MYLAN INC.
Form 8-K
November 07, 2007

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K
CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **November 1, 2007**

MYLAN INC.
(Exact Name of Registrant as Specified in Charter)

Pennsylvania	**1-9114**	**25-1211621**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

1500 Corporate Drive	
Canonsburg, PA	**15317**
(Address of Principal Executive Offices)	(Zip Code)

Registrant s telephone number, including area code: (**724) 514-1800**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2 (b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4 (c))

Item 8.01. Other Events.

Explanatory Note: This Current Report on Form 8-K repeats certain disclosure concerning Mylan Inc. s (the Company s or our) business that is included in our Prospectus Supplements dated November 1, 2007 to our Prospectus dated February 20, 2007 (the Prospectus) that is part of our Registration Statement on Form S-3 (Registration No. 333-140778) for the purpose of incorporating such disclosure by reference into the Prospectus Supplement dated June 12, 2007 to the Prospectus as well as into our other existing Registration Statements.

OVERVIEW OF FINANCIAL CONDITION, LIQUIDITY AND CAPITAL RESOURCES

In connection with our acquisition of the generics business of Merck KGaA (Merck Generics , and such acquisition the Acquisition) we incurred substantial indebtedness. This consisted of $2,500 million of senior secured U.S. dollar term debt and 1,130 ($1,600) million of senior secured Euro term debt pursuant to our Senior Secured Credit Agreement (as defined below) and $2,850 million of senior unsecured interim debt pursuant to our Senior Unsecured Interim Loan Agreement (as defined below). In addition, as part of the Senior Secured Credit Agreement, we put in place a $750 million senior secured revolving credit facility of which approximately $325 million was drawn in connection with the closing of the acquisition. As of September 30, 2007, on a pro forma basis after giving effect to (i) the Acquisition, (ii) the borrowings under the Senior Secured Credit Agreement and the Senior Unsecured Interim Loan Agreement to finance the Acquisition and (iii) the acquisition of a 71.5% controlling interest in Matrix Laboratories Limited (Matrix) (all of the foregoing the Transactions), the issuance of the common stock offered pursuant to a prospectus supplement dated as of November 1, 2007 and the mandatory convertible preferred stock offered pursuant to a prospectus supplement dated as of November 1, 2007, each to our Prospectus dated February 20, 2007 and the use of the net proceeds from the offerings to reduce debt under our Senior Unsecured Interim Loan Agreement, we would have had approximately $6,130.5 million in total debt, including $923 million of debt under our Senior Unsecured Interim Loan Agreement (this assumes an offering price of $15.04, which was the last reported sale price of our common stock on October 31, 2007). On a pro forma basis at September 30, 2007, our availability under our senior secured revolving credit facility would have been approximately $425 million and our cash and marketable securities would have been approximately $501.3 million. We intend, at a later date, to refinance with permanent indebtedness, the indebtedness that will remain outstanding under the Senior Unsecured Interim Loan Agreement following the aforementioned offerings.

Our outstanding indebtedness could limit our financial and operating flexibility, including by requiring us to dedicate a substantial portion of our cash flows from operations and the proceeds of any common stock or preferred stock issuances to the repayment of our debt and the interest on our debt, making it more difficult for us to obtain additional financing on favorable terms, limiting our ability to capitalize on significant business opportunities and making us more vulnerable to economic and operational downturns. See the descriptions below, as well as Risk Factors We have substantial indebtedness and will be required to apply a substantial portion of our cash flow from operations to service our indebtedness. Our substantial indebtedness may have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline contained in Item 1A of Part II of our Quarterly Report on Form 10-Q for the period ended September 30, 2007 (the September 30, 2007 Form 10-Q).

We are required to comply with various covenants contained in the agreements covering our indebtedness. These covenants will limit our discretion in the operation of our business. See the descriptions below, as well as Risk Factors Our credit facilities and any additional indebtedness we incur in the future impose, or may impose, significant operating and financial restrictions, which may prevent us from capitalizing on business opportunities. These factors could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline contained in our September 30, 2007 Form 10-Q.

Our debt maturities. Below is a summary of our long-term debt maturities based on loan balances as of September 30, 3007, on a pro forma basis after giving effect to the Transactions, the aforementioned offerings and the application of the net proceeds from such offerings to reduce outstanding indebtedness under our Senior Unsecured Interim Loan Agreement. On October 2, 2007 the Company changed its year end to December 31. Amounts below for 2007 represent payments to be made during the remainder of the transition period ended December 31, 2007. Thereafter, amounts represent payments to be made in each of the calendar years listed below.

	2007	2008	2009	2010	2011	2012	Thereafter
				($ in millions)			
Senior secured revolving credit facility							325.0
Senior secured U.S. dollar term loans		45.0	70.0	95.0	120.0	145.0	2,025.0
Senior secured Euro term loan		16.0	16.0	16.0	16.0	16.0	1,520.0
Senior unsecured interim loan(1)							923.0
Convertible notes(2)						600.0	
Other debt(3)	11.4	28.5	6.1	2.5			6.1
Scheduled interest payments(4)	115.6	459.5	459.0	450.6	440.5	422.3	889.4

(1) The interim loans have an initial maturity date of October 2, 2008; however, as long as there is no bankruptcy or payment event of default as of such date, the maturity may be extended to October 2, 2017. On and after October 2, 2008, the lenders have the option to convert Interim Term Loans into exchange notes. See Senior Unsecured Interim Loan Agreement.

(2) $600 million of 1.25% senior convertible notes due 2012.

(3) Other debt consists primarily of a 32.5 million term loan held by Matrix.

(4) For the purposes of these payments, we assumed EURIBOR equal to 4.07% per annum and LIBOR equal to 5.125% per annum. Also the calculation assumes that the $923.0 million of the interim loan is outstanding until October 2017.

The chart above does not include (i) short-term borrowings held by Matrix in the amount of approximately $120.4 million, which represent working capital facilities with several banks, which are secured first by Matrix s current assets and second by Matrix s property, plant and equipment and carry interest rates of 4%-14%; and (ii) other long-term obligations of $41.2 million consisting primarily of discounted future payments under individually negotiated agreements with certain key employees and directors; and operating leases of real property and vehicles, which are not material in the aggregate.

Senior Secured Credit Agreement. On October 2, 2007, we entered into a credit agreement (the Senior Secured Credit Agreement) with Mylan as the U.S. borrower, Mylan Luxembourg 5 S.à r.l. as the Euro Borrower, certain lenders and JPMorgan Chase Bank, National Association, as Administrative Agent, pursuant to which we borrowed $500 million in Tranche A Term Loans (the U.S. Tranche A Term Loans) and $2 billion in Tranche B Term Loans (the U.S. Tranche B Term Loans) and the Euro Borrower borrowed approximately 1.13 billion in Euro Term Loans (the Euro Term Loans and, together with the U.S. Tranche A Term Loans and the U.S. Tranche B Term Loans, the Term Loans). The proceeds of the Term Loans were used (1) to pay a portion of the consideration for the Acquisition, (2) to refinance the Credit Agreement dated as of March 26, 2007 (the 2007 Existing Credit Agreement), among the Company, Euro Mylan B.V., the lenders party thereto and JPMorgan Chase Bank, National Association, as Administrative Agent, and the Credit Agreement, dated as of July 24, 2006 (the 2006 Existing Credit Agreement and, together with the 2007 Existing Credit Agreement, the Existing Credit Agreements), by and among us, the lenders party thereto and JPMorgan Chase Bank, National Association, as Administrative Agent, (3) to purchase the 2010 Notes and the 2015 Notes tendered pursuant to the previously announced cash tender offers therefor (see below) and (4) to pay a portion of the fees and expenses in respect of the foregoing transactions. The termination of the Existing Credit Agreements was concurrent with, and contingent upon, the effectiveness of the Senior Secured Credit Agreement.

The Senior Secured Credit Agreement also contains a $750 million revolving facility (the Revolving Facility and, together with the Term Loans, the Senior Credit Facilities) under which we may obtain extensions of credit, subject to the satisfaction of specified conditions. The Revolving Facility includes a $100 million subfacility for the issuance of letters of credit and a $50 million subfacility for swingline borrowings. Borrowings under the Revolving Facility are available in dollars, Euro, pounds sterling and yen. The Euro Term Loans are guaranteed by us, and the Senior Credit Facilities are guaranteed by substantially all of our domestic subsidiaries (the Guarantors). The Senior Credit Facilities are also secured by a pledge of the capital stock of substantially all of our and the Guarantors direct subsidiaries (limited to 65% of outstanding voting stock of foreign holding companies and any foreign subsidiaries) and substantially all of the other tangible and intangible property and assets of the Guarantors and us. The U.S. Tranche A Term Loans and the U.S. Tranche B Term Loans currently bear interest at LIBOR plus 3.25% per annum, if we choose to make LIBOR borrowings, or at a base rate plus 2.25% per annum. The Euro Term Loans currently bear

interest at EURIBOR plus 3.25% per annum. Borrowings under the Revolving Facility currently bear interest at LIBOR (or EURIBOR, in the case of borrowings denominated in Euro) plus 2.75% per annum, if we choose to make LIBOR (or EURIBOR, in the case of borrowings denominated in Euro) borrowings, or at a base rate plus 1.75% per annum. Under the terms of the Senior Secured Credit Agreement, the applicable margins over LIBOR, EURIBOR or the base rate may be increased based on our initial corporate rating following the date of the Senior Secured Credit Agreement. The applicable margins are subject to adjustment based on our initial corporate credit ratings and the applicable margins for the Revolving Facility and the

U.S. Tranche A Term Loans can fluctuate based on our Consolidated Leverage Ratio. We also pay a facility fee on the entire amount of the Revolving Facility. The facility fee is currently 0.50% per annum, but can decrease to 0.375% per annum based on our Consolidated Leverage Ratio. The Senior Secured Credit Agreement contains customary affirmative covenants for facilities of this type, including covenants pertaining to the delivery of financial statements, notices of default and certain other information, maintenance of business and insurance, collateral matters and compliance with laws, as well as customary negative covenants for facilities of this type, including limitations on the incurrence of indebtedness and liens, mergers and certain other fundamental changes, investments and loans, acquisitions, transactions with affiliates, dispositions of assets, payments of dividends and other restricted payments, prepayments or amendments to the terms of specified indebtedness (including the Senior Unsecured Interim Loan Agreement described below) and changes in our lines of business. The Senior Secured Credit Agreement contains financial covenants requiring maintenance of a minimum Consolidated Interest Coverage Ratio and a maximum Consolidated Senior Leverage Ratio. These financial covenants are not tested earlier than the quarter ended June 30, 2008. The Senior Secured Credit Agreement contains default provisions customary for facilities of this type, which are subject to customary grace periods and materiality thresholds, including, among other things, defaults related to payment failures, failure to comply with covenants, misrepresentations, defaults or the occurrence of a change of control under other material indebtedness, bankruptcy and related events, material judgments, certain events related to pension plans, specified changes in control of us and invalidity of guarantee and security agreements. If an event of default occurs under the Senior Secured Credit Agreement, the lenders may, among other things, terminate their commitments, declare all borrowings immediately payable and foreclose on the collateral.

The U.S. Tranche A Term Loans mature on October 2, 2013. The U.S. Tranche A Term Loans require amortization payments of $6.25 million per quarter in 2008, $12.5 million per quarter in 2009, $18.5 million per quarter in 2010, $25 million per quarter in 2011, $31.25 million per quarter in 2012 and $31.25 million per quarter in 2013. The U.S. Tranche B Term Loans and the Euro Term Loans mature on October 2, 2014. The U.S. Tranche B Term Loans and the Euro Term Loans amortize quarterly at the rate of 1.0% per annum beginning in 2008. The Senior Secured Credit Agreement requires prepayments of the Term Loans with (1) up to 50% of Excess Cash Flow beginning with excess cash flow for the year ended 2008, with reductions based on our Consolidated Leverage Ratio, (2) the proceeds from certain asset sales and casualty events, unless our Consolidated Leverage Ratio is equal to or less than 3.5 to 1.0, and (3) the proceeds from issuances of indebtedness not permitted by the Senior Secured Credit Agreement. Amounts drawn on the Revolving Facility become due and payable on October 2, 2013. The Term Loans and amounts drawn on the Revolving Facility may be voluntarily prepaid without penalty or premium.

Senior Unsecured Interim Loan Agreement. On October 2, 2007, we entered into a credit agreement (the Senior Unsecured Interim Loan Agreement) with certain lenders and Merrill Lynch Capital Corporation, as Administrative Agent, pursuant to which we borrowed $2.85 billion in term loans (the Interim Term Loans). The proceeds of the Interim Term Loans were used to finance in part the Transactions. The Interim Term Loans are unsecured and are guaranteed by substantially all of our domestic subsidiaries. The Interim Term Loans currently bear interest at LIBOR plus 4.50% per annum. The interest rate increases by 0.50% per annum on any Interim Term Loans that remain outstanding six months after the closing date, and thereafter increases by 0.25% per annum every three months (up to a maximum of 11.25% per annum). The Senior Unsecured Interim Loan Agreement contains customary affirmative covenants for facilities of this type, including covenants pertaining to the delivery of financial statements, notices of default and certain other information, maintenance of business of insurance and compliance with laws, as well as customary negative covenants for facilities of this type, including limitations on the incurrence of indebtedness and liens, mergers and certain other fundamental changes, investments and loans, acquisitions, transactions with affiliates, dispositions of assets, payments of dividends and other restricted payments, prepayments of any subordinated indebtedness and changes in our lines of business. The Senior Unsecured Interim Loan Agreement contains no financial covenants. In addition, the arrangers of the Interim Term Loans have the right to request, on not more than two occasions between six months and one year after the closing date, that we use commercially reasonable efforts to issue and sell debt securities that will generate proceeds sufficient to refinance the Interim Term Loans. The Senior

Unsecured Interim Loan Agreement contains default provisions customary for facilities of this type, which are subject to customary grace periods and materiality thresholds, including, among other things, defaults related to payment failures, failure to comply with covenants, misrepresentations, acceleration of other indebtedness, bankruptcy and related events, material judgments and certain events

related to pension plans. If an event of default occurs under the Senior Unsecured Interim Loan Agreement, the lenders may, among other things, declare the Interim Term Loans immediately due and payable. The Interim Term Loans have an initial maturity date of October 2, 2008; however, as long as there is no bankruptcy or payment event of default as of such date, the maturity date may be extended to October 2, 2017. There may be a fee payable in connection with such extension. The Interim Term Loans do not require amortization payments. The Senior Unsecured Interim Loan Agreement requires prepayments of the Interim Term Loans (1) with the proceeds from certain asset sales and casualty events, (2) with the proceeds from certain issuances of equity or indebtedness and (3) upon the occurrence of specified changes in control of us. The Interim Term Loans may be voluntarily prepaid without penalty or premium except in the case of fixed rate exchange notes. On and after October 2, 2008, the lenders have the option to convert Interim Term Loans into exchange notes including, under certain circumstances, into fixed rate exchange notes. The exchange notes would have affirmative and negative covenants and events of default which would be similar to those under the Interim Term Loans but include certain additional exceptions and modifications. In addition, we would be required to offer to prepay the exchange notes in all the circumstances in which prepayments are required on the Interim Term Loans (other than out of equity or debt proceeds). The interest rate for exchange notes may be fixed in connection with a transfer of such notes. The Company is obligated to provide for registration of any exchange notes under the securities laws. In addition, on October 2, 2008, the affirmative and negative covenants, default provisions, prepayment provisions and certain other provisions in the Senior Unsecured Interim Loan Agreement are automatically amended so as to conform to the provisions for any exchange notes.

Convertible notes. On March 1, 2007, we issued $600.0 million aggregate principal amount of 1.25% Senior Convertible Notes due 2012 (the Convertible Notes). The Convertible Notes will mature on March 15, 2012, subject to earlier repurchase or conversion. The Convertible Notes have an initial conversion rate of 44.5931 shares of common stock per $1,000 principal amount (equivalent to an initial conversion price of approximately $22.43 per share), subject to adjustment.

In August 2007, the FASB issued an exposure draft of a proposed FASB Staff Position (the Proposed FSP) reflecting new rules that would change the accounting treatment for certain convertible debt instruments, including our Convertible Notes. The Proposed FSP is expected to be effective for fiscal years beginning after December 15, 2007, would not permit early application and would be applied retrospectively to all periods presented. We are currently evaluating the proposed new rules and their potential impact. However, if the Proposed FSP is adopted, we expect to have higher interest expense in 2008, and prior period interest expense associated with the Convertible Notes would also reflect higher than previously reported interest expense due to retrospective application. Please see the discussion in Note 3 to our financial statements included in our September 30, 2007 Form 10-Q.

Other. Other Senior Notes consisted of $2.5 million of 53/4% Senior Notes due 2010 (the 2010 Notes), and $0.2 million of 63/8% Senior Notes due 2015 (the 2015 Notes , and collectively, the Senior Notes). We originally issued $150 million of 2010 Notes and $350 million of 2015 Notes. In connection with the completion of the Acquisition, we completed cash tender offers for substantially all of the original principal amounts of the Senior Notes. In addition, we completed consent solicitations that eliminated substantially all of the restrictive covenants in the indentures under which the Senior Notes were issued.

BUSINESS

Overview

We are a leading pharmaceutical company and have developed, manufactured, marketed, licensed and distributed high quality generic, branded and branded generic pharmaceutical products for more than 45 years. As a result of our recent acquisitions of Merck Generics and a controlling interest in Matrix earlier this year, we are the third largest generic pharmaceutical company in the world based on 2006 combined calendar year revenues, a leader in branded specialty pharmaceuticals and the second largest active pharmaceutical ingredient, or API, manufacturer with respect to the number of drug master files, or DMFs, filed with regulatory agencies. We currently employ more than 11,000 people globally and have sales in over 90 countries. We hold a leading sales position in four of the world s six largest generic pharmaceutical markets: the United States, the United Kingdom, France and Japan, and we also hold leading sales positions in several other key generics markets, including Australia, Belgium, Italy, Portugal and Spain. Our product portfolio is among the largest of all generic pharmaceutical companies, consisting of approximately 570 products in a broad range of therapeutic areas. In addition, we have a significant product pipeline, with more than 255 regulatory applications or dossiers pending approval with regulatory agencies worldwide. Our acquisition of a controlling interest in Matrix provides us with lower cost API supply and a vertically integrated platform. We have extensive research and development capabilities, with 11 sites around the world, and extensive manufacturing capabilities, with the capacity to manufacture more than 45 billion finished doses of pharmaceutical products per year. On a pro forma basis for the fiscal year ended March 31, 2007, we had total net revenues of approximately $4.2 billion.

We achieved our position as one of the leaders in the U.S. generic pharmaceutical industry through our success in obtaining Abbreviated New Drug Application, or ANDA, approvals, our reputation for quality and our ability to consistently deliver large scale commercial volumes to our customers. With the addition of Merck Generics and Matrix, we have created a horizontally and vertically integrated platform with a global scale, a diversified product portfolio and an expanded range of capabilities that position us well for the future. We expect that as a result of these acquisitions we will be less dependent on any single market or product and will be able to compete more effectively on a global basis.

We derive the majority of our U.S. generic product revenues through our subsidiary, Mylan Pharmaceuticals Inc., or MPI. These revenues are derived from approximately 170 products, primarily solid oral dosage pharmaceuticals, in approximately 50 therapeutic areas. Another of our subsidiaries, UDL Laboratories, Inc., or UDL, is the largest re-packager in the United States of pharmaceuticals in unit dose formats, which are used primarily in hospitals, nursing homes and other institutional settings. Our U.S. generics business is further augmented by our subsidiary, Mylan Technologies Inc., or MTI, which is a leader in transdermal drug delivery systems and focuses on the research, development, manufacturing and supply of both brand and generic transdermal products both in the United States and internationally.

Our generic pharmaceutical revenues outside of the United States are primarily derived from Merck Generics, which we acquired on October 2, 2007. Merck Generics consists of a number of former subsidiaries of Merck KGaA, a 300-year-old global chemicals and pharmaceuticals company. Merck Generics, formed in 1984, has sales in more than 90 countries and was the world s third largest generic pharmaceutical business based on 2006 calendar year revenues of 1.8 billion ($2.3 billion). Merck Generics has more than 400 products and approximately 70% of its generic pharmaceutical revenues in calendar year 2006 were generated from countries where it has a top three market share position. Through Merck Generics, we gained a strong presence in some of the world s most important generic pharmaceuticals markets, including France, Germany, the United Kingdom, Japan, Canada and Australia. As part of the Acquisition, we received a right to purchase for a period of two years from the closing of the Acquisition, for actual costs incurred to separate such businesses, Merck KGaA s generic pharmaceutical operations in 17 additional

countries in Latin America, Central and Eastern Europe and the Asia Pacific region, many of which represent emerging generic pharmaceutical markets.

As part of the Merck Generics acquisition we also acquired our U.S. branded specialty pharmaceuticals subsidiary, Dey L.P., or Dey. Founded in 1978, Dey is a fully integrated specialty pharmaceutical business focused on the development, manufacturing and marketing of specialty pharmaceuticals in the respiratory and severe allergy markets. Through its approximately 250-person sales

force, Dey markets six products to physicians and hospitals. Dey s key products include, among others, EpiPen, an epinephirine autoinjector for severe allergy and anaphalaxis, DuoNeb, a nebulized unit dose formulation of ipratropium bromide and albuterol sulfate for chronic obstructive pulmonary disorder, or COPD, and the recently launched Perforomist inhalation solution, a long-acting nebulized unit dose formoterol fumarate for COPD. In 2007, Dey launched three new products, including Perforomist, which we expect will help to replace some of the sales that we anticipate will be lost as a result of the July 2007 loss of market exclusivity for DuoNeb. Further, Dey has a pipeline of next generation and differentiated specialty product candidates that we expect will provide additional growth opportunities in the future.

Through Matrix, an Indian listed company in which we have a 71.5% controlling interest, we manufacture and supply low cost, high quality API for our own products and pipeline, as well as for third parties. Matrix is the world s second largest API manufacturer with respect to the number of DMFs filed with regulatory agencies, with more than 165 APIs in the market or under development. Matrix is also a leader in supplying API for the manufacturing of anti-retroviral drugs, which are utilized in the treatment of HIV/AIDS.

Our Strengths

We believe our competitive strengths are the following:

Leadership and scale in key global markets. We now have a global presence, with sales in more than 90 countries and operations in over 45 countries, including significant operations in each of the top seven largest generic pharmaceutical markets. In addition to our position as one of the leaders in the U.S. market, the globalization of our business established us as leaders in key markets in Europe and the Asia Pacific region. Our global platform creates substantial growth opportunities and will enable us to compete more effectively in the world s largest generics markets, as well as in less developed markets that have higher growth rates and potentially more favorable competitive dynamics. Our scale also creates opportunities to achieve operating efficiencies and reduces risks associated with an over-reliance on any one market.

Broad and diversified product portfolio. We have a robust product portfolio of approximately 570 generic, branded generic and branded pharmaceutical products, which are well-diversified across therapeutic areas. The breadth and diversity of our product portfolio reduces our operating risk profile to ensure that we are not overly reliant on any one product or therapeutic area. We have development and manufacturing capabilities in several specialized dosage forms, some of which are difficult to formulate and manufacture and typically have longer product growth cycles than traditional generic pharmaceuticals. These dosage forms include high potency formulations, steriles, injectables, transdermal patches, controlled-release and respiratory delivery products. Additionally, we benefit from Merck Generics highly successful in-licensing strategy that is designed to develop critical mass in key differentiated dosages in attractive markets globally.

Manufacturing scale with a vertically and horizontally integrated platform. We are an integrated pharmaceutical company with capabilities in research, development, regulatory and legal matters, manufacturing, sales and distribution. Through Matrix, we have access to low-cost API and intermediates. This enables us to compete more effectively with other low-cost producers and potentially enhance margins and extend product lifecycles. In addition to our eight API manufacturing sites we currently have 17 finished dose manufacturing sites in the United States and internationally, including specialized manufacturing such as transdermals, inhalation aerosols and semi-solids, in addition to solid dosage. We expect to recognize significant cost savings as a result of our scale and efficiency, and in particular through our finished dose and Matrix s high quality API manufacturing capacity. Further, our horizontally integrated platform allows us to leverage each of our research and development projects into numerous markets around the world.

Scale in research and development. We have expanded our research and development capabilities through the Merck Generics and Matrix acquisitions, and now have significant scale with a network of 11 research and development sites across the globe. As a result of the expansion of our capabilities, we expect to be able to increase our research and development efficiency and speed to market. As of June 30, 2007, we had more than 255 applications or dossiers pending regulatory approval worldwide. As a result of the Matrix acquisition and excluding any impact from the acquisition of Merck Generics, for the 12 months ending March 31, 2008, we expect to file 60 submissions with the United States Food and Drug Administration, or FDA, as compared to 24 submissions filed with the FDA in the prior 12 months.

Intellectual property expertise. We believe that expertise in intellectual property is a core competency for future product development. Accordingly, we maintain development teams, including legal counsel, focused on the analysis and selection of opportunities to file generic product dossiers, ANDAs and Paragraph IV ANDA patent challenges, which could provide us with 180 days of generic market exclusivity. We have been successful in monetizing many Paragraph IV ANDA opportunities, including launches within the last 12 months of amlodipine besylate and oxybutynin ER, and the recent legal settlements on paroxetine hydrochloride ER and levetiracetam for future launches.

Product quality. Our ability to produce high quality commercial volumes of our products has given us a reputation as a reliable supplier to our customers. We have an excellent manufacturing compliance record with regulatory agencies globally, including the FDA. We believe that, in an era of growing concern among individual consumers regarding the quality of the prescription drugs they purchase, we are in a strong position to leverage our reputation for product excellence.

Specialty pharmaceutical expertise. We have formulation expertise with products that are difficult to develop, formulate and manufacture, such as transdermals, high potency products and nebulized formulations. Our Dey business provides highly differentiated pharmaceutical offerings in the respiratory and severe allergy markets which we expect will provide us with a growth platform in branded pharmaceuticals. Our MTI operation focuses on applying our leading transdermal technology to the potential development of new products through strategic alliances with branded pharmaceutical companies. MTI is also a leader in the development and manufacturing of generic transdermal products in the United States and internationally, including fentanyl, which has been a very important product for us.

Experienced management. Our senior management team collectively has broad experience across the businesses and markets in which we operate. In addition, we have been successful in retaining key Matrix and Merck Generics executive teams including key regional leaders and operators.

Industry Overview

Generic pharmaceutical products provide a safe, effective and cost-efficient alternative to branded pharmaceutical products. Generic pharmaceuticals are the bioequivalent of patented or brand-name pharmaceuticals, and as with their brand-name equivalents, generic pharmaceuticals require regulatory approval prior to their sale. Generic pharmaceuticals may be marketed only if relevant patents on their brand-name equivalents, and any additional government-mandated market exclusivity periods, have expired, have been challenged and invalidated, are licensed by the patent holder, or such patents are shown to not otherwise be infringed.

The generic pharmaceutical market has grown as a result of the ongoing efforts by governments around the world and in the private sector to address the increasing burden of healthcare expenditures, in particular prescription pharmaceuticals. In addition, the market has been positively impacted in recent years by changing demographics as well as by increased acceptance among consumers, physicians and pharmacists that generic pharmaceuticals are lower-cost equivalents of brand-name pharmaceuticals. The average price of a generic pharmaceutical prescription in the United States in 2006 was approximately $32, while the average price of a brand name pharmaceutical prescription was approximately $111. Similar to the United States, in most international markets, brand-name pharmaceuticals, on average, cost substantially more than generic products on a per prescription basis. Many countries are exploring the use of generic products to curtail increasing pharmaceutical expenditures, which is one of the factors causing the generic market to grow faster than the pharmaceutical industry as a whole. A large number of countries now actively promote generic pharmaceuticals through their government reimbursement systems. Generic substitution, whereby a pharmacist substitutes a prescribed brand name product with a generic one, is permitted in many countries and even compulsory in some countries as a cost-saving measure in the purchase of, or reimbursement for, prescription pharmaceuticals.

Worldwide expenditures on generic pharmaceutical products were approximately $84.4 billion in 2006, which represented approximately 11% of the total pharmaceutical market. For 2006, after the United States ($31.0 billion), which accounted for approximately 37% of global expenditures on generic pharmaceuticals, the largest national markets for generic pharmaceuticals in the world were Germany ($14.0 billion), India ($6.6 billion), the United Kingdom ($4.7 billion), France ($3.6 billion) and Japan ($3.3 billion). Spending on generic pharmaceutical products in certain international markets, though smaller in

nominal terms, is expected to grow at a faster rate than in the United States. In particular, over the next five years, the market for generic pharmaceutical products is expected to increase annually at rates of 25% in Brazil, 24% in Switzerland, 20% in France and 15% in Spain, countries in which generic pharmaceuticals currently account for less than 15% of sales in the domestic pharmaceutical market.

The U.S. market for generic pharmaceutical products is expected to increase in value at an average annual rate of approximately 11% over the next five years. We believe that this growth will be driven by certain demographic trends, including an aging population, the lengthening of average life expectancy and the rising incidence of chronic diseases. In addition, we believe that the U.S. generic pharmaceutical market is well positioned to capitalize on cost-cutting initiatives by federal and state governments, as well as managed care providers, which favor the use of lower-cost generics over branded pharmaceuticals. For example, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA, encourages health care providers to utilize generic pharmaceutical products as a tool to manage public healthcare spending. Also, Part D of the Medicare Modernization Act, which became effective on January 1, 2006 and provides for increased coverage of pharmaceutical products, has led to increased usage of pharmaceutical products, which we believe will continue to benefit the generic pharmaceutical industry.

In addition, a large number of high-value branded pharmaceutical patent expirations are expected over the next three years. In 2006, United States sales for branded products expected to face patent expiration between 2007 and 2009 were approximately $45 billion. Also, many countries outside of the United States have later dated patent expirations than in the United States. This means that many of the well known pharmaceuticals that have recently lost patent protection in the United States have not yet lost patent protection in many other jurisdictions around the world. This provides for potential growth opportunities for generic equivalents of these pharmaceuticals in the global markets.

In the United States and certain other traditional generic pharmaceutical markets, generic pharmaceuticals are sold under their generic chemical names to wholesalers and distributors. Market participants in traditional generic markets compete primarily on price, dependability and ability to provide a broad portfolio of offerings to customers. In these markets, generic companies often offer both commoditized and differentiated or difficult to manufacture products.

In contrast to traditional generic markets, in some international markets generic products are sold as branded generics and are marketed in a similar manner as patented brand-name pharmaceuticals. Branded generic products are sold by the generic pharmaceutical company s sales force directly to physicians and pharmacists. As a result of these sales efforts, we believe that brand equity is created and customer relationships are established. These factors result in higher barriers to entry in these markets and often in improved competitive dynamics as compared to the traditional commoditized generic pharmaceutical markets. These benefits include the potential for more sustainable pricing and market share and better growth prospects.

Our Strategy

Our objective is to capitalize upon our position as the third largest generic pharmaceutical company in the world by successfully integrating Merck Generics and by focusing on the principal strategies set forth below:

Capitalize on our global footprint and vertical integration. We intend to sell existing and new products into numerous global markets, creating substantial opportunities for growth and potentially longer product lifecycles. In addition, we intend to capitalize on our combined capabilities by integrating our global operations to drive cost savings, including by rationalizing duplicative research and development programs and by optimizing our manufacturing capacity. We plan to use Matrix s API capabilities and our expertise in finished dosage manufacturing to increase vertical integration of our product portfolio so that we are less reliant on third-party producers. We believe this will be a particularly important strategy for the Merck Generics business, which has relied heavily on third-party suppliers of API and contract manufacturers. We expect this strategy to help us to maintain lower production costs

which will be of particular significance in highly competitive markets where margins may become compressed.

Focus on difficult to develop and specialty pharmaceuticals. We believe that we have differentiated ourselves in the industry by being a leader in the development, formulation and manufacture of various difficult to develop pharmaceuticals. We intend to continue to expand our formulation expertise with products that are difficult to develop, formulate and manufacture. With the addition of Merck Generics we added more

products with high barriers to entry as well as formulation capabilities, including high-potency products, injectables, topicals, liquids, inhalables and controlled-release products. We will strive to maintain our advantage over our competitors in the production of commercial quantities of oral solid dosage, controlled-release and transdermal formulation products, as well as the high barrier to entry products described above and our branded specialty pharmaceuticals such as the respiratory products produced by Dey.

Leverage scale in research and development. We have invested and expect to continue to invest heavily in our generic research and development network. This investment has allowed us to build a robust pipeline of ANDAs and product dossiers. Additionally, we intend to build upon Matrix s strong record of DMF filings, as well as to leverage the significant investments made by Matrix in research and development capabilities, to further bolster our product pipeline. Finally, with the addition of Merck Generics research and development capabilities we are now able to utilize our global expertise to develop products for multiple markets.

Maintain manufacturing excellence. We intend to leverage our scale in manufacturing and our global manufacturing network by increasing our commercial volumes and improving efficiencies, while maintaining our reputation for quality and reliability. We now have the capacity to produce more than 45 billion doses annually. This capacity, coupled with our large high quality product portfolio and track record of compliance and reliability, provide us with marketing advantages to serve our customers. With the Matrix acquisition we have additional manufacturing capacity and manufacturing flexibility. These features allow us to better manage industry cycles while optimizing market share and gross margins, and afford us the capability to manufacture products in additional categories.

Realize our First In-Last Out goal in new markets. We seek to be the first generic pharmaceutical company to penetrate a new market or capture a new product opportunity. Depending on the market, we also try to be the last out by either remaining price competitive as others enter the market or by leveraging our strong brand name and portfolio. In the United States, in some cases we also aim to be the first-to-file with the FDA a Paragraph IV certification, in an effort to gain 180 days of generic market exclusivity. In other markets worldwide, we intend to utilize our country sales forces and distribution networks to leverage strong relationships with key decision makers in order to be the first generic products in those markets. We will strive to maintain our product volumes by being a low-cost producer through vertical integration, and thereby keep our products on the shelves longer and reduce the impact of increased competition.

Our Operations

Our revenues are primarily derived from the sale of generic and branded generic pharmaceuticals, specialty pharmaceuticals and API. Our generic pharmaceuticals business is conducted primarily in three regions: North America, Europe, the Middle East and Africa, or EMEA; and Asia Pacific, or AsiaPac. Our branded specialty pharmaceutical business is conducted principally by Dey, our subsidiary headquartered in Napa, California. Our API business is conducted principally through our majority-owned subsidiary, Matrix, which is headquartered in Hyderabad, India.

Generic Pharmaceuticals North America

Our North American generic pharmaceutical sales are derived principally through MPI and UDL, our global wholly-owned subsidiaries. Additionally, with the acquisition of Merck Generics on October 2, 2007, our North American generic revenues now include those from Genpharm Inc., our wholly-owned Canadian subsidiary. MPI is our primary pharmaceutical research, development, manufacturing, marketing and distribution subsidiary. MPI s net revenues are derived primarily from the sale of solid oral dosage products. Additionally, MPI s net revenues are augmented by transdermal patch products that are developed and manufactured by MTI, our wholly-owned transdermal technology subsidiary. UDL re-packages and markets products either obtained from MPI or purchased

from third parties, in unit dose formats, for use primarily in hospitals and other medical institutions.

In the United States, for the 12 months ended March 31, 2007, we manufactured over 93% of all generic product doses we sold. We have one of the largest product portfolios among all United States generic pharmaceutical companies, consisting of approximately 170 products, of which approximately 160 are in capsule or tablet form in an aggregate of approximately 400 dosage strengths. Included in these totals are 15 extended release products in a total of 38 dosage strengths.

In addition to those products that we manufacture, we also market, principally through UDL, 72 generic products in a total of 118 dosage strengths under supply and distribution agreements with other pharmaceutical companies. We believe that the breadth of our product offerings allows us to successfully meet our customers needs and helps us to better compete in the generic industry over the long term.

Our product portfolio also includes four transdermal patch products in a total of 18 dosage strengths that are developed and manufactured by MTI. MTI s fentanyl transdermal system was the first AB-rated generic alternative to Johnson & Johnson s Duragesic® (fentanyl transdermal system) on the market and was also the first generic class 2 narcotic transdermal product ever approved. MTI s fentanyl product currently remains the only AB-rated generic alternative approved in all strengths.

We believe that the future success of our North American generics business is partially dependent upon continued increasing acceptance of generic products as low cost alternatives to branded pharmaceuticals, a trend which is largely out of our control. However, we believe that we can maximize the profitability of our generic product opportunities by continuing with our proven track record of bringing to market products that are difficult to formulate or manufacture or for which the API is difficult to obtain. Over the last 10 years, in addition to fentanyl, we have successfully introduced generic products with high barriers to entry, including our launches of, among others, extended phenytoin sodium, carbidopa and levodopa, buspirone and levothyroxine sodium. Several of these products continued to be meaningful contributors to our business several years after their initial launch due to their high barriers to entry.

Additionally, we expect to achieve growth in our business by launching new products for which we may attain FDA first-to-file status with Paragraph IV certification. This can result in up to 180 days of generic exclusivity. We currently have 14 first-to-file Paragraph IV ANDA patent challenges. These 14 Paragraph IV ANDAs relate to pharmaceuticals representing approximately $9.4 billion in United States branded sales for the 12 months ended June 30, 2007. Fiscal year 2007 saw the successful monetization of two such first-to-file opportunities with our launches of amlodipine besylate and oxybutynin chloride ER.

We launched our amlodipine besylate product, the generic equivalent of Pfizer s Norvasc®, on March 23, 2007, following an Appellate Court decision declaring the invalidity of Pfizer s patent on the product. Amlodipine besylate was our first product to be fully vertically integrated by self-sourcing API from Matrix. Subsequent to our launch, an additional 19 ANDAs were approved for amlodipine besylate. However, we have been able to retain a market share of greater than 50% and maintain profitability using our First In Last Out strategy.

In the third quarter of fiscal year 2007, we launched 5mg and 10mg strengths of oxybutynin chloride ER, the generic equivalent of Johnson & Johnson s Ditropan® XL, for which we were the first-to-file an ANDA with a Paragraph IV certification. Also in the quarter ended December 31, 2006, we launched the 15mg strength of oxybutynin ER under an agreement with Ortho-McNeil Pharmaceuticals, a wholly-owned subsidiary of Johnson & Johnson. Despite losing our 180 days of exclusivity on oxybutynin ER, we remain one of only two independent generics on the market.

Generic Pharmaceuticals EMEA

Our generic pharmaceutical sales in the EMEA region are principally derived from our wholly owned subsidiaries acquired through the acquisition of Merck Generics. We have operations in 17 countries in the EMEA region. Of the top five generic pharmaceutical markets in Europe, we hold a top three market share position in four, consisting of France, the UK, Spain and Italy.

In France, we market our products through our subsidiary, Merck Generiques, using a salesforce of approximately 160 representatives. The French generics market is primarily a branded generics market, with doctors and pharmacists serving as the key decision makers. France has the third largest generic market in Europe with sales of $3.6 billion in

2006, and we hold the number one market share position in the market, with over 300 products on the market. The generics market made up approximately 9% in 2006 of the total French pharmaceutical market by sales, and some industry observers have projected that the market will grow at approximately 20% per year over the next five years. As of August 2007, Merck Generiques held the number one market share position both in the retail sector, where it holds an estimated market share of 29%, and in the hospital sector, where it maintains a 35% market share in terms of volume. Merck Generiques has a strong injectables portfolio which has helped to position it as the market share leader in the hospital market.

In the UK, our subsidiary, Generics (UK) Limited, offers a broad product portfolio of over 300 pharmaceutical products. The British generics market is a highly competitive traditional generics substitution market, with the wholesalers and pharmacies serving as the key decision makers. The reimbursement market had sales of approximately $4.7 billion, making it the second largest generic market in Europe. As of July 2007, Generics (UK) Limited held an estimated market share of approximately 14%, ranking it as the number two company by generics market share. Generics (UK) Limited is well positioned as a preferred supplier to wholesalers and is focused on independent pharmacies on the retail side.

In Germany, we market our products through our Merck Dura subsidiary. Most generic products in Germany are sold as brands, with the physician serving as the key decision maker and more recently with health insurance companies starting to play a major role. The German generics market had sales of approximately $14.0 billion in 2006 and is the largest generic market in Europe. The generics market made up approximately 33.6% in 2006 of the total German pharmaceutical market by sales. As of August 2006, Merck Dura s key therapeutic area strengths include the central nervous system and cardiovascular areas.

In Spain, where we market our products through our subsidiary Merck Genericos, we are the number three ranked company in terms of generic pharmaceutical market share. The Spanish generics market is a branded generics market, with the physician and/or the pharmacist as the key decision maker depending on the region. The market is focused on brand quality and it is important to be first-to-market in order to capture market share. The generics market in Spain had sales of approximately $1.2 billion in 2006, making it the fourth largest generic market in Europe. The generic market made up approximately 5.9% in 2006 of the total Spanish pharmaceutical market by sales and some industry observers have projected that the market will grow at approximately 15% per year over the next five years. Sales in Spain are expected to be augmented by the recent acquisition of Prasfarma.

In Italy, we are the number three ranked company in terms of generic pharmaceutical market share. The Italian generics market is a branded generics market, and similar to the French market, the Italian market is also focused on brand quality and it is important to be first-to-market in order to capture and maintain market share. The generics market in Italy had sales of approximately $400 million in 2006, making it the sixth largest generic market in Europe. We believe the Italian generic market is underpenetrated, with generics representing only approximately 1.3% in 2006 of the total Italian pharmaceutical market by sales. The Italian government has put forth measures aimed at encouraging generic use; however, the scope of these measures is limited and generic substitution is still in its early stages. Some industry observers have projected that the market will grow at approximately 11% per year over the next five years.

We also operate in several other European markets, including Portugal, where we hold a number one ranking, and Belgium, where we hold a number two ranking. We also have a notable presence in the Netherlands, Scandinavia and Ireland. Additionally, we have an export business which is focused on Africa and the Middle East. Our balanced geographical position, leadership standing in many established and growing markets, and the vertically integrated platform which Matrix provides, will all be key to our future growth and success in the EMEA region.

Generic Pharmaceuticals AsiaPac

Similar to the EMEA region, generic pharmaceutical sales in the AsiaPac region are derived principally through wholly-owned subsidiaries acquired through the acquisition of Merck Generics. We hold the number one market position in both Australia and New Zealand and the number four market position in Japan, the world s second largest pharmaceutical market.

Alphapharm, our Australian subsidiary, is the largest supplier by volume of prescription pharmaceuticals in Australia. It is also the market leader in generics in Australia, holding an estimated 60% market share by volume as of August 2007, and offering the largest portfolio of generic pharmaceutical products in the Australian market. The Australian generics market is a branded generics market, with the pharmacist serving as the key decision maker. The generics market in Australia is underdeveloped, and as a result, the government is increasingly focused on promoting generics in an effort to reduce costs. The generic pharmaceutical market had sales of approximately $800 million in 2006 and made up approximately 9.0% of the total Australian pharmaceutical market by sales and some industry observers have projected that the market will grow at approximately 7% per year over the next five years. In New Zealand, our business

operates under the name Pacific Pharmaceuticals Ltd., our wholly-owned subsidiary and the largest generics company in New Zealand.

Merck Seiyaku, our Japanese subsidiary, offers a broad portfolio of over 450 products with a focus on antibiotics, anti-diabetics, oncology and skin and allergy medications. We have a manufacturing and R&D facility located in Japan which is key to serving the Japanese market. Japan is the second largest pharmaceutical market in the world and the sixth largest generic market worldwide. The market is currently mostly hospitals, but is expected to move into pharmacies as generic substitution becomes more prevalent. The Japanese generic pharmaceutical market had sales of approximately $3.3 billion in 2006. The generic market made up approximately 5% of the total Japanese pharmaceutical market by sales. Recent pro-generics government actions include: higher patient co-pays, fixed hospital reimbursement for certain procedures, and pharmacy substitution. These actions are expected to be key drivers of our future growth and profitability in Japan which we see as our primary growth driver in the AsiaPac region.

Specialty Pharmaceuticals

Our specialty pharmaceutical business is conducted through Dey, which competes primarily in the respiratory and severe allergy markets. Dey s products are primarily branded specialty nebulized and injectable products for life-threatening conditions. Dey s revenues have historically been derived primarily through the sale of two products, EpiPen and DuoNeb.

EpiPen, which is used in the treatment of severe allergies, is an epinephrine auto-injector which has been sold in the United States since 1980 and internationally since the mid-1980 s. EpiPen accounted for approximately 29% of Dey s sales for the 12 months ended December 31, 2006, and is the number one prescribed treatment for severe allergic reactions with a market share of over 95%. The strength of the EpiPen brand name and the promotional strength of the Dey sales force have enabled us to maintain our market share, despite recent competition.

DuoNeb, which accounted for approximately 56% of Dey s sales for the 12 months ended December 31, 2006, is a nebulized unit dose formulation of ipratropium bromide and albuterol sulfate for treatment of COPD. DuoNeb, which was developed and patented by Dey, lost exclusivity in July 2007, at which time generic competition entered the market. As a result we expect sales of DuoNeb to decline. However, three recent specialty pharmaceutical product launches, Perforomist™, Zyflo CR™ and Cyanokit™, will help to offset the loss of exclusivity on DuoNeb.

Perforomist™, Dey s formoterol fumarate inhalation solution, was launched on October 2, 2007, six months earlier than anticipated. Perforomist is a long-acting beta2-adrenergic agonist, or LABA, indicated for long-term, twice-daily administration in the maintenance treatment of bronchoconstriction in COPD patients, including those with chronic bronchitis and emphysema. Perforomist is the authentic formoterol fumarate, which we believe will be a key differentiating factor amongst physicians.

Zyflo CR™, Dey s zileuton extended-release tablets, was launched on September 27, 2007. Sold through a co-promotion with Critical Therapeutics, Zyflo CR is a leukotriene synthesis inhibitor indicated for the prophylaxis and chronic treatment of asthma in adults and children 12 years of age or older. Zyflo CR competes in the approximately $7.9 billion United States asthma market. Zyflo CR provides an alternative therapy for sub-optimally controlled asthma patients.

Curosurf® Intratracheal Suspension was launched in 2000 and is the most recent lung surfactant introduced in the US for the treatment of infant respiratory distress syndrome. Curosurf s growth continues to outpace the competition which we believe is attributable to its fast onset of action, low volume usage and less frequent re-dosing.

Cyanokit[tm], which was launched in March 2007, is indicated for the treatment of smoke inhalation or cyanide poisoning. Cyanokit has been used safely in Europe for over 10 years.

We believe we can continue to drive the long-term growth of Dey by successfully managing our existing product portfolio, growing our newly launched products and bringing to market other product opportunities from Dey s robust pipeline. We intend to continue to build on our proven history of success in developing, in-licensing and launching new specialty products.

Active Pharmaceutical Ingredients

We conduct our API business through Matrix, in which we own a 71.5% interest. Matrix is the world s second largest API manufacturer with respect to the number of DMFs filed with regulatory agencies. Matrix currently has more than 165 APIs in the market or under development, and focuses its marketing efforts on regulated markets such as the United States and the European Union.

Matrix produces API for use in the manufacture of our pharmaceutical products, as well as for use by third parties, in a wide range of categories, including anti-bacterials, central nervous system agents, anti-histamine/anti-asthmatics, cardiovasculars, anti-virals, anti-diabetics, anti-fungals, proton pump inhibitors and pain management drugs. Also included in Matrix s product portfolio are anti-retroviral APIs, used in the treatment of HIV. Matrix is a leading supplier of generic anti-retroviral APIs.

Matrix has 10 API and intermediate manufacturing facilities and one finished dosage form, or FDF, facility. Of these, seven, including the FDF facility, are FDA approved, making Matrix one of the largest companies in India in terms of FDA-approved API manufacturing capacity. In addition, Matrix has manufacturing facilities in China and holds investments in companies located elsewhere in India, South Africa and Europe.

Our future success in API is dependent upon continuing to leverage our research and development capabilities to produce low-cost, high-quality API, while capitalizing on the greater API volumes afforded through our horizontally and vertically integrated platform.

Research and Development

Research and development efforts are conducted primarily to enable us to develop, manufacture and market approved pharmaceutical products in accordance with applicable government regulations. In the United States, our largest market, the FDA is the principal regulatory body with respect to pharmaceutical products. Each of our other markets have separate pharmaceutical regulatory bodies.

With the acquisitions of Merck Generics and a controlling interest in Matrix, we have significantly bolstered our global research and development capabilities. Our research and development strategy includes the following areas:

- development of controlled-release technologies and the application of these technologies to reference products;
- development of both NDA and ANDA products;
- development of drugs that are technically difficult to formulate or manufacture either because of unusual factors that affect their stability or bioequivalence or unusually stringent regulatory requirements;
- development of drugs that target smaller, specialized or underserved markets;
- development of generic drugs that represent first-to-file opportunities;
- expansion of our existing solid oral dosage product portfolio, including with respect to additional dosage strengths;

completion of additional preclinical and clinical studies for approved NDA products required by the FDA, known as post-approval (Phase IV) commitments; and

conducting life-cycle management studies intended to further define the profile of products subject to pending or approved NDAs.

Product Development

Pharmaceuticals United States

All applications for FDA approval must contain information relating to product formulation, raw material suppliers, stability, manufacturing processes, packaging, labeling and quality control. Information to support the bioequivalence of generic drug products or the safety and effectiveness of new drug products for

their intended use is also required to be submitted. There are generally two types of applications used for obtaining FDA approval of new products:

New Drug Application, or NDA. An NDA is filed when approval is sought to market a drug with active ingredients that have not been previously approved by the FDA. NDAs are filed for newly developed branded products and, in certain instances, for a new dosage form, a new delivery system, or a new indication for previously approved drugs.

Abbreviated New Drug Application, or ANDA. An ANDA is filed when approval is sought to market a generic equivalent of a drug product previously approved under an NDA and listed in the FDA s Orange Book or for a new dosage strength or a new delivery system for a drug previously approved under an ANDA.

One requirement for FDA approval of NDAs and ANDAs is that our manufacturing procedures and operations conform to FDA requirements and guidelines, generally referred to as current Good Manufacturing Practices, or cGMP. The requirements for FDA approval encompass all aspects of the production process, including validation and recordkeeping, and involve changing and evolving standards.

Generic Product Development. FDA approval of an ANDA is required before marketing a generic equivalent of a drug approved under an NDA in the United States or for a previously unapproved dosage strength or delivery system for a drug approved under an ANDA. The ANDA development process is generally less time-consuming and complex than the NDA development process. It typically does not require new preclinical and clinical studies because it relies on the studies establishing safety and efficacy conducted for the drug previously approved through the NDA process. The ANDA process, however, does require one or more bioequivalence studies to show that the ANDA drug is bioequivalent to the previously approved drug. Bioequivalence compares the bioavailability of one drug product with that of another formulation containing the same active ingredient. When established, bioequivalence confirms that the rate of absorption and levels of concentration in the bloodstream of a formulation of the previously approved drug and the generic drug are equivalent. Bioavailability indicates the rate and extent of absorption and levels of concentration of a drug product in the bloodstream needed to produce the same therapeutic effect.

Supplemental ANDAs are required for approval of various types of changes to an approved application, and these supplements may be under review for six months or more. In addition, certain types of changes may only be approved once new bioequivalence studies are conducted or other requirements are satisfied.

In the 12 months ended March 31, 2007, excluding Matrix, we received 29 application approvals from the FDA, consisting of 15 final ANDA approvals, nine tentative ANDA approvals, four supplemental ANDA approvals and one tentative supplemental ANDA approval. In the 12 months ended March 31, 2007, Matrix received two ANDA approvals from the FDA and two more approvals for dossiers filed with European regulatory agencies.

We have a robust generic product pipeline. As of June 30, 2007, excluding Matrix, we had 61 product applications pending at the FDA, representing approximately $54.5 billion in United States sales for the 12 months ended June 30, 2007 for the brand name versions of these products, according to IMS Health data. 14 of these applications were first-to-file Paragraph IV ANDA patent challenges, which offer the opportunity for 180 days of generic marketing exclusivity if approved by the FDA and if we are successful in the patent challenge.

In the 12 months ended March 31, 2007, Matrix made 12 regulatory filings for finished dosage forms with the FDA.

A large number of high-value branded pharmaceutical patent expirations are expected over the next three years. Between 2007 and 2009, approximately $45 billion is expected in United States brand sales for such products. These patent expirations should provide additional generic product opportunities. We intend to concentrate our generic product development activities on branded products with significant sales in specialized or growing markets or in

areas that offer significant opportunities and other competitive advantages. In addition, we intend to continue to focus our development efforts on technically difficult-to-formulate products or products that require advanced manufacturing technology.

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 self-

treatment. 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