

ASTRAZENECA PLC
Form 6-K
May 18, 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 May 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: Q1 2018 Results

AstraZeneca PLC
18 May 2018 07:00
Q1 2018 Results

Encouraging launches and the performance of newer medicines underpin reiterated guidance

As expected, the Product Sales performance benefitted from strong launches and the continued growth of newer medicines and China, offset by the erosion of Crestor sales. Progress was made on overall cost discipline, while the level of Externalisation Revenue, divestment timing and investment in launches impacted the overall results. Patients continued to benefit from the progress of the pipeline and AstraZeneca's plans remain on track, with the Company continuing to anticipate Product Sales growth this year, weighted to the second half.

Financial Highlights

	Q1 2018		
	\$m	% change	
		Actual	CER1
Total Revenue	5,178	(4)	(9)
Product Sales	4,985	3	(2)
Externalisation Revenue	193	(66)	(67)
Reported Operating Profit ²	696	(24)	(21)
Core Operating Profit ³	896	(46)	(47)
Reported Earnings Per Share (EPS)	\$0.27	(37)	(29)
Core EPS	\$0.48	(51)	(51)

Product Sales increased by 3% (down by 2% at CER). Strong performance of China and newer medicines across all therapy areas was offset by the decline of Crestor sales in Europe and Japan. Total Revenue declined by 4% (9% at CER) to \$5,178m, reflecting the level of Externalisation Revenue in the quarter

The Reported Gross Margin declined by five percentage points (four at CER) to 77.3%, a result of the favourable impact of manufacturing variances realised in Q1 2017, as well as the agreement on Lynparza with MSD⁴; the Core Gross Margin fell by five percentage points (four at CER) to 78.8%

Good progress on overall cost discipline - Reported Operating Expenses were stable (down by 5% at CER) at \$3,817m; Core Operating Expenses increased by 3% (but declined by 1% at CER) to \$3,349m. Reported R&D costs declined by 12% (16% at CER) to \$1,279m; Core R&D costs declined by 7% (12% at CER) to \$1,240m, driven by efficiency savings. Reported SG&A costs increased by 7% (2% at CER) to \$2,457m; Core SG&A costs increased by 11% (6% at CER) to \$2,028m, reflecting investment in China and new medicine launches

Reported Other Operating Income & Expense increased by 99% (97% at CER) to \$469m, a result of a legal settlement; Core Other Operating Income & Expense declined by 63% (64% at CER) to \$124m, impacted by the

timing of divestments

Reported EPS of \$0.27 and Core EPS of \$0.48

Capital expenditure reduced to \$213m (Q1 2017: \$286m). Restructuring costs reduced to \$95m (Q1 2017: \$312m), supporting an anticipated decline over the full year

FY 2018 guidance reiterated and unchanged

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

“Encouraging launches and strong performances from our newer generation of medicines made a significant contribution to Product Sales in the quarter, paving the way for our anticipated return to growth in 2018. The performance was in line with our expectations and guidance for the year is unchanged. We delivered strong results for Lynparza, Tagrisso and Imfinzi in Oncology, Brilinta and Farxiga in CVRM and a successful launch of Fasentra in Respiratory. Our China sales continued to surpass expectations and we expect that the effects of the Crestor patent expiries in Europe and Japan will recede materially in the second half.

AstraZeneca’s pipeline continued to bring significant benefits for patients, most recently with the expanded US approval of Tagrisso for lung cancer and Lynparza for breast cancer. With our transformation coming into sharper commercial focus as the year progresses, we are confident of delivering on our goals.”

Commercial Highlights

Newer medicines⁵ generated more than \$0.4bn in additional sales at CER in the quarter. Product Sales highlights were:

Oncology: sales growth of 39% in the quarter (33% at CER) to \$1,230m, including:

- Lynparza sales of \$119m, growth of 109% (100% at CER), driven by regulatory approvals in the US
- Tagrisso sales of \$338m, growth of 98% (89% at CER) reflecting growth as the new standard of care in the treatment of 2nd-line EGFR6 T790M-mutated⁷ NSCLC⁸. Approved in the US in April 2018 in the 1st-line setting
- Imfinzi sales of \$62m (FY 2017: \$19m), a result of the recent US approval for the treatment of unresectable, Stage III NSCLC

New CVRM⁹: 13% growth (8% at CER) to \$900m, including:

- Brilinta sales of \$293m, growth of 31% (24% at CER) due to continued market penetration in acute coronary syndrome (ACS) and high-risk periprocedural myocardial infarction (HR PMI)
- Farxiga sales of \$299m, growth of 44% (39% at CER) as the medicine continued to lead the market by volume
- Bydureon sales of \$139m, a decline of 9% (11% at CER). An encouraging BCise device launch, outweighed by the impact of price pressures in the US

Respiratory: stable sales of \$1,181m (a decline of 6% at CER), including:

Edgar Filing: ASTRAZENECA PLC - Form 6-K

- A Symbicort sales decline of 6% (12% at CER) to \$634m, as competitive class pressures in the US continued
- Pulmicort sales growth of 3% (down by 3% at CER) to \$346m, reflecting the inflated level of demand in China in Q4 2017 and a supply delay in China
- Fasenna sales of \$21m. A very strong launch and uptake, especially in the US and Germany

Emerging Markets: the largest region by Product Sales, with growth of 13% (8% at CER) to \$1,765m, including:

- A China sales increase of 31% (22% at CER) to \$1,025m. For the first time, quarterly sales of more than \$1bn were achieved, underpinned by the launch of Tagrisso
- An ex-China sales decline of 5% (7% at CER) to \$740m. A robust performance, outweighed by the impact of divested Product Sales and a Russia sales decline of 38% (40% at CER) to \$34m

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">- Lynparza - ovarian cancer (2nd line; tablets) (EU)- Tagrisso - lung cancer (1st line) (US)- Imfinzi - lung cancer (Stage III) (US)- Lokelma (ZS-9) - hyperkalaemia(EU)
Regulatory Submissions and/or Acceptances	<ul style="list-style-type: none">- Lynparza - breast cancer (EU)- moxetumomab pasudotox - hairy cell leukaemia (3rd line) (US)- Forxiga - type-1 diabetes (EU)
Major Phase III Data Readouts or Other Major Developments	<ul style="list-style-type: none">- Tagrisso - lung cancer (1st line) - priority review status (JP)- Imfinzi + tremelimumab - lung cancer (3rd line) (ARCTIC trial) - did not meet primary endpoints in PDL1-low/neg. patients- moxetumomab pasudotox - hairy cell leukaemia (3rd line) - Priority Review (US)- selumetinib - neurofibromatosis type 1 (NF1) - Orphan Drug Designation (US)- Fasenna - COPD (GALATHEA trial) - did not meet primary endpoint

Guidance

Guidance for FY 2018 is reiterated and unchanged. All measures in this section are at CER. Company guidance is on Product Sales and Core EPS only.

Product Sales A low single-digit percentage increase
Core EPS \$3.30 to \$3.50

The aforementioned anticipated growth in Product Sales is weighted towards the second half of the year. This reflects the remaining impact of generic competition, namely Crestor in Europe and Japan, as well as the growing contribution from newer medicines.

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 today reiterates its additional indications for FY 2018 vs. the prior year:

The sum of Externalisation Revenue and Other Operating Income & Expense is anticipated to decline 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 on its three main therapy areas over time

Core R&D costs in FY 2018 are anticipated to be in the range of a low single-digit percentage decline to stable. This expectation includes the favourable impact on development costs from the MSD collaboration

The Company maintains its focus on reducing operational and infrastructure costs. Total Core SG&A costs are, however, expected to increase by a low to mid single-digit percentage in FY 2018, reflecting targeted support for medicine launches, including Imfinzi in Oncology and Fasenera in Respiratory. The Company also anticipates a reduction in restructuring costs in FY 2018 vs. the prior year

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

Currency Impact

Based only on average exchange rates in the three months to 31 March 2018 and the Company's published currency sensitivities, there would be a low single-digit favourable 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 is committed to being a valued and trusted partner to its stakeholders over the long term. There is a distinct connection between maintaining a strong business and making a positive impact to a fairer, safer and healthier world. AstraZeneca is dedicated to pushing the boundaries of science to deliver sustainable health that transforms the lives of patients around the world.

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 later in this announcement.

Notes

The following notes refer to pages 1-3:

1.
Constant exchange rates. These are non-GAAP financial measures because they remove the effects of currency movements from Reported results.
2.
Reported financial measures are the financial results presented in accordance with IFRS.
3.
Core financial measures. These are non-GAAP financial measures because, unlike Reported performance, they cannot be derived directly from the information in the Group Financial Statements. See the Operating and Financial Review for a definition of Core financial measures and a reconciliation of Core to Reported financial measures.
4.
Merck & Co., Inc., Kenilworth, NJ, US, known as MSD outside the US and Canada.
5.
Here, Lynparza, Tagrisso, Imfinzi, Calquence, Brilinta, Farxiga, Lokelma, Bevespi and Fasenra.
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.

The performance shown in this announcement covers the three-month period to 31 March 2018 (the quarter or Q1 2018) compared to the three-month period to 31 March 2017 (the prior quarter or Q1 2017), 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): data readout¹⁰

Tagrisso - lung cancer: regulatory decision (EU)

Q2 2018 Lokelma - hyperkalaemia: regulatory decision (US)

Duaklir - COPD: regulatory submission (US)

Fasenra - COPD (TERRANOVA): data readout

H2 2018 Lynparza - breast cancer: regulatory decision (JP)

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

Tagrisso - lung cancer: regulatory decision (JP)

Imfinzi - lung cancer (Stage III): regulatory decision (EU, JP)

Imfinzi +/- treme - lung cancer (1st line) (MYSTIC): data readout (final OS¹¹), regulatory submission

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

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Imfinzi +/- treme – head & neck cancer (2nd line) (EAGLE): data readout, regulatory submission

selumetinib - thyroid cancer: data readout, regulatory submission

moxetumomab pasudotox - hairy cell leukaemia (3rd line): regulatory decision (US)

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

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

roxadustat - anaemia: data readout

Bevespi - COPD: regulatory decision (EU)

Bevespi - COPD: regulatory submission (JP)

PT010 - COPD: regulatory submission

Fasenra - COPD: regulatory submission

anifrolumab - lupus: data readout

Lynparza - breast cancer: regulatory decision (EU)

Lynparza - pancreatic cancer: data readout, regulatory submission

Imfinzi - lung cancer (PACIFIC): data readout (final OS)

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

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

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

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

Imfinzi +/- treme - bladder cancer (DANUBE): data readout, regulatory submission

2019

Calquence - Chronic lymphocytic leukaemia (CLL): data readout, regulatory submission

Brilinta - Coronary artery disease (CAD) / type-2 diabetes: data readout, regulatory submission

Farxiga - type-2 diabetes (DECLARE): regulatory submission

Farxiga - heart failure: data readout

roxadustat - anaemia: regulatory submission (US)

anifrolumab - lupus: regulatory submission

lanabecestat - Alzheimer's disease: data readout

Conference Call

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

Reporting Calendar

The Company intends to publish its first-half and second-quarter financial results on Thursday, 26 July 2018.

About AstraZeneca

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

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

Investor Relations

Thomas Kudsk Larsen		+44 203 749 5712
Craig Marks	Finance; Fixed Income; M&A	+44 7881 615 764
Henry Wheeler	Oncology	+44 203 749 5797
Mitchell Chan	Oncology; Other	+1 240 477 3771
Christer Gruvris	Brilinta; Diabetes	+44 203 749 5711
Nick Stone	Respiratory; Renal	+44 203 749 5716
US toll free		+1 866 381 7277
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
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 three-month period to 31 March 2018 (the quarter or Q1 2018) compared to the three-month period to 31 March 2017 (the prior quarter or Q1 2017, respectively). All commentary in the Operating and Financial Review relates to the quarter, 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 better understand the financial performance and position of the Company on a comparable basis from period to period. These non-GAAP financial measures are not a substitute for, or superior to, financial measures prepared in accordance with GAAP. Core financial measures are adjusted to exclude certain significant items, such as:

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

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

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

Details on the nature of Core financial measures are provided on page 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 table 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 the Reconciliation of Interest-Bearing Loans and Borrowings to Net Debt included in the Cash Flow and Balance Sheet section of this announcement.

Ongoing Externalisation Revenue is defined as Externalisation Revenue excluding Initial Externalisation Revenue (which is defined as Externalisation Revenue that is recognised at the date of completion of an agreement or transaction, in respect of upfront consideration). Ongoing Externalisation Revenue comprises, among other items, royalties, milestone revenue and profit-sharing income. Reference should be made to the Breakdown of Externalisation Revenue table in this Operating and Financial Review.

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

	Q1 2018		
	\$m	% change	
		Actual	CER
Total Revenue	5,178	(4)	(9)
Product Sales	4,985	3	(2)
Externalisation Revenue	193	(66)	(67)

Table 2: Product Sales

	Q1 2018		% change	
	\$m	% of total ¹²	Actual	CER
Oncology	1,230	25	39	33
New CVRM	900	18	13	8
Respiratory	1,181	24	-	(6)
Other	1,674	34	(15)	(19)
Total	4,985	100	3	(2)

Table 3: Breakdown Of Externalisation Revenue

Ongoing Externalisation Revenue of \$91m represented 47% of total Externalisation Revenue (Q1 2017: \$181m, 32%). The Company anticipates that Ongoing Externalisation Revenue will grow as a proportion of Externalisation Revenue over time. A breakdown of Externalisation Revenue is shown below:

	\$m	% of total	% change	
			Actual	CER
Royalties	8	4	(83)	(84)
Milestones/Other ¹³	83	43	(39)	(38)
Ongoing Externalisation Revenue	91	47	(50)	(49)
Initial Externalisation Revenue	102	53	(73)	(75)

Total Externalisation Revenue	193	100	(66)	(67)
-------------------------------	-----	-----	------	------

Table 4: Initial Externalisation Revenue

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

Medicine	Partner	Region	\$m
Crestor	Almirall, S.A. (Almirall)	Spain	61
Other			41
Total			102

Table 5: Ongoing Externalisation Revenue

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

Medicine	Partner	Region	\$m
Lynparza	MSD - milestone revenue (breast cancer regulatory approval)	Global	70
Other			21
Total			91

Table 6: Externalised And Divested Medicines

Several AstraZeneca medicines were externalised or divested after Q1 2017, thus adversely impacting the Product Sales performance:

Completion	Medicine	Region	Q1 2018 ¹⁴	Q1 2017	Difference	Adverse Impact on Q1 2018 Product Sales
			\$m	\$m	\$m	
June 2017	Seloken	Europe	6	21	(15)	
June 2017	Zomig	Global (excl. Japan)	7	19	(12)	
October 2017	Anaesthetics	Global	19	85	(66)	
January 2018	Crestor	Spain	3	22	(19)	

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Total 35 147 (112) 2%

Table 7: Ongoing Externalisation Revenue Agreements

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

Completion	Medicine	Partner	Region	Externalisation Revenue
				Initial \$1.0bn revenue
July 2017	Lynparza	MSD	Global	Up to \$0.75bn for certain licence options, including \$0.25bn paid in Q4 2017
				Up to \$6.15bn in regulatory and sales milestones
March 2017	MEDI8897	Sanofi Pasteur, Inc.	Global	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 major medicines is shown below, with a geographical split shown in Note 6.

Table 8: Therapy Area And Medicine Performance

Q1 2018

Therapy Area	Medicine	\$m	% of total ¹⁵	% change	
				Actual	CER
Oncology	Tagrisso	338	7	98	89
	Iressa	132	3	6	(1)
	Lynparza	119	2	109	100
	Imfinzi	62	1	n/m	n/m
	Calquence	8	-	n/m	n/m
	Legacy:				
	Faslodex	254	5	19	14
	Zoladex	184	4	(1)	(6)
	Arimidex	54	1	4	(2)
	Casodex	52	1	(7)	(13)
	Others	27	1	4	(4)
	Total Oncology	1,230	25	39	33
	Brilinta	293	6	31	24
	Farxiga	299	6	44	39
CVRM	Onglyza	129	3	(16)	(19)
	Bydureon	139	3	(9)	(11)
	Byetta	31	1	(33)	(35)
	Symlin	9	-	(36)	(36)
	Legacy:				
	Crestor	389	8	(38)	(42)
Seloken/Toprol-XL	200	4	8	3	

Edgar Filing: ASTRAZENECA PLC - Form 6-K

	Atacand	71	1	(5)	(9)
	Others	85	2	(4)	(10)
	Total CVRM	1,645	33	(8)	(12)
	Symbicort	634	13	(6)	(12)
	Pulmicort	346	7	3	(3)
	Daliresp/Daxas	38	1	(14)	(16)
	Tudorza/Eklira	34	1	(8)	(16)
Respiratory	Duaklir	28	1	47	26
	Fasenra	21	-	n/m	n/m
	Bevespi	5	-	n/m	n/m
	Others	75	2	12	3
	Total Respiratory	1,181	24	-	(6)
	Nexium	448	9	(3)	(7)
	Synagis	224	4	(3)	(3)
	LOSEC/Prilosec	69	1	1	(6)
Other	Seroquel XR	53	1	(21)	(25)
	Movantik/Moventig	28	1	(7)	(7)
	Others	107	2	(25)	(29)
	Total Other	929	19	(7)	(10)
	Total Product Sales	4,985	100	3	(2)

Product Sales Summary

ONCOLOGY

Product Sales of \$1,230m; an increase of 39% (up 33% at CER). Oncology Product Sales represented 25% of total Product Sales, up from 18% in Q1 2017.

Lynparza

Product Sales of \$119m; an increase of 109% (100% at CER). The strong performance was spread across the region and was particularly noticeable in the US. To date, the medicine has received regulatory approval in over 50 countries, with reviews underway in a number of additional markets and for new uses.

US sales grew by 144% to \$66m; the performance partly reflected the H2 2017 launch of Lynparza tablets and regulatory approval as a 2nd-line treatment for ovarian cancer, regardless of BRCA status. The Company announced more recently the approval of Lynparza in the US as a treatment for patients with germline BRCA-mutated breast cancer; this approval was reflected in sequential quarterly US sales growth of 22%, from \$54m in Q4 2017. At the end of Q1 2018, Lynparza was the leading medicine in the poly ADP ribose polymerase (PARP)-inhibitor class in the US, as measured by total prescription volumes.

Sales in Europe increased by 68% (44% at CER) to \$42m, reflecting high BRCA-testing rates, a number of successful launches and encouraging levels of reimbursement. Lynparza sales in Europe in the quarter were for the treatment of ovarian cancer, in capsule formulation. On 8 May 2018, the Company announced that the European Medicines Agency (EMA) had approved Lynparza tablets (300mg twice daily) as a 2nd-line treatment for ovarian cancer, regardless of BRCA status.

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

Lung Cancer

Tagrisso

Product Sales of \$338m; an increase of 98% (89% at CER), partly driven by increased testing rates, led by Japan and the US. The medicine has received regulatory approval in more than 75 countries.

Sales in the US grew by 63% to \$147m, reflecting an increase in EGFR T790M-mutation testing rates. Sequential quarterly sales increased by 15% from \$128m in Q4 2017. In September 2017, US National Comprehensive Cancer Network (NCCN) clinical-practice guidelines were updated to include the use of Tagrisso as a 1st-line treatment of patients with metastatic EGFR-mutated NSCLC. Tagrisso was approved by the US FDA in this setting in April 2018.

Within Emerging Markets, Tagrisso sales were \$71m (Q1 2017: \$6m). Growth in Emerging Markets was led by China, where an encouraging testing rate was observed. Tagrisso was approved in China in March 2017 as the first AstraZeneca medicine under the China FDA's priority-review pathway; China has a relatively-high prevalence of patients with an EGFR mutation.

In Europe, sales of \$69m represented growth of 97% (74% at CER), driven by strong levels of demand, positive reimbursement decisions and further growth in testing rates. Tagrisso was reimbursed in more than 15 European markets at the end of the quarter and was under reimbursement review in a number of additional European countries, with positive decisions anticipated in H2 2018. A regulatory decision on Tagrisso as a 1st-line treatment for EGFR-mutated NSCLC is also expected in the coming weeks.

Sales in Japan increased by 26% (21% at CER) to \$49m. Sequential quarterly sales, however, declined from \$61m in Q4 2017, driven by a decline in T790M ctDNA testing rates from c.90% in Q4 2017 to c.70% in Q1 2018. This followed the mandated expiry of free ctDNA testing in 2017, which was concluded after the start of reimbursement and the fulfilment of the bolus of late-line patients. A regulatory decision on Tagrisso as a 1st-line treatment for EGFR-mutated NSCLC is expected in the second half of the year.

Imfinzi

Product Sales of \$62m; Imfinzi was approved under the US FDA's Accelerated-Approval pathway in May 2017 and launched on the same day as a fast-to-market, limited commercial opportunity, indicated for the 2nd-line treatment of patients with locally-advanced or metastatic urothelial carcinoma (bladder cancer).

In February 2018, immediately following US regulatory approval, the Company launched Imfinzi for the treatment of patients with unresectable, Stage III NSCLC whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy (CRT). The approval followed the award of Priority Review status in 2017. The majority of Imfinzi sales in the quarter were for the treatment of unresectable, Stage III NSCLC.

Iressa

Product Sales of \$132m; an increase of 6% (down by 1% at CER).

Emerging Markets sales increased by 16% (8% at CER) to \$71m. China sales increased by 29% (21% at CER) to \$44m; Iressa was included on the National Reimbursement Drug List (NRDL) in 2017. Sales in the US were stable at \$8m and increased in Europe by 15% (4% at CER) to \$30m.

Other Oncology Medicines

Calquence

Product Sales of \$8m; Calquence was approved and launched in the US on 31 October 2017. The medicine delivered a promising performance in the quarter, illustrated by the number of new-patient starts in previously-treated mantle cell lymphoma (MCL). The medicine was included within NCCN MCL guidelines on 15 November 2017, which helped to facilitate reimbursement.

Legacy: Faslodex

Product Sales of \$254m; an increase of 19% (14% at CER).

Emerging Markets sales grew by 44% (41% at CER) to \$39m. China sales grew by 100% (83% at CER) to \$12m.

US sales increased by 14% to \$134m, mainly reflecting a continued strong uptake of the combination with palbociclib, a medicine approved for the treatment of hormone-receptor-positive breast cancer.

Europe sales increased by 9% (down by 6% at CER) to \$59m, reflecting the impact of generic entrants in certain markets. In June 2017, a label extension, based upon the FALCON trial in the 1st-line setting was approved in Japan, where sales grew by 50% (43% at CER) to \$21m.

Legacy: Zoladex

Product Sales of \$184m; a decline of 1% (6% at CER).

Emerging Markets sales increased by 16% (10% at CER) to \$101m. Sales in Europe increased by 6% (down by 3% at CER) to \$34m. In the Established Rest Of World (ROW) region, sales declined by 17% (21% at CER) to \$48m, driven by the effects of increased competition. On 31 March 2017, the Company completed an agreement with TerSera for the sale of the commercial rights to Zoladex in the US and Canada.

CVRM

New CVRM sales increased by 13% (8% at CER) to \$900m, comprising 18% of total Product Sales. There were further strong performances from Brilinta and Farxiga, after each attained blockbuster-sales status in FY 2017.

Total CVRM sales, which includes Crestor and other legacy medicines, amounted to \$1,645m and represented a decline of 8% (12% at CER); total CVRM comprised 33% of total Product Sales, down from 37% in Q1 2017.

Brilinta

Product Sales of \$293m; an increase of 31% (24% at CER).

Emerging Markets sales of Brilinta grew by 27% (20% at CER) to \$76m, reflecting a continued outperformance of branded oral anti-platelet medicines. Encouraging results were delivered in a number of markets.

US sales of Brilinta, at \$115m, represented an increase of 32%. The performance was driven primarily by an increase in the average duration of therapy and strong growth in the number of patients sent home from hospital with Brilinta. Furthermore, Brilinta achieved a record total-prescription market share at the end of the quarter; days-of-therapy volume market-share data was particularly encouraging.

Sales of Brilique in Europe increased by 32% (15% at CER) to \$86m, reflecting indication leadership across a number of markets and bolstered by the inclusion within HR PMI guidelines by the European Society of Cardiology in 2017. Improvements were delivered across the major markets; Brilique continued to outperform branded oral anti-platelet

medicines in the quarter and gained further reimbursement in key markets in its HR PMI indication with the 60mg dose.

Farxiga

Product Sales of \$299m; an increase of 44% (39% at CER). Farxiga consolidated its global leadership position within the sodium-glucose co-transporter 2 (SGLT2) inhibitor class.

Emerging Markets sales increased by 64% (62% at CER) to \$69m, reflecting ongoing launches and improved levels of patient access. In March 2017, Farxiga became the first SGLT2-inhibitor medicine to be approved in China, with encouraging initial results in access and performance.

US sales increased by 32% to \$127m. The performance in Q1 2017 was adversely impacted by the Company's level of participation in affordability programmes; subsequent changes to the Company's approach to these programmes, however, helped to deliver a much-improved performance in Q1 2018. Despite slower growth in the US, the SGLT2 class continued to be scientifically underpinned by growing evidence around cardiovascular (CV) benefits, including data from the CVD-REAL series of studies, first published in May 2017.

Sales in Europe increased by 48% (30% at CER) to \$74m as the medicine continued to gain overall market share; it also retained leadership in a class that had the strongest growth among innovative oral diabetes medicines in 2017. In Japan, where Ono Pharmaceutical Co., Ltd is a partner and records in-market sales, sales to the partner amounted to \$11m, representing growth of 57% (43% at CER).

Bydureon

Product Sales of \$139m; a decline of 9% (11% at CER). Sales in the US declined by 13% to \$111m, reflecting pricing headwinds that offset an encouraging performance from the recently-launched BCise device. Favourable sales volumes were driven by continued growth in the glucagon-like peptide-1 (GLP-1) class, at the expense of insulin, for more-advanced forms of type-2 diabetes.

Bydureon sales in Europe increased by 5% (stable at CER) to \$23m, partly reflecting market growth.

Onglyza

Product Sales of \$129m, a decline of 16% (19% at CER). The performance reflected adverse pressures on the dipeptidyl peptidase-4 (DPP-4) class and an acceleration of ongoing Diabetes market dynamics, where patients are moving to medicines and classes of medicines with documented CV benefits. Given the significant future potential of Farxiga, the Company continues to prioritise commercial support for Farxiga.

Sales in Emerging Markets increased by 33% (27% at CER) to \$40m. Onglyza, after entry onto the NRDL in China in 2017, led the Emerging Markets sales growth at 167% (150% at CER) to \$16m. Sales in Europe declined by 15% (26% at CER) to \$23m, reflecting the broader trend of a shift away from the DPP-4 class.

Legacy: Crestor

Product Sales of \$389m; a decline of 38% (42% at CER).

Sales in China grew by 39% (30% at CER) to \$145m, a result of underlying demand and an element of benefit from the removal of the 2nd-line usage restriction. Despite the effect of favourable managed-market adjustments, US sales declined by 59% to \$46m, reflecting the impact of multiple Crestor generic medicines. In Europe, sales declined by 67% (70% at CER) to \$65m, driven by the effect of generic medicines in various markets. This impact on Europe

sales is anticipated to continue in 2018, predominantly weighted to the first half of the year.

In Japan, where Shionogi Co. Ltd is a partner, sales declined by 76% (77% at CER) to \$26m, reflecting the recent entry of multiple Crestor competitors in the market in the second half of 2017, plus the effect of government incentives for the increased adoption of generic medicines. This impact on Japan sales is anticipated to be broadly in line with the aforementioned timing in Europe.

RESPIRATORY

Product Sales of \$1,181m; stable (down by 6% at CER). Respiratory Product Sales represented 24% of total Product Sales, unchanged vs. Q1 2017.

Symbicort

Product Sales of \$634m; a decline of 6% (12% at CER). Symbicort continued to lead the global market by volume within the inhaled corticosteroid (ICS) / Long-Acting Beta Agonist (LABA) class.

Emerging Markets sales grew by 14% (10% at CER) to \$128m, partly reflecting growth in China of 38% (29% at CER) to \$66m. In contrast, US sales declined by 28% to \$183m, reflecting pricing pressure and the timing of government buying. The performance was in line with expectations, with challenging market conditions expected to continue.

In Europe, sales increased by 6% (down by 7% at CER) to \$212m; the performance reflected the level of competition from other branded and Symbicort-analogue medicines. Symbicort, however, continued to retain its class-leadership position and stabilise its volume market share in the class. In Japan, where Astellas Pharma Co. Ltd assists as a promotional partner, sales declined by 2% (6% at CER) to \$50m.

Pulmicort

Product Sales of \$346m; an increase of 3% (down by 3% at CER).

Emerging Markets sales increased by 8% (2% at CER) to \$270m, reflecting an inflated level of demand in China in Q4 2017; strong underlying volume growth in China, Middle East & Africa and Asia Pacific was unchanged in Q1 2018; growth in China, however, was limited by the impact of a temporary constraint in supply. Emerging Markets represented 78% of global sales.

Sales in the US and Europe declined by 29% to \$29m and increased by 4% (down by 8% at CER) to \$27m, respectively, a consequence of the medicine's legacy status in these markets.

Daliresp/Daxas

Product Sales of \$38m; a decline of 14% (16% at CER).

US sales, representing 76% of global sales, declined by 24% to \$29m, driven by a reduced adoption of the medicine. It is the only oral, selective, long-acting inhibitor of phosphodiesterase-4, an inflammatory enzyme associated with COPD. Sales in Europe increased by 40% (20% at CER) to \$7m.

Tudorza/Eklira

Product Sales of \$34m; a decline of 8% (16% at CER).

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Sales in the US declined by 27% to \$11m, reflecting lower levels of use of inhaled monotherapy medicines for the treatment of COPD. On 17 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. Circassia began its promotion of Tudorza in the US in May 2017, where AstraZeneca books Product Sales.

Sales in Europe were stable (down by 10% at CER) to \$20m, impacted by the decline of the overall LAMA-monotherapy class.

Duaklir

Product Sales of \$28m; an increase of 47% (26% 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. The growth in sales was favourably impacted by the performances in Germany and the UK, as well as the recent launch in Italy. The LAMA/LABA class continued to grow strongly, albeit below expectations. Duaklir is expected to be submitted for US regulatory review in Q2 2018; the US trademark is to be confirmed. Duaklir is a registered trademark in certain European countries.

Bevespi

Product Sales of \$5m; launched in the US in Q1 2017.

Prescriptions in the period tracked in line with other LAMA/LABA launches. The overall class in the US, however, continues to grow more slowly than anticipated. Bevespi was the first medicine launched using the Company's Aerosphere Delivery Technology delivered in a pressurised metered-dose inhaler.

Fasenra

Product Sales of \$21m.

In November 2017, the Company received approval for Fasenra as a treatment for patients with severe, eosinophilic asthma; the approval was followed immediately by the launch of the medicine. IQVIA new-to-brand prescription data showed that Fasenra, a third-to-market medicine, tracked in-line or ahead of prior biologic-medicine launches in asthma. Initial feedback from physicians and patients was particularly encouraging.

In Europe and Japan, AstraZeneca received regulatory approval in January 2018, respectively, on a similar basis to that in the US. In Europe, a number of launches were executed, including, the Netherlands, Austria, Denmark and Sweden; the launch and uptake of Fasenra in Germany was especially successful.

OTHER

Product Sales of \$929m; a decline of 7% (10% at CER). Other Product Sales represented 19% of total Product Sales, down from 21% in Q1 2017.

Nexium

Product Sales of \$448m; a decline of 3% (7% at CER).

Emerging Markets sales increased by 4% (down by 1% at CER) to \$182m. Despite the benefit of favourable managed-market adjustments, sales in the US declined by 26% to \$100m in the quarter. Sales in Europe were stable (down by 13% at CER) at \$61m. In Japan, where Daiichi Sankyo is a partner, sales increased by 31% (25% at CER) to \$89m.

Synagis

Product Sales of \$224m; a decline of 3%.

US sales declined by 15% to \$134m, impacted by the prevailing guidelines from the American Academy of Pediatrics Committee on Infectious Diseases, which restrict the number of patients eligible for preventative therapy with Synagis. Product Sales to AbbVie Inc. (AbbVie), responsible for the commercialisation of Synagis in over 80 countries outside the US, increased by 22% to \$90m.

Seroquel XR

Product Sales of \$53m; a decline of 21% (25% at CER).

Sales of Seroquel XR in the US, where several competitors launched generic Seroquel XR medicines from November 2016, declined by 33% to \$16m. Sales of Seroquel XR in Europe declined by 27% (32% at CER) to \$16m, also reflecting the impact of generic-medicine competition.

Regional Product Sales

Table 9: Regional Product Sales

	Q1 2018		% change	
	\$m	% of total ¹⁶	Actual	CER
Emerging Markets ¹⁷	1,765	35	13	8
China	1,025	21	31	22
Ex. China	740	15	(5)	(7)
US	1,487	30	-	-
Europe	1,121	22	(1)	(12)
Established ROW	612	12	(8)	(12)
Japan	399	8	(11)	(15)
Canada	126	3	1	(4)
Other Established ROW	87	2	(5)	(10)
Total	4,985	100	3	(2)

Emerging Markets

Product Sales of \$1,765m; an increase of 13% (8% at CER).

China sales grew by 31% (22% at CER) to \$1,025m, representing 58% of total Emerging Markets sales. Onglyza and Iressa were included on the NRDL in China in 2017, as were Brilinta, Faslodex and Seroquel XR; the benefits of this inclusion are anticipated to impact Product Sales favourably in 2018. Crestor also had its 2nd-line usage restriction removed at that time and Zoladex was reclassified from the hormone and endocrine classification to oncology, which is expected to continue to support growth. Tagrisso was launched in China in early 2017.

Emerging Markets sales excluding China, however, declined by 5% (7% at CER) to \$740m in Q1 2018, partly driven by the aforementioned impact from externalised or divested Product Sales, as well as the decline in Russia sales of 38% (40% at CER) to \$34m that resulted from the effect of government intervention in the management of healthcare costs in 2017.

US

Product Sales of \$1,487m;stable.

The performance reflected successful ongoing Oncology launches, including Tagrisso and Imfinzi, plus strong sales of Farxiga and Brilinta, offset by the impact of continued competitive intensity on sales of Symbicort, which declined by 28% to \$183m. Unfavourable managed-care pricing and generic-medicine launches also had adverse effects on overall US sales. Oncology sales in the US grew by 69% to \$426m, primarily driven by encouraging Tagrisso sales growth of 63% to \$147m.

Europe

Product Sales of \$1,121m; a decline of 1% (12% at CER).

Crestor sales declined by 67% (70% at CER) to \$65m, reflecting the entry of generic medicines in various markets in 2017. Excluding sales of Crestor, Europe sales grew by 13% (stable at CER) to \$1,056m.

The newer medicines delivered an encouraging performance in the quarter. Oncology sales in Europe grew by 33% (18% at CER) to \$249m, partly driven by Tagrisso sales growth of 97% (74% at CER) to \$69m. Lynparza sales of \$42m represented growth of 68% (44% at CER). Brilique growth of 32% (15% at CER) to \$86m was accompanied by Forxiga sales growth of 48% (30% at CER) to \$74m.

Established ROW

Product Sales of \$612m;a decline of 8% (12% at CER).

Japan sales declined by 11% (15% at CER) to \$399m. The first generic competitor to Crestor was launched in Japan in Q3 2017 and further generic competition entered the market in the final quarter. Crestor sales in Japan declined by 76% (77% at CER) to \$26m. Excluding sales of Crestor, Japan sales grew by 9% (5% at CER) to \$373m.

As seen in other regions, newer medicines delivered an encouraging performance in the quarter. Tagrisso sales in Japan increased by 26% (21% at CER) to \$49m due to an increase in demand; sequential quarterly sales of Tagrisso, however, declined from \$61m in Q4 2017, driven by a decline in T790M ctDNA testing rates from c.90% in Q4 2017 to c.70% in Q1 2018. This followed the mandated expiry of free ctDNA testing in 2017, which was concluded after the start of reimbursement and the fulfilment of the bolus of late-line patients.

Faslodex sales in Japan were favourably impacted by a new label in 2017, with sales increasing by 50% (43% at CER) to \$21m.

On 19 January 2018, the Company announced that Lynparza tablets, approved as maintenance treatment for women with platinum-sensitive relapsed ovarian cancer regardless of BRCA-mutation status, were approved in Japan and launched in April 2018. A regulatory decision for Lynparza as treatment for breast cancer is anticipated in the second half of the year.

Biennial mandated price reductions became effective in Japan from 1 April 2018.

Financial Performance

Table 10: Reported Profit And Loss

Reported

Edgar Filing: ASTRAZENECA PLC - Form 6-K

	Q1 2018	Q1 2017	% change	
	\$m	\$m	Actual	CER
Total Revenue	5,178	5,405	(4)	(9)
Product Sales	4,985	4,843	3	(2)
Externalisation Revenue	193	562	(66)	(67)
Cost of Sales	(1,134)	(894)	27	14
Gross Profit	4,044	4,511	(10)	(13)
Gross Margin ¹⁸	77.3%	82.3%	-5	-4
Distribution Expense	(81)	(77)	6	(2)
% Total Revenue	1.6%	1.4%	-	-
R&D Expense	(1,279)	(1,453)	(12)	(16)
% Total Revenue	24.7%	26.9%	+2	+2
SG&A Expense	(2,457)	(2,300)	7	2
% Total Revenue	47.5%	42.6%	-5	-5
Other Operating Income & Expense	469	236	99	97
% Total Revenue	9.1%	4.4%	+5	+5
Operating Profit	696	917	(24)	(21)
% Total Revenue	13.4%	17.0%	-4	-2
Net Finance Expense	(308)	(322)	(4)	(11)
Joint Ventures and Associates	(14)	(13)	10	10
Profit Before Tax	374	582	(36)	(27)
Taxation	(58)	(70)		
Tax Rate	16%	12%		
Profit After Tax	316	512	(38)	(30)

Earnings Per Share \$0.27 \$0.42 (37) (29)

Table 11: Reconciliation Of Reported Profit Before Tax To EBITDA¹⁹
Q1 2018

	\$m	% change	
		Actual	CER
Reported Profit Before Tax	374	(36)	(27)
Net Finance Expense	308	(4)	(11)
Joint Ventures and Associates	14	10	10
Depreciation, Amortisation and Impairment	709	8	3
EBITDA	1,405	(11)	(10)

Table 12: Reconciliation Of Reported To Core Financial Measures

Q1 2018	Reported	Restructuring	Intangible Asset Amortisation & Impairments	Diabetes Alliance	Other ²⁰	Core ²¹	Core	
							\$m	\$m
Gross Profit	4,044	32	45	-	-	4,121	(10)	(13)
Gross Margin ²²	77.3%	-	-	-	-	78.8%	-5	-4
Distribution Expense	(81)	-	-	-	-	(81)	6	(2)
R&D Expense	(1,279)	27	12	-	-	(1,240)	(7)	(12)
SG&A Expense	(2,457)	36	349	107	(63)	(2,028)	11	6
Other Operating Income & Expense	469	-	1	-	(346)	124	(63)	(64)
Operating Profit	696	95	407	107	(409)	896	(46)	(47)
% Total Revenue	13.4%	-	-	-	-	17.3%	-14	-13
Net Finance Expense	(308)	-	-	84	53	(171)	(2)	(7)
Taxation	(58)	(20)	(80)	(41)	72	(127)	(51)	(52)

Earnings Per Share	\$0.27	\$0.06	\$0.26	\$0.11	\$(0.22)	\$0.48	(51)	(51)
--------------------	--------	--------	--------	--------	----------	--------	------	------

Profit And Loss Commentary

Gross Profit

Reported Gross Profit declined by 10% (13% at CER) to \$4,044m; Core Gross Profit declined by 10% (13% at CER) to \$4,121m. The declines reflected the movement in the Gross Margin, as well as the aforementioned level of Externalisation Revenue.

The Reported Gross Margin declined by five percentage points (four at CER) to 77.3%. The Core Gross Margin declined by five percentage points (four at CER) to 78.8%. The movements were a result of the favourable impact of manufacturing variances realised in Q1 2017 and the inclusion of the profit share on the aforementioned collaboration with MSD, as well as the effect of losses of exclusivity on Crestor sales in Europe and Japan.

The calculation of Reported and Core Gross Margin excludes the impact of Externalisation Revenue, thereby reflecting the underlying performance of Product Sales.

Operating Expenses

Reported Operating Expenses were stable (down by 5% at CER) at \$3,817m. Core Operating Expenses increased by 3% (down by 1% at CER) to \$3,349m.

Reported R&D costs declined by 12% (16% at CER) to \$1,279m, with the Company continuing to focus on resource prioritisation and cost discipline. Core R&D costs declined by 7% (12% at CER) to \$1,240m, reflecting productivity improvements across every therapy area and the favourable impact on development costs from the MSD collaboration. Targeted investment in the Company's R&D programme is a consistent priority; the level of activity was unchanged in the quarter and Core R&D costs represented 24% of Total Revenue.

Highlights of the progress made included:

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

Reported SG&A costs increased by 7% (2% at CER) to \$2,457m. This reflected investment in medical-affairs capability and capacity in order to support launches and extensions of the newer medicines, including Lynparza, Tagrisso, Imfinzi, Calquence and Fasenra, as well as additional investment to support sales growth in China.

Core SG&A costs increased by 11% (6% at CER) to \$2,028m, reflecting the investment in the launches, as well as the significant reduction in Core SG&A costs in the comparative period. Q1 2017 was a period when the Company delivered its lowest level of Core SG&A investment for a number of years.

Other Operating Income & Expense

Edgar Filing: ASTRAZENECA PLC - Form 6-K

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 99% (97% at CER) to \$469m and included:

\$346m, resulting from a legal settlement

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

Core Other Operating Income & Expense declined by 63% (64% at CER) to \$124m, with the difference to Reported Other Operating Income & Expense reflecting the aforementioned legal settlement.

Operating Profit

Reported Operating Profit declined by 24% (21% at CER) to \$696m, driven by the declines in Total Revenue and the Reported Gross Margin, as well as the increase in Reported SG&A costs. The Reported Operating Profit margin declined by four percentage points (two at CER) to 13% of Total Revenue. Core Operating Profit declined by 46% (47% at CER) to \$896m, driven by the aforementioned factors, as well as the timing of divestments in FY 2018. The Core Operating Profit margin declined by 14 percentage points (13 at CER) to 17% of Total Revenue.

Net Finance Expense

Reported Net Finance Expense declined by 4% (11% at CER) to \$308m, reflecting reduced levels of discount unwind on the put option over the non-controlling interest in Acerta Pharma B.V. (Acerta Pharma). Excluding the discount-unwind on acquisition-related liabilities, Core Net Finance Expense declined by 2% (7% at CER) to \$171m.

Profit Before Tax

Reported Profit Before Tax declined by 36% (27% at CER) to \$374m, reflecting the 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 quarter were 16% and 18% respectively. These tax rates were lower than the UK Corporation Tax Rate of 19%, mainly due to the impact of the geographical mix of profits. The net cash tax paid was \$117m, representing 31% of Reported Profit Before Tax. The Reported and Core tax rates for the comparative period were 12% and 17% respectively. The cash tax paid for the comparative period was \$62m, which was 11% of Reported Profit Before Tax.

Earnings Per Share (EPS)

Reported EPS of \$0.27 represented a decline of 37% (29% at CER). The performance reflected a decline in Total Revenue, the Reported Gross Margin and increased Reported SG&A costs. Core EPS declined by 51% to \$0.48, impacted by the aforementioned factors as well as the decline in Core Other Operating Income & Expense.

Table 13: Cash Flow

	Q1 2018	Q1 2017	Change
	\$m	\$m	\$m
Reported operating profit	696	917	(221)
Depreciation, amortisation and impairment	709	658	51

(Increase)/decrease in working capital and short-term provisions	(993)	(887)	(106)
(Gains)/losses on disposal of intangible assets	(65)	(52)	(13)
Non-cash and other movements	(242)	(297)	55
Interest paid	(128)	(189)	61
Tax paid	(117)	(62)	(55)
Net cash (outflow)/inflow from operating activities	(140)	88	(228)

The Company saw a net cash outflow from operating activities of \$140m in the quarter, compared with an inflow of \$88m in Q1 2017. The increase in the movement of working-capital and short-term provisions partly reflected launch support for newer medicines.

Net cash inflows from investing activities were \$273m, compared with outflows of \$146m in Q1 2017. The difference partly reflected the timing of receipts on disposals of intangible assets, as well as a reduction in capital expenditure. The cash payment of contingent consideration in respect of the BMS share of the global Diabetes alliance amounted to \$62m.

Net cash outflows from financing activities were \$663m in the quarter, compared to \$2,042m in Q1 2017, reflecting higher short-term borrowings in Q1 2018.

Capital Expenditure

Capital expenditure amounted to \$213m in the quarter compared to \$286m in Q1 2017, which included investment in the new global headquarters in Cambridge, UK, as well as strategic biotech manufacturing capacity in Sweden.

Table 14: Debt And Capital Structure

	At 31 March 2018	At 31 Dec 2017	At 31 March 2017
	\$m	\$m	\$m
Cash and cash equivalents	3,005	3,324	3,129
Other investments	868	1,300	548
Net derivatives	565	504	215
Cash, short-term investments and derivatives	4,438	5,128	3,892
Overdrafts and short-term borrowings	(2,776)	(845)	(1,000)

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Finance leases	-	(5)	(80)
Current instalments of loans	(1,394)	(1,397)	(1,762)
Loans due after one year	(15,684)	(15,560)	(14,560)
Interest-bearing loans and borrowings (Gross Debt)	(19,854)	(17,807)	(17,402)
Net Debt	(15,416)	(12,679)	(13,510)

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 15: 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) ²³	
		FY 2017	Q1 2018 ²⁴	% change	Product Sales	Core Operating Profit
EUR	Product Sales	0.89	0.81	+10	+136	+57
JPY	Product Sales	112.18	106.03	+6	+96	+66
CNY	Product Sales	6.75	6.32	+7	+180	+98
SEK	Operating Expenses	8.54	8.24	+4	+4	-70
GBP	Operating Expenses	0.78	0.72	+8	+25	-75
Other ²⁵					+88	+44

Corporate And Business Development Update

a) MedImmune Spin-Out - Early-Stage Inflammation And Autoimmunity Programmes

On 28 February 2018, AstraZeneca announced that its global biologics research and development arm, MedImmune, would spin out six molecules from its early-stage inflammation and autoimmunity programmes into an independent biotech company, Viela Bio. The new company is focusing on developing medicines for severe autoimmune diseases, by targeting the underlying causes of each disease.

MedImmune contributed three clinical and three pre-clinical potential new medicines. This included inebilizumab, currently in Phase II trial development for the treatment of neuromyelitis optica, a rare condition that affects the optic nerve and spinal cord in approximately five in 100,000 people. It was granted Orphan Drug Designation by the US FDA in 2016 and by the EMA in 2017. Viela Bio is based in Gaithersburg, Maryland. It was funded with \$250m from a consortium of investors led by Boyu Capital, 6 Dimensions Capital and Hillhouse Capital. AstraZeneca is the largest non-controlling shareholder of Viela Bio.

The Company realised a \$63m gain in Q1 2018, reflected in the Company's financial statements within Other Operating Income & Expense.

b) Divestment Of Seroquel And Seroquel XR

On 8 May 2018, AstraZeneca 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 international markets. Seroquel, used primarily to treat the disorders schizophrenia and bipolar, has lost its compound patent protection globally; the Seroquel XR formulation patents have also expired in the vast majority of its markets.

Luye Pharma will pay \$538m in consideration, including \$260m immediately following closure of the transaction. The total consideration, adjusted for time value, will be recorded in Q2 2018 in Other Operating Income & Expense within the Company's financial statements, subject to the timing of closure of the agreement. This will include a milestone payable on the successful transition of certain activities to Luye Pharma. AstraZeneca will continue to manufacture and supply Seroquel and Seroquel XR to Luye Pharma during a transition period.

The transaction is expected to close by the end of Q2 2018, subject to customary closing conditions and regulatory clearances. In FY 2017, Seroquel generated sales of \$85m in the markets covered by this agreement, while Seroquel XR generated \$63m.

Sustainability Update

AstraZeneca's sustainability ambition has three priority areas, aligned with the Company's purpose and business strategy:

Access to Healthcare

Environmental Protection

Ethics and Transparency

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 benefit to patients, the Company, broader society and the planet. Progress against the three priorities is reported below:

a) Access To Healthcare

Healthy Heart Africa (HHA) is an innovative programme committed to tackling hypertension and the increasing burden of CV disease across Africa. In Q1 2018, the programme was ahead of its target for blood-pressure screenings. Since launching in Kenya 2014 and in Ethiopia 2016 respectively, HHA has conducted more than 5.5m blood-pressure screenings.

The AstraZeneca Young Health Programme (YHP) is a non-communicable disease (NCD) prevention programme, developed in partnership with John Hopkins Bloomberg School of Public Health and Plan International in the US that

has reached 2.25m young patients since its launch in 2010. It aims to reduce the uptake of unhealthy behaviours in young patients to improve their health outcomes as adults and help address the growing burden of NCDs on health systems. During the period, AstraZeneca launched several new three-year programmes:

YHP Brazil, which aims to reach more than 740,000 direct and indirect beneficiaries

YHP Serbia, which aims to reach 200,000 school children with advocacy and educational programming on tobacco use

YHP Australia, which aims to provide food and nutrition education to 10 secondary schools in Victoria and New South Wales

Additionally, YHP health camps in India, in partnership with Plan International, delivered engaged employee volunteers and provided screening for diabetes, hypertension, anaemia and respiratory disorders to more than 1,000 patients from marginalised communities in Bangalore, India.

During the period, YHP was selected by Global Child Forum, a Swedish not-for-profit foundation, as the subject of a 'Deep Dive'. Global Child Forum is focused on the advancement of children's rights, in accordance with the UN Convention on the Rights of the Child. Its aim is to provide businesses with an understanding of how and where their business may impact children. On 11 April 2018, AstraZeneca presented a YHP case study at the 10th Global Child Forum at the Stockholm Royal Palace, Sweden; this was subsequently followed by the publication of the YHP Deep Dive.

b) Environmental Protection

AstraZeneca is committed to managing its environmental impact across all business activities, with a focus on Greenhouse Gas (GHG) emissions, energy consumption, waste production and water use. The Company's approach focuses on science-based targets, mapped to each of the environmental strategic priorities:

Reducing GHG emissions to combat climate change

Protecting natural resources through energy, waste and water management

Leading the way to minimise Pharmaceuticals in the Environment

Preserving biodiversity

During the period, the Company received recognition from The Climate Group, an international non-profit organisation, focused on accelerating climate action for its increase in renewable energy usage. AstraZeneca was identified as 'Biggest Achiever' for its 300% increase in renewable electricity in a single year. In addition, AstraZeneca was also commended for its use of renewable energy, as one of 122 multinational businesses which have made the RE100 commitment, a collaborative, global initiative uniting influential businesses that are committed to 100% renewable electricity.

In Cambridge, UK, the new R&D centre and global headquarters achieved an 'Excellent' rating from the world-leading Building Research Establishment Environmental Assessment Methodology (BREEAM) assessment; AstraZeneca also received a credit for innovation. BREEAM assesses a building's environmental, social and economic sustainability performance. AstraZeneca's rating status reflected best practice in a number of areas and the Company's accreditation recognised the efforts to ensure the new site becomes an environment that will not only enhance staff well-being, but also help protect natural resources.

c) Ethics And Transparency

During the period, the Third Party Risk Management process, designed to ensure that AstraZeneca can identify and manage risks associated with third-party activities as early and effectively as possible, increased coverage to 79%. In February 2018, a new Counterfeit Medicines Partnership with Chinese company Tencent Holdings Limited was established. The programme involved the development of online tracking systems to fight counterfeit medicines, a particular challenge in China. The Company also implemented an organisational change to bring the functions of Global Compliance, Safety, Health and Environment and the Sustainability Strategy and Engagement team under a new umbrella function called Global Sustainability. The changes signal AstraZeneca's commitment to sustainability.

Other Developments

During the period, AstraZeneca was recognised for its commitment to sustainability with two new external accolades. The Company was listed as one of the 100 most sustainable companies in the world by Corporate Knights, the Toronto-based media and investment advisory firm. During the period, AstraZeneca also received certification from the Top Employers Institute, in recognition of excellent People Management and HR processes across several European markets. The Institute assessed leadership, corporate & social responsibility commitments and how the Company delivers on its commitment to colleague diversity.

On 6 March 2018, the Company published its annual Sustainability Report 2017, which shares the results of AstraZeneca's efforts in the aforementioned priority areas. The report highlighted examples of employee sustainability projects contributing to the Company's global goals.

On 20 March 2018, AstraZeneca published its first gender pay-gap report, providing gender-pay information on the Company in the UK and outlining the Company's support for women, as well as its focus on diversity and inclusion. AstraZeneca reported a median gap in hourly pay of 13.5%, compared to an overall UK median gap of 18.4%. The reporting of the gender pay gap is an annual requirement for all companies in the UK with 250 or more employees.

During the period, the Company commenced a robust programme of training for key areas of the organisation that are responsible for data privacy in preparation for the General Data Protection Regulation (GDPR). GDPR is a new EU regulation, taking effect from 25 May 2018, giving EU and European Economic Area (EEA) citizens and residents better control of their personal data, with one set of data protection rules applicable to all organisations that hold personal data relating to EU/EEA citizens and residents.

Research And Development Update

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. Highlights of developments in the Company's late-stage pipeline since the prior results announcement are shown below:

Table 16: Update From The Late-Stage Pipeline

		- Lynparza - ovarian cancer (2nd line; tablets) (EU)
		- Tagrisso - lung cancer (1st line) (US)
Regulatory Approvals	4	- Imfinzi - lung cancer (Stage III) (US)
		- Lokelma - hyperkalaemia (EU)
		- Lynparza - breast cancer (EU)
Regulatory Submissions and/or Acceptances	3	- moxetumomab pasudotox - hairy cell leukaemia (3rd line) (US)
		- Farxiga - type-1 diabetes (EU)
Major Phase III Data Readouts or Other Major Developments	5	- Tagrisso - lung cancer (1st line) - priority review status (JP)

Edgar Filing: ASTRAZENECA PLC - Form 6-K

- Imfinzi + tremelimumab - lung cancer (3rd line) (ARCTIC trial) - did not meet primary endpoints in PDL1-low/neg. patients
- moxetumomab pasudotox - hairy cell leukaemia (3rd line) - Priority Review (US)
- selumetinib - NF1 - Orphan Drug Designation (US)
- Fasentra - COPD (GALATHEA trial) - did not meet primary endpoint

Oncology

- Lynparza - multiple cancers²⁶
- Tagrisso - lung cancer²⁶
- Imfinzi - multiple cancers²⁶
- Calquence - blood cancers
- moxetumomab pasudotox - leukaemia²⁶
- tremelimumab - multiple cancers
- selumetinib - thyroid cancer
- savolitinib - kidney cancer

CVRM

- Lokelma - hyperkalaemia²⁶
- roxadustat - anaemia²⁶

Respiratory

- Fasentra - COPD
- PT010 - COPD, asthma
- tezepelumab - severe, uncontrolled asthma

Other

- anifrolumab - lupus
- lanabecestat - Alzheimer's disease

New Molecular Entities and Major Lifecycle Medicines in Phase III Trials or Under Regulatory Review 15

Total Projects in Clinical Pipeline 130

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 and Calquence are already benefitting patients. An extensive pipeline of small-molecule and biologic medicines is in development and the Company is committed to advancing Oncology, primarily focused on the treatment of lung, ovarian, breast and blood cancers.

In April 2018, at the American Association for Cancer Research annual meeting, the Company presented data from the portfolios of DNA Damage Response (DDR), Immuno-Oncology (IO) and Tumour Drivers & Resistance.

The Company presented data on its expanded portfolio of potential medicines that exploit DDR dependencies to selectively kill cancer cells across multiple tumour types. The Company reported Lynparza OS data from the pivotal OlympiAD trial in BRCA-mutated, metastatic breast cancer. Data exploring the clinical properties of Lynparza and four other PARP inhibitors were also presented to illustrate clinical efficacy and safety profiles. Data on AZD6738, an Ataxia Telangiectasia and Rad3-related (ATR) inhibitor and AZD0156, an Ataxia Telangiectasia Mutated (ATM)

inhibitor, were also presented.

The Company also presented data and shared new insights into the science of Imfinzi, including IO-IO combination data from Study 006 in 2nd-line NSCLC and Study 10 in 2nd-line bladder cancer. Beyond Imfinzi, the Company presented data on a novel bi-specific antibody, MEDI5752, designed to target dual checkpoints on immune cells and use the potential synergies of combined mechanisms in immunotherapy.

Finally, the Company presented data on AZD4573, a cyclin-dependent kinase 9 (CDK9) inhibitor, which demonstrated rapid cell-death induction in haematological-tumour models through depletion of myeloid leukemia cell differentiation protein Mcl-1. Furthermore, early monotherapy and combination data on the novel extracellular signal-regulated kinase inhibitor AZD0364 showed effects on KRAS-mutated tumours, when used in combination with selumetinib.

a) Lynparza (multiple cancers)

On 8 May 2018, the Company announced that the EMA had approved Lynparza tablets (300mg twice daily) for use as a maintenance therapy for patients with platinum-sensitive relapsed high-grade, epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete response or partial response to platinum-based chemotherapy, regardless of BRCA status. The approval was based on two randomised trials, SOLO-2 and Study 19, which showed that Lynparza reduced the risk of disease progression or death for platinum-sensitive, relapsed patients, compared to placebo.

On 3 April 2018, the Company announced that the EMA had validated for review the Marketing Authorisation Application (MAA) for Lynparza for use as a treatment of patients with deleterious or suspected deleterious BRCA-mutated, HER2-negative, metastatic breast cancer, who have been previously treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting.

At the Society for Gynecological Oncology (SGO) annual meeting in New Orleans, US in March 2018, ovarian-cancer cohort data from the Lynparza + Imfinzi trial, MEDIOLA, was presented, showing promising efficacy and a favourable side-effect profile for the combination of Lynparza + Imfinzi in platinum-sensitive, recurrent (PSR) ovarian-cancer patients. The objective response rate was particularly high among patients who had received one prior line of chemotherapy (77%).

Table 17: Key Lynparza Combination Trials

Name	Phase	Population	Design	Timelines	Status
PAOLA-127	III	Stage IV, 1st-line ovarian cancer	Lynparza maintenance + bevacizumab vs. bevacizumab maintenance	FPCD28 Q2 2015 First data anticipated 2019	Recruitment ongoing
DuO-O	III	Stage IV, 1st-line ovarian cancer	Lynparza + Imfinzi	-	Planning(announced at the aforementioned SGO meeting)
MEDIOLA	I/II	Advanced, 2nd-line gBRCA-mutated ovarian cancer Stage IV, 1st to 3rd-line gBRCA-mutated,	Lynparza + Imfinzi	FPCD Q2 2016	Recruitment ongoing Initial data from lung, breast, prostate and ovarian-cancer cohorts presented in 2017 and 2018

		HER2-negative breast cancer Stage IV, 2nd-line small cell lung cancer (SCLC) Stage IV, 2nd-line gastric cancer			
VIOLETTE	II	-HRRm ²⁹ (BRCA) -HRRm (Non-BRCA) -Non-HRRm	Lynparza + ATR (AZD6738) Lynparza + Wee1 (AZD1775) Lynparza	FPCD Q4 2017	Recruitment ongoing
Study 8	II	Stage IV, advanced, castration-resistant prostate cancer	Lynparza + abiraterone vs. abiraterone	FPCD Q3 2014 LPCD ³⁰ Q3 2015	Data to be presented at American Society Of Clinical Oncology annual meeting in June 2018
BAYOU	II	Stage IV, 1st line cis-platinum chemotherapy-ineligible urothelial bladder cancer	Lynparza + Imfinzi vs. Imfinzi	FPCD Q1 2018	Recruitment ongoing

b) Tagrisso (lung cancer)

On 18 April 2018, AstraZeneca announced that the US FDA had approved Tagrisso as a 1st-line treatment for patients with metastatic NSCLC whose tumours have EGFR mutations, as detected by an approved test. The approval was based on results from the 1st-line NSCLC Phase III FLAURA trial, which showed that patients' progression-free survival (PFS) nearly doubled when treated with Tagrisso, compared to patients treated with current standard of care (SoC) EGFR - tyrosine kinase inhibitors (TKIs). Prior to this, Tagrisso received its first regulatory approval as a 1st-line treatment for patients with metastatic EGFR-mutated NSCLC in Brazil.

On 27 April 2018, AstraZeneca announced that the CHMP had adopted a positive opinion, recommending a change to the terms of the MAA for Tagrisso to include the 1st-line treatment of adult patients with locally-advanced or metastatic NSCLC with EGFR mutations. A regulatory decision by the EMA is anticipated in Q2 2018, vs. the prior expectation of H2 2018.

On 5 February 2018, the Company announced that Tagrisso was granted priority review status, based on the results from the FLAURA trial, by the Ministry of Health, Labor and Welfare in Japan. In March 2016, Tagrisso was approved in Japan for the treatment of EGFR-TKI resistant, EGFR T790M mutation-positive inoperable or relapsed NSCLC. A supplementary new drug application was submitted in November 2017 to expand indications to include 1st-line treatment of EGFR mutation-positive NSCLC patients, regardless of the presence of a T790M mutation.

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 US FDA had approved Imfinzi for the treatment of patients with unresectable, Stage III NSCLC whose disease had not progressed following concurrent platinum-based CRT; this was the second indication approved for Imfinzi. CRT, followed by monitoring for disease progression, has been the SoC in

this setting for over two decades and multiple trials have failed to improve upon this. The approval of Imfinzi was based on positive PFS data from the Phase III PACIFIC trial, in which Imfinzi demonstrated an improvement in median PFS of 11.2 months compared to placebo, representing a 48% reduction in relative risk of progression or death vs. placebo in all patients, regardless of PD-L1 status.

In May 2018, Health Canada also approved Imfinzi for the treatment of patients with unresectable, Stage III NSCLC whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy. The approval was granted under Health Canada's accelerated approval framework and was the second global approval for Imfinzi for the treatment of unresectable, Stage III NSCLC. Regulatory submissions, based on the PACIFIC-trial data, are currently under review in both the EU and Japan, where the Company anticipates regulatory decisions in H2 2018. The PACIFIC trial is ongoing, evaluating OS in unresectable, Stage III NSCLC, with data availability anticipated in 2019.

The Company recently announced an updated timeline for the final analysis of the Phase III MYSTIC trial of Imfinzi as a potential monotherapy and in combination with tremelimumab, vs. platinum-based SoC chemotherapy in previously-untreated patients with metastatic (Stage IV), 1st-line NSCLC. An increased number of events, required for the OS analysis, means that final OS data is now expected to be available in the second half of 2018, vs. the prior expectation of H1 2018.

During the period, the Company also reassessed timelines for the final analysis of data from the Phase III NEPTUNE trial of Imfinzi in combination with tremelimumab, versus platinum-based, SoC chemotherapy in previously-untreated patients with metastatic (Stage IV) 1st-line NSCLC. The trial is now expected to achieve an increased number of required events for OS analysis to be available in 2019, vs. the prior expectation of H2 2018. As previously communicated, the Company has the flexibility to include novel biomarkers in the NEPTUNE statistical-analysis plan.

Continued emerging scientific evidence supports the use of OS over PFS as the key, relevant primary endpoint, to characterise correctly the clinical benefit of IO medicines. Accordingly, the Company recently amended trials in the 1st-line NSCLC setting to increase the emphasis on and robustness of OS as a primary endpoint, including the Phase III PEARL trial (Imfinzi monotherapy), which will now focus the primary-efficacy analysis on OS, rather than PFS.

In the Stage IV, 3rd-line setting, the Company recently reported data from the Phase III ARCTIC trial in patients with locally-advanced or metastatic NSCLC, who have received at least two prior treatments. This randomised, open-label, multi-centre trial assessed the efficacy and safety of the combination of Imfinzi plus tremelimumab, as well as Imfinzi and tremelimumab monotherapies, versus SoC chemotherapy in patients with PDL1-low/negative NSCLC (sub-study B) and Imfinzi monotherapy versus SoC in patients with PDL1-high NSCLC (sub-study A). In sub-study B, the combination of Imfinzi plus tremelimumab in patients with PD-L1 low/negative NSCLC did not meet the primary endpoints of a statistically-significant and clinically-meaningful improvement in PFS and OS, compared to SoC. Activity and safety data from other arms within sub-study B were consistent with prior published data. Sub-study A was not powered for statistical significance; Imfinzi monotherapy, however, showed a clinically-meaningful reduction in the risk of death, compared to chemotherapy. Full data from the ARCTIC trial will be presented at a forthcoming medical meeting.

Table 18: Ongoing Key IO Lung Cancer Late-Stage Trials

Name	Phase	Population	Design	Timelines	Status
Monotherapy					
ADJUVANT (BR 31)31	III	Stage Ib-IIIa NSCLC	Imfinzi vs. placebo	FPCD Q1 2015 First data anticipated 2020	Recruitment ongoing
PACIFIC	III		Imfinzi vs. placebo	FPCD Q2 2014	

Edgar Filing: ASTRAZENECA PLC - Form 6-K

		Unresectable, Stage III NSCLC		LPCD Q2 2016	Recruitment completed
				Final OS data anticipated 2019 FPCD Q2 2018	PFS primary endpoint met
PACIFIC-2	III	Unresectable, Stage III NSCLC	Concurrent chemoradiation +/- Imfinzi	First data anticipated 2021 FPCD Q1 2017	Recruitment ongoing
PEARL	III	Stage IV, 1st line NSCLC (Asia)	Imfinzi vs. SoC chemotherapy	First data anticipated 2020	Recruitment ongoing
Combination therapy				FPCD Q3 2015	
MYSTIC	III	Stage IV, 1st line NSCLC	Imfinzi, Imfinzi + treme vs. SoC chemotherapy	LPCD Q3 2016	Recruitment completed
				Final OS data anticipated H2 2018 FPCD Q4 2015	PFS primary endpoint not met
NEPTUNE	III	Stage IV, 1st line NSCLC	Imfinzi + treme vs. SoC chemotherapy	LPCD Q2 2017	Recruitment completed
				First data anticipated 2019 FPCD Q2 2017	
POSEIDON	III	Stage IV, 1st line NSCLC	Imfinzi + SoC, Imfinzi + treme + SoC vs. SoC chemotherapy	First data anticipated 2019 FPCD Q1 2017	Recruitment ongoing
CASPIAN	III	Stage IV, 1st line small-cell lung cancer	Imfinzi + SoC, Imfinzi + treme + SoC vs. SoC chemotherapy	First data anticipated 2019	Recruitment ongoing

Other Cancers

During the period, the Pharmaceutical Administration, the Medical Devices Department and the Food & Nutrition Services of the Israel Ministry of Health authority granted approval to Imfinzi as a treatment for patients with locally-advanced or metastatic bladder cancer who have suffered disease progression during or following platinum-containing chemotherapy or who have suffered disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. Imfinzi's approval, based on Phase Ib/II clinical-trial data, was received only 10 months after submission, reflecting the importance of a new treatment option for patients and compelling clinical data. Along with the approval in Israel, Imfinzi is now approved as a 2nd-line treatment for bladder cancer in the US, Canada and Brazil, with a review ongoing in Australia.

During the period, the Company amended the Phase III KESTREL trial by focusing the primary-efficacy analysis on OS only, as the primary endpoint. Accordingly, and based on current predictions, the first data are now expected to be available in H2 2018, vs. the prior expectation of H1 2018. Similarly, the timeline for the availability of the first data anticipated for the Phase III EAGLE trial recently moved to H2 2018 vs. the prior expectation of H1 2018.

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Table 19: Key IO Non-Lung Cancer Late-Stage Trials

Name	Phase	Population	Design	Timelines	Status
				FPCD Q4 2015	
DANUBE	III	Stage IV, 1st line cisplatin chemotherapy- eligible/ ineligible bladder cancer	Imfinzi, Imfinzi + treme vs. SoC chemotherapy	LPCD Q1 2017 First data anticipated 2019	Recruitment completed
				FPCD Q4 2015	
KESTREL	III	Stage IV, 1st line head and neck squamous cell carcinoma (HNSCC, head and neck cancer)	Imfinzi, Imfinzi + treme vs. SoC	LPCD Q1 2017 First data anticipated H2 2018	Recruitment completed
				FPCD Q4 2015	
EAGLE	III	Stage IV, 2nd-line HNSCC	Imfinzi, Imfinzi + treme vs. SoC	LPCD Q3 2017 First data anticipated H2 2018	Recruitment completed
				FPCD Q4 2017	
HIMALAYA	III	Stage IV, 1st line hepatocellular carcinoma (HCC, liver cancer)	Imfinzi, Imfinzi + treme (two dosing regimens) vs. sorafenib	First data anticipated 2020	Recruitment ongoing

d) Calquence

On 13 February 2018, the NCCN added Calquence as a category-2A recommended treatment for relapsed / refractory CLL / small lymphocytic lymphoma.

e) Moxetumomab Pasudotox

On 3 April 2018, the Company announced that the US FDA had accepted the Biologics License Application (BLA) for moxetumomab pasudotox, an investigational anti-CD22 recombinant immunotoxin and potential new medicine for the treatment of adult patients with hairy cell leukaemia who have received at least two prior lines of therapy. The US FDA granted the moxetumomab pasudotox BLA Priority Review status, with a Prescription Drug User Fee Act action date in the third quarter of 2018.

f) Selumetinib

On 15 February 2018, the Company announced that the US FDA had granted Orphan Drug Designation for selumetinib, a MEK 1/2 inhibitor, for the treatment of NF1. This is an incurable genetic condition that affects one in 3,000 births, with highly-variable symptoms, including skin, neurological and skeletal manifestations. It can cause secondary complications, including learning difficulties, visual impairment, pain, disfigurement, twisting and curvature of the spine, high blood pressure and epilepsy. NF1 is a devastating condition that can lead to life-threatening complications. There is no known cure for NF1 and there are limited treatment options to manage symptoms.

Selumetinib is being investigated by the US National Cancer Institute in a Phase I/II trial, SPRINT, in paediatric patients with symptomatic, NF1-related Plexiform neurofibromas; data is anticipated in Q2 2018.

CVRM

CV, renal and metabolic diseases are key areas of focus as the Company sets the challenge to better understand how its portfolio of medicines might be used to help address multiple risk factors or co-morbidities. Today, AstraZeneca is delivering life-changing results in the main CV-disease areas and their complications. The Company is investing in science to demonstrate CV and mortality benefits, by slowing the underlying progression of CV-related diseases and protecting the organs of the CV system. Ultimately, AstraZeneca is looking to do more than just slow CV-related disease, by modifying or even halting the natural course of the disease itself and regenerate organs. The net result is a strong, continued commitment to new CVRM-treatment options that have the potential to deliver improved outcomes to hundreds of millions of patients.

a) Brilinta (CV disease)

AstraZeneca presented results of a new analysis of the PLATO (A Study of PLATelet Inhibition and Patient Outcomes) trial at the ACC (American College of Cardiology) meeting in Orlando, US in March 2018, showing that there were fewer deaths in patients suffering from ACS who were treated with Brilinta within seven days prior to having heart bypass surgery (coronary artery bypass graft), compared to those treated with clopidogrel. For patients treated with Brilinta, total mortality was reduced by 51% and CV death was reduced by 48%, in comparison to patients treated with clopidogrel.

At the meeting, the Company also announced initial results from TREAT (Ticagrelor in Patients With ST Elevation Myocardial Infarction (STEMI) Treated With Pharmacological Thrombolysis), a Phase III, investigator-initiated and academically-led trial, financially supported by AstraZeneca, investigating the safety of Brilinta 90mg compared to clopidogrel 75mg for heart-attack patients treated with pharmacological thrombolysis. The trial demonstrated comparable safety profiles in thrombolysed STEMI patients, as measured by major bleeding at 30 days, between Brilinta and clopidogrel ($P < 0.001$ for non-inferiority). Rates of major CV events were similar between Brilinta and clopidogrel at 30 days, although due to the low number of events, statistical power to assess superiority was limited. Further assessment of safety and efficacy data is planned at 12 months.

In February 2018, new data was published in the Journal of the American College of Cardiology. The new data suggested that treatment with Brilinta 60mg significantly reduces the risk of a major adverse cardiac event (MACE) by 19% and coronary death by 36%, in patients who have survived a heart attack and are living with multi-vessel-disease (MVD). The findings from this pre-specified sub-analysis of the PEGASUS-TIMI 54 trial suggested that this high-risk population may benefit from extended, preventative anti-platelet therapy beyond the initial 12-month, post-event period. This sub-analysis also highlighted the increased risk of cardiac events among patients with MVD who have already experienced a heart attack.

b) Farxiga (diabetes)

AstraZeneca presented results of its CVD-REAL 2 study at the aforementioned ACC meeting. This new analysis assessed data from more than 400,000 patients, 74% of whom did not have a history of established CV disease. Results showed that, across this broad population of patients with type-2 diabetes, treatment with an SGLT2 inhibitor (Farxiga, empagliflozin, ipragliflozin, canagliflozin, tofogliflozin or luseogliflozin) was associated with a 49% lower risk of acute coronary death (ACD), 36% lower risk of hospitalisation for heart failure (hHF), 19% lower risk of MI and 32% lower risk of stroke ($P \leq 0.001$ for all), compared to other type-2 diabetes medicines. There was also a 40% lower risk of the composite endpoint of hHF or ACD ($P < 0.001$). This data was consistent with the data from CVD-REAL study presented at the American Diabetes Association annual meeting in 2017.

During the period, the Company announced submission acceptance from the EMA for Forxiga for use as an oral adjunct treatment to insulin in adults with type-1 diabetes. The submission acceptance was based on Phase III data

from the DEPICT (Dapagliflozin Evaluation in Patients with Inadequately Controlled Type 1 diabetes) clinical programme. The safety profile of Forxiga in the DEPICT clinical programme to date was consistent with its established profile in type-2 diabetes, with the exception of a higher number of diabetic ketoacidosis (DKA) events in dapagliflozin-treated patients vs. placebo in these type-1 diabetes trials. DKA is a known complication for patients with diabetes that affects those with type-1 diabetes more frequently than those with type-2 diabetes.

c) Bydureon (type-2 diabetes)

On 3 April 2018, AstraZeneca announced that the US FDA had approved Bydureon for injectable suspension as an add-on therapy to basal insulin in adults with type-2 diabetes with inadequate glycaemic control. The approval was based on the DURATION-7 trial showing significant HbA1c reduction when Bydureon was added to insulin glargine therapy vs. insulin glargine alone.

During the period, the Company received EMA acceptance for Bydureon, based on the CV outcome trial, EXSCEL. This Phase IIIb/IV trial (EXenatide Study of Cardiovascular Event Lowering) compared the effect of once-weekly Bydureon (exenatide extended-release) vs. placebo, when added to usual type-2 diabetes treatments, on the risk of a MACE, a composite endpoint of CV death, non-fatal myocardial infarction (MI) or non-fatal stroke, in adults with type-2 diabetes at a wide range of CV risk. The trial met its primary safety objective of non-inferiority for MACE. Fewer CV events were observed in the Bydureon arm of the trial; the efficacy objective of a superior reduction in MACE, however, did not reach statistical significance.

d) Lokelma (hyperkalaemia)

On 22 March 2018, AstraZeneca announced that the EMA had granted the marketing authorisation for Lokelma (formerly ZS-9, sodium zirconium cyclosilicate) for the treatment of adults with hyperkalaemia.

During the period, the Company also completed enrolment in the Phase III HARMONIZE global trial. The trial was designed, alongside other country specific trials, to evaluate the safety and efficacy of Lokelma in patients with hyperkalaemia in Japan, South Korea, Russia and Taiwan. It will, along with other trials, support the registration of Lokelma in these countries.

e) Roxadustat (anaemia)

During the period, the Company and its partner FibroGen Inc. (Fibrogen) announced an update to roxadustat's Phase III programme. Data is now anticipated in H2 2018, vs. the prior expectation of H1 2018; a US regulatory submission is anticipated in 2019, vs. the prior expectation of H2 2018.

In China, roxadustat was granted priority review by China FDA and the Company continues to anticipate a regulatory decision in H2 2018. If approved, roxadustat will be a first-in-class medicine, with China being the first approval country.

Under the terms of the agreement, Fibrogen and AstraZeneca will develop and commercialise roxadustat in the US, China and all major markets excluding Japan, Europe, the Commonwealth of Independent States, the Middle East and South Africa, which are covered by an existing agreement between Fibrogen and Astellas Pharma Inc.

In February 2018, the first patient was dosed in the roxadustat 082 MDS trial; the purpose of the trial is to determine whether roxadustat is safe and effective in the treatment of anaemia in patients with lower-risk myelodysplastic syndrome and low red blood-cell transfusion burden. This is the first trial in the lifecycle management programme for roxadustat.

Table 20: Major Ongoing Cardiovascular Outcomes Trials

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

Medicine	Trial	Mechanism	Population	Primary Endpoint	Timeline
----------	-------	-----------	------------	------------------	----------

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Farxiga	DECLARE	SGLT2 inhibitor	c.17,000 ³² patients with type-2 diabetes	Time to first occurrence of CV death, non-fatal MI or non-fatal stroke	Data anticipated H2 2018 (final analysis) FPCD
Farxiga	DAPA-HF	SGLT2 inhibitor	c.4,500 patients with HF ³³	Time to first occurrence of CV death or hHF or an urgent HF visit	Q1 2017Data anticipated 2019
Farxiga	DAPA-CKD	SGLT2 inhibitor	c.4,000 patients with CKD ³⁴	Time to first occurrence of $\geq 50\%$ sustained decline in eGFR ³⁵ or reaching ESRD ³⁶ or CV death or renal death	FPCD Q1 2017Data anticipated 2020
Brilinta	THEMIS	P2Y12 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	Data anticipated 2019
Brilinta	THALES	P2Y12 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	Data anticipated 2020
Epanova	STRENGTH	Omega-3 carboxylic acids	c.13,000 patients with mixed dyslipidaemia	Time to first occurrence of CV death, non-fatal MI or non-fatal stroke	Data anticipated 2019

RESPIRATORY

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

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

a) Symbicort (asthma)

On 17 May 2018, positive results from the Phase III SYGMA trials of Symbicort Turbuhaler were published in the New England Journal of Medicine; they will be presented on 20 May 2018 at the American Thoracic Society International Congress. The trials were designed to evaluate efficacy of Symbicort Turbuhaler, taken only as needed, as an anti-inflammatory reliever vs. SoC medicines for mild asthma. In November 2017, the Company announced that both trials had met their individual primary efficacy outcomes.

In March 2018, the China FDA approved Symbicort Turbuhaler as a maintenance and reliever therapy, designed for the treatment of asthma in adolescent patients (12-17 years) in China.

b) Daxas (COPD)

In April 2018, the EMA announced approval of a 250mcg tablet for Daxas to be used as a starting-dose treatment for the first four weeks, followed by an increase to the maintenance dosage of 500mcg. Daxas is indicated for

maintenance treatment of severe COPD associated with chronic bronchitis in adult patients with a history of frequent exacerbations, as add-on to bronchodilator treatment.

c) Bevespi (COPD)

In March 2018, Health Canada granted approval for Bevespi Aerosphere as a long-term treatment for adults with COPD. Canada was the second market, after the US, to approve Bevespi Aerosphere.

d) Fasenra (severe, uncontrolled asthma and COPD)

On 11 May 2018, AstraZeneca announced that the GALATHEA Phase III trial did not meet its primary endpoint of a statistically-significant reduction of exacerbations in patients with COPD. The trial assessed the safety and efficacy of Fasenra, as an add-on treatment to dual or triple inhaled therapy compared to placebo for patients with moderate to very severe COPD with a history of exacerbations across a range of baseline blood eosinophils. The safety and tolerability findings in GALATHEA were consistent with those previously observed in trials with Fasenra and the results do not impact the approved indication in severe eosinophilic asthma. The second Phase III trial, TERRANOVA, is ongoing and the Company anticipates results in Q2 2018. Following the top-line results of TERRANOVA, AstraZeneca will conduct a full evaluation of both trials to determine the next steps for Fasenra in COPD.

In November 2017, Fasenra was approved in the US as a new medicine for patients aged 12 years and older with severe, uncontrolled asthma and with an eosinophilic phenotype. In January 2018, the EMA approved Fasenra as an add-on maintenance treatment in adult patients with severe, inadequately-controlled eosinophilic asthma, despite their treatment with high-dose inhaled corticosteroids plus LABA. In Japan, Fasenra was approved as an add-on treatment for bronchial asthma in patients who continue to experience asthma exacerbations, despite treatment with high-dose inhaled corticosteroid and other asthma controller(s).

During the period, the Company also commenced a Phase III trial of Fasenra for the treatment of nasal polyposis.

e) PT010 (and PT009) (COPD)

During the period, the Phase III SOPHOS trial read out, which compared PT009 (budesonide/formoterol fumarate) to PT005 (formoterol fumarate) and assessed lung function in patients with moderate to very-severe COPD. The trial, which was designed to qualify PT009 as an active comparator in the PT010 clinical-trial programme, met its primary endpoint, with PT009 delivering superior efficacy to PT005 at morning pre-dose trough FEV₁₃₇ at Week 24. A full evaluation of the SOPHOS trial data is ongoing and the Company intends to present the data at a forthcoming medical meeting.

For more details on the development pipeline, please refer to the latest Clinical Trials Appendix.

Development Pipeline 31 March 2018

AstraZeneca-sponsored or -directed trials
Phase III / Pivotal Phase II / Registration
New Molecular Entities (NMEs) and significant additional indications

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

Compound	Mechanism	Area Under Investigation	Date Commenced	Estimated Regulatory Acceptance Date / Submission Status
----------	-----------	--------------------------	----------------	--

Edgar Filing: ASTRAZENECA PLC - Form 6-K

			Phase	US	EU	Japan	China
Oncology							
Calquence <u>38</u>	BTK inhibitor	B-cell malignancy	Q1 2015	Launched			
savolitinib <u>38</u>	MET inhibitor	papillary renal cell carcinoma	Q3 2017	2020	2020		
SAVOIR							
selumetinib ASTRA	MEK inhibitor	differentiated thyroid cancer	Q3 2013	H2 2018 (Orphan Drug Designation) Accepted (Orphan Drug Designation, Priority Review)	H2 2018		
moxetumomab pasudotox <u>38</u> PLAIT	anti-CD22 recombinant immunotoxin	3rd-line hairy cell leukaemia	Q2 2013				
Imfinzi <u>38</u> + tremelimumab MYSTIC	PD-L1 mAb + CTLA-4 mAb	1st-line NSCLC	Q3 2015	H2 2018	H2 2018	H2 2018	
Imfinzi <u>38</u> + tremelimumab NEPTUNE	PD-L1 mAb + CTLA-4 mAb	1st-line NSCLC	Q4 2015	2019	2019	2019	2020
Imfinzi <u>38</u> + tremelimumab + chemotherapy POSEIDON	PD-L1 mAb + CTLA-4 mAb	1st-line NSCLC	Q2 2017	2019	2019	2019	2020
Imfinzi <u>38</u> + tremelimumab + SoC CASPIAN	PD-L1 mAb + CTLA-4 mAb + SoC	1st-line SCLC	Q1 2017	2019	2019	2019	
Imfinzi <u>38</u> + tremelimumab KESTREL	PD-L1 mAb + CTLA-4 mAb	1st-line HNSCC	Q4 2015	2019	2019	2019	
Imfinzi <u>38</u> + tremelimumab EAGLE	PD-L1 mAb + CTLA-4 mAb	2nd-line HNSCC	Q4 2015	H2 2018	H2 2018	H2 2018	
Imfinzi <u>38</u> + tremelimumab DANUBE	PD-L1 mAb + CTLA-4 mAb	1st-line bladder cancer	Q4 2015	2019	2019	2019	
Imfinzi <u>38</u> + tremelimumab HIMALAYA	PD-L1 mAb + CTLA-4 mAb	1st-line hepatocellular carcinoma	Q4 2017	2021	2021	2021	2021
Lynparza <u>38, 39</u> + cediranib CONCERTO CVRM	PARP inhibitor + VEGF inhibitor	recurrent platinum-resistant ovarian cancer	Q1 2017	2019			
Epanova	omega-3 carboxylic acids	severe hypertriglycerid-aemia		Approved		2020	
Lokelma (ZS-9) (sodium zirconium cyclosilicate)	potassium binder	hyperkalaemia		Accepted	Approved	2019	
roxadustat <u>38</u> above	hypoxia-inducible factor prolyl	anaemia in CKD / end-stage renal disease	Q3 2014	2019			Accepted

Edgar Filing: ASTRAZENECA PLC - Form 6-K

OLYMPUS (US) ROCKIES (US)	hydroxylase inhibitor						
<u>roxadustat38 above</u>	hypoxia-inducible factor prolyl hydroxylase inhibitor	anaemia in myelodysplastic syndrome	Q1 2018	2021			2020
Respiratory							
Bevespi (PT003) Fasenra <u>38</u> (benralizumab) CALIMA SIROCCO ZONDA BISE BORA GREGALE	LABA/LAMA	COPD			Launched	Accepted	H2 2018 H2 2018
PT010	LABA/LAMA/ ICS	COPD	Q3 2015	2019	2019		H2 2018 H2 2018
tezepelumab NAVIGATOR SOURCE Other	IL-5R mAb	severe, uncontrolled asthma			Launched	Launched	Launched 2021
NAVIGATOR SOURCE	TSLP mAb	severe, uncontrolled asthma	Q1 2018	2021	2021		2021
Other anifrolumab <u>38 above</u> TULIP	Type I IFN receptor mAb	systemic lupus erythematosus	Q3 2015	2019 (Fast Track)	2019		2019
lanabecestat <u>38 above</u> AMARANTH + extension, DAYBREAK-ALZ	beta-secretase inhibitor	Alzheimer's disease	Q2 2016	2020 (Fast Track)	2020		2020

Phases I and II

NMEs and significant additional indications

Compound	Mechanism	Area Under Investigation	Phase	Date Commenced Phase
Oncology Imfinzi	PD-L1 mAb	solid tumours	II	Q3 2014
Imfinzi <u>38</u> + tremelimumab	PD-L1 mAb + CTLA-4 mAb	gastric cancer	II	Q2 2015
Imfinzi <u>38</u> + tremelimumab	PD-L1 mAb + CTLA-4 mAb	biliary tract, oesophageal	II	Q4 2013
Imfinzi <u>38</u> + tremelimumab + chemo	PD-L1 mAb + CTLA-4 mAb	1st-line pancreatic ductal adenocarcinoma, oesophageal and SCLC	I	Q2 2016
Imfinzi <u>38</u> + AZD5069	PD-L1 mAb + CXCR2 antagonist	pancreatic ductal adenocarcinoma HNSCC	II II	Q2 2017 Q3 2015

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Imfinzi <u>38</u> + AZD5069 or Imfinzi <u>38</u> + PD-L1 mAb + CXCR2 antagonist or PD-L1 mAb + STAT3 inhibitor				
danvatirsen <u>38</u> (AZD9150)				
Imfinzi <u>38</u> + dabrafenib + trametinib	PD-L1 mAb + BRAF inhibitor + MEK inhibitor	melanoma	I	Q1 2014
Imfinzi <u>38</u> + adavosertib <u>38</u> (AZD1775)	PD-L1 mAb + Wee1 inhibitor	solid tumours	I	Q4 2015
Imfinzi <u>38</u> + MEDI0680	PD-L1 mAb + PD-1 mAb	solid tumours	II	Q3 2016
Imfinzi <u>38</u> or Imfinzi <u>38</u> + (tremelimumab or danvatirsen <u>38</u> (AZD9150))	PD-L1 mAb or PD-L1 mAb + (CTLA-4 mAb or STAT3 inhibitor)	diffuse large B-cell lymphoma	I	Q3 2016
Imfinzi <u>38</u> + danvatirsen (AZD9150) + chemotherapy	PD-L1 mAb + STAT3 inhibitor + chemotherapy	solid tumours	I	Q1 2018
Imfinzi <u>38</u> + Iressa	PD-L1 mAb + EGFR inhibitor	NSCLC	I	Q2 2014
Imfinzi <u>38</u> + MEDI0562 <u>38</u>	PD-L1 mAb + humanised OX40 agonist	solid tumours	I	Q2 2016
Imfinzi <u>38</u> + MEDI0197 <u>38</u>	PD-L1 mAb + TLR 7/8 agonist	solid tumours	I	Q2 2017
Imfinzi <u>38</u> + oleclumab	PD-L1 mAb + CD73 mAb	solid tumours	I	Q1 2016
Imfinzi <u>38</u> + monalizumab	PD-L1 mAb + NKG2a mAb	solid tumours	I	Q1 2016
Imfinzi <u>38</u> + selumetinib	PD-L1 mAb + MEK inhibitor	solid tumours	I	Q4 2015
Imfinzi <u>38</u> + tremelimumab	PD-L1 mAb + CTLA-4 mAb	solid tumours	I	Q4 2013
tremelimumab + MEDI0562 <u>38</u>	CTLA-4 mAb + humanised OX40 agonist	solid tumours	I	Q2 2016
Imfinzi <u>38</u> + azacitidine	PD-L1 mAb + azacitidine	myelodysplastic syndrome	I	Q2 2016
Imfinzi <u>38</u> + MEDI0457 <u>38</u>	PD-L1 mAb + DNA HPV vaccine	HNSCC	II	Q4 2017
Imfinzi <u>38</u> + RT (platform) CLOVER	PD-L1 mAb + RT	locally-advanced HNSCC, NSCLC, SCLC	I	Q1 2018
Imfinzi <u>38</u> +/- Lynparza BAYOU	PDL-1 mAb + PARP inhibitor	1st-line unresectable stage IV bladder cancer	II	Q1 2018
Lynparza <u>38</u> + AZD6738	PARP inhibitor + ATR inhibitor	gastric cancer	II	Q3 2016
Lynparza <u>38</u> + adavosertib <u>38</u> (AZD1775#)	PARP inhibitor + Wee1 inhibitor	solid tumours	I	Q3 2015
Lynparza <u>38</u> + Imfinzi <u>38</u> MEDIOLA	PARP inhibitor + PD-L1 mAb	solid tumours	II	Q2 2016
Tagrisso + (selumetinib <u>38</u> or savolitinib <u>38</u>) TATTON	EGFR inhibitor + (MEK inhibitor or MET inhibitor)	advanced EGFRm NSCLC	II	Q2 2016
Tagrisso BLOOM	EGFR inhibitor	CNS metastases in advanced EGFRm NSCLC	II	Q4 2015
adavosertib <u>38</u> (AZD1775 <u>38</u>) + chemotherapy	Wee1 inhibitor + chemotherapy	ovarian cancer	II	Q1 2015
adavosertib <u>38</u> (AZD1775 <u>38</u>)	Wee1 inhibitor	solid tumours	I	Q3 2015
vistusertib	mTOR inhibitor	solid tumours	II	Q1 2013
capivasertib <u>38</u> (AZD5363 <u>38</u>)	AKT inhibitor	breast cancer	II	Q1 2014
AZD4547	FGFR inhibitor	solid tumours	II	Q4 2011

Edgar Filing: ASTRAZENECA PLC - Form 6-K

AZD0156	ATM inhibitor	solid tumours	I	Q4 2015
AZD1390	ATM inhibitor	healthy volunteer trial	I	Q4 2017
AZD281138	Aurora B inhibitor	solid tumours	I	Q4 2015
AZD4573	CDK9 inhibitor	haematological malignancies	I	Q4 2017
AZD4635	A2aR inhibitor	solid tumours	I	Q2 2016
AZD4785	KRAS inhibitor	solid tumours	I	Q2 2017
AZD5153	BRD4 inhibitor	solid tumours	I	Q3 2017
AZD5991	MCL1 inhibitor	haematological malignancies	I	Q3 2017
Calquence + vistusertib	BTK inhibitor + mTor inhibitor	haematological malignancies	I	Q3 2017
Calquence + AZD6738	BTK inhibitor + ATR inhibitor	haematological malignancies	I	Q1 2018
AZD6738	ATR inhibitor	solid tumours	I	Q4 2013
AZD8186	PI3k inhibitor	solid tumours	I	Q2 2013
AZD9496	selective oestrogen receptor degrader	oestrogen receptor +ve breast cancer	I	Q4 2014
MEDI056238	humanised OX40 agonist	solid tumours	I	Q1 2015
MEDI1873	GITR agonist fusion protein	solid tumours	I	Q4 2015
MEDI372638	PSMA antibody drug conjugate	prostate cancer	I	Q1 2017
MEDI4276	HER2 bi-specific antibody drug conjugate	solid tumours	I	Q4 2015
MEDI5083	CD40 ligand fusion protein	solid tumours	I	Q1 2017
MEDI7247	antibody drug conjugate	haematological malignancies	I	Q2 2017
MEDI919738	TLR 7/8 agonist	solid tumours	I	Q4 2015
oleclumab	CD73 mAb	solid tumours	I	Q3 2015
CVRM				
verinurad	URAT1 inhibitor	CKD	II	Q2 2017
MEDI0382	GLP-1 / glucagon dual agonist	type-2 diabetes / obesity	II	Q3 2016
MEDI6012	LCAT	CV disease	II	Q4 2015
AZD4831	myeloperoxidase	HF with a preserved ejection fraction	I	Q3 2016
AZD5718	FLAP	coronary artery disease	II	Q4 2017
AZD860138	VEGF-A	CV disease	II	Q1 2018
AZD9977	MCR	CV disease	I	Q1 2018
MEDI588438	cholesterol modulation	CV disease	II	Q4 2017
MEDI7219	anti-diabetic	type-2 diabetes	I	Q1 2018
Respiratory abediterol38	LABA	asthma / COPD	II	Q4 2007
tezepelumab38	TSLP mAb	atopic dermatitis	II	Q2 2015
AZD141938	inhaled TLR9 agonist	asthma	II	Q4 2016
AZD7594	inhaled SGRM	asthma / COPD	II	Q3 2015
AZD887138	MABA	COPD	II	Q1 2017
PT010	LABA/LAMA/ICS	asthma	II	Q2 2014
AZD5634	inhaled ENaC	cystic fibrosis	I	Q1 2016
AZD7594 + abediterol38	inhaled SGRM + LABA	asthma / COPD	I	Q4 2016
AZD798638	DPP1	COPD	II	Q4 2017

Edgar Filing: ASTRAZENECA PLC - Form 6-K

AZD9567	oral SGRM	rheumatoid arthritis / respiratory	II	Q1 2018
AZD14038	Inhaled IL-4Ra	asthma	I	Q4 2017
MEDI3506	IL-33 mAb	COPD	I	Q2 2017
Other				
anifrolumab38	Type 1 IFN receptor mAb	lupus nephritis systemic lupus	II	Q4 2015
anifrolumab38	Type 1 IFN receptor mAb	erythematosis (subcutaneous)	II	Q1 2017
MEDI3902	Psl/PcrV bispecific mAb	prevention of nosocomial Pseudomonas aeruginosa pneumonia	II (Fast Track, US)	Q2 2016
suvratoxumab	mAb binding to S. aureus toxin	prevention of nosocomial Staphylococcus aureus pneumonia	II (Fast Track, US)	Q4 2014
prezalumab38	B7RP1 mAb	primary Sjögren's syndrome	II	Q3 2015
MEDI8852	influenza A mAb	influenza A treatment	II (Fast Track, US)	Q4 2015
MEDI889738	RSV mAb-YTE	passive RSV prophylaxis	II (Fast Track, US)	Q1 2015
AZD0284	RORg	psoriasis / respiratory	I	Q4 2016
MEDI070038	BAFF/B7RP1 bispecific mAb	systemic lupus erythematosis	I	Q1 2016
MEDI181438	amyloid beta mAb	Alzheimer's disease	I	Q2 2014
MEDI7352	NGF/TNF bi-specific mAb	osteoarthritis pain	I	Q1 2016
MEDI1341	alpha synuclein mAb	Parkinson's disease	I	Q4 2017

Significant Lifecycle Management

Compound	Mechanism	Area Under Investigation	Date Commenced Phase	Estimated Regulatory Acceptance Date / Submission Status			
				US	EU	Japan	China
Oncology							
Calquence38	BTK inhibitor	1st-line chronic lymphocytic leukaemia	Q3 2015	2020 (Orphan Drug Designation)	2020 (Orphan Drug Designation)		
Calquence38	BTK inhibitor	relapsed/refractory chronic lymphocytic leukaemia, high risk	Q4 2015	2019 (Orphan Drug Designation)	2019 (Orphan Drug Designation)		
Calquence38	BTK inhibitor	1st-line mantle cell lymphoma	Q1 2017	2023			
Imfinzi38PACIFIC	PD-L1 mAb	locally-advanced (Stage III), NSCLC	Q2 2014	Approved (Breakthrough Therapy)	Accepted	Accepted	

Edgar Filing: ASTRAZENECA PLC - Form 6-K

				Designation & Priority Review)			
Imfinzi ³⁸ PEARL (China)	PD-L1 mAb	1st-line NSCLC	Q1 2017				2020
Lynparza ³⁸ OlympiAD	PARP inhibitor	gBRCA metastatic breast cancer	Q2 2014	Approved (Priority Review)	Accepted	Accepted (Orphan drug designation, Priority Review)	H2 2018
Lynparza ³⁸ SOLO-2	PARP inhibitor	2nd-line or greater BRCAm PSR ovarian cancer, maintenance monotherapy	Q3 2013	Approved (Priority Review)	Approved	Approved (Orphan drug designation)	Accepted
Lynparza ³⁸ SOLO-1	PARP inhibitor	1st-line BRCAm ovarian cancer	Q3 2013	H2 2018	H2 2018	H2 2018	2019
Lynparza ³⁸ SOLO-3	PARP inhibitor	gBRCA PSR ovarian cancer	Q1 2015	H2 2018			
Lynparza ³⁸ POLO	PARP inhibitor	pancreatic cancer	Q1 2015	2019	2019		
Lynparza ³⁸ PROfound	PARP inhibitor	prostate cancer	Q1 2017	2020 (Breakthrough Therapy Designation)	2020	2020	2020
Lynparza ³⁸ OlympiA	PARP inhibitor	gBRCA adjuvant breast cancer	Q2 2014	2021	2021	2021	
Tagrisso FLAURA	EGFR inhibitor	1st-line advanced EGFRm NSCLC	Q1 2015	Approved (Breakthrough Therapy designation)	Accepted (CHMP positive opinion)	Accepted	H2 2018
Tagrisso ADAURA CVRM	EGFR inhibitor	adjuvant EGFRm NSCLC	Q4 2015	2022	2022	2022	2022
Brilinta ⁴¹ THALES	P2Y12 receptor antagonist	acute ischaemic stroke or transient ischaemic attack	Q1 2018	2020	2020		2020
Brilinta ⁴¹ THEMIS	P2Y12 receptor antagonist	CV outcomes trial in patients with type-2 diabetes and coronary artery disease without a previous history of MI or stroke	Q1 2014	2019	2019	2019	2020
Brilinta ⁴¹ HESTIA	P2Y12 receptor antagonist	prevention of vaso-occlusive crises in paediatric patients with sickle cell disease	Q1 2014	2021	2021		
Farxiga ⁴² DECLARET 58	SGLT2 inhibitor	CV outcomes trial in patients with type-2 diabetes	Q2 2013	2019	2019		
Farxiga ⁴²		type-1 diabetes	Q4 2014	H2 2018	Accepted	H2 2018	

Edgar Filing: ASTRAZENECA PLC - Form 6-K

	SGLT2 inhibitor						
Farxiga ⁴²	SGLT2 inhibitor	worsening HF or CV death in patients with chronic HF	Q1 2017	2020	2020	2020	2020
Farxiga ⁴²	SGLT2 inhibitor	renal outcomes and CV mortality in patients with CKD	Q1 2017	2021	2021	2021	2021
Xigduo XR/ Xigduo ⁴³	SGLT2 inhibitor/ metformin FDC	type-2 diabetes		Launched	Launched		2020
Qtern	DPP-4 inhibitor / SGLT2 inhibitor FDC	type-2 diabetes		Launched	Launched		
BydureonBCise / Bydureon autoinjector ⁴⁴	GLP-1 receptor agonist	type-2 diabetes	Q1 2013	Launched	Accepted		
Bydureon EXSCEL	GLP-1 receptor agonist	type-2 diabetes outcomes trial	Q2 2010	Q2 2018	Accepted		H2 2018
saxagliptin/ dapagliflozin/ metformin	DPP-4 inhibitor / SGLT2 inhibitor	type-2 diabetes	Q2 2017	Q2 2018	Q2 2018		
Epanova STRENGTH	omega-3 carboxylic acids	CV outcomes trial in statin-treated patients at high CV risk, with persistent hypertriglyceridaemia plus low HDL-cholesterol	Q4 2014	2020	2020	2020	2020
Respiratory Fasenra ³⁸ TERRANOVA GALATHEA	IL-5R mAb	COPD	Q3 2014	H2 2018	H2 2018	2019	
Fasenra ³⁸ OSTRO	IL-5R mAb	nasal polyposis	Q1 2018	2020	2020		
Symbicort SYGMA	ICS/LABA	as-needed use in mild asthma	Q4 2014		H2 2018		2019
Duaklir Genuair ³⁸ Other	LAMA/LABA	COPD		Q2 2018	Launched		2019
Nexium	proton-pump inhibitor	stress ulcer prophylaxis					Accepted
Nexium	proton-pump inhibitor	paediatrics		Launched	Launched	Launched	
linaclotide ³⁸	GC-C receptor peptide agonist	irritable bowel syndrome with constipation (IBS-C)					Accepted

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Terminations (discontinued projects: 1 January to 31 March 2018)

NME / Line Extension	Compound	Reason for Discontinuation	Area Under Investigation
NME	MEDI-56538	safety / efficacy	solid tumours
NME	MEDI9314	strategic	atopic dermatitis

Completed Projects/Divestitures (1 January to 31 March 2018)

Compound	Mechanism	Area Under Investigation	Completed/ Divested
Faslodex (FALCON)	oestrogen receptor antagonist	1st-line hormone receptor +ve advanced breast cancer	Completed
mavrilimumab38	GM-CSFR mAb	rheumatoid arthritis	divested
inebilizumab38	CD19 mAb	neuromyelitis optica	divested
MEDI4920	anti-CD40L-Tn3 fusion protein	primary Sjögren's syndrome	divested
MEDI7734	ILT7 mAb	myositis	divested

Condensed Consolidated Statement Of Comprehensive Income

For the quarter ended 31 March	2018	2017
	\$m	\$m
Product Sales	4,985	4,843
Externalisation Revenue	193	562
Total Revenue	5,178	5,405
Cost of sales	(1,134)	(894)
Gross profit	4,044	4,511
Distribution costs	(81)	(77)
Research and development expense	(1,279)	(1,453)
Selling, general and administrative costs	(2,457)	(2,300)
Other operating income & expense	469	236
Operating profit	696	917
Finance income	35	18
Finance expense	(343)	(340)
Share of after tax losses in associates and joint ventures	(14)	(13)
Profit before tax	374	582
Taxation	(58)	(70)
Profit for the period	316	512
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Remeasurement of the defined benefit pension liability	27	1
Fair value movements on equity investments	118	-
Fair value movements related to own credit risk on bonds designated as fair value through profit or loss	(1)	-
Tax on items that will not be reclassified to profit or loss	(27)	(1)
	117	-
Items that may be reclassified subsequently to profit or loss		

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Foreign exchange arising on consolidation	167	154
Foreign exchange arising on designating borrowings in net investment hedges	(99)	100
Fair value movements on cash flow hedges	101	7
Fair value movements on cash flow hedges transferred to profit or loss	(80)	(39)
Fair value movements on derivatives designated in net investment hedges	(46)	(30)
Fair value movements on equity investments	-	(150)
Tax on items that may be reclassified subsequently to profit or loss	20	24
	63	66
Other comprehensive income for the period, net of tax	180	66
Total comprehensive income for the period	496	578
Profit attributable to:		
Owners of the Parent	340	537
Non-controlling interests	(24)	(25)
	316	512
Total comprehensive income attributable to:		
Owners of the Parent	520	603
Non-controlling interests	(24)	(25)
	496	578
Basic earnings per \$0.25 Ordinary Share	\$0.27	\$0.42
Diluted earnings per \$0.25 Ordinary Share	\$0.27	\$0.42
Weighted average number of Ordinary Shares in issue (millions)	1,266	1,265
Diluted weighted average number of Ordinary Shares in issue (millions)	1,267	1,266

Condensed Consolidated Statement Of Financial Position

	At 31 Mar 2018 \$m	At 31 Dec 2017 \$m	At 31 Mar 2017 \$m
ASSETS			
Non-current assets			
Property, plant and equipment	7,721	7,615	6,954
Goodwill	11,834	11,825	11,688
Intangible assets	25,850	26,188	27,386
Derivative financial instruments	594	504	310
Investments in associates and joint ventures	187	103	88
Other investments	987	933	739
Other receivables	525	847	891
Deferred tax assets	2,401	2,189	1,266
	50,099	50,204	49,322
Current assets			
Inventories	3,283	3,035	2,652
Trade and other receivables	5,444	5,009	4,686
Other investments	866	1,230	530
Derivative financial instruments	21	28	13
Income tax receivable	563	524	627
Cash and cash equivalents	3,005	3,324	3,129
	13,182	13,150	11,637

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Total assets	63,281	63,354	60,959
LIABILITIES			
Current liabilities			
Interest-bearing loans and borrowings	(4,170)	(2,247)	(2,839)
Trade and other payables	(11,481)	(11,641)	(9,899)
Derivative financial instruments	(40)	(24)	(1)
Provisions	(1,011)	(1,121)	(1,044)
Income tax payable	(1,462)	(1,350)	(1,646)
	(18,164)	(16,383)	(15,429)
Non-current liabilities			
Interest-bearing loans and borrowings	(15,684)	(15,560)	(14,563)
Derivative financial instruments	(10)	(4)	(107)
Deferred tax liabilities	(3,987)	(3,995)	(4,036)
Retirement benefit obligations	(2,516)	(2,583)	(2,171)
Provisions	(384)	(347)	(378)
Other payables	(7,963)	(7,840)	(9,496)
	(30,544)	(30,329)	(30,751)
Total liabilities	(48,708)	(46,712)	(46,180)
Net assets	14,573	16,642	14,779
EQUITY			
Capital and reserves attributable to equity holders of the Company			
Share capital	317	317	316
Share premium account	4,407	4,393	4,368
Other reserves	2,027	2,029	2,042
Retained earnings	6,164	8,221	6,263
	12,915	14,960	12,989
Non-controlling interests	1,658	1,682	1,790
Total equity	14,573	16,642	14,779

Condensed Consolidated Statement Of Changes in Equity

	Share capital \$m	Share premium account \$m	Other reserves ⁴⁵ \$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	-	-	-	537	537	(25)
Other comprehensive income	-	-	-	66	66	-
Transfer to other reserves	-	-	(5)	5	-	-
Transactions with owners:						
Dividends	-	-	-	(2,404)	(2,404)	-
Issue of Ordinary Shares	-	17	-	-	17	-

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Share-based payments charge for the period	-	-	-	52	52	-
Settlement of share plan awards	-	-	-	(133)	(133)	-
Net movement	-	17	(5)	(1,877)	(1,865)	(25)
At 31 Mar 2017	316	4,368	2,042	6,263	12,989	1,790
	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 ⁴⁶	-	-	-	(91)	(91)	-
Profit for the period	-	-	-	340	340	(24)
Other comprehensive income	-	-	-	180	180	-
Transfer to other reserves	-	-	(2)	2	-	-
Transactions with owners:						
Dividends	-	-	-	(2,402)	(2,402)	-
Issue of Ordinary Shares	-	14	-	-	14	-
Share-based payments charge for the period	-	-	-	52	52	-
Settlement of share plan awards	-	-	-	(138)	(138)	-
Net movement	-	14	(2)	(2,057)	(2,045)	(24)
At 31 Mar 2018	317	4,407	2,027	6,164	12,915	1,658

Condensed Consolidated Statement Of Cash Flows

For the quarter ended 31 March	2018 \$m	2017 \$m
Cash flows from operating activities		

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Profit before tax	374	582
Finance income and expense	308	322
Share of after tax losses in associates and joint ventures	14	13
Depreciation, amortisation and impairment	709	658
Increase in working capital and short-term provisions	(993)	(887)
Gains on disposal of intangible assets	(65)	(52)
Non-cash and other movements	(242)	(297)
Cash generated from operations	105	339
Interest paid	(128)	(189)
Tax paid	(117)	(62)
Net cash (outflow)/inflow from operating activities	(140)	88
Cash flows from investing activities		
Movement in short-term investments and fixed deposits	436	357
Purchase of property, plant and equipment	(213)	(286)
Disposal of property, plant and equipment	2	9
Purchase of intangible assets	(121)	(99)
Disposal of intangible assets	362	51
Purchase of non-current asset investments	(4)	(18)
Disposal of non-current asset investments	1	8
Payments to joint ventures	(161)	-
Payment of contingent consideration from business combinations	(62)	(213)
Interest received	33	45
Net cash inflow/(outflow) from investing activities	273	(146)
Net cash inflow/(outflow) before financing activities	133	(58)
Cash flows from financing activities		
Proceeds from issue of share capital	14	17
Issue of loans	-	3
Dividends paid	(2,363)	(2,368)
Hedge contracts relating to dividend payments	(47)	(32)
Repayment of obligations under finance leases	-	(14)
Movement in short-term borrowings	1,733	352
Net cash outflow from financing activities	(663)	(2,042)
Net decrease in cash and cash equivalents in the period	(530)	(2,100)
Cash and cash equivalents at the beginning of the period	3,172	4,924
Exchange rate effects	13	14
Cash and cash equivalents at the end of the period	2,655	2,838
Cash and cash equivalents consists of:		
Cash and cash equivalents	3,005	3,129
Overdrafts	(350)	(291)
	2,655	2,838

Notes To The Interim Financial Statements

1.
BASIS OF PREPARATION AND ACCOUNTING POLICIES

These unaudited condensed consolidated interim financial statements (interim financial statements) for the three months ended 31 March 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. The other changes introduced have not had a significant impact on the Group. In particular, 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 and, following a review of the existing hedging arrangements, these 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, an increase to trade and other receivables of \$20m, a total 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 has resulted in the deferral of revenues that had previously been recognised under IAS 18 and the recognition of additional Externalisation Revenue of \$7m in Q1 2018. Earnings per share were unchanged.

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.

Going concern

The Group has considerable financial resources available. As at 31 March 2018 the Group has \$1.8bn in financial resources (cash balances of \$3.0bn and undrawn committed bank facilities of \$3.0bn which are available until April 2022, with only \$4.2bn of debt due within one year). The Group's revenues are largely derived from sales of products which are covered by patents which provide a relatively high level of resilience and predictability to cash inflows, although 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 will be 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 quarter ended 31 March 2018 is stated after charging restructuring costs of \$95m (\$312m for the first quarter of 2017). These have been charged to profit as follows:

	Q1 2018\$m	Q1 2017\$m
Cost of sales	32	38
Research and development expense	27	104
Selling, general and administrative costs	36	94
Other operating income and expense	-	76
Total	95	312

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.

	At 1 Jan 2018 \$m	Cash Flow \$m	Non-cash & Other \$m	Exchange Movements \$m	At 31 Mar 2018 \$m
Loans due after one year	(15,560)	-	6	(130)	(15,684)

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Total long-term debt	(15,560)	-	6	(130)	(15,684)
Current instalments of loans	(1,397)	-	3	-	(1,394)
Current instalments of finance leases	(5)	-	5	-	-
Total current debt	(1,402)	-	8	-	(1,394)
Other investments - current	1,230	(436)	71	1	866
Other investments - non-current	70	-	(68)	-	2
Net derivative financial instruments	504	47	14	-	565
Cash and cash equivalents	3,324	(332)	-	13	3,005
Overdrafts	(152)	(198)	-	-	(350)
Short-term borrowings	(693)	(1,733)	-	-	(2,426)
	4,283	(2,652)	17	14	1,662
Net debt	(12,679)	(2,652)	31	(116)	(15,416)

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

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 Q1 2018. These are presented in Fair value gains on equity investments in the Condensed Consolidated Statement of Comprehensive Income.

Financial instruments measured at fair value include \$1,853m of other investments, \$1,238m of loans, and \$565m of derivatives as at 31 March 2018. The total fair value of interest-bearing loans and borrowings at 31 March 2018 which have a carrying value of \$19,854m in the Condensed Consolidated Statement of Financial Position, was \$20,900m. Contingent consideration liabilities arising on business combinations have been classified under Level 3 in the fair value hierarchy and movements in fair value are shown below:

	Diabetes Alliance	Other	Total	Total
	2018	2018	2018	2017
	\$m	\$m	\$m	\$m
At 1 January	4,477	1,057	5,534	5,457
Settlements	(62)	-	(62)	(213)
Discount unwind	84	20	104	104
At 31 March	4,499	1,077	5,576	5,348

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 (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 first quarter of 2018 and to 18 May 2018.

Patent litigation

Calquence (acalabrutinib)

US patent proceedings

As previously disclosed, in November 2017, Pharmacyclics LLC (Pharmacyclics, a company in the AbbVie group) filed a patent infringement lawsuit in the District Court of Delaware (the District Court) against Acerta Pharma and AstraZeneca. A trial has been scheduled for June 2020. In April 2018, AstraZeneca and Acerta Pharma filed a

complaint in the District Court against Pharmacyclics and AbbVie, Inc. alleging that their drug, Imbruvica, infringes a US patent owned by Acerta Pharma.

Brilinta (ticagrelor)

US patent proceedings

As previously disclosed, in 2015, in response to Paragraph IV notices from multiple Abbreviated New Drug Application (ANDA) filers, AstraZeneca filed patent infringement lawsuits in the US District Court for the District of Delaware (the District Court) relating to patents listed in the FDA Orange Book with reference to Brilinta. In the first quarter of 2018, AstraZeneca entered into separate settlements with a number of the ANDA filers and the District Court entered consent judgments to dismiss several of the litigations. AstraZeneca continues to litigate in the District Court against additional ANDA filers. Trial may be scheduled as soon as late August 2018.

Farxiga (dapagliflozin)

US patent proceedings

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' generic version of Farxiga, if approved and marketed, would infringe AstraZeneca's US Patents Nos. 6,414,126 and 6,515,117. AstraZeneca has also filed a further action in the US District Court for the District of New Jersey.

Crestor (rosuvastatin calcium)

Patent proceedings outside the US

As previously disclosed, in Australia, AstraZeneca has taken a provision in respect of damages claims from generic entities and the Commonwealth of Australia in relation to alleged losses suffered in connection with AstraZeneca's enforcement of Crestor patents which were subsequently found invalid. In February 2018, AstraZeneca settled the claim from Apotex Pty Ltd (and other related Apotex entities). The claims from all generic entities have now been settled. The claim from the Commonwealth of Australia remains outstanding.

Pulmicort Respules (budesonide inhalation suspension)

US patent proceedings

As previously disclosed, in February 2015, the US District Court for the District of New Jersey (the District Court) determined that the asserted claims of US Patent No. 7,524,834, which covered Pulmicort Respules, were invalid following challenges brought by Apotex, Inc. and Apotex Corp., Breath Limited, Sandoz, Inc. and Watson Laboratories, Inc. (together, the Generic Challengers). In May 2015, the US Court of Appeals for the Federal Circuit affirmed the District Court's decision. Since 2009, various injunctions were issued in this matter. Damages claims based on those injunctions have been filed by the Generic Challengers. No trial for the damages claims is currently scheduled. A provision has been taken.

Daliresp (roflumilast)

US patent proceedings

As previously disclosed, in 2015, in response to Paragraph IV notices from multiple ANDA filers, AstraZeneca filed patent infringement lawsuits in the US District Court for the District of New Jersey (the District Court) relating to patents listed in the FDA Orange Book with reference to Daliresp. From January through April 2018, AstraZeneca entered into separate settlements with a number of the ANDA filers and the District Court entered consent judgments to dismiss each of the remaining litigations.

Losec/Prilosec (omeprazole)

Patent proceedings outside the US

As previously disclosed, in Canada, in 2004, AstraZeneca brought proceedings against Apotex Inc. (Apotex) for infringement of several patents related to Losec. In February 2015, the Federal Court of Canada (the Federal Court) found that Apotex had infringed the Losec formulation patent (Canadian Patent No. 1,292,693). In July 2017, after a reference to account for Apotex's profits earned as a result of the infringement, the Federal Court issued its decision

describing how the quantification of monies owed to AstraZeneca should proceed. Apotex appealed. In February 2018, AstraZeneca and Apotex entered into a settlement agreement, under which Apotex agreed to pay AstraZeneca CAD 435m (USD 352m), concluding all Losec patent litigation in Canada.

Product liability litigation

Onglyza (saxagliptin) and Kombiglyze (saxagliptin and metformin)

As previously disclosed, in the US, AstraZeneca is defending various lawsuits alleging heart failure, cardiac injuries, and/or death from treatment with Onglyza or Kombiglyze. In February 2018, the Judicial Panel on Multidistrict Litigation ordered the transfer of various pending federal actions to the Eastern District of Kentucky (the District) for consolidated pretrial proceedings with the federal actions pending in the District. The previously disclosed California state court coordinated proceeding remains pending in California.

Commercial litigation

Telephone Consumer Protection Act litigation

As previously disclosed, in the US, in December 2016, AstraZeneca and several other entities were served with a complaint filed in the US District Court for the Southern District of Florida that alleges, among other things, violations of the Telephone Consumer Protection Act caused by the sending of unsolicited advertisements by facsimile. This matter has been dismissed.

Toprol-XL (metoprolol succinate)

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 (the State) against AstraZeneca, which alleged unlawful monopolisation and unfair trade practices in connection with enforcement of patents for Toprol-XL. The State appealed the Trial Court's dismissal. 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. In May 2018, AstraZeneca filed a writ with the Louisiana Supreme Court seeking review of the Appellate Court's decision.

6.

PRODUCT SALES ANALYSIS

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			
	Q1 2018 \$m	Actual %	CER %	Q1 2018 \$m	Actual %	CER %	Q1 2018 \$m	Actual %	Q1 2018 \$m	Actual %	CER %	Q1 2018 \$m	Actual %	CER %
Oncology														
Tagrisso	338	98	89	71	n/m	n/m	147	63	69	97	74	51	28	23
Iressa	132	6	(1)	71	16	8	8	-	30	15	4	23	(21)	(24)
Lynparza	119	109	100	8	100	125	66	144	42	68	44	3	n/m	n/m
Imfinzi	62	n/m	n/m	-	-	-	62	n/m	-	-	-	-	-	-
Calquence	8	n/m	n/m	-	-	-	8	n/m	-	-	-	-	-	-
Legacy:														
Faslodex	254	19	14	39	44	41	134	14	59	9	(6)	22	47	40
Zoladex	184	(1)	(6)	101	16	10	1	n/m	34	6	(3)	48	(17)	(21)
Arimidex	54	4	(2)	35	21	10	-	n/m	8	-	-	11	(21)	(21)
Casodex	52	(7)	(13)	31	3	(3)	-	-	6	-	-	15	(25)	(30)
Others	27	4	(4)	7	-	(14)	-	-	1	-	-	19	6	-
Total Oncology	1,230	39	33	363	45	36	426	69	249	33	18	192	(2)	(6)
CVRM														
Brilinta	293	31	24	76	27	20	115	32	86	32	15	16	33	33
Farxiga	299	44	39	69	64	62	127	32	74	48	30	29	53	42
Onglyza	129	(16)	(19)	40	33	27	49	(40)	23	(15)	(26)	17	6	6
Bydureon	139	(9)	(11)	-	n/m	n/m	111	(13)	23	5	-	5	67	67
Byetta	31	(33)	(35)	5	-	(20)	15	(50)	7	(13)	(13)	4	33	33
Symlyn	9	(36)	(36)	-	-	-	9	(36)	-	-	-	-	-	-
Legacy:														
Crestor	389	(38)	(42)	238	18	11	46	(59)	65	(67)	(70)	40	(67)	(68)
Seloken/Toprol-XL	200	8	3	173	14	9	18	64	6	(71)	(71)	3	50	50
Atacand	71	(5)	(9)	37	(16)	(18)	7	17	22	5	(5)	5	25	25
Others	85	(4)	(10)	60	3	(5)	-	-	20	(13)	(13)	5	(38)	(38)
Total CVRM	1,645	(8)	(12)	698	18	11	497	(12)	326	(25)	(32)	124	(34)	(36)
Respiratory														
Symbicort	634	(6)	(12)	128	14	10	183	(28)	212	6	(7)	111	1	(4)
Pulmicort	346	3	(3)	270	8	2	29	(29)	27	4	(8)	20	-	(5)
Daliresp/Daxas	38	(14)	(16)	2	n/m	n/m	29	(24)	7	40	20	-	-	-
Tudorza/Eklira	34	(8)	(16)	1	n/m	-	11	(27)	20	-	(10)	2	-	-
Duaklir	28	47	26	-	n/m	n/m	-	-	27	42	32	1	n/m	n/m
Fasenra	21	n/m	n/m	-	-	-	19	n/m	2	n/m	n/m	-	-	-
Bevespi	5	n/m	n/m	-	-	-	5	n/m	-	-	-	-	-	-
Others	75	12	3	37	32	21	(5)	n/m	31	11	-	12	33	33
Total Respiratory	1,181	-	(6)	438	12	5	271	(23)	326	9	(3)	146	4	(1)
Other														
Nexium	448	(3)	(7)	182	4	(1)	100	(26)	61	-	(13)	105	18	13

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Synagis	224	(3)	(3)	-	n/m	n/m	134	(15)	90	22	22	-	-	-
Losec/Prilosec	69	1	(6)	46	31	23	1	(80)	16	(11)	(22)	6	(40)	(40)
Seroquel XR	53	(21)	(25)	18	20	7	16	(33)	16	(27)	(32)	3	(50)	(50)
Movantik/Moventig	28	(7)	(7)	-	-	-	28	(7)	-	-	-	-	-	-
Others	107	(25)	(29)	20	(80)	(64)	14	n/m	37	-	(46)	36	(3)	(19)
Total Other	929	(7)	(10)	266	(18)	(17)	293	(8)	220	4	(9)	150	6	(1)
TOTAL PRODUCT SALES	4,985	3	(2)	1,765	13	8	1,487	-	1,121	(1)	(12)	612	(8)	(12)

7.

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 \$m	Actual %	CER %	Q2 2018 \$m	Actual %	CER %	Q3 2018 \$m	Actual %	CER %	Q4 2018 \$m	Actual %	CER %
Oncology												
Tagrisso	338	11	10									
Iressa	132	2	(1)									
Lynparza	119	19	18									
Imfinzi	62	n/m	n/m									
Calquence	8	n/m	n/m									
Legacy:												
Faslodex	254	7	5									
Zoladex	184	(2)	(4)									
Arimidex	54	(5)	(7)									
Casodex	52	(4)	(6)									
Others	27	(7)	(20)									
Total Oncology	1,230	10	8									
CVRM												
Brilinta	293	(2)	(4)									
Farxiga	299	(10)	(11)									
Onglyza	129	(28)	(29)									
Bydureon	139	(5)	(5)									
Byetta	31	(35)	(38)									
Symlin	9	(31)	(31)									
Legacy:												
Crestor	389	(35)	(36)									
Seloken/Toprol-XL	200	19	18									
Atacand	71	(3)	(3)									
Others	85	6	4									
Total CVRM	1,645	(15)	(17)									
Respiratory												
Symbicort	634	(16)	(17)									
Pulmicort	346	(7)	(8)									
Daliresp/Daxas	38	(28)	(30)									
Tudorza/Eklira	34	(19)	(21)									
Duaklir	28	22	17									

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Fasenra	21	n/m	n/m
Bevespi	5	(38)	(38)
Others	75	(12)	(20)
Total Respiratory	1,181	(11)	(13)

Other			
Nexium	448	5	3
Synagis	224	(4)	(4)
Losec/Prilosec	69	-	(4)
Seroquel XR	53	(51)	(51)
Movantik/Moventig	28	(7)	(7)
Others	107	(36)	(37)
Total Other	929	(15)	(16)

TOTAL PRODUCT SALES	4,985	(9)	(11)
---------------------	-------	-----	------

8.

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
Byetta	46	(16)	(16)	43	(7)	(7)	39	(9)	(9)	48	23	23
Symlin	14	-	-	11	(21)	(21)	10	(9)	(9)	13	30	30
Qtern	-	-	-	-	-	-	-	-	-	5	n/m	n/m
Legacy:												
Crestor	631	-	3	560	(11)	(12)	580	4	2	594	2	2
Seloken/Toprol-XL	186	4	6	181	(3)	(4)	160	(12)	(14)	168	5	4
Atacand	75	(7)	(6)	72	(4)	(5)	80	11	8	73	(9)	(6)
Others	89	3	12	90	1	(3)	80	(11)	(12)	80	-	(4)

Edgar Filing: ASTRAZENECA PLC - Form 6-K

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

Interim Financial Statements

9.

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
Casodex	62	(2)	(6)	63	2	-	62	(2)	(5)	60	(3)	(2)
Arimidex	57	(5)	(5)	62	9	7	56	(10)	(13)	57	2	5
Others	21	(22)	(22)	27	29	12	27	-	4	29	7	-
Total Oncology	738	3	3	848	15	12	867	2	2	930	7	7
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)

Edgar Filing: ASTRAZENECA PLC - Form 6-K

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 first half and second quarter 2018 results

26 July 2018

Announcement of nine months and third quarter 2018 results

8 November 2018

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

Trademarks of the AstraZeneca group of companies and of companies other than AstraZeneca appear throughout this document in italics. AstraZeneca, the AstraZeneca logotype and the AstraZeneca symbol are all trademarks of the AstraZeneca group of companies. Trademarks of companies other than AstraZeneca that appear in this document include Duaklir Genuair, Duaklir, Eklira, and Tudorza, trademarks of Almirall, S.A.; Epanova, a trademark of Chrysalis Pharma AG.; Imbruvica, owned by Pharmacyclics, Inc., Johnson & Johnson or Janssen Pharmaceutica NV (depending on geography); Synagis, owned by AstraZeneca or AbbVie Inc. (depending on geography); and Zomig, a trademark of Grünenthal GmbH.

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

Addresses for Correspondence

Registered Office Registrar and

US Depository

Edgar Filing: ASTRAZENECA PLC - Form 6-K

1 Francis Crick Avenue Cambridge Biomedical Campus Cambridge CB2 0AA UK	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	Citibank Shareholder Services PO Box 43077 Providence RI 02940-3077 USA
	Tel (Freephone in UK): 0800 389 1580		Tel: (toll free in the US) +1 (888) 697 8018
Tel: +44 (0)20 3749 5000	Tel (outside UK): +44 (0)121 415 7033	Tel: +46 (0)8 402 9000	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.

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

[11] Overall survival.

[12] Due to rounding, the sum of individual medicine percentages may not agree to totals.

[13] May include, inter alia, option and profit-sharing income.

[14] Q1 2018 Product Sales here comprise sales made to partners under manufacturing and supply agreements.

[15] Due to rounding, the sum of individual medicine percentages may not agree to totals.

[16] Due to rounding, the sum of individual medicine percentages may not agree to totals.

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

[18] Gross Margin, as a percentage of Product Sales, reflects Gross Profit derived from Product Sales, divided by Product Sales. Q1 2018 Cost of Sales included \$nil of costs relating to externalisation activities (Q1 2017: \$38m), which are excluded from the calculation of Gross Margin. Movements in Gross Margin are expressed in percentage points.

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

[20] 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), provision charges related to certain legal matters (see Note 5) and foreign-exchange gains and losses relating to certain non-structural intra-group loans.

[21] 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.

[22] Gross Margin, as a percentage of Product Sales, reflects Gross Profit derived from Product Sales, divided by Product Sales. Q1 2018 Cost of Sales included \$nil of costs relating to externalisation activities (Q1 2017: \$38m), which are excluded from the calculation of Gross Margin. Movements in Gross Margin are expressed in percentage points.

[23] Based on best prevailing assumptions around currency profiles.

[24] Based on average daily spot rates between 1 January and 31 March 2018.

[25] Other important currencies include AUD, BRL, CAD, KRW and RUB.

[26] Under Regulatory Review. The table shown above as at today.

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

[28] First Patient Commenced Dosing.

[29] Homologous Recombination Repair mutated.

[30] Last Patient Commenced Dosing.

[31] Conducted by the National Cancer Institute of Canada.

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

[33] Heart Failure.

[34] Chronic Kidney Disease.

[35] Estimated Glomerular Filtration Rate.

[36] End-Stage Renal Disease.

[37] Forced Expiratory Volume.

[38] Collaboration

[39] Registrational Phase II trial

[40] Fibrogen completed rolling regulatory submission in China

[41] Brilinta in the US and Japan;Brilique in ROW

[42] Farxiga in the US;Forxiga in ROW

[43] Xigduo XR in the US;Xigduo in the EU

[44] Bydureon BCise in the US, Bydureon autoinjector in the EU

[45] Other reserves include the capital redemption reserve and the merger reserve.

[46] 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: 18 May 2018

By: /s/ Adrian Kemp

Name: Adrian Kemp

Title: Company Secretary