

ASTRAZENECA PLC
Form 20-F
March 08, 2016

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 20-F

(Mark One)

**REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES
EXCHANGE ACT OF 1934**

OR

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE
ACT OF 1934
For the fiscal year ended December 31, 2015**

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE
ACT OF 1934
For the transition period from _____ to _____**

OR

**SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE
ACT OF 1934**

Date of event requiring this shell company report _____

For the transition period from _____ **to** _____

Commission file number: 001-11960

ASTRAZENECA PLC

(Exact name of Registrant as specified in its charter)

England and Wales

(Jurisdiction of incorporation or organization)

2 Kingdom Street, London W2 6BD

(Address of principal executive offices)

Adrian Kemp

AstraZeneca PLC

2 Kingdom Street, London W2 6BD

Telephone: +44 20 7604 8000

Facsimile number: +44 20 7604 8151

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

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

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| Title of each class | Name of each exchange on which registered |
|--|---|
| American Depositary Shares, each representing one Ordinary Share of 25¢ each | The New York Stock Exchange |
| Ordinary Shares of 25¢ each | The New York Stock Exchange* |
| 5.900% Notes due 2017 | 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 |
| 3.375% Notes due 2025 | 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.

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

None

(Title of Class)

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, 2015 was:

Ordinary Shares of 25¢ each: 1,264,122,670
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

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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).

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

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 Sections 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

Pursuant to Rule 12b-23(a) of the Securities Exchange Act of 1934, as amended, the information for the 2015 Form 20-F of AstraZeneca PLC (“AstraZeneca” or the “Company”) set out below is being incorporated by reference from the Company’s “Annual Report and Form 20-F Information 2015” included as exhibit 15.1 to this Form 20-F dated and submitted on March 8, 2016.

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. Graphs and tabular data are not included 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, “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 251, “Glossary” on pages 247 to 249, “Trade Marks” on page 246, “Measuring performance” on pages 64 and 65, and the tables on page 65, in each case of the Company’s “Annual Report and Form 20-F Information 2015” included as exhibit 15.1 to this Form 20-F dated March 8, 2016 is incorporated by reference.

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

The information (including graphs and tabular data) set forth under the headings “Financial Statements—Group Financial Record” on page 202 and the first table that appears under “Additional Information—Shareholder Information—AstraZeneca PLC share listings and prices” on page 240, in each case of the Company’s “Annual Report and Form 20-F Information 2015” included as exhibit 15.1 to this Form 20-F dated March 8, 2016 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 the Company’s “Annual Report and Form 20-F Information 2015” included as exhibit 15.1 to this Form 20-F dated March 8, 2016.

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 212 to 226 of the Company’s “Annual Report and Form 20-F Information 2015” included as exhibit 15.1 to this Form 20-F dated March 8, 2016 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—Corporate Information—History and development of the Company” on page 245, “Strategic Report—Financial Review—Financial position – 31 December 2015—Investments, divestments and capital expenditure” on page 72 “Financial Statements—Notes to the Group Financial Statements—Note 24—Acquisitions of business operations” on pages 173 to 177 and “Corporate Governance—Corporate Governance Report—Relations with shareholders” on page 93, in each case of the Company’s “Annual Report and Form 20-F Information 2015” included as exhibit 15.1 to this Form 20-F dated March 8, 2016 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 to 3, “—Chairman’s Statement” on pages 82 to 83, “—Chief Executive Officer’s Review” on pages 4 to 7, “—Strategy” on pages 8 to 20, “—Business Review” on pages 42 to 50, “—Therapy Area Review” on pages 24 to 41, “—Research Review” on pages 52 to 61, “Additional Information—Geographical Review” on pages 227 to 233, “—Risk Overview—Managing Risk” and “—Risk management embedded in business processes” on page 21, “Corporate Governance—Corporate Governance Report—Global Compliance and Internal Audit Services (IA)” on page 95, “Additional Information—Development Pipeline” on pages 205 to 209, “—Patent Expiries” on pages 210 to 211 and “—Sustainability: supplementary information” on pages 234 and 235, “Additional Information—Marketed Products” on pages 203 and 204, “Financial Statements—Notes to the Group Financial Statements—Note 1—Revenue” on page 149, “—Note 6—Segment information” on pages 154 to 155, and “Important information for readers of this Annual Report—Statements of competitive position, growth rates and sales” on page 251, in each case of the Company’s “Annual Report and Form 20-F Information 2015” included as exhibit 15.1 to this Form 20-F dated March 8, 2016 is incorporated by reference.

On February 17, 2016, AstraZeneca and MedImmune, the Group’s global biologics research and development arm, announced that the FDA had granted Breakthrough Therapy designation for durvalumab (MEDI4736), an investigational human monoclonal antibody directed against programmed death ligand-1 (PD-L1), for the treatment of patients with PD-L1 positive inoperable or metastatic urothelial bladder cancer whose tumour has progressed during or after one standard platinum-based regimen.

On February 19, 2016, AstraZeneca announced that the European Commission had granted marketing authorization for *Zurampic* (lesinurad) 200mg in combination with a xanthine oxidase inhibitor (XOI) for the adjunctive treatment of hyperuricemia in adult gout patients (with or without tophi) who have not achieved target serum uric acid (sUA) levels with an adequate dose of a XOI alone.

On February 19, 2016, AstraZeneca announced that the European Commission had granted marketing authorization for *Brilique* (ticagrelor) at a new 60mg dose for the treatment of patients who have suffered a heart attack at least one year prior and are at high risk of developing a further atherothrombotic event.

On February 25, 2016, AstraZeneca and Acerta Pharma BV, a company in which AstraZeneca has a majority equity investment, announced that the European Medicines Agency Committee for Orphan Medicinal Products had adopted three positive opinions recommending acalabrutinib (ACP-196) for designation as an orphan medicinal product. The three positive opinions are for the treatment of chronic lymphocytic leukaemia/small lymphocytic lymphoma, mantle cell lymphoma and lymphoplasmacytic lymphoma.

On February 29, 2016, AstraZeneca announced that it had entered into a licensing agreement with China Medical System Holdings Ltd (“CMS”) for the commercialisation rights in China to its calcium channel blocker, *Plendil* (felodipine). *Plendil* was first approved in China in 1995 for the treatment of hypertension or high blood pressure and in 2015 achieved Product Sales of \$189 million. Under the terms of the agreement, CMS will pay AstraZeneca \$310 million for the license to sell *Plendil* in China. AstraZeneca will maintain a significant, long-term interest in the future value derived from *Plendil* sales in China and will manufacture and supply the medicine to CMS. AstraZeneca will retain the global rights to *Plendil* outside China. The transaction does not include the transfer of any AstraZeneca employees or facilities.

On February 29, 2016, AstraZeneca and MedImmune, the Group's global biologics research and development arm, announced that DETERMINE, the Phase IIb clinical trial of 10 mg/kg tremelimumab monotherapy in second or third-line treatment of unresectable malignant mesothelioma, had not meet its primary endpoint of overall survival. The Company will complete a full evaluation of the final DETERMINE data, which will be submitted for presentation at an upcoming medical meeting in 2016.

On March 1, 2016, AstraZeneca announced that it had entered into an agreement with ProStrakan Group ("ProStrakan"), a subsidiary of Kyowa Hakko Kirin Co. Ltd., for the rights to *Moventig* (naloxegol) in the European Union, Iceland, Norway, Switzerland and Liechtenstein. *Moventig* is the first once-daily, oral peripherally-acting mu-opioid receptor antagonist approved in Europe for the treatment of opioid-induced constipation in adult patients who have had an inadequate response to laxatives. Under the terms of the agreement, ProStrakan will make an upfront payment to AstraZeneca of \$70 million, to acquire the rights to sell and develop *Moventig* in the EU, Iceland, Norway, Switzerland and Liechtenstein. ProStrakan will make additional payments contingent on market access decisions in certain European markets, and will pay AstraZeneca tiered double-digit royalties on sales as well as on sales milestones.

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

The Company is a global, innovation-driven biopharmaceutical business with operations in over 100 countries and our innovative medicines are used by millions of patients worldwide. AstraZeneca does not have a legal entity based in Iran, or any employees or an office located in Iran. The Company, 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 and the Company does not have any agreements, commercial arrangements, or other contracts with the Iranian government. However, the Company understands that one of the independent sub-distributors is likely controlled indirectly by the Iranian government. Further, AstraZeneca's third-party distributor may initiate payments using 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 our medicines may also include the Iranian government.

For the year ended December 31, 2015, the Company's gross revenues and net profits attributable to the above-mentioned Iranian activities were \$12 million and \$4 million respectively. For the same period, the AstraZeneca Group's gross revenues and net profits were \$24.7 billion and \$2.8 billion, respectively. Accordingly, the gross revenues and net profits attributable to the above-mentioned Iranian activities amounted to approximately 0.05% of the AstraZeneca Group gross revenues and approximately 0.14% 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 the AstraZeneca Group.

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 96 and “Financial Statements—Group Subsidiaries and Holdings” on pages 194 and 195, in each case of the Company’s “Annual Report and Form 20-F Information 2015” included as exhibit 15.1 to this Form 20-F dated March 8, 2016 is incorporated by reference.

D. Property, Plant and Equipment

The information (including tabular data) set forth under the headings “Strategic Report—Resources Review—Infrastructure” on page 61, “Strategic Report—Financial Review—Financial position – 31 December 2015—Property, plant and equipment” and “Additional Information—Financials (Prior year)—Financial position – 2014—Property, plant and equipment” on pages 7 and 238, respectively, “Additional Information—Risk—Risks and uncertainties—Legal, regulatory and compliance risks—Failure to adhere to applicable laws, rules and regulations

relating to environment, health and safety; environmental and occupational health and safety liabilities” on page 224, “Financial Statements—Notes to the Group Financial Statements—Note 7—Property, plant and equipment” on page 156, “—Note 27—Commitments and contingent liabilities—Environmental costs and liabilities” on page 186, “—Note 28—Operating leases” on page 192 and “Additional Information—Corporate Information—Property” on page 245, in each case of the Company’s “Annual Report and Form 20-F Information 2015” included as exhibit 15.1 to this Form 20-F dated March 8, 2016 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 “Strategic Report—Financial Review” on pages 62 to 81, “Additional Information—Financials (Prior Year)” on pages 236 to 239, “Additional Information—Geographical Review” on pages 227 to 233, “Strategic Report—Therapy Area Review—Therapy Area Overview—Global product sales by therapy area” on page 25, “Strategic Report—Strategy” on pages 8 to 20, “Strategic Report—Business Review—Research and Development” on pages 42 to 45, “Corporate Governance—Corporate Governance Report—Business organisation—Early Stage Product Committees (ESPCs) and Late Stage Product Committee (LSPC)” on page 94 and 95, “Additional Information—Risk—Commercial risks—Expiry or loss of, or limitations to, IP rights and consequential pressure from generic competition”, “—Emerging Markets”, “—Price controls and reductions”, “—Economic, regulatory and political pressures” on pages 215 to 219, “Financial Statements—Notes to the Group Financial Statements—Note 17—Interest-bearing loans and borrowings” on pages 163 to 164, “—Note 12—Derivative financial instruments” on page 162, “—Note 21—Reserves” on page 172, “—Note 25—Financial risk management objectives and policies” on pages 177 to 182 and “—Note 27—Commitments and contingent liabilities” on pages 186 to 192, in each case of the Company’s “Annual Report and Form 20-F Information 2015” included as exhibit 15.1 to this Form 20-F dated March 8, 2016 is incorporated by reference.

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

Developments in Legal Proceedings

For information in respect of material legal proceedings in which the Company 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 27—Commitments and contingent liabilities” on pages 186 to 192 of the Company’s “Annual Report and Form 20-F Information 2015” included as exhibit 15.1 to this Form 20-F dated March 8, 2016. Unless noted below or in the Company’s “Annual Report on Form 20-F Information 2015”, no

provisions have been established in respect of the proceedings discussed below.

Patent litigation

Crestor (rosuvastatin)

Patent proceedings in the U.S.

AstraZeneca is defending three patent infringement lawsuits in the U.S. District Court for the District of South Carolina (the District Court) which, among other things, claim that AstraZeneca's *Crestor* sales induce infringement of the plaintiffs' patents. In December 2015, the District Court issued an order dismissing the first of these cases, filed by Palmetto Pharmaceuticals, LLC ("Palmetto"), and entered judgment in AstraZeneca's favour, which Palmetto is appealing. In February 2016, the District Court granted AstraZeneca's motions for summary judgment and dismissed the remaining two, consolidated cases filed by co-plaintiffs Medical University of South Carolina Foundation for Research Development and Charleston Medical Therapeutics, and entered judgment in AstraZeneca's favour.

Patent proceedings outside the U.S.

In the Netherlands, in April 2014, AstraZeneca received a writ of summons from Resolution Chemicals Ltd. ("Resolution") alleging partial invalidity and non-infringement of the supplementary protection certificate ("SPC") related to the *Crestor* substance patent. In July 2015, the District Court of the Hague determined that the SPC does not extend to zinc salts of rosuvastatin and that Resolution's rosuvastatin zinc product does not infringe the SPC. AstraZeneca appealed. In February 2016, the Court of Appeal of the Hague overturned the decision and found that Resolution's product does infringe the SPC. Resolution may seek to appeal.

Faslodex (fulvestrant)

Patent proceedings outside the U.S.

In September 2015, AstraZeneca filed a request for a provisional injunction against Hexal AG (“Hexal”) in the Regional Court of Düsseldorf after Hexal threatened to launch a generic *Faslodex* product in Germany. The request was denied in November 2015 and AstraZeneca appealed. In February 2016, the Higher Regional Court of Düsseldorf ruled in AstraZeneca’s favour and ordered the provisional injunction against Hexal.

Product liability litigation

Byetta/Bydureon (exenatide)

Amylin Pharmaceuticals, LLC, a wholly owned subsidiary of AstraZeneca, and/or AstraZeneca are among multiple defendants in various lawsuits filed in federal and state courts in the U.S. involving approximately 2,500 claims of physical injury from treatment with *Byetta* and/or *Bydureon*. The lawsuits allege multiple types of injuries including pancreatitis, pancreatic cancer, thyroid cancer and kidney cancer. A multi-district litigation has been established in the U.S. District for the Southern District of California (the District Court) in regard to the alleged pancreatic cancer cases in U.S. federal courts. Further, a coordinated proceeding has been established in Los Angeles, California with regard to the various lawsuits in California state courts. In November 2015, the District court granted the defendants’ motion for summary judgment and dismissed all claims alleging pancreatic cancer that accrued prior to September 11, 2015. The plaintiffs have appealed that ruling. A similar motion was granted in favour of the defendants in the California state coordinated proceeding and judgment has not yet been entered.

A single case pending in Alabama state court was set for trial on June 21, 2016. The parties have reached a settlement in principle of this matter.

Onglyza (saxagliptin)

Amylin Pharmaceuticals, LLC, a wholly owned subsidiary of AstraZeneca, and/or AstraZeneca are among multiple defendants in various lawsuits filed in state and federal courts in the U.S. involving multiple plaintiffs claiming physical injury from treatment with Onglyza. The lawsuits allege injuries including pancreatic cancer.

In February 2016, AstraZeneca was served with a lawsuit filed in California state court on behalf of six plaintiffs alleging heart failure, congestive heart failure, cardiac failure and death resulting from treatment with *Onglyza/Kombiglyze*.

Commercial litigation

Nexium/Prilosec trademark litigation

AstraZeneca filed separate complaints in the U.S. District Court for the District of Delaware against Camber Pharmaceuticals, Inc. (“Camber”) and Dr. Reddy’s Laboratories, Inc. (“Dr. Reddy’s”) to enforce certain AstraZeneca trademark rights related to *Nexium* and *Prilosec*. Dr. Reddy’s filed its own separate claims against AstraZeneca in both the Delaware District Court and the U.S. District Court for the District of New Jersey. The Delaware District Court issued preliminary injunctions against Camber’s and Dr. Reddy’s sales of generic esomeprazole magnesium in purple capsules. The Camber action is progressing in the Delaware District Court. Dr. Reddy’s appealed the decision of the Delaware District Court to the U.S. Court of Appeals for the Third Circuit, and the appeal is pending. All District Court cases involving Dr. Reddy’s related to this matter have been stayed pending this appeal.

Toprol-XL (metoprolol succinate)

In March 2015, AstraZeneca was served with a state court complaint filed by the Attorney General for the State of Louisiana alleging that, in connection with enforcement of its patents for *Toprol-XL*, it had engaged in unlawful monopolisation and unfair trade practices, causing the state government to pay increased prices for *Toprol-XL*. In February 2016, the Louisiana state court heard oral argument on AstraZeneca’s motion to dismiss and ordered the dismissal of the complaint with prejudice. Entry of judgment is pending.

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” and “—Senior Executive Team” on pages 84 to 89 and “Corporate Governance—Directors’ Remuneration Report—Annual Report on Remuneration (the Implementation Report)—Service contracts” on page 117, in each case of the Company’s “Annual Report and Form 20-F Information 2015” included as exhibit 15.1 to this Form 20-F dated March 8, 2016 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 103 to 135, “Financial Statements—Notes to the Group Financial Statements—Note 20—Post-retirement benefits” on pages 166 to 171, “—Note 26—Employee costs and share plans for employees” on pages 182 to 185 and “—Note 29—Statutory and other information—Key management personnel compensation”, on page 193, in each case of the Company’s “Annual Report and Form 20-F Information 2015” included as exhibit 15.1 to this Form 20-F dated March 8, 2016 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 pages 84 to 85, “Corporate Governance—Corporate Governance Report—Remuneration” on page 93, “—Leadership and responsibilities” on page 90, “—Board effectiveness” on pages 90 to 91, “—Nomination and Governance Committee” on pages 93 and 94, “—Science Committee” on page 94, “—Compliance and Internal Audit Services (IA)” on pages 95, “Corporate Governance—Senior Executive Team” on pages 88 to 89, “Corporate Governance—Directors’ Remuneration Report—Annual Report on Remuneration (the Implementation Report)—Service contracts” on page 117, “Corporate Governance—Remuneration Policy for Non-Executive Directors” on page 134, and “Corporate Governance—Audit Committee Report” on pages 98 to 102, in each case of the Company’s “Annual Report and Form 20-F Information 2015” included as exhibit 15.1 to this Form 20-F dated March 8, 2016 is incorporated by reference.

D. Employees

The information set forth under the headings “Strategic Report—Resources Review—Employees” (comprising the graphical data on page 53, and the “Managing change” and “Employee relations” sections only) on page 54, “—Infrastructure” (other than “R&D spend analysis”) on page 61, and “Financial Statements—Notes to the Group Financial Statements—Note 26—Employee costs and share plans for employees—Employee costs” (including the tabular data) on page 182, in each case of the Company’s “Annual Report and Form 20-F Information 2015” included as exhibit 15.1 to this Form 20-F dated March 8, 2016 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 26—Employee costs and share plans for employees” on pages 182 to 185, “Corporate Governance—Corporate Governance Report—Other matters—Directors’ shareholdings” on page 97, “Corporate Governance—Directors’ Remuneration Report—Annual Report on Remuneration (the Implementation Report)—Directors’ interests in shares (Audited)” on pages 114 and 115, and “Additional Information—Shareholder Information—Options to purchase securities from registrant or subsidiaries” on page 242, in each case of the Company’s “Annual Report and Form 20-F Information 2015” included as exhibit 15.1 to this Form 20-F dated March 8, 2016 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—Major shareholdings” (including tabular data) on pages 241 to 242 of the Company’s “Annual Report and Form 20-F Information 2015” included as exhibit 15.1 to this Form 20-F dated March 8, 2016 is incorporated by reference.

B. Related Party Transactions

The information set forth under the headings “Financial Statements—Notes to the Group Financial Statements—Note 29—Statutory and other information—Related party transactions” on page 193 and “Additional Information—Shareholder Information—Related party transactions” on page 242, in each case of the Company’s “Annual Report and Form 20-F Information 2015” included as exhibit 15.1 to this Form 20-F dated March 8, 2016 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 240 to 244, “Strategic Report—Financial Review—Financial position – 31 December 2015—Dividend and share repurchases” on page 75 and “Corporate Governance—Corporate Governance Report—Other matters—Distributions to shareholders – dividends for 2015” on page 96, in each case of the Company’s “Annual Report and Form 20-F Information 2015” included as exhibit 15.1 to this Form 20-F dated March 8, 2016 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 27—Commitments and contingent liabilities” on pages 186 to 192 of the Company’s “Annual Report and Form 20-F Information 2015” included as exhibit 15.1 to this Form 20-F dated March 8, 2016.

Other than as disclosed herein, since the date of the annual consolidated financial statements included in this Form 20-F dated March 8, 2016, 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—AstraZeneca PLC share listings and prices” on page 240 of the Company’s “Annual Report and Form 20-F Information 2015” included as exhibit 15.1 to this Form 20-F dated March 8, 2016 is incorporated by reference.

In addition, the table below sets forth, for the periods indicated, the reported high and low share prices of AstraZeneca PLC, 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

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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 | | AstraZeneca ADS | | Ordinary SSE | |
|------------------|--------------------|-------------------|--------------------|-------------|---------------|--------------|
| | High (GB pence) | Low (GB pence) | High (\$) | Low (\$) | High (SEK) | Low (SEK) |
| 2016 – February | 4,504.0 | 3,906.0 | 32.53 | 28.59 | 556.0 | 478.8 |
| 2016 – January | 4,562.0 | 4,210.5 | 33.90 | 30.59 | 562.0 | 516.5 |
| 2015 – December | 4,627.5 | 4,285.5 | 34.77 | 32.80 | 597.0 | 550.5 |
| 2015 – November | 4,520.0 | 4,075.0 | 34.11 | 30.85 | 597.5 | 538.0 |
| 2015 – October | 4,247.5 | 3,947.0 | 32.39 | 30.47 | 548.0 | 509.0 |
| 2015 – September | 4,379.0 | 4,033.5 | 34.37 | 30.69 | 567.0 | 523.5 |

| | Ordinary LSE | | AstraZeneca ADS ⁽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 |
| 2015 – Quarter 4 | 4,627.5 | 3,947.0 | 34.77 | 30.47 | 597.5 | 509.0 |
| 2015 – Quarter 3 | 4,424.5 | 3,903.5 | 34.54 | 30.28 | 503.0 | 508.5 |
| 2015 – Quarter 2 | 4,863.0 | 4,019.0 | 36.68 | 31.86 | 638.0 | 522.5 |
| 2015 – Quarter 1 | 4,847.0 | 4,272.0 | 36.35 | 32.22 | 625.0 | 538.0 |

| | Ordinary LSE | | AstraZeneca ADS ⁽¹⁾ | | Ordinary SSE ⁽¹⁾ | |
|------------------|--------------------|-------------------|-----------------------------------|-------------|-----------------------------|--------------|
| | High (GB pence) | Low (GB pence) | High (\$) | Low (\$) | High (SEK) | Low (SEK) |
| 2014 | 4823.5 | 3549.5 | 40.55 | 29.26 | 558.5 | 380.5 |
| 2014 – Quarter 4 | 4780.0 | 4169.5 | 37.69 | 33.58 | 558.5 | 484.5 |
| 2014 – Quarter 3 | 4597.0 | 4092.5 | 38.16 | 34.25 | 536.0 | 467.3 |
| 2014 – Quarter 2 | 4823.5 | 3723.0 | 40.55 | 31.23 | 532.5 | 409.7 |
| 2014 – Quarter 1 | 4103.0 | 3549.5 | 34.19 | 29.26 | 446.3 | 380.5 |

| | Ordinary LSE | | AstraZeneca ADS ⁽¹⁾ | | Ordinary SSE ⁽¹⁾ | |
|------|--------------------|-------------------|-----------------------------------|-------------|-----------------------------|--------------|
| | High (GB pence) | Low (GB pence) | High (\$) | Low (\$) | High (SEK) | Low (SEK) |
| 2013 | 3612.0 | 2909.5 | 29.75 | 22.34 | 387.8 | 284.5 |
| 2012 | 3111.5 | 2591.0 | 24.45 | 20.02 | 329.5 | 286.2 |
| 2011 | 3194.0 | 2543.5 | 26.20 | 20.48 | 328.5 | 269.3 |
| 2010 | 3,385 | 2,732 | 26.75 | 20.46 | 382.2 | 309.3 |

Effective as of July 27, 2015, the Company changed the ADS ratio from one ADS per one ordinary share to two (1) 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 under the heading “Additional Information—Shareholder Information—AstraZeneca PLC share listings and prices” on page 240 of the Company’s “Annual Report and Form 20-F Information 2015” included as exhibit 15.1 to this Form 20-F dated March 8, 2016 is incorporated by reference.

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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—Corporate Information—Articles” on page 245 of the Company’s “Annual Report and Form 20-F Information 2015” included as exhibit 15.1 to this Form 20-F dated March 8, 2016 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 244 of the Company’s “Annual Report and Form 20-F Information 2015” included as exhibit 15.1 to this Form 20-F dated March 8, 2016 is incorporated by reference.

E. Taxation

The information set forth under the headings “Additional Information—Shareholder Information—Taxation for US persons”, “—UK and US income taxation of dividends”, “—Taxation on capital gains”, “—Passive Foreign Investment Company (PFIC) rules”, “—Information reporting and backup withholding”, “—UK inheritance tax” and “—UK stamp duty reserve tax and stamp duty” on pages 242 to 244 of the Company’s “Annual Report and Form 20-F Information 2015” included as exhibit 15.1 to this Form 20-F dated March 8, 2016 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 242 of the Company’s “Annual Report and Form 20-F Information 2015” included as exhibit 15.1 to this Form 20-F dated March 8, 2016 is incorporated by reference.

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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 pages 76 to 77 and “Financial Statements—Note 25—Financial risk management objectives and policies” on pages 177 to 182, in each case of the Company’s “Annual Report and Form 20-F Information 2015” included as exhibit 15.1 to this Form 20-F dated March 8, 2016 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 "Depositary"), as the depositary. Citibank succeeded JPMorgan Chase Bank, N.A. ("J.P. Morgan"), the predecessor depositary, on February 6, 2015. The holder of an ADR may have to pay the following fees and charges to Citibank in connection with ownership of the ADR:

| Category | Depositary 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) |

| 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 | <p>Fees and expenses incurred by the Depositary or the Depositary's agents on behalf of holders, including in connection with:</p> <ul style="list-style-type: none"> · taxes (including applicable interest and penalties) and other governmental charges · 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; · cable, telex and facsimile transmission and delivery expenses · expenses and charges incurred by the Depositary in conversion of foreign currency into U.S. dollars · compliance with exchange control regulations and other regulatory requirements applicable to the shares, deposited securities, ADSs and ADRs · 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) | As incurred by the Depositary. |

(1) \$0.03 per ADR annually

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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, 2015, 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, 2015, we have received approximately \$5.6 million arising out of fees charged in respect of dividends paid during the year and a fixed contribution to the Company's ADR program costs. We also have an agreement with the Depositary that it will waive certain 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

The information set forth under the heading "Corporate Governance—Corporate Governance Report—Accountability" on pages 92 and 93, "—US corporate governance requirements" on page 94 (the first and second paragraphs only), "—Disclosure Committee" on page 95, "Corporate Governance—Audit Committee Report—Internal Controls" on page 101, and "Financial Statements—Directors' Responsibilities for, and Report on, Internal Control over Financial Reporting" on page 135, in each case of the Company's "Annual Report and Form 20-F Information 2015" included as exhibit 15.1 to this Form 20-F dated March 8, 2016 is incorporated by reference.

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 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—Director's Responsibilities for, and Report on, Internal Control over Financial Reporting" on page 135 of the Company's "Annual Report and Form 20-F Information 2015" included as exhibit 15.1 to this Form 20-F dated March 8, 2016, which is incorporated herein by reference.

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders

AstraZeneca PLC:

We have audited AstraZeneca PLC's ('the Company' or 'AstraZeneca') internal control over financial reporting as of 31 December 2015, based on criteria established in Internal Control -Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO)". AstraZeneca's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit 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.

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 (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) 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 (3) 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.

In our opinion, AstraZeneca maintained, in all material respects, effective internal control over financial reporting as of 31 December 2015, based on criteria established in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated statements of financial position of AstraZeneca and subsidiaries as of 31 December 2015 and 2014, and the related consolidated statements of comprehensive income, changes in equity, and cash flows for each of the years then ended, and our report dated 4 February 2016 expressed an unqualified opinion on those consolidated financial statements.

KPMG LLP

London, United Kingdom

4 February 2016

ITEM 16. RESERVED

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

The information set forth under the heading “Corporate Governance—Audit Committee Report—Audit Committee membership and attendance” on page 99 of the Company’s “Annual Report and Form 20-F Information 2015” included as exhibit 15.1 to this Form 20-F dated March 8, 2016 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 Conduct” on pages 95 to 96 and “—Audit Committee Report—Compliance with the Code of Conduct” on page 98 to 99, in each case of the Company’s “Annual Report and Form 20-F Information 2015” included as exhibit 15.1 to this Form 20-F dated March 8, 2016 is incorporated by reference.

The Company’s Code of Conduct is available at www.astrazeneca.com.

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

| | Year ended December 31, | |
|--------------------|-------------------------------|------|
| | 2015 | 2014 |
| | (\$ million) | |
| Audit Fees | 10.4 | 9.3 |
| Audit-Related Fees | 1.3 | 1.2 |
| Tax Fees | 0.1 | 0.3 |
| All Other Fees | 0.5 | 0.5 |
| Total | 12.3 | 11.3 |

Audit fees included \$5.4 million for the audit of subsidiaries pursuant to legislation (2014: \$5.0 million), \$3.2 million for the Group audit (2014: \$2.5 million) and \$1.8 million in respect of section 404 of the Sarbanes-Oxley Act (2014: \$1.8 million).

Audit-related fees included \$0.6 million for the audit of subsidiaries' pension schemes (2014: \$0.5 million), \$0.5 million for assurance services in relation to interim financial statements (2014: \$0.5 million) and \$0.2 million for other audit related fees (2014: \$0.2 million). Tax fees consisted of tax compliance services and, to a lesser extent, tax advice.

All other fees consisted of fees of \$0.5 million (2014: \$0.5 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 Conduct" section) on pages 98 to 102 of the Company's "Annual Report and Form 20-F Information 2015" included as exhibit 15.1 to this Form 20-F dated March 8, 2016 is incorporated by reference.

United States 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 accountant, 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 2014 and 2015, 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

Month
#12

| | | | |
|-------------------|-----|-----|---|
| 0 | N/A | 0 | 0 |
| Dec 1 - Dec 31 | | | |
| Total | 0 | N/A | 0 |

On October 1, 2012, the Company announced the suspension of the then-existing share repurchase program with immediate effect. There have been no share repurchases since October 1, 2012. At the 2015 Annual General Meeting, the Company's shareholders authorized the Company to repurchase 126,328,833 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 2015.

ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT

On December 23, 2015, the Company announced a proposal to appoint PricewaterhouseCoopers LLP ("PwC") as external auditor for the financial year ending December 31, 2017. KPMG (initially through KPMG Audit Plc up to fiscal 2013 and through KPMG LLP for fiscal 2014 and 2015) has been the Group's auditor since 1999. The proposed change of auditor followed a recommendation by the Audit Committee to the Board of Directors based on a formal tender process, in which our current external auditor, KPMG LLP, had not participated as KPMG LLP would have been prohibited to serve as AstraZeneca's external auditor after 2020. A resolution to approve the appointment of PwC will be put to shareholders at the Company's AGM in 2017.

During the years ended:

December 31, 2013, and the subsequent period ended April 24, 2014, and

December 31, 2014 and 2015,

(1) neither KPMG Audit Plc (the former KPMG auditing entity, as explained in the 2014 Form 20-F) nor KPMG LLP (together, "KPMG") has issued 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, (2) there has not been any disagreement 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 its auditors' reports, or any "reportable event" as described in Item 16F(a)(1)(v) of Form 20-F.

The Company has provided each KPMG entity with a copy of the foregoing disclosure and has requested that each of them 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. Copies of KPMG's letters, dated March 8, 2016, in which each KPMG entity states that they agree with such disclosure, are filed herewith as Exhibits 15.8 and 15.9.

ITEM 16G. CORPORATE GOVERNANCE

AstraZeneca PLC 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 UK Corporate Governance Code (the "UK Code") in respect of its corporate governance practices. The 2014 edition of the UK Code came into effect for reporting periods beginning on or after 1 October 2014. The Companies Act 2006 (the "UK 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

AstraZeneca Corporate Governance Practice

- | | |
|--|---|
| <p>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.</p> | <p>Under the UK Act, a company's external auditors are appointed by its shareholders. Under the UK Code, the Company's audit committee is responsible for 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.</p> |
| <p>2. Under the NYSE Standards, the nominating/corporate governance committee and compensation committee are to be composed entirely of</p> | <p>Under the UK 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</p> |

independent directors.

was considered independent on appointment as chairman (under the UK 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.

NYSE Standards

AstraZeneca Corporate Governance Practice

The Company's Nomination and Governance Committee and Remuneration Committee include four and five 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 UK 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 UK 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, Senior Executive Team ("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 UK 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 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 UK 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.

**NYSE
Standards**

AstraZeneca Corporate Governance Practice

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 UK 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 94 of the Company’s “Annual Report and Form 20-F Information 2015” included as exhibit 15.1 to this Form 20-F dated March 8, 2016 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 set forth in Exhibit 15.2 hereto (“Report of Independent Registered Public Accounting Firm to the Board of Directors and Stockholders of AstraZeneca PLC by KPMG LLP”) is incorporated in this section by reference. The information (including tabular data) set forth under the headings “Financial Statements” on pages 136 to 203 (including the information set forth under the subheading “Notes to the Group Financial Statements” on pages 149 to 193, but excluding the information set forth under the subheading “Independent Auditor’s Report to the Members of AstraZeneca PLC only” on pages 136 to 139), “Financial Statements—Group Financial Record” on page 202 and “—Group Subsidiaries and Holdings” on pages 194 to 195, in each case of the Company’s “Annual Report and Form 20-F Information 2015” included as exhibit 15.1 to this Form 20-F dated March 8, 2016 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 information as to recent developments in certain legal proceedings disclosed under the heading “Financial Statements—Notes to the Group Financial Statements—Note 27—Commitments and contingent liabilities” on pages 186 to 192 of the Company’s “Annual Report and Form 20-F Information 2015” included as exhibit 15.1 to this Form 20-F dated March 8, 2016.

The information set out in the above-referenced financial statements does not constitute the Company’s statutory accounts under the UK Companies Act for the years ended December 31, 2015, 2014 or 2013. 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 2014 and 2013 have been delivered to the UK registrar of companies and those for 2015 will be delivered in due course.

ITEM 19. EXHIBITS

1.1 Articles of Association.

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.(1)

4.2 Letter agreement between AstraZeneca PLC and Pascal Soriot, and Agreement for Service between AstraZeneca UK Limited and Pascal Soriot, each dated August 27, 2012.(2)

- 4.3 Letter agreement between AstraZeneca PLC and Marc Dunoyer, dated November 12, 2013, and Agreement for Service between AstraZeneca UK Limited and Marc Dunoyer dated March 19, 2014. (3)
- 4.4 Form of Deed of Indemnity for Directors (used for Directors first appointed prior to April 26, 2012).(4)
- 4.5 License Agreement dated April 20, 1998, by and between Shionogi & Co., Ltd. and Zeneca Limited (the "License Agreement").(5)
- 4.6 Amendment Agreement dated May 14, 2002, by and between Shionogi & Co., Ltd. and AstraZeneca UK Limited, to the License Agreement.(5)
- 4.7 Amendment No. 2, effective as of April 26, 2005, to the License Agreement.(5)
- 4.8 Amendment No. 3, effective as of December 5, 2008, to the License Agreement.(5)
- 4.9 Amendment No. 4, effective as of February 19, 2009, to the License Agreement.(5)
- 4.10 Amendment No. 5, effective as of November 12, 2012, to the License Agreement.(5)
- 4.11 Amendment No. 6, effective as of January 1, 2014, to the License Agreement.(3)
- 4.12 Form of Deed of Indemnity for Directors (used for Directors first appointed on or after April 26, 2012).(3)
- 7.1 Statement explaining calculation of ratio of earnings to fixed charges.
- 8.1 List of subsidiaries.
- 12.1 Certification of Pascal Soriot filed pursuant to 17 CFR 240.13a-14(a).
- 12.2 Certification of Marc Dunoyer filed pursuant to 17 CFR 240.13a-14(a).
- 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 2015.(6)
Report of Independent Registered Public Accounting Firm to the Board of Directors and Stockholders of AstraZeneca PLC by KPMG LLP in respect of the financial statements as of and for the years ending December 31, 2015 and 2014.
- 15.2 Report of Independent Registered Public Accounting Firm to the Board of Directors and Stockholders of AstraZeneca PLC by KPMG Audit Plc in respect of the financial statements as of and for the year ending December 31, 2013.
- 15.3 Consent of KPMG LLP, independent registered public accounting firm.
- 15.4 Consent of KPMG Audit Plc, independent registered public accounting firm.
- 15.5 Consent of IMS Health HQ Limited.
- 15.6 Consent of Bureau Veritas UK Limited.
- 15.7 Letter from KPMG LLP to the SEC.
- 15.8 Letter from KPMG Audit Plc to the SEC.

(1) Incorporated into this Form 20-F by reference to AstraZeneca PLC's Form 20-F filed March 25, 2003 (File No. 001-11960).

(2) Incorporated into this Form 20-F by reference to AstraZeneca PLC's Form 20-F filed March 25, 2012 (File No. 001-11960).

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- (3) Incorporated into this Form 20-F by reference to AstraZeneca PLC's Form 20-F filed March 20, 2014 (File No. 001-11960).
- (4) Incorporated into this Form 20-F by reference to AstraZeneca PLC's Form 20-F filed March 27, 2007 (File No. 001-11960).
- (5) Incorporated into this Form 20-F by reference to AstraZeneca PLC's Form 20-F/A filed September 21, 2012 (File No. 001-11960).

- (6) 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 2015 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 8, 2016

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