

BARR PHARMACEUTICALS INC

Form 10-K

August 24, 2004

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

Form 10-K

(Mark One)

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

For the fiscal year ended June 30, 2004

or

☐ **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
*(Address of principal executive
offices)*

07677-7668
(Zip Code)

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 ☐ 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. ☐

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

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, 2003, 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 11, 2004, there were 104,601,693 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 registrant's definitive proxy statement relating to the annual meeting of shareholders to be held in October 2004, 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.

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FOR THE FISCAL YEAR ENDED JUNE 30, 2004**

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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 specialty pharmaceutical company that develops, manufactures and markets both generic and proprietary pharmaceutical products through its operating subsidiaries, Barr Laboratories, Inc. and Duramed Pharmaceuticals, Inc. We market generic products under the Barr label and almost all proprietary products under the Duramed label. For our fiscal year ended June 30, 2004, we recorded net earnings of \$123.1 million on record revenues of \$1.3 billion. Of our \$1.3 billion of revenues in fiscal 2004, \$1,150.6 million were from sales of our generic products (including sales of products manufactured for us and sold under distribution agreements), \$146.1 million from sales of our proprietary products, and \$12.4 million were attributed to other revenues.

Prior to June 2004, we operated in one business segment. In June 2004 we organized our business into two reportable segments: generic pharmaceuticals and proprietary pharmaceuticals. On the generic side of our business, we currently manufacture and distribute more than 100 different dosage forms and strengths of over 70 different generic pharmaceutical products, including 19 oral contraceptive products, representing the largest category of our generic portfolio.

In our proprietary business, we currently manufacture and distribute 11 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 located in six locations within the United States. Our administrative offices are located in Woodcliff Lake, New Jersey. As the result of a reincorporation merger we effected on December 31, 2003, Barr Pharmaceuticals, Inc. is a Delaware corporation. Our fiscal year ends on June 30.

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:

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developing and marketing selected generic pharmaceuticals;

developing and marketing proprietary pharmaceuticals; and

pursuing development and marketing of generic biopharmaceuticals.

Developing and Marketing Selected Generic Pharmaceuticals

We develop and market under the Barr label the generic equivalent of brand pharmaceuticals that no longer enjoy patent protection. We focus on products that have one or more characteristics that we believe will make it difficult for other competitors to develop competing generics. 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 face limited competition and may produce higher returns for a longer period of time than products without these characteristics. A good example of this strategy is our generic oral contraceptive franchise, where revenues have increased from \$93 million in fiscal 2002 to \$404 million in fiscal 2004.

Our selective generic development strategy also includes developing generic equivalents of branded pharmaceuticals that are purportedly protected by patents that we believe are invalid, unenforceable or not infringed by our competing generic products. Successful patent challenges can result in gaining 180 days of market exclusivity for our generic product, such as when we successfully challenged Eli Lilly's patent on Proza®, 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. 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.

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 95% of sales in fiscal 2002, 94% in fiscal 2003 and 89% in fiscal 2004. The declining percentage over time reflects the increasing contribution from our proprietary products over that same period.

Developing and Marketing Proprietary Pharmaceuticals

We also develop, manufacture and sell proprietary pharmaceutical products under the Duramed label. As part of our diversification strategy, we have increased our focus on proprietary products while at the same time maintaining, or even increasing, our commitment to the generic side of our business. Although they involve substantially higher risk to bring to market and more extensive research and development activities on our part, proprietary products offer the potential for a longer period of market or product exclusivity and greater returns than most generic products. In addition, proprietary products require greater sales and marketing expenses because of the need to promote them directly to physicians 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.

As a percentage of our total product sales, sales of our proprietary products accounted for 5% of sales in fiscal 2002, 6% in fiscal 2003 and 11% in fiscal 2004.

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Pursuing Development and Marketing of Generic Biopharmaceuticals

We are actively pursuing those business development initiatives and internal development activities that will enable us to bring generic versions of biopharmaceutical products to market and intend to build a leadership position in the development and marketing of such products in the future. Biopharmaceuticals represents an industry with more than \$30 billion in annual sales, and more than 150 biopharmaceutical products are on the market today. However, the U.S. Food & Drug Administration (FDA) has not recognized an abbreviated regulatory pathway for the timely and cost-efficient approval of generic versions of these 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.

Investment in Research and Development

Our investment in research and development has increased steadily from approximately \$76 million in fiscal 2002 to \$91 million in fiscal 2003 and to \$169 million in fiscal 2004. Overall, the increase in research and development has been led primarily by higher spending on proprietary product development activities, including the acquisition of in-process research and development. Research and development expenditures for generic development activities typically include those related to internal personnel, third-party bioequivalence studies and costs for raw materials used in developing the 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 will continue to strengthen our commitment to research and development during fiscal 2005 as we continue to invest in proprietary and generic product development.

Business Development

To support our business strategies, we continually evaluate acquisition opportunities to strengthen our product portfolio and help grow our business. We regularly evaluate opportunities particularly in the following areas: strategic product acquisitions, new technology arrangements including new technology platforms, and corporate mergers and acquisitions.

Significant Developments in Fiscal 2004

Launch of SEASONALE® Extended-Cycle Oral Contraceptive

In November 2003, we launched our SEASONALE extended-cycle oral contraceptive product. SEASONALE offers women and healthcare providers a unique choice in oral contraception by reducing the number of menstrual periods to four per year. See [Proprietary Pharmaceuticals Products We Currently Market](#) below.

Leading Market Share of Oral Contraceptive Products

During fiscal 2004, we expanded our portfolio of generic and proprietary oral contraceptive products through the launch of new products and gained market share from oral contraceptive products we launched over the past two years. As a result, we became the leading manufacturer and marketer of oral contraceptive products in the United States, including generic and proprietary oral contraceptives, with a 30% prescription market share, based on industry source data for the month ended June 2004. Currently, we market 19 generic and three proprietary oral contraceptive products.

We also launched six new generic oral contraceptive products. Our generic launches included our Tri-Sprintec® (norgestimate and ethinyl estradiol) oral contraceptive product, the generic version of Ortho-McNeil Pharmaceutical's Ortho Tri-Cyclen®. Ortho Tri-Cyclen was the largest selling oral contraceptive product in the United States with annualized brand sales of approximately \$712 million based on sales for the quarter ended December 31, 2003, according to industry source data. In August 2003, we entered into a settlement of patent litigation with Ortho-McNeil that enabled us to launch Tri-Sprintec on December 29, 2003.

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During fiscal 2004, we added three proprietary oral contraceptive products to our product portfolio. We launched our innovative SEASONALE extended-cycle oral contraceptive product in November 2003, acquired the Plan B® emergency contraceptive in February 2004, and acquired a license for the Loestrin® (norethindrone acetate and ethinyl estradiol) and Loestrin® FE (norethindrone acetate and ethinyl estradiol and ferrous fumarate) oral contraceptives in March 2004.

Ciprofloxacin

During fiscal 2004, we recorded sales of \$385 million for our distributed Ciprofloxacin product, an antibiotic used to treat various types of infections, including urinary tract infections. In 1997, we entered into an agreement with Bayer to settle our patent challenge litigation regarding its Cipro® antibiotic. Pursuant to the terms of the agreement, we began distributing Ciprofloxacin on June 9, 2003. In September 2003, we signed an Amended Supply Agreement with Bayer that enabled us to distribute the product during Bayer's pediatric exclusivity, which ended on June 9, 2004. After June 9, 2004, several other generic competitors entered the market and, as expected, the price for Ciprofloxacin and our market share declined significantly.

ERP System

During fiscal 2004, we initiated implementation of a multi-million dollar, company-wide enterprise resource planning (ERP) system from SAP to replace the current computer system that manages business operations. We are committed to having the information technology base in place that will allow us to better operate and manage all facets of our operations. In addition, we believe the new ERP system will allow us to: (1) more efficiently manage corporate activities, including generic sales and marketing activities; (2) more efficiently manage diverse product lines; (3) integrate mergers and acquisitions more efficiently; and (4) support potential future international operations. We expect this project to take somewhere between 24 and 27 months and will require an investment of approximately \$60 million. To ensure this project is timely implemented and on budget, we have dedicated approximately 25 full-time employees to the project, along with third party consultants.

Solvay Arbitration

On June 17, 2004, a three-member arbitration panel determined that our Duramed subsidiary did not properly terminate its contract with Solvay Pharmaceuticals, Inc., regarding the joint promotion of Cenestin®. A two-member majority of the panel ordered us to pay Solvay \$68 million in monetary damages over the next sixteen months, over the strong disagreement of the panel's Chairman. The majority gave no explanation for its calculation of the damage award. We are seeking to vacate the panel's decision, but nevertheless have accrued for this award and recognized the related charge in our consolidated statement of operations as of June 30, 2004. The panel's decision has no impact on our marketing of Cenestin, which we currently promote in five dosage strengths directly to physicians using our 250-person women's healthcare sales force.

Natural Biologics

In March 2002, we signed a series of agreements with Natural Biologics, LLC (NBL) to develop an AB-rated conjugated estrogens product based on NBL's equine-based raw material. On June 30, 2003, we filed our abbreviated new drug application (ANDA) with the FDA for this product. On September 15, 2003, the U.S. District Court for the District of Minnesota required NBL to withdraw its drug master file for equine-based conjugated estrogens raw material from the FDA. The ruling prevents us from using this raw material in our application for an AB-rated conjugated estrogens product. NBL is appealing the decision. As a result of the District Court's decision, we recorded an expense of \$15.7 million for a reserve we established covering loans we made to NBL from March 2002 to September 2003.

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Acquisitions

Estrostep®/Estrostep® FE and Femhrt® License

On June 17, 2004, our Barr Laboratories subsidiary and Galen Holdings PLC (Galen) agreed to settle pending patent litigation regarding Galen's Estrostep (norethindrone acetate and ethinyl estradiol) and Estrostep FE (norethindrone acetate and ethinyl estradiol and ferrous fumarate) oral contraceptive and Femhrt hormone therapy products. Galen granted us a non-exclusive license to launch a generic version of Estrostep and Estrostep FE in October 2007, six months prior to the expiration of the patent on Estrostep and Estrostep FE. Galen also granted us a non-exclusive license to launch a generic version of Femhrt in November 2009, six months prior to the expiration of the patent on Femhrt.

Oxybutynin TVR

Effective March 31, 2004, we entered into an agreement with Schering AG of Germany to acquire the worldwide marketing and sales rights to an oxybutynin transvaginal ring (TVR) product for urinary incontinence. We had been developing this product for Schering under a Development and License Agreement that we assumed as part of our 2002 acquisition of certain assets from Enhance Pharmaceuticals. As part of our acquisition agreement we assumed all remaining development efforts and costs for the oxybutynin TVR product and agreed to forgo all remaining milestone payments and royalties, but gained greater control over the product's development and will have the opportunity to earn greater profits if the product is approved.

Galen Agreements

On March 25, 2004, our Duramed subsidiary acquired the exclusive rights in the United States and Canada for Loestrin® and Loestrin® FE oral contraceptive products from Galen. Under the terms of a second agreement, we granted Galen an option to acquire an exclusive five-year license for our generic version of Galen's Ovco® 35 (norethindrone and ethinyl estradiol) oral contraceptive. Galen exercised this option on May 6, 2004 and paid us a license fee of \$19 million that we are amortizing over the life of the license. In a separate agreement, Galen granted Barr an exclusive royalty-bearing license to develop certain oral contraceptives under a patent owned by Galen.

Emergency Contraceptive Acquisitions

On February 26, 2004, we completed our acquisition of all outstanding shares of Women's Capital Corporation (WCC), a privately held company, through a merger with a Barr subsidiary. WCC was the owner of the emergency contraceptive product Plan B. In a related transaction, we also acquired certain emergency contraception assets from Gynetics Inc. for an upfront payment and future royalties.

Endeavor Pharmaceuticals, Inc.

On December 3, 2003, we acquired substantially all of the assets of Endeavor Pharmaceuticals, Inc., including the pending new drug application (NDA) and intellectual property related to the Enjuvia® hormone therapy product (synthetic conjugated estrogens product, B), and two other early stage development female healthcare products. Enjuvia is the only plant-derived, synthetic conjugated estrogen product that includes the component delta 8,9-dehydroestrone sulfate, an additional active estrogenic component.

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 new drug applications, or NDAs, that must be filed with the FDA for a branded product. Generic drugs are bioequivalent to their brand-name

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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 2004, we continued our commitment to developing and marketing generic products. More specifically, during fiscal 2004, we:

filed 12 ANDAs

received FDA approvals for 10 generic products

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

launched nine new generic products.

At June 30, 2004, we had 31 ANDAs pending at the FDA targeting branded pharmaceutical products with an estimated \$6.2 billion in sales for the 12 months ended June 30, 2004.

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.

We traditionally have developed generic pharmaceuticals in tablet, capsule and powder forms. During the past year, we have devoted significant research and development resources to developing new dosage forms and more unique delivery technologies for our products. We are actively developing these generic products both on our own and through partnerships with third parties based on delivery technologies such as patches, creams and ointments, injectables, nasal sprays, and sterile ophthalmics. In addition, we are developing generic products delivered through transvaginal rings, or TVR.

At June 30, 2004 we had approximately 15 products in various stages of development that utilize dosage forms other than a solid oral tablet or capsule delivery system. More than half of these products have intellectual property issues associated with them, and therefore may be susceptible to legal challenges by third parties in bringing them to market. Some of them will result in patent challenges while others will have various other issues associated with their development and commercialization.

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We currently market approximately over 70 generic pharmaceutical products in approximately 100 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	Brand Equivalent	Therapeutic Category
Apri® (Desogestrel and Ethinyl Estradiol)	Desogen® Ortho-Cept®	Female Healthcare
Aviane® (Levonorgestrel and Ethinyl Estradiol)	Alesse®	Female Healthcare
Claravis (Isotretinoin)	Accutane®	Dermatology
Amphetamine Salts Combination	Adderall®	Psychotherapeutics
Dextroamphetamine Sulfate Extended Release Capsules	Dexedrine® Spansule®	Psychotherapeutics
Kariva® (Desogestrel and Ethinyl Estradiol)	Mircette®	Female Healthcare
Lessina® (Levonorgestrel and Ethinyl Estradiol)	Levlite®	Female Healthcare
Methotrexate	Rheumatrex®	Rheumatology
Mirtazapine	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

Set forth below are descriptions of certain generic products that contributed significantly to our sales and gross profit in fiscal 2004. Product data are derived from industry sources.

Oral Contraceptives. As of June 30, 2004, we were the largest manufacturer and marketer of oral contraceptive products in the United States. Oral contraceptives are the most common method of reversible birth control, used by up

to 65% 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 19 generic oral contraceptive products under trade names, six of which we launched during the fiscal year ended June 30, 2004. 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.

Mirtazapine orally disintegrating tablets. Our Mirtazapine product, which is used to treat depression, is the generic equivalent of Organon's Remeron® Soltab®. We market Mirtazapine in orally disintegrating tablets in 15 mg and 30 mg strengths. We launched our product on December 18, 2003 into a market that had brand product sales of \$126 million in 2003. The product had been the subject of a patent challenge, and we were granted 180-days of exclusivity as a result of being the first to file an ANDA containing a certification that the applicable listed patent for Mirtazapine was invalid, unenforceable or not infringed (a so-called paragraph IV certification). 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.

Amphetamine Salts Combination. Our Amphetamine Salts Combination product is the generic equivalent of Shire Richwood's Adderall® tablets. Adderall is used to treat moderate to severe distractibility, short attention span, hyperactivity and impulsivity. We launched the first generic Dextro Salt Combo product in April 2002, though today we are one of several generic companies with FDA approval for the product.

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In March 2003, we launched our generic version of Adderall tablets in strengths of 7.5 mg, 12.5 mg and 15 mg and were granted 180-days of generic exclusivity, commencing at launch, as a result of being the first to file an ANDA containing a paragraph IV certification. The patent holder did not file suit against us within the statutory 45-day period, clearing the way for us to launch our product upon receiving FDA approval and today we are one of several generic companies with FDA approval for the product.

Pending Patent Challenges

Our generic development activities also include developing generic versions of select branded products that are alleged to be patent protected, and utilizing the patent challenge process under the Hatch-Waxman Act to seek to invalidate patents or to obtain a declaration that our generic version does not infringe the patent. In this regard, we actively challenge patents on branded 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 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, 2004, we had publicly disclosed the following patent challenges that are in various stages of litigation:

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	Sales In Millions*	Tentative Court Date	Therapeutic Category
Mircette® (Kariva®) (Desogestrel/Ethinyl Estradiol)	\$ 130	Late 2004	Female Healthcare
Allegra Products (Fexofenadine Hydrochloride and Fexofenadine Hydrochloride & Pseudoephedrine Hydrochloride)	1,952	(On Remand) Mid-2005	Antihistamines
Niaspan® (Niacin 3 Strengths)	310	September 2005	Cardiovascular
Evista® (Raloxifene Hydrochloride)	719	February 2006	Female Healthcare
DDAVP® (Desmopressin)	167	Fall 2004	Diabetes
Adderall XR (Dextroamphetamine)	545	January 2006	ADHD
Provigil® (Modafinil)	349	April 2005	Narcolepsy
Prefest® (Estradiol/Norgestimate)	15	Early Stage	Hormone Therapy
Ortho Tri-Cyclen Lo® (Norgestimate/Ethinyl Estradiol)	177	Early Stage	Oral Contraceptive

*Source: IMS Health, last twelve months sales ended June 30, 2004

Kariva®, our generic version of Organon's Mircette, is the only one of the products listed above that we currently market. We launched the product following a District Court ruling that our product did not infringe the patent. 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 and there is a risk that we could be required to pay significant damages for patent infringement in the event of an unfavorable outcome. 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.

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 130 customers that purchase directly from us, and indirectly to approximately 85 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:

	<u>2004</u>	<u>2003</u>	<u>2002</u>
McKesson Drug Company	24%	21%	18%
Cardinal Health	14%	17%	13%
Walgreens	13%	11%	*
Amerisource Bergen	*	13%	12%

*Denotes less than 10% in the period indicated.

Proprietary Pharmaceuticals

Our proprietary product development efforts are handled by our Duramed Research subsidiary, which is headquartered near Philadelphia. Formed in 2001, Duramed Research develops pharmaceutical products identified either through our internal efforts or through strategic company, product and/or technology platform acquisitions. Our proprietary products are marketed under the Duramed Pharmaceuticals, Inc. label and marketed under brand names and generally are promoted directly to physicians and in some cases consumers. Proprietary products often are patent-protected or benefit from other non-patent market exclusivities. These market exclusivities generally provide proprietary products with the ability to maintain their 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.

We focus our proprietary product development activities in three areas:

patent-protected proprietary products in late stages of development;

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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 on expanding our portfolio of female healthcare products including oral contraceptives and treatments for menopause/perimenopause and endometriosis. 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 products in urology, specifically to treat female healthcare issues using the transvaginal ring technology, as well as an oral product targeted to treat the symptoms associated with treatment of prostate cancer. In addition, we are developing an oral vaccine product to prevent Adenovirus (Types 4 & 7) infections. We continue to identify other proprietary product candidates that further expand our product offerings in these areas and evaluate additional therapeutic categories to add to our portfolio.

Research and Development

At the end of fiscal 2004, as a result of our internal and acquisition-based investment in proprietary research and development, we had:

three proprietary product applications pending at the FDA: an NDA for Enjuvia 0.3 mg and 0.45 mg tablets; an NDA for Synthetic Conjugated Estrogens Vaginal Cream; and a supplemental NDA (sNDA) for Over-the-Counter (OTC) status for the Plan[®]B emergency contraceptive; and

six proprietary products in clinical development, three of which are in Phase III studies.

Our proprietary research and development team totals approximately 81 employees with experience in managing clinical development programs and regulatory matters. This team works closely with our generic formulation, manufacturing and regulatory groups.

Products We Currently Market

We currently market 11 proprietary products, which are:

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

Cenestin[®] (Synthetic Conjugated Estrogens, A) hormone therapy

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

Plan B[®] (Levonorgestrel) emergency contraceptive

Trexall (Methotrexate) for rheumatoid arthritis

ViaSpan[®] (Cold Storage Solution) transplant preservation agent

Aygestin[®] (Norethindrone Acetate) for amenorrhea

Revia[®] (Naltrexone Hydrochloride) for alcohol dependence

Ziac® (Bisoprolol Fumarate and Hydrochlorothiazide) for hypertension

Zebeta® (Bisoprolol Fumarate) for hypertension

Diamox® Sequels® (Acetazolamide) for glaucoma

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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. Our Women's Healthcare Sales Force began promoting SEASONALE directly to healthcare providers on November 10, 2003. At the time of FDA approval, SEASONALE was granted a three-year New Product Exclusivity from the date of approval.

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 30,000 physicians who we had determined to be among the most productive prescribers of oral contraceptive products in the United States. Marketing support includes professional education materials, published data from our clinical studies demonstrating the safety and efficacy of the extended cycle concept, and product sampling kits that contained extensive information for patients. We reinforce our detailing activities with a trade-advertising program in leading medical journals. During the second half of fiscal 2004, we initiated a direct-to-consumer (DTC) advertising campaign, first in leading general interest publications, and then with television advertising. As a result of these efforts, we ended the fiscal year with over 170,000 prescriptions filled.

SEASONALE was developed under a patent license from the Medical College of Hampton Roads, Eastern Virginia Medical School (EVMS). EVMS has a patent on SEASONALE that expires in 2017.

On June 3, 2004 EVMS 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. No patent infringement litigation has been initiated with respect to Watson's ANDA. The three-year New Product Exclusivity prevents the FDA from approving Watson's ANDA prior to September 5, 2006. We also may be eligible to obtain an additional six months of market exclusivity on SEASONALE by performing pediatric research on the product.

In July 2004, EVMS submitted the patent covering the SEASONALE extended-cycle oral contraceptive product for reissue with the Patent and Trademark Office (PTO). The reissue process may take about two years 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 EVMS' submission. If the patent covering SEASONALE is reissued, it will have the same remaining term as the existing patent that expires in 2017.

Cenestin®. 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 the Cenestin product and are developing other related products. The 0.3 mg tablet strength of Cenestin is indicated for the treatment of vulvar and vaginal atrophy.

Our supplemental application for a 0.45 mg strength of Cenestin was approved by FDA in February 2004 and we launched the product during the fourth quarter of fiscal 2004. The 0.45 mg strength represents the lowest Cenestin dose approved for the treatment of moderate to severe vasomotor symptoms associated with menopause. Its addition completes the solid oral dosage form of this product family.

Cenestin competes in the \$1.7 billion hormone therapy market with products such as Wyeth's Premarin®, a conjugated equine estrogens product. 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 physicians will continue using these products,

particularly estrogen-only therapies, such as Cenestin, for the short-term treatment of various symptoms associated with menopause.

Plan B® Emergency Contraceptive. During fiscal 2004, we completed the acquisition of all of the outstanding shares of WCC, a privately held company that owns the NDA for the emergency contraceptive product called Plan B. Plan B, which contains the synthetic progestin levonorgestrel, is an emergency oral contraceptive that can be

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used 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. The Plan B emergency contraceptive is currently available by prescription only in the U.S. and Canada.

As part of the WCC acquisition, we assumed responsibility for the sNDA proposing the switch of the product from prescription only to 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. We continue to market Plan B as a prescription-only emergency contraceptive by seeking to educate consumers and healthcare providers about its availability, and have recently submitted to the FDA information under our sNDA that we believe will support 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.

Trexall. Trexall is the brand name for our 5 mg, 7.5 mg, 10 mg and 15 mg methotrexate tablets that received FDA approval in March 2001. Methotrexate is used in the treatment of certain forms of cancer, severe psoriasis and rheumatoid arthritis. Prior to Trexall's approval in March 2001, methotrexate tablets were available only in a 2.5 mg strength tablet. We designed these new dosage strengths to simplify drug therapy and increase patient convenience and compliance.

ViaSpan[®]. We market ViaSpan under a license granted to us by Bristol-Myers Squibb. ViaSpan is a cold storage solution used for hypothermic flushing and storage of organs, including the kidneys, liver and pancreas at the time of their removal from the donor in preparation for storage, transportation and eventual transplantation into a recipient. We exclusively market the product in both the United States and Canada to approximately 200 customers, primarily organ procurement organizations, transplant centers and hospitals. ViaSpan is patented through March 2006.

We also sell, but do not actively market, several other proprietary products, including Loestrin and Loestrin Fe, which we acquired under license from Galen, and Aygestin[®], Ziac[®], Zebeta[®] and Diamox[®] Sequels[®], which we acquired from Wyeth, and Revia.

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:

SEASONALE Line Extension: A lower strength of SEASONALE is under development and was studied as part of the SEASONALE clinical trials. We expect to file a sNDA for the lower strength of SEASONALE with the FDA during the second half of fiscal 2005.

New Extended-Cycle Oral Contraceptive. DP3 is our internal identifier for another of our extended-cycle oral contraceptive products. We have completed two large full-scale Phase III clinical trials involving 12 months of treatment and including approximately 2,600 patients at 35 investigational sites, evaluating DP3 in a 91-day cycle that includes 84 active tablets of levonorgestrel/ethinyl estradiol, followed by seven days of ethinyl estradiol. We anticipate filing a NDA for DP3 with the FDA in the first half of fiscal 2005.

Hormone Therapy/Estrogen Therapy:

Synthetic Conjugated Estrogens Vaginal Cream. At fiscal year-end, we filed an NDA for a synthetic conjugated estrogens vaginal cream product. We are seeking approval to manufacture and market the vaginal cream product for the treatment of moderate to severe symptoms of vulvar and vaginal atrophy associated with menopause. We expect

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approval of this application in late fiscal 2005. We will also continue to evaluate the development of additional products based on medical developments in the hormone therapy area.

Enjuvia . 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, our NDA for Enjuvia 0.625 mg and 1.25 mg tablets was approved by the FDA. In April 2003 Endeavor received a Not Approvable Letter from the FDA for their NDA for the 0.3 mg and 0.45 mg dosage strengths and we are working with FDA to obtain final approval. We are also developing a 0.9 mg strength to provide physicians and patients with a complete portfolio.

Vaginal Ring Products. We have several products in various stages of development based on our proprietary, novel, vaginal ring drug delivery system. Specifically, our development efforts are focused on products that treat endometriosis, fertility, fibroids, and labor and delivery.

Urology

Oxybutynin TVR. During fiscal 2004, we acquired the rights to the urinary incontinence product that had been under development in partnership with Schering AG. The vaginal ring product offers the potential to deliver higher doses of oxybutynin to the bladder neck with much lower systemic exposure. This product is in Phase IIB development.

CyPat . Cyproterone acetate, which 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.

We have completed a trial for the CyPat 50 mg and 100 mg dosages that were in Phase III clinical trials last year. From an efficacy perspective, both strengths reduced hot flashes in men who were surgically or chemically castrated due to their prostate cancer therapy. We are now working with the FDA to determine the safety and efficacy of lower Cyproterone acetate doses for this indication.

Vaccines

Adenovirus Vaccines. We continue to develop 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 vaccines that is located on our Virginia campus. The Adenovirus Investigational New Drug (IND) application was submitted to the FDA in July 2004, we expect to initiate clinical trials in early fiscal 2005, and we have developed and manufactured the tablets for the trials. In addition to supplying the vaccine to the armed forces, we have the rights 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 our three sales teams focused on three core therapeutic categories: female healthcare, rheumatology/dermatology, and transplant products.

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We contract our Women's Healthcare Sales Force from Cardinal Market Force. In January 2003 we expanded that sales force by 104 sales representatives, 11 district sales managers and three area business directors, and by April 2003, our total Women's Healthcare Sales Force had nearly doubled to 250 people, including sales representatives and managers. Our sales force expansion was undertaken in connection with, and prior to, the November 2003 launch of SEASONALE. In addition to the promotion of SEASONALE, the sales force promotes our Cenestin and Plan B emergency contraceptive product and will market additional female healthcare products we may develop or acquire. The contract allows us to convert the Cardinal sales force into our employees upon expiration, which we intend to do in October 2004.

Rheumatology/Dermatology Sales Force

We contract with Innovex, LP, an affiliate of Quintiles Transnational Corp., for a 22-person contract sales force that promotes our Trexall product directly to rheumatologists and dermatologists. These representatives also promote Claravis, our generic version of Roche's Accutane, to dermatologists. Our contract with Quintiles expires in December 2004 though we may extend this term at our option. We expect to use this sales force to promote additional rheumatology and dermatology products as we develop or acquire them.

Transplant Product Sales Force

We employ a national account manager to promote our transplant preservation agent, ViaSpan, to approximately 200 customers in the United States and Canada. These customers are primarily organ procurement organizations, transplant centers and hospitals. We expect to use our national account manager to promote additional transplant products as we develop or acquire them.

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 government/military. Sales to customers who accounted for 10% or more of our proprietary sales over the three years ended June 30, 2004, 2003, and 2002 were as follows:

	<u>2004</u>	<u>2003</u>	<u>2002</u>
McKesson Drug Company	21%	15%	14%
Cardinal Health	20%	19%	21%
AmerisourceBergen	15%	11%	*

*Denotes less than 10% in the period indicated.

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 2003 of more than \$30 billion. More than 150 biopharmaceuticals are on the market, including human insulin,

interferons, human growth hormones and monoclonal antibodies. In the past year, more than 30 new biopharmaceutical products were approved, compared to just only two in 1982. There are more than 370 biotech drug products and vaccines currently in clinical trials targeting more than 200 diseases including cancer, Alzheimer's disease, 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.

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There are, however, three major challenges in pursuing generic biopharmaceuticals: regulatory challenges; intellectual property challenges; and scientific and 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. Although it may be possible to achieve approval of select biopharmaceuticals, based on their historic approval under current law, we are committed to pursuing opportunities through what we believe is a pathway that currently exists, as well as working towards a second, streamlined regulatory approval process that will ensure we can bring these products to market. In addition, we believe that we are well situated, in terms of our experience with intellectual property issues, to overcome patent and other barriers to the introduction of these products. Our background in product formulation, and the experience we are gaining through the production of the Adenovirus vaccine under contract with the Department of Defense is providing additional expertise necessary in this area.

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.

While we do not expect to launch a generic version of a biopharmaceutical for some time, we are taking the steps to position ourselves as a leader in this potential market.

Evaluating Complementary or Strategic Business Opportunities

We continually evaluate acquisition opportunities to strengthen our product portfolio and help grow our business. We recently expanded our activities and resources in this area and regularly evaluate opportunities particularly in the following areas: strategic product acquisitions, new technology arrangements including new technology platforms, and corporate mergers and acquisitions. Set forth in the table below is a list of our significant business development activities dating back to fiscal 2000, and products or opportunities we acquired in connection with such transactions.

FISCAL YEAR	TRANSACTION	ACQUIRED PRODUCT(S)/OPPORTUNITIES
2000	DuPont Pharmaceuticals	Acquired ViaSpan, Revia; Funding for SEASONALE, DP3, CyPat Clinical Studies
2002	Duramed Pharmaceuticals Enhance Pharmaceuticals	Cenestin, Generic Oral Contraceptives Oxybutynin TVR Product/Vaginal Ring Technology
2003	Wyeth	Diamox Sequels, Zebeta, Ziac, Aygestin
2004	Endeavor Pharmaceuticals Women's Capital Corp. Galen (Chemicals) Limited	NDAs for Enjuvia 0.3, 0.45, 0.625 and 1.25 mg Tablets; Two Early Stage Development Products WCC's Plan B Emergency Oral Contraceptive Loestrin, Loestrin Fe Oral Contraceptives

Significant Product Sales; Geography

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.

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 three fiscal years ended June 30:

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	<u>2004</u>	<u>2003</u>	<u>2002</u>
Oral contraceptives (generic and proprietary)	34%	31%	*
Ciprofloxacin	30%	12%	*
Tamoxifen	*	14%	31%
Fluoxetine	*	*	31%

*Denotes less than 10% in the period indicated.

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 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. As a consequence, certain products that account for a significant portion of our revenues and profits are currently available only from sole or limited suppliers, including warfarin sodium, dextro salt combo and several of our oral contraceptives.

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. 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 federal government, principally by the FDA, and, to a lesser extent, by the Drug Enforcement Agency (DEA) and state governments. 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.

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

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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.

Patent Challenges

Background

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 barrier 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

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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 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.

Patent Challenge Process

The Hatch-Waxman Act provides incentives for generic pharmaceutical companies to 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 offers 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. Upon receipt of the notice from the generic company, the patent holder and NDA owner have 45 days in which to bring suit in federal district court against the generic company to enforce the challenged patent. The discovery, trial, and appeals process can take several years.

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.

Under the Hatch-Waxman Act, the developer of a generic drug which 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 a district court decision

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finding the challenged patent invalid, unenforceable, or not infringed, even if 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 ruling.

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

During fiscal 2004, the use of authorized generics has increased significantly. Authorized generics involve the brand pharmaceutical maker licensing its drug to a company that then markets it as a generic product. The authorized generic versions are sometimes made by the brand-name company, and distributed by the generic partner. Because the authorized generic is not sold under an ANDA, but rather is sold under the brand pharmaceutical maker's NDA, it can compete against the patent challenger's generic product during the 180-day exclusivity period that results from a successful patent challenge.

The marketing of authorized generics in competition with the patent challenger during the 180-day generic exclusivity period has undermined the incentive integral to the Hatch-Waxman patent challenge process. We believe that authorized generics may provide disincentives to generic companies seeking to challenge patents on branded pharmaceutical products that may be invalid or unenforceable and ultimately are negative for consumers. We will continue to work with Congress, the Department of Health and Human Services, including the FDA, and the generic industry association to limit the use of authorized generics that undermine the balance brought about by the Hatch-Waxman Act.

Our Patent Challenge History

Our efforts in the area of challenging patents on branded pharmaceutical products have resulted in the successful conclusion of 10 out of 12 cases as of June 30, 2004. 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.

Examples of successful outcomes to our patent challenges include:

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Fluoxetine. We invalidated the patent on Eli Lilly's Prozac®, 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.

Mirtazapine orally disintegrating tablets. Mirtazapine is the generic equivalent of Organon, Inc.'s Remeron Soltab®. After the litigation against us was dismissed, we launched our mirtazapine product in December 2003 and enjoyed 180 days of generic exclusivity. Currently, we market the only generic version of this product.

Ortho Tri-Cyclen®. 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.

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®, which is used to treat advanced breast cancer, impede the recurrence of tumors following surgery, and reduce the incidence of breast cancer in women at high risk for developing the disease. 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. Examples include:

Trazodone Hydrochloride. Trazodone Hydrochloride is the generic name for Bristol-Myers' 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 preclinical 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 preclinical data must provide an adequate basis for evaluating both the safety and the scientific rationale for the initiation of clinical trials.

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.

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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 preclinical 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 develop products containing 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.

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.

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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.

Employees

Our success depends on our ability to hire and retain highly qualified scientific and management personnel. We face competition for personnel from other companies, academic institutions, government entities and other organizations. As of June 30, 2004, we had approximately 1,500 full-time employees. Approximately 86 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 April 1, 2005. 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. As patents and other bases for market exclusivity expire, generic competitors, such as we, enter the marketplace. Normally, there is a unit price decline as the number of generic competitors increases. The timing of these price decreases is unpredictable and can result in a significantly curtailed period of profitability for a 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 controlled-release products or other product improvements;

- increasing marketing initiatives; and

- commencing litigation.

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

We also face competition for our proprietary products from other proprietary and generic products and from promotional activities by other competing pharmaceutical companies. This competition affects our ability to market our proprietary products effectively and customer acceptance of our products.

We compete in varying degrees with numerous other manufacturers of pharmaceutical products, both branded and generic. These competitors include:

- brand pharmaceutical companies whose patent protected therapies compete with both generic and proprietary products marketed or being developed by us, including Johnson & Johnson, Wyeth, Bristol-Myers Squibb and Eli Lilly & Company;

- the generic divisions and subsidiaries of brand pharmaceutical companies, including Sandoz US, a subsidiary of Novartis AG, as well as large independent generic manufacturers/distributors that provide a broad line of products, some of which compete with our products, including Mylan Laboratories and Teva Pharmaceuticals; and

generic manufacturers that target categories in our product lines, such as Watson Pharmaceuticals and Andrx Corporation.

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Some of our competitors have greater financial and other resources than we have, and are therefore able to devote more resources than we can in such areas as sales and marketing support and product development. In order 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; and

make significant investments in plant and equipment to give us a competitive edge in manufacturing.

These factors, when combined with our investment in new product development and our focus on select therapeutic categories, provide the basis for our belief that we will continue to remain a leading independent specialty pharmaceutical company.

Product Liability Insurance

As a pharmaceutical company, we are susceptible to product liability claims in the ordinary course of our business. We utilize a combination of a finite-risk insurance arrangement, self-insurance and traditional third-party insurance policies to cover us for product liability claims, as discussed in greater detail below.

Finite-Risk Arrangement

Through September 2002, we had generally obtained traditional third-party liability insurance for product liability claims. However, following September 11, 2001 obtaining such insurance with the desired amount of coverage and deductibles became, in our view, prohibitively expensive with respect to many of our products. As a result, we explored other options to traditional third-party liability insurance, and on September 30, 2002, we entered into a finite risk insurance arrangement (the Finite Risk Arrangement) with a third party insurer.

Under the Finite Risk Arrangement, we have obtained an aggregate of \$15 million of product liability coverage that spans all of the products we sell during the period of the Finite Risk Arrangement, which commenced on October 1, 2002 and is scheduled to run until September 30, 2007. In exchange for that coverage, we are required to make four equal annual installments to the insurer aggregating \$14.25 million, with two of such payments having been made to date and the third being due on September 30, 2004.

Self Insurance

We are entirely self-insured for costs we may incur relating to product liability claims arising during the current policy period between \$15 million and \$25 million. This means that we would be responsible for paying for any damages we incur in the \$15 million and \$25 million range. Our decision to leave this gap in our current coverage relates directly to the prohibitive cost of certain third-party insurance coverage for product liability claims and to our assessment of our ability to pay claims based on our financial condition. In addition, to the extent the third-party liability insurance discussed below does not cover certain of our products, we would be responsible for all claims relating to those excluded products in excess of the coverage available under our Finite Risk Arrangement.

Traditional Third-Party Liability Insurance

In addition to the Finite Risk Arrangement above, we have purchased traditional third-party insurance that will provide coverage for claims arising during the current policy period for that portion of the exposure to us, if any, of between \$25 million and \$40 million. This supplemental policy, which expires on September 30, 2004, covers all of

our products.

We have purchased another third-party insurance policy that provides coverage for claims arising during the current policy period for that portion of the exposure to us, if any, between \$40 million and \$50 million. For this

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supplemental policy, in addition to the annual premium we pay, we are responsible for paying 20% of all claims paid under the policy by the insurer. This supplemental policy, which expires on September 30, 2004, covers all of our products.

At the time we entered into the Finite Risk Arrangement, we exercised an option under our previous product liability policy to extend the reporting period coverage for that policy. By exercising this option, we have obtained \$10 million of coverage for product liability claims arising from products we sold during the period from September 1987 through September 2002. We can make a claim against this insurance policy at any time, without expiration, provided the underlying claim arose during the relevant period and we have not exceeded the \$10 million of coverage.

Similarly, in connection with our merger with Duramed in October 2001, we purchased a supplemental extended reporting policy under Duramed's prior insurance policy. By exercising this option, we have \$10 million of coverage for product liability claims arising from products sold by Duramed between October 1, 1985 and October 24, 2001. As with our other extended period policy above, we can make a claim against this insurance policy at any time, without expiration, provided the underlying claim arose during the relevant period and we have not exceeded the \$10 million of coverage.

Insurance Reserves

Because we are self insured for a portion of potential claims, we maintain a self-insurance reserve. This reserve provides an estimate of our potential product liability claims not covered by our insurance and an estimate of the future cost of incurred-but-not-reported (IBNR) claims. We develop these estimates in consultation with outside counsel, our insurance consultants and an independent actuary. Our self-insurance reserves do not include estimated administrative or defense costs, which are expensed as incurred.

We are a defendant in many product liability actions. For product liability claims that are not fully or substantially covered by our insurance arrangements described above, the costs incurred to defend such claims, or any adverse judgments or settlements in such matters, could adversely affect our consolidated financial statements.

Indemnity Provisions

From time-to-time, in the normal course of business, we agree to indemnify our employees, suppliers and customers concerning product liability and other matters. We do not believe that the likelihood of paying any amounts related to the indemnity provision is probable. While the maximum amount to which we may be exposed under such agreements cannot be reasonably estimated, we maintain a self insurance reserve and insurance coverage which management believes will effectively mitigate our obligations under these indemnification provisions. No amounts have been recorded in the financial statements with respect to our obligations under such agreements.

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.

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, 2004 and indicates the location and principal use of each of these facilities:

Location	Square Footage	Status	Description
NEW JERSEY			
Woodcliff Lake	90,000	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, Laboratories, Manufacturing
Pomona 2	133,000	Owned	Laboratories, Administrative Offices, Manufacturing, Warehouse
Blauvelt	8,500	Leased	Warehouse
OHIO			
Cincinnati	290,000	Owned	Manufacturing, Laboratories, Packaging
Mason	117,000	Leased	Warehouse, Office
PENNSYLVANIA			
Bala Cynwyd	39,000	Leased	Proprietary Research, Administrative 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 Offices

Over the past three fiscal years, we have spent approximately \$174.7 million on capital expenditures primarily to increase our production, laboratory, warehouse and distribution capacity. We believe that our current facilities are in good condition, are being used productively and are adequate for us to meet the expected demand of our pipeline products and to handle increases in current product sales.

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

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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.

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. A trial on the infringement and damages issue is expected in late 2004. We believe that our product does not infringe BTG's patent and, because of this, we continue to market and sell Kariva. Nevertheless, we expect that Organon will seek to recover lost profits on sales of Mircette and assert that these lost profits and enhanced damages significantly exceed our sales of Kariva, which totaled approximately \$110 million from the date of launch through June 30, 2004. 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.

Class Action Lawsuits

Ciprofloxacin

To date we have been 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®) from 1997 to the present. The complaints allege 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 include 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). Fact discovery in the MDL Case has been completed and the parties are proceeding with summary judgment briefing. The direct purchaser and indirect purchaser plaintiffs also have filed motions for class certification in the MDL Case, but the Court has indicated that it will defer ruling on the motions at the present time. The state court actions remain in a relatively preliminary stage generally, tracked to follow the MDL Case, although defendants have filed dispositive motions and plaintiffs have moved for class certification in certain of the cases, and certification of a California-only end-payor class has been granted in the California consolidated cases.

On May 20, 2003, the District Court entered an order in the MDL Case holding that the Barr-Bayer settlement did not constitute a per se violation of the antitrust laws and restricting the scope of the legal theories the plaintiffs could pursue in the case. On May 28, 2004, pursuant to the Court's instruction and scheduling order, defendants filed motions for summary judgment on all claims. Plaintiffs opposed those motions on July 9, 2004. A hearing date on the motions has not been set. All other proceedings (including the setting of a trial date) have been stayed pending resolution of the summary judgment motions.

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. On April 22, 2004, the District Court of Johnson County, Kansas granted in part and denied in part defendants' motions to dismiss, thereby narrowing some of plaintiffs' claims, although the language of the order

memorializing the Court's oral ruling remains under review. The decisions by the Wisconsin Circuit Court, the New York Supreme Court, and the Kansas District Court do not affect the federal class actions currently pending in the U.S. District Court or the state class actions currently pending in other state courts. On July 24, 2004, the California Court of Appeal for the Fourth Appellate District concluded that the certification of a California-only class was overbroad to the extent that it included purchasers who would have paid the same fixed co-payment for

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generic ciprofloxacin as for branded Cipro under the terms of their prescription drug benefit plans. Discovery is ongoing in the California consolidated cases, with a current trial date of January 2005.

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

Other

As of June 30, 2004, 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, 2004.

Table of Contents**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 splits effected in the form of 50% stock dividends in each of March 2003 and March 2004):

	High	Low
<i>Fiscal year ended June 30, 2004:</i>		
First quarter	\$50.33	\$38.83
Second quarter	56.91	45.17
Third quarter	53.99	45.70
Fourth quarter	49.25	32.89
<i>Fiscal year ended June 30, 2003:</i>		
First quarter	\$32.05	\$21.95
Second quarter	30.10	24.56
Third quarter	38.77	28.93
Fourth quarter	44.35	34.27

As of August 11, 2004, we estimate that there were approximately 1,610 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 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.

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.

Year Ended June 30,				
2004	2003	2002	2001 (1)	2000 (1)
(in thousands, except per share data)				

**Statements of
Operations Data**

Total revenues	\$ 1,309,088	\$ 902,864	\$ 1,188,984	\$ 593,151	\$ 490,972
Earnings before income taxes	194,440	262,715	337,537	101,793	18,602
Income tax expense	71,337	95,149	125,318	38,714	8,042
Net earnings applicable to common shareholders	123,103	167,566	210,269	62,566	10,305
Earnings per common share - basic	1.21	1.69(4)	2.17(4)(5)	0.66(4)(5)	0.11(4)(5)
Earnings per common share - diluted	1.15	1.62(4)	2.06(4)(5)	0.63(4)(5)	0.11(4)(5)

Balance Sheet Data

Working capital	\$ 670,601	\$ 582,183	\$ 457,393	\$ 313,101	\$ 212,275
Total assets	1,333,269	1,180,937	888,554	666,516	548,188
Long-term debt (2)	32,355	34,027	42,634	65,563	59,254
Shareholders' equity (3)	1,042,046	867,995	666,532	416,777	324,698

- (1) Financial data presented has been restated to include the historical financial data of Duramed (See Note 1 to the consolidated financial statements).
- (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).

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. Over the past few years, we have continued to build a deep, diverse and profitable generic product portfolio while strategically diversifying our operations by developing and acquiring several proprietary products. While sales of generic products still account for a great majority of our overall revenues, sales of our proprietary products have grown from \$62 million in fiscal 2002 to \$146 million in fiscal 2004.

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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. By targeting products with some combination of the unique factors set forth above, 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.

Challenging the patents covering certain brand products is another facet of our generic product activities. For many products, the patent provides the unique factor 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 are 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 Prozac®. 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. Despite the volatility, challenging patents continues to be an important component of our generic product strategy.

Macroeconomic factors favoring generic products have also helped to grow sales. 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 47% by 2003, and is predicted to continue to rise in the future.

Proprietary Products

To help diversify our 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 and today have over 80 professionals dedicated to the development of a wide range of proprietary products focused primarily on women's healthcare products.

Our growth in proprietary product sales has been accomplished through product acquisitions and through the November 2003 launch of our first internally-developed proprietary product, SEASONALE®, a novel extended cycle oral contraceptive.

Our proprietary products are promoted directly to physicians by our 250 person sales force and are sold under the Duramed label.

Competition

As with any successful business, the greatest challenge we face 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. For example, we know that other generic pharmaceutical companies have recently started developing and marketing competing generic oral contraceptives in order to capture some of our market share.

Also, as a challenge to the value of our patent challenge strategy, brand pharmaceutical companies have begun to partner with certain generic drug companies to license a so-called "authorized generic" to the generic drug company.

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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 generic drug company with the ability to have the 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, our SEASONALE extended cycle oral contraceptive product was recently targeted for a patent challenge by one of our principal competitors.

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, 2004 and June 30, 2003

(\$ s in millions)

The following table sets forth revenue data for the fiscal years ended June 30, 2004 and 2003:

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

(1) Reflects sales of Tamoxifen product acquired from innovator.

(2) Includes sales of Tamoxifen product manufactured by Barr.

(3) 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 under generic products.

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 Cipr® 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, from the sale of Ciprofloxacin with Aventis, the contractual successor to our partner in the Cipro patent challenge

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case. Bayer's period of pediatric exclusivity expired on June 9, 2004 and, as we expected, several other competing Ciprofloxacin products were launched. As a result of these additional competitors, our market share and product pricing declined dramatically thereby lowering our sales of Ciprofloxacin in the quarter ended June 30, 2004 compared to earlier quarters in the fiscal year. Our sales of Ciprofloxacin are expected to be less than \$2 million in fiscal 2005.

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

The following table sets forth oral contraceptive data for the fiscal years ended June 30, 2004 and 2003:

(\$ in millions)	2004	2003	CHANGE	
			\$	%
Oral contraceptive sales	\$403.9	\$274.4	\$129.5	47%
Number of Marketed Products at End of Period	19	13		

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.

Since the beginning of fiscal 2002, sales of our generic oral contraceptive products have more than quadrupled. This growth has been fueled by new product launches, the addition of new customers and by increasing rates of generic substitution. At the end of fiscal 2004, our generic oral contraceptive portfolio totaled 19 products representing a generic version of nearly all oral contraceptive products on the market. In addition, the percentage of prescriptions filled with a generic version, the generic substitution rate, for many of our oral contraceptives reached 60-70% by the end of the year. As a result, while we believe the substitution rates for many of these products will eventually reach 80% or more over the next 12 months, we will not be able to gain market share as rapidly as we have over the past few years.

We have also recently noted a decline in the total number of prescriptions being written for the branded versions of many of our generic oral contraceptives. This decline is common for products that have generic equivalents available to consumers because demand for pharmaceutical products and the resulting prescriptions are significantly influenced by brand companies use of promotional activities, including the use of sales representatives to market products directly to physicians. When a generic version of a product is launched, brand companies substantially reduce or eliminate sales and promotion programs and refocus those efforts on other products that are not subject to generic competition. In the contraceptive market, the brand companies impacted by the launch of our generics have either stopped sales and promotional activities or have shifted their efforts to other contraceptive products which still enjoy patent protection, including low dose oral contraceptives and patch products. In fiscal 2004, we were able to offset the impact of these declining prescriptions with growth in our market share, but as we previously discussed, our rate of growth in the future will slow.

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Finally, over the past three years, the generic oral contraceptive market has included us and only one other generic competitor. However, two additional competitors have entered during the second half of fiscal 2004. As a result, we anticipate some loss of market share and lower pricing on certain oral contraceptive products during fiscal 2005.

Despite these challenges, we believe our generic oral contraceptive sales will increase in fiscal 2005 compared to 2004 though at a much lower growth rate than we experienced during the past year. Our forecast for fiscal 2005 primarily reflects our expectations that: (1) sales of Tri-Sprintec will increase year-over-year due to a full year contribution in fiscal 2005; (2) most of our products will continue to gain additional market share through increased generic substitution which will offset the negative effects of additional market competitors and declining prescriptions for some of these products; (3) in fiscal 2005, we will receive approval for and launch two new oral contraceptive products; and (4) we will add new customers during the year.

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 (the generic equivalent of Akzo Nobel and Organon, Inc.'s Remeron® Soltab®), which we launched in December 2003, and sales of Clarav® (a generic equivalent of Roche Pharmaceutical's Accutane®), which we launched in May 2003. These increases were partially offset by a significant decline in sales of our Dextro salt combo product (a generic equivalent of Shire Richwood, Inc.'s Adderall®) 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, our extended-cycle oral contraceptive; (3) increased sales of Cenestin; and (4) sales of Loestrin and Loestrin Fe, which we purchased from Galen (Chemicals) Limited (Galen) in March 2004.

In September 2003 we received approval for our SEASONALE extended-cycle oral contraceptive. 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. Since we launched SEASONALE, demand for the product as measured by prescription data obtained from IMS America has risen from 1,736 per week for the week ended December 26, 2003 to 12,731 for the week ended July 30, 2004. The consistent increases in number of prescriptions drives our expectation that sales of SEASONALE will be significantly higher in fiscal 2005 than they were in fiscal 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. However, recent prescription data suggests this decline may be slowing or stopping. Since July 2002, Cenestin prescriptions have 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.

Price increases are expected to continue in fiscal 2005, though they are not expected to be as significant as they were in fiscal 2004. Therefore, while we expect fiscal 2005 Cenestin sales to be relatively consistent with fiscal 2004 levels, the change in Cenestin sales in fiscal 2005 will depend on several factors including prescription trends, customer inventory levels and buying patterns and the extent of additional price increases.

Table of Contents**Cost of Sales**

Our cost of sales includes our acquisition cost for the distributed versions of products we purchase from third parties, our manufacturing and packaging costs for products we manufacture, profit sharing payments made to raw material suppliers and any changes to our inventory reserve. Product mix plays a significant role in our quarterly and annual overall gross margin percentage. Though this is true for many companies, our overall margins have been substantially impacted by the contribution from sales of our distributed versions of products such as Tamoxifen and Ciprofloxacin, which were manufactured for us by the innovator and distributed by us under the terms of patent challenge settlement agreements.

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:

(\$ in millions)	2004	2003	CHANGE	
			\$	%
Cost of sales:				
Generic products ⁽¹⁾	\$604.6	\$415.0	\$189.6	46%
<i>Gross margin</i>	47%	50%		
Proprietary products	\$ 28.1	\$ 9.1	\$ 19.0	209%
<i>Gross margin</i>	81%	84%		
Total cost of sales	\$632.7	\$424.1	\$208.6	49%
<i>Gross margin</i>	51%	53%		

(1) Includes cost of sales of Distributed Alternative Brand products.

The increase in total cost of sales, on a dollar basis, for 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 has a profit split paid to our partner, Ciprofloxacin has 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:

(\$ in millions)	2004	2003	CHANGE	
			\$	%
Selling, general and administrative	\$ 314.5	\$ 161.0	\$ 153.5	95%
Charges included in selling, 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

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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 is 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; (2) higher costs associated with the nearly doubling of our women's healthcare sales force; (3) higher legal costs, primarily related to patent matters, the Solvay arbitration and product liability matters; and (4) 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:

(\$ in millions)	2004	2003	CHANGE	
			\$	%
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 is 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) higher third party development costs; (2) higher headcount costs; and (3) 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 two years ended June 30, 2004 and 2003:

(\$ in millions)	2004	2003	CHANGE	
			\$	%
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.

Comparison of the fiscal years ended June 30, 2003 and June 30, 2002
(\$ in millions)

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The following table sets forth revenue data for the fiscal years ended June 30, 2003 and 2002:

(\$ in millions)	2003	2002	CHANGE	
			\$	%
Generic products:				
Distributed Alternative Brands: ⁽³⁾				
Ciprofloxacin	\$ 111.4	\$	\$ 111.4	N/A
Tamoxifen ⁽¹⁾	112.5	366.3	(253.8)	-69%
Oral contraceptives	274.4	92.8	181.6	196%
Other generic ⁽²⁾	338.9	650.2	(311.3)	-48%
Total generic products	837.2	1,109.3	(272.1)	-25%
Proprietary products	57.7	62.1	(4.4)	-7%
Total product sales	894.9	1,171.4	(276.5)	-24%
Development and other revenue	8.0	17.6	(9.6)	-55%
Total revenues	\$902.9	\$1,189.0	\$(286.1)	-24%

(1) Reflects sales of Tamoxifen product acquired from innovator.

(2) Includes sales of Tamoxifen product manufactured by Barr.

(3) 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 under Generic products.

Revenues Product Sales

Product sales for fiscal 2003 declined from the prior year primarily due to significant decreases in sales of Tamoxifen and Fluoxetine. Fluoxetine sales, which are included in the other generic line in the table above, accounted for \$7.2 million of product sales in fiscal 2003, down from \$367 million in fiscal 2002, while our distributed version of Tamoxifen accounted for \$113 million of product sales in fiscal 2003, down from \$366 million in fiscal 2002. Partially offsetting these declines were higher sales of our generic oral contraceptive products and sales from the June 2003 launch of our distributed version of Ciprofloxacin.

Generic Products***Ciprofloxacin***

In June 2003 we began shipping Ciprofloxacin hydrochloride pursuant to a license from Bayer. Under a 1997 settlement of a patent challenge we initiated against Bayer's Cipro antibiotic, we purchased directly from Bayer

Ciprofloxacin products that were manufactured under Bayer's New Drug Application for Cipro and marketed them under our label. We had the non-exclusive right to distribute the Ciprofloxacin products until Bayer's patent protecting Cipro expired in December 2003. On June 9, 2003, we began distributing Ciprofloxacin pursuant to the terms of the settlement and recorded sales of \$111 million for the period from June 9, 2003 to June 30, 2003. We share one-half of our profits from the sale of Ciprofloxacin, as defined, with Aventis, the contractual successor to our joint venture partner in the Cipro patent challenge case.

Tamoxifen

Sales of our distributed version of Tamoxifen decreased substantially in fiscal 2003. During the quarter ended December 31, 2002, we sold our remaining distributed Tamoxifen inventory previously purchased from AstraZeneca. AstraZeneca's pediatric exclusivity for its Nolvade® brand version of Tamoxifen ended on February 20, 2003. We were unable to supply distributed Tamoxifen to our customers after the depletion of our inventory purchased from AstraZeneca until we launched our manufactured Tamoxifen product at the expiration of

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AstraZeneca's pediatric exclusivity period. At that time, several other generic competitors launched Tamoxifen products, causing the price to decline and causing us to lose market share. Sales of our manufactured version of Tamoxifen totaled less than \$10 million during fiscal 2003.

Oral Contraceptives

The following table sets forth oral contraceptive data for the fiscal years ended June 30, 2003 and 2002:

(\$ in millions)	2003	2002	CHANGE	
			\$	%
Oral contraceptive sales	\$274.4	\$92.8	\$181.6	196%
Number of marketed products at end of period	13	6		

The increase in sales of oral contraceptives reflected increasing market shares for existing products, including our Apri®, Aviane®, Kariva® and Norlebo® products, and sales of seven new oral contraceptive products launched during fiscal 2003.

Generic Products Other

In August 2001, we launched our Fluoxetine 20 mg capsule with 180 days of exclusivity as the only generic manufacturer. Sales of Fluoxetine were \$368 million for fiscal 2002, constituting approximately 31% of product sales in that year. On January 29, 2002, our 180-day generic exclusivity period ended and, as expected, the FDA approved several other competing Fluoxetine products. As a result, the selling price declined dramatically and we lost market share to competing products, causing our sales and profits from Fluoxetine to be substantially lower than those earned during the exclusivity period. Somewhat offsetting the decline in Fluoxetine sales were higher sales of our Dextro salt combo product. We launched our Dextro salt combo product in February 2002 as the first generic manufacturer to enter the market. Sales of our Dextro salt combo product in fiscal 2003 were higher than in fiscal 2002 due to the inclusion of a full-year of sales in our fiscal 2003 results compared with approximately four months of sales in fiscal 2002. Partially offsetting this full year contribution were lower prices in fiscal 2003 due to the entry of competitors into the market.

Proprietary Products

Lower proprietary product sales in fiscal 2003 compared to fiscal 2002 were primarily the result of lower sales of Cenestin. Sales of Cenestin declined approximately 17% from \$42 million in fiscal 2002 to \$35 million in fiscal 2003. The decline in Cenestin sales was due to declining Cenestin prescriptions, which more than offset higher prices for the product, and was consistent with reduced sales of several prominent hormone therapy products due to the July 9, 2002 release of the findings of the Women's Health Initiative (WHI) study. The WHI study involved the long-term usage of estrogen and progestin in healthy post-menopausal women. A portion of the study, which evaluated the use of a combination of conjugated equine estrogens and the progestin medroxyprogesterone acetate, was stopped early by the study's sponsor, because of increased health risks, which the study sponsor felt outweighed the specified long-term benefits. Although Cenestin is not a combination product and was not part of the WHI study, the findings negatively impacted nearly all hormone therapy products. Though we experienced a decline in our Cenestin prescriptions, our

decline was not as significant as other larger products in the hormone therapy market and, as a result, our market share increased.

Cost of Sales

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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, 2003 and 2002:

(\$ in millions)	2003	2002	CHANGE	
			\$	%
Cost of sales:				
Generic products ⁽¹⁾	\$415.0	\$663.6	\$(248.6)	-37%
	<u> </u>	<u> </u>	<u> </u>	
<i>Gross margin</i>	50%	40%		
Proprietary products	\$ 9.1	\$ 12.7	\$ (3.6)	-28%
	<u> </u>	<u> </u>	<u> </u>	
<i>Gross margin</i>	84%	80%		
Total cost of sales	\$424.1	\$676.3	\$(252.2)	-37%
	<u> </u>	<u> </u>	<u> </u>	
<i>Gross margin</i>	53%	42%		

(1) Includes cost of sales of Distributed Alternative Brand products.

The decrease in cost of sales, on a dollar basis, was primarily due to lower sales of Fluoxetine and Tamoxifen. Cost of sales includes the profit split paid to Apotex, Inc., our partner in the Fluoxetine patent challenge, and royalties on certain other products paid to certain of our raw material suppliers.

Margins on our generic products increased in fiscal 2003 due mainly to the fact that higher margin products constituted a larger portion of total product sales in fiscal 2003 compared to fiscal 2002. In addition, as a percentage of total product sales, Fluoxetine, which is subject to a profit split with a partner, decreased from fiscal 2002 to fiscal 2003.

Margins on our proprietary products increased in fiscal 2003 compared to fiscal 2002 due mainly to the reduction in profit splits paid on our Viaspan organ preservation agent.

Selling, General and Administrative Expense

The following table sets forth selling, general and administrative expense data for the two years ended June 30, 2003 and 2002:

(\$ in millions)	2003	2002	CHANGE	
			\$	%
Selling, general and administrative	\$161.0	\$111.9	\$49.1	44%
	<u> </u>	<u> </u>	<u> </u>	

Charges included in selling, general and administrative	\$ 20.0	\$	\$20.0	N/A
	<u> </u>	<u> </u>	<u> </u>	

The increase in selling, general and administrative expenses was primarily due to significant costs incurred for pre-launch activities related to SEASONALE, which we launched in fiscal 2004, and increased marketing and selling expenses for Cenestin. Also contributing to the increase were the amortization of intangible assets and higher legal costs, including a charge of \$20 million relating to a contingent attorney fee paid in connection with a litigation settlement with Wyeth. Partially offsetting these increases were somewhat lower marketing and administrative costs associated with synergies achieved as a result of the integration of Duramed.

Research and Development Expense

The following table sets forth research and development expenses for the two years ended June 30, 2003 and 2002:

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(\$ in millions)	2003	2002	CHANGE	
			\$	%
Research and development	\$91.2	\$75.7	\$15.5	20%

The increase in research and development expenses reflected higher headcount and development costs in our proprietary development program, including costs associated with our vaginal ring product, as well as increased expenditures associated with the development of the Adenovirus Vaccine for the U.S. Department of Defense.

Proceeds from Patent Challenge Settlement

Under the terms of the contingent supply agreement we entered into with Bayer to settle our Cipro patent challenge litigation, Bayer had the option to either supply us with Ciprofloxacin at a predetermined discount for resale or make quarterly cash payments to us. Until June 9, 2003, Bayer elected to make payments to us rather than supply us with Ciprofloxacin. Accordingly, we recognized proceeds from patent challenge settlement of \$31 million for fiscal 2003 and \$32 million for fiscal 2002. Fiscal 2003 was the last year we recognized proceeds from the Cipro patent challenge.

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, 2003 and 2002:

(\$ in millions)	2003	2002	CHANGE	
			\$	%
Income tax expense	\$95.1	\$125.3	\$(30.2)	-24%
Effective tax rate	36.2%	37.1%		

The decrease in the effective tax rate for fiscal 2003 was due primarily to the increase in certain tax credits, the recognition of a deferred tax asset resulting from the identification of additional deductible state operating losses incurred in prior years and the reversal of certain valuation allowances previously established by Duramed.

Liquidity and Capital Resources**Overview**

The following table highlights selected balance sheet and cash flow components as of June 30, 2004 and 2003:

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(\$ s in millions)	2004	2003	CHANGE	
			\$	%
Cash & cash equivalents	\$419.9	\$367.1	\$52.8	14%
Marketable securities:				
Short-term	32.4	31.7	0.7	2%
Long-term	89.1	15.1	74.0	490%
Debt/Capital lease obligations:				
Short-term	8.4	8.5	(0.1)	-1%
Long-term	32.4	34.0	(1.6)	-5%
Cash flow from operations	258.1	160.3	97.8	61%
Working capital	670.6	582.2	88.4	15%

Our primary source of cash from operations is the collection of accounts receivable related to product sales and our primary uses of cash include funding our research and development programs, marketing and selling our proprietary and generic products, financing the production of inventories, funding capital projects 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 and cash equivalents balances have increased.

Investment in Marketable Securities

During fiscal 2004, we increased our investments in short and long-term 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. Our short-term portfolio includes \$29 million in market auction debt securities that are readily convertible into cash at par value with maturity dates ranging from July 2004 to February 2005 while our long-term portfolio includes \$89 million of municipal and corporate debt securities with maturity dates ranging from July 2005 to June 2007.

Operating Activities

Our operating cash flows have increased from \$160 million in fiscal 2003 to \$258 million in fiscal 2004, though over the past couple of years, our operating cash flow levels have fluctuated and are subject to many of the same risks and uncertainties that impact our earnings. Our operating cash in fiscal 2004 was generated principally by our net earnings, adjusted for in-process research and development charges totaling \$46 million and non-cash charges including depreciation and amortization which more than offset increases in certain of our working capital components.

Working Capital

Working capital as of June 30, 2004 and 2003 consisted of the following:

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(\$ in millions)	2004	2003	CHANGE	
			\$	%
Cash & cash equivalents	\$419.9	\$367.1	\$ 52.8	14%
Accounts receivable	153.9	221.7	(67.8)	-31%
Inventories	150.3	163.9	(13.6)	-8%
Prepaid & other current assets	154.1	97.1	57.0	59%
Subtotal	878.2	849.8	28.4	3%
Accounts payable & accrued liabilities	179.1	247.8	(68.7)	-28%
Income taxes payable	20.1	11.3	8.8	78%
Current portion of long-term debt & capital leases	8.4	8.5	(0.1)	-1%
Subtotal	207.6	267.6	(60.0)	-22%
Working capital	\$670.6	\$582.2	\$ 88.4	15%

Working capital increased from June 30, 2003 to June 30, 2004. Accounts receivable were lower at June 30, 2004 primarily due to the balance at June 30, 2003 being unusually high because we launched Ciprofloxacin in mid-June 2003. By June 30, 2003, we had not collected any of the receivables associated with the sales from our Ciprofloxacin launch. In contrast, additional competitors entered the generic Ciprofloxacin market in early June 2004, causing our sales of Ciprofloxacin in the month of June and for the quarter ended June to decline significantly compared to last year's fourth quarter. The decline in our accounts payable and accrued liabilities was mainly due to a reduction in accounts payable owed to Bayer for Ciprofloxacin purchases, partially offset by higher accrued liabilities resulting from current amounts due Solvay under the arbitration award and current amounts of revenue deferred from a product licensing agreement we entered into in April 2004, which we will recognize over a five year period. Prepaid and other current assets increased from June 30, 2003 to June 30, 2004, primarily reflecting a receivable of approximately \$48 million due from Bayer as a price adjustment to reduce the cost of our June 2004 inventory of Ciprofloxacin purchased from Bayer during the second half of our fiscal year.

Cash flows in fiscal 2004 were favorably impacted by approximately \$21 million in part due to a change in the method used to calculate the annual limitation under Section 382 of the Internal Revenue Code. As a result of this change, we have utilized all of the federal net operating losses incurred by Duramed Pharmaceuticals, Inc. prior to our merger with Duramed in October 2001.

In June 2004, an arbitration panel ruled against the Company in its arbitration with Solvay Pharmaceuticals and awarded Solvay \$68 million in damages. This award is required to be paid out in six installments. The first payment of \$18 million was made on July 23, 2004 and five additional quarterly payments of \$10 million will be due over the five quarters ending October 15, 2005. We have filed a petition with the U.S. District Court in Cincinnati seeking to vacate the award.

SEASONALE Royalty

Our current royalty obligation to the SEASONALE patent-holder is a perpetual royalty based on a percentage of net profits, as defined. However, our license agreement gives us the option, at any time prior to September 2004, to make a one-time payment of approximately \$19 million to the patent holder in lieu of future royalty payments. We expect to exercise this option.

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Investing Activities

Capital Expenditures

During the three fiscal years ended June 30, 2004, we have invested approximately \$175 million in upgrades and expansions to our property, plant and equipment. This investment 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.

During the twelve months ended June 30, 2004, we invested \$47 million in capital projects and expect that our capital investments will be between \$60 million and \$80 million over the next twelve months. Our estimate reflects lower spending on our facility expansion programs and higher investments in information technology projects including the purchase and implementation of a new enterprise resource planning system.

We believe we can continue funding our capital requirements using cash provided by operations. However, we may consider obtaining 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 \$91 million in fiscal 2004 and approximately \$162 million for the three years ended June 30, 2004. In fiscal 2004, these transactions included the acquisition of Women's Capital Corporation, certain assets of Gynetics, Inc., substantially all the assets of Endeavor Pharmaceuticals, Inc. and certain product rights from Galen. We continuously evaluate strategic transactions to further improve our business and long-range prospects and expect to make additional investments 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.

Loans to Natural Biologics

In fiscal 2002, we entered into a Loan and Security Agreement (the "Loan Agreement") with Natural Biologics, LLC ("Natural Biologics"), the raw material supplier for our generic equine-based conjugated estrogens product for which we filed an Abbreviated New Drug Application ("ANDA") with the FDA in June 2003. In September 2003, as a result of an adverse legal decision in a lawsuit brought by Wyeth against Natural Biologics, we reserved \$16 million for all loans made to Natural Biologics since the inception of our loan agreement. Natural Biologics is appealing the decision and, pending the outcome of the appeal, we agreed to provide Natural Biologics advances totaling \$1.4 million over four quarters beginning in May 2004, to defray the costs of maintaining the existing conjugated estrogen raw material. We are fully reserving these advances. If Natural Biologics prevails on its appeal, we expect to resume making loans to Natural Biologics on the terms contained in our Loan Agreement.

In fiscal 2002, the Company also entered into a Development, Manufacturing and Distribution Agreement with Natural Biologics which could obligate the Company to make milestone payments totaling an additional \$35 million to Natural Biologics based on achieving certain legal and product approval milestones, including the approval of a generic product.

Investment in Venture Funds

During the second quarter of fiscal 2004, we made investments, as a limited partner, in two separate venture capital funds as part of our continuing efforts to identify new products, new technologies and new licensing opportunities. We have committed up to a total of \$15 million for each of these funds over a five and 10-year period, as defined by each fund. As of August 15, 2004, we have contributed a total of \$8 million to these funds.

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Financing Activities

Debt Repayments and Credit Availability

Debt balances decreased by approximately \$1.7 million from June 30, 2003 to June 30, 2004 reflecting principal repayments of \$8.5 million, offset by our issuance of a \$6.5 million note to finance a portion of our acquisition of Women's Capital Corporation. Scheduled principal repayments on existing debt will be \$8.5 million during the next twelve months.

We have a \$40 million revolving credit facility that expires on February 27, 2005. We currently have \$33 million available under this facility due to the issuance of a \$7.1 million letter of credit in support of our product liability self-insurance program. We expect to replace the existing revolving credit facility with a larger one before it expires in February 2005.

Proceeds from Equity Transactions

Over the three years ending June 30, 2004, we received proceeds of approximately \$70 million from the exercise of employee stock options and share purchases under our employee stock purchase plan. The timing and sustainability of such proceeds are very difficult to predict because they are highly dependent upon our stock price, which can be volatile.

During 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 2,340,610 shares of our common stock. We did not receive any proceeds from the issuance of the shares but we expect to realize a cash tax benefit of approximately \$15 million from this transaction.

Share Repurchase Program

In August 2004, our Board of Directors authorized the repurchase of up to \$300 million of the Company's 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. The Company will hold repurchased shares as treasury shares and may use them for general corporate purposes, including but not limited to acquisition related transactions and for issuance upon exercise of outstanding stock options.

Funding of Employee Savings Plan

On September 23, 2003, we committed to make a minimum aggregate contribution of \$11 million to the Barr Pharmaceuticals, Inc. Savings and Retirement Plan (401(k) Plan) for the fiscal year ending June 30, 2004. We fully funded the contribution commitment during the fiscal year. We expect to make a similar minimum contribution commitment in September 2004 for fiscal 2005.

Sufficiency of Cash Resources

We believe our current cash and 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.

Table of Contents*Contractual Obligations*

Payments due by period for our contractual obligations at June 30, 2004 are as follows:

(\$ in millions)	Payments due by period				
	Total	Less than 1 Year	1 to 3 Years	4 to 5 Years	Thereafter
Long-term debt	\$ 37.1	\$ 7.0	\$ 23.3	\$ 6.8	\$
Capital leases	4.3	1.8	2.5		
Operating leases	36.4	3.7	10.7	3.2	18.8
Purchase obligations ¹	76.8	62.1	11.8	2.2	0.7
Venture Funds commitment	21.5	21.5			
Annual interest on fixed rate debt	1.7	0.8	0.9		
Other long-term liabilities	5.6	4.6	1.0		
	<hr/>	<hr/>	<hr/>	<hr/>	<hr/>
Total	\$183.4	\$ 101.5	\$ 50.2	\$ 12.2	\$ 19.5
	<hr/>	<hr/>	<hr/>	<hr/>	<hr/>

(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.

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 sales returns and allowances; (2) inventories and related inventory reserves; (3) deferred taxes; (4) contingencies; and (5) the assessment of recoverability of goodwill and other intangible assets. 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.

Revenue Recognition and Sales Reserves and Allowances

We recognize revenue from product sales when title and risk of loss have transferred to our customers and when collectibility is reasonably assured. We simultaneously record estimates for price adjustments (including shelf-stock adjustments), product returns, chargebacks, rebates, including Medicaid rebates, prompt payment discounts and other sales allowances. Accruals for these estimates reduce our reported product sales and accounts receivable and, in the

case of Medicaid rebates, are recorded in our accrued liabilities. If we believe we have not met the requirements for recognizing revenue, we defer the recognition of product sales. In November 2003, we launched our extended cycle oral contraceptive product, SEASONALE, but did not recognize the revenue immediately. We monitored SEASONALE's prescription data and other information during the months following our launch and recognized revenues once we concluded that the product had achieved market acceptance. All of the revenues associated with the initial launch were recognized by the end of the year.

Provisions for estimated discounts, rebates, promotional and other credits require a lower degree of subjectivity and are less complex in nature; yet combined, they represent a significant portion of the overall provisions. Other provisions, such as shelf stock adjustments, returns and chargebacks, require more subjective judgments. These provisions are discussed in further detail below.

Shelf-stock Adjustments Shelf stock adjustments are credits issued to reflect decreases in the selling prices of our products 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 usually at our discretion rather than contractually required. We record allowances for shelf-stock adjustments at the time we sell products that we

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determine will be subject to a price decrease or when market conditions indicate that a shelf-stock adjustment is necessary to facilitate the sell-through of our product. When deciding whether to record a reserve for a shelf-stock adjustment, we analyze several variables, including the estimated launch date of a competing product, the estimated decline in market price and estimated levels of inventory held by our customers at the time of the decrease in market price. As a result, a shelf-stock adjustment depends on a product's unique facts and circumstances.

Returns - Consistent with industry practice, we maintain a return policy that allows our customers to return product within a specified period prior to and subsequent to the expiration date. Our estimate of the provision for returns is based upon our historical experience with actual returns. Additionally, we consider factors including product dating and expiration period when we establish our provision for returns.

Chargebacks - The provision for chargebacks is the most significant and complex estimate used in the recognition of revenue. 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 party and the wholesaler's invoice price. Such credit is called a chargeback. The provision for chargebacks is based on expected sell-through levels by our wholesaler customers to indirect customers, as well as estimated wholesaler inventory levels.

Accounts receivable are presented net of allowances related to the above provisions of \$142 million at June 30, 2004 and \$136 million at June 30, 2003. Accrued liabilities include \$11 million and \$9.5 million at June 30, 2004 and 2003, respectively, for estimated Medicaid rebates.

Inventory Reserves

Inventories are stated at the lower of cost, determined on a first-in, first-out basis 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 also capitalize inventory costs associated with certain products prior to regulatory approval and/or resolution of patent infringement litigation, based on management's judgment of probable future commercial use and net realizable value. If final regulatory approval for such products is denied or delayed, or if patent litigation is not resolved in our favor, or if a patent litigation decision is delayed, we may be required to expense such previously capitalized costs.

We establish reserves for our inventory to reflect situations in which the cost of the inventory is not expected to be recovered. We review our inventory for products close to expiration and therefore not expected to be sold, for products that have reached their expiration date and for products that are not expected to be saleable based on our quality assurance and control standards. The reserve for these products 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 \$24 million at June 30, 2004 and \$13 million at June 30, 2003.

Deferred Taxes

Income taxes are accounted for under Statement of Financial Accounting Standards (SFAS) No. 109, Accounting for Income Taxes. Under this method, deferred tax assets and liabilities are recognized for the expected future tax consequences of temporary 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, which are more-likely-than-not to be unrealized. The recoverability of deferred tax assets is dependent upon our assessment of whether it is more-likely-

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than-not that sufficient future taxable income will be generated in the relevant tax jurisdiction to utilize the deferred tax asset. We review our internal sales forecasts and pre-tax earnings estimates to make our assessment about the utilization of deferred tax assets. In the event we determine that future taxable income will not be sufficient to utilize the deferred tax asset, we will record a valuation allowance. If that assessment changes, we would record a benefit on the consolidated statement of earnings.

Deferred income taxes are presented net of a valuation allowance of \$4.7 million at June 30, 2004 and \$6.1 million at June 30, 2003.

Contingencies

We are subject to litigation in the ordinary course of business, including patent, product liability and other litigation and contingencies. Legal fees and other costs related to such litigation and contingencies are expensed as incurred. Additionally, we assess, in consultation with counsel, the need to record a liability for litigation and contingencies. Reserves are recorded when we determine that a loss related to a matter is both probable and reasonably estimable.

We are primarily self-insured for potential product liability claims on products sold on or after September 30, 2002, and we maintain self-insured retentions and deductibles on policies covering periods prior to September 30, 2002. We maintain a self-insurance reserve, which provides an estimate of our potential product liability claims not covered by our insurance and an estimate of the future cost of incurred but not reported (IBNR) claims. We develop these estimates in consultation with outside counsel, our insurance consultants and an independent actuary. The self-insurance reserve does not include estimated administrative or defense costs, which are expensed as incurred.

Goodwill and Other Intangible Assets

In connection with acquisitions, we determine the amounts assigned to goodwill and other intangibles based on purchase price allocations. These allocations, including an assessment of the estimated useful lives of intangible assets, have been performed by qualified independent appraisers using generally accepted valuation methodologies. The valuation of intangible assets is generally based on the estimated future cash flows related to those assets, while the value assigned to goodwill is the residual of the purchase price over the fair value of all identifiable assets acquired and liabilities assumed. 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. As required by SFAS No. 142, Goodwill and Other Intangible Assets, we review goodwill for impairment annually or more frequently if impairment indicators arise.

As a result of our acquisitions, we included goodwill of \$18 million on our balance sheet as of June 30, 2004 and \$14 million as of June 30, 2003.

As a result of our acquisition of product rights and related intangibles and certain product licenses, we have included \$65 million and \$46 million as other intangible assets, net of accumulated amortization, on our balance sheet as of June 30, 2004 and June 30, 2003, respectively.

Recent Accounting Pronouncements

Amendment of Statement 133 on Derivative Instruments and Hedging Activities

In April 2003, the Financial Accounting Standards Board (FASB) issued SFAS No. 149, Amendment of Statement 133 on Derivative Instruments and Hedging Activities (SFAS 149), which is generally effective for contracts entered

into or modified after June 30, 2003 and for hedging relationships designated after June 30, 2003. SFAS 149 clarifies the circumstances under which a contract with an initial net investment meets the characteristic of a derivative as discussed in SFAS No. 133, clarifies when a derivative contains a financing component, amends the definition of an underlying to conform it to the language used in FASB Interpretation No. 45, Guarantor Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others, and amends certain other existing pronouncements. We currently have no involvement with derivative financial

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instruments, and therefore the adoption of SFAS 149 did not have a material impact on our consolidated financial statements.

Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity* (SFAS 150). SFAS 150 modifies the accounting for certain financial instruments that, under previous guidance, issuers could account for as equity. SFAS 150 requires that those instruments be classified as liabilities in statements of financial position and affects an issuer's accounting for (1) mandatorily redeemable shares, which the issuing company is obligated to buy back in exchange for cash or other assets, (2) instruments, other than outstanding shares, that do or may require the issuer to buy back some of its shares in exchange for cash or other assets, or (3) obligations that can be settled with shares, the monetary value of which is fixed, tied solely or predominately to a variable such as a market index, or varies inversely with the value of the issuer's shares. In addition to its requirements for the classification and measurement of financial instruments within its scope, SFAS 150 also requires disclosures about alternative ways of settling those instruments and the capital structure of entities, all of whose shares are mandatorily redeemable. SFAS 150 is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The adoption of SFAS 150 did not have a material impact on our consolidated financial statements.

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.

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*, *sh*, *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 outcome of litigation arising from challenging the validity or non-infringement of patents covering our products;

the difficulty of predicting the timing of U.S. Food and Drug Administration, or 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;

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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 increasing 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.

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 \$538 million and debt instruments of approximately \$13.2 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. government, municipal and corporate obligations, certificates of deposit and money market funds. Over 80% of our portfolio matures in less than three

months. The carrying value of the investment portfolio approximates the market value at June 30, 2004 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.

Approximately 68% of our debt instruments at June 30, 2004 are subject to fixed interest rates and principal payments. The related note purchase agreements permit us to prepay these notes prior to their scheduled maturity, but may require us to pay a prepayment fee based on market rates at the time of prepayment. The remaining 32% of debt instruments are primarily subject to variable interest rates based on the prime rate or LIBOR and have fixed principal payments. The fair value of all debt instruments is approximately \$38 million at June 30, 2004. In addition, borrowings under our \$40 million unsecured revolving credit facility bear interest at a variable rate based on the

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prime rate, the Federal Funds rate or LIBOR. As of June 30, 2004, there was approximately \$33 million available under this facility due to the issuance of a \$7.1 million letter of credit in support of our finite risk insurance program. We do not believe that any market risk inherent in our debt instruments is likely to have a material effect on our consolidated financial statements.

As discussed in Note 15 in the accompanying Notes to Consolidated Financial Statements, as of June 30, 2004, we had approximately \$13.2 million of variable rate debt outstanding. A hypothetical 100 basis point increase in interest rates, based on the June 30, 2004 balance, would reduce our annual net income by approximately \$84 thousand. Any future gains or losses may differ materially from this hypothetical amount based on the timing and amount of actual interest rate changes and the actual term loan balance.

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, 2004, 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.

Changes in Internal Controls

During the last quarter of our fiscal year ended June 30, 2004, 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.

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PART III

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

A description of 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 October 2004 (the Proxy Statement) and is incorporated herein by reference.

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Code of Business Conduct and Ethics

The Company has adopted a Code of Business Conduct and Ethics (the "Code") that applies to all 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 Company's website at www.barrlabs.com. The Company intends 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 auditors will be set forth in the section titled "Independent Registered Public Accountants" of the Proxy Statement and is incorporated herein by reference.

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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 June 29, 2001, by and among Barr Laboratories, Inc., Beta Merger Sub I, Inc. and Duramed Pharmaceuticals, Inc. (10)
- 2.2 Asset Purchase Agreement dated March 16, 2002 between Enhance Pharmaceuticals, Inc. and Barr Laboratories, Inc. (18)
- 2.3 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 (22)
- 2.4 Asset Purchase Agreement dated November 20, 2003 between Endeavor Pharmaceuticals, Inc. and Barr Laboratories, Inc. (2)
- 2.5 Agreement and Plan of Merger, dated February 6, 2004, among Duramed Pharmaceuticals, Inc., WCC Merger Sub, Inc. and Women's Capital Corporation (21)
- 3.1 Amended and Restated Certificate of Incorporation of the Registrant (22)
- 3.2 Restated By-Laws of the Registrant (22)
- 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.
- 4.3 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. (1)
- 10.1 Lease, dated March 3, 2004, between City Line Investors L.P. and Barr Research, Inc. (21)
- 10.2 Lease, dated February 6, 2003, between Mack-Cali Properties Co. No. 11 L.P. and Barr Laboratories, Inc. (18)
- 10.3 Amended and Restated Employment Agreement with Bruce L. Downey, dated as of October 24, 2002 (17)
- 10.4 1993 Stock Incentive Plan (4)
- 10.5 Non-Qualified Deferred Compensation Plan (2)
- 10.6 1993 Employee Stock Purchase Plan (5)

- 10.7 1993 Stock Option Plan for Non-Employee Directors (6)
- 10.8 2002 Stock and Incentive Award Plan (16)
- 10.9 2002 Stock Option Plan for Non-Employee Directors (16)
- 10.10 Supply Agreement for Ciprofloxacin Hydrochloride dated January 8, 1997 (7)
- 10.11 Proprietary Drug Development and Marketing Agreement dated March 20, 2000 (8)

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10.12	Description of Excess Savings and Retirement Plan (9)
10.13	Amended and Restated Employment Agreement with Paul M. Bisaro, dated as of October 24, 2002 (17)
10.14	Amended and Restated Employment Agreement with Carole S. Ben-Maimon, dated as of October 24, 2002 (17)
10.15	Amended and Restated Employment Agreement with Timothy P. Catlett, dated as of February 19, 2003 (20)
10.16	Amended and Restated Employment Agreement with William T. McKee, dated as of February 19, 2003 (19)
10.17	Amended and Restated Employment Agreement with Fredrick J. Killion, dated as of February 19, 2003 (19)
10.18	Amended and Restated Employment Agreement with Salah U. Ahmed, dated as of February 19, 2003 (20)
10.19	Amended and Restated Employment Agreement with Christine A. Mundkur, dated as of February 19, 2003 (20)
10.20	Amended and Restated Employment Agreement with Catherine F. Higgins, dated as of February 19, 2003 (20)
10.21	Employment Agreement with Michael J. Bogda, dated as of May 15, 2003 (20)
10.22	Duramed 1988 Stock Option Plan (11)
10.23	Duramed 1991 Stock Option Plan for Nonemployee Directors (12)
10.24	Duramed 1997 Stock Option Plan (13)
10.25	Duramed 2000 Stock Option Plan (14)
10.26	Duramed 1999 Nonemployee Director Stock Plan (15)
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

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- (1) 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.
 - (2) Previously filed with the Securities and Exchange Commission as an Exhibit to the Registrant's

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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 on January 6, 2004 as an Exhibit to the Registrant's Current Report on Form 8-K and incorporated herein by reference.
- (4) 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.
- (5) 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.
- (6) 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.
- (7) 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.
- (8) 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.
- (9) 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.
- (10) Previously filed with the Securities and Exchange Commission as Annex 1 to the Registrant's Registration Statement No. 333-66986 on Form S-4 on August 7, 2001 and incorporated herein by reference.
- (11) 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.
- (12) 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.
- (13) 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.
- (14) 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.
- (15)

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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.

- (16) 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.
- (17) 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.

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- (18) 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, 2002 and incorporated herein by reference.
- (19) 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.
- (20) 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.
- (21) 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.

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
<u>/s/ Bruce L. Downey</u> Bruce L. Downey	Chairman of the Board and Chief Executive Officer (Principal Executive Officer)	August 23, 2004
<u>/s/ William T. McKee</u> William T. McKee	Vice President, Chief Financial Officer and Treasurer (Principal Financial Officer and Principal Accounting Officer)	August 23, 2004
<u>/s/ Carole S. Ben-Maimon</u> Carole S. Ben-Maimon	Director	August 23, 2004
<u>/s/ Paul M. Bisaro</u> Paul M. Bisaro	Director	August 23, 2004
<u>/s/ Harold N. Chefitz</u> Harold N. Chefitz	Director	August 23, 2004
<u>/s/ Richard R. Frankovic</u> Richard R. Frankovic	Director	August 23, 2004
<u>/s/ James S. Gilmore III</u>	Director	August 23, 2004

James S. Gilmore III

/s/ Jack M. Kay

Director

August 23, 2004

Jack M. Kay

/s/ Peter R. Seaver

Director

August 23, 2004

Peter R. Seaver

/s/ George P. Stephan

Director

August 23, 2004

George P. Stephan

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PART II

Item 8. *Financial Statements and Supplementary Data*

INDEX TO FINANCIAL STATEMENTS AND FINANCIAL STATEMENT SCHEDULE

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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, 2004 and 2003, and the related consolidated statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended June 30, 2004. Our audits also included the financial statement schedule listed in the Index at Item 15. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on the financial statements and financial statement schedule based on our audits.

We conducted our audits in accordance with 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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of the Company at June 30, 2004 and 2003, and the results of their operations and their cash flows for each of the three years in the period ended June 30, 2004, 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.

/s/ DELOITTE & TOUCHE LLP

Stamford, Connecticut
August 17, 2004

Table of Contents**BARR PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS**

(in thousands, except share amounts)

	June 30, 2004	June 30, 2003
Assets		
Current assets:		
Cash and cash equivalents	\$ 419,878	\$ 367,142
Marketable securities	32,376	31,682
Accounts receivable, net	153,890	221,652
Other receivables	60,848	31,136
Inventories, net	150,252	163,926
Deferred income taxes	46,077	27,375
Prepaid expenses and other current assets	14,925	6,873
Total current assets	878,246	849,786
Property, plant and equipment, net	236,831	223,516
Deferred income taxes	35,016	5,589
Marketable securities	89,143	15,055
Other intangible assets	64,897	45,949
Goodwill	18,211	14,118
Other assets	10,925	26,924
Total assets	\$1,333,269	\$1,180,937
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	\$ 61,089	\$ 188,852
Accrued liabilities	117,970	58,925
Current portion of long-term debt and capital lease obligations	8,447	8,510
Income taxes payable	20,139	11,316
Total current liabilities	207,645	267,603
Long-term debt and capital lease obligations	32,355	34,027
Other liabilities	51,223	11,312
Commitments & Contingencies (Note 23)		
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 104,916,103 and 67,066,196 in 2004 and 2003, respectively	1,049	671

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Additional paid-in capital	377,024	326,001
Retained earnings	664,681	542,210
Accumulated other comprehensive loss		(179)
	<u> </u>	<u> </u>
	1,042,754	868,703
Treasury stock at cost; 420,597 and 280,398 shares in 2004 and 2003, respectively	(708)	(708)
	<u> </u>	<u> </u>
Total shareholders' equity	<u>1,042,046</u>	<u>867,995</u>
Total liabilities and shareholders' equity	<u>\$1,333,269</u>	<u>\$1,180,937</u>

SEE ACCOMPANYING NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

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BARR PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

For the Years Ended June 30, 2004, 2003 and 2002

	For the Years Ended June 30,		
	2004	2003	2002
	(in thousands, except per share amounts)		
Revenues:			
Product sales	\$1,296,709	\$894,888	\$1,171,358
Development and other revenue	12,379	7,976	17,626
	<hr/>	<hr/>	<hr/>
Total revenues	1,309,088	902,864	1,188,984
Costs and expenses:			
Cost of sales	632,745	424,099	676,323
Selling, general and administrative	314,500	160,978	111,886
Research and development	168,995	91,207	75,697
Merger-related costs			31,449
	<hr/>	<hr/>	<hr/>
Earnings from operations	192,848	226,580	293,629
Proceeds from patent challenge settlement		31,396	31,958
Interest income	5,768	6,341	7,824
Interest expense	2,643	1,474	3,530
Other (expense) income	(1,533)	(128)	7,656
	<hr/>	<hr/>	<hr/>
Earnings before income taxes	194,440	262,715	337,537
Income tax expense	71,337	95,149	125,318
	<hr/>	<hr/>	<hr/>
Net earnings	123,103	167,566	212,219
Preferred stock dividends			457
Deemed dividend on convertible preferred stock			1,493
	<hr/>	<hr/>	<hr/>
Net earnings available to common shareholders	\$ 123,103	\$167,566	\$ 210,269
	<hr/>	<hr/>	<hr/>
Earnings per common share - basic	\$ 1.21	\$ 1.69	\$ 2.17
	<hr/>	<hr/>	<hr/>
Earnings per common share - diluted	\$ 1.15	\$ 1.62	\$ 2.06

	<u> </u>	<u> </u>	<u> </u>
Weighted average shares	101,823	99,125	96,998
	<u> </u>	<u> </u>	<u> </u>
Weighted average shares - diluted	106,661	103,592	102,203
	<u> </u>	<u> </u>	<u> </u>

SEE ACCOMPANYING NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

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BARR PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

For the Years Ended June 30, 2004, 2003 and 2002
(in thousands, except share amounts)

	Common Stock		Additional	Paid	Accumulated	Treasury Stock		Total
			Paid	Capital -	Retained			Shareholders
	Shares	Amount	in Capital	Warrants	Earnings	Comprehensive	Income	Equity
						(Loss)		
Balance, July 1, 2001	42,333,524	\$ 424	\$ 239,264	\$ 16,418	\$ 160,347	\$ 337	176,932	\$ (13) \$ 416,777
Comprehensive income:								
Net earnings					212,219			212,219
Unrealized loss on marketable securities, net of tax of \$168						(238)		(238)
Total comprehensive income								211,981
Pooling adjustments	125,590	(1)	1,219		2,551			3,769
Tax benefit of stock incentive plans			5,611					5,611
Issuance of stock in connection with benefit plans	2,349		177					177
Issuance of common stock for exercised stock options and employees stock purchase plans	797,380	8	19,882					19,890
Issuance of common stock for exercised warrants	21,565	2	762					764
	512,387	5	8,841					8,846

Conversion of preferred stock									
Deemed dividend on convertible preferred stock			(80)						(80)
Dividend on convertible preferred stock			(457)						(457)
Cash in lieu of fractional shares	(625)				(51)				(51)
Common stock acquired for treasury							10,000	(695)	(695)
Balance, June 30, 2002	43,792,170	438	275,219	16,418	375,066	99	186,932	(708)	666,532
Comprehensive income:									
Net earnings					167,566				167,566
Unrealized loss on marketable securities, net of tax of \$170						(278)			(278)
Total comprehensive income									167,288
Tax benefit of stock incentive plans			10,912						10,912
Issuance of common stock for exercised stock options and employees stock purchase plans	1,020,032	10	23,453						23,463
Issuance of common stock for exercised warrants	83,940	1	(1)						
Stock split (3-for-2)	22,170,054	222			(422)		93,466		(200)
Balance, June 30, 2003	67,066,196	671	309,583	16,418	542,210	(179)	280,398	(708)	867,995

Comprehensive income:									
Net earnings					123,103				123,103
Reclassification adjustment						179			<u>179</u>
Total comprehensive income									123,282
Tax benefit of stock incentive plans and warrants			25,262						25,262
Issuance of common stock for exercised stock options and employees stock purchase plans	1,456,808	14	25,784						25,798
Issuance of common stock for exercised warrants	2,340,610	23	16,395	(16,418)					0
Stock split (3-for-2)	<u>34,052,489</u>	<u>341</u>	<u></u>	<u></u>	<u>(632)</u>	<u></u>	<u>140,199</u>	<u></u>	<u>(291)</u>
Balance, June 30, 2004	<u>104,916,103</u>	<u>\$1,049</u>	<u>\$377,024</u>	<u>\$</u>	<u>\$664,681</u>	<u>\$</u>	<u>420,597</u>	<u>\$(708)</u>	<u>\$1,042,046</u>

SEE ACCOMPANYING NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

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BARR PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

For the Years Ended June 30, 2004, 2003 and 2002
(in thousands of dollars)

	2004	2003	2002
	<hr/>	<hr/>	<hr/>
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net earnings	\$ 123,103	\$ 167,566	\$ 212,219
Adjustments to reconcile net earnings to net cash provided by operating activities:			
Depreciation and amortization	32,059	22,713	15,290
Deferred income tax (benefit) expense	(44,330)	6,684	6,389
Write-off of intangible asset	22,333	1,330	
Provision for losses on loans to Natural Biologics	16,079		
Other	17,699	362	507
Tax benefit of stock incentive plans and warrants	25,262	10,912	5,611
Write-off of in-process research and development associated with acquisitions	45,900	3,946	1,000
Changes in assets and liabilities:			
(Increase) decrease in:			
Accounts receivable and other receivables, net	38,081	(126,390)	(5,155)
Inventories, net	13,771	(12,793)	(8,304)
Prepaid expenses	(8,052)	923	(844)
Other assets	(201)	(10,391)	368
Increase (decrease) in:			
Accounts payable, accrued liabilities and other liabilities	(32,428)	93,951	8,219
Income taxes payable	8,823	1,515	(475)
	<hr/>	<hr/>	<hr/>
Net cash provided by operating activities	258,099	160,328	234,825
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of property, plant and equipment	(46,907)	(80,617)	(47,205)
Acquisitions, net of cash acquired	(90,563)	(25,992)	(46,288)
Purchases of marketable securities, net	(73,443)	(29,400)	(15,000)
Other	(4,935)	(6,169)	(4,835)
	<hr/>	<hr/>	<hr/>
Net cash used in investing activities	(215,848)	(142,178)	(113,328)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Principal payments on long-term debt and capital leases	(8,522)	(5,528)	(12,166)
Net borrowings under line of credit			(20,316)
Principal payment on note assumed in acquisition	(6,500)		
Purchase of treasury stock			(695)
Proceeds from exercise of stock options and employee stock purchases	25,798	23,463	20,655
Dividends paid on preferred stock			(11)
Other	(291)	(200)	(50)

	<u> </u>	<u> </u>	<u> </u>
Net cash provided by (used in) financing activities	10,485	17,735	(12,583)
	<u> </u>	<u> </u>	<u> </u>
Increase in cash and cash equivalents	52,736	35,885	108,914
Cash and cash equivalents at beginning of period	367,142	331,257	222,343
	<u> </u>	<u> </u>	<u> </u>
Cash and cash equivalents at end of period	\$ 419,878	\$ 367,142	\$ 331,257
	<u> </u>	<u> </u>	<u> </u>

SUPPLEMENTAL CASH FLOW DATA:

Cash paid during the period:

Interest, net of portion capitalized	\$ 2,658	\$ 1,455	\$ 3,510
	<u> </u>	<u> </u>	<u> </u>
Income taxes	\$ 80,733	\$ 76,039	\$ 113,563
	<u> </u>	<u> </u>	<u> </u>

SEE ACCOMPANYING NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

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BARR PHARMACEUTICALS, INC.
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. (BPI), a holding company that operates through its principal subsidiaries, Barr Laboratories, Inc. and Duramed Pharmaceuticals, Inc., is engaged in the development, manufacture and marketing of generic and proprietary pharmaceuticals. BPI is a Delaware corporation that was formed in December 2003, in connection with the reincorporation of Barr Laboratories, Inc., a New York corporation (Barr-NY). The reincorporation was accomplished by the merger of Barr-NY into BPI on December 31, 2003, with BPI as the surviving entity. Prior to the merger, Barr-NY contributed its principal operating assets to Barr Laboratories, Inc., a newly formed, wholly-owned subsidiary incorporated in Delaware. References to Barr or the Company herein include BPI and its subsidiaries.

The Company, when used in the context of the Company and Duramed, refers to pre-merger Barr. All significant intercompany balances and transactions have been eliminated in consolidation.

Sherman Delaware, Inc. owned approximately 9.9% of the outstanding common stock of the Company at June 30, 2004. Dr. Bernard C. Sherman is a principal stockholder of Sherman Delaware, Inc. and was a Director of Barr Laboratories, Inc. until October 24, 2002 (see Note 17).

On October 24, 2001, the Company completed a merger with Duramed Pharmaceuticals, Inc. (Duramed), a developer, manufacturer, and marketer of prescription drug products focusing on women's health and the hormone therapy markets. The merger qualified as a tax-free reorganization and was accounted for as a pooling-of-interests for financial reporting purposes. Accordingly, in accordance with accounting principles generally accepted in the United States of America and pursuant to Regulation S-X of the U.S. Securities and Exchange Commission, all financial data of the Company presented in these financial statements has been restated as described below to include the historical financial data of Duramed. The Company and Duramed had different fiscal year-ends. Duramed had a calendar year-end, whereas the Company's fiscal year ends on June 30th. Financial information for the fiscal year ended June 30, 2002 is presented as if the Company and Duramed were merged on July 1, 2001.

On June 6, 2002, the Company completed the purchase of certain assets and assumption of certain liabilities of Enhance Pharmaceuticals, Inc. (Enhance). The operating results of Enhance are included in the consolidated financial statements subsequent to the June 6, 2002 acquisition date.

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.

Certain amounts in the prior year's financial statements have been reclassified to conform with the current year presentation.

(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. Actual results could differ from those estimates.

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The most significant estimates made by management include those made in the areas of revenue recognition and sales returns and allowances, including shelf stock adjustments and chargebacks; inventory reserves; deferred taxes; contingencies; and the assessment of the recoverability of goodwill and other intangible assets.

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

Product sales

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 \$141,873 and \$136,059 at June 30, 2004 and 2003, respectively. Included in accrued liabilities are \$11,413 and \$9,468 relating to estimated Medicaid rebates at June 30, 2004 and 2003, respectively.

Development and other revenue

Development and other revenue includes: reimbursements relating to research and development contracts; licensing fees; and royalties 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 based upon the amounts earned in specific periods.

(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 Barr. Actual experience associated with any of these items may be different than the Company's estimates. Barr 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.

The Company often issues credits to customers for inventory remaining on their shelves following a decrease in the market price of a generic pharmaceutical product. These credits, commonly referred to in the pharmaceutical industry as shelf-stock adjustments, can then be used by customers to offset future amounts owing to the Company under invoices for future product deliveries. The shelf-stock adjustment is intended to reduce a customer's inventory cost to better reflect current market prices. The determination to grant a shelf-stock adjustment to a customer following a price decrease is usually at the Company's discretion rather than contractually required. Allowances for shelf-stock adjustments are recorded at the time Barr sells products it believes will be subject to a price decrease or when market conditions indicate that a shelf-stock adjustment is necessary to facilitate the sell-through of its product. When determining whether to record a shelf-stock adjustment and the amount of any such adjustment, the Company analyzes several variables including the estimated launch dates of a competing product, the estimated decline in

market price and estimated levels of inventory held by the customer at the time of the decrease in market price. As a result, a shelf-stock reserve depends on a product's unique facts and circumstances.

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(e) Inventories

Inventories are stated at the lower of cost, determined on a first-in, first-out (FIFO) basis, or market. The Company establishes reserves for its inventory to reflect situations in which the cost of the inventory is not expected to be recovered. The Company regularly reviews its inventory, including when product is close to expiration and is not expected to be sold, when product has reached its expiration date, or when product is not expected to be saleable based on the Company's quality assurance and control standards. The reserve for these products 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 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 are accounted for under SFAS No. 109, Accounting for Income Taxes. Under this method, 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) Litigation

The Company is subject to litigation in the ordinary course of business and also to certain other contingencies (see Note 23). Legal fees and other expenses related to litigation and contingencies are recorded as incurred. Additionally, the Company, in consultation with its counsel, assesses the need to record a liability for litigation and contingencies on a case-by-case basis. Accruals are recorded when the Company determines that a loss related to a matter is both probable and reasonably estimable.

(h) Self-Insurance

The Company is primarily self-insured for potential product liability claims on products sold on or after September 30, 2002, and it maintains self-insured retentions and deductibles on policies covering periods prior to September 30, 2002. The Company maintains a self-insurance reserve, which provides an estimate of potential product liability claims not covered by insurance and an estimate of the future cost of incurred but not reported (IBNR) claims. The Company develops these estimates in consultation with outside counsel, its insurance consultants and an independent actuary. The self-insurance reserve does not include estimated administrative or defense costs which are expensed as incurred.

(i) Goodwill and Other Intangible Assets

In connection with acquisitions, the Company determines the amounts assigned to goodwill and intangibles based on purchase price allocations. These allocations, including an assessment of the estimated useful lives of intangible assets, have been performed by qualified independent appraisers using generally accepted valuation methodologies. The valuation of intangible assets is generally based on the estimated future cash flows related to those assets, while the value assigned to goodwill is the residual of the purchase price over the fair value of all identifiable assets acquired and liabilities assumed. Useful lives are determined based on the expected future period of benefit of the asset, which considers various characteristics of the asset, including estimated cash flows. As required by Statement of Financial Accounting Standards (SFAS) No. 142, Goodwill and Other Intangible Assets, the Company reviews goodwill for impairment annually, or more frequently if impairment indicators arise.

(j) Credit and Market Risk

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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.

(k) Cash and Cash Equivalents

Cash equivalents consist of short-term, highly liquid investments including market auction debt securities with maturities of three months or less and with interest rates that are re-set in intervals of 7 to 49 days, which are readily convertible into cash at par value, which approximates cost.

(l) 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. 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.

The estimated useful lives of the major classification of depreciable assets are:

	Years
Buildings	30-45
Building improvements	10
Machinery and equipment	3-10
Leasehold improvements	2-10

Maintenance and repairs are charged to operations as incurred; renewals and betterments are capitalized.

(m) 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 19. 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 income. The following table illustrates the effect on net income 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 employee compensation.

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	For the Year Ended June 30,		
	2004	2003	2002
NET INCOME, AS REPORTED	\$ 123,103	\$ 167,566	\$ 210,269
Add: Stock-based employee compensation expense included in reported net income, net of related tax effects			387
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	12,714	6,577	17,572
PRO FORMA NET INCOME	\$ 110,389	\$ 160,989	\$ 193,084
EARNINGS PER SHARE:			
Basic - as reported	\$ 1.21	\$ 1.69	\$ 2.17
Basic - pro forma	\$ 1.08	\$ 1.63	\$ 1.99
Diluted - as reported	\$ 1.15	\$ 1.62	\$ 2.06
Diluted - pro forma	\$ 1.03	\$ 1.55	\$ 1.89

The pro forma results for fiscal 2002 reflect the accelerated vesting of options as a result of the merger with Duramed.

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:

	Year Ended June 30,		
	2004	2003	2002
Average expected term (years)	4	4	3
Risk-free interest rate	2.19%	2.29%	3.62%
Dividend yield	0%	0%	0%
Volatility	54.11%	53.73%	46.96%

Fair value of options granted at market	\$16.78	\$15.77	\$17.11
	<u> </u>	<u> </u>	<u> </u>

(n) Research and Development

Research and development costs, which consist principally of product development costs as well as in-process research and development costs as they relate to acquired products which have not received approval from the U.S. Food and Drug Administration (FDA), are charged to operations as incurred.

(o) Shipping and Handling Costs

Shipping and handling costs, which approximated \$1,702, \$1,591 and \$1,533 in fiscal 2004, 2003 and 2002, respectively, were included in selling, general and administrative expenses.

(p) Stock Split

On February 13, 2004, the Company's Board of Directors declared a 3-for-2 stock split to be effected in the form of a 50% stock dividend payable on March 16, 2004. On that date, approximately 34.5 million additional shares of common stock were distributed to shareholders of record at the close of business on February 23, 2004.

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On February 18, 2003, the Company's Board of Directors declared a 3-for-2 stock split effected in the form of a 50% stock dividend. Approximately 22.2 million additional shares of common stock were distributed on March 17, 2003 to shareholders of record at the close of business on February 28, 2003.

All applicable prior period share and per share amounts have been adjusted for the stock splits.

(q) Earnings Per Share

As discussed above, on October 24, 2001, the Company completed a merger with Duramed where the Company issued approximately 16.875 million shares of its common stock for all the outstanding common stock of Duramed and exchanged all options and warrants to purchase Duramed stock for options and warrants to purchase approximately 2.7 million shares of the Company's common stock.

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:

	2004	2003	2002
Net earnings	\$123,103	\$167,566	\$212,219
Dividends on preferred stock			457
Deemed dividend on convertible preferred stock			1,493
	<hr/>	<hr/>	<hr/>
Numerator for basic and diluted earnings per share - earnings available for common stockholders	\$123,103	\$167,566	\$210,269
	<hr/>	<hr/>	<hr/>
Earnings per common share - basic:			
Numerator: earnings available for common shareholders	\$123,103	\$167,566	\$210,269
	<hr/>	<hr/>	<hr/>
Denominator: weighted average shares	101,823	99,125	96,998
Earnings per common share - basic	\$ 1.21	\$ 1.69	\$ 2.17
	<hr/>	<hr/>	<hr/>
Earnings per common share - diluted:			
Numerator: earnings available for common shareholders	\$123,103	\$167,566	\$210,269
	<hr/>	<hr/>	<hr/>
Denominator: weighted average shares - diluted	106,661	103,592	102,203
Earnings per common share - diluted	\$ 1.15	\$ 1.62	\$ 2.06
	<hr/>	<hr/>	<hr/>
Calculation of weighted average common shares - diluted			

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Weighted average shares	101,823	99,125	96,998
Effect of dilutive options and warrants	4,838	4,467	5,205
	<u> </u>	<u> </u>	<u> </u>
Weighted average shares - diluted	106,661	103,592	102,203
	<u> </u>	<u> </u>	<u> </u>

2004

2003

2002

(In whole share amounts)

Not included in the calculation of diluted earnings per share because their impact is antidilutive:

Stock options outstanding	56,841	1,898,811	1,699,182
Preferred if converted			1,139,229

(r) Deferred Financing Fees

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All debt issuance costs are being amortized on a straight-line basis over the life of the related debt, which matures in 2007 and 2010. The total unamortized amounts of \$194 and \$310 at June 30, 2004 and 2003, respectively, are included in other assets in the consolidated balance sheets.

(s) 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 8).

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, 2004 and 2003 is estimated at \$38,000 and \$40,000, respectively (see Note 15 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, 2004. 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.

(t) 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 \$45,637, \$21,377 and \$4,678 for the years ending June 30, 2004, 2003 and 2002, respectively.

(u) Asset Impairment

The Company reviews the carrying value of its long-term assets for impairment 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.

(v) New Accounting Pronouncements

Amendment of Statement 133 on Derivative Instruments and Hedging Activities

In April 2003, the FASB issued SFAS No. 149, Amendment of Statement 133 on Derivative Instruments and Hedging Activities (SFAS 149), which is generally effective for contracts entered into or modified after June 30, 2003 and for hedging relationships designated after June 30, 2003. SFAS 149 clarifies under what circumstances a contract with an initial net investment meets the characteristic of a derivative as discussed in SFAS No. 133, clarifies when a derivative contains a financing component, amends the definition of an underlying to conform it to the language used in FASB Interpretation No. 45, Guarantor Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others, and amends certain other existing pronouncements. The Company currently has no involvement with derivative financial instruments, and therefore the adoption of SFAS 149 did not

have a material impact on its consolidated financial statements.

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In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity* (SFAS 150). SFAS 150 modifies the accounting for certain financial instruments that, under previous guidance, issuers could account for as equity. SFAS 150 requires that those instruments be classified as liabilities in statements of financial position and affects an issuer's accounting for (1) mandatorily redeemable shares, which the issuing company is obligated to buy back in exchange for cash or other assets, (2) instruments, other than outstanding shares, that do or may require the issuer to buy back some of its shares in exchange for cash or other assets, or (3) obligations that can be settled with shares, the monetary value of which is fixed, tied solely or predominantly to a variable such as a market index, or varies inversely with the value of the issuer's shares. In addition to its requirements for the classification and measurement of financial instruments within its scope, SFAS 150 also requires disclosures about alternative ways of settling those instruments and the capital structure of entities, all of whose shares are mandatorily redeemable. SFAS 150 is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The adoption of SFAS 150 did not have a material impact on the Company's consolidated financial statements.

(2) Acquisitions*Acquisition of Enhance Pharmaceuticals, Inc.*

On June 6, 2002, the Company acquired certain assets from and assumed certain liabilities of Enhance Pharmaceuticals, Inc. The acquisition was accounted for under the purchase method of accounting. The total purchase price, including acquisition costs of \$1,071, was \$46,288.

The fair values of assets acquired and liabilities assumed on June 6, 2002 were:

Current assets	\$ 1,252
Property and equipment	2,012
Intangible assets	28,200
Goodwill	13,941
In-process research and development	1,000
	<hr/>
Total assets acquired	46,405
	<hr/>
Current liabilities	89
Capital lease obligations	28
	<hr/>
Total liabilities assumed	117
	<hr/>
Purchase price	\$46,288
	<hr/>
Total cash paid	\$45,217

Accrued acquisition costs	1,071
	<u> </u>
	\$46,288
	<u> </u>

Intangible assets included \$1,400 of patents and \$26,800 in product license agreements that were each subject to amortization over an estimated useful life of ten years (see Note 9) and were subsequently written off. The fair value of net assets acquired was \$32,464, resulting in goodwill of \$13,941. The Company acquired Enhance to further its expansion into the female healthcare market. Certain of the factors contributing to the purchase price that resulted in goodwill were Enhance's proprietary vaginal ring drug delivery platform and its uses. The entire balance of goodwill is deductible for tax purposes. The operating results of Enhance are included in the consolidated financial statements subsequent to the June 6, 2002 acquisition date.

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Acquired in-process research and development projects in the amount of \$1,000 were written off as research and development expenses upon acquisition because technological feasibility, through FDA or comparable regulatory body approval, had not been established and the projects had no alternative future use.

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 agreements referred to above.

Purchase of Products from Wyeth

On June 9, 2003, the Company acquired from Wyeth the rights to four products and a sublicense on a product in development by Wyeth for initial cash consideration of \$25,992 and an agreement for future royalty payments based on future sales of the products. The Company also entered into an interim supply agreement with Wyeth in relation to these products that will terminate as to certain portions of the agreement on various dates over the next two fiscal years. Of the total \$25,992 purchase price, \$22,046 was allocated to the marketed products (see Note 9) and \$3,946 was allocated to an in-process research and development project. No value was assigned to the supply agreement for the acquired products because the product purchase prices under the agreement approximate the price the Company would expect to pay third party contract manufacturers. The products are being amortized over a weighted-average useful life of 8.75 years.

The \$3,946 was written off as research and development expense upon acquisition because technological feasibility, through the FDA or comparable regulatory body approval, had not been established and the projects 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

On February 25, 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[®]Ban emergency oral contraceptive product and filed an application with the FDA for an over-the-counter version of Plan B. The Company acquired WCC to further its expansion into the emergency contraception segment of the female healthcare market.

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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 on February 25, 2004 were:

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

An intangible asset of \$2,200 representing the fair value of the currently marketed prescription version of Plan B is being amortized over one year (see note 9). 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 Gynetics, Inc.

On February 26, 2004, the Company paid \$4,200 to purchase certain assets from Gynetics, 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 Gynetics that would have prevented the Company from acquiring WCC. As part of the purchase, the Company agreed to pay Gynetics 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, the Company recorded an expense for the \$4,200 purchase price as selling, general and administrative expense.

Acquisition of Products from Galen (Chemicals) Limited

On March 24, 2004, the Company acquired from Galen (Chemicals) Limited (Galen) the exclusive rights to manufacture and market Loestrin[®] products in the United States and Loestrin and Minestrin[®] 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 9).

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(3) Strategic Alliance With DuPont Pharmaceuticals Company

On March 20, 2000, the Company signed definitive agreements to establish a strategic relationship with DuPont Pharmaceuticals Company (DuPont) to develop, market and promote several proprietary products and to terminate all litigation between the two companies. The Company was unable to assess whether the individual terms of each of the agreements would have been different had each of the agreements been negotiated separately with other third parties not involved in litigation.

DuPont has since been acquired by Bristol-Myers Squibb Company (BMS). In April 2002, the Company and BMS agreed to restructure and terminate the proprietary product development funding agreement that was entered into between Barr and DuPont in March 2000.

Under the terms of the March 2000 proprietary product development funding agreement (Product Development Agreement), DuPont agreed to invest up to \$45,000 to support the ongoing development of Barr's CyPat prostate cancer therapy and SEASONALE® and DP3 oral contraceptive products in exchange for co-marketing rights and royalties. Barr and BMS agreed to terminate this agreement and to cap BMS's funding obligations at \$40,000. In return, BMS agreed to forego its royalty interest and other rights regarding the marketing of these three products. In connection with the Product Development Agreement, the Company earned \$0, \$0 and \$15,343 for the years ended June 30, 2004, 2003 and 2002, respectively.

(4) Proceeds From Patent Challenge Settlement

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.

(5) Other Receivables

Included in other receivables at June 30, 2004 is a \$47,517 receivable from Bayer as a price adjustment to reduce the cost of the Company's June 2004 Ciprofloxacin inventory for products purchased from Bayer during the second half of our fiscal year. The balance at June 30, 2003 included \$25,688 in receivables under a Supply Agreement, also with Bayer (see Note 4).

(6) Inventories, Net

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	June 30,	
	2004	2003
Raw materials and supplies	\$ 86,238	\$ 60,075
Work-in-process	17,449	18,561
Finished goods	46,565	85,290
	<u>\$ 150,252</u>	<u>\$ 163,926</u>

Inventories are presented net of reserves of \$23,910 and \$13,201 at June 30, 2004 and 2003, respectively. The Company's distributed version of Ciprofloxacin, purchased as a finished product from Bayer, accounted for approximately \$1,986 and \$48,300 of finished goods inventory as of June 30, 2004 and 2003, respectively.

(7) Property, Plant and Equipment, Net

	June 30,	
	2004	2003
Land	\$ 7,299	\$ 5,819
Buildings and improvements	135,636	105,946
Machinery and equipment	174,858	144,676
Leasehold improvements	5,989	2,759
Automobiles and trucks	149	200
Construction in progress	19,547	64,430
	<u>343,478</u>	<u>323,830</u>
Less: accumulated depreciation and amortization	<u>106,647</u>	<u>100,314</u>
	<u>\$ 236,831</u>	<u>\$ 223,516</u>

For the years ended June 30, 2004, 2003 and 2002, \$21, \$1,761 and \$1,072 of interest was capitalized, respectively. The Company recorded depreciation expense of \$25,678, \$19,547 and \$15,010 for the years ended June 30, 2004, 2003 and 2002, respectively.

(8) 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.

The amortized cost and estimated market values of marketable securities at June 30, 2004 and 2003 are as follows:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized (Losses)	Market Value
<u>June 30, 2004</u>				
Debt Securities	\$ 117,843	\$	\$	\$ 117,843
Equity Securities	3,676	—	—	3,676
	<u>\$ 121,519</u>	<u>\$</u>	<u>\$</u>	<u>\$ 121,519</u>
<u>June 30, 2003</u>				
Debt Securities	\$ 44,400	\$	\$	\$ 44,400
Equity Securities	2,625	—	(288)	2,337
	<u>\$ 47,025</u>	<u>\$</u>	<u>\$ (288)</u>	<u>\$ 46,737</u>

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

Debt Securities

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The Company has invested \$117,843, including \$87,843 in market auction debt securities, which are readily convertible into cash at par value with maturity dates ranging from July 7, 2004 to April 19, 2007 and \$30,000 in municipal bonds with maturity dates ranging from July 30, 2004 to April 1, 2007. We may continue to invest in extended maturity securities based on operating needs and strategic opportunities.

Equity Securities

Equity securities at June 30, 2004 includes amounts invested in connection with the Company's excess 401(k) and other deferred compensation plans. Equity securities at June 30, 2003 also included the value of warrants held in a third party. These warrants expired unexercised in April 2004.

(9) Other Intangible Assets

Intangible assets, excluding goodwill, which are comprised primarily of product licenses and product rights and related intangibles, consist of the following:

	June 30,	
	2004	2003
Product licenses	\$ 2,550	\$26,800
Product rights and related intangibles	67,046	22,046
	<hr/>	<hr/>
	69,596	48,846
Less: accumulated amortization	(4,699)	(2,897)
	<hr/>	<hr/>
Intangible assets, net	\$64,897	\$45,949
	<hr/>	<hr/>

In December 2002, the Company's management decided to suspend development of a product for which \$1,400 in patents had been recorded. As a result, on December 31, 2002, the Company wrote off the remaining \$1,330 of patents, net of accumulated amortization. This amount has been included in selling, general and administrative expense in fiscal 2003.

During fiscal 2004, the Company acquired the exclusive rights to manufacture and market Loestrin products from Galen for a cash payment of \$45,000 (see Note 2). In addition, the \$26,800 product license for a urinary incontinence product which was under development with Schering AG was written off as research and development expense (see Note 2).

Estimated amortization expense on product licenses and product rights and related intangibles in the next five years is as follows:

Year Ending June 30,

2005	\$8,609
2006	7,143
2007	7,143
2008	7,143
2009	7,133

The Company's product licenses and product rights and related intangibles have weighted average useful lives of approximately 10 and 8 years, respectively.

(10) Goodwill

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Goodwill of \$18,211 and \$14,118 at June 30, 2004 and 2003, respectively, is attributable to acquisitions the Company has made over the past three fiscal years. The increase in goodwill from June 30, 2003 is attributable to the acquisition of WCC. The Company recorded \$4,610 related to this acquisition and subsequently reduced the amount for post-closing activity related to the transaction to a net amount of \$4,093. In fiscal 2003, the Company adjusted goodwill by \$177 for post-closing activity related to its acquisition of Enhance. The entire goodwill balance at June 30, 2004 and 2003 is assigned to the Company's proprietary product segment.

(11) Other Assets

Included in other assets at June 30, 2003 was \$14,408 in loans receivable from Natural Biologics which was fully reserved in fiscal 2004 (see Note 23). In addition, the Company records the deposits on its finite risk insurance arrangement as other assets, which total \$6,758 and \$3,405 at June 30, 2004 and 2003, respectively.

(12) Accounts Payable

Included in the accounts payable balance at June 30, 2003 was \$127,990 relating to the purchase of inventory for Ciprofloxacin during the initial product launch. Purchases of Ciprofloxacin inventory were significantly lower in the three months ended June 30, 2004, resulting in a corresponding lower balance in accounts payable.

(13) 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.

(14) Ovcon Licensing Agreement

In March 2004, the Company granted Galen an option to acquire an exclusive license under its ANDA for OVCON® 35, which received FDA approval in April 2004. Galen exercised their option and paid the Company \$19,000 which the Company is amortizing as license fees over a five year period. The Company is recognizing these revenues over the life of the license and has included the unrecognized portion as deferred revenue in accrued and other liabilities, as applicable.

(15) Long-term Debt

A summary of long-term debt is as follows:

	June 30,	
	2004	2003
Senior Unsecured Notes (a)	\$ 17,429	\$ 22,858
Provident Bank mortgage notes (b)	13,200	14,800

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Note Due to WCC Shareholders (c)	<u>6,500</u>	<u></u>
	37,129	37,658
Less: Current installments of long-term debt	<u>(7,029)</u>	<u>(7,029)</u>
Total long-term debt	<u>\$30,100</u>	<u>\$30,629</u>

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- (a) The Senior Unsecured Notes include a \$16,000, 7.01% Note due November 18, 2007 and \$1,429 of 6.61% Notes due November 18, 2004. Annual principal payments under the Notes total \$5,429 in fiscal 2005, and \$4,000 in 2006 through 2008.

The Senior Unsecured Notes contain certain covenants including, among others, a restriction on dividend payments in excess of \$10,000 plus 75% of consolidated net earnings subsequent to June 30, 1997. The Company was in compliance with all covenants under the senior unsecured notes as of June 30, 2004.

- (b) In March 2000, the Company refinanced existing notes payable with a \$12,000 note and an \$8,000 note payable to Provident Bank. Provident holds a first mortgage on the Company's Cincinnati, Ohio manufacturing facility. Both notes are guaranteed by Solvay America, the parent of Solvay Pharmaceuticals.

The \$12,000 note bears interest at the prime rate (4% at June 30, 2004) and requires monthly payments of \$100 plus interest for a ten-year period that commenced on April 1, 2000. The \$8,000 note bears interest at the prime rate and requires monthly payments of \$33 plus interest that commenced on April 1, 2000. Principal payments for the \$8,000 note are based upon a twenty-year amortization with a balloon payment due on March 1, 2010 of \$4,000.

- (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 2).

The Company has a \$40,000 revolving credit facility that expires on February 27, 2005. As of June 30, 2004, there was \$32,875 available to the Company under this facility due to the issuance of a \$7,125 letter of credit in support of the Company's finite risk product liability program (see Note 23). The Company pays a fee on the committed portion of the credit facility equal to 1.0% of the outstanding balance. A fee of 0.25% is paid on the remainder.

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

Year Ending June 30,	
2005	\$ 7,029
2006	5,600
2007	5,600
2008	12,100
2009	1,600
Thereafter	5,200

(16) Mandatorily Redeemable Convertible Preferred Stock***Series G***

On May 12, 2000, the Company completed a private placement of \$10,000 of Series G Convertible preferred stock with an institutional investor. The preferred shares were immediately convertible into shares of the Company's common stock at a fixed price of \$2.25 per share. The preferred stock paid a dividend of 5% annually, payable quarterly in arrears, on all unconverted preferred stock. The investor also received warrants which were valued at \$765 to purchase 288,234 shares of common stock at a price of \$9.54 per share, exercisable at any time before May 12, 2005. In conjunction with the Company's issuance of the Series G Convertible Preferred Stock, it recorded an adjustment of approximately \$1,300 to properly reflect deemed dividends beyond the stated 5% dividend rate and a

beneficial conversion feature as required by EITF 98-5 and 00-27. This adjustment, which reduced the carrying amount of the Series G Convertible Preferred Stock and increased additional paid-in capital, was being amortized through May 12, 2004 and reflected as additional deemed dividends. On September 24 and 28, 2001, the preferred shares were converted to 455,693 and 683,537 shares, respectively, of common stock pursuant to the original terms of the preferred stock. At the election of the holder of the preferred stock, the dividend for the quarter ended September

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30, 2001 of \$120 was satisfied by the issuance of 13,641 shares of common stock. The Company recorded both the dividend and the fair market valuation of \$337 associated with the shares issued to satisfy the dividend as adjustments to additional paid in capital. Additionally, the Company wrote-off the remaining unamortized deemed dividend valuation adjustment of \$913 and the unamortized Series G warrant valuation of \$500 as adjustments to additional paid in capital.

(17) Related-party Transactions

Dr. Bernard C. Sherman

During the years ended June 30, 2004, 2003 and 2002, the Company purchased \$2,808, \$3,583 and \$3,332, respectively, of bulk pharmaceutical material from companies affiliated with Dr. Bernard C. Sherman, the Company's largest shareholder and a director until October 24, 2002. In addition, during the years ended June 30, 2004, 2003 and 2002, the Company sold \$9,486, \$12,727 and \$16,472, respectively, of its pharmaceutical products and bulk pharmaceutical materials to companies owned by Dr. Sherman. As of June 30, 2004 and 2003, the Company's accounts receivable included \$1,203 and \$2,398, respectively, due from such companies.

During fiscal 1996, the Company also entered into an agreement with a company owned by Dr. Sherman to share litigation and related costs in connection with its Fluoxetine patent challenge. For the years ended June 30, 2004, 2003 and 2002, the Company recorded \$1,004, \$585 and \$919, respectively, in connection with such agreement as a reduction to operating expenses. For the years ended June 30, 2004, 2003 and 2002, the Company recorded \$3,680, \$1,440 and \$176,681, respectively, as cost of sales related to this agreement. In addition, during the year ended June 30, 2004, the Company entered into an agreement with a company owned by Dr. Sherman whereby the Company will receive royalties on a product marketed and sold by that company. Royalty revenues totaled \$295 for the year ended June 30, 2004.

As of June 30, 2004 and 2003, the Company's accrued liabilities included \$2,028 and \$648, respectively, related to transactions with these entities.

The Company also incurred \$55 in expenses in the year ended June 30, 2002 which was reimbursed by Dr. Sherman, related to a secondary stock offering, completed in May 2001, for the sale of 7.875 million shares of the Company's common stock, beneficially owned by Dr. Sherman.

Edwin A. Cohen

In accordance with the provisions of a consulting agreement, which expired on June 30, 2002, the Company's founder and former Vice Chairman, Edwin A. Cohen, earned \$200 in the year ended June 30, 2002.

Harold N. Chefitz

Harold N. Chefitz, a member of the Company's Board of Directors, serves as the Chairman of GliaMed, Inc., in which the Company has made an investment of \$500 which is accounted for at cost and included in other assets at June 30, 2004 and 2003.

William T. McKee

In connection with the Company's investment in GliaMed, Inc., William T. McKee, the Company's Chief Financial Officer, became a member of GliaMed's Board of Directors.

Table of Contents**(18) Income Taxes**

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

	Year Ended June 30,		
	2004	2003	2002
Current:			
Federal	\$ 101,477	\$ 77,615	\$ 103,528
State	18,097	10,911	12,719
	<u> </u>	<u> </u>	<u> </u>
	\$ 119,574	\$ 88,526	\$ 116,247
	<u> </u>	<u> </u>	<u> </u>
Deferred:			
Federal	\$ (41,348)	\$ 9,010	\$ 8,981
State	(6,889)	(2,387)	90
	<u> </u>	<u> </u>	<u> </u>
	(48,237)	6,623	9,071
	<u> </u>	<u> </u>	<u> </u>
Total	\$ 71,337	\$ 95,149	\$ 125,318
	<u> </u>	<u> </u>	<u> </u>

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:

	Year Ended June 30,		
	2004	2003	2002
Federal income taxes at statutory rate	\$68,054	\$91,950	\$118,225
State income taxes, net of federal income tax effect	6,687	8,207	8,326
Tax credits	(5,900)	(1,000)	
Write-off of in-process research and development	3,605		
Other, net	(1,109)	(4,008)	(1,233)
	<u> </u>	<u> </u>	<u> </u>
	\$71,337	\$95,149	\$125,318
	<u> </u>	<u> </u>	<u> </u>

The temporary differences that give rise to deferred tax assets and liabilities as of June 30, 2004 and 2003 are as follows:

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	2004	2003
Deferred tax assets:		
Net operating loss	\$ 5,113	\$ 16,205
Receivable reserves	29,888	24,514
Inventory	2,707	2,680
Goodwill amortization	1,463	2,131
Warrants issued		6,536
Tax credit carryforward	15	4,008
Capital loss carryforward	3,122	3,084
Amortization of intangibles	27,210	3,076
Investments		109
Deferred revenue	7,400	
Natural Biologics loan	6,673	
Solvay litigation	20,226	
Other	6,043	3,866
	<hr/>	<hr/>
Total deferred tax assets	109,860	66,209
Deferred tax liabilities:		
Plant and equipment	(19,889)	(14,631)
Proceeds from supply agreement		(10,225)
Other	(4,196)	(2,242)
	<hr/>	<hr/>
Total deferred tax liabilities	(24,085)	(27,098)
Less valuation allowance	(4,682)	(6,147)
	<hr/>	<hr/>
Net deferred tax asset	\$ 81,093	\$ 32,964
	<hr/>	<hr/>

At June 30, 2004 and 2003, as a result of certain acquisitions, the Company had cumulative regular net operating loss carryforwards of approximately \$10,195 and \$38,800, 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 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, 2004, the Company increased the valuation allowance related to preacquisition Women's Capital Corporation state net operating

losses by \$589 and reduced the valuation allowance by a net of \$2,054, due to the utilization of certain tax credits during 2004.

(19) 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

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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 2004, 2003 and 2002, 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. In fiscal 2001, options for 67,500 shares were granted to a key executive as part of her employment agreement at various prices below the market price on the date of grant. The total value of the discount associated with this grant was \$896 and was being amortized over the five-year vesting period of the options. In fiscal 2002, these options fully vested as the result of the Duramed merger and the remaining discount of \$615 was expensed. 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.

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

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	No. of Shares	Weighted-Average Exercise Price
Outstanding at July 1, 2001	7,595,489	\$ 11.39
Granted	1,507,520	35.26
Adjustment for pooling	(71,366)	14.65
Canceled	(125,751)	25.67
Exercised	(1,517,633)	9.72
Outstanding at June 30, 2002	7,388,259	16.43
Granted	2,109,333	26.74
Canceled	(208,047)	27.92
Exercised	(1,354,542)	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
Available for Grant (20,067,188 authorized)	5,784,627	
Exercisable at June 30, 2002	6,759,795	\$ 16.01
Exercisable at June 30, 2003	5,557,977	\$ 16.79
Exercisable at June 30, 2004	4,839,386	\$ 20.02

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 optionee'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.

Duramed had a Stock Option Plan for Non-employee Directors (the 1991 Duramed Directors Plan) under which each new non-employee director was granted, at the close of business on the date he or she first became a director, options to purchase 5,765 shares of common stock. Annually, each then serving non-employee director, other than a new director, was also automatically granted options to purchase 2,882 shares of common stock at a price equal to the closing market price on the date of grant. Options granted under the 1991 Duramed Directors Plan expire 10 years after the date of grant. Subsequent to October 24, 2001, options were no longer granted under this plan.

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

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	No. of Shares	Weighted-Average Exercise Price
Outstanding at July 1, 2001	940,377	\$ 10.41
Granted	202,500	33.30
Adjustment for pooling	23,058	16.41
Canceled	(13,833)	14.90
Exercised	(50,058)	8.17
Outstanding at June 30, 2002	1,102,044	14.77
Granted	101,250	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	(154,498)	17.75
Outstanding at June 30, 2004	643,590	\$ 22.97
Available for Grant (2,798,438 authorized)	951,469	
Exercisable at June 30, 2002	899,565	\$ 10.59
Exercisable at June 30, 2003	578,714	\$ 16.94
Exercisable at June 30, 2004	576,089	\$ 19.92

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, 81,708, 115,704 and 66,715 shares of common stock were purchased during the years ended June 30, 2004, 2003 and 2002, 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, 2004, warrants for 9,046 shares were outstanding with an expiration of 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 and expire on May 12, 2005. As of June 30, 2004, all of these warrants remained outstanding.

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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, 2004:

Range of Exercise Prices	Options and Warrants Outstanding			Options and Warrants Exercisable	
	Number Outstanding at June 30, 2004	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable at June 30, 2004	Weighted Average Exercise Price
\$2.86 - \$11.75	2,672,696	3.30	\$ 9.09	2,665,203	\$ 9.09
\$12.03 - \$26.58	2,728,582	7.32	\$24.69	1,585,058	\$23.33
\$26.61 - \$42.22	1,640,230	7.29	\$33.89	1,462,494	\$34.25
\$43.13 - \$51.61	1,766,694	9.09	\$43.62		
	<u>8,808,202</u>	6.45	\$25.46	<u>5,712,755</u>	\$19.48

(20) Savings and Retirement Plans

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 \$13 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 \$6,534, \$5,549 and \$4,790 for the years ended June 30, 2004, 2003 and 2002, 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 2004, 2003 and 2002, the Company chose to make contributions at the 10% rate to this plan. As of June 30, 2004 and 2003, the Company had an asset and matching liability for the Excess Plan of \$3,563

and \$2,282, 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, 2004 and 2003, the Company has recorded \$466 and \$487, respectively, as a long-term liability representing the present value of the estimated future benefit obligation to the eligible directors. The right of a

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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.

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, 2004, the Company had an asset and matching liability for the Plan of \$114.

(21) Other (Expense) Income, Net

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

	Year Ended June 30,		
	2004	2003	2002
Litigation settlement	\$	\$	\$2,000
Briston-Myers Squibb termination payments			5,600
Loss on limited partnerships	(1,346)		
Other	(187)	(128)	56
	<u> </u>	<u> </u>	<u> </u>
Total other (expense) income, net	<u>\$ (1,533)</u>	<u>\$ (128)</u>	<u>\$ 7,656</u>

(22) Merger-Related Costs

As a result of the Duramed merger, the Company incurred pre-tax merger-related expenses for the year ended June 30, 2002 of approximately \$31,449, which is included in the consolidated statements of operations as merger-related costs. Such expenses included approximately \$13,000 in direct transaction costs such as investment banking, legal and accounting costs, as well as approximately \$7,000 in costs associated with facility and product rationalization and \$11,000 in severance costs. Portions of these expenses were not tax deductible. The severance costs included approximately \$7,000 intended to satisfy the change in control payments under certain previously existing employment contracts along with the expected cost associated with terminating approximately 120 former Duramed employees primarily representing certain manufacturing and general and administrative functions.

(23) 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. Rent expense charged to operations was \$3,543, \$1,875 and \$1,444 in fiscal 2004, 2003 and 2002, respectively. 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, 2004. Such payments total \$36,400 for operating leases. The net present value of such payments on capital leases was \$3,673 after deducting executory costs and imputed interest of \$129 and \$570, respectively.

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	Year Ended June 30,					
	2005	2006	2007	2008	2009	Thereafter
Operating leases	\$3,716	\$3,746	\$3,671	\$3,255	\$3,237	\$18,775
Capital leases	1,825	1,627	792	128	—	—
Minimum lease payments	\$5,541	\$5,373	\$4,463	\$3,383	\$3,237	\$18,775

Business Development Venture***Natural Biologics***

In fiscal 2002, the Company entered into a Loan and Security Agreement (the "Loan Agreement") with Natural Biologics, the raw material supplier for the Company's generic equine-based conjugated estrogens product for which the Company filed an ANDA with the FDA in June 2003. The Company also entered into a Development, Manufacturing and Distribution Agreement with Natural Biologics which could obligate the Company to make milestone payments totaling an additional \$35,000 to Natural Biologics based on achieving certain legal and product approval milestones, including FDA approval of a generic product. The Company believes that the raw material is pharmaceutically equivalent to raw material used to produce Wyeth's Premarin.

Natural Biologics is a defendant in a trade secret lawsuit brought by Wyeth. In September 2003, the U.S. District Court for the District of Minnesota determined that Natural Biologics had misappropriated Wyeth's trade secrets and enjoined Natural Biologics from further involvement in the equine-based raw material business. Unless the ruling is reversed on appeal, the Company will be prohibited from using Natural Biologics' raw material in its ANDA for conjugated estrogens. Natural Biologics has appealed the District Court's ruling.

As of June 30, 2004 and June 30, 2003, the Company had loaned Natural Biologics approximately \$16,079 and \$14,408, respectively, including accrued interest, under the Loan Agreement, and has included such amounts in other assets on its consolidated balance sheets. Under the terms of the Loan Agreement, the loans mature on June 3, 2007 and are collateralized by a security interest in inventory and certain other assets of Natural Biologics and bear interest at the applicable federal rate as defined by the Loan Agreement (3.83% at June 30, 2004).

Due to the unfavorable decision of the District Court and its anticipated negative effects on Natural Biologics operations, as well as the uncertainty surrounding the timing and outcome of any appeal, the Company has established a full valuation allowance against the loan amount and included the allowance in other assets on its consolidated balance sheet and recorded a charge to selling, general and administrative expense.

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, 2004, the Company has invested \$3,500 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 2006, subject to certain renewal provisions.

Product Liability Insurance

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The Company utilizes a combination of a finite risk insurance arrangement, self insurance and traditional third-party insurance policies to cover itself from potential product liability claims. Under a finite risk insurance arrangement (the Arrangement) with a third-party insurer, the Company is insured for \$15,000 in potential product liability claims. In exchange for \$15,000 in product liability coverage over a five-year term expiring on September 30, 2007, the Arrangement provides for the Company to pay approximately \$14,250 in four equal annual installments of \$3,563. At any six-month interval, the Company may, at its option, cancel the Arrangement. In addition, at the earlier of termination or expiry, the Company is eligible for a return of all amounts paid to the insurer, less the insurer's margin and amounts paid for any incurred claims. After termination or expiry of the policy, the Company will be solely liable for any incurred but not reported (IBNR) or unsettled claims under the policy.

The Company is entirely self-insured for potential product liability claims between \$15,000 and \$25,000. The Company has purchased traditional third-party insurance that will provide coverage for claims between \$25,000 and \$40,000. For claims between \$40,000 and \$50,000, the Company has purchased additional third-party insurance that provides for the Company to share 20% of all claims paid under the policy by the insurer.

Simultaneously with entering into the Arrangement, the Company exercised the extended reporting period under its previous insurance policy that provides \$10,000 of product liability coverage of unlimited duration for product liability claims on products sold from September 10, 1987 to September 30, 2002. Additionally, in connection with its merger with Duramed, the Company purchased a supplemental extended reporting policy under Duramed's prior insurance policy that provides \$10,000 of product liability coverage for an unlimited duration for product liability claims on products sold by Duramed between October 1, 1985 and October 24, 2001.

Because the Company is self-insured for a portion of its potential product liability claims, it has established a self-insurance reserve for its estimate of potential product liability claims.

The Company is a defendant in many product liability actions. For product liability claims that are not fully or substantially covered by our insurance arrangements, any adverse judgments or settlements in such matters, may exceed our reserves and could adversely affect the Company's consolidated financial statements.

Indemnity Provisions

From time-to-time, in the normal course of business, we agree to indemnify our employees, suppliers and customers concerning product liability and other matters. The Company does not believe that the likelihood of paying amounts related to the indemnity provision is probable. While the maximum amount to which the Company may be exposed under such agreements cannot be reasonably estimated, the Company maintains a self insurance reserve and insurance coverage which management believes will effectively mitigate the Company's obligations under these indemnification provisions. No amounts have been recorded in the financial statements with respect to the Company's obligations under such agreements.

Litigation Settlement

On October 22, 1999, the Company reached 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 gave up any claim to rights in Cenestin in exchange for a payment of \$15,000, which was paid 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

Ciprofloxacin (Cipro®) Antitrust Class Actions

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To date the Company has been 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®) from 1997 to the present. The complaints allege 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 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. An unfavorable outcome 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. An unfavorable outcome could adversely affect the Company's consolidated financial statements.

Desogestrel/Ethinyl Estradiol Suit

In May 2000, the Company 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. 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 continues to manufacture and market Kariva. Nevertheless, the Company expects that Organon will seek to recover lost profits on sales of Mircette and assert that these lost profits and enhanced damages significantly exceed the Company's approximately \$110,000 in sales of Kariva from its launch to June 30, 2004. If BTG and Organon are successful, the Company could be liable for damages for patent infringement and may be prohibited from continuing to sell its Kariva product. An unfavorable outcome could adversely affect the Company's consolidated financial statements.

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HRT Litigation

The Company and/or Duramed have been named as a defendant in as many as 1,000 personal injury product liability cases brought against the Company and other manufacturers by plaintiffs claiming that they suffered injuries resulting from the use of medroxyprogesterone acetate in conjunction with Premarin or other hormone therapy products, or the use of Cenestin. While Barr and/or Duramed have been named as defendants in these cases, a much smaller number of complaints actually allege the plaintiffs took a product manufactured by Barr and/or Duramed. The majority of these cases are either pending in the Philadelphia Court of Common Pleas or have been filed in other state courts, removed to federal court and transferred to the United States District Court for the Western District of Arkansas for consolidated pretrial proceedings.

The Company believes it has viable defenses to the allegations in the complaints and is defending the actions vigorously. At this juncture, it is impossible to accurately assess the exposure the litigation presents for the Company.

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, 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 have appealed the District Court's decision to the United States Court of Appeals for the Second Circuit. Trial on the merits has been stayed pending the outcome of the appeal.

The Company believes that the suits filed by Invamed and Apothecon are without merit and is vigorously defending its position, but an adverse judgment could adversely affect the Company's consolidated financial statements.

Medicaid Reimbursement Cases

The Company has been named as a defendant in separate actions brought by the Commonwealth of Massachusetts; Suffolk County, New York; Rockland County, New York; and Westchester County, New York against numerous pharmaceutical manufacturers. The plaintiffs seek to recover damages and other relief for alleged overcharges for prescription medications paid for by Medicaid. Along with the other defendants in these suits, the Company has moved to dismiss these complaints. Those motions are now pending. The Company believes that it has not engaged in any improper conduct and is vigorously defending itself. However, an unfavorable outcome in any of the matters could adversely affect the Company's consolidated financial statements.

Other Litigation

As of June 30, 2004, the Company was involved with other lawsuits incidental to its business, including patent infringement actions and personal injury claims. Management of the Company, based on the advice of legal counsel, believes that the ultimate disposition of such other lawsuits will not adversely affect the Company's consolidated financial statements.

(24) Segment Reporting

Prior to June 2004, the Company operated in one business segment - the development, manufacture and marketing of pharmaceutical products. In June 2004, based on the performance of the Company's proprietary product portfolio

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and the increasing focus on those products, Barr has organized its business into two reportable segments: Generic Pharmaceuticals and Proprietary Pharmaceuticals, based on differences in products, marketing and/or regulatory approval. Accordingly, all periods reported have been restated to reflect two reportable segments.

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 2004, three customers separately accounted for over 10% of generic product sales: McKesson Drug Company, Cardinal Health and Walgreen which accounted for 24%, 14% and 13%, respectively. In 2003, McKesson Drug Company, Cardinal Health, Amerisource Bergen and Walgreen accounted for 21%, 17%, 13% and 11% of total generic product sales, respectively. In 2002, McKesson Drug Company, Cardinal Health and Amerisource Bergen accounted for approximately 18%, 13% and 12% of total generic product sales, respectively.

Proprietary Pharmaceuticals

Proprietary pharmaceutical products are generally new, 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 2004, three customers separately accounted for over 10% of proprietary product sales: McKesson Drug Company, Cardinal Health and Amerisource Bergen which accounted for 21%, 20% and 15%, respectively. In 2003, Cardinal Health, McKesson Drug Company and Amerisource Bergen accounted for 19%, 15% and 11% of total proprietary product sales, respectively. In 2002, Cardinal Health and McKesson Drug Company accounted for 21% and 14% of total 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. The other classification consists primarily of revenues from licensing fees and amounts due under research and development agreements. 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:

	2004	% of sales	2003	% of sales	2002	% of sales
Revenues:						
Proprietary	\$ 146,087	11%	\$ 57,662	6%	\$ 62,061	5%
Generic	1,150,622	88%	837,226	93%	1,109,297	93%
Development & Other	12,379	1%	7,976	1%	17,626	2%

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Total revenues	\$ 1,309,088	100%	\$ 902,864	100%	\$ 1,188,984	100%
	<u> </u>		<u> </u>		<u> </u>	
		Margin		Margin		Margin
Gross profit:		%		%		%
Proprietary	\$ 117,994	81%	\$ 48,536	84%	\$ 49,355	80%
Generic	545,970	47%	422,253	50%	445,680	40%
Development & Other	12,379	100%	7,976	100%	17,626	100%
	<u> </u>		<u> </u>		<u> </u>	
Total gross profit	\$ 676,343	52%	\$ 478,765	53%	\$ 512,661	43%
	<u> </u>		<u> </u>		<u> </u>	

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

	Three Month Period Ended			
	Sept. 30	Dec. 31	Mar. 31	June 30
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 applicable to common shareholders	38,535	35,069	35,139	14,360
Earnings per common share - diluted (1) (3) (4)	\$ 0.37	\$ 0.33	\$ 0.33	\$ 0.13
PRICE RANGE OF COMMON STOCK (2)				
(3) (4)				
High	\$ 50.33	\$ 56.91	\$ 53.99	\$ 49.25
Low	\$ 38.83	\$ 45.17	\$ 45.70	\$ 32.89
FISCAL YEAR 2003:				
Total revenues	\$ 220,428	\$ 209,035	\$ 171,923	\$ 301,478
Cost of sales	110,919	94,872	55,182	163,126
Net earnings applicable to common shareholders	41,857	42,747	45,874	37,088
Earnings per common share - diluted (1) (3) (4)	\$ 0.41	\$ 0.42	\$ 0.44	\$ 0.35
PRICE RANGE OF COMMON STOCK (2)				
(3) (4)				
High	\$ 32.05	\$ 30.10	\$ 38.77	\$ 44.35
Low	\$ 21.95	\$ 24.56	\$ 28.93	\$ 34.27

- (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) The Company's common stock is listed and traded on the New York Stock Exchange under the symbol BRL. At June 30, 2004, there were approximately 1,610 shareholders of record of common stock. The Company believes that a significant number of beneficial owners hold their shares in street name.
- (3) Adjusted for the March 17, 2003 3-for-2 stock split effected in the form of a 50% stock dividend (See Note 1).
- (4) Adjusted for the March 16, 2004 3-for-2 stock split effected in the form of a 50% stock dividend (See Note 1).

(26) Subsequent Events

On August 5, 2004, the Company announced the approval by the Board of Directors of a share repurchase program of up to \$300,000, at the discretion of the Company, through December 31, 2005. The program permits the Company to repurchase stock from time to time through open market transactions or privately negotiated transactions. The Company intends to fund any repurchases with cash on hand and cash generated from operations.

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BARR PHARMACEUTICALS, INC.

Years Ended June 30, 2004, 2003 and 2002

	Balance at Beginning of Year	Additions, Costs and Expenses	Recovery Against Write-offs	Deductions, Write-offs	Pooling Adjustment	Balance at End of Year
			(In thousands)			
Allowance for doubtful accounts:						
Year Ended June 30, 2002	\$ 201	\$ 80	\$	\$	\$	\$ 281
Year Ended June 30, 2003	281	60		(52)		289
Year Ended June 30, 2004	289			(99)		190
Reserve for returns and allowances:						
Year Ended June 30, 2002	9,224	76,935		(57,136)	(44)	28,979
Year Ended June 30, 2003	28,979	48,623		(24,926)		52,676
Year Ended June 30, 2004	52,676	64,446		(59,810)		57,312
Inventory reserves:						
Year Ended June 30, 2002	12,439	12,847		(15,364)	314	10,236
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

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