
Net derivative financial instruments	235	32	(52)	-	215
Cash and cash equivalents	5,018	(1,903)	-	14	3,129
Overdrafts	(94)	(197)	-	-	(291)
Short-term borrowings	(357)	(352)	-	-	(709)
	5,700	(2,773)	(52)	17	2,892
Net debt	(10,657)	(2,762)	(48)	(43)	(13,510)

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

4 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 of significance to the accounting policies for financial instruments, including fair value measurement, from those disclosed on pages 144 and 145 of the Company's Annual Report and Form 20-F Information 2016. 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 \$1,269m of other investments, \$1,712m of loans, and \$215m of derivatives as at 31 March 2017. The total fair value of interest-bearing loans and borrowings at 31 March 2017, which have a carrying value of \$17,402m in the Condensed Consolidated Statement of Financial Position, was \$16,338m. 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 2017 \$m	Other 2017 \$m	Total 2017 \$m	Total 2016 \$m
At 1 January	4,240	1,217	5,457	6,411
Settlements	(138)	(75)	(213)	(26)
Discount unwind	82	22	104	124
At 31 March	4,184	1,164	5,348	6,509

Operating & Financial
Review

Corporate & Business
Development

Research & Development

Development Pipeline

Interim Financial
Statements

5 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 2016 (the Disclosures). Unless noted otherwise below or in the Disclosures, no provisions have been established in respect of the claims discussed below.

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

In cases that have been settled or adjudicated, or where quantifiable fines and penalties have been assessed and which are not subject to appeal, or where a loss is probable and we are able to make a reasonable estimate of the loss, AstraZeneca records the loss absorbed or makes 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 recorded. The major factors causing this uncertainty are described more fully in the Disclosures and herein.

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

Matters disclosed in respect of the first quarter of 2017 and to 27 April 2017.

Patent litigation

Faslodex (fulvestrant)

US patent proceedings

As previously disclosed, AstraZeneca has filed patent infringement lawsuits in the US District Court in New Jersey (the District Court) relating to patents listed in the FDA Orange Book with reference to *Faslodex* after AstraZeneca received notice of ANDAs seeking FDA approval to market generic versions of *Faslodex* prior to the expiration of AstraZeneca's patents. AstraZeneca settled the lawsuits with four of the ANDA filers. In April 2017, AstraZeneca settled the lawsuit with a fifth ANDA filer. In February and March 2017, AstraZeneca received notice of three additional ANDAs and filed patent infringement lawsuits against all three in the District Court.

In March 2017, AstraZeneca received a Paragraph IV notice regarding an NDA submitted pursuant to 21 U.S.C. § 355(b)(2) by Teva Pharmaceuticals USA, Inc. (Teva) relating to the same Orange Book-listed patents and, in April 2017, filed a lawsuit against Teva in the District Court.

In February 2017, AstraZeneca was served with three petitions for *inter partes* review by the Patent Trial and Appeal Board of the United States Patent and Trademark Office relating to Orange Book-listed patents with reference to *Faslodex*.

Patent proceedings outside the US

As previously disclosed, in Germany, the Federal Patent Court declared European Patent No. EP 1250138 (the '138 patent) invalid. AstraZeneca intends to appeal. In February 2017, the Regional Court of Mannheim lifted a provisional injunction based on a divisional patent of the '138 patent, European Patent No. EP 2266573, which had been in place against Hexal AG since February 2016.

Onglyza (saxagliptin) and Kombiglyze (saxagliptin and metformin)

US patent proceedings

As previously disclosed, AstraZeneca initiated patent infringement proceedings in the US District Court for the District of Delaware (the District Court) after various entities had submitted ANDAs containing a Paragraph IV Certification which alleged that US Patent No. RE44,186 (the '186 Patent), listed in the FDA Orange Book with reference to *Onglyza* and *Kombiglyze XR*, is invalid and/or will not be infringed by the products as described in their ANDAs. In February 2017, the District Court issued a decision upholding the validity of the '186 Patent which has since been appealed to the US Court of Appeals for the Federal Circuit.

Crestor (rosuvastatin calcium)

Patent proceedings outside the US

In Spain, in February 2017, in response to a marketing declaration from ratiopharm España, S.A. (ratiopharm) regarding its version of rosuvastatin zinc, AstraZeneca requested and received an interim injunction against the launch of ratiopharm's product from the Commercial Courts of Barcelona. In March 2017, AstraZeneca filed an infringement action in relation to ratiopharm's product.

Synagis (palivizumab)

US patent proceedings

In March 2017, MedImmune LLC was served with a complaint filed by UCB BioPharma SPRL in the US District Court for the District of Delaware alleging that *Synagis* infringed US Patent No. 7,566,771. AstraZeneca will respond in due course.

Vimovo (naproxen/esomeprazole magnesium)

Patent proceedings outside the US

As previously disclosed, in Canada, in January 2015, AstraZeneca received two notices of allegation from Mylan Pharmaceuticals ULC (Mylan). In response, AstraZeneca and Pozen Inc. (now Aralez Pharmaceuticals Inc.), the licensee and patent holder respectively, commenced proceedings in relation to the *Vimovo* formulation patent (Canadian Patent No. 2,449,098). On 7 February 2017, the Federal Court of Canada dismissed AstraZeneca's application. The Minister of Health has issued a marketing authorisation to Mylan.

Product liability litigation

Farxiga (dapagliflozin) and Xigduo XR (dapagliflozin/metformin HCl)

As previously disclosed, in several jurisdictions in the US, AstraZeneca has been named as a defendant in lawsuits involving plaintiffs claiming physical injury, including diabetic ketoacidosis and kidney failure, from treatment with *Farxiga* and/or *Xigduo XR*.

In April 2017, the Judicial Panel on Multidistrict Litigation ordered transfer of any currently pending cases as well as any similar, subsequently filed cases to a coordinated and consolidated pre-trial multidistrict litigation proceeding in the US District Court for the Southern District of New York.

Onglyza (saxagliptin) and Kombiglyze (saxagliptin and metformin)

AstraZeneca is defending claims in the US brought by plaintiffs alleging HF, cardiac failure and/or death from treatment with either *Onglyza* or *Kombiglyze*. In February 2017, the California Superior Court granted certain California plaintiffs' Petition for Coordination with the Judicial Council of California, requesting that all similar, currently pending or subsequently filed cases in California state court be coordinated for pre-trial purposes.

Nexium (esomeprazole)

As previously disclosed, AstraZeneca was defending product liability lawsuits brought in US federal and state courts by approximately 1,900 plaintiffs who alleged that *Nexium* caused osteoporotic injuries, such as bone deterioration, loss of bone density and/or bone fractures, but all such claims have now been dismissed with judgment entered in AstraZeneca's favour. In January 2017, the California Second Appellate Division affirmed the dismissal of the fewer than 40 cases in California state court and no further appeal was taken. There are currently no claims pending in the US that allege that *Nexium* caused osteoporotic or other bone-related injuries.

Nexium (esomeprazole) and Prilosec (omeprazole)

As previously disclosed, AstraZeneca is defending various lawsuits in the US involving multiple plaintiffs claiming that they have been diagnosed with kidney injuries following treatment with proton pump inhibitors, including *Nexium* and *Prilosec*. In October 2016, counsel for some of these plaintiffs filed a motion with the Judicial Panel on Multidistrict Litigation (JPML) seeking transfer of any currently pending federal court cases as well as any similar, subsequently filed cases to a coordinated and consolidated pre-trial multidistrict litigation proceeding. In February 2017, the JPML denied this motion.

Commercial litigation

Nexium settlement anti-trust litigation

As previously disclosed, AstraZeneca is a defendant in a multidistrict litigation class action and individual lawsuit alleging that AstraZeneca's settlements of certain patent litigation in the US relating to *Nexium* violated US anti-trust law and various state laws. A trial in the US District Court for the District of Massachusetts (the District Court) commenced in October 2014 and, in December 2014, a jury returned a verdict in favour of AstraZeneca and entered judgment in favour of AstraZeneca in September 2015. The plaintiffs appealed that judgment and, in November 2016, the US Court of Appeals for the First Circuit affirmed the District Court's decision. The plaintiffs did not file a petition for *writ of certiorari* with the US Supreme Court, and the federal appeals for this verdict are accordingly concluded.

As previously disclosed, two lawsuits filed in Pennsylvania state court by various indirect purchasers of *Nexium* for similar matters are pending.

Government investigations/proceedings

Synagis (palivizumab)

As previously disclosed, in June 2011, MedImmune received a demand from the US Attorney's Office for the Southern District of New York requesting certain documents related to the sales and marketing activities of *Synagis*. In July 2011, MedImmune received a similar court order to produce documents from the Office of the Attorney General for the State of New York Medicaid and Fraud Control Unit pursuant to a joint investigation between the previously mentioned government attorneys. MedImmune has cooperated with these inquiries.

In March 2017, MedImmune was served with a lawsuit filed in US Federal Court in New York, primarily under the *qui tam* (whistleblower) provisions of the New York State False Claims Act and anti-kickback statutes. The lawsuit alleges that MedImmune inappropriately provided assistance to a single specialty care pharmacy.

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

Qui tam litigation in New York

In the US, in September 2015, AstraZeneca was served with a lawsuit filed in US Federal Court in New York under the *qui tam* (whistleblower) provisions of the federal and certain state False Claims Acts. The lawsuit alleges that AstraZeneca misrepresented the safety profile of, and improperly promoted, *Seroquel IR* and *Seroquel XR*. The US government and the named states have declined to intervene in this case.

Texas Attorney General litigation

In the US, in October 2014, following a previously disclosed investigation by the State of Texas into AstraZeneca's sales and marketing activities involving *Seroquel*, the Texas Attorney General's Office intervened in a state whistleblower action pending in Travis County Court, Texas. The lawsuit alleges that AstraZeneca engaged in inappropriate promotion of *Seroquel* and made improper payments intended to influence the formulary status of *Seroquel*. The trial is scheduled for October 2017.

Operating & Financial Review

Corporate & Business Development

Research & Development

Development Pipeline

Interim Financial Statements

6 PRODUCT ANALYSIS

	World			Emerging Markets			US		Europe			Established ROW		
	Q1 2017 \$m	Actual %	CER %	Q1 2017 \$m	Actual %	CER %	Q1 2017 \$m	Actual %	Q1 2017 \$m	Actual %	CER %	Q1 2017 \$m	Actual %	CER %
Oncology														
<i>Tagrisso</i>	171	n/m	n/m	6	n/m	n/m	90	100	35	n/m	n/m	40	n/m	n/m
<i>Iressa</i>	124	(8)	(7)	61	(9)	(7)	8	100	26	(24)	(24)	29	(3)	(3)
<i>Lynparza</i>	57	30	32	4	100	150	27	(4)	25	79	79	1	n/m	n/m
Legacy:														
<i>Faslodex</i>	214	13	13	27	29	24	118	19	54	(4)	(2)	15	7	7
<i>Zoladex</i>	185	4	5	87	30	31	8	(20)	32	(18)	(13)	58	(6)	(8)
<i>Casodex</i>	56	(10)	(8)	30	3	7	-	-	6	(14)	(14)	20	(23)	(23)
<i>Arimidex</i>	52	(9)	(7)	29	-	3	1	(75)	8	-	-	14	(13)	(13)
Others	26	24	24	7	-	-	-	-	1	-	-	18	38	38
Total Oncology	885	20	21	251	14	16	252	33	187	13	14	195	21	20
CVMD														
<i>Brilinta/Brilique</i>	224	24	27	60	46	54	87	24	65	8	12	12	20	20
<i>Farxiga/Forxiga</i>	207	25	25	42	100	90	96	2	50	22	24	19	111	111
<i>Onglyza</i>	154	(27)	(27)	30	(17)	(17)	81	(35)	27	(18)	(18)	16	(11)	(11)
<i>Bydureon</i>	153	13	14	1	(50)	-	127	18	22	(4)	(4)	3	50	50
<i>Byetta</i>	46	(26)	(24)	5	-	20	30	(29)	8	(20)	(20)	3	(40)	(40)
Legacy:														
<i>Crestor</i>	631	(45)	(44)	202	10	14	112	(82)	195	(8)	(4)	122	(2)	(4)
<i>Seloken/Toprol-XL</i>	186	1	3	152	9	11	11	(48)	21	(5)	(5)	2	-	-
<i>Atacand</i>	75	4	7	44	26	31	6	(33)	21	(13)	(13)	4	-	-
Others	103	(18)	(16)	58	(29)	(26)	14	180	23	(23)	(23)	8	(11)	(11)
Total CVMD	1,779	(22)	(21)	594	9	12	564	(49)	432	(5)	(3)	189	3	2
Respiratory														
<i>Symbicort</i>	677	(10)	(8)	112	7	10	255	(21)	200	(13)	(9)	110	21	16
<i>Pulmicort</i>	337	9	14	250	21	28	41	(27)	26	(10)	(7)	20	11	11
<i>Daliresp/Daxas</i>	44	42	42	1	n/m	n/m	38	23	5	n/m	n/m	-	-	-
<i>Tudorza/Eklira</i>	37	(5)	(3)	-	-	-	15	(12)	20	(5)	-	2	100	100
<i>Duaklir</i>	19	46	54	-	-	-	-	-	19	58	58	-	-	-
Others	67	3	6	27	(29)	(24)	3	(25)	28	40	40	9	200	200
Total Respiratory	1,181	(2)	-	390	11	17	352	(18)	298	(5)	(1)	141	25	21
Other														
<i>Nexium</i>	461	-	1	175	(1)	3	136	4	61	2	3	89	(6)	(9)
<i>Synagis</i>	230	(6)	(6)	-	-	-	157	(2)	73	(13)	(13)	-	-	-
<i>LOSEC/Prilosec</i>	68	(9)	(7)	35	(10)	(5)	5	150	18	(14)	(14)	10	(23)	(23)
<i>Seroquel XR</i>	67	(67)	(66)	15	(17)	(11)	24	(83)	22	(37)	(37)	6	20	20
<i>Movantik/Moventig</i>	30	76	76	-	-	-	30	76	-	-	-	-	-	-
<i>FluMist/Fluenz</i>	-	(100)	(100)	-	-	-	-	(100)	-	-	-	-	-	-
Others	142	(56)	(56)	102	(10)	(23)	(35)	n/m	38	(57)	(30)	37	(43)	(55)
Total Other	998	(25)	(24)	327	(2)	(3)	317	(39)	212	(5)	(1)	142	(2)	(3)
TOTAL PRODUCT SALES	4,843	(13)	(12)	1,562	7	9	1,485	(34)	1,129	(7)	(3)	667	5	2

Shareholder Information

Annual General Meeting	27 April 2017
Announcement of half year and second quarter 2017 results	27 July 2017
Announcement of nine months and third quarter 2017 results	9 November 2017

Future dividends will normally be paid as follows:

First interim Announced with half-year and second-quarter results and paid in September

Second interim Announced with full-year and fourth-quarter results and paid in March

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

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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; effects of patent litigation in respect of IP rights; 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 that R&D will not yield new products that achieve commercial success; the risk of delay to new product launches; the risk that new products do not perform as we expect; the risk that strategic alliances and acquisitions, including licensing and collaborations, will be unsuccessful; the risks from pressures resulting from generic competition; the impact of competition, price controls and price reductions; the risks associated with developing our business in emerging markets; the risk of illegal trade in our products; the difficulties of obtaining and maintaining regulatory approvals for products; the risk that regulatory approval processes for biosimilars could have an adverse effect on future commercial prospects; the risk of failure to successfully implement planned cost reduction measures through productivity initiatives and restructuring programmes; the risk of failure of critical processes affecting business continuity; economic, regulatory and political pressures to limit or reduce the cost of our products; failure to achieve strategic priorities or to meet targets or expectations; the risk of substantial adverse litigation/government investigation claims and insufficient insurance coverage; the risk of substantial product liability claims; 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 impact of increasing implementation and enforcement of more stringent anti-bribery and anti-corruption legislation; taxation risks; exchange rate fluctuations; 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 impact of failing to attract and retain key personnel and to successfully engage with our employees; the risk of misuse of social medial platforms and new technology; and the risk of failure of information technology and cybercrime. Nothing in this presentation / webcast should be construed as a profit forecast.