BARCLAYS PLC Form F-3ASR June 25, 2008

As filed with the Securities and Exchange Commission on June 25, 2008 Registration No. 333-

SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

Form F-3

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

Barclays PLC (Exact name of registrant as specified in its charter)

England

(State or other jurisdiction of incorporation or organization)

N/A (Translation of registrant s name into English) None (IRS Employer Identification Number)

1 Churchill Place London E14 5HP United Kingdom Tel. No.: 011-44-20-7116-1000

(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

James Walker Barclays Bank PLC 200 Park Avenue New York, New York 10166 United States of America Tel. No.: 1-212-412-4000

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

George H. White Sullivan & Cromwell LLP 1 New Fetter Lane London EC4A 1AN United Kingdom Tel. No.: 011-44-20-7959-8900

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of the Registration Statement.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. o

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, please check the following box. b

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a registration statement pursuant to General Instruction I.C. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. b

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.C. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. o

CALCULATION OF REGISTRATION FEE

		Proposed Maximum	Proposed Maximum	Amount of
Title of Each Class of	Amount to be	Offering Price	Aggregate Offering	Registration
Securities to be Registered	Registered(1)	per Security(2)	Price(2)	Fee(3)

Ordinary shares nominal value				
25p per share	266,000,000	\$5.56	\$1,478,980,446	\$58,124

- (1) A portion of the ordinary shares, nominal value 25p per share, of the registrant may be represented by the registrant s American Depositary Shares (ADS) evidenced by American Depositary Receipts, each of which represents four ordinary shares. ADSs issuable upon deposit of the ordinary shares registered hereby have been registered pursuant to the Registration Statement on Form F-6 (File No. 333-146411) and the Registration Statement on Form F-6 (File No. 333-956562).
- (2) Estimated solely for calculating the registration fee pursuant to Rule 457 under the Securities Act of 1933, as amended, based on an exchange rate of $\pounds 1.00 = \$1.9707$ (the Federal Reserve Bank of New York s noon buying rate on June 24, 2008).
- (3) Barclays PLC previously paid a registration fee of \$558,993 with respect to securities that were previously registered pursuant to the registrant s prior registration statement on Form F-4 (File no. 333-143666) (the Form F-4 Registration Statement), filed on June 12, 2007. Barclays (Netherlands) N.V. previously paid a registration fee of \$512,548 with respect to securities that were previously registered pursuant to Amendment No. 4 to the Form F-4 Registration Statement, filed on August 3, 2007. Of the combined registration fee of \$1,071,541 paid by Barclays PLC and Barclays (Netherlands) N.V., \$958,553.50 has not been used. In accordance with Rule 457(p), the unused amount of registration fee paid with respect to the Form F-4 Registration Statement will be applied to pay the registration fee payable with respect to the securities registered under this registration statement.

Barclays PLC

Open Offer of up to 266,000,000 New Ordinary Shares, in the form of New Ordinary Shares or New American Depositary Shares 282 pence per New Ordinary Share \$22.23 per New American Depositary Share (Estimated)

We, Barclays PLC, a public limited company organized under the laws of England (Barclays), are hereby offering to holders of Barclays ordinary shares, nominal value 25p (ordinary shares), the ability to subscribe for new ordinary shares (new ordinary shares) and, through The Bank of New York, our depositary and subscription agent, to holders of Barclays American Depositary Shares (ADSs) the ability to subscribe for new ADSs (new ADSs), representing new ordinary shares, pursuant to an open offer (the open offer).

1,407,426,864 new ordinary shares are to be issued globally pursuant to the open offer, including up to 266,000,000 new ordinary shares in the form of ordinary shares or ADSs being offered, sold or issued in the United States. Separate offering documentation is being made available to holders of existing ordinary shares located in the United Kingdom and other qualifying jurisdictions outside the United States.

Open offer for ordinary shares. Holders of ordinary shares held of record at the close of business, London time, on June 24, 2008 are being given the opportunity to subscribe for 3 new ordinary shares for every 14 outstanding ordinary shares that they hold at a subscription price of 282 pence per new ordinary share up to a maximum of their pro rata entitlement. Subscriptions will only be accepted for whole new ordinary shares, and any fractional entitlement under the open offer will be rounded down to the nearest whole number of new ordinary shares.

The subscription price of 282 pence per new ordinary share under the open offer represents a discount of 9.3% to the June 24, 2008 closing price of 310.75 pence per ordinary share on the London Stock Exchange. The new ordinary shares, when issued and fully paid, will be fully fungible and rank *pari passu* with each other and all other issued ordinary shares of Barclays.

Completed ordinary share subscription forms and payment should be returned so as to be received by Equiniti Limited, the ordinary share registrar of Barclays, by no later than 11:00 a.m., London time, on July 17, 2008. See Description of the Offering Subscription by Holders of Ordinary Shares .

Open offer for ADSs. Holders of ADSs held of record at 5:00 p.m., New York City time, on July 2, 2008 are being given the opportunity to subscribe for 3 new ADSs for every 14 outstanding ADSs that they hold at an estimated subscription price of \$22.23 per new ADS up to a maximum of their *pro rata* entitlement. To subscribe for new ADSs, a holder of existing ADSs must deposit with The Bank of New York, the ADS subscription agent, \$24.45 per new ADS so subscribed, which represents 110% of the estimated ADS subscription price, to account for possible exchange rate fluctuations, foreign currency conversion expenses, the depositary s issuance fee of \$0.02 per new ADS and the applicable 1.5% U.K. stamp duty reserve tax (SDRT). As each ADS represents four ordinary shares, the estimated subscription price per ADS is four times the U.S. dollar equivalent of the ordinary share subscription price using an exchange rate of \$1.9707 per pound sterling (the Federal Reserve Bank of New York s noon buying rate of June 24, 2008). The actual U.S. dollar subscription price per ADS will be four times the ordinary share subscription price of 282 pence per new ordinary share translated into U.S. dollars on or about July 15, 2008. If the actual U.S. dollar subscription price *plus* foreign currency conversion expenses, the issuance fee and the SDRT is less than the deposit amount, the ADS subscription agent will refund the excess amount to the subscribing ADS holder. Subscriptions will only be accepted for whole new ADSs, and any fractional entitlement under the open offer will be rounded down to the nearest whole number of new ADSs. If there is a deficiency, the ADS subscription agent will not deliver the new ADSs to such subscribing ADS holder until it has received payment of the deficiency. The ADS subscription agent may sell a portion of your new ADSs to cover the deficiency if not paid within 14 calendar days from notice of the

deficiency.

The estimated subscription price of \$22.23 per new ADS represents a discount of 10.0% to the June 24, 2008 closing price of \$24.70 per ADS on the New York Stock Exchange. The new ADSs will be fully fungible and rank *pari passu* with each other and all other issued ADSs.

Completed ADS subscription forms and payment should be returned so as to be received by The Bank of New York, the ADS subscription agent, by no later than 11:00 a.m., New York City time, on July 14, 2008. See Description of the Offering Subscription by Holders of ADSs.

Firm placing and conditional placing outside the United States. In conjunction with the open offer, we are also conducting a firm placing of 168,918,918 new ordinary shares of Barclays to an investor outside the United States at a price of 296 pence per ordinary share (the firm placing). In addition, certain investors outside the United States have severally committed to purchase the ordinary shares that are not subscribed for in the open offer (the conditional placing) at the open offer price of 282 pence per share against commissions specified herein. See Plan of Distribution .

The open offer is not a rights offering. No rights will be issued in connection with the offering, and your entitlement to subscribe for new ordinary shares or new ADSs is not transferable or tradeable, except for *bona fide* market claims in respect of new ordinary shares. If you do not exercise your entitlement to subscribe for new ordinary shares by July 17, 2008 or for new ADSs by July 14, 2008, as applicable, your entitlement will expire and you will not receive any benefit from the sale of new ordinary shares or new ADSs which were not subscribed for. Entitlements for new ordinary shares not subscribed for will not be sold in the market, but will be issued to certain investors who have agreed to subscribe for new ordinary shares to the conditional placing. The open offer is conditional on admission of the new ordinary shares to the official list of the United Kingdom Listing Authority and to trading on the London Stock Exchange.

Outstanding ordinary shares are listed on the London Stock Exchange under the symbol BARC and on the Tokyo Stock Exchange under the symbol BARC (although Barclays has given notice to delist its shares from the Tokyo Stock Exchange, which is expected to become effective on or around June 28, 2008). Outstanding ADSs are listed on the New York Stock Exchange under the symbol BCS.

We will apply to have the new ordinary shares admitted to listing on the official list of the U.K. Listing Authority and to trading on the London Stock Exchange and the new ADSs listed on the New York Stock Exchange. We expect the listings to become effective on July 22, 2008. The first trading day for the new ordinary shares is scheduled to be on July 22, 2008.

The gross proceeds from the firm placing and the placing and open offer, if conducted as planned, will be approximately $\pounds 4.5$ billion. We expect that our expenses in connection with the firm placing and the placing and open offer, if conducted as planned, will be approximately 0.1 billion (inclusive of VAT) and that, as a result, the net proceeds to us will be approximately $\pounds 4.4$ billion. See Plan of Distribution .

An investment in the new ordinary shares and the new ADSs entails risks. See Risk Factors beginning on page 16.

Neither the Securities and Exchange Commission (SEC) nor any state securities commission or other regulatory body has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The ordinary shares are not deposit liabilities of Barclays PLC or Barclays Bank PLC and will not be insured by the United States Federal Deposit Insurance Corporation or any other governmental agency of the United States, the United Kingdom or any other jurisdiction.

Prospectus dated June 25, 2008

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FORWARD-LOOKING STATEMENTS

This prospectus and certain documents incorporated by reference herein contain forward-looking statements within the meaning of Section 21E of the U.S. Securities Exchange Act of 1934, as amended, and Section 27A of the U.S. Securities Act of 1933, as amended, with respect to certain of our plans and our current goals and expectations relating to our future financial condition and performance. These forward-looking statements can be identified by the fact that they do not relate only to historical or current facts. Forward-looking statements sometimes use words such as aim , anticipate , target , expect , estimate , intend , plan , goal , believe , or other words of similar meaning. Exam forward-looking statements include, among others, statements regarding the Group s future financial position, income growth, impairment charges, business strategy, projected levels of growth in the banking and financial markets, projected costs, estimates of capital expenditures, and plans and objectives for future operations.

By their nature, forward-looking statements involve risk and uncertainty because they relate to future events and circumstances, including, but not limited to, U.K. domestic and global economic and business conditions, the effects of continued volatility in credit markets and of further write-downs and credit exposures, market related risks such as changes in interest rates and exchange rates, the policies and actions of governmental and regulatory authorities including classification of financial instruments for regulatory capital purposes, changes in legislation, the further development of standards and interpretations under IFRS applicable to past, current and future periods, evolving practices with regard to the interpretation and application of standards under IFRS, the outcome of pending and future litigation, the success of future acquisitions and other strategic transactions and the impact of competition a number of which factors are beyond the Group s control. As a result, the Group s actual future results may differ materially from the plans, goals, and expectations set forth in the Group s forward-looking statements. Additional risks and factors are identified in our filings with the U.S. Securities and Exchange Commission (the SEC) including in our Annual Report on Form 20-F for the fiscal year ended December 31, 2007 (the 2007 Form 20-F), which is available on the SEC s website at http://www.sec.gov. Any forward-looking statements made by or on our behalf speak only as of the date they are made. We do not undertake to update forward-looking statements to reflect any changes in expectations with regard thereto or any changes in events, conditions or circumstances on which any such statement is based. The reader should, however, consult any additional disclosures that we have made or may make in documents we have filed or may file with the SEC.

INCORPORATION OF DOCUMENTS BY REFERENCE

The SEC allows us to incorporate by reference the information we file with them, which means we can disclose important information to you by referring you to those documents. The most recent information that we file with the SEC automatically updates and supersedes earlier information.

We have filed with the SEC a registration statement on Form F-3 relating to the securities covered by this prospectus. This prospectus is a part of the registration statement and does not contain all the information in the registration statement. Whenever a reference is made in this prospectus to a contract or other document of the company, the reference is only a summary and you should refer to the exhibits that are a part of the registration statement for a copy of the contract or other document. You may review a copy of the registration statement at the SEC s public reference room in Washington, D.C., as well as through the SEC s internet site, as discussed below.

We filed our 2007 Form 20-F with the SEC on March 26, 2008. We are incorporating the 2007 Form 20-F by reference into this prospectus. We are further incorporating by reference our Current Reports on Form 6-K filed with the SEC on May 15, 2008, June 16, 2008 and June 25, 2008.

In addition, we will incorporate by reference into this prospectus all documents that we file with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Exchange Act and, to the extent, if any, we designate therein, reports on Form 6-K we furnish to the SEC after the date of this prospectus and prior to the termination or expiry of any offering contemplated in this prospectus.

We will provide to you, upon your written or oral request, without charge, a copy of any or all of the documents we referred to above which we have incorporated in this prospectus by reference. You should direct your requests to Mellon Investor Services LLC in writing to 480 Washington Blvd, Jersey City, New Jersey 07310, or by calling toll-free from the United States or Canada at 1-877-282-6527 or calling collect from outside the United States or Canada at 1-201-680-6579.

You may read and copy any document that we file with or furnish to the SEC at the SEC s public reference room at 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the public reference room by calling the SEC at 1-800-SEC-0330. The SEC maintains an internet site that contains reports and other information regarding issuers that file electronically with the SEC at <u>http://www.sec.gov</u>.

ABOUT THIS PROSPECTUS

In this prospectus, references to Barclays and the Company refer to Barclays PLC. References to we, our and us to Barclays PLC or, if the context so requires, also to Barclays PLC and its consolidated subsidiaries. References to the Group or the Barclays Group refer to Barclays PLC and its consolidated subsidiaries. References to Barclays Bank refer to Barclays Bank PLC.

References to Challenger refer to Challenger Universal Limited, a company representing the beneficial interests of His Excellency Sheikh Hamad Bin Jassim Bin Jabr Al-Thani, the Chairman of Qatar Holding, and his family; China Development Bank refers to China Development Bank; Qatar Investment Authority refers to Qatar Investment Authority and Qatar Holding refers to Qatar Holding LLC, a wholly-owned subsidiary of Qatar Investment Authority; Sumitomo Mitsui Banking Corporation or SMBC refers to Sumitomo Mitsui Banking Corporation, a wholly-owned subsidiary of Sumitomo Mitsui Financial Group, Inc.; and Temasek refers to Temasek Holdings (Private) Limited.

We publish our consolidated financial statements in U.K. pounds sterling. References to pounds , sterling , \pounds , pence p are to the currency of the United Kingdom. Some of the financial data in this prospectus is also presented in U.S. dollars. References to U.S. dollars , dollars or \$ are to the currency of the United States.

In this prospectus, the conditional placing and the open offer are referred to together as the placing and open offer , and the firm placing, conditional placing and open offer are referred collectively to as the firm placing and the placing and open offer.

SUMMARY

The following summary does not contain all the information that may be important to you. You should read the entire prospectus and the documents incorporated by reference into this prospectus before making an investment decision. You should pay special attention to the Risk Factors section of this prospectus to determine whether an investment in the new ordinary shares or new ADSs is appropriate for you.

Overview

Barclays PLC is a public limited company registered in England under company number 48839. The company, originally named Barclay & Co. Limited, was incorporated in England on July 20, 1896 under the Companies Acts 1862 to 1890 as a company limited by shares. The company name was changed to Barclays Bank Limited on February 17, 1917, and it was reregistered in 1982 as a public limited company under the Companies Acts 1980. On January 1, 1985, the company changed its name to Barclays PLC. Barclays is listed on the New York Stock Exchange, London Stock Exchange and Tokyo Stock Exchange. Barclays principal executive offices are at 1 Churchill Place, London E14 5HP, United Kingdom and its telephone number is +44 20 7116 1000.

Barclays is a major global financial services provider engaged in retail and commercial banking, credit cards, investment banking, wealth management and investment management. Operating in over 50 countries and employing approximately 143,000 people, Barclays moves, lends, invests and protects money for over 38 million customers and clients worldwide.

Based on the closing price of ADSs on the New York Stock Exchange on June 24, 2008, Barclays market capitalization was \$40,557,350,798. As of June 25, 2008, there were 6,567,992,032 ordinary shares issued and outstanding, and, as of June 12, 2008, there were outstanding options to purchase 88,769,407 ordinary shares that would result in the issuance of new shares. At December 31, 2007, Barclays had total assets of £1,227,361 million (\$2,435,432 million) and deposits from banks and customer accounts of £385,533 million¹ (\$765,013 million), converted for convenience using the rate of 1.9843 U.S. dollars per pound, the rate in New York City for cable transfers in foreign currencies as certified for customs purposes by the Federal Reserve Bank of New York (the Federal Reserve Bank of New York s noon buying rate) on December 31, 2007.

Background to and Reasons for the Offering

Barclays believes that in the current market environment, it would be in the interests of its shareholders and ADS holders to strengthen the capital resources of Barclays through a firm placing and placing and open offer. The raising of capital will:

enable Barclays to strengthen its capital base and operate capital ratios that are ahead of its targets;

provide additional financial resources to allow Barclays to capture opportunities for growth;

introduce new investors Qatar Investment Authority, Challenger (a company representing the beneficial interests of His Excellency Sheikh Hamad Bin Jassim Bin Jabr Al-Thani, the Chairman of Qatar Holding, and his family) and Sumitomo Mitsui Banking Corporation (SMBC) to Barclays share register and further Barclays existing relationships with a number of our largest shareholders, including China Development Bank and Temasek; and

provide the opportunity for existing shareholders and ADS holders to participate through the open offer.

Current market turbulence has affected bank balance sheets and capital strength. The disruption in the credit markets and greater uncertainty in the broader economy have affected financial market participants, including Barclays. As of December 31, 2007, Barclays tier one capital ratio was 7.6% and its equity tier one ratio was 5.1% (on a Basel II basis) against long-term target levels of 7.25% and 5.25%, respectively. We

¹ Excludes items in course of collection due to other banks.

estimate that, taking into account the proceeds of the firm placing and the placing and open offer, on a pro forma basis, Barclays would have reported a tier one ratio of 8.8% and an equity tier one ratio of 6.3% on December 31, 2007 (on a Basel II basis). We intend that, following the firm placing and the placing and open offer, we will run ratios ahead of long-term target levels, particularly while current market turbulence persists.

In addition to strengthening the capital base of Barclays, the firm placing and the placing and open offer will also enable Barclays to take advantage of current market circumstances which have created for Barclays an unusual competitive opportunity. That is partly because of the pricing adjustments that have taken place in many asset classes; and partly because of the reduced willingness or ability of certain hitherto strong market participants to compete aggressively. Significant opportunities therefore exist to attract flows of new business at expanded margins consistent with Barclays strategy to seek higher growth over time by diversifying its profits base. Barclays financial performance of 2007 and 2008 has benefited from this diversification. Across the Group, this growth has been underpinned by robust risk and control procedures, and a culture which focuses on risk adjusted returns.

We intend to pursue the following initiatives: in Global Retail and Commercial Banking (GRCB), deepening Barclays presence in existing markets in Asia, the Middle East, Africa and Europe and accelerating growth in new markets such as Russia and Pakistan; and in Investment Banking and Investment Management (IBIM), driving continued growth in asset classes such as commodities, equities and iShares; pursuing the build-out of IBIM s risk management and financing businesses, particularly in the United States and Asia; and continuing to build the wealth management platform.

SMBC has agreed to subscribe for ordinary shares pursuant to the firm placing and Qatar Investment Authority, Challenger, China Development Bank and Temasek and certain other placees named herein in Plan of Distribution Subscription Agreements have agreed to subscribe for new ordinary shares (other than in relation to new ordinary shares for which China Development Bank is entitled to subscribe under the open offer, which China Development Bank has undertaken to take up in full) to the extent that they are not subscribed for by qualifying shareholders pursuant to the open offer. We believe that this is an important endorsement of Barclays long-term strategy and vision, and underscores the confidence of these institutions in Barclays and in its management team. We are also pleased to have entered into an agreement for the provision of advisory services by Qatar Investment Authority to Barclays in the Middle East and to have agreed to explore opportunities for a co-operative business relationship with SMBC. We welcome the support of Qatar Investment Authority, Challenger, SMBC, China Development Bank and Temasek as important investors while ensuring that the open offer structure allows existing shareholders and ADS holders to participate in the issue of the new ordinary shares and new ADSs, as applicable, on a pre-emptive basis.

Summary Consolidated Financial Information

Except as otherwise indicated, the following summary historical financial information for the Barclays Group is based on, and should be read together with, the consolidated financial information of Barclays as set forth in the audited consolidated financial statements of Barclays for the fiscal year ended December 31, 2007, including comparative figures for the fiscal years ended December 31, 2006 and 2005, which are incorporated by reference in this prospectus.

The consolidated financial statements were prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB). The audited consolidated financial statements of Barclays for the fiscal years ended December 31, 2007, 2006 and 2005 were audited by PricewaterhouseCoopers LLP and issued in each case with the unqualified auditor s report incorporated by reference in this prospectus.

The summary consolidated financial information reproduced below is intended only as an introduction. Investors should base their investment decisions on a review of the prospectus as a whole, including on a review of documents incorporated by reference into this prospectus.

Consolidated Income Statement Summary

for the Years Ended December 31,	2007 £m	2006 £m	2005 £m	2004 £m ⁽¹⁾
Net interest income	9,610	9,143	8,075	6,833
Net fee and commission income	7,708	7,177	5,705	4,847
Principal transactions	4,975	4,576	3,179	2,514
Net premiums from insurance contracts	1,011	1,060	872	1,042
Other income	188	214	147	131
Total income	23,492	22,170	17,978	15,367
Net claims and benefits incurred on insurance contracts	(492)	(575)	(645)	(1,259)
Total income net of insurance claims	23,000	21,595	17,333	14,108
Impairment charges and other credit provisions	(2,795)	(2,154)	(1,571)	(1,093)
Net income	20,205	19,441	15,762	13,015
Operating expenses	(13,199)	(12,674)	(10,527)	(8,536)
Share of post-tax results of associates and joints ventures	42	46	45	56
Profit before business disposals Profit on disposal of subsidiaries, associates and joint	7,048	6,813	5,280	4,535
ventures	28	323		45
Profit before tax	7,076	7,136	5,280	4,580
Tax	(1,981)	(1,941)	(1,439)	(1,279)
Profit after tax	5,095	5,195	3,841	3,301
Profit attributable to minority interests	678	624	394	47

Profit attributable to equity holders of the parent	4,417	4,571	3,447	3,254
	5,095	5,195	3,841	3,301
Selected financial statistics				
Basic earnings per share	68.9p	71.9p	54.4p	51.0p
Diluted earnings per share	66.7p	69.8p	52.6p	49.8p
Dividends per ordinary share	34.0p	31.0p	26.6p	24.0p
Dividend payout ratio	49.3%	43.1%	48.9%	47.1%
Profit attributable to the equity holders of the parent as a percentage of:				
average shareholders equity	20.3%	24.7%	21.1%	21.7%
average total assets	0.3%	0.4%	0.4%	0.5%
Selected statistical measures				
Cost: income ratio ⁽²⁾	57%	59%	61%	61%
Average United States dollar exchange rate used in				
preparing the accounts	2.00	1.84	1.82	1.83
Average Euro exchange rate used in preparing the				
consolidated financial statements	1.46	1.47	1.46	1.47

Consolidated Balance Sheet Summary at December 31, 2007 2006 2005 2004 £m⁽¹⁾ £m £m £m Assets Cash and other short-term funds 7,637 9,753 5,807 3,525 Treasury bills and other eligible bills 6,658 n/a n/a n/a Trading portfolio and financial assets designated at fair value 341,171 292,464 251,820 n/a Derivative financial instruments 138,353 136,823 248,088 n/a Debt securities and equity shares n/a n/a n/a 141,710 Loans and advances to banks 80,632 40,120 30,926 31,105 Loans and advances to customers 345,398 282,300 268,896 262,409

Branded Product Development. The process required by the FDA before a pharmaceutical product with active ingredients that have not been previously approved may be marketed in the United States generally involves the following:

laboratory and preclinical tests;

submission of an Investigational New Drug, or IND, application, which must become effective before clinical studies may begin;

adequate and well-controlled human clinical studies to establish the safety and efficacy of the proposed product for its intended use;

submission of an NDA containing the results of the preclinical tests and clinical studies establishing the safety and efficacy of the proposed product for its intended use, as well as extensive data addressing matters such as manufacturing and quality assurance;

scale-up to commercial manufacturing; and

FDA approval of an NDA.

Preclinical tests include laboratory evaluation of the product and its chemistry, formulation and stability, as well as toxicology and pharmacology studies to help define the pharmacological profile of the drug and assess the potential safety and efficacy of the product. The results of these studies are submitted to the FDA as part of the IND. They must demonstrate that the product delivers sufficient quantities of the drug to the bloodstream or intended site of action to produce the desired therapeutic results before human clinical trials may begin. These studies must also provide the appropriate supportive safety information necessary for the FDA to determine whether the clinical studies proposed to be conducted under the IND can safely proceed. The IND automatically becomes effective 30 days after receipt by the FDA unless the FDA, during that 30-day period, raises concerns or questions about the conduct of the proposed trials as outlined in the IND. In such cases, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials may begin. In addition, an independent institutional review board must review and approve any clinical study prior to initiation.

Human clinical studies are typically conducted in three sequential phases, which may overlap:

Phase I: The drug is initially introduced into a relatively small number of healthy human subjects or patients and is tested for safety, dosage tolerance, mechanism of action, absorption, metabolism, distribution and excretion.

Phase II: Studies are performed with a limited patient population to identify possible adverse effects and safety risks, to assess the efficacy of the product for specific targeted diseases or conditions, and to determine dosage tolerance and optimal dosage.

Phase III: When Phase II evaluations demonstrate that a dosage range of the product is effective and has an acceptable safety profile, Phase III trials are undertaken to evaluate further dosage and clinical efficacy and to test further for safety in an expanded patient population at geographically dispersed clinical study sites.

The results of the product development, preclinical studies and clinical studies are then submitted to the FDA as part of the NDA. The NDA drug development and approval process could take from three to more than 10 years.

Pharmaceuticals Rest of World

In Europe and the rest of the world, the manufacture and sale of pharmaceutical products is regulated in a manner substantially similar to that of the United States. Legal requirements generally prohibit the handling, manufacture, marketing and importation of any pharmaceutical product unless it is properly registered in accordance with applicable law. The registration file relating to any particular product must contain medical data related to product efficacy and safety, including results of clinical testing and references to medical publications, as well as detailed information regarding production methods and quality control. Health ministries are authorized to cancel the registration of a product if it is found to be harmful or ineffective or if it is manufactured or marketed other than in accordance with registration conditions.

In November 2005, the European Union introduced legislation in an attempt to simplify and harmonize product registration. A mutual recognition procedure was established whereby after submission and approval by authorities of the so-called reference member state, applications can be submitted in the other chosen member states. As part of this legislation, the EU also established new decentralized procedures that allow simultaneous submission of the application to chosen member states.

Active Pharmaceutical Ingredients

The regulatory process by which API manufacturers generally register their products for commercial sale in the United States and other similarly regulated countries is via the filing of a DMF. DMF s are confidential documents containing information on the manufacturing facility and processes used in the manufacture, characterization, quality control, packaging, and storage of an API. The DMF is reviewed for completeness by the FDA, or other similar regulatory agencies in other countries, in conjunction with applications filed by finished dosage manufacturers, requesting approval to use the given API in the production of their drug products. As of September 30, 2007, Matrix had filed 118 DMFs in the United States and 872 DMFs in the rest of the world.

Government Regulation

United States

All pharmaceutical manufacturers are subject to extensive, complex and evolving regulation by the federal government, principally the FDA and, to a lesser extent, other federal and state government agencies. The Federal Food, Drug, and Cosmetic Act, the Controlled Substances Act, the Waxman-Hatch Act, the Generic Drug Enforcement Act, and other federal government statutes and regulations govern or influence the testing, manufacturing, packaging, labeling, storage, recordkeeping, safety, approval, advertising, promotion, sale and distribution of products.

A sponsor of an NDA is required to identify in its application any patent that claims the drug or a use of the drug that is the subject of the application. Upon NDA approval, the FDA lists the approved drug product and these patents in the Orange Book. Any applicant that files an ANDA seeking approval of a generic equivalent version of a referenced brand drug before expiration of the referenced patent(s) must certify to the FDA either that the listed patent is not infringed or that it is invalid or

unenforceable (a Paragraph IV certification). If the holder of the NDA sues claiming infringement or invalidation within 45 days of notification by the applicant, the FDA may not approve the ANDA application until the earlier of the rendering of a court decision favorable to the ANDA applicant or the expiration of 30 months.

In addition to patent exclusivity, the holder of the NDA for the listed drug may be entitled to a period of non-patent, market exclusivity, during which the FDA cannot approve an application for a bioequivalent product. If the listed drug is a new chemical entity, the FDA may not accept an ANDA for a bioequivalent product for up to five years following approval of the NDA for the new chemical entity. If it is not a new chemical entity, but the holder of the NDA conducted clinical trials essential to approval of the NDA or a supplement thereto, the FDA may not approve an ANDA for a bioequivalent product before expiration of three years. Certain other periods of exclusivity may be available if the listed drug is indicated for treatment of a rare disease or is studied for pediatric indications.

Facilities, procedures, operations and/or testing of products are subject to periodic inspection by the FDA, the Drug Enforcement Administration and other authorities. In addition, the FDA conducts pre-approval and post-approval reviews and plant inspections to determine whether our systems and processes are in compliance with cGMP and other FDA regulations. Certain suppliers are subject to similar regulations and periodic inspections.

Medicaid, Medicare and other reimbursement legislation or programs govern reimbursement levels and require all pharmaceutical manufacturers to rebate a percentage of their revenues arising from Medicare and/or Medicaid-reimbursed drug sales to individual states. The required rebate is currently 11% of the average manufacturer s price for sales of Medicaid-reimbursed products marketed under ANDAs. Sales of Medicare and/or Medicaid-reimbursed products marketed under NDAs generally require manufacturers to rebate the greater of approximately 15% of the average manufacturer s price or the difference between the

average manufacturer s price and the best price during a specific period. We believe that federal or state governments may continue to enact measures aimed at reducing the cost of drugs to the public.

Under Part D of the Medicare Modernization Act, which became effective January 1, 2006, Medicare beneficiaries are eligible to obtain discounted prescription drug coverage from private sector providers. As a result, usage of pharmaceuticals has increased, a trend which we believe will continue to benefit the generic pharmaceutical industry. However, such potential sales increases may be offset by increased pricing pressures due to the enhanced purchasing power of the private sector providers that are negotiating on behalf of Medicare beneficiaries.

The primary regulatory approval required for API manufacturers selling APIs for use in FDFs to be marketed in the United States is approval of the manufacturing facility in which the APIs are produced, as well as the manufacturing processes and standards employed in that facility. The FDA requires that the manufacturing operations of both API and FDF manufacturers, regardless of where in the world they are located, comply with cGMP.

European Union

Pharmaceutical products regulation. In the EU, drug approval and manufacture is regulated at both the national and European levels. Within the EU there are four types of marketing authorization procedures: the centralized procedure, the mutual recognition procedure, the decentralized procedure and the independent national procedure.

An application under the centralized procedure must be submitted to the EMA and, if granted, allows marketing of that product throughout the EU. The centralized procedure is mandatory for all biotechnology products, for medicines indicated for the treatment of AIDS, cancer, diabetes and neurodegenerative diseases, for orphan medicinal products and, from May 20, 2008, for medicines for autoimmune and viral diseases.

Pursuant to the mutual recognition, or MR, procedure, a marketing authorization is first sought in one member state from the national regulatory agency (the Reference Member State, or RMS). The RMS makes its assessment report on the quality, efficacy and safety of the medicinal product available to other Concerned Member States, or CMSs, where marketing authorizations are also sought under the MR procedure. The MR procedure is not automatic: While one CMS may refuse recognition of the marketing authorization granted by the RMS based on grounds of potential serious risk to public health, other CMSs may grant their approval and authorization regardless of an outgoing procedure to ascertain a potential serious risk of the public health.

The decentralized procedure is based on the same fundamental idea as the MR procedure. In contrast to the MR procedure, however, the decentralized procedure does not require a national marketing authorization to have been granted for the medicinal product. The pharmaceutical company applies for marketing authorization simultaneously in all the member states of the EU in which it wants to market the product. After consultation with the pharmaceutical company, one of the member states concerned in the decentralized procedure will become the RMS. The competent agency of the RMS undertakes the scientific evaluation of the medicinal product on behalf of the other CMSs and coordinates the procedure. If all the member states involved (RMS and CMS) agree to grant marketing authorizations, this decision forms the basis for the granting of the national marketing authorizations in the respective member states. The aim of the decentralized procedure is to avoid the problem of member states objecting to the initial marketing authorization. However, if there are any problems they will be dealt with by the CMD (the coordination group for MR and decentralized procedures) under a 60-day referral procedure.

As with the MR procedure, the advantage of the decentralized procedure is that the pharmaceutical company receives identical marketing authorizations for its medicinal product in all the member states of the EU in which it wants to market the product. This leads to a considerable reduction in the future administrative burden on the pharmaceutical company with regard to variations, extensions, renewals, etc., concerning its national marketing authorizations.

Once a decentralized procedure has been completed, the pharmaceutical company can subsequently apply for marketing authorizations for the medicinal product in additional EU member states by means of the MR procedure. All products, whether centrally authorized or authorized by the mutual recognition or decentralized procedure, may only be sold in other member states if the product information is in the official language of the state in which the product will be sold, which effectively requires specific repackaging and labeling of the product.

Under the national procedure, a company applies for a marketing authorization in one member state. The national procedure can now only be used if the pharmaceutical company does not seek authorization in more than one member state. If it does seek wider marketing authorizations, it must use the centralized, MR or decentralized procedure.

Generic pharmaceutical approval. Before a generic pharmaceutical product can be marketed in the EU a marketing authorization must be obtained. If a generic pharmaceutical product is shown to be essentially the same as, or bio-equivalent to, one that is already on the market and which has been authorized in the EU for a specified number of years, as explained in the section on data exclusivity below, no further pre-clinical or clinical trials are required for that new generic pharmaceutical product to be authorized. The generic applicant can file an abridged application for marketing authorization, but in order to take advantage of the abridged procedure, the generic manufacturer must demonstrate specific similarities, including bio-equivalence, to the already authorized product. Access to clinical data of the reference drug is governed by the European laws relating to data exclusivity, which are outlined below. Other products, such as new dosages of established products, must be subjected to further testing, and bridging data in respect of these further tests must be submitted along with the abridged application.

Manufacturing. In addition to obtaining approval for each product, in most EU countries the pharmaceutical product manufacturer s facilities must obtain approval from the national supervisory authority. The European Union has a code of good manufacturing practice, which the marketing authorization holder must comply with. Regulatory authorities in the EU may conduct inspections of the manufacturing facilities to review procedures, operating systems and personnel qualifications.

Pricing and reimbursement. In order to control expenditure on pharmaceuticals, most member states in the European Union regulate the pricing of products and in some cases limit the range of different forms of drugs available for prescription by national health services. These controls can result in considerable price differences between member states. In

addition, in past years, as part of overall programs to reduce healthcare costs, certain European governments have prohibited price increases and have introduced various systems designed to lower prices. Some European governments have also prescribed minimum targets for generics dispensing.

Data exclusivity. An applicant for a generic marketing authorization currently cannot avail itself of the abridged procedure in the EU by relying on the originator pharmaceutical company s data until expiry of the relevant period of exclusivity given to that data. For products first authorized prior to October 30, 2005, this period is six or ten years (depending on the member state in question) after the grant of the first marketing authorization sought for the relevant product, due to data exclusivity provisions which have been in place. From October 30, 2005, the implementation of a new EU directive (2004/27/EC) harmonized the data exclusivity period for originator pharmaceutical products throughout the EU member states which are legally obliged to have implemented the directive by October 30, 2005. The new regime for data exclusivity provides for an eight-year data exclusivity period commencing from the grant of first marketing authorization. After the eight-year period has expired, a generic applicant can refer to the data of the originator pharmaceutical company in order to file an abridged application for approval of its generic equivalent product. Yet, conducting the necessary studies and trials for an abridged application, within the data exclusivity period, is not regarded as contrary to patent rights or to supplementary protection certificates for medicinal products. However, the applicant will not be able to launch its product for a further two years. This ten-year total period may be extended to 11 years if the original marketing authorization holder obtains within those initial eight years a further authorization for a new therapeutic use of the product which is shown to be of significant clinical benefit. Further, a specific data exclusivity for one year may be obtained for a new indication for a well-established substance, provided that significant pre-clinical or clinical studies were carried out in relation to the new indication. This new regime for data exclusivity will apply to products first authorized after October 30, 2005.

Canada

In Canada, the registration process for approval of all generic pharmaceuticals has two tracks which proceed in parallel. The first track is concerned with the quality, safety and efficacy of the proposed generic product, and the second track concerns patent rights of the brand drug owner. Companies may submit an application called an abbreviated new drug submission, or ANDS, to Health Canada for sale of the drug in Canada by comparing the drug to another drug marketed in Canada under a Notice of Compliance, or NOC, issued to a first person. When Health Canada is satisfied that the generic pharmaceutical product described in the ANDS satisfies the statutory requirements, it issues an NOC for that product for the uses specified in the ANDS, subject to any court order that may be made in the second track of the approval process.

The first track of the process involves an examination of the ANDS by Health Canada to ensure that the quality, safety and efficacy of the product meet Canadian standards and bioequivalence.

The second track of the approval process is governed by the Patented Medicines (Notice of Compliance) Regulations. The owner or exclusive licensee, or Originator, of patents relating to the brand drug for which it has an NOC, may have established a list of patents administered by Health Canada enumerating all the patents claiming the medicinal ingredient, formulation, dosage form or the use of the medicinal ingredient. It is possible that even though the patent for the API may have expired, the Originator may have other patents on the list which relate to new forms of the API, a formulation or additional uses. Most brand name drugs have an associated patent list containing one or more unexpired patents claiming the medicinal ingredient itself or a use of the medicinal ingredient (a claim for the use of the medicinal ingredient for the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms). In its ANDS, a generic applicant must make at least one of the statutory allegations with respect to each patent on the patent list, for example, alleging that the patent is invalid or would not be infringed and explaining the basis for that allegation. In conjunction with filing its ANDS, the generic applicant is required to serve a Notice of Allegation, or NOA, on the Originator which gives a detailed statement of the factual and legal basis for its allegations in the ANDS. The Originator may commence a court application within 45 days after it has been served with the NOA if it takes the position that the allegations are not justified. When the application is filed in court and served on Health Canada, Health Canada may not

issue an NOC until the earlier of the determination of the application by the court after a hearing or the expiration of 24 months from the commencement of the application. The period may be shortened or lengthened by the court in certain circumstances. An NOC can be obtained for a generic product only if the applicant is successful in defending the application under the Patented Medicines (Notice of Compliance) Regulations in court. The legal costs incurred in connection with the application could be substantial.

Section C.08.004.1 of the Food and Drug Regulations is the so-called data protection provision and the current version of this section applies in respect of all drugs for which an NOC was issued on or after June 17, 2006. A subsequent applicant for approval to market a drug for which an NOC has already been issued does not need to perform duplicate clinical trials similar to those conducted by the first NOC holder, but is permitted to demonstrate safety and efficacy by submitting data demonstrating that its formulation is bioequivalent to the formulation that was issued for the first NOC. The first party to obtain an NOC for a drug will have an eight-year period of exclusivity starting from the date it received its NOC based on those clinical data. A subsequent applicant for approval who seeks to establish safety and efficacy by comparing its product to the product that received the first NOC will not be able to file its own application until six years following the issuance of the first NOC have expired. The Minister of Health will not be permitted to issue an NOC to that applicant until eight years following the issuance of the first NOC have expired this additional two-year period will correspond in most cases to the 24-month automatic stay under the Regulations. If the first person provides the Minister with the description and results of clinical trials relating to the use of the drug in pediatric populations, it will be entitled to an extra six months of data protection. A drug is only entitled to data protection so long as it is being marketed in Canada.

Facilities, procedures, operations and/or testing of products are subject to periodic inspection by Health Canada and the Health Products and Food Branch Inspectorate. In addition, Health Canada conducts pre-approval and post-approval reviews and plant inspections to determine whether our systems are in compliance with cGMP, Drug Establishment Licensing, or EL, requirements and other provisions of the Regulations. Competitors are subject to similar regulations and inspections. The provinces and territories in Canada operate drug benefit programs through which eligible recipients receive drugs through public funding; these drugs are listed on provincial Drug Benefit Formularies. Eligible recipients include seniors, persons on social assistance, low-income earners, and those with certain specified conditions or diseases. To be considered for listing in a provincial or territorial Formulary, drug products must have been issued an NOC and must be approved through a national common drug review process. The listing recommendation is made by the Canadian Expert Drug Advisory Committee and must be approved by the applicable provincial/territorial health ministry.

The primary regulatory approval for pharmaceutical manufacturers, distributors and importers selling pharmaceuticals to be marketed in Canada is the issuance of an EL. An EL is issued once Health Canada has approved the facility in which the pharmaceuticals are manufactured, distributed or imported. A key requirement for approval of a facility is compliance with cGMP. For pharmaceuticals that are imported, the license for the importing facility must list all foreign sites at which imported pharmaceuticals are manufactured. To be listed, a foreign site must demonstrate cGMP compliance.

Australia

The pharmaceutical industry is one of the most highly regulated industries in Australia. The Australian federal government is heavily involved in the operation of the industry, as it is the main purchaser of medicinal and pharmaceutical products. The Australian federal government also regulates the quality, safety and efficacy of therapeutic goods.

The government exerts a significant degree of control over the pharmaceuticals market through the Pharmaceutical Benefits Scheme, or PBS, which is a governmental program for subsidizing the cost of pharmaceuticals to Australian consumers. Over 80% of all prescription medicines sold in Australia are reimbursed by the PBS. The PBS is operated under the National Health Act 1953 (Cth). This act governs such matters as who may sell pharmaceutical products, recovery of input and raw material costs, the prices at which pharmaceutical products may be sold and governmental subsidies.

For pharmaceutical products listed on the PBS, the price of each product is determined through negotiations between the Pharmaceutical Benefits Pricing Authority (a governmental

agency) and pharmaceutical manufacturers. The Australian government s purchasing power is used to obtain lower prices and restrict volumes as a means of controlling the cost of the program. The PBS also caps the margin that wholesalers may charge for drugs listed on the PBS. Wholesalers therefore have little pricing power over the majority of their product range and as a result are unable to increase profitability by increasing prices or margins. There have been recent changes to the pricing regime for PBS listed medicines which have decreased the margin wholesalers can charge. However, the Australian government has established a fund to compensate wholesalers under certain circumstances for the impact on the wholesale margin resulting from the new pricing arrangements.

Australia has a five year data exclusivity period, whereby any data relating to a pharmaceutical product cannot be referred to in another company s dossier until five years after the original product was approved.

Manufacturers of pharmaceutical products are also regulated by the Therapeutic Goods Administration, or TGA, under the Therapeutic Goods Act 1989 (Cth), or the Act. The TGA regulates the quality, safety and efficacy of pharmaceuticals supplied in Australia. The TGA carries out a range of assessment and monitoring activities to ensure that therapeutic goods available in Australia are of an acceptable standard, with a goal of ensuring that the Australian community has access, within a reasonable time, to therapeutic advances. Australian manufacturers of all medicines must be licensed under Part 4 of the Act and their manufacturing processes must comply with the principles of the cGMP.

All therapeutic goods manufactured for supply in Australia must be listed or registered in the Australian Register of Therapeutic Goods, or ARTG, before they can be supplied. The ARTG is a database of information about therapeutic goods for human use which are approved for supply in, or export from, Australia. Whether a product is listed or registered in the ARTG depends largely on the ingredients, the dosage form of the product and the promotional or therapeutic claims made for the product.

Medicines assessed as having a higher level of risk must be registered, while those with a lower level of risk can be listed. The majority of listed medicines are self-selected by consumers and used for selftreatment. In assessing the level of risk, factors such as the strength of a product, side effects, potential harm through prolonged use, toxicity, and the seriousness of the medical condition for which the product is intended to be used are taken into account.

Labeling, packaging and advertising of pharmaceutical products are also regulated by the TGA. There are best practice guidelines that are in place for each of these areas, to guide TGA assessors in assessing the appropriateness of the labeling, packaging and advertising of pharmaceuticals.

Japan

In Japan we are governed by various laws and regulations, including the Pharmaceutical Law and the Products Liability Law.

Under the Pharmaceutical Law, the retailing or supply of a pharmaceutical, which a person has manufactured (including manufacturing under license) or imported is defined as marketing, and in order to market pharmaceuticals, one has to obtain a license, which we refer to herein as a Marketing License, from the Minister of Health, Labour and Welfare, or the Minister. A Marketing License includes a manufacturing license. There are two types of Marketing License according to the pharmaceuticals to be marketed. The authority to grant the Marketing License is delegated to prefectural governors and therefore the relevant application must be filed with the relevant prefectural governor. A Marketing License will not be granted if the quality control system for the pharmaceutical for which the Marketing License has been applied or the post-marketing safety management system for the relevant pharmaceutical does not comply with the standards specified by the relevant Ministerial Ordinance made under the Pharmaceutical Law.

In addition to the Marketing License, a person intending to market a pharmaceutical must, for each product, obtain marketing approval from the Minister with respect to such marketing, which we refer to herein as Marketing Approval. Marketing Approval is granted subject to examination of the name, ingredients, quantities, structure, dosage, method of use, indications and effects, performance and adverse reactions, and the quality, efficacy and safety of the pharmaceutical. A person intending to obtain Marketing Approval must attach materials such as data related to the results of clinical trials or conditions of usage in foreign countries. Japan provides for market exclusivity through a Re-examination System, which prevents the entry of generic pharmaceuticals until the end of the re-examination period, which is normally six years.

The authority to grant Marketing Approval in relation to pharmaceuticals for certain specified purposes (*e.g.*, cold medicines and decongestants) is delegated to the prefectural governors by the Minister and applications in relation to such pharmaceuticals must be filed with the governor of the relevant prefecture where the relevant company s head office is located. Applications for pharmaceuticals for which the authority to grant the Marketing Approval remains with the Minister must be filed with the Pharmaceuticals and Medical Devices Agency. When an application is submitted for a pharmaceutical whose active ingredients, quantities, administration and dosage, method of use, indications and effects are distinctly different from those of pharmaceuticals which have already been approved, the Minister must seek the opinion of the Pharmaceutical Affairs and Food Sanitation Council.

The Pharmaceutical Law provides that when the pharmaceutical which is the subject of an application is shown not to result in the indicated effects or performance indicated in the application, or when the pharmaceutical is found to have no value as a pharmaceutical since it has harmful effects outweighing its indicated effects or performance, Marketing Approval shall not be granted.

The Minister can order the cancellation or amendment of a Marketing Approval when (1) it is necessary to do so from the viewpoint of public health and hygiene, (2) the necessary materials for re-examination or re-valuation, which the Minister has ordered considering the character of pharmaceuticals, have not been submitted, false materials have been submitted or the materials submitted do not comply with the criteria specified by the Minister, (3) the relevant company s Marketing License has expired or has been canceled (a Marketing License needs to be renewed every three years), (4) the regulations regarding investigations of facilities in relation to manufacturing management standards or quality control have been violated or (5) the conditions set in relation to the Marketing Approval have been violated.

Doctors and pharmacists providing medical services pursuant to state medical insurance are prohibited from using pharmaceuticals other than those specified by the Minister. The Minister also specifies the standards of pharmaceutical prices, which we refer to herein as Drug Price Standards. The Drug Price Standards are used as the basis of the calculation of the price paid by medical insurance for pharmaceuticals. The governmental policy relating to medical services and the health insurance system, as well as the Drug Price Standards, are revised every two years.

Patents, Trademarks and Licenses

We own or license a number of patents in the United States and foreign countries covering certain products and have also developed brand names and trademarks for other products. Generally, the brand pharmaceutical business relies upon patent protection to ensure market exclusivity for the life of the patent. We consider the overall protection of our patents, trademarks and license rights to be of material value and act to prevent these rights from infringement. However, our business is not dependent upon any single patent, trademark or license.

In the branded pharmaceutical industry, the majority of an innovative product s commercial value is usually realized during the period in which the product has market exclusivity. In the United States and some other countries, when market exclusivity expires and generic versions of a product are approved and marketed, there can often be very substantial and rapid declines in the product s sales. The rate of this decline varies by country and by therapeutic category. However, following patent expiration, branded products often continue to have market viability based upon the goodwill of the product name, which typically benefits from trademark protection.

A product s market exclusivity is generally determined by two forms of intellectual property: patent rights held by the innovator company and any regulatory forms of exclusivity to which the innovator is entitled.

Patents are a key determinant of market exclusivity for most branded pharmaceuticals. Patents provide the innovator with the right to exclude others from practicing an invention related to the medicine. Patents may cover, among other things, the active ingredient(s), various uses of a drug product, pharmaceutical formulations, drug delivery mechanisms and processes for (or intermediates useful in) the manufacture of products. Protection for individual products extends for varying periods in accordance with the expiration dates of patents in the various countries. The protection afforded, which may also vary from country to country, depends upon the type of patent, its scope of coverage and the availability of meaningful legal remedies in the country.

Market exclusivity is also sometimes influenced by regulatory intellectual property rights. Many developed countries provide certain non-patent incentives for the development of medicines. For example, the United States, the EU and Japan each provide for a minimum period of time after the approval of a new drug during which the regulatory agency may not rely upon the innovator s data to approve a competitor s generic copy. Regulatory intellectual property rights are also available in certain markets as incentives for research on new indications, on orphan drugs and on medicines useful in treating pediatric patients. Regulatory intellectual property rights are independent of any patent rights that we may possess and can be particularly important when a drug lacks broad patent protection. However, most regulatory forms of exclusivity do not prevent a competitor from gaining regulatory approval prior to the expiration of regulatory data exclusivity on the basis of the competitor s own safety and efficacy data on its drug, even when that drug is identical to that marketed by the innovator.

We estimate the likely market exclusivity period for each of our branded products on a case-by-case basis. It is not possible to predict the length of market exclusivity for any of our branded products with certainty because of the complex interaction between patent and regulatory forms of exclusivity, and inherent uncertainties concerning patent litigation. There can be no assurance that a particular product will enjoy market exclusivity for the full period of time that the Company currently estimates or that the exclusivity will be limited to the estimate. For a discussion on market exclusivity, see Product Development above.

In addition to patents and regulatory forms of exclusivity, we also hold intellectual property in the form of trademarks on products such as Perforomist, Zyflo CR and Cyanokit. Trademarks have no effect on market exclusivity for a product, but are considered to have marketing value. Trademark protection continues in some countries as long as used; in other countries, as long as registered. Registration is for fixed terms and can be renewed indefinitely.

As part of the Merck Generics acquisition, we entered into a Brand License Agreement with Merck KGaA which generally grants us the right to use the Merck name for the acquired businesses for a period of up to two years.

Customers and Marketing

In the United States, we market products directly to wholesalers, distributors, retail pharmacy chains, mail order pharmacies and group purchasing organizations. We also market our generic products indirectly to independent pharmacies, managed care organizations, hospitals, nursing homes, pharmacy benefit management companies and government entities. These customers, called indirect customers, purchase our products primarily through our wholesale customers.

In EMEA and the AsiaPac region, generic pharmaceuticals are sold to wholesalers, pharmacy groups, independent pharmacies and, in certain countries, directly to hospitals. Through a broad network of sales representatives, we adapt our marketing strategy to the different markets as dictated by their respective regulatory and competitive landscapes.

Our APIs are sold primarily to generic finished dosage form manufacturers throughout the world.

Competition

United States

The United States pharmaceutical industry is very competitive. Our competitors vary depending upon therapeutic areas and product categories. Primary competitors include the major manufacturers of brand name and generic pharmaceuticals.

The primary means of competition are innovation and development, timely FDA approval, manufacturing capabilities, product quality, marketing, customer service, reputation and price. To compete effectively on the basis of price and remain profitable, a generic drug manufacturer must manufacture its products in a cost-effective manner. Our competitors include other generic manufacturers, as well as brand companies that license their products to generic manufacturers prior to patent expiration or as relevant patents expire. No further regulatory approvals are required for a brand manufacturer to sell its pharmaceutical products directly or through a third-party to the generic market, nor do such manufacturers face any other significant barriers to entry into such market. The United States pharmaceutical market is undergoing, and is expected to continue to undergo, rapid and significant technological changes, and we expect competition to intensify as technological advances are made. We intend to compete in this marketplace by: (1) developing therapeutic equivalents to branded products that offer unique marketing opportunities; (2) developing or licensing brand pharmaceutical products that are either patented or proprietary; and (3) developing or licensing brand pharmaceutical products that are primarily for indications having relatively large patient populations or that have limited or inadequate treatments available.

Our sales can be impacted by new studies that indicate a competitor s product has greater efficacy for treating a disease or particular form of disease than one of our products. Our sales also can be impacted by additional labeling requirements relating to safety or convenience that may be imposed on our products by the FDA or by similar regulatory agencies in different countries. If competitors introduce new products and processes with therapeutic or cost advantages, our products can be subject to progressive price reductions or decreased volume of sales, or both.

Rest of World

In Europe and the rest of the world, our competitors include other generic companies (several major multinational generic drug companies and various local generic drug companies) and branded drug companies that continue to sell or license branded pharmaceutical products after patent expirations and other statutory expirations. As in the United States, the generic market in Europe is very competitive, with the main competitive factors being price, time to market, reputation, customer service and breadth of product line.

Competitive factors in certain major markets in which we participate can be summarized as follows:

France. Generic penetration in France is relatively low compared to other large pharmaceutical markets, with low prices resulting from government initiatives and aggressive pharmacist buying groups. As pharmacists are the primary customers in this market, established relationships, driven by breadth of portfolio and effective supply chain management, are key competitive advantages.

United Kingdom. The UK is one of the most competitive markets with low barriers to entry and a high degree of fragmentation. Competition among manufacturers along with indirect control of pricing by the government has led to strong downward pricing pressure. Companies in the UK will continue to compete on price, with consistent supply chain and breadth of product portfolio also coming into play.

Germany. The German market has become highly competitive as a result of a large number of generic players and one of the highest generic penetration rates in Europe. The German market is primarily branded generics, with physicians having a great deal of influence over which company s products are dispensed. Recent legislation has resulted in pricing pressures which, along with the desire by health insurers to deal with a select number of generic suppliers, should drive near-term competition.

Spain. Spain is a rapidly growing, highly fragmented generic market with over 100 market participants. Generic substitution by pharmacists is not permitted in Spain, making physicians the key drivers of generic usage. Companies compete in Spain based on name recognition and a consistent supply of quality products.

Italy. The Italian generics market is relatively small due in part to low prices on available brand-name drugs. The Italian government has put forth measures aimed at increasing generic usage; however, generic substitution is still in its early stages.

Australia. The Australian generics market is small by international standards in terms of prescriptions, value and the number of active participants. Patent extensions which delayed patent expiration are somewhat responsible for under-penetration of generic products. With the physicians being the key decision makers in generic substitution, name recognition is a key competitive advantage.

Japan. The Japanese generics market is small by international standards. Historically, government initiatives have kept all drug prices low, resulting in little incentive for generic usage. More recently, pro-generic actions by the government should lead to growth in the generics market, in which doctors, pharmacists and hospital purchasers will all play a key role.

India. Intense competition by other API suppliers in the Indian pharmaceuticals market has, in recent years, led to increased pressure on prices. We expect that Indian pharmaceutical industry growth will be led by the export of API and generic products to developed markets. The success of Indian pharmaceutical companies is attributable to established development expertise in chemical synthesis and process engineering, availability of highly skilled labor and the low-cost manufacturing base.

Raw Materials

The APIs and other materials and supplies used in our pharmaceutical manufacturing operations are generally available and purchased from many different domestic and foreign suppliers, including Matrix. However, in some cases, the raw materials used to manufacture pharmaceutical products in the United States are available only from a single supplier. Even when more than one supplier exists, we may choose, and in some cases have chosen, only to list one supplier in our applications submitted to the FDA. Any change in a supplier not previously approved must then be submitted through a formal approval process with the FDA.

SIGNATURE

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 hereunto duly authorized.

MYLAN INC.

Date: November 7, 2007

By: /s/ Edward J. Borkowski

Edward J. Borkowski Executive Vice President and Chief Financial Officer