ASTRAZENECA PLC
Form 6-K
March 05, 2019

FORM 6-K

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Report of Foreign Issuer

Pursuant to Rule 13a-16 or 15d-16 of
the Securities Exchange Act of 1934

For the month of March 2019

Commission File Number: 001-11960

AstraZeneca PLC

1 Francis Crick Avenue
Cambridge Biomedical Campus
Cambridge CB2 0AA
United Kingdom

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F X Form 40-F __

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): _____

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes __ No X

If “Yes” is marked, indicate below the file number assigned to the Registrant in connection with Rule 12g3-2(b): 82-_____

AstraZeneca PLC

INDEX TO EXHIBITS

1.
Annual Financial Report

5 March 2019 11:00 GMT

ANNUAL FINANCIAL REPORT

AstraZeneca PLC (the Company) announced today the publication of its Annual Report and Form 20-F Information 2018 (Annual Report).

A copy of the Annual Report will be submitted to the National Storage Mechanism and will shortly be available for inspection at www.morningstar.co.uk/uk/nsm.

The Annual Report is also available on the Company's website at www.astrazeneca.com/annualreport2018.

The Annual Report will be dispatched to shareholders in due course.

The Company's Annual General Meeting (AGM) will take place on 26 April 2019 in London, UK and the Notice of AGM and Shareholders' Circular will be published and distributed to shareholders in due course.

EXPLANATORY NOTE AND WARNING

Solely for the purposes of complying with Disclosure and Transparency Rule (DTR) 6.3.5R and the requirements it imposes on issuers as to how to make public annual financial reports, we set out below:

- in Appendix A, the principal risks and uncertainties facing the Company;
- in Appendix B, the Directors' responsibility statement made in respect of the Financial Statements and Directors' Report contained in the Annual Report; and
- in Appendix C, a statement regarding related party transactions.

The appendices have been extracted from the Annual Report in unedited full text. This information should be read in conjunction with the Company's fourth quarter and full year results 2018 announcement, issued on 14 February 2019, which contained a condensed set of financial statements and which can be found at www.astrazeneca.com/investor-relations/results-and-presentations.html. Together, these constitute the material required by DTR 6.3.5R to be communicated to the media in unedited full text through a Regulatory Information Service.

Page numbers and section cross-references in the appendices refer to pages and sections in the Annual Report. Defined terms used in the appendices refer to terms as defined in the Annual Report.

This material is not a substitute for reading the full Annual Report.

APPENDIX A

The Board has carried out a robust assessment of the Principal Risks facing the Group, including those that threaten its business model, future performance, solvency or liquidity. The table overleaf provides insight into the ongoing Principal Risks, outlining why effective management of these risks is important and relevant to the business, how we are managing them and which risks are rising, falling or have remained static during the past 12 months.

Our approach to risk management is designed to encourage clear decision making on which risks we take and how we manage these risks. Fundamental to this process is a sound understanding of every risk's potential strategic, commercial, financial, compliance, legal and reputational implications.

Further information on our key risk management and assurance processes can be found in Risk from pages 220 to 230 which also includes a description of circumstances under which principal and other risks and uncertainties might arise in the course of our business and their potential impact.

Progress in the delivery of Group-wide restructuring initiatives has been sufficient for the Board to determine that the risk 'Delivery of Gains from Productivity Initiatives' (previously listed as a Principal Risk) is no longer a Principal Risk. The Board will, however, continue to monitor strategic initiatives and their impact on employee engagement.

Risk category and Principal Risks	Context/potential impact	Management actions
Product pipeline and intellectual property		
Delivery of pipeline and new products	The development of any pharmaceutical product candidate is a complex, risky and lengthy process involving significant financial, R&D and other resources. A project may fail or be delayed at any stage of the process due to a number of factors, which could reduce our long-term growth, revenue and profit.	> Prioritise and accelerate our pipeline > Strengthen pipeline through acquisitions, licensing and collaborations > Focus on innovative science in three main therapy areas
Meet quality, regulatory and ethical drug approval and disclosure requirements	Our pharmaceutical products and commercialisation processes are subject to extensive regulation. Delays in regulatory reviews and approvals impact patients and market access, and can materially affect our business or financial results.	> Quality management systems incorporating monitoring, training and assurance activities > Collaborating with regulatory bodies and advocacy groups to monitor and respond to changes in the regulatory environment, including revised process, timelines and guidance
Secure and protect product IP	Discovering and developing medicines requires a significant investment of resources. For this to be a viable investment, new medicines must be safeguarded from being copied for a reasonable amount of time. If we are not successful in obtaining, maintaining, defending or enforcing our IP rights, our revenues could be materially adversely affected.	> Active management of IP rights and IP litigation

	Third parties may allege infringement of their IP, and may seek injunctions and/or damages, which, if ultimately awarded, could adversely impact our commercial and financial performance.	
Commercialisation		
Externally driven demand, pricing, access and competitive pressures	Operating in over 100 countries, we are subject to political, socioeconomic and financial factors both globally and in individual countries. There can be additional pressure from governments and other healthcare payers on medicine prices and sales in response to recessionary pressures, reducing our revenue, profits and cash flow.	> Focus on Growth Platforms > Demonstrating value of medicines/health economics > Global footprint > Diversified portfolio
Quality and execution of commercial strategies	If commercialisation of a product does not succeed as anticipated, or its rate of sales growth is slower than anticipated, there is a risk that we may not be able to fully recoup the costs in launching it.	> Focus on Growth Platforms > Accelerate and risk share through business development and strategic collaborations and alliances
Supply chain and business execution		
Maintain supply of compliant, quality product	Delays or interruptions in supply can lead to recalls, product shortages, regulatory action, reputational harm and lost sales.	> Establishment of new manufacturing facilities, creating capacity and technical capability to support new product launches, particularly biologics > Business continuity and resilience initiatives, disaster and data recovery and emergency response plans > Contingency plans including dual sourcing, multiple suppliers and stock levels > Quality management systems
Information technology, data security and privacy	Significant disruption to our IT systems, cybersecurity incidents including breaches of data security, or data privacy failure, could harm our reputation and materially affect our financial condition or results of operations. This could lead to regulatory penalties or non-compliance with laws and regulations.	> Cybersecurity framework and dashboard > Privacy office oversees compliance with data privacy legislation > Disaster and data recovery plans > Strategies to secure critical systems and processes > Regular cybersecurity and privacy training for employees
Attract, develop, engage and retain talented and capable employees at all levels	Failure to attract and retain highly skilled personnel may weaken our succession plans for critical positions in the medium term. Employee uncertainty as a result of, for example, Brexit or organisational change may result in a lower level of employee engagement which could impact productivity and turnover. Both could adversely affect the achievement of our strategic objectives.	> Targeted recruitment and retention strategies deployed > Identification and active support of staff potentially impacted by Brexit > Development of our employees > Evolve our culture > Focus on simplification
Legal, regulatory and compliance		
Safety and efficacy of marketed products	Patient safety is very important to us and we strive to minimise the risks and maximise the benefits of our medicines. Failure to do this could adversely impact our reputation, our business and the results of operations, and could lead to product liability claims.	> Robust processes and systems in place to manage patient safety and efficacy trends as well as externally reported risks through regulatory agencies and other parties. This includes a comprehensive pharmacovigilance programme

		supplemented by close monitoring and review of adverse events
Defence of product, pricing and practices litigation	Investigations or legal proceedings could be costly, divert management attention or damage our reputation and demand for our products. Unfavourable resolutions could subject us to criminal liability, fines, penalties or other monetary or non-monetary remedies, adversely affecting our financial results.	> Combined internal and external counsel management
Meet regulatory and ethical expectations on commercial practices, including bribery and corruption, and scientific exchanges	Any failure to comply with applicable laws, rules and regulations, including bribery and corruption legislation, may result in civil and/or criminal legal proceedings and/or regulatory sanctions, fines or penalties, impacting financial results.	> Strong ethical and compliance culture > Established compliance framework in place including annual Code of Ethics training for all employees > Focus on due diligence and oversight of third-party engagements
Economic and financial		
Achieve strategic plans and meet targets and expectations	Failure to successfully implement our business strategy may frustrate the achievement of our financial or other targets or expectations. This failure could, in turn, damage our reputation and materially affect our business, financial position or results of operations.	> Focus on Growth Platforms and innovative science in three main therapy areas > Strengthen pipeline through acquisitions, licensing and collaborations > Appropriate capital structure and balance sheet > Portfolio-driven decision making process governed by senior executive-led committees

APPENDIX B

This statement relates to and is extracted from the Annual Report. It is repeated here solely for the purpose of complying with DTR 6.3.5. It is not connected to the information presented in this announcement or in the Company's fourth quarter and full year results 2018 announcement that was published on 14 February 2019.

The Directors confirm that to the best of our knowledge:

The Financial Statements, prepared in accordance with the applicable set of accounting standards, give a true and fair view of the assets, liabilities, financial position and profit or loss of the Company and the undertakings included in the consolidation taken as a whole.

The Directors' Report includes a fair review of the development and performance of the business and the position of the issuer and the undertakings included in the consolidation taken as a whole, together with a description of the principal risks and uncertainties that they face.

On behalf of the Board of Directors on 14 February 2019
Pascal Soriot
Director

APPENDIX C

Related party transactions

The Group had no material related party transactions which might reasonably be expected to influence decisions made by the users of these Financial Statements.

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

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Adrian Kemp
Company Secretary
AstraZeneca PLC
SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AstraZeneca PLC

Date: 05 March 2019

By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary