

ASTRAZENECA PLC
Form 6-K
April 26, 2019

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 April 2019

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
26 April 2019 07:00 BST

Q1 2019 Results

Another strong top-line performance, with operating leverage supporting compelling growth in earnings

Results in the first quarter were supported by Product Sales growth of 10% (14% at CER¹) to \$5,465m, a reflection of the sustained performance of new medicines² (+77%, +83% at CER). Global Oncology sales increased by 54% (59% at CER), New CVRM3 by 15% (19% at CER) and, driven by the strength of Fasenra, Respiratory sales increased by 9% (14% at CER). Emerging Markets sales increased by 14% (22% at CER); China sales increased by 21% (28% at CER), with ex-China Emerging Markets also delivering strong growth at CER. US sales increased by 20%, while Europe sales declined by 12% (6% at CER). Japan sales increased by 26% (27% at CER) to \$501m.

The Reported Operating Margin increased by seven percentage points to 20% and the Core Operating Margin increased by 13 percentage points to 30%. These financial results were accompanied by further positive pipeline developments, with 2019 set to be another busy year for news flow.

	Q1 2019		
			% change
	\$m	Actual	CER
Product Sales	5,465	10	14
Collaboration Revenue ⁴	26	(87)	(86)
Total Revenue	5,491	6	11
Reported ⁵ Operating Profit	1,097	58	68
Core ⁶ Operating Profit	1,650	84	96
Reported Earnings Per Share (EPS)	\$0.47	75	90
Core EPS	\$0.89	85	100

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

"Our 14% Product Sales growth in the quarter reflected the success of our new medicines and Emerging Markets. In Oncology, Tagrisso, Imfinzi and Lynparza continued to do well and, in BioPharma, Farxiga, Brilinta and Fasenra also grew strongly. Emerging Markets, our largest sales region, delivered an outstanding performance with a 22% growth rate; all of its sub-regions grew strongly, including China at 28%.

Our Core Operating Profit almost doubled, demonstrating strong operating-margin improvement. Together with this encouraging financial start to the year, our highly-productive and sustainable pipeline continued to deliver, notably with a regulatory approval for Lynparza in the EU for the treatment of metastatic breast cancer and approvals of Farxiga in type-1 diabetes. The recently-announced collaboration with Daiichi Sankyo also broadened an exciting Oncology portfolio with a potentially-transformative cancer treatment that could benefit patients around the world. We appreciate the support from our shareholders in realising this exceptional opportunity."

Financial summary

- Product Sales increased by 10% in the quarter (14% at CER) to \$5,465m
- The Reported Gross Margin increased by two percentage points (three at CER) to 79%, partly reflecting the mix of Product Sales; the Core Gross Margin also increased by two percentage points to 80%

Edgar Filing: ASTRAZENECA PLC - Form 6-K

- Reported Operating Expenses increased by 1% (5% at CER) to \$3,858m and represented 70% of Total Revenue (Q1 2018: 74%). Core Operating Expenses increased by 1% (5% at CER) to \$3,369m and represented 61% of Total Revenue (Q1 2018: 65%)
- Reported R&D Expenses declined by 1% (an increase of 3% at CER) to \$1,266m. Core R&D Expenses declined by 1% (an increase of 3% at CER) to \$1,225m
- Reported SG&A Expenses increased by 2% (7% at CER) to \$2,514m; Core SG&A Expenses increased by 2% (6% at CER) to \$2,066m, reflecting ongoing additional support for new medicines and growth in China
- Reported Other Operating Income and Expense increased by 26% (27% at CER) to \$593m, primarily reflecting the impact of the divestment of US rights to Synagis; Core Other Operating Income and Expense increased by 379% (383% at CER) to \$594m
- The Reported Operating Margin increased by seven percentage points to 20%; the Core Operating Margin increased by 13 percentage points to 30%
- Reported EPS of \$0.47, based on a weighted-average number of shares of 1,267m, represented an increase of 75% (90% at CER); the Reported Tax Rate was 26% (Q1 2018: 16%). Core EPS increased by 85% (100% at CER) to \$0.89; the Core Tax Rate was 23% (Q1 2018: 18%). The tax rates reflected the geographical mix of profits and the impact of divestment transactions
- On 29 March 2019, the Company initiated an equity placing of \$3.5bn in conjunction with the recent strategic collaboration with Daiichi Sankyo Company, Limited (Daiichi Sankyo). The purpose of the placing was to fund the initial upfront and near-term milestone commitments arising from the collaboration, as well to strengthen AstraZeneca's balance sheet. One of the Company's capital-allocation priorities is to maintain a strong, investment-grade credit rating; the share issuance struck an appropriate balance between the Company's equity investors and creditors

Commercial summary

Oncology

Sales growth of 54% in the quarter (59% at CER) to \$1,892m, including:

- Tagrisso sales of \$630m, representing growth of 86% (92% at CER) that was driven by the 2018 regulatory approvals as a standard of care (SoC) in the 1st-line EGFR7-mutated (EGFRm) NSCLC setting. There was a sequential decline in US sales of Tagrisso reflecting inventory and gross-to-net movements; underlying demand growth, however, remained strong. Globally, Tagrisso became AstraZeneca's biggest-selling medicine in the quarter
- Imfinzi sales of \$295m, representing growth of 376% (381% at CER). The performance was a result of ongoing launches for the treatment of patients with unresectable, Stage III NSCLC. The majority of sales of Imfinzi were in the US, where it is the only approved medicine following SoC chemoradiation therapy (CRT) for the curative-intent treatment of patients with Stage III, unresectable NSCLC
- Lynparza sales of \$237m, representing growth of 99% (105% at CER), driven by expanded use in the treatment of ovarian and breast cancer, including a particularly strong launch in the US as a 1st-line ovarian cancer treatment
- Oncology sales growth in Emerging Markets of 35% (46% at CER) to \$490m

New CVRM

Sales growth of 15% in the quarter (19% at CER) to \$1,033m, including:

Edgar Filing: ASTRAZENECA PLC - Form 6-K

- Farxiga sales of \$349m, with growth of 17% (23% at CER), ahead of an anticipated label update in major markets to reflect results from the DECLARE trial
- Brilinta sales of \$348m, representing growth of 19% (24% at CER), due to continued market penetration in the treatment of acute coronary syndrome and high-risk post-myocardial infarction
- Bydureon sales of \$142m, an increase of 2% (4% at CER), despite the impact of supply-chain constraints that are anticipated to ease later in the year
- New CVRM sales growth in Emerging Markets of 26% (40% at CER) to \$239m

Respiratory

Sales growth of 9% in the quarter (14% at CER) to \$1,283m, including:

- A Symbicort sales decline of 8% (3% at CER) to \$585m. US sales, at \$176m, declined by 4%, reflecting continued pricing pressure and the impact of managed-market rebates, partially offset by positive volumes from government buying and a favourable gross-to-net adjustment. Emerging Markets sales increased by 4% (13% at CER) to \$133m
- Pulmicort sales growth of 11% (16% at CER) to \$383m
- Fasenra sales of \$129m, representing growth of 514% (524% at CER). In the US, new-to-brand prescription data showed that Fasenra was the preferred novel-biologic medicine for the treatment of severe asthma during the period, despite being the third medicine to enter the market
- Respiratory sales growth in Emerging Markets of 18% (26% at CER) to \$518m, driven by the aforementioned sales growth of Pulmicort

Emerging Markets

The Company's largest region by Product Sales, with growth of 14% in the quarter (22% at CER) to \$2,004m, including:

- A China sales increase of 21% (28% at CER) to \$1,242m. Highlights included Oncology sales growth of 43% (51% at CER) to \$284m and Respiratory growth of 25% (31% at CER) to \$400m
- An ex-China sales increase of 3% (13% at CER) to \$762m; every Emerging Market sub-region delivered strong growth at CER. Notable performances included sales of \$281m in (non-China) Asia-Pacific (+5%, +9% at CER) and \$49m in Russia (+44%, +68% at CER)

Pipeline highlights

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

Regulatory approvals	- Lynparza - breast cancer (BRCAm9): regulatory approval (EU)
	- Forxiga - T1D10: regulatory approval (EU, JP)
	- Duaklir - COPD11: regulatory approval (US) (by partner)
Regulatory submissions and/or acceptances	- Lynparza - breast cancer (BRCAm): regulatory submission (CN)

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Major Phase III data readouts or other significant developments

- Farxiga - T2D12 (CVOT13): regulatory submission acceptance (US, EU)
- PT010 - COPD: regulatory submission acceptance (US, EU)
- Lynparza - pancreatic cancer (BRCAm): met primary endpoint
- selumetinib - NF114: Breakthrough Therapy Designation (US)
- Brilinta - CAD15 / T2D (CVOT): met primary endpoint
- saracatinib - IPF16: Orphan Drug Designation (US)

FY 2019 guidance reiterated

The Company today reiterates its FY 2019 guidance. All measures in this section are at CER and Company guidance is on Product Sales and Core EPS only. All guidance and indications provided assume that the UK's anticipated exit from the European Union (EU), even in the event of a no-deal exit, proceeds in an orderly manner such that the impact is within the range expected, following the Company's extensive preparations for such an eventuality.

Product Sales A high single-digit percentage increase

In addition to the aforementioned Product Sales growth, the Company anticipates productivity gains and operating leverage in FY 2019. Core Operating Profit is anticipated to grow at a faster rate than Product Sales, despite an anticipated decline in the sum of Collaboration Revenue and Core Other Operating Income and Expense vs. the prior year. More details are provided below.

Core EPS \$3.50 to \$3.70

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

FY 2019 indications

Outside of guidance, the Company provides its indications at CER for FY 2019 vs. the prior year:

- The Company anticipates strong and sustainable Product Sales growth to be accompanied by operating leverage, leading to an improvement in profitability. In FY 2019, the cash performance is expected to be adversely impacted by a number of one-off payments relating to prior business-development transactions; a significant proportion of these payments was made in Q1 2019

- As part of its long-term growth strategy, the Company remains committed to focusing on appropriate cash-generating and value-accretive collaboration and divestment transactions that reflect the ongoing productivity of the pipeline and the Company's increasing focus on its main therapy areas. The sum of Collaboration Revenue and Core Other Operating Income and Expense, however, is anticipated to decline vs. the prior year

- Core Operating Expenses are expected to increase by a low single-digit percentage. Specific support for medicine launches and AstraZeneca in China historically has delivered compelling results and elements of that support will continue. The Company will retain flexibility in its investment approach

- Core Operating Profit is anticipated to increase, ahead of Product Sales, by a mid-teens percentage vs. FY 2018
- Capital expenditure is expected to be broadly stable and restructuring expenses are targeted to reduce vs. the prior year
- A Core Tax Rate of 18-22% (FY 2018: 11%)

Currency impact

If foreign-exchange rates were to remain at the average of rates seen in the period January to March 2019, it is anticipated that there would be a low single-digit percentage adverse impact on Product Sales and Core EPS. In addition, the Company's foreign-exchange rate sensitivity analysis is contained within the operating and financial review.

Sustainability

AstraZeneca's sustainability ambition is founded on making science accessible and operating in a way that recognises the interconnection between the health of the business, people and the planet and that each of these impact one another. 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 healthcare, minimises the environmental footprint of its activities and products of medicines and processes and ensures that all business activities are underpinned by the highest levels of ethics and transparency. A full update on the Company's sustainability progress is shown in the Sustainability section of this announcement.

Notes

The following notes refer to pages 1-4:

1. Constant exchange rates. These are financial measures that are not accounted for according to generally-accepted accounting principles (GAAP) because they remove the effects of currency movements from Reported results.
2. Tagrisso, Imfinzi, Lynparza, Calquence, Farxiga, Brilinta, Lokelma, Fasenra and Bevespi. These new medicines are pillars in the main therapy areas and are important platforms for future growth.
3. New Cardiovascular (CV), Renal and Metabolism, incorporating Diabetes medicines, Brilinta and Lokelma.
4. Formerly Externalisation Revenue. Effective from 1 January 2019, the Company updated the presentation of this element of Total Revenue within the Statement of Comprehensive Income; see Note 1.
5. Reported financial measures are the financial results presented in accordance with International Financial Reporting Standards, as adopted by the EU and as issued by the International Accounting Standards Board.
6. Core financial measures. These are non-GAAP financial measures because, unlike Reported performance, they cannot be derived directly from the information in the Company Financial Statements. See the operating and financial review for a definition of Core financial measures and a reconciliation of Core to Reported financial measures.
7. Epidermal growth factor receptor.
8. Non-small cell lung cancer.
9. Breast cancer susceptibility genes 1/2, mutated.
10. Type-1 diabetes.

11. Chronic obstructive pulmonary disease.

12. Type-2 diabetes.

13. Cardiovascular outcomes trial.

14. Neurofibromatosis type 1.

15. Coronary artery disease.

16. Idiopathic pulmonary fibrosis.

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 and sustainable results from the pipeline.

Q2 2019 - Tagrisso - NSCLC (1st line, EGFRm): regulatory decision (CN)

- roxadustat - anaemia of CKD[17]: data readout (pooled safety)

H2 2019- Tagrisso - NSCLC (1st line, EGFRm): data readout (final OS)

- Imfinzi - unresectable, Stage III NSCLC: regulatory decision (CN)

- Imfinzi + treme - NSCLC (1st line) (NEPTUNE): data readout, regulatory submission

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

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

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

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

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

- Lynparza - ovarian cancer (3rd line, BRCAm): regulatory submission (US)

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

- Lynparza - pancreatic cancer (BRCAm): regulatory submission

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

- trastuzumab deruxtecan - advanced/refractory, metastatic breast cancer (HER2[18]-positive): data readout, regulatory submission (US)

- Calquence - CLL[19]: data readout, regulatory submission

- selumetinib - NF1: regulatory submission

- Farxiga - T1D: regulatory decision (US)

- Farxiga - heart failure CVOT: data readout

- Brilinta - CAD / T2D CVOT: regulatory submission

- Lokelma - hyperkalaemia: regulatory submission (JP)

- roxadustat - anaemia of CKD: regulatory submission (US)

- Symbicort - mild asthma: regulatory decision (EU), regulatory submission (CN)

- Bevespi - COPD: regulatory decision (JP, CN)

- Fasenra - self administration and autoinjector: regulatory decision (US, EU)

- PT010 - COPD: regulatory decision (JP, CN)

- PT010 - COPD: data readout (ETHOS)

Edgar Filing: ASTRAZENECA PLC - Form 6-K

- Imfinzi - neo-adjuvant NSCLC: data readout
 - Lynparza - breast cancer (BRCAm): regulatory decision (CN)
 - Lynparza - ovarian cancer (1st line) (PAOLA-1): regulatory submission
 - Lynparza - prostate cancer (2nd line, castration-resistant): regulatory submission
 - trastuzumab deruxtecan - advanced/refractory, metastatic gastric cancer (HER2-positive): data readout
- 2020
- Farxiga - T2D CVOT: regulatory decision (US, EU)
 - Farxiga - heart failure CVOT: regulatory submission
 - Brilinta - stroke (THALES): data readout, regulatory submission
 - Epanova - hypertriglyceridaemia CVOT: data readout
 - Lokelma - hyperkalaemia: regulatory submission (CN)
 - roxadustat - anaemia of myelodysplastic syndrome: data readout
- Fasenra - nasal polyps: data readout, regulatory submission
 - PT010 - COPD: regulatory decision (US, EU)
 - tezepelumab - severe asthma: data readout

Conference call

A conference call and webcast for investors and analysts will begin at 12pm UK time today. Details can be accessed via astrazeneca.com.

Reporting calendar

The Company intends to publish its first-half and second-quarter financial results on 25 July 2019.

About AstraZeneca

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in its main therapy areas - Oncology, CVRM and Respiratory. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information, please visit astrazeneca.com and follow us on Twitter @AstraZeneca.

Investor Relations

Thomas Kudsk Larsen		+44 203 749 5712
Henry Wheeler	Oncology	+44 203 749 5797
Christer Gruvris	BioPharma (cardiovascular, metabolism)	+44 203 749 5711
Nick Stone	BioPharma (respiratory, renal)	+44 203 749 5716
Josie Afolabi	Other medicines	+44 203 749 5631
Craig Marks	Finance, fixed income	+44 7881 615 764
Jennifer Kretzmann	Corporate access, retail investors	+44 203 749 5824
US toll-free		+1 866 381 7277

Media Relations

Gonzalo Viña		+44 203 749 5916
Rob Skelding	Oncology	+44 203 749 5821
Rebecca Einhorn	Oncology	+1 301 518 4122
Matt Kent	BioPharma	+44 203 749 5906
Jennifer Hursit	Other	+44 7384 799 726
Christina Malmberg Hägerstrand	Sweden	+46 8 552 53 106
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 2019 (the quarter or Q1 2019) compared to the three-month period to 31 March 2018 (Q1 2018) respectively, unless stated otherwise. All commentary in the operating and financial review relates to the quarter, unless stated otherwise.

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

- Amortisation and impairment of intangible assets, including impairment reversals but excluding any charges relating to IT assets
- Charges and provisions related to restructuring programmes, which includes charges that relate to the impact of 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 and legal settlements

Details on the nature of Core financial measures are provided on page 76 of the Annual Report and Form 20-F Information 2018. 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 Note 3 'Net Debt' included in the Notes to the Interim Financial Statements section of this announcement. Ongoing Collaboration Revenue is defined as Collaboration Revenue excluding Initial Collaboration Revenue (which is defined as Collaboration Revenue that is recognised at the date of completion of an agreement or transaction, in respect of upfront consideration). Ongoing Collaboration Revenue comprises, among other items, royalties, milestone revenue and profit-sharing income. Reference should be made to the Collaboration 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.

Due to rounding, the sum of a number of percentages may not agree to totals.

Table 1: Total Revenue

Q1 2019				
	\$m	% change		
		Actual	CER	
Product Sales	5,465	10	14	
Collaboration Revenue	26	(87)	(86)	
Total Revenue	5,491	6	11	

Table 2: Product Sales

Q1 2019				
	\$m	% of total	% change	
			Actual	CER
Oncology	1,892	35	54	59
New CVRM	1,033	19	15	19
Respiratory	1,283	23	9	14
Other medicines	1,257	23	(25)	(21)
Total Product Sales	5,465	100	10	14

Table 3: Top-ten medicines

The top-ten medicines in the quarter by Product Sales are shown in the table below:

Q1 2019					
Medicine	Therapy Area	% change			
		\$m	% of total	Actual	CER
Tagrisso	Oncology	630	12	86	92
Symbicort	Respiratory	585	11	(8)	(3)
Pulmicort	Respiratory	383	7	11	16
Nexium	Other medicines	363	7	(19)	(16)
Farxiga	CVRM	349	6	17	23
Brilinta	CVRM	348	6	19	24
Crestor	CVRM	335	6	(14)	(9)
Imfinzi	Oncology	295	5	n/m	n/m
Faslodex	Oncology	254	5	-	4
Lynparza	Oncology	237	4	99	n/m
Total		3,779	69	19	24

Table 4: Collaboration Revenue

Ongoing Collaboration Revenue of \$26m represented all Collaboration Revenue in the quarter (Q1 2018: \$91m, 47%). A breakdown of Collaboration Revenue is shown below:

	Q1 2019			
	\$m	% of total	% change	
			Actual	CER
Initial Collaboration Revenue	-	-	-	-
Royalties	17	65	n/m	n/m
Milestones/Other[20]	9	35	(89)	(89)
Ongoing Collaboration Revenue	26	100	(72)	(71)
Total Collaboration Revenue	26	100	(87)	(86)

Product Sales

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

Table 5: Therapy area and medicine performance

Therapy Area	Medicine	Q1 2019			
		\$m	% of total	% change	
				Actual	CER
Oncology	Tagrisso	630	12	86	92
	Imfinzi	295	5	n/m	n/m
	Lynparza	237	4	99	n/m
	Iressa	134	2	2	7
	Calquence	29	1	n/m	n/m
	Legacy:				
	Faslodex	254	5	-	4
	Zoladex	194	4	5	13
	Arimidex	51	1	(6)	-

Edgar Filing: ASTRAZENECA PLC - Form 6-K

	Casodex	48	1	(8)	(4)
	Others	20	-	(26)	(22)
	Total Oncology	1,892	35	54	59
	Farxiga	349	6	17	23
	Brilinta	348	6	19	24
	Onglyza	153	3	19	23
	Bydureon	142	3	2	4
	Byetta	30	1	(3)	-
	Symlin	7	-	(22)	(22)
BioPharma - CVRM	Legacy:				
	Crestor	335	6	(14)	(9)
	Seloken/Toprol-XL	225	4	13	21
	Atacand	50	1	(30)	(24)
	Others	75	1	(12)	(6)
	Total BioPharma - CVRM	1,714	31	4	9
	Symbicort	585	11	(8)	(3)
	Pulmicort	383	7	11	16
	Fasenra	129	2	n/m	n/m
	Daliresp/Daxas	48	1	26	29
BioPharma -Respiratory	Tudorza/Eklira	20	-	(29)	(25)
	Duaklir	20	-	(29)	(25)
	Bevespi	10	-	n/m	n/m
	Others	88	2	9	15
	Total BioPharma - Respiratory	1,283	23	9	14
	Nexium	363	7	(19)	(16)
	Losec/Prilosec	76	1	10	16

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Synagis	53	1	(76)	(76)
Seroquel XR/IR	37	1	(61)	(59)
Movantik/Moventig	25	-	(11)	(11)
Others	22	-	(66)	(66)
Total other medicines	576	11	(38)	(36)
Total Product Sales	5,465	100	10	14

Specialty-care medicines comprise all Oncology medicines and Fasenra. At 37% of Product Sales (Q1 2018: 25%), specialty-care medicine sales increased by 62% in the quarter (67% at CER) to \$2,021m.

Product Sales summary

Oncology

Product Sales of \$1,892m; an increase of 54% (59% at CER). Oncology Product Sales represented 35% of total Product Sales, up from 25% in Q1 2018.

Oncology: lung cancer

Tagrisso

Tagrisso has been approved and launched in over 80 countries, including the US, in Europe, Japan and China for the 2nd-line treatment of patients with EGFR T790M[21]-mutated NSCLC. By the end of the quarter, Tagrisso had been approved in over 65 countries including the US, in Europe and Japan for the 1st-line treatment of patients with EGFRm NSCLC; a number of additional regulatory reviews are also underway.

Product Sales of \$630m represented growth of 86% (92% at CER), partly driven by regulatory approvals in the 1st-line setting. Continued growth was also delivered in the 2nd-line indication in other countries, including in Europe and Emerging Markets. Tagrisso became AstraZeneca's largest selling medicine in the quarter.

Sales in the US increased by 76% to \$259m. Tagrisso was established last year as the SoC in the 1st-line setting with a very high penetration rate, following the April 2018 regulatory approval. Underlying demand growth remained strong in the quarter, despite adverse inventory and gross-to-net movements. Within Emerging Markets, Tagrisso sales increased by 94% (108% at CER) to \$138m, with notable growth in China, where the medicine was added to the National Reimbursement Drug List (NRDL) with effect from January 2019. The Asia-Pacific region has a relatively high prevalence of lung-cancer patients with an EGFR mutation; at c.30-40% of the total, this contrasts with c.10-15% in the Western Hemisphere.

In Europe, sales of \$100m represented an increase of 45% (55% at CER), driven by further growth in testing rates, positive reimbursement decisions and strong levels of demand in the 2nd-line setting; additional decisions are expected in 2019. Sales of Tagrisso in Japan increased by 151% (153% at CER) to \$123m, reflecting increasing use as a 1st-line treatment, following the 2018 regulatory approval in this setting where Tagrisso reached a very high penetration rate. Focused activities to maximise testing and utilisation rates in the 2nd-line setting also supported the performance.

Imfinzi

Imfinzi is approved in c.45 countries, including the US, in Europe and Japan for the treatment of patients with unresectable, Stage III NSCLC whose disease has not progressed following platinum-based CRT. It is also approved for the 2nd-line treatment of patients with locally-advanced or metastatic urothelial carcinoma (bladder cancer) in eight countries, including the US.

Global Product Sales of Imfinzi increased by 376% (381% at CER) to \$295m, of which \$231m were in the US, almost entirely for the treatment of unresectable, Stage III NSCLC. Sales of \$34m in Japan reflected strong demand, supported by higher CRT and treatment rates. Sales in Europe of \$23m followed recent regulatory approvals and launches; additional approvals are expected in due course.

Iressa

Product Sales of \$134m; a growth of 2% (7% at CER).

Emerging Markets sales increased by 21% (28% at CER) to \$86m; Iressa entered the NRDL in China in 2017 and was included in the China '4+7' pilot tender scheme in 2018. Given the growing use of Tagrisso, sales of Iressa declined by 50% to \$4m in the US and by 13% (7% at CER) to \$26m in Europe. Japan sales amounted to \$16m, reflecting a decline of 20%.

Oncology: Lynparza

By the end of the quarter, Lynparza was approved in over 60 countries for the treatment of ovarian cancer. Launches in the treatment of breast cancer took place in the US and Japan in 2018 and regulatory approval was received in the EU in April 2019. Lynparza has now been approved in nearly 40 countries for the treatment of breast cancer.

Product Sales of Lynparza amounted to \$237m, an increase of 99% (105% at CER). The strong performance was geographically spread, with launches continuing in Emerging Markets and the Established Rest of World region (RoW). Ongoing MSD[22] co-promotion efforts also contributed to sales.

US sales increased by 80% to \$119m, driven by the launch in the 1st-line BRCAm ovarian cancer indication at the end of 2018 and increased demand that reflected continued growth in the treatment with Lynparza of patients suffering from ovarian or breast cancer. Lynparza remained the leading US medicine in the poly ADP ribose polymerase (PARP)-inhibitor class, as measured by total prescription volumes and in both ovarian and breast cancer.

Sales in Europe increased by 55% (62% at CER) to \$65m, driven by increasing levels of reimbursement and BRCA-testing rates; sales also benefitted from clinical-trial supply. The Company recently rolled out a number of launches in a broad, 2nd-line, maintenance ovarian-cancer indication, regardless of BRCA status. In 2018, the Company announced that the European Medicines Agency (EMA) had approved the use of Lynparza tablets (300mg twice daily) as a treatment for the same patient population.

Following the initial launch in April 2018, Japan sales of Lynparza, as a treatment for 2nd-line maintenance ovarian cancer and BRCAm breast cancer, amounted to \$22m. Emerging Markets sales of \$26m reflected the regulatory approval of Lynparza as a 2nd-line maintenance treatment of patients with ovarian cancer by the China National Medical Products Administration (NMPA), resulting in the subsequent launch of Lynparza in China, the first PARP inhibitor to be approved in the country.

Oncology: haematology and other Oncology medicines

Calquence

Product Sales of \$29m; an increase of 263%.

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Calquence was approved and launched in the US in October 2017. The medicine delivered a promising performance in the quarter, with c.40% of new patients now treated in the 2nd-line setting with Calquence in the approved indication of mantle cell lymphoma (MCL). At the end of 2018, the first regulatory approvals outside the US for the treatment of patients with MCL were granted in Brazil and the UAE.

Legacy: Faslodex

Product Sales of \$254m; a stable performance (4% growth at CER).

Emerging Markets sales of Faslodex increased by 15% (28% at CER) to \$45m. US sales declined by 6% to \$126m; a generic Faslodex medicine did not launch in the quarter. Europe sales declined by 8% (2% at CER) to \$54m, reflecting the continued impact of generic entrants in certain countries. In Japan, sales increased by 33% to \$28m.

Legacy: Zoladex

Product Sales of \$194m; an increase of 5% (13% at CER).

Emerging Markets sales of Zoladex increased by 13% (23% at CER) to \$114m. Sales in Europe increased by 3% (9% at CER) to \$35m. In the Established RoW region, sales declined by 10% (8% at CER) to \$43m, driven by the effects of increased competition.

BioPharma - CVRM

Total CVRM sales, which include Crestor and other legacy medicines, increased by 4% (9% at CER) to \$1,714m. Total CVRM sales represented 31% of total Product Sales. New CVRM sales increased by 15% (19% at CER) to \$1,033m, reflecting strong performances from Farxiga and Brilinta.

CVRM: Diabetes

Farxiga

Product Sales of \$349m; an increase of 17% (23% at CER).

Emerging Markets sales of Farxiga increased by 38% (51% at CER) to \$95m, reflecting ongoing launches, improved levels of patient access and strong performances in key markets, such as Brazil. US sales increased by 3% to \$131m, impacted by changes in formulary access for competitor medicines. Sales in Europe increased by 20% (30% at CER) to \$89m. In Japan, sales to the collaborator, Ono Pharmaceutical Co., Ltd, which records in-market sales in Japan, increased by 55% to \$17m.

Onglyza

Product Sales of \$153m, an increase of 19% (23% at CER) was partly driven by favourable prior year gross-to-net adjustments in the US, where sales increased by 59% to \$78m.

Sales in Emerging Markets increased by 8% (23% at CER) to \$43m, driven by the performance in China. Sales in Europe declined by 17% to \$19m, highlighting the broader trend of a shift away from the dipeptidyl peptidase-4 inhibitor class. Given the significant future potential of Farxiga, the Company continues to prioritise commercial support over Onglyza.

Bydureon

Product Sales of \$142m; an increase of 2% (4% at CER).

Sales were adversely impacted by ongoing supply constraints related to Bydureon BCise; these are anticipated to ease later in the year. Sales in the US increased by 5% to \$117m. Favourable sales volumes were driven by continued growth in the glucagon-like peptide-1 class, at the expense of insulin, for more-advanced T2D

patients. Bydureon sales in Europe declined by 22% (17% at CER) to \$18m.

Other CVRM medicines

Brilinta

Product Sales of \$348m; an increase of 19% (24% at CER).

Emerging Markets sales of Brilinta increased by 28% (38% at CER) to \$97m, bolstered by the entry onto the NRDL in China in 2017. US sales of Brilinta, at \$153m, represented an increase of 33%. The performance was driven primarily by increasing levels of demand in both hospital and retail settings, as well as a lengthening in the average-weighted duration of treatment, reflecting the growing impact of 90-day prescriptions. Sales of Brilique in Europe declined by 3% in the quarter (growth of 3% at CER) to \$83m; volume demand grew in the quarter.

Lokelma

Lokelma was approved in the US and EU in 2018 for the treatment of hyperkalaemia, a serious condition characterised by elevated potassium levels in the blood associated with CV, renal and metabolic diseases. Lokelma's launch programme began in the Nordics in 2018 and further launches are anticipated to commence in major markets in due course, including the US in H2 2019.

Legacy: Crestor

Product Sales of \$335m; a decline of 14% (9% at CER).

Sales in China declined by 6% (stable at CER) to \$137m, partly a result of Crestor being unsuccessful in the '4+7' pilot tender scheme. US sales declined by 43% to \$26m, underlining the ongoing impact of generic Crestor medicines. In Europe, sales declined by 40% (37% at CER) to \$39m, reflecting a similar impact that began in 2017. In Japan, where AstraZeneca collaborates with Shionogi Co. Ltd, sales increased by 23% to \$32m. This followed a period of decline resulting from the entry of multiple generic Crestor medicines in the market at the end of 2017.

BioPharma - Respiratory

Product Sales of \$1,283m; an increase of 9% (14% at CER). Respiratory Product Sales represented 23% of total Product Sales.

Symbicort

Product Sales of \$585m; a decline of 8% (3% 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 of Symbicort increased by 4% (13% at CER) to \$133m. In contrast, US sales declined by 4% to \$176m, reflecting continued pricing pressure and the impact of managed-market rebates. This was partially offset by positive volumes from government buying and a favourable gross-to-net adjustment.

In Europe, sales declined by 14% (8% at CER) to \$182m; the performance partly reflected the level of price competition from other branded and Symbicort-analogue medicines, plus government pricing interventions. Symbicort, however, continued to retain its class-leadership position and stabilised its volume market share in the class, with volume growth achieved in a number of markets.

In Japan, sales declined by 20% (18% at CER) to \$40m following destocking by Astellas Pharma Co. Ltd (Astellas). In January 2019, AstraZeneca and Astellas announced that the sale and distribution of Symbicort, conducted by Astellas in Japan, was to be transferred back to AstraZeneca and that the co-promotion conducted by Astellas and AstraZeneca will be terminated on 30 July 2019. The Company will solely distribute and promote the medicine in Japan from 31 July 2019. In addition, during the period, the first generic Symbicort medicine received regulatory

approval and multiple generic Symbicort medicines are anticipated to enter the Japanese market in due course.

Pulmicort

Product Sales of \$383m; an increase of 11% (16% at CER).

Emerging Markets, where sales increased by 16% (23% at CER) to \$314m, represented 82% of global sales of Pulmicort. China, making up the overwhelming majority of Pulmicort sales in Emerging Markets, delivered a particularly strong double-digit performance, supported by higher demand and strong underlying volume growth, underpinned by the impact of AstraZeneca's investment in over 17,000 nebulisation centres.

Sales in the US and Europe declined by 17% to \$24m and by 7% (4% at CER) to \$25m, respectively, a consequence of the medicine's legacy status.

Fasenra

Product Sales of \$129m, an increase of 514% (524% at CER).

In November 2017, the Company was granted regulatory approval for Fasenra in the US as a treatment of patients with severe, eosinophilic asthma; the approval was followed immediately by the launch of the medicine and US sales amounted to \$93m in the quarter. New-to-brand prescription data showed that Fasenra was the preferred novel-biologic medicine for the treatment of severe asthma during the period, despite being the third medicine to enter the market.

In Europe and Japan, AstraZeneca was granted regulatory approval in January 2018 on a similar basis to that in the US. In Europe, sales totalled \$18m in the quarter, predominantly reflecting strong sales in Germany. Sales in Japan amounted to \$16m, following its launch in the second quarter of 2018. In addition, Fasenra led the novel asthma biologic-medicine class by new patient share in Germany and Japan during the period.

Daliresp/Daxas

Product Sales of \$48m; an increase of 26% (29% at CER).

US sales, representing 85% of the global total, increased by 41% to \$41m, driven by favourable affordability-programme changes and inventory movements. It is the only oral, selective, long-acting inhibitor of phosphodiesterase-4, an inflammatory enzyme associated with COPD.

Duaklir

Product Sales of \$20m; a decline of 29% (25% 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 global LAMA/LABA class continued to grow in the period, albeit below expectations.

Bevespi

Product Sales increased by 100% to \$10m.

Bevespi saw prescriptions in the period track in line with other LAMA/LABA launches; the class in the US, however, continued to grow more slowly than anticipated previously. Bevespi was the first medicine launched using the Company's proprietary Aerosphere Delivery Technology.

Other medicines (outside the main therapy areas)

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Product Sales of \$576m in the quarter; a decline of 38% (36% at CER), partly reflecting the aforementioned divestment of US rights to Synagis, as well as rights to Seroquel in a number of markets. Other Product Sales represented 11% of total Product Sales, down from 19% in Q1 2018.

Nexium

Product Sales of \$363m; a decline of 19% (16% at CER).

Emerging Markets sales increased by 4% (12% at CER) to \$190m. In Europe, sales declined by 74% to \$16m. In October 2018, AstraZeneca announced that it had agreed to divest the prescription medicine rights to Nexium in Europe to Grünenthal GmbH. Sales in the US declined by 34% to \$66m and in Japan, where AstraZeneca collaborates with Daiichi Sankyo, sales declined by 16% (15% at CER) to \$75m.

Regional Product Sales

Table 6: Regional Product Sales

	Q1 2019			
	\$m	% of total	% change Actual CER	
Emerging Markets[23]	2,004	37	14	22
China	1,242	23	21	28
Ex-China	762	14	3	13
US	1,786	33	20	20
Europe	982	18	(12)	(6)
Established RoW	693	13	13	16
Japan	501	9	26	27
Canada	114	2	(10)	(5)
Other Established RoW	78	1	(10)	(2)
TOTAL	5,465	100	10	14

Table 7: Regional Product Sales, Emerging Markets

Product Sales of \$2,004m in the quarter, an increase of 14% (22% at CER), continuing the strong double-digit growth seen in prior periods. New medicines represented 18% of Emerging Markets sales (Q1 2018: 13%). Ex-China Emerging Market sales increased by 3% (13% at CER) to \$762m; every Emerging Market sub-region delivered strong growth at CER. Notable performances included sales of \$281m in (non-China) Asia-Pacific (+5%, +9% at CER) and \$49m in Russia (+44%, +68% at CER).

Q1 2019

\$m	% of total	% change
-----	------------	----------

			Actual	CER
Oncology	490	24	35	46
BioPharma - CVRM	747	37	7	16
BioPharma - Respiratory	518	26	18	26
Other medicines	249	12	(6)	(6)
Total	2,004	100	14	22

China sales, comprising 62% of total Emerging Markets sales, increased by 21% (28% at CER) to \$1,242m. New medicines delivered particularly encouraging sales growth, supported by strong performances from Pulmicort, Seloken, Crestor, Nexium and Symbicort. New medicines represented 13% of China sales (Q1 2018: 9%).

Table 8: Regional Product Sales, US

Product Sales of \$1,786m; an increase of 20%. New medicines represented 57% of US Product Sales, up from 37% in Q1 2018. The performance reflected, in particular, the success of the new Oncology medicines, including Tagrisso, Imfinzi and Lynparza, plus the strong performance of Fasenra in Respiratory.

Q1 2019

	\$m	% of total	% change Actual
Oncology	770	43	81
BioPharma - CVRM	558	31	12
BioPharma - Respiratory	346	19	28
Other medicines	112	6	(62)
Total	1,786	100	20

Table 9: Regional Product Sales, Europe

Product Sales of \$982m; a decline of 12% (6% at CER). This partly reflected adverse continued pricing pressures and the impact of the aforementioned divestment of the prescription medicine rights to Nexium. Declining sales of Crestor were a result of the 2017 market entry of Crestor generic medicines, while sales of Synagis declined by 69% to \$28m due to buying patterns in 2019. Excluding these impacts, the sales performance was encouraging, with new medicines delivering a promising performance in the quarter, representing 38% of Europe Product Sales, up from 24% in Q1 2018.

Q1 2019

	\$m	% of total	% change Actual	CER
Oncology	314	32	26	34
BioPharma - CVRM	283	29	(13)	(8)
BioPharma - Respiratory	285	29	(13)	(7)

Other medicines	100	10	(55)	(49)
Total	982	100	(12)	(6)

Table 10: Regional Product Sales, Established RoW

Product Sales of \$693m; an increase of 13% (16% at CER). New medicines represented 38% of Established RoW sales, up from 16% in Q1 2018. The performance during the quarter reflected, in particular, the successes of Tagrisso, Imfinzi and Forxiga.

Q1 2019

	\$m	% of total	% change	
			Actual	CER
Oncology	318	46	66	67
BioPharma - CVRM	126	18	2	5
BioPharma - Respiratory	134	19	(8)	(5)
Other medicines	115	17	(23)	(18)
Total	693	100	13	16

Japan sales, comprising 72% of total Established RoW, increased by 26% (27% at CER) to \$501m. Despite the entry of generic Crestor medicines in 2018, Crestor sales in Japan increased by 23% to \$32m and represented 6% of Japan sales. New medicines represented 42% of Japan sales, up from 15% in FY 2018, particularly reflecting the strong performance of Tagrisso as a 1st-line treatment for patients with EGFRm NSCLC, following regulatory approval in this setting in the third quarter 2018.

Financial performance

Table 11: Q1 2019 Reported Profit and Loss

	Reported			
	Q1 2019	Q1 2018	% change	
	\$m	\$m	Actual	CER
Product Sales	5,465	4,985	10	14
Collaboration Revenue	26	193	(87)	(86)
Total Revenue	5,491	5,178	6	11
Cost of Sales	(1,129)	(1,134)	-	-
Gross Profit	4,362	4,044	8	13
Gross Margin[24]	79.3%	77.3%	+2	+3

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Distribution Expense	(78)	(81)	(4)	3
% Total Revenue	1.4%	1.6%	-	-
R&D Expense	(1,266)	(1,279)	(1)	3
% Total Revenue	23.1%	24.7%	+2	+2
SG&A Expense	(2,514)	(2,457)	2	7
% Total Revenue	45.8%	47.5%	+2	+2
Other Operating Income & Expense	593	469	26	27
% Total Revenue	10.8%	9.1%	+2	+1
Operating Profit	1,097	696	58	68
Operating Profit Margin	20.0%	13.4%	+7	+7
Net Finance Expense	(312)	(308)	1	4
Joint Ventures and Associates	(27)	(14)	90	90
Profit Before Tax	758	374	n/m	n/m
Taxation	(195)	(58)		
Tax Rate	26%	16%		
Profit After Tax	563	316	78	95
EPS	\$0.47	\$0.27	75	90

Table 12: Reconciliation of Reported Profit Before Tax to EBITDA[25]

	Q1 2019 \$m	Q1 2018 \$m	% change	
			Actual	CER
Reported Profit Before Tax	758	374	n/m	n/m
Net Finance Expense	312	308	1	4
Joint Ventures and Associates	27	14	90	90
Depreciation, Amortisation and Impairment	676	709	(5)	-
EBITDA	1,773	1,405	26	33

Table 13: Q1 2019 Reconciliation of Reported to Core financial measures

	Reported	Restructuring	Intangible Asset Amortisation & Impairments	Diabetes Alliance	Other[26]	Core[27]	Core % change	
	\$m	\$m	\$m	\$m	\$m	\$m	Actual	CER
Gross Profit	4,362	38	25	-	-	4,425	7	13
Gross Margin	79.3%	-	-	-	-	80.5%	2	2
Distribution Expense	(78)	-	-	-	-	(78)	(4)	3
R&D Expense	(1,266)	34	7	-	-	(1,225)	(1)	3
SG&A Expense	(2,514)	31	337	105	(25)	(2,066)	2	6
Other Operating Income & Expense	593	-	1	-	-	594	n/m	n/m

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Operating Profit	1,097	103	370	105	(25)	1,650	84	96
Operating Profit Margin	20.0%	-	-	-	-	30.0%	13	13
Net Finance Expense	(312)	-	-	72	50	(190)	12	10
Taxation	(195)	(22)	(76)	(36)	(1)	(330)	n/m	n/m
EPS	\$0.47	\$0.06	\$0.23	\$0.11	\$0.02	\$0.89	85	100

Profit and loss commentary

Gross Profit

Reported Gross Profit increased by 8% in the quarter (13% at CER) to \$4,362m; Core Gross Profit increased by 7% (13% at CER) to \$4,425m, reflecting the growth in Product Sales. The calculation of Reported and Core Gross Margin excludes the impact of Collaboration Revenue and any associated costs, thereby reflecting the underlying performance of Product Sales. The Reported Gross Margin increased by two percentage points (three at CER) to 79.3%; the Core Gross Margin increased by two percentage points to 80.5%. The increases primarily reflected the phasing of the mix of sales.

Operating Expenses

Reported R&D Expenses declined by 1% (an increase of 3% at CER) to \$1,266m. Core R&D Expenses declined by 1% (an increase of 3% at CER) to \$1,225m and represented 22% of Total Revenue (Q1 2018: 24%). Reported SG&A Expenses increased by 2% (7% at CER) to \$2,514m, primarily reflecting ongoing investment focused on commercial and medical-affairs support for launches and extensions of the Company's new medicines. These included Lynparza, Tagrisso, Imfinzi, Calquence and Fasenra; additional investment was also added to support sales growth in China. Core SG&A Expenses increased by 2% (6% at CER) to \$2,066m, reflecting the aforementioned investments and represented 38% of Total Revenue. (Q1 2018: 39%).

Other Operating Income and Expense

Where AstraZeneca does not retain a significant ongoing interest in medicines or potential new medicines, income from divestments is reported within Other Operating Income and Expense in the Company's financial statements. Reported Other Operating Income and Expense increased by 26% (27% at CER) to \$593m and included \$515m that reflected an agreement to sell US rights to Synagis to Swedish Orphan Biovitrum AB (publ).

As part of the total consideration received, \$150m related to the rights to participate in the future cashflows from the US profits or losses for MEDI8897. This was recognised as a financial liability and is presented in Other Payables within Non-current Liabilities. The associated cash flow is presented within Investing Activities. Core Other Operating Income and Expense increased by 379% (383% at CER) to \$594m.

Operating Profit

Reported Operating Profit increased by 58% in the year (68% at CER) to \$1,097m, partly driven by the increases in Product Sales, the Reported Gross Margin and Other Operating Income and Expense. The Reported Operating Margin increased by seven percentage points to 20.0%. Core Operating Profit increased by 84% (96% at CER) to \$1,650m; the Core Operating Margin increased by 13 percentage points to 30.0%.

Net Finance Expense

Reported Net Finance Expense increased by 1% (4% at CER) to \$312m, partly a result of higher Net Debt. Excluding the discount-unwind on acquisition-related liabilities, Core Net Finance Expense increased by 12% (10% at CER) to \$190m.

Profit Before Tax

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Reported Profit Before Tax increased by 103% (122% at CER) to \$758m, reflecting the growth in Product Sales and the Reported Gross Margin. Core Profit Before Tax increased by 102% (116% at CER) to \$1,433m, also a result of the increase in Core Other Operating Income and Expense.

Taxation

The Reported Tax Rate was 26% for the quarter, while the Core Tax Rate was 23%. These tax rates were higher than the UK Corporation Tax Rate of 19% due to the impacts of the geographical mix of profit, as well as divestment transactions. The net cash tax paid for the quarter was \$334m (Q1 2018: \$117m), representing 44% of Reported Profit Before Tax. Increased net cash tax primarily reflected the phasing of payments.

The Reported and Core Tax Rates in Q1 2018 were 16% and 18%, respectively; the net cash tax paid represented 31% of Reported Profit Before Tax.

EPS

Reported EPS of \$0.47 represented an increase of 75% (90% at CER). Core EPS increased by 85% (100% at CER) to \$0.89.

Table 14: Cash Flow

	Q1 2019	Q1 2018	Change
	\$m	\$m	\$m
Reported Operating Profit	1,097	696	401
Depreciation, Amortisation and Impairment	676	709	(33)
Increase in Working Capital and Short-Term Provisions	(710)	(993)	283
Gains on Disposal of Intangible Assets	(512)	(65)	(447)
Non-Cash and Other Movements	(396)	(242)	(154)
Interest Paid	(208)	(128)	(80)
Tax Paid	(334)	(117)	(217)
Net Cash Outflow From Operating Activities	(387)	(140)	(247)
Net Cash (Outflow)/Inflow Before Financing Activities	(59)	133	(192)
Net Cash Outflow From Financing Activities	(698)	(663)	(35)

A net cash outflow from operating activities of \$387m compared to an outflow of \$140m in Q1 2018, partly a result of increased net tax payments. The Gains on Disposal of Intangible Assets increased to \$512m (Q1 2018: \$65m), reflecting the impact of the aforementioned divestment of US rights to Synagis.

Net cash outflows before financing activities of \$59m compared with an inflow of \$133m in Q1 2018. The difference partly reflected the impact of historic business-development transactions and subsequent payments reported within Payment of Contingent Consideration on Business Combinations, as well as within the Purchase of Intangible Assets. The latter included the impact of a final true-up net payment of \$413m to MSD, based on actual sales of Nexium and Prilosec from 2014 to 2018; this was accrued over the same period. A payment from Pfizer, Inc. of \$175m was received in the quarter, recorded within Disposal of Intangible Assets, as part of a prior agreement to sell the commercialisation and development rights to AstraZeneca's late-stage small molecule antibiotics business in most markets globally outside the US. Reflecting strong sales growth and a pre-defined increase in royalty rates, the cash payment of contingent consideration in respect of the Bristol-Myers Squibb share of the global Diabetes alliance,

amounted to \$110m in the quarter (Q1 2018: \$62m).

Capital expenditure

Capital expenditure amounted to \$174m in the quarter, compared to \$213m in Q1 2018. This included the investment in the new global headquarters in Cambridge, UK. In November 2018, the Company successfully completed the transition to Mace Group as construction manager. Following a detailed review of the construction programme, in order to optimise operational performance on site and produce a predictable schedule to completion, overall full completion of the building is now expected in late 2021. AstraZeneca continues to target an initial occupation in 2020. The Company maintains its anticipation of a broadly stable level of capital expenditure in FY 2019.

Table 15: Debt and capital structure

	At 31 March 2019	At 31 March 2018
	\$m	\$m
Cash and Cash Equivalents	4,136	3,005
Other Investments	876	868
Cash and Investments	5,012	3,873
Overdrafts and Short-Term Borrowings	(2,044)	(2,776)
Leases[28]	(714)	-
Current Instalments of Loans	(1,500)	(1,394)
Loans Due After One Year	(17,320)	(15,684)
Interest-Bearing Loans and Borrowings (Gross Debt)	(21,578)	(19,854)
Net Derivatives	295	565
Net Debt	(16,271)	(15,416)

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 Company'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 companies' reporting currency. In addition, the Company'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 or loss.

Table 16: 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)[29]	
		FY 2018[30]	Q1 2019[31]	% change	Product Sales	Core Operating Profit
CNY	Product Sales	6.62	6.76	(2)	221	126
EUR	Product Sales	0.85	0.88	(4)	145	66
JPY	Product Sales	110.45	110.07	-	114	74
Other[32]					216	105
GBP	Operating Expenses	0.75	0.77	(3)	26	(72)
SEK	Operating Expenses	8.69	9.16	(5)	4	(73)

Corporate and business development

a) AstraZeneca and Daiichi Sankyo enter collaboration for novel HER2-targeting antibody-drug conjugate
In March 2019, AstraZeneca announced that it had entered into a global development and commercialisation collaboration agreement with Daiichi Sankyo for trastuzumab deruxtecan (DS-8201), a proprietary antibody-drug conjugate (ADC) and potential new targeted medicine for cancer treatment.

The companies will develop and commercialise trastuzumab deruxtecan jointly worldwide, except in Japan where Daiichi Sankyo will maintain exclusive rights. Daiichi Sankyo will be solely responsible for manufacturing and supply. Under the terms of the agreement, AstraZeneca will pay Daiichi Sankyo an upfront payment of \$1.35bn, half of which was due upon execution (and settled in Q2 2019), with the remainder payable 12 months later. Contingent payments of up to \$5.55bn comprise \$3.8bn for potential successful achievement of future regulatory and other milestones, as well as \$1.75bn for sales-related milestones. Overall, the transaction will be accounted for as an acquisition of an intangible asset, recognised initially at the present value of non-contingent consideration, with future milestones capitalised into the intangible asset as they are recognised. AstraZeneca and Daiichi Sankyo will share equally development and commercialisation costs as well as profits from trastuzumab deruxtecan worldwide, except for Japan, where Daiichi Sankyo will incur all costs and AstraZeneca will receive a royalty on sales.

Daiichi Sankyo will record sales in the US, certain countries in Europe and certain other markets where Daiichi Sankyo has affiliates. Gross profits and royalties shared with AstraZeneca will be accounted for as Collaboration Revenue by the Company. AstraZeneca is expected to record Product Sales in all other markets worldwide for which profits shared with Daiichi Sankyo will be accounted for within Cost of Sales.

There were no closing conditions to the agreement and the transaction completed in March 2019. The transaction and funding arrangements (see Note 6) did not impact the Company's financial guidance for 2019. The upfront payment and near-term milestones were and will be funded from the proceeds of an equity placement (see Note 6) of approximately \$3.5bn before expenses, of which more than half was and will be used to fund this transaction and the ongoing collaboration.

b) AstraZeneca enters new development and commercialisation agreement for Fasenra
In March 2019, AstraZeneca and Kyowa Hakko Kirin Co., Ltd. (KHK) announced a new development and commercialisation agreement for Fasenra in all indications beyond asthma and COPD in Asia. The Company previously had rights to Fasenra in countries and regions for COPD and asthma indications. Under the new agreement, AstraZeneca will now have global rights to Fasenra for all current and future indications.

Under the terms of the agreement, AstraZeneca made an upfront payment and, in addition, KHK will receive subsequent payments for regulatory and commercial milestones. Other financial terms are the same as prior agreements between the companies. AstraZeneca is now responsible for the development, sales and marketing of Fasenra for all indications globally.

c) Termination of lanabecestat collaboration with Lilly

In March 2019, alongside collaboration partner Eli Lilly and Company (Lilly), AstraZeneca presented the results at the Alzheimer's and Parkinson's Disease Congress of the AMARANTH and DAYBREAK-ALZ trials for lanabecestat, an oral beta secretase-cleaving enzyme inhibitor. The results showed no significant disease-slowing for those patients treated with lanabecestat and supported the decision to discontinue the AMARANTH, AMARANTH Extension and DAYBREAK-ALZ trials. The lanabecestat collaboration with Lilly will be terminated.

Sustainability

AstraZeneca's sustainability ambition has three priority areas[33], aligned with the Company's purpose and business strategy:

- Access to healthcare
- Environmental protection
- Ethics and transparency

Recent developments and progress against the priorities are reported below:

a) Access to healthcare

During the period, the Company continued its investment in healthcare systems by expanding its Healthy Heart Africa programme into Ghana. In March 2019, AstraZeneca signed a Memorandum of Understanding with Ghana Health Services to bring the programme to the country, following a key stakeholder meeting to expedite the development and rollout of Ghana Hypertension Guidelines.

In March 2019, The Economist Intelligence Unit (EIU) published new research, supported by AstraZeneca as part of the Young Health Programme (YHP), that highlighted the need for an increased focus on adolescents as a way to address the growing global burden of non-communicable disease. The EIU research, Addressing Non-Communicable Diseases in Adolescence, assessed how ten representative countries of different income levels are addressing the challenges associated with non-communicable diseases (NCDs) among adolescents. It was based on an NCD scorecard evaluating national efforts in policy, awareness and implementation, with a focus on four risk factors / health areas: healthy diets, nutrition and physical exercise; alcohol and tobacco; sexual and reproductive health; and mental health. The aim of the research was to support policy discussion around the topic of NCD prevention, particularly as it relates to young people.

In March 2019, the Company launched its YHP in Mexico in partnership with Project HOPE, civil-society organisation Yo Quiero Yo Puedo and the National Cancer Institute. The aim is to transform the lives of young people in four districts of Mexico City by helping young people to change their behaviours, especially the use of tobacco, excessive consumption of alcohol, unhealthy diet and lack of physical activity. The programme will also address other barriers to healthy living, such as pollution and will promote education on sexual and reproductive health, gender equality and mental-health issues.

b) Environmental protection

During the period, six research papers co-authored by AstraZeneca were published on Pharmaceuticals in the Environment, a notable example being an article published on environmental exposure and risk predictions resulting

from patient use of medicines in China.

In the first quarter of 2019, AstraZeneca in Gothenburg, Sweden launched two new environmental initiatives. The Tork PaperCircle programme, in partnership with Sodexo and the city of Mölndal, recycles all paper hand towels used in toilets on site, giving all employees a visible and tactile way to participate in sustainability efforts, as well as helping protect the environment and reduce the business's carbon footprint. The site cafeteria also launched a new initiative measuring food carbon footprint, with all dishes labelled based on their climate impact. By choosing dishes with low impact, colleagues can contribute to reducing the carbon footprint. The initiative is led by Sodexo, in cooperation with Klimato. The results of the food's climate impact will be reported monthly on TV screens across the site.

In the US, the Gaithersburg, MD and Wilmington, DE sites installed campus-wide composting facilities and the donation of unused cafeteria food to a local food bank respectively, to support efforts in waste management and the reduction of the Company's environmental footprint.

c) Ethics and transparency

During the period, the Company was recognised in a new report by the Workforce Disclosure Initiative (WDI), which aims to drive transparency from businesses on how they manage their workforce. 90 global companies disclosed to the 2018 WDI survey. AstraZeneca received a score of 71% vs. a sector average of 57% and a UK average of 58% for transparency around workforce practices including pay, conditions and wellbeing.

In the UK Gender Pay Report 2018, the Company provided gender-pay information for AstraZeneca in the UK and outlined plans for supporting women, as well as continuing to improve the diversity of its employee base.

AstraZeneca's 2018 gender-pay gap data compared favourably with the national average in the UK - 15% vs. 18% national average. Globally, at the close of 2018, 45% of roles in the Company were held by women and the Board of Directors comprised 42% women.

In respect of transparency on bioethical topics such as animals in science, human biological samples and clinical trials, a new Bioethics Global Standard was published on the company's website. The updated standard reflected the latest issues in the field as determined by the AstraZeneca Bioethics Advisory Group, a group of subject-matter experts and corporate representatives, sponsored by the Company's Chief Medical Officer.

During the period, new anti-bullying and anti sexual-harassment standards were also published and communicated to global colleagues. The new standards set out the Company's expectations for behaviour to ensure all colleagues feel respected, supported and safe at work from any form of bullying and harassment, be it mental, physical or sexual.

Other developments

During the period, the Company published its fourth annual Sustainability Report, describing progress and challenges in 2018. The content of the report was based on those sustainability issues deemed material through comprehensive stakeholder engagement and analysis; it included three years of data, where available.

For more details on AstraZeneca's sustainability ambition, approach and targets, please refer to the latest Sustainability Report 2018 and Sustainability Data Summary 2018, available at astrazeneca.com/sustainability.

Research and development

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

Table 17: Update from the late-stage pipeline

Regulatory approvals	4	<ul style="list-style-type: none"> - Lynparza - breast cancer (BRCAm): regulatory approval (EU) - Forxiga - T1D: regulatory approval (EU, JP) - Duaklir - COPD: regulatory approval (US) (by partner) - Lynparza - breast cancer (BRCAm): regulatory submission (CN)
Regulatory submissions and/or acceptances	5	<ul style="list-style-type: none"> - Farxiga - T2D (CVOT): regulatory submission acceptance (US, EU) - PT010 - COPD: regulatory submission acceptance (US, EU) - Lynparza - pancreatic cancer (BRCAm): met primary endpoint
Major Phase III data readouts or other major developments	4	<ul style="list-style-type: none"> - selumetinib - NF1: Breakthrough Therapy Designation (US) - Brilinta - CAD/T2D (CVOT): met primary endpoint - saracatinib - IPF: Orphan Drug Designation (US)
New molecular entities and major lifecycle medicines in Phase III trials or under regulatory review	13	<p>Oncology</p> <ul style="list-style-type: none"> - Tagrisso - NSCLC[34] - Imfinzi - multiple cancers³⁴ - Lynparza - multiple cancers³⁴ - trastuzumab deruxtecan - breast and other cancers - Calquence - blood cancers - tremelimumab - multiple cancers - selumetinib - NF1[35] - savolitinib - NSCLC <p>CVRM</p> <ul style="list-style-type: none"> - roxadustat - anaemia of CKD <p>Respiratory</p> <ul style="list-style-type: none"> - PT010 - COPD³⁴ - PT027 - asthma - tezepelumab - severe asthma <p>Other medicines (outside main therapy areas)</p> <ul style="list-style-type: none"> - anifrolumab - lupus
Total projects in clinical pipeline	139	

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

At the 2019 American Association for Cancer Research (AACR) Annual Meeting in Atlanta, several abstracts were presented from the TATTON Phase Ib trial, testing the combination of Tagrisso with potential new medicines savolitinib or selumetinib in NSCLC patients who have progressed on prior EGFR tyrosine kinase inhibitor treatment. In addition, exploratory analyses of blood and tissue tumour mutational burden (TMB) from the Phase III MYSTIC trial were presented at the AACR meeting. These assessed TMB, specifically blood-based, as a potential biomarker of survival in 1st-line use of Imfinzi with or without tremelimumab vs. chemotherapy in metastatic NSCLC.

Oncology: lung cancer

a) Tagrisso

Tagrisso 40mg and 80mg once-daily oral tablets have now received approval in more over 65 countries, including in the US, Japan and in the EU, for the 1st-line treatment of patients with Stage IV EGFRm NSCLC. Multiple other similar reviews are underway, including in China, where a decision is anticipated during the second quarter of 2019, based on a priority review granted in December 2018. Regulatory approvals have been achieved in over 80 countries, including the US, in the EU, Japan and in China for the 2nd-line treatment of patients with EGFR T790M-mutated NSCLC.

Table 18: Key Tagrisso trials in lung cancer

Name	Phase	Population	Design	Timelines FPCD[36] Q4 2015LPCD Q1 2019 First data anticipated 2020+[37]	Status
ADAURA	III	Adjuvant EGFRm NSCLC	Placebo orTagrisso		Recruitmentongoing
LAURA	III	Locally-advanced, unresectable EGFRm NSCLC	Placebo orTagrisso	FPCD Q3 2018 First data anticipated 2020+	Recruitmentongoing
SAVANNAH II	II	EGFRm, MET+ locally advanced or metastatic NSCLC who have progressed on Tagrisso	Tagrisso + savolitinib	FPCD Q1 2019 First data anticipated 2020+	Recruitmentinitiating

b) Imfinzi

Table 19: Key Imfinzi trials in lung cancer

Name	Phase	Population	Design	Timelines	Status
AEGEAN	III			FPCD Q1 2019	Recruitmentongoing

Edgar Filing: ASTRAZENECA PLC - Form 6-K

		Neo-adjuvant (before surgery) NSCLC	SoC chemotherapy +/- Imfinzi, followed by surgery followed by placebo or Imfinzi	First data anticipated 2020	
ADJUVANT BR.31[38]	III	Stage Ib-IIIa NSCLC	Placebo or Imfinzi	FPCD Q1 2015 First data anticipated 2020+	Recruitment ongoing
PACIFIC	III	Unresectable, Stage III NSCLC	Concurrent CRT[39], followed by placebo or Imfinzi	FPCD Q2 2014 LPCD Q2 2016	PFS[40] and OS[41] primary endpoints both met
PACIFIC-2	III	Unresectable, Stage III NSCLC	Concurrent CRT concurrent with placebo or Imfinzi, followed by placebo or Imfinzi	FPCD Q2 2018 First data anticipated 2020+	Recruitment ongoing
PACIFIC-4	III	Unresectable, Stage I-II NSCLC	Stereotactic body radiation therapy, followed by placebo or Imfinzi	FPCD Q1 2019 First data anticipated 2020+	Recruitment ongoing
PACIFIC-5	III	Unresectable, Stage III NSCLC (Asia predominant)	Concurrent or sequential CRT, followed by placebo or Imfinzi	FPCD Q1 2019 First data anticipated 2020+	Recruitment ongoing
ADRIATIC	III	Limited-disease stage small cell lung cancer (SCLC)	Concurrent CRT, followed by placebo or Imfinzi or Imfinzi+ treme	FPCD Q4 2018 First data anticipated 2020+	Recruitment ongoing
PEARL	III	Stage IV, 1st-line NSCLC (Asia)	SoC chemotherapy or Imfinzi	FPCD Q1 2017 LPCD Q1 2019 First data anticipated 2020	Recruitment ongoing
MYSTIC	III			FPCD Q3 2015	Recruitment completed

		Stage IV, 1st-line NSCLC	SoC chemotherapy or Imfinzi or Imfinzi + treme	LPCD Q3 2016 PFS and OS primary endpoints not met	
				FPCD Q4 2015	
NEPTUNE	III	Stage IV, 1st-line NSCLC	SoC chemotherapy or Imfinzi + treme	LPCD Q2 2017 First data anticipated H2 2019	Recruitment completed
				FPCD Q2 2017	
POSEIDON	III	Stage IV, 1st-line NSCLC	SoC chemotherapy or SoC + Imfinzi or SoC + Imfinzi+ treme	LPCD Q3 2018 First data anticipated H2 2019	Recruitment completed
				FPCD Q1 2017	
CASPIAN	III	Extensive-disease stage SCLC	SoC chemotherapy or SoC + Imfinzi or SoC + Imfinzi+ treme	LPCD Q2 2018 First data anticipated H2 2019	Recruitment completed

Imfinzi as a potential new medicine in other tumour types

The Company continues to advance multiple monotherapy trials of Imfinzi and combination trials of Imfinzi with tremelimumab and other potential new medicines in tumour types other than lung cancer.

Imfinzi has received regulatory approval for the 2nd-line treatment of patients with locally-advanced or metastatic urothelial carcinoma (bladder cancer) in the US, Canada, Brazil, Israel, India, Australia, Hong Kong and the UAE.

Table 20: Key Imfinzi trials in tumour types other than lung cancer

Name	Phase	Population	Design	Timelines	Status
Stage I, II & III (non-metastatic disease)					
POTOMAC	III	Non-muscle invasive bladder cancer	SoC BCG or SoC BCG[42] + Imfinzi	FPCD Q3 2018 First data anticipated 2020+	Recruitment ongoing

Edgar Filing: ASTRAZENECA PLC - Form 6-K

NIAGARA	III	Muscle-invasive bladder cancer	Neo-adjuvant cisplatin and gemcitabine SoC chemotherapy or SoC + Imfinzi followed by adjuvant placebo or Imfinzi	FPCD Q1 2019 First data anticipated 2020+	Recruitment ongoing
EMERALD-1	III	Locoregional hepatocellular carcinoma (liver cancer)	Transarterial chemoembolisation (TACE) followed by placebo or TACE + Imfinzi followed by Imfinzi + bevacizumab or TACE + Imfinzi followed by Imfinzi	FPCD Q1 2019 First data anticipated 2020+	Recruitment ongoing
EMERALD-2	III	Locoregional hepatocellular carcinoma at high risk of recurrence after surgery or radiofrequency ablation	Adjuvant Imfinzi or Imfinzi + bevacizumab	-	Initiating
CALLA	III	Locally-advanced cervical cancer	CRT or CRT + Imfinzi followed by placebo or Imfinzi	FPCD Q1 2019 First data anticipated 2020+	Recruitment ongoing
Stage IV (metastatic disease)				FPCD Q4 2015	
DANUBE	III	Stage IV, 1st-line cisplatin chemotherapy-eligible/ineligible bladder cancer	SoC chemotherapy or Imfinzi or Imfinzi+ treme	LPCD Q1 2017 First data anticipated H2 2019	Recruitment completed
NILE	III	Stage IV, 1st-line cisplatin chemotherapy-eligible bladder cancer	SoC chemotherapy or SoC + Imfinzi or SoC + Imfinzi + treme	FPCD Q3 2018 First data anticipated 2020+	Recruitment ongoing
KESTREL	III	Stage IV, 1st-line HNSCC	SoC or Imfinzi or Imfinzi + treme	FPCD Q4 2015 LPCD Q1 2017 First data	Recruitment completed

				anticipated H2 2019	
EAGLE	III	Stage IV, 2nd-line HNSCC	SoC or Imfinzi or Imfinzi + treme	FPCD Q4 2015 LPCD Q3 2017 FPCD Q4 2017	Recruitment completed OS primary endpoints not met
HIMALAYA	III	Stage IV, 1st-line unresectable hepatocellular carcinoma	Sorafenib or Imfinzi or Imfinzi + treme	First data anticipated 2020+	Recruitment ongoing
TOPAZ-1	III	Stage IV, 1st-line biliary-tract cancers	Gemcitabine and cisplatin SoC chemotherapy or SoC + Imfinzi-		Initiating

Oncology: Lynparza (multiple cancers)

During the period, AstraZeneca and MSD announced positive results from the Phase III POLO trial in pancreatic cancer. The results demonstrated a statistically-significant and clinically-meaningful improvement in PFS with Lynparza vs. placebo; the safety and tolerability profile of Lynparza was consistent with previous trials. POLO was a randomised, double-blinded, placebo-controlled trial exploring the efficacy of Lynparza tablets as 1st-line maintenance monotherapy for patients with germline BRCAm (gBRCAm) metastatic adenocarcinoma of the pancreas (pancreatic cancer) whose disease has not progressed on platinum-based chemotherapy.

The Company also recently announced that the EMA had approved Lynparza as a monotherapy for the treatment of gBRCAm adult patients who have HER2-negative, locally-advanced or metastatic breast cancer. Under the aforementioned collaboration with MSD and following this new approval, AstraZeneca received \$30m as Collaboration Revenue in Q2 2019. Also during the period, the Company acknowledged the regulatory submission acceptance in China of the supplemental New Drug Application (sNDA) by the NMPA, seeking approval for Lynparza monotherapy for gBRCAm, HER2-negative, locally-advanced or metastatic breast cancer.

Table 21: Key Lynparza trials

Name	Phase	Population	Design	Timelines	Status
				FPCD Q2 2017 LPCD Q4 2018	
PROfound	III	Metastatic castration-resistant prostate cancer, HRRm 2L+	SoC (abiraterone or enzalutamide) or Lynparza	Data anticipated H2 2019	Recruitment completed
PAOLA-1[43]	III	Stage IV, 1st-line ovarian cancer	Bevacizumab maintenance or bevacizumab + Lynparza maintenance	FPCD Q2 2015 LPCD Q2 2018	Recruitment completed

				First data anticipated H2 2019	
GY004[44]	III	Recurrent platinum-sensitive ovarian cancer	SoC chemotherapy or cediranib or cediranib +Lynparza	FPCD Q1 2016	Recruitment ongoing
GY00544	II/III	Recurrent platinum-resistant/refractory ovarian cancer	SoC chemotherapy or cediranib or cediranib +Lynparza	FPCD Q2 2016 (Phase II)FPCD Q1 2019 (Phase III) First data anticipated 2020+	Recruitment ongoing (Phase III component)
DuO-O	III	Stage IV, 1st-line ovarian cancer	Chemotherapy + bevacizumab or chemotherapy + bevacizumab + Imfinzi +/- Lynparzamaintenance	FPCD Q1 2019 First data anticipated 2020+	Recruitmentongoing
MEDIOLA	I/II	Advanced, 2nd-line gBRCAm ovarian cancer Stage IV, 1st to 3rd-line gBRCAm, HER2-negative breast cancer Stage IV, 2nd-line SCLC Stage IV, 2nd-line gastric cancer	Lynparza + Imfinzi	FPCD Q2 2016 LPCD Q1 2019(all except one cohort)	Recruitmentongoing in one expansion cohort Initial data from lung, breast, prostate and ovarian-cancer cohorts presented in 2017 and 2018
LYNK-002	II	HRRm advanced solid tumours	Lynparza	-	Initiating
VIOLETTE	II	Stage IV, advanced, triple-negative breast cancer: -HRRm[45](BRCA) -HRRm (non-BRCA) -Non-HRRm	Lynparza Lynparza + ATR (AZD6738) Lynparza + WEE1 (AZD1775)	FPCD Q2 2018 First data anticipated 2020+	Recruitmentongoing
PROpel	III	Stage IV, advanced, castration-resistant prostate cancer	Abiraterone or abiraterone + Lynparza	FPCD Q4 2018	Recruitment ongoing

				First data anticipated 2020+	
BAYOU	II	Stage IV, 1st line cis-platinum chemotherapy-ineligible urothelial bladder cancer	Imfinzi or Imfinzi + Lynparza	FPCD Q1 2018First data anticipated 2020	Recruitment ongoing
DuO-LORION	II	Stage IV, 1st-line NSCLC	SoC chemotherapy +Imfinzi, followed by Imfinzi orImfinzi + Lynparza maintenance	FPCD Q1 2019 Data anticipated 2020+	Recruitment ongoing

Table 22: Key trastuzumab deruxtecan trials

Name	Phase	Population	Design	Timelines	Status
DESTINY-Breast01	II	Stage IV, HER2-positive breast cancer post trastuzumab emtansine	Trastuzumab deruxtecan	FPCD Q3 2017Data anticipated H2 2019	Breakthrough Therapy Designation status awarded
DESTINY-Breast02	III	Stage IV, HER2-positive breast cancer post trastuzumab emtansine	SoC or trastuzumab deruxtecan	FPCD Q3 2018 Data anticipated 2020+	Recruitment ongoing
DESTINY-Breast03	III	Stage IV, HER2-positive breast cancer	Trastuzumab emtansine or trastuzumab deruxtecan	FPCD Q3 2018 Data anticipated 2020+	Recruitment ongoing
DESTINY-Breast04	III	Stage IV, HER2-low breast cancer	SoC or trastuzumab deruxtecan	FPCD Q4 2018 Data anticipated 2020+	Recruitment ongoing
DESTINY-Gastric01	II	Stage IV, HER2-positive gastric cancer	SoC or trastuzumab deruxtecan	FPCD Q4 2017 Data anticipated 2020	Recruitment ongoing

Table 23: Key Calquence trials in CLL

Name	Phase	Population	Design	Timelines	Status
ACE-CL-007 ELEVATE-TN	III	Previously-untreated CLL	Chlorambucil + obinutuzumab or obinutuzumab +Calquence or Calquence	FPCD Q2 2015 Data anticipated H2 2019	Recruitment completed

ACE CL-311	III	Previously-untreated CLL	Fludarabine, cyclophosphamide and rituximab or Calquence + venetoclax +/- obinutuzumab	FPCD Q2 2019 Data anticipated 2020+ FPCD Q3 2016	Recruitment ongoing
ACE-CL-309	III	Relapsed/refractory CLL	Bendamustine or idelalisib + rituximab or Calquence	Data anticipated H2 2019 FPCD Q2 2015	Recruitment completed
ACE-CL-006 ELEVATE-RR	III	Relapsed/refractory high risk CLL	Ibrutinib or Calquence	Data anticipated 2020+	Recruitment ongoing

During the period, AstraZeneca received regulatory approval for Calquence in relapsed MCL in Qatar; approval was achieved in prior periods in the US, Brazil and the UAE.

Other Oncology medicines

Selumetinib (NF1)

During the period, the Company announced that the US FDA had granted Breakthrough Therapy Designation status for the MEK 1/2 inhibitor and potential new medicine, selumetinib. The designation was for the treatment of paediatric patients aged three years and older with NF1 symptomatic and/or progressive, inoperable plexiform neurofibromas, a rare, incurable genetic condition.

CVRM

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

a) Farxiga (diabetes)

At the American College of Cardiology's (ACC) 68th Annual Scientific Session in New Orleans, the Company presented positive results from a pre-specified sub-analysis of the Phase III DECLARE-TIMI 58 trial showing that Farxiga reduced the relative risk of major adverse cardiovascular events (MACE) by 16%, compared to placebo in patients with T2D who had a prior heart attack (myocardial infarction). In another pre-specified sub-analysis, Farxiga, compared to placebo reduced the relative risk of hospitalisation for heart failure (hHF) in patients with T2D regardless of their ejection fraction (EF) status, a measurement of the percentage of blood leaving the heart with each contraction.

These pre-specified sub-analyses of DECLARE-TIMI 58 added to the positive primary results of the trial presented in November 2018, which showed that Farxiga significantly reduced the risk of the composite of hHF or CV death compared to placebo, consistently across the trial's entire patient population. Additionally, there were fewer major

adverse cardiovascular events observed with Farxiga in the broad patient population; this did not, however, reach statistical significance. During the period, the Company received regulatory acceptances for the DECLARE submissions in both the US and EU.

In March 2019, the Company announced that the EMA had approved Forxiga for use in T1D as an adjunct to insulin in patients with a body-mass index ≥ 27 kg/m², when insulin alone does not provide adequate glycaemic control, despite optimal insulin therapy. In March 2019, the Company announced that the Japanese Ministry of Health, Labour and Welfare had approved Forxiga as an oral adjunct treatment to insulin for adults with T1D. Forxiga is currently under regulatory review in the US for use as an adjunct treatment to insulin in adults with T1D, with a decision anticipated in the second half of 2019.

b) Bydureon (diabetes)

During the period, the US FDA approved label updates for Bydureon and Bydureon BCise to reflect safety data from the EXSCEL (EXenatide Study of Cardiovascular Event Lowering) trial, which demonstrated that Bydureon did not increase the risk of MACE in patients with T2D and a broad range of CV risk.

c) Brilinta (myocardial infarction)

During the period, the Company announced that the Phase III THEMIS trial had met its primary endpoint and demonstrated that Brilinta, taken in conjunction with aspirin, showed a statistically-significant reduction in a composite of MACE, compared to aspirin alone. THEMIS was conducted in over 19,000 patients with CAD and T2D with no history of prior heart attack (myocardial infarction) or stroke. Preliminary safety results were consistent with the known profile of Brilinta. The Company intends to present a full evaluation of the THEMIS data at a forthcoming medical meeting.

At the aforementioned ACC meeting, the Company presented data from a secondary analysis of the Phase III TREAT trial, demonstrating that that STEMI patients, aged 75 years or less, who received Brilinta following fibrinolysis, had a similar ischemic risk compared to those receiving clopidogrel, as measured by the secondary efficacy endpoint which was a composite of CV death, MI or stroke after 12 months of treatment. Brilinta showed a similar efficacy in preventing CV events compared to clopidogrel, with a numerical reduction in events in the Brilinta arm; this was, however, not statistically significant. The trial was designed primarily to test for non-inferiority, compared to clopidogrel, for safety at 30 days and was not powered statistically to detect significance of any treatment effects. A secondary safety analysis of TREAT was consistent with the known safety profile of Brilinta.

Table 24: Key, large CVRM trials

Major CVRM outcomes trials are highlighted in the following table:

Medicine	Trial	Mechanism	Population	Primary endpoint(s)	Timeline
Farxiga	DECLARE	SGLT2[46]inhibitor	c.17,000[47]patients with type-2 diabetes	Superiority for MACE or superiority for the composite endpoint of CV death or hHF	Primary safety endpoint met One of two primary efficacy endpoints met
Farxiga	DAPA-HF	SGLT2 inhibitor	c.4,500 patients with heart failure (HF) and reduced ejection fraction, with and without type-2 diabetes	Time to first occurrence of CV death or hHF or an urgent HF visit	FPCD Q1 2017 LPCD Q3 2018 Data anticipatedH2 2019
Farxiga	DELIVER	SGLT2 inhibitor	c.4,700 patients with HF and preserved ejection fraction,	Time to first occurrence of CV	FPCD Q3 2018

Edgar Filing: ASTRAZENECA PLC - Form 6-K

			with and without type-2 diabetes	death or worsening heart failure	Data anticipated 2020+
Farxiga	DAPA-CKD	SGLT2 inhibitor	c.4,000 patients with CKD, with and without T2D	Time to first occurrence of $\geq 50\%$ sustained decline in eGFR[48] or reaching ESRD[49] or CV death or renal death	FPCD Q1 2017LPCD Q1 2019Data anticipated 2020+
Brilinta	THEMIS	P2Y12 receptor antagonist	c.19,000 patients with T2D and CAD without a history of MI or stroke	Composite of CV death, non-fatal MI and non-fatal stroke	Primary endpoint metDetails to be presented at a forthcoming medical meeting
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	FPCD Q1 2018 Data anticipated 2020
Epanova	STRENGTH	Omega-3 carboxylic acids	c.13,000 patients with mixed dyslipidaemia/hypertriglycerid-aemia	Time to first occurrence of CV death, non-fatal MI or non-fatal stroke	FPCD Q4 2014 LPCD Q2 2017 Data anticipated 2020

d) Lokelma (hyperkalaemia)

During the period, DIALIZE, a multi-centre, randomised, placebo-controlled, double-blinded Phase IIIb trial investigating the efficacy of Lokelma as a treatment for patients with CKD on haemodialysis with hyperkalaemia, met its primary endpoint. DIALIZE was the first ever randomised, placebo-controlled trial to evaluate a potassium binder in patients on haemodialysis and will potentially inform regulatory updates in major markets. Before DIALIZE, limited scientific research had been conducted on this patient population. The Company intends to present results from the trial at a forthcoming medical meeting.

During the period, patient enrolment in the Phase II PRIORITIZE HF trial was temporarily suspended. The trial was designed to evaluate the benefits and risks of using Lokelma to initiate and intensify renin angiotensin aldosterone system inhibitor (RAASi) therapy in HF patients. The suspension followed the identification of larger than anticipated measurement discrepancies between potassium-concentration levels at point of care vs. those in central laboratories. The differences identified resulted in some patients receiving inappropriate management of RAASi medication. The trial is anticipated to resume, following approval of an amendment to the trial protocol to measure potassium-concentration levels in central laboratories. The safety-monitoring committee recommended the continuation of the trial as planned. AstraZeneca anticipates an update to clinicaltrials.gov in due course.

e) Crestor (CV disease)

During the period, the Company announced that the Phase III METEOR China trial met its primary endpoint, demonstrating that Crestor slowed progression of carotid intima-media thickness (CMT) in adult Chinese patients with subclinical atherosclerosis. The preliminary safety results were consistent with the known safety profile

of Crestor, which add long-term (two years) safety evidence of Crestor in the adult Chinese population. METEOR China was a randomised, double-blinded, placebo-controlled, multi-centre, parallel group trial assessing the effects of Crestor 20mg daily treatment for 104 weeks on the change in CIMT in adult Chinese patients with subclinical atherosclerosis. In total, 543 patients were randomised from 25 sites in China.

Respiratory

AstraZeneca's Respiratory focus is aimed at transforming the treatment of patients with asthma and COPD through combined inhaled therapies and biologic medicines for the unmet medical needs of specific populations and an early pipeline focused on disease modification. The growing range of medicines includes a number of anticipated launches between 2017 and 2020; of these, Bevespi and Fasenra are already benefitting patients, with regulatory reviews for Symbicort as an anti-inflammatory reliever in mild asthma and PT010 in COPD underway. The capability in inhalation technology spans both pressurised metered-dose inhalers and dry-powder inhalers to serve patient needs, including the innovative Aerosphere Delivery Technology, a focus of AstraZeneca's future-platform development for respiratory-disease combination therapies.

a) Symbicort (asthma)

In February 2019, the Brazilian Health Regulatory Agency (ANVISA) granted an expanded indication for Symbicort as a reliever of mild asthma symptoms. In April, a similar approval was also granted by the Ministry of Health of the Russian Federation. These approvals were based on data from the SYGMA 1 and SYGMA 2 trials. SYGMA 1 showed that using Symbicort as an anti-inflammatory reliever, in place of a short-acting beta-agonist alone, has the potential to reduce the risk of severe asthma attacks in this patient population by 64%.

In April 2019, the Global Initiative for Asthma (GINA) announced updated global recommendations for clinical practice and the treatment of patients with differing asthma severities. The 2019 GINA Pocket Guide for Asthma Management and Prevention recommends the use of low dose ICS-formoterol combination therapy, as needed, as the preferred reliever therapy across all asthma severities. Short-acting beta-2 agonist monotherapy, as-needed, is no longer recommended as a preferred reliever therapy.

b) Fasenra (asthma)

During the period, a Phase II trial demonstrated that Fasenra can achieve near-complete depletion of eosinophils and improve clinical outcomes in hypereosinophilic syndrome (HES); the results were published in the New England Journal of Medicine. The US FDA granted Orphan Drug Designation for Fasenra for the treatment of HES in February 2019. Fasenra is currently approved as an add-on maintenance treatment for patients with severe, eosinophilic asthma in the US, EU, Japan and other markets.

c) Tudorza (COPD)

In March 2019, the US FDA granted regulatory approval for Tudorza based on the results from the ASCENT trial, which fulfilled a post-approval commitment to conduct a randomised, controlled trial to evaluate the risk of MACE with Tudorza as a treatment for patients with COPD. The trial achieved its co-primary endpoints for safety (MACE) and efficacy (exacerbation reduction); the data from the ASCENT trial has now been added to the US label. Tudorza is a LAMA, administered twice-daily via the breath-actuated inhaler, Pressair. Tudorza was approved first in the US in 2012 for the maintenance treatment of COPD.

d) Duaklir (COPD)

In March 2019, the US FDA approved Duaklir as a maintenance treatment for patients with COPD. The approval was based on data from three Phase III trials, namely ACLIFORM, AUGMENT and AMPLIFY. The label also included clinical data from the ASCENT trial, which showed that Duaklir was effective at reducing COPD exacerbations. Duaklir is a fixed-dose LAMA/LABA combination, administered twice-daily via Pressair. It is the only twice-daily LAMA/LABA treatment in the US with COPD-exacerbation data included in its prescribing information.

Edgar Filing: ASTRAZENECA PLC - Form 6-K

As part of the collaboration agreement announced in March 2017, Circassia Pharmaceuticals plc will be responsible for Duaklirin the US with AstraZeneca continuing to manufacture and supply the medicine.

e) PT010 (COPD)

During the period, the Company received regulatory submission acceptance for PT010 from the US FDA and the EMA, respectively. The acceptance was based on results from the KRONOS Phase III trial, which was published in The Lancet Respiratory Medicine in October 2018. Results of the Phase III ETHOS exacerbations trial are anticipated in H2 2019, potentially further characterising the overall profile of PT010 as a new medicine for patients with COPD.

f) Tezepelumab (severe, uncontrolled asthma)

During the period, the first patient was recruited into the Phase III DESTINATION trial, evaluating the safety and tolerability of tezepelumab in adults and adolescents with severe, uncontrolled asthma.

g) Saracatinib (IPF)

In March 2019, the US FDA granted Orphan Drug Designation for saracatinib, a potential new medicine for the treatment of IPF, a type of lung disease that results in scarring (fibrosis) of the lungs. IPF is a chronic, progressive, irreversible and ultimately fatal interstitial lung disease which affects c.100,000 patients per year in the US. Saracatinib is an inhibitor of Src kinase, which regulates broad cell functions including cell growth and cell differentiation. Pre-clinical trials of saracatinib showed that it inhibits fibroblast activity and collagen deposition, which are key features of lung fibrosis. More recently, saracatinib completed its Phase I development.

Other medicines

There were no research & development updates for medicines outside of the three main therapy areas in the period.

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

Condensed consolidated statement of comprehensive income

For the quarter ended 31 March	2019 \$m	2018 \$m
Product Sales	5,465	4,985
Collaboration Revenue	26	193
Total Revenue	5,491	5,178
Cost of sales	(1,129)	(1,134)
Gross profit	4,362	4,044
Distribution costs	(78)	(81)
Research and development expense	(1,266)	(1,279)
Selling, general and administrative costs	(2,514)	(2,457)
Other operating income and expense	593	469
Operating profit	1,097	696
Finance income	55	35
Finance expense	(367)	(343)
Share of after-tax losses in associates and joint ventures	(27)	(14)

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Profit before tax	758	374
Taxation	(195)	(58)
Profit for the period	563	316
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Remeasurement of the defined benefit pension liability	10	27
Net gains on equity investments measured at fair value through other comprehensive income	120	118
Fair value movements related to own credit risk on bonds designated as fair value through profit or loss	(1)	(1)
Tax on items that will not be reclassified to profit or loss	(43)	(27)
	86	117
Items that may be reclassified subsequently to profit or loss		
Foreign exchange arising on consolidation	53	167
Foreign exchange arising on designating borrowings in net investment hedges	(180)	(99)
Fair value movements on cash flow hedges	(54)	111
Fair value movements on cash flow hedges transferred to profit or loss	47	(80)
Fair value movements on derivatives designated in net investment hedges	3	(46)
Costs of hedging	(6)	(10)
Tax on items that may be reclassified subsequently to profit or loss	23	20
	(114)	63
Other comprehensive income for the period, net of tax	(28)	180
Total comprehensive income for the period	535	496
Profit attributable to:		
Owners of the Parent	593	340
Non-controlling interests	(30)	(24)
	563	316
Total comprehensive income attributable to:		
Owners of the Parent	565	520
Non-controlling interests	(30)	(24)
	535	496
Basic earnings per \$0.25 Ordinary Share	\$0.47	\$0.27
Diluted earnings per \$0.25 Ordinary Share	\$0.47	\$0.27
Weighted average number of Ordinary Shares in issue (millions)	1,267	1,266
Diluted weighted average number of Ordinary Shares in issue (millions)	1,268	1,267

Condensed consolidated statement of financial position

	At 31 Mar 2019 \$m	At 31 Dec 2018 \$m	At 31 Mar 2018 \$m
ASSETS			
Non-current assets			

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Property, plant and equipment	7,446	7,421	7,721
Right-of-use assets	707	-	-
Goodwill	11,674	11,707	11,834
Intangible assets	22,852	21,959	25,850
Investments in associates and joint ventures	76	89	187
Other investments	1,530	833	987
Derivative financial instruments	94	157	594
Other receivables	496	515	525
Deferred tax assets	2,531	2,379	2,401
	47,406	45,060	50,099
Current assets			
Inventories	3,050	2,890	3,283
Trade and other receivables	5,289	5,574	5,444
Other investments	822	849	866
Derivative financial instruments	234	258	21
Income tax receivable	118	207	563
Cash and cash equivalents	4,136	4,831	3,005
Assets held for sale	-	982	-
	13,649	15,591	13,182
Total assets	61,055	60,651	63,281
LIABILITIES			
Current liabilities			
Interest-bearing loans and borrowings	(3,544)	(1,754)	(4,170)
Lease liabilities	(175)	-	-
Trade and other payables	(13,102)	(12,841)	(11,481)
Derivative financial instruments	(28)	(27)	(40)
Provisions	(397)	(506)	(1,011)
Income tax payable	(1,010)	(1,164)	(1,462)
	(18,256)	(16,292)	(18,164)
Non-current liabilities			
Interest-bearing loans and borrowings	(17,320)	(17,359)	(15,684)
Lease liabilities	(539)	-	-
Derivative financial instruments	(5)	(4)	(10)
Deferred tax liabilities	(3,267)	(3,286)	(3,987)
Retirement benefit obligations	(2,385)	(2,511)	(2,516)
Provisions	(379)	(385)	(384)
Other payables	(6,875)	(6,770)	(7,963)
	(30,770)	(30,315)	(30,544)
Total liabilities	(49,026)	(46,607)	(48,708)
Net assets	12,029	14,044	14,573
EQUITY			
Capital and reserves attributable to equity holders of the Company			
Share capital	317	317	317
Share premium account	4,438	4,427	4,407
Other reserves	2,046	2,041	2,027
Retained earnings	3,682	5,683	6,164
	10,483	12,468	12,915
Non-controlling interests	1,546	1,576	1,658
Total equity	12,029	14,044	14,573

Condensed consolidated statement of changes in equity

	Share capital \$m	Share premium account \$m	Other reserves \$m	Retained earnings \$m	Total attributable to owners \$m	Non- controlling interests \$m	Total equity \$m
At 1 Jan 2018	317	4,393	2,029	8,221	14,960	1,682	16,642
Adoption of new accounting standards	-	-	-	(91)	(91)	-	(91)
Profit for the period	-	-	-	340	340	(24)	316
Other comprehensive income	-	-	-	180	180	-	180
Transfer to other reserves	-	-	(2)	2	-	-	-
Transactions with owners:							
Dividends	-	-	-	(2,402)	(2,402)	-	(2,402)
Issue of Ordinary Shares	-	14	-	-	14	-	14
Share-based payments charge for the period	-	-	-	52	52	-	52
Settlement of share plan awards	-	-	-	(138)	(138)	-	(138)
Net movement	-	14	(2)	(2,057)	(2,045)	(24)	(2,069)
At 31 Mar 2018	317	4,407	2,027	6,164	12,915	1,658	14,573
	Share capital \$m	Share premium account \$m	Other reserves \$m	Retained earnings \$m	Total attributable to owners \$m	Non- controlling interests \$m	Total equity \$m
At 1 Jan 2019	317	4,427	2,041	5,683	12,468	1,576	14,044
Adoption of new accounting standards[50]	-	-	-	54	54	-	54
Profit for the period	-	-	-	593	593	(30)	563
Other comprehensive loss	-	-	-	(28)	(28)	-	(28)
Transfer to other reserves	-	-	5	(5)	-	-	-
Transactions with owners:							
Dividends	-	-	-	(2,403)	(2,403)	-	(2,403)
Issue of Ordinary Shares	-	11	-	-	11	-	11
Share-based payments charge for the period	-	-	-	53	53	-	53
Settlement of share plan awards	-	-	-	(265)	(265)	-	(265)
Net movement	-	11	5	(2,001)	(1,985)	(30)	(2,015)
At 31 Mar 2019	317	4,438	2,046	3,682	10,483	1,546	12,029

Condensed consolidated statement of cash flows

	2019 \$m	2018 \$m
For the quarter ended 31 March		
Cash flows from operating activities		
Profit before tax	758	374
Finance income and expense	312	308
Share of after-tax losses of associates and joint ventures	27	14

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Depreciation, amortisation and impairment	676	709
Increase in working capital and short-term provisions	(710)	(993)
Gains on disposal of intangible assets	(512)	(65)
Non-cash and other movements	(396)	(242)
Cash generated from operations	155	105
Interest paid	(208)	(128)
Tax paid	(334)	(117)
Net cash outflow from operating activities	(387)	(140)
Cash flows from investing activities		
Payment of contingent consideration from business combinations	(219)	(62)
Purchase of property, plant and equipment	(174)	(213)
Disposal of property, plant and equipment	28	2
Purchase of intangible assets	(586)	(121)
Disposal of intangible assets	1,071	362
Movement in profit-participation liability	150	-
Purchase of non-current asset investments	(3)	(4)
Disposal of non-current asset investments	17	1
Movement in short-term investments and fixed deposits	20	436
Payments to joint ventures	(12)	(161)
Interest received	36	33
Net cash inflow from investing activities	328	273
Net cash (outflow)/inflow before financing activities	(59)	133
Cash flows from financing activities		
Proceeds from issue of share capital	11	14
Issue of loans	500	-
Dividends paid	(2,432)	(2,363)
Hedge contracts relating to dividend payments	26	(47)
Repayment of obligations under leases	(42)	-
Movement in short-term borrowings	1,239	1,733
Net cash outflow from financing activities	(698)	(663)
Net decrease in cash and cash equivalents in the period	(757)	(530)
Cash and cash equivalents at the beginning of the period	4,671	3,172
Exchange rate effects	12	13
Cash and cash equivalents at the end of the period	3,926	2,655
Cash and cash equivalents consist of:		
Cash and cash equivalents	4,136	3,005
Overdrafts	(210)	(350)
	3,926	2,655

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 2019 have been prepared in accordance with IAS 34 'Interim Financial Reporting' as adopted by the 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 2018. In addition, from 1 January 2019, AstraZeneca elected to early adopt the October 2018 update to IFRS 3, which changed the definition of a business. The EU has not yet endorsed this update to IFRS 3, but it is considered highly probable that the amendment will be endorsed during 2019 in time for the effective date of 1 January 2020. The change in definition of a business within IFRS 3 allowed the Group to apply the optional concentration test to perform a simplified assessment of whether an acquired set of activities and assets is or is not a business on a transaction by transaction basis. It is considered that adopting this amendment will provide more reliable and comparable information about certain transactions as it provides more consistency in accounting for substantially similar transactions that under the previous definition may have been accounted for in different ways despite limited differences in substance. The Group accounting policies will be updated to reflect the change.

IFRS 16

IFRS 16 'Leases' is effective for accounting periods beginning on or after 1 January 2019 and replaces IAS 17 'Leases'. It eliminates the classification of leases as either operating leases or finance leases and, instead, introduces a single lessee accounting model. The adoption of IFRS 16 resulted in the Group recognising lease liabilities, and corresponding 'right-of-use' assets for arrangements that were previously classified as operating leases.

The Group's principal lease arrangements are for property, most notably a portfolio of office premises, and for a global car fleet, utilised primarily by our sales and marketing teams. The Group has adopted IFRS 16 using a modified retrospective approach with the cumulative effect of initially applying the standard as an adjustment to the opening balance of retained earnings at 1 January 2019. The standard permits a choice on initial adoption, on a lease-by-lease basis, to measure the right-of-use asset at either its carrying amount as if IFRS 16 had been applied since the commencement of the lease, or an amount equal to the lease liability, adjusted for accruals or prepayments. The Group has elected to measure the right-of-use asset equal to the lease liability, with the result of no net impact on opening retained earnings and no restatement of prior period comparatives.

Initial adoption resulted in the recognition of right-of-use assets of \$722m and lease liabilities of \$720m. The weighted average incremental borrowing rate applied to the lease liabilities on 1 January 2019 was 3%.

The Group is using one or more practical expedients on transition, on a lease-by-lease basis, to leases previously classified as operating leases, including electing to not apply the retrospective treatment to leases for which the term ends within 12 months of initial application, electing to apply a single discount rate to portfolios of leases with similar characteristics, reliance on previous assessments on whether leases are onerous, excluding initial direct costs from the initial measurement of the right-of-use asset, and using hindsight in determining the lease term where the contract contains options to extend or terminate the lease.

Key judgements made in calculating the initial impact of adoption include assessing whether arrangements contain a lease and determining the lease term. Extension and termination options have been considered when determining the lease term, along with all facts and circumstances that may create an economic incentive to exercise an extension option, or not exercise a termination option. Extension periods (or periods after termination options) are only included in the lease term if the lease is reasonably certain to be extended (or not terminated). Estimates include calculating the discount rate which is based on the incremental borrowing rate.

The Group is applying IFRS 16's low-value and short-term exemptions. While the IFRS 16 opening lease liability is calculated differently from the previous operating lease commitment calculated under the previous standard, there are no material differences between the positions. The adoption of IFRS 16 has had no impact on the Group's net cash flows, although a presentation change has been reflected whereby cash outflows of \$42m are now presented as financing, instead of operating. There is an immaterial benefit to Operating profit and a corresponding increase in

Finance expense from the presentation of a portion of lease costs as interest costs. Profit before tax, taxation and Earnings per share have not been significantly impacted.

IFRIC 23

IFRIC 23 'Uncertainty Over Income Tax Treatments' is effective for accounting periods beginning on or after 1 January 2019 and provides further clarification on how to apply the recognition and measurement requirements in IAS 12 'Income Taxes'. It is applicable where there is uncertainty over income tax treatments. The EU endorsed IFRIC 23 on 24 October 2018. The adoption of IFRIC 23 has principally resulted in the Group measuring the effect of uncertainty on income tax positions using either the most likely amount or the expected value amount depending on which method is expected to better reflect the resolution of the uncertainty.

The Group has retrospectively applied IFRIC 23 from 1 January 2019 recognising the cumulative effect of initially applying the interpretation as decreases to income tax payable of \$51m and to trade and other payables of \$3m, and a corresponding adjustment to the opening balance of retained earnings of \$54m. There is no restatement of the comparative information as permitted in the interpretation.

Collaboration Revenue

Effective from 1 January 2019, the Group is updating the presentation of an element of Total Revenue within the Statement of Comprehensive Income and changing the classification of some income to reflect the increasing importance of collaborations to AstraZeneca. Historically, Externalisation Revenue formed part of Total Revenue and only included income arising from collaborative transactions involving AstraZeneca's medicines, whether internally developed or previously acquired. Such income included upfront consideration, milestones receipts, profit share income and royalties, as well as other income from collaborations. The updated category of Collaboration Revenue includes all income previously included within Externalisation Revenue, as well as income of a similar nature arising from transactions where AstraZeneca has acquired an interest in a medicine and as part of the acquisition entered into an active collaboration with the seller. This change is a result of the growing importance of collaborations to AstraZeneca and is expected to result in future periods in income arising from all collaborations, other than product sales, being recognised within the Collaboration Revenue element of Total Revenue. No prior year restatement of financial results is therefore required as a result of this change.

Income from royalties and disposals of assets and businesses, where the Group does not retain a significant element of continued interest, continue to be recorded in other operating income.

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 2018.

Going concern

The Group has considerable financial resources available. As at 31 March 2019 the Group has \$8.2bn in financial resources (cash balances of \$4.1bn and undrawn committed bank facilities of \$4.1bn, of which \$3.4bn is available until April 2022, \$0.5bn is available until December 2020 (extendable to December 2021) and \$0.2bn is available until December 2019 (extendable to December 2020), with only \$3.7bn 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. The Group, however, anticipates 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. Subsequent to the quarter end AstraZeneca PLC issued a total of 44,386,214 new ordinary shares of \$0.25 each at a price of £60.50 per share. The share issue completed on 2 April 2019 and generated proceeds of £2.69bn (\$3.5bn); further increasing the Group's financial resources. 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 2018 are not the Group'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 2019 is stated after charging restructuring costs of \$103m (\$95m for the first quarter of 2018). These have been charged to profit as follows:

	Q1 2019\$m	Q1 2018\$m
Cost of sales	38	32
Research and development expense	34	27
Selling, general and administrative costs	31	36
Total	103	95

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 27 of the Annual Report and Form 20-F Information 2018. Net debt is a non-GAAP financial measure.

	At 1 Jan 2019 \$m	Adoption of new accounting standards[51]	Cash Flow \$m	Non-cash & Other \$m	Exchange Movements \$m	At 31 Mar 2019 \$m
Loans due after one year	(17,359)	-	-	(12)	51	(17,320)
Lease liability due after one year	-	(557)	-	19	(1)	(539)
Total long-term debt	(17,359)	(557)	-	7	50	(17,859)
Current instalments of loans	(999)	-	(500)	(1)	-	(1,500)
Current instalments of leases	-	(163)	47	(59)	-	(175)
Commercial paper	(211)	-	(1,320)	-	-	(1,531)

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Bank Collateral	(384)	-	81	-	-	(303)
Overdraft	(160)	-	(51)	-	1	(210)
Total current debt	(1,754)	(163)	(1,743)	(60)	1	(3,719)
Gross borrowings	(19,113)	(720)	(1,743)	(53)	51	(21,578)
Net derivative financial instruments	384	-	(26)	(63)	-	295
Net borrowings	(18,729)	(720)	(1,769)	(116)	51	(21,283)
Cash and cash equivalents	4,831	-	(706)	-	11	4,136
Other investments - current	849	-	(20)	(7)	-	822
Other investments - non-current	46	-	-	8	-	54
Cash and investments	5,726	-	(726)	1	11	5,012
Net debt	(13,003)	(720)	(2,495)	(115)	62	(16,271)

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

Other investments - non-current are included within the balance of \$1,530m (31 December 2018: \$833m) in the Statement of Financial Position. The equivalent GAAP measure to net debt is 'liabilities arising from financing activities' which excludes the amounts for cash and overdrafts, other investments and non-financing derivatives shown above and includes the Acerta put option liability of \$1,844m (31 December 2018: \$1,838m) shown in non-current other payables.

4 Financial instruments

As detailed in the Group's most recent annual financial statements, the principal financial instruments consist of derivative financial instruments, other investments, trade and other receivables, cash and cash equivalents, trade and other payables, leases and interest-bearing loans and borrowings.

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 Group's Annual Report and Form 20-F Information 2018.

The Group holds certain equity investments that are categorised as Level 3 in the fair-value hierarchy and for which fair value gains of nil have been recognised in Q1 2019. These are presented in Net gains on equity investments measured at fair value through other comprehensive income in the Condensed Consolidated Statement of Comprehensive Income.

Financial instruments measured at fair value include \$2,352m of other investments, \$671m of loans, and \$295m of derivatives as at 31 March 2019. The total fair value of interest-bearing loans and borrowings at 31 March 2019 which have a carrying value of \$20,864m in the Condensed Consolidated Statement of Financial Position, was \$22,897m. 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
	2019	2019	2019	2018
	\$m	\$m	\$m	\$m
At 1 January	3,983	1,123	5,106	5,534
Settlements	(110)	(109)	(219)	(62)
Revaluations	-	8	8	-
Discount unwind	72	18	90	104
At 31 March	3,945	1,040	4,985	5,576

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 2018 (the Disclosures). Unless noted otherwise below or in the Disclosures, no provisions have been established in respect of the claims discussed below.

As discussed in the Disclosures, for the majority of claims in which AstraZeneca is involved it is not possible to make a reasonable estimate of the expected financial effect, if any, that will result from ultimate resolution of the proceedings. In these cases, AstraZeneca discloses information with respect only to the nature and facts of the cases but no provision is made.

In cases that have been settled or adjudicated, or where quantifiable fines and penalties have been assessed and which are not subject to appeal, or where a loss is probable and we are able to make a reasonable estimate of the loss, AstraZeneca records 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 2019 and to 26 April 2019

Patent litigation

Imfinzi

US patent proceedings

As previously disclosed, in July 2017, Bristol-Myers Squibb, E.R. Squibb & Sons LLC, Ono Pharmaceutical Co and Tasuku Honjo filed a patent infringement action in the US District Court for the District of Delaware (the District Court) relating to AstraZeneca's commercialisation of Imfinzi. A trial has been scheduled for October 2020. Discovery

is ongoing.

Calquence

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 US District Court for the District of Delaware (the District Court) against Acerta Pharma and AstraZeneca relating to Calquence. 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 medicine, Imbruvica, infringes a US patent owned by Acerta Pharma. In November 2018, Janssen Biotech, Inc. intervened as a defendant. A trial has been scheduled for January 2021.

Faslodex

Patent proceedings outside the US

As previously disclosed, in Germany, in January 2017, the German Federal Patent Court declared the German part of European Patent No. EP 1,250,138 (the '138 patent) invalid. In April 2019, the German Federal Court of Justice upheld the January 2017 decision and determined the '138 patent to be invalid.

Farxiga

US patent proceedings

As previously disclosed, in May 2018, AstraZeneca initiated ANDA litigation against Zydus Pharmaceuticals (USA) Inc. (Zydus) in the US District Court for the District of Delaware (the District Court). In January 2019, following a stipulation filed by the parties, the District Court dismissed claims related to US Patent Nos. 7,851,502, 7,919,598, 8,221,786, 8,361,972, 8,501,698, and 8,716,251. AstraZeneca continues to allege that Zydus' generic version of Farxiga, if approved and marketed, would infringe AstraZeneca's US Patents Nos. 6,414,126, 6,515,117, and 8,685,934. A trial is scheduled for February 2021.

Brilinta

Patent proceedings outside the US

As previously disclosed, in Canada, in September 2017, Apotex Inc. (Apotex) challenged the patents listed on the Canadian Patent Register with reference to Brilinta. AstraZeneca discontinued the proceeding against Apotex in February 2019 after Apotex withdrew its challenge.

Symbicort

US patent proceedings

As previously disclosed, in October 2018 AstraZeneca initiated ANDA litigation against Mylan Pharmaceuticals Inc., Mylan Laboratories Limited, Mylan Inc., and Mylan N.V. in the US District Court for the District of Delaware and in the US District Court for the Northern District of West Virginia. In March 2019, following stipulations filed by the parties, the Delaware and West Virginia Courts dismissed without prejudice Mylan Laboratories Limited, Mylan Inc., and Mylan N.V. from those actions.

Product liability litigation

Nexium and Losec/Prilosec

As previously disclosed, in the US, AstraZeneca is defending various lawsuits brought in federal and state courts involving multiple plaintiffs claiming that they have been diagnosed with various injuries following treatment with proton-pump inhibitors, including Nexium and Prilosec. In May 2017, counsel for a group of such plaintiffs claiming that they have been diagnosed with kidney injuries filed a motion with the Judicial Panel on Multidistrict Litigation (JPML) seeking the transfer of any currently pending federal court cases as well as any similar, subsequently filed cases to a co-ordinated and consolidated pre-trial multidistrict litigation (MDL) proceeding. In August 2017, the JPML granted the motion and consolidated the pending federal court cases in an MDL proceeding in federal court in

New Jersey for pre-trial purposes.

As previously disclosed, in Canada, in July and August 2017, AstraZeneca was served with three putative class action lawsuits. Two of the lawsuits seek authorisation to represent individual residents in Canada who allegedly suffered kidney injuries from the use of proton pump inhibitors, including Nexium and Losec, and the third, pending in Quebec, seeks authorisation to represent such individual residents in Quebec.

Farxiga and Xigduo XR

As previously disclosed, in several jurisdictions in the US, AstraZeneca has been named as a defendant in lawsuits involving plaintiffs claiming physical injury, including diabetic ketoacidosis and kidney failure, from treatment with Farxiga and/or Xigduo XR. In April 2017, the Judicial Panel on Multidistrict Litigation ordered transfer of any currently pending cases as well as of any similar, subsequently filed cases to a co-ordinated and consolidated pre-trial multidistrict litigation proceeding in the US District Court for the Southern District of New York. A majority of these claims have been resolved or dismissed.

Commercial litigation

Toprol-XL

Aralez litigation

As previously disclosed, in October 2016, AstraZeneca completed its sale of certain assets related to the US rights to Toprol-XL and AstraZeneca's authorised generic metoprolol succinate product to Aralez Pharmaceuticals Trading DAC (Aralez). In August 2018, Aralez commenced voluntary insolvency proceedings and AstraZeneca filed a proof of claim in those proceedings asserting its unsecured claims. In October 2018, Aralez filed a motion in the Bankruptcy Court seeking to sell the US rights to Toprol-XL and its authorised generic and AstraZeneca filed an objection to the proposed sale. In March 2019, AstraZeneca entered into an agreement with the senior secured creditor and the settlement has now been approved by the Bankruptcy Court, bringing this matter to a close.

Government investigations/proceedings

Synagis

Litigation in New York

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

In June 2017, MedImmune was served with a lawsuit in US Federal Court in New York by a relator under the qui tam (whistleblower) provisions of the federal and certain state False Claims Acts. The lawsuit was originally filed under seal in April 2009 and alleges that MedImmune made false claims about Synagis. In November 2017, MedImmune was served with an amended complaint in which relator set forth additional false claims allegations relating to Synagis. In September 2018, the US Federal Court in New York dismissed the relator's lawsuit. In January 2019, relator appealed the decision of the US Federal Court in New York.

Toprol-XL

Louisiana Attorney General Litigation

As previously disclosed, in the US, in March 2015, AstraZeneca was served with a state court civil complaint filed by the Attorney General for the State of Louisiana (the State) alleging that, in connection with enforcement of its

patents for Toprol-XL, it had engaged in unlawful monopolisation and unfair trade practices, causing the State government to pay increased prices for Toprol-XL. In April 2019, a Louisiana state court heard oral argument on and granted AstraZeneca's motion for summary judgment, ordering the dismissal of the State's complaint and judgment to be entered in AstraZeneca's favour.

6 Subsequent events

On 2 April 2019 AstraZeneca PLC issued a total of 44,386,214 new ordinary shares of \$0.25 each at a price of £60.50 per share, raising proceeds of £2.69bn (\$3.5bn) before expenses. The new ordinary shares rank pari passu in all respects with the existing ordinary shares of \$0.25 in the capital of AstraZeneca PLC, including the right to receive all dividends and other distributions declared, made or paid on or in respect of such shares after the date of issue. As at 2 April the issued share capital of AstraZeneca PLC with voting rights was 1,311,755,099 ordinary shares of \$0.25.

On 18 April 2019, AstraZeneca repaid early a floating-rate \$500m bank term loan which was included within current interest-bearing loans and borrowings as at 31 March 2019.

On 25 April 2019, the European Commission (the Commission) issued its decision on the State aid review of UK Controlled Foreign Company Group Financing Exemption. The Commission has concluded that part of the UK measures were unlawful and incompatible State aid and have instructed Her Majesty's Revenue and Customs to recover the State aid. AstraZeneca is reviewing the details of the ruling and assessing any impact upon the Company's historic tax positions. Given the complexities of the ruling, tax legislation and the possibility of appeal, the Company has been unable to estimate reliably any additional liability at this time; this is not, however, expected to be material.

7 Product Sales analysis - 2019

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 2019 \$m	Actual %	CER %	Q1 2019 \$m	Actual %	CER %	Q1 2019 \$m	Actual %	Q1 2019 \$m	Actual %	CER %	Q1 2019 \$m	Actual %	CER %
Oncology														
Tagrisso	630	86	92	138	94	n/m	259	76	100	45	55	133	n/m	n/m
Imfinzi	295	n/m	n/m	6	n/m	n/m	231	n/m	23	n/m	n/m	35	n/m	n/m
Lynparza	237	99	n/m	26	n/m	n/m	119	80	65	55	62	27	n/m	n/m
Iressa	134	2	7	86	21	28	4	(50)	26	(13)	(7)	18	(22)	(22)
Calquence	29	n/m	n/m	-	-	-	29	n/m	-	-	-	-	-	-
Legacy:														
Faslodex	254	-	4	45	15	28	126	(6)	54	(8)	(2)	29	32	32
Zoladex	194	5	13	114	13	23	2	n/m	35	3	9	43	(10)	(8)
Arimidex	51	(6)	-	36	3	11	-	-	6	(25)	(25)	9	(18)	(18)
Casodex	48	(8)	(4)	31	-	6	-	-	4	(33)	(33)	13	(13)	(13)
Others	20	(26)	(22)	8	14	29	-	-	1	-	-	11	(42)	(42)
Total Oncology	1,892	54	59	490	35	46	770	81	314	26	34	318	66	67
BioPharma - CVRM														
Farxiga	349	17	23	95	38	51	131	3	89	20	30	34	17	24
Brilinta	348	19	24	97	28	38	153	33	83	(3)	3	15	(6)	-

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Onglyza	153	19	23	43	8	23	78	59	19	(17)	(17)	13	(24)	(24)
Bydureon	142	2	4	2	n/m	n/m	117	5	18	(22)	(17)	5	-	-
Byetta	30	(3)	-	1	(80)	(60)	20	33	6	(14)	(14)	3	(25)	(25)
Symlin	7	(22)	(22)	-	-	-	7	(22)	-	-	-	-	-	-
Legacy:														
Crestor	335	(14)	(9)	225	(5)	1	26	(43)	39	(40)	(37)	45	13	15
Seloken/Toprol-XL	225	13	21	193	12	21	23	28	6	-	-	3	-	-
Atacand	50	(30)	(24)	39	5	16	2	(71)	4	(82)	(82)	5	-	-
Others	75	(12)	(6)	52	(13)	(5)	1	-	19	(5)	(5)	3	(40)	(40)
Total BioPharma - CVRM	1,714	4	9	747	7	16	558	12	283	(13)	(8)	126	2	5
BioPharma														
-Respiratory														
Symbicort	585	(8)	(3)	133	4	13	176	(4)	182	(14)	(8)	94	(15)	(12)
Pulmicort	383	11	16	314	16	23	24	(17)	25	(7)	(4)	20	-	-
Fasenra	129	n/m	n/m	-	-	-	93	n/m	18	n/m	n/m	18	n/m	n/m
Daliresp/Daxas	48	26	29	1	(50)	-	41	41	6	(14)	(14)	-	-	-
Tudorza/Eklira	20	(29)	(25)	1	-	-	2	(60)	16	(20)	(15)	1	(50)	(50)
Duaklir	20	(29)	(25)	1	n/m	-	-	-	19	(30)	(22)	-	-	-
Bevespi	10	n/m	n/m	-	-	-	10	n/m	-	-	-	-	-	-
Others	88	9	15	68	84	95	-	-	19	(39)	(35)	1	(92)	(92)
Total BioPharma - Respiratory	1,283	9	14	518	18	26	346	28	285	(13)	(7)	134	(8)	(5)
Other medicines														
Nexium	363	(19)	(16)	190	4	12	66	(34)	16	(74)	(74)	91	(13)	(11)
Losec/Prilosec	76	10	16	51	11	17	1	-	18	13	19	6	-	-
Synagis	53	(76)	(76)	-	-	-	25	(81)	28	(69)	(69)	-	-	-
Seroquel XR/IR	37	(61)	(59)	14	(64)	(59)	(6)	n/m	23	(18)	(18)	6	(25)	(25)
Movantik/Moventig	25	(11)	(11)	-	-	-	23	(18)	2	n/m	n/m	-	-	-
Others	22	(66)	(66)	(6)	n/m	n/m	3	(67)	13	(48)	(4)	12	(61)	(42)
Total Other medicines	576	(38)	(36)	249	(6)	(6)	112	(62)	100	(55)	(49)	115	(23)	(18)
TOTAL PRODUCT SALES	5,465	10	14	2,004	14	22	1,786	20	982	(12)	(6)	693	13	16

8 Sequential quarterly Product Sales - 2019

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

..

	Q1 2019 \$m	Actual %	CER %	Q2 2019 \$m	Actual %	CER%	Q3 2019 \$m	Actual %	CER %	Q4 2019 \$m	Actual %	CER %
Oncology												
Tagrisso	630	6	5									
Imfinzi	295	13	13									
Lynparza	237	13	13									
Iressa	134	20	19									
Calquence	29	21	21									
Legacy:												
Faslodex	254	(6)	(6)									
Zoladex	194	7	5									
Arimidex	51	11	9									
Casodex	48	4	4									
Others	20	(13)	(17)									
Total Oncology	1,892	7	6									
BioPharma - CVRM												
Farxiga	349	(12)	(12)									
Brilinta	348	(7)	(8)									
Onglyza	153	3	3									
Bydureon	142	3	3									
Byetta	30	(6)	(6)									
Symlin	7	(30)	(30)									
Legacy:												
Crestor	335	(5)	(6)									
Seloken/Toprol-XL	225	41	39									
Atacand	50	(14)	(15)									
Others	75	-	-									
Total BioPharma - CVRM	1,714	(2)	(3)									
BioPharma - Respiratory												
Symbicort	585	(8)	(8)									
Pulmicort	383	(2)	(2)									
Daliresp/Daxas	48	(11)	(13)									
Tudorza/Eklira	20	5	-									
Duaklir	20	(9)	(9)									
Fasenra	129	3	2									
Bevespi	10	-	-									
Others	88	(20)	(19)									
Total BioPharma - Respiratory	1,283	(6)	(6)									

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Other medicines			
Nexium	363	(7)	3
Synagis	53	(79)	(90)
Losec/Prilosec	76	27	27
Seroquel XR/IR	37	(34)	(32)
Movantik/Moventig	25	-	-
Others	22	(29)	(54)
Total Other medicines	576	(35)	(41)

TOTAL PRODUCT SALES	5,465	(5)	(7)
---------------------	-------	-----	-----

9 Sequential quarterly Product Sales - 2018

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

	Q1 2018 \$m	Actual %	CER %	Q2 2018 \$m	Actual %	CER %	Q3 2018 \$m	Actual %	CER %	Q4 2018 \$m	Actual %	CER %
Oncology												
Tagrisso	338	11	10	422	25	25	506	20	23	594	17	19
Iressa	132	2	(1)	143	8	8	131	(8)	(5)	112	(15)	(13)
Lynparza	119	19	18	150	26	26	169	13	15	209	24	25
Imfinzi	62	n/m	n/m	122	98	98	187	53	52	262	40	41
Calquence	8	n/m	n/m	12	51	50	18	50	50	24	33	33
Legacy:												
Faslodex	254	7	5	247	(3)	(2)	258	4	7	269	4	5
Zoladex	184	(2)	(4)	192	4	5	194	1	6	182	(6)	(2)
Arimidex	54	(5)	(7)	57	6	6	55	(4)	-	46	(16)	(13)
Casodex	52	(4)	(6)	52	-	(2)	51	(2)	4	46	(10)	(8)
Others	27	(7)	(20)	37	37	50	28	(24)	(22)	23	(18)	13
Total Oncology	1,230	10	8	1,434	17	17	1,597	11	14	1,767	11	13
BioPharma - CVRM												
Farxiga	299	(10)	(11)	340	14	15	355	4	7	397	12	13
Brilinta	293	(2)	(4)	316	8	9	336	6	9	376	12	13
Onglyza	129	(28)	(29)	126	(2)	(2)	140	11	14	148	6	8
Bydureon	139	(5)	(5)	155	12	11	152	(2)	(1)	138	(9)	(9)
Byetta	31	(35)	(38)	29	(7)	(3)	34	17	17	32	(6)	(6)
Symlin	9	(31)	(31)	7	(22)	(22)	8	14	14	10	25	25
Legacy:												
Crestor	389	(35)	(36)	338	(13)	(12)	353	4	8	353	-	2
Seloken/Toprol-XL	200	19	18	173	(14)	(13)	179	3	10	160	(11)	(8)
Atacand	71	(3)	(3)	66	(8)	(8)	65	(2)	5	58	(11)	(9)
Others	85	6	4	73	(13)	(11)	73	(3)	-	75	3	3
Total BioPharma - CVRM	1,645	(15)	(17)	1,623	(1)	-	1,695	4	8	1,747	3	5
BioPharma - Respiratory												
Symbicort	634	(16)	(17)	672	6	6	619	(8)	(5)	636	3	4

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Pulmicort	346	(7)	(8)	287	(17)	(17)	264	(8)	(4)	389	47	51
Daliresp/Daxas	38	(28)	(30)	45	19	22	52	16	18	54	4	4
Tudorza/Eklira	34	(19)	(21)	39	15	15	18	(54)	(59)	19	6	11
Duaklir	28	22	17	22	(22)	(19)	23	5	5	22	(4)	-
Fasenra	21	n/m	n/m	65	n/m	n/m	86	32	34	125	45	46
Bevespi	5	(38)	(38)	8	61	60	10	25	25	10	-	-
Others	75	(12)	(20)	88	17	16	70	(20)	(13)	107	53	57
Total BioPharma - Respiratory	1,181	(11)	(13)	1,226	4	4	1,142	(7)	(4)	1,362	19	21
Other medicines												
Nexium	448	5	3	442	(1)	(1)	422	(5)	97	390	(8)	(7)
Synagis	224	(4)	(4)	26	(89)	(88)	164	n/m	n/m	251	53	n/m
Seroquel XR/IR	97	n/m	40	131	35	37	77	(41)	6	56	(27)	(31)
Losec/Prilosec	69	-	(4)	76	10	11	67	(12)	85	60	(10)	(8)
Movantik/Moventig	28	(7)	(7)	24	(14)	(14)	32	33	167	25	(22)	(22)
FluMist/Fluenz	-	n/m	n/m	-	n/m	n/m	35	n/m	n/m	75	n/m	n/m
Others	63	(62)	(45)	48	(25)	(26)	35	(27)	n/m	35	-	31
Total Other medicines	929	(15)	(16)	747	(20)	(20)	832	12	15	892	7	22
Total Product Sales	4,985	(9)	(11)	5,030	1	1	5,266	5	8	5,768	10	13

10 Sequential quarterly Product Sales - 2017

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

	Q1 2017 \$m	Actual %	CER %	Q2 2017 \$m	Actual %	CER%	Q3 2017 \$m	Actual %	CER %	Q4 2017 \$m	Actual %	CER %
Oncology												
Tagrisso	171	16	19	232	36	34	248	7	5	304	23	22
Iressa	124	5	8	137	10	9	137	-	(1)	130	(5)	(6)
Lynparza	57	(8)	(6)	59	4	2	81	37	33	100	23	22
Imfinzi	-	-	-	1	n/m	n/m	-	-	-	18	n/m	n/m
Calquence	-	-	-	-	-	-	-	-	-	3	n/m	n/m
Legacy:												
Faslodex	214	(4)	(3)	248	16	15	241	(3)	(5)	238	(1)	(1)
Zoladex	185	(21)	(12)	178	(4)	(5)	185	4	2	187	1	1
Casodex	56	(7)	(2)	54	(4)	(3)	51	(6)	(9)	54	6	6
Arimidex	52	(9)	(7)	54	4	4	54	-	(2)	57	6	6
Others	26	(10)	(3)	30	15	7	29	(3)	(3)	29	-	3
Total Oncology	885	(5)	-	993	12	11	1,026	3	1	1,120	9	9
BioPharma - 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

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Legacy:												
Crestor	631	-	3	560	(11)	(12)	580	4	2	594	2	2
Seloken/Toprol-XL	186	4	6	181	(3)	(4)	160	(12)	(14)	168	5	4
Atacand	75	(7)	(6)	72	(4)	(5)	80	11	8	73	(9)	(6)
Others	89	3	12	90	1	(3)	80	(11)	(12)	80	-	(4)
Total BioPharma - CVRM	1,779	(2)	-	1,775	-	(1)	1,773	-	(2)	1,939	9	9
BioPharma - 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 BioPharma - Respiratory	1,181	(2)	(1)	1,099	(7)	(8)	1,092	(1)	(3)	1,334	22	21
Other medicines												
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
Seroquel XR/IR	104	(36)	(35)	135	30	30	113	(16)	(16)	156	38	36
Losec/Prilosec	68	15	18	68	-	(3)	66	(3)	(6)	69	5	5
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	105	(48)	44	173	65	n/m	140	(19)	(21)	120	(14)	(15)
Total Other medicines	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

1

Shareholder Information

Announcement
of first half and
second quarter
2019 results 25 July 2019

Announcement
of nine months
and third quarter
2019 results 24 October 2019

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 2019, payable on 9 September 2019, will be 9 August 2019. The ex-dividend date will be 8 August 2019.

Trademarks of the AstraZeneca group of companies and of companies other than AstraZeneca appear throughout this document in italics. AstraZeneca, the AstraZeneca logotype and the AstraZeneca symbol are all trademarks of the AstraZeneca group of companies. Trademarks of companies other than AstraZeneca that appear in this document include Duaklir Genuair, Duaklir, Eklira, Tudorza Pressair 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 Arexis AB or AbbVie Inc. (depending on geography).

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

Addresses for Correspondence

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

[17] Chronic kidney disease.

[18] Human epidermal growth factor receptor 2.

[19] Chronic lymphocytic leukaemia.

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

[21] Substitution of threonine (T) with methionine (M) at position 790 of exon 20 mutation.

[22] Merck & Co., Inc., Kenilworth, NJ, US, known as MSD outside the US and Canada.

- [23] Emerging Markets comprises all remaining Rest of World markets, including Brazil, China, India, Mexico, Russia and Turkey.
- [24] Gross Margin, as a percentage of Product Sales, reflects Gross Profit derived from Product Sales, divided by Product Sales. Movements in Gross Margin are expressed in percentage points.
- [25] EBITDA is a non-GAAP financial measure and is defined in the operating and financial review.
- [26] Other adjustments include fair-value adjustments relating to contingent consideration on business combinations (see Note 4), discount unwind on acquisition-related liabilities (see Note 4) and provision movements related to certain legal matters (see Note 5).
- [27] 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.
- [28] Reflects the adoption of IFRS 16 (see Note 1).
- [29] As per the Q4 2018 results announcement.
- [30] Based on average daily spot rates in FY 2018.
- [31] Based on average daily spot rates in Q1 2019.
- [32] Other currencies include AUD, BRL, CAD, KRW and RUB.
- [33] These priorities were determined, along with a set of nine foundational areas, through a materiality assessment with external and internal stakeholders, respectively. Combined, they ensure the maximum possible benefit to patients, the Company, broader society and the planet. AstraZeneca's sustainability priorities, foundations and commitments align with the United Nations Sustainable Development Goals (SDG), and, in particular, SDG three for 'Good Health'.
- [34] Under regulatory review. The table shown above as at today.
- [35] Phase II trial data, with potential for registration.
- [36] First patient commenced dosing.
- [37] Based on current expectations and event rates, data from the ADAURA trial can be expected in 2022.
- [38] Conducted by the Canadian Cancer Trials Group.
- [39] Chemotherapy and radiation therapy.
- [40] Progression-free survival.
- [41] Overall survival.
- [42] Bacillus Calmette-Guerin.
- [43] Conducted by the ARCAGY/Groupe d'Investigateurs National des Etudes des Cancers Ovariens et du sein.
- [44] Conducted by the National Cancer Institute (US).
- [45] Homologous Recombination Repair mutated.
- [46] Sodium-glucose co-transporter-2.
- [47] Included c.10,000 patients who had no prior index event and c.7,000 patients who had suffered an index event.
- [48] Estimated glomerular filtration rate.
- [49] End-stage renal disease.
- [50] The Company adopted IFRIC 23 'Uncertainty over Income Tax Treatments' from 1 January 2019. See Note 1.
- [51] The Company adopted IFRS 16 'Leases' from 1 January 2019. 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: 26 April 2019

By: /s/ Adrian Kemp

Name: Adrian Kemp

Title: Company Secretary