

ASTRAZENECA PLC
Form 6-K
February 02, 2018

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 2018

Commission File Number: 001-11960

AstraZeneca PLC

1 Francis Crick Avenue
Cambridge Biomedical Campus
Cambridge CB2 0AA
United Kingdom

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-_____

AstraZeneca PLC

INDEX TO EXHIBITS

AstraZeneca PLC

2 February 2018 07:00

Full-Year 2017 Results

Encouraging progress made on commercial execution and cost discipline; Product Sales growth in the quarter. AstraZeneca positioned for Product Sales growth from FY 2018

Financial Summary

	FY 2017			Q4 2017		
	\$m	% change	Actual CER1	\$m	% change	Actual CER
Total Revenue	22,465	(2)	(2)	5,777	3	2
Product Sales	20,152	(5)	(5)	5,487	4	3
Externalisation Revenue	2,313	37	38	290	(11)	(12)
Reported Operating Profit ²	3,677	(25)	(28)	686	(73)	(71)
Core Operating Profit ³	6,855	2	-	1,787	(12)	(11)
Reported Earnings Per Share (EPS)	\$2.37	(14)	(15)	\$1.03	(29)	(24)
Core EPS	\$4.28	(1)	(2)	\$1.30	7	13

Financial Highlights

Total Revenue declined by 2% in the year, in line with guidance. Externalisation Revenue increased by 37% (38% at CER) in the year to \$2,313m. Ongoing Externalisation Revenue⁴ of \$821m in the year represented 35% of total Externalisation Revenue (FY 2016: \$356m, 21%)

Cost discipline in the year continued:

- Reported R&D costs declined by 2% (1% at CER) to \$5,757m; Core R&D costs declined by 4% (3% at CER) to \$5,412m

- Reported SG&A costs increased by 9% (10% at CER) to \$10,233m; Core SG&A costs declined by 4% (3% at CER) to \$7,853m

Reported EPS of \$2.37 and Core EPS of \$4.28 for the year, including:

- A \$617m net benefit in Q4 2017 to Reported Profit After Tax, reflecting adjustments to deferred taxes in line with the recently reduced US federal income tax rate from 35% to 21%

- A \$321m benefit to Reported and Core Taxation in Q4 2017; the Reported Tax Rate in FY 2017 was (29)% and the Core Tax Rate in FY 2017 was 14%, driven by reductions in tax provisions

The Board reaffirms its commitment to the progressive dividend policy; a second interim dividend of \$1.90 per share has been declared, taking the full-year dividend per share to \$2.80 (unchanged)

FY 2018 guidance (CER): Product Sales - a low single-digit percentage increase; Core EPS - \$3.30 to \$3.50

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

"AstraZeneca's revenues improved over the course of the year, a sign of how our company is steadily turning a corner. Strong commercial execution helped us bring our science to more patients, making the most of our exciting pipeline. We made encouraging progress across the main therapy areas and delivered strong growth in China. Alongside our CVMD medicines Brilinta and Farxiga reaching blockbuster status, we launched our first Respiratory biologic medicine, Fasenra and new cancer medicines, Imfinzi and Calquence. As well as bringing five new medicines to patients last year, we continued to find more potential uses for existing treatments, including Lynparza and Tagrisso. We remain committed to our progressive dividend policy. Our strategy is working, propelled by a strong pipeline, good sales performance and continued cost discipline."

Commercial Highlights

Product Sales growth of 4% (3% at CER) in Q4 2017 to \$5,487m, which included favourable true-up adjustments relating to the first nine months of 2017; the great majority of these true-up adjustments concerned legacy medicines. The Growth Platforms gathered momentum in the year and represented 68% of Total Revenue. They grew by 5% (6% at CER) in the year and by 12% in the quarter:

Emerging Markets: Full-year growth of 6% (8% at CER), in line with long-term ambitions. China sales in the year grew by 12% (15% at CER) and in the quarter by 33% (30% at CER), supported by the launches of new medicines

Respiratory: Full-year sales declined by 1%; Q4 2017 sales up by 10% (8% at CER), reflecting improved performances by Symbicort and Pulmicort

New CVMD5: Full-year growth of 9%. Growth of 23% in the quarter (21% at CER), with strong performances from Farxiga and Brilinta, each becoming blockbusters by exceeding \$1bn in sales in the year

Japan: 1% full-year growth (4% at CER), underpinned by the growth of Tagrisso and Forxiga, partly mitigated by the impact of the entry of generic competition to Crestor in the second half of the year

New Oncology6: 98% full-year growth. Tagrisso reached \$955m to become AstraZeneca's largest-selling Oncology medicine. Imfinzi sales of \$18m in the quarter vs. \$19m in the full year

FY 2018 Guidance

All measures in this section are at CER. Company guidance is on Product Sales and Core EPS only.

Product Sales A low single-digit percentage increase

Core EPS \$3.30 to \$3.50

The aforementioned growth in Product Sales is anticipated to be weighted towards the second half of the year. This reflects the remaining impact of generic competition, in particular Crestor in Europe and Japan.

Variations in performance between quarters can be expected to continue. The Company is unable to provide guidance and indications on a Reported basis because the Company cannot reliably forecast material elements of the Reported result, including the fair-value adjustments arising on acquisition-related liabilities, intangible asset impairment charges and legal settlement provisions. Please refer to the section 'Cautionary Statements Regarding Forward-Looking Statements' at the end of this announcement.

FY 2018 Currency Impact

Based only on average exchange rates in January 2018 and the Company's published currency sensitivities, there would be a low single-digit percentage favourable impact from currency movements on Product Sales and a minimal impact on Core EPS in the year. Further details on currency sensitivities are contained within the Operating and Financial Review.

FY 2018: Additional Commentary

Outside of guidance, the Company today provides additional indications for FY 2018 vs. the prior year:

The sum of Externalisation Revenue and Other Operating Income and Expense is anticipated to reduce vs. FY 2017. As part of its long-term growth strategy, the Company remains committed to focusing on appropriate cash-generating and value-accretive externalisation activities that reflect the ongoing productivity of the pipeline. It is also committed to the continued management of its portfolio disposals and to increasing the focus on the three main therapy areas over time

Core R&D costs in FY 2018 are anticipated to be in the range of a low single-digit percentage decline to stable. This expectation includes the favourable impact on development costs from the MSD collaboration (Merck & Co., Inc., Kenilworth, NJ, US (known as MSD outside the US and Canada))

The Company maintains its focus on reducing operational and infrastructure costs. Total Core SG&A costs, however, are expected to increase by a low to mid single-digit percentage in FY 2018, wholly reflecting targeted support for launches and potential launches, including Fasentra in severe, uncontrolled asthma and Imfinzi in locally-advanced, unresectable lung cancer. The Company also anticipates a reduction in restructuring costs in 2018 vs. the prior year

A Core Tax Rate of 16-20% (FY 2017: 14%)

Achieving Scientific Leadership

The table below highlights the development of the late-stage pipeline since the prior results announcement:

Regulatory Approvals	Faslodex - breast cancer (combinations) (US, EU) Lynparza - ovarian cancer (JP) Lynparza - breast cancer (US)
Regulatory Submissions and/or Acceptances	Fasentra (benralizumab) - severe, uncontrolled asthma (US, EU, JP) Tagrisso - lung cancer (1st line) (US - Priority Review, EU, JP) ZS-9 - hyperkalaemia (US)
Major Phase III Data Readouts and Developments	Lynparza - ovarian cancer: Priority review (CN) roxadustat - anaemia: Priority review (CN) PT010 - COPD1 (KRONOS trial) (most 2 primary endpoints met) tezepelumab - severe, uncontrolled asthma: First patient commenced dosing

1Chronic Obstructive Pulmonary Disease.

2Eight of the nine primary endpoints in the KRONOS trial were met, including two non-inferiority endpoints to qualify PT009, one of the comparators.

Notes

1. Constant exchange rates. These are non-GAAP financial measures because they remove the effects of currency movements from Reported results.

2. Reported financial measures are our financial results presented in accordance with IFRS, the Generally Accepted Accounting Principles (GAAP) on the basis of which we prepare our financial results.

3. Core financial measures. These are non-GAAP financial measures because, unlike Reported performance, they cannot be derived directly from the information in the Group Financial Statements. See the Operating and Financial Review for a definition of Core financial measures and a reconciliation of Core to Reported financial measures.

4. Ongoing Externalisation Revenue is defined as Externalisation Revenue excluding Initial Externalisation Revenue (which is defined as Externalisation Revenue that is recognised at the date of completion of an agreement or transaction, in respect of upfront consideration). Ongoing Externalisation Revenue comprises, among other items, royalties, milestones and profit sharing income. Ongoing Externalisation Revenue and Initial Externalisation Revenue are non-GAAP financial measures because they cannot be derived directly from the information included in the Group Financial Statements.

5. New Cardiovascular and Metabolic Diseases, incorporating Brilinta and Diabetes.

Edgar Filing: ASTRAZENECA PLC - Form 6-K

6. New Oncology, comprising Lynparza, Tagrisso, Iressa (US), Imfinzi and Calquence.

All growth rates in this announcement are shown at actual exchange rates, unless stated otherwise. Only one rate of growth is shown if the actual and constant exchange rates of growth are identical. All commentary in this announcement refers to the performance in the year and are vs. the prior year, unless stated otherwise.

Pipeline: Forthcoming Major News Flow

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

Lynparza - ovarian cancer (2nd line): Regulatory decision (EU)

Lynparza - ovarian cancer (1st line): Data readout

Lynparza - breast cancer: Regulatory submission (EU)

Tagrisso - lung cancer: Regulatory decision (US)

Imfinzi - lung cancer (PACIFIC): Regulatory decision (US)

Imfinzi +/- treme - lung cancer (ARCTIC) (3rd line): Data readout, regulatory submission

Imfinzi +/- treme - lung cancer (MYSTIC) (1st line): Data readout (final overall-survival (OS))

H1 2018 Imfinzi +/- treme - head & neck cancer (KESTREL) (1st line): Data readout

Imfinzi +/- treme - head & neck cancer (EAGLE) (2nd line): Data readout

selumetinib - thyroid cancer: Data readout

ZS-9 - hyperkalaemia: Regulatory decision (US, EU)

Bevespi - COPD: Regulatory submission (JP)

Duaklir - COPD: Regulatory submission (US)

Lynparza - breast cancer: Regulatory decision (JP)

Lynparza - ovarian cancer (1st line): Regulatory submission

Lynparza - pancreatic cancer: Data readout

Tagrisso - lung cancer: Regulatory decision (EU, JP)

Imfinzi - lung cancer (PACIFIC): Regulatory decision (EU, JP)

Imfinzi +/- treme - lung cancer (MYSTIC): Regulatory submission

Imfinzi + treme - lung cancer (NEPTUNE): Data readout, regulatory submission

Imfinzi +/- treme - head & neck cancer (KESTREL): Regulatory submission

Imfinzi +/- treme - head & neck cancer (EAGLE): Regulatory submission

H2 2018 selumetinib - thyroid cancer: Regulatory submission

Farxiga - type-2 diabetes (DECLARE): Data readout

Bydureon autoinjector - type-2 diabetes: Regulatory decision (EU)

roxadustat - anaemia: Regulatory submission (US)

Bevespi - COPD: Regulatory decision (EU)

Fasenra - COPD: Data readout

PT010 - COPD: Regulatory submission

anifrolumab - lupus: Data readout

2019 Lynparza - pancreatic cancer: Regulatory submission

Lynparza - ovarian cancer (3rd line): Data readout, regulatory submission

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Imfinzi - lung cancer (PACIFIC): Data readout (final OS)
Imfinzi +/- treme - lung cancer (POSEIDON): Data readout, regulatory submission
Imfinzi +/- treme - small-cell lung cancer (CASPIAN): Data readout, regulatory submission
Imfinzi +/- treme - bladder cancer (DANUBE): Data readout, regulatory submission

Calquence - chronic lymphocytic leukaemia: Data readout

Brilinta - coronary artery disease / type-2 diabetes: Data readout, regulatory submission
Farxiga - type-2 diabetes (DECLARE): Regulatory submission
Farxiga - heart failure: Data readout
Fasenra - COPD: Regulatory submission

anifrolumab - lupus: Regulatory submission
lanabecestat - Alzheimer's disease: Data readout

The term 'data readout' in this section refers to Phase III data readouts.

Conference Call

A live presentation and webcast for investors and analysts, hosted by management, will begin at 12:30pm UK time today. Details can be accessed via astrazeneca.com.

Reporting Calendar

The Company intends to publish its first-quarter financial results on 18 May 2018.

About AstraZeneca

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three main therapy areas - Oncology, CVMD and Respiratory. The Company also is selectively active in the areas of autoimmunity, neuroscience and infection. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide.

For more information, please visit astrazeneca.com and follow us on Twitter @AstraZeneca.

Media Relations

Esra Erkal-Paler	UK/Global	+44 203 749 5638
Gonzalo Viña	UK/Global	+44 203 749 5916
Rob Skelding	UK/Global	+44 203 749 5821
Karen Birmingham	UK/Global	+44 203 749 5634
Matt Kent	UK/Global	+44 203 749 5906
Jacob Lund	Sweden	+46 8 553 260 20
Michele Meixell	US	+1 302 885 2677

Investor Relations

Thomas Kudsk Larsen		+44 203 749 5712
Craig Marks	Finance; Fixed Income; M&A	+44 7881 615 764
Henry Wheeler	Oncology	+44 203 749 5797
Mitchell Chan	Oncology; Other	+1 240 477 3771
Christer Gruvris	Brilinta; Diabetes	+44 203 749 5711
Nick Stone	Respiratory; Renal	+44 203 749 5716
US toll free		+1 866 381 7277

Operating and Financial Review

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

periods to 31 December 2017 (the year (FY 2017), or the quarter (Q4 2017), respectively) compared to the twelve and three-month periods to 31 December 2016 (FY 2016 and Q4 2016, respectively). All commentary in the Operating and Financial Review relates to the full year, unless stated otherwise.

Core financial measures, EBITDA, Net Debt, Initial Externalisation Revenue and Ongoing Externalisation Revenue are non-GAAP financial measures because they cannot be derived directly from the Group Condensed Consolidated Financial Statements. Management believes that these non-GAAP financial measures, when provided in combination with Reported results, will provide readers with helpful supplementary information to better understand the financial performance and position of the Company on a comparable basis from period to period. These non-GAAP financial measures are not a substitute for, or superior to, financial measures prepared in accordance with GAAP. Core financial measures are adjusted to exclude certain significant items, such as:

Amortisation and impairment of intangible assets, including impairment reversals but excluding any charges relating to IT assets

Charges and provisions related to global restructuring programmes, which includes charges that relate to the impact of global restructuring programmes on capitalised IT assets

Other specified items, principally comprising acquisition-related costs, which include fair value adjustments and the imputed finance charge relating to contingent consideration on business combinations, legal settlements and foreign-exchange gains and losses on certain non-structural intra-group loans*

Details on the nature of Core financial measures are provided on page 64 of the Annual Report and Form 20-F Information 2016. Reference should be made to the reconciliation of Core to Reported financial information included therein and in the Reconciliation of Reported to Core Financial Measures table included in the Financial Performance section of this announcement.

*This element has been added to the definition of Core financial measures during 2017. There were no such gains and losses in the income statement in prior periods.

EBITDA is defined as Reported Profit Before Tax after adding back Net Finance Expense, results from Joint Ventures and Associates and charges for depreciation, amortisation and impairment. Reference should be made to the Reconciliation of Reported Profit Before Tax to EBITDA included in the Financial Performance section of this announcement.

Net Debt is defined as interest-bearing loans and borrowings net of cash and cash equivalents, other investments and net derivative financial instruments. Reference should be made to the Reconciliation of Interest-Bearing Loans and Borrowings to Net Debt included in the Cash Flow and Balance Sheet section of this announcement.

Ongoing Externalisation Revenue is defined as Externalisation Revenue excluding Initial Externalisation Revenue (which is defined as Externalisation Revenue that is recognised at the date of completion of an agreement or transaction, in respect of upfront consideration). Ongoing Externalisation Revenue comprises, among other items, royalties, milestones and profit sharing income.

The Company strongly encourages readers not to rely on any single financial measure, but to review AstraZeneca's financial statements, including the notes thereto, and other publicly-filed Company reports, carefully and in their entirety.

Total Revenue

	FY 2017		Q4 2017	
	\$m	% change ActualCER	\$m	% change ActualCER
Total Revenue	22,465	(2) (2)	5,777	3 2
Product Sales	20,152	(5) (5)	5,487	4 3
Externalisation Revenue	2,313	37 38	290	(11) (12)

Product Sales

Growth in Product Sales was reached in the final quarter of the year after a number of years of decline. Quarterly growth rates in FY 2017 Product Sales are shown below:

% change

Actual CER

Q1 2017 (13)	(12)
Q2 2017 (10)	(8)
Q3 2017 (3)	(2)
Q4 2017 4	3

The growth in the fourth quarter included the favourable impact from true-up adjustments in the US relating to the first nine months of 2017, resulting from improved data insight and methodology in the estimation of payer rebates, product returns and discounts; AstraZeneca does not anticipate a similar magnitude of adjustments in future periods. Over the full year, Product Sales declined by 5% from \$21,319m to \$20,152m, a difference of \$1,167m; Crestor sales declined by \$1,036m and Seroquel XR sales declined by \$403m. Both medicines lost exclusivity in the US in the second half of 2016.

Emerging Markets sales grew by 6% (8% at CER) to \$6,149m, in line with an unchanged average-growth ambition of a mid to high single-digit percentage. In the quarter, Emerging Markets sales grew by 10% (9% at CER) to \$1,630m. China sales increased by 12% (15% at CER) to \$2,955m in the year and, in the quarter, by 33% (30% at CER) to \$813m. These results reflected strong performances across all three main therapy areas, including the impact of the launches of new medicines.

US sales declined by 16% to \$6,169m and were, alongside the effects of the Crestor and Seroquel XR losses of exclusivity, impacted by the adverse sales performance of Symbicort, which declined by 12% to \$1,099m. US sales, however, grew by 9% to \$1,770m in the quarter as the effects of the Crestor and Seroquel XR losses of exclusivity dissipated. Sales in the quarter also benefitted from favourable true-up adjustments in the US relating to the first nine months of 2017.

Product Sales in Europe declined by 6% (7% at CER) to \$4,753m in the year, partly driven by pricing pressures on Symbicort and the initial impact from generic competition to Crestor.

The Growth Platforms grew by 5% (6% at CER) to \$15,231m, representing 68% of Total Revenue and, in the quarter, by 12% to \$4,180m:

	FY 2017			Q4 2017		
	\$m	% change		\$m	% change	
		Actual	CER		Actual	CER
Emerging Markets	6,149	6	8	1,630	10	9
Respiratory	4,706	(1)	(1)	1,334	10	8
New CVMD	3,567	9	9	1,024	23	21
Japan	2,208	1	4	563	(5)	2
New Oncology	1,313	98	98	437	102	100
Total*	15,231	5	6	4,180	12	12

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

Externalisation Revenue

Where AstraZeneca retains a significant ongoing interest in medicines or potential new medicines, revenue arising from externalisation agreements is reported as Externalisation Revenue in the Company's financial statements. A breakdown of Initial Externalisation Revenue in the year is shown below:

Medicine	Partner	Region	\$m
Lynparza	MSD	Global	997
Zoladex	TerSera Therapeutics LLC (TerSera)	US and Canada	250
MEDI8897	Sanofi Pasteur, Inc. (Sanofi Pasteur)	Global	127
Tudorza/Duaklir	Circassia Pharmaceuticals plc (Circassia)	US	64
MEDI1341	Takeda Pharmaceutical Company Limited	Global	50
Other			4
Total			1,492

Edgar Filing: ASTRAZENECA PLC - Form 6-K

A breakdown of Ongoing Externalisation Revenue in the year is shown below:

Medicine	Partner	Region	\$m
Lynparza	MSD - option payment	Global	250
Anaesthetics	Aspen Global, Inc. (Aspen) ¹ - milestone revenue	Global (excl.US)	150
Siliq	Valeant Pharmaceuticals International, Inc. (Valeant) - milestone revenue	US	130
Lanabecestat	Eli Lilly and Company - milestone revenue	Global	50
Crestor AG2	Daiichi Sankyo Company, Ltd (Daiichi Sankyo) - milestone revenue	Japan	45
Bydureon	3SBio Inc. (3SBio) - milestone revenue	China	25
Other			171
Total			821

¹Following the sale of the remaining rights to the anaesthetics portfolio to Aspen in Q4 2017, any future income relating to these medicines will be recorded as Other Operating Income and Expense.

²Authorised Generic.

Ongoing Externalisation Revenue of \$821m represented 35% of total Externalisation Revenue (FY 2016: \$356m, 21%). The Company anticipates that Ongoing Externalisation Revenue will grow as a proportion of Externalisation Revenue over time.

	FY 2017		% change		Q4 2017		% change	
	\$m	% of total	Actual	CER	\$m	% of total	Actual	CER
Royalties	108	5	(9)	(6)	8	3	(82)	(72)
Milestones/Other ²	713	31	n/m	n/m	282	97	n/m	n/m
Ongoing Externalisation Revenue	821	35	n/m	n/m	290	100	n/m	n/m
Initial Externalisation Revenue	1,492	65	12	12	-	-	n/m	n/m
Total Externalisation Revenue	2,313	100	37	38	290	100	(11)	(12)

¹Due to rounding, the sum of individual medicine percentages may not agree to totals.

²May include, inter alia, option and profit sharing income.

A number of AstraZeneca medicines were externalised or disposed of in FY 2017, thus adversely impacting the Product Sales performance:

Completion	Medicine	Region	FY 2017*	FY 2016	Difference	Adverse Impact on FY 2017 Product Sales
			\$m	\$m	\$m	
March	Zoladex	US and Canada	23	66	(43)	
June	Seloken	Europe	52	90	(38)	
June	Zomig	Global (excl. Japan)	58	78	(20)	
October	Anaesthetics	Global	292	472	(180)	

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Total 425 706 (281) 1%

*FY 2017 Product Sales here comprise sales made to partners under manufacturing and supply agreements.

Examples of transactions that include Ongoing Externalisation Revenue are shown below:

Completion	Medicine	Partner	Region	Externalisation Revenue
				Initial \$1.0bn revenue Up to \$0.75bn for certain licence options, including \$0.25bn paid in Q4 2017 Up to \$6.15bn in regulatory and sales milestones
July 2017	Lynparza	MSD	Global	
March 2017	MEDI8897	Sanofi Pasteur	Global	Initial €120m revenue Up to €495m in sales and development-related milestones
March 2017	Zoladex	TerSera	US and Canada	Initial \$250m revenue Up to \$70m in sales-related milestones Mid-teen percentage royalties on sales
October 2016	Toprol-XL	Aralez Pharmaceuticals Inc.	US	Initial \$175m revenue Up to \$48m milestone and sales-related revenue Mid-teen percentage royalties on sales
August 2016	tralokinumab - atopic dermatitis	LEO Pharma A/S (LEO Pharma)	Global	Initial \$115m revenue Up to \$1bn in commercially-related milestones Up to mid-teen tiered percentage royalties on sales
October 2015	Siliq	Valeant	Global, later amended to US	Initial \$100m revenue Pre-launch milestone of \$130m Sales-related royalties up to \$175m Profit sharing
March 2015	Movantik	Daiichi Sankyo	US	Initial \$200m revenue Up to \$625m in sales-related revenue

Product Sales

The performance of key medicines is shown below, with a geographical split shown in Notes 6 and 7.

Therapy Area	Medicine	FY 2017				Q4 2017			
		\$m	% of total*	% change		\$m	% of total	% change	
				Actual	CER			Actual	CER
	Tagrisso	955	5	126	126	304	6	107	105
	Iressa	528	3	3	3	130	2	10	8
	Lynparza	297	1	36	35	100	2	61	58
	Imfinzi	19	-	n/m	n/m	18	-	n/m	n/m
	Calquence	3	-	n/m	n/m	3	-	n/m	n/m

Edgar Filing: ASTRAZENECA PLC - Form 6-K

	Legacy:								
	Faslodex	941	5	13	13	238	4	7	5
	Zoladex	735	4	(10)	(9)	187	3	(20)	(21)
	Casodex	215	1	(13)	(11)	54	1	(10)	(8)
	Arimidex	217	1	(6)	(4)	57	1	-	(2)
	Others	114	-	10	13	29	1	-	3
	Total Oncology	4,024	20	19	19	1,120	20	20	19
	Brilinta	1,079	5	29	29	299	5	27	24
	Farxiga	1,074	5	29	28	332	6	39	37
	Onglyza	611	3	(15)	(16)	180	3	21	19
	Bydureon	574	3	(1)	(1)	147	3	4	2
	Byetta	176	1	(31)	(30)	48	1	(13)	(13)
	Symlin	48	-	20	20	13	-	-	-
CVMD	Qtern	5	-	n/m	n/m	5	-	n/m	n/m
	Legacy:								
	Crestor	2,365	12	(30)	(30)	594	11	(6)	(7)
	Seloken/Toprol-XL	695	3	(6)	(4)	168	3	(6)	(7)
	Atacand	300	1	(5)	(3)	73	1	(10)	(10)
	Others	339	2	(15)	(13)	80	1	(8)	(10)
	Total CVMD	7,266	36	(10)	(10)	1,939	35	7	6
	Symbicort	2,803	14	(6)	(6)	752	14	2	-
	Pulmicort	1,176	6	11	12	371	7	29	26
	Daliresp/Daxas	198	1	29	28	53	1	29	27
Respiratory	Tudorza/Eklira	150	1	(12)	(12)	42	1	17	11
	Duaklir	79	-	25	25	23	-	21	16
	Bevespi	16	-	n/m	n/m	8	-	n/m	n/m

Edgar Filing: ASTRAZENECA PLC - Form 6-K

	Others	284	1	(10)	(9)	85	2	1	(2)
	Total Respiratory	4,706	23	(1)	(1)	1,334	24	10	8
	Nexium	1,952	10	(4)	(3)	427	8	(13)	(12)
	Synagis	687	3	1	1	234	4	(23)	(23)
	Losec/Prilosec	271	1	(2)	(1)	69	1	17	14
	Seroquel XR	332	2	(55)	(55)	108	2	(8)	(9)
Other	Movantik/Moventig	122	1	34	34	30	1	15	15
	FluMist/Fluenz	78	-	(25)	(28)	58	1	(13)	(18)
	Others	714	4	(38)	(38)	168	3	(32)	(33)
	Total Other	4,156	21	(18)	(17)	1,094	20	(16)	(17)
	Total Product Sales	20,152	100	(5)	(5)	5,487	100	4	3

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

Product Sales Summary

ONCOLOGY

Product Sales of \$4,024m; an increase of 19%. Oncology Product Sales represented 20% of total Product Sales, up from 16% in FY 2016.

Lung Cancer

Tagrisso

Product Sales of \$955m; an increase of 126%. In the year, the medicine became AstraZeneca's largest-selling Oncology medicine and, by the end of 2017, the medicine had received regulatory approval in more than 60 countries. Global growth partly reflected higher testing rates, led by Japan and the US.

Sales in the US were \$405m and grew by 59%, with a steady increase in epidermal growth factor receptor (EGFR) T790M-mutation testing rates. In September 2017, US National Comprehensive Cancer Network (NCCN) clinical-practice guidelines were updated to include the use of Tagrisso as a 1st-line treatment of patients with metastatic EGFR-mutated non-small cell lung cancer (NSCLC). The use of Tagrisso in this indication is not yet approved by the US FDA.

Within Emerging Markets, Tagrisso sales were \$135m in the year (FY 2016: \$10m). In Europe, sales of \$187m represented growth of 146% (142% at CER) and were driven by a continued uptake, positive reimbursement decisions and further growth in testing rates. Tagrisso was reimbursed in 15 European countries at the end of the year and was under reimbursement review in additional European countries, with positive decisions anticipated in 2018.

Testing rates in Japan continued to exceed 90%, with full-year sales of \$219m (FY 2016: \$82m) reflecting a high penetration rate in the currently-approved 2nd-line EGFR T790M-mutation setting.

Iressa

Product Sales of \$528m; an increase of 3%.

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Emerging Markets sales increased by 8% to \$251m. China Product Sales increased by 24% (28% at CER) to \$144m, reflecting an improvement in patient access following the conclusion of the national negotiation process in 2016; Iressa was subsequently included on the National Reimbursement Drug List (NRDL). Other Emerging Markets sales, however, were adversely impacted by competition from branded and generic medicines, most notably in the Republic of Korea.

Sales in the US increased by 70% to \$39m and declined in Europe by 7% (8% at CER) to \$112m. Given the significant future potential of Tagrisso, the Company continues to prioritise commercial support for Tagrisso in established markets over Iressa.

Other Cancers

Lynparza

Product Sales of \$297m; an increase of 36% (35% at CER). By the end of 2017, the medicine had received regulatory approval in 57 countries, with reviews underway in a number of additional markets.

US sales grew by 11% in the year to \$141m. First-half sales were adversely impacted by the introduction of competing poly ADP ribose polymerase (PARP)-inhibitor medicines. A much-improved performance in the second half, however, reflected the launch of Lynparza tablets for patients regardless of BRCA-mutation status, for the treatment of 2nd-line ovarian cancer. This was illustrated by sequential quarterly US sales from Q3 2017 to Q4 2017, where sales grew by 46%, from \$37m to \$54m. By the end of November 2017, Lynparza was the leading PARP inhibitor in the US, measured by total prescription volumes.

Sales in Europe increased by 60% (58% at CER) to \$130m, reflecting high BRCA-testing rates and a number of successful launches, most recently in Finland and the Republic of Ireland.

On 27 July 2017, AstraZeneca and MSD announced a global strategic oncology collaboration to co-develop Lynparza and the potential medicine selumetinib for multiple cancer types as monotherapies and in combinations. The integration of development and commercial activities is progressing well.

Imfinzi

Product Sales of \$19m (\$18m in Q4 2017); launched in the US in May 2017. By the end of 2017, Imfinzi had also received regulatory approvals in Canada, Brazil and Israel.

Imfinzi was approved under the US FDA's Accelerated-Approval pathway and launched on the same day as a fast-to-market, limited commercial opportunity, indicated for the 2nd-line treatment of patients with locally-advanced or metastatic urothelial carcinoma (bladder cancer).

The Company is actively preparing for the potential launch of Imfinzi in locally-advanced, unresectable NSCLC in H1 2018, reflecting the US FDA regulatory submission acceptance and the award of Priority Review status in the quarter.

Calquence

Product Sales of \$3m. Approved and launched in the US on 31 October 2017, Calquence delivered a promising performance in the number of new-patient starts in previously-treated mantle cell lymphoma (MCL). The medicine was included within NCCN MCL guidelines on 15 November 2017.

Legacy: Faslodex

Product Sales of \$941m; an increase of 13%.

Emerging Markets sales grew by 20% (18% at CER) to \$115m. In 2017, the Company received a label extension for Faslodex in Russia in the 1st-line monotherapy setting, based on data from the FALCON trial. Russia sales grew by 29% in the year (14% at CER) to \$18m.

US sales increased by 12% to \$492m, mainly reflecting a continued strong uptake of the combination with palbociclib, a medicine approved for the treatment of hormone-receptor-positive (HR+) breast cancer.

Europe sales increased by 12% (11% at CER) to \$256m but increased by only 5% (down by 3% at CER) to \$62m in the quarter, reflecting the impact of generic entrants in certain markets. In June 2017, a label extension based upon the FALCON trial in the 1st-line setting was approved in Japan, where sales grew by 14% (17% at CER) in the year to \$72m.

Legacy: Zoladex

Product Sales of \$735m; a decline of 10% (9% at CER).

Emerging Markets sales declined by 1% to \$353m in the year. Sales in Europe declined by 10% (8% at CER) to \$141m, reflecting the impact of generic competition, mainly in Central and Eastern Europe. In Established Rest Of

World (ROW, comprising Japan, Canada, Australia and New Zealand), sales fell by 16% (15% at CER) to \$226m, driven by increased competition. On 31 March 2017, the Company completed an agreement with TerSera for the sale of the commercial rights to Zoladex in the US and Canada.

CVMD

Product Sales of \$7,266m; a decline of 10%. CVMD Product Sales represented 36% of total Product Sales, down from 38% in FY 2016.

Within the New CVMD Growth Platform, comprising Brilinta and Diabetes and excluding medicines such as Crestor, sales grew by 9% to \$3,567m. Strong performances were delivered by Farxiga and Brilinta, each becoming blockbusters by exceeding \$1bn in sales in the year.

Brilinta

Product Sales of \$1,079m; an increase of 29%.

Emerging Markets sales of Brilinta in the year grew by 19% (21% at CER) to \$224m. Growth in Emerging Markets was reflected in a continued outperformance of growth in the oral anti-platelet market. Encouraging sales performances were delivered in many markets.

US sales of Brilinta, at \$509m, represented an increase of 46% for the full year, including growth of 47% in the quarter. The performance was driven primarily by an increase in the average duration of therapy and strong growth in the number of patients sent home from hospital with Brilinta. Furthermore, Brilinta achieved a record total-prescription market share of 7.2% at the end of the year; days-of-therapy volume market-share data was particularly encouraging. The performance reflected the growth in demand that was partly supported by updated preferred guidelines from the American College of Cardiology and the American Heart Association in 2016, as well as the narrowing of a competitor's label. Brilinta is the standard of care in the treatment of ST-segment elevation myocardial infarction (STEMI) and remained the branded oral anti-platelet market leader in the US in the period. Sales of Brilique in Europe increased by 14% (13% at CER) to \$295m, reflecting indication leadership across a number of markets and bolstered by the inclusion in high-risk, post myocardial infarction (HR PMI) guidelines from the European Society of Cardiology in 2017. Volume share reached 6.5% at the end of the year, with improvements delivered across the major markets; Brilique continued to outperform the oral anti-platelet market in the year. Brilique gained further reimbursement in key markets in its HR PMI indication with the 60mg dose.

Farxiga

Product Sales of \$1,074m; an increase of 29% (28% at CER), consolidating its global leadership position within the sodium-glucose co-transporter 2 (SGLT2) inhibitor class.

Emerging Markets sales increased by 74% (73% at CER) to \$232m, reflecting ongoing launches and improved levels of patient access. In March 2017, Farxiga became the first SGLT2-inhibitor medicine to be approved in China.

US sales in the year increased by 7% to \$489m. The first-half performance, with a sales decline of 1% to \$206m, was adversely impacted by the Company's level of participation in affordability programmes. Significant changes to the Company's approach to these programmes, however, saw a much-improved performance in the second half, illustrated by Q4 2017 sales growth of 15% to \$150m. SGLT2-class growth was supported by growing evidence around cardiovascular (CV) benefits, including data from the CVD-REAL study that was published in March 2017.

Sales in Europe increased by 29% (28% at CER) to \$242m as the medicine continued to gain market share in the innovative oral class; it also retained leadership in the SGLT2 class, which had the strongest class growth amongst innovative oral diabetes medicines in the year. In Japan, where Ono Pharmaceutical Co., Ltd is a partner and records in-market sales, sales to the partner amounted to \$53m, representing a growth of 89% (93% at CER).

Onglyza

Product Sales of \$611m in the year, a decline of 15% (16% at CER). Onglyza sales, however, grew by 21% in Q4 2017 (19% at CER) to \$180m. The performance in the latter period partly reflected favourable true-up adjustments relating to the first nine months of 2017 in the US, as well as an encouraging performance in Emerging Markets.

Given the significant future potential of Farxiga, the Company continues to prioritise its commercial support over Onglyza.

The full-year performance reflected adverse pressures on the dipeptidyl peptidase-4 (DPP-4) class and an acceleration of ongoing Diabetes market dynamics, where patients are moving to medicines and classes of medicines with documented CV benefits.

Sales in Emerging Markets declined by 8% (10% at CER) to \$130m. Onglyza, however, entered the NRDL in China in the year, underpinning Q4 2017 Emerging Markets sales growth of 16% (13% at CER) in the quarter to \$37m.

Sales in Europe in the year declined by 21% to \$104m, reflecting the broader dynamic of shift away from the DPP-4 class. In Japan, in-market sales are recorded by Kyowa Hakko Kirin Co., Ltd, to whom sales totalled \$13m.

Bydureon

Product Sales of \$574m; a decline of 1%, driven by pricing pressures. Favourable sales volumes were a result of continued growth in the glucagon-like peptide-1 (GLP-1) class at the expense of insulin.

Sales of Bydureon in Emerging Markets were \$9m. In 2016, AstraZeneca entered a strategic collaboration with 3SBio for the rights to commercialise Bydureon in China as the Company focused on its oral Diabetes strategy.

Sales in the US declined by 1% to \$458m, reflecting the level of competition and resulting price pressures. US sales in the quarter grew by 1% to \$115m, partly reflecting market growth and the impact of the aforementioned true-up sales adjustments. In the third quarter of the year, the Company successfully launched the injectable suspension autoinjector, known as Bydureon BCise in the US. The new autoinjector is a new formulation of Bydureon injectable suspension in an improved once-weekly, single-dose autoinjector device. It is designed for patient convenience in a pre-filled device with a pre-attached, hidden needle.

Bydureon sales in Europe declined by 12% (11% at CER) in the year to \$88m, resulting from the impact of increased levels of competition.

Legacy: Crestor

Product Sales of \$2,365m; a decline of 30%.

Sales in China grew by 20% (23% at CER) to \$373m. In the US, sales declined by 70% to \$373m, driven by the market entry in July 2016 of multiple Crestor generic medicines. In the quarter, US sales increased by 34% to \$127m, benefitting from true-up adjustments. In Europe, sales declined by 23% to \$666m; in Q4 2017, Europe sales of Crestor declined by 27% (32% at CER) to \$152m, reflecting the impact of generic medicines in certain markets, such as France and Spain. This impact on Europe sales is anticipated to continue in FY 2018.

In Japan, where Shionogi Co. Ltd is a partner, Crestor maintained its position as the leading statin, despite sales declining by 6% (4% at CER) to \$489m. This decline reflected the recent entry of multiple Crestor competitors in the market in the latter stages of the year.

RESPIRATORY

Product Sales of \$4,706m; a decline of 1%. Respiratory Product Sales represented 23% of total Product Sales, from 22% in FY 2016.

Symbicort

Product Sales of \$2,803m; a decline of 6%. In Q4 2017, sales increased by 2% (stable at CER) to \$752m, partly reflecting the aforementioned favourable true-up adjustments relating to the first nine months of 2017 in the US. Symbicort continued to lead the global market by volume within the inhaled corticosteroids (ICS) / Long-Acting Beta Agonist (LABA) class. Emerging Markets sales grew by 9% (10% at CER) to \$439m, partly reflecting growth in China of 13% (17% at CER) to \$177m and in Latin America (ex-Brazil), where sales grew by 24% (30% at CER) to \$46m.

In contrast, US sales declined by 12% to \$1,099m, in line with expectations of continued challenging market conditions; these conditions were a result of the impact of managed-care access programmes on pricing within the class. Competition also remained intense from other classes, such as Long-Acting Muscarinic Antagonist (LAMA)/LABA combination medicines. Symbicort sales in the US in the quarter grew by 1% to \$288m, driven by market growth, the impact of the aforementioned true-up sales adjustments and increased demand in government and non-retail channels.

In Europe, sales declined by 10% to \$819m, reflecting the level of competition from other branded and Symbicort-analogue medicines. Symbicort, however, continued to retain its class-leadership position and stabilise its

volume market share in the LABA/ICS class.

In Japan, where Astellas Pharma Co. Ltd assists as a promotional partner, sales declined by 3% (stable at CER) to \$205m.

Pulmicort

Product Sales of \$1,176m; an increase of 11% (12% at CER).

Emerging Markets sales increased by 20% (23% at CER) to \$840m, reflecting strong underlying volume growth, with sales in China, Middle East and North Africa proving particularly encouraging. Emerging Markets represented 71% of global sales and, in the quarter, sales increased by 37% (34% at CER), reflecting a significant level of seasonal demand. Usage in China progressed further, with an increasing prevalence of acute COPD and paediatric asthma accompanied by continued investment by the Company in new hospital nebulisation centres by around 2,000 to 15,000.

Sales in the US and Europe declined by 10% to \$156m and by 7% (8% at CER) to \$92m, respectively.

Daliresp/Daxas

Product Sales of \$198m; an increase of 29% (28% at CER).

US sales, representing 84% of global sales, increased by 25% to \$167m, driven by increased adoption of the medicine which is the only oral, selective, long-acting inhibitor of the enzyme phosphodiesterase-4, an inflammatory agent in COPD. Sales in Europe increased by 73% to \$26m.

Tudorza/Eklira

Product Sales of \$150m; a decline of 12%.

Sales in the US declined by 14% to \$66m, reflecting lower levels of use of inhaled monotherapy medicines for COPD and the Company's commercial focus on the launch of Bevespi. On 17 March 2017, AstraZeneca announced that it had entered a strategic collaboration with Circassia for the development and commercialisation of Tudorza in the US. Circassia began its promotion of Tudorza in the US in May 2017 and, in the quarter, sales increased by 19% to \$19m. AstraZeneca books Product Sales of Tudorza in the US.

Sales in Europe declined by 12% (11% at CER) to \$73m, impacted by the decline of the overall LAMA monotherapy class.

Duaklir

Product Sales of \$79m; an increase of 25%.

Duaklir, the Company's first inhaled dual bronchodilator, is now available for patients in over 25 countries, with almost all sales emanating from Europe. The growth in sales in the year was favourably impacted by the performances in Germany and the UK, as well as the recent launch in Italy. The LAMA/LABA class continued to grow strongly, albeit below expectations. Duaklir is expected to be submitted for US regulatory review in H1 2018. Duaklir is a registered trademark in certain European countries. The US trademark is to be confirmed.

Bevespi

Product Sales of \$16m; launched in early 2017. Q4 2017 sales of \$8m.

Bevespi was launched commercially in the US during early 2017. Prescriptions in the period tracked in line with other LAMA/LABA launches. The overall class in the US, however, continued to grow more slowly than anticipated.

Bevespi was the first medicine launched using the Company's Aerosphere Delivery Technology delivered in a pressurised metered-dose inhaler.

OTHER

Product Sales of \$4,156m; a decline of 18% (17% at CER). Other Product Sales represented 21% of total Product Sales, down from 24% in FY 2016.

Nexium

Product Sales of \$1,952m; a decline of 4% (3% at CER).

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Emerging Markets sales declined by 1% (up 2% at CER) to \$684m. Sales in the US declined by 10% to \$499m in the year and by 58% in the quarter to \$57m, reflecting a true-up adjustment. Sales in Europe declined by 1% (3% at CER) in the year to \$248m. In Japan, where Daiichi Sankyo is a partner, sales increased by 1% (4% at CER) to \$439m.

Synagis

Product Sales of \$687m; an increase of 1%.

US sales decreased by 2% to \$317m, constrained by the guidelines from the American Academy of Pediatrics Committee on Infectious Diseases, which restricted the number of patients eligible for preventative therapy with Synagis. Product Sales to AbbVie Inc., which is responsible for the commercialisation of Synagis in over 80 countries outside the US, increased by 5% to \$370m.

Seroquel XR

Product Sales of \$332m; a decline of 55%.

Sales of Seroquel XR in the US, where several competitors launched generic Seroquel XR medicines from November 2016, declined by 66% to \$175m. Sales of Seroquel XR in Europe declined by 42% to \$78m, also reflecting the impact of generic-medicine competition.

FluMist/Fluenz

Product Sales of \$78m; a decline of 25% (28% at CER).

No US sales of FluMist were recorded in the quarter due to the continued absence of a recommendation for use by the US Advisory Committee on Immunization Practices (ACIP) during the 2017-2018 influenza season. FluMist continues to be recommended for use outside the US. Sales in Europe increased by 17% (12% at CER) to \$76m, driven primarily by higher usage rates in the UK, which reflected the favourable impact of the UK National Immunisation Programme.

Regional Product Sales

	FY 2017		% change		Q4 2017		% change	
	\$m	% of total ¹	Actual	CER	\$m	% of total	Actual	CER
Emerging Markets ²	6,149	31	6	8	1,630	30	10	9
China	2,955	15	12	15	813	15	33	30
Ex. China	3,194	16	1	2	817	15	(7)	(6)
US	6,169	31	(16)	(16)	1,770	32	9	9
Europe	4,753	24	(6)	(7)	1,293	24	(3)	(9)
Established ROW	3,081	15	-	1	794	14	(4)	-
Japan	2,208	11	1	4	563	10	(5)	2
Canada	484	2	(3)	(5)	131	2	4	(2)
Other Established ROW	389	2	(6)	(9)	100	2	(7)	(8)
Total	20,152	100	(5)	(5)	5,487	100	4	3

¹Due to rounding, the sum of individual medicine percentages may not agree to totals.

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

Emerging Markets

Product Sales of \$6,149m; an increase of 6% (8% at CER).

China sales grew by 12% (15% at CER) to \$2,955m, representing 48% of total Emerging Markets sales. Onglyza and Iressa were included on the NRDL in China in the year, as were Brilinta, Faslodex and Seroquel XR; the benefits of this inclusion are anticipated to favourably impact Product Sales after FY 2017. Crestor also had its 2nd-line usage restriction removed and Zoladex was reclassified from the hormone and endocrine classification to oncology, which is expected to continue to support growth. In the quarter, China sales grew strongly by 33% (30% at CER), reflecting strong performances from newly-launched medicines. Tagrisso was launched in China in April 2017.

Emerging Markets sales excluding China, however, declined by 7% (6% at CER) in Q4 2017, primarily driven by challenging conditions in Russia and Latin America, as well as the adverse impact of medicines externalised or disposed of in FY 2017. Sales in Latin America (ex-Brazil) declined by 12% (10% at CER) to \$453m. Brazil sales increased by 4% (but declined by 5% at CER) to \$361m. Russia sales declined by 1% (14% at CER) to \$231m. Sales of Symbicort grew by 9% (10% at CER) to \$439m, reflecting higher prescription demand, with notable performances in Latin America and China.

US

Product Sales of \$6,169m; a decline of 16%. Q4 2017 sales in the US grew by 9% to \$1,770m, partly reflecting favourable true-up adjustments relating to the first nine months of 2017.

The decline in sales in the year reflected generic-medicine launches that impacted sales of Crestor and Seroquel XR. Unfavourable managed-care pricing and continued competitive intensity impacted sales of Symbicort, which declined by 12% to \$1,099m.

The New Oncology Growth Platform in the US grew by 50% to \$607m, primarily driven by encouraging Tagrisso sales growth of 59% to \$405m in the year (FY 2016: \$254m). Brilinta sales grew by 46% in the US to \$509m. The New CVMD Growth Platform increased sales by 5% in the US to \$1,942m, reflecting strong performances from Farxiga and Brilinta.

Europe

Product Sales of \$4,753m; a decline of 6% (7% at CER).

The New Oncology Growth Platform in Europe grew by 102% (99% at CER) to \$317m, partly driven by Tagrisso sales of \$187m. Lynparza sales of \$130m represented growth of 60% (58% at CER). Forxiga sales growth of 29% (28% at CER) to \$242m was accompanied by Brilique growth of 14% (13% at CER) to \$295m. These performances were more than offset by declines in other areas, however, including a 10% decline in Symbicort sales to \$819m. Symbicort maintained its position, however, as the number one ICS/LABA medicine, despite competition from branded and analogue medicines. Crestor sales declined by 23% to \$666m, reflecting the entry of generic medicines in certain markets in the year.

Established ROW

Product Sales of \$3,081m; stable (up 1% at CER).

Japan sales increased by 1% (4% at CER) to \$2,208m. EGFR T790M-mutation testing rates in Japan continued to exceed 90% through the year, with full-year Tagrisso sales of \$219m (FY 2016: \$82m) reflecting a high penetration rate in the currently-approved 2nd-line setting. Faslodex sales in Japan were favourably impacted by a new label in the year; Faslodex sales in Japan increased by 14% (17% at CER) to \$72m.

The first generic competitor to Crestor was launched in Japan in Q3 2017 and further generic competition entered the market in the final quarter. Full-year Crestor sales in Japan declined by 6% (4% at CER) to \$489m; in the quarter, they declined by 26% (21% at CER) to \$95m. Nexium sales in Japan increased by 1% (4% at CER) in the year to \$439m and sales of Forxiga increased by 89% (93% at CER) in the year to \$53m.

Financial Performance

	Reported			
	FY 2017	FY 2016	Actual	CER
	\$m	\$m	% change	
Total Revenue	22,465	23,002	(2)	(2)
Product Sales	20,152	21,319	(5)	(5)
Externalisation Revenue	2,313	1,683	37	38
Cost of Sales	(4,318)	(4,126)	5	7
\				
Gross Profit	18,147	18,876	(4)	(4)
Gross Margin*	79.6%	80.8%	-1	-1
Distribution Expense	(310)	(326)	(5)	(3)
% Total Revenue	1.4%	1.4%	-	-
R&D Expense	(5,757)	(5,890)	(2)	(1)
% Total Revenue	25.6%	25.6%	-	-
SG&A Expense	(10,233)	(9,413)	9	10
% Total Revenue	45.5%	40.9%	-5	-5
Other Operating Income and Expense	1,830	1,655	11	11
% Total Revenue	8.1%	7.2%	+1	+1
Operating Profit	3,677	4,902	(25)	(28)
% Total Revenue	16.4%	21.3%	-5	-6
Net Finance Expense	(1,395)	(1,317)	6	(4)
Joint Ventures and Associates	(55)	(33)	66	66
Profit Before Tax	2,227	3,552	(37)	(38)
Taxation	641	(146)		
Tax Rate	(29)%	4%		
Profit After Tax	2,868	3,406	(16)	(16)
Earnings Per Share	\$2.37	\$2.77	(14)	(15)

*Gross Margin, as a percentage of Product Sales, reflects Gross Profit derived from Product Sales, divided by Product Sales.

FY 2017 Cost of Sales included \$198m of costs relating to externalisation activities, which is excluded from the calculation of Gross Margin (FY 2016: \$32m). Movements in Gross Margin are expressed in percentage points.

	Reported			
	Q4 2017	Q4 2016	Actual	CER
	\$m	\$m	% change	
Total Revenue	5,777	5,585	3	2
Product Sales	5,487	5,260	4	3
Externalisation Revenue	290	325	(11)	(12)
Cost of Sales	(1,225)	(1,160)	6	2

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Gross Profit	4,552	4,425	3	2
Gross Margin*	77.6%	77.9%	-	-
Distribution Expense	(85)	(83)	3	-
% Total Revenue	1.5%	1.5%	-	-
R&D Expense	(1,551)	(1,543)	-	(2)
% Total Revenue	26.8%	27.6%	+1	+1
SG&A Expense	(3,078)	(1,386)	n/m	n/m
% Total Revenue	53.3%	24.8%	-28	-28
Other Operating Income and Expense	848	1,120	(24)	(25)
% Total Revenue	14.7%	20.1%	-5	-5
Operating Profit	686	2,533	(73)	(71)
% Total Revenue	11.9%	45.4%	-33	-32
Net Finance Expense	(267)	(339)	(21)	(27)
Joint Ventures and Associates	(12)	(11)	19	19
Profit Before Tax	407	2,183	(81)	(78)
Taxation	854	(366)		
Tax Rate	(210)%	17%		
Profit After Tax	1,261	1,817	(31)	(25)
Earnings Per Share	\$1.03	\$1.46	(29)	(24)

*Gross Margin, as a percentage of Product Sales, reflects Gross Profit derived from Product Sales, divided by Product Sales.

Q4 2017 Cost of Sales included \$2m of income relating to externalisation activities (Q4 2016: \$nil), which is excluded from the calculation of Gross Margin. Movements in Gross Margin are expressed in percentage points.

Reconciliation of Reported Profit Before Tax to EBITDA

	FY 2017		Q4 2017	
	\$m	% change ActualCER	\$m	% change ActualCER
Reported Profit Before Tax	2,227	(37)	407	(81)
Net Finance Expense	1,395	6	267	(21)
Joint Ventures and Associates	55	66	12	19
Depreciation, Amortisation and Impairment	3,036	29	1,107	88
EBITDA*	6,713	(8)	1,793	(43)

*EBITDA is a non-GAAP financial measure. See the Operating and Financial Review for a definition of EBITDA.

Reconciliation of Reported to Core Financial Measures

FY 2017	Reported		Intangible Asset Restructuring Amortisation & Impairments	Diabetes Alliance	Other1	Core2	Core ActualCER	
	\$m	\$m	\$m	\$m	\$m	\$m	% change	
Gross Profit	18,147	181	149	-	-	18,477	(3)	(3)
Gross Margin3	79.6%	-	-	-	-	81.2%	-1	-1
Distribution Expense	(310)	-	-	-	-	(310)	(5)	(3)
R&D Expense	(5,757)	201	144	-	-	(5,412)	(4)	(3)
SG&A Expense	(10,233)	347	1,469	641	(77)	(7,853)	(4)	(3)

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Other Operating Income and Expense	1,830	78	45	-	-	1,953	14	14
Operating Profit	3,677	807	1,807	641	(77)	6,855	2	-
% Total Revenue	16.4%	-	-	-	-	30.5%	+1	+1
Net Finance Expense	(1,395)	-	-	313	432	(650)	(2)	(4)
Taxation	641	(169)	(453)	(198)	(681)	(860)	31	23
Earnings Per Share	\$2.37	\$0.50	\$1.07	\$0.60	\$(0.26)	\$4.28	(1)	(2)

1Other adjustments include fair value adjustments relating to contingent consideration on business combinations (see Note 4), discount unwind on acquisition-related liabilities (see Note 4), provision charges related to certain legal matters (see Note 5), foreign-exchange gains and losses relating to the classification of certain non-structural intra-group loans and a one-off adjustment of \$617m reflecting adjustments to deferred taxes in line with the recently reduced US federal income tax rate.

2Each of the measures in the Core column in the above table are non-GAAP financial measures. See the Operating and Financial Review for related definitions.

3Gross Margin, as a percentage of Product Sales, reflects gross profit derived from Product Sales, divided by Product Sales. FY 2017 Cost of Sales included \$198m of costs relating to externalisation activities (FY 2016: \$32m), which is excluded from the calculation of Gross Margin. Movements in Gross Margin are expressed in percentage points.

Q4 2017	Reported		Intangible Asset	Diabetes Alliance	Other1	Core		Actual CER
	Restructuring	Amortisation & Impairments	Diabetes Alliance			Core2	% change	
	\$m	\$m	\$m	\$m	\$m	\$m		
Gross Profit	4,552	53	46	-	-	4,651	3	3
Gross Margin3	77.6%	-	-	-	-	79.4%	-	+1
Distribution Expense	(85)	-	-	-	-	(85)	3	-
R&D Expense	(1,551)	24	71	-	-	(1,456)	(2)	(4)
SG&A Expense	(3,078)	82	696	406	(281)	(2,175)	6	5
Other Operating Income and Expense	848	3	1	-	-	852	(25)	(26)
Operating Profit	686	162	814	406	(281)	1,787	(12)	(11)
% Total Revenue	11.9%	-	-	-	-	30.9%	-5	-5
Net Finance Expense	(267)	-	-	79	64	(124)	(28)	(31)
Taxation	854	(34)	(213)	(54)	(595)	(42)	(87)	(100)
Earnings Per Share	\$1.03	\$0.10	\$0.48	\$0.34	\$(0.65)	\$1.30	7	13

1Other adjustments include fair value adjustments relating to contingent consideration on business combinations (see Note 4), discount unwind on acquisition-related liabilities (see Note 4), provision charges related to certain legal matters (see Note 5), foreign-exchange gains and losses relating to the classification of certain non-structural intra-group loans and a one-off adjustment of \$617m reflecting adjustments to deferred taxes in line with the recently reduced US federal income tax rate.

2Each of the measures in the Core column in the above table are non-GAAP financial measures. See the Operating and Financial Review for related definitions.

3Gross Margin, as a percentage of Product Sales, reflects gross profit derived from Product Sales, divided by Product Sales. Q4 2017 Cost of Sales included \$2m of income relating to externalisation activities (Q4 2016: \$nil), which is excluded from the calculation of Gross Margin. Movements in Gross Margin are expressed in percentage points.

Profit and Loss Commentary for the Year

Gross Profit

Reported Gross Profit declined by 4% to \$18,147m; Core Gross Profit declined by 3% to \$18,477m, one percentage point more than the Total Revenue decline. Externalisation Revenue of \$2,313m included \$1,247m received as part of the Lynparza and selumetinib collaboration with MSD. This was outweighed by the adverse impact of product mix, the ramp-up of manufacturing capacity for new medicines and the inclusion of the profit-share on the aforementioned collaboration.

The calculation of Reported and Core Gross Margin excludes the impact of Externalisation Revenue, thereby reflecting the underlying performance of Product Sales. The Reported Gross Margin declined by one percentage point to 79.6%. The Core Gross Margin declined by one percentage point to 81.2%. The declines were primarily driven by the effect of losses of exclusivity on higher-margin Crestor and Seroquel XR, as well as the factors mentioned above. In the quarter, the Reported Gross Margin was stable at 77.6%; the Core Gross Margin was stable (increased by one percentage point at CER) to 79.4%.

Operating Expenses: R&D

Reported R&D costs declined by 2% (1% at CER) to \$5,757m, with the Company continuing to focus on resource prioritisation and cost discipline. Core R&D costs declined by 4% (3% at CER) to \$5,412m. The movement vs. the prior year was in line with commitments made in February 2017.

Operating Expenses: SG&A

Reported SG&A costs increased by 9% (10% at CER) to \$10,233m in the year and by 122% (119% at CER) to \$3,078m in the quarter. This reflected the impact of fair-value adjustments to contingent consideration on business combinations in the comparative period and, to a lesser extent, impairment charges recorded in the quarter.

Core SG&A costs declined by 4% (3% at CER) to \$7,853m. This was in line with commitments made in February 2017 and despite strategic investment in new launches.

Core SG&A costs in the quarter increased by 6% (5% at CER) to \$2,175m. This reflected the aforementioned increased investment, including in medical-affairs capability and capacity in order to support the launches and early-stage commercialisation phases of specialty-care medicines such as Tagrisso, Imfinzi, Lynparza and Fasenra. SG&A general infrastructure costs declined in the quarter as the Company maintained its focus on cost discipline. The Company booked a one-time gain of \$92m in the quarter following adjustments to its retirement benefit plans in the US.

In the year, the Company continued to consolidate its operations that support the business. It is committed to driving simplification and standardisation through targeted centralisation of back and middle office activities that are currently performed in various enabling units, including Finance, Compliance, HR, Procurement and IT. As a result, underlying operational-infrastructure costs were consistently reduced, in line with prior trends. The recently-launched Global Business Services organisation provides integration of governance, locations and business practices to shared services and outsourcing activities across AstraZeneca.

Other Operating Income and Expense

Where AstraZeneca does not retain a significant ongoing interest in medicines or potential new medicines, income from disposal transactions is reported within Other Operating Income and Expense in the Company's financial statements. Reported Other Operating Income and Expense increased by 11% in the year to \$1,830m and included:

- \$555m resulting from the sale of remaining rights to the anaesthetics portfolio to Aspen

- \$301m resulting from the sale of rights to Seloken in Europe to Recordati S.p.A (Recordati)

- \$175m of milestone receipts in relation to the disposal of Zavicefta to Pfizer Inc.

- \$165m resulting from the sale of the global rights to Zomig outside Japan to the Grünenthal Group (Grünenthal)

\$161m of gains recognised on the sale of short-term investments

\$73m from the sale of Prilosec royalty streams

Other gains on disposal of intangible assets

Core Other Operating Income and Expense increased by 14% to \$1,953m, with the difference to Reported Other Operating Income and Expense primarily driven by a restructuring charge taken against land and buildings.

Operating Profit

Reported Operating Profit declined by 25% (28% at CER) in the year to \$3,677m. In the quarter, Reported Operating Profit declined by 73% (71% at CER) to \$686m, driven by higher Other Operating Income and Expense in Q4 2016. The Reported Operating Profit margin declined by five percentage points (six percentage points at CER) to 16% of Total Revenue. Core Operating Profit increased by 2% (stable at CER) to \$6,855m. The Core Operating Profit margin increased by one percentage point to 31% of Total Revenue.

Brexit Planning

Following the UK referendum outcome of a decision for the UK to leave the European Union (EU) in June 2016, the progress of current negotiations between the UK Government and the EU will likely determine the future terms of the UK's relationship with the EU, as well as to what extent the UK will be able to continue to benefit from the EU's single market and its regulatory frameworks.

In response to this, the Company has taken the decision to implement certain actions to mitigate the potential risk of disruption to the supply of medicines including but not limited to duplication of release testing and procedures for products based in the EU27 and the UK, transfer of regulatory licenses, customs and duties set up for introduction or amendment of existing tariffs or processes and associated IT systems upgrades. The costs associated with this and certain other actions directly related to Brexit will be charged as restructuring with the majority of such costs expected to be cash costs. However, until the Brexit negotiation process is completed, it is difficult to anticipate the overall potential impact on AstraZeneca's operations and hence the final expected costs to be incurred.

Net Finance Expense

Reported Net Finance Expense increased by 6% in the year to \$1,395m, primarily reflecting a foreign-exchange impact relating to the classification of certain non-structural intra-group loans. Reported Net Finance Expense declined by 4% at CER, reflecting reduced levels of discount unwind on acquisition-related liabilities resulting from the diabetes alliance with Bristol-Myers Squibb Company (BMS). Excluding the discount unwind on acquisition-related liabilities and the adverse foreign-exchange impact, the Core Net Finance Expense declined by 2% (4% at CER) to \$650m.

Profit Before Tax

Reported Profit Before Tax declined by 37% (38% at CER) to \$2,227m, reflecting the lower Reported Gross Margin and an increase in Reported SG&A costs. EBITDA declined by 8% (10% at CER) to \$6,713m.

Taxation

The Reported Tax Rate of (29)% in the year benefitted from a favourable net adjustment of \$617m to deferred taxes, reflecting the recently reduced US federal income tax rate and non-taxable remeasurements of acquisition-related liabilities. Additionally, there was a \$321m benefit in the final quarter to the Reported and Core Tax Rates, reflecting:

- the expiry of statute of limitations
 - favourable progress of discussions with tax authorities
- the recognition of previously unrecognised tax losses
the favourable impact of UK Patent box profits

The Core Tax Rate for the year was 14%. Excluding these benefits, both the Reported and Core Tax Rates would have been 22%. The net cash tax paid for the year was \$454m, representing 20% of Reported Profit Before Tax.

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

Earnings Per Share (EPS)

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Reported EPS of \$2.37 represented a decline of 14% (15% at CER) in the year. The performance was driven by a decline in Total Revenue and increased SG&A costs, partly offset by the aforementioned net tax benefit, continued progress on R&D cost control and an increase in Other Operating Income and Expense. Core EPS declined by 1% (2% at CER) to \$4.28.

Dividend Per Share and Dividend Commitment

The Board has declared a second interim dividend of \$1.90 per share (133.6 pence, 14.97 SEK) bringing the dividend per share for the full year to \$2.80 (202.5 pence, 22.37 SEK). The Board reaffirms its commitment to the Company's progressive dividend policy.

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

Cash Flow and Balance Sheet

Cash Flow

	FY 2017	FY 2016	Difference
	\$m	\$m	\$m
Reported operating profit	3,677	4,902	(1,225)
Depreciation, amortisation and impairment	3,036	2,357	679
(Increase)/decrease in working capital and short-term provisions	(50)	926	(976)
(Gains)/losses on disposal of intangible assets	(1,518)	(1,301)	(217)
Fair value movement on contingent consideration arising from business combinations	109	(1,158)	1,267
Non-cash and other movements	(524)	(492)	(32)
Interest paid	(698)	(677)	(21)
Tax paid	(454)	(412)	(42)
Net cash inflow from operating activities	3,578	4,145	(567)

The Company generated a net cash inflow from operating activities of \$3,578m in the year, compared with \$4,145m in FY 2016. In Q3 2017, the Company received an upfront cash receipt of \$1.6bn from the global strategic oncology collaboration with MSD, \$997m of which was recorded in Operating Profit, with the remainder deferred to the balance sheet.

Net cash outflows from investing activities were \$2,328m in the year compared with \$3,969m in FY 2016. In the final quarter, \$1.5bn was paid to shareholders of Acerta Pharma B.V. (Acerta Pharma), a contractual obligation triggered by the first regulatory approval for Calquence. The prior-period outflow included an upfront payment as part of the majority investment in Acerta Pharma. The cash payment of contingent consideration in respect of the BMS share of the global Diabetes alliance amounted to \$284m in the year, which included a \$100m milestone payment in respect of Qtern and royalty payments.

Net cash outflows from financing activities were \$2,936m in the year compared to \$1,324m in FY 2016, as the Company repaid a loan falling due.

Capital Expenditure

Capital expenditure amounted to \$1,326m in the year, which included investment in the new global headquarters in Cambridge, UK, as well as strategic manufacturing capacity in the UK, the US, Sweden and China.

Debt and Capital Structure

	At 31 Dec 2017	At 31 Dec 2016
	\$m	\$m
Cash and cash equivalents	3,324	5,018
Other investments	1,300	898

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Net derivatives	504	235
Cash, short-term investments and derivatives	5,128	6,151
Overdrafts and short-term borrowings	(845)	(451)
Finance leases	(5)	(93)
Current instalments of loans	(1,397)	(1,769)
Loans due after one year	(15,560)	(14,495)
Interest-bearing loans and borrowings (gross debt)	(17,807)	(16,808)
Net Debt	(12,679)	(10,657)

Capital Allocation

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

Foreign-Exchange Rates

Sensitivity

The Company provides the following currency sensitivity information:

Currency	Primary Relevance	Average Exchange Rates vs. USD			Impact Of 5% Strengthening in Exchange Rate vs. USD (\$m) ¹	
		FY 2017	YTD 2018	2 % change	Product Sales	Core Operating Profit
EUR	Product Sales	0.89	0.82	+8	+160	+93
JPY	Product Sales	112.18	111.07	+1	+117	+82
CNY	Product Sales	6.75	6.43	+5	+146	+75
SEK	Costs	8.54	8.06	+6	+5	-44
GBP	Costs	0.78	0.73	+7	+23	-46
Other ³					+193	+97

¹Based on 2017 results at 2017 actual exchange rates.

²Based on average daily spot rates between 1 January and 31 January 2018.

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

Foreign-Exchange Hedging

The Group's transactional currency exposures on working-capital balances, which typically extend for up to three months, are hedged where practicable using forward foreign-exchange contracts against the individual Group Companies' reporting currency. In addition, the Group's external dividend payments, paid principally in pounds sterling and Swedish krona, are fully hedged from announcement to payment date. Foreign-exchange gains and losses on forward contracts for transactional hedging are taken to profit.

Corporate and Business Development Update

On 20 December 2017, it was announced by ANI Pharmaceuticals, Inc. that it had acquired the rights to market Atacand, Arimidex and Casodex from AstraZeneca for \$47m in cash upfront, recorded as Other Operating Income and Expense in the Company's financial statements in the quarter. AstraZeneca will receive future royalties and sales-based milestones.

Research and Development Update

Edgar Filing: ASTRAZENECA PLC - Form 6-K

comprehensive table comprising AstraZeneca's pipeline of medicines in human trials can be found later in this document. Highlights of developments in the Company's late-stage pipeline since the prior results announcement are shown below:

Regulatory Approvals	7	<ul style="list-style-type: none"> - Faslodex - breast cancer (combinations) (US, EU) - Lynparza - ovarian cancer (JP) - Lynparza - breast cancer (US) - Fasentra - severe, uncontrolled asthma (US, EU, JP)
Regulatory Submissions and/or Acceptances	4	<ul style="list-style-type: none"> - Tagrisso - lung cancer (1st line) (US - Priority Review, EU, JP) - ZS-9 - hyperkalaemia (US) - Lynparza - ovarian cancer: Priority review (CN)
Major Phase III Data Readouts and Developments	4	<ul style="list-style-type: none"> - roxadustat - anaemia: Priority review (CN) - PT010 - COPD (KRONOS trial): Most primary endpoints met¹ - tezepelumab - severe, uncontrolled asthma: First patient commenced dosing <p>Oncology</p> <ul style="list-style-type: none"> - Lynparza - multiple cancers² - Tagrisso - lung cancer² - Imfinzi - multiple cancers² - Calquence - blood cancers - Imfinzi + treme - multiple cancers - moxetumomab pasudotox - leukaemia - selumetinib - thyroid cancer - savolitinib - kidney cancer
New Molecular Entities(NMEs) in Phase III Trials or Under Regulatory Review and Major Lifecycle Medicines	15	<p>CVMD</p> <ul style="list-style-type: none"> - ZS-9 (sodium zirconium cyclosilicate) - hyperkalaemia² - roxadustat - anaemia² <p>Respiratory</p> <ul style="list-style-type: none"> - Fasentra - COPD - PT010 - COPD, asthma - tezepelumab - severe, uncontrolled asthma <p>Other</p> <ul style="list-style-type: none"> - anifrolumab - lupus - lanabecestat - Alzheimer's disease
Projects in Clinical Pipeline	132	

¹Eight of the nine primary endpoints in the KRONOS trial were met, including two non-inferiority endpoints to qualify PT009, one of the comparators

²Under Regulatory Review. The table shown above as at today.

ONCOLOGY

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

During the period, the Company presented Lynparza data at the San Antonio Breast Cancer annual symposium; highlights included data from the MEDIOLA combination trial (Lynparza + Imfinzi) and the Asian-cohort data from the OlympiAD Lynparza metastatic breast-cancer trial. The Company also presented data from the new and emerging haematology portfolio at the American Society of Hematology (ASH) annual meeting; highlights included Calquence data in several cancer types, including MCL and chronic lymphocytic leukaemia (CLL).

a) Faslodex (breast cancer)

On 13 November 2017, the Company announced that the European Medicines Agency (EMA) had approved a new indication for Faslodex in Europe in combination with a CDK4/6 inhibitor, palbociclib, for the treatment of hormone receptor-positive (HR+), human epidermal growth factor receptor 2 negative (HER2-), locally-advanced or metastatic breast cancer in patients who have received prior endocrine therapy.

On 14 November 2017, the Company announced that the US FDA had approved a new indication for Faslodex, expanding the indication to include use with abemaciclib, a CDK4/6 inhibitor, for the treatment of HR+, HER2- advanced or metastatic breast cancer in patients with disease progression after endocrine therapy.

b) Lynparza (multiple cancers)

On 12 January 2018, the Company announced that the US FDA had approved Lynparza for use in patients with deleterious or suspected deleterious germline BRCA (gBRCA)-mutated HER2-negative metastatic breast cancer who have been previously treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. The approval was based on data from the randomised, open-label, Phase III OlympiAD trial, which investigated Lynparza vs. physician's choice of chemotherapy (capecitabine, eribulin or vinorelbine). In the trial, Lynparza significantly prolonged progression-free survival (PFS) compared with chemotherapy and reduced the risk of disease progression or death by 42% (Hazard Ratio (HR) 0.58; median PFS of 7.0 vs 4.2 months).

On 19 January 2018, AstraZeneca and MSD announced that the Japanese Ministry of Health, Labour and Welfare had approved Lynparza tablets (300mg twice daily) for use in patients as a maintenance therapy for platinum-sensitive relapsed ovarian cancer, regardless of their BRCA mutation status, who are in response to their last platinum-based chemotherapy. Lynparza was the first PARP inhibitor to be approved in Japan. During the period, the Company also received priority review status for Lynparza in platinum-sensitive relapsed ovarian cancer from the China FDA.

During the period, the Company presented an analysis of the comparison in endpoints from the Phase III trials of Lynparza and niraparib in patients with platinum-sensitive, relapsed germline BRCA (gBRCA)-mutated ovarian cancer at the International Society for Pharmacoeconomics and Outcomes Research European Congress. Lynparza and niraparib are PARP inhibitors.

A key summary of the efficacy and tolerability measures are detailed in the table below, which includes an investigator-assessed 14.8 months of median PFS (mPFS) for niraparib in gBRCA patients:

Efficacy - platinum-sensitive, relapsed gBRCA-mutated ovarian cancer

PARP inhibitor	Trial	HR and mPFS (Independent Review Committee)	HR and mPFS (Investigator Assessed)	HR (median time to first subsequent therapy or death)
Lynparza 300mg tablets, bid1	SOLO-2 (Lynparza vs. placebo)	0.25 30.2m vs. 5.5m	0.30 19.1m vs. 5.5m	0.28 27.9m vs. 7.1m
	NOVA (niraparib vs. placebo)	0.27 21.0m vs. 5.5m	0.27 14.8m vs. 5.5m	0.31 21.0m vs. 8.4m

1bid = twice daily.

2qd = once daily.

Hettle, et al., ISPOR 20th Annual European Congress, November 2017

Safety - platinum-sensitive, relapsed gBRCA-mutated ovarian cancer

PARP inhibitor	Trial	Grade 3-4 adverse event % (PARP inhibitor vs. placebo)	Treatment interruption % (PARP inhibitor vs. placebo)	Dose reduction % (PARP inhibitor vs. placebo)	Drug discontinuation % (PARP inhibitor vs. placebo)
Lynparza 300mg tablets, bid	SOLO-2 (Lynparza vs. placebo)	36.9 vs. 18.2	45.1 vs. 18.2	25.1 vs. 3.0	10.8 vs. 2.0
niraparib 300mg capsules, qd	NOVA (niraparib vs. placebo)	74.1 vs. 22.9	68.9 vs. 5.0	66.5 vs. 15.5	14.7 vs. 2.2

Hettle, et al., ISPOR 20th Annual European Congress, November 2017

The Company also presented an update on an Asian cohort from the Phase III OlympiAD trial of Lynparza in HER2-negative, gBRCA-mutated metastatic breast-cancer patients. Data from the 87 Asian patients demonstrated that PFS was prolonged in patients receiving Lynparza compared with those treated with physician's choice treatment (median value of 5.7 months vs. 4.2 months, HR 0.53). The findings demonstrated that Lynparza is generally well tolerated in Asian patients and provides a clinically-meaningful PFS benefit compared with physician's choice treatment. Efficacy and safety profiles were generally consistent with those seen in the global population.

Updated data from the gBRCAm HER2-negative metastatic breast-cancer cohort of the MEDIOLA Phase II basket trial of Lynparza and Imfinzi were also presented: 20 patients (80%) had disease control (comprising complete response, partial response and stable disease) at 12 weeks (primary efficacy endpoint) and 12 patients (48%) at 28 weeks (secondary endpoint). The combination was well tolerated and the 12-week disease control rate (80%) exceeded the pre-specified target. The data supported the hypothesis that the addition of Imfinzi may enhance the efficacy of Lynparza monotherapy. Ongoing key Lynparza combination trials include:

Name	Phase	Line of Treatment	Population	Design	Timelines	Status
PAOLA1	III	1st line	Ovarian cancer gBRCA-mutated ovarian cancer 2nd line	Lynparza maintenance + bevacizumab vs. bevacizumab maintenance	FPCD2 Q2 2015 First data anticipated 2022	Recruitment ongoing Recruitment ongoing
MEDIOLA	I/II	Advanced	gBRCA-mutated HER2-negative breast cancer (1st to 3rd line) Small cell lung cancer (SCLC) (2nd line) Gastric cancer (2nd line)	Lynparza + Imfinzi	FPCD Q2 2016	Initial data from lung and breast cancer cohorts presented in 2017
VIOLETTEII	Advanced	Advanced	Triple-negative breast cancer: -HRRm3 (BRCA)	Lynparza + ATR (AZD6738)	FPCD Q4 2017	Recruitment ongoing

Edgar Filing: ASTRAZENECA PLC - Form 6-K

			-HRRm (Non-BRCA) -Non-HRRm	Lynparza + Wee1 (AZD1775)		
				Lynparza	FPCD Q3 2014	
Study 8	II	Advanced	Metastatic castration resistant prostate cancer	Lynparza + abiraterone vs. abiraterone	LPCD4 Q3 2015	Recruitment complete
						11Conducted by the ARCAGY/Groupe d'Investigateurs National des Etudes des Cancers Ovariens et du sein
						2First Patient Commenced Dosing 3Homologous Recombination Repair mutated 4Last Patient Commenced Dosing

c) Tagrisso (lung cancer)

On 18 December 2017, the Company announced that the US FDA had accepted a supplemental New Drug Application (sNDA) for the use of Tagrisso in the 1st-line treatment of patients with metastatic NSCLC whose tumours have EGFR mutations (exon 19 deletions or exon 21 (L858R) substitution mutations). The application was based on data from the Phase III FLAURA trial, which showed that Tagrisso significantly improves PFS compared to current 1st-line EGFR tyrosine kinase inhibitors, erlotinib or gefitinib, in previously-untreated patients with locally-advanced or metastatic EGFR-mutated NSCLC. The US FDA granted Tagrisso Priority Review status in 2017 and previously granted Breakthrough Therapy Designation in the 1st-line treatment of patients with metastatic EGFR-mutated NSCLC.

On 28 November 2017, the Company announced that the EMA had accepted a variation to the Marketing Authorisation Application for Tagrisso. The application was in line with the aforementioned US application. On 27 November 2017, the Company announced the submission of a sNDA to Japan's Pharmaceuticals and Medical Devices Agency for the use of Tagrisso for the 1st-line treatment of patients with inoperable or recurrent EGFR-mutated NSCLC.

d) Imfinzi (lung and other cancers)

The Company continues to advance multiple monotherapy trials of Imfinzi and combination trials of Imfinzi with tremelimumab and other potential new medicines:

Lung Cancer

In November 2017, the Company presented further data at the European Society For Medical Oncology meeting in Singapore in respect of the PACIFIC Phase III trial, including clinical activity, patient-reported outcomes and safety data regarding sequential treatment with Imfinzi in patients with locally-advanced, unresectable NSCLC, who had not progressed following standard platinum-based chemotherapy concurrent with radiation therapy. The analysis demonstrated a PFS improvement across all pre-specified subgroups and the incidence of new lesions, including new brain metastases, was lower with Imfinzi vs. placebo.

During the period, the Brazil Health Regulatory Agency granted Imfinzi an expedited review, based on the PACIFIC trial data, as a sequential treatment in patients with locally-advanced, unresectable NSCLC, who had not progressed following standard platinum-based chemotherapy concurrent with radiation therapy. The Republic of Korea Ministry of Food and Drug Safety also accepted the marketing authorisation application of Imfinzi, based on the aforementioned PACIFIC trial data.

Ongoing key lung cancer late-stage trials include:

Name	Phase	Line of Treatment	Population	Design	Timelines	Status
------	-------	-------------------	------------	--------	-----------	--------

Monotherapy

ADJUVANT1	III	N/A	Stage Ib-IIIa NSCLC	Imfinzi vs placebo	FPCD Q1 2015	Recruitment ongoing
					First data anticipated 2020	
					FPCD Q2 2014	Recruitment completed
PACIFIC	III	N/A	Locally-advanced, unresectable NSCLC	Imfinzi vs placebo	LPCD Q2 2016	PFS primary endpoint met
					OS2 data anticipated 2019	
					FPCD Q1 2017	Recruitment ongoing
PEARL	III	1st line	NSCLC (Asia)	Imfinzi vs SoC3 chemotherapy	First data anticipated 2020	
Combination therapy						
PACIFIC-3	III	N/A	Locally-advanced, unresectable NSCLC	Imfinzi + epacadostat vs Imfinzi	First data anticipated 2021	Recruitment initiating
					FPCD Q3 2015	Recruitment completed
MYSTIC	III	1st line	NSCLC	Imfinzi, Imfinzi + treme vs SoC chemotherapy	LPCD Q3 2016	PFS primary endpoint not met
					Final OS data anticipated H1 2018	
					FPCD Q4 2015	
NEPTUNE	III	1st line	NSCLC	Imfinzi + treme vs SoC chemotherapy	LPCD Q2 2017	Recruitment completed
					First data anticipated H2 2018	
					FPCD Q2 2017	Recruitment ongoing
POSEIDON	III	1st line	NSCLC	Imfinzi + SoC, Imfinzi + treme + SoC vs SoC chemotherapy	First data anticipated 2019	
					FPCD Q2 2015	Recruitment completed
ARCTIC	III	3rd line	PDL1- low/neg. NSCLC	Imfinzi, tremelimumab, Imfinzi + treme vs SoC chemotherapy	LPCD Q3 2016	

Edgar Filing: ASTRAZENECA PLC - Form 6-K

hepatocellular carcinoma (HCC, liver cancer)	Imfinzi, Imfinzi + treme (two dosing regimens) vs sorafenib	Q4 2017 First data anticipated 2020	Recruitment ongoing
---	---	--	------------------------

During the period, it was confirmed that the FUSION programme, conducted by Celgene Corporation (Celgene), will not enrol further patients in the clinical trials in multiple myeloma (MM) (MM-001, MM-002, MM-003, and MM-005). This update followed an announcement in September 2017 that Celgene had been informed that the US FDA had placed a partial clinical hold on five trials and a full clinical hold on one trial in the programme. The trials were testing Imfinzi in combination with immunomodulatory agents such as lenalidomide, with or without chemotherapy, in blood cancers such as MM, CLL and lymphoma. Two ongoing Company trials of Imfinzi in myelodysplastic syndrome (MDS) and diffuse large B-cell lymphoma (DLBCL) will continue as planned. The MDS-001 trial, that has separate cohorts for newly-diagnosed acute myeloid leukaemia and MDS patients, has completed enrolment and will continue as planned. The DLBCL-001 trial will continue to enrol, with all patients receiving Imfinzi + R-CHOP, a chemotherapy treatment using rituximab.

e) Calquence (blood cancer)

Following the US FDA accelerated approval of Calquence on 31 October 2017, AstraZeneca presented data from MCL and CLL clinical trials at the aforementioned ASH meeting. Results were presented in MCL from the open-label, single-arm Phase II ACE-LY-004 clinical trial, which served as the basis for the approval. The data demonstrated an objective response rate of 81%, with a complete response rate of 40%.

Efficacy measure	Patients (percent response)
Objective response rate (Complete response + partial response)	81%
Complete response	40%
Partial response	41%
Stable disease	9%
Progressive disease	8%
Not evaluable	2%

The data shown in the table above are as per the 2014 Lugano classification response criteria for non-Hodgkin lymphoma; high concordance was observed between investigator-assessed and independent review committee-assessed overall response and complete response rates, respectively.

In CLL, data from the Phase Ib/II ACE-CL-003 clinical trial and updated results from the Phase I/II ACE-CL-001 clinical trial that are testing Calquence in combination and alone for the treatment of CLL in multiple treatment settings were also presented. In the ACE-CL-003 trial, the combination of Calquence and obinutuzumab demonstrated an objective response rate (the primary endpoint) of 95% for the 19 patients in the treatment-naïve cohort and 92% in the 26 patients with relapsed or refractory CLL. Additionally, the complete response rate was 16% for treatment-naïve patients and 8% for previously-treated patients. Longer-term safety follow-up of the Calquence monotherapy ACE-CL-001 trial was also presented where safety (primary endpoint) and efficacy (secondary endpoint) data of the full-trial cohort of 134 patients with relapsed or refractory CLL was shown, with a median time on trial and follow-up of 24.5 months.

CVMD

CV and metabolic diseases (CVMD) are key areas of focus for AstraZeneca as the Company sets the challenge to better understand how its portfolio of medicines might be used to help address multiple risk factors or co-morbidities across CVMD. Today, AstraZeneca is delivering life-changing results in the main CV-disease areas and their complications. AstraZeneca is investing in the science to demonstrate CV and mortality benefits by slowing the underlying progression of CV-related disease and protecting the organs of the CV system. Ultimately, AstraZeneca is looking to do more than just slow CV-related disease, by modifying or even halting the natural course of the disease itself and regenerate organs.

The net result is a strong, continued commitment to new CVMD treatment options that have the potential to deliver improved outcomes to hundreds of millions of patients across the globe.

a) Brilinta (CV disease)

In the period, the Company announced the initiation of a new Brilinta outcomes trial, THALES; the decision to initiate another stroke trial followed the encouraging trend data seen in the prior SOCRATES trial. The THALES trial will evaluate the safety and efficacy of 30-day treatment with Brilinta vs. placebo, both in addition to aspirin, for reducing stroke and death in patients who have already suffered an acute ischaemic stroke or high-risk transient ischaemic attack in the preceding 24 hours. During the period, the first patient was dosed in the THALES trial.

b) Farxiga (diabetes)

During the period, top-line results from the ongoing DEPICT clinical programme, exploring the use of Farxiga in type-1 diabetes, became available in-house. These results from the DEPICT-1 52-week and DEPICT-2 24-week trial data demonstrated significant and clinically-relevant reductions from baseline in HbA1c, weight reductions and lowered total daily insulin dosing, compared to placebo at both the 5mg and 10mg dose. The safety profile of Farxiga in the DEPICT-1 52 week and DEPICT-2 24 week trials was similar to the known safety profile of Farxiga in patients with type-2 diabetes, with the exception of a higher proportion of diabetic ketoacidosis (DKA) events in Farxiga-treated patients vs. placebo within these type-1 diabetes trials. Further analysis of the data is required, along with the 52 week results of the DEPICT-2 trial.

During the period, the Company also received top-line results for DERIVE, a trial designed to evaluate the glycaemic efficacy and renal safety of Farxiga in patients with type-2 diabetes and moderate renal impairment who have inadequate glycaemic control. The top-line results showed that, in patients with type-2 diabetes and chronic kidney disease (CKD) stage 3A, treatment with Farxiga for 24 weeks resulted in clinically-relevant and statistically-significant improvements in glycaemic control. Farxiga was well tolerated, with no imbalances in adverse events (AEs) or serious adverse events or no new safety signals in the overall safety summary. Specifically, there were no AEs of hypoglycaemia, DKA or fractures reported in the trial. As these were the initial data, additional sensitivity analyses and safety evaluations are being conducted.

c) Bydureon (type-2 diabetes)

In the period, the EMA approved the use of Bydureon with basal insulin based on the results of the DURATION-7 clinical trial. The decision followed a positive recommendation in October 2017 from the Committee for Medicinal Products for Human Use (CHMP). The DURATION-7 trial assessed the efficacy and safety of Bydureon vs. placebo when added to titrated basal insulin with or without metformin in patients with uncontrolled type-2 diabetes over 28 weeks.

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

During the period, the US FDA accepted the Class II regulatory resubmission for ZS-9 following the progress the Company has made in addressing the deficiencies identified during previous inspections of the dedicated manufacturing facility in Texas.

During the period, the CHMP reiterated its previous positive opinion and recommended the granting of a marketing authorisation for ZS-9 in the EU, for the treatment of hyperkalaemia. A positive opinion was provided in February 2017; the opinion was, however, suspended following concerns relating to the aforementioned manufacturing deficiencies. On the basis of recent inspection findings, the Committee reiterated its original opinion in January 2018.

e) Roxadustat (anaemia)

During the period, the Company and its partner FibroGen Inc. (Fibrogen) announced that roxadustat was granted priority review by the China FDA. The Company anticipates a regulatory decision in H2 2018 based on the data from two Fibrogen-led Phase III trials, conducted in China, that met their primary efficacy endpoints in January 2017. If approved, roxadustat will be a first-in-class medicine, with China being the first approval country, ahead of other major markets.

Major Ongoing Cardiovascular Outcomes Trials

Major ongoing outcomes trials for patients are highlighted in the following table:

Medicine	Trial	Mechanism	Population	Primary Endpoint	Timeline
Farxiga	DECLARE	SGLT2 inhibitor	c.17,000 ¹ patients with type-2 diabetes	Time to first occurrence of CV death, non-fatal myocardial infarction (MI) or non-fatal stroke	Data anticipated H2 2018 (final analysis)
Farxiga	DAPA-HF	SGLT2 inhibitor	c.4,500 patients with heart failure (HF)	Time to first occurrence of CV death or hospitalisation for HF or an urgent HF visit	FPCD Q1 2017 Data anticipated 2019
Farxiga	DAPA-CKD	SGLT2 inhibitor	c.4,000 patients with CKD	Time to first occurrence of $\geq 50\%$ sustained decline in eGFR ² or reaching ESRD ³ or CV death or renal death	FPCD Q1 2017 Data anticipated 2020
Brilinta	THEMIS	P2Y ₁₂ receptor antagonist	c.19,000 patients with type-2 diabetes and coronary artery disease without a history of MI or stroke	Composite of CV death, non-fatal MI and non-fatal stroke	Data anticipated 2019
Epanova	STRENGTH	Omega-3 carboxylic acids	c.13,000 patients with mixed dyslipidaemia	Time to first occurrence of CV death, non-fatal MI or non-fatal stroke	Data anticipated 2019

¹Includes c.10,000 patients who have had no prior index event and c.7,000 patients who have suffered an index event.

²Estimated Glomerular Filtration Rate.

³End-Stage Renal Disease.

RESPIRATORY

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

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

a) Symbicort (asthma)

During the period, the US FDA approved updates to the Symbicort labelling, including removal of the boxed warning for Symbicort and other ICS/LABA medicines for serious asthma-related outcomes. The update followed a 2011 post-marketing requirement from the US FDA, which required all manufacturers of LABA medicines to further evaluate their safety when used in combination with ICS for the treatment of asthma. The agency analysed four clinical trials involving over 42,000 patients and the results did not show a significant increase in the risk of serious asthma-related events (hospitalisation, intubations and death) with an ICS/LABA fixed-dose combination, compared with ICS alone.

b) Tudorza (COPD)

On 4 December 2017, AstraZeneca announced positive top-line results of the Phase IV ASCENT trial for Tudorza, a long-acting muscarinic antagonist (LAMA), in patients with moderate to very severe COPD, with a history of CV disease and/or significant CV risk factors.

The US FDA required data from the ASCENT trial as a post-marketing requirement to evaluate major adverse CV events for up to three years with acclidinium bromide, the active ingredient in Tudorza. The trial included more than 3,600 patients from Canada and the US and demonstrated a reduction in exacerbations and CV safety. A full analysis of the data is ongoing and results will be presented at a forthcoming medical meeting. AstraZeneca intends to submit an sNDA for an expanded Tudorza label.

c) Fasenra (benralizumab) (severe, uncontrolled asthma)

On 15 November 2017, the Company announced that the US FDA had approved Fasenra as a new medicine for patients with severe asthma aged 12 years and older and with an eosinophilic phenotype.

On 10 January 2018, the EMA approved Fasenra as an add-on maintenance treatment in adult patients with severe, inadequately-controlled eosinophilic asthma, despite high-dose inhaled corticosteroids plus LABA. The approvals were based on results from the WINDWARD programme, including the pivotal Phase III exacerbation trials SIROCCO and CALIMA, plus the Phase III oral corticosteroid (OCS)-sparing trial, ZONDA. Regulatory decisions are anticipated in several other jurisdictions in H1 2018.

On 19 January 2018, the Company announced that the Japanese Ministry of Health, Labour and Welfare had approved Fasenra as an add-on treatment for bronchial asthma in patients who continue to experience asthma exacerbations, despite treatment with high-dose inhaled corticosteroid and other asthma controller(s).

During the period, the Phase III GRECO trial met its primary endpoint, showing that patients and caregivers could self-administer Fasenra with an autoinjector. GRECO was a multicentre, open-label trial designed to assess the functionality and reliability of a single use autoinjector of Fasenra, administered subcutaneously in an at-home setting with monitoring of the autoinjector performance after use. The device performed as expected during the clinical trial.

d) Tralokinumab (asthma)

During the period, AstraZeneca decided to discontinue the development of tralokinumab, an investigational anti-IL-13 human immunoglobulin-G4 monoclonal antibody, in severe, uncontrolled asthma. The decision followed the publication of results of the Phase III programme, in which the primary endpoint of a significant reduction in the annual asthma exacerbation rate was not met in the two pivotal trials, STRATOS 1 and STRATOS 2. In an OCS-sparing trial, TROPOS, tralokinumab did not achieve a statistically-significant reduction in OCS use when added to the standard of care, in patients dependent on OCS.

e) PT010 (COPD)

On 26 January 2018, AstraZeneca announced the top-line results of the pivotal Phase III KRONOS trial for PT010, a potential triple-combination therapy (budesonide/glycopyrronium/formoterol fumarate) for the treatment of moderate to very severe COPD. In the trial, PT010 significantly improved lung function compared to PT009

(budesonide/formoterol fumarate), Bevespi (glycopyrronium/formoterol fumarate) and Symbicort Turbuhaler (budesonide/formoterol fumarate). AstraZeneca anticipates presentation of the results at a forthcoming medical meeting and intends to make the first regulatory submission for PT010 in H2 2018.

During the period, the Phase III TELOS trial read out, which compared two doses of PT009 (budesonide/formoterol fumarate) to its individual components, PT005 (formoterol fumarate) and PT008 (budesonide), and to Symbicort. The trial assessed lung function in patients with moderate to very severe COPD to qualify PT009 as an active comparator in the PT010 clinical-trial programme.

PT009, PT005 and PT008 were all delivered using Aerosphere Delivery Technology. All primary endpoints were met, with the exception of the lung-function primary endpoint that compared low-dose PT009 to PT005. A full evaluation of the TELOS trial results is ongoing, and the Company intends to present the results at a forthcoming medical meeting.

f) Tezepelumab (asthma)

In November 2017, the Company and its partner Amgen Inc. initiated the Phase III PATHFINDER programme for tezepelumab. During the period, the first patient was enrolled in the first Phase III trial, NAVIGATOR. The decision to proceed with the programme was based on the results from the Phase IIb PATHWAY trial in patients with severe, uncontrolled asthma. Results from the trial were published in the New England Journal of Medicine and presented at the European Respiratory Society International Congress in September 2017.

Development Pipeline 31 December 2017

Edgar Filing: ASTRAZENECA PLC - Form 6-K

AstraZeneca-sponsored or -directed trials

Phase III / Pivotal Phase II / Registration

New Molecular Entities (NMEs) and significant additional indications

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

Compound	Mechanism	Area Under Investigation	Date Commenced Phase	Estimated Regulatory Acceptance / Submission Status		
				US	EU	Japan
Oncology						
Calquence# (acalabrutinib)	BTK inhibitor	B-cell malignancy	Q1 2015	Launched		
savolitinib#	MET inhibitor	papillary renal cell carcinoma	Q3 2017	2020	2020	
SAVOIR				H2 2018 (Orphan Drug Designation)	H2 2018	
selumetinibASTRA	MEK inhibitor	differentiated thyroid cancer	Q3 2013	H1 2018 (Orphan Drug Designation)		
moxetumomab pasudotox#	anti-CD22 recombinantimmunotoxin	hairy cell leukaemia	Q2 2013	H1 2018 (Orphan Drug Designation)		
PLAIT						
Imfinzi# + tremelimumabARCTIC	PD-L1 mAb + CTLA-4 mAb	3rd-line NSCLC	Q2 2015	H1 2018	H1 2018	H1 2018
Imfinzi# + tremelimumab MYSTIC	PD-L1 mAb + CTLA-4 mAb	1st-line NSCLC	Q3 2015	H2 2018	H2 2018	H2 2018
Imfinzi# + tremelimumab NEPTUNE	PD-L1 mAb + CTLA-4 mAb	1st-line NSCLC	Q4 2015	2019	2019	2019
Imfinzi# + tremelimumab + chemotherapy POSEIDON	PD-L1 mAb + CTLA-4 mAb	1st-line NSCLC	Q2 2017	2019	2019	2019
Imfinzi# + tremelimumab + SoC CASPIAN	PD-L1 mAb + CTLA-4 mAb + SoC	1st-line SCLC	Q1 2017	2019	2019	2019
Imfinzi# + tremelimumabKESTREL	PD-L1 mAb + CTLA-4 mAb	1st-line HNSCC	Q4 2015	H2 2018	H2 2018	H2 2018
Imfinzi# + tremelimumabEAGLE	PD-L1 mAb + CTLA-4 mAb	2nd-line HNSCC	Q4 2015	H2 2018	H2 2018	H2 2018
Imfinzi# + tremelimumab DANUBE	PD-L1 mAb + CTLA-4 mAb	1st-line bladder cancer	Q4 2015	2019	2019	2019
Imfinzi# + tremelimumab HIMALAYA	PD-L1 mAb + CTLA-4 mAb	1st-line hepatocellular carcinoma	Q4 2017	2021	2021	2021
Lynparza# + cediranib CONCERTO	PARP inhibitor + VEGF inhibitor	recurrent platinum-resistant ovarian cancer	Q1 2017	2019		
CVMD						

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Epanova	omega-3 carboxylic acids	severe hypertriglycerid-aemia		Approved		2020
ZS-9 (sodium zirconium cyclosilicate)	potassium binder	hyperkalaemia		-	Accepted ¹	2019
roxadustat# OLYMPUS (US) ROCKIES (US)	hypoxia-inducible factor prolyl hydroxylase inhibitor	anaemia in CKD / end-stage renal disease	Q3 2014	H2 2018		
Respiratory						
Bevespi (PT003)	LABA/LAMA	COPD		Launched	Accepted	H2 2018
Fasenra# (benralizumab#) CALIMA SIROCCO ZONDA BISE BORA GREGALE PT010	IL-5R mAb	severe, uncontrolled asthma		Launched	Approved	Approve
tezepelumab NAVIGATOR SOURCE	LABA/LAMA/ ICS	COPD	Q3 2015	2019	2019	H2 2018
Other	TSLP mAb	severe, uncontrolled asthma	Q1 2018	2021	2021	2021
anifrolumab# TULIP	Type I IFN receptor mAb	systemic lupus erythematosus	Q3 2015	2019 (Fast Track)	2019	2019
lanabecestat# AMARANTH + extension, DAYBREAK-ALZ	beta-secretase inhibitor	Alzheimer's disease	Q2 2016	2020 (Fast Track)	2020	2020

Collaboration

¶ Registrational Phase II trial

1 CHMP positive opinion received

2 Fibrogen completed rolling regulatory submission in China

Phases I and II

NMEs and significant additional indications

Compound	Mechanism	Area Under Investigation	Phase	Date Commenced Phase
Oncology				
Imfinzi#	PD-L1 mAb	solid tumours	II	Q3 2014
Imfinzi# + tremelimumab	PD-L1 mAb + CTLA-4 mAb	gastric cancer	II	Q2 2015
Imfinzi# + tremelimumab	PD-L1 mAb + CTLA-4 mAb	biliary tract, oesophageal	II	Q4 2013
Imfinzi# + tremelimumab + chemo	PD-L1 mAb + CTLA-4 mAb	1st-line pancreatic ductal adenocarcinoma, oesophageal I and SCLC	I	Q2 2016
Imfinzi# + AZD5069	PD-L1 mAb + CXCR2 antagonist	pancreatic ductal adenocarcinoma	II	Q2 2017
Imfinzi# + AZD5069 or Imfinzi# + AZD9150#	PD-L1 mAb + CXCR2 antagonist or PD-L1 mAb + STAT3 inhibitor	HNSCC	II	Q3 2015
		melanoma	I	Q1 2014

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Imfinzi# + dabrafenib + trametinib	PD-L1 mAb + BRAF inhibitor + MEK inhibitor			
Imfinzi# + AZD1775#	PD-L1 mAb + Wee1 inhibitor	solid tumours	I	Q4 2015
Imfinzi# + MEDI0680	PD-L1 mAb + PD-1 mAb	solid tumours	II	Q3 2016
Imfinzi# or Imfinzi# + (tremelimumab or AZD9150#)	PD-L1 mAb or PD-L1 mAb + (CTLA-4 mAb or STAT3 inhibitor)	diffuse large B-cell lymphoma	I	Q3 2016
Imfinzi# + Iressa	PD-L1 mAb + EGFR inhibitor	NSCLC	I	Q2 2014
Imfinzi# + MEDI0562#	PD-L1 mAb + humanised OX40 agonist	solid tumours	I	Q2 2016
Imfinzi# + MEDI9197#	PD-L1 mAb + TLR 7/8 agonist	solid tumours	I	Q2 2017
Imfinzi# + oleclumab (MEDI9447)	PD-L1 mAb + CD73 mAb	solid tumours	I	Q1 2016
Imfinzi# + monalizumab	PD-L1 mAb + NKG2a mAb	solid tumours	I	Q1 2016
Imfinzi# + selumetinib	PD-L1 mAb + MEK inhibitor	solid tumours	I	Q4 2015
Imfinzi# + tremelimumab	PD-L1 mAb + CTLA-4 mAb	solid tumours	I	Q4 2013
tremelimumab + MEDI0562#	CTLA-4 mAb + humanised OX40 agonist	solid tumours	I	Q2 2016
Imfinzi# + azacitidine	PD-L1 mAb + azacitidine	myelodysplastic syndrome	I	Q2 2016
Imfinzi# + MEDI0457#	PD-L1 mAb + DNA HPV vaccine	HNSCC	II	Q4 2017
Imfinzi + RT (platform) CLOVER	PD-L1 mAb + RT	locally-advanced HNSCC, NSCLC, SCLC	I	Q1 2018
Lynparza# + AZD6738	PARP inhibitor + ATR inhibitor	gastric cancer	II	Q3 2016
Lynparza# + AZD1775#	PARP inhibitor + Wee1 inhibitor	solid tumours	I	Q3 2015
Lynparza# + Imfinzi MEDIOLA	PARP inhibitor + PD-L1 mAb	solid tumours	II	Q2 2016
Tagrisso + (selumetinib# or savolitinib#) TATTON	EGFR inhibitor + (MEK inhibitor or MET inhibitor)	advanced EGFRm NSCLC	II	Q2 2016
Tagrisso BLOOM	EGFR inhibitor	CNS metastases in advanced EGFRm NSCLC	II	Q4 2015
AZD1775# + chemotherapy	Wee1 inhibitor + chemotherapy	ovarian cancer	II	Q1 2015
AZD1775#	Wee1 inhibitor	solid tumours	I	Q3 2015
vistusertib	mTOR inhibitor	solid tumours	II	Q1 2013
AZD5363#	AKT inhibitor	breast cancer	II	Q1 2014
AZD4547	FGFR inhibitor	solid tumours	II	Q4 2011
AZD0156	ATM inhibitor	solid tumours	I	Q4 2015
AZD1390	ATM inhibitor	healthy volunteer trial	I	Q4 2017
AZD2811#	Aurora B inhibitor	solid tumours	I	Q4 2015
AZD4573	CDK9 inhibitor	haematological malignancies	I	Q4 2017
AZD4635	A2aR inhibitor	solid tumours	I	Q2 2016
AZD4785	KRAS inhibitor	solid tumours	I	Q2 2017
AZD5153	BRD4 inhibitor	solid tumours	I	Q3 2017
AZD5991	MCL1 inhibitor	haematological malignancies	I	Q3 2017
Calquence + vistusertib	B-cell malignancy + mTor inhibitor	haematological malignancies	I	Q3 2017
AZD6738	ATR inhibitor	solid tumours	I	Q4 2013
AZD8186	PI3k inhibitor	solid tumours	I	Q2 2013

Edgar Filing: ASTRAZENECA PLC - Form 6-K

AZD9496	selective oestrogen receptor degrader	oestrogen receptor +ve breast cancer	I	Q4 2014
MEDI-565#	CEA BiTE mAb	solid tumours	I	Q1 2011
MEDI0562#	humanised OX40 agonist	solid tumours	I	Q1 2015
MEDI1873	GITR agonist fusion protein	solid tumours	I	Q4 2015
MEDI3726#	PSMA antibody drug conjugate	prostate cancer	I	Q1 2017
MEDI4276	HER2 bi-specific antibody drug conjugate	solid tumours	I	Q4 2015
MEDI5083	immune activator	solid tumours	I	Q1 2017
MEDI7247	antibody drug conjugate	haematological malignancies	I	Q2 2017
MEDI9197#	TLR 7/8 agonist	solid tumours	I	Q4 2015
oleclumab (MEDI9447)	CD73 mAb	solid tumours	I	Q3 2015
CVMD				
verinurad	URAT1 inhibitor	CKD	II	Q2 2017
MEDI0382	GLP-1 / glucagon dual agonist	type-2 diabetes / obesity	II	Q3 2016
MEDI6012	LCAT	CV disease	II	Q4 2015
AZD4831	myeloperoxidase	HF with a preserved ejection fraction	I	Q3 2016
AZD5718	FLAP	coronary artery disease	II	Q4 2017
AZD8601#	VEGF-A	CV disease	I	Q1 2017
MEDI5884#	cholesterol modulation	CV disease	II	Q4 2017
Respiratory				
abediterol#	LABA	asthma / COPD	II	Q4 2007
tezepelumab#	TSLP mAb	atopic dermatitis	II	Q2 2015
AZD1419#	inhaled TLR9 agonist	asthma	II	Q4 2016
AZD7594	inhaled SGRM	asthma / COPD	II	Q3 2015
AZD8871#	MABA	COPD	II	Q1 2017
PT010	LABA/LAMA/ICS	asthma	II	Q2 2014
AZD5634	inhaled ENaC	cystic fibrosis	I	Q1 2016
AZD7594 + abediterol#	inhaled SGRM + LABA	asthma / COPD	I	Q4 2016
AZD7986#	DPP1	COPD	II	Q4 2017
AZD9567	oral SGRM	rheumatoid arthritis / respiratory	I	Q4 2015
AZD1402#	Inhaled IL-4Ra	asthma	I	Q4 2017
MEDI3506	IL-33 mAb	COPD	I	Q2 2017
Other				
anifrolumab#	Type 1 IFN receptor mAb	lupus nephritis	II	Q4 2015
anifrolumab#	Type 1 IFN receptor mAb	systemic lupus erythematosus (subcutaneous)	II	Q1 2017
inebilizumab#	CD19 mAb	neuromyelitis optica	II (Orphan drug US, EU)	Q1 2015
mavrilimumab#	GM-CSFR mAb	rheumatoid arthritis	II	Q1 2010
MEDI3902	PsI/PcrV bispecific mAb	prevention of nosocomial Pseudomonas aeruginosa pneumonia	II (Fast Track, US)	Q2 2016
suvratoxumab (MEDI4893)	mAb binding to S. aureus toxin	prevention of nosocomial Staphylococcus aureus pneumonia	II (Fast Track, US)	Q4 2014

Edgar Filing: ASTRAZENECA PLC - Form 6-K

prezalumab# (MEDI5872#)	B7RP1 mAb	primary Sjögren's syndrome	II	Q3 2015
MEDI8852	influenza A mAb	influenza A treatment	II (Fast Track, US)	Q4 2015
MEDI8897#	RSV mAb-YTE	passive RSV prophylaxis	II (Fast Track, US)	Q1 2015
AZD0284	RORg	psoriasis / respiratory	I	Q4 2016
MEDI0700#	BAFF/B7RP1 bispecific mAb	systemic lupus erythematosus	I	Q1 2016
MEDI1814#	amyloid beta mAb	Alzheimer's disease	I	Q2 2014
MEDI4920	anti-CD40L-Tn3 fusion protein	primary Sjögren's syndrome	I	Q2 2014
MEDI7352	NGF/TNF bi-specific mAb	osteoarthritis pain	I	Q1 2016
MEDI7734	ILT7 mAb	myositis	I	Q3 2016
MEDI9314	IL-4R mAb	atopic dermatitis	I	Q1 2016

Collaboration

Significant Lifecycle Management

Compound	Mechanism	Area Under Investigation	Date Commenced Phase	Estimated Regulatory Acceptance Date / Status			
				US	EU	Japan	China
Oncology							
Calquence# (acalabrutinib)	BTK inhibitor	1st-line chronic lymphocytic leukaemia	Q3 2015	2020 (Orphan Drug Designation)	2020 (Orphan Drug Designation)		
Calquence# (acalabrutinib)	BTK inhibitor	relapsed/refractory chronic lymphocytic leukaemia, high risk	Q4 2015	2019 (Orphan Drug Designation)	2019 (Orphan Drug Designation)		
Calquence# (acalabrutinib)	BTK inhibitor	1st-line mantle cell lymphoma	Q1 2017	2023			
Faslodex FALCON	oestrogen receptor antagonist	1st-line hormone receptor +ve advanced breast cancer		Approved	Approved	Approved	Approved
Imfinzi# PACIFIC	PD-L1 mAb	locally-advanced (Stage III), NSCLC	Q2 2014	Accepted (Breakthrough Therapy Designation & Priority Review)	Accepted	Accepted	
Imfinzi# PEARL (China)	PD-L1 mAb	1st-line NSCLC	Q1 2017				2020
Lynparza# OlympiAD	PARP inhibitor	gBRCA metastatic breast cancer	Q2 2014	Approved (Priority Review)	H1 2018	Accepted (Orphan drug designation, Priority Review)	H2 2018
Lynparza# SOLO-2	PARP inhibitor	2nd-line or greater BRCAm PSR ovarian cancer, maintenance monotherapy	Q3 2013	Approved (Priority Review)	Accepted	Accepted (Orphan drug designation)	Accepted
			Q3 2013	H2 2018	H2 2018	H2 2018	2019

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Lynparza# SOLO-1	PARP inhibitor	1st-line BRCAm ovarian cancer					
Lynparza# SOLO-3	PARP inhibitor	gBRCA PSR ovarian cancer	Q1 2015	H2 2018			
Lynparza# POLO	PARP inhibitor	pancreatic cancer	Q1 2015	2019	2019		
Lynparza# PROfound	PARP inhibitor	prostate cancer	Q1 2017	2020 (Breakthrough Therapy Designation)	2020	2020	2020
Lynparza# OlympiA	PARP inhibitor	gBRCA adjuvant breast cancer	Q2 2014	2020	2020	2020	
Tagrisso FLAURA	EGFR inhibitor	1st-line advanced EGFRm NSCLC	Q1 2015	Accepted (Breakthrough Therapy designation)	Accepted	Accepted	H2 2018
Tagrisso ADAURA CVMD	EGFR inhibitor	adjuvant EGFRm NSCLC	Q4 2015	2022	2022	2022	2022
Brilinta1 THALES	P2Y12 receptor antagonist	acute ischaemic stroke or transient ischaemic attack CV outcomes trial in patients with type-2 diabetes and coronary artery disease without a previous history of MI or stroke	Q1 2018	2020	2020	2020	2020
Brilinta1 THEMIS	P2Y12 receptor antagonist	prevention of vaso-occlusive crises in paediatric patients with sickle cell disease CV outcomes trial in patients with type-2 diabetes	Q1 2014	2019	2019	2019	2020
Brilinta1 HESTIA	P2Y12 receptor antagonist	prevention of vaso-occlusive crises in paediatric patients with sickle cell disease CV outcomes trial in patients with type-2 diabetes	Q1 2014	2021	2021		
Farxiga2 DECLARE- TIMI 58	SGLT2 inhibitor	type-1 diabetes	Q2 2013	2019	2019		
Farxiga2	SGLT2 inhibitor	worsening HF or CV death in patients with chronic HF	Q4 2014	H2 2018	H1 2018	H2 2018	
Farxiga2	SGLT2 inhibitor	renal outcomes and CV mortality in patients with CKD	Q1 2017	2020	2020	2020	2020
Farxiga2	SGLT2 inhibitor	type-2 diabetes	Q1 2017	2021	2021	N/A	2021
Xigduo XR/ Xigduo3	SGLT2 inhibitor/ metformin FDC	type-2 diabetes		Launched	Launched		2020
Qtern	DPP-4 inhibitor / SGLT2 inhibitor FDC	type-2 diabetes		Launched	Launched		

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Bydureon BCise / Bydureon autoinjector ⁴	GLP-1 receptor agonist	type-2 diabetes	Q1 2013	Launched	Accepted		
Bydureon EXSCEL	GLP-1 receptor agonist	type-2 diabetes outcomes trial	Q2 2010	H1 2018	H1 2018		H2 2018
saxagliptin/ dapagliflozin/ metformin	DPP-4 inhibitor / SGLT2 inhibitor	type-2 diabetes	Q2 2017	H1 2018	H1 2018		
Epanova STRENGTH	omega-3 carboxylic acids	CV outcomes trial in statin-treated patients at high CV risk, with persistent hypertriglyceridaemia plus low HDL-cholesterol	Q4 2014	2020	2020	2020	2020
Respiratory Fasenra# (benralizumab#) TERRANOVA GALATHEA	IL-5R mAb	COPD	Q3 2014	H2 2018	H2 2018	2019	
Symbicort SYGMA	ICS/LABA	as-needed use in mild asthma	Q4 2014		2018		2019
Duaklir Genuair# Other	LAMA/LABA	COPD		H1 2018	Launched		2019
Nexium	proton-pump inhibitor	stress ulcer prophylaxis					Accepted
Nexium	proton-pump inhibitor	paediatrics		Launched	Launched	Approved	
linaclotide#	GC-C receptor peptide agonist	irritable bowel syndrome with constipation (IBS-C)					Accepted

Collaboration

- 1 Brilinta in the US and Japan; Brilique in ROW
- 2 Farxiga in the US; Forxiga in ROW
- 3 Xigduo XR in the US; Xigduo in the EU
- 4 Bydureon BCise in the US, Bydureon autoinjector in the EU

Terminations (discontinued projects: 1 October to 31 December 2017)

NME / Line Extension	Compound	Reason for Discontinuation	Area Under Investigation
NME	AZD9898#	safety / efficacy	asthma
NME	MEDI-573	safety / efficacy	metastatic breast cancer
NME	STRATOS 1,2 TROPS MESOS	safety / efficacy	severe, uncontrolled asthma

Collaboration

Completed Projects/Divestitures (1 October to 31 December 2017)

Compound	Mechanism	Area Under Investigation	Completed/ Divested	Estimated Regulatory Submission Acceptance			
				US	EU	Japan	China
MEDI0680	PD-1 mAb	solid tumours	completed	-	-	-	-
Kombiglyze XR/Komboglyze1	DPP-4 inhibitor / metformin FDC	type-2 diabetes		Launched	Launched		Launched
	1 Kombiglyze XR in the US; Komboglyze in ROW						

Condensed Consolidated Statement of Comprehensive Income

	2017	2016
	\$m	\$m
For the year ended 31 December		
Product Sales	20,152	21,319
Externalisation Revenue	2,313	1,683
Total Revenue	22,465	23,002
Cost of sales	(4,318)	(4,126)
Gross profit	18,147	18,876
Distribution costs	(310)	(326)
Research and development expense	(5,757)	(5,890)
Selling, general and administrative costs	(10,233)	(9,413)
Other operating income and expense	1,830	1,655
Operating profit	3,677	4,902
Finance income	113	67
Finance expense	(1,508)	(1,384)
Share of after tax losses in associates and joint ventures	(55)	(33)
Profit before tax	2,227	3,552
Taxation	641	(146)
Profit for the period	2,868	3,406
Other comprehensive income/(loss)		
Items that will not be reclassified to profit or loss		
Remeasurement of the defined benefit pension liability	(242)	(575)
Fair value movements related to own credit risk on bonds designated as fair value through profit or loss	(9)	-
Tax on items that will not be reclassified to profit or loss	16	136
	(235)	(439)
Items that may be reclassified subsequently to profit or loss		
Foreign exchange arising on consolidation	536	(1,050)
Foreign exchange arising on designating borrowings in net investment hedges	505	(591)
Fair value movements on cash flow hedges	311	(115)
Fair value movements on cash flow hedges transferred to profit or loss	(315)	195
Fair value movements on derivatives designated in net investment hedges	(48)	(4)
Amortisation of loss on cash flow hedge	1	1
Net available for sale (losses)/gains taken to equity	(83)	139
Tax on items that may be reclassified subsequently to profit or loss	(33)	86
	874	(1,339)
Other comprehensive income/(loss) for the period, net of tax	639	(1,778)
Total comprehensive income for the period	3,507	1,628

Profit attributable to:		
Owners of the Parent	3,001	3,499
Non-controlling interests	(133)	(93)
	2,868	3,406
Total comprehensive income attributable to:		
Owners of the Parent	3,640	1,722
Non-controlling interests	(133)	(94)
	3,507	1,628
Basic earnings per \$0.25 Ordinary Share	\$2.37	\$2.77
Diluted earnings per \$0.25 Ordinary Share	\$2.37	\$2.76
Weighted average number of Ordinary Shares in issue (millions)	1,266	1,265
Diluted weighted average number of Ordinary Shares in issue (millions)	1,267	1,266

Condensed Consolidated Statement of Comprehensive Income

	2017	2016
For the quarter ended 31 December	\$m	\$m
Product Sales	5,487	5,260
Externalisation Revenue	290	325
Total Revenue	5,777	5,585
Cost of sales	(1,225)	(1,160)
Gross profit	4,552	4,425
Distribution costs	(85)	(83)
Research and development expense	(1,551)	(1,543)
Selling, general and administrative costs	(3,078)	(1,386)
Other operating income and expense	848	1,120
Operating profit	686	2,533
Finance income	49	23
Finance expense	(316)	(362)
Share of after tax losses in associates and joint ventures	(12)	(11)
Profit before tax	407	2,183
Taxation	854	(366)
Profit for the period	1,261	1,817
Other comprehensive income/(loss)		
Items that will not be reclassified to profit or loss		
Remeasurement of the defined benefit pension liability	(96)	552
Fair value movements related to own credit risk on bonds designated as fair value through profit or loss	(9)	-
Tax on items that will not be reclassified to profit or loss	(7)	(120)
	(112)	432
Items that may be reclassified subsequently to profit or loss		
Foreign exchange arising on consolidation	5	(360)
Foreign exchange arising on designating borrowings in net investment hedges	(117)	(397)
Fair value movements on cash flow hedges	85	(89)
Fair value movements on cash flow hedges transferred to profit or loss	(34)	154
Fair value movements on derivatives designated in net investment hedges	(9)	92
Net available for sale (losses)/gains taken to equity	(47)	13
Tax on items that may be reclassified subsequently to profit or loss	92	23

Edgar Filing: ASTRAZENECA PLC - Form 6-K

	(25)	(564)
Other comprehensive loss for the period, net of tax	(137)	(132)
Total comprehensive income for the period	1,124	1,685
Profit attributable to:		
Owners of the Parent	1,301	1,842
Non-controlling interests	(40)	(25)
	1,261	1,817
Total comprehensive income attributable to:		
Owners of the Parent	1,164	1,710
Non-controlling interests	(40)	(25)
	1,124	1,685
Basic earnings per \$0.25 Ordinary Share	\$1.03	\$1.46
Diluted earnings per \$0.25 Ordinary Share	\$1.03	\$1.45
Weighted average number of Ordinary Shares in issue (millions)	1,266	1,265
Diluted weighted average number of Ordinary Shares in issue (millions)	1,267	1,266

Condensed Consolidated Statement of Financial Position

	At 31 Dec 2017	At 31 Dec 2016
	\$m	\$m
ASSETS		
Non-current assets		
Property, plant and equipment	7,615	6,848
Goodwill	11,825	11,658
Intangible assets	26,188	27,586
Derivative financial instruments	504	343
Investments in associates and joint ventures	103	99
Other investments	933	727
Other receivables	847	901
Deferred tax assets	2,189	1,102
	50,204	49,264
Current assets		
Inventories	3,035	2,334
Trade and other receivables	5,009	4,573
Other investments	1,230	884
Derivative financial instruments	28	27
Income tax receivables	524	426
Cash and cash equivalents	3,324	5,018
	13,150	13,262
Total assets	63,354	62,526
LIABILITIES		
Current liabilities		
Interest-bearing loans and borrowings	(2,247)	(2,307)
Trade and other payables	(11,641)	(10,486)
Derivative financial instruments	(24)	(18)

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Provisions	(1,121)	(1,065)
Income tax payables	(1,350)	(1,380)
	(16,383)	(15,256)
Non-current liabilities		
Interest-bearing loans and borrowings	(15,560)	(14,501)
Derivative financial instruments	(4)	(117)
Deferred tax liabilities	(3,995)	(3,956)
Retirement benefit obligations	(2,583)	(2,186)
Provisions	(347)	(353)
Other payables	(7,840)	(9,488)
	(30,329)	(30,601)
Total liabilities	(46,712)	(45,857)
Net assets	16,642	16,669

EQUITY

Capital and reserves attributable to equity holders of the Company		
Share capital	317	316
Share premium account	4,393	4,351
Other reserves	2,029	2,047
Retained earnings	8,221	8,140
	14,960	14,854
Non-controlling interests	1,682	1,815
Total equity	16,642	16,669

Condensed Consolidated Statement of Cash Flows

	2017	2016
	\$m	\$m
For the year ended 31 December		
Cash flows from operating activities		
Profit before tax	2,227	3,552
Finance income and expense	1,395	1,317
Share of after tax losses in associates and joint ventures	55	33
Depreciation, amortisation and impairment	3,036	2,357
(Increase)/decrease in working capital and short-term provisions	(50)	926
Gains on disposal of intangible assets	(1,518)	(1,301)
Fair value movements on contingent consideration arising from business combinations	109	(1,158)
Non-cash and other movements	(524)	(492)
Cash generated from operations	4,730	5,234
Interest paid	(698)	(677)
Tax paid	(454)	(412)
Net cash inflow from operating activities	3,578	4,145
Cash flows from investing activities		
Movement in short-term investments and fixed deposits	(345)	(166)
Purchase of property, plant and equipment	(1,326)	(1,446)
Disposal of property, plant and equipment	83	82
Purchase of intangible assets	(294)	(868)
Disposal of intangible assets	1,376	1,427
Purchase of non-current asset investments	(96)	(230)
Disposal of non-current asset investments	70	3
Payments to joint ventures	(76)	(41)

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Non-contingent payments on business combinations	(1,450)	(2,564)
Payment of contingent consideration from business combinations	(434)	(293)
Interest received	164	140
Payments made by subsidiaries to non-controlling interests	-	(13)
Net cash outflow from investing activities	(2,328)	(3,969)
Net cash inflow before financing activities	1,250	176
Cash flows from financing activities		
Proceeds from issue of share capital	43	47
Issue of loans	1,988	2,491
Repayment of loans	(1,750)	-
Dividends paid	(3,519)	(3,561)
Hedge contracts relating to dividend payments	(20)	18
Repayment of obligations under finance leases	(14)	(16)
Movement in short-term borrowings	336	(303)
Net cash outflow from financing activities	(2,936)	(1,324)
Net decrease in cash and cash equivalents in the period	(1,686)	(1,148)
Cash and cash equivalents at the beginning of the period	4,924	6,051
Exchange rate effects	(66)	21
Cash and cash equivalents at the end of the period	3,172	4,924
Cash and cash equivalents consists of:		
Cash and cash equivalents	3,324	5,018
Overdrafts	(152)	(94)
	3,172	4,924

Condensed Consolidated Statement of Changes in Equity

	Share capital \$m	Share premium account \$m	Other reserves* \$m	Retained earnings \$m	Total attributable to owners \$m	Non-controlling interests \$m	Total equity \$m
At 1 Jan 2016	316	4,304	2,036	11,834	18,490	19	18,509
Profit for the period	-	-	-	3,499	3,499	(93)	3,406
Other comprehensive income	-	-	-	(1,777)	(1,777)	(1)	(1,778)
Transfer to other reserves	-	-	11	(11)	-	-	-
Transactions with owners:							
Dividends	-	-	-	(3,540)	(3,540)	-	(3,540)
Dividends paid by subsidiary to non-controlling interest	-	-	-	-	-	(13)	(13)
Acerta put option	-	-	-	(1,825)	(1,825)	-	(1,825)
Changes in non-controlling interest	-	-	-	-	-	1,903	1,903
Issue of Ordinary Shares	-	47	-	-	47	-	47
Share-based payments charge for the period	-	-	-	241	241	-	241
Settlement of share plan awards	-	-	-	(281)	(281)	-	(281)
Net movement	-	47	11	(3,694)	(3,636)	1,796	(1,840)
At 31 Dec 2016	316	4,351	2,047	8,140	14,854	1,815	16,669
	Share capital \$m	Share premium account \$m	Other reserves* \$m	Retained earnings \$m	Total attributable to owners \$m	Non-controlling interests \$m	Total equity \$m
At 1 Jan 2017	316	4,351	2,047	8,140	14,854	1,815	16,669
Profit for the period	-	-	-	3,001	3,001	(133)	2,868

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Other comprehensive income	-	-	-	639	639	-	639
Transfer to other reserves	-	-	(18)	18	-	-	-
Transactions with owners:							
Dividends	-	-	-	(3,543)	(3,543)	-	(3,543)
Issue of Ordinary Shares	1	42	-	-	43	-	43
Share-based payments charge for the period	-	-	-	220	220	-	220
Settlement of share plan awards	-	-	-	(254)	(254)	-	(254)
Net movement	1	42	(18)	81	106	(133)	(27)
At 31 Dec 2017	317	4,393	2,029	8,221	14,960	1,682	16,642

*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 2017 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 noted 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 2016. From 1 January 2017 the Group early adopted the treatment of fair value changes arising from changes in own credit risk in IFRS 9 Financial Instruments. The impact was not significant.

We have revised the balance sheet presentation of deferred tax with effect from 1 January 2017 with no impact upon net deferred tax, the Group's net assets, the cash flow statement or the income statement. This presentation change has resulted in us showing gross, rather than net, deferred tax assets and deferred tax liabilities of a group entity. This change has been made as that entity has transactions that are subject to tax by two different taxation authorities and has the effect of separately disclosing the deferred tax effects for each country. The comparative balance sheet has not been revised for this presentational change. If the 31 December 2016 balances were presented in a comparable way the deferred tax assets would have been \$2,093m. The deferred tax liabilities would have been \$4,947m.

As disclosed in our 2016 Annual Report on Page 181, the Group has entered into a number of financial derivative transactions with commercial banks. The Group has agreements with some bank counterparties whereby the parties agree to post cash collateral, for the benefit of the other, equivalent to the market valuation of the derivative positions above a predetermined threshold. We have revised the balance sheet presentation of these collateral balances with effect from 1 January 2017, so that the cash collateral is included in cash and cash equivalents, with an offsetting liability presented in current interest-bearing loans and borrowings and the movement presented in movement in short-term borrowings in the statement of cash flows. This revision has no impact on the Group's net assets, or the income statement. The comparative balance sheet has not been revised for this presentational change. If the 31 December 2016 balances were presented in a comparable way the cash and cash equivalents balance would have been \$5,260m. Current interest-bearing loans and borrowings would have been \$2,629m, and current investments would have been \$964m.

Following clarification by the IASB Interpretations Committee in September 2017, the Group has revised its presentation of interest and tax positions. Interest income and expense, which was previously presented in the tax charge in the income statement, is now presented in finance income and expense and corresponding assets and liabilities, which were previously presented as income tax receivables and payables in the balance sheet, are now presented in trade and other receivables and trade and other payables. This revision has no impact on the Group's net assets and cash flows, or retained profit. The Group has assessed this presentational change as not material for restatement and, therefore, the comparative income statement and balance sheets have not been revised for this presentational change. If the 31 December 2016 balances were presented in a comparable way, finance income and expense would have been \$1,239m, the tax charge would have been \$224m, income tax payables would have been \$1,287m, and trade and other payables would have been \$10,579m.

Legal proceedings

The information contained in Note 5 updates the disclosures concerning legal proceedings and contingent liabilities in the Group's Annual Report and Form 20-F Information 2016, the interim financial statements for the three months ended 31 March 2017, the interim financial statements for the three months ended 30 June 2017 and the interim financial statements for the three months ended 30 September 2017.

Going concern

The Group has considerable financial resources available. As at 31 December 2017 the Group has \$4.1bn in financial resources (cash balances of \$3.3bn and undrawn committed bank facilities of \$3.0bn which are available until April 2022, with only \$2.2bn of debt due within one year). The Group's revenues are largely derived from sales of products which are covered by patents which provide a relatively high level of resilience and predictability to cash inflows, although our revenue is expected to continue to be significantly impacted by the expiry of patents over the medium term. In addition, government price interventions in response to budgetary constraints are expected to continue to adversely affect revenues in many of our mature markets. However, we anticipate new revenue streams from both recently launched medicines and products in development, and the Group has a wide diversity of customers and suppliers across different geographic areas. Consequently, the Directors believe that, overall, the Group is well placed to manage its business risks successfully.

On the basis of the above paragraph, the going concern basis has been adopted in these interim financial statements.

Financial information

The financial information contained in the preliminary announcement does not constitute statutory accounts of the Group for the years ended 31 December 2017 and 2016 but is derived from those accounts. Statutory accounts for 2016 have been delivered to the registrar of companies and those for 2017 will be delivered in due course. Those accounts have been reported on by the Group's auditors; their report was (i) unqualified, (ii) did not include a reference to any matters to which the auditors drew attention by way of emphasis without qualifying their report, and (iii) did not contain a statement under section 498(2) or (3) of the Companies Act 2006. The quarterly information for the three month period to 31 December 2017 and to 31 December 2016 has not been subject to audit.

2 RESTRUCTURING COSTS

Profit before tax for the year ended 31 December 2017 is stated after charging restructuring costs of \$807m (\$163m for the fourth quarter of 2017). These have been charged to profit as follows:

	FY 2017	FY 2016	Q4 2017	Q4 2016
	\$m	\$m	\$m	\$m
Cost of sales	181	130	53	43
Research and development expense	201	178	24	32
Selling, general and administrative costs	347	823	83	319
Other operating income and expense	78	(24)	3	-
Total	807	1,107	163	394

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. The Group monitors net debt as part of its capital management policy as described in Note 26 of the Annual Report and Form 20-F Information 2016. Net debt is a non-GAAP financial measure.

	At 1 Jan 2017	Cash Flow	Non-cash & Other	Exchange Movements	At 31 Dec 2017
	\$m	\$m	\$m	\$m	\$m
Loans due after one year	(14,495)	(1,988)	1,389	(466)	(15,560)
Finance leases due after one year	(6)	-	6	-	-
Total long-term debt	(14,501)	(1,988)	1,395	(466)	(15,560)

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Current instalments of loans	(1,769)	1,750	(1,378)	-	(1,397)
Current instalments of finance leases	(87)	14	69	(1)	(5)
Total current debt	(1,856)	1,764	(1,309)	(1)	(1,402)
Other investments - current	884	345	-	1	1,230
Other investments - non-current	14	56	-	-	70
Net derivative financial instruments	235	20	249	-	504
Cash and cash equivalents	5,018	(1,629)	-	(65)	3,324
Overdrafts	(94)	(57)	-	(1)	(152)
Short-term borrowings	(357)	(336)	-	-	(693)
	5,700	(1,601)	249	(65)	4,283
Net debt	(10,657)	(1,825)	335	(532)	(12,679)

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

4 4 FINANCIAL INSTRUMENTS

As detailed in the Group's most recent annual financial statements, our principal financial instruments consist of derivative financial instruments, other investments, trade and other receivables, cash and cash equivalents, trade and other payables, and interest-bearing loans and borrowings. The accounting policies for financial instruments, including fair value measurement, can be found on pages 144 and 145 of the Company's Annual Report and Form 20-F Information 2016. There have been no significant new or revised accounting standards applied in the year ended 31 December 2017 and there have been no changes of significance to the categorisation or fair value hierarchy classification of our financial instruments. During the year, we revised the balance sheet presentation of cash collateral balances held with commercial bank counterparties, effective from 1 January 2017 (see Note 1).

Financial instruments measured at fair value include \$1,230m of other investments, \$1,247m of loans, and \$504m of derivatives as at 31 December 2017. The total fair value of interest-bearing loans and borrowings at 31 December 2017 which have a carrying value of \$17,807m in the Condensed Consolidated Statement of Financial Position, was \$19,280m. Contingent consideration liabilities arising on business combinations have been classified under Level 3 in the fair value hierarchy and movements in fair value are shown below:

	Diabetes Alliance 2017 \$m	Other 2017 \$m	Total 2017 \$m	Total 2016 \$m
At 1 January	4,240	1,217	5,457	6,411
Settlements	(284)	(150)	(434)	(293)
Revaluations	208	(99)	109	(1,158)
Discount unwind	313	89	402	497
Foreign exchange -	-	-	-	-

At 31 December 4,477 1,057 5,534 5,457

5 5 LEGAL PROCEEDINGS AND CONTINGENT LIABILITIES

AstraZeneca is involved in various legal proceedings considered typical to its business, including litigation and investigations relating to product liability, commercial disputes, infringement of intellectual property rights, the validity of certain patents, anti-trust law and sales and marketing practices. The matters discussed below constitute the more significant developments since publication of the disclosures concerning legal proceedings in the Company's Annual Report and Form 20-F Information 2016, the interim financial statements for the three months ended 31 March 2017, the interim financial statements for the three months ended 30 June 2017, and the interim financial statements for the three months ended 30 September 2017 (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 2017 and to 2 February 2018.

Patent litigation

Faslodex (fulvestrant)

US patent proceedings

As previously disclosed, in March and October 2017, AstraZeneca received Paragraph IV notices regarding NDAs submitted pursuant to 21 U.S.C. § 355(b)(2) by Teva Pharmaceuticals USA, Inc. (Teva) and Fresenius Kabi USA LLC (Fresenius), respectively, relating to four FDA Orange Book-listed patents. As previously disclosed, in April 2017, AstraZeneca filed a lawsuit against Teva in the US District Court for the District of New Jersey (the District Court). In December 2017, AstraZeneca filed lawsuits against Fresenius in both the District Court and the US District Court for the District of Delaware. In January 2018, AstraZeneca settled the lawsuits against both Teva and Fresenius and consent judgements have been entered, ending the lawsuits.

Calquence (acalabrutinib)

US patent proceedings

As previously disclosed, in November 2017, Pharmacyclics LLC filed a complaint in the US District Court for the District of Delaware against Acerta Pharma B.V., Acerta Pharma LLC, and AstraZeneca (collectively, AstraZeneca) alleging that Calquence infringes certain claims of US Patent Nos. 9,079,908; 9,139,591; and 9,556,182. In January 2018, AstraZeneca filed an answer to the complaint alleging, inter alia, that the asserted patents are invalid and not infringed.

Byetta (exenatide)

US patent proceedings

As previously disclosed, in December 2015, AstraZeneca filed a patent infringement lawsuit in response to a Paragraph IV notice from Amneal Pharmaceuticals LLC (Amneal) relating to patents listed in the FDA Orange Book with reference to Byetta. In October 2017, AstraZeneca settled the patent litigation against Amneal. A consent judgment was entered in the US District Court for the District of Delaware which will enjoin Amneal from launching its proposed exenatide Abbreviated New Drug Application product until April 2018, subject to regulatory approval.

Patent proceedings outside the US

In December 2017, the Barcelona Court of Appeals lifted a nationwide interim injunction that AstraZeneca had previously obtained against Sandoz Farmaceutica, S. A. (Sandoz) after Sandoz received regulatory approval to market

generic versions of Faslodex in Spain.

Tagrisso (osimertinib)

Patent proceedings outside the US

In Europe, in October 2016, Stada Arzneimittel AG filed an opposition to the grant of European Patent No. 2,736,895 (the '895 patent). The European Patent Office Opposition Hearing took place in January 2018 and the '895 patent was upheld.

Product liability litigation

Byetta/Bydureon (exenatide)

As previously disclosed, in the US, 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 involving claims of physical injury from treatment with Byetta and/or Bydureon. The lawsuits allege several 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 coordinated 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. In November 2017, the US Court of Appeals for the Ninth Circuit annulled the District Court's order and remanded for further discovery. The appeal of a similar motion, which was granted in favour of defendants in the California state coordinated proceeding in May 2016, remains pending

Crestor (rosuvastatin calcium)

As previously disclosed, in the US, AstraZeneca was defending a number of lawsuits alleging multiple types of injuries caused by the use of Crestor, including diabetes mellitus, various cardiac injuries, rhabdomyolysis, and/or liver and kidney injuries. AstraZeneca has resolved all active claims with regard to this matter.

Seroquel (quetiapine fumarate)

In November 2017, AstraZeneca was named as one of several defendants in a lawsuit filed in Missouri involving one plaintiff alleging, among other things, wrongful death from treatment with Seroquel.

Commercial litigation

Array BioPharma

In December 2017, AstraZeneca was served with a complaint filed in New York State court by Array BioPharma, Inc. (Array) that alleged, among other things, breaches of contractual obligations relating to a 2003 collaboration agreement between AstraZeneca and Array.

6 product analysis - FY 2017

The table below provides an analysis of year-on-year Product Sales, with Actual and CER growth rates reflecting year-on-year growth.

	World			Emerging Markets			US		Europe			Established ROW		
	FY 2017 \$m	Actual %	CER %	FY 2017 \$m	Actual %	CER %	FY 2017 \$m	Actual %	FY 2017 \$m	Actual %	CER %	FY 2017 \$m	Actual %	CER %
Oncology														
Tagrisso	955	126	126	135	n/m	n/m	405	59	187	146	142	228	175	183
Iressa	528	3	3	251	8	8	39	70	112	(7)	(8)	126	(8)	(6)
Lynparza	297	36	35	18	n/m	n/m	141	11	130	60	58	8	n/m	n/m
Imfinzi	19	n/m	n/m	-	-	-	19	n/m	-	-	-	-	-	-
Calquence	3	n/m	n/m	-	-	-	3	n/m	-	-	-	-	-	-
Legacy:														
Faslodex	941	13	13	115	20	18	492	12	256	12	11	78	15	18
Zoladex	735	(10)	(9)	353	(1)	(1)	15	(57)	141	(10)	(8)	226	(16)	(15)

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Casodex	215	(13)	(11)	108	1	4	(1)	n/m	22	(19)	(19)	86	(23)	(21)
Arimidex	217	(6)	(4)	118	7	10	7	(50)	34	(8)	(8)	58	(18)	(15)
Others	114	10	13	28	12	16	-	-	3	(63)	(63)	83	17	20
Total Oncology	4,024	19	19	1,126	19	20	1,120	25	885	21	20	893	10	12
CVMD														
Brilinta	1,079	29	29	224	19	21	509	46	295	14	13	51	16	11
Farxiga	1,074	29	28	232	74	73	489	7	242	29	28	111	91	90
Onglyza	611	(15)	(16)	130	(8)	(10)	320	(15)	104	(21)	(21)	57	(19)	(20)
Bydureon	574	(1)	(1)	9	125	75	458	(1)	88	(12)	(11)	19	73	73
Byetta	176	(31)	(30)	12	(50)	(50)	114	(30)	34	(24)	(22)	16	(24)	(24)
Symlyn	48	20	20	-	-	-	48	20	-	-	-	-	-	-
Qtern	5	n/m	n/m	1	n/m	n/m	4	n/m	-	-	-	-	-	-
Legacy:														
Crestor	2,365	(30)	(30)	784	9	11	373	(70)	666	(23)	(23)	542	(8)	(6)
Seloken/Toprol-XL	695	(6)	(4)	593	11	12	37	(61)	52	(42)	(41)	13	(19)	(19)
Atacand	300	(5)	(3)	178	10	12	19	(47)	86	(11)	(11)	17	(15)	(15)
Others	339	(15)	(13)	204	(11)	(7)	-	-	92	(23)	(24)	43	(14)	(12)
Total CVMD	7,266	(10)	(10)	2,367	11	12	2,371	(26)	1,659	(12)	(13)	869	(1)	-
Respiratory														
Symbicort	2,803	(6)	(6)	439	9	10	1,099	(12)	819	(10)	(10)	446	2	2
Pulmicort	1,176	11	12	840	20	23	156	(10)	92	(7)	(8)	88	(2)	(1)
Daliresp/Daxas	198	29	28	4	-	-	167	25	26	73	73	1	-	-
Tudorza/Eklira	150	(12)	(12)	2	n/m	n/m	66	(14)	73	(12)	(11)	9	-	-
Duaklir	79	25	25	-	n/m	n/m	-	-	77	24	24	2	-	-
Bevespi	16	n/m	n/m	-	-	-	16	n/m	-	-	-	-	-	-
Others	284	(10)	(9)	103	(25)	(24)	5	(44)	129	10	10	47	(6)	(8)
Total Respiratory	4,706	(1)	(1)	1,388	12	13	1,509	(8)	1,216	(5)	(5)	593	1	1
Other														
Nexium	1,952	(4)	(3)	684	(1)	2	499	(10)	248	(1)	(3)	521	(3)	(1)
Synagis	687	1	1	-	-	-	317	(2)	370	5	5	-	-	-
Losec/Prilosec	271	(2)	(1)	140	9	10	11	10	77	(7)	(7)	43	(22)	(20)
Seroquel XR	332	(55)	(55)	62	(10)	(12)	175	(66)	78	(42)	(42)	17	-	-
Movantik/Moventig	122	34	34	-	n/m	n/m	120	33	2	n/m	n/m	-	-	-
FluMist/Fluenz	78	(25)	(28)	(1)	n/m	n/m	-	(100)	76	17	12	3	(50)	(50)
Others	714	(38)	(38)	383	(34)	(32)	47	(55)	142	(47)	(49)	142	(28)	(28)
Total Other	4,156	(18)	(17)	1,268	(14)	(12)	1,169	(28)	993	(14)	(15)	726	(11)	(9)
TOTAL PRODUCT SALES	20,152	(5)	(5)	6,149	6	8	6,169	(16)	4,753	(6)	(7)	3,081	-	1

7 product analysis - Q4 2017

The table below provides an analysis of year-on-year Product Sales, with Actual and CER growth rates reflecting year-on-year growth.

	World			Emerging Markets			US		Europe			Established ROW		
	Q4 2017 \$m	Actual %	CER %	Q4 2017 \$m	Actual %	CER %	Q4 2017 \$m	Actual %	Q4 2017 \$m	Actual %	CER %	Q4 2017 \$m	Actual %	CER %

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Oncology														
Tagrisso	304	107	105	50	n/m	n/m	128	73	63	133	115	63	58	68
Iressa	130	10	8	51	11	7	12	71	32	10	3	35	(3)	3
Lynparza	100	61	58	7	n/m	n/m	54	74	36	44	32	3	n/m	n/m
Imfinzi	18	n/m	n/m	-	-	-	18	n/m	-	-	-	-	-	-
Calquence	3	n/m	n/m	-	-	-	3	n/m	-	-	-	-	-	-
Legacy:														
Faslodex	238	7	5	27	4	4	124	6	62	5	(3)	25	25	30
Zoladex	187	(20)	(21)	93	(21)	(22)	(1)	n/m	37	(5)	(10)	58	(18)	(14)
Casodex	54	(10)	(8)	30	20	20	(2)	n/m	5	(38)	(38)	21	(22)	(19)
Arimidex	57	-	(2)	33	22	22	2	-	8	(20)	(20)	14	(22)	(17)
Others	29	-	3	7	40	40	-	-	(1)	-	-	23	15	20
Total Oncology	1,120	20	19	298	17	15	338	41	242	20	12	242	3	9
CVMD														
Brilinta	299	27	24	49	(8)	(8)	154	47	82	24	15	14	17	8
Farxiga	332	39	37	72	76	76	150	15	71	39	31	39	129	124
Onglyza	180	21	19	37	16	13	103	43	26	(13)	(17)	14	(7)	(13)
Bydureon	147	4	2	4	n/m	n/m	115	1	23	(8)	(8)	5	67	67
Byetta	48	(13)	(13)	3	(40)	(40)	33	(11)	8	-	-	4	(20)	(20)
Symlyn	13	-	-	-	-	-	13	-	-	-	-	-	-	-
Qtern	5	n/m	n/m	1	n/m	n/m	4	n/m	-	-	-	-	-	-
Legacy:														
Crestor	594	(6)	(7)	207	14	14	127	34	152	(27)	(32)	108	(26)	(23)
Seloken/Toprol-XL	168	(6)	(7)	156	16	14	3	(79)	4	(83)	(83)	5	(17)	(17)
Atacand	73	(10)	(10)	43	(4)	(4)	2	(75)	23	-	-	5	-	-
Others	80	(8)	(10)	47	4	-	(2)	n/m	23	(23)	(27)	12	-	-
Total CVMD	1,939	7	6	619	15	14	702	19	412	(11)	(16)	206	(7)	(5)
Respiratory														
Symbicort	752	2	-	117	17	17	288	1	229	-	(7)	118	(6)	(6)
Pulmicort	371	29	26	269	37	34	49	36	26	-	(4)	27	(7)	(7)
Daliresp/Daxas	53	29	27	-	n/m	n/m	43	30	10	n/m	n/m	-	-	-
Tudorza/Eklira	42	17	11	2	-	-	19	19	18	-	-	3	50	50
Duaklir	23	21	16	-	n/m	n/m	-	-	23	28	22	-	-	-
Bevespi	8	n/m	n/m	-	-	-	8	n/m	-	-	-	-	-	-
Others	85	1	(2)	35	21	17	4	n/m	31	(14)	(17)	15	(12)	(18)
Total Respiratory	1,334	10	8	423	29	26	411	10	337	1	(5)	163	(7)	(7)
Other														
Nexium	427	(13)	(12)	168	15	15	57	(58)	72	18	11	130	(12)	(7)
Synagis	234	(23)	(23)	-	-	-	135	(12)	99	(33)	(33)	-	-	-
Losec/Prilosec	69	17	14	36	57	43	2	(33)	20	-	-	11	(15)	(8)
Seroquel XR	108	(8)	(9)	15	(6)	(13)	72	1	17	(39)	(39)	4	33	33
Movantik/Moventig	30	15	15	-	n/m	n/m	29	12	1	n/m	n/m	-	-	-
FluMist/Fluenz	58	(13)	(18)	(1)	n/m	n/m	-	(100)	58	32	25	1	(75)	(75)
Others	168	(32)	(33)	72	(60)	(53)	24	n/m	35	9	(50)	37	48	64
Total Other	1,094	(16)	(17)	290	(21)	(18)	319	(24)	302	(9)	(17)	183	(5)	1
TOTAL PRODUCT SALES	5,487	4	3	1,630	10	9	1,770	9	1,298	(3)	(9)	794	(4)	-

8 QUARTERLY PRODUCT SALES - 2017

The table below provides an analysis of sequential quarterly Product Sales, with Actual and CER growth rates reflecting quarter-on-quarter growth.

	Q1 2017 Actual			CER			Q2 2017 Actual			CER			Q3 2017 Actual			CER			Q4 2017 Actual			CER			
	\$m	%	%	\$m	%	%	\$m	%	%	\$m	%	%	\$m	%	%	\$m	%	%	\$m	%	%	\$m	%	%	
Oncology																									
Tagrisso	171	16	19	232	36	34	248	7	5	304	23	22													
Iressa	124	5	8	137	10	9	137	-	(1)	130	(5)	(6)													
Lynparza	57	(8)	(6)	59	4	2	81	37	33	100	23	22													
Imfinzi	-	-	-	1	n/m	n/m	-	-	-	18	n/m	n/m													
Calquence	-	-	-	-	-	-	-	-	-	3	n/m	n/m													
Legacy:																									
Faslodex	214	(4)	(3)	248	16	15	241	(3)	(5)	238	(1)	(1)													
Zoladex	185	(21)	(12)	178	(4)	(5)	185	4	2	187	1	1													
Casodex	56	(7)	(2)	54	(4)	(3)	51	(6)	(9)	54	6	6													
Arimidex	52	(9)	(7)	54	4	4	54	-	(2)	57	6	6													
Others	26	(10)	(3)	30	15	7	29	(3)	(3)	29	-	3													
Total Oncology	885	(5)	-	993	12	11	1,026	3	1	1,120	9	9													
CVMD																									
Brilinta	224	(5)	(4)	272	21	20	284	4	3	299	5	5													
Farxiga	207	(13)	(13)	250	21	20	285	14	11	332	16	16													
Onglyza	154	3	3	150	(3)	(3)	127	(15)	(17)	180	42	42													
Bydureon	153	8	8	146	(5)	(5)	128	(12)	(14)	147	15	15													
Byetta	46	(16)	(16)	43	(7)	(7)	39	(9)	(9)	48	23	23													
Symlin	14	-	-	11	(21)	(21)	10	(9)	(9)	13	30	30													
Qtern	-	-	-	-	-	-	-	-	-	5	n/m	n/m													
Legacy:																									
Crestor	631	-	3	560	(11)	(12)	580	4	2	594	2	2													
Seloken/Toprol-XL	186	4	6	181	(3)	(4)	160	(12)	(14)	168	5	4													
Atacand	75	(7)	(6)	72	(4)	(5)	80	11	8	73	(9)	(6)													
Others	89	3	12	90	1	(3)	80	(11)	(12)	80	-	(4)													
Total CVMD	1,779	(2)	-	1,775	-	(1)	1,773	-	(2)	1,939	9	9													
Respiratory																									
Symbicort	677	(9)	(7)	706	4	3	668	(5)	(7)	752	13	12													
Pulmicort	337	17	19	226	(33)	(33)	242	7	5	371	53	51													
Daliresp/Daxas	44	7	10	48	9	9	53	10	8	53	-	(2)													
Tudorza/Eklira	37	3	6	34	(8)	(8)	37	9	6	42	14	14													
Duaklir	19	-	-	16	(16)	(15)	21	31	18	23	10	10													
Bevespi	1	(67)	(50)	3	n/m	n/m	4	33	33	8	100	100													
Others	66	(20)	(19)	66	-	(4)	67	2	4	85	27	30													
Total Respiratory	1,181	(2)	(1)	1,099	(7)	(8)	1,092	(1)	(3)	1,334	22	21													
Other																									
Nexium	461	(6)	(4)	595	29	28	469	(21)	(22)	427	(9)	(9)													
Synagis	230	(24)	(24)	70	(70)	(70)	153	n/m	n/m	234	53	53													
Losec/Prilosec	68	15	18	68	-	(3)	66	(3)	(6)	69	5	5													
Seroquel XR	67	(43)	(42)	95	42	38	62	(35)	(36)	108	74	66													
Movantik/Moventig	30	15	15	32	7	7	30	(6)	(6)	30	-	-													

Edgar Filing: ASTRAZENECA PLC - Form 6-K

FluMist/Fluenz	-	n/m	n/m	-	-	-	20	n/m	n/m	58	190	175
Others	142	(42)	(41)	213	50	51	191	(10)	(11)	168	(12)	(12)
Total Other	998	(24)	(22)	1,073	8	7	991	(8)	(9)	1,094	10	10
TOTAL PRODUCT SALES	4,843	(8)	(6)	4,940	2	1	4,882	(1)	(3)	5,487	12	12

9 QUARTERLY PRODUCT SALES - 2016

The table below provides an analysis of sequential quarterly Product Sales, with Actual and CER growth rates reflecting quarter-on-quarter growth.

	Q1 2016 Actual		CER		Q2 2016 Actual		CER		Q3 2016 Actual		CER		Q4 2016 Actual		CER	
	\$m	%	%	\$m	%	%	\$m	%	%	\$m	%	%	\$m	%	%	
Oncology																
Tagrisso	51	183	200	92	80	82	133	45	44	147	11	11				
Iressa	135	5	5	135	-	(2)	125	(7)	(8)	118	(6)	(4)				
Lynparza	44	22	22	54	23	23	58	7	7	62	7	9				
Imfinzi	-	-	-	-	-	-	-	-	-	-	-	-				
Calquence	-	-	-	-	-	-	-	-	-	-	-	-				
Legacy:																
Faslodex	190	3	3	211	11	9	207	(2)	(2)	222	7	9				
Zoladex	178	(10)	(8)	204	15	8	199	(2)	(2)	235	18	11				
Casodex	62	(2)	(6)	63	2	-	62	(2)	(5)	60	(3)	(2)				
Arimidex	57	(5)	(5)	62	9	7	56	(10)	(13)	57	2	5				
Others	21	(22)	(22)	27	29	12	27	-	4	29	7	-				
Total Oncology	738	3	3	848	15	12	867	2	2	930	7	7				
CVMD																
Brilinta	181	4	5	214	18	16	208	(3)	(2)	236	13	15				
Farxiga	165	9	10	211	28	26	220	4	4	239	9	9				
Onglyza	211	10	12	191	(9)	(11)	169	(12)	(11)	149	(12)	(11)				
Bydureon	135	(13)	(16)	156	16	14	145	(7)	(6)	142	(2)	(1)				
Byetta	62	(14)	(14)	76	23	21	61	(20)	(19)	55	(10)	(10)				
Symlin	5	(64)	(64)	10	n/m	n/m	11	10	10	14	27	27				
Qtern	-	-	-	-	-	-	-	-	-	-	-	-				
Legacy:																
Crestor	1,156	(13)	(13)	926	(20)	(21)	688	(26)	(26)	631	(8)	(7)				
Seloken/Toprol-XL	185	16	11	189	2	-	185	(2)	(2)	178	(4)	(2)				
Atacand	71	(17)	(15)	89	25	22	74	(17)	(19)	81	9	14				
Others	121	(9)	(16)	106	(12)	(11)	84	(21)	(19)	86	2	-				
Total CVMD	2,292	(7)	(7)	2,168	(5)	(7)	1,845	(15)	(15)	1,811	(2)	(1)				
Respiratory																
Symbicort	749	(13)	(12)	803	7	6	697	(13)	(13)	740	6	8				
Pulmicort	310	13	14	239	(23)	(23)	224	(6)	(6)	288	29	31				
Daliresp/Daxas	31	(3)	(3)	40	29	29	42	5	5	41	(2)	(2)				
Tudorza/Eklira	39	(17)	(17)	48	23	21	47	(2)	-	36	(23)	(23)				
Duaklir	13	8	8	17	31	31	14	(18)	(18)	19	36	43				
Bevespi	-	-	-	-	-	-	-	-	-	3	n/m	n/m				
Others	65	-	(3)	79	22	18	86	9	12	83	(3)	1				
Total Respiratory	1,207	(6)	(6)	1,226	2	1	1,110	(9)	(9)	1,210	9	10				

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Other												
Nexium	463	(18)	(18)	562	21	20	516	(8)	(9)	491	(5)	(4)
Synagis	244	(11)	(11)	27	(89)	(89)	104	n/m	n/m	302	n/m	n/m
Losec/Prilosec	75	(3)	(4)	70	(7)	(9)	72	3	4	59	(18)	(17)
Seroquel XR	202	(16)	(16)	225	11	11	190	(16)	(16)	118	(38)	(37)
Movantik/Moventig	17	13	13	23	35	35	25	9	9	26	4	4
FluMist/Fluenz	5	(97)	(97)	6	20	20	26	n/m	n/m	67	n/m	n/m
Others	322	(15)	(7)	314	(2)	(4)	270	(14)	(16)	246	(9)	(8)
Total Other	1,328	(24)	(22)	1,227	(8)	(9)	1,203	(2)	(3)	1,309	9	10
TOTAL PRODUCT SALES	5,565	(10)	(10)	5,469	(2)	(3)	5,025	(8)	(8)	5,260	5	6

10 QUARTERLY PRODUCT SALES - 2015

The table below provides an analysis of sequential quarterly Product Sales, with Actual and CER growth rates reflecting quarter-on-quarter growth.

	Q1 2015 Actual		CER		Q2 2015 Actual		CER		Q3 2015 Actual		CER		Q4 2015 Actual		CER	
	\$m	%	%	\$m	%	%	\$m	%	%	\$m	%	%	\$m	%	%	
Oncology																
Tagrisso	-	-	-	-	-	-	-	-	-	18	n/m	n/m				
Iressa	144	(4)	-	129	(10)	(8)	141	9	10	129	(9)	(7)				
Lynparza	9	n/m	n/m	21	133	133	28	33	33	36	29	29				
Imfinzi	-	-	-	-	-	-	-	-	-	-	-	-				
Calquence	-	-	-	-	-	-	-	-	-	-	-	-				
Legacy:																
Faslodex	161	(12)	(6)	172	7	8	186	8	8	185	(1)	1				
Zoladex	194	(15)	(9)	215	11	11	209	(3)	-	198	(5)	(2)				
Casodex	70	(5)	1	69	(1)	-	65	(6)	(4)	63	(3)	(1)				
Arimidex	62	(9)	(5)	64	3	7	64	-	-	60	(6)	(5)				
Others	34	(13)	(10)	37	9	9	35	(5)	-	27	(23)	(16)				
Total Oncology	674	(9)	(4)	707	5	6	728	3	5	716	(2)	-				
CVMD																
Brilinta	131	(2)	3	144	10	13	170	18	19	174	2	4				
Farxiga	76	(19)	(18)	129	70	75	135	5	5	152	13	14				
Onglyza	183	(9)	(5)	208	14	15	203	(2)	(2)	192	(5)	(5)				
Bydureon	123	-	8	140	14	11	162	16	13	155	(4)	(1)				
Byetta	90	30	35	82	(9)	(9)	72	(12)	(12)	72	-	1				
Symlyn	16	60	60	13	(19)	(19)	5	(62)	(62)	14	n/m	n/m				
Qtern	-	-	-	-	-	-	-	-	-	-	-	-				
Legacy:																
Crestor	1,167	(16)	(13)	1,310	12	14	1,218	(7)	(7)	1,322	9	9				
Seloken/Toprol-XL	194	11	22	184	(5)	(4)	172	(7)	(3)	160	(7)	-				
Atacand	95	(19)	(11)	99	4	9	78	(21)	(19)	86	10	13				
Others	155	(7)	7	143	(8)	(7)	132	(8)	(7)	133	1	4				
Total CVMD	2,230	(10)	(6)	2,452	10	12	2,347	(4)	(4)	2,460	5	7				
Respiratory																
Symbicort	845	(14)	(9)	842	-	2	848	1	1	859	1	3				
Pulmicort	286	6	11	232	(19)	(17)	222	(4)	(6)	274	23	26				

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Daliresp/Daxas	7	n/m	n/m	32	n/m	n/m	33	3	3	32	(3)	(3)
Tudorza/Eklira	30	n/m	n/m	55	83	90	58	5	5	47	(19)	(19)
Duaklir	2	n/m	n/m	5	n/m	n/m	8	60	60	12	50	50
Bevespi	-	-	-	-	-	-	-	-	-	-	-	-
Others	73	(4)	12	59	(19)	(20)	61	3	3	65	7	11
Total Respiratory	1,243	(7)	(2)	1,225	(1)	1	1,230	-	-	1,289	5	6
Other												
Nexium	644	(23)	(20)	647	-	3	641	(1)	(2)	564	(12)	(10)
Synagis	204	(50)	(50)	66	(68)	(68)	117	77	77	275	135	135
Losec/Prilosec	96	(13)	(8)	85	(11)	(9)	82	(4)	(5)	77	(6)	(2)
Seroquel XR	262	(15)	(13)	264	1	4	258	(2)	(2)	241	(7)	(6)
Movantik/Moventig	3	n/m	n/m	1	(67)	(67)	10	n/m	n/m	15	50	50
FluMist/Fluenz	7	(95)	(94)	14	n/m	n/m	76	n/m	n/m	191	n/m	n/m
Others	385	12	16	375	(3)	1	361	(4)	2	379	5	2
Total Other	1,601	(25)	(24)	1,452	(9)	(7)	1,545	6	8	1,742	13	13
TOTAL PRODUCT SALES	5,748	(14)	(10)	5,836	2	3	5,850	-	1	6,207	6	7

Shareholder Information

Announcement

of first quarter 18 May 2018

2018 results

Annual General Meeting 18 May 2018

Announcement

of first half and second quarter 26 July 2018

2018 results

Announcement

of nine months and third 8 November 2018

quarter 2018

results

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 2017, payable on 19 March 2018, will be 16 February 2018. The ex-dividend date will be 15 February 2018.

The record date for the first interim dividend for 2018, payable on 10 September 2018, will be 10 August 2018. The ex-dividend date will be 9 August 2018.

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 Duaklir Genuair, Duaklir, Eklira, and Tudorza, trademarks of Almirall, S.A.; Epanova, a trademark of Chrysalis Pharma AG.; Siliq, owned by Leo Pharma A/S or Valeant Pharmaceuticals Luxembourg S.á.r.l (depending on geography); Synagis, owned by AstraZeneca or AbbVie Inc. (depending on geography); Zovance, a trademark of Pfizer Inc.; and Zomig, a trademark of Grünenthal GmbH.

Information on or accessible through AstraZeneca's websites, including astrazeneca.com, does not form part of and is not incorporated into this announcement.

Addresses for Correspondence

Registered Office	Registrar and	Swedish Central Securities	US Depository
1 Francis Crick Avenue	Transfer Office	Depository	Citibank Shareholder Services
Cambridge Biomedical	Equiniti Limited	Euroclear Sweden AB	PO Box 43077
Campus	Aspect House	PO Box 191	Providence
Cambridge	Spencer Road	SE-101 23 Stockholm	RI 02940-3077
CB2 0AA	Lancing	Sweden	USA
UK	West Sussex		
	BN99 6DA		
	UK		
	Tel (Freephone in		Tel: (toll free in the US)
	UK):		+1 (888) 697 8018
Tel: +44 (0)20 3749 5000	0800 389 1580	Tel: +46 (0)8 402 9000	Tel: (outside the US)
	Tel (outside UK):		+1 (781) 575 4555
	+44 (0)121 415 7033		
			citibank@shareholders-online.com

Cautionary Statements Regarding Forward-Looking Statement

In order, among other things, to utilise the 'safe harbour' provisions of the US Private Securities Litigation Reform Act 1995, we are providing the following cautionary statement:

This document contains certain forward-looking statements with respect to the operations, performance and financial condition of the Group, including, among other things, statements about expected revenues, margins, earnings per share or other financial or other measures. Although we believe our expectations are based on reasonable assumptions, any forward-looking statements, by their very nature, involve risks and uncertainties and may be influenced by factors that could cause actual outcomes and results to be materially different from those predicted. The forward-looking statements reflect knowledge and information available at the date of preparation of this document and AstraZeneca undertakes no obligation to update these forward-looking statements. We identify the forward-looking statements by using the words 'anticipates', 'believes', 'expects', 'intends' and similar expressions in such statements. Important factors that could cause actual results to differ materially from those contained in forward-looking statements, certain of which are beyond our control, include, among other things: the loss or expiration of, or limitations to, patents, marketing exclusivity or trademarks, or the risk of failure to obtain and enforce patent protection; effects of patent litigation in respect of IP rights; the impact of any delays in the manufacturing, distribution and sale of any of our products; the impact of any failure by third parties to supply materials or services; the risk of failure of outsourcing;

the risks associated with manufacturing biologics; the risk that R&D will not yield new products that achieve commercial success; the risk of delay to new product launches; the risk that new products do not perform as we expect; the risk that strategic alliances and acquisitions, including licensing and collaborations, will be unsuccessful; the risks from pressures resulting from generic competition; the impact of competition, price controls and price reductions; the risks associated with developing our business in emerging markets; the risk of illegal trade in our products; the difficulties of obtaining and maintaining regulatory approvals for products; the risk that regulatory approval processes for biosimilars could have an adverse effect on future commercial prospects; the risk of failure to successfully implement planned cost reduction measures through productivity initiatives and restructuring programmes; the risk of failure of critical processes affecting business continuity; economic, regulatory and political pressures to limit or reduce the cost of our products; failure to achieve strategic priorities or to meet targets, expectations, guidance or indications; the risk of substantial adverse litigation/government investigation claims and insufficient insurance coverage; the risk of substantial product liability claims; the risk of failure to adhere to applicable laws, rules and regulations; the risk of failure to adhere to applicable laws, rules and regulations relating to anti-competitive behaviour; the impact of increasing implementation and enforcement of more stringent anti-bribery and anti-corruption legislation; taxation risks; exchange rate fluctuations; the risk of an adverse impact of a sustained economic downturn; political and socio-economic conditions; the risk of environmental liabilities; the risk of occupational health and safety liabilities; the risk associated with pensions liabilities; the impact of failing to attract and retain key personnel and to successfully engage with our employees; the risk of misuse of social medial platforms and new technology; and the risk of failure of information technology and cybercrime. Nothing in this document, or any related 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: 02 February 2018

By: /s/ Adrian Kemp

Name: Adrian Kemp

Title: Company Secretary