

AstraZeneca PLC

2 February 2017 07:00

Full-Year and Q4 2016 Results Performance in line with expectations; 2017 has the potential to be a defining year

Financial Summary

| | FY 2016 | | | | Q4 2016 | | | |
|------------------------------------|---------|------------------|--------|--|---------|----------|--------|--|
| | ¢m | % ch | ange | | \$m | % change | | |
| | \$m | CER ¹ | Actual | | φIII | CER | Actual | |
| Total Revenue | 23,002 | (5) | (7) | | 5,585 | (12) | (13) | |
| Product Sales | 21,319 | (8) | (10) | | 5,260 | (15) | (15) | |
| Externalisation Revenue | 1,683 | 59 | 58 | | 325 | 77 | 69 | |
| Reported Operating Profit | 4,902 | 9 | 19 | | 2,533 | n/m | n/m | |
| Core Operating Profit ² | 6,721 | (7) | (3) | | 2,026 | 15 | 30 | |
| Reported Earnings Per Share (EPS) | \$2.77 | 9 | 24 | | \$1.46 | 93 | n/m | |
| Core EPS | \$4.31 | (5) | 1 | | \$1.21 | 9 | 29 | |

The fall in Product Sales primarily reflected the entry of *Crestor* generic medicines in the US; *Crestor* represents the last anticipated blockbuster³ patent expiry, ahead of significant late-stage pipeline news flow
 Good progress on cost control in the year, reflecting the evolving shape of the business:

Reported and Core R&D cost growth of 2% to \$5,890m and 5% to \$5,631m, respectively, including the absorption of the R&D costs of Acerta Pharma and ZS Pharma

- Reported and Core SG&A costs declined by 12% to \$9,413m and by 9% to \$8,169m, respectively

- Reported EPS increased by 9% in the year to \$2.77, reflecting a revaluation of acquisition-related liabilities. A 5% fall in Core EPS was driven by a corresponding rate of decline in Total Revenue
- A second interim dividend of \$1.90 per share has been declared, bringing the dividend for the full year to \$2.80 per share. The Board reaffirms its commitment to the Company's progressive dividend policy

Commercial Highlights

The Growth Platforms grew by 5% in the year (Q4 2016: Up by 3%). Highlights included:

- Emerging Markets: 6% growth (Q4 2016: Up by 7%) to \$5,794m, supported by China, up by 10% to \$2,636m
- Diabetes: Growth of 11%, as Farxiga became the Company's largest-selling Diabetes medicine
- Japan: A sales decline of 3% to \$2,184m, reflecting the biennial price reduction in the year
- Brilinta: Sales grew by 39% to \$839m; on track to be a blockbuster medicine
- Respiratory: A decline of 3% to \$4,753m (Q4 2016: Down by 5%), reflecting US pricing pressure for Symbicort
- New Oncology: Strong sales of \$664m (Q4 2016: \$216m); Tagrisso delivered sales of \$423m in its first year

Achieving Scientific Leadership

The pipeline-driven progress of AstraZeneca continued in the year. Twelve potential new medicines are in Phase III/under regulatory review, primarily within the three therapy areas of Oncology, Cardiovascular & Metabolic Diseases and Respiratory. The Oncology pipeline, which attracted over 40% of R&D investment in the year, is progressing ahead of the Company's expectations, in particular *Tagrisso* and the Immuno-Oncology programmes. The table below highlights successes in the late-stage pipeline since the last results announcement:

| Regulatory Submission Acceptances | durvalumab - bladder cancer (US) <i>Tagrisso</i> - lung cancer (AURA3 trial) (US, EU) <i>Faslodex</i> - breast cancer (1st line) (US, EU) roxadustat - anaemia (CN) (rolling submission) benralizumab - severe, uncontrolled asthma (US, EU) |
|-----------------------------------|--|
| Other Key Developments | Priority Review Designation: durvalumab (US) Priority Review Designation: <i>Tagrisso</i> (US) |



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

"Our financial results in the year were in line with expectations and reflected the ongoing transition of our company. We brought a sharper strategic focus to our three main therapy areas, boosting pipeline productivity further as we saw with Priority Review Designations for durvalumab and *Tagrisso*, as well as regulatory submission acceptances for durvalumab in bladder cancer and for benralizumab in severe, uncontrolled asthma. Our underlying business is growing as a new AstraZeneca emerges, driven by competitive franchises and Emerging Markets.

2017 has the potential to be a turning point for our company as we near the end of our patent-expiry period and bring new medicines to patients across the globe. We anticipate defining data, in particular from our outstanding pipeline of Immuno-Oncology and targeted treatments. This year we have the opportunity to launch several life-changing medicines for cancer, respiratory and metabolic diseases. It is an exciting time as we rapidly approach the inflection point for our anticipated return to long-term growth, built on the solid foundations of a science-led pipeline."

FY 2017 Guidance

The Company provides guidance on Total Revenue and Core EPS only. All measures in this section are at constant exchange rates¹:

| 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 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 the second half of FY 2017, when the impact of the entry of *Crestor* generic medicines in the US will annualise.

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

In addition to the guidance listed 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 income⁴ is expected to increase further as a proportion of 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, 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 January 2017 and the Company's published currency sensitivities, there is expected to be a low single-digit percentage adverse impact from currency movements on Total Revenue and Core EPS in the year. Further details on currency sensitivities are contained within the Operating and Financial Review.

Notes

- 1. All growth rates and guidance are shown at constant exchange rates (CER) unless specified otherwise.
- 2. See the Operating and Financial Review for a definition of Core financial measures and a reconciliation of Core to Reported financial measures.
- 3. The term 'blockbuster' is defined as a medicine with Product Sales in excess of \$1bn over a period of 12 months.
- 4. Sustainable and ongoing income is defined as Externalisation Revenue excluding upfront receipts.



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.

| H1 2017 | Faslodex - breast cancer (1st line): Regulatory decision (JP) Lynparza - ovarian cancer (2nd line): Regulatory submission Lynparza - breast cancer: Data readout Tagrisso - lung cancer (AURA3): Regulatory decision (US) durvalumab - bladder cancer: Regulatory decision (US) durva +/- treme - lung cancer (ARCTIC): Data readout acalabrutinib - blood cancer: Data readout, regulatory submission (US) (Phase II)# Bydureon - autoinjector: Regulatory submission (US) saxagliptin/dapagliflozin - type-2 diabetes: Regulatory decision (US) ZS-9 (sodium zirconium cyclosilicate) - hyperkalaemia: Regulatory decision (US, EU) Bevespi - COPD: Regulatory submission (EU) benralizumab - severe, uncontrolled asthma: Regulatory submission (JP) |
|----------|---|
| Mid-2017 | durva +/- treme - lung cancer (MYSTIC): Data readout |
| H2 2017 | Faslodex - breast cancer (1st line): Regulatory decision (US, EU) Lynparza - breast cancer: Regulatory submission Lynparza - ovarian cancer (1st line): Data readout Tagrisso - lung cancer: Regulatory decision (CN) Tagrisso - lung cancer (AURA3): Regulatory decision (EU) Tagrisso - lung cancer (1st line): Data readout durvalumab - lung cancer (PACIFIC): Data readout, regulatory submission durva +/- treme - lung cancer (MYSTIC): Regulatory submission durva +/- treme - lung cancer (ARCTIC): Regulatory submission durva +/- treme - lung cancer (KESTREL): Data readout moxetumomab - leukaemia: Data readout benralizumab - severe, uncontrolled asthma: Regulatory decision (US) tralokinumab - severe, uncontrolled asthma: Data readout |
| 2018 | Lynparza - ovarian cancer (1st line): Regulatory submission Tagrisso - 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 Brilinta - type-2 diabetes / coronary artery disease: Data readout, regulatory submission Bydureon - cardiovascular (CV) outcomes trial: Data readout, regulatory submission Duaklir - COPD: Regulatory submission (US) benralizumab - severe, uncontrolled asthma: Regulatory decision (EU) tralokinumab - severe, uncontrolled asthma: Regulatory submission PT010 - COPD: Data readout, regulatory submission anifrolumab - lupus: Data readout |

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.



Results Presentation

A presentation and accompanying live webcast for investors and analysts, hosted by management, will begin at 12.30pm UK time today. Details can be accessed via <u>astrazeneca.com/investors</u>.

Reporting Calendar

The Company intends to publish its first quarter financial results on 27 April 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 CER unless stated otherwise. Financial figures are in US\$ millions (\$m). The performance shown in this announcement covers the twelve and three-month periods to 31 December 2016 (the year and the quarter, respectively) compared to the twelve and three-month periods to 31 December 2015.

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

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

Details on the nature of these measures are provided on page 64 of the <u>Annual Report</u> and Form 20-F Information 2015.

Total Revenue

| | FY | 2016 | Q4 2016 | | |
|-------------------------|--------|--------------------------------|---------|------|--|
| | \$m | \$m % CER change \$m % CER cha | | | |
| Product Sales | 21,319 | (8) | 5,260 | (15) | |
| Externalisation Revenue | 1,683 | 59 | 325 | 77 | |
| Total Revenue | 23,002 | (5) | 5,585 | (12) | |

Based on actual exchange rates, Total Revenue declined by 7% in the year and by 13% in the quarter.

Product Sales

The level of decline in Product Sales was driven by the impact of the entry of *Crestor* generic medicines in the US, as well as the reducing impact of *Nexium* generic medicines in the US. Sales of *Crestor* and *Nexium* in the US declined by 57% and 39%, respectively. Overall US Product Sales declined by 22% in the year to \$7,365m (Q4 2016: Down by 37% to \$1,618m). Product Sales in Europe declined by 3% in the year to \$5,064m (Q4 2016: Down by 3% to \$1,332m).

Within Product Sales, the Growth Platforms grew by 5% in the year, representing 63% of Total Revenue:

| | FY 2 | 2016 | Q4 2016 | | |
|---------------------------|------------------------|--------------|------------------------|--------------|--|
| Growth Platform | Product Sales (\$m) | % CER change | Product Sales (\$m) | % CER change | |
| Emerging Markets | 5,794 | 6 | 1,486 | 7 | |
| Respiratory | 4,753 | (3) | 1,210 | (5) | |
| Diabetes | 2,427 | 11 | 598 | 3 | |
| Japan | 2,184 | (3) | 591 | (5) | |
| Brilinta | 839 | 39 | 236 | 37 | |
| New Oncology ¹ | 664 | n/m | 216 | n/m | |
| Total ² | 14,491 | 5 | 3,728 | 3 | |

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

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



Externalisation Revenue

Where AstraZeneca retains a significant economic interest in medicines or potential new medicines, income from transactions is reported as Externalisation Revenue in the Company's financial statements. The table below illustrates the level of sustainable and ongoing income¹ within the total of Externalisation Revenue. Sustainable and ongoing income is anticipated to grow as a proportion of Externalisation Revenue over time.

| | | FY 2016 | | | | Q4 2016 | | | |
|--|-------|--------------|------|--------|-----|---------|----------|--------|--|
| | ¢m | % o f | % ch | ange | ¢ | % of | % change | | |
| | \$m | Total | CER | Actual | \$m | Total | CER | Actual | |
| Royalties ² | 119 | 7 | 69 | 58 | 45 | 14 | 222 | 230 | |
| Milestones | 237 | 14 | 35 | 33 | 10 | 3 | (87) | (87) | |
| Sub-total Sustainable and Ongoing Externalisation Revenue | 356 | 21 | 45 | 40 | 55 | 17 | (37) | (40) | |
| Upfront Receipts | 1,327 | 79 | 63 | 63 | 270 | 83 | 172 | 171 | |
| Total Externalisation Revenue | 1,683 | 100 | 59 | 58 | 325 | 100 | 77 | 69 | |

¹Sustainable and ongoing income is defined as Externalisation Revenue excluding upfront receipts.

²Royalties in FY 2016 included those derived from the Aspen Global Incorporated (Aspen) transaction highlighted below.

Externalisation Revenue recognised in the year amounted to \$1,683m. Highlights included:

| Medicine | Partner | Region | \$m |
|---|--|-------------------|-------|
| Anaesthetics | Aspen - initial revenue | Global (excl. US) | 520 |
| <u>Plendil</u> | China Medical System Holdings Ltd - commercialisation rights - initial revenue | China | 298 |
| <u>Toprol-XL</u> | Aralez Pharmaceuticals Trading DAC (Aralez) - initial revenue | US | 175 |
| <u>Tralokinumab - atopic</u> <u>dermatitis</u> | LEO Pharma A/S (LEO Pharma) - initial revenue | Global | 115 |
| AZD3293 | Eli Lilly and Company (Lilly) - milestone revenue | Global | 100 |
| Nexium OTC 20mg | Pfizer Inc. (Pfizer) - milestone revenue | Global | 93 |
| <u>Moventig</u> | ProStrakan Group plc - commercialisation rights - initial and milestone revenue | EU | 78 |
| Others | | | 304 |
| Total | | | 1,683 |

Statements



Examples of sustainable and ongoing Externalisation Revenue streams are shown below:

| Announcement Date | Medicine | Partner | Region | Externalisation Revenue | ncial |
|-------------------------|--|--|--------------------------------------|---|-------------------------------------|
| <u>4 October 2016</u> | Toprol-XL | Aralez | US | Initial \$175m milestone Up to \$48m milestone and sales- related revenue Mid-teen percentage royalties on sales | Operating & Financial Review |
| <u>1 July 2016</u> | Tralokinumab - atopic dermatitis | LEO Pharma | Global | Initial \$115m milestone Up to \$1bn in commercially-related milestones Up to mid-teen tiered percentage royalties on sales | Corporate & Business Development |
| <u>9 June 2016</u> | Anaesthetics | Aspen | Global (excl. US) | Initial \$520m milestone Up to \$250m in sales-related revenue Double-digit percentage trademark royalties on sales | Research & Development |
| <u>1 September 2015</u> | Brodalumab - psoriasis | Valeant Pharmaceuticals International, Inc. (Valeant) | Global, later amended to US | Initial \$100m milestone Pre-launch milestone up to \$170m Sales-related royalties up to \$175m | Development Pipeline |
| <u>19 March 2015</u> | Movantik | Daiichi Sankyo | US | Initial \$200m milestone Up to \$625m in Product Sales- related revenue | Preliminary Financial Statements |

Product Sales

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

| | | FY 2 | 2016 | | | Q4 2016 | |
|-------------------------------------|--------|-------|------|--------|-------|---------|--------|
| | \$m | % of | % ch | ange | \$m | % cł | nange |
| | φIII | Total | CER | Actual | φIII | CER | Actual |
| Oncology | | | | | | | |
| Iressa | 513 | 2 | (5) | (6) | 118 | (11) | (9) |
| Tagrisso | 423 | 2 | n/m | n/m | 147 | n/m | n/m |
| Lynparza | 218 | 1 | n/m | n/m | 62 | 72 | 72 |
| Legacy: | | | | | | | |
| Faslodex | 830 | 4 | 19 | 18 | 222 | 19 | 20 |
| Zoladex | 816 | 4 | - | - | 235 | 13 | 19 |
| Casodex | 247 | 1 | (9) | (7) | 60 | (8) | (5) |
| Arimidex | 232 | 1 | (6) | (7) | 57 | (7) | (5) |
| Others | 104 | - | (26) | (21) | 29 | - | 12 |
| Total Oncology | 3,383 | 16 | 20 | 20 | 930 | 26 | 30 |
| Cardiovascular & Metabolic Diseases | | | | | | | |
| Brilinta | 839 | 4 | 39 | 36 | 236 | 37 | 36 |
| Farxiga | 835 | 4 | 72 | 70 | 239 | 57 | 57 |
| Onglyza | 720 | 3 | (6) | (8) | 149 | (21) | (22) |
| Bydureon | 578 | 3 | - | - | 142 | (8) | (8) |
| Byetta | 254 | 1 | (19) | (20) | 55 | (22) | (24) |
| Legacy: | | | | | | | |
| Crestor | 3,401 | 16 | (32) | (32) | 631 | (53) | (52) |
| Seloken/Toprol-XL | 737 | 3 | 9 | 4 | 178 | 14 | 11 |
| Atacand | 315 | 1 | (8) | (13) | 81 | (5) | (6) |
| Others | 437 | 2 | (26) | (28) | 100 | (31) | (32) |
| Total Cardiovascular & Metabolic | 8,116 | 38 | (13) | (1.4) | 1,811 | (26) | (26) |
| Diseases | 0,110 | 30 | (13) | (14) | 1,011 | (20) | (20) |
| Respiratory | | | | | | | |
| Symbicort | 2,989 | 14 | (10) | (12) | 740 | (13) | (14) |
| Pulmicort | 1,061 | 5 | 8 | 5 | 288 | 8 | 5 |
| Tudorza/Eklira | 170 | 1 | (9) | (11) | 36 | (23) | (23) |
| Daliresp/Daxas | 154 | 1 | 48 | 48 | 41 | 28 | 28 |
| Duaklir | 63 | - | n/m | n/m | 19 | 58 | 58 |
| Others | 316 | 1 | 27 | 22 | 86 | 37 | 32 |
| Total Respiratory | 4,753 | 22 | (3) | (5) | 1,210 | (5) | (6) |
| Other | | | | | | | |
| Nexium | 2,032 | 10 | (18) | (19) | 491 | (15) | (13) |
| Seroquel XR | 735 | 3 | (27) | (28) | 118 | (51) | (51) |
| Synagis | 677 | 3 | 2 | 2 | 302 | 10 | 10 |
| Losec/Prilosec | 276 | 1 | (17) | (19) | 59 | (23) | (23) |
| FluMist/Fluenz | 104 | - | (59) | (64) | 67 | (60) | (65) |
| Movantik/Moventig | 91 | - | n/m | n/m | 26 | 73 | 73 |
| Others | 1,152 | 5 | (20) | (23) | 246 | (34) | (35) |
| Total Other | 5,067 | 24 | (19) | (20) | 1,309 | (25) | (25) |
| Total Product Sales | 21,319 | 100 | (8) | (10) | 5,260 | (15) | (15) |

Operating & Financial Review

Corporate & Business Development

Research & Development

Development Pipeline

Preliminary Financial Statements

AstraZeneca 😕 What science can do

ONCOLOGY

Full-year sales of \$3,383m; up by 20%. Oncology sales represented 16% of Total Product Sales.

Iressa (full-year sales of \$513m; down by 5%)

Sales in the US amounted to \$23m, with sales in Europe declining by 5% to \$120m. The Company prioritised the launch of *Tagrisso* in the year, given its potential impact for patients and the Company. Emerging Markets sales (defined in the Regional Product Sales section on page 13) declined by 10% to \$233m. China sales declined by 16% to \$116m, a result of a new price following national reimbursement listing obtained in June 2016. Strong competition from branded and generic medicines in Korea also contributed to the decline.

Tagrisso (full-year sales of \$423m)

In the second half of the year, sales of *Tagrisso* surpassed those of *Iressa*, with *Tagrisso* becoming the leading AstraZeneca medicine for the treatment of lung cancer. Regulatory approvals were granted in a number of markets, including Brazil, Hong Kong, Singapore, Taiwan and the United Arab Emirates; the Company anticipates additional regulatory approvals and reimbursement decisions in due course. To date, *Tagrisso* has received regulatory approval in 46 countries worldwide.

Sales in the US amounted to \$254m. After regulatory approval in the EU and Japan earlier in the year, sales in the year were \$76m in Europe and \$82m in Japan.

On 27 December 2016, a third-party, blood-based companion-diagnostic test for *Tagrisso* was approved in Japan. The test is designed to confirm the presence of a T790M mutation in patients. Similarly, the blood-based companion-diagnostic partner test for *Tagrisso* was approved in the US on 29 September 2016.

Lynparza (full-year sales of \$218m)

Lynparza was available to patients in 31 countries by the end of 2016, 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. Sales in the US increased by 81% in the year to \$127m; *Lynparza* now has a high market penetration. Sales in Europe increased to \$81m, following a number of successful launches.

Legacy: Faslodex (full-year sales of \$830m; up by 19%)

Sales in the US in the year increased by 23% to \$438m, mainly driven by an expanded label in March 2016 for 2nd-line advanced or metastatic breast cancer, in combination with palbociclib. Europe full-year sales increased by 11% to \$228m. An increase in demand in Japan led to sales growth of 12% to \$63m. China sales, up by 91% to \$20m, supported Emerging Markets sales of \$96m, representing an increase of 25%.

Legacy: Zoladex (full-year sales of \$816m; stable)

The stable performance was attributed to Europe sales (down by 4% to \$156m) and Established Rest Of World (ROW) sales (down by 7% to \$270m) being offset by favourable sales performances in the US (up by 25% to \$35m) and Emerging Markets (up by 6% to \$355m).

CARDIOVASCULAR & METABOLIC DISEASES

Full-year sales of \$8,116m; down by 13%.

Cardiovascular & Metabolic Diseases sales represented 38% of Total Product Sales.

Brilinta (full-year sales of \$839m; up by 39%)

Sales of *Brilinta* in the US were \$348m, representing an increase of 45%. The performance reflected updated preferred guidelines from the American College of Cardiology and the American Heart Association in the first half of the year; *Brilinta* remained the branded oral anti-platelet market leader in the US. *Brilinta*'s new-to-brand weekly prescription market share jumped to around 15% at the end of the year, representing an increase of around three percentage points.

Full-year sales of *Brilique* in Europe increased by 15% to \$258m, reflecting indication leadership across a number of markets. In the year, the German Institute for Quality and Efficiency in Healthcare (IQWiG) gave its assessment

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of the additional benefit from *Brilique* at the 60mg dose as tested in the PEGASUS trial, as did the National Institute for Health and Clinical Excellence in England, UK.

Emerging Markets full-year sales grew by 80% to \$189m, with China sales more than doubling. China represented 47% of Emerging Markets sales of the medicine at \$89m, despite it not being included on the National Reimbursement Drug List. The Company anticipates inclusion in due course. Growth was underpinned by a combination of strong levels of hospital-listing expansion and increased use in existing hospitals.

Farxiga (full-year sales of \$835m; up by 72%)

In the year, sales of *Farxiga* surpassed those of *Onglyza* and *Farxiga* became the leading AstraZeneca medicine for the treatment of diabetes, consolidating its position as global leader in the SGLT2 class.

Sales of *Farxiga* in the US increased by 75% to \$457m, primarily reflecting overall market growth and a higher net price. A stronger emphasis on promotional activity and improved levels of patient access resulted in market-share growth. Full-year sales of *Forxiga* in Europe increased by 52% to \$187m, as the medicine continued to lead the growing class. Emerging Markets sales increased by 96% to \$133m, driven by ongoing launches and improved access. In particular, strong performances were seen in the Asia-Pacific region (up by 108% to \$52m), Brazil (up by 50% to \$28m), and the Middle East, Africa & Others region (up to \$32m).

Onglyza (full-year sales of \$720m; down by 6%)

Sales in the US declined by 10% to \$376m, as the Company prioritised sales and marketing resources towards *Farxiga*. Continued competitive pressures in the DPP-4 class led to lower market share but were partially offset by reduced levels of utilisation of patient-access programmes. Full-year sales in Europe declined by 5% to \$132m and by 4% in Emerging Markets to \$142m, again reflecting the Company's focus on *Farxiga*.

In the quarter, global sales declined by 21%, due to adverse pressures on the DPP-4 class and reflecting an acceleration of the previously-mentioned market dynamics.

Bydureon/Byetta (full-year sales of \$832m; down by 7%)

Combined full-year US sales for *Bydureon/Byetta* were \$627m. *Bydureon* sales in the US declined by 4% to \$463m, representing 74% of total *Bydureon/Byetta* US sales. Around 75% of sales came from the new dualchamber pen compared to the prior tray presentation. The decline in US *Byetta* sales of 22% to \$164m was attributed to the Company's promotional focus on *Bydureon*. The decline in both *Bydureon* and *Byetta* US sales reflected lower net pricing; a regulatory submission for the new *Bydureon* autoinjector is anticipated in the US in the first half of 2017.

Full-year sales in Europe increased by 3% to \$145m, reflecting the Company's ongoing effort to expand its Diabetes presence. Full-year sales of *Byetta* and *Bydureon* in Emerging Markets increased by 13% to \$24m and decreased by 25% to \$4m, respectively. On 10 October 2016, AstraZeneca entered into a strategic collaboration with 3SBio Inc. (3SBio) for the rights to commercialise *Bydureon* and *Byetta* in the Chinese market. The agreement allowed the Company to benefit from 3SBio's established local expertise in injectable medicines as well as focus on its oral type-2 diabetes medicines.

Legacy: Crestor (full-year sales of \$3,401m; down by 32%)

In the US, *Crestor* full-year sales declined by 57% to \$1,223m, reflecting the market entry of *Crestor* generic medicines. Sales in the quarter declined by 88% to \$95m. In Europe, full-year sales declined by 4% to \$866m, reflecting the increasing use of generic medicines. In contrast, *Crestor* consolidated its position as the leading statin in Japan, with full-year sales stable at \$521m. Full-year sales in China grew by 27% to \$311m, while Russia sales grew by 28% to \$29m.

RESPIRATORY

Full-year sales of \$4,753m; down by 3%. Respiratory sales represented 22% of Total Product Sales.

Symbicort (full-year sales of \$2,989m; down by 10%)

Full-year sales in the US declined by 18% to \$1,242m. This primarily reflected the impact of the continued effects of pricing pressure from managed-care access within the ICS/LABA class. Competition also remained intense from other classes. In Europe, full-year sales declined by 12% to \$909m, primarily a result of competition from

branded and analogue medicines. The performance improved during the year, with Q4 2016 sales in Europe declining by only 3% to \$230m.

In contrast, full-year Emerging Markets sales grew by 10% to \$402m, reflecting sales growth in China of 32% to \$156m and Latin America (ex-Brazil) sales growth of 12% to \$37m.

Symbicort continued to lead the global market by volume within the class; the medicine provides a platform for the launch of *Bevespi* and potential launch of benralizumab.

Pulmicort (full-year sales of \$1,061m; up by 8%)

Pulmicort returned to being a blockbuster medicine in the year.

Strong underlying volume growth in Emerging Markets drove a 21% sales increase in that region to \$698m. Emerging Markets, representing 66% of *Pulmicort* sales, more than offset sales declines in the US, Europe and Established ROW. China sales increased by 24% to \$570m and represented 54% of sales of *Pulmicort*. Volume demand in China partly reflected the long-term increase in China of acute chronic obstructive pulmonary disease (COPD) and paediatric asthma. AstraZeneca continued its expansion of treatment centres and provided increased access to home-based patient-care systems.

Tudorza/Eklira (full-year sales of \$170m; down by 9%)

Sales in the US declined by 25% to \$77m, reflecting adverse market demand, limited Medicare Part D access and the focus on the launch of *Bevespi*. Sales in Europe increased by 9% to \$83m.

Daliresp/Daxas (full-year sales of \$154m; up by 48%)

Sales in the US increased by 29% to \$134m in the year, driven primarily by favourable market penetration. US sales represented 87% of global sales. ROW sales rights were added in May 2016 and, since completion, *Daxas* sales in Europe amounted to \$15m.

Duaklir (full-year sales of \$63m)

Duaklir has been launched successfully in excess of 25 countries; sales more than doubled in the year. This followed the strategic transaction with Almirall, S.A., which was completed in October 2014.

<u>Bevespi</u>

Bevespi Aerosphere inhalation aerosol was launched commercially in the US in January 2017 and is available in pharmacies for the long-term, maintenance treatment of airflow obstruction in patients with COPD. It is the only LAMA/LABA combination treatment to be delivered in a pressurised metered-dose inhaler (pMDI) and the first FDA-approved therapy to be formulated with AstraZeneca's co-suspension delivery technology, a focus of the Company's future-platform development for respiratory-disease combination therapies. *Bevespi* also demonstrated a 381mL improvement in peak inspiratory capacity, a potentially differentiating factor.

OTHER

Full-year sales of \$5,067m; down by 19%. Other sales represented 24% of Total Product Sales.

Nexium (full-year sales of \$2,032m; down by 18%)

Sales in the US declined by 39% to \$554m in the year, reflecting lower demand and inventory de-stocking, which followed the loss of exclusivity in 2015. Sales in Europe declined by 11% to \$251m, and Emerging Markets sales decreased 3% to \$690m. Japan sales declined by 4% to \$436m, reflecting the mandated biennial price reduction, effective from April 2016.

Seroquel XR (full-year sales of \$735m; down by 27%)

Sales of *Seroquel XR* in the US declined by 28% to \$515m in the year (Q4 2016: Down by 60% to \$71m). Since 1 November 2016, two companies have launched generic medicines in the US. Full-year sales of *Seroquel XR* in Europe declined by 32% to \$134m reflecting the impact of generic-medicine competition.

Synagis (full-year sales of \$677m; up by 2%)

Sales in the US increased by 14% to \$325m for the full year due to greater market demand. Sales to AbbVie Inc., which is responsible for the commercialisation of *Synagis* in over 80 countries outside the US, declined by 7% to \$352m.



<u>FluMist/Fluenz (full-year sales of \$104m; down by 59%)</u> The Company confirmed on 23 June 2016 that the Advisory Committee on Immunization Practices (ACIP) of the US Centers for Disease Control and Prevention had provided its interim recommendation not to use FluMist Quadrivalent Live Attenuated Influenza Vaccine (FluMist Quadrivalent) in the US for the 2016-2017 influenza season.

The Company wrote down the value of its inventory of FluMist by \$47m in the year, which was reflected within the Cost of Sales. Full-year sales of FluMist in the US declined by 84% to \$33m. Europe sales increased by 3% in the year to \$64m.

Regional Product Sales

| | | FY 2016 | | | | Q4 2016 | | | |
|-------------------------------|--------|---------------|-------------|-----------------|-------|-------------|----------------|--|--|
| | \$m | % of Total | % cł CER | nange Actual | \$m | % ch CER | ange Actual | | |
| US | 7,365 | 35 | (22) | (22) | 1,618 | (37) | (37) | | |
| Europe | 5,064 | 24 | (3) | (5) | 1,332 | (3) | (6) | | |
| Established ROW ¹ | 3,096 | 15 | (4) | 2 | 824 | (6) | 5 | | |
| Japan | 2,184 | 10 | (3) | 8 | 591 | (5) | 9 | | |
| Canada | 497 | 2 | (2) | (7) | 126 | (5) | (6) | | |
| Other Established ROW | 415 | 2 | (10) | (12) | 107 | (10) | (4) | | |
| Emerging Markets ² | 5,794 | 27 | 6 | - | 1,486 | 7 | 4 | | |
| China | 2,636 | 12 | 10 | 4 | 609 | 8 | 2 | | |
| Ex. China | 3,158 | 15 | 3 | (4) | 877 | 6 | 5 | | |
| Total | 21,319 | 100 | (8) | (10) | 5,260 | (15) | (15) | | |

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

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

US (full-year sales of \$7,365m; down by 22%)

The full-year decline in US sales reflected the competition from *Crestor* generic medicines that entered the US market from July 2016. Unfavourable managed-care pricing and continued competitive intensity also impacted sales of *Symbicort*.

Europe (full-year sales of \$5,064m; down by 3%)

Strong growth in sales of *Forxiga* (up by 52% to \$187m) and *Brilique* (up by 15% to \$258m) was more than offset by a 12% decline in *Symbicort* sales to \$909m. However, *Symbicort* maintained its position as the number one ICS/LABA medicine by volume, despite competition from branded and analogue medicines. *Lynparza* and *Tagrisso* sales increased to \$81m and \$76m respectively.

Established ROW (full-year sales of \$3,096m; down by 4%)

Full-year sales of *Forxiga* in Established ROW increased by 72% to \$58m. *Nexium* sales declined by 10% to \$537m.

Japan sales declined by 3% to \$2,184m, reflecting the biennial price reduction, effective from April 2016, of around 6%. The decline was partly mitigated by stable sales of *Crestor* of \$521m in the year. Since the launch of *Tagrisso* in Japan in May 2016, sales amounted to \$82m.

Emerging Markets (full-year sales of \$5,794m; up by 6%) Emerging Markets, representing 27% of global Product Sales, is the second-largest sales region for AstraZeneca.

Sales growth for the year in Emerging Markets was impacted by challenging macro-economic conditions in Latin America, where ex-Brazil full-year sales declined by 7% to \$516m. The effect of reductions in Saudi Arabian governmental healthcare spending, as well as the reduction of AstraZeneca's activities in Venezuela, also adversely impacted sales. China sales, however, grew by 10% to \$2,636m, representing 45% of Emerging Markets sales in the year.

Sales in Brazil increased by 2% to \$348m, reflecting the strong performances of *Forxiga* (up by 50% to \$28m), Oncology medicines (up by 1% to \$82m) and *Seloken* (up by 6% to \$63m). Russia sales increased by 13% to \$233m, led by strong performances in Cardiovascular & Metabolic Diseases medicine sales (up by 38% to \$80m).



A number of AstraZeneca medicines were externalised or disposed of in the year, adversely impacting the level of Product Sales:

| Medicine | Region | Externalisation / Disposal Completion Date | FY 2015 Impacted Region Product Sales (\$m) |
|--|-------------------|---|---|
| <u>Bydureon &</u> <u>Byetta</u> | China | 11 October 2016 | 15 |
| Anaesthetics | Global (excl. US) | 1 September 2016 | 594 |
| <u>Plendil</u> | China | 29 February 2016 | 189 |
| <u>Moventig</u> | Europe | 1 March 2016 | 1 |
| <u>Toprol-XL</u> | US | 31 October 2016 | 89 |
| <u>Imdur</u> | Global (excl. US) | 3 May 2016 | 55 |
| Total | | | 943 |

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Financial Performance

| | Repo | orted | % cł | nange | Co | re | % change | |
|---------------------------|------------|------------|------|--------|------------|------------|----------|--------|
| Year | FY 2016 | FY 2015 | CER | Actual | FY 2016 | FY 2015 | CER | Actual |
| Product Sales | 21,319 | 23,641 | (8) | (10) | 21,319 | 23,641 | (8) | (10) |
| Externalisation Revenue | 1,683 | 1,067 | 59 | 58 | 1,683 | 1,067 | 59 | 58 |
| Total Revenue | 23,002 | 24,708 | (5) | (7) | 23,002 | 24,708 | (5) | (7) |
| Cost of Sales | (4,126) | (4,646) | (7) | (11) | (3,872) | (4,119) | (2) | (6) |
| Gross Profit | 18,876 | 20,062 | (5) | (6) | 19,130 | 20,589 | (6) | (7) |
| Gross Margin ¹ | 80.8% | 80.3% | -0.1 | +0.5 | 82.0% | 82.6% | -1.1 | -0.6 |
| Distribution Expense | (326) | (339) | 1 | (4) | (326) | (339) | 1 | (4) |
| % Total Revenue | 1.4% | 1.4% | - | - | 1.4% | 1.4% | - | - |
| R&D Expense | (5,890) | (5,997) | 2 | (2) | (5,631) | (5,603) | 5 | - |
| % Total Revenue | 25.6% | 24.3% | -2 | -1 | 24.5% | 22.7% | -2 | -2 |
| SG&A Expense | (9,413) | (11,112) | (12) | (15) | (8,169) | (9,265) | (9) | (12) |
| % Total Revenue | 40.9% | 45.0% | +3 | +4 | 35.5% | 37.5% | +1 | +2 |
| Other Operating Income | 1,655 | 1,500 | 12 | 10 | 1,717 | 1,520 | 14 | 13 |
| % Total Revenue | 7.2% | 6.1% | +1 | +1 | 7.5% | 6.2% | +1 | +1 |
| Operating Profit | 4,902 | 4,114 | 9 | 19 | 6,721 | 6,902 | (7) | (3) |
| % Total Revenue | 21.3% | 16.7% | +3 | +5 | 29.2% | 27.9% | - | +1 |
| Net Finance Expense | (1,317) | (1,029) | 37 | 28 | (661) | (505) | 46 | 31 |
| Joint Ventures | (33) | (16) | | | (33) | (16) | | |
| Profit Before Tax | 3,552 | 3,069 | - | 16 | 6,027 | 6,381 | (11) | (6) |
| Taxation | (146) | (243) | | | (658) | (990) | | |
| Tax Rate % | 4% | 8% | | | 11% | 16% | | |
| Profit After Tax | 3,406 | 2,826 | 6 | 21 | 5,369 | 5,391 | (6) | - |
| Non-controlling Interests | 93 | (1) | | | 86 | (1) | | |
| Net Profit | 3,499 | 2,825 | 9 | 24 | 5,455 | 5,390 | (5) | 1 |
| Weighted Average Shares | 1,265 | 1,264 | | | 1,265 | 1,264 | | |
| Earnings Per Share (\$) | 2.77 | 2.23 | 9 | 24 | 4.31 | 4.26 | (5) | 1 |

¹ Gross Margin reflects Gross Profit derived from Product Sales, divided by Product Sales ² All financial figures, except Earnings Per Share, are in \$ millions (\$m). Weighted Average Shares are in millions.

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| | Repo | orted | % ch | ange | Со | .e | % ch | ange |
|---------------------------|------------|------------|------|--------|------------|------------|------|--------|
| Quarter | Q4 2016 | Q4 2015 | CER | Actual | Q4 2016 | Q4 2015 | CER | Actual |
| Product Sales | 5,260 | 6,207 | (15) | (15) | 5,260 | 6,207 | (15) | (15) |
| Externalisation Revenue | 325 | 192 | 77 | 69 | 325 | 192 | 77 | 69 |
| Total Revenue | 5,585 | 6,399 | (12) | (13) | 5,585 | 6,399 | (12) | (13) |
| Cost of Sales | (1,160) | (1,269) | (2) | (9) | (1,087) | (1,209) | (4) | (10) |
| Gross Profit | 4,425 | 5,130 | (15) | (14) | 4,498 | 5,190 | (14) | (13) |
| Gross Margin ¹ | 77.9% | 79.6% | -3.1 | -1.7 | 79.3% | 80.5% | -2.6 | -1.2 |
| Distribution Expense | (83) | (99) | (11) | (16) | (83) | (99) | (11) | (16) |
| % Total Revenue | 1.5% | 1.5% | - | - | 1.5% | 1.5% | - | - |
| R&D Expense | (1,543) | (1,746) | (5) | (12) | (1,481) | (1,567) | 2 | (5) |
| % Total Revenue | 27.6% | 27.3% | -2 | - | 26.5% | 24.5% | -4 | -2 |
| SG&A Expense | (1,386) | (2,668) | (44) | (48) | (2,050) | (2,461) | (14) | (17) |
| % Total Revenue | 24.8% | 41.7% | +15 | +17 | 36.7% | 38.5% | +1 | +2 |
| Other Operating Income | 1,120 | 471 | n/m | n/m | 1,142 | 493 | n/m | n/m |
| % Total Revenue | 20.1% | 7.4% | +13 | +13 | 20.4% | 7.7% | +13 | +13 |
| Operating Profit | 2,533 | 1,088 | n/m | n/m | 2,026 | 1,556 | 15 | 30 |
| % Total Revenue | 45.4% | 17.0% | +23 | +28 | 36.3% | 24.3% | +8 | +12 |
| Net Finance Expense | (339) | (279) | 36 | 22 | (172) | (150) | 36 | 15 |
| Joint Ventures | (11) | (7) | | | (11) | (7) | | |
| Profit Before Tax | 2,183 | 802 | n/m | n/m | 1,843 | 1,399 | 13 | 32 |
| Taxation | (366) | 6 | | | (333) | (200) | | |
| Tax Rate % | 17% | (1)% | | | 18% | 14% | | |
| Profit After Tax | 1,817 | 808 | 91 | n/m | 1,510 | 1,199 | 7 | 26 |
| Non-controlling Interests | 25 | - | | | 23 | - | | |
| Net Profit | 1,842 | 808 | 94 | n/m | 1,533 | 1,199 | 9 | 28 |
| Weighted Average Shares | 1,265 | 1,264 | | | 1,265 | 1,264 | | |
| Earnings Per Share (\$) | 1.46 | 0.63 | 93 | n/m | 1.21 | 0.94 | 9 | 29 |

¹ Gross Margin reflects Gross Profit derived from Product Sales, divided by Product Sales ² All financial figures, except Earnings Per Share, are in \$ millions (\$m). Weighted Average Shares are in millions

Corporate & Business Development

Research & Development

Operating & Financial Review



Reconciliation Of Reported To Core Performance

| FY 2016 | Reported | Restructuring | Intangible Asset Amortisation & Impairments | Diabetes Alliance | Other ¹ | Core |
|---------------------------|----------|---------------|---|----------------------|--------------------|---------|
| | \$m | \$m | \$m | \$m | \$m | \$m |
| Cost of Sales | (4,126) | 130 | 124 | - | - | (3,872) |
| R&D Expense | (5,890) | 178 | 81 | - | - | (5,631) |
| SG&A Expense | (9,413) | 823 | 1,000 | (627) | 48 | (8,169) |
| Other Operating Income | 1,655 | (24) | 86 | - | - | 1,717 |
| Net Finance Expense | (1,317) | - | - | 389 | 267 | (661) |
| Taxation | (146) | (232) | (307) | 23 | 4 | (658) |
| Non-controlling Interests | 93 | (7) | - | - | - | 86 |
| Total | | 868 | 984 | (215) | 319 | |

| Q4 2016 | Reported \$m | Restructuring \$m | Intangible Asset Amortisation & Impairments \$m | Diabetes Alliance \$m | Other ¹ \$m | Core \$m |
|---------------------------|-----------------|----------------------|--|-----------------------------|---------------------------|----------------|
| Cost of Sales | (1,160) | 43 | 30 | φili | - - | ۹۱۱ (1,087) |
| CUSE OF Sales | (1,100) | 43 | | - | - | (1,007) |
| R&D Expense | (1,543) | 32 | 30 | - | - | (1,481) |
| SG&A Expense | (1,386) | 319 | 246 | (938) | (291) | (2,050) |
| Other Operating Income | 1,120 | - | 22 | - | - | 1,142 |
| Net Finance Expense | (339) | - | - | 97 | 70 | (172) |
| Taxation | (366) | (82) | (86) | 162 | 39 | (333) |
| Non-controlling Interests | 25 | (2) | - | - | - | 23 |
| Total | | 310 | 242 | (679) | (182) | |

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



Profit And Loss Commentary

Gross Profit

Reported Gross Profit declined by 5% in the year to \$18,876m reflecting the market entry of *Crestor* generic medicines in the US. Excluding the impact of Externalisation Revenue, the Reported Gross Profit Margin was broadly stable at 80.8%, with lower restructuring and amortisation charges offset by an adverse impact from the mix of sales and a write-down of *FluMist* inventory in the US. Excluding these lower restructuring and amortisation charges, Core Gross Profit declined by 6% in the year to \$19,130m and, excluding the impact of externalisation, the Core Gross Profit margin declined by one percentage point to 82.0%.

In the quarter, Reported Gross Profit declined by 15% to \$4,425m and Reported Gross Margin declined by three percentage points to 77.9%. Excluding restructuring and amortisation charges, Core Gross Profit declined by 14% to \$4,498m and the Core Gross Margin declined by three percentage points to 79.3%.

Operating Expenses: R&D

Reported R&D costs increased by 2% in the year to \$5,890m (Q4 2016: \$1,543m, a decline of 5%). The full-year increase reflected the number of potential new medicines in pivotal trials as well as the absorption of the R&D costs of ZS Pharma and Acerta Pharma. These costs were partially offset by lower restructuring costs and impairment charges. Without the impact of ZS Pharma and Acerta Pharma, Reported R&D costs in the year would have declined by 3%.

Excluding the impact of lower restructuring and impairment charges, Core R&D costs increased by 5% in the year to \$5,631m (Q4 2016: \$1,481m, an increase of 2%). Without the impact of the previously-mentioned investments in ZS Pharma and Acerta Pharma, Core R&D costs in the year would have declined by 1%. This compares to the 21% increase in Core R&D costs in FY 2015.

Operating Expenses: SG&A

Reported SG&A costs declined by 12% in the year to \$9,413m, reflecting the evolving shape of the business. The decline was also driven by efficiency savings in sales and marketing operations and further reductions in IT costs. These actions included a material reduction in the sales and head-office structure in the US marketing business. Reported SG&A costs declined by 44% in the quarter to \$1,386m, reflecting the fair-value adjustment to acquisition-related liabilities.

Core SG&A costs declined by 9% in the year to \$8,169m, in line with full-year expectations of a material reduction. Core SG&A costs declined by 14% in the quarter to \$2,050m.

Other Operating Income

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

\$m Sale of the small-molecule antibiotics business to 368 Pfizer net of carrying values disposed and other costs to sell Sale of the ex-US rights to Rhinocort Aqua to Cilag 321 GmbH International (Cilag) Sale of ex-US rights of Imdur 183 Crestor royalties 165 Out-licensing of a potential medicine (MEDI2070) 148 for inflammatory diseases to Allergan plc (Allergan) net, reflecting an agreement with Amgen Inc. (Amgen) **HPV** royalties 134 Other 336 Total 1,655

Reported Other Operating Income of \$1,655m in the year included:



Reported Operating Profit increased by 9% in the year to \$4,902m. The Reported Operating Margin increased by three percentage points to 21% of Total Revenue.

Core Operating Profit declined by 7% in the year to \$6,721m. The Core Operating Margin was stable at 29% of Total Revenue.

Net Finance Expense

Reported Net Finance Expense increased by 37% in the year to \$1,317m, reflecting an increase in Net Debt that was driven by the acquisition of ZS Pharma and the majority investment in Acerta Pharma. Excluding the discount unwind on acquisition-related liabilities, Core Net Finance Expense increased by 46% in the year to \$661m.

Taxation

Excluding a one-off benefit of \$453m following agreements between the Canadian tax authority and the UK and Swedish tax authorities in respect of transfer pricing arrangements for the 13-year period from 2004-2016, the Reported and Core tax rates for the year were 17% and 18% respectively. Including the impact of this benefit, the Reported and Core tax rates for the year were 4% and 11% respectively. The cash tax paid for the year was \$412m, which was 12% of Reported Profit Before Tax and 7% of Core Profit Before Tax.

The Reported and Core tax rates in FY 2015 were 22% and 21% respectively when excluding a one-off tax benefit of \$186m following the agreement of US federal tax liabilities of open years up to 2008, other provision releases and the benefit of the UK patent box. Including the impact of these benefits, the Reported and Core tax rates in FY 2015 were 8% and 16% respectively.

Earnings Per Share (EPS)

Reported EPS of \$2.77 in the year represented growth of 9%; this included a gain of \$0.76 on the revaluation of acquisition-related liabilities. Core EPS in the year declined by 5% to \$4.31, driven by the same rate of decline in Total Revenue. Both Reported and Core EPS in the year included a non-recurring benefit of \$0.36, following the previously-mentioned agreements between the Canadian tax authority and the UK and Swedish tax authorities.

Dividends

The Board has declared a second interim dividend of \$1.90 per share (150.2 pence, 16.57 SEK) bringing the dividend per share for the full year to \$2.80 (218.9 pence, 24.38 SEK). The Board reaffirms its commitment to the Company's progressive dividend policy.

For holders of the Company's American Depositary Shares (ADSs), the \$1.90 per Ordinary Share equates to \$0.95 per ADS. Two ADSs equal one Ordinary Share.

Productivity

AstraZeneca's evolution and the changing shape of the business have enabled productivity improvements through the implementation of restructuring initiatives. These included those announced on 29 April 2016. Restructuring charges of \$1,107m were incurred in the year. The Company remains on track to realise benefits and incur costs in line with prior announcements.

Cash Flow And Balance Sheet

Cash Flow

The Company generated a net cash inflow from operating activities of \$4,145m in the year, compared with \$3,324m in the comparative period. The increase reflected improved cash management performance and one-off tax refunds.

Net cash outflows from investing activities were \$3,969m compared with \$4,239m in the comparative period. The outflows partly reflected the net cash outflow of \$2,383m in relation to the majority investment in Acerta Pharma, as well as \$1,446m for the purchase of property, plant and equipment.

Net cash outflows from financing activities were \$1,324m, incorporating \$2,491m of new long-term loans, net of dividend payments in the year of \$3,561m. This compared to an inflow of \$878m in the comparative period.



The cash payment of contingent consideration in respect of the Bristol-Myers Squibb Company share of the global Diabetes alliance amounted to \$242m in the year. The consideration is based on a tiered structure, whereby a higher royalty rate is applied until a specified level of sales is achieved in the year; thereafter a lower rate is applied to the remaining sales in the year and settled in the guarter following the application of the charge. From FY 2017 a single annual rate will be applied.

Capital Expenditure

Capital expenditure amounted to \$1,449m in the year, representing an increase of 3%; the majority of capital expenditure was in maintenance. Investment in AstraZeneca's return to growth continued, with an element of capital expenditure split between expansion of biologics manufacturing capacity and the impending completion of the R&D centre and global headquarters in Cambridge, UK.

Debt and Capital Structure

At 31 December 2016, outstanding gross debt (interest-bearing loans and borrowings) was \$16,808m (31 December 2015; \$15.053m). Of the gross debt outstanding at 31 December 2016. \$2.307m was due within one year (31 December 2015: \$916m). The Company's net debt position at 31 December 2016 was \$10,657m (31 December 2015: \$7,762m).

Shares in Issue

During the year, 1.1 million shares were issued in respect of share option exercises for consideration of \$47m. The total number of shares in issue as at 31 December 2016 was 1,265 million.

Capital Allocation

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

Sensitivity: Foreign-Exchange Rates

The Company provides the following currency sensitivity information:

| | | Average Exchange Rates Versus USD | | | Impact Of 5% Strengthening In Exchange Rate Versus USD (\$m) ² | | |
|--------------------|----------------------|---|--------------------------|-------------|---|-----------------------------|--|
| Currency | Primary Relevance | FY 2016 | YTD 2017 ¹ | change % | Total Revenue | Core Operating Profit | |
| EUR | Product Sales | 0.90 | 0.94 | -4% | +179 | +123 | |
| JPY | Product Sales | 108.84 | 115.14 | -5% | +104 | +71 | |
| CNY | Product Sales | 6.65 | 6.87 | -3% | +131 | +74 | |
| SEK | Costs | 8.56 | 8.97 | -5% | +7 | -98 | |
| GBP | Costs | 0.74 | 0.81 | -9% | +29 | -131 | |
| Other ³ | | | | | +194 | +124 | |

¹Based on average daily spot rates between 1st January and 30th January 2017

²Based on 2016 actual results at 2016 actual exchange rates

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

Currency Hedging

AstraZeneca monitors the impact of adverse currency movements on a portfolio basis, recognising correlation effects. The Company may hedge to protect against adverse impacts on cash flow over the short to medium term. As at 31 December 2016, 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) Sale Of Small-Molecule Antibiotics Business

On 24 August 2016, the Company announced that it had entered into an agreement with Pfizer to sell the commercialisation and development rights to its small-molecule antibiotics business and late-stage pipeline in most markets outside the US. The transaction closed in the quarter. As AstraZeneca will not maintain a significant ongoing interest in the late-stage, small-molecule antibiotics business, all payments were and will be reported as Other Operating Income in the Company's financial statements. This includes the upfront payment of \$550m and an unconditional payment of \$175m in 2019 (both recognised net of the carrying value of assets disposed and other costs to sell in 2016). The future payments include the milestones of up to \$250m, sales-related payments of up to \$600m and recurring double-digit royalties on sales of *Zavicefta* and ATM AVI.

b) Sale Of Respiratory Medicine Rhinocort Aqua (Nasal Spray)

On 7 October 2016, the Company announced that it had entered an agreement with Cilag, an affiliate of Johnson & Johnson, for the divestment of the rights to *Rhinocort Aqua* outside the US. The transaction closed in the quarter.

c) Externalisation Of Beta-Blocker Medicine Toprol-XL

On 31 October 2016, the Company completed an agreement with Aralez Pharmaceuticals Trading DAC, a subsidiary of Aralez Pharmaceuticals Inc., for the rights to branded and authorised generic *Toprol-XL* (metoprolol succinate) in the US. AstraZeneca will retain a significant ongoing interest in *Toprol-XL* through retained ownership of the medicine in ROW markets and product supply to Aralez. Therefore, the upfront payment of \$175m, milestones and sales-related payments of up to \$48m and mid-teen percentage royalties was and will be reported as Externalisation Revenue in the Company's financial statements.

d) Licensing Agreement: Monoclonal Antibody MEDI2070 (Crohn's Disease)

On 3 October 2016, the Company announced that MedImmune, its global biologics research and development arm, had entered a licensing agreement with Allergan for the global rights to MEDI2070 (moderate-to-severe Crohn's disease). The transaction closed in the quarter. AstraZeneca retained \$148m of the upfront payment and will retain up to approximately \$847m in future potential milestones, as well as the tiered royalty payments of up to low double-digit percent, following payment to Amgen under the provisions of the original agreement.

e) Externalisation Of Diabetes Medicines Bydureon And Byetta In China

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

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

f) MEDI1814 (Alzheimer's Disease)

AstraZeneca continues to collaborate with Lilly in the development of medicines for patients impacted by Alzheimer's disease (AD). Building on the current collaboration for the BACE inhibitor, AZD3293, currently in two Phase III trials, the companies are now also co-developing MEDI1814, an antibody selective for amyloid-beta 42 (Aβ42), which is currently in Phase I development as a potential disease-modifying treatment for AD. The build-up of plaque in the brain containing the peptide amyloid-beta (Aβ) is one of the pathological hallmarks of AD. MEDI1814 binds selectively to Aβ42, which is believed to be a more toxic Aβ species. In pre-clinical models, MEDI1814 dose-dependently reduces levels of this peptide, potentially slowing the progression of AD.



g) Senior Executive Team Changes

In January 2017, Leon Wang was appointed to the newly-created SET role of Executive Vice-President, Asia Pacific, with responsibility for the Company's activities in China and Hong Kong, Asia Area, Australia and New Zealand. Leon joined AstraZeneca China in 2013 as a Vice-President and became President in 2014. Under his leadership China became AstraZeneca's second-largest market worldwide. Leon has twenty years of experience in the pharmaceutical industry.

As Executive Vice-President, International West, Mark Mallon retains responsibility for AstraZeneca's businesses in Russia, Latin America, and the Middle East and Africa in addition to his role as EVP, Global Product and Portfolio Strategy, Global Medical Affairs & Corporate Affairs.

It was announced in January 2017 that Luke Miels, formerly Executive Vice-President, Europe would leave AstraZeneca to take up a senior position with a main competitor.

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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 10 November 2016 (the period):

| Regulatory Submission Acceptances | 8 | durvalumab - bladder cancer (US) <i>Tagrisso</i> - lung cancer (AURA3 trial) (US, EU) <i>Faslodex</i> - breast cancer (1L) (US, EU) roxadustat - anaemia (CN) (rolling submission) benralizumab - severe, uncontrolled asthma (US, EU) |
|---|-----|--|
| Other Key Developments | 2 | Priority Review Designation: durvalumab (US) Priority Review Designation: <i>Tagrisso</i> (US) |
| New Molecular Entities (NMEs) In Phase III Trials Or Under Regulatory Review*# | 12 | Oncology durvalumab* - multiple cancers durva + treme - multiple cancers acalabrutinib - blood cancers moxetumomab pasudotox - leukaemia selumetinib - thyroid cancer Cardiovascular & Metabolic Diseases ZS-9* - hyperkalaemia roxadustat* - anaemia Respiratory benralizumab* - severe, uncontrolled asthma tralokinumab - severe, uncontrolled asthma PT010 - COPD Other anifrolumab - lupus AZD3293 - Alzheimer's disease |
| Projects in clinical pipeline [#] #As at 2 February 2017 | 120 | |

#As at 2 February 2017



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 two have already been launched (*Lynparza* and *Tagrisso*). A broad pipeline of small molecules and biologics is in development and the Company is committed to advancing Oncology as one of AstraZeneca's Growth Platforms primarily focused on lung, ovarian, breast and blood cancers.

In addition to its own existing cancer medicine capabilities, the Company is actively pursuing innovative collaborations and investments that are designed to accelerate the delivery of AstraZeneca's strategy, as illustrated by the Company's majority investment in Acerta Pharma in haematology that closed in 2016.

At three recent medical meetings, ASH (American Society of Hematology), WCLC (World Conference on Lung Cancer) and the San Antonio Breast Cancer Symposium, AstraZeneca highlighted its continued momentum in Oncology with a total of 50 abstracts, including 15 oral presentations. Abstracts and presentations provided a comprehensive update on recent data from *Faslodex*, *Iressa*, *Tagrisso* and the Company's emerging presence in blood cancers, through acalabrutinib.

a) Faslodex (breast cancer)

During the period, the Company received regulatory submission acceptances for *Faslodex* in 1st-line metastatic breast cancer in the US and the EU. The submissions were based on the Phase III FALCON trial that compared *Faslodex* 500mg to *Arimidex* 1mg for the treatment of locally-advanced or metastatic breast cancer, in post-menopausal women who have not had prior hormonal treatment for hormone receptor-positive breast cancer. *Faslodex* demonstrated superiority compared with *Arimidex* and met its primary endpoint of extended progression-free survival (PFS).

b) Tagrisso (lung cancer)

In December 2016, data from the AURA3 trial were presented at WCLC. AURA3 was the first randomised and controlled trial for *Tagrisso* and tested the medicine in 2nd-line treatment of patients with epidermal growth factor receptor (EGFR) T790M mutation-positive locally-advanced or metastatic NSCLC against standard-of-care (SoC) platinum-based doublet chemotherapy. The trial showed that *Tagrisso* significantly improved PFS by 5.7 months with a hazard ratio of 0.30 (equal to a risk reduction of 70%).

Additionally, in the 34% of patients with central nervous system (CNS) metastases at baseline, PFS was also significantly greater (4.3 months, hazard ratio 0.32) with *Tagrisso*. The medicine's ability to provide benefit in patients with CNS metastases is encouraging and *Tagrisso* continues to be tested in the BLOOM trial. Based on results from AURA3, regulatory submissions were made in the US and EU during the period; acceptances were received on both submissions and Priority Review Designation was obtained in the US.

c) Durvalumab (multiple cancers)

In December 2016, AstraZeneca received FDA acceptance with Priority Review status of the Biologics License Application (BLA) for durvalumab in patients with locally-advanced or metastatic urothelial carcinoma, whose disease has progressed during or after one standard platinum-based regimen. This acceptance was based on the results of the urothelial cancer cohort of Study 1108 and follows the FDA's Breakthrough Therapy Designation for durvalumab in bladder cancer in February 2016. The Prescription Drug User Fee Act (PDUFA) date is in the second quarter of 2017.

The Company is also advancing durvalumab alone and in combination with tremelimumab in bladder cancer.

Operating & Financial Review



METASTATIC UROTHELIAL BLADDER CANCER

| Name | Phase | Line of Treatment | Population | Design | Timelines | Status |
|-------------|---------|----------------------|---|--|--|---------|
| Combination | therapy | | | | | |
| DANUBE | 111 | 1st Line | Cisplatin chemo- therapy- eligible/ ineligible bladder cancer | durvalumab, durva + treme vs SoC chemotherapy | FPD ¹ Q4 2015 First data anticipated 2018 | Ongoing |

The Company continues to advance multiple monotherapy trials of durvalumab and combination trials of durvalumab with tremelimumab and other potential new medicines in Immuno-Oncology (IO). An update on key AstraZeneca-sponsored ongoing trials with durvalumab outside bladder cancer is provided below:

LUNG CANCER

| Name | Phase | Line of Treatment | Population | Design | Timelines | Status |
|-----------------------|--------|----------------------|------------------------------------|--|--|--------------------------|
| Monotherapy | | | | | | |
| ADJUVANT ² | | N/A | Stage lb-IIIa NSCLC | durvalumab vs placebo | FPD Q1 2015 First data anticipated 2020 | Ongoing |
| PACIFIC | 111 | N/A | Stage III unresectable NSCLC | durvalumab vs placebo | FPD Q2 2014 LPCD ³ Q2 2016 First data anticipated H2 2017 | Recruitment completed |
| PEARL | 111 | 1st line | NSCLC (Asia) | durvalumab vs SoC chemotherapy | First data anticipated 2020 | Initiating |
| Combination th | nerapy | | - | · | | |
| MYSTIC | | 1st line | NSCLC | durvalumab, durva + treme vs SoC chemotherapy | FPD Q3 2015 LPCD Q3 2016 First data anticipated mid-2017 | Recruitment completed |
| NEPTUNE | III | 1st line | NSCLC | durva + treme vs SoC chemotherapy | FPD Q4 2015 First data anticipated 2018 | Ongoing |

Operating & Financial Review

| - | | 1st line | NSCLC | durvalumab + chemotherapy +/- tremelimumab | - | Ongoing in safety lead-in Phase I/II trial |
|---------|-----|----------|---------------------------|---|---|--|
| ARCTIC | | 3rd line | PD-L1 neg. NSCLC | durvalumab, tremelimumab, durva + treme vs SoC chemotherapy | FPD Q2 2015 LPCD Q3 2016 First data anticipated H1 2017 | Recruitment completed |
| CASPIAN | 111 | 1st line | Small-cell lung cancer | durvalumab + SoC, durva + treme + SoC vs SoC chemotherapy | - | Initiating |

¹ FPD = First Patient Dosed

² Conducted by the National Cancer Institute of Canada

³LPCD = Last Patient Commenced Dosing

On 17 January 2017, the Company provided an update on its late-stage IO clinical-development programme in 1st-line NSCLC, including a refinement of the Phase III MYSTIC trial. The trial was initially designed to assess the benefit of durvalumab monotherapy and durvalumab and tremelimumab (durva + treme) combination therapy versus SoC chemotherapy, focused on PFS.

The MYSTIC trial will now assess PFS and overall survival (OS) endpoints in patients with PDL1-expressing tumours for both durvalumab monotherapy and the combination of durva + treme, as well as in 'all comers' for the combination of durva + treme, versus SoC chemotherapy. While the focus remains on exploring the benefit of durva + treme as combination therapy, the Company has updated the endpoints of the MYSTIC trial to include OS and PFS in durvalumab monotherapy. This is based on recent internal and external data, including durvalumab's strong efficacy in monotherapy presented at recent medical meetings, as well as significant opportunities in the competitive landscape.

The estimated primary completion date was updated to reflect both an increase in patient recruitment (as reported in February 2016 with the inclusion of OS as a co-primary endpoint) and the event-based nature of the trial. As a result, the Company anticipates MYSTIC PFS data in mid-2017 and final OS data, at the latest, in 2018. MYSTIC also includes several undisclosed interim analyses for OS.

Additionally, the ongoing Phase III NEPTUNE trial will be expanded with local patients to support regulatory submission of durva + treme combination therapy in China for 1st-line NSCLC patients, without delaying the anticipated OS data readout in 2018 from the global cohort, which is approaching full recruitment. The Company has also initiated the new Phase III PEARL trial of durvalumab monotherapy versus SoC chemotherapy in 1st-line NSCLC patients, whose tumours express PD-L1. The PEARL trial focuses on Asian countries, primarily China, due to the prevalence of NSCLC in the region.

At WCLC, AstraZeneca presented safety findings from the safety lead-in Phase Ib trial of durvalumab with or without tremelimumab in combination with doublet chemotherapy. The conclusion of this trial was that in a PD-L1 unselected patient population, durvalumab and tremelimumab can be safely combined with full doses of pemetrexed/cisplatin chemotherapy.

Operating & Financial

AstraZeneca 😕 What science can do

METASTATIC OR RECURRENT HEAD AND NECK CANCER

| Name | Phase | Line of Treatment | Population | Design | Timelines | Status | | | |
|----------------|---------------------|----------------------|------------|--|--|---------|--|--|--|
| Combination th | Combination therapy | | | | | | | | |
| KESTREL | | 1st line | HNSCC* | durvalumab, durva + treme vs SoC | FPD Q4 2015 First data anticipated H2 2017 | Ongoing | | | |
| EAGLE | 111 | 2nd line | HNSCC | durvalumab, durva + treme vs SoC | FPD Q4 2015 First data anticipated 2018 | Ongoing | | | |

*Head and Neck Squamous Cell Carcinoma

As communicated on 15 December 2016, the Company has reviewed data from the CONDOR trial, a randomised, but non-controlled Phase II trial in 2nd-line PDL1-negative HNSCC patients. While the data show efficacy and safety of the experimental medicines, AstraZeneca does not believe that a non-controlled trial can facilitate a regulatory submission for accelerated approval in a setting where a PD1-targeted medicine was approved during 2016, based on an OS benefit in all-comers.

On 22 November 2016, AstraZeneca announced that the FDA had lifted the partial clinical hold on the enrolment of new patients with HNSCC for clinical trials of durvalumab as monotherapy and in combination with tremelimumab or other potential new medicines. The partial clinical hold on new patient enrolment was communicated on 27 October 2016, after preliminary findings from ongoing clinical trials related specifically to HNSCC. The FDA lifted the hold following a review of the comprehensive analysis provided by AstraZeneca of bleeding events that were observed as part of the routine safety monitoring of the Phase III KESTREL and EAGLE trials.

d) Acalabrutinib (blood cancers)

Less than a year after announcing a majority investment in Acerta Pharma, AstraZeneca provided new clinical data on acalabrutinib, a highly-selective, potent Bruton tyrosine-kinase (BTK) inhibitor in Phase III development for B-cell malignancies. At the 2016 ASH annual meeting, two oral presentations were shared on acalabrutinib, in patients with Richter's transformation and in patients with ibrutinib intolerance, both Phase I/II trials.

In patients with Richter's transformation, acalabrutinib monotherapy produced a partial or complete response in 38% of patients, with a median time on treatment of 3.4 months. In 21 Richter-transformation patients evaluable for efficacy measures in the trial, median PFS was 2.1 months and the median duration of response was 5.2 months. Acalabrutinib monotherapy demonstrated a tolerable safety profile in patients with Richter's transformation and these data suggested that further investigation, in combination with immunotherapy or other targeted therapies, is warranted.

Acalabrutinib was well tolerated in ibrutinib-intolerant patients, with a total of 12 of 33 (36%) patients experiencing adverse event (AE) recurrence, most of which reduced or had the same severity as before; no patients discontinued treatment because of a recurrent AE. This safety profile was coupled with promising activity (objective response rate of 79%) and response duration (81% of responding patients had a duration of response ≥12 months).

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Preliminary Financial

Statements



CARDIOVASCULAR & METABOLIC DISEASES

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

a) Bydureon (type-2 diabetes)

During the period, the DURATION-7 trial met its primary endpoint of a reduction in blood glucose (HbA1c) at 28 weeks as well as key secondary endpoints. No new safety findings were observed and the overall rates of AEs and serious AEs were low in both groups.

DURATION-7 was a multi-centre, randomised, double-blind, placebo-controlled, parallel group, Phase III trial that evaluated the safety and efficacy of once-weekly *Bydureon* therapy added to titrated basal insulin glargine, compared with placebo added to titrated basal insulin glargine, in patients with type-2 diabetes who have inadequate glycaemic control on basal insulin glargine with or without metformin.

b) 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. Two significant type-2 diabetes outcomes trials are progressing:

| Medicine | Trial | Mode of Action | Number of Patients | Primary Endpoint | Timeline |
|----------|---------|-----------------|-----------------------|--|---------------------------------|
| Bydureon | EXSCEL | GLP-1 agonist | ~14,000 | Time to first occurrence of CV death, non-fatal MI or non-fatal stroke | Latest 2018 (final analysis) |
| Farxiga | DECLARE | SGLT2 inhibitor | ~17,000* | Time to first occurrence of CV death, non-fatal MI or non-fatal stroke | Latest 2019 (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).

c) Roxadustat (anaemia)

Roxadustat is a potential first-in-class oral HIF-PH inhibitor in Phase III development for the treatment of anaemia in CKD patients. AstraZeneca, FibroGen, Inc. (FibroGen) and Astellas Pharma Inc. are jointly undertaking an extensive worldwide Phase III trial programme, enrolling more than 8,000 patients.

In addition to evaluating efficacy, the US/global programme is designed to demonstrate the CV safety of roxadustat in comparison to epoetin alfa in dialysis patients (based on data pooled from four clinical trials) and in comparison to placebo in non-dialysis patients (based on data pooled from three clinical trials). AstraZeneca and FibroGen anticipate data readout and US regulatory submission in 2018.

FibroGen is responsible for development and regulatory activities in China, and recently announced that the submission process had initiated and is expected to complete in the second or third quarter of 2017.

Additionally, on 30 January 2017, FibroGen reported positive results from two Phase III clinical trials of roxadustat in China. The two Phase III clinical trials evaluated roxadustat for anaemia in CKD in patients on dialysis and not on dialysis. Both Phase III trials met their primary efficacy endpoints, confirming earlier results. Initial analysis suggests that adverse events were consistent with previous clinical trials of roxadustat in the CKD patient population.



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 launches between 2017 and 2020. The capability in inhalation technology spans both pMDIs 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 (asthma, COPD)

During the period, the Company received EU approval for *Symbicort* SMART (*Symbicort* Maintenance And Reliever Therapy) for adolescent asthma patients (aged 12 to <18 years). The SMART regimen for adolescents is the same as for adult patients, with a daily maintenance dose of *Symbicort Turbuhaler* plus additional doses as needed in response to symptoms. *Symbicort* SMART is a key component of the Company's commitment to 'patient-adjusted therapy' in treating asthma.

On 26 January 2017, AstraZeneca announced that the FDA had granted six months of paediatric exclusivity for *Symbicort*, based on the evaluation of trials conducted in children with asthma aged six up to 12 years.

b) Benralizumab (severe, uncontrolled asthma)

During the period, AstraZeneca announced that the FDA accepted a BLA for benralizumab, an anti-eosinophil monoclonal antibody (mAb), with a PDUFA date anticipated in Q4 2017. The Company also announced that the European Medicines Agency accepted the Marketing Authorisation Application (MAA) for benralizumab.

The BLA and MAA submissions, for the treatment of patients with severe, uncontrolled asthma with an eosinophilic phenotype, were based on the results of the pivotal Phase III trials, SIROCCO and CALIMA, that demonstrated that adding benralizumab to SoC significantly reduced exacerbations and improved lung function and asthma symptoms. To date, five positive Phase III trials (BISE, SIROCCO, CALIMA, GREGALE and ZONDA) have supported the efficacy and safety profile of benralizumab.



ASTRAZENECA DEVELOPMENT PIPELINE 31 DECEMBER 2016

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.

| Mechanism | Area Under | Date Commenced | Estima | Date / | | |
|---|---|--|--|--|---|---|
| | Investigation | Phase | US | EU | Japan | China |
| | | | | | | |
| EGFR inhibitor | ≥2nd-line advanced EGFRm T790M NSCLC | | Launched (Breakthrough Therapy, Priority Review, Orphan drug) | Launched (Accelerated assessment) | Launched | Accepted |
| EGFR inhibitor | ≥2nd-line advanced EGFRm T790M NSCLC | | Accepted (Priority Review) | Accepted | | |
| PD-L1 mAb | ≥2nd-line advanced bladder cancer | | Accepted (Breakthrough Therapy & Priority Review) | | | |
| BTK inhibitor | B-cell malignancy | Q1 2015 | H1 2017 (Orphan drug) | | | |
| BTK inhibitor | 1st-line CLL | Q3 2015 | 2020 (Orphan drug) | 2020 (Orphan drug) | | |
| BTK inhibitor | r/r CLL, high risk | Q4 2015 | 2020 (Orphan drug) | 2020 (Orphan drug) | | |
| MEK inhibitor | differentiated thyroid cancer | Q3 2013 | 2018 (Orphan drug) | 2018 | | |
| anti-CD22 recombinant immunotoxin | hairy cell leukaemia | Q2 2013 | 2018 (Orphan drug) | | | |
| PD-L1 mAb | stage III NSCLC | Q2 2014 | H2 2017 | H2 2017 | H2 2017 | |
| PD-L1 mAb + CTLA-4 mAb | 3rd-line NSCLC | Q2 2015 | H2 2017 | H2 2017 | H2 2017 | |
| PD-L1 mAb + CTLA-4 mAb | 1st-line NSCLC | Q3 2015 | H2 2017 | H2 2017 | H2 2017 | |
| PD-L1 mAb + CTLA-4 mAb | 1st-line NSCLC | Q4 2015 | 2019 | 2019 | 2019 | 2020 |
| PD-L1 mAb + CTLA-4 mAb | 1st-line HNSCC | Q4 2015 | 2018 | 2018 | 2018 | |
| PD-L1 mAb + CTLA-4 mAb | 2nd-line HNSCC | Q4 2015 | 2018 | 2018 | 2018 | |
| PD-L1 mAb + CTLA-4 mAb | 1st-line bladder cancer | Q4 2015 | 2018 | 2018 | 2018 | |
| | EGFR inhibitor EGFR inhibitor PD-L1 mAb BTK inhibitor BTK inhibitor PD-L1 mAb + CTLA-4 mAb PD-L1 mAb + CTLA-4 mAb PD-L1 mAb + CTLA-4 mAb | MechanismInvestigationEGFR inhibitor≥2nd-line advanced EGFRm T790M NSCLCEGFR inhibitor≥2nd-line advanced EGFRm T790M NSCLCPD-L1 mAb BTK inhibitor≥2nd-line advanced bladder cancerBTK inhibitorB-cell malignancyBTK inhibitorB-cell malignancyBTK inhibitorIst-line CLLBTK inhibitorIst-line CLLBTK inhibitorIst-line CLLBTK inhibitorfr/r CLL, high riskMEK inhibitordifferentiated thyroid canceranti-CD22 recombinant immunotoxinhairy cell leukaemiaPD-L1 mAb CTLA-4 mAb3rd-line NSCLCPD-L1 mAb + CTLA-4 mAb1st-line HNSCCPD-L1 mAb + CTLA-4 mAb2nd-line HNSCCPD-L1 mAb + CTLA-4 mAb2nd-line HNSCC | MechanismArea Under InvestigationCommenced PhaseEGFR inhibitor≥2nd-line advanced EGFRm T790M NSCLCEGFR inhibitor≥2nd-line advanced EGFRm T790M NSCLCPD-L1 mAb BTK inhibitor≥2nd-line advanced bladder cancerBTK inhibitorB-cell malignancyQ1 2015BTK inhibitorIst-line CLLQ3 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drug)2018 (Orphan drug)BTK inhibitorrtr CLL, high riskQ2 2013 (Q2 2013 (Orphan drug))2018 (Orphan drug)2018 (Q2 2017PD-L1 mAb CTLA-4 mAbst |

| Compound | Mechanism | Area Under Investigation | Date Commenced | Estimated Regulatory Acceptance Date / Submission Status | | | | |
|--|--|------------------------------------|-------------------|---|----------|----------|------------------------|--|
| | | | Phase | US | EU | Japan | China | |
| Cardiovascular | & Metabolic Dis | seases | | | | | | |
| Brilinta ¹ | P2Y12 receptor antagonist | arterial thrombosis | | Launched | Launched | Approved | Launched | |
| Farxiga ² | SGLT2 inhibitor | type-2 diabetes | | Launched | Launched | Launched | Accepted | |
| Epanova [#] | omega-3 carboxylic acids | severe hypertriglyceride mia | | Approved | | 2018 | | |
| ZS-9 (sodium zirconium cyclosilicate) | potassium binder | hyperkalaemia | | Accepted | Accepted | | | |
| 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 ⁴ | H1 2017 | 2018 | 2018 | |
| benralizumab [#] CALIMA SIROCCO ZONDA BISE BORA GREGALE | IL-5R mAb | severe asthma | | Accepted | Accepted | H1 2017 | 2020 | |
| benralizumab [#] TERRANOVA GALATHEA | IL-5R mAb | COPD | Q3 2014 | 2018 | 2018 | 2019 | | |
| PT010 | LABA/LAMA/I CS | COPD | Q3 2015 | 2018 | 2018 | 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 | | |
| AZD3293 [#] AMARANTH DAYBREAK- ALZ | beta- secretase inhibitor | Alzheimer's disease | Q2 2016 | 2020 (Fast Track) | 2020 | 2020 | | |

Registrational Phase II trial Collaboration ¶ #

1 2 3

Brilinta in the US and Japan; Brilique in ROW Farxiga in the US; Forxiga in ROW Rolling New Drug Application (NDA) regulatory submission initiated in Q4 2016 Bevespi Aerosphere (glycopyrrolate and formoterol fumarate) inhalation aerosol was launched commercially in the US in January 2017 4

What science can do

Operating & Financial Review

AstraZeneca

Corporate & Business Development



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) | | 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 [#] durvalumab [#] + dabrafenib + | PD-L1 mAb + STAT3 inhibitor PD-L1 mAb+ BRAF inhibitor + | melanoma | II | Q1 2014 |
| trametinib durvalumab [#] + AZD1775 [#] | MEK inhibitor PD-L1 mAb + Wee1 inhibitor | solid tumours | | Q4 2015 |
| durvalumab [#] + MEDI0680 | PD-L1 mAb + Wee1 inhibitor PD-L1 mAb + PD-1 mAb | solid tumours | 1 | Q4 2015 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 | | Q3 2016 |
| durvalumab [#] + Iressa | PD-L1 mAb+ EGFR inhibitor | NSCLC | 1 | 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 | 1 | Q4 2013 |
| tremelimumab + MEDI0562 [#] | CTLA-4 mAb + humanised OX40 agonist | solid tumours | I | Q2 2016 |
| Lynparza + AZD6738 | PARP inhibitor + ATR inhibitor | gastric cancer | II | Q3 2016 |
| Lynparza + 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 | 11 | Q2 2016 |
| Tagrisso BLOOM | EGFR inhibitor | CNS metastases in advanced EGFRm NSCLC | 11 | Q4 2015 |
| AZD1775 [#] + chemotherapy | Wee1 inhibitor + chemotherapy | ovarian cancer | | Q4 2012 |
| AZD1775 [#] | Wee1 inhibitor | solid tumours | II | Q1 2016 |
| vistusertib (AZD2014) | mTOR inhibitor | solid tumours | | 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 | | Q4 2015 |
| AZD4635 | A2aR inhibitor | solid tumours | 1 | Q2 2016 |
| AZD6738 | ATR inhibitor | solid tumours | Ι | Q4 2013 |
| AZD8186 | PI3k inhibitor | solid tumours | | 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 |

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| | | Area Under Investigation | Phase | Date Commenced Phase |
|---------------------------|-------------------------------------|---|----------|-----------------------------|
| MED10562# | humanised OX40 agonist | solid tumours | I | Q1 2015 |
| MED10680 | PD-1 mAb | solid tumours | I | Q4 2013 |
| MEDI1873 | GITR agonist fusion protein | solid tumours | I | Q4 2015 |
| MEDI4276 | HER2 bispecific ADC mAb | solid tumours | 1 | Q4 2015 |
| MEDI9197 [#] | TLR 7/8 agonist | solid tumours | | Q4 2015 |
| MEDI9447 | CD73 mAb | solid tumours | I | Q3 2015 |
| | | | • | 40 2010 |
| Cardiovascular & Metabol | | 1 | | |
| MED10382 | 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 | non-alcoholic fatty liver | | Q4 2016 |
| | oligonucleotide | disease/non-alcoholic steatohepatitis (NASH) | | Q+2010 |
| AZD4831 | Myeloperoxidase | Heart failure with a preserved ejection fraction | Ι | Q3 2016 |
| AZD5718 | FLAP | CAD | I | Q1 2016 |
| AZD8601# | VEGF-A | cardiovascular | 1 | Q1 2017 |
| MEDI8111 | Rh-factor II | trauma / bleeding | | Q1 2014 |
| Respiratory | | | • | |
| tezepelumab [#] | TSLP mAb | asthma / atopic dermatitis | II | Q2 2014 |
| abediterol# | LABA | asthma/COPD | II | Q4 2007 |
| AZD7594 | inhaled SGRM | asthma/COPD | | Q3 2015 |
| AZD9412 [#] | inhaled interferon beta | asthma/COPD | | Q3 2015 |
| PT010 | LABA/LAMA/ICS | asthma | | Q2 2014 |
| AZD1419 [#] | TLR9 agonist | asthma | | Q4 2016 |
| AZD8871 [#] | MABA | COPD | | Q1 2017 |
| AZD0284 | Inhaled RORg | psoriasis | | Q4 2016 |
| AZD5634 | inhaled ENaC | cystic fibrosis | I | Q1 2016 |
| | | - | 1 | |
| AZD7594+abediterol# | Inhaled SGRM+LABA | asthma/COPD | <u> </u> | Q4 2016 |
| AZD7986 [#] | DPP1 | COPD | I | Q4 2014 |
| AZD9567 | oral SGRM | rheumatoid arthritis | | Q4 2015 |
| Other | | | | 1 |
| anifrolumab# | IFN-alphaR mAb | lupus nephritis | II | Q4 2015 |
| anifrolumab [#] | IFN-alphaR mAb | systemic lupus erythematosus (subcutaneous) | Ι | Q4 2015 |
| inebilizumab [#] | CD19 mAb | neuromyelitis optica | II | Q1 2015 (Orphan drug) |
| mavrilimumab# | GM-CSFR mAb | rheumatoid arthritis | 11 | Q1 2010 |
| verinurad ¹ | selective uric acid | chronic treatment of | | Q3 2013 |
| volinaraa | reabsorption inhibitor (URAT- | hyperuricemia in patients with gout | | |
| MEDI5872 [#] | B7RP1 mAb | primary Sjögren's syndrome | II | Q3 2016 |
| AZD3241 | myeloperoxidase inhibitor | multiple system atrophy | II | Q2 2015 (Orphan drug) |
| MEDI3902 | Psl/PcrV bispecific mAb | prevention of nosocomial pseudomonas pneumonia | II | Q2 2016 (Fast Track, US) |
| MEDI4893 | mAb binding to S. aureus toxin | hospital-acquired pneumonia / serious <i>S.</i> <i>aureus</i> infection | II | Q4 2014 (Fast Track, US) |

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| Compound | Mechanism | Area Under Investigation | Phase | Date Commenced Phase |
|------------------------|-------------------------------|---------------------------------|-------|-----------------------------|
| MED18852 | influenza A mAb | influenza A treatment | II | Q4 2015 (Fast Track, US) |
| MED18897 [#] | RSV mAb-YTE | passive RSV prophylaxis | Ш | Q1 2015 (Fast Track, US) |
| MED10700 [#] | BAFF/B7RP1 bispecific mAb | systemic lupus erythematosus | Ι | Q1 2016 |
| MEDI1814 ^{#2} | amyloid beta mAb | Alzheimer's disease | | Q2 2014 |
| MED14920 | anti-CD40L-Tn3 fusion protein | primary Sjögren's syndrome | Ι | Q2 2014 |
| MEDI7352 | NGF/TNF bispecific mAb | osteoarthritis pain | Ι | Q1 2016 |
| MEDI7734 | ILT7 mAb | myositis | I | Q3 2016 |
| MEDI9314 | IL-4R mAb | atopic dermatitis | I | Q1 2016 |

Collaboration
1 Planning to initiate a programme for CKD
2 Co-development collaboration with Eli Lilly for MEDI1814

Significant Lifecycle Management

| Compound | Mechanism | Area Under Investigation | Date Commenced | Estimated Regulatory Acceptance Date / Submission Status | | | |
|--|-------------------------------------|---|-------------------|---|----------|----------|----------|
| - | | investigation | Phase | US | EU | Japan | China |
| Oncology | | | • | | | | |
| <i>Faslodex</i> FALCON | oestrogen receptor antagonist | 1st-line hormone receptor +ve advanced breast cancer | | Accepted | Accepted | Accepted | H2 2017 |
| <i>Lynparza</i> OlympiAD | PARP inhibitor | gBRCA metastatic breast cancer | Q2 2014 | H2 2017 | H2 2017 | H2 2017 | |
| Lynparza SOLO-2 | PARP inhibitor | 2nd-line or greater BRCAm PSR ovarian cancer, maintenance monotherapy | Q3 2013 | H1 2017 (Fast Track) | H1 2017 | H2 2017 | |
| <i>Lynparza</i> SOLO-1 | PARP inhibitor | 1st-line BRCAm ovarian cancer | Q3 2013 | 2018 | 2018 | 2018 | |
| <i>Lynparza</i> SOLO-3 | PARP inhibitor | gBRCA PSR ovarian cancer | Q1 2015 | 2018 | | | |
| <i>Lynparza</i> POLO | PARP inhibitor | pancreatic cancer | Q1 2015 | 2018 | 2018 | | |
| Lynparza | PARP inhibitor | prostate cancer | Q3 2014 | (Breakthrough Therapy) | | | |
| <i>Lynparza</i> OlympiA | PARP inhibitor | gBRCA adjuvant breast cancer | Q2 2014 | 2020 | 2020 | 2020 | |
| <i>Tagrisso</i> FLAURA | EGFR inhibitor | 1st-line advanced EGFRm NSCLC | Q1 2015 | H2 2017 | H2 2017 | H2 2017 | H2 2017 |
| <i>Tagrisso</i> ADAURA | EGFR inhibitor | adjuvant EGFRm NSCLC | Q4 2015 | 2022 | 2022 | 2022 | 2022 |
| Cardiovascular | & Metabolic Dis | eases | | | | | |
| <i>Brilinta</i> 1 PEGASUS- TIMI 54 | P2Y12 receptor antagonist | outcomes trial in patients with prior myocardial infarction | | Launched (Priority Review) | Launched | Approved | Accepted |
| 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 | 2018 | 2018 | 2018 | 2019 |

Operating & Financial Review

AstraZeneca What science can do

| Compound | Mechanism | Area Under Investigation | Date Commenced | Submission Status | | | |
|---|---|---|-------------------|-------------------|----------|----------|-----------|
| | | | Phase | US | EU | Japan | China |
| <i>Brilinta</i> ¹ HESTIA | P2Y12 receptor antagonist | prevention of vaso- occlusive crises in paediatric patients with sickle cell disease | Q1 2014 | 2020 | 2020 | | |
| Onglyza SAVOR-TIMI 53 | DPP-4 inhibitor | type-2 diabetes outcomes trial | | Launched | Launched | | Accepted |
| Kombiglyze XR/Komboglyze 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 | | |
| Farxiga ³ | SGLT2 inhibitor | type-1 diabetes | Q4 2014 | 2018 | 2018 | 2018 | |
| Xigduo XR/ Xigduo⁴ | SGLT2 inhibitor/ metformin FDC | type-2 diabetes | | Launched | Launched | | |
| Qtern (saxagliptin/ dapagliflozin FDC) | DPP-4 inhibitor/ SGLT2 inhibitor FDC | type-2 diabetes | | Accepted | Approved | | |
| <i>Bydureon</i> weekly suspension | GLP-1 receptor agonist | type-2 diabetes | Q1 2013 | H1 2017 | H2 2017 | | |
| Bydureon EXSCEL | GLP-1 receptor agonist | type-2 diabetes outcomes trial | Q2 2010 | 2018 | 2018 | | 2018 |
| Epanova 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 | | | | | | | |
| Symbicort SYGMA | ICS/LABA | as-needed use in mild asthma | Q4 2014 | | 2018 | | 2019 |
| Symbicort | ICS/LABA | breath actuated Inhaler asthma/COPD | | 2018 | | | |
| Duaklir Genuair [#] | LAMA/LABA | COPD | | 2018 | Launched | | 2019 |
| Other | T | I | r | I | | | |
| Nexium | proton pump inhibitor | stress ulcer prophylaxis | | | | | Submitted |
| Nexium | proton pump inhibitor | paediatrics | | Launched | Launched | Accepted | |
| linaclotide# | GC-C receptor peptide agonist | irritable bowel syndrome with constipation (IBS-C) | | | | | Accepted |

Date

Corporate & Business Development

Operating & Financial Review

Collaboration

1

Brilinta in the US and Japan; Brilique in ROW Kombiglyze XR in the US; Komboglyze in the EU Farxiga in the US; Forxiga in ROW Xigduo XR in the US; Xigduo in the EU

2 3

4



Estimated Regulatory Acceptance Date /



Terminations (discontinued projects between 1 October 2016 and 31 December 2016)

| NME / Line Extension | Compound | Reason for Discontinuation | Area Under Investigation |
|----------------------|-------------------------------------|-------------------------------|---|
| NME | durvalumab# + tremelimumab ALPS¶ | Safety/Efficacy | metastatic pancreatic ductal carcinoma |
| NME | MEDI7510 | Safety/Efficacy | Prevention of respiratory syncytial virus disease in older patients |

Completed Projects / Divestitures

| 0 | Maakaniam | Area Under | Completed/ | Estimated Regulatory Submission Acceptance [†] | | | | |
|---|---|---|------------|---|----------|-------|-----------|--|
| Compound | Mechanism | Investigation | Divested | US | EU | Japan | China | |
| MEDI2070 ^{#1} | IL-23 mAb | Crohn's disease | Divested | | | | | |
| Zinforo ^{#2} | extended spectrum cephalosporin with affinity to penicillin-binding proteins | pneumonia/skin infections | Divested | | Launched | | Submitted | |
| Zavicefta ^{#2} (CAZ AVI) | cephalosporin/ beta lactamase inhibitor | hospital-acquired pneumonia/ ventilator- associated pneumonia | Divested | | Approved | | | |
| Zavicefta ^{#2} (CAZ AVI) | cephalosporin/ beta lactamase inhibitor | serious infections, complicated intra- abdominal infection, complicated urinary tract infection | Divested | | Approved | | | |
| ATM AVI ^{#2} | monobactam/ beta lactamase inhibitor | targeted serious bacterial infections | Divested | | | | | |
| CXL ^{#2} | beta lactamase inhibitor / cephalosporin | methicillin- resistant <i>S.</i> <i>aureus</i> | Divested | | | | | |
| AZD8108 | NMDA antagonist | suicidal ideation | Divested | | | | | |
| durvalumab [#] HAWK ^{¶3} | PD-L1 mAb | 2nd-line HNSCC (PD-L1 positive) | Completed | | | | | |
| durvalumab [#] + tremelimumab CONDOR ^{¶3} | PD-L1 mAb + CTLA-4 mAb | 2nd-line HNSCC (PD-L1 negative) | Completed | | | | | |

1 AstraZeneca licensing agreement with Allergan

2 AstraZeneca completed the transaction with Pfizer to sell the commercialisation and development rights to its late-stage, small-molecule antibiotics business in most markets globally outside the US

3 Registrational trials now complete (data will contribute towards subsequent HNSCC regulatory submissions)

Operating & Financial Review



Condensed Consolidated Statement of Comprehensive Income

| For the year ended 31 December | 2016 \$m | 2015 \$m |
|---|-------------|-------------|
| Product sales | 21,319 | 23,641 |
| Externalisation revenue | 1,683 | 1,067 |
| Total revenue | 23,002 | 24,708 |
| Cost of sales | (4,126) | (4,646) |
| Gross profit | 18,876 | 20,062 |
| Distribution costs | (326) | (339) |
| Research and development expense | (5,890) | (5,997) |
| Selling, general and administrative costs | (9,413) | (11,112) |
| Other operating income and expense | 1,655 | 1,500 |
| Operating profit | 4,902 | 4,114 |
| Finance income | 67 | 46 |
| Finance expense | (1,384) | (1,075) |
| Share of after tax losses in associates and joint ventures | (33) | (16) |
| Profit before tax | 3,552 | 3,069 |
| Taxation | (146) | (243) |
| Profit for the period | 3,406 | 2,826 |
| Other comprehensive income Items that will not be reclassified to profit or loss | | |
| Remeasurement of the defined benefit pension liability | (575) | 652 |
| Tax on items that will not be reclassified to profit or loss | 136 | (199) |
| | (439) | 453 |
| Items that may be reclassified subsequently to profit or loss | (100) | 100 |
| Foreign exchange arising on consolidation | (1,050) | (528) |
| Foreign exchange arising on designating borrowings in net investment hedges | (1,000) | (333) |
| Fair value movements on cash flow hedges | (115) | (000) |
| Fair value movements on cash flow hedges transferred to profit or loss | 195 | - |
| Fair value movements on derivatives designated in net investment hedges | (4) | 14 |
| Amortisation of loss on cash flow hedge | 1 | 1 |
| Net available for sale gains/(losses) taken to equity | 139 | (32) |
| Tax on items that may be reclassified subsequently to profit or loss | 86 | 87 |
| · · · · · · · · · · · · · · · · · · · | (1,339) | (791) |
| Other comprehensive income for the period, net of tax | (1,778) | (338) |
| Total comprehensive income for the period | 1,628 | 2,488 |
| | | |
| Profit attributable to: Owners of the Parent | 3,499 | 2,825 |
| Non-controlling interests | (93) | 2,025 |
| | 3,406 | 2,826 |
| | | |
| Total comprehensive income attributable to: | 4 700 | 0.400 |
| Owners of the Parent | 1,722 | 2,488 |
| Non-controlling interests | (94) | - |
| | 1,628 | 2,488 |
| Basic earnings per \$0.25 Ordinary Share | \$2.77 | \$2.23 |
| Diluted earnings per \$0.25 Ordinary Share | \$2.76 | \$2.23 |
| | | |
| Weighted average number of Ordinary Shares in issue (millions) | 1,265 | 1,264 |



Condensed Consolidated Statement of Comprehensive Income

| For the quarter ended 31 December | 2016 \$m | 2015 \$m |
|---|---------------|-------------|
| Product sales | 5,260 | 6,207 |
| Externalisation revenue | 325 | 192 |
| Total revenue | 5,585 | 6,399 |
| Cost of sales | (1,160) | (1,269) |
| Gross profit | 4,425 | 5,130 |
| Distribution costs | (83) | (99) |
| Research and development expense | (1,543) | (1,746) |
| Selling, general and administrative costs | (1,386) | (2,668) |
| Other operating income and expense | 1,120 | 471 |
| Operating profit | 2,533 | 1,088 |
| Finance income | 23 | 13 |
| Finance expense | (362) | (292) |
| Share of after tax losses in associates and joint ventures | (11) | (7) |
| Profit before tax | 2,183 | 802 |
| Taxation | (366) | 6 |
| Profit for the period | 1,817 | 808 |
| Other comprehensive income | | |
| Items that will not be reclassified to profit or loss | | |
| Remeasurement of the defined benefit pension liability | 552 | 618 |
| Tax on items that will not be reclassified to profit or loss | (120) | (187) |
| | 432 | 431 |
| Items that may be reclassified subsequently to profit or loss | | |
| Foreign exchange arising on consolidation | (360) | (169) |
| Foreign exchange arising on designating borrowings in net investment hedges | (397) | (11) |
| Fair value movements on cash flow hedges | (89) | - |
| Fair value movements on cash flow hedges transferred to profit or loss | 154 | - |
| Fair value movements on derivatives designated in net investment hedges | 92 | (10) |
| Net available for sale gains taken to equity | 13 | |
| Tax on items that may be reclassified subsequently to profit or loss | 23 | 3 |
| | (564) | (156) |
| Other comprehensive income for the period, net of tax | (132) | 275 |
| Total comprehensive income for the period | 1,685 | 1,083 |
| | | |
| Profit attributable to: Owners of the Parent | 1,842 | 808 |
| Non-controlling interests | | |
| | (25) | - 808 |
| | | |
| Total comprehensive income attributable to: Owners of the Parent | 4 740 | 4 000 |
| | 1,710 | 1,083 |
| Non-controlling interests | (25) 1,685 | - 1,083 |
| | 1,000 | 1,000 |
| Basic earnings per \$0.25 Ordinary Share | \$1.46 | \$0.63 |
| Diluted earnings per \$0.25 Ordinary Share | \$1.45 | \$0.63 |
| 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 |



Condensed Consolidated Statement of Financial Position

| | At 31 Dec 2016 \$m | Restated* At 31 Dec 2015 \$m |
|---|-----------------------|------------------------------------|
| ASSETS | | |
| Non-current assets | | |
| Property, plant and equipment | 6,848 | 6,413 |
| Goodwill | 11,658 | 11,800 |
| Intangible assets | 27,586 | 22,646 |
| Derivative financial instruments | 343 | 446 |
| Investments in associates and joint ventures | 99 | 85 |
| Other investments | 727 | 458 |
| Other receivables | 901 | 907 |
| Deferred tax assets | 1,102 | 1,294 |
| | 49,264 | 44,049 |
| Current assets | | |
| Inventories | 2,334 | 2,143 |
| Trade and other receivables | 4,573 | 6,622 |
| Other investments | 884 | 613 |
| Derivative financial instruments | 27 | 2 |
| Income tax receivable | 426 | 387 |
| Cash and cash equivalents | 5,018 | 6,240 |
| | 13,262 | 16,007 |
| Total assets | 62,526 | 60,056 |
| LIABILITIES | 02,020 | 00,000 |
| Current liabilities | | |
| Interest-bearing loans and borrowings | (2,307) | (916) |
| Trade and other payables | (10,486) | (11,663) |
| Derivative financial instruments | (10,400) | (11,003) |
| Provisions | | |
| | (1,065) (1,380) | (798) (1,483) |
| Income tax payable | | |
| Non-current liabilities | (15,256) | (14,869) |
| | (14 501) | (11107) |
| Interest-bearing loans and borrowings | (14,501) | (14,137) |
| Derivative financial instruments | (117) | (1) |
| Deferred tax liabilities | (3,956) | (2,665) |
| Retirement benefit obligations | (2,186) | (1,974) |
| Provisions | (353) | (444) |
| Other payables | (9,488) | (7,457) |
| | (30,601) | (26,678) |
| Total liabilities | (45,857) | (41,547) |
| Net assets | 16,669 | 18,509 |
| EQUITY | | |
| Capital and reserves attributable to equity holders | | |
| of the Company | | |
| Share capital | 316 | 316 |
| Share premium account | 4,351 | 4,304 |
| Other reserves | 2,047 | 2,036 |
| Retained earnings | 8,140 | 11,834 |
| | 14,854 | 18,490 |
| Non-controlling interests | 1,815 | 19 |
| Total equity | 16,669 | 18,509 |
| | | |

*2015 comparatives have been restated to reflect an adjustment to the acquisition accounting for ZS Pharma (see Note 5).



Condensed Consolidated Statement of Cash Flows

| For the year ended 31 December | 2016 \$m | 2015 \$m |
|---|-------------|-------------|
| Cash flows from operating activities | | |
| Profit before tax | 3,552 | 3,069 |
| Finance income and expense | 1,317 | 1,029 |
| Share of after tax losses in associates and joint ventures | 33 | 16 |
| Depreciation, amortisation and impairment | 2,357 | 2,852 |
| Decrease/(increase) in working capital and short-term provisions | 926 | (49 |
| Gain on disposal of intangible assets | (1,301) | (961 |
| Fair value movements on contingent consideration arising from business combinations | (1,158) | (432 |
| Non-cash and other movements | (492) | (350 |
| Cash generated from operations | 5,234 | 5,174 |
| Interest paid | (677) | (496 |
| Tax paid | (412) | (1,354 |
| Net cash inflow from operating activities | 4,145 | 3,324 |
| Cash flows from investing activities | | |
| Movement in short-term investments and fixed deposits | (166) | 283 |
| Purchase of property, plant and equipment | (1,446) | (1,328 |
| Disposal of property, plant and equipment | 82 | 47 |
| Purchase of intangible assets | (868) | (1,460 |
| Disposal of intangible assets | 1,427 | 1,130 |
| Purchase of non-current asset investments | (230) | (57 |
| Disposal of non-current asset investments | 3 | 93 |
| Payments to joint ventures | (41) | (45 |
| Upfront payments on business combinations | (2,564) | (2,446 |
| Payment of contingent consideration from business combinations | (293) | (579 |
| Interest received | 140 | 123 |
| Payments made by subsidiaries to non-controlling interests | (13) | - |
| Net cash outflow from investing activities | (3,969) | (4,239 |
| Net cash inflow/(outflow) before financing activities | 176 | (915 |
| Cash flows from financing activities | | |
| Proceeds from issue of share capital | 47 | 43 |
| New long-term loans | 2,491 | 5,928 |
| Repayment of loans | - | (884 |
| Dividends paid | (3,561) | (3,486 |
| Hedge contracts relating to dividend payments | 18 | (51 |
| Repayment of obligations under finance leases | (16) | (42 |
| Movement in short-term borrowings | (303) | (630 |
| Net cash (outflow)/inflow from financing activities | (1,324) | 878 |
| Net decrease in cash and cash equivalents in the period | (1,148) | (37 |
| Cash and cash equivalents at the beginning of the period | 6,051 | 6,164 |
| Exchange rate effects | 21 | (76 |
| Cash and cash equivalents at the end of the period | 4,924 | 6,051 |
| Cash and cash equivalents consists of: | | |
| Cash and cash equivalents | 5,018 | 6,240 |
| Overdrafts | (94) | (189 |
| | 4,924 | 6,051 |

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 | ancial |
|--|-------------------------|------------------------------------|---------------------------|-----------------------------|--------------|---|------------------------|-------------------------------------|
| At 1 Jan 2015 | 316 | 4,261 | 2,021 | 13,029 | 19,627 | 19 | 19,646 | ing & Fina Review |
| Profit for the period | - | - | - | 2,825 | 2,825 | 1 | 2,826 | Operating & Financial Review |
| Other comprehensive income | - | - | - | (337) | (337) | (1) | (338) | Oper |
| Transfer to other reserves | - | - | 15 | (15) | - | - | - | |
| Transactions with owners: | | | | | | | | siness nt |
| Dividends | - | - | - | (3,537) | (3,537) | - | (3,537) | & Bus pme |
| Issue of Ordinary Shares | - | 43 | - | - | 43 | - | 43 | Corporate & Business Development |
| Share-based payments | - | - | - | (131) | (131) | - | (131) | CO |
| Net movement | - | 43 | 15 | (1,195) | (1,137) | - | (1,137) | |
| At 31 Dec 2015 | 316 | 4,304 | 2,036 | 11,834 | 18,490 | 19 | 18,509 | ent |
| 114 Jan 2010 | Share capital \$m | Share premium account \$m | Other reserves* \$m | Retained earnings \$m | Total \$m | Non- controlling interests \$m | Total equity \$m | Research & Development |
| At 1 Jan 2016 | 316 | 4,304 | 2,036 | 11,834 | 18,490 | 19 | 18,509 | Res |
| Profit for the period | - | - | - | 3,499 | 3,499 | (93) | 3,406 | |
| Other comprehensive income | - | - | - | (1,777) | (1,777) | (1) | (1,778) | De |
| Transfer to other reserves | - | - | 11 | (11) | - | - | - | Development Pipeline |
| Transactions with owners: | | | | | | | | bmei |
| Dividends | - | - | - | (3,540) | (3,540) | - | (3,540) | evelo |
| Dividend paid by subsidiary to non- controlling interest | - | - | - | - | - | (13) | (13) | |
| Acerta put option | - | - | - | (1,825) | (1,825) | - | (1,825) | |
| Changes in non- controlling interest | - | - | - | - | - | 1,903 | 1,903 | ancial s |
| Issue of Ordinary Shares | - | 47 | - | - | 47 | - | 47 | Preliminary Financial Statements |
| Share-based payments | - | - | - | (40) | (40) | - | (40) | elimin Sta |
| Net movement | - | 47 | 11 | (3,694) | (3,636) | 1,796 | (1,840) | Pre |
| At 31 Dec 2016 | 316 | 4,351 | 2,047 | 8,140 | 14,854 | 1,815 | 16,669 | |
| | | | | | | | | |

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



Notes to the Interim Financial Statements 1 BASIS OF PREPARATION AND ACCOUNTING POLICIES

The preliminary announcement for the year ended 31 December 2016 has been prepared in accordance with International Financial Reporting Standards (IFRSs) 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 IFRSs as adopted by the EU and as issued by the IASB. The preliminary announcement has been prepared applying the accounting policies and presentation that were applied in the preparation of the Group's published consolidated financial statements for the year ended 31 December 2015. There have been no significant new or revised accounting standards applied in the 12 months ended 31 December 2016.

Legal proceedings

The information contained in Note 7 updates the disclosures concerning legal proceedings and contingent liabilities in the Group's Annual Report and Form 20-F Information 2015 and Interim Financial Statements for the six months ended 30 June 2016 and the Third Quarter and Nine Months Results 2016.

Going concern

The Group has considerable financial resources available. As at 31 December 2016 the Group has \$5.7bn in financial resources (cash balances of \$5bn and undrawn committed bank facilities of \$3bn which are available until April 2021, with only \$2.3bn 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 preliminary announcement has been prepared on a going concern basis.

Financial information

The financial information contained in the preliminary announcement does not constitute statutory accounts of the Group for the years ended 31 December 2016 and 2015 but is derived from those accounts. Statutory accounts for 2015 have been delivered to the registrar of companies and those for 2016 will be delivered in due course. Those accounts have been reported on by the Group's auditors; their report 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. The quarterly information for the three month period to 31 December 2016 and to 31 December 2016 and to 31 December 2016.

2 RESTRUCTURING COSTS

Profit before tax for the year ended 31 December 2016 is stated after charging restructuring costs of \$1,107m (\$394m for the fourth quarter of 2016). These have been charged to profit as follows:

| | FY 2016 \$m | FY 2015 \$m | Q4 2016 \$m | Q4 2015 \$m |
|---|----------------|----------------|----------------|----------------|
| Cost of sales | 130 | 158 | 43 | 34 |
| Research and development expense | 178 | 258 | 32 | 78 |
| Selling, general and administrative costs | 823 | 618 | 319 | 260 |
| Other operating income and expense | (24) | - | - | - |
| Total | 1,107 | 1,034 | 394 | 372 |



3 NET DEBT

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

| | At 1 Jan 2016 \$m | Cash Flow \$m | Acquisitions \$m | Non-cash & Other \$m | Exchange Movements \$m | At 31 Dec 2016 \$m |
|--|-------------------------|---------------------|---------------------|----------------------------|------------------------------|--------------------------|
| Loans due after one year | (14,109) | (2,491) | - | 1,793 | 312 | (14,495) |
| Finance leases due after one year | (28) | - | - | 22 | - | (6) |
| Total long-term debt | (14,137) | (2,491) | - | 1,815 | 312 | (14,501) |
| Current instalments of loans | - | - | - | (1,769) | - | (1,769) |
| Current instalments of finance leases | (67) | 16 | - | (37) | 1 | (87) |
| Total current debt | (67) | 16 | - | (1,806) | 1 | (1,856) |
| Other Investments | 613 | 164 | 140 | 54 | (73) | 898 |
| Net derivative financial instruments | 438 | (2) | - | (201) | - | 235 |
| Cash and cash equivalents | 6,240 | (1,231) | - | - | 9 | 5,018 |
| Overdrafts | (189) | 83 | - | - | 12 | (94) |
| Short-term borrowings | (660) | 303 | | 1 | (1) | (357) |
| | 6,442 | (683) | 140 | (146) | (53) | 5,700 |
| Net debt | (7,762) | (3,158) | 140 | (137) | 260 | (10,657) |

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



4 MAJORITY EQUITY INVESTMENT IN ACERTA PHARMA

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

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

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

Goodwill is principally attributable to the value of the specialist knowhow inherent in the acquired workforce and the accounting for deferred taxes. Goodwill is not expected to be deductible for tax purposes. Acerta Pharma's results have been consolidated into the Group's results from 2 February 2016. From the period from acquisition to 31 December 2016, Acerta Pharma had no revenues and its loss after tax was \$212m.

In the period since 2 February 2016, the acquisition accounting has been adjusted to reflect new information regarding the value of net assets acquired with Acerta. This has resulted in an increase in other assets of \$15m, a decrease in deferred tax liabilities of \$50m, and a decrease in goodwill of \$65m.

| | Fair value |
|--|---------------|
| | \$m |
| Intangible assets | 7,307 |
| Other assets including cash and cash equivalents | 253 |
| Deferred tax liabilities | (1,777) |
| Other liabilities | (90) |
| Total net assets acquired | 5,693 |
| Non-controlling interests | (1,903) |
| Goodwill | 19 |
| Fair value of total consideration | 3,809 |
| Less: fair value of deferred consideration | (1,332) |
| Total upfront consideration | 2,477 |
| Less: cash and cash equivalents acquired | (94) |
| Net cash outflow | 2,383 |

5 ACQUISITION OF ZS PHARMA

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

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

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

6 FINANCIAL INSTRUMENTS

As detailed in the Group's most recent annual financial statements, our principal financial instruments consist of derivative financial instruments, other investments, trade and other receivables, cash and cash equivalents, trade and other payables, and interest-bearing loans and borrowings. As indicated in Note 1, there have been no changes to the accounting policies for financial instruments, including fair value measurement, from those disclosed on pages 146 and 147 of the Company's Annual Report and Form 20-F Information 2015. In addition, there have been no changes of significance to the categorisation or fair value hierarchy of our financial instruments. Financial instruments measured at fair value include \$1,611m of other investments, \$1,719m of loans, and \$235m of derivatives as at 31 December 2016. The total fair value of interest-bearing loans and borrowings at 31 December 2016 which have a carrying value of \$16,808m in the Condensed Consolidated Statement of Financial Position, was \$18,174m. 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 | Other | Total | Tota | |
|------------------|----------------------|-------------|-------------|-------------|--|
| | 2016 \$m | 2016 \$m | 2016 \$m | 2015 \$m | |
| At 1 January | 5,092 | 1,319 | 6,411 | 6,899 | |
| Settlements | (242) | (51) | (293) | (579) | |
| Revaluations | (999) | (159) | (1,158) | (432) | |
| Discount unwind | 389 | 108 | 497 | 524 | |
| Foreign exchange | - | - | - | (1) | |
| At 31 December | 4,240 | 1,217 | 5,457 | 6,411 | |



7 LEGAL PROCEEDINGS AND CONTINGENT LIABILITIES

AstraZeneca is involved in various legal proceedings considered typical to its business, including litigation and investigations relating to product liability, commercial disputes, infringement of intellectual property rights, the validity of certain patents, anti-trust law and sales and marketing practices. The matters discussed below constitute the more significant developments since publication of the disclosures concerning legal proceedings in the Company's Annual Report and Form 20-F Information 2015 and as part of the Company's Half-Yearly Financial Report for the six-month period to 30 June 2016 and the Third Quarter and Nine-Month Results 2016 (the Disclosures). Unless noted otherwise below or in the Disclosures, no provisions have been established in respect of the claims discussed below.

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

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

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

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

Matters disclosed in respect of the fourth quarter of 2016 and to 2 February 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 four patents listed in the FDA Orange Book with reference to *Faslodex* after AstraZeneca received Paragraph IV notices relating to six Abbreviated New Drug Applications (ANDAs) seeking FDA approval to market generic versions of *Faslodex* prior to the expiration of AstraZeneca's patents. In December 2016, AstraZeneca settled the lawsuit against one of the ANDA filers, and the District Court entered a consent judgment in January 2017 which ended that particular lawsuit. AstraZeneca continues to litigate in the District Court against two other ANDA filers.

As previously disclosed, in July 2016, AstraZeneca was served with four petitions for *inter partes* review by the Patent Trial and Appeal Board (PTAB) relating to each of the four Orange Book-listed patents. In December 2016, the PTAB issued an order denying institution of the first of the four petitions. In January 2017, the PTAB terminated the remaining petitions at the request of the parties.

Patent proceedings outside the US

As previously disclosed, in Germany, in July 2015, AstraZeneca was served with complaints filed by Hexal AG (Hexal) and ratiopharm GmbH (ratiopharm) requesting the revocation of the German part of European Patent No. EP 1250138 (the '138 Patent). Following an oral hearing in January 2017, the German Federal Patent Court declared the patent invalid. AstraZeneca intends to appeal. In January 2017, the Regional Court of Düsseldorf suspended the effects of a provisional injunction based on the '138 patent which had been in place against Hexal since February 2016. Hexal is also seeking to lift a provisional injunction based on European Patent No. EP 2266573. In January 2017, the Higher Regional Court of Düsseldorf lifted a provisional injunction based on the '138 patent which had been in place against ratiopharm since September 2016.

As previously disclosed, in China, in March 2014, AstraZeneca received a request for invalidation of the *Faslodex* formulation patent, CN01803546.9, filed by Jiangsu Hansoh Pharmaceutical Co. Ltd. at the Chinese Patent Office. In September 2014, the Patent Re-examination Board of the Chinese Patent Board declared the patent invalid. AstraZeneca appealed to the Beijing IP Court and the appeal was rejected in April 2016. AstraZeneca appealed this decision to the Beijing Higher People's Court and the appeal was rejected in December 2016. AstraZeneca is considering its options.



Onglyza (saxagliptin) and Kombiglyze (saxagliptin and metformin)

US patent proceedings

As previously disclosed, in June 2016, the US Court of Appeals for the Federal Circuit denied Mylan Pharmaceuticals Inc.'s (Mylan) petition for rehearing en banc of the decision affirming the denial of Mylan's motion to dismiss for lack of jurisdiction. In September 2016, Mylan filed a petition for writ of certiorari with the Supreme Court of the United States seeking an appeal of that decision and, in January 2017, the writ was denied.

As previously disclosed, in May 2016, the US Patent and Trademark Office (USPTO) instituted an inter partes review brought by Mylan Pharmaceuticals Inc. challenging the validity of US Patent No. RE44,186 (the '186 Patent) (the Mylan IPR). Subsequently, Wockhardt Bio AG, Teva Pharmaceuticals USA Inc., Sun Pharmaceutical Industries Ltd., Sun Pharma Global FZE, and Amneal Pharmaceuticals LLC also filed petitions for inter partes review challenging the validity of the '186 Patent and joined the Mylan IPR. A hearing in the Mylan IPR was held in January 2017. A decision is awaited.

Crestor (rosuvastatin)

US patent proceedings

As previously disclosed, in December 2015, the US District Court for the District of South Carolina (the District Court) dismissed and entered judgment in AstraZeneca's favour in a patent infringement lawsuit filed by plaintiff Palmetto Pharmaceuticals, LLC (Palmetto), which, among other things, claimed that AstraZeneca's *Crestor* sales induced infringement of Palmetto's patent. Palmetto subsequently appealed. In December 2016, the Federal Circuit Court of Appeals affirmed the District Court's order dismissing the lawsuit.

Patent proceedings outside the US

As previously disclosed, in Japan, in March 2015, an individual filed a patent invalidation request with the Japanese Patent Office (JPO) in relation to the Crestor substance patent. In July 2016, the JPO dismissed the request. The individual has appealed to the Intellectual Property High Court of Japan (the High Court) with the intervention of Nippon Chemiphar Co. Ltd (Nippon). In addition, Nippon commenced a separate patent invalidation request with the JPO in relation to the *Crestor* substance patent. In November 2016, the JPO denied the request. Nippon has appealed to the High Court.

Synagis (palivizumab)

US patent proceedings

In December 2016, UCB BioPharma SPRL (UCB) filed a complaint against MedImmune LLC in the US District Court for the District of Delaware alleging infringement of US Patent No. 7,566,771. The complaint relates to a royalty-bearing license between Celltech R&D LTD and MedImmune which was terminated by MedImmune in 2010.

Losec/Prilosec (omeprazole)

Patent proceedings outside the US

As previously disclosed, in Canada, in 2004, AstraZeneca brought proceedings against Apotex Inc. (Apotex) for infringement of several patents related to *Losec*. In February 2015, the Federal Court of Canada (the Federal Court) found that Apotex had infringed AstraZeneca's *Losec* formulation patent (Canadian Patent No. 1,292,693). Apotex appealed. In January 2017, the Federal Court of Appeal upheld the trial court's findings of infringement and validity. However, the Federal Court upheld one aspect of Apotex's appeal relating to a limitation period defence, which may lower the amount of damages owed by Apotex. A reference to determine patent infringement damages is scheduled to commence in February 2017.

Product liability litigation

Farxiga (dapagliflozin)

As previously disclosed, 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*. Cases with these allegations have been filed in several jurisdictions. As previously disclosed, in October 2016 one of these cases was dismissed with prejudice in favour of AstraZeneca. Since then, several other cases have been dismissed either voluntarily or by the courts. Motions to dismiss are pending in many of the jurisdictions where AstraZeneca has been served.

As previously disclosed, in the US, counsel for plaintiffs in a product liability action pertaining to *Invokana* (a product in the same class as *Farxiga*) filed a motion with the Judicial Panel on Multidistrict Litigation (JPML) seeking transfer of any currently pending cases as well as any similar, subsequently filed cases to a coordinated and consolidated pre-trial multidistrict litigation (MDL) proceeding on a class-wide basis. In December 2016, the JPML granted an MDL to only those plaintiffs alleging injury from Invokana.

OnglyzalKombiglyze (saxagliptin)

As previously disclosed, in the US, AstraZeneca is defending various lawsuits filed in state and federal courts involving multiple plaintiffs claiming heart failure, cardiac failure and/or death from treatment with either *Onglyza* or *Kombiglyze*. In December 2016, plaintiffs in the California Superior Court filed a Petition for Coordination with the Judicial Council of California, requesting that all similar, currently pending or subsequently filed cases in California be coordinated for pre-trial purposes.



Nexium (esomeprazole)

As previously disclosed, in the US, AstraZeneca has been 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. Approximately 270 plaintiffs appealed the dismissal of their claims to the US Court of Appeals for the Ninth Circuit, and fewer than 40 plaintiffs appealed the dismissal of their claims to the California Second Appellate Division. In October 2016, the US Court of Appeals for the Ninth Circuit. In January 2017, the California Second Appellate Division affirmed the dismissal of the less than 40 cases in California state court.

Commercial litigation

Crestor (rosuvastatin calcium)

As previously disclosed, in Israel, in November 2012, a Motion to Certify a Claim as a Class Action and Statement of Claim (together, a Motion to Certify) were filed in the District Court in Tel Aviv, Jaffa, (the District Court) against AstraZeneca and four other pharmaceutical companies for alleged deception and failure to disclose material facts to consumers regarding potential adverse events associated with certain drugs, including *Crestor*. In July 2013, an amended Motion to Certify containing similar allegations to those in the first action were filed in the same District Court against the same defendants. In November 2016, the plaintiff filed a motion to withdraw from the action, which the District Court granted in December 2016. This matter has now concluded.

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 petitioned for rehearing and rehearing *en banc*, both of which were denied in January 2017.

Telephone Consumer Protection Act litigation

In December 2016, in the US, AstraZeneca and several other entities were served with a complaint filed in the US District Court for the Southern District of Florida (the District Court) that alleges, among other things, violations of the Telephone Consumer Protection Act caused by the sending of unsolicited advertisements by facsimile. AstraZeneca's motion to dismiss is pending. The plaintiff also made a motion for class certification, which, in January 2017, was denied without prejudice by the District Court.



8 PRODUCT ANALYSIS – FY 2016

| | World | | US | | | | Established ROW | | Emerging Markets | |
|---|---------|-------------|-----------|------|----------|------|-----------------|------|------------------|------------|
| | FY 2016 | CER | FY 2016 | CER | FY 2016 | CER | FY 2016 | CER | FY 2016 | CER |
| | \$m | % | \$m | % | \$m | % | \$m | % | \$m | % |
| Oncology: | | | | | | | | | | |
| Iressa | 513 | (5) | 23 | n/m | 120 | (5) | 137 | (8) | 233 | (10) |
| Tagrisso | 423 | n/m | 254 | n/m | 76 | n/m | 83 | 100 | 10 | 100 |
| Lynparza | 218 | n/m | 127 | 81 | 81 | n/m | 3 | n/m | 7 | n/m |
| Legacy: | | | | | | | | | | |
| Faslodex | 830 | 19 | 438 | 23 | 228 | 11 | 68 | 15 | 96 | 25 |
| Zoladex | 816 | - | 35 | 25 | 156 | (4) | 270 | (7) | 355 | 6 |
| Casodex | 247 | (9) | 2 | 100 | 27 | (7) | 111 | (23) | 107 | 8 |
| Arimidex | 232 | (6) | 14 | (26) | 37 | (24) | 71 | (18) | 110 | 15 |
| Others | 104 | (26) | - | n/m | 8 | (65) | 71 | 7 | 25 | (13) |
| Total Oncology | 3,383 | 20 | 893 | 74 | 733 | 18 | 814 | 2 | 943 | 6 |
| Cardiovascular & Metabolic Diseases: | | | | | | | | | | |
| Brilinta | 839 | 39 | 348 | 45 | 258 | 15 | 44 | 22 | 189 | 80 |
| Farxiga | 835 | 72 | 457 | 75 | 187 | 52 | 58 | 72 | 133 | 96 |
| Onglyza | 720 | (6) | 376 | (10) | 132 | (5) | 70 | 11 | 142 | (4) |
| Bydureon | 578 | - | 463 | (4) | 100 | 23 | 11 | 25 | 4 | (25) |
| Byetta | 254 | (19) | 164 | (22) | 45 | (25) | 21 | (9) | 24 | 13 |
| Legacy: | | | | | | | | | | |
| Crestor | 3,401 | (32) | 1,223 | (57) | 866 | (4) | 591 | (5) | 721 | 12 |
| Seloken/Toprol-XL | 737 | 9 | 95 | 7 | 90 | (5) | 16 | 25 | 536 | 12 |
| Atacand | 315 | (8) | 36 | 6 | 97 | (8) | 20 | (20) | 162 | (9) |
| Others | 437 | (26) | 40 | (27) | 119 | (17) | 50 | (21) | 228 | (30) |
| Total Cardiovascular & Metabolic Diseases | 8,116 | (13) | 3,202 | (31) | 1,894 | 1 | 881 | (1) | 2,139 | 8 |
| Respiratory: | · | | | | · · · | | | | <u> </u> | |
| Symbicort | 2,989 | (10) | 1,242 | (18) | 909 | (12) | 436 | 5 | 402 | 10 |
| Pulmicort | 1,061 | 8 | 174 | (13) | 99 | (14) | 90 | (3) | 698 | 21 |
| Tudorza/ Eklira | 170 | (9) | 77 | (25) | 83 | 9 | 9 | - | 1 | n/m |
| Daliresp/Daxas | 154 | 48 | 134 | 29 | 15 | 100 | 1 | n/m | 4 | n/m |
| Duaklir | 63 | n/m | - | | 60 | n/m | 2 | n/m | 1 | n/m |
| Others | 316 | 27 | 11 | (39) | 118 | 38 | 50 | 108 | 137 | 13 |
| Total Respiratory | 4,753 | (3) | 1,638 | (16) | 1,284 | (4) | 588 | 8 | 1,243 | 17 |
| Other: | | | ., | (14) | ., | | | | ., | |
| Nexium | 2,032 | (18) | 554 | (39) | 251 | (11) | 537 | (10) | 690 | (3) |
| Seroquel XR | 735 | (10) | 515 | (28) | 134 | (32) | 17 | (32) | 69 | (7) |
| Synagis | 677 | 2 | 325 | 14 | 352 | (7) | | (02) | - | (,,) |
| Losec/Prilosec | 276 | (17) | 10 | (44) | 83 | (13) | 55 | (31) | 128 | (9) |
| FluMist/Fluenz | 104 | (59) | 33 | (84) | 64 | 3 | 6 | (14) | 120 | (9) n/m |
| Novantik/Moventig | 91 | (39) n/m | 90 | n/m | - | - | - | (17) | 1 | - |
| | 1,152 | (20) | 90 105 | (54) | - 269 | (21) | 198 | (27) | 580 | (4) |
| Others | | . , | | | | . , | | | | |
| Total Other | 5,067 | (19) | 1,632 | (31) | 1,153 | (15) | 813 | (17) | 1,469 | (4) |
| Total Product Sales | 21,319 | (8) | 7,365 | (22) | 5,064 | (3) | 3,096 | (4) | 5,794 | 6 |



9 PRODUCT ANALYSIS – Q4 2016

| | World | | US | | Europe | | Established ROW | | Emerging Markets | |
|---|---------|----------|------------|------|---------|------|-----------------|------|------------------|------|
| | Q4 2016 | CER | Q4 2016 | CER | Q4 2016 | CER | Q4 2016 | CER | Q4 2016 | CER |
| | \$m | % | <u>\$m</u> | % | \$m | % | \$m | % | \$m | % |
| Oncology: | | | | | | | | | | |
| Iressa | 118 | (11) | 7 | 75 | 29 | (6) | 36 | (6) | 46 | (22) |
| Tagrisso | 147 | n/m | 74 | n/m | 27 | n/m | 40 | 100 | 6 | n/m |
| Lynparza | 62 | 72 | 31 | 29 | 25 | 127 | 3 | n/m | 3 | n/m |
| Legacy: | | | | | | | | | | |
| Faslodex | 222 | 19 | 117 | 23 | 59 | 11 | 20 | 20 | 26 | 23 |
| Zoladex | 235 | 13 | 8 | 33 | 39 | 2 | 71 | (9) | 117 | 36 |
| Casodex | 60 | (8) | - | - | 8 | 14 | 27 | (27) | 25 | 13 |
| Arimidex | 57 | (7) | 2 | (50) | 10 | (17) | 18 | (24) | 27 | 22 |
| Others | 29 | - | | - | 4 | 33 | 20 | 6 | 5 | (29) |
| Total Oncology | 930 | 26 | 239 | 61 | 201 | 26 | 235 | 11 | 255 | 16 |
| Cardiovascular & Metabolic Diseases: | | | | | | | | | | |
| Brilinta | 236 | 37 | 105 | 50 | 66 | 13 | 12 | 10 | 53 | 62 |
| Farxiga | 239 | 57 | 130 | 69 | 51 | 37 | 17 | 50 | 41 | 56 |
| Onglyza | 149 | (21) | 72 | (27) | 30 | (6) | 15 | (17) | 32 | (23) |
| Bydureon | 142 | (8) | 114 | (7) | 25 | (7) | 3 | 50 | - | n/m |
| Byetta | 55 | (22) | 37 | (14) | 8 | (43) | 5 | (29) | 5 | (25) |
| Legacy: | | | | | | | | | | |
| Crestor | 631 | (53) | 95 | (88) | 209 | (6) | 146 | (16) | 181 | 14 |
| Seloken/Toprol-XL | 178 | 14 | 14 | (26) | 23 | (4) | 6 | 67 | 135 | 23 |
| Atacand | 81 | (5) | 8 | 14 | 23 | (12) | 5 | 25 | 45 | (6) |
| Others | 100 | (31) | 13 | (7) | 30 | (21) | 12 | (29) | 45 | (41) |
| Total Cardiovascular & Metabolic Diseases | 1,811 | (26) | 588 | (52) | 465 | (3) | 221 | (11) | 537 | 6 |
| Respiratory: | | | | | | | | | | |
| Symbicort | 740 | (13) | 284 | (31) | 230 | (3) | 126 | 15 | 100 | 5 |
| Pulmicort | 288 | 8 | 36 | (31) | 26 | (10) | 29 | - | 197 | 25 |
| Tudorza/Eklira | 36 | (23) | 16 | (36) | 18 | (5) | 2 | - | - | n/m |
| Daliresp/Daxas | 41 | 28 | 33 | 3 | 5 | 100 | - | - | 3 | n/m |
| Duaklir | 19 | 58 | - | - | 18 | 46 | 1 | n/m | - | - |
| Others | 86 | 37 | 4 | (33) | 35 | 85 | 17 | 143 | 30 | (3) |
| Total Respiratory | 1,210 | (5) | 373 | (29) | 332 | 5 | 175 | 19 | 330 | 16 |
| Other: | | | | | | | | | | |
| Nexium | 491 | (15) | 135 | (23) | 61 | (19) | 148 | (5) | 147 | (12) |
| Seroquel XR | 118 | (51) | 71 | (60) | 28 | (32) | 3 | (40) | 16 | (16) |
| Synagis | 302 | 10 | 154 | 20 | 148 | 1 | - | - | - | - |
| Losec/Prilosec | 59 | (23) | 3 | 100 | 20 | (19) | 13 | (33) | 23 | (30) |
| FluMist/Fluenz | 67 | (60) | 20 | (83) | 43 | (21) | 4 | (43) | - | - |
| Movantik/Moventig | 26 | 73 | 26 | 73 | - | - | - | - | - | - |
| Others | 246 | (34) | 9 | (84) | 34 | (57) | 25 | (69) | 178 | 8 |
| Total Other | 1,309 | (25) | 418 | (38) | 334 | (21) | 193 | (28) | 364 | (5) |
| Total Product Sales | 5,260 | (15) | 1,618 | (37) | 1,332 | (3) | 824 | (6) | 1,486 | 7 |
| | -, | <u> </u> | , | N= 7 | , | 1-7 | - | 1.7 | , | |



Shareholder Information

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

Future dividends will normally be paid as follows:

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

The record date for the second interim dividend for 2016, payable on 20 March 2017, will be 17 February 2017. Ordinary Shares listed in London and Stockholm will trade ex-dividend from 16 February 2017. American Depositary Shares listed in New York will trade ex-dividend from 15 February 2017.

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

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Cautionary Statements Regarding Forward-Looking Statements

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