BARR PHARMACEUTICALS INC Form 10-K September 13, 2005

#### **Table of Contents**

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

(Mark One)

þ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended June 30, 2005

or

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_\_ to \_\_\_\_\_

Commission file number 1-9860

# Barr Pharmaceuticals, Inc.

(Exact name of Registrant as specified in its charter)

Delaware 42-1612474

(State or Other Jurisdiction of Incorporation or Organization)

(I.R.S. Employer Identification No.)

400 Chestnut Ridge Road Woodcliff Lake, New Jersey

**07677-7668** (*Zip Code*)

(Address of principal executive offices)

201-930-3300

(Registrant s telephone number)
Securities registered pursuant to Section 12(b) of the Act:

Title of each class

Name of each exchange on which registered:

Common Stock, Par Value \$0.01

New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes R No £

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. R

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes R No  $\pounds$ 

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  $\pounds$  No R

The aggregate market value of the common equity held by non-affiliates of the Registrant computed by reference to the price at which the common equity was last sold on December 31, 2004, the last business day of the Registrant s

most recently completed second fiscal quarter, was approximately \$4,800,000,000. For purposes of this calculation, shares held by directors, executive officers and 10% shareholders of the Registrant have been excluded. Such exclusion should not be deemed a determination or an admission by the Registrant that these individuals are, in fact, affiliates of the Registrant.

As of August 25, 2005, there were 106,446,844 shares of common stock outstanding.

# DOCUMENTS INCORPORATED BY REFERENCE

The information required by Part III of this Report, to the extent not set forth herein, is incorporated herein by reference from the registration s definitive proxy statement relating to the annual meeting of shareholders to be held in November 2005, which definitive proxy statement shall be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year to which this Report relates.

# BARR PHARMACEUTICALS, INC. INDEX TO ANNUAL REPORT ON FORM 10-K FOR THE FISCAL YEAR ENDED JUNE 30, 2005

	Page
PART I	
Item 1: Business	3
Item 2: Properties	28
Item 3: Legal Proceedings	29
Item 4: Submission of Matters to a Vote of Security Holders	31
PART II	
Item 5: Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of	32
Equity Securities	
Item 6: Selected Financial Data	33
Item 7: Management s Discussion and Analysis of Financial Condition and Results of Operations	34
Item 7A:Quantitative and Qualitative Disclosures About Market Risk	54
Item 8: Financial Statements and Supplementary Data	54
Item 9: Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	54
Item 9A:Controls and Procedures	54
Item 9B:Other Information	55
PART III	
Item 10:Directors and Executive Officers of the Registrant	56
Item 11:Executive Compensation	56
Item 12:Security Ownership of Certain Beneficial Owners and Management and Related Stockholder	56
<u>Matters</u>	
Item 13:Certain Relationships and Related Transactions	56
Item 14:Principal Accountant Fees and Services	56
PART IV	
Item 15:Exhibits and Financial Statement Schedules	57
<u>SIGNATURES</u>	60
EX-21.0: SUBSIDIARIES OF THE COMPANY	
EX-23.1: CONSENT OF DELOITTE & TOUCHE LLP	
EX-31.1: CERTIFICATION EX-31.2: CERTIFICATION	
EA-31.2. CERTIFICATION	

2

#### **Table of Contents**

#### PART I

# Item 1. *Business*Safe Harbor Statement

#### Forward-Looking Statements

This Annual Report on Form 10-K and the documents incorporated herein by reference contain forward-looking statements based on expectations, estimates and projections as of the date of this filing. Actual results may differ materially from those expressed in forward-looking statements. See Item 7 of Part II Management s Discussion and Analysis of Financial Condition and Results of Operations Forward-Looking Statements.

#### Overview

Barr Pharmaceuticals, Inc. is a Delaware holding company whose principal subsidiaries, Barr Laboratories, Inc. and Duramed Pharmaceuticals, Inc., develop, manufacture and market generic and proprietary pharmaceutical products, respectively. For our fiscal year ended June 30, 2005, we recorded net earnings of \$215 million on revenues of \$1 billion. Of our \$1 billion of revenues in fiscal 2005, \$751 million were from sales of our generic products, \$279 million were from sales of our proprietary products, and \$17 million were attributed to revenues derived from co-promotion alliances, development agreements and other sources.

Our business has two reportable segments: generic pharmaceuticals and proprietary pharmaceuticals. In the generic pharmaceutical segment, we currently manufacture and distribute more than 150 different dosage forms and strengths of over 75 different generic pharmaceutical products, including 22 oral contraceptive products, representing the largest category of our generic product portfolio.

In our proprietary pharmaceutical segment, we currently manufacture and distribute 13 proprietary pharmaceutical products, largely concentrated in the female healthcare arena. These products include our SEASONALE® (levonorgestrel and ethinyl estradiol) extended-cycle oral contraceptive product, our Cenestin® (synthetic conjugated estrogens, A) line of hormone therapy products and our Plan B® emergency contraceptive (levonorgestrel) product.

We operate manufacturing, research and development and administrative facilities that are located in six locations within the United States. Our administrative offices are located in Woodcliff Lake, New Jersey.

Our Internet address is www.barrlabs.com. On our Investor Relations portion of the web site we post the following filings as soon as reasonably practicable after they are electronically filed with or furnished to the SEC: our annual report on Form 10-K, our quarterly reports on Form 10-Q, our current reports on Form 8-K and any amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act. All such filings on our Investor Relations web site are available free of charge.

#### **Business Strategies**

We focus our resources on three principal strategies:

developing and marketing selected generic pharmaceuticals;

developing and marketing proprietary pharmaceuticals; and

pursuing development and marketing of generic biopharmaceuticals.

3

#### **Table of Contents**

# Developing and Marketing Selected Generic Pharmaceuticals

We develop and market the generic equivalent of brand pharmaceuticals. These products are marketed under the Barr Laboratories, Inc. (BARR) label. We focus on generic products that have one or more characteristics that we believe will make it difficult for other competitors to develop competing generic products. The characteristics of the selected generic products we pursue may include one or more of the following:

those with complex formulation or development characteristics;

those requiring specialized manufacturing capabilities;

those where sourcing the raw material may be difficult; and

those that must overcome unusual regulatory or legal challenges, including patent challenges.

We believe generic products with some or all of these characteristics may produce higher returns for a longer period of time than products without these characteristics.

In connection with our generic products, we generally conduct studies to establish that our product is bioequivalent to the brand product, and obtain legal advice that our product does not infringe the patents of the owner of the New Drug Application (NDA) relating to that product or of the innovator or that such patents are invalid or unenforceable and/or have expired. Approval by the U.S. Food & Drug Administration (FDA) is required before a generic version of a previously approved drug or certain new dosage forms of an existing drug can be marketed. Approval for such products generally is sought using an Abbreviated New Drug Application ( ANDA ). In most cases, bioavailability and bioequivalence studies, and not clinical studies, are required in support of an ANDA. Bioavailability indicates the rate of absorption and levels of concentration of a drug in the blood stream. Bioequivalence compares the bioavailability of one drug product with another and, when established, indicates that the rate of absorption and levels of concentration in the body are substantially equivalent to the previously approved reference listed drug. An ANDA may be submitted for a drug product on the basis that it is the equivalent of a previously approved drug product or, in the case of a new dosage form, that it is suitable for use for the indications specified without the need to conduct additional safety or efficacy testing. We capitalize the costs associated with certain products prior to such products receiving FDA final marketing approval ( pre-launch inventories ). Each of our ANDA submissions is made with the expectation that: (i) the FDA will approve the marketing of the product therein described, (ii) we will validate our process for manufacturing that ANDA product within the specifications that have been or will be approved by the FDA and (iii) the cost of the inventory will be recovered from the commercialization of our ANDA product.

The regulatory process for approval of an ANDA is discussed in greater detail below under Government Regulation Abbreviated New Drug Application Process .

Developing generic equivalents of branded pharmaceuticals that are protected by patents and challenging those that we believe are invalid, unenforceable or not infringed by our competing generic versions of these branded products has been an important part of our success in the past. Successful patent challenges may result in gaining 180 days of market exclusivity for our generic product, such as when we successfully challenged Eli Lilly s patent on Prozae, or in settlements that allow us to market the products before the patents expire, such as the settlement that resulted in our launch of a distributed brand alternative of Bayer s Cipr® product in June 2003, or our settlement with Kos Pharmaceuticals, Inc. in April 2005 that resulted in our Niaspan®/Advicor® co-promotion agreements, as discussed below. As branded pharmaceutical companies have increased the number of patents protecting their products, the number of our generic products in development facing intellectual property issues and possible litigation has also increased. In addition, several companies, including Barr have launched products prior to the rendering of a final decision in their patent challenge litigation, a so-called at-risk-launch. See Pending Patent Challenges.

As a percentage of our total product sales, sales of our generic products, including sales of products manufactured for us and sold under distribution agreements, accounted for 94% in fiscal 2003, 89% in fiscal 2004,

#### **Table of Contents**

and 73% in fiscal 2005. The declining percentage over time reflects the increasing contribution from our proprietary products over that same period.

# Developing and Marketing Proprietary Pharmaceuticals

As part of our diversification strategy, we also develop, manufacture and market proprietary pharmaceutical products under the Duramed Pharmaceuticals, Inc. ( Duramed ) label. These products include both products that we develop internally and products that we acquire, whether through license or an outright acquisition. Although the proprietary products that we develop involve substantially higher risk to bring to market and more extensive research and development activities on our part when compared with our generic products, they offer the potential for a longer period of market or product exclusivity and greater returns than most of our generic products. The same is true for the proprietary products that we acquire, although they involve less development risk. Actively promoted proprietary products typically require greater sales and marketing expenses than generic products because of the need to promote them directly to healthcare providers and in some cases directly to consumers. An example of this is our SEASONALE® extended-cycle oral contraceptive product that we launched in November 2003.

FDA approval is required before any new drug can be marketed. An NDA is a filing submitted to the FDA to obtain approval of a new drug and must contain complete pre-clinical and clinical safety and efficacy data or a right of reference to such data. Before dosing a new drug in healthy human subjects or patients may begin, stringent government requirements for pre-clinical data must be satisfied. The pre-clinical data, typically obtained from studies in animal species as well as from laboratory studies, are submitted in an Investigational New Drug, or IND, application, or its equivalent in countries outside the United States where clinical trials are to be conducted. The pre-clinical data must provide an adequate basis for evaluating both the safety and the scientific rationale for the initiation of clinical trials. Typically, we capitalize pre-launch inventories associated with the filing of an NDA based on the same expectations as we have with an ANDA, but we do not begin to capitalize costs until the related product candidates have an NDA filed or in the case of components to an NDA product, the product development process has progressed to a point where we have determined that the product has a high probability of regulatory approval.

The regulatory process for approval of an NDA is discussed in greater detail below under Government Regulation New Drug Application Process.

As a percentage of our total product sales, sales of our proprietary products accounted for 6% in fiscal 2003, 11% in fiscal 2004 and 27% in fiscal 2005.

#### Pursuing Development and Marketing of Generic Biopharmaceuticals

We actively pursue those business development initiatives and internal development activities that will enable us to bring generic versions of biopharmaceutical products to market and we intend to build a leadership position in the development and marketing of such products in the future. Biopharmaceuticals represent an industry with approximately \$30 billion in annual sales, and more than 150 biopharmaceutical products are on the market today. However, the FDA has not recognized an abbreviated regulatory pathway for the timely and cost-efficient approval of generic versions of biopharmaceutical products, many of which have lost patent protection or will lose patent protection within the next several years. We are working with Congress, the Department of Health and Human Services (HHS), including the FDA, and the generic industry s trade association, the Generic Pharmaceutical Association (GPhA), to help define the regulatory pathway for approval of these products. We currently do not sell any generic biopharmaceutical products, though in March 2005 we entered into a development, supply and marketing agreement for the generic biopharmaceutical G-CSF, which is discussed in greater detail in Business Development Activities below.

#### **Investment in Research and Development**

Our commitment to research and development, including acquired in-process research and development, resulted in investments of \$91 million in fiscal 2003, \$169 million in fiscal 2004 and \$128 million in fiscal 2005. We have consistently made these significant investments because of our belief that a broad portfolio of products in development is critical to our long-term success. Research and development expenditures for generic development

#### **Table of Contents**

activities typically include those related to internal personnel, third-party bioequivalence studies, costs paid to third-party development partners and costs for raw materials used in developing products. Proprietary development costs typically include those related to internal personnel, clinical studies, third-party toxicology studies, clinical trials conducted by third-party clinical research organizations, and raw materials. We expect to continue to invest aggressively in research and development projects in fiscal 2006 and beyond.

# **Business Development**

To supplement our internal efforts in support of our business strategies, we continually evaluate business development opportunities that we believe will strengthen our product portfolio and help grow both our generic and proprietary businesses. We regularly evaluate opportunities, particularly in the areas of strategic product acquisitions and/or corporate mergers and acquisitions. We also evaluate partnership arrangements that may involve: new technology platforms on which to expand our barrier to entry generic strategy, women s healthcare products in late stage development, and products or companies for a new, second proprietary therapeutic category. As we continue our growth strategy, we expect that our business development activities, including product and company acquisitions will continue to increase.

# Significant Developments in Fiscal 2005

# Agreements with Kos Pharmaceuticals, Inc.

In April 2005, we entered into Co-Promotion, Licensing and Manufacturing, and Settlement and License Agreements with Kos Pharmaceuticals, Inc. ( Kos ) relating to the resolution of the patent litigation involving Kos Niaspan® products.

Under the Co-Promotion Agreement, we are co-promoting Kos Niaspan and Advicor® products to obstetricians, gynecologists and other practitioners with a focus on women s healthcare in the United States. These products are marketed by our 43-person Duramed Specialty Sales Force. We also have the right to co-promote future dosage formulations, strengths or modified versions of Niaspan® and Advicor® products (the Kos Products). In return, we receive a royalty on sales of the Kos Products.

Under the Licensing and Manufacturing Agreement, we serve as a stand-by, alternate supply source for the Kos Products, and in exchange have received an upfront fee and will continue to receive quarterly fees thereafter. In addition, should we supply product to Kos, we would receive an agreed-upon supply price from Kos.

Under the Settlement and License Agreement, we will be able to launch generic versions of the Kos Products on September 20, 2013, approximately four years before the last of the applicable Kos patents is set to expire. We will pay Kos a royalty on a portion of our profits from the sale of generic versions of the Kos Products.

# Oral Contraceptive Portfolio

During fiscal 2005, we expanded our portfolio of generic and proprietary oral contraceptive products through the launch of two new generic products and the acquisition of one proprietary product. Currently, we market 22 generic and four proprietary oral contraceptive products. Our oral contraceptive products compete against other generic and branded contraceptive products in an approximately \$3.8 billion market, based on industry source data for the twelve months ended June 2005. At June 30, 2005, we had a 31% prescription market share including generic and proprietary oral contraceptives, based on industry source data for the twelve months ended June 2005.

Generic: We received approval for two new generic oral contraceptive products. In September 2004, we obtained approval for our Aranelle (norethindrone and ethinyl estradiol) oral contraceptive product, the generic version of Watson Laboratories, Inc. s Tri-Norinyl. In May 2005, we obtained approval for our Kelnor (ethynodiol diacetate and ethinyl estradiol) oral contraceptive product, the generic version of Pfizer s Demule 1/35-28.

6

# **Table of Contents**

*Proprietary:* We added one proprietary oral contraceptive product to our product portfolio. We acquired the exclusive rights in the United States to Nordette<sup>®</sup> (levonorgestrel acetate and ethinyl estradiol) oral contraceptive product in December 2004.

# Stock Repurchase Program

On August 5, 2004, our Board of Directors authorized the repurchase of up to \$300 million of common stock, at the discretion of our senior management, in the open market or in privately negotiated transactions through December 31, 2005. Through June 30, 2005, we have repurchased \$100 million of our shares under the repurchase program.

#### \$175 Million Revolving Credit Facility

In August 2004, we entered into a new \$175 million, five-year, senior unsecured revolving credit facility with a bank group. Upon entering into the new credit facility, we terminated our prior \$40 million credit facility.

#### ERP System

Throughout fiscal 2005, we continued work to implement a company-wide enterprise resource planning (ERP) system from SAP, designed to allow us to: (1) more efficiently manage corporate activities; (2) more efficiently manage diverse product lines; (3) integrate mergers and acquisitions more efficiently; and (4) support potential future international operations. Currently, the SAP system is scheduled to be implemented utilizing a phased approach beginning in October 2005. We expect the project to be completed by the end of fiscal 2006 and to cost up to \$70 million. To ensure this project is implemented in a timely fashion and on budget, we have dedicated approximately 40 full-time employees to the project, along with third-party consultants.

# **Business Development Activities**

We continually evaluate strategic business development opportunities that will strengthen and help grow our business. We regularly evaluate opportunities in the following areas: strategic product acquisitions, new technology arrangements including new technology platforms, and corporate mergers and acquisitions. Set forth below is a list of our significant business development activities during fiscal 2005.

# Product Development Acquisitions/Licenses:

License for Cephalon s ACTIO

On August 10, 2004, our Barr Laboratories subsidiary entered into an agreement with Cephalon, Inc. that provides us with a license to manufacture and market a generic version of Cephalon s ACTIQ (oral transmucosal fentanyl citrate) [C-II] cancer pain management treatment. The license becomes effective on February 3, 2007, or earlier, depending on certain contingencies. The agreement also obligates Cephalon to supply us with a Cephalon-manufactured product for resale if we cannot obtain FDA approval of our ANDA for the generic product prior to the license s effective date. Under certain circumstances, the agreement also would provide us with the right to manufacture and market a generic version of Cephalon s proposed sugar-free formulation of ACTIQ.

Acquired Rights to Prefest®

On November 22, 2004, our Duramed subsidiary and King Pharmaceuticals, Inc. entered in to an agreement under which we acquired the exclusive rights to manufacture and market Prefest® (estradiol/norgestimate) Tablets hormone therapy in the United States from King for approximately \$15 million. Under the agreement, King assigned to Duramed regulatory approval for the product in the United States. Barr and King were parties to pending patent litigation regarding the patents related to Prefest®. Following our acquisition of Prefest® from King, the Prefest® patent litigation was voluntarily dismissed.

7

# **Table of Contents**

Acquired Rights to Nordette®

On December 28, 2004, our Duramed subsidiary acquired from King Pharmaceuticals, Inc. the exclusive rights in the United States for Nordette<sup>®</sup> (levonorgestrel and ethinyl estradiol) Tablets that are indicated for the prevention of pregnancy in women who elect to use this product as a method of contraception. We acquired from King the exclusive rights to manufacture and market Nordette<sup>®</sup> in the United States and King assigned to Duramed regulatory approval for the product in the United States. We paid approximately \$12 million for the exclusive rights to Nordette<sup>®</sup>.

# Development/Marketing Agreements:

Agreement with PLIVA on G-CSF

On March 30, 2005, our Barr Laboratories subsidiary and PLIVA Croatia Ltd. and PAM Kft. entered into a development, supply and marketing agreement for the generic biopharmaceutical Granulocyte Colony Stimulating Factor (G-CSF). The parties intend to develop and seek approval to market the product in the United States and Canada as a generic version of Amgen s NEUPOGE® (filgrastim) product that is primarily indicated for the regulation of white blood cell production in the treatment of cancer patients with chemotherapy induced neutropenia. Under terms of the agreement, we paid PAM Kft. \$5 million upon signing, and will make additional payments as additional milestones are achieved.

#### **Generic Pharmaceuticals**

Generic pharmaceutical products are the chemical and therapeutic equivalent of branded drug products listed in the FDA publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, popularly known in the pharmaceutical industry as the Orange Book. The Drug Price Competition and Patent Term Restoration Act of 1984, as amended, which is known as the Hatch-Waxman Act , has been largely credited with launching the generic drug industry. Among other things, the Hatch-Waxman Act provides that generic drugs may enter the market upon approval of an ANDA. ANDAs are abbreviated versions of NDAs that must be filed with the FDA for a branded product. Generic drugs are bioequivalent to their brand-name counterparts, meaning they deliver the same amount of active ingredient at the same rate as the brand-name drug. Accordingly, generic products provide safe, effective and cost-efficient alternatives to branded products, typically at a significantly lower price than the branded equivalent.

#### Research and Development

During fiscal 2005, we continued our commitment to develop and market generic products. More specifically, during fiscal 2005, we:

filed 9 ANDAs:

received FDA approvals for 11 generic products;

received tentative FDA approvals for an additional five generic products that are related to patent challenge activities; and

launched seven new generic products.

At June 30, 2005, we had approximately 35 ANDAs, including tentatively approved applications, pending at the FDA targeting branded pharmaceutical products with an estimated \$10 billion in sales for the 12 months ended June 30, 2005, based on industry source data.

We are committed to maintaining a full pipeline of generic products and have continued to increase our investment in generic research and development in support of this commitment. We have a significant number of full-time employees working in the areas of research and development, manufacturing, production and quality assurance/control, who help support our generic drug activities.

8

#### **Table of Contents**

We traditionally have developed generic pharmaceuticals in tablet and capsule forms. During the past year, we have devoted significant research and development resources to developing new dosage forms for our generic products. We are actively developing these generic products, both on our own and through agreements with third parties, using delivery technologies such as patches, rings, creams, injectables, nasal sprays, and sterile ophthalmics. In addition, we are developing generic products that would be delivered through our transvaginal ring (TVR) technology.

# **Products We Currently Market**

We currently market approximately 75 generic pharmaceutical products in approximately 150 dosage forms and strengths. Presently, our products are manufactured in tablet, capsule and powder form. Examples of the generic products we currently market are set forth below:

Barr Label	<b>Brand Equivalent</b>	Therapeutic Category
Apri® (Desogestrel and Ethinyl Estradiol)	Desogen® Ortho-Cept®	Female Healthcare
Aviane® (Levonorgestrel and Ethinyl Estradiol)	Alesse®	Female Healthcare
Claravis (Isotrentinoin)	Accutane®	Dermatology
Amphetamine Salts Combination	Adderall®	Psychotherapeutics
Dextroamphetamine Sulfate Extended Release Capsules	Dexedrine® Spansule®	Psychotherapeutics
Didanosine Delayed-Release Capsules	Videx® EC	Antiviral
Kariva® (Desogestrel and Ethinyl Estradiol)	Mircette®	Female Healthcare
Lessina® (Levonorgestrel and Ethinyl Estradiol)	Levlite <sup>®</sup>	Female Healthcare
Methotrexate	Rheumatrex®	Rheumatology
Metformin HCl Extended Release Tablets	Glucophage® XL	Diabetes
Mirtazapine Orally Disintegrating Tablets	Remeron® Soltabs®	Psychotherapeutics
Nortrel® 7/7/7 (Norethindrone and Ethinyl Estradiol)	Ortho-Novum® 7/7/7	Female Healthcare
Sprintec® (Norgestimate and Ethinyl Estradiol)	Ortho-Cyclen®	Female Healthcare
Tri-Sprintec® (Norgestimate and Ethinyl Estradiol)	Ortho Tri-Cyclen®	Female Healthcare

Warfarin Sodium Coumadin® Cardiovascular 9

#### **Table of Contents**

Set forth below are descriptions of certain generic products that contributed significantly to our sales and gross profit in fiscal 2005. Product data are derived from industry sources.

Oral Contraceptives. Oral contraceptives are the most common method of reversible birth control, used by up to 82% of women in the United States at some time during their reproductive years. Oral contraceptives have a long history with widespread use attributed to many factors including efficacy in preventing pregnancy, safety and simplicity in initiation and discontinuation, medical benefits and relatively low incidence of side effects. We currently manufacture and market 22 generic oral contraceptive products under trade names, two of which we launched during the fiscal year ended June 30, 2005. Our generic oral contraceptives compete with the branded versions of the products, and in most instances, with other generic products and/or authorized generic versions of the branded product. Authorized generics involve the brand pharmaceutical maker either marketing a generic version of its brand product itself or licensing its brand drug to a company that then markets it as a generic product.

Our most significant generic competitor in this category is Watson Pharmaceuticals, Inc., a large independent generic pharmaceutical company that markets and distributes a sizeable portfolio of generic oral contraceptive products. Additional generic competitors include Teva Pharmaceutical Industries, a global pharmaceutical company that currently markets two generic oral contraceptive products through an alliance with Andrx Corporation, and a small, privately held pharmaceutical company that distributes authorized generic versions of two oral contraceptive products that we manufacture and market.

Sales of our portfolio of 22 generic oral contraceptives were down slightly in fiscal 2005 compared to fiscal 2004, due to lower pricing and lower volumes resulting from new and increased competition and a slow-down of generic substitution rates in this category, even as certain products within our portfolio gained market share. Sales from our generic oral contraceptives will likely experience a further decline in fiscal 2006, as these trends continue. However, we believe that our large portfolio of generic oral contraceptives will remain a significant component of our total revenues.

Didanosine Delayed-Release Capsules. Our Didanosine product is the generic equivalent of Bristol-Myers Squibb s Videx® EC (Didanosine) Delayed-Release capsules. In combination with other anti-retroviral agents, the Didanosine product is indicated for the treatment of HIV-1 infections in adults. Having launched the product on December 15, 2004, we market Didanosine Delayed-Release capsules in 200 mg, 250 mg and 400 mg strengths. Our ANDA contained a certification that the Orange Book patents on the drug were invalid, unenforceable or would not be infringed by our product (a so-called paragraph IV certification ). Following FDA notification of acceptance for filing, we notified Bristol-Myers Squibb, the NDA holder, and the National Institute of Health (NIH), the patent owner, of our ANDA filing. No action was filed against us within the 45-day period specified in the Hatch-Waxman Act. We were the first applicant to file an ANDA containing a paragraph IV certification for the product and, consequently, under the provisions of Hatch-Waxman, were granted 180 days of generic exclusivity. Currently, we market the only generic version of this product.

*Warfarin Sodium.* Our Warfarin Sodium product is the generic equivalent of Bristol-Myers Squibb s Coumadin, an anticoagulant for patients with heart disease and/or high risk of stroke. We launched Warfarin Sodium in July 1997 and are presently one of three generic suppliers of the product.

Claravis (Isotretinoin Capsules). Our Claravis is the generic equivalent of Roche Pharmaceuticals Accutane® capsules for the treatment of severe recalcitrant nodular acne. We market the 10 mg, 20 mg and 40 mg strengths under the Claravis trade name. We launched our product in May 2003. Currently, Claravis competes in a market that includes two additional generic isotretinoin products and Roche s Accutane product. Claravis, which is prescribed for the treatment of severe recalcitrant nodular acne that is not responsive to other treatments, is known to cause birth defects and prescribed under a highly restrictive risk management program. Manufacturers and marketers of isotretinoin products, in cooperation with the FDA, are currently implementing an enhanced risk management program that is designed to minimize fetal exposure to isotretinoin. The enhanced risk management program, which is being implemented in stages, will replace the existing risk management program starting on January 1, 2006.

Table of Contents 13

10

#### **Table of Contents**

#### **Pending Patent Challenges**

As part of our generic development activities, we develop generic versions of select branded products where we believe the patents relating to the brand products are invalid, unenforceable, or not infringed by our competing generic products. Utilizing the patent challenge process under the Hatch-Waxman Act, we seek to invalidate patents or to obtain a declaration that our generic version does not infringe the patent. Our development activities in this area, including sourcing raw materials and developing equivalent products, are designed to obtain FDA approval for our product. Our legal activities in this area, performed by outside counsel, are designed to eliminate the barrier to market entry created by the patents.

For a detailed discussion of FDA regulations and court decisions regarding patent challenges, and for a discussion of certain patent challenges that have been concluded to date, see Government Regulation Patent Challenges .

As of June 30, 2005, we had publicly disclosed the following patent challenges that are in various stages of litigation:

	Sales In \$	Therapeutic
	Millions*	Category
Allegra® & Allegra® D Products (Fexofenadine Hydrochloride and Fexofenadine Hydrochloride & Pseudoephedrine Hydrochloride)	\$ 1,874	Antihistamines
Evista® (Raloxifene Hydrochloride)	\$ 717	Female Healthcare
Adderall XR® (Amphetamine Salts Combination)	\$ 873	ADHD
Provigil® (Modafinil)	\$ 496	Narcolepsy
Ortho Tri-Cyclen® Lo (Norgestimate/Ethinyl Estradiol)	\$ 284	Oral Contraceptive
ZYPREXA® Zydis® (Olanzipine)	\$ 241	Psychotherapeutic
ACTIQ® (Fentanyl Citrate)	\$ 406	Oncology
Yasmin® (Drospirenone & Ethinyl Estradiol)	\$ 372	Oral Contraceptive
Razadyne® (Galantamine Hydrobromde)	\$ 245	Alzheimer s
Total	\$ 5,508	

\* Source:IMS
Health last
twelve months
sales ended
June 30, 2005

11

# **Table of Contents**

In addition to the patent challenges listed above, we are involved in on-going litigation related to two products that we launched following the receipt of favorable summary judgment rulings from the lower trial courts. We launched both of these products—at risk—, meaning prior to the rendering of a final decision in the patent challenge litigation by the appellate courts. As patent challenge litigation takes longer to complete, we anticipate that in the future we may launch additional products—at risk—. The patent challenge litigation related to the two products launched—at risk—are described below:

Kariva®, our generic version of Organon s Mircette, is indicated for the prevention of pregnancy. We launched the product following a District Court ruling that our product did not infringe the patent of the brand product. In April 2003, the Court of Appeals reversed the District Court s decision and remanded the case for further proceedings. As a result, the patent challenge case involving Kariva has not been finally resolved. On June 15, 2005 we entered into a non-binding Letter of Intent ( LOI ) with Organon (Ireland) Ltd., Organon USA and Savient Pharmaceuticals, Inc. to acquire the NDA for Mircette, obtain a royalty free patent license to promote Mircette in the United States and dismiss all pending litigation between the parties in exchange for a payment by us of up to \$155 million. The total amount to be paid by us may be reduced if the transaction does not close by September 15, 2005. In July 2005, the parties made the required filing with the Federal Trade Commission (FTC) regarding the proposed transaction. On August 1, 2005, the FTC issued a second request to the parties, seeking additional information about the transaction. The parties are currently in the process of responding to this request. The second request signals possible FTC concerns about a proposed transaction and raise doubts about whether the proposal as structured will be consummated at all. If the FTC objects to the proposal, the parties cannot agree to potential conditions required by the FTC or the parties cannot negotiate definitive agreements, the proposed transaction could be terminated. In the absence of a transaction substantially similar to the one proposed, we expect to continue to vigorously defend our position in the Mircette litigation. See Item 3, Legal Proceedings and Note 17 to the consolidated financial statements for a further description of this matter.

Desmopression Acetate, our generic version of Ferring B.V. s DDAVP Tablets, 0.1 mg and 0.2 mg, is indicated as antidiuretic replacement therapy in the management of central diabetes insipidus and for the management of the temporary polyuria and polydipsia following head trauma or surgery in the pituitary region. It is also indicated for the management of primary nocturnal enuresis. In February 2005, a District Court ruled that the patent alleged to cover DDAVP is unenforceable and not infringed by our product. The Court s decision ended the 30-month stay and allowed the FDA to approve our product on July 1, 2005. We launched our product immediately upon receiving FDA approval. In February 2005, Ferring B.V. filed an appeal of the District Court s decision and we expect the Federal Circuit to hold an oral argument on Ferring s appeal in Fall 2005. Because we are selling the products at risk, we could be liable for damages if the District Court is reversed on appeal. See Item 3, Legal Proceedings, for a further description of this matter.

# Sales and Marketing

We market our generic products to customers in the United States and Puerto Rico under the Barr Laboratories, Inc. label through an integrated sales and marketing team that includes a four-person national accounts sales force. The activities of the sales force are supported by our marketing and customer service organization in our Woodcliff Lake, New Jersey offices.

#### **Customers**

The customer base for our generic products includes drug store chains, supermarket chains, mass merchandisers, wholesalers, distributors, managed care organizations, mail order accounts, government/military and repackagers.

We sell our generic products to approximately 145 customers that purchase directly from us, and indirectly to approximately 90 customers that purchase our products from wholesalers. Sales to customers who accounted for 10% or more of our generic sales during the three years ended June 30, were as follows:

12

#### **Table of Contents**

	2005	2004	2003
McKesson Drug Company	23%	24%	21%
Cardinal Health	17%	14%	17%
Amerisource Bergen	11%	*	13%
Walgreens	*	13%	11%

<sup>\*</sup> Denotes less than 10% in the period indicated.

# **Proprietary Pharmaceuticals**

We develop our proprietary pharmaceutical products through internal efforts or through company, product and/or technology platform acquisitions. Our proprietary products are marketed under the Duramed Pharmaceuticals, Inc. label and several are promoted directly to healthcare providers and in some cases consumers. Proprietary products often are patent-protected or benefit from other non-patent market exclusivities. These market exclusivities generally allow proprietary products to maintain higher profitability for longer periods of time than generic products. If a proprietary product has achieved physician and customer loyalties, it will often remain profitable even following the onset of generic competition, but generate lower profits than it realized prior to generic competition.

# Research and Development

We focus our proprietary product development activities in three areas: patent-protected proprietary products in late stages of development;

existing chemical compounds where the development of new forms (liquid vs. tablets, different dosages or other drug delivery systems, such as our proprietary, novel vaginal ring delivery system) offer therapeutic or marketing advantages; and

new chemical entities in selected therapeutic categories, including some that are marketed in other countries but not currently sold in the United States.

Our proprietary development activities are currently focused primarily on expanding our portfolio of female healthcare products including oral contraceptives and treatments for menopause/perimenopause and endometriosis, through internal development and business development activities. An important part of our product development strategy in the area of female healthcare is to develop a broad line of products designed to meet the unmet medical needs of women. We are also pursuing two urology products, one that utilizes our transvaginal ring technology to treat urinary incontinence, and a second that is an oral product targeted to treat the symptoms associated with the treatment of prostate cancer. In addition, we are developing two oral vaccine products to prevent Adenovirus (Types 4 & 7) infections in U.S. military personnel under contract with the Department of Defense (DOD). We continue to identify other proprietary product candidates that further expand our product offerings in these areas and are actively evaluating additional therapeutic categories to add to our proprietary portfolio.

As a result of internal development and business development activities, at the end of fiscal 2005 we had a broad pipeline of short, mid- and long-term opportunities that include several proprietary products in clinical development, one of which is in Phase III studies, and four NDAs pending at the FDA.

The four proprietary product applications pending at the FDA are:

a supplemental NDA ( sNDA ) for Over-the-Counter ( OTC ) status for the Plantergency contraceptive;

a NDA for Bijuva Synthetic Conjugated Estrogens Vaginal Cream;

13

#### **Table of Contents**

a NDA for SEASONIQUE (levonorgestrel/ethinyl estradiol tablets 0.15 mg/0.03 mg and ethinyl estradiol tablets 0.01 mg) extended-cycle oral contraceptive; and

a NDA for SEASONALE® Lo (levonorgestrel/ethinyl estradiol tablets 0.10 mg/0.02 mg and ethinyl estradiol tablets) extended-cycle oral contraceptive.

Our proprietary research and development team has experience in managing clinical development programs and regulatory matters. This team works closely and leverages synergies with our generic formulation, manufacturing and regulatory groups.

# **Products We Currently Market**

We currently market 13 proprietary products, which are:

Aygestin® (Norethindrone Acetate) for amenorrhea

Cenestin® (Synthetic Conjugated Estrogens, A) hormone therapy

Diamox® Sequels® (Acetazolamide) for glaucoma

Loestrin®/Loestrin® Fe (Norethindrone Acetate and Ethinyl Estradiol) oral contraceptives

Nordette® (Levonorgestrel and Ethinyl Estradiol) oral contraceptive

Plan B® (Levonorgestrel) emergency oral contraceptive

Prefest® (Etradiol/Nogestimate) hormone therapy

Revia® (Naltrexone Hydrochloride) for alcohol dependence

SEASONALE® (Levonorgestrel and Ethinyl Estradiol) extended-cycle oral contraceptive

Trexall (Methotrexate) for rheumatoid arthritis

ViaSpan® (Cold Storage Solution) transplant preservation agent

Zebeta® (Bisprolol Fumarate) for hypertension

Ziac® (Bisoprolol Fumarate and Hydrochlorothiazide) for hypertension

SEASONALE®. Our NDA for SEASONALE, an extended-cycle oral contraceptive indicated for the prevention of pregnancy, was approved by the FDA on September 5, 2003 and was granted a three-year New Product Exclusivity, which expires in September 2006. We also may be eligible to obtain an additional six months of market exclusivity on SEASONALE by performing pediatric research on the product. For fiscal year 2005, we recorded sales for SEASONALE of \$87 million and filled over 807,000 prescriptions, an increase over sales of \$25 million and 170,000 prescriptions filled in fiscal 2004 (with the prescription data based on industry sources for the twelve months ended June 2004 and June 2005).

The majority of oral contraceptive products currently available in the United States are based on a regimen of 21 treatment days of active ingredient and then a seven-day placebo interval. By contrast, under the SEASONALE extended-cycle regimen, women take the active product for 84 consecutive days, and then have a seven-day placebo interval. The SEASONALE regimen results in only 4 menstrual cycles per year, or one per season .

Our 250-person Women s Healthcare Sales Force details SEASONALE to approximately 40,000 healthcare providers who we have determined to be among the most productive prescribers of oral contraceptive products in the United States. Marketing support includes professional education materials, medical education initiatives, published

data from our clinical studies demonstrating the safety and efficacy of the extended-cycle concept, and product sampling kits that contain extensive information for patients. We reinforce our detailing activities with a trade-advertising program in leading medical journals and a direct-to-consumer ( DTC ) advertising campaign (including television advertising), and leading general interest publications.

14

# **Table of Contents**

Over the last year, the FDA s Office of Medical Policy Division of Drug Marketing, Advertising and Communications (DDMAC) has been reassessing industry guidelines for DTC advertisements to ensure that they do not minimize risks or make unsubstantiated product claims. We anticipate that DDMAC will require DTC advertisements to focus more on education and less on product promotion. In this environment, we received a letter from DDMAC in December 2004 related to our television commercial for SEASONALE. In its letter DDMAC raised several issues with our commercial, all of which we addressed and re-submitted to the FDA.

SEASONALE was developed under a patent license from the Medical College of Hampton Roads, Eastern Virginia Medical School (EVMS). Under the terms of the patent licensing agreement, we had the option of paying a perpetual royalty to EVMS based on a percentage of net profits, or exercising our right to make a one-time payment to EVMS, in lieu of future royalty payments, prior to the first anniversary of the FDA approval date for SEASONALE. In September 2004, we exercised this option and paid \$19 million to EVMS. As a result, we now hold the patent covering SEASONALE, which expires in 2017.

In June 2004, EVMS (then still the patent holder) and Barr received notification that Watson Laboratories had filed an ANDA containing a paragraph IV certification asserting that the patent covering SEASONALE is invalid, unenforceable or would not be infringed by Watson s generic product. Neither Barr nor EVMS initiated patent infringement litigation with respect to Watson s ANDA. As a result, Watson s generic version of SEASONALE may be launched as a competing product when our new product exclusivity expires in September 2006, or six months later if we are successfull in obtaining pediatric exclusivity.

In July 2004, EVMS submitted the patent covering the SEASONALE extended-cycle oral contraceptive product for reissue with the Patent and Trademark Office (PTO). At this time, as the current patent holder, we have not received a determination from the PTO and believe that the reissue process may take about two years from submission to complete. The patent covering SEASONALE will remain in effect and continue to be listed in the FDA s Orange Book while the PTO reviews the request for reissuance. If the patent covering SEASONALE is reissued, it will have the same remaining term as the existing patent that expires in 2017.

*Cenestin*<sup>®</sup>. Cenestin is indicated for the treatment of moderate-to-severe vasomotor symptoms associated with menopause. We currently market the 0.3 mg, 0.45 mg, 0.625 mg, 0.9 mg and 1.25 mg tablet strengths of Cenestin and are developing other related products. The 0.3 mg tablet strength of Cenestin is indicated for the treatment of vulvar and vaginal atrophy.

Cenestin competes in the \$1.8 billion hormone therapy market with products such as Wyeth s Premarin, a conjugated equine estrogens product. The hormone therapy market has declined over the last several years as findings by the National Institutes of Health (NIH) publicized in July 2002 have created uncertainty in the minds of many healthcare providers and consumers regarding the risk/reward benefit of long-term hormone therapy products and has resulted in a reduction in the use of hormone therapy products, including Cenestin. However, we believe that a number of women and their healthcare providers will continue using and recommending these products, particularly estrogen-only therapies such as Cenestin, for the short-term treatment of various symptoms associated with menopause.

*Plan B*<sup>®</sup> *Emergency Contraceptive*. Plan B, which contains the synthetic progestin levonorgestrel, is an emergency oral contraceptive that is intended to prevent pregnancy following unprotected intercourse or contraceptive failure. To be effective, the product needs to be taken as soon as possible within 72 hours. Plan B is currently available by prescription only in the U.S., although it is available without a prescription under pharmacy access programs at select pharmacies in seven states.

As part of our acquisition of the outstanding shares of Women s Capital Corporation (WCC) in March 2004, we assumed responsibility for the Supplemental New Drug Application (sNDA) proposing the switch of Plan B from prescription only to Over-The-Counter (OTC) status. On May 6, 2004, we received a Not Approvable Letter from FDA, which noted that our application did not provide adequate data to support a conclusion that Plan B can be used safely by young adolescent women... without professional supervision. In response to the Not Approvable letter, we re-submitted our sNDA in July 2004 to the FDA with information supporting the marketing of Plan B as a prescription-only product for women 15 years of age and younger and a nonprescription product for women 16 years of age and older. In January 2005, the FDA informed us that it was unable to complete its review of the sNDA to

market the Plan  $B^{\circledR}$  emergency contraceptive OTC by the January  $21^{st}$  Prescription Drug User Fee Act (PDUFA) 15

#### **Table of Contents**

date. In August 2005, we received a letter from the FDA that stated that the Center for Drug Evaluation and Research . . . has completed its review of this application, as amended, and has concluded that the available scientific data are sufficient to support the safe use of Plan B as an OTC product.... for women who are 17 years of age and older. Notwithstanding this clear scientific determination, the FDA delayed any action on the application. Instead, the FDA informed us that it intends to seek public comment on issues related to the approval of a product that has OTC status for patients 17 and older and prescription status for patients 16 and under. In its communication with us, the FDA did not commit to any timetable for initiating or concluding the rulemaking proceeding. We continue to market Plan B as a prescription-only emergency contraceptive, and continue to educate consumers and healthcare providers about its availability.

As an on-going part of our product acquisition strategy, we have made opportunistic acquisitions of mature branded products, through litigation settlements, licensing agreements or direct acquisitions. While sales of these mature products tend to decline over time, we have undertaken some marketing for select products in an effort to maintain sales levels. Such product acquisitions made over the past years include: Aygestin<sup>®</sup>, Diamox<sup>®</sup> Sequels<sup>®</sup>, Loestrin<sup>®</sup> and Loestrin<sup>®</sup> Fe, Nordette<sup>®</sup>, Prefest<sup>®</sup>, Revia<sup>®</sup>, Ziac<sup>®</sup> and Zebeta<sup>®</sup>.

# Products in Development

We have several proprietary products in clinical development in multiple product categories. Examples of these products are discussed in detail below.

# Female Healthcare

Oral Contraception:

SEASONIQUE. In December 2004, we received notification that the FDA had accepted our NDA for SEASONIQUE (levonorgestrel/ethinyl estradiol tablets 0.15 mg/0.03 mg and ethinyl estradiol tablets 0.01 mg) extended-cycle oral contraceptive for review. Under the SEASONIQUE extended-cycle regimen, women would take active tablets of 0.15 mg levonorgestrel/0.03 mg of ethinyl estradiol for 84 consecutive days, followed by seven days of 0.01 mg of ethinyl estradiol. In August 2005, the FDA issued an Approvable letter for our SEASONIQUE application. To achieve final approval, the FDA has requested that we provide additional data to support SEASONIQUE s unique regimen of 84 days of combination therapy, followed by seven days of unopposed estrogen. We are working closely with the FDA to provide them with the additional data they have requested. If approved, we will market SEASONIQUE extended-cycle oral contraceptive for the prevention of pregnancy.

SEASONALE® Lo. In June 2005, we filed an NDA for a lower strength of SEASONALE®, which we intend to market under the name SEASONALE® Lo. Under the SEASONALE® Lo extended-cycle regimen, women would take active tablets of 0.10 mg levonorgestrel/0.02 mg of ethinyl estradiol for 84 consecutive days, followed by seven days of placebo. SEASONALE® Lo was studied as part of the SEASONALE® clinical trials.

Hormone Therapy/Estrogen Therapy:

*Enjuvia* (Synthetic Conjugated Estrogen, B). In November 2003, we completed the acquisition of the development-stage Enjuvia (synthetic conjugated estrogen, B) products from Endeavor Pharmaceuticals. Enjuvia has the nine major components of Wyeth s Premarin conjugated estrogens product, as well as Delta 8,9-dehydroestrone sulfate, an estrogenic compound found only in Premarin. In May 2004, we received FDA approval for our Enjuvia 0.625mg and 1.25 mg tablet strengths products and in December 2004 we received approval for our 0.3 mg and 0.45 mg tablet strengths products. All strengths are indicated for the treatment of vasomotor symptoms. We intend to launch these products in fiscal 2006. An application for the 0.9 mg strength of Enjuvia is being prepared. The patent on Enjuvia expires in 2020.

Bijuva (Synthetic Conjugated Estrogens, A) Cream. In June 2004, we filed an NDA for Bijuva (Synthetic Conjugated Estrogens, A) vaginal cream product. In April 2005, the FDA issued a Not Approvable letter for our Bijuva application. We are working with FDA to identify the additional information needed to support the Bijuva application. If approved, we intend to market Bijuva for the treatment of moderate to severe symptoms of vulvar and vaginal atrophy associated with menopause.

16

#### **Table of Contents**

Transvaginal Ring (TVR) Products:

We have several products in early stages of development based on our proprietary, novel, TVR drug delivery system. Specifically, our development efforts are focused on products that treat endometriosis, fertility, fibroids, labor and delivery, and urinary incontinence.

#### Urology

*Oxybutynin TVR*. We are currently developing a urinary incontinence product utilizing our TVR technology. The TVR product offers the potential to deliver higher doses of oxybutynin to the bladder neck with lower systemic exposure. This product is in Phase IIB development.

CyPat. Cyproterone acetate, which, if approved, we intend to market in the United States under the name CyPat, is a steroid that blocks the action of testosterone. Cyproterone acetate is not currently approved for marketing in the United States. Internationally, cyproterone acetate is mainly used in the management of prostate cancer, both as a single agent and in combination with other products. In addition, it is used as a component of oral contraceptives and in the treatment of acne, seborrhea, hirsutism in women, precocious puberty in children, and hypersexuality/deviant behavior in men. Currently, Cyproterone acetate is approved for use in over 80 countries throughout Europe, Asia, South America, Australia and North America.

#### **Vaccines**

Adenovirus Vaccines. We are developing Adenovirus Vaccines Type 4 and 7 under a \$42.3 million, six-year contract awarded in September 2001 by the United States Department of Defense ( DOD ). The Adenovirus Vaccines are intended to be dispensed to armed forces recruits to prevent epidemics of an acute respiratory disease that has been a leading cause of hospitalizations of military trainees. In July 2003, we completed construction of our Adenovirus Vaccine Virus Types 4 and 7 manufacturing and packaging facility, a 20,000 square foot building designed specifically to produce these vaccines. The facility is located on our Virginia manufacturing and distribution campus. We have initiated clinical trials and at the end of fiscal 2005 had completed Phase I studies. In addition to supplying the vaccine to the armed forces, we have the right to market the product to other populations, such as immunosuppressed patients, and foreign markets where the same needs exist as with the DOD.

#### Sales And Marketing

Our proprietary products are marketed under the Duramed Pharmaceuticals, Inc. label by two sales teams: our Women s Healthcare Sales Force and our Specialty Products Sales Force.

Women s Healthcare Sales Force

Our 250-person Women s Healthcare Sales Force currently promotes SEASONAL® our Cenestin® hormone therapy products and our Plan B® emergency contraceptive product to female healthcare practitioners. This sales force may market additional female healthcare products we are developing or may acquire.

Specialty Products Sales Force

We doubled the size of our Specialty Products Sales Force to 43 by the end of fiscal 2005. This sale force promotes our Trexall product directly to rheumatologists and dermatologists; Kos Niaspan and Advicor® cholesterol treatments to obstetricians, gynecologists and other practitioners with a focus on women s healthcare; and SEASONALE® to obstetricians, gynecologists and other practitioners with a focus on women s healthcare. The promotion of Niaspan® and Advicor® is the result of a co-promotion agreement with Kos discussed above.

17

#### **Table of Contents**

#### **Customers**

The customer base for our proprietary products includes drug store chains, supermarket chains, mass merchandisers, wholesalers, distributors, managed care organizations, mail order accounts, and the government/military. Sales to customers who accounted for 10% or more of our proprietary sales over the last three fiscal years ended June 30, were as follows:

	2005	2004	2003
McKesson Drug Company	25%	21%	15%
Cardinal Health	18%	20%	19%
AmeriSource Bergen	10%	15%	11%

#### **Generic Biopharmaceuticals**

As we evaluate new product development and new technologies to expand our generic and proprietary operations, we are also investing in the effort to open an exciting new frontier for future growth: generic biopharmaceuticals.

Biopharmaceuticals represent one of the fastest growing segments of the pharmaceutical industry, with sales in 2004 of approximately \$30 billion, based on industry source data, with more than 150 biopharmaceuticals on the market, including human insulin, interferons, human growth hormones and monoclonal antibodies. In 2004, 40 new biopharmaceutical products were approved, compared to just two in 1982, according to figures published by the Biotechnology Industry Organization. There are more than 370 biotech drug products and vaccines currently in clinical trials targeting more than 200 diseases including cancer, Alzheimer s, heart disease, multiple sclerosis, AIDS and arthritis. Biopharmaceuticals are a major driver of increasing prescription drug costs. This area represents a major growth opportunity for Barr, and the generic pharmaceutical industry as a whole.

There are, however, three major challenges in pursuing generic biopharmaceuticals: regulatory challenges; intellectual property challenges; and scientific/manufacturing challenges. The key regulatory challenge facing us is that the FDA has not recognized an abbreviated regulatory pathway that would enable the timely and cost-efficient approval of generic versions of biopharmaceuticals. We are working with Congress and the FDA to overcome this barrier. We are committed to pursuing the approval of products through what we believe is a pathway that currently exists, given that select biopharmaceuticals were historically approved under current law. We are also committed to working towards a second, streamlined regulatory approval process that will ensure we can bring generic versions of biopharmaceutical products to market that have been approved under the biopharmaceutical approval pathway in place since 1997.

Because biopharmaceuticals are highly complex, brand innovators have protected the intellectual property associated with all aspects of biopharmaceutical development and manufacturing, including processes, characterization, naturally occurring by-products of biopharmaceutical raw material production and processes related to scale-up, manufacturing and analysis of the purity, quality and efficacy of the finished product. We believe that we are well situated, in terms of our experience with complex intellectual property issues, to overcome patent and other barriers to the introduction of these products.

To support our efforts in this area, we are actively pursuing the identification of sources for biopharmaceutical active ingredients, as well as exploring potential partnerships and product acquisitions as we work to bring generic biopharmaceuticals to market. An example of our partnering strategy is our March 2005 agreement with PLIVA to develop and market a generic version of G-CSF in the United States and Canada, as discussed above.

While we do not expect to launch a generic version of a biopharmaceutical for some time, nor can we predict the timing of an FDA approval pathway for generic biopharmaceutical products, we are taking the steps to position ourselves as a leader in this potential market.

18

#### **Table of Contents**

#### Significant Product Sales; Geography

The table below sets forth for each of the last three fiscal years those products, or classes of products that accounted for 10% or more of our total product sales during the last three fiscal years ended June 30:

	2005	2004	2003
Oral contraceptives (generic and proprietary)	54%	34%	31%
Ciprofloxacin	*	30%	12%
Tamoxifen	*	*	14%

\* Denotes less than 10% in the period indicated.

Presently, all of our operations are located within the United States. Over the last three fiscal years, sales of our products have been primarily to our direct customers located within the United States.

# **Raw Materials & Manufacturing Suppliers**

We purchase the bulk pharmaceutical chemicals and raw materials that are essential to our business from numerous U.S. and foreign suppliers. We also purchase certain finished dosage form products, such as our Plan B emergency contraceptive and our ViaSpan® transplant preservation agent, from third-party suppliers. As we previously described, our generic product development strategy includes identifying products where there are a limited number of raw material suppliers.

Arrangements with foreign suppliers are subject to certain additional risks, including obtaining governmental clearances, export duties, political instability, currency fluctuations and restrictions on the transfer of funds. In addition, the DEA regulates allocation to us of raw materials used in the production of controlled substances based on historical sales data. Any inability to obtain raw materials or finished products on a timely basis, or any significant price increases that cannot be passed on to customers, could adversely affect us. Because prior FDA approval of raw material suppliers or product manufacturers is required, if raw materials or finished products from an approved supplier or manufacturer were to become unavailable, the required FDA approval of a new supplier could cause a significant delay in the manufacture or supply of the affected drug product.

# **Patents and Proprietary Rights**

We file patent applications and obtain patents to protect our products, technologies, inventions and improvements that we consider important to the development of our business. We also rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position. Preserving our trade secrets and protecting our proprietary rights are important to our long-term success.

From time-to-time, we may find it necessary to initiate litigation to enforce our patent rights, to protect our trade secrets or know-how or to determine the scope and validity of the proprietary rights of others. Litigation concerning patents, trademarks, copyrights and proprietary technologies can often be protracted and expensive and, as with litigation generally, the outcome is often uncertain.

# **Government Regulation**

We are subject to extensive regulation by the FDA, the DEA and state governments, among others. The Federal Food, Drug, and Cosmetic Act, the Controlled Substances Act, the Prescription Drug Marketing Act and other federal statutes and regulations govern or influence the testing, manufacturing, safety, labeling, storage, record keeping, approval, marketing, advertising and promotion of our products. Non-compliance with applicable requirements can result in fines, recalls and seizure of products.

19

#### **Table of Contents**

#### Abbreviated New Drug Application Process

FDA approval is required before a generic equivalent can be marketed. We seek approval for such products by submitting an ANDA to the FDA. When processing an ANDA, the FDA waives the requirement of conducting complete clinical studies, although it normally requires bioavailability and/or bioequivalence studies. Bioavailability indicates the rate and extent of absorption and levels of concentration of a drug product in the blood stream needed to produce a therapeutic effect. Bioequivalence compares the bioavailability of one drug product with another, and when established, indicates that the rate of absorption and levels of concentration of the active drug substance in the body are equivalent for the generic drug and the previously approved drug. An ANDA may be submitted for a drug on the basis that it is the equivalent of a previously approved drug or, in the case of a new dosage form, is suitable for use for the indications specified.

Before approving a product, the FDA also requires that our procedures and operations conform to Current Good Manufacturing Practice ( cGMP ) regulations, relating to good manufacturing practices as defined in the U.S. Code of Federal Regulations. We must follow the cGMP regulations at all times during the manufacture of our products. We continue to spend significant time, money and effort in the areas of production and quality testing to help ensure full compliance with cGMP regulations.

If the FDA believes a company is not in compliance with cGMP, sanctions may be imposed upon that company including:

withholding from the company new drug approvals as well as approvals for supplemental changes to existing applications;

preventing the company from receiving the necessary export licenses to export its products; and

classifying the company as an unacceptable supplier and thereby disqualifying the company from selling products to federal agencies.

We believe we are currently in compliance with cGMP regulations.

The timing of final FDA approval of an ANDA depends on a variety of factors, including whether the applicant challenges any listed patents for the drug and whether the brand-name manufacturer is entitled to one or more statutory exclusivity periods, during which the FDA may be prohibited from accepting applications for, or approving, generic products. In certain circumstances, a regulatory exclusivity period can extend beyond the life of a patent, and thus block ANDAs from being approved on the patent expiration date. For example, in certain circumstances the FDA may extend the exclusivity of a product by six months past the date of patent expiry if the manufacturer undertakes studies on the effect of their product in children, a so-called pediatric extension. The pediatric extension results from a 1997 law designed to reward branded pharmaceutical companies for conducting research on the effects of pharmaceutical products in the pediatric population. As a result, under certain circumstances, a branded company can obtain an additional six months of market exclusivity by performing pediatric research.

In May 1992, Congress enacted the Generic Drug Enforcement Act of 1992, which allows the FDA to impose debarment and other penalties on individuals and companies that commit certain illegal acts relating to the generic drug approval process. In some situations, the Generic Drug Enforcement Act requires the FDA to not accept or review ANDAs for a period of time from a company or an individual that has committed certain violations. It also provides for temporary denial of approval of applications during the investigation of certain violations that could lead to debarment and also, in more limited circumstances, provides for the suspension of the marketing of approved drugs by the affected company. Lastly, the Generic Drug Enforcement Act allows for civil penalties and withdrawal of previously approved applications. Neither we nor any of our employees have ever been subject to debarment.

20

#### **Table of Contents**

#### Patent Challenges

We actively challenge patents on branded pharmaceutical products where we believe such patents are invalid, unenforceable, or not infringed by our competing generic products. Our development activities in this area, including sourcing raw materials and developing equivalent products, are designed to obtain FDA approval for our product. Our legal activities in this area, performed primarily by outside counsel, are designed to eliminate the barriers to market entry created by the patents. Under the Hatch-Waxman Act, the first generic ANDA applicant whose filing includes a certification that a listed patent on the brand name drug is invalid, unenforceable, or not infringed (a so-called paragraph IV certification), may be eligible to receive a 180-day period of generic market exclusivity. This period of market exclusivity may provide the patent challenger with the opportunity to earn a significant return on the risks taken and its legal and development costs. Patent challenge product candidates typically must have several years of remaining patent protection to ensure that the legal process can be completed prior to patent expiry. Because of the potential value of being the only generic in the market for the 180-day generic exclusivity period, we typically seek to be the first company to file an ANDA containing a paragraph IV certification for a targeted product.

The process for initiating a patent challenge begins with the identification of a drug candidate and evaluation by qualified legal counsel of the patents purportedly protecting that product. We have reviewed a number of potential challenges and have pursued only those that we believe have merit. Our general practice is to disclose patent challenges after the patent holder has sued us. Thus, at any time, we could have several undisclosed patent challenges in various stages of development.

Patent challenges are complex, costly, and can take three to six years to complete. As a result, we have in the past and may elect in the future to have partners on selected patent challenges. These arrangements typically provide for a sharing of the costs and risks, and generally provide for a sharing of the benefits of a successful outcome. In addition, our patent challenges may result in settlements that we believe are reasonable, lawful, and in our shareholders best interests.

Over the past couple of years the use of so-called authorized generics has increased significantly. Authorized generics involve the brand pharmaceutical maker either marketing a generic version of its brand product itself or licensing its brand drug to a company which then markets it as a generic product. Because the authorized generic is not sold under an ANDA, but rather is sold under the brand pharmaceutical maker s NDA, the courts have held it can compete against the patent challenger s generic product during the 180-day exclusivity period that results from a patent challenge.

# Patent Challenge Process

The Hatch-Waxman Act offers an incentive to generic pharmaceutical companies that challenge suspect patents on branded pharmaceutical products. The legislation recognizes that there is a potential for non-infringement of an existing patent or the improper issuance of patents by the United States Patent and Trademark Office, or PTO, resulting from a variety of technical, legal, or scientific factors. The Hatch-Waxman legislation places significant burdens on the challenger to ensure that such suits are not frivolous, but also may offer the opportunity for significant financial reward if successful.

All of the steps involved in the filing of an ANDA with the FDA, including research and development, are identical with those taken in development of any generic drug. At the time an ANDA is filed with the FDA, the generic company that wishes to challenge the patent files a paragraph IV certification. After receiving notice from the FDA that its application is accepted for filing, the generic company sends the patent holder and NDA owner a notice explaining why it believes that the patents in question are invalid, unenforceable, or not infringed. If the patent holder and NDA owner bring suit in federal district court against the generic company to enforce the challenged patent within 45 days of the receipt of the notice from the generic company, the Hatch-Waxman Act provides for an automatic stay of the FDA s authority to grant the approval that would otherwise give the patent challenger the right to market its generic product. This stay is set at 30 months, or such shorter or longer period as may be ordered by the court. The 30 months may or may not, and often does not, coincide with the timing of a trial or the expiration of a patent. The discovery, trial, and appeals process can take several years.

# **Table of Contents**

Under the Hatch-Waxman Act, the developer of a generic drug that files the first ANDA containing a paragraph IV certification may be eligible to receive a 180-day period of generic market exclusivity. This period of market exclusivity may provide the patent challenger with the opportunity to earn a return on the risks taken and its legal and development costs.

The FDA adopted regulations implementing the 180-day generic marketing exclusivity provision of the Hatch-Waxman Act. However, over the years, courts have found various provisions of the regulations to be in conflict with the statute. For example, in *Mova Pharmaceutical Corp. v. Shalala*, 140 F.3d 1060 (D.C. Cir. 1998), the court of appeals held that the Hatch-Waxman Act required generic exclusivity to be awarded to the first generic company to file an ANDA containing a paragraph IV certification, regardless of whether that company prevailed in a court challenge to the relevant patent before another company was ready for approval. In contrast, the FDA s regulations had required the first patent challenger to successfully defend its challenge to the patent before another generic company was ready to receive approval. In *Mylan Pharmaceuticals v. Shalala*, 81 F. Supp. 2d 30 (D.D.C. 2000), the court found that the statute requires the 180-day generic period to commence on the date of the first court decision in favor of the generic applicant, even if the first successful decision was a district court decision finding the challenged patent invalid, unenforceable, or not infringed and the innovator company appealed the court s decision. The decision was in contrast to the FDA s regulation under which the exclusivity period would not commence until the appellate court affirmed the district court s invalidity, unenforceability, or non-infringement ruling.

In December 2003, the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) was signed into law that included provisions clarifying Hatch-Waxman and generic exclusivity related to patent challenges. The MMA includes several provisions regarding the patent challenge process designed to level the playing field for generic companies. Generally speaking, the MMA provisions apply when the first ANDA containing a paragraph IV certification was filed after December 8, 2003. These reforms included:

Only one 30-month stay allowed per drug.

Product-by-product exclusivity.

Shared 180-day exclusivity in limited circumstances.

Counterclaim for an Orange Book delisting allowed.

180-day exclusivity cannot be triggered by a district court decision.

First, under the MMA, only patents submitted to the FDA before an ANDA is filed can result in a 30-month stay. No additional 30-month stay can be obtained on patents listed in the Orange Book after the ANDA has been filed. Second, exclusivity is expressly on a product-by-product basis, meaning that there will only be one 180-day exclusivity period per listed drug. Third, because exclusivity is product-by-product, shared exclusivity will result only when multiple companies submit the first ANDA containing a paragraph IV certification on the same day. Fourth, ANDA applicants now have the ability to challenge the propriety of a patent listing. If an ANDA applicant is sued, the company can now bring a counterclaim seeking to have a patent delisted from the Orange Book. Finally, for ANDAs where the first paragraph IV certification was filed before December 8, 2003, the 180-day exclusivity period cannot be triggered by a district court decision that is on appeal. Where the first paragraph IV ANDA was submitted after the enactment of the MMA, exclusivity can only be triggered by the first ANDA filer s marketing of its own generic product or a product made by the brand company. While exclusivity could be forfeited as a result of a court decision, that court decision must either be an unappealed district court decision or an appellate court decision. Where the first paragraph IV ANDA was submitted before December 8, 2003, Congress reinstated FDA s prior interpretation of court decision, meaning that exclusivity for such applications can be triggered by first commercial marketing or by the appellate court s affirmance of an appealed district court s ruling.

# Our Patent Challenge History

Our efforts in the area of challenging patents on branded pharmaceutical products have resulted in the successful conclusion of 11 out of 13 cases as of June 30, 2005. Successful outcomes have included: court rulings in our favor

invalidating patents or finding that our product does not infringe; situations in which we have not been sued for patent infringement; and settlements with the patent holder. Unfavorable outcomes have resulted from a loss resulting in our not being able to launch our generic product until the patent on the brand pharmaceutical product expires.

22

#### **Table of Contents**

Examples of successful outcomes to our patent challenges include:

Niacin. Niacin is the generic equivalent of Kos Pharmaceuticals, Inc. s Niaspan product. In April 2005, we entered into Co-Promotion, Licensing and Manufacturing, and Settlement and License Agreements relating to the resolution of the patent litigation involving Kos Niaspan products. Under the terms of the agreements, we: (1) co-promote the current Niaspan® and Advicor® products (the Kos Products) to obstetricians, gynecologists and other practitioners with a focus on women s healthcare in the United States using our 43-person Duramed specialty sales force; (2) serve as a stand-by, alternate supply source for the Kos Products, and in exchange have received an upfront fee and will continue to receive quarterly fees thereafter; and (3) are able to launch generic versions of the Kos Products on September 20, 2013, about four years before the last of the applicable Kos patents is set to expire.

Mirtazapine orally disintegrating tablets. Mirtazapine is the generic equivalent of Organon, Inc. s Remeron Soltabs<sup>®</sup>. After the litigation against us was dismissed, we launched our Mirtazapine product in December 2003 and enjoyed 180 days of generic exclusivity.

*Ortho Tri-Cyclen*<sup>®</sup>. Ortho Tri-Cyclen is a regimen of oral contraceptives that includes three different tablet combinations of norgestimate and ethinyl estradiol. In August 2003 we settled pending litigation regarding Ortho-McNeil Pharmaceutical, Inc. s patents protecting Ortho Tri-Cyclen. Under the terms of the settlement, we launched our generic version of Ortho Tri-Cyclen on December 29, 2003, approximately three months prior to the expiration of pediatric exclusivity.

Fluoxetine. We invalidated the patent on Eli Lilly s Prozæ, which enabled us to launch our generic Fluoxetine product nearly three years earlier than would otherwise have been possible and recorded sales of approximately \$365 million in fiscal 2002 during the 180-day period granted to us under the Hatch-Waxman Act.

*Ciprofloxacin*. Ciprofloxacin is the generic name for Bayer's antibiotic Cipr®. In 1997, we entered into an agreement with Bayer to settle our patent challenge litigation under which we distributed a brand alternative Ciprofloxacin product from June 9, 2003 until June 9, 2004. We recorded sales of approximately \$111 million in fiscal 2003 and \$385 million in fiscal 2004.

Tamoxifen Citrate. Tamoxifen Citrate is the generic name for AstraZeneca s Nolvade<sup>®</sup>. In 1993, as a result of a settlement of a patent challenge against AstraZeneca, we entered into a non-exclusive supply and distribution agreement. Under the terms of the Tamoxifen agreement, we distributed a Tamoxifen Citrate product that we purchased directly from AstraZeneca. The Tamoxifen agreement expired in August 2002.

A loss in our patent litigation results in our not being able to launch our generic product until the patent on the brand pharmaceutical product expires. An example of this follows:

*Trazodone Hydrochloride*. Trazodone Hydrochloride is the generic name for Bristol-Myers Squibb s Desyrel. We had sought to bring our generic version of Desyrel to market but were unsuccessful in invalidating the patent. We launched our product in April 1999, following the expiration of the patent.

# **New Drug Application Process**

FDA approval is required before any new drug can be marketed. An NDA is a filing submitted to the FDA to obtain approval of a new drug and must contain complete pre-clinical and clinical safety and efficacy data or a right of reference to such data. Before dosing a new drug in healthy human subjects or patients may begin, stringent government requirements for pre-clinical data must be satisfied. The pre-clinical data, typically obtained from studies in animal species as well as from laboratory studies, are submitted in an Investigational New Drug, or IND, application, or its equivalent in countries outside the United States where clinical trials are to be conducted. The pre-clinical data must provide an adequate basis for evaluating both the safety and the scientific rationale for the initiation of clinical trials.

23

#### **Table of Contents**

Clinical trials are typically conducted in three sequential phases, although the phases may overlap.

In Phase I, which frequently begins with the initial introduction of the compound into healthy human subjects prior to introduction into patients, the product is tested for safety, adverse effects, dosage, tolerance absorption, metabolism, excretion and other elements of clinical pharmacology.

Phase II typically involves studies in a small sample of the intended patient population to assess the efficacy of the compound for a specific indication, to determine dose tolerance and the optimal dose range, and to gather additional information relating to safety and potential adverse effects.

Phase III trials are undertaken to further evaluate clinical safety and efficacy in an expanded patient population at typically dispersed study sites, in order to determine the overall risk-benefit ratio of the compound and to provide an adequate basis for product labeling.

Each trial is conducted in accordance with certain standards under protocols that detail the objectives of the study, the parameters to be used to monitor safety and the efficacy criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND. In some cases, the FDA allows a company to rely on data developed in foreign countries, or previously published data, which eliminates the need to independently repeat some or all of the studies.

Data from pre-clinical testing and clinical trials are submitted to the FDA as an NDA for marketing approval and to other health authorities as a marketing authorization application. The process of completing clinical trials for a new drug may take several years and require the expenditure of substantial resources. Preparing an NDA or marketing authorization application involves considerable data collection, verification, analysis and expense, and there can be no assurance that approval from the FDA or any other health authority will be granted on a timely basis, if at all. The approval process is affected by a number of factors, primarily the risks and benefits demonstrated in clinical trials as well as the severity of the disease and the availability of alternative treatments. The FDA or other health authorities may deny an NDA or marketing authorization application if the regulatory criteria are not satisfied, or such authorities may require additional testing or information.

Even after initial FDA or other health authority approval has been obtained, further studies, including Phase IV post-marketing studies, may be required to provide additional data on safety. The post-marketing studies could be used to gain approval for the use of a product as a treatment for clinical indications other than those for which the product was initially tested.

Also, the FDA or other regulatory authorities require post-marketing reporting to monitor the adverse effects of the drug. Results of post-marketing programs may limit or expand the further marketing of the products. Further, if there are any modifications to the drug, including changes in indication, manufacturing process or labeling or a change in the manufacturing facility, an application seeking approval of such changes must be submitted to the FDA or other regulatory authority. Additionally, the FDA regulates post-approval promotional labeling and advertising activities to assure that such activities are being conducted in conformity with statutory and regulatory requirements. Failure to adhere to such requirements can result in regulatory actions that could have an adverse effect on our business, results of operations and financial condition.

# **Drug Enforcement Agency**

Because we sell and are currently developing several other products that contain controlled substances, we must meet the requirements and regulations of the Controlled Substances Act, which are administered by the DEA. These regulations include stringent requirements for manufacturing controls and security to prevent diversion of or unauthorized access to the drugs in each stage of the production and distribution process. The DEA regulates allocation to us of raw materials used in the production of controlled substances based on historical sales data. We believe we are currently in compliance with all applicable DEA requirements.

24

#### **Table of Contents**

#### Medicaid

In November 1990, a law regarding reimbursement for prescribed Medicaid drugs was passed as part of the Congressional Omnibus Budget Reconciliation Act of 1990. The law requires drug manufacturers to enter into a rebate contract with the Federal Government. All generic pharmaceutical manufacturers whose products are covered by the Medicaid program are required to rebate to each state a percentage of their average net sales price for the products in question. These percentages are currently 11% in the case of products sold by us which are covered by an ANDA and 15% of products sold by us which are covered by an NDA. We accrue for these future estimated rebates in our consolidated financial statements.

We believe that federal and/or state governments may continue to enact measures in the future aimed at reducing the cost of providing prescription drug benefits to the public, particularly senior citizens. We cannot predict the nature of such measures or their impact on our profitability.

#### Medicare

Since June 2004, under the guidelines of the Medicare Part B benefit of the Medicare Prescription Drug Improvement and Modernization Act of 2003, we have been paying rebates on two of our proprietary products, Cenestin® and Trexall, to various managed care organizations and pharmacy benefit management companies (PBMs) that have received an endorsement from the Centers for Medicare and Medicaid Services (CMS) as sponsors of one or more established Medicare drug discount card programs. We have signed negotiated agreements with these entities under which we have agreed to pay rebates and, in some cases administrative fees, based on the wholesale acquisition cost (WAC) for units dispensed to eligible cardholders. In January 2006, a Medicare Part D prescription drug benefit will take effect. We expect to finalize negotiated rebate agreements involving Cenestin and/or Trexall with numerous Part D sponsors during the first half of fiscal 2006.

# **Seasonality**

Our business is not materially affected by seasonal factors.

#### **Backlog**

Due to the relatively short lead-time required to fill orders for our products, backlog of orders is not material to our business.

#### **Employees**

Our success depends on our ability to recruit and retain highly qualified scientific and management personnel. We face competition for personnel from other companies (including other pharmaceutical companies), academic institutions, government entities and other organizations. As of June 30, 2005, we had approximately 1,900 full-time employees. Approximately 90 of our employees are represented by Local 2-149 of the Paper, Allied, Chemical and Energy (PACE) Union International under a collective bargaining agreement that expires on March 31, 2011. We believe that our relations with our employees are good and we have no history of work stoppages.

# Competition

The pharmaceutical business is subject to intense competition. We compete with numerous branded and generic pharmaceutical companies and face competition for both our generic and proprietary products. Our competitors include:

the generic divisions and subsidiaries of brand pharmaceutical companies, including Sandoz US, a subsidiary of Novartis AG;

large independent domestic and international generic manufacturers including Mylan Laboratories, Watson Pharmaceuticals, Inc., Teva Pharmaceuticals and distributors with large product lines where there is competition with some of our products;

25

#### **Table of Contents**

brand pharmaceutical companies whose therapies compete with our generic and proprietary products, including Johnson & Johnson, Wyeth, Bristol-Myers Squibb and Eli Lilly & Company.

In the generic pharmaceutical environment, the expiration of patents and other market exclusivities results in generic competitors, including Barr, entering the marketplace. Normally, there is unit price decline as additional generic competitors enter the market and we may lose market share. The timing of price decreases is unpredictable and can result in a significantly curtailed period of profitability for a particular generic product. In addition, brand-name manufacturers frequently take actions to prevent or discourage the use of generic equivalents. These actions may include:

filing new patents on drugs whose original patent protection is about to expire;

developing patented second-generation products such as controlled-release products or other product improvements;

increasing marketing initiatives;

launching authorized generic versions of their branded products; and

commencing litigation.

Generic pharmaceutical market conditions have been affected by industry consolidation and a fundamental shift in industry distribution, purchasing and stocking patterns resulting in the increased importance of sales to major chain drug stores and major wholesalers and a concurrent reduction in sales to private label generic distributors.

Our proprietary pharmaceutical products compete with products manufactured by branded pharmaceutical companies in competitive markets throughout the United States and Canada. The competitive factors that impact this part of our business include product efficacy, safety, market acceptance, price, marketing effectiveness, patent protection, and research and development of new products. Our proprietary products often must compete with other products that already have an established position in the market. If competitors introduce new products, delivery systems or processes with therapeutic or cost advantages, our products could be subject to price reductions or decreased volume of sales, or both. Our proprietary products may also face competition from manufacturers of generic pharmaceuticals, following the expiration of non-patent product exclusivities or a successful challenge to our patents.

To ensure our ability to compete effectively, we:

focus our proprietary and generic product development in areas of historical strength or competitive advantage;

target generic products for development that have unique characteristics, including: difficulty in sourcing raw materials; difficulty in formulation or establishing bioequivalence; and manufacturing that requires unique facilities, processes or expertise;

develop innovative, cost-effective proprietary products that serve unmet medical needs; and

make significant investments in plant and equipment to improve our efficiency.

These strategies provide the basis for our belief that we will continue to remain a leading independent specialty pharmaceutical company.

26

#### **Table of Contents**

# **Insurance**

Our insurance coverage at any given time reflects market conditions, including cost and availability, existing at the time it is written, and the decision to obtain insurance coverage or to self-insure varies accordingly. If we were to incur substantial liabilities that are not covered by insurance or that substantially exceed coverage levels or accruals for probable losses, there could be a material adverse effect on our financial statements in a particular period.

We utilize a combination of self-insurance and traditional third-party insurance policies to cover product liability claims. On September 30, 2004, we elected to terminate the finite-risk insurance arrangement that we had in place for two years, and in connection with such termination increased our traditional third-party product liability coverage, as discussed below.

We maintain third-party insurance that provides coverage, subject to specified co-insurance requirements, for the cost of product liability claims arising during the current policy period, which began on October 1, 2004 and ends on September 30, 2005, between an aggregate amount of \$25 million and \$75 million. We are self-insured for the first \$25 million of costs incurred relating to product liability claims arising during the current policy period. In addition, we have obtained extended reporting periods under previous policies for claims arising prior to the current policy period. The current period and extended reporting period policies exclude certain products; we would be responsible for all product liability costs arising from these excluded products.

#### **Environmental**

We believe that our operations comply in all material respects with applicable laws and regulations concerning the environment. While it is impossible to predict accurately the future costs associated with environmental compliance and potential remediation activities, we do not expect compliance with environmental laws to require significant capital expenditures nor do we expect such compliance to have a material adverse effect on our consolidated financial statements.

#### **Government Relations Activities**

Because a balanced and fair legislative and regulatory arena is critical to the generic pharmaceutical industry, we have and will continue to place a major emphasis in terms of management time and financial resources on government affairs activities. We currently maintain an office and staff a full-time government affairs department in Washington, D.C., which has responsibility for coordinating state and federal legislative activities and coordinating with the generic industry trade association and other associations, such as the National Association of Chain Drug Stores, whose interests and goals are aligned with ours.

27

# **Table of Contents**

#### Item 2. Properties

We have facilities and operations in New York, New Jersey, Ohio, Pennsylvania, Virginia and Washington, D.C. The following table presents the facilities owned or leased by us as of June 30, 2005 and indicates the location and principal use of each of these facilities:

	Square		
Location	Footage	Status	Description
NEW JERSEY			
Woodcliff Lake	90,000	Leased	Administrative Offices
Upper Saddle River	20,000	Leased	Administrative Offices
Northvale	27,500	Owned	Manufacturing
Plainsboro	27,000	Leased	Research and Development, Administration
NEW YORK			
Pomona 1	41,000	Owned	Research and Development,
Pomona 2	133,000	Owned	Laboratories, Manufacturing Laboratories, Administrative Offices,
romona 2	133,000	Owned	Manufacturing, Warehouse
Blauvelt	8,500	Leased	Warehouse
Diauveit	8,500	Leased	w archouse
OHIO			
Cincinnati	290,000	Owned	Manufacturing, Laboratories, Packaging
PENNSYLVANIA			
Bala Cynwyd	39,000	Leased	Proprietary Research, Administrative
Bula Cylinya	37,000	Lousea	Offices
VIRGINIA			
Forest	375,000	Owned	Administrative Offices, Manufacturing,
			Warehouse, Packaging,
			Distribution, Laboratories,
			Adenovirus Manufacturing Facility
WASHINGTON D.C.	2,700	Leased	Government Affairs & Administrative
	2,700	Louised	Offices

Over the past three fiscal years, we have spent approximately \$183 million on capital expenditures primarily to increase our production, laboratory, warehouse and distribution capacity. We believe that our current facilities are in good condition and are being used productively. We constantly assess our ongoing investments in property, plant and equipment to ensure that our facilities are adequate for us to meet the expected demand of our pipeline products and to handle increases in current product sales.

28

#### **Table of Contents**

# Item 3. *Legal Proceedings*Patent Challenge Litigation

Desogestrel/Ethinyl Estradiol (Mircette®)

In May 2000, we filed an ANDA seeking approval from the FDA to market the tablet combination of desogestrel/ethinyl estradiol tablets and ethinyl estradiol tablets, the generic equivalent of Organon Inc. s Mircette oral contraceptive regimen. We notified Bio-Technology General Corp. (BTG), the owner of the patent for the Mircette product, pursuant to the provisions of the Hatch-Waxman Act and BTG filed a patent infringement action in the United States District Court for the District of New Jersey seeking to prevent us from marketing the tablet combination. In December 2001, the District Court granted summary judgment in our favor, finding that our product did not infringe the patent at issue in the case. BTG appealed the District Court s decision. In April 2002, we launched our Kariva® product, the generic version of Mircette. One year later, in April 2003, the U.S. Court of Appeals for the Federal Circuit reversed the District Court s decision granting summary judgment in our favor and remanded the case to the District Court for further proceedings on, among other things, the issue of whether our product infringes BTG s patent.

In July 2003, BTG (now Savient) filed an amended complaint adding Organon (Ireland) Ltd. and Organon USA as plaintiffs. The amended complaint seeks damages and enhanced damages based upon willful infringement. We filed an answer to BTG s amended complaint in July 2003. No trial date on the infringement and damages issue has been set. We believe that our product does not infringe BTG s patent and, because of this, we continue to market and sell Kariva. Nevertheless, Organon seeks to recover lost profits or a reasonable royalty of up to \$100 million from the date of launch through June 30, 2005. If BTG and Organon were to receive a favorable ruling in the District Court and that ruling were to be upheld on any further appeal, we could be liable for patent infringement, and the damages could be significant. Any such unfavorable outcome in the case could adversely affect our consolidated financial statements.

On June 15, 2005 we entered into a non-binding Letter of Intent (LOI), with Organon (Ireland) Ltd., Organon USA and Savient Pharmaceuticals, Inc. to acquire the NDA for Mircette, obtain an exclusive, royalty free license to sell Mircette and Kariva in the United States and dismiss all pending litigation between the parties in an exchange for a payment by us of up to \$155 million. The parties will not be contractually bound unless and until they negotiate and execute definitive agreements and the pending anti-trust review is satisfactorily resolved, as discussed below. If consummated, the transaction would permit us to promote Mircette through our Duramed sales force, which could increase sales of both Mircette and Kariva. If the transaction is not consummated, we expect to continue to vigorously defend our position in the Mircette litigation.

In July 2005, the parties made the required Hart Scott Rodino filings with the Federal Trade Commission (FTC) regarding the proposed transaction. On August 1, 2005, the FTC issued a second request, asking us and Organon to provide detailed information concerning the proposed transaction. The second request signals possible FTC concerns about the proposed transaction and creates additional uncertainty whether the transaction will be consummated on the proposed, or other terms.

The proposed transaction is contingent upon both satisfactory completion of the FTC s Hart Scott Rodino review and the negotiation of mutually satisfactory definitive agreements. However, because the proposed transaction includes as one of its components a payment in settlement of litigation, it is presumed under Generally Accepted Accounting Principles (GAAP) to give rise to a probable loss, as defined in Statement of Financial Accounting Standards No. 5, Accounting for Contingencies. In consultation with outside advisors and based on preliminary valuations of the assets we would acquire if the transaction closes on the terms presently contemplated, we have recorded a charge of \$63.2 million as of June 30, 2005 to reflect the proposed litigation settlement. We may reverse the charge, in whole or in part, in the future if the transaction does not close and we prevail in the litigation or are ultimately held liable for a lesser amount of damages. If the transaction does not close and an unfavorable verdict were to be rendered against us at trial, the ultimate amount of damages payable by us could be significantly more or less than the \$63.2 million charge we have recorded in connection with the proposed litigation settlement.

29

#### **Table of Contents**

# **Class Action Lawsuits**

### Ciprofloxacin

We were named as co-defendants with Bayer Corporation, The Rugby Group, Inc. and others in approximately 38 class action complaints filed in state and federal courts by direct and indirect purchasers of Ciprofloxacin (Cipro<sup>o</sup>) from 1997 to the present. The complaints alleged that the 1997 Bayer-Barr patent litigation settlement agreement was anti-competitive and violated federal antitrust laws and/or state antitrust and consumer protection laws. A prior investigation of this agreement by the Texas Attorney General s Office on behalf of a group of state Attorneys General was closed without further action in December 2001.

The lawsuits included nine consolidated in California state court, one in Kansas state court, one in Wisconsin state court, one in Florida state court, and two consolidated in New York state court, with the remainder of the actions pending in the United States District Court for the Eastern District of New York for coordinated or consolidated pre-trial proceedings (the MDL Case ).

On March 31, 2005, the Court in the MDL case granted summary judgment in our favor and dismissed all of the federal actions before it. On June 7, 2005, plaintiffs filed notices of appeal to the United States Court of Appeals, but a briefing schedule and argument date have not yet been set.

On September 19, 2003, the Circuit Court for the County of Milwaukee dismissed the Wisconsin state class action for failure to state a claim for relief under Wisconsin law. Plaintiffs appealed, but the appeal has been stayed pending a decision by the Wisconsin Supreme Court in another case involving similar legal issues. On October 17, 2003, the Supreme Court of the State of New York for New York County dismissed the consolidated New York state class action for failure to state a claim upon which relief could be granted and denied the plaintiffs motion for class certification. Plaintiffs have appealed that decision, with briefing scheduled to occur in summer 2005. On April 13, 2005, the Superior Court of San Diego, California ordered a stay of the California state class actions until after the resolution of any appeal in the MDL case. On April 22, 2005, the District Court of Johnson County, Kansas similarly stayed the action before it, until after any appeal in the MDL case. The Florida state class action remains at a very early stage, with no status hearings, dispositive motions, pre-trial schedules, or a trial date set as of yet.

We believe that our agreement with Bayer Corporation reflects a valid settlement to a patent suit and cannot form the basis of an antitrust claim. Based on this belief, we are vigorously defending ourselves in these matters. We anticipate that these matters may take several years to resolve, and although it is not possible to forecast the outcome of these matters, an adverse judgment in any of the pending cases could adversely affect our consolidated financial statements.

### **Tamoxifen**

To date approximately 31 consumer or third-party payer class action complaints have been filed in state and federal courts against Zeneca, Inc., AstraZeneca Pharmaceuticals LP and Barr alleging, among other things, that the 1993 settlement of patent litigation between Zeneca, Inc. and Barr violated the antitrust laws, insulates Zeneca, Inc. and us from generic competition and enables Zeneca, Inc. and Barr to charge artificially inflated prices for Tamoxifen citrate. A prior investigation of this agreement by the U.S. Department of Justice was closed without further action.

The Judicial Panel on Multidistrict Litigation has transferred these cases to the United States District Court for the Eastern District of New York for pretrial proceedings. On May 19, 2003, the District Court entered judgment dismissing the cases for failure to state a viable antitrust claim. Plaintiffs have filed an appeal, which is currently pending in the United States Court of Appeals for the Second Circuit.

We believe that our agreement with Zeneca reflects a valid settlement to a patent suit and cannot form the basis of an antitrust claim. Although it is not possible to forecast the outcome of this matter, we intend to vigorously

#### **Table of Contents**

defend ourselves. We anticipate that this matter may take several years to resolve, but an adverse judgment could adversely affect our consolidated financial statements.

# Hormone Therapy Litigation

We have been named as a defendant in approximately 3,100 personal injury product liability cases brought against us and other manufacturers by plaintiffs claiming that they suffered injuries resulting from the use of certain estrogen and progestin medications prescribed to treat the symptoms of menopause. The cases against Barr and our subsidiary Duramed involve either or both of our Cenestin product or the use of our medroxyprogesterone acetate product, which typically has been prescribed for use in conjunction with Premarin or other hormone therapy products. All of these products remain approved by the FDA and continue to be marketed and sold to customers. While we have been named as defendants in these cases, fewer than a third of the complaints actually allege the plaintiffs took a product manufactured by us, and our experience to date suggests that, even in these cases, a high percentage of the plaintiffs will be unable to demonstrate actual use of a Barr and/or Duramed product. For that reason, by the end of June 30, 2005, nearly 1,500 of the 3,100 cases had been dismissed and, based on discussions with our outside counsel, several hundred more are expected to be dismissed in the near future.

We believe that we have viable defenses to the allegations in the complaints and are defending our actions vigorously.

#### Medicaid Reimbursement Cases

We have been named, along with numerous other pharmaceutical companies, as a defendant in separate actions brought by the states of Alabama, Kentucky and Illinois, the Commonwealth of Massachusetts, the City of New York, and the following counties in New York: Albany, Allegany, Broome, Cattaraugus, Cayuga, Chautauqua, Chenango, Erie, Fulton, Genesee, Greene, Herkimer, Jefferson, Madison, Monroe, Nassau, Niagara, Oneida, Onondaga, Putnam, Rensselaer, Rockland, Saratoga, St. Lawrence, Steuben, Suffolk, Tompkins, Warren, Washington, Wayne, Westchester, and Yates. In each of these matters, the plaintiffs seek to recover damages and other relief for alleged overcharges for prescription medications paid for or reimbursed by their respective Medicaid programs. We believe that we have not engaged in any improper conduct and are vigorously defending ourselves.

The Commonwealth of Massachusetts case and the New York cases, with the exception of the action filed by Erie County, are currently pending in the United States District Court for the District of Massachusetts. Those actions are at an early stage with no trial dates set. The Erie County case is currently stayed in the United States District Court for the Western District of New York, and the Judicial Panel on Multi-District Litigation has been asked to transfer the action to the District of Massachusetts.

The Alabama case was filed in Alabama state court, removed to the United States District Court for the Middle District of Alabama, and recently returned to state court with no trial date currently set. The Illinois case was filed in Illinois state court and recently removed to the United States District Court for the Northern District of Illinois, with a pending motion to return the case to state court and no trial date currently set. The Kentucky case was filed in Kentucky state court and recently removed to the United States District Court for the Eastern District of Kentucky, with a pending motion to return the case to state court and no trial date currently set.

#### Other

As of June 30, 2005, Barr Pharmaceuticals and its subsidiaries were involved in various other disputes, governmental inquiries, investigations and proceedings, and litigation matters that arise from time-to-time in the ordinary course of business, some of which may involved substantial damages. The process of resolving matters through litigation or other means is inherently uncertain and it is possible that the resolution of these matters will adversely affect our consolidated financial statements.

# Item 4. Submission of Matters to a Vote of Security Holders

There were no matters put to the vote of our shareholders during the quarter ended June 30, 2005.

31

#### PART II

# Item 5. Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our common stock is traded on the New York Stock Exchange under the symbol BRL. The following table sets forth the quarterly high and low share trading price information for the periods indicated (as adjusted for the three-for-two stock split effected in the form of a 50% stock dividend in March 2004):

	High	Low
Fiscal year ended June 30, 2005:	_	
First quarter	\$ 42.80	\$ 32.01
Second quarter	46.90	35.07
Third quarter	50.45	43.71
Fourth quarter	54.29	47.00
Fiscal year ended June 30, 2004:		
First quarter	\$ 50.33	\$ 38.83
Second quarter	56.91	45.17
Third quarter	53.99	45.70
Fourth quarter	49.25	32.89

As of August 30, 2005, we estimate that there were approximately 1,567 holders of record of our common stock. We believe that a significant number of investors in our common stock hold their shares in street name. Therefore, the number of beneficial owners of our common stock is much greater than the number of record holders of our common stock.

We have not paid any cash dividends on our common stock in the last two fiscal years and we do not anticipate paying any cash dividends in the foreseeable future.

In April 2005, holders of warrants to purchase an aggregate of 288,226 shares of our common stock, at \$9.54 per share, exercised the warrants in full. As a result, we issued to the investors 288,226 unregistered shares of our common stock and received proceeds of \$2,749,676. The issuance of the shares to the investors was based on the exemption from registration under Section 4(2) of the Securities Act.

In March 2004, holders of warrants to purchase an aggregate of 3,375,000 shares of our common stock, consisting of 1,687,500 shares at \$13.93 per share and 1,687,500 shares at \$16.89 per share, exercised the warrants in full through a cashless exercise. As a result, we issued to the investors 2,340,610 unregistered shares of our common stock. We did not receive any proceeds from the issuance of the shares. The issuance of the shares to the investors was based on the exemption from registration under Section 4(2) of the Securities Act.

32

#### **Table of Contents**

#### Item 6. Selected Financial Data

The following data has been derived from our consolidated financial statements and should be read in conjunction with those statements, which are included in Item 8 of this report, together with Management s Discussion and Analysis of Financial Condition and Results of Operations included in Item 7 of this report.

		Ţ	Year Ended June 3	30,	
	2005	2004	2003	2002	2001 (1)
		(in thous	ands, except per s	share data)	
Statements of					
Operations Data					
Total revenues	\$ 1,047,399	\$ 1,309,088	\$ 902,864	\$ 1,188,984	\$ 593,151
Earnings before income					
taxes	329,876	194,440	262,715	337,537	101,793
Income tax expense	114,888	71,337	95,149	125,318	38,714
Net earnings applicable					
to common shareholders	214,988	123,103	167,566	210,269	62,566
Earnings per common					
share basic	2.08	1.21	1.69(4)	2.17(4)(5)	0.66(4)(5)
Earnings per common					
share diluted	2.03	1.15	1.62(4)	2.06(4)(5)	0.63(4)(5)
<b>Balance Sheet Data</b>					
Working capital	\$ 780,386	\$ 670,601	\$ 582,183	\$ 457,393	\$ 313,101
Total assets	1,482,846	1,333,269	1,180,937	888,554	666,516
Long-term debt (2)	15,493	32,355	34,027	42,634	65,563
Shareholders equity (3)	1,233,970	1,042,046	867,995	666,532	416,777

- (1) Financial data presented for the fiscal year ended June 30, 2001 has been restated to include the historical financial data of Duramed, which Barr acquired in October 2001.
- (2) Includes capital leases and excludes current installments.
- (3) The Company has not paid a cash dividend in any of the above

years.

(4) Amounts have been adjusted for the March 16, 2004 3-for-2 stock split effected in the form of a 50% stock dividend (See Note 1 to the consolidated financial statements).

(5) Amounts have been adjusted for the March 17, 2003 3-for-2 stock split effected in the form of a 50% stock dividend (See Note 1 to the consolidated financial

statements).

33

#### **Table of Contents**

# Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations Executive Overview

We are a specialty pharmaceutical company that develops, markets and sells both generic and proprietary (or branded) pharmaceutical products. We have a deep, diverse and profitable generic product portfolio, and have diversified our operations by developing and acquiring several proprietary products. Sales of generic products accounted for 73% of our product sales in fiscal 2005, while sales of our proprietary products grew from \$57.7 million in fiscal 2003, accounting for just 6% of our product sales that year, to \$278.8 million in fiscal 2005, accounting for 27% of product sales.

#### Generic Products

For many years, we have successfully utilized a strategy of developing the generic versions of branded products that possess some combination of unique factors that we believe have the effect of limiting competition for generics. Such factors include difficult formulation, complex and costly manufacturing requirements or limited raw material availability. To date, our strategy has focused on developing solid oral dosage forms of products. By targeting products with some combination of these unique factors, we believe that our generic products will, in general, be less affected by the intense and rapid pricing pressure often associated with more commodity-type generic products. As a result of this focused strategy, we have been able to successfully identify, develop and market generic products that generally have few competitors or that are able to enjoy longer periods of limited competition and thus generate profit margins higher than those often associated with commodity-type generic products. The development and launch of our generic oral contraceptive products is an example of our generic development strategy. While we believe there are more tablet and capsule products that may fit our barrier-to-entry criteria, we recognize that finding highly profitable generic tablet and capsule products that will grow our generics business is difficult. As a result, we have recently expanded our development resources to include non-tablet and capsule products (such as patches, sterile ophthalmics and nasal sprays).

Challenging the patents covering certain brand products continues to be an important component of our generic strategy. For many products, the patent provides the unique barrier that we seek to identify in our product selection process. We try to be the first company to initiate a patent challenge because in certain cases, we may be able to obtain 180 days of exclusivity for selling the generic version of the product. For example, this occurred with fluoxetine, our generic version of Eli Lilly s Prozae. If we do receive exclusivity for a product, we typically experience significant revenues and profitability associated with that product for the six-month exclusivity period, but at the end of that period experience significant decreases in our revenues and market share associated with the product as other generic competitors enter the market. This happened with our fluoxetine product after expiration of our generic exclusivity period. Our record of successfully resolving patent challenges has contributed to our growth, but has created periods of revenue and earnings volatility and will likely do so in the future. While earnings and cash flow volatility may result from the launch of products subject to patent challenges, we remain committed to this part of our business.

Macroeconomic factors also continue to favor the use of generic pharmaceutical products. The aging population, rising health care costs and the vigilance of health care providers, insurance companies and others to lower such costs have helped drive an increase in the substitution of lower-cost generic products for higher-cost brand products. As evidence of this, the percentage of overall prescriptions filled with generic products grew from 43% in 2000 to 53% by 2004, and is predicted to continue to rise in the future.

#### **Proprietary Products**

To help diversify our existing revenue base and to provide for additional long-term opportunities, we initiated a program more than five years ago to develop and market proprietary pharmaceutical products. We formalized this program in 2001 by establishing Duramed Research. Today we have a substantial number of employees dedicated to the development and marketing of our proprietary products including approximately 300 sales representatives that promote directly to physicians four of our products and two products related to the Co-Promotion Agreement with Kos Pharmaceuticals. In addition, we sell but do not actively market seven other proprietary products.

#### **Table of Contents**

Growth in proprietary product sales over the last three fiscal years has been accomplished through product acquisitions and through higher sales of our first internally-developed proprietary product, SEASONALEÒ.

# Competition

One of our greatest challenges is continuing to stay ahead of the competition, both for generic and proprietary products. Our successful generic product strategy has attracted new competitors seeking to launch competing generic products as well as to be first to file for potentially lucrative patent challenges. For example, other generic pharmaceutical companies have recently started developing and marketing competing generic oral contraceptives in order to capture some of our market share. In addition, there has been an increase in the number of competitors in the generic industry that are based outside U.S., with several of such competitors based in India. Many of these companies claim to have equivalent technological capabilities to U.S.-based generic companies but at significant cost advantages over their U.S. counterparts.

Also, as a detriment to the value of the patent challenge strategy of Barr and other leading generic manufacturers, brand pharmaceutical companies continue to partner with certain generic drug companies to license a so-called authorized generic to the generic drug company. The use of authorized generics by certain brand and generic companies undermines the value of the 180 day exclusivity period enjoyed by the first company to file an ANDA containing a Paragraph IV certification by providing another company with the ability to have the generic product on the market at the same time.

Finally, as our proprietary pharmaceutical products grow, we anticipate that competing generic pharmaceutical companies will challenge the patents protecting our branded products. For example, one of our competitors, Watson, has filed a Paragraph IV certification challenging the patent on SEASONALE.

To address these and other challenges, we continue to (1) invest aggressively in research and development, (2) develop and launch new generic and proprietary products and (3) maintain an active acquisition and licensing effort to complement our internal development activities.

# Comparison of the fiscal years ended June 30, 2005 and June 30, 2004

The following table sets forth revenue data for the fiscal years ended June 30, 2005 and 2004 (\$ s in millions):

			Change		
	2005	2004	\$	%	
Generic products:					
Distributed alternative brands(1)	\$	\$ 385.3	(385.3)	-100%	
Oral contraceptives	396.6	403.9	(7.3)	-2%	
Other generic(2)	354.8	361.4	(6.6)	-2%	
Total generic products	751.4	1,150.6	(399.2)	-35%	
Proprietary products	278.8	146.1	132.7	91%	
Total product sales	1,030.2	1,296.7	(266.5)	-21%	
Alliance, development and other revenue	17.2	12.4	4.8	39%	
Total revenues	\$ 1,047.4	\$ 1,309.1	\$ (261.7)	-20%	

(1) Reflects sales of
Ciprofloxacin
sold during
Bayer s pediatric
exclusivity
period which
ended on

June 9, 2004.

(2) Includes sales of Ciprofloxacin after June 9, 2004.

35

#### **Table of Contents**

### **Revenues Product Sales**

Product sales for the year ended June 30, 2005 decreased as compared to the prior year primarily due to the expected decline in sales of our distributed version of Ciprofloxacin, as discussed in detail below. Partially offsetting the decrease in Ciprofloxacin sales was a significant increase in sales of our proprietary products.

## Generic Products

Distributed Alternative Brands (Ciprofloxacin)

On June 9, 2003 we began distributing Ciprofloxacin hydrochloride tablets and oral suspension pursuant to a license from Bayer Corporation obtained under a 1997 settlement of a patent challenge we initiated regarding Bayer s Cipro<sup>â</sup> antibiotic. In September 2003, we entered into an amended supply agreement with Bayer that enabled us to distribute Ciprofloxacin during and after Bayer s period of pediatric exclusivity, which ended on June 9, 2004. As a result of the exclusivity we enjoyed, Ciprofloxacin was our largest selling product in fiscal 2004. We have shared and continued to share one-half of our profits, as defined, from the sale of Ciprofloxacin with Aventis, the contractual successor to our partner in the Cipro patent challenge case. Upon expiration of Bayer s period of pediatric exclusivity on June 9, 2004, as expected, several other competing Ciprofloxacin products were launched. As a result of the flood of competing products, our market share and product pricing declined dramatically for Ciprofloxacin almost immediately. Since the expiration of the exclusivity period, we have included sales of Ciprofloxacin in the Other generic line item in the table above. Such sales were not significant for fiscal 2005. *Oral Contraceptives* 

Sales of our generic oral contraceptive products decreased 2% in fiscal 2005 compared to fiscal 2004. Price declines and lower volumes resulting from additional competitors reduced sales on certain of our products, mainly Apri and Aviane, and a slowdown in the growth rate of generic substitution more than offset (1) full year contributions from products launched during fiscal 2004, (2) two new products launched in fiscal 2005 and (3) market share gains on other existing products.

Oral contraceptives are the most common method of reversible birth control, used by up to 82% of women in the United States at some time during their reproductive years. Oral contraceptives have a long history with widespread use attributed to many factors including efficacy in preventing pregnancy, safety and simplicity in initiation and discontinuation, medical benefits and relatively low incidence of side effects. From fiscal 2002 to fiscal 2004, sales of our generic oral contraceptive products more than quadrupled. This growth was fueled by new product launches, the addition of new customers and by increasing rates of generic substitution. We currently manufacture and market 22 generic oral contraceptive products under trade names, two of which we launched during the fiscal year ended June 30, 2005. This portfolio now represents nearly all oral contraceptives that are eligible for generics. Additionally, the growth in generic substitution rates for this heavily genericized portfolio of products slowed, even as we continued to gain market share on certain products within the portfolio. We anticipate that these trends will continue in fiscal 2006 as competitors launch new products and as the portfolio continues to experience a slowing of overall growth in generic substitution. However, despite our expectation that sales of our generic oral contraceptive portfolio will decline in fiscal 2006 versus fiscal 2005, we believe that we are well positioned to maintain market share for many of our products and that our portfolio of oral contraceptives will continue to be a significant component of our revenues in fiscal 2006.

### Generic Products Other

Sales of other generic products decreased 2% in fiscal 2005 as compared to the prior year period, as sales from new products launched since the end of last year, including Didanosine and Metformin XR 750mg, were more than offset by declines in other existing product sales. The decline in other existing product sales was primarily due to a significant decrease in sales of our Dextroamphetamine group of products due to both declining volumes and lower prices caused by the launch of competing versions in late 2004. In April 2005, our generic exclusivity period on Metformin XR 750mg ended and several other generic companies launched competing versions of the product. As a result, we experienced a significant decline in sales of Metformin XR 750mg and would expect that decline to continue during fiscal 2006. However, we expect that higher sales of Didanosine and sales from our generic version of DDAVP, which we launched in July 2005, will more than offset these declines leading to higher sales of our other generic products in

fiscal 2006.

### **Proprietary Products**

Sales of our proprietary products almost doubled in fiscal 2005 as compared to the prior year. This increase relates primarily to: (1) higher sales of Seasonale, which totaled \$87.2 million for the fiscal year, reflecting higher unit sales in support of prescription growth and higher pricing compared to last year; (2) full year sales of Loestrin/Loestrin Fe and Plan B which we acquired in February 2004 and March 2004, respectively; and (3) sales of Nordette and Prefest, which we acquired in November 2004 and December 2004, respectively.

Seasonale prescriptions, according to IMS data, topped 800,000 for our fiscal year ended June 30, 2005, a 370% increase over prescriptions in the prior fiscal year. This increase is a direct result of our significant marketing initiatives, including direct-to-consumer advertising and the detailing efforts by our Women s Healthcare Sales force. While we look for growth in fiscal 2006 for Seasonale prescriptions and sales, we expect much lower growth rates than those achieved in fiscal 2005.

We have been active in acquiring proprietary products over the last two fiscal years and the contribution from those products has increased our proprietary revenues substantially over that period. Certain of the products which we have acquired no longer enjoy patent protection and are experiencing declining prescription volumes. As a result, while these products are expected to still generate healthy margins and predictable cash flows, we do not expect them to generate the year-over-year sales growth we experienced in fiscal 2005. In fact, some may show year-over-year decreases in sales. As a result, growth in our proprietary product sales in fiscal 2006 will be mainly dependent on growth in Seasonale, Cenestin and Plan B, and the launch of our Enjuvia product during the second half of fiscal 2006.

#### **Cost of Sales**

Our cost of sales includes the cost of products we purchase from third parties, our manufacturing and packaging costs for products we manufacture, profit sharing or royalty payments made to third parties, including raw material suppliers and any changes to our inventory reserve. Amortization costs arising from the acquisition of product rights and our distribution costs are included in selling, general and administrative costs.

Product mix plays a significant role in our quarterly and annual overall gross margin percentage. In the past, our overall gross margins have been negatively impacted by sales of lower-margin distributed versions of products such as Ciprofloxacin and Tamoxifen, which were manufactured for us by brand companies and distributed by us under the terms of the respective patent challenge settlement arrangements.

The following table sets forth cost of sales data in dollars as well as the resulting gross margins, for the two years ended June 30, 2005 and 2004 (\$ s in millions):

			Change	
	2005	2004	\$	<b>%</b>
Generic products	\$ 264.8	\$ 604.6	\$ (339.8)	-56%
Gross margin	65%	47%		
Proprietary products	\$ 39.3	\$ 28.1	\$ 11.2	40%
Gross margin	86%	81%		
Total cost of sales	\$ 304.1	\$ 632.7	\$ (328.6)	-52%
Gross margin	70%	51%		

The decrease in total cost of sales, on a dollar basis, for the year ended June 30, 2005, as compared to the prior year, was primarily due to the year-over-year decrease in sales of Ciprofloxacin, which in the prior year we had purchased from Bayer.

#### **Table of Contents**

Margins on our generic products increased significantly in fiscal 2005 due mainly to the decrease in year-over-year distributed Ciprofloxacin sales. As a distributed product for which we shared the profits with our partner in the Cipro patent challenge, Ciprofloxacin had a higher cost of sales and a lower margin than our other products.

Margins on our proprietary products increased in fiscal 2005 compared to fiscal 2004 due to increased sales of higher margin products, primarily Seasonale and Loestrin/Loestrin Fe.

# Selling, General and Administrative Expense

The following table sets forth selling, general and administrative expense data for the two years ended June 30, 2005 and 2004 (\$ s in millions):

			Chan	ge
	2005	2004	\$	%
Selling, general and administrative	\$ 298.9	\$ 314.5	\$ (15.6)	-5%
Charges included in general and administrative	\$ 63.2	\$ 96.6	\$ (33.4)	-35%

Lower selling, general and administrative expenses in fiscal 2005 compared to last year were primarily due to lower 2005 charges compared to 2004 charges partially offset by (1) \$8.1 million in higher marketing costs in fiscal 2005 associated with our proprietary product portfolio and (2) \$7.1 million in higher product intangible amortization expense in fiscal 2005 due to full year amortization on products purchased in the prior year and amortization of products purchased in the current year.

Charges taken in the twelve months ended June 30, 2004 and 2005 are as follows: *Fiscal 2004:* 

- (1) A \$16 million valuation allowance we established in September 2003 for our loans to Natural Biologics, LLC, the raw material supplier for our generic equine-based conjugated estrogens product, as the result of an unfavorable court decision rendered in September 2003;
- (2) The February 2004 write-off of \$4.2 million associated with the acquisition of certain emergency contraception assets from Gynetics, Inc;
- (3) An arbitration panel s decision in June 2004 to award Solvay Pharmaceuticals, Inc. \$68 million in damages on a claim that we improperly terminated an agreement with Solvay; and
- (4) An \$8.5 million charge in June 2004 related to costs associated with our settlement of the Estrostep and Femhrt patent challenge litigation against Galen.

Fiscal 2005:

On June 15, 2005 we entered into a non-binding Letter of Intent (LOI) with Organon (Ireland) Ltd., Organon USA and Savient Pharmaceuticals, Inc. to acquire the NDA for Mircette, obtain an exclusive royalty free license to sell Mircette and Kariva in the United States and dismiss all pending litigation between the parties in exchange for a payment by us of up to \$155 million. The parties will not be contractually bound unless and until they negotiate and execute definitive agreements. If consummated, the transaction would permit us to promote Mircette through our Duramed sales force, which could increase sales of both Mircette and Kariva. If the transaction is not consummated, we expect to continue to vigorously defend our position in the Mircette litigation.

In July 2005, the parties made the required filings with the Federal Trade Commission (FTC) regarding the proposed transaction. On August 1, 2005, the FTC issued a second request, asking the parties to provide detailed information concerning the proposed transaction.

38

#### **Table of Contents**

The proposed transaction is contingent upon both satisfactory completion of the FTC s Hart Scott Rodino review and the negotiation of mutually satisfactory definitive agreements. However, because the proposed transaction includes, as one of its components, a payment in settlement of litigation, it is presumed under GAAP to give rise to a probable loss, as defined in Statement of Financial Accounting Standards No. 5, Accounting for Contingencies. In consultation with outside advisors and based on preliminary valuations of the assets we would acquire if the transaction closes on the terms presently contemplated, we have recorded a charge of \$63.2 million as of June 30, 2005 to reflect the proposed litigation settlement. We may reverse the charge, in whole or in part, in the future if the transaction does not close and we prevail in the litigation or are ultimately held liable for a lesser amount of damages. If the transaction does not close and an unfavorable verdict were to be rendered against us at trial, the ultimate amount of damages payable by us could be significantly more or less than the \$63.2 million charge we have recorded in connection with the propose litigation settlement.

# **Research and Development**

The following table sets forth research and development expenses for the two years ended June 30, 2005 and 2004 (\$ s in millions):

			Change	e
	2005	2004	\$	<b>%</b>
Research and development	\$ 128.4	\$ 169.0	\$ (40.6)	-24%
Charges included in research and development	\$	\$ 68.2	\$ (68.2)	-100%

For the year ended June 30, 2004 our total research and development costs reflected charges relating to strategic acquisitions or similar activities including: (1) a write-off of \$22 million in March 2004 resulting from our agreement to acquire Schering s rights and obligations under a Product Development and License Agreement that had been capitalized at the time of our acquisition of Enhance Pharmaceuticals, Inc. in June 2002; (2) a write-off of \$10 million for in-process research and development acquired in connection with our acquisition of Women s Capital Corporation in February 2004; and (3) a write-off of \$36 million of in-process research and development costs in connection with our purchase of substantially all of the assets of Endeavor Pharmaceuticals, Inc. in November 2003.

The remaining \$28 million increase in research and development for the year ended June 30, 2005 as compared to the prior year was primarily due to: (1) \$9.1 million in higher third party development costs, including a \$5.0 million payment to PLIVA related to the development, supply and marketing agreement that we entered into in March 2005 for the generic biopharmaceutical Granulocyte Colony Stimulating Factor (G-CSF); (2) \$9.4 million in higher bioequivalence study costs, reflecting both an increase in the number and the cost of the studies; (3) \$5.0 million in higher internal production costs in support of internal development projects; and (4) \$4.5 million in higher headcount costs in support of the increased number of products in development.

# **Income Taxes**

The following table sets forth income tax expense and the resulting effective tax rate stated as a percentage of pre-tax income for the two years ended June 30, 2005 and 2004 (\$ s in millions):

			Change		
	2005	2004	\$	%	
Income tax expense	\$ 114.9	\$ 71.3	\$ 43.6	61%	
Effective tax rate	34.8% 39	36.7%			

#### **Table of Contents**

The effective tax rate for fiscal 2005 was favorably impacted by the completion of several tax audits, the change of the mix in income between various taxing jurisdictions and the enactment of favorable tax legislation in certain jurisdictions.

As indicated above, we have recently completed an audit by the IRS for our federal income tax returns for fiscal years 2002 and 2003. The resolution favorably impacted our effective tax rate for the fiscal year but did not have a material effect on our financial position or liquidity. Periods prior to 2002 have either been audited or are no longer subject to audit. We are currently being audited by the IRS for our fiscal year ended June 30, 2004.

# Comparison of the fiscal years ended June 30, 2004 and June 30, 2003

The following table sets forth revenue data for the fiscal years ended June 30, 2004 and 2003 (\$ s in millions):

			Change	
	2004	2003	\$	<b>%</b>
Generic products:				
Distributed alternative brands:(1)				
Ciprofloxacin	\$ 385.3	\$ 111.4	273.9	246%
Tamoxifen (2)		112.5	(112.5)	-100%
Oral contraceptives	403.9	274.4	129.5	47%
Other generic (3)	361.4	338.9	22.5	7%
Total generic products	1,150.6	837.2	313.4	37%
Proprietary products	146.1	57.7	88.4	153%
Total product sales	1,296.7	894.9	401.8	45%
Alliance, development and other revenue	12.4	8.0	4.4	55%
Total revenues	\$ 1,309.1	\$ 902.9	\$ 406.2	45%

- (1) Distributed alternative brands are distributed by us under terms of agreements entered into as part of patent challenge settlements. Therefore, for reporting purposes, they are classified as Generic products.
- (2) Refects sales of Tamoxifen acquired from innovator.

(3) Includes sales of Tamoxifen manufactured by Barr.

# **Revenues Product Sales**

Product sales for the year ended June 30, 2004 increased as compared to the prior year primarily due to the sales of our distributed version of Ciprofloxacin and to increased sales of our generic and proprietary products, which more than offset the large decline in sales of our distributed version of Tamoxifen.

### **Generic Products**

Ciprofloxacin

On June 9, 2003, we began distributing Ciprofloxacin hydrochloride tablets and oral suspension pursuant to a license from Bayer obtained under a 1997 settlement of a patent challenge we initiated against Bayer s Ciprô antibiotic. In September 2003, we signed an Amended Supply Agreement with Bayer that enabled us to distribute Ciprofloxacin during and after Bayer s period of pediatric exclusivity, which ended on June 9, 2004. As a result, Ciprofloxacin was our largest selling product in fiscal 2004. We have shared one-half of our profits, as defined,

40

# **Table of Contents**

from the sale of Ciprofloxacin with Aventis, the contractual successor to our partner in the Cipro patent challenge case. Bayer s period of pediatric exclusivity expired on June 9, 2004 and, as we expected, several other competing Ciprofloxacin products were launched.

Tamoxifen

For most of the first six months of fiscal 2003 we sold a distributed version of Tamoxifen that we purchased from AstraZeneca under the terms of a 1993 Supply and Distribution Agreement entered into as part of a patent challenge settlement. This Agreement ended in December 2002. We began selling our manufactured Tamoxifen product when AstraZeneca s pediatric exclusivity for Nolvadex ended on February 20, 2003. Therefore, we recorded no sales from a distributed version of Tamoxifen in fiscal 2004.

Oral Contraceptives

Sales of our generic oral contraceptive products increased throughout fiscal 2004 and by June 2004, we became the largest supplier of oral contraceptives in the U.S. as determined by prescription market share data provided by IMS America.

The revenue growth in fiscal 2004 was fueled by (1) increasing volumes resulting from growth in market share by products launched in prior periods and (2) first year sales of new generic oral contraceptives launched during fiscal 2004. The largest new product addition was Tri-Sprintec, our generic equivalent to Ortho s Tri-Cyclen oral contraceptive. We launched Tri-Sprintec in December 2003 in accordance with the terms of a patent challenge settlement we entered into with Ortho.

Generic Products Other

Sales of other generic products increased approximately 7% in fiscal 2004 as compared to the prior year period, primarily due to sales of our Mirtazapine Orally Disintegrating Tablet, which we launched in December 2003, and sales of Claravisò, which we launched in May 2003. These increases were partially offset by a significant decline in sales of our Dextro salt combo product due to lower pricing and lower volumes resulting from the entry of two additional generic competitors.

# **Proprietary Products**

Sales of our proprietary products more than doubled in fiscal 2004 as compared to the prior year. This increase relates primarily to: (1) sales from the four products we purchased from Wyeth in June 2003; (2) the launch of SEASONALE; (3) increased sales of Cenestin; and (4) sales of Loestrin/Loestrin Fe, which we purchased from Galen (Chemicals) Limited (Galen) in March 2004.

In September 2003 we received approval for SEASONALE. We began promoting SEASONALE directly to physicians in November 2003 and initiated our direct-to-consumer television and print advertising program during our fourth quarter. Demand for the product as measured by prescription data obtained from IMS America rose from 1,736 per week for the week ended December 26, 2003 to 12,731 for the week ended July 30, 2004.

Sales of Cenestin increased at a higher than expected rate of 36% in fiscal 2004 compared to fiscal 2003 primarily due to year-over-year price increases of approximately 24%, the launch of one additional strength and customer buying patterns, which more than offset a 9% decline in Cenestin prescriptions. Prescription declines began after the results of the Women s Health Initiative (WHI) study was published in July 2002 and continued through fiscal 2004. Since July 2002, Cenestin prescriptions declined at a slower rate than those written for competing conjugated estrogen products, thus allowing us to increase our market share to 6.8% as of June 30, 2004 compared to 5.6% as of June 30, 2003.

41

#### **Cost of Sales**

The following table sets forth cost of sales data in dollars as well as the resulting gross margins, for the two years ended June 30, 2004 and 2003 (\$ s in millions):

			Char	ıge
	2004	2003	\$	<b>%</b>
Generic products	\$ 604.6	\$ 415.0	\$ 189.6	46%
Gross margin	47%	50%		
Proprietary products	\$ 28.1	\$ 9.1	\$ 19.0	209%
Gross margin	81%	84%		
Total cost of sales	\$ 632.7	\$ 424.1	\$ 208.6	49%
Gross margin	51%	53%		

The increase in total cost of sales, on a dollar basis, for the year ended June 30, 2004, as compared to the prior year was primarily due to increased product sales, principally relating to Ciprofloxacin.

Margins on our generic products declined slightly in fiscal 2004 due mainly to the higher percentage of Ciprofloxacin sales in fiscal 2004 compared to fiscal 2003. As a distributed product that had a profit split paid to our partner, Ciprofloxacin had a higher cost of sales and a lower margin than our other products.

Margins on our proprietary products declined in fiscal 2004 compared to fiscal 2003 as increased sales of somewhat lower margin products, including the products acquired from Wyeth in late fiscal 2003, more than offset higher sales of Cenestin and SEASONALE.

## Selling, General and Administrative Expense

The following table sets forth selling, general and administrative expense data for the two years ended June 30, 2004 and 2003 (\$ s in millions):

			Char	ıge
Calling and and administration	2004	2003	\$ 152.5	- % 05.07
Selling general and administrative	\$314.5	\$161.0	\$153.5	95%
Charges included in general and administrative	\$ 96.6	\$ 20.0	\$ 76.6	383%

Selling, general and administrative expenses for the year ended June 30, 2004 included charges related to strategic acquisitions or other similar activities including: (1) a \$16 million valuation allowance we established in September 2003 for our loans to Natural Biologics, LLC, the raw material supplier for our generic equine-based conjugated estrogens product, as the result of an unfavorable court decision rendered in September 2003; (2) the February 2004 write-off of \$4.2 million associated with the acquisition of certain emergency contraception assets from Gynetics, Inc; (3) an arbitration panel s decision in June 2004 to award Solvay Pharmaceuticals, Inc. \$68 million in damages on a claim that we improperly terminated an agreement with Solvay; and (4) an \$8.5 million charge in June 2004 related to costs associated with our settlement of the Estrostep and Femhrt patent challenge litigation against Galen. Included in the year ended June 30, 2003 was a \$20 million contingent attorney fee paid in connection with a litigation settlement with Wyeth.

The remaining increase in selling, general and administrative expenses for the year ended June 30, 2004 as compared to the prior year period was primarily due to: (1) increased marketing costs for SEASONALE of \$28

# **Table of Contents**

million; (2) higher costs of \$12 million associated with the nearly doubling of our women shealthcare sales force; (3) \$14 million in higher legal costs, primarily related to patent matters, the Solvay arbitration and product liability matters; and (4) \$8 million of increased information technology costs, including consulting costs related to the initial phases of designing and implementing our new enterprise resource planning system.

# **Research and Development**

The following table sets forth research and development expenses for the two years ended June 30, 2004 and 2003 (\$ s in millions):

			Cha	ange
	2004	2003	\$	%
Research and development	\$169.0	\$91.2	\$77.8	85%
Charges included in research and development	\$ 68.2	\$ 3.9	\$64.3	1649%

For the year ended June 30, 2004 our total research and development costs reflected charges relating to strategic acquisitions or similar activities including: (1) a write-off of \$22 million in March 2004 resulting from our agreement to acquire Schering s rights and obligations under a Product Development and License Agreement that had been capitalized at the time of our acquisition of Enhance Pharmaceuticals, Inc. in June 2002; (2) a write-off of \$10 million for in-process research and development acquired in connection with our acquisition of Women s Capital Corporation in February 2004; and (3) the write-off of \$36 million of in-process research and development costs in connection with our purchase of substantially all of the assets of Endeavor Pharmaceuticals, Inc. in November 2003. Included in the year ended June 30, 2003 was a \$3.9 million write-off of in-process research and development associated with our June 2003 purchase from Wyeth of four products and the product rights to an oral contraceptive in development.

The remaining increase in research and development for the year ended June 30, 2004 as compared to the prior year was primarily due to: (1) \$8 million in higher third party development costs; (2) \$4 million in higher headcount costs; and (3) \$3 million higher raw material costs in support of internal development projects.

## **Income Taxes**

The following table sets forth income tax expense and the resulting effective tax rate stated as a percentage of pre-tax income for the years ended June 30, 2004 and 2003 (\$ s in millions):

			Change		
	2004	2003	\$	%	
Income tax expense	\$71.3	\$95.1	\$(23.8)	-25%	
Effective tax rate	36.7%	36.2%			

The effective tax rate for fiscal 2004 was unfavorably impacted by the write-off of in-process research and development costs associated with our February 2004 acquisition of Women s Capital Corporation, which was not deductible for federal and state income tax purposes. Offsetting the unfavorable impact of the in-process research and development costs was a favorable impact of a tax benefit of \$3.7 million related to the completion of several tax audits and the Internal Revenue Service s approval of a change in our method of computing certain tax credits.

#### **Table of Contents**

### Liquidity and Capital Resources

#### Overview

The following table highlights selected measures of our liquidity and capital resources as of June 30, 2005 and 2004 (\$ s in millions):

			Change			
	2005	2004	\$	<b>%</b>		
Cash & cash equivalents, short term marketable securities	\$ 643.3	\$ 452.2	\$ 191.1	42%		
Working capital	780.4	670.6	109.8	16%		
Cash flow from operations	363.0	258.1	104.9	41%		
	4.7:	4.2:				
Ratio of current assets to current liabilities	1	1				

#### **Operating Activities**

Our operating cash flows increased from \$258 million in fiscal 2004 to \$363 million in fiscal 2005. Our higher operating cash in fiscal 2005 was generated principally by our higher net earnings adjusted for non-cash charges, including depreciation and amortization, which more than offset increases in certain of our working capital components described below.

Our primary source of cash from operations is the collection of accounts and other receivables related to product sales. Our primary uses of cash include financing inventory, research and development programs, marketing and selling, capital projects, our share repurchase program and investing in business development activities.

Our cash flows from operations have been more than sufficient to fund our operations, capital expenditures and business development activities. As a result, our cash, cash equivalents and short-term marketable securities balances have increased.

#### Investment in Marketable Securities

During fiscal 2005, we increased our investments in marketable securities to provide a greater return on our cash balances. Our investments in marketable securities are governed by our investment policy which seeks to optimize our returns while preserving our capital, maintaining adequate liquidity and investing in tax advantaged securities, as appropriate.

44

#### **Table of Contents**

Working Capital

Working capital as of June 30, 2005 and 2004 consisted of the following (\$ s in millions):

			Char	ıge
	2005	2004	\$	<b>%</b>
Cash, cash equivalents and marketable securities	\$ 643.3	\$ 452.2	\$ 191.1	42%
Accounts receivable	152.6	153.9	(1.3)	-1%
Inventories	137.6	150.3	(12.7)	-8%
Prepaid & other current assets	59.9	121.8	(61.9)	-51%
Total current assets	993.4	878.2	115.2	13%
Accounts payable & accrued liabilities	194.2	179.1	15.1	8%
Income taxes payable	13.4	20.1	(6.7)	-33%
Current portion of long-term debt & capital leases	5.4	8.4	(3.0)	-36%
Total current liabilities	213.0	207.6	5.4	3%
Working capital	\$ 780.4	\$ 670.6	\$ 109.8	16%

Working capital increased in 2005 compared to 2004 primarily due to an increase in cash and marketable securities resulting from our current period operations. Changes in certain other components of working capital include: (1) a decrease in prepaid and other current assets primarily due to a \$47.5 million payment we received from Bayer in fiscal 2004 related to a price adjustment for Ciprofloxacin inventory we purchased during the second half of fiscal 2004 and (2) an increase in accounts payable and accrued liabilities largely as a result of the \$63.2 million charge taken in connection with the proposed litigation settlement regarding Mircette, partially offset by \$48.0 million in payments made to Solvay Pharmaceuticals under an arbitration decision rendered against us in fiscal 2004.

In fiscal 2004 holders of warrants to purchase an aggregate of 3,375,000 shares of our common stock exercised the warrants in full through a cashless exercise. We estimated a total cash tax benefit of approximately \$44 million from this exercise. We have realized a cash tax benefit of approximately \$28 million through June 30, 2005. A deferred tax asset of \$16 million is expected to reduce income taxes payable over the next 11 years.

### **Investing Activities**

Our net cash used in investing activities was \$177.0 million in 2005 compared to \$267.3 million in 2004. This decrease was primarily due to a decrease in cash paid for acquisitions and a reduction in the net cash used to purchase marketable securities.

#### Capital Expenditures

During the three fiscal years ended June 30, 2005, we have invested approximately \$183 million in upgrades and expansions to our property, plant and equipment as well as technology investments, including the purchase and implementation of a new enterprise resource planning (ERP) system. The investment in property, plant and equipment has significantly expanded our production, laboratory, warehouse and distribution capacity in our facilities and was designed to help ensure that we have the facilities necessary to manufacture, test, package and distribute our current and future products. Our investment in the ERP system will ensure that we have a platform to grow our business, including better integration of acquired businesses, expansion into new drug delivery systems and the ability to expand internationally.

Table of Contents 59

45

#### **Table of Contents**

During the twelve months ended June 30, 2005, we invested \$55 million in capital projects and expect that our capital investments will be between \$40 million and \$60 million over the next twelve months. Our estimate reflects continued spending on our facility expansion programs and investments in information technology projects including the final stages of the implementation of our new ERP system.

We believe we can continue funding our capital requirements using cash provided by operations. However, we may issue long-term debt to finance a portion of our projects. We believe we have the capital structure and cash flow to complete any such financing.

# Strategic Transactions

Our investment in strategic product and company acquisitions was \$46 million in fiscal 2005 and approximately \$163 million for the three years ended June 30, 2005. In fiscal 2005, these transactions included the buy-out of the royalty on Seasonale from Eastern Virginia Medical School, and the acquisition of certain product rights from King Pharmaceuticals, Inc. We continuously evaluate strategic transactions to further improve our business and long-range prospects and expect to make additional investments or acquisitions over the next twelve months. We are unable to predict the timing of potential transactions, though the cash required to complete them could equal or exceed the average amounts invested over the past three years. These transactions typically range from product development and license agreements to asset or corporate acquisitions.

### Financing Activities

Net cash used in financing activities increased to \$98.7 million in fiscal 2005 from net cash provided by financing activities of \$10.5 million in fiscal 2004 primarily due to funding share repurchases under the our share repurchase program in fiscal 2005 and higher debt repayments in fiscal 2005 as discussed below.

### Share Repurchase Program

In August 2004, our Board of Directors authorized the repurchase of up to \$300 million of our common stock in open market or in privately negotiated transactions, pursuant to terms we deem appropriate and at such times as we designate through the end of December 2005. We hold repurchased shares as treasury shares and may use them for general corporate purposes, including but not limited to acquisitions and for issuance upon exercise of outstanding stock options. During fiscal 2005, we repurchased approximately 2.6 million shares of our common stock for approximately \$100 million.

# Debt Repayments and Credit Availability

Debt balances decreased by approximately \$20 million from June 30, 2004 to June 30, 2005 reflecting principal repayments. On August 30, 2004, we entered into a new \$175 million, five-year credit facility. To date, no draws have been made under the credit facility. If and when drawn, borrowings will bear interest at a floating rate based on a base rate or a Eurodollar rate. We may use the proceeds of the credit facility for working capital, capital expenditures, and general corporate purposes (including share repurchases and permitted acquisitions). Upon entering into the new credit facility, we terminated the \$40 million credit facility we had in place at the time.

In February 2005, we made a \$12 million payment in complete satisfaction of mortgage notes held by a bank. The notes were secured by our Cincinnati, Ohio manufacturing facility.

Scheduled principal repayments on existing debt will be \$4 million during fiscal 2006.

# Proceeds from Equity Transactions

Over the three years ending June 30, 2005, we received proceeds of approximately \$71 million from the exercise of warrants and employee stock options and share purchases under our employee stock purchase plan. Whether we will continue to derive proceeds at a similar level in the future is difficult to predict because the proceeds are highly

46

#### **Table of Contents**

dependent upon our stock price, which can be volatile, and the type of equity based compensation we may grant in future years.

# Sufficiency of Cash Resources

We believe our current cash and cash equivalents, marketable securities, investment balances, cash flows from operations and un-drawn amounts under our revolving credit facility are adequate to fund our operations and planned capital expenditures and to capitalize on strategic opportunities as they arise. We have and will continue to evaluate our capital structure as part of our goal to promote long-term shareholder value. To the extent that additional capital resources are required, we believe that such capital may be raised by additional bank borrowings or debt offerings or other means.

# **Contractual Obligations**

Payments due by period for our contractual obligations at June 30, 2005 are as follows (\$ s in millions):

	Payments due by period								
		Le	ss than						
			1			4	to 5		
				1	to 3				
(\$ in millions)	Total	,	Year	Y	ears	Y	ears	Therea	after
Long-term debt	\$ 18.5	\$	4.0	\$	14.5	\$		\$	
Capital leases	2.9		1.7		1.2				
Operating leases	33.8		4.4		10.6		3.2		15.6
Purchase obligations <sup>(1)</sup>	85.2		84.4		0.8				
Venture Funds commitment	15.6		15.6						
Annual interest on fixed rate debt	1.8		0.7		1.1				
Other long-term liabilities	21.0		21.0						
Total	<b>\$ 178.8</b>	\$	131.8	\$	28.2	\$	3.2	\$	<b>15.6</b>

(1) Purchase obligations consist mainly of commitments for raw materials used in our manufacturing and research and development operations.

In addition to the above, we have committed to make potential future milestone payments to third parties as part of licensing and development programs. Payments under these agreements generally become due and payable only upon the achievement of certain developmental, regulatory and/or commercial milestones. Because it is uncertain if and when these milestones will be achieved, such contingencies have not been recorded on our consolidated balance sheet.

# **Critical Accounting Policies**

The methods, estimates and judgments we use in applying the accounting policies most critical to our financial statements have a significant impact on our reported results. The Securities and Exchange Commission has defined the most critical accounting policies as the ones that are most important to the portrayal of our financial condition and

results, and/or require us to make our most difficult and subjective judgments. Based on this definition, our most critical policies are the following: (1) revenue recognition and related provisions for estimated reductions to gross revenues; (2) inventories and related inventory reserves; (3) income taxes; (4) contingencies; and (5) accounting for acquisitions. Although we believe that our estimates and assumptions are reasonable, they are based upon information available at the time the estimates and assumptions were made. We review the factors that influence our estimates and, if necessary, adjust them. Actual results may differ significantly from our estimates.

47

#### **Table of Contents**

### Revenue Recognition and Provisions for Estimated Reductions to Gross Revenues

We recognize revenue from product sales when title and risk of loss have transferred to our customers and when collectibility is reasonably assured. This is generally at the time products are received by the customer. From time to time the Company provides incentives, such as trade show allowances or stocking allowances, that provide incremental allowances to customers who in turn use such incremental allowances to accelerate distribution to the end customer. We believe that such incentives are normal and customary in the industry. Additionally, we understand that certain of our wholesale customers anticipate the timing of price increases and have made and may continue to make business decisions to buy additional product in anticipation of future price increases. This practice has been customary in the industry and would be part of a customer sordinary course of business inventory level.

We evaluate inventory levels at our wholesale customers, which account for approximately 50% of our sales, through an internal analysis that considers, among other things, wholesaler purchases, wholesaler contract sales, available end consumer prescription information and inventory data from our largest wholesale customer. We believe that our evaluation of wholesaler inventory levels as described in the preceding sentence, allows us to make reasonable estimates for our applicable reserves. Further, our products are typically sold with sufficient dating to permit sufficient time for our wholesaler customers to sell our products in their inventory through to the end consumer.

Upon recognizing revenue from a sale, we simultaneously record estimates for the following items that reduce gross revenues:

returns and allowances (including shelf-stock adjustments)

chargebacks

rebates

Medicaid rebates

prompt payment discounts and other allowances

For each of the items listed above other than Medicaid rebates, the estimated amounts serve to reduce our accounts receivable balance. We include our estimate for Medicaid rebates in accrued liabilities. A table showing the activity of each reserve is set forth below (dollars in millions):

			pr	Current provision related to		Current provision related to		Actual returns				
	Beginning balance		related to sales made in the current period		sales ng made in th current		s ma p	ales ide in rior riods	c	credits in the urrent period		nding llance
Fiscal year ended June 30, 2005					•		•					
Accounts receivable reserves:												
Returns and allowances	\$	57.5	\$	64.8	\$	1.0	\$	(70.6)	\$	52.7		
Chargebacks		38.8		267.6		6.0		(267.5)		44.9		
Rebates		39.4		200.6				(194.7)		45.3		
Cash discounts		6.2		32.0				(31.1)		7.1		
Total	\$	141.9	\$	565.0	\$	7.0	\$	(563.9)	\$	150.0		

Accrued liabilities:

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Medicaid rebates	\$ 11.4	\$ 17.2	\$ 3.0	\$ (21.5)	\$	10.1
Fiscal year ended June 30, 2004						
Accounts receivable reserves:						
Returns and allowances	\$ 52.9	\$ 70.1	\$	\$ (65.5)	\$	57.5
Chargebacks	30.0	189.8		(181.0)		38.8
Rebates	45.6	172.5		(178.7)		39.4
Cash discounts	7.6	35.2		(36.6)		6.2
Total	\$ 136.1	\$ 467.6	\$	\$ (461.8)	\$ 1	141.9
Accrued liabilities:						
Medicaid rebates	\$ 9.5	\$ 26.0	\$	\$ (24.1)	\$	11.4
		48				

#### **Table of Contents**

Returns and allowances Our provision for returns and allowances consists of our estimates of future product returns, pricing adjustments, delivery errors, and our estimate of price adjustments arising from shelf stock adjustments (which are discussed in greater detail below). Consistent with industry practice, we maintain a return policy that allows our customers to return product within a specified period of time both prior and subsequent to the product s expiration date. The primary factors we consider in estimating our potential product returns include:

the shelf life or expiration date of each product;

historical levels of expired product returns; and

the estimated date of return.

Shelf-stock adjustments are credits issued to our customers to reflect decreases in the selling prices of our products. These credits are customary in the industry and are intended to reduce a customer s inventory cost to better reflect current market prices. The determination to grant a shelf-stock credit to a customer following a price decrease is at our discretion rather than contractually required. The primary factors we consider when deciding whether to record a reserve for a shelf-stock adjustment include:

the estimated launch date of a competing product, which we determine based on market intelligence;

the estimated decline in the market price of our product, which we determine based on historical experience and input from customers; and,

the estimated levels of inventory held by our customers at the time of the anticipated decrease in market price, which we determine based upon historical experience and customer input.

Chargebacks We market and sell products directly to wholesalers, distributors, warehousing pharmacy chains, mail order pharmacies and other direct purchasing groups. We also market products indirectly to independent pharmacies, non-warehousing chains, managed care organizations, and group purchasing organizations, collectively referred to as indirect customers. We enter into agreements with some indirect customers to establish contract pricing for certain products. These indirect customers then independently select a wholesaler from which to purchase the products at these contracted prices. Alternatively, we may pre-authorize wholesalers to offer specified contract pricing to other indirect customers. Under either arrangement, we provide credit to the wholesaler for any difference between the contracted price with the indirect customer and the wholesaler s invoice price. Such credit is called a chargeback. The primary factors we consider in developing and evaluating our provision for chargebacks include:

the average historical chargeback credits; and

an estimate of the inventory held by our wholesalers, based on internal analysis of a wholesaler s historical purchases and contract sales.

*Rebates* Our rebate programs can generally be categorized into the following four types: direct rebates:

indirect rebates;

managed care rebates; and

Medicaid rebates.

The direct and indirect rebates relate primarily to the generic segment of our business whereas our managed care rebates are solely associated with the proprietary segment of our business. Medicaid rebates apply to both of our segments. Direct rebates are generally rebates paid to direct purchasing customers based on a percentage applied to a direct customer s purchases from us. Indirect rebates are rebates paid to indirect customers which have purchased Barr products from a wholesaler under a contract with us. Managed care and Medicaid rebates are amounts owed based upon contractual agreements or legal requirements with private sector and public sector (Medicaid) benefit providers,

after the final dispensing of the product by a pharmacy to a benefit plan participant.

We maintain reserves for our direct rebate programs based on purchases by our direct purchasing customers. Indirect rebate reserves are based on actual contract purchases in a period and an estimate of wholesaler inventory subject to an indirect rebate. Managed care and Medicaid reserves are based on expected payments, which are driven by patient usage, contract performance, as well as field inventory that will be subject to a managed care or Medicaid rebate.

49

#### **Table of Contents**

*Prompt Pay Discounts* We offer many of our customers 2% prompt pay discounts. We evaluate the amounts accrued for prompt pay discounts by analyzing the unpaid invoices in our accounts receivable aging subject to a prompt pay discount.

Alliance Revenue We have agreements to co-promote products developed by other companies. Revenue from the sale of the co-promoted product is recorded as alliance revenue and is included in net revenue. Revenue is recognized when the co-promotion company ships the product and title and risk of loss pass to a third party. Revenue is primarily based upon a percentage of the co-promotion company s net sales or gross margin. Our selling and marketing expenses related to alliance revenue are included in selling, general and administrative expenses.

### Inventory Reserves

Inventories are stated at the lower of cost or market and consist of finished goods purchased from third party manufacturers and held for distribution, as well as raw materials, work-in-process and finished goods manufactured by us. We determine cost on a first-in, first-out basis.

We capitalize the costs associated with certain products prior to receiving final marketing approval from the FDA for such products (pre-launch inventories). For our generic products, each ANDA submission is made with the expectation that: (i) the FDA will approve the marketing of the applicable product, (ii) we will validate our process for manufacturing the applicable product within the specifications that have been or will be approved by the FDA, and (iii) the cost of the inventory will be recovered from the commercialization of our ANDA product. Typically, we capitalize inventory related to our proprietary products based on the same expectations as above, but we do not begin to capitalize costs until the NDA is filed or in the case of components to a NDA product, the product development process has progressed to a point where we have determined that the product has a high probability of regulatory approval. The accumulation of pre-launch inventory involves risks such as (i) the FDA may not approve such product(s) for marketing on a timely basis, if ever, (ii) approvals may require additional or different testing and/or specifications than what was performed in the manufacture of such pre-launch inventory, and (iii) in those instances where the pre-launch inventory is for a product that is subject to litigation, the litigation may not be resolved or settled to our satisfaction. If any of these risks were to materialize and the launch of such product were significantly delayed, we may have to write-off all or a portion of such pre-launch inventory and such amounts could be material. As of June 30, 2005 and 2004, the amount of pre-launch inventory was not material to our net earnings.

We establish reserves for our inventory, including pre-launch inventory, to reflect situations in which the cost of the inventory is not expected to be recovered. We review our inventory for products that are close to or have reached their expiration date and therefore are not expected to be sold, for products where market conditions have changed or are expected to change, and for products that are not expected to be saleable based on our quality assurance and control standards. In addition, for our pre-launch inventory, we take into consideration the substance of communications with the FDA during the approval process and the views of patent and litigation counsel. The reserves we establish in these situations is equal to all or a portion of the cost of the inventory based on the specific facts and circumstances. In evaluating whether inventory is properly stated at the lower of cost or market, we consider such factors as the amount of product inventory on hand, estimated time required to sell such inventory, remaining shelf life and current and expected market conditions, including levels of competition. We record provisions for inventory reserves as part of cost of sales.

Inventories are presented net of reserves of \$13 million at June 30, 2005 and \$24 million at June 30, 2004. *Income Taxes* 

Our effective tax rate is based on pre-tax income, statutory tax rates and available tax incentives (i.e. credits) and planning opportunities in the various jurisdictions in which we operate. We establish reserves when, despite our belief that the tax return positions are fully supportable, certain positions may be challenged and may not be upheld on audit. We adjust our reserves upon the occurrence of a discrete event, such as the completion of an income tax audit. The effective tax rate includes the impact of reserve provisions and charges to reserves that are considered appropriate. This rate is applied to our quarterly operating results.

50

#### **Table of Contents**

Tax regulations require certain items to be included in the income tax return at different times than the items are reflected in the financial statements. As a result, the effective tax rate reflected in the financial statements is different than that reported in the income tax return. Some of the differences are permanent, such as tax-exempt interest income, and some are timing differences such as depreciation expense. Deferred tax assets generally represent items that can be used as a tax deduction or credit in future years for which we have already recorded the tax benefit in the financial statements. We establish valuation allowances for our deferred tax assets when the amount of expected future taxable income is not likely to support the use of the deduction or credit. Deferred tax liabilities generally represent tax expense recognized in the financial statements for which payment has been deferred or expenses for which we have already taken a deduction on the tax return, but have not yet recognized as expense in the financial statements.

# **Contingencies**

We are involved in various patent, product liability, commercial litigation and claims, government investigations and other legal proceedings that arise from time to time in the ordinary course of our business. We assess, in consultation with counsel, the need to accrue a liability for such contingencies and record a reserve when we determine that a loss related to a matter is both probable and reasonably estimable. Because litigation and other contingencies are inherently unpredictable, our assessment can involve judgments about future events. We record anticipated recoveries under existing insurance contracts when collection is reasonably assured.

We utilize a combination of self-insurance and traditional third-party insurance policies to cover potential product liability claims on products sold on or after September 30, 2002, and we have obtained extended reporting periods under previous policies for claims arising on products sold prior to September 30, 2002.

\*\*Acausistions\*\*

We account for acquired businesses using the purchase method of accounting which requires that the assets acquired and liabilities assumed be recorded at the date of acquisition at their respective fair values. Our consolidated financial statements and results of operations reflect an acquired business after the completion of the acquisition and are not restated. The cost to acquire a business, including transaction costs, is allocated to the underlying net assets of the acquired business in proportion to their respective fair values. Any excess of the purchase price over the estimated fair values of the net assets acquired is recorded as goodwill. Amounts allocated to acquired in-process research and development are expensed at the date of acquisition. When we acquire net assets that do not constitute a business, no goodwill is recognized.

The judgments made in determining the estimated fair value assigned to each class of assets acquired and liabilities assumed, as well as asset lives, can materially impact our results of operations. Accordingly, for significant items, we typically obtain assistance from third party valuation specialists. Useful lives are determined based on the expected future period of benefit of the asset, which considers various characteristics of the asset, including projected cash flows. We review goodwill for impairment annually or more frequently if impairment indicators arise.

As a result of our acquisitions, we have recorded goodwill of \$18 million on our balance sheets as of June 30, 2005 and 2004. In addition, as a result of our acquisition of product rights and related intangibles and certain product licenses, we have recorded \$98 million and \$65 million as other intangible assets, net of accumulated amortization, on our balance sheets as of June 30, 2005 and 2004, respectively.

## **Recent Accounting Pronouncements**

In December 2004, the Financial Accounting Standards Board (the FASB) issued Statement of Financial Accounting Standard (SFAS) No. 123(R), Share-Based Payment, which revises SFAS No. 123, Accounting for Stock-Based Compensation (SFAS No. 123), and supersedes Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees (APB No. 25) and amends SFAS No. 95 Statement of Cash Flows. SFAS No. 123(R) requires companies to recognize in their income statement the grant-date fair value of stock options and other equity-based compensation issued to employees and directors. Pro forma disclosure is no longer

Table of Contents 68

5

#### **Table of Contents**

an alternative. We adopted SFAS No. 123(R) on July 1, 2005. This Standard requires that compensation expense for most equity-based awards be recognized over the requisite service period, usually the vesting period, while compensation expense for liability-based awards (those usually settled in cash rather than stock) be re-measured to fair-value at each balance sheet date until the award is settled. As permitted by SFAS No. 123, we currently account for share-based payments to employees and directors using the intrinsic value method and, as such, recognize no compensation cost for equity-based awards. Accordingly, the adoption of SFAS No. 123(R) s fair value method will have an impact on our results of operations, although it will have no net impact on our overall financial position or cash flows.

We use the Black-Scholes formula to estimate the value of stock-based compensation granted to employees and directors and expect to continue to use this acceptable option valuation model in the future. Because SFAS No. 123(R) must be applied not only to new awards, but to previously granted awards that are not fully vested on the effective date, compensation cost for some previously granted options will be recognized under SFAS No. 123(R). However, had we adopted SFAS No. 123(R) in prior periods, the impact of that Statement would have approximated the impact described in the disclosure of pro forma net earnings and earnings per share.

SFAS No. 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as currently required.

We will follow the modified prospective method, which requires us (1) to record compensation expense for the non-vested portion of previously issued awards that remain outstanding at the initial date of adoption and (2) to record compensation expense for any awards issued or modified after July 1, 2005. Based on the adoption of the modified prospective method, we expect to record pre-tax stock based compensation expense of approximately \$27 million in fiscal 2006. This amount represents awards granted in prior years which are vesting in fiscal 2006 and 2006 fiscal year awards expected to be granted.

In November 2004, the FASB issued Statement No. 151, Inventory Costs, an amendment of ARB No. 43, Chapter 4 (SFAS No. 151), to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted materials (spoilage). ARB No. 43 allowed some of these abnormal costs to be carried as inventory whereas SFAS No. 151 requires that these costs be recognized in income as incurred. This Statement is effective for the Company s fiscal year beginning July 1, 2005. We have evaluated the effect of adopting SFAS No. 151 and have determined that this statement will not have a significant effect on our current consolidated financial statements.

In December 2004, the FASB issued FSP FAS 109-1, Application of FASB Statement No. 109, Accounting for Income Taxes, to the Tax Deduction on Qualified Production Activities Provided by the American Jobs Creation Act of 2004 (the Act ), to provide accounting guidance on the appropriate treatment of tax benefits generated by the enactment of the Act. The FSP requires that the manufacturer s deduction be treated as a special deduction in accordance with SFAS No. 109 and not as a tax rate reduction. We assessed the impact of adopting FSP FAS 109-1 on our consolidated financial statements and expect to realize a slight reduction in our effective tax rate during fiscal 2006. The Act will be effective for our fiscal year beginning July 1, 2005.

#### **Environmental Matters**

We may have obligations for environmental safety and clean-up under various state, local and federal laws, including the Comprehensive Environmental Response, Compensation and Liability Act, commonly known as Superfund. Based on information currently available, environmental expenditures have not had, and are not anticipated to have, any material effect on our consolidated financial statements.

# **Effects of Inflation; Seasonality**

Inflation has had only a minimal impact on our operations in recent years. Similarly, our business is generally not affected by seasonality.

52

#### **Table of Contents**

### **Forward-Looking Statements**

The preceding sections contain a number of forward-looking statements. To the extent that any statements made in this report contain information that is not historical, these statements are essentially forward-looking. Forward-looking statements can be identified by their use of words such as expects, plans, will, may, anticipates, believes, intends, estimates and other words of similar meaning. These statements are subject to risks and uncertainties that cannot be predicted or quantified and, consequently, actual results may differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, in no particular order:

the difficulty in predicting the timing and outcome of legal proceedings, including patent-related matters such as patent challenge settlements and patent infringement cases;

the difficulty of predicting the timing of FDA approvals;

court and FDA decisions on exclusivity periods;

the ability of competitors to extend exclusivity periods for their products;

our ability to complete product development activities in the timeframes and for the costs we expect;

market and customer acceptance and demand for our pharmaceutical products;

our dependence on revenues from significant customers;

reimbursement policies of third party payors;

our dependence on revenues from significant products;

the use of estimates in the preparation of our financial statements;

the impact of competitive products and pricing on products, including the launch of authorized generics;

the ability to launch new products in the timeframes we expect;

the availability of raw materials;

the availability of any product we purchase and sell as a distributor;

the regulatory environment;

our exposure to product liability and other lawsuits and contingencies;

the cost of insurance and the availability of product liability insurance coverage;

our timely and successful completion of strategic initiatives, including integrating companies and products we acquire and implementing our new enterprise resource planning system;

fluctuations in operating results, including the effects on such results from spending for research and development, sales and marketing activities and patent challenge activities; and

other risks detailed from time-to-time in our filings with the Securities and Exchange Commission.

We wish to caution each reader of this report to consider carefully these factors as well as specific factors that may be discussed with each forward-looking statement in this report or disclosed in our filings with the SEC, as such factors, in some cases, could affect our ability to implement our business strategies and may cause actual results to differ materially from those contemplated by the statements expressed herein. Readers are urged to carefully review and consider these factors. We undertake no duty to update the forward-looking statements even though our situation may change in the future.

53

# **Table of Contents**

### Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Our exposure to market risk for a change in interest rates relates primarily to our investment portfolio of approximately \$691.6 million. We do not use derivative financial instruments.

Our investment portfolio consists of cash and cash equivalents and market auction debt securities primarily classified as available for sale. The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we maintain our portfolio in a variety of high credit quality debt securities, including U.S., state and local government and corporate obligations, certificates of deposit and money market funds. Over 78% of our portfolio matures in less than three months, or is subject to an interest-rate reset date that occurs within 90 days. The carrying value of the investment portfolio approximates the market value at June 30, 2005 and the value at maturity. Because our investments consist of cash equivalents and market auction debt securities, a hypothetical 100 basis point change in interest rates is not likely to have a material effect on our consolidated financial statements.

None of our outstanding debt at June 30, 2005 bears interest at a variable rate. Any borrowings under our \$175 million unsecured revolving credit facility will bear interest at a variable rate based on the prime rate, the Federal Funds rate or LIBOR. At June 30, 2005, no amounts were drawn under this facility.

# Item 8. Financial Statements and Supplementary Data

Our financial statements are filed together with this Form 10-K. See the Index to Financial Statements and Financial Statement Schedules on page F-1 for a list of the financial statements filed together with this Form 10-K.

# Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosures None.

#### Item 9A. Controls and Procedures

#### **Evaluation of Disclosure Controls and Procedures**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms, and that such information is accumulated and communicated to our management, including our Chairman and Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Management necessarily applied its judgment in assessing the costs and benefits of such controls and procedures, which, by their nature, can provide only reasonable assurance regarding management s control objectives.

At the conclusion of the period ended June 30, 2005, we carried out an evaluation, under the supervision and with the participation of our management, including the Chairman and Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based upon that evaluation, the Chairman and Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective in alerting them in a timely manner to information relating to Barr and its consolidated subsidiaries required to be disclosed in this report.

## **Internal Control Over Financial Reporting**

Management s report on our internal control over financial reporting is included on page F-2 hereof. The report of our independent registered public accounting firm related to management s assessment of the effectiveness of internal control over financial reporting is included on page F-3 hereof.

54

#### **Table of Contents**

## **Changes in Internal Controls**

During the last quarter of our fiscal year ended June 30, 2005, there have been no changes to our internal controls over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

## Item 9B. Other Information

None.

55

#### **PART III**

#### Item 10. Directors and Executive Officers of the Registrant

Certain information regarding our directors and executive officers will be set forth in the sections titled Election of Directors , Executive Officers and Security Ownership of Certain Beneficial Owners and Management Section 16(a) Beneficial Ownership Reporting Compliance in our definitive Proxy Statement for our Annual Meeting of Stockholders scheduled for November 3, 2005 (the Proxy Statement) and is incorporated herein by reference.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics (the Code ) that applies to all Barr companies, their officers, directors and employees. This Code and the charters of the Audit, Compensation, and Nominating and Corporate Governance committees are posted on the Our website at www.barrlabs.com. We intend to post any amendments to or waivers from the Code on our website.

#### Item 11. Executive Compensation

A description of our executive officers compensation will be set forth in the sections titled Executive Compensation , Option Grants , Option Exercises and Option Values and Executive Agreements of the Proxy Statement and is incorporated herein by reference.

#### Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

A description of the security ownership of certain beneficial owners and management, as well as equity compensation plan information, will be set forth in the sections titled Ownership of Securities of the Proxy Statement and is incorporated herein by reference.

#### Item 13. Certain Relationships and Related Transactions

A description of certain relationships and related transactions will be set forth in the section titled Certain Relationships and Related Transactions of the Proxy Statement and is incorporated herein by reference.

#### Item 14. Principal Accounting Fees and Services

A description of the fees paid to our independent registered public accounting firm will be set forth in the section titled Independent Registered Public Accountants of the Proxy Statement and is incorporated herein by reference.

56

#### **Table of Contents**

#### **PART IV**

#### Item 15. Exhibits and Financial Statement Schedules

(a) Financial Statement Schedules:

See the Index on page F-1 below.

- (b) Exhibits
  - 2.1 Agreement and Plan of Merger, dated as of December 31, 2003 between Barr Pharmaceuticals, Inc., a Delaware corporation, and Barr Laboratories, Inc., a New York corporation (1)
  - 2.2 Asset Purchase Agreement dated November 20, 2003 between Endeavor Pharmaceuticals, Inc. and Barr Laboratories, Inc. (2)
  - 2.3 Agreement and Plan of Merger, dated February 6, 2004, among Duramed Pharmaceuticals, Inc., WCC Merger Sub, Inc. and Women s Capital Corporation (3)
  - 3.1 Amended and Restated Certificate of Incorporation of the Registrant (1)
  - 3.2 Restated By-Laws of the Registrant (1)
  - 4.1 The Registrant agrees to furnish to the Securities and Exchange Commission, upon request, a copy of any instrument defining the rights of the holders of its long-term debt wherein the total amount of securities authorized thereunder does not exceed 10% of the total assets of the Registrant and its subsidiaries on a consolidated basis.
  - 4.2 Note Purchase Agreement dated November 18, 1997 relating to \$10 million of Series A Senior Notes due November, 2004 and \$20 million of Series B Senior Notes due November, 2007 (4)
  - 10.1 Lease, dated February 6, 2003, between Mack-Cali Properties Co. No. 11 L.P. and Barr Laboratories, Inc. (5)
  - 10.2 Amended and Restated Employment Agreement with Bruce L. Downey, dated as of October 24, 2002 (6)
  - 10.3 1993 Stock Incentive Plan (7)
  - 10.4 Non-Qualified Deferred Compensation Plan (2)
  - 10.5 1993 Employee Stock Purchase Plan (8)
  - 10.6 1993 Stock Option Plan for Non-Employee Directors (9)
  - 10.7 2002 Stock and Incentive Award Plan (10)
  - 10.8 2002 Stock Option Plan for Non-Employee Directors (10)
  - 10.9 Supply Agreement for Ciprofloxacin Hydrochloride dated January 8, 1997 (11)

10.10

Proprietary Drug Development and Marketing Agreement, dated March 20, 2000, between Barr Laboratories, Inc. and DuPont Pharmaceuticals Company (12)

- 10.11 Description of Excess Savings and Retirement Plan (13)
- 10.12 Amended and Restated Employment Agreement with Paul M. Bisaro, dated as of October 24, 2002 (6)
- 10.13 Amended and Restated Employment Agreement with Carole S. Ben-Maimon, dated as of October 24, 2002 (6)
- 10.14 Amended and Restated Employment Agreement with Timothy P. Catlett, dated as of February 19, 2003 (14)

57

#### **Table of Contents**

- 10.15 Amended and Restated Employment Agreement with William T. McKee, dated as of February 19, 2003 (5)
- 10.16 Amended and Restated Employment Agreement with Fredrick J. Killion, dated as of February 19, 2003 (5)
- 10.17 Amended and Restated Employment Agreement with Salah U. Ahmed, dated as of February 19, 2003 (14)
- 10.18 Amended and Restated Employment Agreement with Christine A. Mundkur, dated as of February 19, 2003 (14)
- 10.19 Amended and Restated Employment Agreement with Catherine F. Higgins, dated as of February 19, 2003 (14)
- 10.20 Employment Agreement with Michael J. Bogda, dated as of May 15, 2003 (14)
- 10.21 Duramed 1988 Stock Option Plan (15)
- 10.22 Duramed 1991 Stock Option Plan for Nonemployee Directors (16)
- 10.23 Duramed 1997 Stock Option Plan (17)
- 10.24 Duramed 2000 Stock Option Plan (18)
- 10.25 Duramed 1999 Nonemployee Director Stock Plan (19)
- 21.0 Subsidiaries of the Company
- 23.1 Consent of Deloitte & Touche LLP
- 31.1 Certification of Bruce L. Downey pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 31.2 Certification of William T. McKee pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 32.0 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(1) Previously filed

with the

Securities and

Exchange

Commission on

January 6, 2004

as an Exhibit to

the Registrant s

**Current Report** 

on Form 8-K and incorporated herein by reference.

- (2) Previously filed with the Securities and Exchange Commission as an Exhibit to the Registrant s Quarterly Report on Form 10-Q for the quarter ended December 31, 2003 and incorporated herein by reference.
- (3) Previously filed with the Securities and Exchange Commission as an Exhibit to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2004 and incorporated herein by reference.
- (4) Previously filed with the Securities and Exchange Commission as Exhibit 4-3 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended

December 31, 1997 and incorporated herein by reference.

(5) Previously filed with the Securities and Exchange Commission as an Exhibit to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2003 and incorporated herein by reference.

(6) Previously filed with the Securities and Exchange Commission as an Exhibit to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2003 and incorporated herein by reference.

58

(7) Previously filed with the Securities and Exchange Commission as an Exhibit to the Registrant s Registration Statement on Form S-8 Nos. 33-73696 and 333-17349 and incorporated herein by

reference.

- (8) Previously filed with the Securities and Exchange Commission as an Exhibit to the Registrant s Registration Statement on Form S-8 No. 33-73700 and incorporated herein by reference.
- (9) Previously filed with the Securities and Exchange Commission as an Exhibit to the Registrant s Registration Statement on Form S-8 Nos. 33-73698 and 333-17351 incorporated herein by reference.
- (10) Previously filed with the

Securities and Exchange
Commission as an Appendix to the Registrant s
Proxy Statement relating to the 2002 Annual Meeting of
Stockholders and incorporated herein by reference.

# (11) Previously filed with the Securities and Exchange Commission as an Exhibit to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 1997 and incorporated herein by reference.

- (12) Previously filed with the Securities and Exchange Commission as an Exhibit to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2000 and incorporated herein by reference.
- (13) Previously filed with the Securities and Exchange Commission as an Exhibit to the Registrant s

Annual Report on Form 10-K for the year ended June 30, 2000 and incorporated herein by reference.

# (14) Previously filed with the Securities and Exchange Commission as an Exhibit to the Registrant s Annual Report on Form 10-K for the year ended June 30, 2003 and incorporated herein by reference.

## (15) Previously filed with the Securities and Exchange Commission as an Exhibit to the Duramed Pharmaceuticals, Inc. Proxy Statement relating to the 1993 Annual Meeting of Stockholders and incorporated herein by reference.

(16) Previously filed with the Securities and Exchange Commission as an Exhibit to the Duramed Pharmaceuticals, Inc. Proxy Statement

relating to the 1998 Annual Meeting of Stockholders and incorporated herein by reference.

# (17) Previously filed

with the

Securities and

Exchange

Commission as

an Exhibit to the

Duramed

Pharmaceuticals,

Inc. Proxy

Statement

relating to the

1997 Annual

Meeting of

Stockholders and

incorporated

herein by

reference.

#### (18) Previously filed

with the

Securities and

Exchange

Commission as

an Exhibit to the

Duramed

Pharmaceuticals,

Inc. Proxy

Statement

relating to the

2000 Annual

Meeting of

Stockholders and

incorporated

herein by

reference.

#### (19) Previously filed

with the

Securities and

Exchange

Commission as

an Exhibit to the

Duramed

Pharmaceuticals, Inc. Annual Report on Form 10-K for the year ended December 31, 1998 and incorporated herein by reference.

59

#### **Table of Contents**

#### **SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

BARR PHARMACEUTICALS, INC.

By: /s/ Bruce L. Downey

Bruce L. Downey
Chairman of the Board and
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Bruce L. Downey	Chairman of the Board and Chief Executive Officer	September 12, 2005
Bruce L. Downey	(Principal Executive Officer)	
/s/ William T. McKee	Vice President, Chief Financial Officer and Treasurer	September 12, 2005
William T. McKee	(Principal Financial Officer and Principal Accounting Officer)	
/s/ Carole S.Ben-Maimon	Director	September 12, 2005
Carole S. Ben-Maimon		
/s/ Paul M. Bisaro	Director	September 12, 2005
Paul M. Bisaro		
/s/ Harold N. Chefitz	Director	September 12, 2005
Harold N. Chefitz		
/s/ Richard R. Frankovic	Director	September 12, 2005
Richard R. Frankovic		
/s/ James S. Gilmore III	Director	September 12, 2005
James S. Gilmore III		
/s/ Jack M. Kay	Director	September 12, 2005
Jack M. Kay		
/s/ Peter R. Seaver	Director	September 12, 2005
Peter R. Seaver		
/s/ George P. Stephan	Director	September 12, 2005
George P. Stephan		
	60	

#### **Table of Contents**

#### **PART II**

# Item 8. Financial Statements and Supplementary Data

# INDEX TO FINANCIAL STATEMENTS AND FINANCIAL STATEMENT SCHEDULE

	Page
Management s Report on Internal Control Over Financial Reporting	F-2
Report of Independent Registered Public Accounting Firm	F-3
Consolidated Balance Sheets as of June 30, 2005 and 2004	F-5
Consolidated Statements of Operations for the years ended June 30, 2005, 2004 and 2003	F-6
Consolidated Statements of Shareholders Equity for the years ended June 30, 2005, 2004 and 2003	F-7
Consolidated Statements of Cash Flows for the years ended June 30, 2005, 2004 and 2003	F-8
Notes to The Consolidated Financial Statements	F-9
Schedule II Valuation and Qualifying Accounts for the years ended June 30, 2005, 2004 and 2003	S-1

#### **Table of Contents**

#### MANAGEMENT S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

Management is responsible for establishing and maintaining adequate internal control over financial reporting. We maintain internal control over financial reporting designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States of America.

Because of its inherent limitations, any system of internal control over financial reporting, no matter how well designed, may not prevent or detect misstatements due to the possibility of collusion or improper override of controls, or that misstatements due to error or fraud may occur that are not detected. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management conducted an assessment of the effectiveness of the Company's internal control over financial reporting as of June 30, 2005 using criteria established in *Internal Control-Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). This assessment included an evaluation of the design of the Company's internal control over financial reporting and testing of the operational effectiveness of its internal control over financial reporting. Based on this assessment, management has concluded that the Company maintained effective internal control over financial reporting as of June 30, 2005, based upon the COSO framework criteria.

Management s assessment of the effectiveness of the Company s internal control over financial reporting as of June 30, 2005 has been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report which appears herein.

September 9, 2005

F-2

#### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Barr Pharmaceuticals, Inc.:

We have audited the accompanying consolidated balance sheets of Barr Pharmaceuticals, Inc. and subsidiaries (the Company ) as of June 30, 2005 and 2004, and the related consolidated statements of operations, shareholders equity, and cash flows for each of the three years in the period ended June 30, 2005. Our audits also included the financial statement schedule listed in the Index at Item 15. We also have audited management s assessment, included in the accompanying Management s Report on Internal Control over Financial Reporting, that the Company maintained effective internal control over financial reporting as of June 30, 2005, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company s management is responsible for these financial statements and financial statement schedule, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on these financial statements and financial statements schedule, an opinion on management s assessment, and an opinion on the effectiveness of the Company s internal control over financial reporting based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audit of financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, evaluating management s assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

A company s internal control over financial reporting is a process designed by, or under the supervision of, the company s principal executive and principal financial officers, or persons performing similar functions, and effected by the company s board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of June 30, 2005 and 2004, and the results of its operations and its cash flows for each of the three years in the period ended June 30, 2005, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein. Also, in our opinion, management s assessment that the Company maintained effective internal control over financial reporting as of June 30, 2005, is fairly stated, in all material respects, based on the

#### **Table of Contents**

criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Furthermore, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of June 30, 2005, based on the criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

/s/ DELOITTE & TOUCHE LLP

Parsippany, New Jersey September 9, 2005

F-4

# BARR PHARMACEUTICALS, INC. AND SUBSIDIARIES CONSOLIDATED BALANCE SHEETS

	Year Ended Ju			ne 30,	
(in thousands, except share and per share data)		2005		2004	
Assets					
Current assets:					
Cash and cash equivalents	\$	115,793	\$	28,508	
Marketable securities		527,462		423,746	
Accounts receivable, net		152,599		153,890	
Other receivables		21,411		60,848	
Inventories, net		137,638		150,252	
Deferred income taxes		30,224		46,077	
Prepaid expenses and other current assets		8,229		14,925	
Total current assets		993,356		878,246	
Property, plant and equipment, net		249,485		236,831	
Deferred income taxes		60,504		35,016	
Marketable securities		53,793		89,143	
Other intangible assets		98,343		64,897	
Goodwill		17,998		18,211	
Other assets		9,367		10,925	
Other assets		7,307		10,723	
Total assets	\$1	,482,846	\$ 1	1,333,269	
Liabilities and Shareholders Equity					
Current liabilities:					
Accounts payable	\$	49,743	\$	61,089	
Accrued liabilities		144,428		117,970	
Current portion of long-term debt and capital lease obligations		5,446		8,447	
Income taxes payable		13,353		20,139	
Total current liabilities		212,970		207,645	
Long-term debt and capital lease obligations		15,493		32,355	
Other liabilities		20,413		51,223	
Other naomities		20,413		31,223	
Commitments & Contingencies (Note 17)					
Shareholders equity: Preferred stock \$1 par value per share; authorized 2,000,000; none issued Common stock \$.01 par value per share; authorized 200,000,000; issued					
106,340,470 and 104,916,103 in 2005 and 2004, respectively		1,063		1,049	
Additional paid-in capital		454,489		377,024	
Retained earnings		879,669		664,681	
Accumulated other comprehensive loss		(561)			

	1,334,660	1,042,754
Treasury stock at cost: 2,972,997 and 420,597 shares in 2005 and 2004, respectively	(100,690)	(708)
Total shareholders equity	1,233,970	1,042,046
Total liabilities and shareholders equity	\$ 1,482,846	\$1,333,269

# SEE ACCOMPANYING NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS F-5

# BARR PHARMACEUTICALS, INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended June 30			0,		
(in thousands, except per share data)		2005		2004	2003	
Revenues:						
Product sales	\$ 1	1,030,174	\$ 1	,296,709	\$ 894,888	
Alliance, development and other revenue		17,225		12,379	7,976	
Total revenues	1	1,047,399	1	,309,088	902,864	
Costs and expenses:						
Cost of sales		304,080		632,745	424,099	
Selling, general and administrative		298,908		314,500	160,978	
Research and development		128,384		168,995	91,207	
Earnings from operations		316,027		192,848	226,580	
		,			,	
Proceeds from patent challenge settlement					31,396	
Interest income		11,449		5,768	6,341	
Interest expense		1,463		2,643	1,474	
Other income (expense)		3,863		(1,533)	(128)	
Earnings before income taxes		329,876		194,440	262,715	
Income tax expense		114,888		71,337	95,149	
Net earnings	\$	214,988	\$	123,103	\$ 167,566	
Earnings per common share basic	\$	2.08	\$	1.21	\$ 1.69	
Zamingo per common onare	Ψ	2.00	Ψ	1.21	Ψ 1.09	
Earnings per common share diluted	\$	2.03	\$	1.15	\$ 1.62	
Weighted average shares		103,180		101,823	99,125	
Weighted average shares diluted		106,052		106,661	103,592	

#### SEE ACCOMPANYING NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

F-6

# BARR PHARMACEUTICALS, INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY

n thousands, except shares)

n thousands, except shares)			Additional	Additional Paid in	Ac	ccumulate Other	ed		Total
	Common	Stock	Paid in		Retain@dr	mprehens Income	ive Treasury	y Stock	Shareholde
	Shares	Amount	Capital	Warrants	Earnings	(Loss)	Shares	Amount	Equity
alance, July 1, 2002 omprehensive income:	43,792,170		-		\$375,066	\$ 99	186,932 \$		\$ 666,533
et earnings nrealized loss on marketable curities, net of tax of \$170					167,566	(278)			167,56
curries, let of tax of \$170						(278)			(27)
otal comprehensive income ax benefit of stock incentive									167,28
ans suance of common stock for kercised stock options and nployees stock purchase			10,912						10,91
ans suance of common stock for	1,020,032	10	23,453						23,46
kercised warrants tock split (3-for-2)	83,940 22,170,054	1 222	(1)	)	(422)	)	93,466		(20
alance, June 30, 2003 omprehensive income:	67,066,196	671	309,583	16,418	542,210	(179)	280,398	(708)	867,99
et earnings eclassification adjustment					123,103	179			123,10 17
otal comprehensive income ax benefit of stock incentive									123,28
ans and warrants suance of common stock for kercised stock options and mployees stock purchase			25,262						25,26
ans suance of common stock for	1,456,808	14	25,784						25,79
kercised warrants tock split (3-for-2)	2,340,610 34,052,489	23 341	16,395	(16,418)	(632)	)	140,199		(29
alance, June 30, 2004 omprehensive income:	104,916,103	1,049	377,024		664,681		420,597	(708)	1,042,04
et earnings nrealized loss on marketable					214,988	(5(1)			214,98
ecurities, net of tax of \$320						(561)			(56

alance, June 30, 2005	106,340,470	\$ 1,063	\$ 454,489	\$ \$ 879,669	\$ (561)	2,972,997	\$ (100,690)	\$ 1,233,970
urchases of common stock						2,552,400	(99,982)	(99,982
suance of common stock for kercised warrants	288,226	3	2,747					2,750
suance of common stock for kercised stock options and nployees stock purchase lans	1,136,141	11	18,506					18,517
otal comprehensive income ax benefit of stock incentive ans and warrants			56,212					214,42° 56,21°

# SEE ACCOMPANYING NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS $\operatorname{F-}\!7$

# BARR PHARMACEUTICALS, INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands) CASH FLOWS FROM OPERATING ACTIVITIES:	2005	Years Ended June 30, 2004	30, 2003	
	\$ 214,988	\$ 123,103	\$ 167,566	
Net earnings	\$ 214,988	5 \$ 125,105	\$ 107,300	
Adjustments to reconcile net earnings to net cash provided by				
operating activities:	40.920	22.050	22.712	
Depreciation and amortization	40,820 7,100	·	22,713 6,684	
Deferred income tax expense (benefit)	7,100	` ' '	•	
Write-off of intangible asset	1.050	22,333	1,330	
Provision for losses on loans to Natural Biologics	1,050	·	262	
Other	2,480	·	362	
Tax benefit of stock incentive plans and warrants	39,846	5 25,262	10,912	
Write-off of in-process research and development associated		45,000	2.046	
with acquisitions		45,900	3,946	
Changes in assets and liabilities:				
(Increase) decrease in:	40.726	20.001	(126,200)	
Accounts receivable and other receivables, net	40,728	· ·	(126,390)	
Inventories, net	12,614	·	(12,793)	
Prepaid expenses	6,396	* ' '	923	
Other assets	6,668	(201)	(10,391)	
Increase (decrease) in:				
Accounts payable, accrued liabilities and other liabilities	(2,881		93,951	
Income taxes payable	(6,774	8,823	1,515	
Net cash provided by operating activities	363,035	258,099	160,328	
CASH FLOWS FROM INVESTING ACTIVITIES:				
Purchases of property, plant and equipment	(55,157	(46,907)	(80,617)	
Acquisitions, net of cash acquired	(46,500	(90,563)	(25,992)	
Purchases of marketable securities	(1,220,869	(1,126,043)	(492,675)	
Sales of marketable securities	1,152,485	1,001,130	349,190	
Other	(6,990	(4,935)	(6,169)	
Net cash used in investing activities	(177,031	(267,318)	(256,263)	
CASH FLOWS FROM FINANCING ACTIVITIES:				
Principal payments on long-term debt and capital leases	(20,004	(8,522)	(5,528)	
Principal payment on note assumed in acquisition		(6,500)		
Purchase of treasury stock	(99,982	2)		
Proceeds from exercise of stock options, employee stock				
purchases and warrants	21,267	25,798	23,463	
Other		(291)	(200)	
Net cash (used in) provided by financing activities	(98,719	0) 10,485	17,735	

Increase (decrease) in cash and cash equivalents Cash and cash equivalents at beginning of period	87,285 28,508	1,266 27,242	(78,200) 105,442
Cash and cash equivalents at end of period	\$ 115,793	\$ 28,508	\$ 27,242
SUPPLEMENTAL CASH FLOW DATA: Cash paid during the period:			
Interest, net of portion capitalized	\$ 1,458	\$ 2,658	\$ 1,455
Income taxes	\$ 74,711	\$ 80,733	\$ 76,039

## SEE ACCOMPANYING NOTES TO THE CONSOLIDATED FIANANCIAL STATEMENTS

F-8

#### **Table of Contents**

# BARR PHARMACEUTICALS, INC. AND SUBSIDIARIES NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(In thousands, except for per share amounts)

#### (1) Summary of Significant Accounting Policies

#### (a) Principles of Consolidation and Other Matters

Barr Pharmaceuticals, Inc. is a Delaware holding company whose principal subsidiaries, Barr Laboratories, Inc. and Duramed Pharmaceuticals, Inc., are engaged in the development, manufacture and marketing of generic and proprietary pharmaceuticals.

Certain amounts in the 2003 and 2004 financial statements have been reclassified to conform with the 2005 presentation.

On February 13, 2004 the Company s Board of Directors declared a 3-for-2 stock split in the form of a 50% stock dividend. Approximately 34.5 million shares of common stock were distributed on March 16, 2004 to shareholders of record at the close of business on February 23, 2004. All applicable prior period share and per share amounts have been adjusted for stock splits.

On November 20, 2003, the Company completed the purchase of substantially all of the assets of Endeavor Pharmaceuticals, Inc. ( Endeavor ). The operating results of Endeavor are included in the consolidated financial statements subsequent to the November 20, 2003 acquisition date. On February 25, 2004, the Company completed the purchase of 100% of the outstanding shares of Women s Capital Corporation ( WCC ). The operating results of WCC are included in the consolidated financial statements subsequent to the February 25, 2004 acquisition date.

#### (b) Use of Estimates in the Preparation of Financial Statements

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and use assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. These estimates are often based on judgments, probabilities and assumptions that management believes are reasonable but that are inherently uncertain and unpredictable. As a result, actual results could differ from those estimates. Management periodically evaluates estimates used in the preparation of the consolidated financial statements for continued reasonableness. Appropriate adjustments, if any, to the estimates used are made prospectively based on such periodic evaluations.

#### (c) Revenue Recognition

The Company recognizes product sales revenue when title and risk of loss have transferred to the customer, when estimated provisions for product returns, rebates, including Medicaid rebates, chargebacks and other sales allowances are reasonably determinable, and when collectibility is reasonably assured. Accruals for these provisions are presented in the consolidated financial statements as reductions to revenues. Accounts receivable are presented net of allowances relating to the above provisions of \$149,945 and \$141,873 at June 30, 2005 and 2004, respectively. Included in accrued liabilities are \$10,060 and \$11,413 relating to estimated Medicaid rebates at June 30, 2005 and 2004, respectively.

Alliance, development and other revenue includes: reimbursements relating to research and development contracts, licensing fees, royalties earned under co-promotion agreements and profit splits on certain products. The Company recognizes revenues under: (1) research and development agreements as it performs the related research and development; (2) license fees over the life of the product license; and (3) royalties under co-promotion agreements and profit splits at the time its partner ships the product and title and risk of loss pass to a third party.

F-9

#### **Table of Contents**

#### (d) Sales Returns and Allowances

At the time of sale, the Company simultaneously records estimates for various costs, which reduce product sales. These costs include estimates for price adjustments, product returns, chargebacks, rebates, including Medicaid rebates, prompt payment discounts and other sales allowances. In addition, the Company records allowances for shelf-stock adjustments when the conditions are appropriate. Estimates for sales allowances such as product returns, rebates and chargebacks are based on a variety of factors including actual return experience of that product or similar products, rebate arrangements for each product, and estimated sales by our wholesale customers to other third parties who have contracts with the Company. Actual experience associated with any of these items may be different than the Company is estimates. The Company regularly reviews the factors that influence its estimates and, if necessary, makes adjustments when it believes that actual product returns, credits and other allowances may differ from established reserves.

#### (e) Inventories

Inventories are stated at the lower of cost or market. Cost is determined on a first-in, first-out (FIFO) basis. The Company establishes reserves for its inventory to reflect situations in which the cost of the inventory is not expected to be recovered. In evaluating whether inventory is stated at the lower of cost or market, management considers such factors as the amount of inventory on hand, estimated time required to sell such inventory, remaining shelf life and current and expected market conditions, including levels of competition. The Company records provisions for inventory reserves as part of cost of sales.

#### (f) Income Taxes

Income taxes have been provided for using an asset and liability approach in which deferred tax assets and liabilities are recognized for the differences between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the years in which the differences are expected to reverse. A valuation allowance is provided for the portion of deferred tax assets that are more-likely-than-not to be unrealized. Deferred tax assets and liabilities are measured using enacted tax rates and laws.

#### (g) Contingencies

The Company is involved in various patent, product liability and, commercial litigation and claims, government investigations and other legal proceedings that arise from time to time in the ordinary course of its business (see note 17). The Company assesses, in consultation with counsel, the need to accrue a liability for such contingencies and record a reserve when it determines that a loss related to a matter is both probable and reasonably estimable. Because litigation and other contingencies are inherently unpredictable, the Company s assessment can involve judgments about future events. The Company records anticipated recoveries under existing insurance contracts when collection is reasonably assured.

## (h) Acquisitions

The Company accounts for acquired businesses using the purchase method of accounting which requires that the assets acquired and liabilities assumed be recorded at the date of acquisition at their respective fair values. The Company s consolidated financial statements and results of operations reflect an acquired business after the completion of the acquisition and are not restated. The cost to acquire a business, including transaction costs, is allocated to the underlying net assets of the acquired business in proportion to their respective fair values. Any excess of the purchase price over the estimated fair values of the net assets acquired is recorded as goodwill. Amounts allocated to acquired in-process research and development are expensed at the date of acquisition. When the Company acquires net assets that do not constitute a business, no goodwill is recognized.

F-10

#### **Table of Contents**

The judgments made in determining the estimated fair value assigned to each class of assets acquired and liabilities assumed, as well as asset lives, can materially impact the Company's results of operations. Accordingly, for significant items, the Company typically obtains assistance from third party valuation specialists. Useful lives are determined based on the expected future period of benefit of the asset, which considers various characteristics of the asset, including projected cash flows. The Company reviews goodwill for impairment annually or more frequently if impairment indicators arise.

#### (i) Credit and Market Risk

Financial instruments that potentially subject the Company to credit risk consist principally of interest-bearing investments and trade receivables. The Company performs ongoing credit evaluations of its customers financial condition and generally does not require collateral from its customers.

#### (j) Cash and Cash Equivalents

Cash equivalents consist of short-term, highly liquid investments including money market securities. In March 2005, the Company concluded that it was appropriate to reclassify its investment in auction rate securities as short-term marketable securities. Previously, such investments had been classified on the balance sheet as cash and cash equivalents. Accordingly, the Company has revised its June 30, 2004 consolidated balance sheet to reclassify auction rate securities in the amount of \$391,370 from cash and cash equivalents to short-term marketable securities.

## (k) Property, Plant and Equipment

Property, plant and equipment is recorded at cost. Depreciation is recorded on a straight-line basis over the estimated useful lives of the related assets (3 to 10 years for machinery, equipment, furniture and fixtures and 10 to 45 years for buildings and improvements). Amortization of capital lease assets is included in depreciation expense. Leasehold improvements are amortized on a straight-line basis over the shorter of their useful lives or the terms of the respective leases, with such amortization periods generally ranging from 2 to 10 years. Maintenance and repairs are charged to operations as incurred; renewals and betterments are capitalized.

#### (1) Stock-Based Compensation

The Company has three stock-based employee compensation plans, two stock-based non-employee director compensation plans and an employee stock purchase plan, which are described more fully in Note 14. The Company accounts for these plans under the intrinsic value method described in Accounting Principles Board Opinion No. 25 Accounting for Stock Issued to Employees, and related Interpretations. Under the intrinsic value method, no stock-based employee compensation cost is reflected in net earnings. The following table illustrates the effect on net earnings and earnings per share if the Company had applied the fair value recognition provisions of SFAS No. 123, Accounting for Stock-Based Compensation , to stock-based compensation.

F-1

#### **Table of Contents**

	Years Ended June				e 30,		
(in thousands, expect per share data)	20	005	20	004	20	003	
NET EARNINGS, AS REPORTED	\$21	4,988	\$12	3,103	\$ 16	7,566	
Add: Stock-based employee compensation expense included in							
reported net income, net of related tax effects							
Deduct: Total stock-based employee compensation expense							
determined under fair value based method for all awards, net of	_					· -	
related tax effects	2	0,178	1	3,747		6,047	
DDO FORMA NET FARNINGS	¢ 10	4.010	¢ 10	0.256	¢ 16	1 5 1 0	
PRO FORMA NET EARNINGS	\$ 19	4,810	\$ 10	9,356	\$ 10	1,519	
EARNINGS PER SHARE:							
Basic as reported	\$	2.08	\$	1.21	\$	1.69	
•							
Basic pro forma	\$	1.89	\$	1.07	\$	1.63	
Diluted as reported	\$	2.03	\$	1.15	\$	1.62	
Dilutad pro forms	¢	1 0/	Ф	1.02	Φ	1 56	
Diluted pro forma	\$	1.84	\$	1.03	\$	1.56	

For all plans, the fair value of each option grant was estimated at the date of grant using the Black-Scholes Option Pricing Model with the following weighted-average assumptions:

	Years Ended June 30,				
	2005	2004	2003		
Average expected term (years)	3.3	3.5	3.7		
Risk-free interest rate	2.40%	2.20%	2.31%		
Dividend yield	0%	0%	0%		
Volatility	48.22%	54.15%	53.73%		
Fair value of each option granted at market	\$ 12.90	\$ 17.79	\$ 11.19		

#### (m) Research and Development

Research and development costs are expensed as incurred. These expenses include the costs of the Company s research and development efforts, acquired in-process research and development, as well as costs incurred in connection with the Company s third party collaboration efforts. Pre-approved milestone payments made under contract research and development arrangements prior to regulatory approval are expensed when the milestone is achieved. Once the product receives regulatory approval, the Company records any subsequent milestone payments as intangible assets.

#### (n) Advertising and Promotion Costs

Costs associated with advertising and promotion are expensed in the period in which the advertising is used and these costs are included in selling, general and administrative expenses. Advertising and promotion expenses totaled approximately \$52,006, \$45,637 and \$21,377 for the years ended June 30, 2005, 2004 and 2003, respectively.

F-12

#### **Table of Contents**

#### (o) Earnings Per Share

The following is a reconciliation of the numerators and denominators used to calculate earnings per common share (EPS) as presented in the consolidated statements of operations:

(In thousands, except per share data) Numerator for basic and diluted earnings per share Net earnings	<b>2005</b> \$ 214,988	<b>2004</b> \$ 123,103	<b>2003</b> \$ 167,566
Earnings per common share basic: Numerator: Net earnings	\$ 214,988	\$ 123,103	\$ 167,566
Denominator: Weighted average shares	103,180	101,823	99,125
Earnings per common share basic	\$ 2.08	\$ 1.21	\$ 1.69
Earnings per common share diluted: Numerator: Net earnings	\$ 214,988	\$ 123,103	\$ 167,566
Denominator: Weighted average shares diluted	106,052	106,661	103,592
Earnings per common share diluted	\$ 2.03	\$ 1.15	\$ 1.62
Calculation of weighted average common shares diluted Weighted average shares Effect of dilutive options and warrants Weighted average shares diluted	103,180 2,872 106,052	101,823 4,838 106,661	99,125 4,467 103,592
Not included in the calculation of diluted earnings per share because their impact is antidilutive:  Stock options outstanding	84	57	1,899
(n) Fair Value of Financial Instruments			

#### (p) Fair Value of Financial Instruments

Cash, Accounts Receivable, Other Receivables and Accounts Payable The carrying amounts of these items are a reasonable estimate of their fair value.

Marketable Securities Marketable securities are recorded at their fair value (see Note 7).

Other Assets Investments that do not have a readily determinable market value are recorded at cost, as it is a reasonable estimate of fair value or current realizable value.

Long-Term Debt The fair value at June 30, 2005 and 2004 is estimated at \$18,000 and \$38,000, respectively (see Note 11 for carrying value). Estimates were determined by discounting the future cash flows using rates currently available to the Company.

The fair value estimates presented herein are based on pertinent information available to management as of June 30, 2005. Although management is not aware of any factors that would significantly affect the estimated fair value amounts, such amounts have not been comprehensively revalued for purposes of these financial statements since that date, and current estimates of fair value may differ significantly from the amounts presented herein.

#### (q) Asset Impairment

#### **Table of Contents**

The Company reviews the carrying value of its long-term assets for impairment annually and whenever events and circumstances indicate that the carrying value of an asset may not be recoverable from the estimated future cash flows expected to result from its use and eventual disposition. In cases where undiscounted expected future cash flows are less than the carrying value, an impairment loss is recognized equal to an amount by which the carrying value exceeds the fair value of assets.

#### (r) New Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board (the FASB) issued Statement of Financial Accounting Standard (SFAS) No. 123(R), Share-Based Payment, which revises SFAS No. 123, Accounting for Stock-Based Compensation (SFAS No. 123), and supersedes Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees (APB No. 25) and amends SFAS No. 95 Statement of Cash Flows. SFAS No. 123(R) requires companies to recognize in their income statement the grant-date fair value of stock options and other equity-based compensation issued to employees and directors. Pro forma disclosure is no longer an alternative. The Company adopted SFAS No. 123(R) on July 1, 2005. This Statement requires that compensation expense for most equity-based awards be recognized over the requisite service period, usually the vesting period, while compensation expense for liability-based awards (those usually settled in cash rather than stock) be re-measured to fair-value at each balance sheet date until the award is settled. As permitted by SFAS No. 123, the Company currently accounts for share-based payments to employees and directors using the intrinsic value method and, as such, recognizes no compensation cost for equity-based awards. Accordingly, the adoption of SFAS No. 123(R) s fair value method will have an impact on the Company s results of operations, although it will have no net impact on the Company s overall financial position or cash flows.

Currently, the Company uses the Black-Scholes formula to estimate the value of stock-based compensation granted to employees and directors and expects to continue to use this acceptable option valuation model in the future. Because SFAS No. 123(R) must be applied not only to new awards, but to previously granted awards that are not fully vested on the effective date, compensation cost for some previously granted options will be recognized under SFAS No. 123(R). However, had the Company adopted SFAS No. 123(R) in prior periods, the impact of that Statement would have approximated the impact described in pro forma net income and earnings per share disclosed in Note 1(1) above.

SFAS No. 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as currently required.

The Company will follow the modified prospective method, which requires companies to record compensation expense for (1) the non-vested portion of previously issued awards that remain outstanding at the initial date of adoption and (2) any awards issued or modified after July 1, 2005. Based on the adoption of the modified prospective method, the Company expects to record a pre-tax stock based compensation expense of approximately \$27 million in fiscal 2006. This amount represents previously issued awards vesting in fiscal 2006 and 2006 fiscal year awards expected to be granted.

In November 2004, the FASB issued Statement No. 151, Inventory Costs, an amendment of ARB No. 43, Chapter 4 (SFAS No. 151), to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted materials (spoilage). ARB No. 43 allowed some of these abnormal costs to be carried as inventory whereas SFAS No. 151 requires that these costs be recognized in income as incurred. This Statement is effective for the Company s fiscal year beginning July 1, 2005. The Company has evaluated the effect of adopting SFAS No. 151 and has determined that this statement will not have a significant effect on its current consolidated financial statements.

In December 2004, the FASB issued FSP FAS 109-1, Application of FASB Statement No. 109, Accounting for Income Taxes, to the Tax Deduction on Qualified Production Activities Provided by the American Jobs Creation Act of 2004 (the Act ), to provide accounting guidance on the appropriate treatment of tax benefits generated by the enactment of the Act. The FSP requires that the manufacturer s deduction be treated as a special deduction in accordance with SFAS No. 109 and not as a tax rate reduction. The Company assessed the impact of adopting FSP

Table of Contents 104

F-14

#### **Table of Contents**

FAS 109-1 on its consolidated financial statements and is expected to realize a slight reduction in its effective tax rate during fiscal 2006. The Act will be effective for the Company s fiscal year beginning July 1, 2005.

### (2) Acquisitions

#### Acquisition of a Urinary Incontinence Product

In June 2002, the Company acquired certain assets and liabilities from Enhance Pharmaceuticals, Inc. As part of the Enhance acquisition, the Company acquired a Product Development and License Agreement with Schering AG pursuant to which Barr has been developing a vaginal ring urinary incontinence product that Schering intended to market and distribute worldwide. On March 31, 2004, Barr and Schering agreed that Barr would (i) acquire the worldwide rights to the product, (ii) forgo all remaining expense reimbursements, development milestones and royalties, (iii) assume all remaining responsibilities for the development and marketing of the product and (iv) pay Schering a milestone payment upon product approval and a royalty on future product sales. As a result of this agreement, the cash payments Barr expected to receive pursuant to the Product Development and License Agreement terminated as of March 31, 2004. Accordingly, the Company wrote-off, as research and development expense, the remaining \$22,333 of net book value associated with the initial intangible asset for the product license.

#### Acquisition of Products from Wyeth

In June 2003, the Company acquired from Wyeth product rights and a sublicense on a product in development. The Company also entered into a supply agreement for royalty payments on future sales. Upon acquisition, \$3,946 was written off as research and development expense because technological feasibility had not been established and the project had no alternative future use.

#### Acquisition of Endeavor Pharmaceuticals, Inc.

On November 20, 2003, the Company completed the acquisition of substantially all of the assets of Endeavor Pharmaceuticals, Inc. ( Endeavor ). The Company acquired Endeavor to broaden its line of hormone therapy and other female healthcare products. In the transaction, the Company acquired the currently pending New Drug Applications and intellectual property related to Endeavor s Enjuvia synthetic conjugated estrogens product and two other female healthcare products in early-stage development.

The total purchase price, including transaction costs of \$517, was \$35,600 and was allocated to acquired in-process research and development. This amount was written-off upon acquisition as research and development expense because the projects to develop the acquired products, which had not received approval from the FDA, were incomplete and had no alternative future use.

The operating results of Endeavor are included in the Company s consolidated financial statements subsequent to the November 20, 2003 acquisition date.

#### Acquisition of Women s Capital Corporation

In February 2004, the Company acquired 100% of the outstanding shares of Women's Capital Corporation (WCC), a privately held company that marketed the prescription version of Plan  $B^{\oplus}$ , an emergency oral contraceptive product and had filed an application with the FDA for an over-the-counter version of Plan B. The total purchase price, including acquisition costs of \$198 and net of cash acquired, was \$12,273. In addition, at the time of the purchase, the Company made a payment of \$6,690, including principal and interest, to settle a note payable assumed from WCC as part of the acquisition. The fair values of the assets acquired and liabilities assumed in connection with the acquisition were:

F-15

#### **Table of Contents**

Current assets Deferred tax assets Intangible assets Goodwill In-process research and development	\$ 885 3,201 2,200 4,610 10,300
Total assets acquired	21,196
Current liabilities Debt	1,423 7,500
Total liabilities assumed	8,923
Net assets acquired	\$ 12,273
Cash paid, net of cash acquired Note issued to WCC stockholders	\$ 5,773 6,500
Purchase price	\$ 12,273

An intangible asset of \$2,200 representing the fair value of the currently marketed prescription version of Plan B was amortized over one year. An acquired in-process research and development asset in the amount of \$10,300, representing the estimated fair value of the unapproved over-the-counter version of Plan B, was written-off upon acquisition as research and development expense because the project was incomplete and had no alternative future use. The difference between the fair value of the net assets acquired and the purchase price resulted in goodwill of \$4,610. The goodwill and in-process research and development amounts are not deductible for tax purposes.

The operating results of WCC are included in the Company s consolidated financial statements subsequent to the February 25, 2004 acquisition date. WCC s results of operations prior to the acquisition date were not significant in relation to the Company s results of operations.

#### Acquisition of Certain Assets from Gynétics, Inc.

In February 2004, the Company paid \$4,200 to purchase certain assets from Gynétics, Inc. that were being used to develop, manufacture, distribute, promote, market, use and sell the emergency oral contraceptive known as Preven® and all rights to an additional emergency oral contraceptive product. The transaction also terminated the Company s obligations under a non-compete agreement between Barr and Gynétics that would have prevented the Company from acquiring WCC. As part of the purchase, the Company agreed to pay Gynétics a royalty on Plan B sales until royalty payments equal \$2,500. The Company has consolidated its emergency contraception business in the Plan B product. Accordingly, for the year ended June 30, 2004, the Company recorded an expense for the \$4,200 purchase price as selling, general and administrative expense.

#### Acquisition of Products from Galen (Chemicals) Limited

In March 2004, the Company acquired from Galen (Chemicals) Limited the exclusive rights to manufacture and market Loestrin<sup>®</sup> products in the United States and Loestrin and Minestrin<sup>®</sup> products in Canada for a \$45,000 cash payment. These product rights are recorded as other intangible assets on the consolidated balance sheets and are being amortized over an estimated useful life of 10 years (see Note 8).

#### Acquisition of Product from Eastern Virginia Medical School

In September 2004, the Company exercised its option and paid \$19,250 to buy-out the future royalty interests on certain extended cycle oral contraception products, including SEASONALE, from the former patent holder for

SEASONALE. This payment is recorded as other intangible assets on the consolidated balance sheets and are being amortized over an estimated useful life of 15 years (see Note 8).

F-16

#### **Table of Contents**

#### Acquisition of Products from King Pharmaceuticals, Inc.

In November 2004 and December 2004, the Company acquired the exclusive rights in the United States for Prefest® Tablets and Nordette® Tablets from King Pharmaceuticals, Inc. for \$15,000 and \$12,000, respectively. These product rights are recorded as other intangible assets on the consolidated balance sheets and are being amortized over an estimated useful life of 15 and 5 years, respectively (see Note 8).

#### (3) Proceeds From Patent Challenge

In January 1997, Bayer AG, Bayer Corporation (collectively, Bayer) and the Company agreed to settle the then pending litigation regarding Bayer s patent protecting Ciprofloxacin hydrochloride. Under the settlement agreement, the Company withdrew its patent challenge by amending its Abbreviated New Drug Application (ANDA) from a paragraph IV certification (claiming invalidity) to a paragraph III certification (seeking approval upon patent expiry) and acknowledged the validity and enforceability of the Ciprofloxacin patent. As consideration for this settlement, the Company received a non-refundable payment of \$24,550 in January 1997, which it recorded as proceeds from patent challenge settlement. Concurrent with the Settlement Agreement, the Company also signed a contingent, non-exclusive Supply Agreement (Supply Agreement) with Bayer that ended at patent expiry in December 2003.

Under the terms of the Supply Agreement, until June 9, 2003, Bayer, at its sole option could either (i) allow Barr and Aventis, the contractual successor to Barr s joint venture partner in the Cipro patent challenge case, to purchase, at a predetermined discount to Bayer s then selling price, quantities of Ciprofloxacin for resale under market conditions or (ii) make quarterly cash payments as defined in the Agreement. Bayer elected to make payments rather than supply the Company with Ciprofloxacin. Barr recognized the amounts due under the Supply Agreement as such amounts were realized based on the outcome of Bayer s election. The amounts realized are reported as proceeds from patent challenge settlement. On June 9, 2003, the Company began distributing Ciprofloxacin tablets.

#### (4) Other Receivables

Included in other receivables at June 30, 2004 was a \$47,517 receivable from Bayer that was collected during the quarter ended September 30, 2004.

#### (5) Inventories, net

The components of inventory are as follows:

	June	June 30,	
	2005	2004	
Raw materials and supplies	\$ 79,120	\$ 86,238	
Work-in-process	16,405	17,449	
Finished goods	42,113	46,565	
	\$ 137,638	\$ 150,252	

F-17

#### **Table of Contents**

#### (6) Property, plant and equipment, net

The major categories of the Company s property, plant and equipment are as follows:

	June 30,		
	2005	2004	
Land	\$ 7,461	\$ 7,299	
Buildings and improvements	135,737	135,636	
Machinery and equipment	189,906	175,007	
Leasehold improvements	8,414	5,989	
Construction in progress	37,584	19,547	
	379,102	343,478	
Less: accumulated depreciation and amortization	129,617	106,647	
	\$ 249,485	\$ 236.831	

Depreciation expense was \$31,591, \$25,678 and \$19,547 for the years ended June 30, 2005, 2004 and 2003, respectively.

## (7) Marketable Securities

The Company's investments in marketable securities are primarily classified as available for sale and, accordingly, are recorded at current market value with offsetting adjustments to shareholders equity, net of income taxes. During fiscal 2005, the Company concluded that it was appropriate to reclassify its investment in auction rate securities as short-term marketable securities. Previously, such investments had been classified on the balance sheet as cash and cash equivalents. Accordingly, the Company has revised its June 30, 2004 consolidated balance sheet to reclassify auction rate securities in the amount of \$391,370 from cash and cash equivalents to short-term marketable securities. The Company s investment in auction rate securities is classified as short or long-term based on the Company s expected holding period.

The amortized cost and estimated market values of marketable securities at June 30, 2005 and 2004 are as follows:

L 20, 2005	Amort Cos		Unr	ross ealized osses)	Market Value
June 30, 2005 Debt securities Equity securities		,687 \$ ,449	\$	(881)	\$ 575,806 5,449
	\$ 582	,136 \$	\$	(881)	\$ 581,255
June 30, 2004 Debt securities Equity securities		,213 \$ ,676	\$		\$ 509,213 3,676
	\$ 512	,889 \$	\$		\$512,889

The cost of investments sold is determined by the specific identification method.

Debt securities at June 30, 2005 with a market value of \$575,806 include \$474,194 in market auction debt securities, which are readily convertible into cash at par value with interest rate reset and underlying maturity dates ranging from July 1, 2005 to December 1, 2037 and \$101,612 in municipal bonds and federal agency issues with maturity dates ranging from September 28, 2005 to July 1, 2007.

Equity securities include amounts invested in connection with the Company  $\, s \, excess \, 401(k)$  and other deferred compensation plans.

F-18

#### **Table of Contents**

#### (8) Goodwill and Other Intangible Assets

Goodwill and other intangible assets consist of the following at June 30, 2005 and 2004:

	June 30,			
	2005	2004		
Goodwill	\$ 17,998	\$ 18,211		
Product licenses	\$ 45,600	\$ 45,350		
Product rights and related intangibles	70,796	24,246		
	116,396	69,596		
Less: accumulated amortization	(18,053)	(4,699)		
Intangible assets, net	\$ 98,343	\$ 64,897		

The entire goodwill balance at June 30, 2005 and 2004 is related to the Company s proprietary products segment. In fiscal 2004, the Company recorded \$4,610 related to the acquisition of WCC and subsequently reduced the amount for post-closing activity related to the transaction to a net amount of \$4,093. The \$213 decrease in goodwill from June 30, 2004 is attributable to additional post-closing activity related to the acquisition of WCC.

In fiscal 2005, the Company exercised its option and paid \$19,250 to buy-out the future royalty interests on certain extended cycle oral contraception products, including SEASONALE, from the former patent holder for SEASONALE. This payment is included in product rights and related intangibles (see Note 2).

In fiscal 2005, the Company acquired the exclusive rights in the United States for Prefest® Tablets and Nordette® Tablets from King Pharmaceuticals, Inc. for \$15,000 and \$12,000, respectively. These acquisition costs are included in product rights and related intangibles (see Note 2).

The annual estimated amortization expense for the next five years on product licenses and product rights and related intangibles is as follows:

## Year Ending June 30,

2006	\$ 12,760
2007	12,226
2008	11,745
2009	11,228
2010	9,889

The Company s product licenses and product rights and related intangibles have weighted average useful lives of approximately 10 and 11 years, respectively.

# (9) Other Liabilities

In fiscal 2002, the Company entered into a development agreement with the U.S. Department of Defense for the development of the Adenovirus Vaccine Type 4 and Type 7. Among other things, the contract provided for the Company to build a dedicated facility for the development and future commercialization of the vaccine. The Company s costs were reimbursed by the Department of Defense and the reimbursements were treated as deferred revenues and classified in other liabilities. In March 2005, the Company and the Department of Defense amended the development agreement, resulting in a \$10,000 write-down in both property, plant and equipment and other liabilities.

#### (10) Solvay Arbitration Award

On March 31, 2002, the Company gave notice of its intention to terminate, as of June 30, 2002, its relationship with Solvay Pharmaceuticals, Inc. which covered the joint promotion of the Company's Cenestin tablets and Solvay's Prometrium® capsules. Solvay disputed the Company's right to terminate the relationship, claiming it was entitled to substantial damages and initiated formal arbitration proceedings. The arbitration hearing was held in January 2004. On June 17, 2004, the arbitration panel determined that the Company did not properly terminate its contract with Solvay and awarded Solvay \$68,000 in monetary damages to be paid over sixteen months. The Company has included these amounts in selling, general and administrative expenses on its statement of operations and in accrued and other liabilities on its balance sheet, as applicable.

## (11) Long-term Debt

A summary of long-term debt is as follows:

	June 30,		
	2005	2004	
Senior Unsecured Notes (a)	\$ 12,000	\$ 17,429	
Mortgage notes (b)		13,200	
Note Due to WCC Shareholders (c)	6,500	6,500	
	18,500	37,129	
Less: Current installments of long-term debt	(4,000)	(7,029)	
Total long-term debt	\$ 14,500	\$ 30,100	

(a) The Senior
Unsecured Note
consists of a
\$12,000, 7.01%
Note due
November 18,
2007. Annual
principal
payments under
the Note amount
to \$4,000 in
each of fiscal
years 2006,

The Senior
Unsecured Note
contains certain
covenants
including,
among others, a
restriction on
dividend
payments in
excess of

2007 and 2008.

\$10,000 plus 75% of consolidated net earnings subsequent to June 30, 1997.

#### (b) In

February 2005, the Company made a \$12,200 payment in complete satisfaction of its mortgage note.

#### (c) In

February 2004, the Company acquired all of the outstanding shares of WCC. In connection with that acquisition, a four-year \$6,500 promissory note was issued to WCC. The note bears interest at 2%. The entire principal amount and all accrued interest is payable on February 25, 2008 (see Note

In August 2004, the Company entered into a new \$175,000 revolving credit facility that replaced its prior \$40,000 facility. This new facility has a five-year term that expires on August 30, 2009. The Company may use the funds available under the new credit facility for working capital, capital expenditures, acquisitions and other general corporate purposes. As of June 30, 2005, there were no borrowings outstanding under this facility.

Principal maturities of existing long-term debt for the next five years and thereafter are as follows:

## Years Ending June 30,

	0 -	,	
2006			\$ 4,000
2007			4,000
2008			10,500
2009			

#### (12) Related-party Transactions

Dr. Bernard C. Sherman and Jacob M. Kay

The Company purchases bulk pharmaceutical materials and sells certain pharmaceutical products and bulk pharmaceutical materials to companies owned or controlled by Dr. Bernard C. Sherman. Dr. Sherman was a member of the Company s Board of Directors until October 24, 2002 and is the principal stockholder of Sherman Delaware, Inc. which owned approximately 8.5% of the Company s outstanding common stock at June 30, 2005. In addition, Jacob M. Kay, a member of the Board of Directors, is president of Apotex, Inc., one of the companies owned or controlled by Dr. Sherman.

The Company entered into an agreement with Apotex Inc. to share litigation and related costs in connection with the Company s Fluoxetine (generic Prozac) patent challenge. Under this agreement certain costs were shown as a reduction to operating expenses while other costs were included as cost of sales. Separately, the Company receives a royalty on a product marketed and sold by Apotex Inc.

The table below sets forth the statement of operations for transactions with companies owned or controlled by Dr. Sherman.

	Years Ended June 30,		
	2005	2004	2003
Purchases from the Sherman Cos.	\$ 5,575	\$ 2,808	\$ 3,583
Sales to the Sherman Cos.	\$ 10,149	\$ 9,486	\$ 12,727
Recovery of shared litigation costs included in operating expenses	\$ 77	\$ 1,004	\$ 585
Profit split charged to cost of goods	\$ 1,027	\$ 3,680	\$ 1,440
Royalty revenue	\$ 216	\$ 295	\$

#### (13) Income Taxes

A summary of the components of income tax expense is as follows:

		Years Ended June 30,			
		2005	2004	2003	
Current: Federal State		\$ 101,355 6,482	\$ 101,477 18,097	\$ 77,615 10,911	
		\$ 107,837	\$ 119,574	\$ 88,526	
Deferred: Federal State		\$ 4,441 2,610	\$ (41,348) (6,889)	\$ 9,010 (2,387)	
		7,051	(48,237)	6,623	
Total		\$ 114,888	\$ 71,337	\$ 95,149	
	F-21				

## **Table of Contents**

The provision for income taxes differs from amounts computed by applying the statutory federal income tax rate to earnings before income taxes due to the following:

	Years Ended June 30,			
	2005	2004	2003	
Federal income taxes at statutory rate	\$ 115,457	\$ 68,054	\$ 91,950	
State income taxes, net of federal income tax effect	9,092	6,687	8,207	
Tax credits	(6,900)	(5,900)	(1,000)	
Write-off of in-process research and development		3,605		
Other, net	(2,761)	(1,109)	(4,008)	
	\$ 114,888	\$71,337	\$ 95,149	

The temporary differences that give rise to deferred tax assets and liabilities as of June 30, 2005 and 2004 are as follows:

	Years Ended June 30,		
	2005	2004	
Deferred tax assets:			
Net operating loss	\$ 3,677	\$ 5,113	
Receivable reserves	17,833	29,888	
Inventory	2,865	2,707	
Warrants issued	16,366*		
Capital loss carryforward	2,864	3,122	
Amortization of intangibles/goodwill	60,467	28,673	
Deferred revenue	7,239	7,400	
Natural Biologics loan		6,673	
Tax credit carryforward		15	
Investments	320*		
Solvay litigation	4,003	20,226	
Other	7,108	6,043	
Total deferred tax assets	122,742	109,860	
Deferred tax liabilities:			
Plant and equipment	(24,905)	(19,889)	
Other	(3,452)	(4,196)	
Total deferred tax liabilities	(28,357)	(24,085)	
Less valuation allowance	(3,657)	(4,682)	
Net deferred tax asset	\$ 90,728	\$ 81,093	

<sup>\*</sup> changes reflected directly in equity

At June 30, 2005 and 2004, as a result of certain acquisitions, the Company had cumulative regular net operating loss carryforwards of approximately \$3,568 and \$10,195, respectively, for federal and state income tax purposes, which will expire in the years 2018 to 2023. There is an annual limitation on the utilization of the net operating loss carryforward, which is calculated under Internal Revenue Code Section 382.

The tax credit carryforward is primarily comprised of credits related to alternative minimum tax payments, which have no expiration.

The Company has established a valuation allowance to reduce the deferred tax asset recorded for certain tax credits, capital loss carryforwards, and certain net operating loss carryforwards. A valuation allowance is recorded F-22

#### **Table of Contents**

because based on available evidence, it is more-likely-than-not that a deferred tax asset will not be realized. The valuation allowance reduces the deferred tax asset to the Company s best estimate of the net deferred tax asset that, more-likely-than-not, will be realized. The valuation allowance will be reduced when and if the Company determines that the deferred income tax assets are likely to be realized. Accordingly, during the year ended June 30, 2005, the Company reduced the valuation allowance by a net of \$1,018 due to the utilization of certain tax capital losses and the write-off of certain deferred tax assets and related valuation allowances.

#### (14) Shareholders Equity

(Shares and Per Share amounts expressed in whole numbers)

## **Employee Stock Option Plans**

The Company has three employee stock option plans, the Barr Pharmaceuticals, Inc. 2002 Stock and Incentive Award Plan (the 2002 Option Plan ), the Barr Pharmaceuticals, Inc. 1993 Stock Incentive Plan (the 1993 Option Plan ) and the Barr Pharmaceuticals, Inc. 1986 Option Plan, which were approved by the shareholders and which authorize the granting of options to officers and employees to purchase the Company s common stock. On February 20, 2003, all shares available for grant in the 1993 Option Plan were transferred to the 2002 Option Plan and all subsequent grants have been made under the 2002 Option Plan. Effective June 30, 1996, options were no longer granted under the 1986 Option Plan. For fiscal 2005, 2004 and 2003, there were no options that expired under this plan.

All options granted prior to June 30, 1996 under the 1993 Option Plan and 1986 Option Plan, become exercisable between one and two years from the date of grant and expire ten years after the date of grant except in cases of death or termination of employment as defined in each Plan. All options outstanding on October 24, 2001 became fully vested upon completion of the Duramed merger. Options granted after October 24, 2001 are exercisable between one and five years from the date of grant. Through fiscal 2000, no option had been granted under either the 1993 Option Plan or the 1986 Option Plan at a price below the current market price of the Company s common stock on the date of grant. Options granted after February 20, 2003 become exercisable between one and three years from the date of grant and expire ten years after the date of grant except in cases of death or termination of employment.

In addition, the Company has options outstanding under the terms of various former Duramed plans. These include the 1986 Stock Option Plan (the Duramed 1986 Plan ), the 1988 Stock Option Plan (the 1988 Plan ), the 1997 Stock Option Plan (the 1997 Plan ), and the 2000 Stock Option Plan (the 2000 Plan ). All outstanding options under the Duramed plans, with the exception of options held by certain senior executives of Duramed, vested as of October 24, 2001, the effective date of the merger. Such options were assumed by Barr under the same terms and conditions as were applicable under the Duramed stock option plans under which the options were granted. The number of options and related exercise prices have been adjusted to a Barr equivalent number of options and exercise price pursuant to the merger. Subsequent to October 24, 2001, additional options are no longer granted under these Duramed plans.

F-23

#### **Table of Contents**

A summary of the activity for the three fiscal years ended June 30, 2005, adjusted for the March 2004 and 2003 3-for-2 stock splits, is as follows:

	No. of Shares	_	d-Average se Price
Outstanding at July 1, 2002	7,388,259	\$	16.43
Granted	2,109,333	Ψ	26.74
Canceled	(208,047)		27.92
Exercised	(1,354,542)		12.57
LACICIOCA	(1,331,312)		12.57
Outstanding at June 30, 2003	7,935,003		19.51
Granted	1,779,545		43.01
Canceled	(148,026)		28.74
Exercised	(1,699,190)		11.82
Outstanding at June 30, 2004	7,867,332		26.26
Granted	1,419,300		35.41
Canceled	(103,965)		37.60
Exercised	(961,609)		15.46
Outstanding at June 30, 2005	8,221,058	\$	28.96
Available for grant (20,067,188 authorized)	4,469,292		
Exercisable at June 30, 2003	5,557,977	\$	16.79
Exercisable at June 30, 2004	4,839,386	\$	20.02
Exercisable at June 30, 2005	5,236,178	\$	24.57
A1-11- f	1 1	20 200	24!

Available for grant and authorized amounts are for the 2002 Option Plan only, because as of June 30, 2003 options are no longer granted under any of the other option plans discussed above.

## Non-Employee Directors Stock Option Plans

During fiscal year 1994, the shareholders approved the Barr Pharmaceuticals, Inc. 1993 Stock Option Plan for Non-Employee Directors (the 1993 Directors Plan ). All options granted under the 1993 Directors Plan have ten-year terms and are exercisable at an option exercise price equal to the market price of the common stock on the date of grant. Each option is exercisable on the date of the first annual shareholders meeting immediately following the date of grant of the option, provided there has been no interruption of the optione s service on the Board before that date.

On October 24, 2002, the shareholders approved the Barr Pharmaceuticals, Inc. 2002 Stock Option Plan for Non-Employee Directors (the 2002 Directors Plan ). This plan, among other things, enhances the Company s ability to attract and retain experienced directors. On February 20, 2003, all shares available for grant under the 1993 Directors Plan were transferred to the 2002 Directors Plan.

F-24

#### **Table of Contents**

A summary of the activity for the three fiscal years ended June 30, 2005, adjusted for the March 2004 and 2003 3-for-2 stock splits is as follows:

	No of	Weight	ed-Average
	No. of Shares	Ever	cise Price
Outstanding at July 1, 2002	1,102,044	\$	14.77
Granted	101,250	Ψ	26.76
Canceled	(59,270)		32.87
Exercised	(464,061)		9.75
Outstanding at June 30, 2003	679,963		18.40
Granted	118,125		49.02
Canceled			
Exercised	(154,499)		17.75
Outstanding at June 30, 2004	643,589		22.97
Granted	45,000		37.87
Canceled			
Exercised	(58,568)		5.28
Outstanding at June 30, 2005	630,021	\$	25.68
Available for Grant (2,798,438 authorized)	906,469		
Exercisable at June 30, 2003	578,714	\$	16.94
Exercisable at June 30, 2004	576,089	\$	19.92
Exercisable at June 30, 2005	585,021	\$	24.74

Available for grant and authorized amounts are for the 2002 Directors Plan only, because as of June 30, 2003, options are no longer granted under the 1993 Directors Plan and the 1991 Duramed Directors Plan.

# Employee Stock Purchase Plan

During fiscal 1994, the shareholders ratified the adoption by the Board of Directors of the 1993 Employee Stock Purchase Plan (the Purchase Plan ) to offer employees an inducement to acquire an ownership interest in the Company. The Purchase Plan permits eligible employees to purchase, through regular payroll deductions, an aggregate of 1,518,750 shares of common stock at approximately 85% of the fair market value of such shares. Under the Purchase Plan, 159,620, 81,708 and 115,704 shares of common stock were purchased during the years ended June 30, 2005, 2004 and 2003, respectively.

#### Warrants

During 1999, in conjunction with an amendment to a financing agreement, the Company granted to a bank warrants to purchase 63,410 shares of the Company s common stock at an exercise price of \$22.19. These warrants vested immediately. In December 1999, the financing agreement was amended to reset the exercise price of 50% of the warrants to \$15.62 per share. During 2000, based on an antidilutive clause in the agreement, the number of warrants was adjusted to 66,340. The price of 33,426 warrants was adjusted to \$21.05 and the remaining 32,918 warrants were repriced to \$15.03. In November 2001 and January 2002 a total of 57,294 of the warrants were exercised. As of June 30, 2005, warrants for 9,046 shares were outstanding and remain exercisable until July 2009.

On May 12, 2000, in combination with the issuance of Series G preferred stock, the Company granted warrants to purchase 288,234 common shares at a price of \$9.54 per share. The warrants vested immediately. In April 2005 all

#### **Table of Contents**

In March 2000, the Company issued warrants granting DuPont the right to purchase 1,687,500 shares of Barr s common stock at \$13.93 per share, and 1,687,500 shares at \$16.89 per share, respectively. Each warrant was immediately exercisable. In March 2004, holders of these warrants exercised the warrants through a cashless exercise which resulted in the issuance of 2,340,610 shares of our common stock.

The following table summarizes information about stock options and warrants outstanding at June 30, 2005:

	Options and	d Warrants Ou Weighted	itstanding	Options and Exercis		
	Number Outstanding at June	Average Remaining Contractual	Weighted Average Exercise	Number Exercisable at June 30,	Weighted Average Exercise Price	
Range of Exercise Prices	30, 2005	Life	Price	2005		
\$3.06 - \$24.57	2,593,015	3.48	\$ 13.39	2,593,015	\$	13.39
\$25.26 - \$33.70	2,232,002	6.89	\$ 27.79	1,681,269	\$	28.05
\$33.91 - \$37.87	2,253,615	7.90	\$ 35.57	907,265	\$	36.26
\$37.91 - \$51.61	1,781,493	8.15	\$ 43.50	648,696	\$	43.97
	8.860.125	6.40	\$ 28.72	5.830.245	\$	24.58

#### (15) Savings and Retirement

The Company has a savings and retirement plan (the 401(k) Plan ) which is intended to qualify under Section 401(k) of the Internal Revenue Code. Employees are eligible to participate in the 401(k) Plan in the first month following the month of hire. Participating employees may contribute up to a maximum of 60% of their earnings before or after taxes, limited to a maximum of \$14 for pre-tax contributions. The Company is required, pursuant to the terms of its collective bargaining agreement, to contribute to each union employee s account an amount equal to the 2% minimum contribution made by such employee. The Company may, at its discretion, make cash contributions equal to a percentage of the amount contributed by an employee to the 401(k) Plan up to a maximum of 10% of such employee s compensation. Participants are always fully vested with respect to their own contributions and any profits arising therefrom. Participants become fully vested in the Company s contributions and related earnings after five full years of employment.

The Company s contributions to the 401(k) Plans were \$7,650, \$6,534 and \$5,549 for the years ended June 30, 2005, 2004 and 2003, respectively.

The Company has a non-qualified plan ( Excess Plan ) that enables certain executives to defer up to 60% of their compensation in excess of the qualified plan. The Company may, at its discretion, contribute a percentage of the amount contributed by the individuals covered under this Excess Plan to a maximum of 10% of such individual s compensation. In fiscal years 2005, 2004 and 2003, the Company chose to make contributions at the 10% rate to this plan. As of June 30, 2005 and 2004, the Company had an asset and matching liability for the Excess Plan of \$5,141 and \$3,563, respectively.

The Company has an unfunded pension plan covering two non-employee directors of Duramed who were elected prior to 1998 and who had served on Duramed s Board for at least five years. At the time of the merger with Barr, two Duramed directors were eligible to receive benefits. The plan provides an annual benefit, payable monthly over each director s life, from the time a participating director ceased to be a member of the Board, equal to 85% and 60%, respectively, of the director s most recent annual Board fee, as adjusted annually to reflect changes in the Consumer Price Index. As of June 30, 2005 and 2004, the Company has recorded \$447 and \$466, respectively, as a long-term liability representing the present value of the estimated future benefit obligation to the eligible directors. The right of a director to receive benefits under the plan is forfeited if the director engages in any activity determined by the Board to be contrary to the best interests of the Company.

#### **Table of Contents**

In October 2003, the Board of Directors approved the Barr Pharmaceuticals, Inc. Non-Qualified Deferred Compensation Plan (the Plan ) that was adopted effective November 1, 2003. The Plan provides for certain executives to defer all or a portion of their salary or bonus for a particular calendar year. In addition, the Company will make a matching contribution subject to certain limitations as defined in the Plan. The matching contribution as well as the employee deferral are invested in the Plan as directed by the participant, and are payable on the terms and subject to the conditions provided in the Plan. As of June 30, 2005 and 2004, the Company had an asset and matching liability for the Plan of \$308 and \$114, respectively.

# (16) Other Income (Expense), Net

A summary of other income (expense), net is as follows:

	Year Ended June 30,			
	2005	2004	2003	
Proceeds from insurance settlement	\$ 4,600	\$	\$	
Loss on limited partnerships	(796)	(1,346)		
Other	59	(187)	(128)	
Total other income (expense), net	\$ 3,863	\$ (1,533)	\$ (128)	

#### (17) Commitments and Contingencies

#### Leases

The Company is party to various leases, which relate to the rental of office facilities and equipment. The Company believes it will be able to extend such leases, if necessary. The table below shows the future minimum rental payments, exclusive of taxes, insurance and other costs under noncancellable long-term lease commitments at June 30, 2005.

	Years Ended June 30,						
	2006	2007	2008	2009	2010	The	ereafter
Operating leases Capital leases	\$ 4,359 1,692	\$ 3,981 856	\$ 3,379 204	\$ 3,281 95	\$ 3,189 32	\$	15,586
Minimum lease payments	\$ 6,051	\$ 4,837	\$ 3,583	\$ 3,376	\$ 3,221	\$	15,586

#### Investment in Venture Funds

During the second quarter of fiscal 2004, the Company made investments, as a limited partner, in two separate venture capital funds as part of its continuing efforts to identify new products, new technologies and new licensing opportunities. The Company has committed up to a total of \$15,000 for each of these funds over a five and 10-year period, as defined by each fund. As of June 30, 2005 and June 30, 2004, the Company had invested \$5,941 and \$3,500, respectively, in these funds. The Company accounts for these investments using the equity method of accounting.

## **Employment Agreements**

The Company has entered into employment agreements with certain key employees. The current terms of these agreements expire at various dates through 2007, subject to certain renewal provisions.

F-27

## **Table of Contents**

#### Product Liability Insurance

The Company s insurance coverage at any given time reflects market conditions, including cost and availability, existing at the time it is written, and the decision to obtain insurance coverage or to self-insure varies accordingly. If the Company were to incur substantial liabilities that are not covered by insurance or that substantially exceed coverage levels or accruals for probable losses, there could be a material adverse effect on its financial statements in a particular period.

The Company uses a combination of self-insurance and traditional third-party insurance policies to cover product liability claims. On September 30, 2004, the Company elected to terminate a finite-risk insurance arrangement that it had in place for two years, and in connection with such termination increased its traditional third-party product liability coverage, as discussed below.

The Company maintains third-party insurance that provides coverage, subject to specified co-insurance requirements, for the cost of product liability claims arising during the current policy period, which began on October 1, 2004 and ends on September 30, 2005, between an aggregate amount of \$25,000 and \$75,000. The Company is self-insured for up to the first \$25,000 of costs incurred relating to product liability claims arising during the current policy period. In addition, the Company has obtained extended reporting periods under previous policies for claims arising prior to the current policy period. The current period and extended reporting period policies exclude certain products; the Company would be responsible for all product liability costs arising from these excluded products.

The Company has been incurring significant legal costs associated with its hormone therapy litigation (see below). To date, these costs have been covered under extended reporting period policies that provide up to \$25,000 of coverage. As of June 30, 2005, there was approximately \$13,000 of coverage remaining under these policies. The Company has recorded a receivable for legal costs incurred and expected to be recovered under these policies. Once the coverage from these extended reporting period policies has been exhausted, future legal and settlement costs will be covered by a combination of self-insurance and other third-party insurance layers.

## **Indemnity Provisions**

From time-to-time, in the normal course of business, the Company agrees to indemnify its suppliers, customers and employees concerning product liability and other matters. For certain product liability matters, the Company has incurred legal defense costs on behalf of certain of its customers under these agreements. No amounts have been recorded in the financial statements for probable losses with respect to the Company s obligations under such agreements.

In September 2001, Barr filed an ANDA for the generic version of Aventis Allegra® tablets. Aventis has filed a lawsuit against Barr claiming patent infringement. A trial date for the patent litigation has not been scheduled, but trial is expected in early 2006. In June 2005, the Company entered into an agreement with Teva Pharmaceuticals USA, Inc. which allows Teva to manufacture and launch Teva s generic version of Aventis Allegra® product during the Company s 180 day exclusivity period, in exchange for Teva s obligation to pay the Company a specified percentage of Teva s operating profit, as defined, earned on sales of the product. The Company intends to recognize the amounts it earns under this arrangement at the time Teva ships product to its customers and will classify such amounts on the

Alliance, development and other revenue line of the statement of operations. The agreement also provides that each company will indemnify the other for a portion of any patent infringement damages they might incur, so that the parties will share any such damage liability in proportion to their respective shares of Teva s net profits.

On September 1, 2005, Teva launched its generic version of Allegra. At September 30, 2005, the Company, in accordance with FASB Interpretation No. 45 Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness to Others may be required to record a liability to reflect the fair value of the indemnification obligation it has undertaken. Because the Company continues to believe that it and

F-28

#### **Table of Contents**

Teva have meritorious defenses in the litigation, the Company expects this liability to be significantly smaller than the income it expects to earn from the arrangement with Teva.

## Litigation Settlement

On October 22, 1999, the Company entered into a settlement agreement with Schein Pharmaceutical, Inc. (now part of Watson Pharmaceuticals, Inc.) relating to a 1992 agreement regarding the pursuit of a generic conjugated estrogens product. Under the terms of the settlement, Schein relinquished any claim to rights in Cenestin in exchange for a payment of \$15,000 made to Schein in 1999. An additional \$15,000 payment is required under the terms of the settlement if Cenestin achieves total profits (product sales less product-specific cost of goods sold, sales and marketing and other relevant expenses) of greater than \$100,000 over any five year or less period prior to October 22, 2014.

## Litigation Matters

The Company is involved in various legal proceedings incidental to its business, including product liability, intellectual property and other commercial litigation and antitrust actions. The Company records accruals for such contingencies to the extent that it concludes a loss is probable and the amount can be reasonably estimated. Additionally, the Company records insurance receivable amounts from third party insurers when appropriate.

Many claims involve highly complex issues relating to causation, label warnings, scientific evidence and other matters. Often these issues are subject to substantial uncertainties and therefore, the probability of loss and an estimate of the amount of the loss are difficult to determine. The Company s assessments are based on estimates that the Company, in consultation with outside counsel, believes are reasonable. Although the Company believes it has substantial defenses in these matters, litigation is inherently unpredictable. Consequently, the Company could in the future incur judgments or enter into settlements that could have a material adverse effect on its consolidated financial statements in a particular period.

Summarized below are the more significant matters pending to which the Company is a party. As of June 30, 2005, the Company s reserve for the liability associated with claims or related defense costs for these matters, other than the Desogestrel/Ethinyl Estradiol matter described below, is not material.

#### **Patent Matters**

Desogestrel/Ethinyl Estradiol Suit

In May 2000, the Company filed an abbreviated new drug application ( ANDA ) seeking approval from the FDA to market the tablet combination of desogestrel/ethinyl estradiol tablets and ethinyl estradiol tablets, the generic equivalent of Organon Inc. s Mircette ® oral contraceptive regimen. The Company notified Bio-Technology General Corp. ( BTG ), the owner of the patent for the Mircette product, pursuant to the provisions of the Hatch-Waxman Act and BTG filed a patent infringement action in the United States District Court for the District of New Jersey seeking to prevent the Company from marketing the tablet combination. In December 2001, the District Court granted summary judgment in favor of the Company, finding that its generic product did not infringe the patent at issue in the case. BTG appealed the District Court s decision. In April 2002, the Company launched its Kariva® product, the generic version of Mircette. In April 2003, the U.S. Court of Appeals for the Federal Circuit reversed the District Court s decision granting summary judgment in the Company s favor and remanded the case to the District Court for further proceedings.

In July 2003, BTG (now Savient) filed an amended complaint adding Organon (Ireland) Ltd. and Organon USA as plaintiffs. The amended complaint seeks damages and enhanced damages based upon willful infringement. The Company filed an answer to BTG s amended complaint in July 2003. The Company believes that it has not infringed BTG s patent and, because of this, it continues to market and sell Kariva. Nevertheless, Organon seeks to recover lost profits or a reasonable royalty of up to \$100,000 from the date of launch through June 30, 2005. If BTG and Organon are successful, the Company could be liable for damages for

F-29

## **Table of Contents**

patent infringement and the damages could be significant. In addition, an adverse ruling likely would prohibit the Company from continuing to sell its Kariva product.

On June 15, 2005 the Company entered into a non-binding Letter of Intent (LOI) with Organon (Ireland) Ltd., Organon USA and Savient Pharmaceuticals, Inc. to acquire the NDA for Mircette, obtain a royalty free patent license to promote Mircette in the United States and dismiss all pending litigation between the parties in exchange for a payment by the Company of up to \$155,000. The parties will not be contractually bound unless and until they negotiate and execute definitive agreements and the pending anti-trust review is satisfactorily resolved, as discussed below. If consummated, the transaction would permit the Company to promote Mircette through its Duramed sales force, which could increase sales of both Mircette and Kariva. If the transaction is not consummated, the Company expects to continue to vigorously defend its position in the Mircette litigation.

In July 2005, the parties made the required Hart Scott Rodino filings with the Federal Trade Commission (FTC) regarding the proposed transaction. On August 1, 2005, the FTC issued a second request, asking the Company and Organon to provide detailed information concerning the proposed transaction. The second request signals possible FTC concerns about the proposed transaction and creates additional uncertainty whether the transaction will be consummated on the proposed, or other terms.

The proposed transaction is contingent upon satisfactory completion of the FTC s Hart Scott Rodino review and the negotiation of mutually satisfactory definitive agreements. However, because the proposed transaction includes, as one of its components, a payment in settlement of litigation, it is presumed under Generally Accepted Accounting Principles (GAAP) to give rise to a probable loss, as defined in SFAS No. 5, Accounting for Contingencies. In consultation with outside advisors and based on preliminary valuations of the assets the Company would acquire if the transaction closes on the terms presently contemplated, the Company has recorded a charge of \$63,238 as of June 30, 2005 to reflect the proposed litigation settlement. The Company may reverse the charge, in whole or in part, in the future if the transaction does not close and it prevails in the litigation or is ultimately held liable for a lesser amount of damages. If the transaction does not close and an unfavorable verdict were to be rendered against the Company at trial, the ultimate amount of damages payable by it could be significantly more or less than the \$63,238 charge it has recorded in connection with the propose litigation settlement.

Desmopressin Acetate Suit

In July 2002, the Company filed an ANDA seeking approval from the FDA to market desmopressin acetate tablets, the generic equivalent of Aventis DDAVP product. The Company notified Ferring AB, the patent holder, and Aventis pursuant to the provisions of the Hatch-Waxman Act in October 2002. Ferring and Aventis filed a suit in the United States District Court for the Southern District of New York in December 2002 for infringement of one of the four patents listed in the Orange Book for desmopressin acetate tablets, seeking to prevent the Company from marketing desmopressin acetate tablets until the patent expires in 2008. In January 2003, the Company filed an answer and counterclaim asserting non-infringement and invalidity of all four listed patents. In January 2004, Ferring amended their complaint to add a claim of willful infringement.

On February 7, 2005, the court granted summary judgment in the Company s favor. Ferring and Aventis have appealed. On July 5, 2005, the Company launched its generic product. If Ferring and Aventis are successful in reversing the grant of summary judgment and ultimately prevail in the case, the Company could be liable for damages for patent infringement that could exceed the Company s profit on the sale of Desmopressin Acetate. In addition, an adverse ruling likely would prohibit the Company from continuing to sell its Desmopressin Acetate product.

# **Product Liability Matters**

Hormone Therapy Litigation

The Company has been named as a defendant in approximately 3,100 personal injury product liability cases brought against the Company and other manufacturers by plaintiffs claiming that they suffered injuries resulting

Table of Contents 127

F-30

## **Table of Contents**

from the use of certain estrogen and progestin medications prescribed to treat the symptoms of menopause. The cases against the Company involve either or both of the Company's Cenestin product or the use of the Company's medroxyprogesterone acetate product, which typically has been prescribed for use in conjunction with Premarin or other hormone therapy products. All of these products remain approved by the FDA and continue to be marketed and sold to customers. While the Company has been named as defendants in these cases, fewer than a third of the complaints actually allege the plaintiffs took a product manufactured by the Company, and the Company's experience to date suggests that, even in these cases, a high percentage of the plaintiffs will be unable to demonstrate actual use of a Company product. For that reason, by the end of June 2005, nearly 1,500 of the 3,100 cases had been dismissed and, based on discussions with the Company's outside counsel, several hundred more are expected to be dismissed in the near future.

The Company believes it has viable defenses to the allegations in the complaints and is defending the actions vigorously.

## **Anti-trust Matters**

Invamed, Inc./Apothecon, Inc.

In February 1998, Invamed, Inc. and Apothecon, Inc., both of which have since been acquired by Sandoz, Inc., which is a subsidiary of Novartis AG, named the Company and several others as defendants in lawsuits filed in the United States District Court for the Southern District of New York, alleging violations of antitrust laws and also charging that the Company unlawfully blocked access to the raw material source for Warfarin Sodium. The two actions have been consolidated. On May 10, 2002, the District Court granted summary judgment in the Company s favor on all antitrust claims in the case, but found that the plaintiffs could proceed to trial on their allegations that the Company interfered with an alleged raw material supply contract between Invamed and the Company s raw material supplier. Invamed and Apothecon appealed the District Court s decision to the United States Court of Appeals for the Second Circuit. Trial on the merits was stayed pending the outcome of the appeal.

On October 18, 2004, the Court of Appeals reversed the District Court s grant of summary judgment and held that the plaintiffs have raised triable issues of material fact on their antitrust claims.

The Company believes that the suits filed by Invamed and Apothecon are without merit and is vigorously defending its position. The plaintiffs were seeking damages of approximately \$120,000 as of December 31, 2000, and if successful on their underlying claims may seek to obtain treble damages.

Ciprofloxacin (Cipro<sup>O</sup>) Antitrust Class Actions

The Company has been named as a co-defendant with Bayer Corporation, The Rugby Group, Inc. and others in approximately 38 class action complaints filed in state and federal courts by direct and indirect purchasers of Ciprofloxacin (Cipro<sup>o</sup>) from 1997 to the present. The complaints alleged that the 1997 Bayer-Barr patent litigation settlement agreement was anti-competitive and violated federal antitrust laws and/or state antitrust and consumer protection laws. A prior investigation of this agreement by the Texas Attorney General s Office on behalf of a group of state Attorneys General was closed without further action in December 2001.

The lawsuits included nine consolidated in California state court, one in Kansas state court, one in Wisconsin state court, one in Florida state court, and two consolidated in New York state court, with the remainder of the actions pending in the United States District Court for the Eastern District of New York for coordinated or consolidated pre-trial proceedings (the MDL Case ). On March 31, 2005, the Court in the MDL case granted summary judgment in the Company s favor and dismissed all of the federal actions before it. On June 7, 2005, plaintiffs filed notices of appeal to the United States Court of Appeals, but a briefing schedule and argument date have not yet been set.

On September 19, 2003, the Circuit Court for the County of Milwaukee dismissed the Wisconsin state class action for failure to state a claim for relief under Wisconsin law. Plaintiffs appealed, but the appeal has been stayed

Table of Contents 128

F-31

#### **Table of Contents**

pending a decision by the Wisconsin Supreme Court in another case involving similar legal issues. On October 17, 2003, the Supreme Court of the State of New York for New York County dismissed the consolidated New York state class action for failure to state a claim upon which relief could be granted and denied the plaintiffs motion for class certification. Plaintiffs have appealed that decision, with briefing to be completed in the fall of 2005. On April 13, 2005, the Superior Court of San Diego, California ordered a stay of the California state class actions until after the resolution of any appeal in the MDL case. On April 22, 2005, the District Court of Johnson County, Kansas similarly stayed the action before it, until after any appeal in the MDL case. The Florida state class action remains at a very early stage, with no status hearings, dispositive motions, pre-trial schedules, or a trial date set as of yet.

The Company believes that its agreement with Bayer Corporation reflects a valid settlement to a patent suit and cannot form the basis of an antitrust claim. Based on this belief, the Company is vigorously defending itself in these matters. The Company anticipates that these matters may take several years to resolve, and although it is not possible to forecast the outcome of these matters, an adverse judgment in any of the pending cases could adversely affect the Company s consolidated financial statements.

## Tamoxifen Antitrust Class Actions

To date approximately 31 consumer or third-party payor class action complaints have been filed in state and federal courts against Zeneca, Inc., AstraZeneca Pharmaceuticals L.P. and the Company alleging, among other things, that the 1993 settlement of patent litigation between Zeneca and the Company violated the antitrust laws, insulated Zeneca and the Company from generic competition and enabled Zeneca and the Company to charge artificially inflated prices for Tamoxifen citrate. A prior investigation of this agreement by the U.S. Department of Justice was closed without further action. On May 19, 2003, the U.S. District Court dismissed the complaints for failure to state a viable antitrust claim. The cases are now on appeal.

The Company believes that its agreement with Zeneca reflects a valid settlement to a patent suit and cannot form the basis of an antitrust claim. Based on this belief, the Company is vigorously defending itself in these matters. The Company anticipates that these matters may take several years to resolve.

## Medicaid Reimbursement Cases

The Company, along with numerous other pharmaceutical companies, has been named as a defendant in separate actions brought by the states of Alabama, Kentucky and Illinois, the Commonwealth of Massachusetts, the City of New York, and the following counties in New York: Albany, Allegany, Broome, Cattaraugus, Cayuga, Chautauqua, Chenango, Erie, Fulton, Genesee, Greene, Herkimer, Jefferson, Madison, Monroe, Nassau, Niagara, Oneida, Onondaga, Putnam, Rensselaer, Rockland, Saratoga, St. Lawrence, Steuben, Suffolk, Tompkins, Warren, Washington, Wayne, Westchester, and Yates. In each of these matters, the plaintiffs seek to recover damages and other relief for alleged overcharges for prescription medications paid for or reimbursed by their respective Medicaid programs. The Company believes that it has not engaged in any improper conduct and is vigorously defending itself.

The Commonwealth of Massachusetts case and the New York cases, with the exception of the action filed by Erie County, are currently pending in the United States District Court for the District of Massachusetts. Those actions are at an early stage with no trial dates set. The Erie County case is currently stayed in the United States District Court for the Western District of New York, and the Judicial Panel on Multi-District Litigation has been asked to transfer the action to the District of Massachusetts.

The Alabama case was filed in Alabama state court, removed to the United States District Court for the Middle District of Alabama, and recently returned to state court with no trial date currently set. The Illinois case was filed in Illinois state court and recently removed to the United States District Court for the Northern District of Illinois, with a pending motion to return the case to state court and no trial date currently set. The Kentucky case was filed in Kentucky state court and recently removed to the United States District Court for the Eastern District of Kentucky, with a pending motion to return the case to state court and no trial date currently set.

F-32

#### **Table of Contents**

#### Other Litigation

As of June 30, 2005, the Company was involved with other lawsuits incidental to its business, including patent infringement actions, product liability, and personal injury claims. Management, based on the advice of legal counsel, believes that the ultimate outcome of these matters will not have a material adverse effect on the Company s consolidated financial statements.

# (18) Segment Reporting

The Company operates in two reportable business segments: generic pharmaceuticals and proprietary pharmaceuticals.

#### Generic Pharmaceuticals

Generic pharmaceutical products are therapeutically equivalent to a brand name product and are marketed primarily to wholesalers, retail pharmacy chains, mail order pharmacies and group purchasing organizations. These products are approved for distribution by the FDA through the ANDA process. The Company also distributes, from time to time, product manufactured for Barr by the brand name company. Tamoxifen and Ciprofloxacin are examples of products Barr has distributed and are included in the generic pharmaceuticals segment.

In fiscal year 2005, three customers accounted for 23%, 17% and 11% of generic sales. In fiscal year 2004, three customers accounted for 24%, 14% and 13% of generic product sales. In 2003, four customers accounted for 21%, 17%, 13% and 11% of total generic product sales.

## **Proprietary Pharmaceuticals**

Proprietary pharmaceutical products are generally patent-protected products marketed directly to health care professionals. These products are approved by the FDA primarily through the New Drug Application process. Barr s proprietary segment also includes products whose patents have expired but continue to be sold under trade names to capitalize on prescriber and customer loyalties and brand recognition.

In fiscal year 2005, 2004 and 2003, three customers accounted for 25%, 18%, 10% and 21%, 20%, 15% and 15%, 19%, 11% of proprietary product sales, respectively.

The accounting policies of the segments are the same as those described in Note 1. The Company evaluates the performance of its operating segments based on net revenues and gross profit. Barr does not report depreciation expense, total assets and capital expenditures by segment as such information is neither used by management nor accounted for at the segment level. Net revenues and gross profit information for the Company s operating segments consisted of the following:

Product Product Sales:	2005	% of sales		2004	% of sales	2003	% of sales
Proprietary	\$ 278,786	27%	\$	146,087	11%	\$ 57,662	6%
Generic	751,388	73%		1,150,622	89%	837,226	94%
Total product sales	\$ 1,030,174	100%	\$	1,296,709	100%	\$ 894,888	100%
Gross profit:		Margin %			Margin %		Margin %
Proprietary	\$ 239,516	86%	\$	117,994	81%	\$ 48,536	84%
Generic	486,578	65%		545,970	47%	422,253	50%
Total gross profit	\$ 726,094	70%	\$	663,964	51%	\$ 470,789	53%
		F-	33				

## **Table of Contents**

# (19) Quarterly Data (Unaudited)

A summary of the quarterly results of operations is as follows:

	Three Month Period Ended				
	Sept. 30	Dec. 31	<b>Mar. 31</b>	<b>Jun. 30</b>	
FISCAL YEAR 2005:	-				
Total revenues	\$ 244,508	\$ 257,369	\$ 265,007	\$ 280,515	
Cost of sales	69,638	78,059	77,653	78,730	
Net earnings	52,135	59,387	61,345	42,121	
Earnings per common share diluted (1)	\$ 0.49	\$ 0.56	\$ 0.58	\$ 0.40	
PRICE RANGE OF COMMON STOCK					
High	\$ 42.80	\$ 46.90	\$ 50.45	\$ 54.29	
Low	\$ 32.01	\$ 35.07	\$ 43.71	\$ 47.00	
2011	Ψ 32.01	Ψ 33.07	Ψ 13.71	Ψ 17.00	
FISCAL YEAR 2004:					
Total revenues	\$310,711	\$ 374,124	\$ 321,085	\$ 303,168	
Cost of sales	160,901	207,722	145,288	118,834	
Net earnings	38,535	35,069	35,139	14,360	
Earnings per common share diluted (1) (2)	\$ 0.37	\$ 0.33	\$ 0.33	\$ 0.13	
PRICE RANGE OF COMMON STOCK (2)					
High	\$ 50.33	\$ 56.91	\$ 53.99	\$ 49.25	
Low	\$ 38.83	\$ 45.17	\$ 45.70	\$ 32.89	

(1) The sum of the individual quarters may not equal the full year amounts due to the effects of the market prices in the application of the treasury stock method. During its three most recent fiscal years, the Company did not pay any cash dividends.

(2) Adjusted for the March 16, 2004

3-for-2 stock split effected in the form of a 50% stock dividend (See Note 1).

F-34

# SCHEDULE II BARR PHARMACEUTICALS, INC. VALUATION AND QUALIFYING ACCOUNTS Years Ended June 30, 2005, 2004 and 2003

	Balance at Beginning	Additions, Costs and	Deductions,	Balance at End of
(In thousands) Reserve for returns and allowances:	of Year	Expenses	Write-offs	Year
Year Ended June 30, 2003	\$ 29,260	\$ 48,683	\$ (24,978)	\$ 52,965
Year Ended June 30, 2004	52,965	64,446	(59,909)	57,502
Year Ended June 30, 2005	57,502	84,033	(88,816)	52,719
Inventory reserves:				
Year Ended June 30, 2003	\$ 10,236	\$ 10,280	\$ (7,315)	\$ 13,201
Year Ended June 30, 2004	13,201	17,058	(6,349)	23,910
Year Ended June 30, 2005	23,910	2,787	(13,282)	13,415
	S-1			