

ASTRAZENECA PLC
Form 6-K
February 04, 2016

FORM 6-K

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Report of Foreign Issuer

Pursuant to Rule 13a-16 or 15d-16 of
the Securities Exchange Act of 1934

For the month of February 2016

Commission File Number: 001-11960

AstraZeneca PLC

2 Kingdom Street, London W2 6BD

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): _____

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes No

If "Yes" is marked, indicate below the file number assigned to the Registrant in connection with Rule 12g3-2(b): 82- _____

4 February 2016

Full-Year and Q4 2015 Results

Financial Summary

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Tagrisso: Regulatory decision (JP)
tremelimumab - mesothelioma: Data readout
Lynparza - gastric cancer: Data readout

benralizumab - severe asthma: Regulatory submission (US, EU)

Brilinta/Brilique - peripheral arterial disease: Data readout
saxagliptin/dapagliflozin: Regulatory decision (EU)
roxadustat - anaemia: Rolling regulatory submission (CN)

H2 2016

Lynparza - ovarian cancer: Data readout
Lynparza - breast cancer: Data readout
tremelimumab - mesothelioma: Regulatory submission
cediranib - ovarian cancer: Regulatory decision (EU)
durvalumab - head & neck cancer: Data readout
acalabrutinib - blood cancer: Data readout, regulatory submission (US)
selumetinib - lung cancer: Data readout

CAZ AVI - serious infections: Regulatory decision (EU)

Notes

1. All growth rates and guidance are shown at constant exchange rates (CER) unless specified otherwise.
2. Total Revenue defined as Product Sales and Externalisation Revenue.
3. See the Operating and Financial Review for a definition of Core financial measures and a reconciliation of Core to Reported financial measures.
4. Q4 2014 results reflected a Reported Operating Loss of \$349m and a Reported Loss Per Share of \$0.25; a percentage comparison to the Reported results in Q4 2015 is not meaningful.

The performance shown in this announcement covers the twelve and three month periods to 31 December 2015 (the year and the quarter respectively) compared to the twelve and three month periods to 31 December 2014 (the prior year and the prior quarter respectively).

Results Presentation

A presentation and accompanying live webcast for investors and analysts, hosted by management, will begin at midday GMT today. Details can be accessed via www.astrazeneca.com/investors.

Reporting Calendar

The Company intends to publish its first-quarter financial results on 29 April 2016.

About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three main therapy areas - Respiratory, Inflammation and Autoimmunity (RIA), Cardiovascular and Metabolic Disease (CVMD) and Oncology - as well as in Infection and Neuroscience. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information, please visit: www.astrazeneca.com.

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

Operating and Financial Review

All narrative on growth and results in this section relates to Core performance, based on constant exchange rates (CER) unless stated otherwise. Financial figures are in \$ millions (\$m). The performance shown in this announcement covers the twelve and three-month periods to 31 December 2015 (the year and the fourth quarter respectively) compared to the twelve and three months to 31 December 2014. Core measures, which are presented in addition to Reported financial information, are non-GAAP measures provided to enhance understanding of the Company's underlying financial performance. Core financial measures are adjusted to exclude certain significant items, such as:

– amortisation and impairment of intangibles, including impairment reversals but excluding any charges relating to IT assets

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

More detail on the nature of these measures is given on page 72 of the 2014 Annual Report and Form 20-F Information.

Total Revenue

Total Revenue increased by 1% to \$24,708m in the year, comprising Product Sales of \$23,641m (down by 1%) and Externalisation Revenue of \$1,067m (up by 140%). Based on actual exchange rates, Total Revenue declined by 7% in the year, reflecting the particular weakness of key trading currencies against the US dollar.

Product Sales

The decline in Product Sales was primarily driven by the US market entry of Nexium generic products from February 2015, as well as full-year adverse impacts from Synagis guideline changes in 2014 and the change in accounting for the US Branded Pharmaceutical Fee, following issuance of final regulations in 2014.

Within Product Sales, the Growth Platforms grew by 11% in the year, representing 57% of Total Revenue. ‘New Oncology’ is included for the first time, given its long-term importance for the Company’s future growth:

| Growth Platform | FY 2015 | | Q4 2015 | |
|--------------------------|---------------------|--------------|---------------------|--------------|
| | Product Sales (\$m) | % CER change | Product Sales (\$m) | % CER change |
| Respiratory | 4,987 | 7 | 1,289 | 4 |
| Brilinta/Brilique | 619 | 44 | 174 | 43 |
| Diabetes | 2,224 | 26 | 585 | 24 |
| Emerging Markets | 5,822 | 12 | 1,428 | 10 |
| Japan | 2,020 | 4 | 541 | 8 |
| New Oncology | 119 | n/m | 57 | n/m |
| TOTAL¹ | 14,003 | 11 | 3,588 | 11 |

¹ Total Product Sales for Growth Platforms adjusted to remove duplication on a product and regional basis.

Externalisation Revenue

Externalisation Revenue of \$1,067m for the year (Q4 2015: \$192m) primarily reflected income generated from a strategic collaboration in haematology with Celgene Corporation (upfront receipt of \$450m) and a co-development and co-commercialisation arrangement with Daiichi Sankyo Co., Ltd. (Daiichi Sankyo) for Movantik in the US (upfront receipt of \$200m). Other Externalisation Revenue reflected a number of collaboration agreements, including the acceleration of the development of brodalumab with Valeant Pharmaceuticals International, Inc. (upfront receipt of \$100m) and the co-commercialisation of Nexium in Japan (milestone income of \$123m) with Daiichi Sankyo.

Product Sales

The performance of a selection of key medicines is shown below. A geographical split of the performance is shown in Notes 8 and 9.

| | FY 2015 | | | Q4 2015 | | |
|--|---------|----------|--------|---------|----------|--------|
| | \$m | % Change | | \$m | % Change | |
| | | CER | Actual | | CER | Actual |
| | | | | | | |

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Respiratory, Inflammation
& Autoimmunity

| | | | | | | |
|----------------|-------|-----|------|-------|-----|------|
| Symbicort | 3,394 | (3) | (11) | 859 | (6) | (12) |
| Pulmicort | 1,014 | 15 | 7 | 274 | 9 | 2 |
| Tudorza/Eklira | 190 | n/m | n/m | 47 | n/m | n/m |
| Daliresp | 104 | n/m | n/m | 32 | n/m | n/m |
| Duaklir | 27 | n/m | n/m | 12 | n/m | n/m |
| Others | 258 | (5) | (15) | 65 | (4) | (14) |
| TOTAL | 4,987 | 7 | (2) | 1,289 | 4 | (4) |

Cardiovascular &
Metabolic Disease

| | | | | | | |
|-------------------|-----|-----|-----|-----|----|-----|
| Brilinta/Brilique | 619 | 44 | 30 | 174 | 43 | 31 |
| Onglyza | 786 | 2 | (4) | 192 | 3 | (4) |
| Bydureon | 580 | 35 | 32 | 155 | 28 | 26 |
| Farxiga/Forxiga | 492 | 137 | 119 | 152 | 76 | 63 |
| Byetta | 316 | 2 | (3) | 72 | 10 | 4 |

Legacy:

| | | | | | | |
|-------------------|-------|------|------|-------|------|------|
| Crestor | 5,017 | (3) | (9) | 1,322 | - | (5) |
| Seloken/Toprol-XL | 710 | 4 | (6) | 160 | 5 | (8) |
| Atacand | 358 | (15) | (29) | 86 | (15) | (26) |

| | | | | | | |
|--------|-------|------|------|-------|-----|------|
| Others | 611 | (10) | (18) | 147 | (9) | (17) |
| TOTAL | 9,489 | 4 | (3) | 2,460 | 6 | (1) |

Oncology

| | | | | | | |
|----------|-----|-----|------|-----|-----|------|
| Iressa | 543 | (2) | (13) | 129 | (5) | (14) |
| Lynparza | 94 | n/m | n/m | 36 | n/m | n/m |
| Tagrisso | 19 | n/m | n/m | 18 | n/m | n/m |

Legacy:

| | | | | | | |
|----------|-----|-----|------|-----|-----|------|
| Zoladex | 816 | 7 | (12) | 198 | 4 | (13) |
| Faslodex | 704 | 9 | (2) | 185 | 12 | 2 |
| Casodex | 267 | (6) | (17) | 63 | (7) | (15) |
| Arimidex | 250 | (5) | (16) | 60 | (1) | (12) |

| | | | | | | |
|--------|-------|---|-----|-----|------|------|
| Others | 132 | 6 | (7) | 27 | (26) | (33) |
| TOTAL | 2,825 | 7 | (7) | 716 | 9 | (3) |

Infection, Neuroscience &
Gastrointestinal

| | | | | | | |
|-------------------|-------|------|------|-----|------|------|
| Nexium | 2,496 | (26) | (32) | 564 | (26) | (32) |
| Seroquel XR | 1,025 | (12) | (16) | 241 | (18) | (22) |
| Synagis | 662 | (26) | (26) | 275 | (32) | (32) |
| Losec/Prilosec | 340 | (10) | (19) | 77 | (23) | (30) |
| FluMist/Fluenz | 288 | - | (2) | 191 | 46 | 43 |
| Movantik/Moventig | 29 | n/m | n/m | 15 | n/m | n/m |

| | | | | | | |
|--------|-------|---|------|-----|----|----|
| Others | 1,500 | - | (12) | 379 | 25 | 11 |
|--------|-------|---|------|-----|----|----|

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| | | | | | | |
|---------------------|--------|------|------|-------|------|------|
| TOTAL | 6,340 | (16) | (23) | 1,742 | (13) | (18) |
| TOTAL PRODUCT SALES | 23,641 | (1) | (9) | 6,207 | - | (7) |

FY 2015 Product Sales Summary

During 2014, final regulations relating to the US Branded Pharmaceutical Fee were issued, affecting how the fee is recognised. AstraZeneca accrues for the obligation as each sale occurs, and, as under the final guidelines the fee is based on actual Product Sales in the current year, the fee is recognised as a deduction from Product Sales rather than a charge to SG&A, impacting individual medicine sales in the US by an average of 2%.

Respiratory, Inflammation & Autoimmunity

Symbicort

FY 2015 sales declined by 3% to \$3,394m.

In the US, sales of \$1,520m represented growth of 1%, with lower net prices reflecting additional access and co-pay assistance. Strong volume growth was driven by higher market share within a growing market.

In Europe, sales declined by 14% to \$1,076m with a modest volume decline and a significant price decline reflecting increased competition from recently-launched analogue medicines. In contrast, Emerging Markets sales grew by 22% to \$394m with China sales growing by 38% to \$124m, primarily reflecting volume growth.

Pulmicort

Pulmicort sales in the year were \$1,014m, an increase of 15%. Growth was driven primarily by the performance of Pulmicort Respules in Emerging Markets, where Pulmicort sales grew by 35% to \$609m. China sales increased by 43% to \$485m, reflecting sustained investment in supporting asthma and chronic obstructive pulmonary disease (COPD) patients, both in hospitals and at home.

Tudorza/Eklira

Sales in the year were \$190m; over half of the medicine's sales were in the US, where the brand name is Tudorza. In March 2015, the Company completed the acquisition of the Actavis plc (Actavis) rights to the product.

Daliresp

Rights were acquired in March 2015 from Actavis for Daliresp in the US and Canada. Sales were \$104m in the year.

Duaklir

Duaklir was successfully launched in the year, principally in Europe. Sales of \$27m reflected good progress of this leading LAMA/LABA medicine, with an encouraging formulary uptake in the UK and a strong market-share performance in Germany.

The encouraging performances of Tudorza/Eklira, Daliresp and Duaklir under the Company's ownership were in line with expectations.

Cardiovascular & Metabolic Disease

Brilinta/Brilique

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Sales in the year were \$619m, an increase of 44%. AstraZeneca announced in H2 2015 that the US Food and Drug Administration (FDA) had approved Brilinta tablets at a new 60mg dose to be used in patients with a history of heart attack beyond the first year of treatment.

FY 2015 sales in the US increased by 64% to \$240m. The expanded indication launched in the second half of the year, underpinned ongoing new-to-brand prescription share growth, with share standing at 12% at the end of the year; this represented a four percentage point increase in the twelve-month period.

In Europe, Brilique continued to perform strongly, with an increase in full-year sales of 18% to \$230m, reflecting indication leadership across a number of markets. Emerging Markets sales grew by 91% to \$112m, with China representing the largest single market for the medicine, where sales were up by 160% to \$38m.

Onglyza

Sales were up 2% in the year to \$786m, with sales in Q4 2015 increasing by 3%.

US sales in the year declined by 13% to \$420m as a consequence of a greater emphasis on the promotion of Farxiga. Competitive pressures in the DPP-4 class drove lower volumes and a decline in the net price.

Sales in Europe grew by 8% to \$141m, while Emerging Markets sales increased by 41% to \$159m.

Farxiga/Forxiga

Sales of Farxiga/Forxiga were up 137% in the year to \$492m.

In the US, sales of \$261m represented growth of 114%. Promotional activity underpinned increasing total-prescription market-share growth in the year; this was accompanied by overall growth in the market.

Sales in Europe reached \$126m in the year, up by 126%. Launches of Forxiga in the year in a number of international markets, such as Australia, have been successful.

Bydureon/Byetta

Combined sales were \$896m in the year, representing growth of 21%; Bydureon represented approximately 65% of total Bydureon/Byetta sales.

In the US, sales were \$691m, up by 21%, with higher volumes driven by market growth and higher net prices. The majority of the remaining sales of Bydureon/Byetta were in Europe, totalling \$143m; Bydureon sales in Europe grew by 65% to \$81m, reflecting the Company's ongoing effort to expand its Diabetes presence.

Legacy: Crestor

Sales of Crestor declined in the year by 3% to \$5,017m; pricing was stable. The volume performance primarily reflected ongoing competition from generic statins.

In the US, Crestor sales declined by 3% to \$2,844m, driven by lower market share and destocking, partially offset by favourable price movements.

In Europe, sales declined by 9% to \$916m, reflecting prevailing competitive trends. Crestor consolidated its position as the leading statin in Japan, with sales growth in the year of 8% to \$468m. Sales in China grew by 13% to \$258m.

Oncology

Iressa

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Sales of Iressa in the year declined by 2% to \$543m, driven by the competitive environment in Europe where sales were down by 8% to \$128m; Japan sales declined by 13% to \$121m. Following the US launch in July 2015, Iressa saw an encouraging number of new-patient starts.

Emerging Markets sales grew by 4% to \$272m, with China sales increasing by 5% to \$146m and Latin America sales increasing by 17% to \$11m.

Lynparza

Sales of Lynparza reached \$94m in 2015. US sales of \$70m followed the launch of the medicine in December 2014. Growth was driven by addressing the accumulated needs of eligible patients awaiting treatment, as well as patients newly tested for BRCA mutation. By the end of 2015, the medicine had been launched in 15 countries, including France and Germany.

Tagrisso

Sales of Tagrisso were \$19m in 2015; the medicine was launched in November 2015 in the US with a strong performance in the number of new-patient starts.

Legacy: Zoladex

Sales increased by 7% to \$816m, with a notable performance in China where sales reached \$121m, reflecting growth of 29%.

Legacy: Faslodex

Sales were up 9% to \$704m in 2015. US sales grew by 5% to \$356m, accompanied by Europe sales of \$207m, up by 2% in the year. The notable performance was in the Emerging Markets, where sales of \$87m represented growth of 49%. Supported by the launch of 500mg Faslodex, China sales accelerated in the year to \$11m (Q4 2015: growth of 100%, Q3 2015: growth of 50%). AstraZeneca Russia also achieved federal reimbursement for the medicine in the year.

Infection, Neuroscience & Gastrointestinal

Nexium

Sales of Nexium declined by 26% in the year to \$2,496m.

US sales declined by 52% to \$902m following the loss of exclusivity at the start of the year, directly impacting both pricing and volumes. Sales in Europe declined by 7% to \$284m.

Nexium sales in Emerging Markets were up by 3% to \$761m, with growth in Latin America of 18% to \$127m. Japan sales increased by 30% in the year to \$405m.

Seroquel XR

Sales declined by 12% in the year to \$1,025m.

In the US, sales were down 3% at \$716m. Sales in Europe declined by 30% to \$202m, a function of generic-product competition.

Synagis

FY 2015 sales of Synagis declined by 26% to \$662m.

A 43% decline in US sales in the year to \$285m reflected the reduction in demand as a result of the American Academy of Pediatrics Committee on Infectious Disease guidelines issued in 2014. These guidelines were more restrictive than the approved label, which further reduced patients eligible for preventative therapy with Synagis.

FluMist/Fluenz

Sales in the year were stable at \$288m. US sales declined by 6% to \$206m, reflecting supply issues. In contrast, Europe sales increased by 16% to \$76m.

Movantik/Moventig

Sales in the year totalled \$29m (Q4 2015: \$15m); the medicine was launched in March 2015. The majority of sales were in the US, where the Company announced a co-commercialisation agreement in 2015 with Daiichi Sankyo for Movantik.

Regional Product Sales

| | \$m | FY 2015 % Change | | \$m | Q4 2015 % Change | |
|-------------------------------|--------|---------------------|--------|-------|---------------------|--------|
| | | CER | Actual | | CER | Actual |
| US | 9,474 | (6) | (6) | 2,572 | (3) | (3) |
| Europe | 5,323 | (6) | (19) | 1,421 | (7) | (17) |
| Established ROW ¹ | 3,022 | - | (14) | 786 | 4 | (8) |
| Japan | 2,020 | 4 | (9) | 541 | 8 | - |
| Canada | 533 | 4 | (10) | 134 | 2 | (14) |
| Other Established ROW | 469 | (19) | (32) | 111 | (10) | (26) |
| Emerging Markets ² | 5,822 | 12 | (1) | 1,428 | 10 | (4) |
| China | 2,530 | 15 | 13 | 599 | 10 | 6 |
| Ex. China | 3,292 | 10 | (9) | 829 | 9 | (10) |
| Total | 23,641 | (1) | (9) | 6,207 | - | (7) |

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

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

US

US sales declined in the year by 6% to \$9,474m. The US Branded Pharmaceutical Fee was recognised as a deduction from Product Sales in the year rather than as a charge to SG&A, impacting individual medicine sales by an average of around 2%.

The decline in sales in the US also reflected the entry of Nexium generic products from February 2015; Nexium sales in the US declined by 52% to \$902m in the year. Adverse Synagis guideline changes were reflected in a 43% decline in US Synagis sales to \$285m in the year.

Favourable performances were delivered by Brilinta, Farxiga, Bydureon and Lynparza as well as the acquired Respiratory medicines Tudorza and Daliresp. Tagrisso, launched earlier than originally anticipated in the fourth quarter, delivered an encouraging number of new-patient starts.

Continued growth in demand for Farxiga was supported by a strong promotional programme. Bydureon benefitted from the launch of the Bydureon Pen as well as growth in demand in the overall GLP-1 class.

Europe

Sales in Europe declined by 6% to \$5,323m in the year. Strong growth from the Diabetes portfolio was more than offset by continued generic competition facing Crestor and Seroquel XR. A 14% decline in Symbicort sales to \$1,076m reflected adverse pricing movements driven by competition from analogues in key markets. Duaklir more than doubled its first-half sales in the final quarter, bringing the full-year total to \$26m. Lynparza was launched in Europe in 2015, contributing sales of \$23m in the year.

Established ROW

Sales in the Established Rest Of World (ROW) were stable in the year at \$3,022m.

Japan sales in the year increased by 4% to \$2,020m. Sales of Crestor continued to grow strongly in the full year, up 8% to \$468m. This reflected a continued increase in the usage of the 5mg dosage. Nexium sales rose by 30% to \$405m, flattered by the impact of a product recall in FY 2014. Symbicort sales in the year fell by 2% to \$176m in Japan, with a Q4 2015 sales decline of 16%. The strong performance in Q4 2014 reflected restocking. Underlying Symbicort sales growth in the year was estimated at around 5%. The Established ROW market share of Symbicort was broadly stable in the fourth quarter and over the full year.

Canada sales grew by 4% to \$533m in the year, driven by the performances of Onglyza with sales up 27% to \$53m and Symbicort sales increasing by 8% to \$149m.

Emerging Markets

The Company continues to focus on delivering innovative medicines by accelerating investment in its Emerging Markets capabilities, with a focus on China and other leading markets, such as Russia and Brazil.

Emerging Markets sales in the year increased by 12% to \$5,822m, with contributions to growth generated from across the region. Around 60% of Emerging Markets sales were derived outside of China in the year. Emerging Markets sales in the final quarter increased by 10% to \$1,428m, ahead of the Company's long-term forecast of mid to high single-digit percentage growth in the region's Product Sales.

China sales in the year increased by 15% to \$2,530m, while Brazil sales grew by 16% to \$381m and Russia sales grew by 21% to \$231m.

Financial Performance

| FY 2015 | Reported | Restructuring | Intangible | | | Core | | % Change | |
|----------------------------|----------|---------------|----------------------------------|----------------------|--------------------|------------|-------------------------|----------|--------|
| | | | Amortisation & Impairments | Diabetes Alliance | Other ¹ | FY 2015 | FY 2014 ² | CER | Actual |
| Product Sales | 23,641 | - | - | - | - | 23,641 | 26,095 | (1) | (9) |
| Externalisation Revenue | 1,067 | - | - | - | - | 1,067 | 452 | 140 | 136 |
| Total Revenue | 24,708 | - | - | - | - | 24,708 | 26,547 | 1 | (7) |
| Cost of Sales | (4,646) | 158 | 369 | - | - | (4,119) | (4,888) | (6) | (16) |
| Gross Profit | 20,062 | 158 | 369 | - | - | 20,589 | 21,659 | 2 | (5) |
| Gross Margin ³ | 80.3% | | | | | 82.6% | 81.3% | +0.8 | +1.3 |

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|---------------------------|----------|-------|-------|-------|-------|---------|----------|------|------|
| Distribution | (339) | - | - | - | - | (339) | (324) | 17 | 5 |
| % Total Revenue | 1.4% | | | | | 1.4% | 1.2% | -0.2 | -0.2 |
| R&D | (5,997) | 258 | 136 | - | - | (5,603) | (4,941) | 21 | 13 |
| % Total Revenue | 24.3% | | | | | 22.7% | 18.6% | -3.8 | -4.1 |
| SG&A | (11,112) | 618 | 921 | 54 | 254 | (9,265) | (10,216) | (2) | (9) |
| % Total Revenue | 45.0% | | | | | 37.5% | 38.5% | +1.1 | +1.0 |
| Other Operating Income | 1,500 | - | 178 | - | (158) | 1,520 | 759 | 104 | 100 |
| % Total Revenue | 6.1% | | | | | 6.2% | 2.9% | +2.9 | +3.3 |
| Operating Profit | 4,114 | 1,034 | 1,604 | 54 | 96 | 6,902 | 6,937 | 6 | (1) |
| % Total Revenue | 16.7% | | | | | 27.9% | 26.1% | +1.3 | +1.8 |
| Net Finance Expense | (1,029) | - | - | 409 | 115 | (505) | (493) | | |
| Joint Ventures | (16) | - | - | - | - | (16) | (6) | | |
| Profit Before Tax | 3,069 | 1,034 | 1,604 | 463 | 211 | 6,381 | 6,438 | 7 | (1) |
| Taxation | (243) | (217) | (344) | (152) | (34) | (990) | (1,040) | | |
| Tax Rate | 8% | | | | | 16% | 16% | | |
| Profit After Tax | 2,826 | 817 | 1,260 | 311 | 177 | 5,391 | 5,398 | 7 | - |
| Non-controlling Interests | (1) | - | - | - | - | (1) | (2) | | |
| Net Profit | 2,825 | 817 | 1,260 | 311 | 177 | 5,390 | 5,396 | 7 | - |
| Weighted Average Shares | 1,264 | 1,264 | 1,264 | 1,264 | 1,264 | 1,264 | 1,262 | | |
| Earnings Per Share | 2.23 | 0.65 | 1.00 | 0.24 | 0.14 | 4.26 | 4.28 | 7 | - |

1 Other adjustments include provision charges and settlement income related to certain legal matters (see Note 7) and fair value adjustments to contingent consideration liabilities arising on business combinations (see Note 6).

2 2014 comparatives have been restated to reflect the reclassification of Externalisation Revenue from Other Operating Income.

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

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

| Q4 2015 | Reported | Restructuring | Intangible | Other ¹ | Core | % Change |
|---------|----------|---------------|------------|--------------------|------|----------|
|---------|----------|---------------|------------|--------------------|------|----------|

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| | | | Amortisation & Impairments | Diabetes Alliance | | Q4 2015 | Q4 20142 | CER | Actual |
|------------------------------|---------|-------|----------------------------------|----------------------|-------|---------|-------------|------|--------|
| Product Sales | 6,207 | - | - | - | - | 6,207 | 6,683 | - | (7) |
| Externalisation Revenue | 192 | - | - | - | - | 192 | 33 | 490 | 482 |
| Total Revenue | 6,399 | - | - | - | - | 6,399 | 6,716 | 2 | (5) |
| Cost of Sales | (1,269) | 34 | 26 | - | - | (1,209) | (1,359) | 3 | (11) |
| Gross Profit | 5,130 | 34 | 26 | - | - | 5,190 | 5,357 | 2 | (3) |
| Gross Margin ³ | 79.6% | | | | | 80.5% | 79.7% | -0.7 | +0.8 |
| Distribution | (99) | - | - | - | - | (99) | (88) | 23 | 13 |
| % Total Revenue | 1.5% | | | | | 1.5% | 1.3% | -0.3 | -0.2 |
| R&D | (1,746) | 78 | 101 | - | - | (1,567) | (1,360) | 21 | 15 |
| % Total Revenue | 27.3% | | | | | 24.5% | 20.3% | -3.7 | -4.2 |
| SG&A | (2,668) | 260 | 237 | (270) | (20) | (2,461) | (2,953) | (11) | (17) |
| % Total Revenue | 41.7% | | | | | 38.5% | 44.0% | +5.7 | +5.5 |
| Other Operating Income | 471 | - | 22 | - | - | 493 | 228 | 100 | 116 |
| % Total Revenue | 7.4% | | | | | 7.7% | 3.4% | +3.2 | +4.3 |
| Operating Profit | 1,088 | 372 | 386 | (270) | (20) | 1,556 | 1,184 | 28 | 31 |
| % Total Revenue | 17.0% | | | | | 24.3% | 17.6% | +4.8 | +6.7 |
| Net Finance Expense | (279) | - | - | 104 | 25 | (150) | (112) | | |
| Joint Ventures | (7) | - | - | - | - | (7) | (4) | | |
| Profit Before Tax | 802 | 372 | 386 | (166) | 5 | 1,399 | 1,068 | 29 | 31 |
| Taxation | 6 | (78) | (97) | (11) | (20) | (200) | (119) | | |
| Tax Rate | (1)% | | | | | 14% | 11% | | |
| Profit After Tax | 808 | 294 | 289 | (177) | (15) | 1,199 | 949 | 22 | 26 |
| Non-controlling Interests | - | - | - | - | - | - | - | | |
| Net Profit | 808 | 294 | 289 | (177) | (15) | 1,199 | 949 | 22 | 26 |
| | 1,264 | 1,264 | 1,264 | 1,264 | 1,264 | 1,264 | 1,263 | | |

Weighted
Average Shares

Earnings Per
Share

| | | | | | | | | |
|------|------|------|--------|--------|------|------|----|----|
| 0.63 | 0.24 | 0.23 | (0.15) | (0.01) | 0.94 | 0.76 | 22 | 26 |
|------|------|------|--------|--------|------|------|----|----|

1 Other adjustments include provision charges and settlement income related to certain legal matters (see Note 7) and fair value adjustments to contingent consideration liabilities arising on business combinations (see Note 6).

2 2014 comparatives have been restated to reflect the reclassification of Externalisation Revenue from Other Operating Income.

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

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

Profit and Loss

Gross Profit

Core Gross Profit increased by 2% in the year to \$20,589m. Excluding the impact of externalisation, the Core Gross-Profit margin increased by one percentage point. Drivers of the margin increase included the mix of Product Sales and manufacturing efficiencies.

Operating Expenses

Core R&D costs were up 21% in the year to \$5,603m as the Company continued to focus on its pipeline. Oncology attracted over 40% of total Core R&D investment in the year, reflecting a number of active trials.

In line with commitments made in early 2015 to reduce Core SG&A costs for the full year, Core SG&A costs declined by 2% to \$9,265m. Core SG&A costs also declined in the year by one percentage point as a proportion of Total Revenue. A number of ongoing programmes designed to address Core SG&A costs are progressing. These initiatives are focused on:

- Sales, marketing and medical-cost effectiveness
- Centralisation of selected functions and process improvements
 - Reduced third-party spend
- Additional efficiencies gained across support functions and IT
- Continued footprint optimisation, including presence in the UK and US

Resources will continue to be deployed selectively to meet changing customer needs and the evolving portfolio, while driving top-line growth.

Other Operating Income

Core Other Operating Income of \$1,520m in the year increased by 104% and included:

- \$380m of income related to the disposal of the US rights to Entocort
 - \$322m of royalty income arising from a number of agreements
- \$215m of income related to the disposal of the rest-of-world rights to Entocort
 - \$193m of income related to the disposal of Myalept
 - \$165m of income related to the disposal of Caprelsa

Operating Profit

Core Operating Profit increased by 6% to \$6,902m in the year. The Core Operating Margin increased by one percentage point to 28% of Total Revenue. The increase reflected the decline in Core SG&A costs and the increase in Externalisation Revenue and Core Other Operating Income, while the Company continued to invest in the pipeline and the Growth Platforms.

Reported Operating Profit of \$4,114m was \$1,977m higher than FY 2014 principally due to the difference in Core adjustments between FY 2015 and FY 2014. Most significantly, fair value adjustments to contingent consideration relating to the Bristol-Myers Squibb Company (BMS) share of the global Diabetes alliance increased Reported Operating Profit by \$378m in FY 2015, whereas fair value adjustments to contingent consideration reduced Reported Operating Profit by \$529m in FY 2014. These fair value movements reflect estimates for future liabilities that can change materially over time. In addition, restructuring costs of \$1,034m in FY 2015 were significantly lower than restructuring costs of \$1,558m in FY 2014.

Finance Expense

The Core Net Finance Expense was \$505m in the year, compared with \$493m in FY 2014. The Reported Net Finance Expense of \$1,029m included a charge of \$524m relating to the discount unwind on contingent consideration liabilities recognised on business combinations, principally relating to the acquisition of the BMS share of the global Diabetes alliance.

Taxation

Excluding the previously disclosed one-off tax benefit of \$186m following agreement of US federal tax liabilities of open years up to 2008, other net reductions in provisions for tax contingencies and non-Core revaluations of contingent consideration arising on business combinations, partially offset by the impact of internal transfers of intellectual property, the Core and Reported tax rates for the year ended 31 December 2015 were 21% and 22% respectively. Including the impact of these items, the Core and Reported tax rates for the year were 16% and 8% respectively. The cash tax paid for the year was \$1,354m, which was 44% of Reported Profit Before Tax and 21% of Core Profit Before Tax.

Both the underlying Reported and underlying Core tax rates for the year ended 31 December 2014 were around 18%. Taking into account the one-off benefits totalling \$309m in respect of a transfer pricing matter, non-Core revaluations of contingent consideration arising on business combinations, and the benefit of the UK Patent Box, the Reported and Core tax rates fell to 1% and 16% respectively.

Earnings Per Share (EPS)

Core EPS in the year increased by 7% to \$4.26.

Reported EPS was up by 137% at \$2.23. Core profit adjustments were lower in the year and represented 40% of Core Operating Profit compared to 69% in 2014, mainly as a result of the fair value movements described above.

Dividends

The Board has declared a second interim dividend of \$1.90 per share (131.0 pence, 16.26 SEK) bringing the dividend per share for the full year to \$2.80 (188.5 pence, 23.97 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. Following the ratio change to the Company's NYSE-listed sponsored Level 2 American Depositary Receipt programme on 27 July 2015, two ADSs equal one Ordinary Share.

Productivity

Restructuring charges of \$372m were recognised in the fourth quarter, bringing the full-year total to \$1,034m, as the Company continued to make good progress in implementing its restructuring plans.

These charges included \$683m related to the Phase 4 programme, initially announced in March 2013 and subsequently expanded. A \$233m charge was associated with previously-announced site exits (including Avlon in the UK) and the integration of the Diabetes and Respiratory businesses acquired from BMS and Almirall respectively. A charge of \$102m was associated with targeted restructuring of the Company's commercial business, implemented in late 2015, principally in Venezuela, in response to challenging economic conditions, and Europe.

Furthermore, as part of the ongoing commitment to improve productivity, the Company is initiating multi-year transformation programmes within back-office functions (principally finance and human resources) with anticipated costs by the end of 2018 of \$270m. Once complete, these should deliver annualised benefits of approximately \$100m by the end of 2018.

Final estimates for programme costs, benefits and headcount impacts in all functions will be subject to completion of the requisite consultation in the various areas. The Company's priority in undertaking these restructuring initiatives is to work with affected employees on the proposed changes, acting in accordance with relevant local consultation requirements and employment law.

Cash Flow and Balance Sheet

Cash Flow

The Company generated a cash inflow from operating activities of \$3,324m in the year compared with \$7,058m in the comparative period. Cash generated from operating activities reflects a modest increase in investment in working capital of \$49m compared to a decline of \$2,508m in 2014. Working capital improvements made in 2014 have been sustained, minimising the impact of increased acquired diabetes and launch product inventory balances.

Net cash outflows from investing activities were \$4,239m compared with \$7,032m in the prior year. This reflects cash payments relating to business acquisitions in FY 2014 of \$4,461m, which primarily related to the BMS Diabetes alliance and Almirall acquisitions, being higher than those in FY 2015 of \$3,025m, which primarily related to the ZS Pharma acquisition. In addition, there was a cash inflow from the disposal of intangible assets of \$1,130m in FY 2015, principally related to the disposals of Entocort, Myalept and Caprelsa.

Debt and Capital Structure

At 31 December 2015, outstanding gross debt (interest-bearing loans and borrowings) was \$15,053m (31 December 2014: \$10,843m). In November 2015, the Company issued a total of \$6bn of notes, with the proceeds of the issue to be used to fund corporate and business development activity, repay certain outstanding commercial paper obligations and for general corporate purposes. Of the gross debt outstanding at 31 December 2015, \$916m was due within one year (31 December 2014: \$2,446m). The Company's net debt position at 31 December 2015 was \$7,762m (31 December 2014: \$3,223m).

Shares in Issue

During the year, one million shares were issued in respect of share option exercises for a consideration of \$43m. The total number of shares in issue as at 31 December 2015 was 1,264 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 investment in earnings-accretive opportunities.

Sensitivity: Foreign-Exchange Rates

The Company provides the following currency sensitivity information:

| Currency | Primary Relevance | Average Exchange Rates Versus USD | | Change % | Impact Of 5% Weakening In Exchange Rate Versus USD (\$m) ² | |
|--------------------|-------------------|-----------------------------------|-----------------------|----------|---|-----------------------|
| | | FY 2015 | YTD 2016 ¹ | | Total Revenue | Core Operating Profit |
| EUR | Product Sales | 0.90 | 0.92 | (2) | (178) | (103) |
| JPY | Product Sales | 121.04 | 118.27 | 2 | (102) | (66) |
| CNY | Product Sales | 6.28 | 6.57 | (4) | (133) | (62) |
| SEK | Costs | 8.43 | 8.54 | (1) | (8) | 71 |
| GBP | Costs | 0.65 | 0.69 | (6) | (34) | 96 |
| Other ³ | | | | | (201) | (122) |

¹Based on average daily spot rates between 1 January 2016 and 29 January 2016

²Based on 2015 actual results at 2015 actual exchange rates

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

Currency Hedging

AstraZeneca monitors the impact of adverse currency movements on a portfolio basis, recognising correlation effects. The Company may hedge to protect against adverse impacts on cash flow over the short to medium term. As at 31 December 2015, AstraZeneca had hedged around 85% of forecast short-term currency exposure that arises between the booking and settlement dates on non-local currency purchases and Product Sales.

Corporate and Business Development Update

The highlights of the Company's corporate and business development activities since the prior results announcement on 5 November 2015 are shown below.

a) Investment in Acerta Pharma

On 17 December 2015, AstraZeneca announced that it had entered into an agreement to invest in a majority equity stake in Acerta Pharma B.V. (Acerta), a privately-owned biopharmaceutical company based in the Netherlands and the US. The transaction will provide AstraZeneca with a potentially best-in-class irreversible oral Bruton's tyrosine kinase (BTK) inhibitor, acalabrutinib (ACP-196), currently in Phase II/III development for B-cell blood cancers and in Phase I/II clinical trials in multiple solid tumours.

On 2 February 2016, on completion of the agreement, AstraZeneca acquired 55% of the entire 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 in the US, or the end of 2018, whichever is sooner. 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 (see Note 5).

b) Acquisition of ZS Pharma

On 6 November 2015, AstraZeneca announced that it had entered into an agreement to acquire ZS Pharma Inc. (ZS Pharma), a biopharmaceutical company based in San Mateo, California. The transaction, completed in Q4 2015, gives AstraZeneca access to the potassium-binding compound ZS-9. This is a potential best-in-class treatment for hyperkalaemia, a condition associated with increased mortality in chronic kidney disease (CKD) and chronic heart failure (CHF). Under the terms of the agreement, AstraZeneca acquired ZS Pharma for \$90 per share (see Note 4).

c) Respiratory portfolio acquisition

On 16 December 2015, AstraZeneca announced that it had entered into a definitive agreement to acquire the core Respiratory business of Takeda Pharmaceutical Company Limited (Takeda). The transaction, once completed, will include the expansion of rights to roflumilast (marketed as Daliresp in the US and Daxas in other countries), the only approved oral PDE4 inhibitor for the treatment of COPD.

Under the terms of the agreement, AstraZeneca will make a payment of \$575m. Upon completion approximately 200 staff will transfer to AstraZeneca.

d) Allergan - ATM-AVI

On 29 January 2016, it was announced that AstraZeneca had entered into a global agreement with Allergan plc (Allergan) to develop and commercialise ATM-AVI, an investigational, fixed-dose antibiotic, combining aztreonam and avibactam. Together, the two companies will evaluate the combination to treat serious infections caused by metallo β -lactamase MBL-producing Gram-negative pathogens, a difficult-to-treat sub-type of carbapenem-resistant Enterobacteriaceae, for which there are currently very limited treatments. ATM-AVI may present a new treatment option for patients with MBL-producing pathogens.

Under the terms of the agreement, Allergan will maintain commercialisation rights in the US and Canada and AstraZeneca will retain commercialisation rights in all other countries. AstraZeneca initiated a Phase I trial for ATM-AVI in 2012.

e) Agreement on rights to Entocort in the US

On 15 December 2015, AstraZeneca completed an agreement with Perrigo Company plc (Perrigo) for the divestment of US rights to Entocort (budesonide), a gastroenterology medicine for patients with mild to moderate Crohn's disease. Under the terms of the agreement, Perrigo paid AstraZeneca \$380m to acquire the rights to sell Entocort capsules and the authorised generic Entocort capsules marketed by Par Pharmaceuticals Companies, Inc.

The transaction did not include the transfer of any AstraZeneca employees or facilities. As a divestment, the income was recorded within Other Operating Income.

f) Strategic investments in China

On 16 December 2015, AstraZeneca announced a range of strategic initiatives to accelerate the delivery of innovative biologics and targeted medicines to patients in China. The initiatives and investments include a strategic alliance with WuXi AppTec, a leading Chinese biologics manufacturer and contract research organisation, to produce innovative biologics locally in China. Under the agreement, AstraZeneca has the option to acquire WuXi AppTec's biologics manufacturing capacity in Wuxi City in the next few years through an overall investment approximating \$100m. Prior to that, WuXi AppTec remains the Company's exclusive partner for R&D manufacturing for innovative biologics in China.

Research and Development Update

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

Since the prior results announcement on 5 November 2015:

| | | |
|--|---|---|
| Regulatory Approvals | 3 | <ul style="list-style-type: none"> - Zurampic (US) - Tagrisso (US, EU) |
| Regulatory Submission Acceptances | 3 | <ul style="list-style-type: none"> - brodalumab (US, EU) - ZS-9 (EU) |
| Other Key Developments | 3 | <ul style="list-style-type: none"> - CHMP positive recommendations (EU): Zurampic, Brilique, Tagrisso |
| New Molecular Entities (NMEs) in 15 Pivotal Trials or under Regulatory Review* | | <p>RIA</p> <ul style="list-style-type: none"> - PT003* - COPD - brodalumab* - benralizumab - tralokinumab - severe asthma - PT010 - COPD - anifrolumab - lupus (SLE) <p>CVMD</p> <ul style="list-style-type: none"> - roxadustat - ZS-9* <p>Oncology</p> <ul style="list-style-type: none"> - cediranib* - tremelimumab - durvalumab - multiple cancers - acalabrutinib - moxetumomab pasudotox - leukaemia - selumetinib <p>ING</p> <ul style="list-style-type: none"> - CAZ AVI* |

Projects in clinical pipeline 125

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

1. Respiratory, Inflammation & Autoimmunity (RIA)

Steady progress continues to be made in the RIA pipeline, which now includes six programmes in pivotal trials or under registration. AstraZeneca's Respiratory portfolio includes a range of differentiated potential medicines such as novel combinations, biologics and devices for the treatment of asthma and COPD. The pipeline also includes a number of assets in inflammatory and autoimmune diseases within areas such as psoriasis, systemic lupus and rheumatoid arthritis.

a) Symbicort (asthma)

Symbicort comprises budesonide (a corticosteroid, ICS) and formoterol (a long-acting beta agonist, LABA). The FDA required all manufacturers of medicines indicated for the treatment of asthma, containing LABA-based medicines, to conduct identical trials evaluating the safety when used in combination with an inhaled corticosteroid compared to the ICS alone.

The Symbicort LABA safety trial met its primary endpoint in the period, based on top-line results, demonstrating that the risk of serious asthma-related events for Symbicort is no different to that of budesonide alone. The trial was a randomised, double-blind, 26-week, active-controlled trial in 11,700 patients, aged at least 12 years of age and suffering from asthma.

b) Zurampic (gout)

On 22 December 2015, AstraZeneca announced that the FDA had approved Zurampic (lesinurad) 200mg tablets in combination with a xanthine oxidase inhibitor (XOI) for the treatment of hyperuricemia associated with gout in patients who have not achieved target serum uric-acid levels with an XOI alone. The approval was based on data from three pivotal Phase III trials, CLEAR1, CLEAR2 and CRYSTAL. These represent the largest clinical trial data set of gout patients (n=1,537) treated with combination urate-lowering therapy.

On 18 December 2015, AstraZeneca announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending the marketing authorisation of Zurampic 200mg tablets. Zurampic is recommended for the adjunctive treatment of hyperuricaemia in adult gout. Zurampic will now be reviewed by the European Commission (EC). AstraZeneca anticipates a final decision in the first half of 2016.

c) Brodalumab (psoriasis)

During the period, regulatory submissions for brodalumab for the treatment of moderate-to-severe psoriasis were accepted in the US and EU. The submissions were supported by data from the three AMAGINE Phase III pivotal trials. The results indicated that brodalumab has an effective mechanism of action that delivers clinical benefit and could help a significant number of moderate-to-severe plaque psoriasis patients achieve total clearance of skin disease.

Under a collaboration agreement, Valeant Pharmaceuticals International Inc. (Valeant) has an exclusive license to develop and commercialise brodalumab globally, except in Japan and certain other Asian countries. Valeant assumes decisions on future development and development costs associated with the regulatory approval of brodalumab, as well as decisions on future development.

d) Tralokinumab (IPF)

A Phase II trial for tralokinumab in idiopathic pulmonary fibrosis (IPF), a potential exploratory indication for the medicine, was terminated in the period due to lack of efficacy on endpoints of IPF progression. No safety issues were detected. The Phase III programme for severe asthma, the lead indication for tralokinumab, is ongoing, with top-line results expected in 2017. Tralokinumab is anticipated to become AstraZeneca's second biologic medicine in Respiratory diseases after benralizumab.

e) Anifrolumab (lupus)

Positive new data on anifrolumab in systemic lupus erythematosus (SLE) were presented at the American College of Rheumatology's annual scientific meeting in San Francisco. The trial met primary and secondary endpoints in Phase II, with anifrolumab significantly reducing lupus disease activity compared with placebo across multiple endpoints.

In line with the Company's dedication to personalised medicines, anifrolumab is being developed with an interferon-gene signature test designed to identify patients who may be more likely to benefit from treatment. The anifrolumab Phase III programme in SLE was initiated in July 2015 and is expected to read out with top-line results in 2018. Additional ongoing trials include a Phase II lupus nephritis trial and a Phase I trial with a subcutaneous route of administration.

2. Cardiovascular & Metabolic Disease (CVMD)

AstraZeneca's strategy in CVMD focuses on ways to reduce morbidity, mortality and organ damage by addressing multiple risk factors across CV disease, Diabetes and CKD indications. The patient-centric approach is reinforced by science-led life-cycle management programmes and technologies, including early research into regenerative methods.

a) Brilinta/Brilique (CV disease)

On 18 December 2015, AstraZeneca announced that the CHMP adopted a positive opinion, recommending approval of the 60mg dose of Brilique for the treatment of patients with a history of heart attack and at high risk of having a further coronary event. The opinion stated that treatment may be started as continuation therapy after an initial one-year treatment with dual anti-platelet therapy. The 90mg dose of Brilique is currently indicated in the EU to reduce the rate of cardiovascular death, myocardial infarction (MI, also known as heart attack) and stroke in patients with acute coronary syndrome.

b) Saxagliptin/dapagliflozin (type-2 diabetes)

AstraZeneca has continued to work closely with the FDA following the receipt of a Complete Response Letter in October 2015. The Company plans to submit additional clinical data for saxagliptin/dapagliflozin from a trial that is now completed and anticipates a new regulatory submission in the first half of 2016.

c) ZS-9 (hyperkalaemia)

The acquisition of ZS Pharma was completed on 17 December 2015 and ZS-9 (sodium zirconium cyclosilicate), a potential best-in-class treatment for hyperkaeleemia, was accepted in the period by CHMP for regulatory review, in line with the Company's expectations.

3. Oncology

AstraZeneca has a deep-rooted heritage in Oncology with a rejuvenating portfolio of medicines that has the potential to transform patients' lives and the Company's future. With at least six new medicines molecular entities to be launched between 2014 and 2020 and a broad pipeline of small molecules and biologics in development, the Company is committed to advance Oncology as one of AstraZeneca's six Growth Platforms, focusing on lung, ovarian, breast and blood cancers. By exploiting the power of four scientific platforms -- immuno-oncology (IO), the genetic drivers of cancer and resistance, DNA damage repair and antibody drug conjugates -- and by championing the development of personalised medicines combinations, AstraZeneca has the vision to redefine cancer treatment and, one day, eliminate cancer as a cause of death.

a) Faslodex (breast cancer)

On 29 January 2016, the Company received notification that the FDA had accepted for regulatory submission a supplemental new drug application (sNDA) for Faslodex. The aim of the sNDA is to supplement the currently-approved indication for Faslodex to encompass the positive results of the Phase III PALOMA-3 trial. This trial tested adding Ibrance (palbociclib) to Faslodex versus Faslodex alone in women with HR-positive, HER2-negative metastatic breast cancer. The trial was conducted by Pfizer Inc., in collaboration with AstraZeneca.

b) Lynparza (ovarian and other cancers)

In January 2016 Breakthrough Therapy designation was granted by the FDA for Lynparza for prostate cancer patients with BRCA1/2 or ATM gene-mutated metastatic castrate-resistant prostate cancer (mCRPC) who have received previous taxane-based chemotherapy and one newer hormonal agent (abiraterone or enzalutamide). Accompanying this designation, Lynparza received a positive Phase III investment decision in the period from the Company for development in mCRPC.

These developments highlighted Lynparza's significant future potential, in addition to the approved use in treating patients with a particular form of ovarian cancer.

c) Tagrisso (lung cancer)

On 13 November 2015, Tagrisso was approved by the FDA for patients with epidermal growth factor receptor (EGFR) T790M mutation-positive metastatic non-small cell lung cancer (NSCLC) who have progressed on an EGFR tyrosine kinase inhibitor (TKI). This followed one of the fastest medicine-development programmes in history, from the start of clinical trials to approval in two years and eight months. Tagrisso provides an important new option for patients, with an objective response rate of 59% and a median duration of response of over one year.

On 3 February 2016, Tagrisso received conditional approval in the EU for the treatment of adult patients with locally-advanced or metastatic EGFR T790M mutation-positive NSCLC. Tagrisso is the first T790M-directed inhibitor to receive marketing authorisation by the EU. Tagrisso's indication includes patients with T790M NSCLC regardless of previous treatment with an EGFR TKI, underlining the unmet medical need in the small number of EGFR-mutated NSCLC patients who are initially (de novo) diagnosed with the T790M mutation. The approval follows the positive opinion received on 18 December 2015.

Interactions with regulatory authorities in the rest of the world, including the accelerated review process in Japan, are ongoing.

The ADAURA Phase III trial in adjuvant EGFRm NSCLC began enrollment in the quarter and will measure disease-free survival.

d) Durvalumab (multiple cancers)

Monotherapy

As announced on 18 December 2015, the preliminary findings of the ATLANTIC trial supported the clinical activity of durvalumab. In the trial of 3rd-line or later-stage NSCLC patients, durvalumab demonstrated expected clinical activity and durable response in heavily pre-treated patients. The treatment and regulatory landscape in lung cancer is evolving however, and the Company does not anticipate any regulatory submission as a monotherapy for 3rd-line PD-L1-positive NSCLC patients. Durvalumab is a cornerstone of the IO portfolio, with a fast-advancing development programme focused primarily on novel combinations.

Combination therapy

New data from the Phase Ib durvalumab + tremelimumab (durva + treme) combination trial in NSCLC were presented at the Society for Immunotherapy of Cancer meeting in November 2015. The trial investigators presented updated safety and efficacy results for 102 patients. In 84 of the patients evaluable for efficacy, results showed an overall response rate of 25% (21/84, 95% CI of 16-36%), consistent with data presented at the American Society of Clinical Oncology's meeting in 2015. Response rates did not appear dependent on PD-L1 status: 35% (PD-L1-positive), 22% (PD-L1-negative, <25% tumour-cell staining) and 33% (PD-L1-negative, 0% tumour-cell staining). Higher response rates were observed in those patients who had only received one prior treatment: 47% (15/32, 95% CI of 29-65%).

The CAURAL trial, combining Tagrisso and durvalumab, remains on clinical hold, based on an increase in the incidence of interstitial lung disease, compared to what has been previously reported with each medicine used on its own. Investigation of the safety signal is ongoing.

During the period, first patients were dosed in a number of durva + treme combination trials, including NEPTUNE, EAGLE, KESTREL, DANUBE and ALPS as well as in the safety lead-in of the triple combination trial in NSCLC with chemotherapy. AstraZeneca is planning a Phase III trial with durvalumab in small cell lung cancer that will include the first IO-IO-chemotherapy triple-combination arm. A second, earlier-stage trial will also pair durvalumab with other portfolio medicines such as Lynparza and AZD1775 (WEE-1).

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The MYSTIC trial saw its primary endpoint updated to a co-primary endpoint of progression-free survival (PFS) and overall survival. The trial is recruiting ahead of expectations and is expected to be the first IO-IO combination 1st-line NSCLC trial to provide PFS data, in the first half of 2017.

An update on ongoing trials with durvalumab is provided over the page:

LUNG CANCER

| Name | Phase | Line of treatment | Population | Design | Timelines | Status |
|-----------------------------|-------|-------------------|------------------------------------|---|---|--|
| Early disease | | | | | | |
| Monotherapy ADJUVANT1 | III | N/A | Stage Ib-IIIa NSCLC | durvalumab vs placebo | FPD Q1 2015 Data expected 2020 | Recruiting |
| PACIFIC | III | N/A | Stage III unresectable NSCLC | durvalumab vs placebo | FPD Q2 2014 Data expected 2017 | Recruiting; >50% of patients now randomised |
| Advanced/metastatic disease | | | | | | |
| Combination therapy | | | | | | |
| ARCTIC | III | 3rd line | PD-L1 neg. NSCLC | durvalumab vs tremelimumab vs durva + treme vs SoC | FPD Q2 2015 Data expected H1 2017 | Recruiting |
| MYSTIC | III | 1st line | NSCLC | durvalumab vs durva + treme vs SoC | FPD Q3 2015 Data expected H1 2017 | Recruiting |
| NEPTUNE | III | 1st line | NSCLC | durva + treme vs SoC | FPD Q4 2015 Data expected 2018 | First patient now dosed |
| - | III | 1st line | NSCLC | durvalumab + chemotherapy +/- tremelimumab | - | First patient now dosed in safety lead-in |
| - | III | 1st line | SCLC | durva + treme + chemotherapy vs SoC | - | Awaiting first patient dosed |

¹Conducted by the National Cancer Institute of Canada

METASTATIC OR RECURRENT HEAD AND NECK CANCER

| Name | Phase | Line of treatment | Population | Design | Timelines | Status |
|---------------------|-------|-------------------|---------------------|----------------------------|---|---|
| Monotherapy HAWK | II | 2nd line | PD-L1 pos. SCCHN | durvalumab (single arm) | FPD Q1 2015 Data expected H2 2016 | Recruiting Indication granted FDA Fast Track |

| | | | | | | designation |
|-------------------------------|-----|----------|---------------------|--|--------------------------------------|----------------------------|
| Combination therapy CONDOR | II | 2nd line | PD-L1 neg. SCCHN | durvalumab vs tremelimumab vs durva + treme | FPD Q2 2015 Data expected 2017 | Recruiting |
| EAGLE | III | 2nd line | SCCHN | durvalumab vs durva + treme vs SoC | FPD Q4 2015 Data expected 2018 | First patient now dosed |
| KESTREL | III | 1st line | SCCHN | durvalumab vs durva + treme vs SoC | FPD Q4 2015 Data expected 2018 | First patient now dosed |

OTHER METASTATIC CANCERS

| Name | Phase | Line of treatment | Population | Design | Timelines | Status |
|--------|-------|-------------------|--|--|--------------------------------------|----------------------------|
| DANUBE | III | 1st line | C i s p l a t i n chemo- t h e r a p y eligible/ i n e l i g i b l e bladder cancer | durvalumab vs durva + treme -vs SoC | FPD Q4 2015 Data expected 2018 | First patient now dosed |
| ALPS | II | 2nd line | M e t a s t a t i c p a n c r e a t i c cancer | durva + treme (single arm) | FPD Q4 2015 Data expected 2017 | First patient now dosed |
| - | II | 2nd/3rd line | M e t a s t a t i c gastric cancer | durvalumab vs tremelimumab vs durva + treme | - | In preparation |
| - | II | 2nd line | U n r e s e c t a b l e liver cancer | durvalumab vs tremelimumab vs durva + treme | - | In preparation |

FPD=First Patient Dosed, LPD=Last Patient Dosed, SoC=Standard of Care, SCCHN = Squamous Cell Carcinoma of the Head and Neck

e) Early-stage Oncology

New Oncology programmes that progressed into human trials during the period included MEDI9197, a TLR 7/8 agonist, in solid tumours and a GITR fusion protein, MEDI1873. Furthermore, two small-molecule programmes developed in collaboration with BIND Therapeutics moved into clinical trials: AZD0156, a first-in-class ATM kinase inhibitor which further strengthens the Company's leading position in DNA damage response and AZD2811, a nanoparticle formulation of a novel, selective inhibitor of Aurora B kinase that has been shown to be active in both solid and haematological tumours.

Additionally the Company now has a HER2-targeted, bi-specific antibody drug conjugate, MEDI4276, in a Phase I trial in solid tumours. HER2 (receptor tyrosine-protein kinase) is over-expressed in several cancers, including breast and gastric cancers. AZD3759, an EGFR inhibitor designed to cross the blood brain barrier, progressed into Phase II

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expansion cohorts in leptomeningeal disease, a form of brain cancer, and in patients with brain metastases.

ASTRAZENECA DEVELOPMENT PIPELINE 31 DECEMBER 2015

Includes AstraZeneca-sponsored or directed studies only

Phase III / Pivotal Phase II / Registration

NMEs and significant additional indications

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

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

Partnered and/or in collaboration.

| Compound | Mechanism | Area Under Investigation | Date Commenced Phase | Estimated Regulatory Submission / Submission Acceptance† | | | |
|---|---|--|----------------------|--|-----------------------|----------|----------|
| | | | | US | EU | Japan | China |
| Respiratory, Inflammation and Autoimmunity | | | | | | | |
| anifrolumab# TULIP | IFN-alphaR mAb | systemic lupus erythematosus | Q3 2015 | 2019 (Fast Track) | 2019 | 2019 | |
| benralizumab# CALIMA SIROCCO ZONDA BISE BORA GREGALE | IL-5R mAb | severe asthma | Q4 2013 | H2 2016 | H2 2016 | N/A | N/A |
| benralizumab# TERRANOVA GALATHEA | IL-5R mAb | COPD | Q3 2014 | 2018 | 2018 | N/A | N/A |
| brodalumab# AMAGINE-1,2,3 | IL-17R mAb | psoriasis | Q3 2012 | Accepted ¹ | Accepted | N/A | N/A |
| Zurampic (lesinurad) CLEAR 1,2 CRYSTAL | selective uric acid reabsorption inhibitor (URAT-1) | chronic treatment of hyperuricemia in patients with gout | Q4 2011 | Approved | Accepted ² | | |
| PT003 GFF PINNACLE | LABA/LAMA | COPD | Q2 2013 | Accepted | H2 2016 | 2017 | 2017 |
| PT010 | LABA/LAMA/ ICS | COPD | Q3 2015 | 2018 | 2018 | 2017 | 2019 |
| tralokinumab STRATOS 1,2 TROPOS MESOS | IL-13 mAb | severe asthma | Q3 2014 | 2018 | 2018 | 2018 | |
| Cardiovascular and Metabolic Diseases | | | | | | | |
| Brilinta/Brilique ³ | P2Y ₁₂ receptor antagonist | arterial thrombosis | | Launched | Launched | Accepted | Launched |
| Epanova# | omega-3 carboxylic acids | severe hypertrigly-ceridemia | | Approved | | 2018 | 2019 |

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| Drug Name | Drug Class | Indication | Phase | Timeline | Regulatory Status | Approval | Commercialization |
|---|--|---|---------|--------------------------|------------------------------|-----------------|----------------------|
| Farxiga/Forxiga4 roxadustat# OLYMPUS ROCKIES | SGLT2 inhibitor | type-2 diabetes anaemia in CKD/ESRD | Q3 2014 | Launched 2018 | Launched N/A | Launched N/A | Accepted H2 20165 |
| ZS-9 (sodium zirconium cyclosilicate) | potassium binder | hyperkalaemia | | Accepted | Accepted | | |
| Oncology acalabrutinib#6 | Bruton's tyrosine kinase (BTK) inhibitor | B-cell blood cancers | | H2 2016 | | | |
| cediranib ICON 6 | VEGFR tyrosine kinase inhibitor | PSR ovarian cancer | Q2 2007 | | Accepted (Orphan Drug) | | |
| durvalumab# + tremelimumab ALPS¶ | PD-L1 mAb + CTLA-4 mAb | metastatic pancreatic ductal carcinoma | Q4 2015 | 2017 | 2017 | 2017 | |
| durvalumab# PACIFIC | PD-L1 mAb | stage III NSCLC | Q2 2014 | 2017 | 2020 | 2020 | |
| durvalumab# HAWK¶ | PD-L1 mAb | 2nd-line SCCHN (PD-L1 positive) | Q1 2015 | 2017 (Fast Track) | 2019 | 2019 | |
| durvalumab# + tremelimumab ARCTIC | PD-L1 mAb + CTLA-4 mAb | 3rd-line NSCLC | Q2 2015 | 2017 | 2017 | 2017 | |
| durvalumab# + tremelimumab CONDOR¶ | PD-L1 mAb + CTLA-4 mAb | 2nd-line SCCHN (PD-L1 negative) | Q2 2015 | 2017 | 2019 | 2019 | |
| durvalumab# + tremelimumab DANUBE | PD-L1 mAb + CTLA-4 mAb | 1st-line bladder | Q4 2015 | 2018 | 2018 | 2018 | |
| durvalumab# + tremelimumab EAGLE | PD-L1 mAb + CTLA-4 mAb | 2nd-line SCCHN | Q4 2015 | 2019 | 2019 | 2019 | |
| durvalumab# + tremelimumab KESTREL | PD-L1 mAb + CTLA-4 mAb | 1st-line SCCHN | Q4 2015 | 2018 | 2018 | 2018 | |
| durvalumab# + tremelimumab MYSTIC | PD-L1 mAb + CTLA-4 mAb | 1st-line NSCLC | Q3 2015 | 2017 | 2017 | 2017 | |
| durvalumab# + tremelimumab NEPTUNE | PD-L1 mAb + CTLA-4 mAb | 1st-line NSCLC | Q4 2015 | 2019 | 2019 | 2019 | |
| moxetumomab pasudotox# PLAIT | anti-CD22 recombinant immunotoxin | hairy cell leukaemia | Q2 2013 | 2017 (Orphan Drug) | 2018 | | |
| selumetinib# ASTRA | MEK inhibitor | differentiated thyroid cancer | Q3 2013 | 2018 | 2018 | | |
| selumetinib# SELECT-1 | MEK inhibitor | 2nd-line KRASm NSCLC | Q4 2013 | 2017 | 2017 | | |

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| | | | | | | |
|--|--|--|---------|--|------------------------------------|---------------------------------|
| Tagrisso (AZD9291) AURA, AURA 2 | EGFR tyrosine kinase inhibitor | ≥2nd-line advanced EGFRm T790M NSCLC | Q2 2014 | Launched (Breakthrough designation, Priority Review, Orphan Drug) 2017 | Approved (Accelerated Review) 2017 | Accepted (Priority Review) 2017 |
| Tagrisso (AZD9291) AURA 3 | EGFR tyrosine kinase inhibitor | ≥2nd-line advanced EGFRm T790M NSCLC | Q3 2014 | 2017 | 2017 | 2017 |
| tremelimumab¶ DETERMINE | CTLA-4 mAb | mesothelioma | Q2 2014 | H2 2016 (Orphan Drug, Fast Track) | H2 2016 | H2 2016 |
| Infection, Neuroscience and Gastrointestinal | | | | | | |
| CAZ AVI# | cephalosporin/beta lactamase inhibitor | serious infections, complicated intra-abdominal infection, complicated urinary tract infection | Q1 2012 | N/A | Accepted | 2017 |
| CAZ AVI# | cephalosporin/beta lactamase inhibitor | hospital-acquired pneumonia/ventilator-associated pneumonia | Q2 2013 | N/A | Accepted | 2017 |
| MEDI-550 | pandemic influenza virus vaccine | pandemic influenza prophylaxis | | N/A | H1 2016 ⁸ | N/A N/A |
| Zinforo# | extended spectrum cephalosporin with affinity to penicillin-binding proteins | pneumonia/skin infections | | N/A | Launched | N/A Submitted |

¶ Registrational Phase II/III trial.

1 US regulatory submission accepted Q1 2016.

2 CHMP Positive Opinion received December 2015.

3 Brilinta in the US; Brilique in rest of world.

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

5 Rolling NDA submission to be initiated in H2 2016.

6 Completion of the agreement with Acerta Pharma Q1 2016

7 CHMP Positive Opinion received December 2015. Approval received Q1 2016.

8 MAA submitted December 2015. Regulatory acceptance anticipated H1 2016.

Phases I and II

NMEs and significant additional indications

| Compound | Mechanism | Area Under Investigation | Phase | Date Commenced Phase |
|----------|-----------|--------------------------|-------|----------------------|
|----------|-----------|--------------------------|-------|----------------------|

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| | | | | |
|--|--|--|----|---------|
| Respiratory, Inflammation and Autoimmunity | | | | |
| abediterol (AZD0548) | LABA | asthma/COPD | II | Q4 2007 |
| anifrolumab# | IFN-alphaR mAb | lupus nephritis | II | Q4 2015 |
| AZD7594 | inhaled SGRM | asthma/COPD | II | Q3 2015 |
| AZD7624 | inhaled P38 inhibitor | COPD | II | Q4 2014 |
| AZD9412# | inhaled interferon beta | asthma/COPD | II | Q3 2015 |
| mavrilimumab# | GM-CSFR mAb | rheumatoid arthritis | II | Q1 2010 |
| MEDI-551# | CD19 mAb | neuromyelitis optica1 | II | Q1 2015 |
| MEDI2070# | IL-23 mAb | Crohn's disease | II | Q1 2013 |
| abrilumab# | alpha(4)beta(7) mAb | Crohn's disease / ulcerative colitis | II | Q4 2012 |
| MEDI9929# | TSLP mAb | asthma / atopic dermatitis | II | Q2 2014 |
| PT010 | LABA/LAMA/ICS | asthma | II | Q2 2014 |
| RDEA3170 | selective uric acid reabsorption inhibitor (URAT-1) | chronic treatment of hyperuricemia in patients with gout | II | Q3 2013 |
| tralokinumab | IL-13 mAb | atopic dermatitis | II | Q1 2015 |
| anifrolumab# | IFN-alphaR mAb | systemic lupus erythematosus (subcutaneous) | I | Q4 2015 |
| lesinurad+allopurinol | selective uric acid reabsorption inhibitor (URAT-1)+xanthine oxidase inhibitor | chronic treatment of hyperuricemia in patients with gout | I | Q4 2015 |
| AZD1419# | TLR9 agonist | Asthma | I | Q3 2013 |
| AZD7986 | DPP1 | COPD | I | Q4 2014 |
| AZD8871 | MABA | COPD | I | Q4 2015 |
| AZD8999 | MABA | COPD | I | Q4 2013 |
| AZD9567 | oral SGRM | rheumatoid arthritis | I | Q4 2015 |
| MEDI4920 | anti-CD40L-Tn3 fusion protein | primary Sjögren's syndrome | I | Q2 2014 |
| MEDI5872# | B7RP1 mAb | systemic lupus erythematosus | I | Q4 2008 |
| MEDI7836 | IL-13 mAb-YTE | Asthma | I | Q1 2015 |
| Cardiovascular and Metabolic Diseases | | | | |
| AZD4076 | anti-miR103/107 oligonucleotide | non-alcoholic fatty liver disease/non-alcoholic steatohepatitis (NASH) | I | Q4 2015 |
| MEDI6012 | LCAT | ACS | II | Q4 2015 |
| MEDI0382 | GLP-1/ glucagon dual agonist | diabetes / obesity | I | Q1 2015 |
| MEDI4166 | PCSK9/GLP-1 mAb + peptide fusion | diabetes / cardiovascular | I | Q4 2015 |
| MEDI8111 | Rh-factor II | trauma / bleeding | I | Q1 2014 |
| Oncology | | | | |

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| | | | | |
|---|---|---------------------------------------|----|---------|
| AZD1775# | WEE-1 inhibitor | ovarian cancer | II | Q4 2012 |
| AZD2014 | mTOR serine/ threonine kinase inhibitor | solid tumours | II | Q1 2013 |
| AZD3759 BLOOM | EGFR tyrosine kinase inhibitor | brain metastases in advanced EGFRm | II | Q4 2015 |
| Tagrisso (AZD9291) BLOOM | EGFR tyrosine kinase inhibitor | NSCLC | | |
| AZD4547 | FGFR tyrosine kinase inhibitor | solid tumours | II | Q4 2011 |
| AZD5069+durvalumab# | CXCR2 + PD-L1 mAb | | | |
| AZD9150#+durvalumab# | STAT3 inhibitor + PD-L1 mAb | SCCHN | II | Q3 2015 |
| AZD5363# | AKT kinase inhibitor | breast cancer | II | Q1 2014 |
| durvalumab# | PD-L1 mAb | solid tumours | II | Q3 2014 |
| durvalumab# + tremelimumab | PD-L1 mAb + CTLA-4 mAb | gastric cancer | II | Q2 2015 |
| MEDI-551# | CD19 mAb | diffuse B-cell lymphoma | II | Q1 2012 |
| MEDI-573# | IGF mAb | metastatic breast cancer | II | Q2 2012 |
| savolitinib/ volitinib# | MET tyrosine kinase inhibitor | papillary renal cell carcinoma | II | Q2 2014 |
| selumetinib# | MEK inhibitor | 2nd-line KRAS wt NSCLC | II | Q1 2013 |
| AZD0156 | ATM serine/threonine kinase inhibitor | solid tumours | I | Q4 2015 |
| AZD2811 | Aurora B kinase inhibitor | solid tumours | I | Q4 2015 |
| AZD5312# | androgen receptor inhibitor | solid tumours | I | Q2 2014 |
| AZD6738 | ATR serine/threonine kinase inhibitor | solid tumours | I | Q4 2013 |
| AZD8186 | PI3 kinase beta inhibitor | solid tumours | I | Q2 2013 |
| AZD8835 | PI3 kinase alpha inhibitor | solid tumours | I | Q4 2014 |
| AZD9150# | STAT3 inhibitor | haematological malignancies | I | Q1 2012 |
| Tagrisso (AZD9291) + (durvalumab# or selumetinib# or savolitinib#) TATTON | EGFR tyrosine kinase inhibitor + (PD-L1 mAb or MEK inhibitor or MET tyrosine kinase inhibitor) | advanced EGFRm NSCLC | I | Q3 2014 |
| AZD9496 | selective oestrogen receptor downregulator | ER+ breast cancer | I | Q4 2014 |

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| | (SERD) | | | |
|--|--|---|----|-----------------------------|
| durvalumab# | PD-L1 mAb | solid tumours | I | Q3 2014 |
| durvalumab# + MEDI0680 | PD-L1 mAb + PD-1 mAb | solid tumours | I | Q2 2014 |
| durvalumab# + MEDI6383# | OX40 agonist + PD-L1 mAb | solid tumours | I | Q2 2015 |
| durvalumab# + dabrafenib + trametinib2 | PD-L1 mAb+ BRAF inhibitor + MEK inhibitor | melanoma | I | Q1 2014 |
| durvalumab# + tremelimumab | PD-L1 mAb + CTLA-4 mAb | solid tumours | I | Q4 2013 |
| Iressa + durvalumab# | PD-L1 mAb+ EGFR tyrosine kinase inhibitor | NSCLC | I | Q2 2014 |
| MEDI0562# | humanised OX40 agonist | solid tumours | I | Q1 2015 |
| MEDI-551# + rituximab | CD19 mAb + CD20 mAb | haematological malignancies | I | Q2 2014 |
| MEDI-565# | CEA BiTE mAb | solid tumours | I | Q1 2011 |
| MEDI0639# | DLL-4 mAb | solid tumours | I | Q2 2012 |
| MEDI0680 | PD-1 mAb | solid tumours | I | Q4 2013 |
| MEDI1873 | GITR agonist fusion protein | solid tumours | I | Q4 2015 |
| MEDI3617# | ANG-2 mAb | solid tumours | I | Q4 2010 |
| MEDI4276 | HER2 bispecific ADC mAb | solid tumours | I | Q4 2015 |
| MEDI6383# | OX40 agonist | solid tumours | I | Q3 2014 |
| MEDI9197# | TLR 7/8 agonist | solid tumours | I | Q4 2015 |
| MEDI9447 | CD73 mAb | solid tumours | I | Q3 2015 |
| Infection, Neuroscience and AZD3241 | Gastrointestinal myeloperoxidase inhibitor | multiple system atrophy | II | Q2 2015 (Orphan Drug) |
| AZD3293# | beta-secretase inhibitor | Alzheimer's disease | II | Q4 2014 |
| CXL# | beta lactamase inhibitor / cephalosporin | methicillin-resistant S. aureus | II | Q4 2010 |
| MEDI7510 | RSV sF+GLA-SE | prevention of RSV disease in older adults | II | Q3 2015 |
| MEDI8852 | influenza A mAb | influenza A treatment | II | Q4 2015 |
| MEDI8897# | RSV mAb-YTE | passive RSV prophylaxis | II | Q1 2015 (FDA Fast Track) |
| MEDI4893 | mAb binding to S. aureus toxin | hospital-acquired pneumonia / serious S. aureus infection | II | Q4 2014 (FDA Fast Track) |
| ATM AVI# | monobactam/ beta lactamase inhibitor | targeted serious bacterial infections | I | Q4 2012 |
| AZD8108 | NMDA antagonist | suicidal ideation | I | Q4 2014 |
| MEDI1814 | amyloid beta mAb | Alzheimer's disease | I | Q2 2014 |
| MEDI3902 | anti-Psl/PcrV | prevention of nosocomial | I | Q3 2014 (FDA Fast Track) |

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pseudomonas
pneumonia

- 1 Neuromyelitis optica: Now lead indication. Multiple sclerosis trial completed in 2015.
- 2 MedImmune-sponsored trial in collaboration with Novartis AG.

Significant Life-Cycle Management

| Compound | Mechanism | Area Under Investigation | Date Commenced Phase | Estimated Regulatory Submission Acceptance† | | | |
|--|---------------------|--|----------------------|---|-----------|----------|---------|
| | | | | US | EU | Japan | China |
| Respiratory, Inflammation and Autoimmunity | | | | | | | |
| Duaklir Genuair# | LAMA/LABA | COPD | | 2018 | Launched | 2018 | 2018 |
| Symbicort | ICS/LABA | as-needed use in mild asthma | Q4 2014 | N/A | 2018 | | 2019 |
| SYGMA | | | | | | | |
| Symbicort | ICS/LABA | breath actuated Inhaler asthma/COPD | | 2018 | | | |
| Cardiovascular and Metabolic Diseases | | | | | | | |
| Brilinta/Brilique1 | P2Y12 | outcomes trial in patients with peripheral artery disease | Q4 2012 | 2017 | 2017 | 2017 | 2018 |
| EUCLID | receptor antagonist | | | | | | |
| Brilinta/Brilique1 | P2Y12 | prevention of vaso-occlusive crises in paediatric patients with sickle cell disease | Q4 2014 | 2020 | 2020 | | |
| HESTIA | receptor antagonist | | | | | | |
| Brilinta/Brilique1 | P2Y12 | outcomes trial in patients with prior myocardial infarction | Q4 2010 | Launched (Priority Review) | Accepted2 | Accepted | H2 2016 |
| PEGASUS-TIMI 54 | receptor antagonist | | | | | | |
| Brilinta/Brilique1 | P2Y12 | outcomes trial in patients with stroke or TIA | Q1 2014 | H1 2016 | H1 2016 | H2 2016 | 2017 |
| SOCRATES | receptor antagonist | | | | | | |
| Brilinta/Brilique1 | P2Y12 | outcomes trial in patients with type-2 diabetes and CAD, but without a previous history of MI or stroke | Q1 2014 | 2018 | 2018 | 2018 | 2019 |
| THEMIS | receptor antagonist | | | | | | |
| Bydureon | GLP-1 | type-2 diabetes | Q2 2010 | 2018 | 2018 | 2018 | |
| EXSCEL | receptor agonist | outcomes trial | | | | | |
| Bydureon weekly suspension | GLP-1 | type-2 diabetes | Q1 2013 | 2017 | 2017 | | |
| | receptor agonist | | | | | | |
| Epanova | omega-3 | outcomes trial in statin-treated patients at high CV risk, with persistent hypertriglyceridemia plus low | Q4 2014 | 2020 | 2020 | 2020 | 2020 |
| STRENGTH | carboxylic acids | | | | | | |

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| | | | | | | | | |
|---|---|---|---------|---|----------|---------|------|-----------|
| Epanova/ Farxiga/Forxiga3 | omega-3 carboxylic acids/ SGLT2 inhibitor | HDL-cholesterol non-alcoholic fatty liver disease/non-alcoholic steatohepatitis (NASH) | Q1 2015 | | | | | |
| Farxiga/Forxiga3 DECLARE- TIMI 58 | SGLT2 inhibitor | type-2 diabetes outcomes trial | Q2 2013 | 2020 | 2020 | | | |
| Farxiga/Forxiga3 | SGLT2 inhibitor | type-1 diabetes | Q4 2014 | 2018 | 2017 | 2018 | | |
| Kombiglyze XR/Komboglyze4 | DPP-4 inhibitor/ metformin FDC | type-2 diabetes | | Launched | Launched | | | Submitted |
| Onglyza SAVOR-TIMI 53 | DPP-4 inhibitor | type-2 diabetes outcomes trial | Q2 2010 | Accepted | Launched | | | H2 20165 |
| saxagliptin/ dapagliflozin FDC | DPP-4 inhibitor/ SGLT2 inhibitor FDC | type-2 diabetes | Q2 2012 | Accepted6 | Accepted | | | |
| Xigduo XR/ Xigduo7 | SGLT2 inhibitor/ metformin FDC | type-2 diabetes | | Launched | Launched | | | |
| Oncology Faslodex FALCON | oestrogen receptor antagonist | 1st-line hormone receptor +ve advanced breast cancer | Q4 2012 | H2 2016 | H2 2016 | H2 2016 | 2020 | |
| Lynparza (olaparib) SOLO-1 | PARP inhibitor | 1st-line BRCAm ovarian cancer | Q3 2013 | 2017 | 2017 | 2017 | | |
| Lynparza (olaparib) SOLO-2 | PARP inhibitor | 2nd-line or greater BRCAm PSR ovarian cancer, maintenance monotherapy | Q3 2013 | H2 2016 | 2017 | 2017 | | |
| Lynparza (olaparib) SOLO-3 | PARP inhibitor | gBRCA PSR ovarian cancer | Q1 2015 | 2018 | | | | |
| Lynparza (olaparib) GOLD | PARP inhibitor | 2nd-line gastric cancer | Q3 2013 | | | 2017 | | |
| Lynparza (olaparib) OlympiA | PARP inhibitor | gBRCA adjuvant breast cancer | Q2 2014 | 2020 | 2020 | 2020 | | |
| Lynparza (olaparib) OlympiAD | PARP inhibitor | gBRCA metastatic breast cancer | Q2 2014 | H2 2016 | 2017 | 2017 | | |
| Lynparza (olaparib) POLO | PARP inhibitor | pancreatic cancer | Q1 2015 | 2018 | 2018 | 2018 | | |
| Lynparza (olaparib) | PARP inhibitor | prostate cancer | Q3 2014 | (Breakthrough Therapy Designation)8 | | | | |
| Tagrisso (AZD9291) | | | Q4 2015 | 2022 | 2022 | | | |

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| | | | | | | | |
|--|--|--|---------|----------|----------|----------|------------------------|
| ADAURA | EGFR tyrosine kinase inhibitor | adjuvant EGFRm NSCLC | | | | | |
| Tagrisso (AZD9291) FLAURA | EGFR tyrosine kinase inhibitor | 1st-line advanced EGFRm NSCLC | Q1 2015 | 2017 | 2017 | 2017 | 2020 |
| Tagrisso (AZD9291) +dur-valumab# CAURAL9 | EGFR tyrosine kinase inhibitor + PD-L1 mAb | ≥2nd-line advanced EGFRm T790M NSCLC | Q3 2015 | | | | |
| Infection, Neuroscience and Gastrointestinal Diprivan# | sedative and anaesthetic | conscious sedation | | N/A | Launched | Accepted | Launched |
| linaclotide# | GC-C receptor peptide agonist | irritable bowel syndrome with constipation (IBS-C) | | N/A | N/A | N/A | Accepted ¹⁰ |
| Nexium | proton pump inhibitor | stress ulcer prophylaxis | | | | | H2 2016 |
| Nexium | proton pump inhibitor | paediatrics | | Launched | Launched | H2 2016 | Accepted |

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

2 CHMP Positive Opinion received December 2015.

3 Farxiga in the US; Forxiga in rest of world.

4 Kombiglyze XR in the US; Komboglyze in the EU.

5 Timing of China submission dependent on US regulatory approval.

6 Complete Response Letter received October 2015.

7 Xigduo XR in the US; Xigduo in the EU.

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

9 Temporarily closed to enrolment.

10 Submission accepted January 2016.

Terminations (discontinued projects between 1 October and 31 December 2015)

| NME / Line Extension | Compound | Reason for Discontinuation | Area Under Investigation |
|----------------------|-------------|----------------------------|--------------------------|
| NME | AZD5847 | Safety / efficacy | tuberculosis |
| NME | AZD9977 | Safety / efficacy | diabetic kidney disease |
| NME | durvalumab# | Strategic | |

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| | | | |
|-----|---|-------------------|------------------------------------|
| | ATLANTIC | | 3rd-line NSCLC (PD-L1 positive) |
| LCM | durvalumab# after Tagrisso (AZD9291) or Iressa or selumetinib# +docetaxel or tremelimumab | Strategic | NSCLC |
| LCM | tralokinumab | Safety / efficacy | idiopathic pulmonary fibrosis |

Completed Projects / Divestitures

| Compound | Mechanism | Area Under Investigation | Completed/ Divested | Estimated Regulatory Submission US | EU | Japan | Acceptance† China |
|----------|----------------------------|-----------------------------------|-------------------------|---------------------------------------|----|-------|----------------------|
| AZD49011 | NK3 receptor antagonist | polycystic ovarian syndrome | Divested in Phase II | | | | |

1 Divested to Millendo Therapeutics, Inc. Agreement announced January 2016.

Condensed Consolidated Statement of Comprehensive Income

| | 2015 | Restated 2014* |
|---|----------|-------------------|
| | \$m | \$m |
| For the year ended 31 December | | |
| Product sales | 23,641 | 26,095 |
| Externalisation revenue | 1,067 | 452 |
| Total revenue | 24,708 | 26,547 |
| Cost of sales | (4,646) | (5,842) |
| Gross profit | 20,062 | 20,705 |
| Distribution costs | (339) | (324) |
| Research and development expense | (5,997) | (5,579) |
| Selling, general and administrative costs | (11,112) | (13,000) |
| Other operating income and expense | 1,500 | 335 |
| Operating profit | 4,114 | 2,137 |
| Finance income | 46 | 78 |
| Finance expense | (1,075) | (963) |
| Share of after tax losses in joint ventures | (16) | (6) |
| Profit before tax | 3,069 | 1,246 |
| Taxation | (243) | (11) |
| Profit for the period | 2,826 | 1,235 |
| Other comprehensive income | | |
| Items that will not be reclassified to profit or loss | | |
| Remeasurement of the defined benefit pension liability | 652 | (766) |
| Tax on items that will not be reclassified to profit or loss | (199) | 216 |
| | 453 | (550) |
| Items that may be reclassified subsequently to profit or loss | | |
| Foreign exchange arising on consolidation | (528) | (823) |
| | (333) | (529) |

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| | | |
|---|--------|---------|
| Foreign exchange arising on designating borrowings in net investment hedges | | |
| Fair value movements on derivatives designated in net investment hedges | 14 | 100 |
| Amortisation of loss on cash flow hedge | 1 | 1 |
| Net available for sale (losses)/gains taken to equity | (32) | 245 |
| Tax on items that may be reclassified subsequently to profit or loss | 87 | 50 |
| | (791) | (956) |
| Other comprehensive income for the period, net of tax | (338) | (1,506) |
| Total comprehensive income for the period | 2,488 | (271) |
| Profit attributable to: | | |
| Owners of the Parent | 2,825 | 1,233 |
| Non-controlling interests | 1 | 2 |
| | 2,826 | 1,235 |
| Total comprehensive income attributable to: | | |
| Owners of the Parent | 2,488 | (266) |
| Non-controlling interests | - | (5) |
| | 2,488 | (271) |
| Basic earnings per \$0.25 Ordinary Share | \$2.23 | \$0.98 |
| Diluted earnings per \$0.25 Ordinary Share | \$2.23 | \$0.98 |
| Weighted average number of Ordinary Shares in issue (millions) | 1,264 | 1,262 |
| Diluted weighted average number of Ordinary Shares in issue (millions) | 1,265 | 1,264 |
| * 2014 comparatives restated for reclassification of Externalisation revenue (see Note 1) | | |

Condensed Consolidated Statement of Comprehensive Income

| | 2015 | Restated 2014* |
|---|---------|-------------------|
| | \$m | \$m |
| For the quarter ended 31 December | | |
| Product sales | 6,207 | 6,683 |
| Externalisation revenue | 192 | 33 |
| Total revenue | 6,399 | 6,716 |
| Cost of sales | (1,269) | (1,667) |
| Gross profit | 5,130 | 5,049 |
| Distribution costs | (99) | (88) |
| Research and development expense | (1,746) | (1,499) |
| Selling, general and administrative costs | (2,668) | (4,084) |
| Other operating income and expense | 471 | 273 |
| Operating profit | 1,088 | (349) |
| Finance income | 13 | 33 |
| Finance expense | (292) | (260) |
| Share of after tax losses of joint ventures | (7) | (4) |
| Profit before tax | 802 | (580) |
| Taxation | 6 | 259 |
| Profit for the period | 808 | (321) |

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| | | |
|---|--------|----------|
| Other comprehensive income | | |
| Items that will not be reclassified to profit or loss | | |
| Remeasurement of the defined benefit pension liability | 618 | (268) |
| Tax on items that will not be reclassified to profit or loss | (187) | 89 |
| | 431 | (179) |
| Items that may be reclassified subsequently to profit or loss | | |
| Foreign exchange arising on consolidation | (169) | (411) |
| Foreign exchange arising on designating borrowings in net investment hedges | (11) | (237) |
| Fair value movements on derivatives designated in net investment hedges | (10) | 64 |
| Net available for sale gains taken to equity | 31 | 172 |
| Tax on items that may be reclassified subsequently to profit or loss | 3 | 20 |
| | (156) | (392) |
| Other comprehensive income for the period, net of tax | 275 | (571) |
| Total comprehensive income for the period | 1,083 | (892) |
| Profit attributable to: | | |
| Owners of the Parent | 808 | (321) |
| Non-controlling interests | - | - |
| | 808 | (321) |
| Total comprehensive income attributable to: | | |
| Owners of the Parent | 1,083 | (892) |
| Non-controlling interests | - | - |
| | 1,083 | (892) |
| Basic earnings/(loss) per \$0.25 Ordinary Share | \$0.63 | (\$0.25) |
| Diluted earnings/(loss) per \$0.25 Ordinary Share | \$0.63 | (\$0.25) |
| Weighted average number of Ordinary Shares in issue (millions) | 1,264 | 1,263 |
| Diluted weighted average number of Ordinary Shares in issue (millions) | 1,265 | 1,265 |
| * 2014 comparatives restated for reclassification of Externalisation revenue (see Note 1) | | |

Condensed Consolidated Statement of Financial Position

| | At 31 Dec 2015 \$m | At 31 Dec 2014 \$m |
|----------------------------------|--------------------------|--------------------------|
| ASSETS | | |
| Non-current assets | | |
| Property, plant and equipment | 6,413 | 6,010 |
| Goodwill | 11,868 | 11,550 |
| Intangible assets | 22,646 | 20,981 |
| Derivative financial instruments | 446 | 465 |
| Investments in joint ventures | 85 | 59 |
| Other investments | 458 | 502 |

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| | | |
|---|-----------------|-----------------|
| Other receivables | 907 | 1,112 |
| Deferred tax assets | 1,294 | 1,219 |
| | 44,117 | 41,898 |
| Current assets | | |
| Inventories | 2,143 | 1,960 |
| Trade and other receivables | 6,622 | 7,232 |
| Other investments | 613 | 795 |
| Derivative financial instruments | 2 | 21 |
| Income tax receivable | 387 | 329 |
| Cash and cash equivalents | 6,240 | 6,360 |
| | 16,007 | 16,697 |
| Total assets | 60,124 | 58,595 |
| LIABILITIES | | |
| Current liabilities | | |
| Interest-bearing loans and borrowings | (916) | (2,446) |
| Trade and other payables | (11,663) | (11,886) |
| Derivative financial instruments | (9) | (21) |
| Provisions | (798) | (623) |
| Income tax payable | (1,483) | (2,354) |
| | (14,869) | (17,330) |
| Non-current liabilities | | |
| Interest-bearing loans and borrowings | (14,137) | (8,397) |
| Derivative financial instruments | (1) | - |
| Deferred tax liabilities | (2,733) | (1,796) |
| Retirement benefit obligations | (1,974) | (2,951) |
| Provisions | (444) | (484) |
| Other payables | (7,457) | (7,991) |
| | (26,746) | (21,619) |
| Total liabilities | (41,615) | (38,949) |
| Net assets | 18,509 | 19,646 |
| EQUITY | | |
| Capital and reserves attributable to equity holders of the Company | | |
| Share capital | 316 | 316 |
| Share premium account | 4,304 | 4,261 |
| Other reserves | 2,036 | 2,021 |
| Retained earnings | 11,834 | 13,029 |
| | 18,490 | 19,627 |
| Non-controlling interests | 19 | 19 |
| Total equity | 18,509 | 19,646 |

Condensed Consolidated Statement of Cash Flows

| | 2015 | 2014 |
|--|-------|-------|
| | \$m | \$m |
| For the year ended 31 December | | |
| Cash flows from operating activities | | |
| Profit before tax | 3,069 | 1,246 |
| Finance income and expense | 1,029 | 885 |
| Share of after tax losses in joint ventures | 16 | 6 |
| Depreciation, amortisation and impairment | 2,852 | 3,282 |
| (Increase)/decrease in working capital and short-term provisions | (49) | 2,508 |

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| | | |
|--|---------|---------|
| Gains on disposal of intangible assets | (961) | - |
| Non-cash and other movements | (782) | 865 |
| Cash generated from operations | 5,174 | 8,792 |
| Interest paid | (496) | (533) |
| Tax paid | (1,354) | (1,201) |
| Net cash inflow from operating activities | 3,324 | 7,058 |
| Cash flows from investing activities | | |
| Movement in short-term investments and fixed deposits | 283 | 34 |
| Purchase of property, plant and equipment | (1,328) | (1,012) |
| Disposal of property, plant and equipment | 47 | 158 |
| Purchase of intangible assets | (1,460) | (1,740) |
| Disposal of intangible assets | 1,130 | - |
| Purchase of non-current asset investments | (57) | (130) |
| Disposal of non-current asset investments | 93 | 59 |
| Payments to joint ventures | (45) | (70) |
| Upfront payments on business acquisitions | (2,446) | (3,804) |
| Payment of contingent consideration on business acquisitions | (579) | (657) |
| Interest received | 123 | 140 |
| Payments made by subsidiaries to non-controlling interests | - | (10) |
| Net cash outflow from investing activities | (4,239) | (7,032) |
| Net cash (outflow)/inflow before financing activities | (915) | 26 |
| Cash flows from financing activities | | |
| Proceeds from issue of share capital | 43 | 279 |
| Issue of loans | 5,928 | 919 |
| Repayment of loans | (884) | (750) |
| Dividends paid | (3,486) | (3,521) |
| Hedge contracts relating to dividend payments | (51) | (14) |
| Repayment of obligations under finance leases | (42) | (36) |
| Payments to acquire non-controlling interest | - | (102) |
| Movement in short-term borrowings | (630) | 520 |
| Net cash inflow/(outflow) from financing activities | 878 | (2,705) |
| Net decrease in cash and cash equivalents in the period | (37) | (2,679) |
| Cash and cash equivalents at the beginning of the period | 6,164 | 8,995 |
| Exchange rate effects | (76) | (152) |
| Cash and cash equivalents at the end of the period | 6,051 | 6,164 |
| Cash and cash equivalents consists of: | | |
| Cash and cash equivalents | 6,240 | 6,360 |
| Overdrafts | (189) | (196) |
| | 6,051 | 6,164 |

Condensed Consolidated Statement of Changes in Equity

| | Share capital | Share premium account | Other reserves* | Retained earnings | Total | Non-controlling interests | Total equity |
|-----------------------|---------------|-----------------------|-----------------|-------------------|---------|---------------------------|--------------|
| | \$m | \$m | \$m | \$m | \$m | \$m | \$m |
| At 1 Jan 2014 | 315 | 3,983 | 1,966 | 16,960 | 23,224 | 29 | 23,253 |
| Profit for the period | - | - | - | 1,233 | 1,233 | 2 | 1,235 |
| | - | - | - | (1,499) | (1,499) | (7) | (1,506) |

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| | | | | | | | |
|--|-----|-------|-------|---------|---------|------|---------|
| Other comprehensive income | | | | | | | |
| Transfer to other reserves | - | - | 40 | (40) | - | - | - |
| Transactions with owners: | | | | | | | |
| Dividends | - | - | - | (3,532) | (3,532) | - | (3,532) |
| Issue of Ordinary Shares | 1 | 278 | - | - | 279 | - | 279 |
| Share-based payments | - | - | - | (93) | (93) | - | (93) |
| Transfer from non-controlling interests to payables | - | - | - | - | - | (5) | (5) |
| True-up to Astra AB non-controlling interest buy out | - | - | 15 | - | 15 | - | 15 |
| Net movement | 1 | 278 | 55 | (3,931) | (3,597) | (10) | (3,607) |
| At 31 Dec 2014 | 316 | 4,261 | 2,021 | 13,029 | 19,627 | 19 | 19,646 |

| | Share capital \$m | Share premium account \$m | Other reserves* \$m | Retained earnings \$m | Total \$m | Non-controlling interests \$m | Total equity \$m |
|----------------------------|----------------------|------------------------------|------------------------|--------------------------|--------------|----------------------------------|---------------------|
| At 1 Jan 2015 | 316 | 4,261 | 2,021 | 13,029 | 19,627 | 19 | 19,646 |
| Profit for the period | - | - | - | 2,825 | 2,825 | 1 | 2,826 |
| Other comprehensive income | - | - | - | (337) | (337) | (1) | (338) |
| Transfer to other reserves | - | - | 15 | (15) | - | - | - |
| Transactions with owners: | | | | | | | |
| Dividends | - | - | - | (3,537) | (3,537) | - | (3,537) |
| Issue of Ordinary Shares | - | 43 | - | - | 43 | - | 43 |
| Share-based payments | - | - | - | (131) | (131) | - | (131) |
| 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 |

* 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 2015 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. Except as detailed below, 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 2014.

Externalisation revenue

As announced on 6 March 2015, the Group updated its revenue accounting policy with effect from 1 January 2015. The Group's business model includes externalisation as a component of our portfolio management strategy. Externalisation stems from our increased R&D productivity and our focus on three main therapy areas. Historically, reported revenue reflected only product sales, with externalisation revenue forming part of other operating income presented below gross profit. From 1 January 2015 externalisation revenue, alongside product sales, is included in total revenue. Externalisation revenue includes development, commercialisation and collaboration revenue, such as royalties and milestone receipts, together with income from services or repeatable licences. Income is recorded as externalisation revenue when the Group has a significant ongoing interest in the product and/or it is repeatable business and there is no derecognition of an intangible asset. Disposals of assets and businesses, where the Group does not retain an interest, will continue to be recorded in other operating income. The updated financial presentation reflects the Group's entrepreneurial approach and provides a clearer picture of this additional revenue stream. The updated revenue accounting policy results in a presentational change to the Statement of Comprehensive Income only, and has no impact on the Group's net results or net assets. The prior period Condensed Consolidated Statement of Comprehensive Income has been restated accordingly, resulting in \$452m of income being reclassified from other operating income to externalisation revenue for the year ended 31 December 2014, and \$33m for the quarter ended 31 December 2014.

New accounting standards

The Group has adopted the amendments to IAS 19 Employee Benefits, issued by IASB in November 2013 and effective for periods beginning on or after 1 July 2014. The adoption has not had a significant impact on the Group's profit for the period, net assets or cash flows. There have been no other significant new or revised accounting standards applied in the year ended 31 December 2015.

Legal proceedings

The information contained in Note 7 updates the disclosures concerning legal proceedings and contingent liabilities included in the Group's Annual Report and Form 20-F Information 2014 and Interim Financial Statements for the year ended 31 December 2015.

Going concern

The Group has considerable financial resources available. As at 31 December 2015 the Group has \$8.3bn in financial resources (cash balances of \$6.2bn and undrawn committed bank facilities of \$3.0bn which are available until April 2020, with only \$0.9bn of debt due within one year). Although no liability was recognised at 31 December 2015, the Group had entered into an agreement to invest in a majority equity stake in Acerta with an upfront payment of \$2.5bn which was paid on 2 February 2016. 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 2015 and 2014 but is derived from those accounts. Statutory accounts for 2014 have been delivered to the registrar of companies and those for 2015 will be delivered in due course. Those accounts have been reported on by the Group auditor; their report was (i) unqualified, (ii) did not include a reference to any matters to which the auditor 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 2015 and to 31 December 2014 has not been subject to audit.

2 RESTRUCTURING COSTS

Profit before tax for the year ended 31 December 2015 is stated after charging restructuring costs of \$1,034m (\$372m for the fourth quarter of 2015). These have been charged to profit as follows:

| | FY 2015 | FY 2014 | Q4 2015 | Q4 2014 |
|---|---------|---------|---------|---------|
| | \$m | \$m | \$m | \$m |
| Cost of sales | 158 | 107 | 34 | 35 |
| Research and development expense | 258 | 497 | 78 | 97 |
| Selling, general and administrative costs | 618 | 662 | 260 | 259 |
| Other operating income and expense | - | 292 | - | - |
| Total | 1,034 | 1,558 | 372 | 391 |

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 2015 \$m | Cash Flow \$m | Non-cash & Other \$m | Exchange Movements \$m | At 31 Dec 2015 \$m |
|--|-------------------------|---------------------|----------------------------|------------------------------|-----------------------------|
| Loans due after one year | (8,337) | (5,928) | 40 | 116 | (14,109) |
| Finance leases due after one year | (60) | - | 31 | 1 | (28) |
| Total long-term debt | (8,397) | (5,928) | 71 | 117 | (14,137) |
| Current instalments of loans | (912) | 884 | - | 28 | - |
| Current instalments of finance leases | (48) | 42 | (63) | 2 | (67) |
| Total current debt | (960) | 926 | (63) | 30 | (67) |

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| | | | | | |
|--------------------------------------|---------|---------|------|-------|---------|
| Other investments – current | 795 | (244) | 103 | (41) | 613 |
| Net derivative financial instruments | 465 | 12 | (39) | - | 438 |
| Cash and cash equivalents | 6,360 | (39) | - | (81) | 6,240 |
| Overdrafts | (196) | 2 | - | 5 | (189) |
| Short-term borrowings | (1,290) | 630 | - | - | (660) |
| | 6,134 | 361 | 64 | (117) | 6,442 |
| Net debt | (3,223) | (4,641) | 72 | 30 | (7,762) |

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

4 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 CHF.

The acquisition gives AstraZeneca access to the potassium-binding compound ZS-9, a potential best-in-class treatment for hyperkalaemia, which is under regulatory review by the US Food and Drug Administration with a Prescription Drug User Fee Act goal date of 26 May 2016. A submission for European Marketing Application Authorisation was made late in 2015.

ZS Pharma represents a strong fit with AstraZeneca's pipeline and portfolio in Cardiovascular and Metabolic Disease, one of the Company's three main therapy areas. AstraZeneca's strategy focuses on reducing morbidity, mortality and organ damage by addressing multiple risk factors across cardiovascular disease, diabetes and chronic kidney disease. ZS-9 complements the Company's increasing focus on CKD and CHF, including the investigational medicine roxadustat, which is currently in Phase III development for patients with anaemia associated with CKD, as well as its leading diabetes portfolio.

Under the terms of the agreement, AstraZeneca has acquired 100% of the share capital of ZS Pharma for \$90 per share in an all-cash transaction, or approximately \$2.7bn in aggregate transaction value.

ZS Pharma has around 200 employees across three sites in California, Texas and Colorado. The combination of intangible product rights with an established workforce and their associated operating processes, principally those related to research and development and manufacturing, requires that the transaction is accounted for as a business combination in accordance with IFRS 3.

Goodwill is principally attributable to the commercial synergies AstraZeneca expects to be able to realise upon launch of ZS-9, the value of the specialist know-how inherent in the acquired workforce and the accounting for deferred taxes. Goodwill of nil is expected to be deductible for tax purposes.

ZS Pharma's results have been consolidated into the Company's results from 17 December 2015. From the period from acquisition to 31 December 2015, ZS Pharma's revenue and loss were immaterial.

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

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 | (1,045) |
| Other liabilities | (13) |
| | (1,058) |
| Total net assets acquired | 2,244 |
| Goodwill | 456 |
| Total upfront consideration | 2,700 |
| Less: cash and cash equivalents acquired | (73) |
| Less: deferred upfront consideration | (181) |
| Net cash outflow | 2,446 |

5 AGREEMENT WITH ACERTA PHARMA

On 2 February 2016, AstraZeneca completed an agreement to invest in a majority equity stake in Acerta Pharma, a privately-owned biopharmaceutical company based in the Netherlands and US. The transaction provides AstraZeneca with a potential best-in-class irreversible oral Bruton's tyrosine kinase (BTK) inhibitor, acalabrutinib (ACP-196), currently in Phase II/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 in the US, or the end of 2018, depending on whichever is sooner. 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. Acerta's results and net assets will be consolidated into the Company's results from 2 February 2016.

Given the close proximity of the completion of the transaction to the date the Financial Statements were approved, the accounting entries for this transaction have not yet been determined. Our provisional assessment of the fair values of the assets and liabilities acquired will be completed in 2016.

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 140 and 141 of the Company's Annual Report and Form 20-F Information 2014. 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 \$1,071m of other investments, \$1,753m of loans, and \$438m of derivatives as at 31 December 2015. The total fair value of interest-bearing loans and borrowings at 31 December 2015, which have a carrying value of \$15,053m in the Condensed Consolidated Statement of Financial Position, was \$16,277m. 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 | Total |
|---|----------------------|-------|-------|-------|
| | 2015 | 2015 | 2015 | 2014 |
| | \$m | \$m | \$m | \$m |
| At 1 January | 5,386 | 1,513 | 6,899 | 514 |
| Additions through business combinations | - | - | - | 6,138 |
| Settlements | (325) | (254) | (579) | (657) |
| Revaluations | (378) | (54) | (432) | 512 |
| Discount unwind | 409 | 115 | 524 | 391 |
| Foreign exchange | - | (1) | (1) | 1 |
| At 31 December | 5,092 | 1,319 | 6,411 | 6,899 |

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 2014, the Company's Half-Yearly Financial Report for the six-month period to 30 June 2015, and the Third Quarter and Nine-Month Results 2015 (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 2015 to 4 February 2016.

Patent litigation

Byetta (exenatide)

Patent proceedings in the US

In November 2015, Sanofi-Aventis U.S. LLC and Sanofi-Aventis Deutschland GmbH (together, Sanofi) served AstraZeneca with a complaint for declaratory judgment that Sanofi's proposed lixisenatide product would not infringe three AstraZeneca patents. Sanofi also alleges invalidity of the patents. In December 2015, AstraZeneca filed an answer including counterclaims that Sanofi's proposed lixisenatide product would infringe several AstraZeneca patents. Certain patents-at-issue are listed in the FDA Orange Book with reference to Byetta. Proceedings are in early stages in the US District Court for the District of Delaware. No trial date has been set.

Separately, in December 2015, Sanofi filed petitions in the US Patent Trial and Appeals Board for inter partes review of certain patents that are also at issue in the above-referenced District Court litigation. Proceedings are in early stages.

In December 2015, AstraZeneca commenced patent litigation in response to a Paragraph IV notice from Amneal Pharmaceuticals LLC (Amneal) in the US District Court for the District of Delaware. The Amneal proceedings are at an early stage and no trial date has been set.

Crestor (rosuvastatin)

Patent proceedings in the US

As previously disclosed, AstraZeneca has been defending three patent infringement lawsuits in the US District Court for the District of South Carolina which, among other things, claim that AstraZeneca's Crestor sales induce infringement of the plaintiffs' patents. In December 2015, the court issued an order dismissing the first of these cases, which was filed by Palmetto Pharmaceuticals, LLC (Palmetto), and entered judgment in AstraZeneca's favour. In January 2015, Palmetto filed a notice of appeal.

Patent proceedings outside the US

As previously disclosed, in the UK, in October 2015, Resolution Chemicals Ltd. commenced an action alleging partial invalidity and non-infringement of the supplementary protection certificate related to the Crestor substance patent. AstraZeneca has responded.

As previously disclosed, in Australia, AstraZeneca was unsuccessful in defending the validity of Crestor-related patents, at trial and on appeal. This patent litigation concluded in September 2015 when the High Court of Australia dismissed an appeal filed by AstraZeneca. Relevant parties could pursue damages claims against AstraZeneca. A provision has been taken in respect of generic entities which were prevented by court order from launching their products in Australia before AstraZeneca's patents were subsequently found invalid.

Faslodex (fulvestrant)

Patent proceedings in the US

As previously disclosed, AstraZeneca is engaged in patent litigation against several companies that are seeking to market generic versions of Faslodex prior to the expiry of AstraZeneca's relevant FDA Orange Book listed patents. In November 2015 and February 2016, AstraZeneca filed patent infringement lawsuits against two additional companies that sent Paragraph IV notices relating to Faslodex to AstraZeneca.

Patent proceedings outside the US

As previously disclosed, in Brazil, in February 2013, Eurofarma Laboratorios S.A. (Eurofarma) filed a nullity action against a formulation patent for Faslodex in the 31st Specialized Intellectual Property Federal Court of Rio de Janeiro (the Court). In October 2015, the Court ruled in Eurofarma's favour and invalidated AstraZeneca's patent. In November 2015, AstraZeneca appealed the decision.

As previously disclosed, in Germany, in July 2015, AstraZeneca was served with a nullity complaint by Hexal AG (Hexal), commencing invalidity proceedings before the Federal Patent Court, and requesting revocation of the German part of a Faslodex formulation use patent, European Patent No. 1,250,138. In September 2015, AstraZeneca filed a request for a provisional injunction against Hexal in the Regional Court of Düsseldorf after Hexal threatened to launch a generic Faslodex product in the fourth quarter of 2015. The provisional injunction request was denied and AstraZeneca filed an appeal against this decision in November 2015. In December 2015, AstraZeneca filed an infringement suit against Hexal in the Regional Court of Mannheim referring to their threatened launch of a generic Faslodex product.

In October 2015, Hexal filed a notice of opposition against European Patent No. 2,266,573, a patent granted in June 2015. European Patent No. 2,266,573 is related to European Patent No. 1,250,138 referred to above.

Onglyza (saxagliptin) and Kombiglyze (saxagliptin and metformin)
Patent proceedings in the US

As previously disclosed, in June 2015, Mylan Pharmaceuticals, Inc. (Mylan) filed a petition for an inter partes review (IPR) with the US Patent and Trademark Office (USPTO) challenging the validity of US Patent No. RE44,186. In December 2015 the USPTO declined to institute the IPR (the December Decision). In January 2016, Mylan filed a Request for Rehearing with the USPTO seeking reconsideration of the December Decision.

Seroquel XR (quetiapine fumarate)
Patent proceedings outside the US

As previously disclosed, in France, in the third quarter of 2015, Mylan SAS (Mylan) launched its generic Seroquel XR product at-risk. In November 2015, AstraZeneca obtained a preliminary injunction against Mylan, which was overturned on appeal in December 2015.

As previously disclosed, Accord Healthcare France SAS and Accord Healthcare Limited (together, Accord) and AstraZeneca were involved in patent litigation in France regarding the French designation of the Seroquel XR formulation patent, European Patent No. 0,907,364. In January 2016, AstraZeneca settled the litigation with Accord.

In Germany, generic entities have claimed, or could claim, damages relating to the preliminary injunction issued in April 2012 that prevented generic Seroquel XR sales by those entities until the injunction was lifted following a November 2012 Federal Patent Court decision that held that the Seroquel XR patent was invalid. A provision has been taken.

Product liability litigation

Byetta/Bydureon (exenatide)

As previously disclosed, Amylin Pharmaceuticals, LLC, a wholly owned subsidiary of AstraZeneca, and/or AstraZeneca are among multiple defendants in various lawsuits filed in federal and state courts in the US involving approximately 2,500 claims of physical injury from treatment with Byetta and/or Bydureon. The lawsuits allege multiple types of injuries including pancreatitis, pancreatic cancer, thyroid cancer, and kidney cancer. A multi-district litigation has been established in the US District Court for the Southern District of California (the District Court) in regard to the alleged pancreatic cancer cases in federal courts. Further, a co-ordinated proceeding has been established in Los Angeles, California in regard to the various lawsuits in California state courts.

In November 2015, the District Court granted the defendants' motion for summary judgment and dismissed all claims alleging pancreatic cancer that accrued prior to 11 September 2015. The plaintiffs have appealed that ruling. A similar motion was granted in favour of the defendants in the California state co-ordinated proceeding, and judgment has not yet been entered.

A single case pending in Alabama state court has been set for trial on 21 June 2016. A motion for summary judgment is pending.

Farxiga (dapagliflozin)

AstraZeneca has been named as one of multiple defendants in a lawsuit filed in the US District Court for the Western District of Kentucky involving one plaintiff claiming physical injury, including diabetic ketoacidosis and kidney failure, from treatment with Farxiga.

Onglyza (saxagliptin)

As previously disclosed, Amylin Pharmaceuticals, LLC, a wholly owned subsidiary of AstraZeneca, and/or AstraZeneca are among multiple defendants in various lawsuits filed in federal and state courts in the US involving multiple plaintiffs claiming physical injury from treatment with Onglyza. The lawsuits allege injuries including pancreatic cancer. The lawsuit that was pending, and was previously disclosed, claiming congestive heart failure from treatment with Onglyza has been dismissed.

Commercial litigation

Nexium/PriLOSEC trademark litigation

As previously disclosed, AstraZeneca filed separate complaints in the US District Court for the District of Delaware against Camber Pharmaceuticals, Inc. (Camber) and Dr. Reddy's Laboratories, Inc. (Dr. Reddy's) to enforce certain AstraZeneca trademark rights related to Nexium and PriLOSEC. Dr. Reddy's has filed its own separate claims against AstraZeneca in both the US District Court for the District of Delaware (the Delaware District Court) as well as the US District Court for the District of New Jersey. The Delaware District Court has issued preliminary injunctions against Camber's and Dr. Reddy's sales of generic esomeprazole magnesium in purple capsules. Dr. Reddy's has appealed the decision of the Delaware District Court to the US Court of Appeals for the Third Circuit, and the appeal is pending. All cases related to this matter have been stayed pending this appeal.

Synagis (palivizumab)

As previously disclosed, in September 2011, MedImmune filed an action against AbbVie, Inc. (AbbVie) (formerly Abbott International, LLC) in the Circuit Court of Montgomery County, Maryland, seeking a declaratory judgment in a contract dispute. AbbVie's motion to dismiss was granted. In September 2011, AbbVie filed a parallel action against MedImmune in Illinois State Court and, as previously disclosed, trial began in August 2015. In September 2015, a jury returned a verdict in favour of AbbVie and awarded AbbVie damages in the amount of approximately \$94m. In December 2015, MedImmune and AbbVie reached a settlement of this matter bringing this litigation to a conclusion.

Ocimum Lawsuit

In December 2015, AstraZeneca was served with a complaint filed by Ocimum Biosciences, Ltd. (Ocimum) in the Superior Court for the State of Delaware that alleges, among other things, breaches of contractual obligations and misappropriation of trade secrets, relating to a now terminated 2001 licensing agreement between AstraZeneca and Gene Logic, Inc. (Gene Logic), the rights to which Ocimum purports to have acquired from Gene Logic.

Government investigations/proceedings

Good Manufacturing Practices subpoena

As previously disclosed, in March 2013, AstraZeneca received a subpoena duces tecum from the US Attorney's Office in Boston seeking documents and information relating to products manufactured or packaged at AstraZeneca's Macclesfield facility in the UK. AstraZeneca co-operated with this inquiry which is now closed.

8 PRODUCT ANALYSIS – FY 2015

World

US

Europe

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| | FY | | FY | | FY | | Established ROW | | Emerging Markets | |
|--|-------|------|-------|------|-------|------|-----------------|------|------------------|-------|
| | 2015 | CER | 2015 | CER | 2015 | CER | 2015 | CER | 2015 | CER |
| | \$m | % | \$m | % | \$m | % | \$m | % | \$m | % |
| Respiratory, Inflammation & Autoimmunity: | | | | | | | | | | |
| Symbicort | 3,394 | (3) | 1,520 | 1 | 1,076 | (14) | 404 | 2 | 394 | 22 |
| Pulmicort | 1,014 | 15 | 200 | (5) | 117 | (13) | 88 | 4 | 609 | 35 |
| Tudorza/Eklira | 190 | n/m | 103 | n/m | 76 | n/m | 9 | n/m | 2 | n/m |
| Daliresp | 104 | n/m | 104 | n/m | - | - | - | - | - | - |
| Duaklir | 27 | n/m | - | - | 26 | n/m | 1 | n/m | - | - |
| Others | 258 | (5) | 18 | (31) | 88 | (6) | 25 | 4 | 127 | (1) |
| Total Respiratory, Inflammation & Autoimmunity | 4,987 | 7 | 1,945 | 11 | 1,383 | (7) | 527 | 5 | 1,132 | 25 |
| Cardiovascular & Metabolic disease: | | | | | | | | | | |
| Brilinta/Brilique | 619 | 44 | 240 | 64 | 230 | 18 | 37 | 33 | 112 | 91 |
| Onglyza | 786 | 2 | 420 | (13) | 141 | 8 | 66 | 27 | 159 | 41 |
| Bydureon | 580 | 35 | 482 | 29 | 81 | 65 | 8 | 80 | 9 | 150 |
| Farxiga/Forxiga | 492 | 137 | 261 | 114 | 126 | 126 | 32 | 124 | 73 | n/m |
| Byetta | 316 | 2 | 209 | 5 | 62 | (11) | 22 | (7) | 23 | 30 |
| Legacy: | | | | | | | | | | |
| Crestor | 5,017 | (3) | 2,844 | (3) | 916 | (9) | 571 | (1) | 686 | 2 |
| Seloken/Toprol-XL | 710 | 4 | 89 | (2) | 97 | (6) | 12 | (26) | 512 | 9 |
| Atacand | 358 | (15) | 34 | (23) | 105 | (26) | 26 | (30) | 193 | (4) |
| Others | 611 | (10) | 55 | (28) | 143 | (15) | 60 | (15) | 353 | (3) |
| Total Cardiovascular & Metabolic Disease | 9,489 | 4 | 4,634 | 4 | 1,901 | (1) | 834 | 1 | 2,120 | 11 |
| Oncology: | | | | | | | | | | |
| Iressa | 543 | (2) | 6 | n/m | 128 | (8) | 137 | (10) | 272 | 4 |
| Lynparza | 94 | n/m | 70 | n/m | 23 | n/m | - | - | 1 | n/m |
| Tagrisso | 19 | n/m | 15 | n/m | 4 | n/m | - | - | - | - |
| Legacy: | | | | | | | | | | |
| Zoladex | 816 | 7 | 28 | 8 | 171 | (12) | 272 | (2) | 345 | 27 |
| Faslodex | 704 | 9 | 356 | 5 | 207 | 2 | 54 | 5 | 87 | 49 |
| Casodex | 267 | (6) | 1 | (80) | 30 | (14) | 131 | (11) | 105 | 9 |
| Arimidex | 250 | (5) | 19 | 27 | 49 | (24) | 79 | (17) | 103 | 16 |
| Others | 132 | 6 | 19 | (24) | 23 | (18) | 60 | 44 | 30 | - |
| Total Oncology | 2,825 | 7 | 514 | 25 | 635 | (4) | 733 | (4) | 943 | 18 |
| Infection, Neuroscience & Gastrointestinal: | | | | | | | | | | |
| Nexium | 2,496 | (26) | 902 | (52) | 284 | (7) | 549 | 5 | 761 | 3 |
| Seroquel XR | 1,025 | (12) | 716 | (3) | 202 | (30) | 25 | (34) | 82 | (1) |
| Synagis | 662 | (26) | 285 | (43) | 377 | (6) | - | - | - | - |
| Losec/Prilosec | 340 | (10) | 18 | (32) | 97 | (10) | 74 | (19) | 151 | (1) |
| FluMist/Fluenz | 288 | - | 206 | (6) | 76 | 16 | 7 | 14 | (1) | (100) |
| Movantik/Moventig | 29 | n/m | 28 | n/m | 1 | n/m | - | - | - | - |
| Others | 1,500 | - | 226 | 50 | 367 | (15) | 273 | (3) | 634 | 1 |
| | 6,340 | (16) | 2,381 | (32) | 1,404 | (13) | 928 | (1) | 1,627 | 2 |

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Total Infection,
Neuroscience &
Gastrointestinal

TOTAL PRODUCT SALES 23,641 (1) 9,474 (6) 5,323 (6) 3,022 - 5,822 12

9 PRODUCT SALES ANALYSIS – Q4 2015zz

| | World | | US | | Europe | | Established ROW | | Emerging Markets | |
|--|-------|------|-------|-------|--------|------|-----------------|------|------------------|------|
| | Q4 | CER | Q4 | CER | Q4 | CER | Q4 | CER | Q4 | CER |
| | 2015 | % | 2015 | % | 2015 | % | 2015 | % | 2015 | % |
| | \$m | | \$m | | \$m | | \$m | | \$m | |
| Respiratory, Inflammation & Autoimmunity: | | | | | | | | | | |
| Symbicort | 859 | (6) | 410 | 4 | 251 | (18) | 100 | (5) | 98 | (3) |
| Pulmicort | 274 | 9 | 52 | (7) | 29 | (20) | 27 | 7 | 166 | 24 |
| Tudorza/Eklira | 47 | n/m | 26 | n/m | 19 | n/m | 2 | n/m | - | n/m |
| Daliresp | 32 | n/m | 32 | n/m | - | - | - | - | - | - |
| Duaklir | 12 | n/m | - | - | 12 | n/m | - | - | - | - |
| Others | 65 | (4) | 6 | 50 | 22 | (8) | 7 | 33 | 30 | (13) |
| Total Respiratory, Inflammation & Autoimmunity | 1,289 | 4 | 526 | 15 | 333 | (12) | 136 | - | 294 | 9 |
| Cardiovascular & Metabolic disease: | | | | | | | | | | |
| Brilinta/Brilique | 174 | 43 | 70 | 63 | 60 | 15 | 10 | 33 | 34 | 86 |
| Onglyza | 192 | 3 | 98 | (3) | 33 | (14) | 18 | 24 | 43 | 29 |
| Bydureon | 155 | 28 | 122 | 18 | 25 | 56 | 2 | 100 | 6 | n/m |
| Farxiga/Forxiga | 152 | 76 | 77 | 45 | 37 | 72 | 10 | 71 | 28 | n/m |
| Byetta | 72 | 10 | 43 | 10 | 17 | - | 7 | 14 | 5 | 67 |
| Legacy: | | | | | | | | | | |
| Crestor | 1,322 | - | 777 | 2 | 225 | (9) | 154 | 5 | 166 | 2 |
| Seloken/Toprol-XL | 160 | 5 | 19 | 27 | 24 | (10) | 3 | (25) | 114 | 6 |
| Atacand | 86 | (15) | 7 | (36) | 25 | (19) | 5 | (33) | 49 | (7) |
| Others | 147 | (9) | 14 | (7) | 35 | (13) | 16 | - | 82 | (9) |
| Total Cardiovascular & Metabolic Disease | 2,460 | 6 | 1,227 | 8 | 481 | (2) | 225 | 8 | 527 | 11 |
| Oncology: | | | | | | | | | | |
| Iressa | 129 | (5) | 4 | n/m | 32 | (12) | 35 | (7) | 58 | (5) |
| Lynparza | 36 | n/m | 24 | n/m | 11 | n/m | - | - | 1 | n/m |
| Tagrisso | 18 | n/m | 15 | n/m | 3 | n/m | - | - | - | - |
| Legacy: | | | | | | | | | | |
| Zoladex | 198 | 4 | 6 | (25) | 43 | (8) | 70 | (4) | 79 | 21 |
| Faslodex | 185 | 12 | 95 | 6 | 53 | 7 | 15 | 7 | 22 | 60 |
| Casodex | 63 | (7) | - | - | 7 | (20) | 33 | (10) | 23 | 4 |
| Arimidex | 60 | (1) | 4 | 33 | 12 | (13) | 20 | (22) | 24 | 27 |
| Others | 27 | (26) | - | (100) | 2 | (75) | 16 | 13 | 9 | (10) |
| Total Oncology | 716 | 9 | 148 | 40 | 163 | 1 | 189 | (6) | 216 | 15 |
| Infection, Neuroscience & Gastrointestinal: | | | | | | | | | | |
| Nexium | 564 | (26) | 175 | (63) | 75 | 1 | 138 | 47 | 176 | 14 |

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| | | | | | | | | | | |
|--|-------|------|-------|-------|-------|------|-----|------|-------|-------|
| Seroquel XR | 241 | (18) | 176 | (10) | 42 | (38) | 5 | (40) | 18 | (12) |
| Synagis | 275 | (32) | 128 | (45) | 147 | (14) | - | - | - | - |
| Losec/Prilosec | 77 | (23) | - | 100 | 26 | - | 19 | (19) | 32 | (26) |
| FluMist/Fluenz | 191 | 46 | 118 | 57 | 67 | 31 | 7 | 60 | (1) | (100) |
| Movantik/Moventig | 15 | n/m | 15 | n/m | - | - | - | - | - | - |
| Others | 379 | 25 | 59 | (238) | 87 | (15) | 67 | (19) | 166 | 11 |
| Total Infection, Neuroscience & Gastrointestinal | 1,742 | (13) | 671 | (29) | 444 | (10) | 236 | 11 | 391 | 7 |
| TOTAL PRODUCT SALES | 6,207 | - | 2,572 | (3) | 1,421 | (7) | 786 | 4 | 1,428 | 10 |

Shareholder Information

Announcements and Meetings

| | |
|---|------------------|
| Announcement of first quarter 2016 results | 29 April 2016 |
| A Annual General Meeting | 29 April 2016 |
| Announcement of half year and second quarter 2016 results | 28 July 2016 |
| A Announcement of nine months and third quarter 2016 results | 10 November 2016 |

D Dividends

Future dividends will normally be paid as follows:

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

The record date for the second interim dividend for 2015, payable on 21 March 2016, will be 19 February 2016. Ordinary Shares listed in London and Stockholm will trade ex-dividend from 18 February 2016. American Depositary Shares listed in New York will trade ex-dividend from 17 February 2016.

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

T Trademarks

Trademarks of the AstraZeneca group of companies and of companies other than AstraZeneca appear throughout this document in italics. AstraZeneca, the AstraZeneca logotype and the AstraZeneca symbol are all trademarks of the AstraZeneca group of companies. Trademarks of companies other than AstraZeneca that appear in this document include Caprelsa, a trademark of Genzyme Corporation; Daliresp and Daxas, trademarks of Takeda GmbH; Duaklir Genuair, Duaklir, Eklira, and Tudorza, trademarks of Almirall, S.A.; Epanova, a trademark of Chrysalis Pharma AG; Ibrance, a trademark of Pfizer Inc.; Myalept, a trademark of Aegerion Pharmaceuticals, Inc.; and Zinforo, a trademark of Forest Laboratories.

A Addresses for Correspondence

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| | | | |
|--|---|---|---|
| Registrar and Transfer Office Equiniti Limited Aspect House Spencer Road Lancing West Sussex BN99 6DA UK | US Depository Citibank Shareholder Services PO Box 43077 Providence RI 02940-3077 USA | Registered Office 2 Kingdom Street London W2 6BD UK | Swedish Central Securities Depository Euroclear Sweden AB PO Box 191 SE-101 23 Stockholm Sweden |
|--|---|---|---|

| | | | |
|---|--|-----------------------------|---------------------------|
| Tel (freephone in UK): 0800 389 1580 Tel (outside UK): +44 (0)121 415 7033 | Tel: +44 (0)207 500 2030 or +1 877 248 4237 (1 877-CITI-ADR)/ E-mail: citiadr@citi.com | Tel: +44 (0)20 7604 8000 | Tel: +46 (0)8 402 9000 |
|---|--|-----------------------------|---------------------------|

C Cautionary Statements Regarding Forward-Looking Statements

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

profit forecast.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AstraZeneca PLC

Date: 04 February 2016

By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary