

ASTRAZENECA PLC
Form 6-K
April 29, 2016

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 2016

Commission File Number: 001-11960

AstraZeneca PLC

2 Kingdom Street, London W2 6BD

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-_____

29 April 2016

Q1 2016 Results

Financial Summary

\$m

% change

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		CER1	Actual
Total Revenue ²	6,115	5	1
Core ³ Op. Profit	1,593	(8)	(12)
Core EPS	\$0.95	(7)	(12)
Reported Op. Profit	1,038	17	11
Reported EPS	\$0.51	26	17

- Total Revenue grew by 5%, driven by a significant increase in Externalisation Revenue
- Core R&D costs increased by 15%, reflecting recent acquisitions; Core R&D costs declined versus Q4 2015
- Core SG&A costs fell by 6% and represented 35% of Total Revenue (Q1 2015: 39%)
- Core EPS declined by 7%, reflecting a significant reduction in Other Operating Income
- Reported Operating Profit grew by 17% to \$1,038m. Reported EPS grew by 26% to \$0.51
- FY 2016 CER guidance unchanged

Commercial Highlights

The Growth Platforms grew by 6%, representing 56% of Total Revenue:

1. Respiratory: +2%. Growth of Pulmicort and newly-acquired medicines offset by a decline in sales of Symbicort
2. Brilinta/Brilique: +46%. Continued encouraging progress; post-MI approval in the EU
3. Diabetes: +23%. Strong sales growth included an increase of +65% in Emerging Markets. Global Farxiga/Forxiga growth of 128%
4. Emerging Markets: +6%. Good China sales growth of +11%; slowdowns in other regions
5. Japan: -7%, reflecting destocking ahead of mandated biennial price reductions from April 2016
6. New Oncology: Contributed \$99m. Launch of Tagrisso in key markets progressing well

Achieving Scientific Leadership: Progress since the last results announcement

Bevespi Aerosphere (previously PT003) - COPD (US)

Regulatory Approvals

Zurampic - gout (EU)

Brilique - post-myocardial infarction (post-MI) (EU)

Tagrisso - lung cancer (JP)

Breakthrough Therapy Designation: durvalumab - bladder cancer (US)

Other Key

Orphan Drug Designation: acalabrutinib - blood cancers (EU); MEDI-551 -

Developments

neuromyelitis optica (US)

Fast Track Designation: MEDI8852 - hospitalised influenza (US)

Advancing The Strategy

- A sharper focus on main therapy areas; additional investment to Oncology
- Collaborations in opportunistic areas to be accelerated
- Streamlining operations, supporting the sharper focus and the reduction in SG&A costs
- Strengthening ability to deliver strategic ambitions

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

“We delivered a first-quarter performance in line with expectations, with the growth in Total Revenue underpinned by the performance of the Growth Platforms. I was particularly pleased with the results in China, where we continued to deliver double-digit sales growth, and with the progress of our New Oncology launches.

“Strong advances were made in our late-stage pipeline, with regulatory approvals for Bevespi Aerosphere in the US for COPD, Brilique in the EU for post-myocardial infarction and Tagrisso in Japan for lung cancer. Looking ahead, we anticipate increased newsflow across the pipeline, including a number of regulatory decisions and data readouts, particularly in Oncology.

“As we continue to make encouraging progress with our priorities and our pipeline grows faster than anticipated, we are further sharpening our strategic focus on our main therapy areas, intensifying our efforts in Oncology and accelerating collaborations in opportunistic areas. We are also driving greater efficiency across the organisation to support the advancement of our strategy.”

Advancing The Strategy Through Sharper Focus

AstraZeneca continues to make significant progress towards the Total Revenue target of \$45bn* by 2023. The Company has increased pipeline productivity, built therapy-area leadership, developed the Growth Platforms and transformed AstraZeneca’s culture. The shape of the business is evolving rapidly, with a growing number of specialty-care medicines, in particular in Oncology.

In line with the strategy designed to deliver benefits to patients and value for shareholders, the Company today announces further focus on the main therapy areas to drive greater productivity across the organisation. The prioritisation of investments will be sharpened, enabling the allocation of additional investment to Oncology. Alongside this, the Company will continue to work with others in the opportunity-led parts of the portfolio, such as Infection, Neuroscience and inflammatory diseases outside Respiratory.

This focus will streamline further AstraZeneca’s operations, primarily in commercial and manufacturing. This, together with the drive for greater efficiency, will deliver a material decline in Core SG&A costs in FY 2016 and FY 2017.

These changes will enhance operational effectiveness and, once implemented by the end of FY 2017, are expected to generate net annualised benefits of \$1.1bn1 that will be reflected primarily within Core SG&A costs. Associated with the changes, the Company expects to incur \$1.5bn1 in one-time restructuring charges, the majority of which will be cash costs. Final estimates for programme costs, benefits and colleague impacts will be subject to consultation.

FY 2016 Guidance

All guidance for FY 2016 is unchanged and is shown at CER1.

Total Revenue	A low to mid single-digit percentage decline
Core Earnings Per Share	A low to mid single-digit percentage decline

The above guidance incorporates the dilutive effects arising from the Acerta Pharma B.V. (Acerta Pharma) and ZS Pharma, Inc. (ZS Pharma) transactions announced in FY 2015. The guidance also assumes the loss of exclusivity for Crestor in the US from May 2016.

Externalisation Revenue is expected to be ahead of that in FY 2015, including an increasing element of recurring income arising from prior agreements. This is in line with the Company’s long-term business model, which includes externalisation as part of the portfolio-management strategy.

Externalisation activities, a result of increasing R&D productivity and the focus on three main therapy areas, relate to specific risk and reward-sharing strategic collaborations. They broaden, accelerate and maximise the development and commercialisation potential for a number of the Company’s medicines. Initial and milestone revenue, together with sales-related revenue arising from externalisation activities, are included in the Company’s financial statements as Externalisation Revenue.

Core R&D costs are expected to be at a similar level to FY 2015. The Company is committed to materially reducing Core SG&A costs in FY 2016 versus the prior year. These measures are based on constant exchange rates.

FY 2016 Currency Impact

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Based on average exchange rates in the quarter and the Company's published currency sensitivities, an adverse full-year impact of around 2% from currency movements on Total Revenue would be anticipated. A similar impact is anticipated in respect of Core EPS in the full year. Further details on currency sensitivities are contained within the Operating and Financial Review.

* At FY2013 exchange rates

Pipeline: Forthcoming Major Newsflow

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

benralizumab - severe asthma: Data readout

Q2 2016 saxagliptin/dapagliflozin - type-2 diabetes: Regulatory submission (US)
ZS-9 - hyperkalaemia: Regulatory decision (US)

Lynparza - gastric cancer: Data readout

Bevespi Aerosphere - COPD (EU): Regulatory submission (EU)
benralizumab - severe asthma: Regulatory submission (US, EU)

Brilinta/Brilique - peripheral arterial disease (PAD): Data readout
saxagliptin/dapagliflozin: Regulatory decision (EU)
roxadustat - anaemia: Rolling regulatory submission (CN)

H2 2016 Lynparza - breast cancer: Data readout
Lynparza - ovarian cancer (2nd line): Data readout
cediranib - ovarian cancer: Regulatory decision (EU)
selumetinib - lung cancer: Data readout
durvalumab - head and neck cancer (HAWK): Data readout
acalabrutinib - blood cancer: Data readout, regulatory submission (US)

CAZ AVI - serious infections: Regulatory decision (EU)

H1 2017

brodalumab - psoriasis: Regulatory decision

Brilinta/Brilique - PAD: Regulatory submission
ZS-9: Regulatory decision (EU)

Lynparza - gastric cancer: Regulatory submission
Lynparza - breast cancer: Regulatory submission
Lynparza - ovarian cancer (2nd line): Regulatory submission
Lynparza - ovarian cancer (1st line): Data readout
selumetinib - lung cancer: Regulatory submission
durvalumab - head and neck cancer (HAWK): Regulatory submission
durvalumab - lung cancer (PACIFIC): Data readout
durva + treme - lung cancer (MYSTIC, ARCTIC): Data readout

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durva + treme - head and neck cancer (CONDOR): Data readout

Notes

1. All growth rates and guidance are shown at constant exchange rates (CER) unless otherwise specified.
2. Total Revenue is defined as Product Sales and Externalisation Revenue.
3. See the Operating and Financial Review for a definition of Core financial measures and a reconciliation of Core to Reported financial measures.

The performance shown in this announcement covers the three-month period to 31 March 2016 (the quarter) compared to the three-month period to 31 March 2015 (the comparative quarter).

Results Presentation

A conference call for investors and analysts, hosted by management, will begin at midday UK time today. Details can be accessed via www.astrazeneca.com/investors.

Reporting Calendar

The Company intends to publish its first-half financial results on 28 July 2016.

About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three main therapy areas - Respiratory, Inflammation and Autoimmunity, Cardiovascular and Metabolic Disease and Oncology - as well as in Infection and Neuroscience. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information, please visit: www.astrazeneca.com.

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Key: RIA - Respiratory, Inflammation & Autoimmunity, CVMD - Cardiovascular & Metabolic Disease, ING - Infection, Neuroscience & Gastrointestinal

Operating and Financial Review

All narrative on growth and results in this section relates to Core performance, based on constant exchange rates (CER) unless stated otherwise. Financial figures are in US\$ millions (\$m). The performance shown in this announcement covers the three-month period to 31 March 2016 (the quarter) compared to the three-month period to 31 March 2015 (the comparative quarter). Core measures, which are presented in addition to Reported financial information, are non-GAAP measures provided to enhance understanding of the Company's underlying financial performance. Core financial measures are adjusted to exclude certain significant items, such as:

- amortisation and impairment of intangibles, including impairment reversals but excluding any charges relating to IT assets
- charges and provisions related to our global restructuring programmes (this will include such charges that relate to the impact of our global restructuring programmes on our capitalised IT assets)
- other specified items, principally comprising legal settlements and acquisition-related costs, which include fair value adjustments and the imputed finance charge relating to contingent consideration on business combinations

More detail on the nature of these measures is given on page 64 of the Annual Report and Form 20-F Information 2015.

Total Revenue

Total Revenue increased by 5% to \$6,115m, comprising Product Sales of \$5,565m (up by 1%) and Externalisation Revenue of \$550m (up by 78%). Based on actual exchange rates, Total Revenue increased by 1%, reflecting the particular weakness of key trading currencies against the US dollar.

Product Sales

The level of growth in Product Sales reflected the US market entry of Nexium generic products in 2015, as well as the level of competition impacting sales of Symbicort. Overall US sales grew by 4% in the quarter, with sales in Europe down by 4%.

Within Product Sales, the Growth Platforms grew by 6%, representing 56% of Total Revenue:

Growth Platform	Product Sales (\$m)	% CER change
Respiratory	1,207	2
Brilinta/Brilique	181	46
Diabetes	578	23
Emerging Markets	1,465	6
Japan	429	(7)
New Oncology ¹	99	n/m
TOTAL²	3,435	6

¹New Oncology comprises Lynparza, Iressa (US) and Tagrisso

²Total Product Sales for Growth Platforms adjusted to remove duplication on a product and regional basis

Externalisation Revenue

Externalisation Revenue recognised in the quarter amounted to \$550m and primarily comprised the following:

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Medicine	Partner	Region	\$m
Plendil	China Medical System Holdings Ltd (CMS) - commercialisation rights - initial revenue	China	298
Nexium OTC 20mg	Pfizer Inc. - milestone revenue	Global Rights	93
Moventig	ProStrakan Group plc (ProStrakan) - commercialisation rights - initial revenue	EU	70
Authorised Crestor generic	Daiichi Sankyo Company (Daiichi Sankyo) - distribution rights - initial revenue	Japan	42

Examples of sustainable future Externalisation Revenue are shown below:

Announcement Date	Medicine / NME*	Partner	Region	Externalisation Revenue
29 October 2010	Nexium	Daiichi Sankyo	Japan	· Initial \$100m milestone · Sales-related revenue (undisclosed)
19 March 2015	Movantik	Daiichi Sankyo	US	· Initial \$200m milestone · Up to \$625m in sales-related revenue
1 September 2015	brodalumab	Valeant Pharmaceuticals Inc.	Global (excl. Japan and other Asian markets)	· Initial \$100m milestone · \$170m pre-launch · \$175m upon launch · Ongoing profit share
2 September 2015	FluMist	Daiichi Sankyo	Japan	· Initial (undisclosed) milestone · Sales-related revenue (undisclosed)

*NME = New Molecular Entity

Product Sales

The performance of a selection of key medicines is shown below. A geographical split of the performance is shown in Note 7.

	\$m	% Change	
		CER	Actual
Respiratory, Inflammation & Autoimmunity			
Symbicort	749	(7)	(11)
Pulmicort	310	14	8
Tudorza/Eklira	39	33	30
Daliresp	31	n/m	n/m
Duaklir	13	n/m	n/m
Others	65	(4)	(11)
TOTAL	1,207	2	(3)

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Cardiovascular & Metabolic Disease			
Brilinta/Brilique	181	46	38
Onglyza	211	20	15
Farxiga/Forxiga	165	128	117
Bydureon	135	11	10
Byetta	62	(30)	(31)
Legacy:			
Crestor	1,156	2	(1)
Seloken/Toprol-XL	185	5	(5)
Atacand	71	(17)	(25)
Others	126	(21)	(26)
TOTAL	2,292	7	3
Oncology			
Iressa	135	(1)	(6)
Tagrisso	51	n/m	n/m
Lynparza	44	n/m	n/m
Legacy:			
Faslodex	190	24	18
Zoladex	178	(1)	(8)
Casodex	62	(9)	(11)
Arimidex	57	(3)	(8)
Others	21	(37)	(40)
TOTAL	738	15	9
Infection, Neuroscience & Gastrointestinal			
Nexium	463	(24)	(28)
Synagis	244	20	20
Seroquel XR	202	(21)	(23)
Losec/Prilosec	75	(18)	(22)
FluMist/Fluenz	5	(29)	(29)
Movantik/Moventig	17	n/m	n/m
Others	322	(9)	(16)
TOTAL	1,328	(13)	(17)
TOTAL PRODUCT SALES	5,565	1	(3)

Product Sales Summary

Respiratory, Inflammation & Autoimmunity

Symbicort

Symbicort sales declined during the quarter by 7% to \$749m. The decline was driven primarily by continuing price pressures, partly offset by volume growth.

In the US, sales of \$322m represented a decline of 6%. This reflected the impact of the level of competition in the quarter, partly offset by encouraging volume growth that was driven by sustained total and new-to-brand prescription share gains.

In Europe, sales declined by 19% to \$231m, a result of declining market demand in the class, as well as increased competition from analogue medicines. In contrast, Emerging Markets sales grew by 18% to \$105m; China sales grew by 48% to \$41m.

Pulmicort

Pulmicort sales were \$310m in the quarter, an increase of 14%. Growth reflected the performance of Pulmicort Respules in Emerging Markets, where Pulmicort sales grew by 24% to \$207m. China sales increased by 34% to \$182m partly reflecting the increasing prevalence of acute chronic obstructive pulmonary disease (COPD) and paediatric asthma. To address this growing prevalence, AstraZeneca continued its expansion of treatment centres, as well as provided increased access to home-based patient care systems.

Tudorza/Eklira

Sales in the quarter of \$39m were driven by the strong volume performance in Rest of World markets, where Eklira continued to outperform the long-acting muscarinic antagonist (LAMA) market.

Daliresp

Rights were acquired in March 2015 from Actavis for Daliresp in the US and Canada. During the quarter sales were \$31m; new-to-brand prescriptions increased by 10% versus Q4 2015.

Duaklir

Duaklir has launched successfully in more than 25 countries, with sales of \$13m during the quarter reflecting the encouraging levels of share achieved in major European markets. Further launches will follow in due course.

Cardiovascular & Metabolic Disease

Brilinta/Brilique

During the quarter, sales of Brilinta/Brilique increased by 46% to \$181m.

US sales for the quarter were \$70m, an increase of 52%. The expanded indication launched in the second half of 2015 and was underpinned by new-to-brand prescription market share of 12%. Brilinta remains the branded oral anti-platelet market leader in the US.

Sales of Brilique in Europe delivered growth of 19% to \$60m, which reflected the indication-leadership position attained across a number of markets.

Emerging Markets sales grew by 109% to \$41m, with China representing the largest single market in the region for Brilinta, where sales were up by 229% to \$22m, despite the medicine not being included in the National Drug Reimbursement List.

Onglyza

Sales were up by 20% in the quarter to \$211m as the DPP-4 class continued to demonstrate volume growth.

Sales in the US increased by 27% to \$124m following the impact of changes in the level of access support. Continued competitive pressures in the DPP-4 class, however, drove further market share erosion, which was partially offset by a higher net price.

Sales in Europe declined by 6% to \$33m, a lower rate of decline compared to the overall DPP-4 class. Emerging Markets sales increased by 20% to \$36m.

Farxiga/Forxiga

Sales of Farxiga/Forxiga were \$165m, up 128%; sales in the US of \$94m represented growth of 154%. Encouraging levels of patient access and greater promotional activity drove volume and total prescription share growth during the period.

Sales in Europe for Forxiga were up 72% to \$41m in the quarter. The medicine continued to lead the SGLT2 class. Emerging Markets sales increased by 145% to \$21m, reflecting launch activity.

Bydureon/Byetta

GLP-1 class volumes grew by 25% during the quarter and continues to be the fastest-growing class for patients with type-2 diabetes. Combined sales for Bydureon/Byetta were \$197m, with Bydureon sales, up 11%, representing approximately 69% of total Bydureon/Byetta sales. Byetta sales declined by 30% to \$62m with the Company's focus switching to Bydureon.

In the US, Bydureon sales were \$108m, an increase of 2% despite increased competition from new market entrants. Sales in Europe increased by 44% to \$23m, reflecting the Company's ongoing effort to expand its Diabetes presence.

Legacy: Crestor

Sales of Crestor increased in the quarter by 2% to \$1,156m.

In the US, Crestor sales increased by 4% to \$636m, driven by a higher net price that was partially offset by the impact of destocking. Crestor continued to maintain both total and new-to-brand prescription levels of market share.

In Europe, sales declined by 7% to \$212m, reflecting the increasing prevalence of generic-medicine competition. Crestor consolidated its position as the leading statin in Japan, with sales growth in the quarter of 2% to \$108m. Sales in China grew by 24% to \$89m.

Oncology

Iressa

Sales of Iressa in the quarter declined by 1% to \$135m, driven by the competitive environment in Japan where sales were down by 7% to \$26m. In Emerging Markets sales decreased by 6% to \$67m, with China sales decreasing by 11% to \$37m, again a result of strong levels of competition.

Following the US launch in July 2015, Iressa saw an encouraging number of new-patient starts as demand volume grew. In Europe, sales increased by 3% to \$34m; volume share was maintained.

Tagrisso

Sales of Tagrisso were \$51m, with the US representing 88% of the total, with increasing testing rates driving the number of new-patient starts. During the period, Tagrisso also received regulatory approvals in the EU and Japan.

Lynparza

Sales of Lynparza reached \$44m in the quarter; US sales of \$28m were driven primarily by higher demand and net price. Sales in Europe were \$14m, following successful launches in France and Germany. Further launches included Spain, Australia, Israel and Switzerland, and the medicine is now available in 21 countries.

Legacy: Faslodex

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Faslodex sales increased by 24% to \$190m. US sales grew by 19% to \$99m, reflecting higher levels of demand. Europe sales were up 18% to \$56m in the quarter, with Emerging Market sales of \$21m representing growth of 69%. Supported by the 2015 launch of 500mg Faslodex, China sales accelerated to \$5m, up 150%.

Legacy: Zoladex

Sales declined by 1% to \$178m, primarily driven by a decline in Europe of 9% to \$39m. China sales were \$32m, reflecting growth of 10%.

Infection, Neuroscience & Gastrointestinal

Nexium

Sales of Nexium declined by 24% in the quarter to \$463m due primarily to the impact of generic-medicine competition in the US and Europe.

US sales declined by 42% to \$131m following the loss of exclusivity and changes in managed-care contracts. Sales in Europe declined by 16% to \$60m with Emerging Markets sales declining by 9% to \$177m. Japan sales decreased by 24% to \$69m.

Synagis

Sales of Synagis increased by 20% to \$244m. A 1% decline in US sales in the quarter to \$160m reflected the ongoing reduction in demand due to the results of the American Academy of Pediatrics Committee on Infectious Disease guidelines issued in 2014. These guidelines were more restrictive than the approved label, which further reduced patients eligible for preventative therapy with Synagis.

Seroquel XR

Sales declined by 21% to \$202m. In the US sales were \$144m, representing a decline of 15%. Sales in Europe fell by 41% to \$35m, due primarily to the impact of generic-medicine competition.

FluMist/Fluenz

Sales in the quarter declined to \$5m, a decrease of 29%, reflecting primarily in lower volumes.

Movantik/Moventig

Sales for the quarter totalled \$17m, with all of the sales coming from the US where patients switched from over-the-counter laxative medicines or prescription laxative medicines to Movantik. The medicine is the leading branded gastrointestinal medicine amongst opioid-induced constipation prescribing specialists.

Regional Product Sales

	\$m	Q1 2016 % Change	
		CER	Actual
US	2,246	4	4
Europe	1,218	(4)	(9)
Established ROW	636	(7)	(10)
Japan	429	(7)	(6)
Canada	116	(1)	(14)
Other Established ROW	91	(12)	(22)

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Emerging Markets		1,465	6	(4)
	China	774	11	7
	Ex. China	691	-	(14)
Total		5,565	1	(3)

US

US sales increased in the quarter by 4% to \$2,246m, driven primarily by the performance of several of the Company's Growth Platforms. The growth was underpinned by favourable performances for Farxiga (up by 154% to \$94m), Brilinta (up by 52% to \$70m) and Onglyza (increasing by 27% to \$124m). Crestor sales were \$636m, a 4% increase versus the comparative quarter; destocking continued, ahead of the loss of exclusivity in May 2016.

Europe

Sales in Europe declined by 4% to \$1,218m, driven primarily by ongoing price erosion. The strong growth of Forxiga (up by 72% to \$41m) and Brilique (increasing by 19% to \$60m) was offset by a 19% decline in Symbicort sales to \$231m, which reflected adverse pricing and lower volumes driven by competition from analogue medicines. Duaklir sales increased to \$12m, representing strong market-share growth in Germany and UK.

Established ROW

Sales in the Established Rest Of World (ROW) declined by 7% to \$636m. Japan sales declined by 7% to \$429m, reflecting impact of destocking ahead of the biennial price cut in April 2016. Sales of Crestor increased by 2% to \$108m. Nexium sales declined by 24% to \$69m; the medicine however retained the position as the number one brand by market share volume and new-to-brand prescription share. Canada sales declined by 1% to \$116m.

Emerging Markets

Emerging Markets sales increased by 6% to \$1,465m, despite downward pressure from macro-economic conditions in Latin America and government price initiatives in the Middle East. China, with sales up by 11% to \$774m, represented 53% of Emerging Markets sales. Brazil sales grew by 19% to \$83m. Sales in CVMD (\$37m) and Oncology (\$17m) contributed 65% to the overall sales achieved in Brazil, reflecting the number of innovative products available to physicians and patients. Russia sales were up by 5% to \$48m.

Financial Performance

	Reported	Restructuring	Intangible Amortisation & Impairments	Diabetes Alliance	Other	Core Q1 2016	Core Q1 2015	% Change CER	% Change Actual
Product Sales	5,565	-	-	-	-	5,565	5,748	1	(3)
Externalisation Revenue	550	-	-	-	-	550	309	78	78
Total Revenue	6,115	-	-	-	-	6,115	6,057	5	1
Cost of Sales	(1,004)	9	29	-	-	(966)	(953)	6	1
Gross Profit	5,111	9	29	-	-	5,149	5,104	5	1
Gross Margin1	82.5%					83.1%	83.4%	-0.7	-0.3
Distribution	(76)	-	-	-	-	(76)	(77)	6	(1)

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% Total Revenue	1.2%					1.2%	1.3%	-	-0.1
R&D	(1,480)	38	13	-	-	(1,429)	(1,280)	15	12
% Total Revenue	24.2%					23.4%	21.1%	-2.0	-2.3
SG&A	(2,572)	108	229	108	-	(2,127)	(2,368)	(6)	(10)
% Total Revenue	42.1%					34.8%	39.1%	+4.2	+4.3
Other Operating Income	55	-	21	-	-	76	426	(81)	(82)
% Total Revenue	0.9%					1.2%	7.0%	-5.7	-5.8
Operating Profit	1,038	155	292	108	-	1,593	1,805	(8)	(12)
% Total Revenue	17.0%					26.1%	29.8%	-3.6	-3.7
Net Finance Expense	(311)	-	-	97	57	(157)	(118)		
Joint Ventures	(4)	-	-	-	-	(4)	(5)		
Profit Before Tax	723	155	292	205	57	1,432	1,682	(10)	(15)
Taxation	(98)	(33)	(66)	(47)	(5)	(249)	(312)		
Tax Rate	14%					17%	19%		
Profit After Tax	625	122	226	158	52	1,183	1,370	(9)	(14)
Non-controlling Interests	21	(5)	-	-	-	16	(2)		
Net Profit	646	117	226	158	52	1,199	1,368	(7)	(12)
Weighted Average Shares	1,264	1,264	1,264	1,264	1,264	1,264	1,263		
Earnings Per Share	0.51	0.09	0.18	0.13	0.04	0.95	1.08	(7)	(12)

1 Gross Margin reflects Gross Profit derived from Product Sales, divided by Product Sales

2 All financial figures, except Earnings Per Share, are in \$ millions (\$m). Weighted Average Shares are in millions.

Profit and Loss

Gross Profit

Core Gross Profit increased by 5% in the quarter to \$5,149m. Excluding the impact of externalisation, the Core Gross-Profit margin decreased by one percentage point, reflecting a 6% increase in the Cost of Sales.

Operating Expenses

Core R&D costs were up 15% in the quarter to \$1,429m as the Company continued to focus on its pipeline. The increase reflected the number of potential medicines in pivotal trials as well as the absorption of the R&D costs of ZS Pharma and Acerta Pharma. Excluding the impact of these two investments, Core R&D costs would have increased by 9%. Full-year total Core R&D costs are expected to be at a similar level to FY 2015.

In line with prior commitments to materially reduce Core SG&A costs over the full year, Core SG&A costs declined by 6% in the quarter to \$2,127m. Core SG&A costs declined by four percentage points as a proportion of Total

Revenue.

Other Operating Income

Core Other Operating Income of \$76m primarily reflected royalty income arising from a number of prior agreements, including those relating to HPV vaccines and ertapenem. The level of income decreased by 81% versus the comparative quarter.

Core Operating Profit

Core Operating Profit declined by 8% to \$1,593m in the quarter. The Core Operating Margin declined by four percentage points to 26% of Total Revenue. The declines primarily reflected the level of Core Other Operating Income versus the comparative quarter, while the Company continued to invest in the pipeline and the Growth Platforms.

Reported Operating Profit

Reported Operating Profit increased by 17% to \$1,038m, principally due to lower amortisation charges versus the comparative quarter.

Finance Expense

The Core Net Finance Expense was \$157m in the quarter, compared to \$118m in the comparative quarter. The increase reflected the increase in net debt, driven itself by the acquisition of ZS Pharma and the investment in Acerta Pharma.

The Reported Net Finance Expense of \$311m included a charge of \$154m relating to the discount unwind on acquisition-related liabilities recognised on business combinations.

Taxation

The Core and Reported tax rates for the quarter were 17% and 14% respectively. These tax rates were lower than the UK Corporation Tax Rate of 20%, mainly due to the impact of the geographical mix of profits. The cash tax paid for the quarter was \$205m, representing 14% of Core Profit Before Tax and 28% of Reported Profit Before Tax. Both the Core and Reported tax rates for the comparative quarter were around 19%.

Earnings Per Share (EPS)

Core EPS in the quarter declined by 7% to \$0.95. Reported EPS increased by 26% to \$0.51, again, principally relating to the lower amortisation charge.

Productivity

AstraZeneca continues to make significant progress towards the Total Revenue target of \$45bn* by 2023. The Company has increased pipeline productivity, built therapy-area leadership, developed the Growth Platforms and transformed AstraZeneca's culture. The shape of the business is evolving rapidly, with a growing number of specialty-care medicines, in particular in Oncology.

In line with the strategy designed to deliver benefits to patients and value for shareholders, the Company today announces further focus on the main therapy areas to drive greater productivity across the organisation. The prioritisation of investments will be sharpened, enabling the allocation of additional investment to Oncology. Alongside this, the Company will continue to work with others in the opportunity-led parts of the portfolio, such as Infection, Neuroscience and inflammatory diseases outside Respiratory.

This focus will streamline further AstraZeneca's operations, primarily in commercial and manufacturing. This, together with the drive for greater efficiency, will deliver a material decline in Core SG&A costs in FY 2016 and FY 2017.

These changes will enhance operational effectiveness and, once implemented by the end of FY 2017, are expected to generate net annualised benefits of \$1.1bn that will be reflected primarily within Core SG&A costs. Associated with the changes, the Company expects to incur up to \$1.5bn in one-time restructuring charges, the majority of which will be cash costs. Final estimates for programme costs, benefits and colleague impacts will be subject to consultation.

These new initiatives are in addition to the ongoing restructuring programmes described in the Annual Report and Form 20-F Information 2015. The restructuring charges over the period from April 2016 through to the end of FY 2017 for all programmes are anticipated to be \$2.4bn in aggregate, with approximately \$1.5bn of these restructuring costs expected to be taken in the remainder of FY 2016, with the balance in FY 2017.

* At FY2013 exchange rates

Cash Flow and Balance Sheet

Cash Flow

The Company generated a cash inflow from operations of \$1,583m, compared with \$415m in the comparative quarter. Cash generated from operations reflected a decrease in working capital and short-term provisions of \$64m compared to an increase of \$664m.

Net cash outflows from investing activities were \$2,887m compared with \$556m in the comparative quarter. The increase reflected the net cash outflow of \$2,383m on the investment in Acerta Pharma.

Net cash outflows from financing activities were \$1,361m. This compared to an outflow of \$2,569m in the comparative quarter. The reduction reflected the impact of a loan repayment in the comparative quarter.

The cash payment of contingent consideration on business considerations in respect of the Bristol-Myers Squibb Company share of the global Diabetes alliance amounted to \$26m in the quarter.

Debt and Capital Structure

At 31 March 2016, outstanding gross debt (interest-bearing loans and borrowings) was \$16,312m (31 March 2015: \$10,569m). Of the gross debt outstanding at 31 March 2016, \$2,168m was due within one year (31 March 2015: \$2,299m). The Company's net debt position at 31 March 2016 was \$11,751m (31 December 2015: \$7,762m).

Shares in Issue

During the quarter, 0.4 million shares were issued in respect of share option exercises for a consideration of \$18m. The total number of shares in issue as at 31 March 2016 was 1,265 million.

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 opportunities.

Sensitivity: Foreign-Exchange Rates

The Company provides the following currency sensitivity information:

Average Exchange Rates
Versus USD

Impact Of 5% Weakening In
Exchange Rate Versus USD

Currency	Primary Relevance	FY 2015	YTD 2016 ¹	Change %	Total Revenue	Core Operating Profit
EUR	Product Sales	0.90	0.91	(1)	(178)	(103)
JPY	Product Sales	121.04	115.35	5	(102)	(66)
CNY	Product Sales	6.28	6.54	(4)	(133)	(62)
SEK	Costs	8.43	8.45	-	(8)	71
GBP	Costs	0.65	0.70	(6)	(34)	96
Other ³					(201)	(122)

¹Based on average daily spot rates YTD to the end of March 2016

²Based on 2015 actual results at 2015 actual exchange rates

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

Currency Hedging

AstraZeneca monitors the impact of adverse currency movements on a portfolio basis, recognising correlation effects. The Company may hedge to protect against adverse impacts on cash flow over the short to medium term. As at 31 March 2016, AstraZeneca had hedged around 91% of forecast short-term currency exposure that arises between the booking and settlement dates on non-local currency purchases and Product Sales.

Corporate and Business Development Update

The highlights of the Company's corporate and business development activities since the prior results announcement on 4 February 2016 are shown below.

a) Agreement with CMS - Plendil in China

On 29 February 2016, AstraZeneca announced it had entered into a licensing agreement with CMS for the commercialisation rights in China to its calcium channel blocker, Plendil (felodipine). Plendil was first approved in China in 1995 for the treatment of hypertension, or high blood pressure, and in FY 2015 achieved Product Sales of \$189m. AstraZeneca recognised income of \$298m in the quarter.

AstraZeneca will maintain a significant, long-term interest in the future value derived from Plendil sales in China. As such, the aforementioned income has been presented as Externalisation Revenue within the Company's financial statements. AstraZeneca will manufacture and supply the medicine to CMS and will retain the global rights to Plendil outside China.

b) Agreement with CMS - Imdur outside the US

On 29 February 2016, AstraZeneca announced that it had entered into an agreement with CMS and its associated company, Tibet Rhodiola Pharmaceutical Holding Co., for the divestment of the global rights to Imdur outside the US. Imdur is a mature medicine for the prevention of angina in patients with heart disease; its global sales outside the US were \$57m in FY 2015. Under the terms of this agreement, AstraZeneca will receive \$190m for the rights to Imdur in all markets outside the US. The divestment is expected to close in the second quarter of 2016 and income from the agreement will be reported as Core Other Operating Income.

c) Agreement with ProStrakan - Moventig in Europe

On 1 March 2016, AstraZeneca announced that it had entered into an agreement with ProStrakan for the rights to Moventig (naloxegol) in the EU, Iceland, Norway, Switzerland and Liechtenstein. Moventig is the first once-daily, oral peripherally-acting mu-opioid receptor antagonist approved in Europe for the treatment of opioid-induced constipation in adult patients who have had an inadequate response to laxatives.

Under the terms of the agreement, ProStrakan made an initial payment to AstraZeneca of \$70m in the quarter to acquire the rights to sell and develop Moventig in the aforementioned geographies. AstraZeneca will maintain a significant, long-term interest in the future of Moventig. As such, the income described has been presented as Externalisation Revenue within the Company's financial statements.

d) Agreement with Eli Lilly and Company (Lilly) - AZD3293

On 8 April 2016 Lilly announced that AMARANTH, a Phase II trial of AZD3293, an oral beta secretase cleaving enzyme (BACE) inhibitor currently in development as a potential treatment for early Alzheimer's disease, will move fully into Phase III of the programme.

Under the terms of the agreement, the decision to move AZD3293 into Phase III testing triggered a further milestone payment from Lilly to AstraZeneca of \$100m, which will be reported as Externalisation Revenue within the Company's financial statements in the second quarter.

e) Agreement with Ironwood Pharmaceuticals, Inc. (Ironwood) - Zurampic in US

On 26 April 2016, AstraZeneca announced that it had entered into a licensing agreement with Ironwood Pharmaceuticals, Inc. (Ironwood) for the exclusive US rights to Zurampic (lesinurad). Zurampic was approved by the FDA in December 2015, in combination with a xanthine oxidase inhibitor (XOI), for the treatment of hyperuricemia associated with uncontrolled gout.

Under the terms of the agreement, Ironwood will acquire exclusive US rights to Zurampic. In addition, Ironwood will gain the exclusive US rights to the fixed-dose combination of lesinurad and allopurinol. AstraZeneca plans to submit the fixed-dose combination programme for regulatory review in the second half of 2016. Ironwood will pay AstraZeneca sales-related and other milestone payments of up to \$265m and tiered single-digit royalties on Product Sales. AstraZeneca will manufacture and supply Zurampic, provide certain support and services to Ironwood and undertake the FDA post-approval commitment on their behalf.

Research and Development Update

A comprehensive table with AstraZeneca's pipeline of medicines in human trials can be found later in this document.

Since the results announcement on 4 February 2016 (the period):

Regulatory Approvals	4	- Bevespi Aerosphere - COPD (US) - Zurampic - gout (EU) - Brilique - post-MI (EU) - Tagrisso - lung cancer (JP)
Other Key Developments	4	- Breakthrough Therapy Designation: - durvalumab - bladder cancer (US)

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- Orphan Drug Designation:
 - acalabrutinib - blood cancers (EU)
 - MEDI-551 - neuromyelitis optica (US)
- Fast Track Designation:
 - MEDI8852 - hospitalised influenza (US)

New Molecular Entities
(NMEs) in Pivotal Trials or
under Regulatory Review*

13

RIA

- brodalumab - psoriasis*
- benralizumab - severe asthma
- tralokinumab - severe asthma
- PT010 - COPD
- anifrolumab - lupus (SLE)

CVMD

- roxadustat - anaemia
- ZS-9* - hyperkalaemia

Oncology

- cediranib* - ovarian cancer
- durvalumab - multiple cancers
- acalabrutinib - blood cancers
- moxetumomab pasudotox - leukaemia
- selumetinib - lung cancer

ING

- CAZ AVI* - serious infections

Projects in clinical pipeline

124

Key: RIA - Respiratory, Inflammation & Autoimmunity, CVMD - Cardiovascular & Metabolic Disease, ING - Infection, Neuroscience & Gastrointestinal

1. Respiratory, Inflammation & Autoimmunity (RIA)

Five potential medicines in RIA remain in pivotal trials or under registration. AstraZeneca's Respiratory portfolio includes a range of differentiated potential medicines such as novel combinations, biologics and devices for the treatment of asthma and COPD. The pipeline also includes a number of potential medicines in inflammatory and autoimmune diseases within areas such as psoriasis, systemic lupus and rheumatoid arthritis.

a) Symbicort (COPD)

During the period, AstraZeneca obtained approval for Symbicort pMDI (pressurised metered dose inhaler device) in the EU. Symbicort pMDI is now indicated for use in adults, aged 18 and older, for the symptomatic treatment of COPD in patients with a forced expiratory volume in one second (FEV1) below 70% of the predicted normal (post-bronchodilator) level and an exacerbation history, despite regular bronchodilator therapy. This development further augments Symbicort's prevailing approvals in the EU.

b) Bevespi Aerosphere (COPD)

During the period the FDA approved Bevespi Aerosphere (glycopyrrolate and formoterol fumarate) inhalation for the long-term, maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema. Bevespi Aerosphere is the first LAMA/LABA medicine to be delivered in a pMDI and the first medicine using AstraZeneca's unique Co-Suspension technology.

c) Zurampic (gout)

On 19 February 2016, Zurampic (lesinurad) 200mg tablets received marketing authorisation in the EU in combination with a XOI for the adjunctive treatment of hyperuricemia in adult gout patients who have not achieved target serum uric-acid levels with an XOI alone. The EU approval of Zurampic was based on data from three pivotal Phase III trials, CLEAR1, CLEAR2 and CRYSTAL, which represented the largest clinical-trial data set of gout patients (n=1,537 total) treated with combination urate-lowering therapy.

d) Tralokinumab (atopic dermatitis)

A Phase II trial of tralokinumab in atopic dermatitis was completed in the period. Top-line results from the trial showed that at week 12, a statistically-significant improvement from baseline in EASI score (Eczema Area and Severity Index) was observed in the two highest tralokinumab dosage arms tested compared to the placebo arm. Significant improvements in DLQI (dermatology life quality index) were also observed. No safety issues were detected. Full trial results will be disclosed at a future medical congress.

e) MEDI-551 (neuromyelitis optica)

In the period AstraZeneca's global biologics research and development arm, MedImmune, obtained Orphan Drug Designation from the FDA for MEDI-551, a CD19 monoclonal antibody, for the treatment of patients with neuromyelitis optica (NMO), as well as NMO spectrum disorders. NMO is a rare, life-threatening autoimmune disease of the central nervous system, in which the body's immune system attacks healthy cells most commonly present in the optic nerves and spinal cord, resulting in severe damage. MEDI-551 is currently in Phase IIb clinical development.

2. Cardiovascular & Metabolic Disease (CVMD)

AstraZeneca's CVMD therapy area focuses on ways to reduce morbidity, mortality and organ damage by addressing multiple risk factors across cardiovascular (CV) disease, diabetes and chronic kidney disease (CKD) indications. This patient-centric approach is reinforced by science-led life-cycle management programmes and technologies, including early research into regenerative methods.

a) Brilinta/Brilique (CV disease)

On 19 February 2016, the European Commission granted marketing authorisation for Brilique for long-term prevention of cardiovascular death, heart attack and stroke for patients with a history of heart attack. The EU approval was based on the results from the PEGASUS TIMI-54 trial, a large-scale outcomes trial involving more than 21,000 patients. PEGASUS TIMI-54 investigated Brilinta/Brilique tablets plus low-dose aspirin, compared to placebo plus low dose aspirin, for the long-term prevention of death from CV disease, heart attack and stroke in patients who had experienced a heart attack one to three years prior to trial enrollment.

On 23 March 2016, the SOCRATES trial top-line results read out. The trial assessed the efficacy of Brilinta/Brilique 90mg tablets twice daily when compared to aspirin 100mg once daily in patients with acute ischaemic stroke or transient ischaemic attack. Fewer events were observed on Brilinta/Brilique versus the comparator in the overall trial population; the trend however did not reach statistical significance and the primary efficacy endpoint of time to first occurrence of any event from the composite of stroke (ischaemic or haemorrhagic), myocardial infarction (MI) and death was not met. AstraZeneca does not anticipate that the results will support a regulatory submission for the stroke indication.

On 29 March 2016, the American College of Cardiology (ACC) and American Heart Association (AHA) updated their treatment-guidelines for Acute Coronary Syndrome (ACS) and the duration of dual antiplatelet therapy. Brilinta is now preferred over clopidogrel for the management of patients with ACS who have received a coronary stent and in non-ST Elevation ACS patients treated with medical therapy alone. This update was also the first time that the ACC and AHA have recommended Brilinta over clopidogrel for patients who have experienced an ST-elevation myocardial infarction (STEMI). The update was also the first US guideline to provide the medical community with insights drawn from the PEGASUS-TIMI 54 trial. The guideline supported continuation of P2Y12 therapy beyond 12 months in prior MI patients who are not at high bleeding risk.

b) Onglyza and Kombiglyze XR (type-2 diabetes)

In early April 2016, the Company received a communication from the FDA on proposed label changes related to a potential risk for an increase in heart failure in the SAVOR outcomes trial for Onglyza (saxagliptin). The Company initially submitted the trial findings to the FDA in February 2014. The SAVOR trial met the primary safety endpoint, demonstrating that Onglyza did not increase the composite risk for CV death, non-fatal MI and non-fatal ischaemic stroke when added to a patient's current standard of care (with or without other anti-diabetic therapies), as compared to placebo. To reflect the recent communication from the FDA, the Onglyza label was updated accordingly and the FDA's review of the data is now complete.

c) Type-2 diabetes outcomes trials

Two significant type-2 diabetes outcomes trials are underway and fully recruited. Details and updates on those two trials are listed below:

Medicine	Trial	Mode of Action	Number of Patients	Primary Endpoint	Timeline
Bydureon	EXSCEL	GLP-1 agonist	~15,000	Time to first occurrence of CV death, non-fatal MI or non-fatal stroke	2018 (final analysis)
Farxiga/ Forxiga	DECLARE	SGLT2 inhibitor	~17,000*	Time to first occurrence of CV death, non-fatal MI or non-fatal stroke	2019 (final analysis) 2017 (anticipated interim analysis)

*Includes ~10,000 patients who have had no prior index event (primary prevention) and ~7,000 patients who have suffered an index event (secondary prevention).

3. Oncology

AstraZeneca has a deep-rooted heritage in Oncology and offers a quickly-growing portfolio of new medicines that has the potential to transform patients' lives and the Company's future. With at least six new medicines to be launched between 2014 and 2020 and a broad pipeline of small molecules and biologics in development, the Company is committed to advancing New Oncology as one of AstraZeneca's six Growth Platforms focused on lung, ovarian, breast and blood cancers. In addition to core capabilities, the Company is actively pursuing innovative collaborations and investments that accelerate the delivery of AstraZeneca's strategy, as illustrated by the Company's investment in Acerta Pharma in haematology.

By harnessing the power of four scientific platforms - immuno-oncology (IO), the genetic drivers of cancer and resistance, DNA damage response and antibody drug conjugates - and by championing the development of personalised combinations, AstraZeneca has the vision to redefine cancer treatment and, one day, eliminate cancer as a cause of death.

a) Faslodex (breast cancer)

AstraZeneca announced on 2 March 2016 that the FDA had approved a new indication expanding the use of Faslodex, to include use in combination with palbociclib. The combination use is for the treatment of women with hormone receptor-positive, human epidermal growth factor receptor 2 negative advanced or metastatic breast cancer whose cancer has progressed after endocrine therapy. The approval was based on data from the Phase III PALOMA-3 trial, which met the primary endpoint of progression-free survival.

b) Tagrisso (lung cancer)

On 14 April 2016 AstraZeneca reported new Phase I extended follow-up data on Tagrisso in both 1st- and 2nd-line treatment of patients with non-small cell lung cancer (NSCLC) at the European Lung Cancer Conference. Late-breaker presentations reinforced the efficacy and safety profile for Tagrisso previously seen in the AURA clinical-trials programme.

The FLAURA Phase III trial for 1st-line use of Tagrisso in epidermal growth factor receptor (EGFR)-mutated NSCLC randomised its last patient during the period. Data is expected in 2017 for potential regulatory submission in the earlier metastatic setting, compared to the prevailing 2nd-line use of the medicine.

On 29 March 2016 the Japanese Ministry of Health, Labour and Welfare approved Tagrisso 80mg once-daily tablets for the treatment of patients with EGFR T790M mutation-positive inoperable or recurrent NSCLC that is resistant to EGFR tyrosine kinase inhibitor therapy. The approval follows the EU and US approvals in late 2015. Given the high prevalence of EGFR mutations (30-40% of lung cancer patients) and, subsequently, T790M mutations in Asia, Japan is anticipated to be a proportionally significant market for Tagrisso.

During the period, the Company decided not to restart enrolment of patients into CAURAL, a Phase III trial assessing Tagrisso in combination with durvalumab as a potential second and later-line treatment for patients with EGFR T790M NSCLC. The decision not to restart enrolment reflects the view that the trial design no longer offers the best setting to assess this combination. There has been no change in the safety or data findings following the suspension of enrolment into the trial in October 2015.

On 2 March 2016, the National Comprehensive Cancer Network, a US guideline-setting organisation, included Tagrisso in its guidelines for the treatment of patients with brain metastasises who have progressed on 1st-line therapies. This important recommendation will expand the utilisation of Tagrisso to patients with limited treatment options.

c) Tremelimumab (mesothelioma)

On 29 February 2016, the Company announced that DETERMINE, a Phase IIb clinical trial of 10mg/kg tremelimumab monotherapy in 2nd or 3rd-line treatment of unresectable malignant mesothelioma, did not meet its primary endpoint of overall survival. It was encouraging however that the safety profile of this potential medicine was consistent with expectations.

The results did not have an impact on ongoing combination trials with tremelimumab at the ten-fold lower dose of 1mg/kg every four weeks. Mesothelioma remains a difficult-to-treat disease with no approved medicine beyond

1st-line treatment.

d) Durvalumab (multiple cancers)

Monotherapy

Durvalumab continues to be the cornerstone in the IO pipeline and is currently being tested in monotherapy, combination therapy and through numerous collaborations. Current combination trials include both large and small molecules, as well as chemotherapy. Through a broad and diverse development programme, the Company is committed to finding the patients who benefit most from unique combinations and targeted approaches using multiple biomarkers.

In the period, Breakthrough Therapy Designation was granted for durvalumab for the treatment of patients with programmed death-ligand 1 (PD-L1) positive inoperable or metastatic urothelial bladder cancer, whose tumour has progressed during or after the current standard of care. This designation was based on early clinical data from a large cohort Phase I/II trial (Study 1108), which has now enrolled more than 1,000 patients with various cancers.

Combination therapy

Pre-clinical data have suggested that targeting both PD-L1 and cytotoxic T-lymphocyte-associated protein 4 (CTLA-4) may have additive or synergistic effects and, to date, data from the combination treatment with durvalumab and tremelimumab have demonstrated anti-tumour activity in patients with locally advanced or metastatic NSCLC, irrespective of PD-L1 status. New data from the Phase Ib durvalumab + tremelimumab (durva + treme) combination trial in NSCLC (Study 006) were published on 5 February 2016 in The Lancet Oncology. The data cut-off of 1 June 2015 was the same date as per the Society for Immunotherapy of Cancer publication on 6 November 2015. This was, however, a more mature and robust data set of confirmed responses, with a longer follow-up period.

In patients receiving the combination at the dose chosen for Phase III (durvalumab 20mg/kg Q4W equivalent + tremelimumab 1mg/kg Q4W), the overall response rate was 29% in patients with PD-L1 negative tumours (<25% tumour staining) and 40% in patients with zero tumour staining. Disease control was 43% and 50% respectively, with a manageable safety profile, given the advanced disease setting.

An update on key AstraZeneca-sponsored ongoing trials with durvalumab is provided below:

LUNG CANCER

Name	Phase	Line of treatment	Population	Design	Timelines	Status
Early disease						
Monotherapy						
ADJUVANT1	III	N/A	Stage Ib-IIIa NSCLC	durvalumab vs placebo	FPD2 Q1 2015	Recruiting
					Data expected 2020	
PACIFIC	III	N/A	Stage III unresectable NSCLC	durvalumab vs placebo	FPD Q2 2014 LPCD3 Q2 2016	Recruitment completed
					Data expected H1 2017	

Advanced/metastatic disease

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Combination therapy						
ARCTIC	III	3rd line	PD-L1 neg.4NSCLC	durvalumab vs tremelimumab vs durva + treme vs SoC	FPD Q2 2015	Recruiting Data expected H1 2017
MYSTIC	III	1st line	NSCLC	durvalumab vs durva + treme vs SoC	FPD Q3 2015	Recruiting Data expected H1 2017
NEPTUNE	III	1st line	NSCLC	durva + treme vs SoC	FPD Q4 2015	Recruiting Data expected 2018
-	III	1st line	NSCLC	durvalumab + chemotherapy +/- tremelimumab	-	Recruiting in safety lead-in
-	III	1st line	SCLC6	durva + treme + chemotherapy vs SoC	-	Awaiting first patient dosed

1 Conducted by the National Cancer Institute of Canada

2 FPD = First Patient Dosed

3LPCD = Last Patient Commenced Dosing

4 PD-L1 negativity cut-off measured at <25% of tumour-cell staining

5 SoC = Standard of Care

6 SCLC = Small Cell Lung Cancer

METASTATIC OR RECURRENT HEAD AND NECK CANCER

Name	Phase	Line of treatment	Population	Design	Timelines	Status
Monotherapy						
HAWK	II	2nd line	PD-L1 pos. SCCHN1	durvalumab (single arm)	FPD Q1 2015 LPCD Q2 2016 Data expected H2 2016	Recruitment completed Indication granted FDA Fast Track Designation
Combination therapy						
CONDOR	II	2nd line	PD-L1 neg. SCCHN	durvalumab vs tremelimumab vs durva + treme	FPD Q2 2015 LPCD Q2 2016 Data expected H1 2017	Recruitment completed
EAGLE	III	2nd line	SCCHN		FPD Q4 2015	Recruiting

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KESTREL	III	1st line	SCCHN	durvalumab vs	Data expected	Recruiting
				durva + treme vs SoC		
				durvalumab vs	FPD Q4 2015	Recruiting
				durva + treme vs SoC		

1SCCHN = Squamous Cell Carcinoma of the Head and Neck

OTHER METASTATIC CANCERS

Name	Phase	Line of treatment	Population	Design	Timelines	Status
Combination therapy DANUBE	III	1st line	Cisplatin chemotherapy-eligible/ineligible bladder cancer	durvalumab vs durva + treme vs SoC	FPD Q4 2015 Data expected 2018	Recruiting
ALPS	II	2nd line	Pancreatic ductal carcinoma	durva + treme (single arm)	FPD Q4 2015 Data expected 2017	Recruiting
-	II	2nd line	Unresectable liver cancer	durvalumab vs tremelimumab vs durva + treme	FPD Q1 2016	Recruiting
-	II	2nd/3rd line	Metastatic gastric cancer	durvalumab vs - tremelimumab vs durva + treme		In preparation

e) Acalabrutinib (blood cancers)

On 25 February 2016, the European Medicines Agency adopted and approved three positive opinions recommending acalabrutinib for Orphan Drug Designation in chronic lymphocytic leukaemia (CLL)/small lymphocytic lymphoma (SLL), mantle cell lymphoma (MCL) and lymphoplasmacytic lymphoma (Waldenström’s macroglobulinaemia, WM).

Acalabrutinib has the potential for regulatory submission in the second half of the year in one type of blood cancer, for which it is currently being assessed in Phase II/III trials.

f) Early-stage pipeline

During the period, the Company initiated a Phase I trial for monalizumab, a humanised, monoclonal antibody targeting natural-killer cell NKG2A. This potential medicine is being developed with Innate Pharma SA under a co-development and commercialisation agreement. The trial is a combination with durvalumab and will explore the medicine’s safety, tolerability and anti-tumour activity in solid tumours.

a) MEDI8852 (hospitalised influenza)

On 7 March 2016, AstraZeneca's global biologics research and development arm, MedImmune, received Fast Track Designation from the FDA for its potential new medicine MEDI8852, a human, monoclonal antibody for the treatment of patients hospitalised with type-A strain influenza. MEDI8852 is currently being evaluated in a Phase Ib/IIa clinical trial to assess the safety and efficacy of a single intravenous dose in combination with oseltamivir and as a monotherapy in adult patients with confirmed acute, uncomplicated influenza caused by type-A strains.

b) AZD3293 (Alzheimer's disease)

On 8 April 2016, AstraZeneca announced that AMARANTH, a Phase II/III trial of AZD3293, an oral BACE inhibitor in development as a potential treatment for early Alzheimer's disease, will move into the Phase III portion of the trial.

The transition into Phase III will also trigger the start of an additional Phase III trial with AZD3293. DAYBREAK will focus on patients with mild Alzheimer's disease and is scheduled to begin enrolling patients in the second half of the year. Emerging evidence suggests that cognitive decline precedes and predicts a functional decline in Alzheimer's disease, particularly during earlier stages of the disease. Accordingly, AMARANTH will be amended and DAYBREAK will use a single, cognitive endpoint, ADAS-cog13.

ASTRAZENECA DEVELOPMENT PIPELINE 31 MARCH 2016

Includes AstraZeneca-sponsored or -directed studies only

Phase III / Pivotal Phase II / Registration

NMEs and significant additional indications

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

† US and EU dates correspond to anticipated acceptance of the regulatory submission.

Collaboration.

Compound	Mechanism	Area Under Investigation	Date Commenced Phase	Estimated Regulatory Submission / Submission Acceptance†			
				US	EU	Japan	China
Respiratory, Inflammation and Autoimmunity							
Zurampic# (lesinurad)							
CLEAR 1,2							
CRYSTAL							