

ASTRAZENECA PLC  
Form 6-K  
November 08, 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 November 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

1.  
AZN: Year-to-Date and Q3 2018 Results

AstraZeneca PLC  
8 November 2018 07:00 GMT  
Year-to-Date and Q3 2018 Results  
AstraZeneca Returns to Sales Growth; New Medicines and Emerging Markets Lead the Way

Product Sales increased by 4% in the year to date (2% at CER<sup>1</sup>), supporting full-year guidance. For the quarter, Product Sales increased by 8% (9% at CER), driven by the strong performance of new medicines<sup>2</sup> (+85%, +86% at CER) and the sustained strength of Emerging Markets (+12%, +16% at CER). Oncology sales increased by 56% in the quarter (57% at CER); China and US sales increased by 32% and 25%, respectively. The pipeline, designed to deliver sustainable growth and advances in treatment for patients, produced further positive news flow in the period; regular, additional news will continue. The Company is on track to deliver its FY 2018 Product Sales and Core EPS guidance.

	YTD 2018			Q3 2018		
	\$m	% change		\$m	% change	
		Actual	CER		Actual	CER
Total Revenue	15,673	(6)	(8)	5,340	(14)	(13)
Product Sales	15,281	4	2	5,266	8	9
Externalisation Revenue	392	(81)	(81)	74	(95)	(95)
Reported Operating Profit <sup>3</sup>	2,310	(23)	(20)	851	(26)	(21)
Core Operating Profit <sup>4</sup>	3,480	(31)	(31)	1,319	(29)	(26)
Reported Earnings Per Share (EPS)	\$0.88	(34)	(34)	\$0.34	(37)	(36)
Core EPS	\$1.88	(37)	(37)	\$0.71	(37)	(33)

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

"Today marks an important day for the future of AstraZeneca, with the performance in the quarter and year to date showing what we expect will be the start of a period of sustained growth for years to come. Commercial execution has been exceptional and our new medicines are now firmly established as the drivers of growth, supporting our continued success in Emerging Markets.

## Edgar Filing: ASTRAZENECA PLC - Form 6-K

These new medicines are showing great promise, including Tagrisso, Imfinzi, Lynparza in cancer, Farxiga in diabetes and Fasenra in severe asthma. We're also continuing to replenish our early-stage pipeline as we bring our innovative medicines to patients around the world."

### Financial Highlights

Product Sales increased by 4% in the year to date (2% at CER) to \$15,281m; new medicines generated additional sales of \$1.8bn at CER

The Reported Gross Margin declined by two percentage points to 78% in the year to date, partly reflecting the favourable impact of manufacturing variances in the first half of 2017 and the dilutive effect of the Lynparza collaboration with MSD5; the Core Gross Margin declined by two percentage points to 80%

Productivity gains, simplification and the focus on costs continued, with prioritised investment in new medicines and in China delivering strong returns

o Total Reported Operating Expenses were stable in the year to date (down by 2% at CER) to \$11,589m. Total Core Operating Expenses increased by 4% (2% at CER) to \$10,253m

o Reported R&D costs declined by 7% in the year to date (8% at CER) to \$3,920m; Core R&D costs declined by 4% (6% at CER) to \$3,800m, driven by efficiency savings and resource optimisation. Reported SG&A costs increased by 4% in the year to date (1% at CER) to \$7,431m; Core SG&A costs increased by 10% (7% at CER) to \$6,215m, reflecting support for new medicines and growth in China

Externalisation Revenue declined by 81% in the year to date to \$392m, partly driven by the impact of \$997m of income in YTD 2017 as part of the aforementioned collaboration with MSD. Reported Other Operating Income & Expense increased by 55% to \$1,525m; Core Other Operating Income & Expense increased by 4% in the year to date (3% at CER) to \$1,143m, with the difference between the Reported and Core performances reflecting a legal settlement in the first half of the year. The Company anticipates a significant sum of Externalisation Revenue and Other Operating Income & Expense in the final quarter of the year

Restructuring costs declined to \$271m in the year to date (YTD 2017: \$645m); capital expenditure also declined to \$728m (YTD 2017: \$849m). The Company continues to anticipate declines in restructuring costs and capital expenditure over the full year

Reported EPS of \$0.88 in the year to date represented a decline of 34%. The performance reflected a decline in Total Revenue, the Reported Gross Margin and the increase in Reported SG&A costs. Core EPS declined by 37% to \$1.88.

### Commercial Highlights

Oncology: sales growth of 47% in the year to date (44% at CER) to \$4,261m, including:

Tagrisso sales of \$1,266m, representing growth of 94% (91% at CER), with increased use in the treatment of 2nd-line EGFR6 T790M-mutated7 NSCLC8patients and the 2018 approvals in the 1st-line EGFR-mutated (EGFRm) setting as a new standard of care (SoC). Tagrisso sales increased by 104% (105% at CER) to \$506m in the quarter

Lynparza sales of \$438m, representing growth of 122% (118% at CER), driven by expanded use in the treatment of ovarian cancer and the approval for use in the treatment of breast cancer

Imfinzi sales of \$371m (YTD 2017: \$1m), reflecting ongoing launches for the treatment of unresectable, Stage III NSCLC

New CVRM9: 14% growth in the year to date (12% at CER) to \$2,901m, including:

## Edgar Filing: ASTRAZENECA PLC - Form 6-K

Brilinta sales of \$945m, representing growth of 21% (18% at CER), due to continued market penetration in acute coronary syndrome and high-risk post-myocardial infarction (HR PMI)

Farxiga sales of \$994m, with growth of 34% (32% at CER), including a sales increase of 51% in Emerging Markets (57% at CER) to \$242m

Bydureon sales of \$446m, an increase of 4% (3% at CER), reflecting an encouraging Bydureon BCise device launch in the US earlier in the year. Sales increased by 19% in the quarter to \$152m. Bydureon BCise was also approved in the EU in the quarter

Respiratory: 5% growth in the year to date (2% at CER) to \$3,549m, including:

A Symbicort sales decline of 6% (9% at CER) to \$1,925m, as competitive class pressures in the US continued unabated. Emerging Markets sales of Symbicort increased by 13% (12% at CER) to \$364m

Pulmicort sales growth of 11% (7% at CER) to \$897m. China sales increased by 24% (17% at CER) to \$572m

Fasenra sales of \$172m (Q3 2018: \$86m), consolidating its leadership position among novel biologic severe-asthma medicines

Emerging Markets: the Company's largest region by Product Sales, with growth of 13% in the year to date (12% at CER) to \$5,124m, including:

A China sales increase of 33% (27% at CER) to \$2,847m. Oncology sales in China increased by 55% in the year to date (48% at CER) to \$646m, partly underpinned by the launch of Tagrisso in China in 2017, which was added to the National Reimbursement Drug List (NRDL) with effect from Q1 2019 for the treatment of 2nd-line EGFRm T790M-mutated NSCLC. In the quarter, overall China sales increased by 32% to \$954m

An ex-China sales decline of 4% (2% at CER) to \$2,277m, partly impacted by the impact from the loss of Product Sales through externalisation activities. The quarter saw an ex-China sales decline of 6% to \$746m; this, however, represented an improved performance at CER (+1%). Asia-Pacific sales increased by 6% in the quarter to \$269m and Russia sales increased by 2% (11% at CER) to \$56m

### Pipeline Highlights

The table below highlights significant developments in the late-stage pipeline since the prior results announcement:

Regulatory Approvals	<ul style="list-style-type: none"><li>- Lynparza - ovarian cancer (2nd line) (CN)</li><li>- Tagrisso - lung cancer (1st line) (JP)</li><li>- Imfinzi - locally-advanced, unresectable NSCLC (EU)</li><li>- Lumoxiti (moxetumomab pasudotox-tdfk) - hairy cell leukaemia (3rd line) (US)</li><li>- Bydureon BCise autoinjector - type-2 diabetes (EU)</li></ul>
Regulatory Submissions and/or Acceptances	<ul style="list-style-type: none"><li>- Lynparza - ovarian cancer (1st line) (EU, JP, CN)</li><li>- Tagrisso - lung cancer (1st line) (CN)</li><li>- Symbicort - mild asthma (EU)</li><li>- Duaklir - COPD10 (US)</li><li>- Bevespi - COPD (JP, CN)</li><li>- PT010 - COPD (JP, CN)</li></ul>
	<ul style="list-style-type: none"><li>- Lynparza - pancreatic cancer: Orphan Drug Designation (US)</li></ul>

## Edgar Filing: ASTRAZENECA PLC - Form 6-K

Major Phase III Data Readouts or Other Major Developments	- selumetinib - NF111: orphan designation (EU)
	- Farxiga - type-2 diabetes: CVOT12 primary safety endpoint met; one of two primary efficacy endpoints met
	- Bevespi - COPD: CHMP13 positive opinion (EU)
	- tezepelumab - severe asthma: Breakthrough Therapy Designation (US)
	- anifrolumab - lupus (TULIP 1 trial): primary endpoint not met

### Guidance

The Company is on track to deliver its 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

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.

### Additional Commentary

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

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 through divestments and to increasing the focus, over time, on its three main therapy areas

The sum of Externalisation Revenue and Core Other Operating Income & Expense is anticipated to decline. In the year to date, the Company generated a sum of \$1,535m (FY 2017: \$4,266m). Additions to this over the remainder of the year are anticipated to include the impact of:

- o Transactions recently announced - see the Corporate & Business Development section for details. These transactions are subject to customary closing conditions
- o \$400m in potential option payments from the Lynparza collaboration with MSD, which, if MSD chooses to exercise the option, would be recorded in Externalisation Revenue in Q4 2018
- o A sales-related milestone under the same collaboration of \$150m, achieved during October 2018 and to be recorded in Externalisation Revenue in Q4 2018

Core R&D costs in FY 2018 are now anticipated to decline by a low single-digit percentage. The prior indication was for a stable to low single-digit percentage decline. Productivity savings, simplification and improved development processes are helping to deliver cost reductions. High levels of activity remain unchanged, illustrated by the 63 Phase III projects ongoing as at the end of the quarter (end of Q3 2017: 56)

Total Core SG&A costs are now expected to increase broadly in line with the rate seen in the year to date, reflecting support for medicine launches, including Imfinzi in Oncology and Fasenra in Respiratory, as well as additional investment in China. The prior indication was for a low to mid single-digit percentage increase. The Company will retain flexibility in its investment approach, watching closely its impact on Product Sales

AstraZeneca anticipates declines in restructuring costs and capital expenditure

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

#### Currency Impact

Based only on average exchange rates in the nine months to 30 September 2018 and the Company's published currency sensitivities, the Company anticipates a favourable low single-digit percentage impact from currency movements on Product Sales and Core EPS in FY 2018. Details on currency sensitivities are contained within the Operating and Financial Review.

#### Sustainability

AstraZeneca's sustainability ambition is founded on making science accessible and operating in a way that recognises the interconnection between business growth, the needs of society and the limitations of the planet. The Company's sustainability ambition is reinforced by its purpose and values, which are intrinsic to its business model and ensures that the delivery of its strategy broadens access to medicines, minimises the environmental footprint of medicines and processes and ensures that all business activities are underpinned by the highest levels of ethics and transparency. A full update on the Company's sustainability progress is shown in the Sustainability Update section of this announcement.

#### Notes

The following notes refer to pages 1-4:

1. Constant exchange rates. These are not generally-accepted accounting principles (GAAP) financial measures because they remove the effects of currency movements from Reported results.
2. Lynparza, Tagrisso, Imfinzi, Calquence, Lumoxiti, Brilinta, Farxiga, Lokelma, Bevespi and Fasenra. These new medicines are pillars in the three main therapy areas and are important platforms for future growth.
3. Reported financial measures are the financial results presented in accordance with International Financial Reporting Standards.
4. 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.
5. Merck & Co., Inc., Kenilworth, NJ, US, known as MSD outside the US and Canada.
6. Epidermal growth factor receptor.
7. Substitution of threonine (T) with methionine (M) at position 790 of exon 20 mutation.
8. Non-small cell lung cancer.
9. New Cardiovascular, Renal and Metabolism, incorporating Brilinta, Diabetes medicines and Lokelma.
10. Chronic obstructive pulmonary disease.
11. Neurofibromatosis type 1.
12. Cardiovascular outcomes trial.

13. Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA).

The performance shown in this announcement covers the nine-month period to 30 September 2018 (the year to date or YTD 2018) and the three-month period to 30 September 2018 (the quarter, the third quarter or Q3 2018) compared to the nine-month period to 30 September 2017 (YTD 2017) and the three-month period to 30 September 2017 (Q3 2017) respectively, unless stated otherwise. All commentary in the Operating and Financial Review relates to the year to date, 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 (1st line): regulatory submission (US)

Imfinzi +/- treme - lung cancer (1st line) (MYSTIC): data readout (final OS14), regulatory submission

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

Q4 2018

Farxiga - type-1 diabetes: regulatory submission acceptance (US)

roxadustat - anaemia: data readout, regulatory approval (CN)

Bevespi - COPD: regulatory decision (EU)

Lynparza - breast cancer: regulatory decision (EU)

Lynparza - pancreatic cancer: data readout

Imfinzi +/- treme - head & neck cancer (1st line): data readout, regulatory submission

Imfinzi +/- treme - head & neck cancer (2nd line): regulatory submission

Imfinzi + treme - lung cancer (1st line) (NEPTUNE): data readout

H1 2019

Brilinta - CAD15 / type-2 diabetes CVOT: data readout

Farxiga - type-2 diabetes CVOT: regulatory submission

roxadustat - anaemia: data readout (pooled safety), regulatory submission (US)

Duaklir - COPD: regulatory decision (US)

H2 2019 Lynparza - ovarian cancer (1st line): regulatory decision (EU, JP, CN)

Lynparza - pancreatic cancer: regulatory submission

Lynparza - ovarian cancer (1st line) (PAOLA-1): data readout

Lynparza - prostate cancer (2nd line, castration resistant): data readout

Tagrisso - lung cancer (1st line): regulatory decision (CN)

Tagrisso - lung cancer (1st line): data readout (final OS)

selumetinib - NF1: regulatory submission

Imfinzi + treme - lung cancer (1st line) (NEPTUNE): regulatory submission

Imfinzi +/- treme - lung cancer (1st line) (POSEIDON): data readout, regulatory submission

Imfinzi +/- treme - small-cell lung cancer: data readout, regulatory submission

Imfinzi +/- treme - bladder cancer (1st line): data readout, regulatory submission

Calquence - CLL16: data readout, regulatory submission

Brilinta - CAD / type-2 diabetes CVOT: regulatory submission

Forxiga - type-1 diabetes: regulatory decision (EU, JP)

Lokelma - hyperkalaemia: regulatory submission (JP)

Symbicort - mild asthma: regulatory decision (EU)

## Edgar Filing: ASTRAZENECA PLC - Form 6-K

Bevespi - COPD: regulatory decision (JP, CN)  
PT010 - COPD: regulatory decision (JP), regulatory submission (US, EU)  
PT010 - COPD: data readout (ETHOS)

Lynparza - ovarian cancer (1st line) (PAOLA-1): regulatory submission  
Lynparza - prostate cancer (2nd line, castration resistant): regulatory submission  
Imfinzi - lung cancer (Stage I-III; adjuvant): data readout  
Imfinzi - lung cancer (1st line) (PEARL): data readout, regulatory submission

Brilinta - stroke: data readout, regulatory submission  
Farxiga - heart failure CVOT: data readout, regulatory submission  
2020 Farxiga - CKD17: data readout  
Epanova - hypertriglyceridaemia (CVOT): data readout  
Lokelma - hyperkalaemia: regulatory submission (CN)  
roxadustat - anaemia of myelodysplastic syndrome: data readout

Fasenra - nasal polyps: data readout, regulatory submission  
PT010 - COPD: regulatory decision (CN)  
tezepelumab - severe asthma: data readout

### Conference Call

A conference call and webcast for investors and analysts will begin at 12pm UK time today. Details can be accessed via [astrazeneca.com](http://astrazeneca.com).

### Reporting Calendar

The Company intends to publish its full-year and fourth-quarter financial results on 14 February 2019.

### 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 therapy areas - Oncology, CVRM and Respiratory. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information, please visit [astrazeneca.com](http://astrazeneca.com) and follow us on Twitter @AstraZeneca.

### Investor Relations

Thomas Kudsk Larsen		+44 203 749 5712
Henry Wheeler	Oncology	+44 203 749 5797
Christer Gruvris	Cardiovascular; Metabolism	+44 203 749 5711
Nick Stone	Respiratory; Renal	+44 203 749 5716
Josie Afolabi	Other	+44 203 749 5631
Craig Marks	Finance; Fixed Income	+44 7881 615 764
Jennifer Kretzmann	Retail Investors	+44 203 749 5824
US toll-free		+1 866 381 7277

### Media Relations

Gonzalo Viña	UK/Global	+44 203 749 5916
Karen Birmingham	UK/Global	+44 203 749 5634
Rob Skelding	UK/Global	+44 203 749 5821
Matt Kent	UK/Global	+44 203 749 5906
Jennifer Hursit	UK/Global	+44 7384 799 726
Jacob Lund	Sweden	+46 8 553 260 20



Michele Meixell

US

+1 302 885 2677

## 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 nine-month period to 30 September 2018 (the year to date or YTD 2018) and the three-month period to 30 September 2018 (the quarter, the third quarter or Q3 2018) compared to the nine-month period to 30 September 2017 (YTD 2017) and the three-month period to 30 September 2017 (Q3 2017) respectively, unless stated otherwise. All commentary in the Operating and Financial Review relates to the year to date, 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 investors and analysts with helpful supplementary information to understand better 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 68 of the Annual Report and Form 20-F Information 2017. Reference should be made to the reconciliation of Core to Reported financial information and the Reconciliation of Reported to Core Financial Measures tables included in the Financial Performance section of this announcement.

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 Note 3 'Net Debt' included in the Notes to the Interim Financial Statements 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, milestone revenue and profit-sharing income. Reference should be made to the Breakdown of Externalisation Revenue table in this Operating and Financial Review.

Edgar Filing: ASTRAZENECA PLC - Form 6-K

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

Table 1: Total Revenue

	YTD 2018			Q3 2018		
	\$m	% change		\$m	% change	
		Actual	CER		Actual	CER
Total Revenue	15,673	(6)	(8)	5,340	(14)	(13)
Product Sales	15,281	4	2	5,266	8	9
Externalisation Revenue	392	(81)	(81)	74	(95)	(95)

Table 2: Product Sales

	YTD 2018				Q3 2018			
	\$m	% of total18	% change		\$m	% of total	% change	
			Actual	CER			Actual	CER
Oncology	4,261	28	47	44	1,597	30	56	57
New CVRM	2,901	19	14	12	1,027	20	18	19
Respiratory	3,549	23	5	2	1,142	22	5	5
Other	4,570	30	(22)	(23)	1,500	28	(21)	(19)
Total	15,281	100	4	2	5,266	100	8	9

Table 3: Top-Ten Medicines

The top-ten medicines in the year to date by sales are shown in the table below:

Medicine	Therapy Area	\$m	% of Total Product Sales <sup>19</sup>
Symbicort	Respiratory	1,925	13
Nexium	Other	1,312	9
Tagrisso	Oncology	1,266	8
Crestor	CVRM	1,080	7
Farxiga	CVRM	994	7
Brilinta	CVRM	945	6
Pulmicort	Respiratory	897	6
Faslodex	Oncology	759	5
Zoladex	Oncology	570	4
Seloken/Toprol-XL	CVRM	552	4
Total		10,300	67

Table 4: Breakdown of Externalisation Revenue

Ongoing Externalisation Revenue of \$280m represented 71% of total Externalisation Revenue in the year to date (YTD 2017: \$531m, 26%). The Company anticipates that Ongoing Externalisation Revenue, including the impact of the aforementioned MSD collaboration will grow as a proportion of Externalisation Revenue over time. A breakdown of Externalisation Revenue is shown below:

	YTD 2018				Q3 2018			
	\$m	% of total	% change		\$m	% of total	% change	
			Actual	CER			Actual	CER
Initial Externalisation Revenue	112	29	(93)	(93)	10	14	(99)	(99)
Royalties	38	10	(62)	(62)	17	23	(43)	(40)
Milestones/Other <sup>21</sup>	242	62	(44)	(44)	47	64	(83)	(84)
Ongoing Externalisation Revenue	280	71	(47)	(47)	64	86	(79)	(79)
Total Externalisation Revenue	392	100	(81)	(81)	74	100	(95)	(95)

Table 5: Initial Externalisation Revenue

A breakdown of Initial Externalisation Revenue in the year to date is shown below:

Medicine	Party	Region	\$m
Crestor	Almirall, S.A.	Spain	61
Other			51
Total			112

Table 6: Ongoing Externalisation Revenue

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

Medicine	Party	Region	\$m
Lynparza	MSD - milestone revenue (regulatory milestone)	Global	70
Lynparza	MSD - milestone revenue (sales-related milestone)	Global	100
Other			110
Total			280

Table 7: Externalised and Divested Medicines

Several AstraZeneca medicines were externalised or divested after 30 September 2017, thus adversely impacting the Product Sales performance:

Completion	Medicine	Region	YTD 2018 <sup>22</sup>	YTD 2017
------------	----------	--------	------------------------	----------

					Adverse Impact on YTD 2018 Product Sales			
					\$m	\$m	\$m	%
October 2017	Anaesthetics		Global		36	242	(206)	
January 2018	Crestor		Spain		5	61	(56)	
June 2018	Seroquel and Seroquel XR		UK, China and other countries		110	99	-23	
Total							(262)	2%

Table 8: Ongoing Externalisation Revenue Agreements

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

Completion	Medicine	Party	Region	Externalisation Revenue
July 2017	Lynparza	MSD	Global	Initial \$1bn revenue Up to \$750m for certain licence options, including \$250m paid in Q4 2017 and \$400m anticipated in Q4 2018
March 2017	MEDI8897	Sanofi Pasteur, Inc. (Sanofi Pasteur)	Global	Up to \$6.15bn in regulatory and sales milestones Initial €120m revenue Up to €495m in sales and development-related milestones
March 2017	Zoladex	TerSera Therapeutics LLC (TerSera)	US and Canada	Initial \$250m revenue Up to \$70m in sales-related milestones Mid-teen percentage royalties on sales

#### Product Sales

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

Table 9: Therapy Area and Medicine Performance

Therapy Area	Medicine	YTD 2018				Q3 2018			
		\$m	% of total <sup>24</sup>	% change		\$m	% of total	% change	
				Actual	CER			Actual	CER
	Tagrisso	1,266	8	94	91	506	10	n/m	n/m
	Lynparza	438	3	n/m	n/m	169	3	n/m	n/m
	Iressa	406	3	2	(2)	131	2	(4)	(4)

Edgar Filing: ASTRAZENECA PLC - Form 6-K

	Imfinzi	371	2	n/m	n/m	187	4	n/m	n/m
	Calquence	38	-	n/m	n/m	18	-	n/m	n/m
	LEGACY:								
	Faslodex	759	5	8	6	258	5	7	8
	Zoladex	570	4	4	2	194	4	5	8
	Arimidex	166	1	4	1	55	1	2	4
	Casodex	155	1	(4)	(7)	51	1	-	2
	Others	92	1	8	5	28	1	(3)	(6)
	Total Oncology	4,261	28	47	44	1,597	30	56	57
	Brilinta	945	6	21	18	336	6	18	20
	Farxiga	994	7	34	32	355	7	25	27
	Bydureon	446	3	4	3	152	3	19	19
	Onglyza	395	3	(8)	(10)	140	3	10	12
	Byetta	94	1	(27)	(27)	34	1	(13)	(10)
	Symlin	24	-	(31)	(31)	8	-	(20)	(20)
CVRM	LEGACY:								
	Crestor	1,080	7	(39)	(41)	353	7	(39)	(38)
	Seloken/Toprol-XL	552	4	5	4	179	3	12	17
	Atacand	202	1	(11)	(11)	65	1	(19)	(15)
	Others	231	2	(11)	(14)	73	1	(9)	(6)
	Total CVRM	4,963	32	(7)	(8)	1,695	32	(4)	(3)
	Symbicort	1,925	13	(6)	(9)	619	12	(7)	(7)
	Pulmicort	897	6	11	7	264	5	9	10
	Fasenra	172	1	n/m	n/m	86	2	n/m	n/m
	Daliresp/Daxas	135	1	(7)	(8)	52	1	(2)	(2)
Respiratory	Tudorza/Eklira	91	1	(16)	(19)	18	-	(51)	(51)

Edgar Filing: ASTRAZENECA PLC - Form 6-K

	Duaklir	73	-	30	20	23	-	10	5
	Bevespi	23	-	n/m	n/m	10	-	n/m	n/m
	Others	233	2	17	12	70	1	4	6
	Total Respiratory	3,549	23	5	2	1,142	22	5	5
	Nexium	1,312	9	(14)	(16)	422	8	(10)	(9)
	Synagis	414	3	(9)	(9)	164	3	7	7
	Losec/Prilosec	212	1	5	-	67	1	2	2
Other	Seroquel XR	169	1	(25)	(26)	40	1	(35)	(35)
	Movantik/Moventig	84	1	(9)	(9)	32	1	7	7
	FluMist/Fluenz	35	-	75	75	35	1	75	75
	Others	282	2	(49)	(50)	72	1	(62)	(62)
	Total Other	2,508	16	(18)	(20)	832	16	(16)	(15)
	Total Product Sales	15,281	100	4	2	5,266	100	8	9

Specialty-care medicines comprise all Oncology medicines and Fasenra. At 29% of Product Sales, specialty-care-medicine sales increased by 53% in the year to date (50% at CER) to \$4,433m. In the first nine months of 2017, speciality-care medicines comprised 20% of Product Sales.

#### Product Sales Summary

##### Oncology

Product Sales of \$4,261m in the year to date; an increase of 47% (44% at CER). Oncology Product Sales represented 28% of total Product Sales, up from 20% in first nine months of 2017.

##### Lynparza

By the end of the period, Lynparza was approved in over 60 countries for the treatment of ovarian cancer. Launches in the treatment of breast cancer took place in the US and Japan in 2017 and the indication is under regulatory review in Europe.

Product Sales of Lynparza amounted to \$438m, an increase of 122% (118% at CER). The strong performance was geographically spread, with ongoing launches in the Established Rest of World (ROW) and Emerging Markets. The ongoing MSD co-promotion efforts also contributed to sales.

US sales increased by 168% in the year to date to \$233m; the performance reflected continued growth in the treatment by Lynparza in both ovarian and breast cancer patients. Lynparza remained the leading US medicine in the poly ADP ribose polymerase (PARP)-inhibitor class in the year to date, as measured by total prescription volumes. A reduction in sequential growth in the quarter reflected returns associated with the discontinuation of capsules and switch to tablets.

Sales in Europe increased by 46% in the year to date (37% at CER) to \$137m, driven by strong levels of reimbursement and high BRCA-testing rates. The Company also rolled out a number of launches in a broad, 2nd-line, ovarian-cancer indication, regardless of BRCA status. In the first half of the year, the Company announced that the EMA had approved the use of Lynparza tablets (300mg twice daily) for the same patient population.

Japan sales in the year to date of \$25m followed the initial launch in April 2018 as a treatment for 2nd-line ovarian cancer. In July 2018, an additional approval was granted as a targeted chemotherapy-sparing treatment for BRCAm, metastatic breast cancer.

Emerging Markets sales of \$33m in the year to date reflected the approval by the China National Medical Products Administration (NMPA), resulting in the subsequent launch of Lynparza in China, the first PARP inhibitor to be approved in the country.

## Lung Cancer

### Tagrisso

By the end of the period, Tagrisso had been approved in c.40 countries including the US, in the EU and in Japan, for the treatment of 1st-line EGFRm NSCLC; a number of additional regulatory reviews are also underway. In the 2nd-line setting, Tagrisso has been approved and launched in over 80 countries, including the US, in Europe, Japan and China for patients with EGFR T790M-mutated NSCLC.

Product Sales of \$1,266m in the year to date represented growth of 94% (91% at CER), partly driven by increased testing rates and the aforementioned approvals in the 1st-line setting. Continued growth was also delivered in the 2nd-line indication in other countries. Tagrisso is now AstraZeneca's third-largest selling medicine and best-selling Oncology medicine.

Sales in the US increased by 109% in the year to date to \$580m, with sequential growth in the quarter of 23% to \$239m, reflecting a rapid uptake in the 1st-line setting that followed the April 2018 approval of Tagrisso as a 1st-line treatment for patients with metastatic, EGFRm NSCLC. The medicine achieved market leadership in new patient starts. During the period, Tagrisso was also assigned Category 1 status as a preferred regimen in the treatment of EGFRm NSCLC within the National Comprehensive Cancer Network (NCCN) guidelines.

Within Emerging Markets, Tagrisso sales increased by 213% in the year to date (206% at CER) to \$266m, with notable growth in China, where the medicine was approved in March 2017 as a 2nd-line treatment for patients with EGFR T790M-mutated NSCLC. The Asia-Pacific region has a relatively high prevalence of lung-cancer patients with an EGFR mutation, namely c.30-40% of the total, contrasting with c.10-15% in the Western hemisphere. During the period, it was announced that Tagrisso will enter the NRDL from Q1 2019 for the treatment of 2nd-line, EGFRm NSCLC patients with the T790M mutation.

In Europe, sales of \$222m in the year to date represented growth of 79% (68% at CER), driven by further growth in testing rates, positive reimbursement decisions and strong levels of demand. Sales in Europe increased sequentially from Q2 2018 to Q3 2018 by 19% (23% at CER) to \$83m, as the medicine reached more patients in each country and the benefit was felt from the EU regulatory approval in June 2018 for the 1st-line treatment of patients with EGFRm NSCLC. Tagrisso was subsequently launched in a number of countries in this setting, including in France and Germany; reimbursement negotiations are underway elsewhere.

Sales of Tagrisso in Japan increased by 21% in the year to date (18% at CER) to \$191m, reflecting focused activities to maximise testing and utilisation rates in the 2nd-line indication. During the third quarter, Tagrisso was approved in Japan as a 1st-line treatment for patients with EGFRm NSCLC.

#### Imfinzi

Imfinzi is approved for the treatment of patients with unresectable, Stage III NSCLC whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy (CRT); it is approved in more than 40 countries, including the US, in the EU and Japan. It is also approved for the 2nd-line treatment of patients with locally-advanced or metastatic urothelial carcinoma (bladder cancer) in a number of countries, including the US.

During the period, approval was granted for Imfinzi in the EU for the treatment of locally-advanced, unresectable NSCLC in adult patients whose tumours express programmed death-ligand 1 (PD-L1) on 1% or more of tumour cells and whose disease has not progressed following platinum-based CRT. All approvals granted since approval was received in the EU have been based on an all-comer population.

Global Product Sales of Imfinzi amounted to \$371m in the year to date (Q3 2018: \$187m), with sales for the treatment of unresectable, Stage III NSCLC representing the overwhelming majority. The US represented the greater part of the global sales, where Imfinzi was assigned Category 1 status for the treatment of unresectable, Stage III NSCLC within the NCCN guidelines. \$23m of sales were recorded in other markets following approvals and launches, with time taken to achieve reimbursement decisions in many markets. Additional regulatory approvals are anticipated in due course.

#### Iressa

Product Sales of \$406m in the year to date; an increase of 2% (down by 2% at CER).

Emerging Markets sales increased by 13% (10% at CER) to \$226m; Iressa entered the NRDL in China in 2017. Sales in the US declined by 26% to \$20m and increased in Europe by 6% (down 3% at CER) to \$85m.

#### Other Oncology Medicines

##### Calquence

Product Sales of \$38m in the year to date; Calquence was approved and launched in the US in October 2017. The medicine delivered a promising performance, with more than one third of new patients now treated with Calquence in the approved indication.

##### Legacy: Faslodex

Product Sales of \$759m in the year to date; an increase of 8% (6% at CER), reflecting volume growth.

Emerging Markets sales of Faslodex increased by 26% in the year to date (28% at CER) to \$111m. US sales increased by 7% to \$394m, highlighting a continued strong uptake of the combination with the CDK4/6 class, medicines approved for the treatment of hormone-receptor-positive breast cancer.

Europe sales declined by 12% in the year to date (19% at CER) to \$171m, reflecting the impact of generic entrants in certain countries. In June 2017, a label extension, based upon the FALCON trial in the 1st-line setting, was approved in Japan, where sales increased by 56% in the year to date (52% at CER) to \$78m, despite the impact of the biennial price cut, implemented in April 2018.

##### Legacy: Zoladex

Product Sales of \$570m in the year to date; an increase of 4% (2% at CER).



## Edgar Filing: ASTRAZENECA PLC - Form 6-K

Emerging Markets sales of Zoladex increased by 20% in the year to date to \$313m. Sales in Europe declined by 5% (12% at CER) to \$99m. In the Established ROW region, sales declined by 10% (11% at CER) to \$152m, driven by the effects of increased competition. In March 2017, the Company completed an agreement with TerSera for the sale of the commercial rights to Zoladex in the US and Canada.

### CVRM

New CVRM sales increased by 14% in the year to date (12% at CER) to \$2,901m, partly reflecting the strong performance of Farxiga. Total CVRM sales, which includes Crestor and other legacy medicines, declined by 7% (8% at CER) to \$4,963m. Total CVRM sales comprised 32% of total Product Sales in the year to date.

### Brilinta

Product Sales of \$945m in the year to date; an increase of 21% (18% at CER).

Emerging Markets sales of Brilinta increased by 33% in the year to date (31% at CER) to \$232m, bolstered by the entry onto the NRDL in China in 2017. US sales of Brilinta, at \$411m, represented an increase of 16%. The performance, underlined by volume growth, was driven primarily by an increase in the number of patients initiated on Brilinta in hospitals and an increase in the volume of 90-day prescriptions. Furthermore, Brilinta continued to deliver increasing levels of market share during the period. US sales increased by 9% in the quarter to \$152m.

Sales of Brilique in Europe increased by 21% in the year to date (12% at CER) to \$257m, highlighting indication leadership across a number of markets.

### Farxiga

Product Sales of \$994m in the year to date; an increase of 34% (32% at CER). Farxiga maintained a global leading position within the growing sodium-glucose co-transporter 2 (SGLT2)-inhibitor class.

Emerging Markets sales increased by 51% in the year to date (57% at CER) to \$242m, reflecting ongoing launches and improved levels of patient access. In March 2017, Farxiga became the first SGLT2-inhibitor medicine to be approved in China; since the subsequent launch, the medicine has seen growing levels of access.

US sales increased by 24% in the year to date to \$420m. The performance in the first half of 2017 was adversely impacted by the Company's affordability programmes; subsequent changes to the Company's approach to these programmes, however, helped to deliver a much-improved performance from Q3 2017 onwards. Despite slowing growth in the US, the SGLT2 class continues to be underpinned by growing evidence around cardiovascular benefits, including data from the CVD-REAL series of studies (first published in May 2017), showing a statistically-significant reduced rate of hospitalisation for heart failure (hHF) and death from any cause compared to other type-2 diabetes medicines.

Sales in Europe increased by 35% in the year to date (25% at CER) to \$231m. In Japan, sales increased by 48% (45% to CER) to \$46m. Ono Pharmaceutical Co., Ltd, collaborating with AstraZeneca, records in-market sales in Japan.

### Bydureon

Product Sales of \$446m in the year to date; an increase of 4% (3% at CER). An encouraging Bydureon BCise device launch in the US earlier in the year underpinned a global increase in Q3 2018 sales of 19% to \$152m.

Sales in the US increased by 5% in the year to date to \$360m; in the quarter, US sales increased by 26% to \$126m. This illustrated a continued encouraging performance from the aforementioned Bydureon BCise launch. Favourable sales volumes were driven by continued growth in the glucagon-like peptide-1 class, at the expense of insulin, for more-advanced type-2 diabetes. Bydureon sales in Europe declined by 5% (12% at CER) to \$62m. In August 2018, the Company announced that Bydureon BCise had been approved in the European market.

### Onglyza

Product Sales of \$395m in the year to date, a decline of 8% (10% at CER).

The overall 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 proven CV benefits. Given the significant future potential of Farxiga, the Company continues to prioritise commercial support over Onglyza.

Sales in Emerging Markets increased by 30% in the year to date (29% at CER) to \$121m; this partly reflected the entry onto the NRDL in China in 2017. Sales in Europe declined by 13% (18% at CER) to \$68m, highlighting the broader trend of a shift away from the DPP-4 class.

### Lokelma

Lokelma's launch programme recently began in the Nordic region. It is approved in the US and EU for the treatment of hyperkalaemia, a serious condition characterised by elevated potassium levels in the blood associated with CV, renal and metabolic diseases.

### Legacy: Crestor

Product Sales of \$1,080m in the year to date; a decline of 39% (41% at CER).

Sales in China increased by 29% in the year to date (22% at CER) to \$351m, a result of underlying demand. Market growth in statin usage, AstraZeneca's commercial strength in China and the Company's successful strategy of broader coverage in China also continued to impact sales favourably.

US sales declined by 48% in the year to date to \$128m, underlining the ongoing impact of the entry of multiple Crestor generic medicines in 2016. In Europe, sales declined by 69% (71% at CER) to \$159m, reflecting a similar impact that began in 2017. AstraZeneca expects these impacts to recede over time.

In Japan, where AstraZeneca collaborates with Shionogi Co. Ltd, sales declined by 69% in the year to date (70% at CER) to \$122m, reflecting the impact of the entry of multiple Crestor competitors in the market in the final quarter of 2017; AstraZeneca expects this impact to recede significantly from 2019. The decline also reflected actions by the Japanese government to focus further on incentives to increase the adoption of generic medicines.

### Respiratory

Product Sales of \$3,549m in the year to date; an increase of 5% (2% at CER). Respiratory Product Sales represented 23% of total Product Sales, unchanged on the first nine months of 2017.

### Symbicort

Product Sales of \$1,925m in the year to date; a decline of 6% (9% at CER).

Symbicort continued to lead the global market by volume within the inhaled corticosteroid / long-acting beta agonist (LABA) class.

Emerging Markets sales of Symbicort increased by 13% in the year to date (12% at CER) to \$364m. In contrast, US sales declined by 19% to \$655m, reflecting continued pricing pressure, the timing of government buying and the impact of managed-market rebates. The performance was in line with expectations, with challenging pricing pressure expected to continue.

In Europe, sales were stable in the year to date (down by 8% at CER) to \$588m; the performance reflected the level of competition from other branded and Symbicort-analogue medicines, plus government pricing interventions. Symbicort, however, continued to retain its class-leadership position and stabilise its volume market

share in the class, with a number of markets achieving volume growth. In Japan, where Astellas Pharma Co. Ltd (Astellas) assists as a promotional collaborator, sales were stable in the year to date (down by 2% at CER) to \$151m, despite the impact of the aforementioned biennial price cut.

#### Pulmicort

Product Sales of \$897m in the year to date; an increase of 11% (7% at CER).

Emerging Markets, where sales increased by 20% in the year to date (16% at CER) to \$688m, represented 77% of global sales of Pulmicort. China, making up the overwhelming majority of Pulmicort sales in Emerging Markets, delivered a particularly strong performance, supported by higher demand, strong underlying volume growth and AstraZeneca's investment in increasing the number of nebulisation centres.

Sales in the US and Europe declined by 24% in the year to date to \$81m and increased by 3% (down by 5% at CER) to \$68m, respectively, a consequence of the medicine's legacy status in the Western hemisphere.

#### Fasenra

Product Sales of \$172m in the year to date (Q3 2018: \$86m).

In November 2017, the Company was granted approval for Fasenra in the US as a treatment for patients with severe, eosinophilic asthma; the approval was followed immediately by the launch of the medicine and US sales amounted to \$129m in the year to date. New-to-brand prescription data showed that Fasenra led the class of novel biologic medicines in asthma at the end of the period, despite being third to market.

In Europe and Japan, AstraZeneca was granted regulatory approval in January 2018 on a similar basis to that in the US. In Europe, sales totalled \$17m in the year to date, with launches progressing in a number of countries. Sales in Japan amounted to \$26m in the year to date, following its launch in the second quarter; Fasenra is already leading the class by value share in Japan.

#### Daliresp/Daxas

Product Sales of \$135m in the year to date; a decline of 7% (8% at CER).

US sales, representing 81% of the global total, declined by 11% to \$110m, driven by the impact of low market growth and payer pressures. It is the only oral, selective, long-acting inhibitor of phosphodiesterase-4, an inflammatory enzyme associated with COPD. Sales in Europe increased by 25% (19% at CER) to \$20m.

#### Tudorza/Eklira

Product Sales of \$91m in the year to date; a decline of 16% (19% at CER).

Sales in the US declined by 40% to \$28m, reflecting the impact of federal purchases. In March 2017, AstraZeneca announced that it had entered a strategic collaboration with Circassia Pharmaceuticals plc (Circassia) for the development and commercialisation of Tudorza in the US, where AstraZeneca records Product Sales. Sales in Europe declined 2% in the year to date (7% at CER) to \$54m, impacted by the decline of the overall long-acting muscarinic antagonist (LAMA) monotherapy class.

#### Duaklir

Product Sales of \$73m in the year to date; an increase of 30% (20% at CER).

Duaklir, the Company's first inhaled dual bronchodilator medicine, is now available for patients in over 25 countries, with almost all sales emanating from Europe. Germany and the UK accounted for 54% of all European sales in the year to date. The global LAMA/LABA class continued to grow in the period, albeit below expectations.

#### Bevespi

Product Sales increased by 188% in the year to date to \$23m.

Introduced in the US in Q1 2017, Bevespi saw prescriptions in the period track in line with other LAMA/LABA launches; the overall class in the US, however, continued to grow more slowly than anticipated previously. Bevespi was the first medicine launched using the Company's proprietary co-suspension technology.

#### Other

Product Sales of \$2,508m; a decline of 18% (20% at CER). Other Product Sales represented 16% of total Product Sales, down from 21% in the first nine months of 2017.

#### Nexium

Product Sales of \$1,312m in the year to date; a decline of 14% (16% at CER).

Emerging Markets sales increased by 2% in the year to date (stable at CER) to \$524m, while sales in the US declined by 44% to \$249m; in Europe, sales increased by 2% (down by 5% at CER) at \$179m. On 30 October 2018, AstraZeneca announced that it had agreed to divest the prescription medicine rights to Nexium in Europe. In Japan, where AstraZeneca collaborates with Daiichi Sankyo Company, Limited, sales declined by 6% (8% at CER) to \$309m, reflecting the aforementioned biennial price cut.

#### Synagis

Product Sales of \$414m in the year to date; a decline of 9%.

US sales declined by 27% to \$133m and continued to be impacted by the prevailing guidelines from the American Academy of Pediatrics Committee on Infectious Diseases. Product Sales to AbbVie Inc., responsible for the commercialisation of Synagis in over 80 countries outside the US, increased by 4% to \$281m.

#### Seroquel XR

Product Sales of \$169m in the year to date; a decline of 25% (26% at CER).

Sales of Seroquel XR in the US declined by 35% to \$67m, reflecting the ongoing impact of generic-medicine competition. Sales of Seroquel XR in Europe declined by 21% (26% at CER) to \$48m, highlighting a similar impact. In May 2018, the Company announced that it had entered into an agreement with Luye Pharma Group, Ltd. (Luye Pharma) for the sale and licence of the rights to Seroquel and Seroquel XR in the UK, China and other markets, impacting Product Sales growth in the quarter.

#### FluMist/Fluenz

Product Sales of \$35m in the year to date; an increase of 75%. FluMist returned to the US market in Q3 2018 in time for the 2018-2019 influenza season and US sales amounted to \$15m (H1 2018: \$nil). Sales of Fluenz in Europe increased by 11% to \$20m.

#### Regional Product Sales

Table 10: Regional Product Sales

YTD 2018

Q3 2018

Edgar Filing: ASTRAZENECA PLC - Form 6-K

	\$m	% of total	% change 25	Actual	\$m	% change of Actual total	CER
Emerging Markets	5,124	34	13	12	1,700	32	16
China	2,847	19	33	27	954	38	32
Ex-China	2,277	15	(4)	(2)	746	(6)	1
US	4,839	32	10	10	1,737	33	25
Europe	3,286	22	(5)	(11)	1,132	(5)	(5)
Established ROW	2,032	13	(11)	(13)	697	(12)	(11)
Japan	1,416	9	(14)	(16)	501	(13)	(13)
Canada	358	2	1	(1)	114	(1)	2
Other Established ROW	258	2	(11)	(11)	82	(17)	(11)
Total	15,281	100	4	2	5,266	800	9

#### Emerging Markets

Product Sales of \$5,124m in the year to date, an increase of 13% (12% at CER). Q3 2018 sales of \$1,700m represented an increase of 12% (16% at CER) and continued the strong double-digit growth seen in prior periods.

China sales, comprising 56% of total Emerging Markets sales, increased by 33% in the year to date (27% at CER) to \$2,847m and by 32% in the quarter to \$954m. New medicines delivered particularly encouraging sales growth, compounded by strong performances from Pulmicort, Seloken, Crestor, Symbicort and Zoladex. The new medicines represented 11% of China sales in the year to date, up from 7% in the first nine months of 2017. On 25 October 2018, the Chinese National Health Commission and the State Administration of Traditional Chinese Medicines published the 2018 Essential Drug List (EDL), which expands the listing from 520 medicines on the 2012 list to 685 medicines in the updated version; six additional AstraZeneca medicines were included in the updated EDL, namely Iressa, Brilinta, Forxiga, Crestor, Pulmicort and Symbicort.

Oncology sales in China increased by 55% in the year to date (48% at CER) to \$646m, reflecting primarily the contribution from Tagrisso, Zoladex and Iressa. Tagrisso was launched in China in 2017 for the 2nd-line treatment of patients with EGFR T790M-mutated NSCLC. During the period, AstraZeneca and the Chinese government also agreed on a public price for Tagrisso and subsequent inclusion on the NRDL with effect from 2019. The 1st-line regulatory submission for Tagrisso is currently under review in China, with a decision expected in the second half of 2019. During the period, Lynparza received approval and was subsequently launched in China for the maintenance treatment of patients with recurrent platinum-sensitive ovarian cancer. The medicine was the first PARP inhibitor to be approved in China.

CVRM medicine sales increased 31% in the year to date (25% at CER) to \$991m with New CVRM medicines, namely, Brilinta and Farxiga, representing 15% of all CVRM sales in China. Respiratory sales in Emerging Markets increased by 19% in the year to date (15% at CER) to \$1,147m, primarily due to sales of Pulmicort, in which AstraZeneca has invested in over 15,000 nebulisation centres, as well as the growth of Symbicort.

Emerging Markets sales excluding China, however, declined by 4% in the year to date (2% at CER) to \$2,277m, impacted by the Company's externalisation activities and the consequent loss of Product Sales. Macro-economic challenges in Argentina and Turkey, together with government interventions in Russia, impacted sales. The performance in Russia, where sales declined by 28% (24% at CER) to \$123m, was primarily due to the performance of a number of medicines including Zoladex, Faslodex, Iressa, Nexium and Symbicort. Russia sales in the quarter, however, increased by 2% (11% at CER) to \$56m. In the Middle East, Africa & Other region, sales declined by 15% (12% at CER) to \$731m, reflecting the slowdown in the Gulf region, import restrictions in North Africa and the entry of generic Nexium and Crestor in South Africa.

## US

Product Sales of \$4,839m; an increase of 10%. Q3 2018 sales increased by 25% to \$1,737m.

New medicines represented 45% of US Product Sales in the year to date. The performance during the period reflected, in particular, the success of the new Oncology medicines, including Tagrisso, Lynparza, Imfinzi and Calquence, plus the strong performance of Fasentra in Respiratory.

Oncology sales increased by 107% in the year to date to \$1,620m; Q3 2018 Oncology sales increased 138% to \$656m. The new Oncology medicines comprised 74% of total Oncology sales in the US, up from 47% in the first nine months of 2017. Tagrisso sales increased by 109% in the year to date to \$580m, following the approval in April 2018 as a 1st-line treatment for patients with EGFR-mutated NSCLC. Lynparza sales amounted to \$233m and represented growth of 168% in the year to date. Imfinzi sales in the US were \$348m, following the approval of Imfinzi in February 2018 as a medicine for the treatment of unresectable, Stage III NSCLC. Calquence sales in the year to date were \$38m, primarily reflecting demand from patients with previously-treated mantle cell lymphoma.

CVRM sales declined by 4% in the US in the year to date to \$1,602m; they increased by 1%, however, to \$573m in the quarter. The decline was driven principally by established medicines but was offset by the strong sales performance of new CVRM medicines, including Brilinta, Farxiga and Bydureon BCise, which represented 30% of US Product Sales in the year to date.

Respiratory sales declined by 6% in the US in the year to date to \$1,030m (Q3 2018: +1%), reflecting continued competitive intensity on sales of Symbicort, which itself saw a sales decline of 19% in the year to date to \$655m. In contrast, Fasentra continued its strong launch, following the approval for the treatment of severe eosinophilic asthma in November 2017, with sales amounting to \$129m in the year to date.

## Europe

Product Sales of \$3,286m in the year to date; a decline of 5% (11% at CER), reflecting the impact of the entry of generic Crestor medicines in various European markets in 2017 and continued competitive and price pressures. Crestor sales in Europe declined by 69% in the year to date (71% at CER) to \$159m and represented 5% of Europe sales. AstraZeneca expects this impact to recede in the future. Excluding sales of Crestor, Europe sales increased by 6% (down by 1% at CER) to \$3,127m.

The new medicines delivered an encouraging performance in the year to date, representing 27% of Europe Product Sales. Oncology sales in Europe increased by 19% (11% at CER) to \$766m, partly driven by Tagrisso sales growth of 79% (68% at CER) to \$222m. In June 2018, the medicine was approved in the EU for the treatment of patients in the 1st-line EGFRm setting, with immediate launches supporting the performance.

Lynparza sales of \$137m represented growth of 46% (37% at CER), partly benefitting from the approval in May 2018 for Lynparza tablets for patients with platinum-sensitive ovarian cancer, regardless of BRCA status. Imfinzi was approved by the EMA for the majority of patients with locally-advanced, unresectable NSCLC in September 2018; sales in Europe in the year to date amounted to \$9m.

CVRM sales declined by 25% in the year to date (30% at CER) to \$935m, driven by the aforementioned entry of generic Crestor medicines in various European markets in 2017. New CVRM sales increased 16% in the year to date in Europe (8% at CER) to \$640m, representing 68% of total CVRM sales, up from 44% in the first nine months of 2017. Brilique sales increased by 21% (12% at CER) to \$257m, primarily due to strong growth in Spain and Germany. Forxiga sales increased by 35% (25% at CER) to \$231m following the growth of the SGLT2 inhibitor class in Europe and increased demand.

Respiratory sales of \$922m represented growth of 5% (down by 2% at CER). Symbicort sales were stable (down by 8% at CER) at \$588m in the year to date. The medicine continued to retain its class-leadership position and stabilise its volume market share in the class, with some markets achieving volume growth. Fasenra was launched successfully in Europe, with a strong initial uptake and sales of \$17m in the year to date (Q3 2018 \$9m).

#### Established ROW

Product Sales of \$2,032m; a decline of 11% (down by 13% at CER).

Japan sales declined by 14% (16% at CER) to \$1,416m. The impact of the entry of generic Crestor medicines in 2017 was felt faster than expected; the biennial price reduction also adversely affected sales. Crestor sales in Japan declined by 69% (70% at CER) to \$122m and represented 9% of Japan sales in the year to date. AstraZeneca expects the generic Crestor impact to recede significantly from 2019. Excluding sales of Crestor, Japan sales increased by 3% (1% at CER) to \$1,294m. The impact of the biennial price reduction was 8.6% across AstraZeneca medicines; adjusting for the Nexium 'huge-seller' repricing adjustment of 16%, the price decline was c.7%.

The new medicines delivered an encouraging performance in Japan and comprised 21% of Product Sales in the year to date. Oncology sales increased by 8% (6% at CER) to \$626m, reflecting the strong performance of Tagrisso, which increased by 21% (18% at CER) to \$191m; Tagrisso was approved for the treatment of patients in the 1st-line EGFRm setting in August 2018. Lynparza sales in Japan amounted to \$25m in the year to date, following the aforementioned approvals in breast and ovarian cancer. The approval of Imfinzi in August 2018 for the treatment of patients with unresectable, Stage III NSCLC also benefitted the performance.

CVRM, representing 14% of Japan sales, saw Forxiga sales increase by 48% in the year to date (45% at CER) to \$46m. Respiratory sales of \$223m represented growth of 15% (13% at CER), underpinned by stable Symbicort sales (down by 2% at CER) of \$151m and stable Pulmicort sales (down by 3% at CER) of \$40m. Fasenra sales amounted to \$26m in the year to date, representing 12% of Respiratory sales, up from 8% in H1 2018, to become the leading asthma biologic medicine in Japan. Overall Established ROW sales, excluding Japan, declined by 4% in the year to date (5% at CER) to \$615m, due primarily to the performance of Symbicortin Australia; new medicines, however, demonstrated strong growth.

#### Financial Performance

Table 11: YTD 2018 Reported Profit and Loss

Reported

Edgar Filing: ASTRAZENECA PLC - Form 6-K

	YTD 2018	YTD 2017	% change
	\$m	\$m	Actual
			CER
Total Revenue	15,673	16,688	(8)
Product Sales	15,281	14,665	4
Externalisation Revenue	392	2,023	(81)
Cost of Sales	(3,299)	(3,093)	3
Gross Profit	12,374	13,595	(9)
Gross Margin <sup>27</sup>	78.4%	80.3%	-2
Distribution Expense	(238)	(225)	6
% Total Revenue	1.5%	1.3%	-
R&D Expense	(3,920)	(4,206)	(8)
% Total Revenue	25.0%	25.2%	-
SG&A Expense	(7,431)	(7,155)	4
% Total Revenue	47.4%	42.9%	-4
Other Operating Income & Expense	1,525	982	55
% Total Revenue	9.7%	5.9%	+4
Operating Profit	2,310	2,991	(20)
% Total Revenue	14.7%	17.9%	-3
Net Finance Expense	(970)	(1,128)	(44)
Joint Ventures and Associates	(77)	(43)	81
Profit Before Tax	1,263	1,820	(31)
Taxation	(222)	(213)	
Tax Rate	18%	12%	
Profit After Tax	1,041	1,607	(35)
Earnings Per Share	\$0.88	\$1.34	(34)

Table 12: Q3 2018 Reported Profit and Loss

	Reported		
	Q3 2018	Q3 2017	% change
	\$m	\$m	
			Actual



			CER
Total Revenue	5,340	6,232	(143)
Product Sales	5,266	4,882	8.9
Externalisation Revenue	74	1,350	(95)
Cost of Sales	(1,153)	(1,249)	(10)
Gross Profit	4,187	4,983	(14)
Gross Margin <sup>28</sup>	78.1%	77.7%	- 1
Distribution Expense	(73)	(76)	(3)
% Total Revenue	1.4%	1.2%	- -
R&D Expense	(1,279)	(1,404)	(98)
% Total Revenue	24.0%	22.5%	-1-1
SG&A Expense	(2,423)	(2,497)	(32)
% Total Revenue	45.4%	40.1%	-5-5
Other Operating Income & Expense	439	143	n/m
% Total Revenue	8.2%	2.3%	6.6
Operating Profit	851	1,149	(21)
% Total Revenue	15.9%	18.4%	-3-2
Net Finance Expense	(330)	(386)	(15)
Joint Ventures and Associates	(44)	(17)	n/m
Profit Before Tax	477	746	(34)
Taxation	(71)	(97)	
Tax Rate	15%	13%	
Profit After Tax	406	649	(36)
Earnings Per Share	\$0.34	\$0.54	(36)

Table 13: Reconciliation of Reported Profit Before Tax to EBITDA<sup>29</sup>

	YTD 2018		
	\$m	% change	
		Actual	CER
Reported Profit Before Tax	1,263	(31)	(31)
Net Finance Expense	970	(14)	(4)
Joint Ventures and Associates	77	81	81
Depreciation, Amortisation and Impairment	2,091	8	7
EBITDA	4,401	(11)	(10)

Table 14: YTD 2018 Reconciliation of Reported to Core Financial Measures

Edgar Filing: ASTRAZENECA PLC - Form 6-K

	Reported	Restructuring	Intangible Asset Amortisation & Impairments	Diabetes Alliance	Other <sup>30</sup>	Core <sup>31</sup>	Core % change		
	\$m	\$m	\$m	\$m	\$m	\$m		Actual	CER
Gross Profit	12,374	77	139	-	-	12,590	(9)	(11)	
Gross Margin <sup>32</sup>	78.4%	-	-	-	-	79.8%	-2	-2	
Distribution Expense	(238)	-	-	-	-	(238)	6	3	
R&D Expense	(3,920)	95	25	-	-	(3,800)	(4)	(6)	
SG&A Expense	(7,431)	110	1,067	320	(281)	(6,215)	10	7	
Other Operating Income & Expense	1,525	(11)	3	-	(374)	1,143	4	3	
Operating Profit	2,310	271	1,234	320	(655)	3,480	(31)	(31)	
% Total Revenue	14.7%	-	-	-	-	22.2%	(8)	(8)	
Net Finance Expense	(970)	-	-	253	156	(561)	7	4	
Taxation	(222)	(57)	(249)	(120)	104	(544)	(33)	(32)	
Earnings Per Share	\$0.88	\$0.17	\$0.78	\$0.36	\$(0.31)	\$1.88	(37)	(37)	

Table 15: Q3 2018 Reconciliation of Reported to Core Financial Measures

	Reported	Restructuring	Intangible Asset Amortisation & Impairments	Diabetes Alliance	Other <sup>33</sup>	Core <sup>34</sup>	Core % change		
	\$m	\$m	\$m	\$m	\$m	\$m		Actual	CER
Gross Profit	4,187	22	47	-	-	4,256	(16)	(14)	
Gross Margin <sup>35</sup>	78.1%	-	-	-	-	79.4%	-	(1)	
Distribution Expense	(73)	-	-	-	-	(73)	(3)	-	
R&D Expense	(1,279)	37	-	-	-	(1,242)	(7)	(6)	
SG&A Expense	(2,423)	26	372	107	(143)	(2,061)	6	7	
Other Operating Income & Expense	439	(1)	1	-	-	439	n/m	n/m	
Operating Profit	851	84	420	107	(143)	1,319	(29)	(26)	
% Total Revenue	15.9%	-	-	-	-	24.7%	(5)	(4)	
Net Finance Expense	(330)	-	-	85	53	(192)	13	12	
Taxation	(71)	(18)	(86)	(39)	1	(213)	(26)	(22)	

Earnings Per Share	\$0.34	\$0.05	\$0.27	\$0.12	\$(0.07)	\$0.71	(37)	(33)
--------------------	--------	--------	--------	--------	----------	--------	------	------

## Profit and Loss Commentary

### Gross Profit

Reported Gross Profit declined by 9% in the year to date (11% at CER) to \$12,374m; Core Gross Profit declined by 9% (10% at CER) to \$12,590m. The declines primarily reflected the lower level of Externalisation Revenue and the Gross Margin.

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 two percentage points in the year to date to 78.4%; the Core Gross Margin declined by two percentage points to 79.8%. The movements were a result of the favourable impact of manufacturing variances realised in H1 2017, the inclusion of the profit share on the collaboration with MSD, as well as the effect of losses of exclusivity on Crestor sales in Europe and Japan, partly offset by the growing favourable impact of Oncology sales.

### Operating Expenses: R&D

Reported R&D costs declined by 7% in the year to date (8% at CER) to \$3,920m. Targeted investment in the Company's pipeline of medicines is a consistent priority; AstraZeneca, however, is continuing to focus on resource prioritisation, productivity improvements across every therapy area, simplification and improved development processes, all helping to deliver cost reductions. Importantly, high levels of activity remain unchanged, illustrated by the 63 Phase III projects ongoing as at the end of the quarter (end of Q3 2017: 56).

### Highlights of the progress made include:

- Moving late-stage-execution roles to lower-cost locations
- Reducing supply waste
- Optimising protocols, including a review of the number of procedures, countries involved and in-sourcing a larger proportion of clinical trials

Core R&D costs declined by 4% in the year to date (6% at CER) to \$3,800m, reflecting the aforementioned productivity improvements. Core R&D costs represented 24% of Total Revenue (23% in Q3 2018). Core R&D costs in FY 2018 are now anticipated to decline by a low single-digit percentage at CER.

### Operating Expenses: SG&A

Reported SG&A costs increased by 4% in the year to date (1% at CER) to \$7,431m. Investment focused on commercial and medical-affairs support for launches and extensions of the new medicines. These included Lynparza, Tagrisso, Imfinzi, Calquence and Fasenra; additional investment was also added to support sales growth in China. Intangible Asset Amortisation and Impairment charges of \$1,067m, recorded within Reported SG&A Costs, partly reflected the impact of recent regulatory approvals granted for acquired medicines.

Core SG&A costs increased by 10% in the year to date (7% at CER) to \$6,215m, reflecting the aforementioned investments. Total Core SG&A costs are now expected to increase, at CER, broadly in line with the rate seen in the year to date, reflecting support for medicine launches. The Company will retain flexibility in its investment approach, watching closely its impact on Product Sales.

### Other Operating Income & Expense

Where AstraZeneca does not retain a significant ongoing interest in medicines or potential new medicines, income from divestments is reported within Other Operating Income & Expense in the Company's financial statements. Reported Other Operating Income & Expense increased by 55% in the year to date to \$1,525m and included:

## Edgar Filing: ASTRAZENECA PLC - Form 6-K

\$527m, reflecting an agreement with Luye Pharma for the rights to Seroquel and Seroquel XR in the UK, China and other international markets

\$346m, resulting from a legal settlement

\$210m, recognised in the third quarter, reflecting an agreement with Cheplapharm Arzneimittel GmbH for the commercial rights to Atacand and Atacand Plus in Europe

\$174m, recognised in the third quarter, reflecting a milestone payment under an agreement with Aspen Global Incorporated, part of the Aspen Group, for the commercialisation rights to anaesthetic medicines in markets outside the US

\$63m, representing a gain on the spin-out of six potential new medicines from MedImmune's early-stage inflammation and autoimmunity programme into an independent biotech company, as announced on 28 February 2018

Core Other Operating Income & Expense increased by 4% in the year to date (3% at CER) to \$1,143m, with the difference to Reported Other Operating Income & Expense reflecting the aforementioned legal settlement.

### Operating Profit

Reported Operating Profit declined by 23% in the year to date (20% at CER) to \$2,310m, partly driven by the declines in Total Revenue and the Reported Gross Margin, as well as the increase in Reported SG&A costs. Restructuring costs reduced to \$271m in the year to date (YTD 2017: \$645m). The Reported Operating Profit margin declined by three percentage points in the year to date (two at CER) to 15% of Total Revenue.

Core Operating Profit declined by 31% in the year to date to \$3,480m, driven by the aforementioned factors, as well as the timing of divestments in FY 2018. The Core Operating Profit margin declined by eight percentage points to 22% of Total Revenue.

### Net Finance Expense

Reported Net Finance Expense declined by 14% in the year to date (4% at CER) to \$970m, reflecting an adverse foreign-exchange impact in the comparative period and reduced levels of discount unwind on Acerta Pharma B.V. (Acerta Pharma) liabilities. Excluding the discount-unwind on acquisition-related liabilities and the adverse foreign exchange impact in the comparative period, Core Net Finance Expense increased by 7% in the year to date (4% at CER) to \$561m, partly reflecting the level of Net Debt.

### Profit Before Tax

Reported Profit Before Tax declined by 31% in the year to date to \$1,263m, reflecting the lower level of Externalisation Revenue, the lower Reported Gross Margin and the increase in Reported SG&A costs.

### Taxation

The Reported and Core Tax Rates for the year to date were 18% and 19% respectively. The net cash tax paid for the year to date was \$406m, representing 32% of Reported Profit Before Tax. The Reported and Core Tax rates for the comparative period were 12% and 18% respectively. The net cash tax paid for the comparative period was \$473m, which was 26% of Reported Profit Before Tax.

### Earnings Per Share (EPS)

Reported EPS of \$0.88 in the year to date represented a decline of 34%. The performance reflected a decline in Total Revenue, the Reported Gross Margin and the increase in Reported SG&A costs. Core EPS declined by 37% to \$1.88.

### Table 16: Cash Flow

	YTD 2018	YTD 2017	Change
	\$m	\$m	\$m
Reported Operating Profit	2,310	2,991	(681)
Depreciation, Amortisation and Impairment	2,091	1,929	162
(Increase)/Decrease in Working Capital and Short-Term Provisions	(1,741)	(228)	(1,513)
(Gains)/Losses on Disposal of Intangible Assets	(975)	(735)	(240)
Non-Cash and Other Movements	(428)	(384)	(44)
Interest Paid	(457)	(519)	62
Tax Paid	(406)	(473)	67
Net Cash Inflow from Operating Activities	394	2,581	(2,187)
Net Cash Inflow/(Outflow) from Investing Activities	36	(686)	722
Net Cash Outflows from Financing Activities	(312)	(2,924)	2,612

The Company delivered a net cash inflow from operating activities of \$394m in the year to date, compared with an inflow of \$2,581m in the first nine months of 2017, reflecting the increase in the movement of working-capital and short-term provisions impacted by the reduction of provisions related to legal settlements, as well as launch support for new medicines. The performance also reflected the reduction in Reported Operating Profit.

Net cash inflows from investing activities were \$36m, compared with outflows of \$686m in the first nine months of 2017. The difference partly reflected the increase in Reported Other Operating Income & Expense, a reduction in capital expenditure as well as movements in short-term investments and fixed deposits. The cash payment of contingent consideration, in respect of the Bristol-Myers Squibb share of the global Diabetes alliance, amounted to \$247m in the year to date.

Net cash outflows from financing activities were \$312m in the year to date, compared to outflows of \$2,924m in the first nine months of 2017; the difference reflected new long-term loans and the repayment of loans in the earlier period.

#### Capital Expenditure

Capital expenditure amounted to \$728m in the year to date, compared to \$849m in the first nine months of 2017, which included the investment in the new global headquarters in Cambridge, UK, as well as strategic biotech manufacturing capacity in Sweden. AstraZeneca anticipates a reduction in capital expenditure over the full year vs. FY 2017.

Table 17: Debt and Capital Structure

	At 30 Sept 2018	At 31 Dec 2017	At 30 Sept 2017
	\$m	\$m	\$m
Cash and Cash Equivalents	3,420	3,324	4,036
Other Investments	860	1,300	1,255

Cash and Investments	4,280	4,624	5,291
Overdrafts and Short-Term Borrowings	(1,092)	(845)	(930)
Finance Leases	-	(5)	(12)
Current Instalments of Loans	(1,399)	(1,397)	-
Loans Due After One Year	(18,422)	(15,560)	(16,910)
Interest-Bearing Loans and Borrowings (Gross Debt)	(20,913)	(17,807)	(17,852)
Net Derivatives	448	504	427
Net Debt	(16,185)	(12,679)	(12,134)

### 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

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.

Table 18: Currency Sensitivities

The Company provides the following currency-sensitivity information:

Currency	Primary Relevance	Average Exchange Rates vs. USD			Annual Impact Of 5% Strengthening in Exchange Rate vs. USD (\$m) <sup>36</sup>	
		FY 2017	YTD 2018 <sup>37</sup>	% change	Product Sales	Core Operating Profit
EUR	Product Sales	0.89	0.84	+6	+135	+57
JPY	Product Sales	112.18	109.66	+2	+95	+66
CNY	Product Sales	6.75	6.51	+4	+182	+100
SEK	Operating Expenses	8.54	8.58	-	+3	-68
GBP	Operating Expenses	0.78	0.74	+5	+23	-76
Other <sup>38</sup>					+85	+43

### Corporate and Business Development Update

#### a) Nexium Divestment in the EU and Vimovo Divestment in Ex.US/JP Markets

On 30 October 2018, AstraZeneca announced that it had agreed to divest the prescription medicine rights to Nexium in Europe, as well as the global rights (excluding the US and Japan) to Vimovo to Grünenthal. The divestments are expected to complete in 2018. For Nexium, Grünenthal will make an upfront payment of \$700m upon completion. AstraZeneca may also receive future milestones and sales-related payments of up to \$90m. For Vimovo,

Grünenthal will make an upfront payment of \$115m upon completion. AstraZeneca may also receive future milestones and sales-related payments of up to \$17m. Upfront and milestone receipts, excluding a proportionate derecognition of an intangible asset relating to Vimovo, will be reported as Other Operating Income & Expense in the Company's financial statements.

AstraZeneca will continue to commercialise Nexium in all markets outside Europe, where the Company retains the rights. On completion of the agreements, AstraZeneca will not retain any ownership rights to Vimovo globally, or to Nexium in Europe. Nexium sales in Europe in H1 2018 were \$121m; Vimovo global sales excluding the US and Japan in the same period were \$37m. AstraZeneca will continue to manufacture and supply Nexium under a long-term supply agreement.

b) Divestment of Global Rights to Alvesco, Omnaris and Zetonna

On 6 November 2018, AstraZeneca announced an agreement with Covis Pharma B.V. (Covis Pharma) to sell its rights to respiratory medicines Alvesco, Omnaris and Zetonna. The active ingredient in all three medicines is ciclesonide, a synthetic corticosteroid that helps relieve inflammation. The rights cover markets outside the US and the US royalties for the medicines. Covis Pharma currently commercialises Alvesco, Omnaris and Zetonna in the US and will become the owner of the medicines upon closing.

Under the terms of the agreement, Covis Pharma will pay AstraZeneca \$350m upon closing, in addition to conditional sales-related payments of up to \$21m over four years from 2019. As AstraZeneca will not maintain a significant ongoing interest in the medicines following completion, the upfront (excluding a derecognition of an intangible asset) and future receipts, will be recognised as Other Operating Income & Expense in the Company's financial statements. The agreement is expected to complete by the end of 2018.

c) Atacand Divestment in Europe

In July 2018, AstraZeneca announced that it had agreed to sell the commercial rights to Atacand (candesartan cilexetil) and Atacand Plus (fixed-dose combination of candesartan cilexetil and hydrochlorothiazide) in Europe to Cheplapharm Arzneimittel GmbH (Cheplapharm). Atacand is a prescription medicine for the treatment of heart failure (HF) and hypertension. The agreement completed later in the quarter. AstraZeneca will continue to manufacture and supply Atacand and Atacand Plus under a supply agreement and will continue to commercialise the medicines in all markets where it still holds the rights.

Cheplapharm paid AstraZeneca \$200m on completion of the agreement and will pay a time-bound payment of \$10m and sales-contingent milestones. The present value of the upfront and time-bound payment, \$210m, was reported as Other Operating Income in the Company's financial statements.

d) Zurampic Return of Rights in the US

In April 2016, AstraZeneca announced that it had entered into a licensing agreement with Ironwood Pharmaceuticals Inc. (Ironwood) for the exclusive US rights to Zurampic (lesinurad). Zurampic was approved by the US FDA in December 2015, in combination with a xanthine oxidase inhibitor, for the treatment of hyperuricaemia associated with uncontrolled gout.

In August 2018, Ironwood issued a contract termination letter, with an effective date of 180 days from date of receipt, with respect to Zurampic and Duzallo (Zurampic/allopurinol fixed-dose combination). The Company is evaluating the implications of Ironwood's notification and will consider patient needs in the process.

e) AstraZeneca Strengthens Oncology Development and Commercialisation Collaboration with Innate Pharma

In October 2018, AstraZeneca and its global biologics research and development arm MedImmune announced a new multi-term agreement with Innate Pharma, building on an existing collaboration. The extension enriches AstraZeneca's immuno-oncology (IO) portfolio with pre-clinical and clinical potential new medicines. AstraZeneca obtained full Oncology rights to the first-in-class humanised anti-NKG2A antibody, monalizumab. AstraZeneca also

gained option rights to IPH5201, an antibody targeting CD39, as well as four preclinical molecules from Innate Pharma's pipeline. Innate Pharma licenced the US and EU commercial rights to recently US FDA-approved Lumoxiti for hairy cell leukaemia; Lumoxiti launched in the US in October 2018.

AstraZeneca will recognise \$50m upfront for Lumoxiti in Q4 2018 as Other Operating Income and anticipates receipt of \$25m for future commercial and regulatory milestones, in consideration for its intellectual property and clinical and manufacturing development of the medicine. AstraZeneca will pay Innate Pharma \$100m in the first quarter of 2019 for the expansion of the monalizumab collaboration. Additional financial arrangements related to monalizumab are detailed and available in the 2015 collaboration announcement. Further, AstraZeneca will pay Innate Pharma \$50m upfront for the development collaboration and option for further co-development and co-commercialisation of Innate Pharma's CD39 monoclonal antibody, IPH5201.

AstraZeneca also paid Innate Pharma \$20m upfront for an exclusive license option on four to-be-agreed molecules from Innate Pharma's pre-clinical portfolio. These options can be exercised before the molecules reach clinical development, triggering an option exercise fee in addition to milestones and royalties. Innate Pharma will have the potential for co-promotion and profit sharing in the EU, dependent on future progress. Given the long-term collaboration between the two companies, AstraZeneca recently acquired a 9.8% equity stake in Innate Pharma, in line with the agreement, through the issuance of 6,260,500 new shares to AstraZeneca at €10/share (€62.6m).

## Sustainability Update

AstraZeneca's sustainability ambition has three priority areas<sup>39</sup>, aligned with the Company's purpose and business strategy:

- Access to healthcare
- Environmental protection
- Ethics and transparency

Recent developments and progress against the priorities are reported below:

### a) Access to Healthcare

In October 2018, Pascal Soriot, Chief Executive Officer and Katarina Ageborg, Executive Vice President, Sustainability and Chief Compliance Officer, visited Kenya to celebrate the fourth anniversary of the Healthy Heart Africa (HHA) programme. The visit included co-hosting an event on Public-Private-Partnerships to combat NCDs with the UN and Kenyan Ministry of Health, as well as the local launch of the Dunga Beach programme, announced in May 2018, with Kenyan media.

One of the key aims of the HHA programme is to educate and raise awareness about hypertension. During the period, five AstraZeneca employees were selected to join the HHA Ambassador programme, a skills-based mentoring initiative that matches AstraZeneca employees with local partners in Kenya, bringing expertise and experience to make a real impact to the HHA programme.

During the period, the Young Health Programme (YHP) was recognised at the Ethical Corporation 2018 Responsible Business Awards, winning the Community Investment of the Year award, with particular commendation for the programme's investment-to-output ratio and its clear link to the business strategy.

### b) Environmental Protection

In October 2018, AstraZeneca published a paper in the journal Environmental Science and Technology, together with researchers at Kings College London, the Universities of Northumbria and Suffolk and the Francis Crick Institute,



calling for the wider application of machine learning in environmental toxicology research, to improve environmental protection, reduce the burden on animal testing and better meet the future challenges of scientific discovery. The publication is the result of a recent collaboration between these academic and industry bodies and highlights the impact of chemicals on the environment.

During the period, the Company published a position statement on Pharmaceuticals in the Environment (PIE). AstraZeneca proactively manages the risks associated with PIE to ensure the environmental safety of its products. The AMR Industry Alliance has also published manufacturing discharge targets for antibiotics to limit antimicrobial resistance risk in environmental waters downstream of medicine production. On 25 September 2018, the targets were launched at the Center for Disease Control (CDC) meeting at the 73rd Session of the UN General Assembly (UNGA). The wider industry has followed the approach that AstraZeneca published in 2017 in Environmental International; where the Company co-funded and co-authored the work of Le Page et al. and Brandt et al. that formed the basis of this industry-consensus position.

Table 19: Environmental Protection Targets<sup>40</sup>

Target	Plan year	Performance in the period
Reach 25m patients through AstraZeneca's portfolio of access programmes	2025	On plan: AstraZeneca has reached more than 9m patients through its portfolio of Access to Healthcare programmes (hHF, Phakamisa, Healthy Lung Asia). The Company recently expanded the Healthy Lung programme to the United Arab Emirates and Mexico
Lead the industry to manage pharmaceuticals in the environment	2025	On plan: ecopharmacovigilance (EPV) spatial environmental risk-map updates have been commissioned and product-specific concentration (measured vs. predicted safe) distributions are being developed. These will form the basis for a first published EPV report  AstraZeneca's Pharmaceuticals in the Environment statement was published during the period
Ensure 90% of active pharmaceutical ingredient syntheses meet resource-efficiency targets at launch	2025	Lagging: overall reduction in H1 2018, with a 2% decline across the Company's portfolio
Develop resource-efficiency targets for biological medicines	2025	On plan: benchmarking of biologics-process resource-efficiency data through American Chemical Society Green Chemistry Institute Pharmaceutical Roundtable
Develop a product-sustainability index and pilot approach	2019	On plan: project launched to develop a product environmental-sustainability rating system, to be piloted internally prior to external publication in 2019
Achieve Science Based Targets for greenhouse gas emissions	2025	

## Edgar Filing: ASTRAZENECA PLC - Form 6-K

Lagging: AstraZeneca's Operational Green House Gas footprint is +2% vs. half-year 2015  
 Scope 1 -8%  
 Scope 2 -47%  
 Scope 3 emissions +20%<sup>41</sup>

100% renewable power consumption globally by 2025; interim ambition of 100% in the US and Europe by 2020	2025	On plan: 60% of sites already powered by renewable energy
Reduce energy consumption by 10% against a 2015 baseline	2025	On plan: energy consumption -2% compared with 2015
Expand the number of 'green fleet' vehicles	2025	On plan: a number of European locations are implementing green fleet vehicles through their 'Green Mobility' programmes. AstraZeneca US launched the 'GoGreen' initiative and it is expected that by 2022 our entire US fleet will be made up of hybrid vehicles
Maintain water usage as our business grows against a 2015 baseline	2025	On plan: water use -11% vs. 2015 Water audits and energy efficiency projects have driven large reductions and cost savings
Reduce waste 10% below the 2015 baseline	2025	On plan: waste generated: -1% vs. 2015 Hazardous waste: +14% Non-hazardous waste: -7% Significant increase in hazardous waste generation offset by reductions in non-hazardous volumes. Target currently on track but quarterly results subject to significant fluctuations

### c) Ethics and Transparency

The Company launched its annual Code of Ethics training to all employees in September 2018. The Code of Ethics supports employees around the globe in understanding why and how the Company's Values guide behaviour and help colleagues make better decisions in the long-term interests of the Company.

At its Annual General Meeting 2018, AstraZeneca committed to providing greater transparency around payments to healthcare professionals (HCPs) and Healthcare Organisations (HCOs). The Company currently discloses payments to HCPs, HCOs and patient groups across 38 countries, including Europe, the US, Japan and Australia, in accordance with all current regulations and reporting requirements. AstraZeneca's current disclosures comprise over 90% of all such disclosures possible worldwide; the Company is committed, however, to expanding its payments disclosure to a further 11 countries across Latin America, Asia Pacific, North Africa and the Middle East regions by the end of 2019.

During the period, the Company made further progress against these plans by focusing on reporting requirements in markets with current and pending regulations; completing a gap assessment to develop an understanding of market-level operations and beginning to design, build, and formally integrate countries into its reporting platform.

From data gathered from existing filings, and internal financial systems for countries with no existing regulatory requirements<sup>42</sup>, progress against this commitment is as follows:

## Edgar Filing: ASTRAZENECA PLC - Form 6-K

Existing reporting across the US, Europe, Australia, Japan, the Philippines and Indonesia accounts for 93% of reportable activity with HCPs across the 38 countries with existing requirements

The Company is currently working to integrate Brazil, Korea, Mexico, and Saudi (by end 2018) and Argentina, Canada, Chile, India, Morocco, New Zealand (by end 2019) with these countries accounting for an additional 2% of coverage of reportable spend/activity with HCPs

Countries due to commence work to meet this commitment account for the remaining 5% of coverage

### Other Developments

During the period, the Company was recognised for its sustainability efforts in the 2018 World Dow Jones Sustainability Index (DJSI) World, retaining third position in the pharmaceutical industry. The DJSI is the longest-running, global sustainability benchmark system and is based on an in-depth analysis of companies economic, social and environmental performance. Of 50 companies assessed from the Pharmaceuticals Industry Group, only seven qualified for inclusion in the DJSI. AstraZeneca received the industry's top score in the areas of Environmental Reporting, Labour Practice Indicators and Health Outcome Contribution. AstraZeneca's overall percentile increased by one point to the 96th percentile. The DJSI uses a consistent, rules-based methodology to convert an average of 600 data points per company into one overall score. This score determines inclusion in the DJSI. This marked the 17th time the Company has been included in the Index.

### Research and Development

A comprehensive data pack comprising AstraZeneca's pipeline of medicines in human trials can be found in the clinical-trials appendix, available on [astrazeneca.com](http://astrazeneca.com). Highlights of developments in the Company's late-stage pipeline since the prior results announcement are shown below:

Table 20: Update from the Late-Stage Pipeline

Regulatory Approvals	5	<ul style="list-style-type: none"><li>- Lynparza - ovarian cancer (2nd line) (CN)</li><li>- Tagrisso - lung cancer (1st line) (JP)</li><li>- Imfinzi - locally-advanced, unresectable NSCLC (EU)</li><li>- Lumoxiti - hairy cell leukaemia (3rd line) (US)</li><li>- Bydureon BCise autoinjector - type-2 diabetes (EU)</li></ul>
Regulatory Submissions and/or Acceptances	10	<ul style="list-style-type: none"><li>- Lynparza - ovarian cancer (1st line) (EU, JP, CN)</li><li>- Tagrisso - lung cancer (1st line) (CN)</li><li>- Symbicort - mild asthma (EU)</li><li>- Duaklir - COPD (US)</li><li>- Bevespi - COPD (JP, CN)</li><li>- PT010 - COPD (JP, CN)</li></ul>
Major Phase III Data Readouts or Other Major Developments	6	<ul style="list-style-type: none"><li>- Lynparza - pancreatic cancer: Orphan Drug Designation (US)</li><li>- selumetinib - NF1: orphan designation (EU)</li><li>- Farxiga - type-2 diabetes: CVOT primary safety endpoint met; one of two primary efficacy endpoints met</li><li>- Bevespi - COPD: CHMP positive opinion (EU)</li></ul>

Edgar Filing: ASTRAZENECA PLC - Form 6-K

- tezepelumab - severe asthma: Breakthrough Therapy Designation (US)
- anifrolumab - lupus (TULIP 1 trial): primary endpoint not met

Oncology

- Lynparza - multiple cancers<sup>43</sup>
- Tagrisso - lung cancer<sup>44</sup>
- Imfinzi - multiple cancers<sup>44</sup>
- Calquence - blood cancers<sup>44</sup>
- tremelimumab - multiple cancers
- selumetinib - NF1<sup>44</sup>
- savolitinib - multiple cancers

New Molecular Entities and Major Lifecycle Medicines in Phase III Trials or Under Regulatory Review

11

CVRM

- roxadustat - anaemia<sup>44</sup>

Respiratory

- PT010 - COPD<sup>44</sup>
- tezepelumab - severe asthma

Other

- anifrolumab - lupus

Total Projects in Clinical Pipeline

135

Oncology

AstraZeneca has a deep-rooted heritage in Oncology and offers a new generation of medicines that have 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, Calquence and Lumoxiti are already benefitting patients. An extensive pipeline of small-molecule and biologic medicines is in development and the Company is committed to advancing Oncology medicines, primarily focused on the treatment of patients with lung, ovarian, breast and blood cancers.

In September and October 2018, the Company presented further evidence of its progress at the International Association for the Study of Lung Cancer World Congress on Lung Cancer (WCLC) in Toronto and the European Society for Medical Oncology (ESMO) Congress in Munich. This was illustrated by Presidential sessions for the Imfinzi PACIFIC and Lynparza SOLO-1 presentations.

a) Lynparza (multiple cancers)

In August 2018, the Company was granted approval from the China NMPA for Lynparza for the maintenance treatment of adult patients with platinum-sensitive relapsed epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in a complete or partial response to platinum-based chemotherapy. This made Lynparza the first PARP inhibitor to be approved in China and was the latest example of the Company's commitment to develop and deliver innovative medicines for patients in China. Approval was granted based on two pivotal trials - the Phase III SOLO-2 trial and the Phase II Study 19 trial.

Edgar Filing: ASTRAZENECA PLC - Form 6-K

During the period, the Company announced that it had been granted Orphan Drug Designation by the US FDA for Lynparza for the treatment of pancreatic cancer. Pancreatic cancer is a rare, life-threatening disease that accounts for c.3% of all cancers in the US. Due to the late onset of symptoms, patients are often diagnosed after the cancer has progressed to locally-advanced or metastatic stages of the disease; five-year survival rates remain low in the US, below 10%.

In October 2018, AstraZeneca and MSD announced detailed results from the aforementioned SOLO-1 trial, testing Lynparza tablets as a maintenance treatment for patients with newly-diagnosed, advanced BRCAm ovarian cancer who were in complete or partial response, following 1st-line standard platinum-based chemotherapy. Results of the trial confirmed the statistically-significant and clinically-meaningful improvement in progression-free survival (PFS) for Lynparza compared to placebo, reducing the risk of disease progression or death by 70% (HR 0.30 [95% CI 0.23-0.41], p<0.001). At 41 months of follow-up, the median PFS for patients treated with Lynparza was not reached, compared to 13.8 months for patients treated with placebo. Of those patients receiving Lynparza, 60% remained progression-free at 36 months, compared to 27% of patients in the placebo arm. The data were presented at the ESMO Congress and published simultaneously online in the New England Journal of Medicine.

Based on the SOLO-1 trial data, the Company made regulatory submissions in the EU, Japan and China for Lynparza in newly-diagnosed patients with BRCAm advanced ovarian cancer, following 1st-line platinum-based chemotherapy.

Table 21: Lynparza Combination Trials

Name	Phase	Population	Design	Timelines	Status
				FPCD46 Q2 2015	
PAOLA-145	III	Stage IV, 1st-line ovarian cancer	bevacizumab maintenance vs. bevacizumab +Lynparzaintenance	LPCD47 Q2 2018	Recruitment completed
				First data anticipated H2 2019 FPCD Q3 2018	
DuO-O	III	Stage IV, 1st-line ovarian cancer	chemotherapy + bevacizumab vs. chemotherapy + bevacizumab +Imfinzi +/-Lynparzaintenance	First data anticipated 2020+	Recruitmentongoing
		Advanced, 2nd-line gBRCAm48 ovarian cancer			Recruitmentongoing
MEDIOLA	I/II	Stage IV, 1st to 3rd-line gBRCAm, HER2-negative breast cancer	Lynparza + Imfinzi	FPCD Q2 2016	Initial data from lung, breast, prostate and ovarian-cancer cohorts presented in 2017 and 2018
		Stage IV, 2nd-line small cell lung cancer			
		Stage IV, 2nd-line gastric cancer			
VIOLETTE	II		Lynparza		Recruitmentongoing

Edgar Filing: ASTRAZENECA PLC - Form 6-K

		Stage IV, advanced, triple-negative breast cancer:	Lynparza + ATR (AZD6738)	FPCD Q2 2018	
		-HRRm49 (BRCA) -HRRm (non-BRCA) -Non-HRRm	Lynparza + WEE1 (AZD1775)	First data anticipated 2020+	
PROpel	III	Stage IV, advanced, castration-resistant prostate cancer	abiraterone vs. abiraterone +Lynparza	-	Planning (announced at the ASCO 2018 annual meeting)
BAYOU	II	Stage IV, 1st line cis-platinum chemotherapy-ineligible urothelial bladder cancer	Imfinzi vs. Imfinzi + Lynparza	FPCD Q1 2018 First data anticipated 2020	Recruitment ongoing
DuO-L	II	Stage IV, 1st-line NSCLC	chemotherapy +Imfinzi followed by Imfinzi + Lynparza maintenance	-	Planning

b) Tagrisso (lung cancer)

In August 2018, AstraZeneca announced that the Japan Ministry of Health, Labour and Welfare (MHLW) had approved Tagrisso for the 1st-line treatment of patients with inoperable or recurrent EGFRm NSCLC, following priority review. The approval was based on results from the global Phase III FLAURA trial, which included Japanese patients. In Japan, the EGFR mutation can be detected via tumour biopsy and circulating tumour DNA-based test. During the period, the Company made a regulatory submission in China, based on global, Asian and China data from the FLAURA trial.

During the period, the Company also presented an update on the SAVANNAH and ORCHARD trials at the WCLC. The SAVANNAH trial is a Phase II, single-arm trial assessing the efficacy of Tagrisso in combination with savolitinib for patients with EGFRm, MET-amplified, locally-advanced or metastatic NSCLC who have progressed, following treatment with Tagrisso.

Amplification of the MET receptor tyrosine kinase, which activates downstream intracellular signalling, independent of EGFR, is one of the clinically-observed acquired resistance mechanisms to EGFR tyrosine kinase inhibitors, such as Tagrisso. The SAVANNAH trial is exploring the efficacy of the combination of Tagrisso with the MET inhibitor, savolitinib, to overcome this resistance, following 1st- or 2nd-line treatment with Tagrisso. The SAVANNAH trial follows encouraging anti-tumour activity seen with this combination in the ongoing Phase I trial, TATTON, for patients who have MET-amplified EGFRm NSCLC, following treatment with Tagrisso.

ORCHARD (Osimertinib Resistance CoHorts Addressing 1st-line Relapse Drivers) is an open-label, multi-centre, Phase II platform trial in patients with advanced NSCLC whose disease has progressed on or after 1st-line treatment with Tagrisso. The trial was designed to increase understanding of 1st-line Tagrisso resistance and explore potential treatment options to improve treatment outcomes in this patient population, providing the data to support and inform physicians' treatment choice for patients whose disease progressed on or after treatment with Tagrisso in the 1st-line setting. The initial trial is expected to have six treatment arms and recruit c.150 patients; as the Company's knowledge further expands on the resistance mechanisms to Tagrisso, additional treatment arms may be added.

c) 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

During the period, the Company announced that the EMA had granted approval for Imfinzi as a monotherapy for the treatment of locally-advanced, unresectable NSCLC in adult patients whose tumours express PD-L1 on  $\geq 1\%$  of tumour cells and whose disease has not progressed following platinum-based CRT.

On 25 September 2018, the Company presented OS data from the Phase III PACIFIC trial of Imfinzi at the aforementioned WCLC. Results demonstrated that Imfinzi significantly improved OS, the second primary endpoint of the trial, compared to SoC, regardless of PD-L1 expression, reducing the risk of death by 32% (HR 0.68, 99.73% [CI 0.47-0.997];  $p=0.0025$ ). The trial results were published simultaneously in the New England Journal of Medicine.

During the period, the Phase III POSEIDON trial of Imfinzi + SoC vs. Imfinzi + tremelimumab + SoC vs. SoC chemotherapy in Stage IV, 1st-line NSCLC, completed patient enrolment ahead of schedule and OS was elevated to become a primary endpoint, with the first data anticipated in H2 2019. Previously, patient enrolment had been increased to c.1,000 patients. In the Phase III CASPIAN trial in small cell lung cancer (SCLC), the Company recently elevated OS to become the only primary endpoint.

The changes in the two trials followed other recently-communicated changes to the Company's late-stage clinical trials development programme for Imfinzi, to emphasise OS as a meaningful endpoint to characterise the benefit that immunotherapy can provide to patients with early and advanced cancers.

Table 22: IO Lung-Cancer Late-Stage Trials

Name	Phase	Population	Design	Timelines	Status
Stage I, II & III (treatment with curative intent)					
ADJUVANT (BR.31)50	III	Stage Ib-IIIa NSCLC	placebo vs. Imfinzi	FPCD Q1 2015 First data anticipated 2020	Recruitment ongoing
PACIFIC	III	Unresectable, Stage III NSCLC	placebo post concurrent CRT vs. Imfinzi	FPCD Q2 2014 LPCD Q2 2016 FPCD Q2 2018	PFS and OS primary endpoints both met
PACIFIC-2	III	Unresectable, Stage III NSCLC	placebo concurrent with CRT vs. Imfinzi followed by placebo vs. Imfinzi	First data anticipated 2020+	Recruitment ongoing
PACIFIC-5	III	Unresectable, Stage III NSCLC (Asia predominant)	placebo concurrent CRT (PACIFIC regimen) vs. Imfinzi concurrent with CRT followed by Imfinzi (PACIFIC-2 regimen)	FPCD Q3 2018 First data anticipated 2020+	Recruitment ongoing
ADRIATIC	III	Limited-disease stage SCLC	placebo post concurrent CRT vs. Imfinzi or Imfinzi + treme	FPCD Q4 2018 First data anticipated 2020+	Recruitment ongoing
Stage IV (metastatic disease)					
PEARL	III	Stage IV, 1st-line NSCLC (Asia)	SoC chemotherapy vs. Imfinzi	FPCD Q1 2017 First data anticipated 2020	Recruitment ongoing
MYSTIC	III	Stage IV, 1st-line NSCLC	SoC chemotherapy vs. Imfinzi or Imfinzi + treme	FPCD Q3 2015 LPCD Q3 2016	Recruitment completed PFS primary endpoint not met

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Name	Phase	Population	Design	Timelines	Status
NEPTUNE	III	Stage IV, 1st-line NSCLC	SoC chemotherapy vs. Imfinzi + treme	Final OS data anticipated Q4 2018 FPCD Q4 2015 LPCD Q2 2017 First data anticipated H1 2019 FPCD Q2 2017 LPCD Q3 2018	Recruitment completed
POSEIDON	III	Stage IV, 1st-line NSCLC	SoC chemotherapy vs. SoC +Imfinzi or SoC +Imfinzi + treme	First data anticipated H2 2019 FPCD Q1 2017 LPCD Q2 2018	Recruitment completed
CASPIAN	III	Stage IV, 1st-line small-cell lung cancer	SoC chemotherapy vs. SoC +Imfinzi or SoC +Imfinzi + treme	First data anticipated H2 2019 FPCD Q1 2017 LPCD Q2 2018	Recruitment completed

Other Cancers

During the period, the Company received confirmation that the Australia Therapeutic Goods Administration had granted approval for Imfinzi for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or who have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

Table 23: IO Non-Lung Cancer Late-Stage Trials

Name	Phase	Population	Design	Timelines	Status
Stage I, II & III (non-metastatic disease)					
POTOMAC	III	Non-muscle invasive bladder cancer	SoC BCG vs. SoC BCG51 +Imfinzi	FPCD Q3 2018 First data anticipated 2020+	Recruitment ongoing
NIAGARA	III	Muscle-invasive bladder cancer	SoC chemotherapy vs. SoC + Imfinzi	FPCD Q3 2018 First data anticipated 2020+	Recruitment initiating
Stage IV (metastatic disease)					
DANUBE	III	Stage IV, 1st-line cisplatin chemotherapy-eligible/ineligible bladder cancer	SoC chemotherapy vs.Imfinzi or Imfinzi + treme	FPCD Q4 2015 LPCD Q1 2017 First data anticipated H2 2019	Recruitment completed
NILE	III	Stage IV, 1st-line cisplatin chemotherapy- eligible bladder cancer	SoC chemotherapy vs. SoC + Imfinzi or SoC + Imfinzi + treme	FPCD Q3 2018 First data anticipated 2020+	Recruitment ongoing
KESTREL	III	Stage IV, 1st-line HNSCC52 (head and neck cancer)	SoC vs. Imfinzi or Imfinzi + treme	FPCD Q4 2015 LPCD Q1 2017	Recruitment completed



EAGLE	III	Stage IV, 2nd-line HNSCC	SoC vs. Imfinzi or Imfinzi + treme	First data anticipated H1 2019 FPCD Q4 2015 LPCD Q3 2017	Recruitment completed
HIMALAYA	III	Stage IV, 1st-line hepatocellular carcinoma (liver cancer)	sorafenib vs. Imfinzi or Imfinzi + treme	First data anticipated Q4 2018 FPCD Q4 2017 First data anticipated 2020+	Recruitment ongoing

During the period, the KESTREL trial of Imfinzi vs. Imfinzi + tremelimumab vs. SoC in Stage IV, 1st-line HNSCC saw the estimated primary completion date updated to reflect the event-based nature of the trial. As a result, the Company now anticipates KESTREL data to be available in H1 2019.

d) Lumoxiti (hairy cell leukaemia)

In 14 September 2018, the Company announced that the US FDA had approved Lumoxiti (moxetumomab pasudotox-tdfk) for the treatment of adult patients with relapsed or refractory hairy cell leukaemia who have received at least two prior systemic therapies, including treatment with a purine nucleoside analogue. The approval was based on the '1053' Phase III trial, which demonstrated that 75% (95% confidence interval: 64, 84) of patients receiving Lumoxiti achieved an overall response and 30% (95% confidence interval: 20, 41) had a durable complete response.

e) Selumetinib (NF1)

During the period, AstraZeneca and MSD announced that the EMA had granted orphan designation to selumetinib, a MEK 1/2 inhibitor, for the treatment NF1, an incurable genetic condition that affects one in 3,000 new-borns worldwide.

f) Vistusertib (multiple cancers)

During the period, the Company decided to cease all trials relating to vistusertib for strategic purposes, including the availability of already-approved medicines using the mTOR pathway.

CVRM

Cardiovascular (CV), renal and metabolism together form one of AstraZeneca's main therapy areas and a key growth driver for the Company. By following the science to understand more clearly the underlying links between the heart, kidneys and pancreas, AstraZeneca is investing in a portfolio of medicines to protect organs and improve outcomes by slowing disease progression, reducing risks and tackling co-morbidities. The Company's ambition is to modify or halt the natural course of CVRM diseases and potentially regenerate organs and restore function, by continuing to deliver transformative science that improves treatment practices and CV health for millions of patients worldwide.

At the 54th Annual Meeting of the European Association for the Study of Diabetes in Berlin in October 2018, the Company presented more than 50 abstracts. Data presented included that for Farxiga and Bydureon in type-2 diabetes, alone and in combination with other diabetes therapies.

a) Farxiga (diabetes)

In September 2018, AstraZeneca announced positive results from the Phase III DECLARE (Dapagliflozin Effect on Cardiovascular Events)-TIMI 58 CVOT for Farxiga, the broadest SGLT2 inhibitor CVOT conducted to date. The trial evaluated CV outcomes of Farxiga vs. placebo over a period of up to five years, across 33 countries and in more than 17,000 adult patients with type-2 diabetes who have multiple CV risk factors or established CV disease. Farxiga met

its primary safety endpoint of non-inferiority for major adverse cardiovascular events (MACE). It also achieved a statistically-significant and clinically-important reduction in the composite endpoint of hospitalisation for HF or CV death, one of the two primary efficacy endpoints. Additionally, fewer MACE events were observed with Farxiga for the other primary efficacy endpoint; this, however, did not reach statistical significance.

On 31 July 2018, patient enrolment was completed in the DAPA-HF trial. This is a Phase III outcomes trial with Farxiga, evaluating the effects of Farxiga on CV death or worsening HF in patients with HF and reduced ejection fraction (HFrEF), a condition where the heart muscle does not contract effectively and less oxygen-rich blood is pumped out to the body. This large global outcomes trial of 4,500 patients will help to define the potential role of Farxiga in the management of chronic HF, in patients with and without type-2 diabetes. Data is anticipated to be available in 2020.

During the period, the first patient was dosed in the Farxiga DELIVER trial (Dapagliflozin Evaluation to Improve the LIVES of Patients with PReserved Ejection Fraction Heart Failure). This is an international Phase III trial, evaluating the effects of Farxiga on reducing CV death or worsening HF in patients with HF and a preserved ejection fraction (HFpEF), a condition where the heart muscle contracts normally but the ventricles do not relax as they should. DELIVER is the latest outcomes trial added to AstraZeneca's global DapaCare clinical programme, exploring the CV and renal profile of Farxiga across a spectrum of patients, both with and without type-2 diabetes, who have CV risk factors, established CV disease and varying stages of renal disease. The trial will complement the aforementioned HFrEF-trial in defining the potential role of Farxiga in the management of chronic HF.

During the period the Company received a positive CHMP opinion for Farxiga, based on results from the DERIVE trial. This is a Phase III trial, designed to evaluate the clinical efficacy and safety of Farxiga in patients with type-2 diabetes and moderate renal impairment (CKD Stage 3A).

b) Onglyza (diabetes)

During the period, the China NMPA granted the approval of Onglyza for combination therapy with insulin for inadequately-controlled type-2 diabetes mellitus, following two previously-approved indications. The approval was based on results from a Phase IIIb trial evaluating the efficacy and safety of Onglyza added to insulin monotherapy or to insulin, in combination with metformin, in Chinese patients with type-2 diabetes who have inadequate glycaemic control on insulin alone or on insulin in combination with metformin.

c) Bydureon (diabetes)

On 30 August 2018, the Company announced that the EMA had approved Bydureon BCise in an improved, easy-to-use device for the treatment of patients with type-2 diabetes. This new formulation of once-weekly Bydureon BCise was first approved by the US FDA in October 2017.

During the period, the Company received notification from the CHMP that it had adopted a positive opinion on a type-II variation update for Bydureon in the European label to include CV data from the EXSCEL (EXenatide Study of Cardiovascular Event Lowering) trial in adult patients with type-2 diabetes at a wide range of CV risk.

Table 24: CV Outcomes Trials

Major CVRM outcomes trials are highlighted in the following table:

Medicine	Trial	Mechanism	Population	Primary endpoint(s)	Timeline
Farxiga	DECLARE	SGLT2 inhibitor	c.17,00053 patients with type-2 diabetes	Superiority for MACE or superiority for the composite endpoint	Primary safety endpoint met; one of two primary efficacy

Farxiga	DAPA-HF	SGLT2 inhibitor	c.4,500 patients with HF <sub>r</sub> EF	of CV death or hHF Time to first occurrence of CV death or hHF or an urgent HF visit	endpoints met FPCD Q1 2017 LPCDQ3 2018Data anticipated 2020
Farxiga	DELIVER	SGLT2 inhibitor	c.4,700 patients with HF <sub>p</sub> EF	Time to first occurrence of CV death or worsening heart failure	FPCDQ3 2018Data anticipated 2020+
Farxiga	DAPA-CKD	SGLT2 inhibitor	c.4,000 patients with CKD	Time to first occurrence of $\geq 50\%$ sustained decline in eGFR <sub>54</sub> or reaching ESRD <sub>55</sub> or CV death or renal death	FPCD Q1 2017Data anticipated 2020
Brilinta	THEMIS	P2Y <sub>12</sub> receptor antagonist	c.19,000 patients with type-2 diabetes and CAD without a history of MI or stroke	Composite of CV death, non-fatal MI and non-fatal stroke	FPCD Q1 2014 LPCD Q2 2016 Data anticipated H1 2019
Brilinta	THALES	P2Y <sub>12</sub> receptor antagonist	c.13,000 patients with acute ischaemic stroke or transient ischaemic attack	Prevention of the composite of subsequent stroke and death at 30 days	FPCD Q1 2018 Data anticipated 2020
Epanova	STRENGTH	Omega-3 carboxylic acids	c.13,000 patients with mixed dyslipidaemia/hypertriglyceridaemia	Time to first occurrence of CV death, non-fatal MI or non-fatal stroke	FPCD Q4 2014 LPCD Q2 2017 Data anticipated 2020

#### d) Lokelma (hyperkalaemia)

During the period, the HARMONIZE-Global Phase III trial, a multi-centre, prospective, randomised, double-blinded, placebo-controlled trial to investigate the safety and efficacy of Lokelma in patients with hyperkalaemia, met its primary endpoint. The data from the trial, presented at the American Society of Nephrology Kidney Week on 25 October 2018 in San Diego, are expected to support regulatory submissions in Japan, Russia, Taiwan and South Korea.

Hyperkalaemia is a serious condition characterised by elevated potassium levels in the blood associated with CV, renal and metabolic diseases. An estimated 10m patients worldwide experience hyperkalaemia in a year and, if not managed properly, can experience serious adverse events, including cardiac arrest and death.

#### e) Roxadustat (anaemia)

In September 2018, Astellas announced that the ALPS Phase III trial, part of the ALPINE programme for roxadustat in CKD, met its primary endpoint. AstraZeneca anticipates high-level results from the OLYMPUS and ROCKIES trials in Q4 2018, with pooled safety data anticipated in H1 2019. The ALPINE clinical-trial programme is being conducted by FibroGen, Inc. (FibroGen), Astellas and AstraZeneca. AstraZeneca and FibroGen are collaborating on the development and commercialisation of roxadustat in the US, China and other rest-of-world countries, not covered by the agreement between FibroGen and Astellas.

#### Respiratory

AstraZeneca's Respiratory focus is aimed at transforming the treatment of asthma and COPD through combined inhaled therapies and biologic medicines 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.

AstraZeneca attended the European Respiratory Society (ERS) International Congress in September 2018 in Paris; the Company presented new data from the BORA Phase III extension trial of Fasenra during a late-breaking oral presentation. This trial evaluated the long-term safety and efficacy of Fasenra as an add-on maintenance treatment for patients with severe, eosinophilic asthma who had previously completed participation in one of the pivotal SIROCCO or CALIMA Phase III trials.

The Company also presented the latest data regarding its inhaled combination medicines, including an oral presentation of the KRONOS Phase III trial which evaluated the efficacy and safety of PT010 (budesonide/glycopyrronium/formoterol) triple-combination therapy vs. dual-combination therapies in patients with moderate to very severe COPD.

a) Symbicort (asthma)

During the period, AstraZeneca submitted a type II variation in the EU to expand the indication of its Symbicort Turbuhaler, as an anti-inflammatory reliever, to patients with mild asthma, 'as needed.' The submission was based on results from the SYGMA 1 and 2 trials, published in the New England Journal of Medicine and presented at this year's American Thoracic Society International Congress. In China, the Chinese Journal of General Practitioners guidelines were updated to incorporate the SYGMA data. This update recommended Symbicort as a potential treatment for all asthma severities. It is estimated that about half of all asthma patients are poorly controlled on their existing medicines; many experts have suggested that anti-inflammatory relievers are a credible alternative to Short Acting Beta Agonist relievers.

b) Duaklir (COPD)

During the period, the US FDA accepted the New Drug Application for Duaklir for the maintenance treatment of patients with COPD and the reduction of exacerbations. The acceptance was based on results from three Phase III trials, including the AMPLIFY trial, which demonstrated statistically-significant and clinically-meaningful improvements in lung function for the combination of aclidinium bromide/formoterol twice-daily, compared with the combination's individual components of either aclidinium bromide or formoterol. The Company anticipates a Prescription Drug User Fee Act action date in the first quarter of 2019.

c) Bevespi (COPD)

In October 2018, the CHMP adopted a positive opinion, recommending the marketing authorisation for Bevespi Aerosphere (glycopyrronium/formoterol fumarate) in a pMDI as a maintenance dual bronchodilator treatment to relieve symptoms in adult patients with COPD. The CHMP recommendation was based on the Phase III PINNACLE programme, which demonstrated the efficacy and safety of Bevespi Aerosphere and involved more than 5,000 patients with moderate to very severe COPD.

In Japan and China, the regulatory submissions for Bevespi Aerosphere were accepted during the period, based on a global Phase III trial, PINNACLE 4, which assessed the efficacy and safety of Bevespi Aerosphere in patients with moderate to very severe COPD. In Japan, c.4.5m patients have been diagnosed with COPD, a top-10 cause of death. The overall prevalence of spirometry-defined COPD in China is c.100m patients and is expected to increase primarily due to smoking, air pollution and ageing.

In August 2018, the Company announced top-line results from the AERISTO Phase IIIb trial for Bevespi Aerosphere in patients with moderate to very severe COPD. The 24-week AERISTO Phase IIIb trial was a randomised, double-blinded, double-dummy, multi-centre, parallel-group trial designed to assess the efficacy and safety of Bevespi Aerosphere compared with umeclidinium/vilanterol. The primary endpoints were peak change from baseline in forced expiratory volume in one second (FEV1) where non-inferiority and superiority were measured and change from baseline in trough FEV1, where non-inferiority was measured. In the trial, Bevespi Aerosphere demonstrated non-inferiority to umeclidinium/vilanterol on peak FEV1 but did not demonstrate superiority on peak FEV1 or non-inferiority on trough FEV1. The performance of Bevespi Aerosphere in AERISTO was inconsistent with previous data. A full analysis is underway to understand and characterise these findings and will be presented at a forthcoming medical meeting.

The medicine is approved in the US and Canada for the long-term maintenance treatment of airflow obstruction in COPD and is currently under review by the EMA with a regulatory decision anticipated in the second half of 2018.

d) PT010 (COPD)

In July 2018, the ETHOS Phase III trial completed recruitment of 8,400 patients across 28 countries, including in Japan and China. The trial is investigating the efficacy and safety of PT010 (budesonide/glycopyrronium/ formoterol fumarate) relative to PT003 and PT009, in patients with moderate to very severe COPD and is part of the ATHENA Phase III clinical-trial programme for PT010, which includes more than 15,500 patients globally across 11 trials. The four key trials are ETHOS, KRONOS, TELOS and SOPHOS. ETHOS and TELOS include low and high doses of inhaled corticosteroid and stratification of patients by eosinophil levels as part of randomisation for PT010 and PT009 (budesonide/formoterol fumarate), respectively.

In September 2018, AstraZeneca announced the publication of results from the KRONOS Phase III trial which evaluated the efficacy and safety of PT010 vs. dual-combination therapies Bevespi Aerosphere, Symbicort Turbuhaler and PT009 in patients with moderate to very severe COPD regardless of whether or not they had an exacerbation in the prior year. PT009 is being characterised to qualify as a relevant comparator in clinical trials for PT010. The data were presented at the aforementioned ERS International Congress and were published in The Lancet Respiratory Medicine.

In addition, AstraZeneca also announced results from the TELOS Phase III trial, which investigated the efficacy and safety of PT009 in patients with moderate to very severe COPD, regardless of whether or not they had an exacerbation in the prior year. The data were presented at the ERS meeting and were published in the European Respiratory Journal.

During the period, the regulatory submissions for PT010 were made to the Japan MHLW and China NMPA, based on the KRONOS Phase III trial.

e) Fasentra (severe asthma)

During the period, the SOLANA Phase IIIb trial did not meet its primary endpoint. SOLANA is a randomised, double-blinded, parallel group, placebo-controlled Phase IIIb trial designed to evaluate the onset and maintenance of effect and the safety of a fixed 30mg dose of Fasentra in patients with severe, eosinophilic asthma. The trial did not meet the primary endpoint of maintenance of effect of improvement of lung function over days 28, 56 and 84, compared to placebo. AstraZeneca is evaluating the full data set and anticipates the results will be submitted for publication in a medical journal.

In the aforementioned BORA Phase III trial, Fasentra was given for an additional 56 weeks and showed a safety and tolerability profile similar to that observed in the placebo-controlled SIROCCO and CALIMA trials, with no increase in the frequencies of overall or serious adverse events. The improvements in efficacy measures observed with Fasentra in the SIROCCO or CALIMA trials were maintained over the second year of treatment. Patients treated with placebo in the SIROCCO and CALIMA trials and subsequently transitioned to Fasentra in the BORA trial

experienced improvements in efficacy outcomes consistent with those observed for Fasenra-treated patients in the previous trials. The BORA trial data was presented during a late-breaking oral session at the ERS International Congress and published in the *Lancet Respiratory Medicine*.

The safety and tolerability findings in SOLANA and BORA respectively were consistent with those observed in previous trials.

f) Tezepelumab (severe asthma)

In September 2018, AstraZeneca and its partner Amgen Inc. announced that the US FDA had granted a Breakthrough Therapy Designation for tezepelumab in patients with severe asthma, without an eosinophilic phenotype, who are receiving inhaled corticosteroids/long-acting beta2-agonists with or without oral corticosteroids and additional asthma controllers.

Tezepelumab is a potential first-in-class new medicine that blocks thymic stromal lymphopoietin, an upstream modulator of multiple inflammatory pathways. A Breakthrough Therapy Designation is designed to expedite the development and regulatory review of medicines that are intended to treat a serious condition and that have shown encouraging early clinical results, which may demonstrate substantial improvement on a clinically-significant endpoint over available medicines. The designation was based on the Phase IIb PATHWAY trial data that showed a significant reduction in the annual asthma-exacerbation rate, compared with placebo, in a broad population of severe-asthma patients, irrespective of patient phenotype, including type 2 biomarker status.

Other

a) FluMist (influenza)

In September 2018, the Company announced the first shipment of FluMist Quadrivalent (Influenza Vaccine Live, Intranasal) in the US for the 2018-2019 influenza seasons, after two seasons off the market.

Earlier this year, the Advisory Committee on Immunization Practices (ACIP) of the CDC reinstated the recommendation for the use of FluMist as an option for influenza vaccination in the US for the 2018-2019 season. This was published in the *Morbidity and Mortality Weekly Report* in June 2018. FluMist remains the only CDC-recommended, needle-free nasal spray influenza vaccine and has been approved in the US since 2012.

b) Anifrolumab (lupus)

In August 2018, the Company announced top-line results from the TULIP 1 Phase III trial for anifrolumab in adult patients with moderate-to-severe systemic lupus erythematosus (SLE). The trial did not meet the primary endpoint of a statistically-significant reduction in disease activity as measured by the SLE Responder Index 4 (SRI4) at 12 months.

This pivotal trial was a randomised, double-blinded, 52-week placebo-controlled, multi-centre trial. A full evaluation of the data will be conducted when TULIP 2 data are available in due course. TULIP 1 data will be presented at a forthcoming medical meeting.

c) MEDI8897 (lower respiratory tract infection)

During the period, the Company concluded primary efficacy analysis for the Phase IIb trial to evaluate the safety and efficacy of MEDI8897. The trial met the primary endpoint, defined as a statistically-significant reduction in the incidence of medically-attended lower respiratory tract infection (LRTI) caused by reverse transcriptase polymerase chain reaction-confirmed respiratory syncytial virus (RSV) for 150 days after dosing.

Edgar Filing: ASTRAZENECA PLC - Form 6-K

MEDI8897 is a monoclonal antibody being developed for the prevention of LRTI caused by RSV, the most-prevalent cause among infants and young children. Full results will be presented at a forthcoming medical meeting. MEDI8897 is being developed in partnership with Sanofi Pasteur.

For more details on the development pipeline, including anticipated timelines for regulatory submission/acceptances, please refer to the latest Clinical Trials Appendix available on [astrazeneca.com](http://astrazeneca.com).

Condensed Consolidated Statement of Comprehensive Income

For the nine months ended 30 September	2018	2017
	\$m	\$m
Product Sales	15,281	14,665
Externalisation Revenue	392	2,023
Total Revenue	15,673	16,688
Cost of sales	(3,299)	(3,093)
Gross profit	12,374	13,595
Distribution costs	(238)	(225)
Research and development expense	(3,920)	(4,206)
Selling, general and administrative costs	(7,431)	(7,155)
Other operating income & expense	1,525	982
Operating profit	2,310	2,991
Finance income	112	71
Finance expense	(1,082)	(1,199)
Share of after tax losses in associates and joint ventures	(77)	(43)
Profit before tax	1,263	1,820
Taxation	(222)	(213)
Profit for the period	1,041	1,607
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Remeasurement of the defined benefit pension liability	138	(146)
Fair value movements on equity investments	159	-
Fair value movements related to own credit risk on bonds designated as fair value through profit or loss	3	(11)
Tax on items that will not be reclassified to profit or loss	(65)	23
	235	(134)
Items that may be reclassified subsequently to profit or loss		
Foreign exchange arising on consolidation	(351)	542
Foreign exchange arising on designating borrowings in net investment hedges	(449)	622
Fair value movements on cash flow hedges	(34)	226
Fair value movements on cash flow hedges transferred to profit or loss	72	(281)
Fair value movements on derivatives designated in net investment hedges	10	(39)
Amortisation of loss on cash flow hedge	-	1

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Fair value movements on equity investments	-	(36)
Tax on items that may be reclassified subsequently to profit or loss	39	(125)
	(713)	910
Other comprehensive (loss)/income for the period, net of tax	(478)	776
Total comprehensive income for the period	563	2,383
Profit attributable to:		
Owners of the Parent	1,121	1,700
Non-controlling interests	(80)	(93)
	1,041	1,607
Total comprehensive income attributable to:		
Owners of the Parent	644	2,476
Non-controlling interests	(81)	(93)
	563	2,383
Basic earnings per \$0.25 Ordinary Share	\$0.88	\$1.34
Diluted earnings per \$0.25 Ordinary Share	\$0.88	\$1.34
Weighted average number of Ordinary Shares in issue (millions)	1,267	1,266
Diluted weighted average number of Ordinary Shares in issue (millions)	1,267	1,266

Condensed Consolidated Statement of Comprehensive Income

For the quarter ended 30 September	2018	2017
	\$m	\$m
Product Sales	5,266	4,882
Externalisation Revenue	74	1,350
Total Revenue	5,340	6,232
Cost of sales	(1,153)	(1,249)
Gross profit	4,187	4,983
Distribution costs	(73)	(76)
Research and development expense	(1,279)	(1,404)
Selling, general and administrative costs	(2,423)	(2,497)
Other operating income & expense	439	143
Operating profit	851	1,149
Finance income	34	32
Finance expense	(364)	(418)
Share of after tax losses in associates and joint ventures	(44)	(17)
Profit before tax	477	746
Taxation	(71)	(97)
Profit for the period	406	649
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Remeasurement of the defined benefit pension liability	(49)	125
Fair value movements on equity investments	3	-
Fair value movements related to own credit risk on bonds designated as fair value through profit or loss	5	(5)
Tax on items that will not be reclassified to profit or loss	2	(48)



Edgar Filing: ASTRAZENECA PLC - Form 6-K

	(39)	72
Items that may be reclassified subsequently to profit or loss		
Foreign exchange arising on consolidation	(67)	159
Foreign exchange arising on designating borrowings in net investment hedges	67	239
Fair value movements on cash flow hedges	(18)	99
Fair value movements on cash flow hedges transferred to profit or loss	3	(81)
Fair value movements on derivatives designated in net investment hedges	12	(4)
Fair value movements on equity investments	-	58
Tax on items that may be reclassified subsequently to profit or loss	(16)	(55)
	(19)	415
Other comprehensive (loss)/income for the period, net of tax	(58)	487
Total comprehensive income for the period	348	1,136
Profit attributable to:		
Owners of the Parent	431	686
Non-controlling interests	(25)	(37)
	406	649
Total comprehensive income attributable to:		
Owners of the Parent	374	1,173
Non-controlling interests	(26)	(37)
	348	1,136
Basic earnings per \$0.25 Ordinary Share	\$0.34	\$0.54
Diluted earnings per \$0.25 Ordinary Share	\$0.34	\$0.54
Weighted average number of Ordinary Shares in issue (millions)	1,267	1,266
Diluted weighted average number of Ordinary Shares in issue (millions)	1,267	1,267

Condensed Consolidated Statement of Financial Position

	At 30 Sep 2018	At 31 Dec 2017	At 30 Sep 2017
	\$m	\$m	\$m
<b>ASSETS</b>			
Non-current assets			
Property, plant and equipment	7,591	7,615	7,329
Goodwill	11,729	11,825	11,841
Intangible assets	24,418	26,188	27,124
Derivative financial instruments	449	504	440
Investments in associates and joint ventures	110	103	78
Other investments	1,124	933	1,004
Other receivables	708	847	953
Deferred tax assets	2,206	2,189	2,184
	48,335	50,204	50,953
Current assets			
Inventories	3,027	3,035	3,162
Trade and other receivables	5,509	5,009	4,540
Other investments	808	1,230	1,175
Derivative financial instruments	34	28	-
Income tax receivable	310	524	721

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Cash and cash equivalents	3,420	3,324	4,036
	13,108	13,150	13,634
Total assets	61,443	63,354	64,587
<b>LIABILITIES</b>			
Current liabilities			
Interest-bearing loans and borrowings	(2,491)	(2,247)	(941)
Trade and other payables	(10,992)	(11,641)	(10,832)
Derivative financial instruments	(33)	(24)	(10)
Provisions	(508)	(1,121)	(1,167)
Income tax payable	(1,224)	(1,350)	(1,513)
	(15,248)	(16,383)	(14,463)
Non-current liabilities			
Interest-bearing loans and borrowings	(18,422)	(15,560)	(16,911)
Derivative financial instruments	(2)	(4)	(3)
Deferred tax liabilities	(3,685)	(3,995)	(5,079)
Retirement benefit obligations	(2,267)	(2,583)	(2,490)
Provisions	(393)	(347)	(387)
Other payables	(7,889)	(7,840)	(9,807)
	(32,658)	(30,329)	(34,677)
Total liabilities	(47,906)	(46,712)	(49,140)
Net assets	13,537	16,642	15,447
<b>EQUITY</b>			
Capital and reserves attributable to equity holders of the Company			
Share capital	317	317	316
Share premium account	4,417	4,393	4,381
Other reserves	2,040	2,029	2,027
Retained earnings	5,162	8,221	7,001
	11,936	14,960	13,725
Non-controlling interests	1,601	1,682	1,722
Total equity	13,537	16,642	15,447







## 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
At 1 Jan 2017	316	4,351	2,047	8,140	14,854	1,815
Profit for the period	-	-	-	1,700	1,700	(93)
Other comprehensive income	-	-	-	776	776	-
Transfer to other reserves	-	-	(20)	20	-	-
Transactions with owners:						
Dividends	-	-	-	(3,543)	(3,543)	-
Issue of Ordinary Shares	-	30	-	-	30	-
Share-based payments charge for the period	-	-	-	163	163	-
Settlement of share plan awards	-	-	-	(255)	(255)	-
Net movement	-	30	(20)	(1,139)	(1,129)	(93)
At 30 Sep 2017	316	4,381	2,027	7,001	13,725	1,722
	Share capital \$m	Share premium account \$m	Other reserves \$m	Retained earnings \$m	Total attributable to owners \$m	Non- controlling interests \$m
At 1 Jan 2018	317	4,393	2,029	8,221	14,960	1,682
Adoption of new accounting standards <sup>57</sup>	-	-	-	(91)	(91)	-
Profit for the period	-	-	-	1,121	1,121	(80)
Other comprehensive income	-	-	-	(477)	(477)	(1)
Transfer to other reserves	-	-	11	(11)	-	-
Transactions with owners:						
Dividends	-	-	-	(3,542)	(3,542)	-
	-	24	-	-	24	-

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Issue of Ordinary Shares						
Share-based payments charge for the period	-	-	-	151	151	-
Settlement of share plan awards	-	-	-	(210)	(210)	-
Net movement	-	24	11	(3,059)	(3,024)	(81)
At 30 Sep 2018	317	4,417	2,040	5,162	11,936	1,601





## Condensed Consolidated Statement of Cash Flows

For the nine months ended 30 September	2018	2017
	\$m	\$m
Cash flows from operating activities		
Profit before tax	1,263	1,820
Finance income and expense	970	1,128
Share of after tax losses in associates and joint ventures	77	43
Depreciation, amortisation and impairment	2,091	1,929
Increase in working capital and short-term provisions	(1,741)	(228)
Gains on disposal of intangible assets	(975)	(735)
Fair value movements on contingent consideration arising from business combinations	(88)	(62)
Non-cash and other movements	(340)	(322)
Cash generated from operations	1,257	3,573
Interest paid	(457)	(519)
Tax paid	(406)	(473)
Net cash inflow from operating activities	394	2,581
Cash flows from investing activities		
Movement in short-term investments and fixed deposits	434	(288)
Purchase of property, plant and equipment	(728)	(849)
Disposal of property, plant and equipment	12	57
Purchase of intangible assets	(234)	(220)
Disposal of intangible assets	842	894
Purchase of non-current asset investments	(46)	(91)
Disposal of non-current asset investments	24	14
Payments to joint ventures	(172)	(11)
Payment of contingent consideration from business combinations	(247)	(310)
Interest received	151	118
Net cash inflow/(outflow) from investing activities	36	(686)
Net cash inflow before financing activities	430	1,895
Cash flows from financing activities		
Proceeds from issue of share capital	24	30
Issue of loans	2,974	1,988
Repayment of loans	-	(1,750)
Dividends paid	(3,484)	(3,519)
Hedge contracts relating to dividend payments	(67)	(20)
Repayment of obligations under finance leases	-	(14)
Movement in short-term borrowings	241	361
Net cash outflow from financing activities	(312)	(2,924)
Net increase/(decrease) in cash and cash equivalents in the period	118	(1,029)
Cash and cash equivalents at the beginning of the period	3,172	4,924
Exchange rate effects	(28)	(71)
Cash and cash equivalents at the end of the period	3,262	3,824
Cash and cash equivalents consist of:		
Cash and cash equivalents	3,420	4,036
Overdrafts	(158)	(212)
	3,262	3,824

## Notes to the Interim Financial Statement

### 1 Basis of Preparation and Accounting Policies

These unaudited condensed consolidated interim financial statements (interim financial statements) for the nine months ended 30 September 2018 have been prepared in accordance with IAS 34 'Interim Financial Reporting' as adopted by the European Union (EU) and as issued by the International Accounting Standards Board (IASB).

The annual financial statements of the Group are prepared in accordance with IFRSs as adopted by the EU and as issued by the IASB. Except as noted below, the interim financial statements have been prepared applying the accounting policies and presentation that were applied in the preparation of the Group's published consolidated financial statements for the year ended 31 December 2017.

IFRS 9 'Financial Instruments' is effective for accounting periods beginning on or after 1 January 2018 and replaces existing accounting standards. It is applicable to financial assets and liabilities and introduces changes to existing accounting concerning classification and measurement, impairment (introducing an expected-loss method), hedge accounting, and on the treatment of gains arising from the impact of own credit risk on the measurement of liabilities held at fair value. The Group early adopted the treatment of fair value changes arising from changes in own credit risk from 1 January 2017 and has adopted the remainder of the standard from 1 January 2018. The principal impact is that equity investments previously classified as available for sale have been re-categorised on initial application and the Group has elected to record fair value movements on certain non-current equity investments in other comprehensive income from 1 January 2018. There is no future recycling of such gains and losses to profit or loss. Fair value movements on other equity investments are recorded in profit. Given the general quality and short-term nature of the trade receivables, there is no material impact on the introduction of an expected-loss impairment method. Other changes include classifying factored receivables and investments in money market funds at fair value through profit and loss, but these changes have not had a material measurement impact. The Group's existing hedging arrangements have been assessed as compliant with the new rules.

IFRS 15 'Revenue from Contracts with Customers' is effective for accounting periods beginning on or after 1 January 2018 and replaces existing accounting standards. It provides enhanced detail on the principle of recognising revenue to reflect the transfer of goods and services to customers at a value which the Company expects to be entitled to receive. The standard also updates revenue disclosure requirements.

The standard has not had a material impact on the revenue streams from the supply of goods and associated rebates and returns provisions. The timing of the recognition of product sales and the basis for the estimates of sales deductions under IAS 18 are consistent with those adopted under IFRS 15.

The previous accounting for externalisation transactions under IAS 18 includes an analysis of the performance obligations under the arrangement and upfront revenue recognition requires the transfer of substantive rights, for example a licence to use the intellectual property and an appropriate allocation of revenue to the remaining performance obligations. While the basis for such allocation is different in IFRS 15, the impact of the adoption of the new standard on the historical allocations is not material. The licences we grant are typically rights to use the intellectual property, which does not change during the period of the licence. Those licences are generally unique and therefore the basis of allocation of revenue to performance obligations makes use of the residual approach as permitted by IFRS 15. The related sales milestones and royalties to these licences qualify for the royalty exemption available under IFRS 15 and will continue to be recognised as the underlying sales are made. Furthermore, there is no material change to the assessment of whether the performance obligations are distinct from applying the new standard.

The Group has retrospectively applied the standard from 1 January 2018 recognising the cumulative effect of initially applying the standard as an increase to trade and other payables of \$133m to defer externalisation revenue previously recognised, an increase to trade and other receivables of \$20m to recognise externalisation revenue previously not

recognised, a total related tax adjustment of \$22m and a corresponding net adjustment to the opening balance of retained earnings of \$91m. There is no restatement to prior periods as permitted in the transition rules for IFRS 15. The impact of initial application in the nine months to 30 September 2018 as compared with the nine months to 30 September 2017 is the recognition of additional Externalisation Revenue of \$21m in the nine months to 30 September 2018. Earnings per share increased by \$0.02.

#### 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 2017 and interim financial statements for the six months ended 30 June 2018.

#### Going concern

The Group has considerable financial resources available. As at 30 September 2018 the Group has \$3.9bn in financial resources (cash balances of \$3.4bn and undrawn committed bank facilities of \$3.0bn which are available until April 2022, with only \$2.5bn 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 the 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 the 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 comparative figures for the financial year ended 31 December 2017 are not the Company's statutory accounts for that financial year. Those accounts have been reported on by the Group's auditors and have been delivered to the registrar of companies; 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.

#### 2 Restructuring Costs

Profit before tax for the nine months ended 30 September 2018 is stated after charging restructuring costs of \$271m (\$645m for the nine months ended 30 September 2017). These have been charged to profit as follows:

	YTD 2018\$m	YTD 2017\$m	Q3 2018 \$m	Q3 2017 \$m
Cost of sales	77	128	22	47
Research and development expense	95	177	37	35
Selling, general and administrative costs	110	265	26	68
Other operating income and expense	(11)	75	(1)	(1)
Total	271	645	84	149

#### 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 2017. Net Debt is a non-GAAP financial measure.

Edgar Filing: ASTRAZENECA PLC - Form 6-K

	At 1 Jan 2018 \$m	Cash Flow \$m	Non-cash & Other \$m	Exchange Movements \$m	At 30 Sep 2018 \$m
Loans due after one year	(15,560)	(2,974)	8	104	(18,422)
Total long-term debt	(15,560)	(2,974)	8	104	(18,422)
Current instalments of loans	(1,397)	-	(2)	-	(1,399)
Current instalments of finance leases	(5)	-	5	-	-
Commercial paper	(180)	(288)	-	-	(468)
Bank Collateral	(513)	47	-	-	(466)
Overdraft	(152)	(16)	-	10	(158)
Total current debt	(2,247)	(257)	3	10	(2,491)
Gross borrowings	(17,807)	(3,231)	11	114	(20,913)
Net derivative financial instruments	504	67	(123)	-	448
Net Borrowings	(17,303)	(3,164)	(112)	114	(20,465)
Cash and cash equivalents	3,324	134	-	(38)	3,420
Other investments - current	1,230	(434)	14	(2)	808
Other investments - non-current	70	-	(18)	-	52
Cash and investments	4,624	(300)	(4)	(40)	4,280
Net funds / (debt)	(12,679)	(3,464)	(116)	74	(16,185)

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

Other investments - non-current are included within the balance of \$1,124m (31 December 2017: \$933m) in the Statement of Financial Position.

The equivalent GAAP measure to net debt is 'liabilities arising from financing activities' which excludes the amounts for cash and overdrafts, other investments and non-financing derivatives shown above and includes the Acerta put option liability of \$1,793m (31 December 2017: \$1,823m) shown in non-current other payables.

#### 4 Financial Instruments

As detailed in the Group's most recent annual financial statements, the 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.

Other than changes resulting from the Group's adoption of IFRS 9 'Financial Instruments' from 1 January 2018, as detailed in Note 1, there have been no changes of significance to the categorisation or fair value hierarchy classification of our financial instruments from those detailed in the Notes to the Group Financial Statements in the Company's Annual Report and Form 20-F Information 2017.

The Group holds certain equity investments that are categorised as Level 3 in the fair value hierarchy and for which fair value gains of \$71m have been recognised in the nine months to 30 September 2018. These are presented in Fair value gains on equity investments in the Condensed Consolidated Statement of Comprehensive Income.

## Edgar Filing: ASTRAZENECA PLC - Form 6-K

Financial instruments measured at fair value include \$1,932m of other investments, \$1,280m of loans, and \$448m of derivatives as at 30 September 2018. The total fair value of interest-bearing loans and borrowings at 30 September 2018 which have a carrying value of \$20,913m in the Condensed Consolidated Statement of Financial Position, was \$21,570m. 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 2018 \$m	Other 2018 \$m	Total 2018 \$m	Total 2017 \$m
At 1 January	4,477	1,057	5,534	5,457
Settlements	(247)	-	(247)	(310)
Revaluations	-	38	38	(62)
Discount unwind	253	60	313	305
At 30 September	4,483	1,155	5,638	5,390

A description of the methods and assumptions used in our valuation approach for financial instruments, and an analysis of the key sensitivities, is included in Notes 11, 12, 17 and 18 to the Financial Statements in our Annual Report on Form 20-F Information 2017.

### 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 2017 and the interim financial statements for the six months ended 30 June 2018 (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 Third Quarter of 2018 and to 8 November 2018

Patent Litigation

Faslodex (fulvestrant)

US patent proceedings

As previously disclosed, AstraZeneca has filed patent infringement lawsuits in the US District Court for the District of New Jersey (the District Court) relating to four patents listed in the FDA Orange Book with reference to Faslodex against generic companies seeking to market generic versions of Faslodex, prior to the expiration of AstraZeneca's patents. As also previously disclosed, AstraZeneca settled the lawsuits against all but two of those Abbreviated New Drug Application (ANDA) filers. In August and September 2018, AstraZeneca settled the lawsuits against the remaining two ANDA filers and the District Court entered consent judgments ending those lawsuits.

Farxiga (dapagliflozin)

US patent proceedings

As previously disclosed, in May 2018, AstraZeneca initiated ANDA litigation against Zydus Pharmaceuticals (USA) Inc. (Zydus) in the US District Court for the District of Delaware. In its complaint, AstraZeneca alleges that Zydus's generic version of Farxiga, if approved and marketed, would infringe AstraZeneca's US Patents Nos. 6,414,126 and 6,515,117. In June 2018, Zydus filed its answer and counterclaims for noninfringement of AstraZeneca's US Patent Nos. 7,851,502; 7,919,598; 8,221,786; 8,361,972; 8,501,698; 8,685,934; and 8,716,251. Trial is scheduled for February 2021.

Symbicort (budesonide/formoterol fumarate dihydrate)

US Patent Proceedings

In October 2018, AstraZeneca initiated ANDA litigation against Mylan Pharmaceuticals Inc., Mylan Laboratories Limited, Mylan Inc., and Mylan N.V. (collectively, Mylan) and, separately, ANDA litigation against Teva Pharmaceuticals USA, Inc. (Teva) in the US District Court for the District of Delaware. In its complaints, AstraZeneca alleges that Mylan's and Teva's generic versions of Symbicort, if approved and marketed, would infringe AstraZeneca's US Patents Nos. 7,759,328; 8,143,239; 8,575,137; and 7,967,011. AstraZeneca has also filed a similar action against Mylan in the US District Court for the Northern District of West Virginia.

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 and the California state coordinated proceeding granted the defendants' motion for summary judgment and dismissed all claims alleging pancreatic cancer that accrued prior to 11 September 2015 and 8 October 2015, respectively. As previously disclosed, in November 2017, the US Court of Appeals for the Ninth Circuit annulled the District Court's order and remanded for further discovery. In November 2018, the Court of Appeal for the State of California annulled the judgment from the California state coordinated proceeding and remanded for further discovery.

Seroquel (quetiapine fumarate)

As previously disclosed, in the US, in June 2018, AstraZeneca was named in a lawsuit filed in Illinois involving one plaintiff alleging Brugada Syndrome from treatment with Seroquel. In September 2018, the US District Court for the Southern District of Illinois entered judgment in favour of AstraZeneca and terminated AstraZeneca as a party to the action.

## Edgar Filing: ASTRAZENECA PLC - Form 6-K

As previously disclosed, in the US, 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. The litigation remains pending.

### Commercial Litigation

#### Toprol-XL (metoprolol succinate)

##### Aralez Litigation

In October 2016, AstraZeneca completed its sale of certain assets related to the US rights to Toprol-XL and AstraZeneca's authorised generic metoprolol succinate product to Aralez Pharmaceuticals Trading DAC (Aralez). In the US, in August 2018, Aralez commenced voluntary insolvency proceedings and filed voluntary petitions for relief under Chapter 11 of the US Bankruptcy Code. Aralez identified AstraZeneca as an unsecured creditor in the US Bankruptcy Proceedings with a claim of \$14m. In October 2018, AstraZeneca filed a notice of objection stating, among other things, that AstraZeneca's unsecured claim is c.\$63m.

### Government Investigations/Proceedings

#### Crestor (rosuvastatin calcium)

##### Texas Attorney General Litigation

As previously disclosed, in the US, in January 2015, AstraZeneca was served with a lawsuit in which the Texas Attorney General's office intervened in a state whistle-blower action pending in Travis County Court, Texas. The lawsuit alleged that AstraZeneca engaged in inappropriate promotion of Crestor and improperly influenced the formulary status of Crestor. In July 2018, this matter was resolved and is now concluded.

#### Toprol-XL (metoprolol succinate)

##### Louisiana Attorney General Litigation

As previously disclosed, in the US, in February 2016, a Louisiana state court (the Trial Court) dismissed a civil lawsuit that was filed by the Attorney General for the State of Louisiana against AstraZeneca, which alleged unlawful monopolisation and unfair trade practices in connection with enforcement of patents for Toprol-XL. As also previously disclosed, in April 2018, the Louisiana Court of Appeals for the First Circuit (the Appellate Court) reversed the dismissal and remanded the case back to the Trial Court for further proceedings and, in May 2018, AstraZeneca filed a writ with the Louisiana Supreme Court seeking review of the Appellate Court's decision. In September 2018, the Louisiana Supreme Court denied that writ and declined to review the Appellate Court's decision.

#### Synagis (palivizumab)

##### Litigation in New York

As previously disclosed, in June 2011, MedImmune received a demand from the US Attorney's Office for the Southern District of New York requesting certain documents related to the sales and marketing activities of Synagis. In July 2011, MedImmune received a similar court order to produce documents from the Office of the Attorney General for the State of New York Medicaid and Fraud Control Unit pursuant to what the government attorneys advised was a joint investigation. MedImmune has cooperated with these inquiries. In March 2017, MedImmune was served with a lawsuit filed in US Federal Court in New York by the Attorney General for the State of New York alleging that MedImmune inappropriately provided assistance to a single specialty care pharmacy. In September 2018, the US Federal Court in New York denied MedImmune's motion to dismiss the lawsuit brought by the Attorney General for the State of New York.

In June 2017, MedImmune was served with a lawsuit in US Federal Court in New York by a relator under the qui tam (whistle-blower) provisions of the federal and certain state False Claims Acts. The lawsuit was originally filed under seal in April 2009 and alleges that MedImmune made false claims about Synagis. In November 2017, MedImmune was served with an amended complaint in which relator set forth additional false claims allegations relating to Synagis. In September 2018, the US Federal Court in New York dismissed the relator's lawsuit.

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

#### Qui tam Litigation in New York

As previously disclosed, in the US, in September 2015, AstraZeneca was served with a lawsuit filed in US Federal Court in New York under the qui tam (whistle-blower) provisions of the federal and certain state False Claims Acts. The lawsuit alleges that AstraZeneca misrepresented the safety profile of, and improperly promoted, Seroquel. In July 2018, this matter was resolved and is now concluded.

#### Qui Tam Litigation in Delaware

As previously disclosed, in the US, in April 2014, AstraZeneca was served with lawsuits filed in the US District Court for the District of Delaware under the qui tam (whistle-blower) provisions of the federal False Claims Act and related state statutes, alleging that AstraZeneca directed certain employees to promote Seroquel off-label and provided unlawful remuneration to physicians in connection with the promotion of Seroquel. In July 2018, this matter was resolved and is now concluded.

#### Texas Attorney General Litigation

As previously disclosed, in the US, in October 2014, the Texas Attorney General's Office intervened in a State whistle-blower action pending in Travis County Court, Texas. The lawsuit alleged that AstraZeneca engaged in inappropriate promotion and made improper payments intended to influence the formulary status of Seroquel. In July 2018, this matter was resolved and is now concluded.

## 6 Subsequent Events

On 26 October 2018, the High Court issued a judgement relating to Guaranteed Minimum Pensions (GMPs) in the "Lloyds case". Although the ruling relates to the Lloyds Banking Group pension schemes, it is expected to create a precedent for other UK defined benefit pension schemes and therefore potentially impact the AstraZeneca Pension Fund (AZPF), which is the Company's legacy defined-benefit pension scheme in the UK.

The ruling requires the equalisation of member benefits to address gender inequality in instances where GMP benefits are currently unequal. There appear to be various methods by which this equalisation could be achieved. At the time of writing, the Company is working through the details of the ruling and assessing its impact on the liability valuation of the AZPF. Given the complexities involved and the possibility of an appeal to the ruling, there remain a number of uncertainties surrounding any potential changes and it is likely to take some time for the Company and Trustee of the AZPF to consider and therefore the Company is unable to make a reliable estimate of any additional liability at this time.

During October 2018, a further \$150m sales-related milestone under the Lynparza collaboration with MSD was achieved and will be recorded in Externalisation Revenue in Q4 2018.

Additional post balance-sheet events include the divestment of the prescription medicine rights to Nexium in Europe, the divestment of the global rights (excluding the US and Japan) to Vimovo to Grünenthal, the divestment of the global rights to Alvesco, Omnaris and Zetonna to Covis Pharma B.V., as well as an extension to an existing collaboration with Innate Pharma. Further details on each of these events can be found within the Corporate and Business Development Update section.

## 7 Product Sales Analysis - YTD 2018

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



Edgar Filing: ASTRAZENECA PLC - Form 6-K

	World			Emerging Markets			US			Europe			Established ROW	
	YTD 2018 \$m	Actual %	CER %	YTD 2018 \$m	Actual %	CER %	YTD 2018 \$m	Actual %	YTD 2018 \$m	Actual %	CER %	YTD 2018 \$m	Actual %	CER %
<b>Oncology</b>														
Tagrisso	1,266	94	91	266	213	206	580	n/m	222	79	68	198	20	18
Lynparza	438	n/m	n/m	33	n/m	n/m	233	n/m	137	46	37	35	n/m	n/m
Iressa	406	2	(2)	226	13	10	20	(26)	85	6	(3)	75	(18)	(20)
Imfinzi	371	n/m	n/m	4	n/m	n/m	348	n/m	9	n/m	n/m	10	n/m	n/m
Calquence	38	n/m	n/m	-	-	-	38	n/m	-	-	-	-	-	-
<b>Legacy:</b>														
Faslodex	759	8	6	111	26	28	394	7	171	(12)	(19)	83	57	53
Zoladex	570	4	2	313	20	20	6	(63)	99	(5)	(12)	152	(10)	(11)
Arimidex	166	4	1	106	25	22	-	n/m	23	(12)	(15)	37	(16)	(18)
Casodex	155	(4)	(7)	90	15	10	1	0	15	(12)	(12)	49	(25)	(26)
Others	92	8	5	24	14	6	-	-	5	25	25	63	5	3
<b>Total Oncology</b>	<b>4,261</b>	<b>47</b>	<b>44</b>	<b>1,173</b>	<b>42</b>	<b>39</b>	<b>1,620</b>	<b>107</b>	<b>766</b>	<b>19</b>	<b>11</b>	<b>702</b>	<b>8</b>	<b>6</b>
<b>CVRM</b>														
Brilinta	945	21	18	232	33	31	411	16	257	21	12	45	22	22
Farxiga	994	34	32	242	51	57	420	24	231	35	25	101	40	38
Bydureon	446	4	3	9	80	80	360	5	62	(5)	(12)	15	7	7
Onglyza	395	(8)	(10)	121	30	29	162	(25)	68	(13)	(18)	44	2	-
Byetta	94	(27)	(27)	6	(33)	(44)	55	(32)	22	(15)	(15)	11	(8)	(8)
Symlin	24	(31)	(31)	-	-	-	24	(31)	-	-	-	-	-	-
<b>Legacy:</b>														
Crestor	1,080	(39)	(41)	631	9	7	128	(48)	159	(69)	(71)	162	(63)	(63)
Seloken/Toprol-XL	552	5	4	493	13	12	33	(3)	16	(67)	(67)	10	25	25
Atacand	202	(11)	(11)	114	(16)	(13)	11	(35)	62	(2)	(8)	15	25	25
Others	231	(11)	(14)	156	(1)	(4)	(2)	n/m	58	(16)	(19)	19	(39)	(39)
<b>Total CVRM</b>	<b>4,963</b>	<b>(7)</b>	<b>(8)</b>	<b>2,004</b>	<b>15</b>	<b>14</b>	<b>1,602</b>	<b>(4)</b>	<b>935</b>	<b>(25)</b>	<b>(30)</b>	<b>422</b>	<b>(36)</b>	<b>(37)</b>
<b>Respiratory</b>														
Symbicort	1,925	(6)	(9)	364	13	12	655	(19)	588	-	(8)	318	(3)	(5)
Pulmicort	897	11	7	688	20	16	81	(24)	68	3	(5)	60	(2)	(3)
Fasenra	172	n/m	n/m	-	-	-	129	n/m	17	n/m	n/m	26	n/m	n/m
Daliresp/Daxas	135	(7)	(8)	4	-	(25)	110	(11)	20	25	19	1	-	-
Tudorza/Eklira	91	(16)	(19)	1	n/m	-	28	(40)	54	(2)	(7)	8	33	33
Duaklir	73	30	20	1	n/m	-	-	-	70	30	20	2	-	-
Bevespi	23	n/m	n/m	-	-	-	23	n/m	-	-	-	-	-	-
Others	233	17	12	89	31	24	4	(30)	105	7	3	35	9	6
<b>Total Respiratory</b>	<b>3,549</b>	<b>5</b>	<b>2</b>	<b>1,147</b>	<b>19</b>	<b>15</b>	<b>1,030</b>	<b>(6)</b>	<b>922</b>	<b>5</b>	<b>(2)</b>	<b>450</b>	<b>5</b>	<b>3</b>
<b>Other</b>														
Nexium	1,312	(14)	(16)	524	2	-	249	(44)	179	2	(5)	360	(8)	(10)
Synagis	414	(9)	(9)	-	-	-	133	(27)	281	4	4	-	-	-
Losec/Prilosec	212	5	-	131	26	20	5	(44)	51	(11)	(18)	25	(22)	(22)
Seroquel XR	169	(25)	(26)	45	(4)	(6)	67	(35)	48	(21)	(26)	9	(31)	(31)
Movantik/Moventig	84	(9)	(9)	-	-	-	81	(11)	2	n/m	n/m	1	n/m	n/m
FluMist/Fluenz	35	75	75	-	-	-	15	n/m	20	11	11	-	n/m	n/m

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Others	282	(49)	(50)	100	(68)	(63)	37	61	82	(23)	(42)63	(41)	(45)
Total Other	2,508	(18)	(20)	800	(18)	(18)	587	(31)	663	(4)	(10)458	(16)	(18)
Total Product Sales	15,281	4	2	5,124	13	12	4,839	10	3,286	(5)	(11)2,032	(11)	(13)

8 Product Sales Analysis - Q3 2018

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	
	Q3 2018 \$m	Actual %	CER %	Q3 2018 \$m	Actual %	CER %	Q3 2018 \$m	Actual %	Q3 2018 \$m	Actual %	CER %	Q3 2018 \$m	Actual %	CER %
<b>Oncology</b>														
Tagrisso	506	n/m	n/m	107	n/m	n/m	239	n/m	83	73	75	77	33	33
Lynparza	169	n/m	n/m	15	n/m	n/m	84	n/m	50	39	39	20	n/m	n/m
Iressa	131	(4)	(4)	78	10	13	6	(40)	24	(8)	(12)	23	(23)	(23)
Imfinzi	187	n/m	n/m	1	n/m	n/m	170	n/m	6	n/m	n/m	10	n/m	n/m
Calquence	18	n/m	n/m	-	-	-	18	n/m	-	-	-	-	-	-
<b>Legacy:</b>														
Faslodex	258	7	8	40	18	26	135	6	53	(13)	(13)	30	58	58
Zoladex	194	5	8	111	21	25	3	50	31	(16)	(16)	49	(9)	(7)
Arimidex	55	2	4	35	25	29	-	n/m	8	(11)	(11)	12	(20)	(20)
Casodex	51	-	2	31	41	45	1	-	4	(33)	(33)	15	(32)	(32)
Others	28	(3)	(6)	8	-	(9)	-	-	2	n/m	n/m	18	(10)	(10)
Total Oncology	1,597	56	57	426	39	43	656	138	261	17	17	254	15	16
<b>CVRM</b>														
Brilinta	336	18	20	84	56	61	152	9	85	9	9	15	25	33
Farxiga	355	25	27	85	42	53	154	16	79	20	20	37	42	42
Bydureon	152	19	19	2	n/m	n/m	126	26	19	(17)	(17)	5	-	-
Onglyza	140	10	12	40	33	39	64	10	21	(19)	(19)	15	15	15
Byetta	34	(13)	(10)	2	(50)	(25)	23	-	6	(25)	(25)	3	(25)	(25)
Symlin	8	(20)	(20)	-	-	-	8	(20)	-	-	-	-	-	-
<b>Legacy:</b>														
Crestor	353	(39)	(38)	207	10	13	38	(59)	48	(68)	(69)	60	(59)	(59)
Seloken/Toprol-XL	179	12	17	165	11	17	7	75	4	(33)	(33)	3	50	50
Atacand	65	(19)	(15)	38	(24)	(18)	1	(80)	21	-	-	5	25	25
Others	73	(9)	(6)	47	-	4	-	n/m	20	-	-	6	(45)	(45)
Total CVRM	1,695	(4)	(3)	670	15	21	573	1	303	(24)	(25)	149	(33)	(33)
<b>Respiratory</b>														
Symbicort	619	(7)	(7)	123	13	17	216	(16)	177	(7)	(8)	103	(7)	(5)
Pulmicort	264	9	10	206	18	19	22	(24)	18	-	-	18	(10)	(5)
Fasenra	86	n/m	n/m	-	-	-	62	n/m	9	n/m	n/m	15	n/m	n/m
Daliresp/Daxas	52	(2)	(2)	3	n/m	n/m	43	(4)	6	(14)	(14)	-	-	-
Tudorza/Eklira	18	(51)	(51)	1	n/m	-	(1)	n/m	16	(6)	-	2	-	-
Duaklir	23	10	5	-	-	n/m	-	-	23	15	15	-	n/m	n/m

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Bevespi	10	n/m	n/m	-	-	-	10	n/m	-	-	-	-	-	-
Others	70	4	6	28	33	38	3	n/m	30	(19)	(19)	9	(10)	(10)
Total Respiratory	1,142	5	5	361	18	20	355	1	279	(4)	(4)	147	2	4
Other														
Nexium	422	(10)	(9)	181	5	8	62	(40)	57	2	4	122	(12)	(11)
Synagis	164	7	7	-	-	-	8	(47)	156	13	13	-	-	-
Losec/Prilosec	67	2	2	43	26	29	1	-	15	(21)	(26)	8	(33)	(33)
Seroquel XR	40	(35)	(35)	5	(67)	(67)	18	(31)	15	(17)	(17)	2	(33)	(33)
Movantik/Moventig	32	7	7	(1)	n/m	n/m	30	3	2	n/m	n/m	1	n/m	n/m
FluMist/Fluenz	35	75	75	-	-	-	15	n/m	20	11	11	-	n/m	n/m
Others	72	(62)	(62)	15	(85)	(83)	19	19	24	-	(13)	14	(70)	(68)
Total Other	832	(16)	(15)	243	(25)	(22)	153	(19)	289	5	4	147	(28)	(27)
Total Product Sales	5,266	8	9	1,700	12	16	1,737	25	1,132	(5)	(5)	697	(12)	(11)

9 Sequential Quarterly Product Sales - 2018

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

	Q1 2018	Actual	CER	Q2 2018	Actual	CER	Q3 2018	Actual	CER	Q4	Actual	CER
	\$m	%	%	\$m	%	%	\$m	%	%	2018	%	%
										\$m		
Oncology												
Tagrisso	338	11	10	422	25	25	506	20	23			
Iressa	132	2	(1)	143	8	8	131	(8)	(5)			
Lynparza	119	19	18	150	26	26	169	13	15			
Imfinzi	62	n/m	n/m	122	98	98	187	53	52			
Calquence	8	n/m	n/m	12	51	50	18	50	50			
Legacy:												
Faslodex	254	7	5	247	(3)	(2)	258	4	7			
Zoladex	184	(2)	(4)	192	4	5	194	1	6			
Arimidex	54	(5)	(7)	57	6	6	55	(4)	-			
Casodex	52	(4)	(6)	52	-	(2)	51	(2)	4			
Others	27	(7)	(20)	37	37	50	28	(24)	(22)			
Total Oncology	1,230	10	8	1,434	17	17	1,597	11	14			
CVRM												
Brilinta	293	(2)	(4)	316	8	9	336	6	9			
Farxiga	299	(10)	(11)	340	14	15	355	4	7			
Onglyza	129	(28)	(29)	126	(2)	(2)	140	11	14			
Bydureon	139	(5)	(5)	155	12	11	152	(2)	(1)			
Byetta	31	(35)	(38)	29	(7)	(3)	34	17	17			
Symlin	9	(31)	(31)	7	(22)	(22)	8	14	14			
Legacy:												
Crestor	389	(35)	(36)	338	(13)	(12)	353	4	8			
Seloken/Toprol-XL	200	19	18	173	(14)	(13)	179	3	10			
Atacand	71	(3)	(3)	66	(8)	(8)	65	(2)	5			
Others	85	6	4	73	(13)	(11)	73	(3)	-			

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Total CVRM	1,645	(15)	(17)	1,623	(1)	-	1,695	4	8
Respiratory									
Symbicort	634	(16)	(17)	672	6	6	619	(8)	(5)
Pulmicort	346	(7)	(8)	287	(17)	(17)	264	(8)	(4)
Daliresp/Daxas	38	(28)	(30)	45	19	22	52	16	18
Tudorza/Eklira	34	(19)	(21)	39	15	15	18	(54)	(59)
Duaklir	28	22	17	22	(22)	(19)	23	5	5
Fasenra	21	n/m	n/m	65	n/m	n/m	86	32	34
Bevespi	5	(38)	(38)	8	61	60	10	25	25
Others	75	(12)	(20)	88	17	16	70	(20)	(13)
Total Respiratory	1,181	(11)	(13)	1,226	4	4	1,142	(7)	(4)
Other									
Nexium	448	5	3	442	(1)	(1)	422	(5)	97
Synagis	224	(4)	(4)	26	(89)	(88)	164	n/m	n/m
Losec/Prilosec	69	-	(4)	76	10	11	67	(12)	85
Seroquel XR	53	(51)	(51)	76	44	42	40	(47)	(8)
Movantik/Moventig	28	(7)	(7)	24	(14)	(14)	32	33	167
FluMist/Fluenz	-	n/m	n/m	-	n/m	n/m	35	n/m	n/m
Others	107	(36)	(37)	103	(4)	(5)	72	(29)	n/m
Total Other	929	(15)	(16)	747	(20)	(20)	832	12	15

Total Product Sales 4,985 (9) (11) 5,030 1 1 5,266 5 8

10 Sequential 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 \$m	Actual %	CER %	Q2 2017 \$m	Actual %	CER%	Q3 2017 \$m	Actual %	CER %	Q4 2017 \$m	Actual %	CER %
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
CVRM												
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

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Byetta	46	(16)	(16)	43	(7)	(7)	39	(9)	(9)	48	23	23
Symlyn	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 CVRM	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	-	-
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

11 Sequential 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 \$m	Actual %	CER %	Q2 2016 \$m	Actual %	CER%	Q3 2016 \$m	Actual %	CER %	Q4 2016 \$m	Actual %	CER %
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
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
Arimidex	57	(5)	(5)	62	9	7	56	(10)	(13)	57	2	5
Casodex	62	(2)	(6)	63	2	-	62	(2)	(5)	60	(3)	(2)
Others	21	(22)	(22)	27	29	12	27	-	4	29	7	-

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Total Oncology	738	3	3	848	15	12	867	2	2	930	7	7
CVRM												
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
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 CVRM	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
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

Shareholder Information

Announcement  
of full year and  
final quarter 14 February 2019  
2018 results  
Announcement  
of first quarter  
2019 results and 26 April 2019  
Annual General  
Meeting

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 2018, payable on 27 March 2019, will be 1 March 2019. The ex-dividend date will be 28 February 2019. The record date for the first interim dividend for 2019, payable on 9 September 2019, will be 9 August 2019. The ex-dividend date will be 8 August 2019.

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, Eklira, and Tudorza, trademarks of Almirall, S.A.; Epanova, a trademark of Chrysalis Pharma AG; Atacand and Atacand Plus owned by AstraZeneca or Cheplapharm Arzneimittel GmbH (depending on geography); Synagis, owned by AstraZeneca or AbbVie Inc. (depending on geography).

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

Cautionary Statements Regarding Forward-Looking Statements

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

This document contains certain forward-looking statements with respect to the operations, performance and financial condition of the Group, including, among other things, statements about expected revenues, margins, earnings per share or other financial or other measures. Although we believe our expectations are based on reasonable assumptions, any forward-looking statements, by their very nature, involve risks and uncertainties and may be influenced by factors that could cause actual outcomes and results to be materially different from those predicted. The forward-looking statements reflect knowledge and information available at the date of preparation of this document and AstraZeneca undertakes no obligation to update these forward-looking statements. We identify the forward-looking statements by using the words 'anticipates', 'believes', 'expects', 'intends' and similar expressions in such statements. Important factors that could cause actual results to differ materially from those contained in forward-looking statements, certain of which are beyond our control, include, among other things: the loss or expiration of, or limitations to, patents, marketing exclusivity or trademarks, or the risk of failure to obtain and enforce patent protection; effects of patent litigation in respect of IP rights; the impact of any delays in the manufacturing, distribution and sale of any of our products; the impact of any failure by third parties to supply materials or services; the risk of failure of outsourcing; the risks associated with manufacturing biologics; the risk that R&D will not yield new products that achieve commercial success; the risk of delay to new product launches; the risk that new products do not perform as we expect; the risk that strategic alliances and acquisitions, including licensing and collaborations, will be unsuccessful; the risks from pressures resulting from generic competition; the impact of competition, price controls and price reductions; the risks associated with developing our business in emerging markets; the risk of illegal trade in our products; the difficulties of obtaining and maintaining regulatory approvals for products; the risk that regulatory approval processes for biosimilars could have an adverse effect on future commercial prospects; the risk of failure to successfully implement planned cost reduction measures through productivity initiatives and restructuring programmes; the risk of failure of critical processes affecting business continuity; economic, regulatory and political pressures to limit or reduce the cost of our products; failure to achieve strategic priorities or to meet targets, 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.

14 Overall survival.

15 Coronary artery disease.

16 Chronic lymphocytic leukaemia.

17 Chronic kidney disease.

18 Due to rounding, the sum of therapy-area percentages may not agree to the total.

19 Due to rounding, the sum of Product Sales percentages may not agree to the total.

20 Due to rounding, the sum of category percentages may not agree to totals.

21 May include, inter alia, option income and profit-sharing income.

22 YTD 2018 Product Sales here comprise sales made to collaborators under manufacturing and supply agreements.



23 Due to the proximity to 30 September 2018 of the completion of the Seroquel and Seroquel XR divestment and the relatively stronger sales seen in the nine months to 30 September 2018, there is no adverse impact on YTD 2018 Product Sales. An adverse impact is expected from Q4 2018 onwards.

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

25 Due to rounding, the sum of region or country percentages may not agree to totals.

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

27 Gross Margin, as a percentage of Product Sales, reflects Gross Profit derived from Product Sales, divided by Product Sales. YTD 2018 Cost of Sales included \$nil of costs relating to externalisation activities (YTD 2017: \$200m), which are excluded from the calculation of Gross Margin. Movements in Gross Margin are expressed in percentage points.

28 Gross Margin, as a percentage of Product Sales, reflects Gross Profit derived from Product Sales, divided by Product Sales. Q3 2018 Cost of Sales included \$nil of costs relating to externalisation activities (Q3 2017: \$159m), which are excluded from the calculation of Gross Margin. Movements in Gross Margin are expressed in percentage points.

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

30 Other adjustments include fair-value adjustments relating to contingent consideration on business combinations (see Note 4), discount unwind on acquisition-related liabilities (see Note 4) and provision movements related to certain legal matters (see Note 5).

31 Each 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.

32 Gross Margin, as a percentage of Product Sales, reflects Gross Profit derived from Product Sales, divided by Product Sales. YTD 2018 Cost of Sales included \$nil of costs relating to externalisation activities (YTD 2017: \$200m), which are excluded from the calculation of Gross Margin. Movements in Gross Margin are expressed in percentage points.

33 Other adjustments include fair-value adjustments relating to contingent consideration on business combinations (see Note 4), discount unwind on acquisition-related liabilities (see Note 4) and provision movements related to certain legal matters (see Note 5).

34 Each 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.

35 Gross Margin, as a percentage of Product Sales, reflects Gross Profit derived from Product Sales, divided by Product Sales. Q3 2018 Cost of Sales included \$nil of costs relating to externalisation activities (Q3 2017: \$159m), which are excluded from the calculation of Gross Margin. Movements in Gross Margin are expressed in percentage points.

36 Based on best prevailing assumptions around currency profiles.

37 Based on average daily spot rates between 1 January and 30 September 2018.

38 Other important currencies are AUD, BRL, CAD, KRW and RUB.

39 These priorities were determined, along with a set of nine foundational areas, through a materiality assessment with external and internal stakeholders, respectively. Combined, they ensure the maximum possible benefit to patients, the Company, broader society and the planet. AstraZeneca's sustainability priorities, foundations and commitments align with the United Nations Sustainable Development Goals (SDG), and, in particular, SDG three for 'Good Health'.

40 Data reported as of 30 September 2018.

41 Scope 3 increase is primarily a result of growing pressurised metered device inhalation (pMDI) emissions in the Respiratory-medicines platform; also due to air travel, outweighing savings made in logistics.

42 Until formal on-boarding of a new market begins there is not full sight of all spend made by third parties on the Company's behalf, therefore there may be some variance in overall coverage.

43 Under regulatory review. The table shown above as at today.

44 Phase II trial data, with potential for registration.

45 Conducted by the ARCAGY/Groupe d'Investigateurs National des Etudes des Cancers Ovariens et du sein.

- 46 First patient commenced dosing.
- 47 Last patient commenced dosing.
- 48 Germline BRCAm.
- 49 Homologous Recombination Repair mutated.
- 50 Conducted by the Canadian Cancer Trials Group.
- 51 Bacillus Calmette-Guerin.
- 52 Head and neck squamous cell carcinoma.
- 53 Includes c.10,000 patients who have had no prior index event and c.7,000 patients who have suffered an index event.
- 54 Estimated glomerular filtration rate.
- 55 End-stage renal disease.
- 56 Other reserves include the capital redemption reserve and the merger reserve.
- 57 The Group adopted IFRS 15 'Revenue from Contracts with Customers' from 1 January 2018. See Note 1.

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: 08 November 2018

By: /s/ Adrian Kemp

Name: Adrian Kemp

Title: Company Secretary