4 FINANCIAL INSTRUMENTS

As detailed in the Group's most recent annual financial statements, our principal financial instruments consist of derivative financial instruments, other investments, trade and other receivables, cash and cash equivalents, trade and other payables, and interest-bearing loans and borrowings. As indicated in Note 1, there have been no changes to the accounting policies for financial instruments, including fair value measurement, from those disclosed on pages 140 and 141 of the Company's Annual Report and Form 20-F Information 2014. In addition, there have been no changes of significance to the categorisation or fair value hierarchy of our financial instruments. Financial instruments measured at fair value include $940m of other investments, $1,175m of loans, and $484m of derivatives as at 30 September 2015. The total fair value of interest-bearing loans and borrowings at 30 September 2015, which have a carrying value of $10,947m in the Condensed Consolidated Statement of Financial Position, was $12,038m. Contingent consideration liabilities arising on business combinations have been classified under Level 3 in the fair value hierarchy and movements in fair value are shown below:

	Diabetes Alliance 2015 $m	Other 2015 $m	Total 2015 $m	Total 2014 $m
At 1 January	5,386	1,513	6,899	514
Additions through business combinations	-	-	-	5,169
Settlements	(298)	(255)	(553)	(572)
Revaluations	-	58	58	6
Discount unwind	305	90	395	277
Foreign exchange	-	2	2	(3)
At 30 September	5,393	1,408	6,801	5,391

5 LEGAL PROCEEDINGS AND CONTINGENT LIABILITIES

AstraZeneca is involved in various legal proceedings considered typical to its business, including litigation and investigations relating to product liability, commercial disputes, infringement of intellectual property rights, the validity of certain patents, anti-trust law and sales and marketing practices. The matters discussed below constitute the more significant developments since publication of the disclosures concerning legal proceedings in the Company's Annual Report and Form 20-F Information 2014 and Interim Management Statement 2015 as part of the Company's Half-Yearly Financial Report for the six-month period to 30 June 2015 (the Disclosures). Unless noted otherwise below or in the Disclosures, no provisions have been established in respect of the claims discussed below.

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

In cases that have been settled or adjudicated, or where quantifiable fines and penalties have been assessed and which are not subject to appeal, or where a loss is probable and we are able to make a reasonable estimate of the loss, we record the loss absorbed or make a provision for our best estimate of the expected loss.

The position could change over time and the estimates that we have made and upon which we have relied in calculating these provisions are inherently imprecise. There can, therefore, be no assurance that any losses that result from the outcome of any legal proceedings will not exceed the amount of the provisions that have been booked in the accounts. The major factors causing this uncertainty are described more fully in the Disclosures and herein.

AstraZeneca has full confidence in, and will vigorously defend and enforce, its intellectual property.

Matters disclosed in respect of the third quarter of 2015 to 5 November 2015.

Patent litigation

***Brilinta* (ticagrelor)**
Patent proceedings in the US
In September and October 2015, AstraZeneca received Paragraph IV notices challenging patents listed in the FDA Orange Book with reference to *Brilinta*. AstraZeneca has received notice from 15 companies that each submitted an Abbreviated New Drug Application (ANDA) seeking to market ticagrelor. In October and November 2015, in the

US District Court for the District of Delaware, AstraZeneca filed patent infringement lawsuits in response to these Paragraph IV notices from ANDA filers. Litigation is at an early stage and no trial dates have been set.

***Crestor* (rosuvastatin)**
Patent proceedings outside the US
As previously disclosed, in April 2014, AstraZeneca received a writ of summons from Resolution Pharmaceuticals Inc. (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 product does not infringe the SPC. AstraZeneca has appealed and the appeal is scheduled to be heard on 12 November 2015.

In October 2015, in the UK, AstraZeneca received a notice letter from Resolution Chemicals Ltd. indicating that it has commenced an action in the UK Patent Courts alleging partial invalidity and non-infringement of the SPC related to the *Crestor* substance patent.

As previously disclosed, in 2014, in Japan, Shionogi & Co., Ltd. the licensor of the *Crestor* patent, received confirmation of a request for trial for patent invalidation in the Japanese Patent Office (JPO). The request was initiated by Teva Pharma Japan Inc. (Teva) and relates to the *Crestor* substance patent. In June 2015, the JPO dismissed Teva's claim. Teva appealed the decision but subsequently withdrew the appeal.

As previously disclosed, in Australia, in 2011 and 2012, AstraZeneca instituted proceedings against Actavis Australia Pty Ltd, Apotex Pty Ltd and Watson Pharma Pty Ltd asserting infringement of three formulation and method patents for *Crestor*. In March 2013, the Federal Court of Australia held all three patents at issue invalid. AstraZeneca appealed in relation to two patents. In August 2014, the Full Court of the Federal Court of Australia held the two patents invalid. In March 2015, the High Court granted AstraZeneca leave to appeal in relation to one method patent. On 2 September 2015, the High Court dismissed AstraZeneca's appeal.

***Faslodex* (fulvestrant)**
Patent proceedings in the US
As previously disclosed, in June and September 2014 and in January 2015, AstraZeneca filed patent infringement lawsuits against Sandoz Inc., Sandoz International GmbH, Sagent Pharmaceuticals, Inc. and Glenmark Generics, Inc. USA in the US District Court in New Jersey relating to four patents listed in the FDA Orange Book with reference to *Faslodex*, after those companies sent Paragraph IV notices seeking FDA approval to market generic versions of *Faslodex* prior to the expiration of AstraZeneca's patents. Also as previously disclosed, in July 2015, AstraZeneca received a Paragraph IV notice from Agila Specialties Inc. (Agila), on behalf of Onco Therapies Limited (Onco), which was also seeking FDA approval to market a generic version of *Faslodex* prior to the expiration of the same four patents. In September 2015, AstraZeneca received a Paragraph IV notice from Mylan Pharmaceuticals, Inc., on behalf of Mylan Laboratories Limited (collectively, Mylan), after Agila and Onco assigned their ANDA to Mylan. In September 2015, AstraZeneca filed patent infringement lawsuits against Agila, Onco, and Mylan in the US District Court in New Jersey and also against Mylan in the US District Court in West Virginia relating to all four Orange Book listed patents. In October 2015, AstraZeneca received a Paragraph IV notice from Teva Pharmaceuticals USA Inc., which is also seeking FDA approval to market a generic version of *Faslodex* prior to the expiration of the same four patents.

Patent proceedings outside the US
As previously disclosed, in Brazil, in February 2013, Eurofarma Laboratorios S.A. (Eurofarma) filed a nullity action against a formulation patent for *Faslodex* in the 31st Specialized Intellectual Property Federal Court of Rio de Janeiro. In October 2015, the Court ruled in Eurofarma's favour and invalidated AstraZeneca's patent. AstraZeneca is considering all available options, including appeal.

As previously disclosed, in Germany in July 2015, AstraZeneca was served with a nullity complaint by Hexal AG (Hexal), commencing invalidity proceedings before the Federal Patent Court, and requesting the revocation of the German part of the *Faslodex* formulation use patent, EP 1,250,138. In September 2015, AstraZeneca filed a request for a provisional injunction against Hexal in Regional Court Düsseldorf after Hexal threatened to launch a generic *Faslodex* product in the fourth quarter of 2015 which, following a hearing in October, remains pending.

***Movantik* (naloxegol)**
Patent proceedings in the US
In October 2015, Neptune Generics LLC, an affiliate of Gerchen Keller Capital LLC, filed for Inter Partes Review (IPR) with the US Patent Office challenging the validity of one of the six patents listed in the FDA Orange Book with reference to *Movantik*. The IPR relates to US Patent No. 7,786,133, which is licensed to AstraZeneca from Nektar Therapeutics. AstraZeneca is considering its response.

***Nexium* (esomeprazole)**
Patent proceedings in the US
In September 2015, AstraZeneca received a Paragraph IV notice from Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. (together Zydus) challenging certain patents listed in the FDA Orange Book with reference

to *Nexium* oral suspension. Zydus submitted an ANDA seeking to market esomeprazole magnesium oral suspension. In October 2015, in response to Zydus' notice, AstraZeneca filed a patent infringement lawsuit against Zydus in the US District Court for the District of New Jersey. The litigation is at an early stage and no trial date has been set.

In October 2015, AstraZeneca received a Paragraph IV notice from Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories, Inc. (together DRL) challenging certain patents listed in the FDA Orange Book with reference to *Nexium* 24HR (OTC). DRL has submitted an ANDA seeking to market OTC esomeprazole magnesium capsules. AstraZeneca is reviewing DRL's notice.

Patent proceedings outside the US
As previously disclosed, in July 2014, in Canada, the Federal Court found Canadian Patent No. 2,139,653 invalid and not infringed by Apotex Inc. On 6 July 2015, AstraZeneca's appeal was dismissed. AstraZeneca has sought leave to appeal to the Supreme Court of Canada.

***Onglyza* (saxagliptin) and *Kombiglyze* (saxagliptin and metformin)**
Patent proceedings in the US
As previously disclosed, AstraZeneca filed lawsuits against a number of generics companies who sent notices that they had submitted ANDAs alleging that patents listed in the FDA Orange Book with reference to *Onglyza* and *Kombiglyze*, are invalid, unenforceable and/or will not be infringed by the products as described in the ANDAs. In August 2015, Teva Pharmaceuticals USA, Inc. sent a Paragraph IV certification with respect to the formulation patent, US Patent No. 8,628,799, on *Kombiglyze* and in October 2015 AstraZeneca filed a lawsuit in the US District Court for the District of Delaware.

***Pulmicort Respules* (budesonide inhalation suspension)**
Patent proceedings in the US
As previously disclosed, in February 2015, the US District Court for the District of New Jersey (the District Court) determined that the asserted claims of US Patent No. 7,524,834 (the '834 Patent) was invalid. AstraZeneca appealed that decision and, on 7 May 2015, the US Court of Appeals for the Federal Circuit affirmed the District Court's decision and lifted the injunction that was issued pending the appeal. Since 2009, various injunctions were issued in this matter. Damages claims to recover under those injunctions have been filed and a provision has been taken.

***Seroquel XR* (quetiapine fumarate)**
Patent proceedings outside the US
As previously disclosed, in Germany, Ratiopharm GmbH, CT Arzneimittel GmbH and AbZ Pharma GmbH brought a claim for damages relating to the preliminary injunction issued in April 2012 that prevented generic *Seroquel XR* sales by those entities until the injunction was lifted following a November 2012 Federal Patent Court decision that held that the *Seroquel XR* patent was invalid. That claim has now been settled. AstraZeneca had taken a reserve in relation to this matter.

In April 2015, Mylan SAS (Mylan) brought a patent invalidation action against AstraZeneca's French designation of the *Seroquel XR* formulation patent, European Patent No. 0 907 364 (the '364 Patent). AstraZeneca is defending that action and has brought a claim against Mylan for infringement of the '364 Patent. In the third quarter of 2015, Mylan launched its generic *Seroquel XR* product at-risk. As previously disclosed, in July 2014, AstraZeneca has a similar action pending with Accord Healthcare France SAS and Accord Healthcare Limited (together, Accord), wherein Accord asserts that the '364 Patent is invalid. AstraZeneca is defending against that claim and claims patent infringement.

Product liability litigation

***Onglyza* (saxagliptin)**
As previously disclosed, in 2014, 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 US involving plaintiffs claiming injuries, including pancreatic cancer. AstraZeneca was recently served with a case, claiming congestive heart failure, from treatment with *Onglyza*.

Commercial litigation

***Nexium* settlement anti-trust litigation**
As previously disclosed, a jury returned a verdict in favour of AstraZeneca in a Multi-District Litigation class action and individual lawsuits alleging that AstraZeneca's settlements of certain patent litigation in the US relating to *Nexium* violated US anti-trust law and various state laws. In July 2015, the Court denied the plaintiffs' motions for a new trial and preliminary injunction. In September 2015, the Court entered judgment in favour of AstraZeneca. Plaintiffs have appealed the judgment.

***Nexium*/*Prilosec* trademark litigation**
In October 2015, AstraZeneca filed separate complaints in the US Federal District Court in 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*. The Court has issued a temporary restraining order against Camber's sales of generic esomeprazole magnesium in purple capsules and is yet to consider the case against Dr. Reddy's.

***Synagis* (palivizumab)**
As previously disclosed, in September 2011, MedImmune filed an action against AbbVie, Inc. (AbbVie) (formerly Abbott International, LLC) in the Circuit Court for Montgomery County, Maryland, seeking a declaratory judgment in a contract dispute. AbbVie's motion to dismiss was granted. In September 2011, AbbVie filed a parallel action against MedImmune in Illinois State Court and, as previously disclosed, trial began in August 2015. In September 2015, a jury returned a verdict in favour of AbbVie and awarded AbbVie damages in the amount of approximately $93.8m. MedImmune intends to appeal the jury's verdict.

Government investigations/proceedings

***Crestor* (rosuvastatin calcium)**
As previously disclosed, the DOJ and all US states have declined to intervene in the civil component of an investigation regarding *Crestor*. Prior to September 2015, one additional component of the investigation remained. In September 2015, AstraZeneca was informed that the additional component of the investigation has been closed.

***Seroquel IR* and *Seroquel XR* (quetiapine fumarate) Qui Tam litigation**
AstraZeneca has been named as a defendant in a lawsuit filed in US Federal Court in New York under the *qui tam* (whistleblower) provisions of the federal and certain state False Claims Acts. The lawsuit alleges that the Company misrepresented the safety profile of and improperly promoted *Seroquel IR* and *Seroquel XR*. The US government and the named states have declined to intervene in this case.

Other government investigations/proceedings

Foreign Corrupt Practices Act
As previously disclosed, in connection with investigations into anti-bribery and corruption issues in the pharmaceutical industry, AstraZeneca has received inquiries from enforcement agencies, including the DOJ and the Securities and Exchange Committee, regarding, among other things, sales practices, internal controls, certain distributors and interactions with healthcare providers and other government officials in several countries. AstraZeneca is cooperating with these inquiries. AstraZeneca's investigation has involved indications of inappropriate conduct in certain countries, including China. Resolution of these matters could involve the payment of fines and/or other remedies.