

BENTLEY PHARMACEUTICALS INC  
Form 10-K  
March 16, 2005

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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 **December 31, 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 1-10581**

**BENTLEY PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of incorporation or organization)

**No. 59-1513162**  
(I.R.S. Employer Identification No.)

**Bentley Park**  
**2 Holland Way**  
**Exeter, New Hampshire**  
(Address of principal executive offices)

**03833**  
(Zip Code)

(Registrant's telephone number, including area code) **(603) 658-6100**

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

Title of each class	Name of each exchange on which registered
<b>Common Stock, \$.02 par value</b>	<b>New York Stock Exchange and Pacific Exchange</b>
<b>Preferred Stock Purchase Rights</b>	<b>New York Stock Exchange and Pacific Exchange</b>

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 Rule 12b-2 of the Act). Yes  No

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State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked prices of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter.

Title of Class	Aggregate Market Value *	As of Close of Business on
<b>Common Stock, \$.02 par value</b>	<b>\$200,072,468</b>	<b>June 30, 2004</b>

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date.

Title of Class	Shares Outstanding	As of Close of Business on
<b>Common Stock, \$.02 par value</b>	<b>21,317,677</b>	<b>March 14, 2005</b>

DOCUMENTS INCORPORATED BY REFERENCE

**Proxy Statement for the 2005 Annual Meeting of Stockholders Incorporated by  
Reference into Part III of this Annual Report on Form 10-K**

\*

Excludes the Common Stock held by executive officers, directors and stockholders whose ownership exceeds 5% of the Common Stock outstanding at June 30, 2004. This calculation does not reflect a determination that such persons are affiliates for any other purposes. Calculation assumes no changes in ownership positions of institutional holders with ownership positions greater than 5% from positions reported on their Schedule 13 filings for the year ended December 31, 2003.

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**Part I**

**Item 1. Business**

**Overview**

Bentley Pharmaceuticals, Inc., headquartered in the U.S., is an international specialty pharmaceutical company, incorporated in the State of Delaware. References in this report to "the Company", "we", "us" or "our" refer to Bentley and its subsidiaries as a whole, without regard to the separate operations and obligations of each entity in the group, unless the context clearly indicates one of the entities in the group.

The Company is focused on:

development, licensing and sales of generic and branded pharmaceutical products and active pharmaceutical ingredients (API) and the manufacturing of pharmaceuticals for others; and

research, development and licensing/commercialization of advanced drug delivery technologies and pharmaceutical products.

Our pharmaceutical product sales and licensing activities are based primarily in Spain, where we have a significant commercial presence and manufacture and market approximately 120 pharmaceutical products through three wholly-owned Spanish subsidiaries, Laboratorios Belmac, Laboratorios Davur and Laboratorios Rimafar. These products represent various dosage strengths and product formulations of more than 30 chemical entities in four primary therapeutic areas: cardiovascular, gastrointestinal, neurological and infectious diseases. We continually add to our product portfolio in response to increasing market demand for generic and branded therapeutic agents, and when appropriate, divest portfolio products that we consider to be redundant or that have become non-strategic. Although most of our sales of these products are currently in the Spanish market, we have recently focused on increasing our sales in other European countries and other geographic regions through strategic alliances with companies in these territories.

In April 2004, we purchased a manufacturing facility located in Zaragoza, Spain that specializes in the manufacture of certain active pharmaceutical ingredients. The facility has been approved by the U.S. Food and Drug Administration (FDA) for the manufacture of one ingredient for marketing and sale in the U.S. We are manufacturing and marketing these products through our subsidiary, Bentley API. Additionally, we have a strategic alliance with Teva Pharmaceutical Industries Ltd. (Teva) granting us the right to register and market certain of Teva's pharmaceutical products in Spain through our sales force of approximately 160 full-time personnel who focus on major cities throughout Spain. In November 2004, we entered into a multi-product collaboration agreement with Perrigo Company (Perrigo), the largest U.S. manufacturer of over-the-counter pharmaceutical and nutritional products for the store brand market, to co-develop and market, in the U.S. and potentially other markets, generic pharmaceutical products that we manufacture in Spain.

In our research and development activities, we have U.S. and international patents and other proprietary rights to technologies that facilitate the absorption of drugs. We are developing products that incorporate our drug delivery technologies and have licensed applications of our proprietary CPE-215® drug delivery technology to Auxilium Pharmaceuticals, Inc., which launched Testim® in the U.S. market, in February 2003. Testim, which incorporates our CPE-215 drug delivery technology, is a gel indicated for testosterone replacement therapy, which restores serum testosterone levels in men and thereby improves symptoms of health problems associated with low testosterone levels (hypogonadism). In early 2005, Testim received marketing authorizations in two additional European countries, bringing the total number of countries in which Testim is approved outside the U.S. to 11. Additionally, Testim was launched in Germany in January 2005 by Auxilium's partner, Ipsen. We are in discussions with other pharmaceutical and biotechnology companies to form additional strategic alliances to facilitate

the development and commercialization of other products using our drug delivery technologies, including product candidates that deliver insulin to diabetic patients intranasally and treat nail fungus infections topically.

Our Common Stock began trading on the New York Stock Exchange (*NYSE*) on May 12, 2004, under the trade symbol *BNT*. Previously our Common Stock was traded on the American Stock Exchange under the same symbol.

## **Industry Overview**

### *Pharmaceutical Industry in Europe*

The European Union, with an increasingly affluent population of approximately 375 million people and approximately \$75 billion in pharmaceutical sales in 2000, represents the second largest pharmaceutical market in the world, according to IMS Health. With the addition of 10 new countries to the European Union in May 2004, its population has increased to more than 450 million people. Healthcare expenditures in Western Europe, as in the U.S., are growing at a rate faster than the overall economy and drug expenditures as a percentage of total gross domestic product are lower than in the U.S., according to IMS Health.

Many European countries exercise strict controls over the prices of, and reimbursement for, pharmaceutical products. These countries often have national health insurance systems that provide reimbursement for prescription pharmaceuticals. The prices that these systems are willing to pay for products affects the profitability of the product sales. However, given the varying priorities and economies of each of the European countries, price consistency has not been achieved and both the prices and reimbursement rates often vary dramatically from country to country.

A basic tenet of the European Union has been encouraging the free movement of goods among all member states. Many European governments have policies in place that encourage sale of pharmaceutical products at the lowest price available. As a result, an active network of parallel importation has evolved in which products manufactured in one country flow into other European countries. This effectively favors manufacturers whose cost of goods are lower, enabling them to more effectively compete on the basis of price.

Since Spain's entry into the European Union in 1986, the Spanish pharmaceutical market has been evolving steadily into a market that is increasingly similar to those of other countries in Western Europe and the U.S. With a population of approximately 40 million, Spain was ranked in 2004 as the seventh largest pharmaceutical market in the world and fifth largest in the European Union. Pharmaceutical sales in Spain reached approximately \$10 billion in 2003, according to IMS Health, and have been growing at approximately 10% per year in recent years.

Over the last decade, there has been significant evolution of patent and similar protections of pharmaceutical products in Spain. Prior to 1992, manufacturing processes for active pharmaceutical ingredients could be patented in Spain, but active pharmaceutical ingredients could not be patented as products. Commencing in late 1992 active ingredients could be patented in Spain with protection running for 20 years from the date of application. This was followed by Spanish legislation in December 1996 that created a legal class of generic pharmaceuticals. In Spain, generic products are required to be therapeutically equivalent, have a similar composition to that of the original branded product and have demonstrated safety and efficacy. Safety and efficacy is presumed if the original reference product has been commercialized in Spain for 10 years. Generic products also must comply with product labeling requirements and be priced at a discount, which is typically at least 30% lower than the original branded product price.

Although comprising less than five percent of the Spanish pharmaceutical market (less than eight percent of the units of pharmaceutical products sold in Spain), generic pharmaceuticals are expected to

significantly increase their market penetration due to increases in drug usage driven by an aging population and opportunities to launch new generic products as patents expire for blockbuster drugs. Several initiatives are underway by the Spanish government in response to the rise in healthcare costs, including education, financial incentives to prescribing physicians and public campaigns to stimulate the use of generic pharmaceuticals. Due to the structure of the Spanish market for pharmaceutical products, producers generally market their products to physicians and pharmacies to whom they emphasize a combination of quality and price.

Generic pharmaceutical products in other European countries have attained greater market share, with generics in major markets such as the United Kingdom and Germany achieving over 40% market share. Generic products have achieved a high proportion of the market in many of these countries due to government programs that encourage the prescription of generic pharmaceuticals. In some of these markets, competition has made price the single most significant factor in determining market share. This has favored producers of products that have cost structures that can support competitive pricing. In these markets, emphasis can be placed on selling to distributors at favorable prices rather than the more expensive alternative of marketing to physicians or consumers.

#### *Drug Delivery Industry*

Drug delivery companies develop technologies to improve the administration of therapeutic compounds. These technologies are designed to enhance safety, efficacy, ease-of-use and patient compliance with prescribed therapy. Drug delivery technologies provide opportunities for pharmaceutical and biotechnology companies to extend their drug franchises as well as develop new and innovative products. The worldwide market for drug delivery systems was estimated to be more than \$40 billion in 2000 and is projected to approach \$90 billion by 2005.

The vast majority of the drugs currently on the market are taken orally or are administered by injection. Oral drug delivery methods, while simple to use, typically subject drugs to degradation in the stomach, and during first-pass metabolism in the liver, before reaching the bloodstream. In order to achieve efficacy, higher drug dosages are often used, with increased risks of side effects. The injection of pharmaceuticals, while avoiding first-pass metabolism in the liver, also has limitations, including pain, which can lead to decreased patient acceptance and decreased compliance with prescribed therapy. A decline in patient compliance can increase the risk of medical complications and lead to higher healthcare costs. Also, the costs of injectable drugs typically are higher as a result of the additional costs associated with medical personnel to administer the injections, the need to prepare the product under sterile conditions and the costs associated with the purchase and disposal of syringes.

Pharmaceutical and biotechnology companies look to drug delivery enhancements as a way of gaining a competitive advantage. Alternative drug delivery technologies, which avoid first-pass metabolism and are less invasive, may also be sought by pharmaceutical and biotechnology companies for product line extensions for a branded drug and, in some cases, may possibly postpone competition from generic equivalents. In order to maintain the competitiveness of their proprietary drug candidates, large pharmaceutical companies seek delivery enhancements that will increase safety and efficacy, reduce side effects and make administration more convenient. Further, drug delivery companies can apply their technologies to off-patent products to formulate their own proprietary products, which they often commercialize by seeking marketing collaborations with larger pharmaceutical companies that have greater capabilities and resources.

Developing safer and more efficacious methods of delivering existing drugs generally is less risky than attempting to discover new drugs, because of lower development costs. On average, it takes 10 to 15 years for an experimental new drug to progress from the laboratory to commercialization in the U.S., with an average cost of approximately \$900 million. Typically, only one in 5,000 compounds entering preclinical testing advances into human testing and only one in five compounds tested in

humans is approved for commercialization. By contrast, drug delivery companies typically target drugs that already have been approved, have a track record of safety and efficacy and have established markets for which there is a proven medical need. Consequently, clinical trials related to drug delivery technologies applied to previously-approved pharmaceuticals need only show that the new technologies deliver the drug without adverse side effects and with the same clinical efficacy.

### **Our Strategy**

Our objective is to be a leading specialty pharmaceutical company focused on:

development, licensing and sale of a broad range of generic and branded pharmaceutical products and active pharmaceutical ingredients in Spain, other parts of Europe, and other international markets, including the U.S. market; and

advanced drug delivery and formulation technologies to improve the delivery of new and existing pharmaceuticals.

Our strategies to accomplish this objective include:

*Increase our domestic product sales through targeted promotion and expansion of our product portfolio and increase international sales*

We plan to increase our generic and branded product sales by expanding the portfolio of products manufactured in Spain and by forming strategic alliances to increase our sales outside of Spain. We are expanding our product portfolio through the acquisition or licensing of currently marketed and late stage pharmaceutical products. We directly promote and sell these products in Spain through our own sales force of approximately 160 full-time personnel focused on major cities throughout Spain and outside Spain through the development of alliances with partners in other countries in Europe and elsewhere.

We focus on obtaining the rights to pharmaceutical products that are less actively promoted by larger pharmaceutical companies or are in a late stage of development and have good potential for acceptance in our markets. We believe that we have expertise in assessing potential market opportunities related to particular pharmaceuticals and in negotiating and acquiring from pharmaceutical companies the rights to market pharmaceuticals in Spain and other countries. Products that already are selling in the U.S. or other major markets demonstrate commercial viability and typically encounter fewer barriers to regulatory approval for introduction into other countries. The acquisition and subsequent manufacture of these products will permit our Spanish operations to more fully utilize our existing manufacturing capacity and allow us to further leverage our sales force by providing them with more products to sell. We believe that we have developed particular expertise in marketing pharmaceutical products to physicians and pharmacies in Spain.

Additionally, we have a strategic alliance with Teva granting us the right to register and market certain of Teva's pharmaceutical products in Spain through our sales force of approximately 160 full-time personnel who focus on major cities throughout Spain.

We are expanding the sales of products outside of Spain by developing alliances with strategic partners in targeted markets that offer compatible regulatory approval regimes and attractive margins. Most of these alliances relate to specific products that our partners have expertise in marketing. We have already developed alliances in Portugal, Greece, the United Kingdom, Germany, Austria, Morocco, Poland and the Czech Republic for targeted products in these and other countries. In certain European countries that have a highly developed competitive market for generics based primarily on price, we intend to sell either directly or through our alliances to distributors. In countries that require a sales force to market to physicians or consumers, we intend to continue to concentrate our efforts through alliances with entities that have marketing forces already in place. We are also evaluating and

making modifications to our finished pharmaceutical products manufacturing facility so that it will comply with Good Manufacturing Practices (GMP) of the FDA. These modifications should enable us to submit our products for U.S. marketing approval by the FDA.

*Focus on commercializing our CPE-215® permeation platform technology and developing proprietary products based on our other technologies*

We apply our drug delivery and oral drug formulation technologies in an effort to improve the performance of existing pharmaceutical products with respect to their method of delivery and effectiveness. We also may be able to reduce manufacturing costs for certain products as a result of our proprietary manufacturing processes.

Our CPE-215 technology enables the absorption of drugs across membranes of the skin, mouth, nose, vagina and eye. We believe our CPE-215 technology can be incorporated into a wide variety of pharmaceutical formats and products, including those formulated as creams, ointments, gels, solutions, lotions, sprays or patches. CPE-215 has a record of safety in humans as a food additive and fragrance and is currently listed on the FDA's inactive ingredient list for approved drug products. Testim, the first product incorporating our CPE-215 drug delivery technology, was approved by the FDA in October 2002 and was launched in the U.S. market by our licensee, Auxilium, in February of 2003. We are optimistic that this past experience with CPE-215 may result in reduced preclinical development time relating to its use in new formulations of previously approved compounds. We market our CPE-215 technology to pharmaceutical and biotechnology companies whose products we believe would benefit from its permeation properties.

We believe these benefits include:

improving efficacy as compared to oral administration, which subjects the drug to the effects of first-pass metabolism;

extending the period of market exclusivity for a branded compound based on the grant of a patent that incorporates new drug delivery methods;

allowing branded and generic drug companies to differentiate their products from those of competitors;

improving utilization of costly and/or scarce drugs and active ingredients;

expanding the market to patients less suitable for injection, especially children and the elderly; and

improving patient convenience and compliance, and lowering costs relative to a doctor's office visit for an injection.

In addition to marketing our CPE-215 technology to pharmaceutical companies for application with their branded or generic products, we selectively apply this technology to our own development of certain products. We target compounds with established market demand or that face limited market acceptance as a result of less efficient drug delivery methods. We are currently working on applications of the CPE-215 technology to the intranasal delivery of insulin to diabetic patients and the topical treatment of nail fungus infections.

We have been granted a patent in the U.S. for our oral formulation of acetaminophen. We have pending applications in Europe and elsewhere. We have also been granted a Spanish patent for our oral formulations of omeprazole and lansoprazole. In the case of acetaminophen, we believe that we have developed dosages that result in:

increased solubility in water for administration to patients who have difficulty swallowing pills;

faster relief of pain and inflammation; and

better taste.

With respect to omeprazole and lansoprazole, we believe that we have created manufacturing processes that require less time to efficiently produce our versions of these products.

Once we bring our internally developed products to an advanced stage of development, we intend to develop collaborative relationships that leverage the clinical development and marketing and sales capabilities of our strategic partners. We believe that this will allow us to license our products on terms that are more favorable than those that would be possible earlier in the development cycle. In Spain we may market these new products directly through our existing sales force. We also seek to manufacture and supply our pharmaceutical partners with the products they license from us.

## **Our Proprietary Drug Technologies**

### *Proprietary Drug Manufacturing Technologies*

We believe that there are several opportunities to enter into additional collaborations with pharmaceutical and biotechnology companies and expand our product lines using our proprietary drug technologies. For example, in November 2004, we entered into a multi-product collaboration agreement with Perrigo Company, the largest U.S. manufacturer of over-the-counter pharmaceutical and nutritional products for the store brand market, to co-develop and market in the U.S. and potentially other markets generic pharmaceutical products that we manufacture in Spain.

### *CPE-215 Permeation Platform Technology*

Our permeation platform technology consists of a series of related chemical compounds that enable the absorption of a wide variety of products across various biological membranes. Our primary compound and the foundation for our drug delivery platform technology is CPE-215 (pentadecalactone). CPE-215, when combined with certain drugs, has been shown to significantly increase the amount and rate of absorption of those drugs through various biological membranes. By controlling the amount of CPE-215 that is combined with certain drugs, we have the ability to positively affect the quantity and rate at which the drug is absorbed through biological membranes. We believe that our CPE-215 technology is superior to certain other non-injection and non-oral drug delivery systems based on the following characteristics:

broad applicability works with a wide range of pharmaceutical compounds, including water soluble and oil soluble and insoluble compounds as well as high and low molecular weight compounds, including peptides and proteins;

format independence can be formulated into creams, ointments, gels, solutions, lotions and patches;

biological membrane independence works across the biological membranes of the skin, mouth, nose, vagina and eye; and

well tolerated approved by the FDA for long-term topical use in Testim.

CPE-215 has a record of safety in humans as a food additive and fragrance and is currently listed on the FDA's inactive ingredient list for approved drug products. Testim, the first product incorporating our CPE-215 drug delivery technology, was approved by the FDA in October 2002 and was launched in the U.S. market by our licensee, Auxilium, in February of 2003. We are optimistic that this past experience with CPE-215 may result in reduced preclinical development activities required for new product formulations of previously approved pharmaceutical compounds.



*Solubility Enhancement Technology*

Our solubility enhancement technology involves chemical and manufacturing procedures that enhance compound solubility without changing the compound's therapeutic properties. Although this technology may be applied to other chemical entities, to date we have incorporated this technology only in acetaminophen compounds, which are known to have problems of insolubility and undesirable taste. Based upon clinical studies completed in Europe in 2001 and 2002, we believe that our technology enables us to develop and deliver dosages of acetaminophen that make it highly dispersible, rapidly soluble in water, better tasting and faster in reaching peak blood levels to deliver pain relief and reduce fever than other tablets or capsules. We believe the use of our technology will increase solubility, which will lessen undesirable side effects, such as flatulence in effervescent formulations and the bitter taste of pills, which commonly are associated with acetaminophen and many other oral medications. Patents have been filed on this technology, of which one has been granted in the United States and others are pending in Europe and elsewhere.

*Oral Formulation Technologies*

Our oral formulation technologies involve the application of a proprietary manufacturing process as well as specialized equipment, each of which plays a role in producing pharmaceutical products, while reducing manufacturing time and costs. We have developed new methods for manufacturing products such as omeprazole, lansoprazole and other similar products that are stability-sensitive to humidity and temperature. We have been granted a Spanish patent relating to these processes. The patent claims as innovative the manufacturing process that renders these products more stable, while protecting active substances from gastric degradation utilizing microgranulation and microencapsulation techniques. These patented technologies can contribute to our ability to compete against other companies whose manufacturing processes are more costly and time consuming.

**Licensed Product**

*Topical Testosterone Gel*

In February 2003, our licensee, Auxilium Pharmaceuticals, Inc. launched Testim, a testosterone gel containing our CPE-215 drug delivery system, in the United States. Testim is marketed by Auxilium under a license of our drug delivery technology.

Testosterone replacement therapy is used to treat men whose bodies produce insufficient amounts of testosterone (hypogonadism). Symptoms associated with low testosterone levels in men include depression, decreased libido, erectile dysfunction, muscular atrophy, loss of energy, mood alterations, increased body fat and reduced bone density. Currently marketed hormone replacement therapies involve delivery of hormones by injections, through transdermal patches and by gels. Injection therapy has limitations, including pain, which can lead to decreased patient acceptance and decreased compliance with prescribed therapy. Although patches have been able to alleviate many of the gastrointestinal side effects associated with oral delivery of hormones, patches, even in their smallest form, are often conspicuous and may result in skin irritation or even inaccurate dosing, should the patch fall off. The transdermal delivery of hormones through gels, creams and lotions provides commercially attractive and efficacious alternatives to other current methods of delivery. As more baby-boomers enter middle age and more attention is focused on male hormonal deficiencies, the worldwide testosterone replacement market has increased. According to IMS Health, in 2003, U.S. testosterone replacement therapy sales grew by 32% to approximately \$400 million from 2002.

Testim resulted from our May 2000 research agreement with Auxilium, a specialty pharmaceutical company that develops and markets products for urologic and sexual health, pursuant to which Auxilium agreed to develop and test various pharmaceutical compositions of topical testosterone using our CPE-215 technology. We licensed to Auxilium exclusive worldwide rights to develop, market and

sell Testim, which rights became effective in September 2000. After Auxilium conducted clinical trials, a New Drug Application (NDA) was approved by the FDA on October 31, 2002. Testim was launched in the United States by Auxilium in February 2003. In June 2003, Testim was approved in the United Kingdom and in January 2004, Auxilium entered into an agreement with Bayer Inc., a division of Bayer AG, to market Testim in Canada upon approval of Testim by the Canadian authorities. In early 2005, Testim received marketing authorizations in two additional European countries, bringing the total number of countries in which Testim is approved outside the U.S. to 11. Additionally, Testim was launched in Germany in January 2005 by Auxilium's partner, Ipsen.

### **Manufactured and Marketed Products**

In Spain, we manufacture approximately 120 pharmaceutical products, representing various dosage strengths and product formulations of more than 30 chemical entities. We market these products primarily in Spain and have developed alliances with other companies that market our products, pursuant to license and supply agreements, in other countries, including Portugal, Greece, the United Kingdom, Germany, Austria, Morocco, Poland and the Czech Republic. In addition, we manufacture products that are marketed by other companies both in Spain and elsewhere. Our product lines consist of generic and branded products within four primary therapeutic areas: cardiovascular, gastrointestinal, infectious and neurological diseases. Our generic and branded products are marketed to physicians, pharmacists and hospitals by our three Spanish sales and marketing organizations, Laboratorios Belmac, Laboratorios Davur and Laboratorios Rimafar. We also market over-the-counter products through Laboratorios Rimafar. There are approximately 179,000 physicians and 21,000 pharmacies in Spain.

We continually review and modify our product portfolio. We add to our portfolio to respond to increasing market demand for generic and branded products in Spain and, when appropriate, we divest from our portfolio products that we consider to be redundant or that have become non-strategic. We export a growing percentage of the pharmaceuticals manufactured by Laboratorios Belmac outside of Spain through local distributors and brokers, particularly in Europe and Northern Africa.

#### *Branded Pharmaceutical Products*

Our branded pharmaceutical product line consists of 40 pharmaceutical products representing various product presentations, formulations and dosage strengths of 29 chemical entities, which are represented by 20 trademarked brand names. Sales of branded pharmaceuticals accounted for 25% of our revenues in 2004, compared to 29% in 2003 and 32% in 2002. We market our branded and, to a lesser extent, certain of our generic and over-the-counter products through our Laboratorios Belmac subsidiary, which has approximately 75 full-time sales personnel who focus on major cities throughout Spain. A few branded products are also marketed by the sales forces of Laboratorios Davur and Laboratorios Rimafar. We supplement our sales and marketing efforts for branded products through advertising in trade publications. Most of our branded products are known in the industry as "branded generics" as they are being marketed by us under a "brand" name even though we are not the innovator of the product.

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The following are descriptions of the branded products that contribute significantly to our sales and gross profits:

Our Branded Product Name	Active Ingredient	Innovator Product	Used to Treat
Belmalip®	simvastatin	Zocor® (Merck)	elevated cholesterol
Belmazol®	omeprazole	Prilosec® (AstraZeneca)	gastroesophageal reflux disease
Cimascal D Forte®	calcium carbonate and vitamin D3	Calcite-D® (Riva)	osteoporosis
Codeisan®	codeine	Tricodein® (Solco)	cough and bronchitis
Enalapril Belmac®	enalapril maleate	Vasotec® (Merck)	cardiovascular disease and hypertension
Ibumac®	ibuprofen	Motrin® (McNeil)	rheumatoid arthritis
Lanzol®	lansoprazole	Prevacid® (Tap)	gastroesophageal reflux disease
Mio Relax®	carisoprodol	Soma® (MedPointe)	muscle spasms
Pentoxifilina Belmac®	pentoxifylline	Trental® (Aventis)	peripheral arterial disease
Senioral®	oxymetazoline and chlorpheniramine	Denoral® (Aventis)	cold and sinus congestion
Xetin®	paroxetine	Paxil® (GlaxoSmithKline)	depression

### *Generic Pharmaceutical Products*

Our generic pharmaceutical product line consists of 54 pharmaceutical products representing various product presentations, formulations and dosage strengths of 17 chemical entities. We entered the generic pharmaceutical market in Spain in September 2000. Laboratorios Davur, our sales and marketing organization devoted primarily to generic products, markets generic pharmaceutical products to physicians and pharmacists through a sales force of approximately 60 full-time sales personnel who focus on major cities throughout Spain. Laboratorios Rimafar, our sales and marketing organization devoted primarily to generics and over-the-counter products, all of which are generic, markets to pharmacists through a sales force of approximately 23 full-time sales personnel throughout Spain. Laboratorios Belmac also sells certain generic products. We supplement our sales and marketing efforts for generic products through advertising in trade publications.

We believe we can grow by providing a more extensive line of products to our generic products sales force for marketing to our physician and pharmacy clients.

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The following are descriptions of our generic products that contribute significantly to our sales and gross profits:

<b>Our Generic Product Name</b>	<b>Active Ingredient</b>	<b>Innovator Product</b>	<b>Used to Treat</b>
Amoxicilina Davur® Amoxicilina Belmac®	amoxicillin trihydrate	Amoxil® (GlaxoSmithKline)	infections
Azitromicina Davur®	azithromycin	Zithromax® (Pfizer)	infections
Ciprofloxacino Davur®	ciprofloxacin hydrochloride	Cipro® (Bayer)	microbial infections, including anthrax
Enalapril Davur®	enalapril maleate	Vasotec® (Merck)	cardiovascular disease and hypertension
Fluoxetina Davur® Fluoxetina Rimafar® Fluoxetina Belmac®	fluoxetine hydrochloride	Prozac® (Eli Lilly)	depression
Ibuprofeno Davur®	ibuprofen	Motrin® (McNeil)	pain, fever
Lansoprazol Davur® Lansoprazol Rimafar®	lanoprazole	Prevacid® (Tap)	gastroesophageal reflux disease
Loratadina Davur® Loratadina Rimafar®	loratadine	Claritin® (Schering)	seasonal allergic rhinitis
Mirtzapina Davur®	mirtazapine	Remeron® (Organon)	depression
Omeprazol Davur® Omeprazol Rimafar®	omeprazole	Prilosec® (AstraZeneca)	gastroesophageal reflux disease
Paroxetina Davur® Paroxetina Rimafar®	paroxetine	Paxil® (GlaxoSmithKline)	depression
Pentoxifilina Davur®	pentoxifylline	Trental® (Aventis)	peripheral arterial disease
Selegilina Davur®	selegiline hydrochloride	Eldepryl® (Somerset)	Parkinson's disease
Sertralina Davur®	sertraline hydrochloride	Zoloft® (Pfizer)	depression
Simvastatina Davur® Simvastatina Rimafar®	simvastatin	Zocor® (Merck)	elevated cholesterol
Trimetazidina Davur®	trimetazidine	Idaptan® (Servier)	coronary therapy
Zolpidem Davur® <i>Strategic Alliance with Teva</i>	zolpidem tartrate	Ambien® (Sanofi-Synthelabo)	insomnia

In July 2000, we entered into a five year strategic alliance with Teva, a world leader in generic pharmaceutical products, pursuant to which we were granted a royalty-free, non-exclusive license to register and sell certain of Teva's pharmaceutical products. Under this license agreement, we register these products with Spain's Ministry of Health and, upon approval, sell these products in Spain. We have a non-exclusive obligation to purchase the products from Teva, allowing us to purchase any of the products from sources other than Teva if we can demonstrate that Teva's price for a product exceeds the current price from another qualified source and if Teva has not exercised its right to match the

lower price. The collaboration with Teva expires in July 2005 and is renewable automatically for one-year terms. We have received marketing approval for 12 of these products, of which, one was launched in 2004, and 27 other product registrations have been submitted to the Ministry of Health and are pending approval. While there can be no assurance that any future products will be co-developed and licensed from Teva beyond July 2005, the existing licensed products (approved and pending) will remain the property of the Company and Teva is expected to continue to supply either raw materials or finished goods for those products.

In addition, under a rights agreement entered into with Teva in July 2000, we have granted Teva a right of first refusal to purchase Laboratorios Davur in the event that we decide to sell Laboratorios Davur or Laboratorios Belmac. We also granted Teva the right to bid for Laboratorios Belmac in the event we intend to sell Laboratorios Belmac.

#### *Sales to Licensees and Others*

In addition to manufacturing and selling our own branded and generic products, we license the right to market products to others within and outside of Spain. These license agreements are usually accompanied by long-term exclusive supply agreements, whereby our licensees purchase the licensed products from our manufacturing facility. As of December 31, 2004, the Company's Spanish operations have executed 119 license agreements, of which 14 with customers in Spain and 41 with customers outside of Spain, cover actively marketed products that are generating revenues. The remaining licenses, four with customers in Spain and 60 with customers outside of Spain, are for products that are awaiting regulatory approvals. Our Spanish manufacturing facility also supplies branded and generic products under 14 license agreements and 15 contract manufacturing agreements in Spain. Our clients market these products under their own names and with their own labeling. Many of the products we manufacture for others use the same active ingredients that are used in our own marketed products.

#### *Strategic Alliance with Perrigo Company*

We entered into a product development, license and manufacturing agreement with Perrigo Company in November 2004. Perrigo has agreed to co-develop, market and sell in the U.S., and potentially other markets, selected generic products manufactured by our active pharmaceutical ingredients manufacturing subsidiary, Bentley API, and finish dosage forms produced by our manufacturing subsidiary, Laboratorios Belmac.

Under the agreement, Abbreviated New Drug Applications (ANDA) for the co-developed products will be submitted by Perrigo to the FDA. We, together with Perrigo, have identified certain prescription drugs for co-development and commercialization that are no longer under patent protection or are soon to lose patent protection in the U.S. Under the agreement, we and Perrigo share undisclosed percentages of the cost of development for each ANDA. The specific products and percentage of development expenses have not been disclosed for competitive reasons.

#### *Manufacturing*

Our 108,000 square-foot pharmaceutical product manufacturing facility is located in Zaragoza, Spain. Our manufacturing facility complies with GMPs in Europe and is capable of producing tablets, capsules, ointments, lotions, liquids and sachets, as well as microgranulated products. The facility also includes analytical chemistry, quality control, quality assurance and formulation research laboratories. We are also evaluating and making modifications to this manufacturing facility so that it will comply with U.S. GMPs. These modifications should enable us to submit our products for marketing approval by the FDA.

We have fully integrated manufacturing support systems, including quality assurance, quality control, regulatory compliance and inventory control. These support systems are designed to maintain

high standards of quality for our products and deliver reliable products and services to our customers on a timely basis. We require a supply of quality raw materials and packaging materials to manufacture and package drug products. Historically we have not had difficulty obtaining raw materials and packaging materials from suppliers. Currently, we rely on approximately 43 suppliers to deliver our required raw materials and packaging materials, most of which are supplied by 20 of these entities. We have no reason to believe that we will be unable to procure adequate supplies of raw materials and packaging materials on a timely basis. Union Quimico Farmaceutica, S.A. is our sole supplier of omeprazole. We believe that alternative sources of omeprazole are available and we will obtain required governmental approval to source from them, if necessary.

### Products in Development

The following are products that we are currently developing, listed in the order of our current priorities. Before they are commercialized, they must be approved by regulatory authorities, such as the FDA or the Spanish Ministry of Health, in each jurisdiction where they will be marketed or sold. See "Regulation" section of Item 1 for a discussion of the regulatory approval process.

<b>Product Candidate</b>	<b>Technology</b>	<b>Used to Treat</b>	<b>Status</b>
Generic products	Various	Various	Bioequivalence and/or submitted for approval in Spain
Intranasal insulin	CPE-215	Diabetes	Phase I/II
Antifungal nail lacquer	CPE-215	Onychomycosis	Phase I/II
Improved acetaminophen	Solubility enhancement	Pain; fever	Submitted for approval in Spain
Topical hormonal therapy	CPE-215	Osteoporosis; Erectile dysfunction	Preclinical
Intranasal pain management	CPE-215	Pain	Preclinical

*Generic Products*

We continually evaluate which pharmaceutical products are good candidates for us to develop, test and market in Spain, the U.S. and elsewhere. We select products based on factors including the timing of expiration of the patent on the innovator's product, the ability of our manufacturing facility to efficiently produce the product, the availability and cost of the raw materials to produce the product as well as the potential market size and pricing that can be obtained for the product. Once we select a product, our scientists develop a generic formulation of the product, which then must be tested to determine if it is bioequivalent to the innovator's product. Products are then submitted for marketing approval by the relevant regulatory authorities, generally starting with Spain's Ministry of Health. Through our agreement with Perrigo, they have agreed to co-develop, market and sell in the U.S., and potentially other markets, selected products produced by our active pharmaceutical ingredients manufacturing subsidiary, Bentley API, and finish dosage forms produced by our pharmaceutical product manufacturing subsidiary, Laboratorios Belmac.

We attempt to have several products in each stage of development so that we can have a steady pipeline of product introductions. For competitive reasons, we generally do not disclose which generic products we are developing.

*Intranasal Insulin*

We are developing intranasal formulations of insulin to treat patients suffering from Type I and Type II diabetes. Based on preclinical studies at various universities and the results of our Phase I study and preliminary results of our Phase II study, we believe our intranasal insulin formulation can potentially achieve higher levels of bioavailability compared to other drug delivery systems currently being developed. Our product is designed to deliver insulin through a small, discreet nasal spray that can be carried in a patient's pocket. Our formulation is designed to blunt the increase in glucose following meals which may greatly reduce the number of insulin injections required to be taken by Type I diabetics (those requiring insulin); and it may reduce the number of medications currently required to be taken by Type II diabetics (those not requiring insulin).

In January 2004, we completed a Phase I clinical trial of an intranasal insulin product formulation in healthy volunteers. The study was conducted by a clinical research organization in a hospital setting in Ireland in compliance with U.S. and European clinical standards, and provided encouraging results. The clinical study consisted of 8 healthy (non-diabetic) human volunteers who, over several weeks, each received up to four intranasal sprays of insulin utilizing our proprietary drug delivery technology. The study, which is designed to demonstrate safety, also demonstrated a consistent response in the group. Elevated blood insulin levels were detected within 10 minutes of nasal administration, a peak increase at about 20 minutes and return to pre-dose levels by 60-90 minutes. Baseline blood glucose levels were quickly depressed in a dose-related manner, with a peak decrease at about 40 minutes after nasal insulin administration. These results were also consistent with a decrease in the normal volunteers' baseline blood insulin levels, as measured by plasma C-peptide, which occurred at about 60 minutes after nasal insulin dosing.

Based on the results of this Phase I study, we proceeded with a Phase II protocol for evaluation in insulin-dependent diabetics, which was completed in late 2004 and is in the final stages of reporting. Preliminary results of the study indicate that the preparation was well absorbed and diminished the rise in glucose following a standard meal. Additional work is planned, including continued formulation development and additional Phase II studies.

Diabetes is a metabolic disorder affecting approximately 100 million people worldwide and is projected to affect more than 300 million people worldwide in the next 25 years. The market for insulin treatment of diabetes in the United States is estimated at \$1.25 billion annually, and Frost & Sullivan estimates that the worldwide market is approximately \$3 billion. Diabetic patients who must endure frequent injections prefer less invasive methods of administering their medications. Alternative and more desirable methods of delivery would not only improve quality of life but also would contribute to patient compliance with prescribed therapy.

*Antifungal Nail Lacquer*

We are developing a topical nail lacquer for treating fingernail and toenail fungal infections (onychomycosis). We completed two Phase I/II clinical trials for the treatment of nail fungal infections at the University of Alabama at Birmingham in 2002 and 2003 utilizing a clotrimazole lacquer formulation containing CPE-215. In February 2004, our leading candidate to license our topical Antifungal Nail Lacquer product line decided not to move forward with a collaboration following a change in their senior management. We have since opened discussions with other potential licensees.

According to the National Onychomycosis Society, nail fungus affects almost 30 million people, primarily between the ages of 40 and 65. Patients electing to take oral therapy must undergo blood monitoring during the course of treatment to monitor for liver damage. The cost of oral therapy is in excess of \$800 for a twelve-week treatment regimen, not including physician costs or other periodic monitoring costs.

#### *Acetaminophen*

We have developed and patented oral formulations of acetaminophen, the active ingredient in such products as McNeil Consumer Healthcare's Tylenol® line of products, which is commonly used for controlling pain and fever. We believe that our oral formulations of acetaminophen make it highly dispersible, rapidly soluble in water, better tasting and achieve faster onset than other tablets or capsules. These characteristics give our oral formulations superior properties over many currently marketed products, which do not dissolve easily in water and may cause bitter taste and flatulence. These improvements are particularly useful for treating children, the elderly and those who have difficulty swallowing pills. Clinical studies in Europe documenting the product's improved dissolution and absorption were conducted in 2001 and 2002. We have also completed bioequivalence studies, which compare the rate and extent of absorption and levels of concentration of our oral formulations needed to produce a therapeutic effect, with other formulations of acetaminophen. We submitted this product for approval in Spain in July 2002, and are in preliminary discussions with potential collaborators to license and market this product outside of Spain.

#### *Topical Hormonal Therapy*

Our topical hormonal therapy incorporates the use of metabolic steroids that regulate most of the hormonal action in adult males. Hormone replacement therapies using these metabolic steroids may have significant benefits in treating a number of medical afflictions, including osteoporosis and sexual dysfunction. We have granted to Auxilium a worldwide license to develop, market and sell a topical hormonal therapy containing our CPE-215 technology. Auxilium, which has already incorporated our CPE-215 technology into Testim, is evaluating the formulations of this topical hormonal therapy product.

#### *Intranasal Pain Management*

Many people suffer from chronic moderate-to-severe pain that is related to cancer, back problems and orthopedic injury. These people also may experience intermittent flares of pain that can occur even though they are taking analgesic medications on a fixed schedule for pain control. A severe flare of pain is called breakthrough pain because the pain breaks through the regular pain medication. About one-half to two-thirds of patients with chronic cancer-related pain also experience episodes of breakthrough cancer pain. Generally, breakthrough pain occurs without prior onset symptoms and may last from seconds to minutes or hours. Recent regulatory concerns regarding the safety of COX-2 inhibitors and other non-steroidal anti-inflammatory drugs may provide opportunities for alternative methods for treating pain. The U.S. prescription market for the treatment of moderate to severe pain, including breakthrough pain, is approximately \$2 billion annually.

Orally delivered pain products may not provide rapid relief and typically demonstrate considerable patient-to-patient variability in absorption. Injectable formulations of pain products provide rapid and effective pain relief, but administration often requires professional assistance or hospitalization. We believe our intranasal pain product under development could provide significant medical benefits over oral and injectable formulations as it is intended to combine patient convenience and ease of use with the rapid onset of pain relief and the same potency as injectable delivery routes. Our intranasal pain product is in preclinical development for the treatment of chronic pain and acute episodes of chronic pain.

Under a research agreement with Auxilium, we formulated the intranasal delivery of a pain management chemical agent using our CPE-215 technology. Auxilium is evaluating these formulations.



## **Intellectual Property**

We actively seek to protect our products and proprietary information by means of U.S. and foreign patents, trademarks and contractual arrangements. Our success will depend in part on our ability to obtain and enforce patents on our products, processes and technologies to preserve our trade secrets and other proprietary information and to avoid infringing on the patents or proprietary rights of others. Our CPE-215 technology is covered by our U.S. patent and 11 foreign patents, including those in Japan, Korea and most major European countries. These patents for our CPE-215 technology expire in the U.S. in 2008 and in foreign countries between 2006 and 2014. In 2003, we acquired a U.S. patent regarding our antifungal nail lacquer product which expires in 2020. Patent applications for our antifungal nail lacquer are currently pending in Europe and other foreign countries. We also have four international patents pending covering various applications of our CPE-215 technology, including testosterone and insulin compositions.

We have been granted a patent in the United States for our oral formulation of acetaminophen. We have pending applications in Europe and elsewhere. We have also been granted a Spanish patent for our oral formulations of omeprazole and lansoprazole.

We own approximately 110 trademarks for pharmaceutical products in Spain. In addition, we also rely on unpatented proprietary technologies in the development and commercialization of our products. We also depend upon the unpatentable skills, knowledge and experience of our scientific and technical personnel, as well as those of our advisors, consultants and other contractors. To help protect our proprietary know-how that is not patentable, and for inventions for which patents may be difficult to enforce, we rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we require employees, consultants and advisors to enter into agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions that arise from their activities for us. Additionally, these confidentiality agreements require that our employees, consultants and advisors do not bring to us, or use without proper authorization, any third party's proprietary technology.

## **Competition**

All of our current and future products face strong competition both from new and existing drugs and drug delivery technologies. This competition potentially includes national and multi-national pharmaceutical and healthcare companies of all sizes. Many of these other pharmaceutical and healthcare companies have far greater financial resources, technical staffs, research and development, and manufacturing and marketing capabilities. We believe that owning our own development, manufacturing and marketing facilities in Spain allows us to effectively compete with other pharmaceutical companies in many markets. Our access to these resources enables us to control costs otherwise associated with contracting for the development, manufacture or marketing of our products by other companies. These lower costs allow us to sell our products at competitive prices while maintaining profitable margins.

We compete with both large multinational companies and national Spanish companies, which produce products that compete with most of the products that we manufacture and market. In Spain, our principal competitors include companies such as Ratiopharm International GmbH, Merck Sharp & Dohme de España, S.A. and Laboratorios Bayvit S.A.

## **Customers**

In Spain, our sales representatives from Laboratorios Belmac, Laboratorios Davur and Laboratorios Rimafar actively promote our products to physicians and retail pharmacists. We sell our products directly to pharmaceutical distributors and indirectly to customers who purchase our products from distributors. Outside Spain, we currently sell our products to our strategic partners who then

distribute our products directly or through distributors in their respective territories. We have begun to market certain products directly to distributors in selected markets outside of Spain. Our manufacturing facility also supplies branded and generic products to customers both within and outside of Spain, including the European Union, geographical Europe, Northern Africa and the Middle East, under licensing and supply agreements or contract manufacturing arrangements. The wholesale distributor network for pharmaceutical products in Europe and more specifically in Spain in recent years has been subject to consolidation, which has increased and we expect will continue to increase our, and other industry participants', customer concentration.

In the United States, we have entered into research and license agreements with pharmaceutical companies, whereby we perform research activities and license product candidates in exchange for milestone payments and royalties and/or a share of profits derived from product sales.

In 2004, 2003 and 2002, only one of our customers, Cofares, accounted for more than ten percent of our consolidated total revenues. Sales to this customer accounted for approximately 14% of our consolidated total revenues in each of the three years ended December 31, 2004, 2003 and 2002. See Note 14 of the Notes to the Consolidated Financial Statements in Item 15 for financial information regarding geographic areas.

### **Employees**

We employ approximately 349 people, 18 of whom are employed in the U.S. and 331 of whom are employed in Spain, as of March 3, 2005. Approximately 117 of these employees are principally engaged in manufacturing activities, 160 in sales and marketing, 23 in product development and 49 in management and administration. In general, we consider our relations with our employees to be good.

### **Regulation**

Numerous governmental authorities in the U.S., Spain and other countries extensively regulate the activities of pharmaceutical manufacturers. If we fail to comply with the applicable requirements of governmental authorities, we may be subject to administrative or judicial sanctions such as refusal or delay by governmental authorities to approve pending marketing approval applications or supplements to approved applications, warning letters, total or partial suspension of production, fines, injunctions, product seizures or recalls, as well as criminal prosecution.

#### *United States*

Prior to marketing most pharmaceutical products in the U.S., the product must first be approved by the FDA. For new compounds, the regulatory approval process begins with preclinical laboratory and animal testing. The approval process generally consists of the following five principal stages:

Preclinical testing;

Submission and review by the FDA of an Investigational New Drug Exemption (IND) Application;

Clinical trials;

Preparation and submission of the NDA; and

FDA's review and approval/disapproval of the NDA.

In some cases, further clinical trials may also be required following approval.

The IND is submitted to the FDA when the appropriate preclinical studies are completed and must be submitted to the FDA 30 days before beginning clinical studies. The IND becomes effective if the FDA does not put the investigations described in the IND on clinical hold within 30 days of receiving the IND for filing.

Human clinical trials typically are conducted in three sequential phases. Some clinical trials may include aspects of more than one phase.

Phase I involves the initial introduction of the pharmaceutical compound into patients or healthy human volunteers; the emphasis is on testing for dosage tolerance, metabolism, excretion, clinical pharmacology, safety (adverse effects) and possibly early evidence of effectiveness.

Phase II involves the first controlled clinical trial involving patients who have the targeted disease or condition and consists of safety and efficacy studies. The studies may be divided into early Phase II (or II A), during which studies are performed to determine initial efficacy and late Phase II (or II B) which may consist of placebo-controlled trials in a larger number of patients.

Phase III involves large scale, long-term, well controlled efficacy and safety studies within an expanded patient population, frequently at multiple clinical study sites.

Throughout the drug development process, the IND must be updated continually with protocol amendments, information amendments, IND Safety Reports and Annual Reports. The FDA carefully reviews all data submitted and holds meetings with the sponsor at key stages to discuss the preclinical and clinical plans and results.

The clinical, chemistry, statistics, biopharmaceuticals, microbiology (if applicable) and nonclinical data that has been collected over many years of development is submitted to the FDA in an NDA. Additionally, an NDA will contain complete chemistry, manufacturing and controls information, demonstrating that the applicant is capable of consistently manufacturing a drug product of appropriate strength, quality and purity. An NDA is an application requesting FDA approval to market a new drug for human use in interstate commerce. The current User Fee Rate for Fiscal Year 2005 for the submission of an NDA is \$627,000.

NDAs are allocated varying review priorities based on a number of factors, including the severity of the disease, the availability of alternative treatments and the risks and benefits demonstrated in clinical trials. Additional animal studies or clinical trials may be requested during the FDA review process and may delay marketing approval. After FDA approval for the initial indications, further clinical trials are necessary to gain approval for the use of the product for any additional indications. The FDA may also require post-marketing testing to monitor for adverse effects, and in some cases to provide additional information on efficacy, which can involve significant expense. Our products under development and future products to be developed must go through the approval process delineated above prior to gaining approval by the FDA for commercialization.

FDA approval is also required for the marketing of generic equivalents of an existing drug. An ANDA is required to be submitted to the FDA for approval. When processing an ANDA, the FDA, in lieu of the requirement for conducting complete clinical studies, requires bioavailability and/or bioequivalence studies. Bioavailability indicates the rate and extent of absorption and levels of concentration of a drug product in the body. Bioequivalence compares the bioavailability of one drug product (in this case, the generic product under review) with another (usually the innovator product). When bioequivalence is established, the rate of absorption and levels of concentration of the generic drug in the body will closely approximate those of the previously approved drug. An ANDA may only be submitted for a drug on the basis that it is the equivalent to a previously approved drug.

In addition to obtaining FDA approval for each product, each manufacturer of drugs must register its manufacturing facilities with the FDA, and must list the drug products it manufactures at each facility. Domestic manufacturing establishments are subject to biennial inspections by the FDA and must comply with current GMPs for drugs. To supply products for use in the U.S., foreign manufacturing establishments must also comply with U.S. GMPs and are subject to inspection by the FDA. Such inspections generally take place upon submission of an NDA or ANDA to the FDA or at

any other time deemed necessary by the FDA and can impact both the approval of drugs, and a company's ability to continue manufacturing following approval.

*Europe*

As a pharmaceutical manufacturer in Spain, which is a member of the European Union, we are subject to the regulations enacted by the European Union that require us to obtain manufacturing, marketing and pricing authorizations to commercialize pharmaceutical products in Spain.

Pharmaceutical manufacturers in Europe must obtain marketing approval from the regulatory authority of each country in which they intend to market a product. In Spain, that authority is the Spanish Ministry of Health. The development process in Europe is similar to that in the United States described above, with the same three clinical phases for branded drugs and bioequivalence studies for generic drugs to assure their safety and efficacy. A dossier must be prepared for each pharmaceutical product and, upon approval of the product, it may be marketed in that country. In Spain, generic products are generally approved approximately one year after submission, while branded products take considerably longer. Spain and certain other European countries also regulate the price that can be charged to the patient for each product as well as set the amount that the public insurance programs will reimburse for each product, directly affecting a product's profitability. In late October 2003, the Spanish government enacted a regulation that reduced the prices that the government reimburses for certain prescription pharmaceutical products. These new prices became effective on December 26, 2003, but were voluntarily implemented by some companies, including our Spanish subsidiaries, on December 1, 2003. In 2005, the Spanish government temporarily suspended the reference-price system that was implemented by the Spanish government in late 2003 and proposed a 67-point plan to replace the reference price system. The new plan includes a 4.2% price reduction in 2005 (and an additional 2% reduction in 2006) on only those drugs that have been on the market in Spain for over one year and were not already subject to the reference-price reductions for 2004. (See Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations.)

In order to speed approvals within European Union countries, the European Union has established a mutual recognition procedure. When a manufacturer submits a pharmaceutical product for marketing approval, it must designate whether the filing will serve as a reference authorization for other European Union countries and, if so, which specific European countries. If the filing is not designated as a mutual recognition reference filing, then other applications must be made individually to other countries for approval to be granted in those other countries. If the filing is designated as a reference authorization, then the authority in the initial country is required to evaluate the submission on the basis of its own domestic standards as well as the standards of each of the countries listed by the manufacturer. As the standards for pharmaceutical approvals have not been harmonized among the various European Union members, certain aspects of the filing must comply with standards that vary by country. In addition, the process for initial evaluation of mutual recognition filings is generally significantly longer than that for national filings and, as a result, companies often choose not to use this process for their first approval. However, if the filing is approved for the reference and the mutual recognition countries, the manufacturer would be permitted to market the product in all of the jurisdictions selected.

A manufacturing facility is required to obtain a general permit to operate a pharmaceutical business certifying that its facilities comply with European GMPs. These permits are granted by the national authorities in the country of manufacture and other European countries rely on regulation by the authority of the country of manufacture.

*Trends in Healthcare Regulation*

The cost of healthcare continues to be a subject of investigation and action by governmental agencies, legislative bodies and private organizations. Many countries, in Europe and elsewhere, directly or indirectly through reimbursement limitations, control the selling prices and reimbursement prices of certain healthcare products. For example, in Spain, prices for prescription pharmaceutical products must be approved by Spain's Ministry of Health. In order to help control rising healthcare costs, the Ministry of Health, in recent years, has encouraged the substitution of generic-equivalent products. In further efforts to reduce healthcare costs, the Ministry of Health had been contemplating new laws and regulations that would significantly reduce the market prices of certain pharmaceutical products, including generic-equivalent drugs. In late October 2003, the Spanish government enacted a regulation that reduced the prices that the government reimburses for certain prescription pharmaceutical products. These new prices became effective on December 26, 2003, but were voluntarily implemented by some companies, including our Spanish subsidiaries, on December 1, 2003. As a result, certain of our selling prices for these products have been reduced. The regulation affected six of our chemical entities sold in Spain, including the chemical entities omeprazole, simvastatin and enalapril, and reduced our 2004 revenues by approximately \$13,800,000 million. In 2005, the Spanish government temporarily suspended the reference-price system that was implemented by the Spanish government in late 2003 and proposed a 67-point plan to replace the reference price system. The new plan includes a 4.2% price reduction in 2005 (and an additional 2% reduction in 2006) on only those drugs that have been on the market in Spain for over one year and were not already subject to the reference-price reductions for 2004. (See Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations.) There can be no assurance that the government in Spain or in other countries will not implement additional price reductions in the future.

In Spain and in certain other European countries, there are regulations that prohibit a pharmacy from substituting another product if a doctor's prescription has specified a specific product for that patient. Recently, there has been intense scrutiny of pharmacists to assure that they are complying with this regulation. Other European countries permit the pharmacist to substitute products more freely than Spain. Any change in this regulation may negatively affect our sales in Spain, as our products are often prescribed by brand name by the physicians.

In Western Europe, efforts are under way by the European Union to harmonize technical standards for many products, including drugs, to make more uniform the requirements for marketing approval from the various regulatory agencies.

In the United States, most states have enacted generic substitution legislation requiring or permitting a dispensing pharmacist to substitute a generic version of a prescribed innovator drug. Federal and state governments continue their efforts to reduce costs of subsidized healthcare programs, including restrictions on amounts agencies will reimburse for the use of products. Efforts to reduce healthcare costs are also being made in the private sector. Healthcare providers have responded by instituting various cost reduction and containment measures of their own. It is not possible to predict the extent to which we or the healthcare industry in general might be affected by these changes.

Continuing reviews of the utilization, safety and efficacy of healthcare products and their components are being conducted by industry, government agencies and others. These studies, which employ increasingly sophisticated methods and techniques, can call into question the utilization, safety and efficacy of previously marketed products and in some cases have resulted, and may in the future result, in the discontinuance of such products and give rise to claims for damages from persons who believe they have been injured as a result of their use. Similar consequences can arise as a result of adverse events, which can impact both innovator and generic versions of the same drug. We maintain product liability insurance for such potential claims; however, no such claims have ever been asserted against us.

*Other Regulations*

We believe that we comply with environmental laws that apply to us and we do not anticipate that continuing compliance will have a material effect on our financial condition or results of operations.

**Item 2. Properties**

We own a 15,700 square foot commercial building situated on approximately 14 acres of land in Exeter, New Hampshire that serves as our corporate headquarters and research and development laboratory. It is located approximately 45 minutes north of Boston, Massachusetts.

We also own a 108,000 square foot facility in Zaragoza, Spain, which accommodates our pharmaceutical products manufacturing plant, warehouse, research and development laboratory and office space.

We purchased a 11,000 square foot active pharmaceutical ingredients manufacturing facility in Zaragoza, Spain in April 2004 and subsequently purchased adjacent parcels of land totaling approximately 4 acres for expansion of our active pharmaceutical ingredients manufacturing operation. The API manufacturing facility is located in an industrial park and we have acquired sufficient acreage adjacent thereto to accommodate future expansion.

We lease a 10,700 square foot facility in San Sebastian de los Reyes, Spain, an area northwest of Madrid, which houses the administrative offices for our Spanish and European operations. The lease for this facility expires in 2006.

We believe that each of our facilities has sufficient space for our current needs and our contemplated expansion in the near future. Our manufacturing facilities are currently operating at approximately 50% of capacity, if operating for two shifts per day, five days per week.

**Item 3. Legal Proceedings**

On February 4, 2002, we were notified that a legal proceeding had been commenced against us by Merck & Co. Inc. and its Spanish subsidiary, Merck Sharp & Dohme de España, S.A., alleging that we violated their patents in our production of simvastatin products and requested an injunction ordering us not to manufacture or market the products. The case was brought against our Spanish subsidiaries in the 39th First Instance Court of the City of Madrid. After a hearing on February 18, 2002, the court refused to grant the requested injunction and dismissed the case on February 25, 2002, awarding court costs and legal fees to us. Merck has appealed the award of fees. Merck re-instituted its claim against us in another proceeding brought in the 19th First Instance Court of the City of Madrid, of which we received notice on January 23, 2003. This case also alleged violation of Merck's patents in the production of simvastatin products, requested an order that we cease manufacturing the products and demanded damages during the period of manufacture. After a trial with respect to this matter held on February 19 and 20, 2004, the court, on April 8, 2004, ruled in our favor, again awarding us court costs and legal fees. Merck has subsequently appealed this ruling.

On January 10, 2004, we were notified that a legal proceeding had been commenced against us by Smith Kline Beecham PLC, Smith Kline Beecham, S.A. and GlaxoSmithKline S.A. alleging that we violate their patents in our production of paroxetine products and they requested an order requiring us to not manufacture or market the products. The case was brought against our Spanish subsidiaries in the 50th First Instance Court of the City of Madrid. This proceeding followed a preliminary injunction that the same plaintiffs attempted to bring against us in 2003, which was dismissed. We filed a response to this suit in February 2004 that included a counterclaim requesting that the court declare the asserted patent invalid. We intend to vigorously oppose this claim as we believe the claim is without merit. Our paroxetine product line was launched in 2003.

In September 2004, a legal action was filed against us in the U.S. District Court of the District of Delaware by Ethypharm S.A., a French-based drug delivery company, primarily claiming misappropriation of unspecified alleged trade secrets in connection with the manufacture of omeprazole since March 2002 by Laboratorios Belmac, one of our Spanish subsidiaries. A related claim was previously brought against Laboratorios Belmac in the 72<sup>nd</sup> First Instance Court of the City of Madrid requesting an injunction, which remains unresolved. We intend to vigorously defend against the claims in the U.S. and Laboratorios Belmac is doing the same in the Spanish proceeding.

We are a party to various other legal actions that arose in the ordinary course of business. We do not expect that resolution of these matters will have, individually or in the aggregate, a material adverse effect on our financial position, results of operations or cash flows.

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

Not applicable.

## Part II

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

The following table sets forth, for the periods indicated, the range of quarterly high and low sales prices for our common stock as reported on the New York Stock Exchange (beginning May 12, 2004 and on the American Stock Exchange prior thereto) under the symbol "BNT." Our common stock began trading on the New York Stock Exchange on May 12, 2004 and on the Pacific Exchange on March 27, 1996.

	<u>High</u>	<u>Low</u>
<b>Fiscal Year Ended December 31, 2003</b>		
First Quarter	\$ 9.70	\$ 7.85
Second Quarter	14.05	8.20
Third Quarter	18.80	12.81
Fourth Quarter	17.15	11.34
<b>Fiscal Year Ended December 31, 2004</b>		
First Quarter	14.76	10.62
Second Quarter	14.10	11.20
Third Quarter	13.89	9.52
Fourth Quarter	11.40	8.35
<b>Fiscal Year Ending December 31, 2005</b>		
First Quarter (through March 13, 2005)	10.94	8.51

As of March 9, 2005 there were 1,045 holders of record of our common stock, which does not reflect stockholders whose shares are held in street name.

**Dividends**

We have never paid cash dividends on our common stock and we do not intend to pay dividends in the foreseeable future. We intend to retain future earnings in order to finance the growth and development of our business.



**Item 6. Selected Financial Data**

The following sets forth the selected Consolidated Income Statement data for the years ended December 31, 2000, 2001, 2002, 2003 and 2004 and Consolidated Balance Sheet data as of December 31, 2000, 2001, 2002, 2003 and 2004, all of which are derived from our audited Consolidated Financial Statements and related notes. The following Consolidated Income Statement data for the years ended December 31, 2002, 2003 and 2004 and Consolidated Balance Sheet data as of December 31, 2003 and 2004 should be read together with our Consolidated Financial Statements and related notes appearing elsewhere in Item 15 and "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Annual Report on Form 10-K. The Consolidated Income Statement data for the years ended December 31, 2000 and 2001 and the Consolidated Balance Sheet data as of December 31, 2000, 2001 and 2002 are derived from our audited Consolidated Financial Statements and related notes not included in this Annual Report on Form 10-K.

**Consolidated Income Statement Data****For The Year Ended December 31,**

	<b>2000</b>	<b>2001</b>	<b>2002</b>	<b>2003</b>	<b>2004(a)</b>
	(in thousands, except per share data)				
Total revenues	\$ 18,617	\$ 26,411	\$ 39,136	\$ 64,676	\$ 73,393
Cost of net product sales	7,189	11,462	16,477	26,399	34,551
Gross profit	11,428	14,949	22,659	38,277	38,842
Operating expenses	11,942	16,137	19,277	26,848	30,147
Gain on sale of drug licenses		5,050	650		
Other income (expenses)	(9)	(49)	138	91	1,800
Income (loss) before income taxes	(523)	3,813	4,170	11,520	10,495
Provision for income taxes	222	2,452	2,534	5,423	4,805
Net income (loss)	\$ (745)	\$ 1,361	\$ 1,636	\$ 6,097	\$ 5,690
Net income (loss) per common share basic	\$ (0.06)	\$ 0.10	\$ 0.10	\$ 0.34	\$ 0.27
Net income (loss) per common share diluted	\$ (0.06)	\$ 0.08	\$ 0.08	\$ 0.28	\$ 0.25
Weighted average common shares outstanding basic	12,981	14,196	16,569	17,997	20,901
Weighted average common shares outstanding diluted	12,981	16,147	19,798	21,637	22,627

(a)

*Other income (expenses)* for the year ended December 31, 2004 includes the reversal of previously accrued tax assessments totaling \$1,467,000. These assessments had been accrued to be paid to the Spanish government as a vehicle to help reduce the impact of the rising health care costs in Spain. Due to changes in the pharmaceutical industry in Spain and a change in the Spanish political environment, these liabilities no longer exist. Accordingly, these accruals were reversed during the second quarter of 2004.

## Consolidated Balance Sheet Data

	December 31,				
	2000	2001	2002	2003	2004
	(in thousands)				
Working capital	\$ 3,742	\$ 6,276	\$ 30,703	\$ 46,181	\$ 47,114
Current assets	\$ 13,104	\$ 15,839	\$ 43,972	\$ 66,899	\$ 74,710
Non-current assets	15,773	16,280	20,720	33,564	47,220
Total assets	\$ 28,877	\$ 32,119	\$ 64,692	\$ 100,463	\$ 121,930
Current liabilities	\$ 9,362	\$ 9,563	\$ 13,269	\$ 20,718	\$ 27,596
Long-term debt	908	142	345	369	349
Other non-current liabilities	791	1,990	2,327	3,211	4,328
Total liabilities	\$ 11,061	\$ 11,695	\$ 15,941	\$ 24,298	\$ 32,273
Redeemable preferred stock	\$	\$	\$	\$	\$
Stockholders' equity	\$ 17,816	\$ 20,424	\$ 48,751	\$ 76,165	\$ 89,657

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

The following discussion and analysis should be read in conjunction with the Financial Statements and related Notes included in Item 8 of this Annual Report on Form 10-K. Except for the historical information contained herein the foregoing discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those projected in the forward-looking statements discussed herein.

### Cautionary Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995.

Words such as "expects", "anticipates", "intends", "believes", "will" and similar words are used to identify forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements, including, but not limited to, the statements in the Risk Factors and other sections in this Annual Report on Form 10-K, are not based on historical facts, but rather reflect our current expectations concerning future results and events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, such statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be different from any future results, performance and achievements expressed or implied by these statements, including the risks outlined in the Risk Factors section and elsewhere in this Annual Report on Form 10-K. You are cautioned not to place undue reliance on these forward-looking statements. We undertake no obligation to publicly update or revise any forward-looking statements, whether as the result of new information, future events or otherwise.

### Overview

We are a specialty pharmaceutical company focused on:

development, licensing and sales of generic and branded pharmaceutical products and active pharmaceutical ingredients and the manufacturing of pharmaceuticals for others in Spain, other parts of Europe and international markets, including the U.S. market; and

research, development and licensing/commercialization of advanced proprietary drug delivery technologies for new and existing pharmaceutical products.

### *Branded and Generic Pharmaceuticals*

Our pharmaceutical product sales activities are based in Spain, where we have a significant commercial presence and we manufacture and market approximately 120 pharmaceutical products. These products represent various dosage strengths and product formulations of more than 30 chemical entities in four primary therapeutic areas: cardiovascular, gastrointestinal, neurological and infectious diseases. In 2004 approximately 30% of our product revenues were derived from two of our product lines. We market our branded and generic products to physicians, pharmacists and hospitals through our three separate sales and marketing organizations based in Spain: Laboratorios Belmac, Laboratorios Davur and Laboratorios Rimafar. As prices for prescription pharmaceuticals have been lowered in Spain by action of the Ministry of Health, which has authority to approve pharmaceutical prices, we are working to improve the efficiency of our manufacturing operations to reduce our costs, while also increasing sales. We have recently focused on increasing our sales in other European countries and other geographic regions through strategic alliances with distributors in these territories. We also target markets that offer compatible regulatory approval regimes and attractive product margins.

We also expect to grow our business by acquiring additional products to sell through our organization and our strategic alliances. We continually acquire rights to new products in response to increasing market demand for generic and branded therapeutic products and, when appropriate, we divest products that we consider to be redundant or that have become non-strategic. For example, in November 2004, we entered into a multi-product collaboration agreement with Perrigo Company, the largest U.S. manufacturer of over-the-counter pharmaceutical and nutritional products for the store brand market, to co-develop and market in the U.S. and potentially other markets selected generic pharmaceutical products that we produce in Spain.

We also manufacture pharmaceuticals for other drug companies. In April 2004, we purchased a manufacturing facility located in Spain that specializes in the manufacture of active pharmaceutical ingredients. The facility has been approved by the FDA for the manufacture of one ingredient for marketing and sale in the U.S. We are manufacturing and marketing these ingredients through our subsidiary, Bentley API. In addition, our Spanish pharmaceutical product manufacturing facility produces pharmaceutical products that are marketed by other pharmaceutical companies both in Spain and in other international markets.

*Proprietary Drug Delivery Technologies and Products*

We develop products that incorporate our drug delivery technologies that we have developed in the United States. We have licensed applications of our proprietary CPE-215 drug delivery technology to Auxilium Pharmaceuticals, Inc., which launched Testim the first product incorporating our CPE-215 drug delivery technology, in the United States in February 2003. Testim is a gel indicated for testosterone replacement therapy. In 2005 Testim was launched in Germany and received marketing authorizations in two additional European countries, bringing the total number of countries in which Testim is approved outside the U.S. to 11. We are also in discussions with other pharmaceutical and biotechnology companies to form additional strategic alliances to facilitate the development and commercialization of other products using our drug delivery technologies, including product candidates that deliver insulin to diabetic patients intranasally and to treat nail fungus infections topically.

**Consolidated Results of Operations**

*Fiscal Year Ended December 31, 2004 Compared To Fiscal Year Ended December 31, 2003*

*Revenues*

	2004		2003		Increase	
	\$	%	\$	%	\$	%
(in thousands)						
<b>Revenues:</b>						
Net product sales	\$ 69,942	95%	\$ 62,955	97%	\$ 6,987	11%
Licensing and collaboration revenues	3,451	5%	1,721	3%	1,730	101%
<b>Total revenues</b>	<b>\$ 73,393</b>	<b>100%</b>	<b>\$ 64,676</b>	<b>100%</b>	<b>\$ 8,717</b>	<b>13%</b>

Total revenues for the year ended December 31, 2004 increased 13% from the year ended December 31, 2003. However, our total revenues increased approximately 3% when expressed in constant currency. An increase in the weighted average value of the Euro, in relation to the U.S. Dollar, had the effect of increasing revenues by approximately \$6,502,000, partially offsetting the impact of price reductions in Spain. Sales of active pharmaceutical ingredients from our new manufacturing facility (included in "All other products" in the table below) added \$1,742,000 to our consolidated revenues in 2004. The advancement of our proprietary drug delivery programs in the U.S., evidenced by

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the growing royalty stream from sales of Testim, and other licensing revenues, increased our 2004 revenues by approximately \$1,730,000, when compared to the prior year.

Our revenues are generated through our primary sales channels of branded pharmaceuticals, generic pharmaceuticals, sales to licensees and others and licensing and collaboration revenues. The following is a summary of our revenues by sales channel and top-selling product lines:

For the year ended December 31, 2004 (in thousands):

Product Line	Revenues Within Spain			Revenues Outside of Spain	Total	% of Total Revenues
	Branded Products	Generic Products	Other			
Omeprazole	\$ 2,721	\$ 13,520	\$	\$	\$ 16,241	22%
Simvastatin	1,392	3,638			5,030	7%
Enalapril	3,192	1,243			4,435	6%
Paroxetine	1,045	2,928			3,973	5%
Codeisan	3,131				3,131	4%
All other products	6,910	7,690	576	1,166	16,342	23%
Sales to licensees and others			10,502	10,288	20,790	28%
Licensing and collaborations			607	2,844	3,451	5%
<b>Total Revenues</b>	<b>\$ 18,391</b>	<b>\$ 29,019</b>	<b>\$ 11,685</b>	<b>\$ 14,298</b>	<b>\$ 73,393</b>	<b>100%</b>
% of 2004 Revenues	25%	40%	16%	19%	100%	

For the year ended December 31, 2003 (in thousands):

Product Line	Revenues Within Spain			Revenues Outside of Spain	Total	% of Total Revenues
	Branded Products	Generic Products	Other			
Omeprazole	\$ 6,099	\$ 13,863	\$	\$	\$ 19,962	31%
Simvastatin	2,176	4,412			6,588	10%
Enalapril	2,610	1,878			4,488	7%
Paroxetine		749			749	1%
Codeisan	2,713				2,713	4%
All other products	5,463	6,065			11,528	18%
Sales to licensees and others			9,536	7,391	16,927	26%
Licensing and collaborations			203	1,518	1,721	3%
<b>Total Revenues</b>	<b>\$ 19,061</b>	<b>\$ 26,967</b>	<b>\$ 9,739</b>	<b>\$ 8,909</b>	<b>\$ 64,676</b>	<b>100%</b>
% of 2003 Revenues	29%	42%	15%	14%	100%	

*Spanish Operations.* The core of our Spanish operations has been the efficient manufacturing and domestic marketing of branded and generic pharmaceutical products. Historically, our pharmaceutical products were sold only within Spain. However, the execution of our long-term strategic plan has created an opportunity for our Spanish operations to expand beyond the borders of Spain and into other European countries and other countries outside of Europe. The 11% increase in net product sales for the year ended December 31, 2004 over the prior year was primarily due to an increase in the weighted average value of the Euro in relation to the U.S. Dollar, increased sales outside of Spain, increased sales of our paroxetine product line, which was initially launched in May 2003, and increases in sales of other generic products, such as trimetazidine, pentoxifylline and increases in sales to licensees and others. Our paroxetine product line generated net sales of \$3,973,000, representing 5% of our total revenues during 2004 and 37% of our total growth in 2004. These increases helped to offset or lessen the impact of price reductions in Spain, which are discussed below. Our revenues from our



omeprazole products in 2004 declined to 22% of our total revenues, compared to 31% in the prior year, due to reduced selling prices in Spain.

Prices for prescription pharmaceutical products in Spain must be approved by the Ministry of Health. For several years, the Ministry of Health has encouraged the substitution of generic-equivalent products in order to help control rising healthcare costs. In late October 2003, the Spanish government enacted a regulation that reduced the prices that the government reimburses for nine of our chemical entities, including the chemical entities omeprazole, simvastatin and enalapril, which accounted for approximately two thirds of revenues in the year ended December 31, 2003. We implemented these new prices on December 1, 2003.

Although the law required laboratories to begin selling at the new prices in December 2003, pharmacies in Spain were able to continue to sell at the old higher prices until January 31, 2004. This transition period was an attempt to reduce returns of the higher priced products by allowing the higher priced products to pass through the distribution channel to the end users. On average, our customers maintain a stock of approximately one to two months' supply of our products. As we began selling at the new lower prices on December 1, 2003 we expected the majority of our products that were labeled at the old higher prices to have cleared the distribution channel by January 31, 2004. We experienced an unforeseen level of returns totaling approximately \$3,323,000 in 2004. These product returns exceeded our allowance for estimated sales returns at that time. A majority of the products returned were either expired, nearing expiration or otherwise not resalable and consequently were destroyed.

The reduced selling prices resulted in a reduction in total revenues of approximately \$13,800,000 in 2004. Consequently our gross margins on pharmaceutical net product sales were negatively impacted, resulting in a decline in our gross margins from 58% in 2003 to 52% in 2004.

In response to the risk of government mandated price reductions, we implemented several initiatives which have effectively reduced our production costs on several of our products and increased our gross margins. These initiatives include the purchase of new high speed manufacturing equipment, new product launches, and increased sales volume and market share through strategic pricing. We expect to continue to increase our future sales volume through our pipeline of approximately 100 products. Additionally, in April 2004, we purchased a manufacturing facility, located in Zaragoza, Spain, which specializes in the manufacture of active pharmaceutical ingredients. The ability to manufacture active pharmaceutical ingredients has diversified our revenue base. We will continue to focus on acquiring, developing and launching new products that will improve our product mix. We will also continue our efforts to increase our sales outside of Spain through additional registration, marketing, and supply agreements. We will also continue to make significant investments in renovating and increasing capacity in our manufacturing facilities, as well as continued investments in new high speed, high volume equipment. We anticipate that our gross margins will gradually increase as we continue to implement our strategy and benefit from economies of scale.

*Branded Pharmaceutical Products*

	2004		2003		Change	
	\$	%	\$	%	\$	%
(in thousands)						
<b>Branded Product Sales:</b>						
Enalapril	\$ 3,192	17%	\$ 2,610	14%	\$ 582	22%
Codeisan	3,131	17%	2,713	14%	418	15%
Omeprazole	2,721	15%	6,099	32%	(3,378)	-55%
Mio Relax	1,485	8%	1,114	6%	371	33%
Simvastatin	1,392	8%	2,176	11%	(784)	-36%
All other branded products	6,470	35%	4,349	23%	2,121	49%
<b>Total branded sales</b>	<b>\$ 18,391</b>	<b>100%</b>	<b>\$ 19,061</b>	<b>100%</b>	<b>\$ (670)</b>	<b>-4%</b>

Sales of our branded pharmaceutical products decreased in 2004 by approximately 12% when expressed in constant currency. An increase in the weighted average value of the Euro, in relation to the U.S. Dollar, had the effect of increasing branded product sales by approximately \$1,675,000, resulting in a 4% decrease in branded pharmaceutical sales in the year ended December 31, 2004 when expressed in U.S. Dollars. Branded sales accounted for 25% of total revenues during 2004, compared to 29% of total revenues during 2003. Price reductions that took effect in December 2003 continued to negatively impact our branded product sales during 2004. Most significantly, sales of our branded omeprazole decreased by approximately \$3,378,000 from the prior year, as a result of the price reductions, although sales increased 2% during the year in terms of number of units sold. Sales of our branded enalapril, which experienced a 50% increase in unit volume compared to the prior year, increased 22% from the prior year in spite of price cuts, and now accounts for 17% of our branded product sales. Strong sales of our cough and cold medicine, Codeisan, and the launch of our branded version of paroxetine in May 2003 also helped to mitigate the impact of the price reductions.

*Generic Pharmaceutical Products*

	2004		2003		Change	
	\$	%	\$	%	\$	%
(in thousands)						
<b>Generic Product Sales:</b>						
Omeprazole	\$ 13,520	47%	\$ 13,863	51%	\$ (343)	-2%
Simvastatin	3,638	12%	4,412	16%	(774)	-18%
Paroxetine	2,928	10%	749	3%	2,179	291%
Pentoxifylline	2,622	9%	2,070	8%	552	27%
Trimetazidine	1,983	7%	532	2%	1,451	273%
All other generic products	4,328	15%	5,341	20%	(1,013)	-19%
<b>Total generic sales</b>	<b>\$ 29,019</b>	<b>100%</b>	<b>\$ 26,967</b>	<b>100%</b>	<b>\$ 2,052</b>	<b>8%</b>

Sales of our generic pharmaceutical products increased in terms of units sold, but decreased by approximately 2% in 2004 when expressed in constant currency. An increase in the weighted average value of the Euro, in relation to the U.S. Dollar, had the effect of increasing generic product sales by approximately \$2,643,000, resulting in an 8% increase in generic pharmaceutical sales in the year ended December 31, 2004, when expressed in U.S. Dollars. Sales of our generic omeprazole, which experienced an 8% increase in unit volume, decreased by 2% when expressed in U.S. Dollars as a result of price reductions that took effect in December 2003. These sales accounted for 47% of our



generic pharmaceutical revenues in 2004, compared to 51% of generic revenues in the prior year. Sales of our generic simvastatin, which experienced a 16% increase in unit volume, decreased by approximately 18%, when expressed in U.S. Dollars as a result of the price reductions. Our generic paroxetine, which was launched in May 2003, added approximately \$2,179,000 to our generic sales in 2004, when compared to 2003, positioning it third behind our generic omeprazole and simvastatin products. Sales of our generic trimetazidine increased by approximately \$1,451,000 in 2004, or approximately 273% from 2003, while sales of our generic pentoxifylline increased by \$552,000, or approximately 27%.

*Sales to Licensees and Others*

	2004	2003	Increase	
			\$	%
(in thousands)				
Sales to licensees and others	\$ 20,790	\$ 16,927	\$ 3,863	23%

In addition to manufacturing and selling products our own branded and generic products, we license the right to market products to others within and outside of Spain. These license agreements are usually accompanied by long-term exclusive supply agreements, whereby our licensees purchase the licensed products from our manufacturing facility. As of December 31, 2004, our Spanish operations have executed 119 license agreements, of which 14 with customers in Spain and 41 with customers outside of Spain, cover actively marketed products that are generating revenues. The remaining licenses, four with customers in Spain and 60 with customers outside of Spain, are for products that are awaiting regulatory approvals. Additionally, we have 15 contract manufacturing agreements in effect in Spain and 6 contract manufacturing agreements in effect for international customers. Our clients market these products under their own name and with their own labeling. Many of the products we manufacture for others use the same active ingredients that are used in our own marketed products. Sales under these agreements increased by 23%, 12% in constant currency, over the prior year. An increase in the weighted average value of the Euro, in relation to the U.S. Dollar, had the effect of increasing our revenues from sales to licensees and others by approximately \$1,894,000.

*Licensing and Collaboration Revenues.* Licensing and collaboration revenues now account for 5% of total revenues and increased by approximately \$1,730,000, or approximately 101%, in 2004. These revenues include royalties totaling \$2,844,000 from the commercialization and continued sales of Testim, the first product incorporating our CPE-215 drug delivery technology, which was launched by our licensee, Auxilium, in February 2003. Testim is currently reported to capture approximately 12% - 13% of all new testosterone replacement prescriptions in the market. Also included in *licensing and collaboration revenues* in 2004 are revenues of approximately \$607,000 related to product licensing activities in Europe.

*Gross Profit.* Gross profit decreased by approximately 7% in constant currency in 2004 as a direct result of the December 2003 price reductions in Spain. An increase in the weighted average value of the Euro, in relation to the U.S. Dollar, had the effect of increasing gross profit by approximately \$3,359,000. Gross margins on net product sales decreased from 58% in 2003 to 51% in 2004 (52% gross margins on sales of pharmaceutical products, excluding sales of active pharmaceutical ingredients). Product returns, including returns related to the government mandated price reductions, reduced 2004 revenues by approximately \$3,323,000. Product returns decreased to levels consistent with our historical experience by June 2004. In 2005 the Spanish government temporarily suspended the reference-price system that was implemented by the Spanish government in late 2003 and proposed a 67-point plan to replace the reference system. The new plan includes a 4.2% price reduction in 2005 (and an additional 2% reduction in 2006) on only those drugs that have been on the market in Spain



