

ASTRAZENECA PLC

(Exact name of Registrant as specified in its charter)

England and Wales

(Jurisdiction of incorporation or organization)

1 Francis Crick Avenue

Cambridge Biomedical Campus

Cambridge CB2 0AA

England

(Address of principal executive offices)

Adrian Kemp

AstraZeneca PLC

1 Francis Crick Avenue

Cambridge Biomedical Campus

Cambridge CB2 0AA

England

Telephone: +44 20 3749 5000

Facsimile number: +44 1223 352 858

(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
American Depositary Shares, each representing one half of an Ordinary Share of 25¢ each	The New York Stock Exchange
Ordinary Shares of 25¢ each	The New York Stock Exchange*
Floating Rate Notes due 2018	The New York Stock Exchange
1.750% Notes due 2018	The New York Stock Exchange
1.950% Notes due 2019	The New York Stock Exchange
2.375% Notes due 2020	The New York Stock Exchange
7.000% Notes due 2023	The New York Stock Exchange
2.375% Notes due 2022	The New York Stock Exchange
Floating Rate Notes due 2022	The New York Stock Exchange
3.375% Notes due 2025	The New York Stock Exchange
3.125% Notes due 2027	The New York Stock Exchange
6.450% Notes due 2037	The New York Stock Exchange
4.000% Notes due 2042	The New York Stock Exchange
4.375% Notes due 2045	The New York Stock Exchange

* Not for trading, but only in connection with the registration of American Depositary Shares representing such Ordinary Shares pursuant to the requirements of the Securities and Exchange Commission.

Edgar Filing: ASTRAZENECA PLC - Form 20-F

Securities registered or to be registered pursuant to Section 12(g) of the Act:

None
(Title of Class)

Edgar Filing: ASTRAZENECA PLC - Form 20-F

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:

None
(Title of Class)

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report.

The number of outstanding shares of each class of stock of AstraZeneca PLC as of December 31, 2017 was:

Ordinary Shares of 25¢ each: 1,266,221,605

Redeemable Preference Shares of £1 each: 50,000

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

Yes No

Note: Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 from their obligations under those Sections.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Edgar Filing: ASTRAZENECA PLC - Form 20-F

Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Emerging growth company

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

The term new or revised financial accounting standard refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP

International Financial Reporting Standards as issued
by the International Accounting Standards Board

Other

If Other has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow.

Item 17 Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

(APPLICABLE ONLY TO ISSUERS INVOLVED IN BANKRUPTCY PROCEEDINGS DURING THE PAST FIVE YEARS)

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Section 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court.

Yes No

Edgar Filing: ASTRAZENECA PLC - Form 20-F

Pursuant to Rule 12b-23(a) of the Securities Exchange Act of 1934, as amended, the information for the 2017 Form 20-F of AstraZeneca PLC (the Company) set out below is being incorporated by reference from AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated and submitted on March 6, 2018.

References below to major headings include all information under such major headings, including subheadings, unless such reference is a reference to a subheading, in which case such reference includes only the information contained under such subheading. Unless the context otherwise requires, AstraZeneca or Group refers to the Company and its consolidated entities. Other information contained within AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F, including graphs and tabular data, is not included in this Form 20-F unless specifically identified below. Photographs are also not included.

In addition to the information set out below, the information (including tabular data) set forth under the headings Important information for readers of this Annual Report, Definitions, and Use of terms on the inside front cover, Strategic Report Financial Review Measuring performance on pages 68 and 69, and the tables on page 70, Additional Information Trade Marks on page 234, Glossary on pages 235 to 238 and Important information for readers of this Annual Report Cautionary statement regarding forward-looking statements, Inclusion of Reported performance, Core financial measures and constant exchange rate growth rates, Statements of competitive position, growth rates and sales, AstraZeneca websites, External/third party websites and Figures on page 240, in each case of AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated March 6, 2018 is incorporated by reference. References herein to AstraZeneca websites are textual references only and information on or accessible through such websites does not form part of and is not incorporated into this Form 20-F dated March 6, 2018.

PART 1

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3. KEY INFORMATION

A. Selected Financial Data

Edgar Filing: ASTRAZENECA PLC - Form 20-F

The information (including graphs and tabular data) set forth under the headings "Financial Statements - Group Financial Record" on page 199, "Additional Information - Shareholder Information - Issued share capital, shareholdings and share prices" and the first table that appears under "Ordinary Shares in issue" on page 229, in each case of AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated March 6, 2018 is incorporated by reference. The selected financial data incorporated by reference herein is derived from audited financial statements of the Company and its consolidated entities, prepared in accordance with International Financial Reporting Standards (IFRS) as adopted by the European Union and as issued by the International Accounting Standards Board, included in AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated March 6, 2018.

B. Capitalization and Indebtedness

Not applicable.

C. Reason for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

The information (including tabular data) set forth or referenced under the heading *Additional Information Risk* on pages 210 to 220 of AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated March 6, 2018 is incorporated by reference.

ITEM 4. INFORMATION ON THE COMPANY

A. History and Development of the Company

The information (including tabular data) set forth under the headings *Additional Information Shareholder Information History and development of the Company* on page 229, *Strategic Report Financial Review Externalisation Revenue* on pages 71 and 72, *Strategic Report Financial Review Financial position 31 December 2017 Business combinations* on page 75, *Investments, divestments and capital expenditure* on pages 77 and 78, *Financial Statements Notes to the Group Financial Statements Note 25 Acquisitions of business operations* on pages 173 and 174 and *Corporate Governance Corporate Governance Report Relations with shareholders* on page 96, in each case of AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated March 6, 2018 is incorporated by reference.

B. Business Overview

The information (including graphs and tabular data) set forth under the headings *Strategic Report AstraZeneca at a glance* on pages 2 and 3, *Chairman's Statement* on page 4, *Chief Executive Officer's Review* on pages 5 to 7, *Strategy and key performance indicators* on pages 17 to 21, *Business Review* on pages 22 to 45, *Therapy Area Review* on pages 46 to 62, *Risk Overview Managing Risk*, *Risk Overview Risk management embedded in business processes* and *Risk Overview Brexit* on page 63, *Corporate Governance Corporate Governance Report Business organisation Global Compliance and Internal Audit Services (IA)* on pages 97 and 98, *Additional Information Development Pipeline* on pages 202 to 207, *Patent Expiries of Key Marketed Products* on pages 208 and 209, *Sustainability: supplementary information* on page 227 and *Geographical Review* on pages 221 to 226, *Financial Statements Notes to the Group Financial Statements Note 1 Revenue* on page 145, *Note 6 Segment information* on pages 151 and 152, and *Additional Information Important information for readers of this Annual Report Statements of competitive position, growth rates and sales* on page 240, in each case of AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated March 6, 2018 is incorporated by reference.

On February 15, 2018, AstraZeneca and MSD announced that the FDA has granted Orphan Drug designation for selumetinib, a MEK 1/2 inhibitor, for the treatment of neurofibromatosis type 1. The FDA's Orphan Drug programme provides orphan status to medicines that are defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases or disorders that affect fewer than 200,000 people in the U.S.

On February 19, 2018, AstraZeneca and MedImmune, its global biologics research and development arm, announced that the FDA had approved *Imfinzi* for the treatment of patients with unresectable Stage III NSCLC whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.

On February 23, 2018, AstraZeneca and MSD announced that the CHMP of the European Medicines Agency had adopted a positive opinion, which recommended a marketing authorization of *Lynparza* (olaparib) tablets (300mg twice daily) for use as a maintenance therapy for patients with platinum-sensitive relapsed high grade, epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete response or partial response to platinum-based chemotherapy. *Lynparza* is recommended for treatment in this setting regardless of patients' BRCA mutation status.

On February 28, 2018, AstraZeneca announced that MedImmune was spinning out six molecules from its early-stage inflammation and autoimmunity programmes into an independent biotech company, Viela Bio, Inc. The new company will focus on developing medicines for severe autoimmune diseases by targeting the underlying causes of each disease.

Disclosures Under the Iran Threat Reduction and Syria Human Rights Act of 2012

AstraZeneca is a global, innovation-driven biopharmaceutical business with operations in over 100 countries and its innovative medicines are used by millions of patients worldwide. AstraZeneca has a legal entity based in Iran, AstraZeneca Pars Company (AstraZeneca Pars), which has no employees, and is owned by non-U.S. Group companies. In July 2017, AstraZeneca Pars submitted regulatory applications in its name with a view to commencing business in 2018. AstraZeneca, through one of its non-U.S. Group companies that is neither a U.S. person nor a foreign subsidiary of a U.S. person, currently has sales of prescription pharmaceuticals in Iran solely through a single third-party distributor, which uses three known entities in the Iranian distribution chain. None of AstraZeneca's U.S. entities are involved in any business activities in Iran, or with the Iranian government. To the best knowledge of the management of AstraZeneca, the third-party distributor used by AstraZeneca is not owned or controlled by the Iranian government. However, AstraZeneca understands that one of the independent sub-distributors of AstraZeneca's third-party distributor is likely to be indirectly controlled by the Iranian government. Further, AstraZeneca's third-party distributor may initiate payments using local banks associated with the government of Iran for the purchase of AstraZeneca products. Finally, in view of the types of products created and distributed by AstraZeneca, it is anticipated that the ultimate end-payers for its medicines may also include the Iranian government. To the best knowledge of management of AstraZeneca, AstraZeneca does not have any agreements, commercial arrangements, or other contracts with the Iranian government. On 11 February 2017, a non-U.S. Group company, that is neither a U.S. person nor a foreign subsidiary of a U.S. person, entered into a memorandum of understanding with the Iranian Ministry of Health, whereby AstraZeneca committed to improving the overall quality of healthcare and ensuring that Iranian patients have access to the latest innovative and cost-effective medicines.

For the year ended December 31, 2017, the Company's gross revenues and net profits attributable to the above-mentioned Iranian activities were \$18 million and \$7 million respectively. For the same period, AstraZeneca's gross revenues and net profits were \$22.5 billion and \$2.9 billion, respectively. Accordingly, the gross revenues and net profits attributable to the above-mentioned Iranian activities amounted to approximately 0.08% of AstraZeneca's gross revenues and approximately 0.24% of its net profits.

At the time of publication, the management of AstraZeneca does not anticipate any change in its activities in Iran that would result in a material impact on AstraZeneca.

C. Organizational Structure

The information (including tabular data) set forth under the headings Corporate Governance Corporate Governance Report Other matters Subsidiaries and principal activities on page 98 and Financial Statements Group Subsidiaries and Holdings on pages 190 to 193, in each case of AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated March 6, 2018 is incorporated by reference.

D. Property, Plant and Equipment

The information below under the heading Item 5 Operating and Financial Review and Prospects Operating Results 2017 compared with 2016 Financial position 31 December 2017 Property, plant and equipment on page 75. The information (including tabular data) set forth under the headings Strategic Report Business Review 1. Achieve Scientific Leadership R&D Resources on page 25, 2. Return to growth Operations on pages 30 to 31 and 2. Return to growth Information technology and information services resources on page 33, Strategic Report Financial Review Financial position 31 December 2017 Property, plant and equipment on page 75, Additional Information Risk Risks and uncertainties Legal, regulatory and compliance risks Failure to adhere to applicable laws, rules and regulations on page 218, Financial Statements Notes to the Group Financial Statements Note 7 Property, plant and equipment on page 153, Note 28 Commitments and contingent

Edgar Filing: ASTRAZENECA PLC - Form 20-F

liabilities Environmental costs and liabilities on page 182, Note 29 Operating leases on page 189 and Additional Information Shareholder Information Property on page 232, in each case of AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated March 6, 2018 is incorporated by reference.

ITEM 4A. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

The information (including graphs and tabular data) set forth under the headings *Additional Information Geographical Review* on pages 221 to 226, *Chief Executive Officer's Review Global Product Sales by therapy area* on page 6, *Strategic Report Strategy and key performance indicators* on pages 17 to 21, *Strategic Report Business Review 1. Achieve scientific leadership* on pages 23 to 25, *Corporate Governance Overview Early Stage Product Committees (ESPCs) and Late Stage Product Committee (LSPC)* on page 90, *Additional Information Risk Commercialisation risks* on pages 212 to 215, *Financial Statements Notes to the Group Financial Statements Note 17 Interest-bearing loans and borrowings* on pages 161 and 162, *Note 12 Derivative financial instruments* on page 159, *Note 21 Reserves* on page 171, *Note 26 Financial risk management objectives and policies* on pages 175 to 179 and *Note 28 Commitments and contingent liabilities* on pages 182 to 188, in each case of AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated March 6, 2018 is incorporated by reference.

We consider the Group's working capital to be sufficient for its present requirements.

Operating Results**2017 compared with 2016**

The Information set forth under the heading *Strategic Report Financial Review* on pages 66 to 83 of AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated March 6, 2018 is incorporated by reference.

2016 compared with 2015**Results of operations summary analysis of year ended 31 December 2016**

2016 Reported operating profit

	2016			2015 Reported \$m	Percentage of Total Revenue		2016 compared with 2015	
	Reported \$m	CER growth \$m	Growth due to exchange effects \$m		Reported 2016 %	Reported 2015 %	Actual growth %	CER growth(1) %
Product Sales	21,319	(1,990)	(332)	23,641			(10)	(8)
Externalisation Revenue	1,683	634	(18)	1,067			58	59
Total Revenue	23,002	(1,356)	(350)	24,708			(7)	(5)
Cost of sales	(4,126)	332	188	(4,646)	(17.9)	(18.8)	(11)	(7)

Edgar Filing: ASTRAZENECA PLC - Form 20-F

Gross profit	18,876	(1,024)	(162)	20,062	82.1	81.2	(6)	(5)
Distribution costs	(326)	(4)	17	(339)	(1.5)	(1.4)	(4)	1
Research and development expense	(5,890)	(150)	257	(5,997)	(25.6)	(24.3)	(2)	2
Selling, general and administrative costs	(9,413)	1,373	326	(11,112)	(40.9)	(44.9)	(15)	(12)
Other operating income and expense	1,655	178	(23)	1,500	7.2	6.1	10	12
Operating profit	4,902	373	415	4,114	21.3	16.7	19	9
Net finance expense	(1,317)			(1,029)				
Share of after tax losses of joint ventures and associates	(33)			(16)				
Profit before tax	3,552			3,069				
Taxation	(146)			(243)				
Profit for the period	3,406			2,826				
Basic earnings per share (\$)	2.77			2.23				

(1) CER growth is calculated using prior year actual results adjusted for certain exchange effects including hedging.

Edgar Filing: ASTRAZENECA PLC - Form 20-F

2016 Reconciliation of Reported results to Core results

	2016 Reported \$m	Restructuring costs \$m	Intangible amortisation and impairments \$m	BMS s share of diabetes alliance \$m	Legal provisions and other \$m	2016 Core(1) \$m	Core(1) 2016 Actual growth %	CER growth %
Gross profit	18,876	130	124			19,130	(7)	(6)
<i>Product Sales gross margin</i> %(2)	80.8%					82.0%		
<i>Total Revenue gross margin</i> %	82.1%					83.2%		
Distribution costs	(326)					(326)	(4)	1
Research and development expense	(5,890)	178	81			(5,631)		5
Selling, general and administrative costs	(9,413)	823	1,000	(627)	48	(8,169)	(12)	(9)
Other operating income and expense	1,655	(24)	86			1,717	13	14
Operating profit	4,902	1,107	1,291	(627)	48	6,721	(3)	(7)
<i>Operating margin as a % of Total Revenue</i>	21.3%					29.2%		
Net finance expense	(1,317)			389	267	(661)		
Taxation	(146)	(232)	(307)	23	4	(658)		
Basic earnings per share (\$)	2.77	0.69	0.78	(0.17)	0.24	4.31		

(1) Each of the measures in the Core column in the above table are non-GAAP measures.

(2) Gross margin as a % of Product Sales reflects gross profit derived from Product Sales, divided by Product Sales.

Total Revenue

Total Revenue for 2016 was down 7% to \$23,002 million, comprising Product Sales of \$21,319 million (down 10%) and Externalisation Revenue of \$1,683 million (up 58%). At CER, Total Revenue declined by 5% in 2016.

Product Sales

The decline in Product Sales primarily reflected the entry in the U.S. of multiple *Crestor* generic medicines.

By Geography

Edgar Filing: ASTRAZENECA PLC - Form 20-F

U.S. Product Sales were down 22% to \$7,365 million in 2016, reflecting the competition from multiple generic *Crestor* medicines that entered the U.S. market from July 2016 as well as lower Product Sales of *Nexium* and *Symbicort*. In Europe, strong growth in Product Sales of *Forxiga* and *Brilique* were more than offset by a decline in *Symbicort*, leading to a decrease of 5% (CER: decrease of 3%) in the region in total to \$5,064 million. Established Markets were up 2% in 2016 (CER: down 4%) at \$3,096 million including an increase of 8% in Japan (CER: decrease of 3%) to \$2,184 million, with *Crestor* Product Sales in Japan stable at \$521 million. Product Sales in Emerging Markets were flat (CER: up 6%) at \$5,794 million in 2016 despite growth in China of 4% (CER: growth of 10%) to \$2,636 million, as the Group encountered challenging macro-economic conditions in Latin America, where full-year 2016 Product Sales declined by 20% (CER: declined by 7%) to \$516 million.

By Product

The largest selling products in 2016 were *Crestor* (\$3,401 million), *Symbicort* (\$2,989 million), *Nexium* (\$2,032 million) and *Pulmicort* (\$1,061 million). Global Product Sales of *Crestor* declined in 2016 by 32% (CER: declined by 32%), which primarily reflected the market entry of multiple *Crestor* generic medicines. *Symbicort* global Product Sales declined by 12% (CER: down 10%) including a reduction of 18% in the U.S. due to the impact of a competitive environment on net pricing. *Nexium* Product Sales were down 19% (CER: down 18%), including a 39% decrease in the U.S., reflecting lower demand and inventory de-stocking as a result of the loss of exclusivity in 2015. Strong underlying volume growth in Emerging Markets in 2016 drove a 5% Global Product Sales increase (CER: 8% increase) in *Pulmicort*, with 66% of Product Sales of the medicine coming from that region in 2016.

Growth Platforms

In the 2016 and 2015 periods, the Growth Platforms included products in three main therapy areas, and a focus on the Emerging Markets and Japan. The Growth Platforms grew by 4% (CER: 5%), representing 63% of Total Revenue after removing the effect of certain Product Sales which are included in more than one Growth Platform.

Growth Platforms

	2016 Product Sales \$m	2015 Product Sales \$m	Actual growth %	CER growth %
Respiratory	4,753	4,987	(5)	(3)
<i>Brilinta</i>	839	619	36	39
Diabetes	2,427	2,224	9	11
Emerging Markets	5,794	5,822		6
Japan	2,184	2,020	8	(3)
New Oncology(1)	664	119	n/m	n/m
Total Growth Platform Product Sales(2)	14,491	14,003	4	5

(1) New Oncology comprises *Lynparza*, *Iressa* (U.S.) and *Tagrisso*.

(2) Certain Product Sales are included in more than one Growth Platform. Total Growth Platform sales represents the net total sales for all Growth Platforms.

Product Sales of Respiratory medicines in 2016 declined by 5% (CER: declined by 3%) reflecting pricing pressure in the U.S. for *Symbicort*. Sales of *Brilinta* in 2016 were \$839 million, an increase of 36% (CER: increase of 39%). *Brilinta* sales in the U.S. were up 45% to \$348 million in 2016, as it remained the branded oral anti-platelet market leader in the U.S. Diabetes Product Sales for 2016 were 9% higher than in 2015 (CER: 11% higher), driven primarily by growth of 70% (CER: growth of 72%) on *Farxiga* with global sales of \$835 million as it became the largest-selling Diabetes medicine. Product Sales in Emerging Markets for 2016 were flat compared to 2015 (CER: increase of 6%). Product Sales in China increased by 4% in 2016 (CER: increased by 10%) representing 45% of Emerging Markets Product Sales. Japan Product Sales increased by 8% in 2016 (CER: declined by 3%). Product Sales of New Oncology medicines were up to \$664 million in 2016 (2015: \$119 million), \$423 million of which came from *Tagrisso* (2015: \$19 million) which became the leading medicine for the treatment of lung cancer in 2016.

Externalisation Revenue

Externalisation Revenue, alongside Product Sales, is included in Total Revenue. Externalisation Revenue includes development, commercialisation and collaboration revenue, such as royalties and milestone receipts. Income is recorded as Externalisation Revenue when the Group has a significant ongoing interest in the product and/or it is repeatable business.

Edgar Filing: ASTRAZENECA PLC - Form 20-F

Details of significant business development transactions which give rise to Externalisation Revenue, are set forth in a table, under the heading Strategic Report Financial Review Externalisation Revenue on page 70 and under the heading Strategic Report Financial Review Externalisation Revenue on pages 71 to 72 of AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated March 6, 2018. An analysis of Externalisation Revenue by transaction for 2016 and 2015 is given below.

Edgar Filing: ASTRAZENECA PLC - Form 20-F

	2016	2015
	\$m	\$m
Upfronts and Milestones		
Global non-US anaesthetics portfolio (Aspen) upfront	520	
<i>Plendil</i> (China Medical System Holdings) upfront	298	
<i>Toprol-XL</i> (Aralez) upfront	175	
tralokinumab (LEO Pharma) upfront	115	
AZD3293 (Lilly) milestone	100	50
durvalumab (Celgene) upfront		450
<i>Movantik</i> (Daiichi Sankyo) upfront		200
brodalumab (Valeant) upfront		100
<i>Nexium</i> (Daiichi Sankyo) milestone		123
Others	356	57
Total upfront/milestones	1,564	980
Royalties	119	87
Total Externalisation Revenue	1,683	1,067

Gross margin, operating margin and earnings per share

Reported gross margin as a percentage of Product Sales was 80.8%, 0.5 percentage points higher than 2015. Excluding the impact of Externalisation Revenue, the Reported gross margin was broadly flat compared to 2015 at CER, with lower restructuring and amortisation charges offset by an adverse impact from the mix of sales, the market entry of multiple *Crestor* generic medicines in the U.S. and a write-down of *FluMist* inventory in the U.S.

In 2016, Reported R&D expense in 2016 was down 2% (CER: up 2%) to \$5,890 million, as the Group continued its focused investment in the pipeline. Adjusting for exchange rate movements, the full-year increase at CER reflected the number of potential medicines in pivotal trials as well as the inclusion of the R&D costs of ZS Pharma and Acerta Pharma. These costs were partially offset by lower restructuring costs and impairment charges.

Reported SG&A costs declined by 15% in 2016 (CER: declined by 12%) to \$9,413 million reflecting the fair value adjustment to acquisition-related liabilities based on revised milestone probabilities and revenue and royalty forecasts relating to the acquisition of BMS's share of the Global Diabetes Alliance and the acquisition of Almirall. The decline was also driven by the movement to a more even split between the sale of primary and specialty care medicines and efficiency savings in sales and marketing operations and further reductions in IT costs. These actions included a material reduction in the sales and head-office structure in the U.S. marketing business.

Reported other operating income in 2016 was up 10% (CER: up 12%) at \$1,655 million which, in addition to royalty income of \$165 million for *Crestor* and \$134 million for Human Papillomavirus (HPV) vaccine, includes \$368 million on the sale of the small-molecule antibiotics business to Pfizer, \$321 million on the sale of non-U.S. rights to *Rhinocort Aqua* to Cilag, \$183 million on the sale of non-U.S. rights to *Imdur* and \$148 million (after deduction of \$83 million payable to Amgen) on the disposal of global rights to *MEDI2070* to Allergan. As these elements of income arose from product divestments, where the Group no longer retains a significant element of continued interest, in accordance with the Group's Externalisation Revenue definition and the requirements of IFRS, proceeds from these divestments are recorded as other operating income.

Edgar Filing: ASTRAZENECA PLC - Form 20-F

In 2015, Reported other operating income included \$380 million for the divestment of rights to the *Entocort* business in the U.S. to Elan Pharma International Limited, part of the Perrigo Group, \$215 million for the divestment of the rights to sell and develop *Entocort* capsules and enema formulations outside the U.S. to Tillotts Pharma AG, \$193 million gain on the divestment of the global rights to develop, manufacture and commercialise *Myalept* subject to an existing

distributor licence with Shionogi covering Japan, South Korea, and Taiwan with Aegerion and \$165 million for the divestment of *Caprelsa* in an agreement with Genzyme Corporation, part of Sanofi S.A.

Reported operating profit increased by 19% (CER: increased by 9%) to \$4,902 million in 2016. The Reported operating margin increased by 4.6 percentage points (CER: 2.6 percentage points) to 21.3% of Total Revenue. The increase reflected the reduction in SG&A costs which more than offset the decline in Product Sales and Externalisation Revenue, while the Group continued to invest in its pipeline and Growth Platforms.

Core operating profit declined by 3% (CER: declined by 7%) in 2016 to \$6,721 million. Fair value adjustments to acquisition-related liabilities reduced SG&A costs and increased Reported operating profit by \$1,158 million in 2016 (2015: \$432 million). These fair value movements reflected estimates for future liabilities that can change materially over time.

Reported net finance expense was \$1,317 million (2015: \$1,029 million) in 2016. The increase of \$288 million was largely due to an increase in Net Debt that was driven by the acquisition of ZS Pharma and the majority investment in Acerta Pharma. Excluding the discount unwind on acquisition-related liabilities and other adjustments, Core Net Finance Expense increased by 31% (CER: increased by 46%) in 2016 to \$661 million.

Profit before tax amounted to \$3,552 million in 2016 (2015: \$3,069 million). Pre-tax adjustments to arrive at Core profit before tax amounted to \$2,475 million in 2016 (2015: \$3,312 million), comprising \$1,819 million adjustments to operating profits (2015: \$2,788 million) and \$656 million to net finance expenses (2015: \$524 million). Excluded from Core results for the financial year ending 31 December 2016 were:

- Restructuring costs totalling \$1,107 million (2015: \$1,034 million), incurred as the Group continues to enhance productivity through the implementation of its restructuring initiatives. To continue the focus on cost discipline, in 2016 the Group announced plans to advance its strategy through sharper focus by streamlining operations, primarily in Commercial and Manufacturing, to redeploy investment to key therapy areas, particularly Oncology. The Group incurred restructuring costs totalling \$555 million relating to this programme in 2016. The Group also disposed of its R&D facility in Bangalore, India in 2016 and announced plans to bring together five of the San Francisco Bay Area, U.S. sites into one location.
- Amortisation totalling \$1,247 million (2015: \$1,460 million) relating to intangible assets, except those relating to IT and to the acquisition of BMS's share of the Group's Global Diabetes Alliance (which are separately detailed below). Further information on the intangible assets is set forth under the heading Financial Statements Notes to the Group Financial Statements Note 9 Intangible Assets on pages 155 to 157 of AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated March 6, 2018.
- Intangible impairment charges of \$44 million (2015: \$143 million) excluding those relating to IT. Further details relating to intangible asset impairments are set forth under the heading Financial Statements Notes to the Group Financial Statements Note 9 Intangible Assets on pages 155 to 157 of AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated March 6, 2018.
- A net credit associated with the acquisition of BMS's share of the Group's Global Diabetes Alliance in February 2015 amounting to \$238 million (2015: net cost of \$463 million). A 2016 contingent consideration fair value decrease of \$999 million reflecting lower expected Diabetes portfolio revenues in line with latest forecasts was

partially offset by \$372 million of amortisation charges and \$389 million of interest charges relating to a discount unwind on contingent consideration arising on the acquisition.

- Net legal provisions and other charges of \$315 million (2015: \$211 million), including \$267 million discount unwind charges, offset by \$199 million of net fair value adjustments relating to contingent consideration arising on other business combinations as detailed under the heading Financial Statements Notes to the Group Financial Statements Note 18 Trade and other payables on page 163 of AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated March 6, 2018. The net charge of \$315 million also included legal charges relating to the unsuccessful defence of the validity of *Crestor*-related patents in Australia, damages claims in Europe relating to *Seroquel XR* and other matters. Further details of legal proceedings the Group is currently involved in are set forth under the heading Financial Statements Notes to the Group Financial Statements Note 28 Commitments and contingent liabilities on pages 182 to 188 of AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated March 6, 2018.

Edgar Filing: ASTRAZENECA PLC - Form 20-F

Reported EPS of \$2.77 in 2016 represented growth of 24% (CER: growth of 9%), partly reflecting the revaluation of acquisition-related liabilities described above. Core EPS in 2016 increased by 1% (CER: declined by 5%) to \$4.31. The CER decline of 5% mirrored the rate of decline in Total Revenue. Both Reported and Core EPS in 2016 included a non-recurring benefit of \$0.36, following agreements between the Canadian tax authority and the U.K. and Swedish tax authorities.

The Reported taxation charge for 2016 of \$146 million (2015: \$243 million) consisted of a current tax charge of \$370 million (2015: \$633 million) and a credit arising from movements on deferred tax of \$224 million (2015: \$390 million). The current tax charge included a prior period current tax credit of \$14 million (2015: \$404 million).

The Reported tax rate for 2016 was 4% (2015: 8%). The Reported tax rate of 4% benefited from a \$453 million adjustment following agreements between the Canadian tax authority and the U.K. and Swedish tax authorities. Excluding these effects, the Reported tax rate for 2016 was 17%. The Core tax rate for 2016 was 11%. Excluding the benefit following agreements between the Canadian tax authority and the U.K. and Swedish tax authorities in respect of transfer pricing arrangements for the 13-year period from 2004-2016, the Core tax rate was 18%.

The tax paid for 2016 was \$412 million (12% of Reported profit and 7% of Core profit). The cash tax paid in 2016 was \$266 million higher than the tax charge for that year as a result of certain items with no cash impact including a \$453 million adjustment following the agreement between the Canadian tax authority and the U.K. and Swedish tax authorities referred to above, other net reductions in provisions for tax contingencies of \$52 million, \$244 million of deferred tax credits, net cash refunds received following agreement of prior period tax liabilities and audit settlements of \$274 million and other cash tax timing differences.

Reported post-tax profit for 2016 was \$3,406 million, an increase of 21% (CER: increase of 6%). Reported earnings per share was up 24% (CER: up 9%) to \$2.77.

Total comprehensive income decreased by \$860 million from 2015, resulting in a net income of \$1,628 million for 2016. This was driven by the increase in profit for 2016 of \$580 million being more than offset by a reduction of \$1,440 million in other comprehensive income. The decrease in other comprehensive income arose principally from losses recorded on the remeasurement of the defined benefit pension liability of \$575 million (2015: gains of \$652 million) due to a decrease in the discount rate applied to pension liabilities reflecting an increase in corporate bond yields and other reference interest rate instruments, and foreign exchange losses arising on consolidation of the Group numbers of \$1,050 million (2015: losses of \$528 million) as a result of the strong performance of the U.S. dollar against other major currencies in 2016.

Cash flow and liquidity 2016

Net cash generated from operating activities was \$4,145 million in the year ended 31 December 2016, compared with \$3,324 million in 2015. The increase of \$821 million reflected improved cash management performance and one-off tax refunds in 2016 compared to an increase of \$49 million in working capital and short-term provisions in 2015.

Gains on disposal of intangible assets of \$1,301 million in 2016 included \$368 million on the disposal of the late-stage antibiotics business, \$321 million on the sale of the Group's rights to *Rhinocort Aqua* outside of the U.S., \$231 million on the out-licence agreement for MEDI-2070, and \$183 million for the divestment of the global rights to *Imdur* outside the U.S. 2015 included \$380 million on the disposal of U.S. rights to

Edgar Filing: ASTRAZENECA PLC - Form 20-F

Entocort, \$215 million on the disposal of Rest of World rights to *Entocort*, \$193 million on the disposal of global rights to *Myalept* and \$165 million on the disposal of global rights to *Caprelsa*. Fair value adjustments on acquisition-related liabilities were a credit of \$1,158 million in 2016 (2015: a credit of \$432 million) including \$999 million on the acquisition of BMS's share of the Group's Global Diabetes Alliance in February 2015. Other non-cash movements amounted to \$492 million in 2016 (2015: \$350 million).

Investment cash outflows of \$3,703 million (2015: \$4,681 million) included \$2,383 million relating to the majority investment in Acerta Pharma. This compared to cash payments relating to business acquisitions in 2015 of \$2,446 million, primarily related to the ZS Pharma acquisition. Further details of business combination acquisitions and their impact on the Group's cash flows and balance sheet are set forth under the heading "Financial Statements - Notes to the Group Financial Statements - Note 25 - Acquisitions of business operations" on pages 173 to 174 of AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated March 6, 2018. Investment cash outflows also include \$293 million (2015: \$579 million) of payments against contingent consideration arising on business combinations and \$868 million (2015: \$1,460 million) for the purchase of other intangible assets, which included

\$561 million on the purchase of the core respiratory assets of Takeda. The comparative period of 2015 included \$684 million on the acquisition of the rights to Actavis branded respiratory portfolio in the U.S. and Canada.

Investment cash inflows include \$1,427 million (2015: \$1,130 million) from the sale of intangible assets, including \$552 million for the disposal of the late-stage antibiotics business, \$330 million for the sale of the Group's rights to *Rhinocort Aqua* outside of the U.S. and \$250 million on the out-licence agreement for MEDI-2070. The comparative period in 2015 included the divestments of *Entocort* in the U.S. for \$380 million, and in the Rest of World for \$215 million and of *Myalept* for \$325 million.

Net cash distributions to shareholders were \$3,514 million (2015: \$3,443 million) including dividends of \$3,561 million (2015: \$3,486 million). Proceeds from the issue of shares on the exercise of share options amounted to \$47 million (2015: \$43 million).

In May 2016, the Group issued 2.2 billion of bonds in the euro debt capital markets with maturities of 5, 8 and 12 years. The bonds are listed in a table under the heading Strategic Report Financial Review Cash flow and liquidity for the year ended 2017 Bonds issued in 2017 and 2016 on page 74 of AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated March 6, 2018. In November 2015, the Group issued bonds worth \$6 billion to fund the acquisition of ZS Pharma, to repay certain of the Group's outstanding commercial paper obligations and for general corporate purposes.

In 2015, the Group also repaid a 5.125% non-callable euro bond which had a 31 December 2015 carrying value of \$912 million.

At 31 December 2016, outstanding gross debt (interest-bearing loans and borrowings) was \$16,808 million (2015: \$15,053 million). Of the gross debt outstanding at 31 December 2016, \$2,307 million is due within one year (2015: \$916 million). Net debt at 31 December 2016 was \$10,657 million, compared to \$7,762 million at 31 December 2015, as a result of the net cash outflow as described above.

Financial position 31 December 2016

In 2016, net assets decreased by \$1,840 million to \$16,669 million. The decrease in net assets was broadly as a result of dividends of \$3,540 million and adverse movements on exchange taken to reserves of \$1,641 million, partially offset by the Group profit of \$3,406 million.

Business combinations

In 2016, the Group acquired a majority equity stake in Acerta Pharma. In 2015, AstraZeneca completed the acquisition of ZS Pharma. Further details of the business combinations are set forth under the heading Financial Statements Notes to the Group Financial Statements Note 25 Acquisitions of business operations on pages 173 to 174 of AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated March 6, 2018.

Property, plant and equipment

Property, plant and equipment increased by \$435 million in 2016 to \$6,848 million. Additions of \$1,449 million (2015: \$1,422 million) were offset by depreciation of \$609 million (2015: \$677 million), impairments of \$2 million (2015: \$28 million) and disposals of \$74 million (2015: \$70 million).

Goodwill and intangible assets

Goodwill of \$11,658 million at 31 December 2016 (2015: \$11,800 million) principally arose on the acquisition of MedImmune in 2007, the restructuring of the U.S. joint venture with Merck in 1998 and the acquisition of BMS's share of the Global Diabetes Alliance. Goodwill of \$19 million arising on the acquisition of Acerta Pharma was capitalised in 2016.

Intangible assets amounted to \$27,586 million at 31 December 2016 (2015: \$22,646 million). Intangible asset additions were \$8,205 million in 2016 (2015: \$4,640 million), including product rights acquired in the acquisition of Acerta Pharma of \$7,307 million (\$3,162 million on the acquisition of ZS Pharma in 2015). Amortisation in 2016 was

Edgar Filing: ASTRAZENECA PLC - Form 20-F

\$1,701 million (2015: \$1,999 million). Impairment charges in 2016 amounted to \$45 million (2015: \$148 million), including \$15 million for RDEA119. Disposals of intangible assets totalled \$331 million in 2016 (2015: \$169 million).

Further details of additions to intangible assets, and impairments recorded, are set forth under the heading *Financial Statements Notes to the Group Financial Statements Note 9 Intangible assets* on pages 155 to 157 of AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated March 6, 2018.

Receivables, payables and provisions

Trade and other receivables decreased by \$2,055 million in 2016 with trade receivables reduced by \$2,050 million to \$2,583 million as a result of more factored invoices during 2016 and lower gross invoiced sales in the U.S. Non-current other receivables decreased by \$6 million to \$901 million, driven by a reduction in the Shionogi *Crestor* royalty prepayment.

Trade and other payables increased by \$854 million in 2016 to \$19,974 million, including a \$1,901 million put option, and \$1,332 million deferred consideration on the majority investment in Acerta Pharma, partially offset by reductions in contingent consideration of \$954 million, a decrease in trade payables of \$479 million, and a decrease of \$495 million on rebates and chargebacks driven by reduced Product Sales in the U.S.

The increase in provisions of \$176 million in 2016 included \$988 million of additional charges recorded in 2016, partially offset by \$686 million of cash payments. Included within the \$988 million of charges for 2016 were \$578 million for the global restructuring initiatives and \$223 million in respect of legal charges. Cash payments included \$433 million for the global restructuring programmes.

Tax payable and receivable

Net income tax payable decreased by \$142 million to \$954 million in 2016, principally due to a \$453 million adjustment following agreements between the Canadian tax authority and the U.K. and Swedish tax authorities in respect of transfer pricing arrangements for the 13-year period from 2004-2016, partially offset by net cash refunds received following agreement of the 2015 tax liabilities and audit settlements of \$274 million. The tax receivable balance of \$426 million at 31 December 2016 (2015: \$387 million) comprises tax owing to the Group from certain governments expected to be received on settlements of transfer pricing audits and disputes of \$161 million and cash tax timing differences of \$265 million.

Net deferred tax liabilities increased by \$1,483 million in 2016 mainly due to deferred tax liabilities arising from the acquisition of Acerta Pharma.

Retirement benefit obligations

Net retirement benefit obligations increased by \$212 million in 2016 (2015: decrease of \$977 million) to \$2,186 million. Net remeasurement adjustments of \$575 million in the U.K., Sweden and Germany arising from reductions in discount rate assumptions were partially offset by a \$312 million impact of exchange rate movements in 2016 as the U.S. dollar strengthened against pound sterling, euro and Swedish krona and employer contributions to the pension scheme of \$192 million. Benefits paid amounted to \$500 million (2015: \$580 million).

Developments in Legal Proceedings

For information in respect of material legal proceedings in which AstraZeneca is currently involved, including those discussed below, please see the information (including tabular data) set forth under the heading "Financial Statements - Notes to the Group Financial Statements - Note 28 - Commitments and contingent liabilities" on pages 182 to 188 of AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated March 6, 2018.

The proceedings discussed below are provided to supplement and update the corresponding disclosure in AstraZeneca's Annual Report and Form 20-F Information 2017. Unless noted below or in AstraZeneca's Annual Report on Form 20-F Information 2017, no provisions have been established in respect of these proceedings.

Patent litigation

Brilinta (ticagrelor)

U.S. patent proceedings

In 2015, in response to Paragraph IV notices from multiple ANDA filers, AstraZeneca filed patent infringement lawsuits in the U.S. District Court for the District of Delaware (the District Court) relating to patents listed in the FDA Orange Book with reference to *Brilinta*. In February 2018, AstraZeneca entered into separate settlements with a number of the ANDA filers and the District Court entered consent judgments to dismiss several of the litigations. AstraZeneca continues to litigate in the District Court against additional ANDA filers. Trials are scheduled for March and April 2018.

Crestor (rosuvastatin calcium)

Patent proceedings outside the U.S.

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

Pulmicort Respules (budesonide inhalation suspension)

U.S. patent proceedings

In February 2015, the U.S. District Court for the District of New Jersey (the District Court) determined that the asserted claims of U.S. Patent No. 7,524,834, which covered *Pulmicort Respules*, were invalid following challenges brought by Apotex, Inc., Apotex Corp., Breath Limited, Sandoz, Inc. and Watson Laboratories, Inc. (together, the Generic Challengers). In May 2015, the U.S. Court of Appeals for the Federal Circuit affirmed the District Court's decision. Since 2009, various injunctions were issued in this matter. Damages claims based on those injunctions have been filed by the Generic Challengers and a trial for the damages claims is scheduled for May 2018. A provision has been taken.

Losec/Prilosec (omeprazole)

Patent proceedings outside the U.S.

In Canada, in 2004, AstraZeneca brought proceedings against Apotex, Inc. (Apotex) for infringement of several patents related to *Losec*. In February 2015, the Federal Court of Canada (the Federal Court) found that Apotex had infringed the *Losec* formulation patent (Canadian Patent No. 1,292,693). In July 2017, after a reference to account for Apotex 's profits earned as a result of the infringement, the Federal Court issued its decision describing how the quantification of monies owed to AstraZeneca should proceed. Apotex appealed. In February 2018, AstraZeneca and Apotex entered into a settlement agreement, under which Apotex agreed to pay AstraZeneca CAD 435 million (U.S.\$ 352 million), concluding all *Losec* patent litigation in Canada.

Product liability litigation

Onglyza (saxagliptin) and Kombiglyze (saxagliptin and metformin)

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

Commercial litigation

Array BioPharma

In the U.S., in December 2017 and February 2018, AstraZeneca was served with complaints filed in New York state court by Array BioPharma, Inc. (Array) that alleged, among other things, breaches of contractual obligations relating to a 2003 collaboration agreement between AstraZeneca and Array.

Telephone Consumer Protection Act litigation

In the U.S., in December 2016, AstraZeneca and several other entities were served with a complaint filed in the U.S. District Court for the Southern District of Florida that alleges, among other things, violations of the Telephone Consumer Protection Act caused by the sending of unsolicited advertisements by facsimile. The litigation is ongoing.

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. Directors and Senior Management

The information (including tabular data) set forth under the headings Corporate Governance Corporate Governance Overview Board of Directors on pages 88 and 89 and Senior Executive Team on pages 90 and 91 and Corporate Governance Annual Report on Remuneration Governance Directors service contracts and letters of appointment on page 125, in each case of AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated March 6, 2018 is incorporated by reference.

No Director has a family relationship with any other Director.

B. Compensation

The information (including graphs and tabular data) set forth under the headings Corporate Governance Directors Remuneration Report on pages 105 to 107, Corporate Governance Annual Report on Remuneration on pages 105 to 125, Financial Statements Notes to the Group Financial Statements Note 20 Post-retirement benefits on pages 164 to 170, Note 27 Employee costs and share plans for employees on pages 179 to 181 and Note 30 Statutory and other information Key management personnel compensation, on page 189, in each case of AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated March 6, 2018 is incorporated by reference.

C. Board Practices

The information (including graphs and tabular data) set forth under the headings Corporate Governance Corporate Governance Overview on page 87, Corporate Governance Board of Directors on pages 88 and 89, Corporate Governance Senior Executive Team (SET) on pages 90 and 91, Corporate Governance Corporate Governance Report Leadership and responsibilities on page 92, Board effectiveness on pages 93 to 94, Remuneration on page 96, Nomination and Governance Committee on page 96 Science Committee on page 97, Business Organisation Global Compliance and Internal Audit Services (IA) on pages 97 and 98, Corporate Governance Directors Remuneration Report Directors service contracts and letters of appointment on page 125 and Corporate Governance Audit Committee Report on pages 100 to 104, in each case of AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated March 6, 2018 is incorporated by reference.

D. Employees

The information set forth under the headings Strategic Report Business Review 1. Achieve Scientific Leadership R&D resources (other than R&D spend analysis) on page 25, 2. Return To Growth Operations on pages 30 and 31, 2. Return To Growth Information technology and information services resources on page 33, 3. Be A Great Place To Work Employees (comprising the graphical data on page 36, and the Managing change and Employee relations sections on page 37 only) and Financial Statements Notes to the Group Financial Statements Note 27 Employee costs and share plans for employees Employee costs (including the tabular data) on page 179, in each case of AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated March 6, 2018 is incorporated by reference.

E. Share Ownership

The information (including graphs and tabular data) set forth under the headings Financial Statements Notes to the Group Financial Statements Note 27 Employee costs and share plans for employees on pages 179 to 181, Corporate Governance Corporate Governance Report Other matters Directors shareholdings on page 99, Corporate Governance Annual Report on Remuneration Directors interests in shares on pages 116 to 117, and Additional Information Shareholder Information Options to purchase securities from registrant or subsidiaries

on page 231, in each case of AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated March 6, 2018 is incorporated by reference.

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. Major Shareholders

The information set forth under the heading Additional Information Shareholder Information US holdings and Major shareholdings (including tabular data) on page 230 of AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated March 6, 2018 is incorporated by reference.

B. Related Party Transactions

The information set forth under the headings Financial Statements Notes to the Group Financial Statements Note 30 Statutory and other information Related party transactions on page 189, Additional Information Shareholder Information Related party transactions on page 231, Issued share capital, shareholdings and share prices on page 229, US holdings on page 230 and Major shareholdings on page 230, in each case of AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated March 6, 2018 is incorporated by reference.

C. Interests of Experts and Counsel

Not applicable.

ITEM 8. FINANCIAL INFORMATION

A. Consolidated Statements and Other Financial Information

Please see the information below under the heading Item 18 Financial Statements. The information (including graphs and tabular data) set forth under the headings Additional Information Shareholder Information on pages 228 to 233, Strategic Report Financial Review Financial position 31 December 2017 Capitalisation and Shareholder Return Dividends for 2017 and Dividend and share repurchases on page 78 and Corporate Governance Corporate Governance Report Other matters Distributions to shareholders dividends for 2017 on page 98, in each case of AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated March 6, 2018 is incorporated by reference.

B. Significant Changes

Please see the information above under the heading Item 5 Operating and Financial Review and Prospects Developments in Legal Proceedings for information as to recent developments in certain legal proceedings disclosed under the heading Financial Statements Notes to the Group Financial Statements Note 28 Commitments and contingent liabilities on pages 182 to 188 of AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated March 6, 2018.

Other than as disclosed in this Item, since the date of the annual consolidated financial statements included in this Form 20-F dated March 6, 2018, no significant change has occurred.

ITEM 9. THE OFFER AND LISTING

A. Offer and Listing Details

The information (including tabular data) set forth under the heading Additional Information Shareholder Information Ordinary shares in issue on page 229 of AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated March 6, 2018 is incorporated by reference.

In addition, the table below sets forth, for the periods indicated, the reported high and low share prices of the Company, on the following bases:

- for shares listed on the London Stock Exchange (LSE) the reported high and low middle market closing quotations are derived from the Daily Official List;

- for shares listed on the Stockholm Stock Exchange (SSE) the high and low closing sales prices are as stated in the Official List; and

- for American Depositary Shares (ADS) listed on the New York Stock Exchange the reported high and low sales prices are as reported by Dow Jones (ADR quotations).

		Ordinary LSE		ADS NYSE		Ordinary SSE	
		High (GB pence)	Low (GB pence)	High (\$)	Low (\$)	High (SEK)	Low (SEK)
2018	February	5,036.0	4,712.5	35.90	33.19	568.70	531.70
2018	January	5,204.0	4,866.5	36.63	34.99	583.80	552.90
2017	December	5,121.0	4,705.0	34.70	32.09	568.50	541.00
2017	November	5,180.0	4,777.0	34.56	32.87	581.00	546.50
2017	October	5,176.0	5,022.0	34.78	33.49	568.00	552.50
2017	September	4,955.0	4,573.5	34.00	30.07	547.50	479.60

		Ordinary LSE		ADS NYSE		Ordinary SSE	
		High (GB pence)	Low (GB pence)	High (\$)	Low (\$)	High (SEK)	Low (SEK)
2017		5,508.0	4,210.5	35.36	26.72	619.00	466.20
2017	Quarter 4	5,180.0	4,705.0	34.78	32.09	581.00	541.00
2017	Quarter 3	5,192.0	4,325.0	34.16	28.88	578.00	466.20
2017	Quarter 2	5,508.0	4,566.0	35.36	29.76	619.00	534.00
2017	Quarter 1	4,974.5	4,194.0	31.80	26.72	558.00	470.60

		Ordinary LSE		ADS NYSE		Ordinary SSE	
		High (GB pence)	Low (GB pence)	High (\$)	Low (\$)	High (SEK)	Low (SEK)
2016		5,220.0	3,774.0	34.50	25.81	592.0	448.5
2016	Quarter 4	5,096.0	4,007.0	33.00	25.81	581.5	448.5
2016	Quarter 3	5,220.0	4,469.5	34.50	29.97	556.0	456.6
2016	Quarter 2	4,467.0	3,774.0	30.25	27.26	592.0	458.2
2016	Quarter 1	4,562.0	3,890.0	33.90	27.95	584.0	452.8

		Ordinary LSE		ADS NYSE(1)		Ordinary SSE	
		High (GB pence)	Low (GB pence)	High (\$)	Low (\$)	High (SEK)	Low (SEK)
2015		4,863.0	3,903.5	36.68	30.28	638.0	508.5
2014		4,823.5	3,549.5	40.55	29.26	558.5	380.5
2013		3,612.0	2,909.5	29.75	22.34	387.8	284.5
2012		3,111.5	2,591.0	24.45	20.02	329.5	286.2

(1) Effective as of July 27, 2015, the Company changed the ADS ratio from one ADS per one ordinary share to two ADSs per one ordinary share. The prices per ADS listed in this item 9.A for any dates or periods prior to such date have been retroactively adjusted to reflect this ratio change.

B. Plan of Distribution

Not applicable.

C. Markets

The information (including tabular data) set forth in the introductory paragraph under the heading **Additional Information** **Shareholder Information** on page 228 and **Issued share capital, shareholdings and share prices**

on page 229 of AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated March 6, 2018 is incorporated by reference.

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

ITEM 10. ADDITIONAL INFORMATION

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

The information set forth under the heading Additional Information Shareholder Information Articles of Association on page 231 of AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated March 6, 2018 is incorporated by reference.

C. Material Contracts

Not applicable.

D. Exchange Controls

The information set forth under the headings Additional Information Shareholder Information Exchange controls and other limitations affecting security holders on page 233 of AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated March 6, 2018 is incorporated by reference.

E. Taxation

The information set forth under the headings Additional Information Shareholder Information Tax information for shareholders on pages 232 to 233 of AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated March 6, 2018 is incorporated by reference.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

The information set forth under the heading Additional Information Shareholder Information Documents on display on page 232 of AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated March 6, 2018 is incorporated by reference.

In addition, we file reports and other information with the United States Securities and Exchange Commission (the SEC). You can read and copy these reports and other information at the SEC's Public Reference Room at 100

F Street, N.E., Washington, D.C. 20549. You can call the SEC at 1-800-SEC-0330 for further information on the Public Reference Room. The SEC also maintains a website at www.sec.gov which contains in electronic form each of the reports and other information that we have filed electronically with the SEC.

I. Subsidiary Information

Not applicable.

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The information (including graphs and tabular data) set forth under the headings Strategic Report Financial Review Financial risk management on page 79 and Financial Statements Note 26 Financial risk management objectives and policies on pages 175 to 179, in each case of AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated March 6, 2018 is incorporated by reference.

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable.

C. Other Securities

Not applicable.

D. American Depositary Shares

Fees and Charges Payable by ADR Holders

The Company's American Depositary Receipt (ADR) program is administered by Citibank, N.A. (Citibank or the Depository), as the depository. The holder of an ADR may have to pay the following fees and charges to Citibank in connection with ownership of the ADR:

Category	Depository actions	Associated fee or charge
(a) Depositing or substituting the underlying shares	Issuances upon deposits of shares (excluding issuances as a result of stock distributions or the exercise of rights)	Up to \$5.00 for each 100 ADSs (or fraction thereof) issued
(b) Receiving or distributing dividends(1)	Distributions of stock dividends or other free stock distributions, cash dividends or other cash distributions (i.e., sale of rights and other entitlements), distributions of securities other than ADSs or rights to purchase additional ADSs	Up to \$5.00 for each 100 ADSs (or fraction thereof)
(c) Selling or exercising rights	The exercise of rights to purchase additional ADSs	Up to \$5.00 for each 100 ADSs (or fraction thereof)
(d) Withdrawing, cancelling or reducing an underlying security	Surrendering ADSs for cancellation and withdrawal of deposited property	Up to \$5.00 for each 100 ADSs (or portion thereof) surrendered or cancelled (as the case may be)

(1) \$0.03 per ADR annually

Edgar Filing: ASTRAZENECA PLC - Form 20-F

Category	Depositary actions	Associated fee or charge
(e) Transferring, combination or split-up of receipts		Not applicable.
(f) General depositary services, particularly those charged on an annual basis(1)	Depositary services fee	A fee not in excess of U.S. \$5.00 per 100 ADSs (or fraction thereof) held on the applicable record date(s) established by the Depositary.
(g) Fees and expenses of the depositary	Fees and expenses incurred by the Depositary or the Depositary's agents on behalf of holders, including in connection with:	As incurred by the Depositary.
	<ul style="list-style-type: none"> <li data-bbox="515 695 943 793">• taxes (including applicable interest and penalties) and other governmental charges <li data-bbox="515 898 1021 1136">• registration of shares or other deposited securities on the share register and applicable to transfers of shares or other deposited securities to or from the name of the custodian, the Depositary or any nominees upon the making of deposits and withdrawals, respectively; <li data-bbox="515 1241 932 1304">• cable, telex and facsimile transmission and delivery expenses <li data-bbox="515 1409 1018 1507">• expenses and charges incurred by the Depositary in conversion of foreign currency into U.S. dollars <li data-bbox="515 1612 986 1745">• compliance with exchange control regulations and other regulatory requirements applicable to the shares, deposited securities, ADSs and ADRs <li data-bbox="515 1850 986 1913">• the fees and expenses incurred by the Depositary, the custodian, or any 	

nominee in connection with the delivery
or servicing of deposited property (as
defined in the Deposit Agreement)

Fees and Payments Made by the Depositary to Us

Pursuant to the deposit agreement, the Depositary may charge a fee up to \$0.05 per ADR in respect of dividends paid by us. For the year ended December 31, 2017, we agreed that the Depositary could charge an annual fee of \$0.03 per ADR in respect of dividends paid by us. As at December 31, 2017, we have received approximately \$10.42 million arising out of fees charged in respect of dividends paid during the year and \$1.5 million as a fixed contribution to the Company's ADR program costs. We also have an agreement with the Depositary that it will waive a certain amount of its fees for standard costs associated with the administration of the ADR program up to \$300,000 per year.

PART II

ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

Not applicable.

ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

Not applicable.

ITEM 15. CONTROLS AND PROCEDURES

A. Internal Controls and Procedures

The information set forth under the heading "Corporate Governance" Corporate Governance Report "Accountability" on page 96, "US corporate governance requirements" on page 97 (the first and second paragraphs only), "Business organisation Disclosure Committee" on page 97, "Corporate Governance Audit Committee Report Internal Controls" on page 104, and "Financial Statements Directors Annual Report on Internal Controls over Financial Reporting" on page 128, in each case of AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated March 6, 2018 is incorporated by reference.

B. Management's Annual Report on Internal Control over Financial Reporting

As required by U.S. regulations, management is responsible for establishing and maintaining adequate internal control over financial reporting for the Company, and is required to identify the framework used to evaluate the effectiveness of the Company's internal control over financial

Edgar Filing: ASTRAZENECA PLC - Form 20-F

reporting and to assess the effectiveness of such internal control. In this regard, management has made the same assessment and reached the same conclusion as that set forth in the section entitled "Financial Statements - Directors' Annual Report on Internal Controls over Financial Reporting" on page 128 of AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated March 6, 2018 which is incorporated herein by reference. AstraZeneca's independent registered public accounting firm has issued an audit report on the effectiveness of AstraZeneca's internal controls over financial reporting. That report is included under Item 18 "Financial Statements."

C. Report of Independent Registered Public Accounting Firm

The effectiveness of the Company's internal control over financial reporting as of December 31, 2017 has been audited by PricewaterhouseCoopers LLP, independent registered public accounting firm, as stated in their report which is included below under the heading Item 18 – Financial Statements .

D. Changes to Internal Controls

The information set forth under the heading – Corporate Governance – Corporate Governance Report – Accountability – Risk management and internal control – on page 96 and – Corporate Governance – Audit Committee Report – Internal Controls – on page 104 of AstraZeneca's Annual Report and Form 20-F Information 2017 – included as exhibit 15.1 to this Form 20-F dated March 6, 2018 is incorporated by reference. Management has evaluated whether any changes to AstraZeneca's internal control over financial reporting that occurred during 2017 have materially affected, or are reasonably likely to materially affect, AstraZeneca's internal control over financial reporting. Based on the evaluation conducted, management has concluded that no such changes have occurred.

ITEM 16. RESERVED

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

The information set forth under the heading – Corporate Governance – Audit Committee Report – Committee membership and attendance – on page 102 of AstraZeneca's Annual Report and Form 20-F Information 2017 – included as exhibit 15.1 to this Form 20-F dated March 6, 2018 is incorporated by reference.

ITEM 16B. CODE OF ETHICS

The information set forth under the headings – Corporate Governance – Corporate Governance Report – Business organisation – Code of Ethics – on page 98 and – Audit Committee Report – Compliance with the Code of Ethics – on page 101, in each case of AstraZeneca's Annual Report and Form 20-F Information 2017 – included as exhibit 15.1 to this Form 20-F dated March 6, 2018 is incorporated by reference. AstraZeneca's Code of Ethics is available within the – Ethics and transparency – section of our website at www.astrazeneca.com/sustainability/ethics-and-transparency.html.

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Edgar Filing: ASTRAZENECA PLC - Form 20-F

The following table sets forth the aggregate fees for professional services rendered by PricewaterhouseCoopers LLP in 2017 and by KPMG LLP in 2016:

	Year ended December 31,	
	2017	2016
	(\$ million)	
Audit Fees	10.7	10.0
Audit-Related Fees	0.4	1.3
Tax Fees		
All Other Fees		0.2
Total	11.1	11.5

Audit fees included \$5.7 million for the audit of subsidiaries pursuant to legislation (2016: \$5.4 million), \$3.0 million for the Group audit (2016: \$2.8 million) and \$2.0 million in respect of section 404 of the Sarbanes-Oxley Act (2016: \$1.8 million).

Audit-related fees included \$0.0 million for the audit of subsidiaries pension schemes (2016: \$0.6 million), \$0.3 million for assurance services in relation to interim financial statements (2016: \$0.5 million) and \$0.1 million for other audit related fees (2016: \$0.2 million).

All other fees consisted of fees of \$0.0 million (2016: \$0.2 million) for assurance services.

The information (including tabular data) set forth under the heading Corporate Governance Audit Committee Report (excluding the Compliance with the Code of Ethics section) on pages 100 to 104 of AstraZeneca's

Edgar Filing: ASTRAZENECA PLC - Form 20-F

Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated March 6, 2018 is incorporated by reference.

U.S. law and regulations permit the Audit Committee pre-approval requirement to be waived with respect to engagements for non-audit services aggregating to no more than five percent of the total amount of revenues paid by AstraZeneca to its principal accountants, if such engagements were not recognized by AstraZeneca at the time of engagement and were promptly brought to the attention of the Audit Committee or a designated member thereof and approved prior to the completion of the audit. In 2017 and 2016, the percentage of the total amount of revenues paid by AstraZeneca to its principal accountant for non-audit services in each category that was subject to such a waiver was less than five per cent for each year.

ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES

Not applicable.

ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

Period	(a) Total number of Shares (or Units) Purchased	(b) Average Price Paid per Share (or Unit) (\$)	(c) Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	(d) Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs (\$ billion)
Month #1				
Jan 1 - Jan 31	0	N/A	0	0
Month #2				
Feb 1 - Feb 28	0	N/A	0	0
Month #3				
Mar 1 - Mar 31	0	N/A	0	0
Month #4				
Apr 1 - Apr 30	0	N/A	0	0
Month #5				
May 1 - May 31	0	N/A	0	0
Month #6				
Jun 1 - Jun 30	0	N/A	0	0
Month #7				
Jul 1 - Jul 31	0	N/A	0	0
Month #8				
Aug 1 - Aug 31	0	N/A	0	0
Month #9				
Sep 1 - Sep 30	0	N/A	0	0
Month #10				
Oct 1 - Oct 31	0	N/A	0	0
Month #11				
Nov 1 - Nov 30	0	N/A	0	0
Month #12				
Dec 1 - Dec 31	0	N/A	0	0
Total	0	N/A	0	0

There have been no share repurchases since October 1, 2012, when the Company announced the suspension of its share repurchase program. At the 2017 Annual General Meeting the Company's shareholders authorized the Company to repurchase 126,541,153 of its own shares, but the Company's Board of Directors did not lift the suspension on share repurchases and, accordingly, the Company did not repurchase any of its shares in 2017.

ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT

At the 2017 Annual General Meeting on April 27, 2017, a resolution to approve the appointment of PricewaterhouseCoopers LLP (PwC) as the independent registered public accounting firm and U.K. statutory auditor for the financial year ending December 31, 2017 was approved by the Company's shareholders. PwC was engaged as U.K. statutory auditor with immediate effect on April 27, 2017, at which time KPMG LLP (KPMG), our prior U.K. statutory auditor was dismissed. PwC was engaged as the independent registered public accounting firm with immediate effect on July 24, 2017, following KPMG being dismissed as our prior independent registered public accounting firm on July 20, 2017. The change of auditor followed a recommendation by the Audit Committee to the Board of Directors based on a formal tender process held in 2015, in which KPMG had not participated as KPMG would have been prohibited to serve as AstraZeneca's U.K. statutory auditor after 2020 due to U.K. auditor rotation rules. PwC will hold office until the 2018 Annual General Meeting of the Company, when it will be proposed to the shareholders that PwC are re-elected as auditors of the Company.

During the years ended December 31, 2016 and 2015, KPMG did not issue any reports on the financial statements of the Company or on the effectiveness of internal control over financial reporting that contained an adverse opinion or a disclaimer of opinion, nor were the auditors reports of KPMG qualified or modified as to uncertainty, audit scope, or accounting principles. Furthermore, during the years ended December 31, 2016 and 2015, and in the subsequent interim period through July 20, 2017, no disagreement occurred over any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedures, which disagreements if not resolved to KPMG's satisfaction would have caused it to make reference to the subject matter of the disagreement in connection with reports it issued during such period, or any reportable event as described in Item 16F(a)(1)(v) of Form 20-F.

The Company has provided KPMG with a copy of the foregoing disclosure and has requested that they furnish the Company with a letter addressed to the SEC stating whether they agree with such disclosure and, if not, stating the respects in which they do not agree. A copy of KPMG's letter, dated March 6, 2018, in which KPMG states that they agree with such disclosure, is filed herewith as Exhibit 15.7.

During the years ended December 31, 2016 and 2015, and in the subsequent interim period through July 24, 2017, neither the Company, nor anyone on its behalf, consulted PwC regarding either: (1) the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on Company's financial statements and neither a written report was provided to the Company or oral advice was provided that PwC concluded was an important factor considered by the Company in reaching a decision as to the accounting, auditing or financial reporting issue, or (2) any matter that was either the subject of a disagreement, as that term is defined in Item 16F(a)(1)(iv) of Form 20-F and the related instructions to Item 16F of Form 20-F, or a reportable event, as that term is described in Item 16F(a)(1)(v) of Form 20-F.

ITEM 16G. CORPORATE GOVERNANCE

The Company is a public limited company incorporated in England and Wales, admitted to the Official List of the Financial Conduct Authority (FCA) and to trading on the main market of the London Stock Exchange. As a result, it follows the U.K. Corporate Governance Code (the U.K. Code) in respect of its corporate governance practices. The 2014 edition of the U.K. Code came into effect for reporting periods beginning on or

Edgar Filing: ASTRAZENECA PLC - Form 20-F

after 1 October 2014. The Companies Act 2006 (the U.K. Act) imposes certain statutory requirements that also influence the Company's corporate governance practices. The Company has ADRs listed on the NYSE and, under the NYSE Corporate Governance Standards (the NYSE Standards) applicable to listed companies, as a foreign private issuer, the Company is permitted to follow the corporate governance practice of its home country in lieu of certain provisions of the NYSE Standards.

A summary of the significant ways in which the Company's corporate governance practices differ from those followed by U.S. domestic companies under the NYSE Standards is set forth below.

NYSE Standards

1. Under the NYSE Standards, the audit committee is to be directly responsible for the appointment, compensation, retention and oversight of a listed company's external auditor, unless there is a conflicting requirement under the home country laws of the company.

AstraZeneca Corporate Governance Practice

Under the U.K. Act, a company's external auditors are appointed by its shareholders. Under the U.K. Code, the Company's audit committee is responsible for, amongst other things, making recommendations to the Board of Directors, for the Board of Directors to propose to the Company's shareholders in general meeting, in relation to the appointment, re-appointment and removal of the external auditors, and for approving the remuneration and terms of engagement of the external auditor. If the Board of Directors does not accept the audit committee's recommendation, it should include in the annual report, and in any papers recommending appointment or re-appointment, a statement from the audit committee explaining the recommendation and should set out reasons why the Board of Directors has taken a different position.

2. Under the NYSE Standards, the nominating/corporate governance committee and compensation committee are to be composed entirely of independent directors.

Under the U.K. Code, a majority of the members of a company's nomination committee, and all of the members of its remuneration committee, should be independent non-executive directors. The chairman of the company may be a member of, but not chair, the remuneration committee, provided he or she was considered independent on appointment as chairman (under the U.K. Code, the test of independence is not appropriate in relation to the chairman thereafter), and in the case of the nomination committee, the chairman may chair such committee.

The Company's Nomination and Governance Committee and Remuneration Committee have three and four members respectively, including the chairman of the Company's Board of Directors, with the remainder all being considered by the Company's Board of Directors to be independent in accordance with the principles and criteria of the U.K. Code. The Company's chairman was considered to be independent upon his appointment as chairman.

3. Under the NYSE Standards, the compensation committee is to make recommendations to the listed company's Board of Directors with respect to non-CEO executive officer compensation and certain other compensation plans which are subject to Board approval.

In compliance with the U.K. Code, the Company's Remuneration Committee determines the Company's global remuneration frameworks and principles, approves individual salary decisions and related matters for members of the Company's Board of Directors, SET and the Company Secretary, and reviews annual bonus payments for all executives reporting directly to SET members. While the Remuneration Committee does not make initial recommendations to the Board of Directors in this respect, it does report to the Board of Directors on these matters.

Under the U.K. Act, the Company is required to offer shareholders: (i) a binding vote on the Company's forward looking remuneration policy for its directors at least every three years; and (ii) a separate annual advisory vote on the implementation of the Company's existing remuneration policy in terms of the payments

NYSE Standards

AstraZeneca Corporate Governance Practice

and share awards made to its directors during the year, which is disclosed in an annual remuneration report.

4. Under the NYSE Standards, shareholders are entitled to vote on all equity compensation plans and material revisions thereto, with certain limited exemptions.

Under the listing rules of the U.K. Listing Authority (the UKLA Rules), with which the Company complies, shareholder approval is required to be obtained by the Company for the adoption of equity compensation plans which are either long-term incentive schemes in which directors of the Company can participate or schemes which may involve the issue of new shares. Under the UKLA Rules, these plans may not be changed to the benefit of the plan participants unless shareholder approval is obtained (with certain minor exceptions, for example, to benefit the administration of the plan or to take account of tax benefits). The UKLA Rules in respect of shareholder approval regarding equity compensation plans, or any material revision thereto, may differ from the NYSE Standards.

5. Under the NYSE Standards, each listed company Chief Executive Officer must certify to the NYSE each year that he or she is not aware of any violation by the listed company of any NYSE corporate governance listing standards.

As the Company is a foreign private issuer, the Company's Chief Executive Officer is not required to make this certification. He is, however, required to promptly notify the NYSE in writing after any executive officer of the Company becomes aware of any non-compliance with any NYSE corporate governance rules applicable to the Company.

The UKLA Rules require the Company to include a statement in its annual report and accounts as to whether it has complied throughout the applicable accounting period with all relevant provisions set out in the U.K. Code or, if it has not complied, set out those provisions it has not complied with and its reasons for non-compliance.

The information set forth under the heading Corporate Governance Corporate Governance Report US corporate governance requirements (final paragraph only) on page 97 of AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated March 6, 2018 is incorporated by reference.

ITEM 16H. MINE SAFETY DISCLOSURE

Not applicable.

PART III

ITEM 17. FINANCIAL STATEMENTS

The Company has responded to Item 18 in lieu of this item.

ITEM 18. FINANCIAL STATEMENTS

The information (including tabular data) set forth under the headings "Financial Statements" on pages 126 to 198 (including the information set forth under the subheading "Notes to the Group Financial Statements" on pages 145 to 189, but excluding the information set forth under the subheadings "Independent Auditors' Report to the Members of AstraZeneca PLC" on pages 129 to 134) and "Financial Statements - Group Financial Record" on page 199, in each case of AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated March 6, 2018 is incorporated by reference.

Please see the information above under the heading "Item 5 - Operating and Financial Review and Prospects - Developments in Legal Proceedings" for unaudited information as to recent developments in certain legal proceedings disclosed under the heading "Financial Statements - Notes to the Group Financial Statements - Note 28 - Commitments and contingent liabilities" on pages 182 to 188 of AstraZeneca's Annual Report and Form 20-F Information 2017 included as exhibit 15.1 to this Form 20-F dated March 6, 2018 which is incorporated herein by reference.

The information set out in the above-referenced financial statements does not constitute the Company's statutory accounts under the U.K. Companies Act for the years ended December 31, 2017, 2016 or 2015. Those accounts have been reported on by the Company's auditors; their reports were unqualified and did not contain a statement under section 498(2) or (3) of the Companies Act 2006. The accounts for 2016 and 2015 have been delivered to the U.K. registrar of companies and those for 2017 will be delivered in due course.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of AstraZeneca PLC

Opinion on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying Consolidated Statement of Financial Position of AstraZeneca PLC and its subsidiaries as of 31 December 2017, and the related Consolidated Statement of Comprehensive Income, Consolidated Statement of Changes in Equity and Consolidated Statement of Cash Flows for the year ended 31 December 2017, including the related notes (collectively referred to as the consolidated financial statements). We also have audited the Company's internal control over financial reporting as of 31 December 2017, based

Edgar Filing: ASTRAZENECA PLC - Form 20-F

on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of 31 December 2017, and the results of its operations and its cash flows for the year ended 31 December 2017 in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board and in conformity with International Financial Reporting Standards as adopted by the European Union. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of 31 December 2017, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Basis for Opinion

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the Directors' Annual Report on Internal Controls over Financial Reporting. Our responsibility is to express an opinion on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with

respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audit of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PricewaterhouseCoopers LLP
London, United Kingdom
2 February 2018

We have served as the Company's auditor since 2017.

ITEM 19. EXHIBITS(1)

- 1.1 Articles of Association of AstraZeneca PLC (incorporated into this Form 20-F by reference to Exhibit 1.1 of AstraZeneca PLC's Form 20-F filed March 8, 2016 (File No. 001-11960)).
- 4.1 Master Restructuring Agreement dated as of June 19, 1998 between Astra AB, Merck & Co., Inc., Astra Merck Inc., Astra USA, Inc., KB USA, L.P., Astra Merck Enterprises, Inc., KBI Sub Inc., Merck Holdings, Inc. and Astra Pharmaceuticals, L.P (incorporated into this Form 20-F by reference to Exhibit 2.1 of AstraZeneca AB's Form 6-K/A filed October 16, 1998 (File No. 001-14388)).
- 4.2 Letter agreement between AstraZeneca PLC and Pascal Soriot, dated August 27, 2012 (incorporated into this Form 20-F by reference to Exhibit 4.2 of AstraZeneca PLC's Form 20-F filed March 25, 2013 (File No. 001-11960)).
- 4.3 Employment Agreement between AstraZeneca UK Limited and Pascal Soriot, dated December 15, 2016 (incorporated into this Form 20-F by reference to Exhibit 4.3 of AstraZeneca PLC's Form 20-F filed March 7, 2017 (File No. 001-11960)).
- 4.4 Letter agreement between AstraZeneca PLC and Marc Dunoyer, dated November 12, 2013 (incorporated into this Form 20-F by reference to Exhibit 4.4 of AstraZeneca PLC's Form 20-F filed March 20, 2014 (File No. 001-11960)).
- 4.5 Employment Agreement between AstraZeneca UK Limited and Marc Dunoyer, dated December 6, 2016 (incorporated into this Form 20-F by reference to Exhibit 4.5 of AstraZeneca PLC's Form 20-F filed March 7, 2017 (File No. 001-11960)).
- 4.6 Form of Deed of Indemnity for Directors (used for Directors first appointed prior to April 26, 2012) (incorporated into this Form 20-F by reference to Exhibit 4.6 of AstraZeneca PLC's Form 20-F filed March 27, 2007 (File No. 001-11960)).
- 7.1 Statement explaining calculation of ratio of earnings to fixed charges.
- 8.1 List of significant subsidiaries of AstraZeneca PLC.
- 12.1 Certification of Pascal Soriot filed pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.
- 12.2 Certification of Marc Dunoyer filed pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.
- 13.1 Certification of Pascal Soriot and Marc Dunoyer furnished pursuant to 17 CFR 240.13a-14(b) and 18 U.S.C. 1350.
- 15.1 Annual Report and Form 20-F Information 2017.(2)
- 15.2 Report of Independent Registered Public Accounting Firm to the Board of Directors and Shareholders of AstraZeneca PLC by KPMG LLP in respect of the financial statements as of and for the years ending December 31, 2016 and 2015.
- 15.3 Consent of PricewaterhouseCoopers LLP, independent registered public accounting firm.
- 15.4 Consent of KPMG LLP, independent registered public accounting firm.
- 15.5 Consent of IQVIA Solutions HQ Limited.
- 15.6 Consent of Bureau Veritas UK Limited.

15.7	<u>Letter from KPMG LLP to the SEC.</u>
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Scheme Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Scheme Definition Linkbase
101.LAB	XBRL Taxonomy Extension Scheme Label Linkbase
101.PRE	XBRL Taxonomy Extension Scheme Presentation Linkbase

(1) Exhibits other than those listed above are omitted when in the opinion of the registrant they are either not applicable or not material. Other Exhibits previously filed have been omitted when in the opinion of the registrant such Exhibits are no longer material.

(2) Certain of the information included within Exhibit 15.1, which is provided pursuant to Rule 12b-23(a)(3) of the Securities Exchange Act of 1934, as amended, is incorporated by reference in this Form 20-F, as specified elsewhere in this Form 20-F. With the exception of the items and pages so specified, the Annual Report and Form 20-F Information 2017 is not deemed to be filed as part of this Annual Report on Form 20-F.

SIGNATURE

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

AstraZeneca PLC

By: */s/ A C N Kemp*
Name: A C N Kemp
Title: Authorized Signatory

London, England
March 6, 2018