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)

ý 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

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 for the transition period from to

Commission file number 1-10581

BENTLEY PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**No. 59-1513162**
(State or other jurisdiction of incorporation or organization)	(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
Common Stock, $.02 par value	**New York Stock Exchange and Pacific Exchange**
Preferred Stock Purchase Rights	**New York Stock Exchange and Pacific Exchange**

Securities registered pursuant to Section 12(g) of the Act: **None**

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

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. ý

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

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
Common Stock, $.02 par value	**$200,072,468**	**June 30, 2004**

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
Common Stock, $.02 par value	**21,317,677**	**March 14, 2005**

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.

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.

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.

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

Our Generic Product Name	Active Ingredient	Innovator Product	Used to Treat
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
Mirtazapina 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®	trimetazedine	Idaptan® (Servier)	coronary therapy
Zolpidem Davur®	zolpidem tartrate	Ambien® (Sanofi-Synthelabo)	insomnia

Strategic Alliance with Teva

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.

Product Candidate	Technology	Used to Treat	Status
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 72nd 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.

	High	Low
Fiscal Year Ended December 31, 2003		
First Quarter	$ 9.70	$ 7.85
Second Quarter	14.05	8.20
Third Quarter	18.80	12.81
Fourth Quarter	17.15	11.34
Fiscal Year Ended December 31, 2004		
First Quarter	14.76	10.62
Second Quarter	14.10	11.20
Third Quarter	13.89	9.52
Fourth Quarter	11.40	8.35
Fiscal Year Ending December 31, 2005		
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.

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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,				
	2000	**2001**	**2002**	**2003**	**2004(a)**
	(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
Currrent 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

					Increase	
	2004	**%**	**2003**	**%**	**$**	**%**
	(in thousands)					
Revenues:						
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%
Total revenues	$ 73,393	100%	$ 64,676	100%	$ 8,717	13%

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

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):

	Revenues Within Spain					
Product Line	**Branded Products**	**Generic Products**	**Other**	**Revenues Outside of Spain**	**Total**	**% of Total Revenues**
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%
Total Revenues	$ 18,391	$ 29,019	$ 11,685	$ 14,298	$ 73,393	100%
% of 2004 Revenues	25%	40%	16%	19%	100%	

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

	Revenues Within Spain					
Product Line	**Branded Products**	**Generic Products**	**Other**	**Revenues Outside of Spain**	**Total**	**% of Total Revenues**
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%
Total Revenues	$ 19,061	$ 26,967	$ 9,739	$ 8,909	$ 64,676	100%
% 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 trimetazedine, 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

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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 $	Change %
	(in thousands)					
Branded Product Sales:						
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%
Total branded sales	$ 18,391	100%	$ 19,061	100%	$ (670)	-4%

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 $	Change %
	(in thousands)					
Generic Product Sales:						
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%
Total generic sales	$ 29,019	100%	$ 26,967	100%	$ 2,052	8%

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

			Increase	
	2004	2003	$	%
	(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

for over one year and were not already subject to the reference-price reductions effected in December 2003.

Selling and Marketing Expenses

	2004	2003	Increase $	Increase %
	(in thousands)			
Selling and marketing	$ 14,808	$ 14,212	$ 596	4%

Selling and marketing expenses decreased by approximately 5% in constant currency in 2004; however, an increase in the weighted average value of the Euro, in relation to the U.S. Dollar, had the effect of increasing selling and marketing expenses by approximately $1,351,000, resulting in a net increase of 4% when expressed in U.S. Dollars. Selling and marketing expenses as a percentage of net product sales decreased to 21% in 2004, compared to 23% of net product sales in 2003.

General and Administrative Expenses

	2004	2003	Increase $	Increase %
	(in thousands)			
General and administrative	$ 9,126	$ 7,001	$ 2,125	30%

General and administrative expenses for 2004 increased 30% over the prior year. The $2,125,000 increase was the result of increased general and administrative activities required to support our continued growth and prepare for our anticipated growth in the future. These expenditures include increased costs in the current year for additional employees, outside services, insurance and other costs to support the growth of our organization and costs associated with our response to the requirements of the Sarbanes-Oxley Act of 2002. General and administrative expenses would have been approximately $460,000 lower, absent the 2004 increase in the weighted average value of the Euro, in relation to the U.S. Dollar. General and administrative expenses as a percent of total revenues increased to approximately 12% in 2004, from approximately 11% of total revenues in 2003.

Research and Development Expenses

	2004	2003	Increase $	Increase %
	(in thousands)			
Research and development	$ 4,419	$ 4,295	$ 124	3%

Research and development expenses in 2004 remained consistent with 2003 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 research and development expenses by approximately $114,000, representing 92% of the increase when expressed in U.S. Dollars.

In the first quarter of 2004, we completed and reported the results of a Phase I intranasal insulin trial. Our Phase I trial demonstrated the effective delivery of insulin intranasally in healthy human subjects. We have recently completed the in-patient stage of a Phase II study of our clinical program for the intranasal delivery of insulin and are in the data analysis and reporting stages of that study. Additionally, we initiated certain clinical programs to support our strategy for the eventual distribution of certain of our Spanish generic pharmaceutical products in other countries, including the U.S. In order to further our strategy, we entered into a multi-product collaboration agreement with Perrigo

Company to co-develop and market certain generic pharmaceutical products in the U.S. and potentially other markets. We expect to continue to incur costs to conduct clinical trials and support the required regulatory submissions for our clinical programs. We also incur costs related to pre-clinical programs for product formulation and testing efforts being performed in the laboratory in our U.S. headquarters and at our facilities in Spain. The expenditures in research and development reflect our focus on projects that are necessary for expansion of our portfolio of marketed products and clinical trials involving our drug delivery technologies. Although some of our cost estimates are preliminary, and the specific timing is not known, we project that our research and development expenses in 2005 could be approximately $1,500,000 higher than in the year ended December 31, 2004.

Other income (expenses)

			Change	
	2004	2003	$	%
	(in thousands)			
Other income (expenses)	$ 1,800	$ 91	$ 1,709	*

*

Not meaningful

Other income (expenses) for the year ended December 31, 2004 increased by $1,709,000 over the same period in the prior year. The increase is primarily due to the reversal of previously accrued tax assessments totaling $1,467,000 partially offset by interest and penalties totaling $193,000 associated with the settlement of the tax audit of our Spanish subsidiary (see *Provision for Income Taxes*) during the second quarter of 2004. We recorded a pre-tax benefit totaling $1,467,000 ($954,000 after taxes) as a component of *other income (expenses)* as the result of the reversal of previously accrued pharmaceutical tax assessments in Spain. These assessments had been accrued to be paid to the Spanish government to help reduce the impact of the rising health care costs in Spain. Due to recent changes in the pharmaceutical industry in Spain and a change in the Spanish political environment, the basis for these liabilities no longer exists. Accordingly, these accruals were reversed during the second quarter of 2004.

Provision for Income Taxes

	2004		
	Spain	U.S.	Consolidated
	(in thousands)		
Income (loss) before income taxes	$ 13,408	$ (2,913)	$ 10,495
Provision (benefit) for income taxes	4,693	(990)	3,702
Tax credits, changes in deferred taxes and other	(492)	1,807	1,315
Tax liability, 1998 2000 audit	604		604
Total provision (benefit) for income taxes	4,805	817	5,622
Valuation allowance		(817)	(817)
Net provision (benefit) for income taxes	4,805		4,805
Net income (loss)	$ 8,603	$ (2,913)	$ 5,690
Effective tax rate	36%	0%	46%

A tax review of our Spanish subsidiary, Laboratories Belmac S.A., by the Spanish tax authorities for the tax years 1998, 1999 and 2000, was completed in the quarter ended June 30, 2004. As a result of this audit, our subsidiary was assessed an additional tax liability of approximately $604,000, which has

been recorded as a component of *provision for income taxes* for the year ended December 31, 2004, and approximately $193,000 for related interest and penalties, which have been recorded as components of *other income and expenses,* in the consolidated income statement for the year ended December 31, 2004.

We have recorded provisions for foreign income taxes totaling $4,805,000 ($4,201,000 income tax expense on operations plus $604,000 recorded as a result of the 1998 2000 tax audit of our Spanish subsidiary) for the year ended December 31, 2004, compared to $5,423,000 for the year ended December 31, 2003. The effective tax rate in Spain for the year ended December 31, 2004 was 36%; however, when the $604,000 tax audit settlement related to prior years is excluded, the effective tax rate is 31%, compared to the prior year effective rate of 34%. The provision for foreign income taxes would have been approximately $457,000 lower than reported, absent the increase in the weighted average value of the Euro, in relation to the U.S. Dollar, during the year ended December 31, 2004.

We generated additional U.S. federal net operating loss carry-forwards in the year ended December 31, 2004 and 2003 as a result of U.S. pre-tax losses of $2,913,000 and $3,571,000, respectively. As future domestic operating profits cannot be reasonably assured, no tax benefit has been recorded for U.S. losses. Accordingly, we have established a valuation allowance equal to the full amount of the U.S. deferred tax assets.

Should we determine that it is more likely than not that we will realize certain of our net deferred tax assets for which we have previously provided a valuation allowance, an adjustment would be required to reduce the existing valuation allowance. In addition, we operate within multiple taxing jurisdictions and are subject to audit in those jurisdictions. These audits can involve complex issues, which may require an extended period of time for resolution. During 2004, we identified certain tax contingencies that we determined are probable and reasonably estimable. Consequently, we have included a charge totaling $188,000 related to these contingencies in the *provision for income taxes* for the year ended December 31, 2004. No other potential tax contingencies were considered to be probable and reasonably estimable as of December 31, 2004. However, there is the possibility that the ultimate resolution of such potential contingencies could have an adverse effect on our Consolidated Financial Statements in the future.

Net Income

			Change	
	2004	2003	$	%
	(in thousands)			
Net income	$ 5,690	$ 6,097	$ (407)	-7%
Net income per common share:				
Basic	$ 0.27	$ 0.34	$ (0.07)	-21%
Diluted	$ 0.25	$ 0.28	$ (0.03)	-11%
Weighted average common shares outstanding:				
Basic	20,901	17,997	2,904	16%
Diluted	22,627	21,637	990	5%

We reported 2004 income from operations of $8,695,000, compared to 2003 income from operations of $11,429,000. In 2004, the combination of income from operations of $8,695,000 and the non-operating items, primarily the provision for income taxes of $4,805,000, resulted in 2004 net income of $5,690,000, or $.27 per basic common share ($.25 per diluted common share) on 20,901,000 weighted average basic common shares outstanding (22,627,000 weighted average diluted common shares outstanding), compared to 2003 net income of $6,097,000, or $.34 per basic common share ($.28 per diluted common share) on 17,997,000 weighted average basic common shares outstanding (21,637,000 weighted average diluted common shares outstanding).

Fiscal Year Ended December 31, 2003 Compared To Fiscal Year Ended December 31, 2002

Revenues

	2003	%	2002	%	Increase $	Increase %
	(in thousands)					
Revenues:						
Net product sales	$ 62,955	97%	$ 38,718	99%	$ 24,237	63%
Licensing and collaboration revenues	1,721	3%	418	1%	1,303	312%
Total revenues	$ 64,676	100%	$ 39,136	100%	$ 25,540	65%

Our total revenues increased 65% from 2002. The increase is primarily attributed to the continuing growth of our Spanish operations and secondarily to the advancement of our proprietary drug delivery programs in the U.S., as evidenced by the launch of Testim.

The following is a summary of our revenues by sales channel and top-selling product lines below:

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

	Revenues Within Spain					
Product Line	Branded Products	Generic Products	Other	Revenues Outside of Spain	Total	% of Total Revenues
Omeprazole	$ 6,099	$ 13,863	$	$	$ 19,962	31%
Simvastatin	2,176	4,412			6,588	10%
Enalapril	2,610	1,878			4,488	7%
Codeisan	2,713				2,713	4%
Pentoxifylline		2,070			2,070	3%
All other products	5,463	4,744			11,528	16%
Sales to licensees and others			9,536	7,391	16,927	26%
Licensing and collaborations			203	1,518	1,721	3%
Total Revenues	$ 19,061	$ 26,967	$ 9,739	$ 8,909	$ 64,676	100%
% of 2003 Revenues	29%	42%	15%	14%	100%	

For the year ended December 31, 2002 (in thousands):

	Sales Within Spain					
Product Line	Branded Products	Generic Products	Contract Manufacturing	Other Revenues	Total	% of Total Revenues
Omeprazole	$ 5,051	$ 9,813	$	$	$ 14,864	38%
Simvastatin	322	1,261			1,583	4%
Enalapril	955	1,515			2,470	6%
Codeisan	1,944				1,944	5%
Pentoxifylline		1,348			1,348	3%
All other products	4,103	2,738			6,841	18%
Sales to licensees and others			7,406	2,262	9,668	25%
Licensing and collaborations				418	418	1%

	Sales Within Spain					
Total Revenues	$ 12,375	$ 16,675	$ 7,406	$ 2,680	$ 39,136	100%
% of 2002 Revenues	32%	43%	19%	6%	100%	

Spanish Operations. The 65% growth in revenues was fueled by an increase in sales of our two major product lines, omeprazole and simvastatin. Sales of omeprazole and simvastatin increased 61% to $26,550,000 in 2003 compared to $16,447,000 in 2002. The growth of these two product lines accounted for 40% of our growth in revenues in the current year. 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 $10,449,000, or 27%, during the year ended December 31, 2003.

Branded Pharmaceutical Products

					Increase	
	2003	%	2002	%	$	%
	(in thousands)					
Branded Product Sales:						
Simvastatin	$ 2,176	11%	$ 322	2%	$ 1,854	576%
Enalapril	2,610	14%	955	8%	1,655	173%
Omeprazole	6,099	32%	5,051	41%	1,048	21%
Codeisan	2,713	14%	1,944	16%	769	40%
All other branded products	5,463	29%	4,103	33%	1,360	33%
Total branded sales	$ 19,061	100%	$ 12,375	100%	$ 6,686	54%

Sales of our branded pharmaceutical products increased by 54% compared to 2002, although they accounted for only 29% of total revenues in 2003 compared to 32% in 2002. Sales of our branded simvastatin increased by approximately $1,854,000, or approximately 576% from 2002. Sales of our branded enalapril increased by approximately $1,655,000, or approximately 173% from 2002. Sales of our branded omeprazole increased by approximately $1,048,000, or 21% from 2002. Sales of our branded codeisan increased by approximately $769,000, or approximately 40% from 2002. While we expect to continue to develop, acquire, and launch new branded products, our focus on generics and sales outside of Spain are expected to increase at a significantly higher pace than that of our branded products. An increase in the weighted average value of the Euro, in relation to the U.S. Dollar, had the effect of increasing branded net product sales by approximately $3,153,000, or 25%, during the year ended December 31, 2003.

Generic Pharmaceutical Products

					Increase	
	2003	%	2002	%	$	%
	(in thousands)					
Generic Product Sales:						
Omeprazole	$ 13,863	51%	$ 9,813	59%	$ 4,050	41%
Simvastatin	4,412	16%	1,261	8%	3,151	250%
Pentoxifylline	2,070	8%	1,348	8%	722	54%
Enalapril	1,878	7%	1,515	9%	363	24%
All other generic products	4,744	18%	2,738	16%	2,006	73%
Total generic sales	$ 26,967	100%	$ 16,675	100%	$ 10,292	62%

Sales of our generic pharmaceutical products increased by 62% compared to 2002. Sales of our generic omeprazole increased by approximately $4,050,000, or approximately 41% from 2002. Sales of our generic simvastatin increased by approximately $3,151,000, or approximately 250% from 2002. Sales of our generic pentoxifylline increased by approximately $722,000, or approximately 54% from 2002. Generic products launched in 2003, such as trimetazedine and paroxetine, accounted for approximately

$1,600,000 of our 2003 revenues. An increase in the weighted average value of the Euro, in relation to the U.S. Dollar, had the effect of increasing generic net product sales by approximately $4,461,000, or 27%, during the year ended December 31, 2003.

Sales to licensees and others

			Increase	
	2003	2002	$	%
	(in thousands)			
Sales to licensees and others	$ 16,927	$ 9,668	$ 7,259	75%

In addition to manufacturing our own products, our Spanish manufacturing facility supplies branded and generic products to 14 entities in Spain which market these products under their own name and with their own labeling. Additionally, we have entered into license and supply agreements with more than 15 entities to sell our products outside of Spain. Revenues generated in 2003 from sales to licensees and others have increased by approximately 75% from 2002, and represented 26% of total revenues in 2003, compared to 25% of total revenues in 2002. An increase in the weighted average value of the Euro, in relation to the U.S. Dollar, had the effect of increasing revenues generated by sales to licensees and others by approximately $2,800,000, or 29%, during the year ended December 31, 2003.

Licensing and Collaboration Revenues. Licensing and collaboration revenues now account for 3% of total revenues and increased by approximately $1,303,000, or approximately 312%, in 2003 and include milestone payments and royalties from the commercialization and continued sales of Testim. We have also recognized revenues totaling $203,000 during the year ended December 31, 2003, related to product licensing activities in Europe, which we have included in the Consolidated Income Statements as *licensing and collaboration revenues*.

Gross Profit. Gross profit increased by approximately 69% from 2002. Approximately $14,315,000, or 92% of the increase, is due to the 63% increase in net product sales (and slightly improved gross margins in 2003) and $1,303,000, or 8% of the increase, is due to the increased licensing and collaboration revenues in the current year. Our gross margins on net product sales in 2003 increased slightly to 58.0% compared to 57.4% in 2002 as a result of economies of scale (allocation of fixed costs over a larger number of units, reducing the per-unit cost), partially offset by lower margins of generic products, which typically have lower prices, and the sales of certain of our products in the month of December 2003 at reduced selling prices. We experienced an increase in gross profit of 42% in local currency in 2003 compared to 2002. 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 $6,065,000 during the year ended December 31, 2003.

Selling and Marketing Expenses

			Increase	
	2003	2002	$	%
	(in thousands)			
Selling and marketing	$ 14,212	$ 10,400	$ 3,812	37%

Selling and marketing expenses increased by approximately 37% from 2002. The $3,812,000 increase, of which approximately 75% represented increased sales force costs and approximately 25% represented increased promotion and marketing programs, was instrumental in achieving a 63% increase in net product sales. However, the increase in the weighted average value of the Euro, in relation to the U.S. Dollar, had the effect of increasing selling and marketing expenses by

approximately $2,361,000 in 2003, accounting for approximately 62% of the increase. Selling and marketing expenses as a percentage of net product sales decreased to 23% in 2003 compared to 27% of net product sales in 2002.

General and Administrative Expenses

			Increase	
	2003	2002	$	%
	(in thousands)			
General and administrative	$ 7,001	$ 4,902	$ 2,099	43%

General and administrative expenses increased 43% from 2002. The $2,099,000 increase was the result of increased general and administrative activities required to support our revenue growth in 2003 and prepare for our anticipated future growth. Such expenditures included costs of additional employees, outside services, occupancy costs, corporate communications, insurance, etc. General and administrative expenses as a percent of total revenues decreased to 11% in 2003, compared to 13% of total revenues in 2002. General and administrative expenses would have been approximately $642,000 lower in 2003, absent the increase in the weighted average value of the Euro, in relation to the U.S. Dollar.

Research and Development Expenses

			Increase	
	2003	2002	$	%
	(in thousands)			
Research and development	$ 4,295	$ 2,960	$ 1,335	45%

Research and development expenses increased approximately 45% from 2002. The $1,335,000 increase is due to pre-clinical programs underway in collaboration with universities and with product formulation and testing efforts being performed in the laboratory in our U.S. headquarters and at our facility in Zaragoza, Spain.

Provision for Income Taxes

	2003		
	Spain	U.S.	Consolidated
	(in thousands)		
Income (loss) before income taxes	$ 15,091	$ (3,571)	$ 11,520
Provision (benefit) for income taxes	5,092	(1,017)	4,075
Valuation allowance		1,348	1,348
Net provision (benefit) for income taxes	5,092	331	5,423
Net income (loss)	$ 9,999	$ (3,902)	$ 6,097
Effective tax rate	34%	(9)%	47%

We recorded a provision for foreign income taxes totaling $5,092,000 (approximately 34% of the Spanish pretax income of $15,091,000) for the year ended December 31, 2003 compared to a provision for foreign income taxes of $2,534,000 (approximately 37% of the Spanish pretax income of $6,913,000) in 2002. The 2003 provision for Spanish income taxes results from reporting taxable income from operations in Spain, whereas the 2002 Spanish provision for income taxes included approximately $2,304,000 as a result of reporting taxable income from

operations in Spain and approximately $230,000 as a result of capital gains taxes arising from the sale of Biolid®, Lactoliofil® and other drug licenses.

The 2003 provision for foreign income taxes would have been approximately $854,000 lower than reported, absent the increase in the weighted average value of the Euro, in relation to the U.S. Dollar.

Our U.S. Company recorded a provision for foreign income taxes payable totaling $331,000 for the year ended December 31, 2003. This amount represents payments due to the Spanish tax authorities by our U.S. Company for withholding taxes on certain of our intercompany fee arrangements with our Spanish subsidiaries. No such amounts were recorded in prior years.

We generated additional U.S. federal net operating loss carry-forwards in 2003 and 2002 as a result of U.S. pretax losses of ($3,571,000) and ($2,743,000), respectively. However, since we are not assured of future profitable domestic operations, we have recorded a valuation allowance for any future tax benefit of such losses in the U.S. Therefore, no tax benefit has been recognized with respect to U.S. losses reported in 2003 or 2002.

Net Income

			Increase	
	2003	**2002**	**$**	**%**
	(in thousands)			
Net income	$ 6,097	$ 1,636	$ 4,461	273%
Net income per common share:				
Basic	$ 0.34	$ 0.10	$ 0.24	243%
Diluted	$ 0.28	$ 0.08	$ 0.20	241%
Weighted average common shares outstanding:				
Basic	17,997	16,569	1,428	9%
Diluted	21,637	19,798	1,839	9%

We reported 2003 income from operations of $11,429,000 compared to 2002 income from operations of $4,032,000 (including the $650,000 pre-tax gain on sale of the Biolid, Lactoliofil and other drug licenses). The combination of income from operations of $11,429,000 and the non-operating items, primarily the provision for income taxes of $5,423,000, resulted in 2003 net income of $6,097,000, or $.34 per basic common share ($.28 per diluted common share) on 17,997,000 weighted average basic common shares outstanding (21,637,000 weighted average diluted common shares outstanding), compared to 2002 net income of $1,636,000, or $.10 per basic common share ($.08 per diluted common share) on 16,569,000 weighted average basic common shares outstanding (19,798,000 weighted average diluted common shares outstanding).

Selected Quarterly Financial Data

The following table sets forth certain operating data for our last eight quarters. We have derived this data from our unaudited quarterly financial statements.

	Fiscal 2003				Fiscal 2004			
	Three Months Ended (Unaudited)							
	3/31/2003	6/30/2003	9/30/2003	12/31/2003	3/31/2004	6/30/2004(a)	9/30/2004	12/31/2004
	(in thousands, except per share data)							
Total revenues	$ 14,988	$ 16,754	$ 14,875	$ 18,059	$ 17,302	$ 18,470	$ 18,103	$ 19,518
Cost of net product sales	6,121	6,819	5,744	7,715	8,196	8,396	8,568	9,391
Gross profit	8,867	9,935	9,131	10,344	9,106	10,074	9,535	10,127
Operating expenses	6,213	6,619	6,290	7,726	7,433	7,491	7,016	8,207
Gain on sale of drug licenses								
Income from operations	2,654	3,316	2,841	2,618	1,673	2,583	2,519	1,920
Other income (expenses)	29	18	20	24	57	1,348	238	157
Provision for income taxes	1,151	1,805	1,513	954	921	2,441	1,344	99
Net income	$ 1,532	$ 1,529	$ 1,348	$ 1,688	$ 809	$ 1,490	$ 1,413	$ 1,978
Net income per common share:								
Basic	$ 0.09	$ 0.09	$ 0.08	$ 0.09	$ 0.04	$ 0.07	$ 0.07	$ 0.09
Diluted	$ 0.08	$ 0.07	$ 0.06	$ 0.08	$ 0.04	$ 0.07	$ 0.06	$ 0.09
Weighted average common shares outstanding:								
Basic	17,455	17,534	17,911	19,071	20,597	20,644	21,049	21,308
Diluted	20,350	20,878	22,228	22,418	22,784	22,800	22,746	22,487

(a) *Other income (expenses)* for the three months ended June 30, 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.

Liquidity and Capital Resources

Total assets increased 21% from $100,463,000 at December 31, 2003 to $121,930,000 at December 31, 2004, while stockholders' equity increased 18% from $76,165,000 at December 31, 2003 to $89,657,000 at December 31, 2004. The increase in stockholders' equity reflects primarily net income of $5,690,000, the positive impact of the fluctuation of the Euro/US Dollar exchange rate which totaled $4,553,000 and the net proceeds from the exercise of stock options and warrants totaling $3,083,000.

Working capital increased 2% from $46,181,000 at December 31, 2003 to $47,114,000 at December 31, 2004, primarily as a result of proceeds from exercises of options and warrants totaling $3,083,000 and profits during the year ended December 31, 2004. These amounts were partially offset by additions to fixed assets and the purchase of active pharmaceutical ingredient manufacturing assets, as well as investments in drug licenses.

Cash, cash equivalents and marketable securities decreased 14% from $40,645,000 at December 31, 2003 to $34,758,000 at December 31, 2004, primarily as a result of additions to fixed assets totaling $10,049,000, the purchase of API manufacturing assets for $3,309,000, and additions to drug licenses and related costs of $1,204,000, partially offset by net proceeds received from exercises of stock options and warrants totaling $3,083,000 and cash provided by operating activities of $4,233,000. Also included in cash and cash equivalents at December 31, 2004 are approximately $3,684,000 of short-term liquid investments considered to be cash equivalents.

Receivables increased from $18,036,000 at December 31, 2003 to $27,860,000 at December 31, 2004 as a direct result of the increase in net product sales and the effect of fluctuations in foreign currency exchange rates. Trade receivables comprise 85% of total 2004 receivables, totaling $23,586,000. Receivables at December 31, 2004 also include royalties receivable totaling $1,882,000 and taxes receivable totaling $2,428,000. Receivables increased by approximately $7,867,000 in local currency, and fluctuations in foreign currency exchange rates further increased receivables reported in U.S. Dollars by approximately $1,957,000. Write-offs of our receivables representing uncollectible accounts have not had a material effect on our financial position, results of operations or cash flows. Inventories increased from $7,106,000 at December 31, 2003 to $10,258,000 at December 31, 2004, primarily as a result of raw materials purchases and strategic increases in finished goods inventories in anticipation of continuing demand for our generic products. Inventories increased by approximately $2,333,000 in local currency, and fluctuations in foreign currency exchange rates further increased inventories reported in U.S. Dollars by approximately $819,000.

The combined total of accounts payable and accrued expenses increased from $17,257,000 at December 31, 2003 to $23,217,000 at December 31, 2004, primarily due an increase in co-marketing costs payable of approximately $2,481,000, increases in amounts owed for purchases of fixed assets and drug licenses of $2,265,000 and the effect of fluctuations in foreign currency exchange rates (approximately $1,787,000), partially offset by a $1,467,000 decrease in accrued expenses as a result of the reversal of previously accrued tax assessments.

Short-term borrowings and current portion of long-term debt increased from $1,985,000 at December 31, 2003 to $2,785,000 at December 31, 2004, as a result of additional net borrowings of approximately $595,000 and the effect of fluctuations in foreign currency exchange rates. The weighted average interest rate on our short-term borrowings is 5.0%.

Long-term debt, which totaled $369,000 at December 31, 2003, decreased to $349,000 during the year ended December 31, 2004, as a result of classifying $31,000, the amount due within one year, as current portion of long-term debt. This decrease was partially offset by imputed interest on interest-free loans in Spain and the effect of fluctuations in foreign currency exchange rates. The weighted average interest rate (including imputed interest) on our long-term debt is 5.7%.

Contractual Obligations

In addition to our short-term borrowings and long-term debt, we have fixed contractual obligations under various lease agreements. Our contractual obligations were comprised of the following as of December 31, 2004 (in thousands):

		Payments Due By Period			
	Total	Less than 1 year	1-3 years	4-6 years	7-10 years
		(in thousands)			
Long-term debt, including imputed interest of $65	$ 445	$ 31	$ 146	$ 251	$ 17
Capital leases					
Operating leases	2,131	1,167	964		
Purchase obligations(1)	2,234	2,234			
Other long-term liabilities(2)	2,319	334	1,029	956	
Total contractual cash obligations (3)	$ 7,129	$ 3,766	$ 2,139	$ 1,207	$ 17

(1) Included in purchase obligations are contractual obligations for the purchase of machinery, construction and engineering services and a new inventory management software application. The construction and engineering services and new inventory management software application are associated with the expansion of our manufacturing facilities in Zaragoza, Spain. Purchase orders

or contracts for the purchase of raw materials and other goods and services are not included in the table above as our purchase orders represent authorizations to purchase rather than binding agreements. For the purposes of this table, contractual obligations for purchase of goods or services are defined as agreements that are enforceable and legally binding and that specify all significant terms, including: fixed or minimum quantities to be purchased; fixed, minimum or variable price provisions; and the approximate timing of the transaction. Our purchase orders are based on our current manufacturing needs and are fulfilled by our vendors within short time frame. We do not have agreements for the purchase of raw materials or other goods specifying minimum quantities. We also enter into contracts for outsourced services including payroll, information technology and maintenance; however, the obligations under these contracts are not significant and the contracts contain clauses allowing for cancellation at will, without significant penalty.

(2)

Other long-term liabilities represents other long-term liabilities as reflected in the Company's Consolidated Balance Sheet as of December 31, 2004 excluding long-term deferred income of approximately $1,944,000 and long-term debt and related imputed interest of approximately $445,000. These amounts are primarily tax payments due to the Spanish Ministry of Taxes from the sale of certain drug licenses in prior years.

(3)

Not included in the chart above are key executive compensation agreements that have been renewed whereby the Company is currently obligated to pay approximately $1,500,000 to its key executives in 2005. Such agreements renew annually unless terminated by any of the parties.

The expected timing of payments of the obligations discussed above are estimated based on current information. Timing of payments and actual amounts paid may be different depending on the time of receipt of goods or services or changes to agreed-upon amounts for obligations. Amounts disclosed as contingent or milestone-based obligations are dependent on the achievement of the milestones or the occurrence of the contingent events and can vary significantly.

Operating activities for the year ended December 31, 2004 provided net cash of $4,233,000. Investing activities, primarily additions to machinery and equipment and capital improvements made to the manufacturing facility in Spain, the purchase of active pharmaceutical ingredients manufacturing assets and additions to drug licenses used net cash of $13,687,000 during the year ended December 31, 2004. Financing activities, consisting primarily of the proceeds received from the exercise of stock options and warrants (approximately $3,083,000), and proceeds from net borrowings (approximately $595,000) provided net cash of $3,678,000 during the year ended December 31, 2004.

In accordance with the terms of the license agreement whereby we granted to Auxilium an exclusive royalty-based worldwide license, to develop, market and sell a topical testosterone gel containing our CPE-215 technology, we have been earning and receiving royalty payments from Auxilium on Testim sales since the product launch in early 2003 and we expect to continue receiving royalty payments for the foreseeable future.

We plan to continue making improvements to our manufacturing facilities during 2005 that include the acquisition of additional manufacturing equipment and expansion of our active pharmaceutical ingredients manufacturing facility, in order to accommodate our expected growth. We have budgeted approximately $19,200,000 for capital expenditures during 2005. We plan to finance these expenditures from a combination of cash flow from operations and borrowings.

Seasonality, Effect of Inflation and Liquidity. In the past, we have experienced lower sales in the third calendar quarter and higher sales in the fourth calendar quarter due to seasonality of our pharmaceutical business. As we market more pharmaceutical products whose sales are seasonal, seasonality of sales may become more significant. Neither inflation nor changing prices has materially impacted our revenues or income from operations for the periods presented. We expect to have

sufficient liquidity to fund operations for at least the next twenty-four months. We continue to search both domestically and internationally for opportunities that will enable us to continue expanding our business and explore alternative financing sources for these activities, including the possibility of public and/or private offerings of our securities. In appropriate situations, that will be strategically determined, we may seek financial assistance from other sources, including contribution by others to joint ventures and other collaborative or licensing arrangements for the development, testing, manufacturing and marketing of products under development.

Off-Balance-Sheet Arrangements

We do not have any significant off-balance-sheet arrangements, as defined in Item 303(a)(4)(ii) of SEC Regulation S-K.

Critical Accounting Policies and Estimates

Our significant accounting policies are more fully described in Note 2 to our consolidated financial statements in this Annual Report on Form 10-K for the year ended December 31, 2004. However, certain of our accounting policies are particularly important to the portrayal of our financial position, and results of operations and cash flows and require the application of significant judgment by our management; as a result they are subject to an inherent degree of uncertainty. In applying those policies, our management uses its judgment to determine the appropriate assumptions to be used in the determination of certain estimates. Those estimates are based on our historical experience, terms of existing contracts, our observance of trends in the industry, information provided by our customers and information available from other outside sources, as appropriate. Our critical accounting policies and estimates include:

Revenue recognition and accounts receivable.

Revenue on product sales is recognized when persuasive evidence of an arrangement exists, the price is fixed and final, delivery has occurred and there is a reasonable assurance of collection of the sales proceeds. We generally obtain purchase authorizations from our customers for a specified amount of product at a specified price and consider delivery to have occurred when the customer takes possession of the products and/or risk of loss has passed to the customer. We provide our customers with a right of return. Revenue is recognized upon delivery of products, at which time a reserve for sales returns is recorded. We have demonstrated the ability to make reasonable and reliable estimates of product returns in accordance with Statement of Financial Accounting Standards ("SFAS") No. 48, *Revenue Recognition When Right of Return Exists*, and of allowances for doubtful accounts based on significant historical experience.

Revenue from service, research and development, and licensing and supply agreements is recognized when the service procedures have been completed or as revenue recognition criteria have been met for each separate unit of accounting (as defined in Emerging Issues Task Force ("EITF") Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*.)

Royalty revenue is recognized based on an estimate of sell-through of product based on prescriptions written, until such time that returns from wholesalers and pharmacies can be reasonably estimated.

Inventories. Inventories are stated at the lower of cost or market, cost being determined on the first-in, first-out method. Reserves for slow moving and obsolete inventories are provided based on historical experience and current product demand. We evaluate the adequacy of these reserves quarterly.

Drug licenses and related costs. Drug licenses and related costs incurred in connection with acquiring licenses, patents and other proprietary rights related to our commercially developed products are capitalized. Capitalized drug licenses and related costs are being amortized on a straight-line basis for periods not exceeding 15 years from the dates of acquisition. Carrying values of such assets are reviewed at least annually by comparing the carrying amounts to their estimated undiscounted cash flows and adjustments are made for any diminution in value.

Provision for income taxes. We have provided for current and deferred U.S. federal, state and foreign income taxes for the current and all prior periods presented. Current and deferred income taxes have been provided with respect to jurisdictions where certain of our subsidiaries produce taxable income. We have provided a valuation allowance with respect to the remainder of our U.S. deferred income taxes, consisting primarily of net operating loss carryforwards in the U.S., because of uncertainty regarding their realization.
Should we determine that it is more likely than not that we will realize certain of our net deferred tax assets for which we have previously provided a valuation allowance, an adjustment would be required to reduce the existing valuation allowance. In addition, we operate within multiple taxing jurisdictions and are subject to audit in those jurisdictions. These audits can involve complex issues, which may require an extended period of time for resolution. Although we believe that adequate consideration has been made for such issues, there is the possibility that the ultimate resolution of such issues could have an adverse effect on our financial position, results of operations or cash flows.

Foreign currency translation. The financial position, results of operations and cash flows of our foreign subsidiaries are measured using local currency as the functional currency. Assets and liabilities of each foreign subsidiary are translated at the rate of exchange in effect at the end of the period. Revenues and expenses are translated at the average exchange rate for the period. Foreign currency translation gains and losses are credited to or charged against *other comprehensive income* in the Consolidated Balance Sheets. Foreign currency gains and losses arising from cash transactions are credited to or charged against current earnings.

New Accounting Standards

In December 2004, the Financial Accounting Standards Board ("FASB") issued SFAS No. 123 (Revised), Share-Based Payment. This Statement is a revision of SFAS No. 123, Accounting for Stock-Based Compensation, and supersedes APB Opinion No. 25, Accounting for Stock Issued to Employees, and its related implementation guidance. SFAS No. 123 (Revised) focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions. The Statement requires entities to recognize stock compensation expense for awards of equity instruments to employees based on the grant-date fair value of those awards (with limited exceptions). SFAS No. 123 (Revised) is effective for the first interim or annual reporting period that begins after June 15, 2005. Management of the Company is evaluating the two methods of adoption allowed by SFAS No. 123 (Revised), the modified-prospective transition method and the modified-retrospective transition method, and the related impact on its Consolidated Financial Statements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Foreign Currency. A substantial amount of our business is conducted in Europe and is therefore influenced to the extent to which there are fluctuations in the U.S. Dollar's value against other currencies, specifically the Euro. The exchange rate at December 31, 2004 and 2003 was .73 Euros and .80 Euros per U.S. Dollar, respectively. The weighted average exchange rate for the years ended December 31, 2004, 2003 and 2002 was .81 Euros, .89 Euros and 1.06 Euros per U.S. Dollar, respectively. The net effect of foreign currency translation on the Company's Consolidated Financial Statements during the year ended December 31, 2004 was an increase of $4,553,000 and the cumulative historical effect was an increase of $9,722,000, as reflected in our Consolidated Balance Sheets as *accumulated other comprehensive income*. The carrying value of assets and liabilities can be materially impacted by foreign currency translation, as can the translated amounts of revenues and expenses. Nonetheless, we do not plan to modify our business practices.

We have relied primarily upon financing activities to fund our operations in the U.S. In the event that we are required to fund U.S. operations or cash needs with funds generated in Europe or cash requirements in Europe with U.S. funds, currency rate fluctuations in the future could have a significant impact on us. However, at the present time, we do not anticipate altering our business plans and practices to compensate for future currency fluctuations.

Interest Rates. The weighted average interest rate on our short-term borrowings and current portion of long-term debt is 5.0% and the balance outstanding is $2,785,000 as of December 31, 2004. Our long-term borrowings are non-interest bearing and the balance outstanding on these borrowings at December 31, 2004 is $445,000 including imputed interest (ranging from 5.2% to 6.0%) of $65,000. Amounts due within one year totaling $31,000 have been classified as current on the Consolidated Balance Sheet at December 31, 2004. The weighted average interest rate on our long-term borrowings is 5.7%. The effect of an increase in the interest rate of one percentage point (one hundred basis points) to 6.0% on short-term borrowings and to an average of 6.7% on long-term borrowings would have the effect of increasing interest expense by approximately $32,000 annually.

Risk Factors

You should carefully consider the following risk factors and warnings. The risks described below are not the only risks we face. Additional risks that we do not yet know of or that we currently think are immaterial may also impair our business operations. If any of the events or circumstances described in the following risks actually occurs, our business, financial condition, or results of operations could be materially adversely affected. In such case, the trading price of our common stock could decline and you may lose all, or part of your investment.

Our growth depends on identifying drugs suitable for our drug delivery technologies and expanding our generic and branded drug operations.

Our growth depends on the identification of pharmaceutical products that are suitable for delivery using our technologies. Our principal drug delivery technology is our CPE-215 technology. This technology, like certain other drug delivery technologies, operates to increase the amount and rate of absorption of certain drugs across biological membranes. This technology does not operate independently and must be coupled with suitable pharmaceutical products in order to provide value. Consequently, our growth will depend to a great extent on identifying and commercializing these suitable drugs with respect to which we intend to expend significant resources and efforts. Identifying suitable products is a lengthy and complex process that may not succeed. Even if identified, products may not be available to us or we may otherwise be unable to enter into licenses or other agreements for their use. In our efforts to identify suitable products, we compete with other drug delivery companies with greater research and development, financial, marketing and sales resources. If we do

not effectively identify drugs to be used with our technologies, improve the delivery of drugs with our technologies and bring the improved drugs to commercial success, then we may not be able to continue our growth and we will be adversely affected.

We intend to expend significant resources and efforts toward identifying and commercializing products and technologies to expand our generic and branded drug operations in Spain and to expand sales of these products outside Spain. Although we already manufacture and market generic and branded drugs in Spain, the growth of these operations in particular and the Company in general will depend to a great extent on identifying and commercializing additional such drugs for which we have existing capacity and infrastructure and, to a lesser extent, on increasing sales of existing products. Identifying and pursuing these new opportunities involves significant time and expense and we may not succeed. Even if identified, these products and technologies may not be commercially successful. Once identified, products to be manufactured and/or marketed by us under generic or branded names are subject to successful negotiation of acceptable economic and legal terms, and successful progress of the product through commercialization, as to which we cannot assure you. When expanding outside Spain, we expect to compete in new geographic areas which are governed by regulatory regimes that we have not operated under before. In these efforts, we compete with other pharmaceutical companies having generic and branded drug operations with greater financial, marketing and sales resources and experience in the geographic areas in which they operate. If we do not effectively identify generic and branded drugs and technologies and bring them to commercial success, then we will not be able to continue our growth and we will be adversely affected.

The growth of our generic and branded operations may be adversely impacted by claims by others that our products infringe on the proprietary rights of their existing "brand-name" products. Companies that produce brand pharmaceutical products routinely bring litigation against companies who seek regulatory approval to manufacture and market generic forms of their branded products and may attempt to secure injunctions that will prevent the generic competitors from eroding their market share. These companies may allege patent infringement or other violations of intellectual property rights, which must be decided by the courts.

Products using our technologies are in various stages of development and may not achieve commercial success.

Independently as well as in conjunction with strategic partners, we are investigating the use of our technologies with respect to a variety of pharmaceutical compounds and products that are in various stages of development. We are unable to predict whether any of these products will receive regulatory approvals or be successfully developed, manufactured or commercialized. Further, due to the extended testing and regulatory review process required before marketing clearance can be obtained, the time periods before commercialization of any of these products are long and uncertain. Risks during development include the possibility that:

any or all of the proposed products will be found to be ineffective;

the proposed products will have adverse side effects or will otherwise fail to receive necessary regulatory approvals;

the proposed products may be effective but uneconomical to market; or

other pharmaceutical companies may market equivalent or superior products.

If medical doctors do not prescribe our products or the medical profession does not accept our products, our ability to grow our revenues will be limited.

Our business is dependent on market acceptance of our products by physicians, hospitals, pharmacists, patients and the medical community. Willingness to prescribe our products depends on many factors, including:

perceived efficacy of our products;

convenience and ease of administration;

prevalence and severity of adverse side effects in both clinical trials and commercial use;

availability of alternative treatments;

cost effectiveness;

effectiveness of our marketing strategy and the pricing of our products;

publicity concerning our products or competing products; and

our ability to obtain third-party coverage or reimbursement.

Even though we have received regulatory approval for Testim, and even if we receive regulatory approval and satisfy the above criteria for any of our other product candidates, physicians may not prescribe our products if we do not promote our products effectively. Factors that could affect our success in marketing our products include:

the effectiveness of our sales force;

the effectiveness of our production, distribution and marketing capabilities;

the success of competing products; and

the availability and extent of reimbursement from third-party payors.

If any of our products or product candidates fails to achieve market acceptance, we may not be able to market and sell the products successfully, which would limit our ability to generate revenue.

We will rely on strategic partners to conduct clinical trials and commercialize products that use our drug delivery technologies.

In light of our resources and the significant time, expense, expertise and infrastructure necessary to bring new drugs and formulations from inception to market, we are particularly dependent on resources from third parties to commercialize products incorporating our technologies. Our strategy involves forming alliances with others to develop, manufacture, market and sell our products in the United States and other countries. We entered into an agreement with Perrigo Company in November 2004 and continue to pursue strategic partners for these purposes. We may not be successful in finding other strategic partners or in otherwise obtaining financing, in which case the development of our products would be delayed or curtailed.

We must enter into agreements with strategic partners to conduct clinical trials, manufacturing, marketing and sales necessary to commercialize product candidates. In addition, our ability to apply our drug delivery technologies to any proprietary drugs will depend on our

ability to establish and maintain strategic partnerships or other collaborative arrangements with the holders of proprietary rights to such drugs. Arrangements with strategic partners may be established through a single comprehensive agreement or may evolve over time through a series of discrete agreements, such as letters of intent, research agreements and license agreements. We cannot assure you that we will be able to establish such strategic partnerships or collaborative arrangements on favorable terms or at all or that any

agreement entered into with a strategic partner will lead to further agreements or ultimately result in commercialization of a product.

In collaborative arrangements, we will depend on the efforts of our strategic partners and will have limited participation in the development, manufacture, marketing and commercialization of the products subject to the collaboration. We cannot assure you that these strategic partnerships or collaborative arrangements will be successful, nor can we assure you that strategic partners or collaborators will not pursue alternative technologies or develop alternative products on their own or with others, including our competitors. In addition, our collaborators or contract manufacturers may be subject to regulatory oversight which could delay or prohibit our development and commercialization efforts. Moreover, we could have disputes with our existing or future strategic partners or collaborators. Any such disagreements could lead to delays in the research, development or commercialization of potential products or could result in time-consuming and expensive litigation or arbitration.

If we are unable to meet our responsibilities under any of our agreements, we may lose potential business and be subject to penalties and other damages.

We are a party to a number of agreements pursuant to which we are required to perform certain tasks in accordance with specified schedules. Should we not meet these deadlines and requirements, our counterparties can take actions specified in these agreements which could substantially reduce the amount of revenues the Company would receive or terminate the related agreements. Additionally, in accordance with the terms of these agreements, the Company may be forced to pay penalties or other damages to our counterparties for breaching these agreements.

We expect to enter into additional agreements in the future. These agreements may impose various development, funding or other obligations on us. If we breach any of these obligations, the counterparty may have the right to terminate the agreement or seek other remedies which could significantly reduce expected profits to the Company.

Disputes may arise with respect to agreements regarding the manufacturing, development and commercialization of any products, including products which incorporate our intellectual property. These disputes could lead to delays in commercialization of products incorporating our technologies or termination of the agreements.

A significant portion of our revenues are generated by the sale of products formulated from one active ingredient.

Spanish sales from our omeprazole product line accounted for approximately 22% and 31% of our consolidated total revenues in 2004 and 2003, respectively. The active pharmaceutical ingredient for our omeprazole products is currently purchased from one supplier. If we lose and cannot effectively replace our supplier or are otherwise unable to continue the sales of our omeprazole products, our revenues would decline significantly.

Pharmaceutical pricing, changes in third-party reimbursement and governmental mandates are uncertain and may adversely affect us.

Our revenues and profitability may be adversely affected by the continuing efforts of governmental and third-party payors to contain or reduce the costs of healthcare. A substantial portion of our operations consists of marketing and manufacturing, primarily in Spain, generic and branded pharmaceutical products. The use of generic drugs is regulated in Spain, the U.S. and many other countries, and is subject to many changing and competing public policy considerations. In addition, in certain markets, such as Spain, pricing or profitability of prescription pharmaceuticals is subject to government control through reimbursement limitations. Specifically, prices for prescription pharmaceutical products in Spain 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; however, we voluntarily implemented the lower prices beginning December 1, 2003. The regulation affected six of our chemical entities sold in Spain, including the chemical entities omeprazole, simvastatin and enalapril, that reduced our 2004 revenues by approximately $13,800,000. 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.

Successful commercialization of many of our products, including those using our permeation technologies as well as our generic and branded products, may depend on the availability of reimbursement for the cost of such products and related treatment from third-party healthcare payors, such as the government, private insurance plans and managed care organizations. Third-party payors are increasingly challenging the price of medical products and services. Such reimbursement may not be available for any of our products at all or for the duration of the recommended treatment with a drug, which could materially adversely affect our ability to commercialize that drug. The increasing emphasis on managed care in the U.S. continues to increase the pressure on pharmaceutical pricing. Some governmental agencies, including those in Spain, can compel companies to continue to produce products that are not profitable for the company due to insufficient supply. In the U.S., there have been a number of federal and state proposals to implement similar government controls. We anticipate that there will continue to be a number of proposals in the U.S., as has been the case in many foreign markets. The announcement or adoption of such proposals could adversely affect us. Further, our ability to commercialize our products may be adversely affected to the extent that such proposals materially adversely affect the business, financial condition and profitability of companies that are prospective strategic partners.

The cost of healthcare in Spain, the U.S. and elsewhere continues to be a subject of investigation and action by various governmental agencies. Certain resulting legislative proposals may adversely affect us. For example, governmental actions to further reduce or eliminate reimbursement for drugs may directly diminish our markets. In addition, legislative safety and efficacy measures may be invoked that lengthen and increase the costs of drug approval processes. Further, social, economic and other broad policy legislation may induce unpredictable changes in the healthcare environment. We cannot assure you whether any of these measures may be enacted in some form, if at all, or the impact they may have if enacted.

If our clinical trials fail, we will be unable to market products.

Any human pharmaceutical product developed by us would require clearance by the FDA for sales in the United States, by Spain's Ministry of Health for sales in Spain and by comparable regulatory agencies for sales in other countries. In the case of non-generic products, the process of conducting clinical trials and obtaining FDA and other regulatory approvals is lengthy and expensive and we cannot be assured of success. In order to obtain FDA approval of any new product candidates using our technologies, an NDA must be submitted to the FDA demonstrating that the product candidate, based on preclinical research, animal studies and human clinical trials, is safe for humans and effective for its intended use. Positive results from preclinical studies and early clinical trials do not ensure positive results in more advanced clinical trials designed to permit application for regulatory approval.

We may suffer significant setbacks in clinical trials, even in cases where earlier clinical trials show promising results. Any of our new product candidates may produce undesirable side effects in humans that could cause us or regulatory authorities to interrupt, delay or halt clinical trials of a product candidate. We, the FDA or other regulatory authorities, may suspend our clinical trials at any time if we or they believe the trial participants face unacceptable health risks or if they find deficiencies in any of our regulatory submissions. Other factors that can cause delay or terminate our clinical trials include:

slow or insufficient patient enrollment;

slow recruitment and completion of necessary institutional approvals at clinical sites;

longer treatment time required to demonstrate efficacy;

lack of sufficient supplies of the product candidate;

adverse medical reactions or side effects in treated patients;

lack of effectiveness of the product candidate being tested;

regulatory requests for additional clinical trials; and

instability of the pharmaceutical formulations.

Our patent positions and intended proprietary or similar protections are uncertain.

We have filed numerous patent applications and have been granted licenses to, or have acquired, a number of patents. We cannot assure you, however, that our pending applications will be issued as patents or that any of our issued or licensed patents will afford adequate protection to us or our licensees. We cannot determine the ultimate scope and validity of patents that are now owned by or may be granted to third parties, the extent to which we may wish, or be required, to acquire rights under such patents or the cost or availability of such rights. In the event that patent protection for our technologies expire, or are not extended, revenues derived from such technologies may be reduced significantly.

Competitors may interfere with our patent process in a variety of ways. Competitors may claim that they invented the claimed invention prior to us. Competitors also may claim that we are infringing their patents, interfering with or preventing the use of our technologies. Competitors also may contest our patents by showing the patent examiner that the invention was not original, was not novel or was obvious. A competitor could claim that our issued patents are not valid for a variety of other reasons as well. If a person claims we infringe their technology, we could face a number of consequences, including lawsuits, which take significant time and can be very expensive, payment of substantial damages for infringement, prohibition from selling or licensing the product unless the patent holder licenses the patent to us, or reformulation, if possible, of the product so it does not infringe, which could require substantial time and expense.

As an example of the risk of infringement claims, in 2003 we were notified that a legal proceeding had been commenced in Madrid against us by Merck & Co. Inc. and its Spanish subsidiary alleging that we violated their patents in our production of the product simvastatin and in 2004 we were notified that a legal proceeding had been commenced in Madrid against us by GlaxoSmithKline S.A. and its Spanish subsidiaries alleging that we violated their patents in our production of the product paroxetine. We cannot assure you that similar such actions will not be brought nor that they will not have an adverse effect on us.

We also rely on trade secrets, unpatented proprietary technologies and continuing technological innovations in the development and commercialization of our products. We cannot assure you that others will not independently develop the same or similar technologies or obtain access to our

proprietary technologies. It is unclear whether our trade secrets will be protected under law. While we use reasonable efforts to protect our trade secrets, our employees or consultants may unintentionally or willfully disclose our information to competitors. Our employees and consultants with access to our proprietary information have entered into or are subject to confidentiality arrangements with us and have agreed to disclose and assign to us any ideas, developments, discoveries and inventions that arise from their activities for us. We cannot assure you, however, that others may not acquire or independently develop similar technologies or, if effective patents in applicable countries are not issued with respect to our products or technologies, that we will be able to maintain information pertinent to such research as proprietary technologies or trade secrets. Enforcing a claim that another person has illegally obtained and is using our trade secrets, like patent litigation, is expensive and time consuming, and the outcome is unpredictable. In addition, we may be subject to the jurisdiction of courts outside the U.S., some of which may be less willing to protect trade secrets.

Regulatory approvals must be obtained and maintained for products incorporating our technologies and, if approvals are delayed or withdrawn, we will be unable to commercialize these products.

Government regulations in the United States, Spain and other countries have a significant impact on our business and affect the research and development, manufacture and marketing of products incorporating our technologies. In the United States, Spain and other countries, governmental agencies have the authority to regulate the distribution, manufacture and sale of drugs. Failure to comply with applicable regulatory requirements can, among other things, result in fines, suspension or withdrawal of regulatory approvals, product recalls, operating restrictions and/or criminal prosecution. In addition, governmental regulations may be established that could prevent, delay, modify or rescind regulatory approval of our products.

Our business will suffer if we fail to comply with federal regulations and rules of the Securities and Exchange Commission and New York Stock Exchange relating to corporate governance reform.

As a public company, we are subject to certain federal regulations and the rules and regulations of the Securities and Exchange Commission and the New York Stock Exchange. The Sarbanes-Oxley Act of 2002 required more stringent accounting, corporate fraud and securities laws. To implement this legislation, the Securities and Exchange Commission has adopted new rules and may adopt additional rules pertaining to, among other things, additional disclosure and reporting requirements, including requirements relating to internal control procedures. The New York Stock Exchange has also adopted various rules relating to corporate governance. Our reputation and financial results could be materially harmed by any failure by us to comply with any current or future rules or regulations relating to the Sarbanes-Oxley Act or to any other federal corporate or stock exchange reform measures.

Compliance with the requirements of the Sarbanes-Oxley Act of 2002 may require a reallocation of resources that would otherwise be dedicated to operating our business.

The Sarbanes-Oxley Act of 2002 imposed significant new administrative burdens on publicly traded companies. We expect to incur significant incremental costs in complying with the provisions of the Sarbanes-Oxley Act. We cannot assure you that these additional costs will result in any increase in revenue or that they will not have a material adverse effect on our financial results. In addition, because we are a small company with relatively few employees, the individuals responsible for complying with the new statutory and regulatory requirements also have responsibility for business matters. As a result, our business may suffer if these individuals are forced to spend a disproportionate amount of time on compliance matters.

Implementation of new information systems could cause business interruptions and negatively affect our profitability and cash flows.

We are in the process of implementing a new inventory warehouse system to enhance operational efficiencies and provide more effective management of our logistics. This implementation will enable us to better meet the challenges related to our continued growth and the needs of our customers. We also plan to upgrade and replace certain of our financial systems to help enable us to meet the new challenges of the new regulatory environment including regulations imposed by the Sarbanes-Oxley Act of 2002. We expect that, over time, new systems will result in improved business processes and increased operating efficiencies. As our employees become familiar with the new systems, we expect that some errors may occur, some of which could adversely impact our business and financial results. There can be no assurance that the systems will perform as expected or that the anticipated improvements in business processes and operating efficiencies will be achieved. In the event of serious system malfunctions or deficiencies, we might experience business interruptions, which could adversely impact on our results of operations, financial condition and cash flows.

If we are unable to obtain marketing approvals to sell our products in countries other than Spain, we may not be able to obtain additional revenues from sales in those countries.

We cannot assure you that products that have obtained marketing approval in Spain will be approved for marketing elsewhere. If we are unable to obtain marketing approval for our products in countries other than Spain, we may not be able to obtain additional revenues from sales in those countries.

We must comply with Good Manufacturing Practices in the production of pharmaceutical products.

Any manufacturing facility for pharmaceutical products to be marketed in the United States is subject to FDA inspection and inspections by other government agencies both before and after approval of a NDA to determine compliance with the FDA's GMPs requirements, as well as local, state and other federal regulations. Manufacturing facilities for our compounds to be marketed in European countries and elsewhere are also subject to European Union and/or other applicable GMP regulations. Facilities used to produce our compounds may not achieve or maintain compliance with GMP or other requirements. The GMP regulations are complex and, if we fail to comply with them, it could lead to rejection or delay of an NDA or comparable application. Any delay in approval of an NDA or comparable application would delay product launch. Violation of GMP requirements after approval of an NDA or comparable application, could result in remedial action, penalties and/or delays in production.

We have only one manufacturing facility that can be used to manufacture our pharmaceutical products for sale to others. We have only one manufacturing facility that can be used to manufacture active pharmaceutical ingredients for sale to others.

All of our manufactured pharmaceutical products are manufactured in one factory in Zaragoza, Spain. Although we have constructed the factory with redundant lines for our most significant products that are in separate areas of the factory, and installed a fire suppression system, the destruction of the factory by a fire or other catastrophe would have a material impact on our revenues until we are able to rebuild the factory or secure an alternative manufacturing site.

Similarly, all of our manufactured active pharmaceutical ingredients are manufactured in one factory in Zaragoza, Spain. A fire or other catastrophe would have a material impact on our revenues until we are able to rebuild the factory or secure an alternative manufacturing site.

We operate a significant portion of our business in, and plan to expand further into, markets outside the United States, which subjects us to additional business risks.

During the year ended December 31, 2004, 81% of our revenues were derived from sales made by our Spanish subsidiaries in Spain and 16% of our revenues were derived from sales made by our Spanish subsidiaries to customers in other foreign countries. We believe that a significant portion of our revenues will continue to be derived from sales in foreign countries. Conducting business internationally subjects us to a number of risks and uncertainties, including:

- unexpected delays or changes in regulatory requirements;
- difficulties and costs related to complying with a wide variety of complex foreign laws and treaties;
- delays and expenses associated with tariffs and other trade barriers;
- restrictions on and impediments to repatriation of our funds and our customers' ability to make payments to us;
- political and economic instability;
- acts of terrorism or war;
- difficulties and costs associated with staffing and managing international operations and implementing, maintaining and improving financial controls;
- dependence upon independent sales representatives and other indirect resellers who may not be as effective and reliable as our employees;
- inadequate or uncertain protection of intellectual property in foreign countries;
- increased difficulty in collecting accounts receivable and longer accounts receivable cycles in certain foreign countries;
- adverse tax consequences or overlapping tax structures; and
- limitations on the remittance of dividends by foreign subsidiaries.

Currency fluctuations could have a material adverse impact on our business.

Our revenues may be impacted by fluctuations in local currencies due to the fact that 96% of our revenues currently are generated by our Spanish subsidiaries, Laboratorios Belmac, Laboratorios Davur and Laboratorios Rimafar. Our Spanish subsidiaries reported an increase in net sales of 1% in constant currency for the year ended December 31, 2004 compared to the prior year. An increase in the value of the Euro, in relation to the U.S. Dollar, had the effect of increasing revenues by approximately $6,502,000 during the year ended December 31, 2004. We do not currently engage in foreign exchange hedging transactions to manage our foreign currency exposure because much of our expenditures are in the same currency as our revenues. Our foreign operations expose us to a number of currency related risks, including the following:

- fluctuations in currency exchange rates;

limitations on the conversion of foreign currency; and

fluctuations of the carrying value of long lived assets.

If we cannot keep pace with rapid technological change and meet the intense competition in our industry, we may not succeed.

Our success depends, in part, on achieving and maintaining a competitive position in the development of products and technologies in a rapidly evolving industry. If we unable to continue to develop and/or acquire competitive products and technologies, our current and potential strategic partners may choose to adopt the drug delivery technologies of our competitors. We also compete generally with other drug delivery, biotechnology and pharmaceutical companies engaged in the development of alternative drug delivery technologies or new drug research and testing. Many of these competitors have substantially greater financial, technological, manufacturing, marketing, managerial and research and development resources and experience than we do and represent significant competition for us. Our competitors may succeed in developing competing technologies or obtaining governmental approval for products before we achieve success, if at all. The products of our competitors may gain market acceptance more rapidly than our products. Developments by competitors may render our existing or proposed products noncompetitive or obsolete.

Our competitive positions in our generic and branded drug operations as well as with our drug delivery technologies are uncertain and subject to risks. In Spain, and in other countries, we must demonstrate bioequivalence of our generic products, which may be challenged by branded and other generic competitors as well as regulatory authorities. In order to demonstrate bioequivalence of our generic products, we must show that the rate and extent of absorption and levels of concentration of our generic products are not statistically different from innovators' products that have previously been approved by the regulatory authorities of the respective country, when administered at the same dosage level under similar clinical conditions.

The competitive position of our drug delivery technologies is subject to the possible development by others of superior technologies. Other drug delivery technologies, including oral and injection methods, have wide acceptance, notwithstanding certain drawbacks, and are the subject of improvement efforts by other entities having greater resources. In addition, our drug delivery technologies are limited by the number and commercial magnitude of drugs with which they can successfully be combined.

We may be unable to meet increasing expenses and demands on our resources from future growth, if any, or to effectively pursue additional business opportunities.

We routinely consider acquisition and investment opportunities, although we have no current agreements or commitments with respect to any acquisitions or investments. Any future acquisitions or investments would further challenge our resources. If we do not properly meet the increasing expenses and demands on our resources from future growth, we will be adversely affected. To properly manage our growth, we must, among other things, implement additional and improve existing administrative, financial, marketing, operational and research and development systems, procedures and controls on a timely basis. We may also need to expand our staff in these and other areas. We may not be able to complete the improvements to our systems, procedures and controls necessary to support our future operations in a timely manner. We may not be able to hire, train, integrate, retain, motivate and manage required personnel, successfully integrate acquisitions or investments, nor successfully identify, manage and pursue existing and potential market opportunities. We plan to invest approximately $19.2 million in capital expenditures during the year ending December 31, 2005, to expand our API manufacturing facility, expand our pharmaceutical product manufacturing facility and add new production lines in order to be able to accommodate the level of operations and growth that is anticipated as a result of the Company's expansion beyond the borders of Spain and the U.S. market. We plan to finance these expenditures from a combination of cash flow from operations and borrowings. If we fail to generate additional revenue in excess of increased operating expenses in any fiscal period, we may incur losses.

Our operations could be adversely affected if we are unable to raise or obtain needed funding.

Substantial time and financial and other resources will be required to complete ongoing development and clinical testing of our products. Regulatory efforts and collaborative arrangements also will be necessary for our products that are currently under development and testing in order for them to be marketed. Assuming we continue our operations as presently conducted, we believe that we have sufficient working capital to meet our needs for at least the next twenty-four months. However our revenues from operations and cash may not be sufficient over the next several years for commercializing all of the products we are currently developing. Consequently, we may seek strategic partners for various phases of development, marketing and commercialization of product candidates employing our technologies. Further, we cannot assure you as to the sufficiency of our resources or the time required to complete any ongoing development and clinical testing, since the extent to which we conduct such testing is dependent on resource allocation decisions that we make from time to time based on numerous financial as well as operational conditions.

In addition to development and other costs, we expect to incur capital expenditures from time to time. These capital expenditures will be influenced by our regulatory compliance efforts, our success, if any, at developing collaborative arrangements with strategic partners, our needs for additional facilities and capital equipment and the growth, if any, of our business in general. There can be no assurance that we will receive additional funding on favorable terms if at all, or that we will be successful in attracting strategic partners. If we cannot raise funds or engage strategic partners on acceptable terms when needed, we may not be able to continue our research and development activities, develop or enhance our products and services, take advantage of future opportunities, grow our business or respond to competitive pressures or unanticipated requirements.

If we undertake an acquisition, we will incur a variety of costs, and we may never realize the anticipated benefits of the acquisition.

One of our strategies for business expansion is the acquisition of additional technologies, products and product candidates. We may attempt to acquire these product candidates, or other potentially beneficial technologies, through the acquisition of businesses, services or products that we believe are a strategic fit with our business. Although we currently have no commitments or agreements with respect to any acquisitions, if we undertake an acquisition, the process of integrating the acquired business, technology, service or product may result in unforeseen operating difficulties and expenditures and may divert significant management attention from our ongoing business operations. Moreover, we may fail to realize the anticipated benefits of any acquisition for a variety of reasons such as an acquired technology or product candidate proving to not be safe or effective in later clinical trials. We may fund any future acquisition by issuing equity or debt securities, which could dilute your ownership percentage or limit our financial or operating flexibility as a result of restrictive covenants related to new debt. Acquisition efforts can consume significant management attention and require substantial expenditures, which could detract from our other programs. In addition, we may devote resources to potential acquisitions that are never completed.

If we do not successfully manage our growth, our business goals may not be achieved.

Expansion has placed, and is expected to continue to place, a significant strain on our management, operational and financial resources. To manage further growth, we will be required to continue to improve existing, and implement additional, operational and financial systems, procedures and controls, and hire, train and manage additional employees. Our current and planned personnel, systems, procedures and controls may not be adequate to support our anticipated growth and we may not be able to hire, train, retain, motivate and manage required personnel. Our failure to manage growth effectively could limit our ability to achieve our business goals.

Changes in accounting for expensing of stock options could result in unfavorable charges or require us to change our compensation policies.

We have relied heavily on stock options to compensate existing employees and attract new employees. We currently are not required to record stock-based compensation charges if the employee's stock option exercise price equals or exceeds the fair value of our common stock at the date of grant. In December 2004, the Financial Accounting Standards Board ("FASB") issued SFAS No. 123 (Revised), *Share-Based Payment*. This Statement is a revision of SFAS No. 123, *Accounting for Stock-Based Compensation*, and supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and its related implementation guidance. SFAS No. 123 (Revised) focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions. The Statement requires entities to recognize stock compensation expense for awards of equity instruments to employees based on the grant-date fair value of those awards (with limited exceptions). SFAS No. 123 (Revised) is effective as of the beginning of the first interim or annual reporting period that begins after June 15, 2005. Management of the Company is evaluating the two methods of adoption allowed by SFAS No. 123 (Revised), the modified-prospective transition method and the modified-retrospective transition method, and the related impact on our Consolidated Financial Statements. When we change our accounting policy to record the fair value of stock options granted, our expenses will increase which will reduce our net income and earnings per share. We may choose to reduce our reliance on stock options as a compensation tool as a result of the impact of recording stock options at their fair value. If we reduce our use of stock options, it may be more difficult for us to attract and retain qualified employees.

If we cannot attract and retain key personnel, we may not be able to execute our business plan as anticipated.

Our success is dependent on our ability to attract and retain qualified, experienced personnel. We face significant competition in recruiting competent personnel. Because the location of our headquarters is in an area with relatively few pharmaceutical companies recruiting candidates has been more difficult, as many candidates prefer to work in places with a broad pharmaceutical industry presence. The loss of key personnel, or the inability to attract and retain additional, competent employees, could adversely affect our business and financial results.

We have assigned many key responsibilities within our company to, and are dependent on, a relatively small number of individuals. If we lose the services of our Chief Executive Officer, Chief Financial Officer, Chief Medical Officer, or the General Manager of our Spanish subsidiary, our ability to execute our business plan in the manner we currently anticipate would be adversely affected. We maintain key person life insurance only for our Chief Executive Officer. We have an employment agreement with each of our key personnel.

We may incur substantial liabilities and may be required to limit commercialization of our products in response to product liability claims.

The testing and marketing of medical products entails an inherent risk of product liability. We may be held liable to the extent that there are any adverse reactions from the use of our products. Some of our products involve new methods of delivery for drugs, some of which may require precautions to prevent unintended use, especially since they are designed for patients' self-use rather than being administered by medical professionals. The FDA may require us to develop a comprehensive risk management program for our products. The failure of these measures could result in harmful side effects or death. As a result, consumers, regulatory agencies, pharmaceutical companies or others might make claims against us. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities, lose market share or be required to limit commercialization of our products.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could inhibit or prevent the commercialization of pharmaceutical

products we develop alone or with corporate collaborators. We maintain product liability insurance in the amount of $3 million Euros (approximately $4 million U.S. Dollars) and clinical trial insurance in connection with our clinical testing activities in various amounts on a study-by-study basis. While management believes that this insurance is reasonable, we cannot assure you that any of this coverage will be adequate to protect us in the event of a claim. We, or any corporate collaborators, may not be able to obtain or maintain insurance at a reasonable cost, if at all. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate if any claim arises. Our agreement with Perrigo Company requires us to secure product liability insurance equal to $10 million upon commercialization of the products being developed. There can be no assurance that we will be able to secure such an amount of coverage at a reasonable cost or at all or that if secured, that it will be adequate to protect us in the event of a claim.

Our revenues, operating results and cash flows may fluctuate in future periods and we may fail to meet investor expectations, which may cause the price of our common stock to decline.

Variations in our quarterly and year-end operating results are difficult to predict and may fluctuate significantly from period to period. If our sales or operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. In addition to the other factors discussed under these "Risk Factors," specific factors that may cause fluctuations in our operating results include:

- demand and pricing for our products, including changes in wholesaler purchasing;
- government or private healthcare reimbursement policies;
- physician, pharmacy and patient acceptance of any of our current or future products;
- patterns or cost structures for our products;
- introduction of competing products, including generics;
- any interruption in the manufacturing or distribution of Testim or any of our future products;
- our operating expenses which fluctuate due to growth of our business;
- timing and size of any new product or technology acquisitions we may complete; and
- variations in our rates of product returns and allowances.

Forecasting our revenues is complicated by difficulties in estimating inventory levels at our wholesalers and pharmacies, the timing of purchases by wholesalers and retailers to replenish inventory and the occurrence and amount of product returns.

Your percentage of ownership and voting power and the price of our common stock may decrease as a result of events that increase the number of our outstanding shares.

As of December 31, 2004, we had the following capital structure:

	No. of Shares
Common stock outstanding	21,312,465
Common stock issuable upon:	
Exercise of options which are outstanding	4,087,078
Exercise of options which are available for grant	1,079,750

	No. of Shares
Total common stock outstanding assuming exercise of all of the above	26,479,293

As of December 31, 2004, we had outstanding options to purchase approximately 4,087,078 shares of common stock at exercise prices ranging from $2.00 to $15.83 (exercisable at a weighted average of $7.44 per share), of which approximately 3,338,800 were then vested and exercisable. We may conduct

future offerings of our common stock or other securities with rights to convert the securities into shares of our common stock. Exercise of our outstanding options into shares of our common stock may significantly and negatively affect the market price for our common stock as well as decrease your percentage ownership and voting power.

Our stock is volatile.

The market prices for our securities and for securities of emerging growth companies have historically been highly volatile. During the last two years, the price of our common stock has ranged from a high of $18.80 to a low of $7.85. Future announcements concerning us or our competitors may have a significant impact on the market price of our common stock. Factors which may affect our market price include:

progress of our relationships with strategic partners;

results of clinical studies and regulatory reviews;

technological innovations by us or our competitors;

market conditions in the pharmaceutical, drug delivery and biotechnology industries;

effect of regulatory authorities on pricing of products;

competitive products;

financings;

sales or the possibility of sales of our common stock;

our results of operations and financial condition;

proprietary rights;

public concern as to the safety or commercial value of our products; and

general economic conditions.

These uncertainties have adversely affected and may continue to adversely affect the market price of our common stock. Furthermore, the stock market has experienced significant price and volume fluctuation unrelated to the operating performance of particular companies. These market fluctuations may also adversely affect the market price of our common stock.

Delaware law and provisions in our certificate of incorporation, bylaws and stockholder rights plan may prevent or discourage third parties or stockholders from attempting to replace the management of the Company.

As a Delaware company, we are subject to Section 203 of the Delaware General Corporation Law, as amended, which is a statutory provision intended to discourage certain takeover attempts that are not approved by the board of directors. Section 203 prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that such stockholder became an interested stockholder subject to certain exceptions.

Our certificate of incorporation and bylaws include provisions that also may have the effect of discouraging, delaying or preventing a change in control or an unsolicited acquisition proposal that a stockholder might consider favorable. Our board of directors is divided into three classes with staggered three-year terms, which makes it more difficult for an acquiror to change the overall composition of the board in a short period of time. The affirmative vote of at least two-thirds of our outstanding shares is required to approve a merger, a sale or lease of all or substantially all of our assets, certain other business combinations or dissolution or liquidation, and an affirmative vote of two-thirds of our outstanding shares is required to amend or repeal any provision in our certificate of incorporation relating to our directors and officers as well as certain other provisions in our certificate of

incorporation. Additionally, our certificate of incorporation authorizes our board of directors to issue preferred stock in one or more series with the rights, obligations and preferences of each series to be determined by our board without stockholder approval. Our staggered board, the super-majority voting provisions and the potential issuance of preferred stock may have the effect of delaying, preventing or discouraging third parties or stockholders from attempting to replace our management.

To the same potential effect, we have a stockholder rights plan designed to prevent a potential acquirer from gaining control of us without adequately compensating our shareholders and to protect us from coercive takeover attempts. The rights will become exercisable only if any person or group of affiliated persons beneficially acquires 15% or more of our common stock. Under certain circumstances, each holder of a right (other than the person or group who acquired 15% or more of our common stock) is entitled to purchase a defined number of shares of our common stock at 50% of its market price at the time that the right becomes exercisable.

Item 8. Financial Statements and Supplementary Data

See Item 15 of this Annual Report on Form 10-K.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure

Not applicable.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

The Company maintains disclosure controls and procedures that are designed to ensure that information required to be disclosed in the Company's reports that are filed with the Securities and Exchange Commission is recorded, processed and reported within the time periods required for each report and that such information is reported to the Company's management, including its principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

The Company's management, with the participation of its principal executive officer and principal financial officer, carried out an evaluation of the effectiveness of the Company's disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act") as of the end of the period covered by this report. Based on that evaluation, the Company's principal executive officer and principal financial officer concluded that the Company's disclosure controls and procedures were effective as of December 31, 2004. Although the Company's management continues to evaluate the internal control structure and strengthen its control procedures, particularly in connection with the requirements of Section 404 of the Sarbanes-Oxley Act of 2002, there have been no changes that have materially affected, or are reasonably likely to materially affect the Company's internal controls over financial reporting during the year ended December 31, 2004.

Internal Control over Financial Reporting

As of the filing of this Annual Report on Form 10-K, we are in the process of testing our internal control procedures in order to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act, which requires an annual management report assessing the effectiveness of our internal controls over financial reporting, accompanied by an attestation to this report by our independent registered public accounting firm. The Company is eligible for a 45-day extension offered by the SEC to companies of a certain size for filing this report and the attestation. We have elected to utilize this 45-day extension and, accordingly, this Annual Report on Form 10-K does not include either the management report or the attestation. We anticipate completing this process and filing these reports in an amendment to this Form 10-K, which we intend to file in April 2005. Based on our testing to date, we are not aware of any material weakness in our internal controls over financial reporting and related disclosures.

There was no change in the Company's internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) identified in connection with the evaluation of the Company's internal controls that occurred during the Company's last fiscal quarter that has materially affected, or is reasonably likely to materially affect, such controls.

Item 9B. Other Information

Not applicable.

Part III

Item 10. Directors and Executive Officers of the Registrant

Name	Age	Position
James R. Murphy	55	Chairman, President, Chief Executive Officer and Director
Michael McGovern	61	Vice Chairman and Director
Michael D. Price	47	Vice President, Chief Financial Officer, Treasurer and Secretary
Adolfo Herrera	45	President of European Operations
Miguel Fernandez	74	Director
F. Ross Johnson	73	Director
Edward J. Robinson	64	Director
John W. Spiegel	64	Lead Director

James R. Murphy has served as one of our directors since 1993. Mr. Murphy became President of the Company in September 1994, was named Chief Executive Officer effective January 1995 and became Chairman of the Board in June 1995. Prior to rejoining the Company, Mr. Murphy served as Vice President of Business Development at MacroChem Corporation, a publicly owned pharmaceutical and drug delivery company, from March 1993 through September 1994. From S