ASTRAZENECA PLC Form 6-K May 10, 2005

### 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 April 2005

Commission File Number: 001-11960

### AstraZeneca PLC

15 Stanhope Gate, London W1K 1LN, England

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. Press release entitled,  $\Box$ FDA Approves Intravenous Formulation for Nexium $@\Box$ , dated 1 April 2005.

- Press release entitled, ☐Dealing by Directors ☐ Companies Act 1985 Sections 324/329☐, dated 2. 7 April 2005.
- Press release entitled, [AstraZeneca First Quarter Results 2005], dated 27 April 2005.
- Press release entitled, ∏AstraZeneca PLC First Quarter Results 2005∏, dated 28 April 2005.
- Press release entitled, ∏AstraZeneca PLC Annual General Meeting: 27 April 2005∏, dated 28 5. April 2005.

### **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: 10 May 2005 By: /s/ G H R Musker

Name: G H R Musker

Title: Secretary & Solicitor

#### Item 1

### FDA APPROVES INTRAVENOUS FORMULATION FOR **NEXIUM®**

AstraZeneca today announced that a new administration formulation for its prescription proton pump inhibitor NEXIUM ® (esomeprazole magnesium) has been approved by the US Food and Drug Administration (FDA). NEXIUM I.V. is now approved as an intravenous infusion or injection for the short-term treatment (up to 10 days) of gastroesophageal reflux disease (GERD) patients, with a history of erosive esophagitis, who are unable to take capsules.

NEXIUM® I.V. (esomeprazole sodium) for injection is administered once daily as either a 10 to 30 minute intravenous infusion or by intravenous injection (no less than 3 minutes). Treatment is given for up to 10 days and does not require an in-line filter.

Hospitalised patients with GERD are often unable to take their oral medication. The availability of NEXIUM in an intravenous formulation provides these patients with an effective alternative route of administration that they can tolerate easily.

The approval of NEXIUM I.V. was based, in part, on the findings of four multi-centre, open-label, two-period crossover studies. These studies compared the pharmacodynamic efficacy of the intravenous formulation with NEXIUM delayed-release capsules at corresponding doses of 20 mg and 40 mg in GERD patients with or without a history of erosive esophagitis. They demonstrated that, after 10 days of once-daily administration, NEXIUM I.V. 20 mg and 40 mg are similar in their ability to suppress acid to the corresponding oral dosage form of NEXIUM.

There were no relevant changes in acid suppression when switching between intravenous and oral dosage forms.

NEXIUM (delayed release capsules) is indicated for treating frequent, persistent heartburn and other symptoms associated with acid reflux disease. The drug was recently approved for reducing the risk of gastric (stomach) ulcers developing among at risk patients on continuous NSAID therapy. It also is approved for healing erosive

esophagitis. Studies show that up to 94 percent of patients were healed with NEXIUM. Most erosions heal in 4 to 8 weeks.

NEXIUM I.V. formulation was first approved via the European Mutual Recognition Process in August 2003 and launches in Europe are ongoing. NEXIUM capsules have been launched in 89 countries. Worldwide NEXIUM sales totalled \$3.9 billion in 2004, with US sales reaching \$2.7 billion.

1 April 2005

### **Media Enquiries:**

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### **Investor Relations:**

Jonathan Hunt, Tel: +44 (0) 207 304 5087

#### Item 2

### Dealing by Directors Companies Act 1985 Sections 324/329

We hereby inform you that, with effect from 7 April 2005, Marcus Wallenberg, a Director of the Company, is no longer deemed to have an interest in 3,618 AstraZeneca Ordinary Shares of USD0.25 each, held in the name of one of his children who, on 7 April 2005, attained the age of eighteen years. Consequently, Mr Wallenberg\(\text{\text{\text{\text{\text{eq}}}}\) interest in AstraZeneca Ordinary Shares has reduced to 67,264 shares, which represents approximately 0.004 per cent of the number of shares currently in issue.

G H R Musker Company Secretary

#### Item 3

#### **AstraZeneca First Quarter Results 2005**

Tomorrow, Thursday, 28 April 2005, AstraZeneca will release First Quarter Results 2005 at 10:00BST.

There will be an analyst teleconference at 13:30BST for which the numbers are: UK: 0800 559 3282, for Europe: +44 (0)20 7784 1017 and for the US: 1 866 239 0750. These numbers, and details of the replay facility available through 09:00BST Thursday, 12 May 2005, are available on the Investor Relations part of the AstraZeneca website at <a href="https://www.astrazeneca.com">www.astrazeneca.com</a>.

#### Item 4

## AstraZeneca PLC First Quarter Results 2005

□Record quarterly profits, with first quarter Earnings per Share up 33 percent.
Sales up 9 percent.

**Financial Highlights** (Financial statements prepared in accordance with International Financial Reporting Standards)

<u>Group</u>	1st Quarter 2005	1st Quarter 2004	Actual <u>%</u>	CER <u>%</u>
	<u>\$m</u>	<u>\$m</u>		
Sales	5,743	5,074	+13	+9
Operating Profit	1,453	1,052	+38	+34
Profit before Tax	1,486	1,084	+37	+34
Earnings per Share	\$0.63	\$0.47	+34	+33

All narrative in this section refers to growth rates at constant exchange rates (CER)

- First quarter sales were \$5,743 million, up 9 percent. Underlying sales of key growth products up 33 percent.
- Progress on productivity continues; combined R&D and SG&A expenditure down 4 percent.
- Operating profit in the first guarter increased 34 percent to \$1,453 million.
- Free cashflow of \$1,322 million in the quarter; share repurchases in the first quarter totalled \$481 million.
- Nexium sales were \$1,055 million in the first quarter, up 11 percent. Intravenous formulation approved in the US on 31 March 2005.
- Crestor sales in the first quarter were \$273 million, and have reached \$1,052 million in the last 12 months.
- Seroquel sales were \$633 million in the first quarter, up 39 percent.
- Arimidex<sup>©</sup>sales were \$256 million in the first quarter, up 49 percent.

**Sir Tom McKillop, Chief Executive, said**: 

These record profits derive from a strong sales performance, especially for our key growth products, and from ongoing productivity improvements in R&D and SG&A. This excellent start to the year has set us on track to deliver our financial targets for the year.

London, 28 April 2005

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#### AstraZeneca PLC

<u>Business Highlights</u> All narrative in this section refers to growth rates at constant exchange rates (CER) unless otherwise indicated

Sales in the first quarter increased 9 percent at CER, or 13 percent on an as reported basis (including positive exchange rate benefit of 4 percent). Sales outside the US were up 9 percent. Sales in the US in the first quarter were up 10 percent. Adjusted for inventory movements (principally wholesaler stockbuilding in the first quarter 2004) estimated underlying sales growth in the US was 17 percent.

Good management of expenditure in R&D and SG&A continues to benefit operating results. In aggregate, these expenses were 4 percent lower at CER than first quarter 2004 (and broadly unchanged as reported). Operating

profit was up 34 percent. Earnings per share in the first quarter were \$0.63 versus \$0.47 in 2004, an increase of 33 percent.

Nexium sales were \$1,055 million in the first quarter, up 11 percent. Dispensed tablet volume in the US was up 15 percent, whereas reported sales growth was up 3 percent as a consequence of wholesaler stockbuilding in the first quarter 2004. Nexium sales outside the US were up 30 percent.

Crestor sales in the first quarter were \$273 million, more than double the sales in the first quarter last year. In March, Crestor share of new prescriptions in the US statin market was 6.0 percent, up from 5.8 percent in January 2005. On 14 March, based on a thorough analysis of clinical trial safety data and post-marketing data, the US Food and Drug Administration (FDA) formally denied Public Citizen shealth Research Group (HRG) petition to remove Crestor from the market, and as part of their formal response, reaffirmed that Crestor is safe and effective when used according to the prescribing information.

Sales of Iressa were \$81 million in the first quarter. Sales in Asia Pacific were up 18 percent which includes sales made since launch in China in February. Sales in Japan were down 8 percent. Sales declined by 41 percent in the US since the announcement of the ISEL trial results, where promotion of Iressa remains voluntarily suspended whilst the FDA completes its assessment of the implications of the full ISEL trial data set.

Good sales growth in the first quarter was achieved for Symbicort (up 23 percent), Casodex (up 16 percent), and Seroquel (up 39 percent). Arimidex sales were up 49 percent to \$256 million. In the US, Arimidex new prescription share of hormonal treatments for breast cancer reached 31.4 percent in March, a market-leading 1.3 percentage point increase since December 2004.

#### **Future Prospects**

The Company continues to anticipate full year earnings per share in the range of \$2.35 to \$2.50. In contrast to the quarterly progression of earnings last year, the growth rate in earnings per share in 2005 is anticipated to be stronger in the first half than in the second half of the year.

Disclosure Notice: The preceding forward-looking statements relating to expectations for earnings and business prospects for AstraZeneca PLC are subject to risks and uncertainties, which may cause results to differ materially from those set forth in the forward-looking statements. These include, but are not limited to: the rate of growth in sales of generic omeprazole in the US, continued growth in currently marketed products (in particular CrestorTM, NexiumTM, SeroquelTM, SymbicortTM, ArimidexTM and CasodexTM), the growth in costs and expenses, interest rate movements, exchange rate fluctuations and the tax rate. For further details on these and other risks and uncertainties, see AstraZeneca PLC\(\sigma\)s Securities and Exchange Commission filings, including the 2004 Annual Report on Form 20-F.

AstraZeneca PLC

Sales

All narrative in this section refers to growth rates at constant exchange rates (CER) unless otherwise indicated

Gastrointestinal

First Quarter

			CER %
	2005	2004	
Nexium <sup>[]</sup> Losec/Prilosec <sup>[]</sup>	1,055 427	935 540	+11 -25
Total	1,499	1,496	-3

- In the US, dispensed tablet volume for Nexium Increased by 15 percent in the first quarter, nearly double the rate of growth for the prescription PPI market. Market share of total prescriptions in March reached 27.5 percent, up nearly 2 points over March 2004. Reported sales for Nexium in the US were up just 3 percent as a consequence of wholesaler stocking which occurred in the first quarter last year. Although pricing had little impact on sales growth this quarter, the Company expects that volume growth for the full year will be partially offset by lower realised prices.
- Sales of Nexium in markets outside the US were up 30 percent in the first quarter.
- Prilosecsales in the US were down 34 percent in the first quarter. Sales of Losec butside the US were down 22 percent, although sales in Japan continue to grow (up 22 percent).

### Cardiovascular

	First Quarter		CER %
	2005	2004	
Seloken   Toprol-XL   Atacand   Plendil   Zestril	408 235 93 87	333 209 111 105	+21 +7 -19 -22
Crestor[]	273	129	+106
Total	1,257	1,055	+15

- Sales of Seloken Toprol-XL were up 21 percent in the first quarter, chiefly on the 24 percent increase in sales of Toprol-XL in the US.
- Sales for Atacand were up 7 percent in the first quarter. Sales outside the US were up 19 percent. Total prescriptions for Atacand in the US were down 9 percent, but reported sales were down 18 percent as a result of wholesaler stocking in the first quarter 2004.
- On 23 February, Atacand became the first angiotensin receptor blocker in the US to receive regulatory approval for heart failure, based on data that showed reductions in both cardiovascular mortality and hospitalisations in patients with heart failure.

- Crestor sales in the first quarter were \$273 million, up 106 percent versus the first quarter last year. Sales in the last 12 months reached \$1,052 million.
- In markets outside the US, Crestor Gales were \$119 million in the quarter. Volume share of the statin market is now at double-digit levels in Canada (12.2 percent), Italy (11.8 percent), and the Netherlands (10.4 percent). Good progress continues in France, with market share reaching 5.0 percent in the latest month. Market share in the UK is 3.5 percent, down slightly from that reported at the year end.

3

#### AstraZeneca PLC

- In the US, Crestor sales in the first quarter were \$154 million. For the month of March, Crestor share of >new prescriptions in the US statin market was 6.0 percent, up from 5.8 percent in January. In the week ending 15 April, Crestor share of new prescriptions was 6.2 percent. Market share in the dynamic segment (new and switch patients) was 8.3 percent.
- On 14 March, based on a thorough analysis of clinical trial safety data and post-marketing data, which involved more than 15 million prescriptions and 4 million patients, the US Food and Drug Administration formally denied Public Citizen s Health Research Group (HRG) petition to remove Crestor the market.
- The launch of Crestor in Japan, announced on 27 April, will be followed by implementation of programme of Post-Marketing Surveillance studies at specific medical institutions. The programme will take approximately 18 to 24 months to complete. Significant sales of Crestor in Japan are not anticipated before completion of an interim report in late 2006 which will determine the subsequent full-scale launch schedule.

#### Respiratory and Inflammation

	First Q	uarter	CER %
	2005	2004	
Symbicort[]	247	188	+23
Pulmicort[]	314	282	+8
Rhinocort[]	92	81	+13
Accolate[]	28	30	-7
Oxis[]	23	25	-16
Total	746	648	+11

• Sales of Symbicort In the first quarter were up 23 percent to \$247 million. In February, Symbicort Imarket share in the fast growing combination products segment of the asthma and COPD markets was up more than 2 points versus the same month last year.

- On 9 March, the Company announced that the European Patent Office has ruled that the European combination patent for Symbicort still valid, despite a challenge from several generic manufacturers.
- Pulmicort sales were up 8 percent, as sales increased by 11 percent in the US, and increased by 5 percent elsewhere.
- Sales of Rhinocort were up 13 percent. Sales growth in the US (up 20 percent) was ahead of the prescription trend (down 4 percent) as a result of wholesaler destocking in the first quarter 2004.

#### Oncology

	First Quarter		CER %
	2005	2004	
Casodex[]	277	229	+16
Zoladex□	231	213	+3
Arimidex[]	256	166	+49
lressa <u></u>	81	93	-15
Faslodex[]	29	26	+8
Nolvadex[]	28	31	-13
Total	905	762	+14

• Casodex ales were up 16 percent in the first quarter, fuelled by an 18 percent growth in markets outside the US, including a strong performance in Japan (up 21 percent). Sales in the US were up 11 percent in the quarter, ahead of estimated underlying sales growth of around 4 percent.

4

#### AstraZeneca PLC

- Arimidex sales increased by 49 percent in the first quarter, with strong growth recorded in the US (up 63 percent), Europe (up 42 percent) and Japan (up 38 percent). Arimidex street the only aromatase inhibitor indicated for primary adjuvant treatment of early breast cancer.
- In the US, Arimidex hew prescription market share for hormonal treatments for breast cancer reached 31.4 percent in March, a market-leading 1.3 percentage point increase versus December 2004.
- Sales for Iressalln the first quarter were \$81 million, down 15 percent. Sales in Asia Pacific were up 18 percent, which includes sales since launch in China in February. Sales in Japan were \$26 million, 8 percent below the first quarter last year. During the first quarter, Iressallwas reviewed by an Expert Committee advising the Japanese Ministry of Health, Labour and Welfare, who recommended no change to the indications for use in Japan, and recommended that prescribing information be updated to make reference to the Iressallspecific treatment guidelines issued by the Japanese Lung Cancer Society.

• Iressa sales in the US declined by 41 percent to \$30 million in the first quarter. It is believed that these sales largely represent prescriptions dispensed to previously treated patients who, in consultation with their physician, wish to continue treatment with Iressa. In the US, promotion of Iressa remains under voluntary suspension whilst discussions with the FDA continue. In March, new prescriptions for Iressa in the US are nearly 70 percent below the level in November 2004.

#### Neuroscience

	First Quarter		CER %
	2005	2004	
Seroquel[]	633	448	+39
Zomig□	68	95	-32
Diprivan□	107	122	-14
Local anaesthetics	127	130	-7
Others	17	17	-6
Total	952	812	+14

- Seroquel ales in the first quarter reached \$633 million, up 39 percent, on good growth in the US (up 35 percent), Europe (up 56 percent), Canada (up 35 percent), and Asia Pacific (up 20 percent).
- In the US, the 35 percent growth in Seroquel ales was somewhat ahead of estimated underlying sales growth of around 28 percent as wholesalers edged up inventories toward the upper end of the target range. In March, new prescription market share in the US was 28.6 percent, up a full percentage point versus December 2004 and 2.8 points clear of its closest competitor.
- The Company recently received a request from the FDA that the product labelling for all atypical antipsychotics, including Seroquel, be updated to include a black-box warning noting an increased risk of mortality in elderly patients with dementia-related psychosis taking these drugs, compared to patients taking placebo. The proposed warning also notes that these drugs are not approved for treatment of elderly patients with dementia-related psychosis. The Company is reviewing the FDA request.
- Sales of Zomiglin markets outside the US were up 12 percent in the first quarter.
- In the US, supply sales of Zomigto Medpointe Inc. were only \$9 million (down 80 percent) in anticipation of the end of the partnership arrangement on 31 March. Effective 1 April 2005, AstraZeneca assumed full responsibility for the US commercialization of Zomigton.

5

#### Geographic Sales

-			
	First Quarter		CER %
_	2005	2004	
US Europe Japan RoW	2,500 2,165 337 741	2,279 1,875 290 630	+10 +8 +12 +11

- Underlying sales growth in the US in the first quarter was estimated to be 17 percent when adjusted for the wholesaler stocking that occurred in the first quarter 2004. The key growth drivers in the quarter were Nexium Crestor Seroquel Toprol-XL and Arimidex
- Sales growth in Europe was driven by Nexium up 31 percent), oncology products (up 22 percent), Seroquel up 56 percent), Symbicort up 23 percent) and Crestor up 115 percent).
- First quarter sales in Japan reflect a strong performance for oncology products (up 14 percent) and Losec[ (up 22 percent).

6

#### AstraZeneca PLC

#### **Financial Review**

All narrative in this section refers to growth rates at constant exchange rates (CER) unless otherwise indicated

#### **Operating Results**

Reported sales increased by 13 percent and operating profit by 38 percent. At constant exchange rates, sales increased by 9 percent and operating profit by 34 percent.

In the US, sales in the quarter were unaffected by wholesaler inventory movements, as inventory levels were near target levels specified in the Inventory Management Agreements. Sales in the first quarter 2004, however, did benefit from inventory movements. Adjusting for these, underlying US sales growth is estimated at 17 percent, compared with 10 percent reported growth. European sales benefited by an estimated \$50 million due to accelerated deliveries at the end of the quarter, ahead of a brief shut down to allow a system upgrade.

The weakness of the US dollar benefited EPS by around 1 cent. In comparison to quarter one last year, the dollar weakened against the euro (5 percent), benefiting sales, and also against the Swedish krona (6 percent) and sterling (3 percent), increasing costs. Should the exchange rates stay at current levels for the remainder of the year, no further benefits are expected to accrue.

Reported operating margin increased by 4.6 percentage points from 20.7 percent to 25.3 percent. Currency depressed operating margin by 0.1 percentage points, implying an underlying margin improvement of 4.7 percentage points.

Gross margin decreased by 1.8 percentage points to 75.4 percent of sales. Payments to Merck at 4.5 percent of sales were 0.5 percentage points lower than first quarter last year. Currency benefited gross margin by 0.2 percentage points which, combined with Merck, implies an underlying decline in margin of 2.5 percentage points. The resulting underlying decline in gross margin is attributable to IFRS fair value adjustments of foreign exchange contracts and termination of the Medpointe Zomig distribution agreement in the US.

In aggregate, R&D and SG&A expenses of \$2,872 million decreased by 4 percent over last year due to continued disciplined management of expenditure and some phasing to the benefit of the first quarter. In comparison to the first quarter last year, R&D and SG&A expenditure decreased by 3 and 4 percent respectively, and combined added 6.7 percentage points to operating margin.

Fair value adjustments arising from financial instruments amounted to a \$44 million charge in the quarter, of which \$23 million was charged to cost of sales, \$22 million was charged to R&D, with a \$1 million benefit to interest income.

#### Interest and Dividend Income

Net interest and dividend income for the quarter was \$33 million, compared with \$32 million for the same period last year. This includes net interest income of \$5 million arising from employee benefit fund assets and liabilities as required by IAS 19, [Employee Benefits].

#### **Taxation**

The tax rate for the quarter is 29.8 percent compared to 26.3 percent for the first quarter of 2004. The increase is attributable to a different geographical mix of profits and the impact of IFRS. For the full year the tax rate is anticipated to be around 29 percent.

#### **Cash Flow**

Cash generated from operating activities in the quarter was \$1.5 billion, about \$500 million higher than in the corresponding quarter of 2004. Higher trading profits and lower working capital outflows were the main drivers of this improvement, offset by a slight increase in tax paid.

7

#### AstraZeneca PLC

Cash outflows from investing activities of \$29 million in the first quarter compare with \$555 million outflows in the equivalent period in 2004. Net capital expenditure, including fixed asset investments, fell by \$73 million to \$226 million. However, the change was primarily as a result of short term management of funds on deposit ☐ inflows in the current quarter of \$158 million contrasted with outflows of \$265 million in the first quarter of 2004.

Free cash flow (which represents cash flows before returns to shareholders and financing and which therefore excludes the effects of short term management of funds) for the period was \$1,322 million compared to \$721 million in the first quarter of 2004. After accounting for net issues and repurchases of shares of \$477 million, the \$1,079 million dividend payment to shareholders and foreign exchange effects, there was a \$88 million decrease in cash and cash equivalents.

Cash and cash equivalents at 31 March 2005 amounted to \$3,839 million compared to \$742 million at 31 March 2004. The apparent increase reflects a movement of short term deposits into cash equivalents in the latter part of 2004.

### **Share Repurchase Programme**

During the quarter 11.95 million shares were repurchased for cancellation at a total cost of \$481 million.

The total number of shares in issue at 31 March 2005 was 1,633 million.

### Calendar

28 April Annual General Meeting
 28 July Announcement of second quarter and half year results
 27 October Announcement of third quarter and nine months results

Sir Tom McKillop Chief Executive

8

## **Consolidated Balance Sheet**

For the quarter ended 31 March	2005 \$m	2004 \$m
Sales	5,743	5,074
Cost of sales	(1,410)	(1,158)
Distribution costs	(50)	(42)
Research and development	(865)	(857)
Selling, general and administrative expenses	(2,007)	(2,003)
Other operating income	42	38
Operating profit	1,453	1,052
Net finance income	33	30
Income from dividends		2
Profit before tax	1,486	1,084
Taxation	(443)	(285)
Profit for the period	1,043	799
Attributable to:		
Equity holders of the Company	1,040	797

Minority interest	3	2
	1,043	799
Basic earnings per \$0.25 Ordinary Share Diluted earnings per \$0.25 Ordinary Share	\$ 0.63 \$0.63	\$0.47 \$0.47
Weighted average number of Ordinary Shares in issue (millions) Diluted average number of Ordinary Shares in issue (millions)	1,640 1,640	1,688 1,690

9

# **Consolidated Balance Sheet**

	2005	2004
As at 31 March	\$m 	\$m
ASSETS		
Non-current assets		
Property, plant and equipment	7,800	7,556
Goodwill and intangible assets	2,901	2,910
Other investments	221	58
Deferred tax assets	1,229	1,407
	12,151	11,931
Current assets		
Inventories	2,903	3,099
Trade and other receivables	4,932	4,555
Short term investments	958	3,386
Cash and cash equivalents	3,905	814
	12,698	11,854
Total assets	24,849	23,785
LIABILITIES		
Current liabilities		
Short term borrowings and overdrafts	(66)	(72)
Other creditors	(6,770)	(7,675)
	(6,836)	(7,747)

(1,070)	(305)
(1,171)	(1,423)
(1,995)	(1,811)
(91)	(84)
(4,327)	(3,623)
(11,163)	(11,370)
13,686	12,415
	(1,171) (1,995) (91) (4,327) (11,163)

## **EQUITY**

Capital and reserves attributable to equity holders