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

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

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Yes __ No X

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AstraZeneca PLC

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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 Profit2	3,677	(25)	(28)	686	(73)	(71)
Core Operating Profit3	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 Fasenra 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) Fasenra (benralizumab) - severe, uncontrolled asthma (US, EU, JP)
Regulatory Submissions and/or Acceptances	Tagrisso - lung cancer (1st line) (US - Priority Review, EU, JP) ZS-9 - hyperkalaemia (US) Lynparza - ovarian cancer: Priority review (CN) roxadustat - anaemia: Priority review (CN)
Major Phase III Data Readouts and Developments	PT010 - COPD1 (KRONOS trial) (most2 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.

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.

H1 2018	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)) 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)
H2 2018	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 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)
2019	Bevespi - COPD: Regulatory decision (EU) Fasenra - COPD: Data readout PT010 - COPD: Regulatory submission anifrolumab - lupus: Data readout Lynparza - pancreatic cancer: Regulatory submission Lynparza - ovarian cancer (3rd line): Data readout, regulatory submission

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.

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Operating and Financial Review

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

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

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				Q4 2017			
	$m	% of total1	% change Actual	CER	$m	% of total	% change Actual	CER
Royalties	108	5	(9)	(6)	8	3	(82)	(72)
Milestones/Other2	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* $m	FY 2016 $m	Difference $m	Adverse Impact on FY 2017 Product Sales
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)	

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
July 2017	Lynparza	MSD	Global	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
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		FY 2017				Q4 2017			
				% change				% change	
	Medicine	$m	% of total*	Actual	CER	$m	% of total	Actual	CER
Oncology	Tagrisso	955	5	126	126	304	6	107	105
	Iressa	528	3	3					