BENTLEY PHARMACEUTICALS INC
Form 10-K
March 08, 2004

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

FORM 10-K

(Mark One)

X --- ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 for the fiscal year ended December 31, 2003

OR

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

Commission File Number 1-10581

BENTLEY PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	No. 59-1513162
(State or other jurisdiction of incorporation or organization)	(I.R.S. employer No. identification no.)
Bentley Park, 2 Holland Way, Exeter, NH (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	American 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 X No

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

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

State the aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant. The aggregate market value shall be computed by reference to the price at which the common equity was 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	$210,950,604	June 30, 2003

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	20,598,875	March 2, 2004

DOCUMENTS INCORPORATED BY REFERENCE
Proxy Statement for the 2004 Annual Meeting of Stockholders - Incorporated by Reference into Part III of this Form 10-K

Part I

Item 1. Business

Overview

We are a specialty pharmaceutical company focused on:

- research, development and licensing/commercialization of advanced drug delivery technologies and pharmaceutical products; and
- development, licensing and sales of generic and branded pharmaceutical products and the manufacturing of pharmaceuticals for others.

In our research and development activities, we have patents and other proprietary rights to technologies that facilitate the absorption of drugs. Our pharmaceutical product sales activities are based in Spain, where we have a significant commercial presence and we manufacture and market approximately 100 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. We also manufacture pharmaceuticals for other drug companies.

We develop products which incorporate our drug delivery technologies and have licensed applications of our proprietary CPE-215(R) drug delivery technology to Auxilium Pharmaceuticals, Inc., which launched Testim(TM), the first product incorporating our drug delivery technology, in February 2003. Testim 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), including loss of muscle mass and a decrease in sexual desire, sexual motivation and frequency of spontaneous erections. 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 generic and branded products are marketed to physicians, pharmacists and hospitals by our three separate sales and marketing organizations based in Spain: Laboratorios Belmac, Laboratorios Davur and Laboratorios Rimafar. We continually add to our product portfolio in response to

increasing market demand for generic and branded therapeutic agents and 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 countries. We have a strategic alliance with Teva Pharmaceutical Industries Ltd. granting us the right to register and market in Spain more than 75 of Teva's pharmaceutical products through our sales force of approximately 151 full-time personnel located in major cities throughout Spain. In addition, our Spanish manufacturing facility produces pharmaceutical products which are marketed by pharmaceutical companies both in Spain and in other markets.

Industry Overview

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 $35 billion in 2000 and is projected to increase to $75 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 major limitations, including pain, which can lead to decreased patient acceptance and 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, are often sought by pharmaceutical and biotechnology companies to extend the period of market exclusivity for a branded drug and thus 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 15 years for an experimental new drug to progress from the laboratory to commercialization in the U.S., with an

average cost of approximately $500 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 harming the patient or changing the clinical attributes of the drug.

Pharmaceutical Industry in Europe and Spain

The European Union, with an increasingly affluent population of approximately 375 million people, represents the second largest pharmaceutical market in the world with approximately $75 billion in pharmaceutical sales in 2000, according to IMS Health. With the addition of 10 new countries to the European Union in May 2004, the population will increase 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 which includes reimbursement for prescription pharmaceuticals. The prices that these systems are willing to pay for products affects the profitability of the products. However, given the varying priorities and economies of each of the European countries, price consistency has not been achieved and both the prices set 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 which 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.

With 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 2000 as the seventh largest pharmaceutical market in the world. Pharmaceutical sales in Spain reached approximately $8.8 billion in 2003, according to IMS Health, and have been growing at approximately 10% per year in the recent past.

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 may 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 demonstrate their 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. Such discount is typically 30% of the original branded product price.

Although comprising less than five percent of the Spanish pharmaceutical market (less than six 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, including education, financial incentives to

prescribing physicians and public campaigns to stimulate the use of generic pharmaceuticals in response to the rise in healthcare costs. Due to the structure of the Spanish market for pharmaceutical products, producers generally target physicians and pharmacies to market their products, emphasizing a combination of quality and price.

The market for generic pharmaceutical products in other European countries has attained greater penetration, with major markets such as the United Kingdom, Germany and France achieving generic penetrations of over 40%. 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 marketing to physicians or consumers.

Our Strategy

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

- advanced drug delivery and formulation technologies to improve the delivery of new and existing pharmaceuticals; and
- development, licensing and sale of a broad range of generic and branded pharmaceutical products in Spain, other parts of Europe, and other international markets.

Our strategies to accomplish this objective include:

Focus on commercializing our CPE-215(R) permeation platform technology and developing proprietary products based on our other technologies

We apply our drug delivery and oral drug formulation technologies 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, which result in improved purity, stability and production yields.

Our CPE-215 technology enables the absorption of drugs across membranes of the skin, mouth, nose, vagina and eye. 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 received its first approval by the U.S. Food and Drug Administration (FDA) in October 2002 as the delivery system in the Testim

testosterone replacement gel. We believe 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.

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 also developed and filed a patent for improved oral dosage forms of acetaminophen, and an improved method of manufacturing for drugs requiring protection from stomach acid, such 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 improved manufacturing processes, requiring less time, that efficiently produces products with increased stability.

Once we have brought 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 have licensed from us.

Increase our 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 Spain. We are expanding our product portfolio through the acquisition or license of currently marketed and late stage pharmaceutical products. We directly promote and sell these products in Spain through our own sales force of approximately 151 full-time personnel located in 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.

In July 2000, we entered into a 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 generic and/or branded versions of more than 75 pharmaceutical products representing more than 25 different chemical entities. Under this license agreement, we will register these products with Spain's Ministry of Health and, upon approval, sell these products in Spain. We received marketing approval for certain of the Teva products in 2003 and intend to begin marketing these products in 2004.

We are expanding the sales of products outside 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, the United Kingdom, Germany, France, Austria, the Netherlands, Morocco, Poland and Romania and are working on adding additional alliances for targeted products in these and other countries. In certain European countries which have a highly developed competitive market for generics that is mostly based on price, we intend to sell either directly or through our alliances to distributors. In countries which 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 manufacturing facility in Spain so that it will comply with U.S. regulatory requirements. These modifications should enable us to perform additional clinical studies under U.S. regulatory standards so that we may submit our products for marketing approval by the FDA.

Our Proprietary Drug Technologies

We believe that there are numerous opportunities to enter into

additional collaborations with pharmaceutical and biotechnology companies and expand our product lines using our proprietary drug technologies.

CPE-215 Permeation Technology

Our permeation 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 long history of safe use in humans as a food additive and fragrance and our preclinical testing to date on CPE-215 for drug delivery has further indicated its safety. In October 2002 it was approved as the delivery technology for Testim testosterone replacement gel. We believe 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 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. 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.

Improved 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 that are more stable and pure, while reducing manufacturing time and costs. We have developed this technology to create new methods for manufacturing products such as omeprazole, lansoprazole and other similar products that are stability sensitive to humidity and temperature. We have filed patents relating to these processes. The patents claim as innovative the manufacturing process that renders these products more stable, while protecting active substances from gastric degradation utilizing microgranulation and microencapsulation techniques. These patent pending technologies can contribute to our ability to compete against other companies whose manufacturing processes are more costly and time consuming.

Hydrogel Technology

Our hydrogel technology involves a patented synthetic material, which produces a water soluble drug release system capable of being formulated for immediate onset or sustained release over a 24 hour period. We believe that the hydrogel technology is capable of adhering to the mucous membranes of the vagina for extended periods of time without typical discharge, which would improve the treatment of conditions such as yeast and fungal infections or conditions requiring moisturizers or antibiotics. We seek to license this technology to other pharmaceutical companies for co-development and marketing of potential applications of this technology.

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. Testim is a testosterone replacement therapy which restores serum testosterone levels in men and thereby improves symptoms of health problems associated with low testosterone levels, including loss of muscle mass and a decrease in sexual desire, sexual motivation and frequency of spontaneous erections.

Testosterone replacement therapy is used to treat men whose bodies produce insufficient amounts of testosterone (hypogonadism), which can be a natural result of aging. 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 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 typically result in skin irritation or 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 from $49 million in 1997 to over $200 million in 2002 according to IMS Health, and is expected to reach $400 million in 2004 and continue to grow at an annual rate of 40%.

Testim resulted from a May 2000 research agreement with Auxilium, an emerging pharmaceutical company focused on urology 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 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. Auxilium is currently in discussions with a strategic partner to market the product in Europe and elsewhere.

In accordance with the terms of the license agreement with Auxilium, we have received payments, based upon Auxilium's completion of certain milestones, in the aggregate of $550,000 since 2000. Terms of the license agreement also entitle us to royalties based on net sales of Testim. We recognized royalty income totaling $1,018,000 in the year ended December 31, 2003, and have deferred the recognition of royalty income totaling $634,000 as of December 31, 2003 subject to meeting all requirements of our revenue recognition policies.

Manufactured and Marketed Products

In Spain, we manufacture approximately 100 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 to market our products in other countries, including Portugal, the United Kingdom, Germany, France, Austria, the Netherlands, Morocco, Poland and Romania. 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 130,000 physicians and 20,000 pharmacies in Spain. Spanish sales from two product lines, whose active ingredients are omeprazole and simvastatin, accounted for approximately 31% and 10% of our total revenues in 2003, respectively.

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 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 Spain through local distributors and brokers, particularly in Europe, Northern Africa, Central and South America.

Revenues

Our revenues are generated through our five primary sales channels (branded, generic, contract manufacturing, sales outside of Spain and licensing

and collaborations). See a summary of our revenues by sales channel and top-selling product lines below:

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

	Sales Within Spain				
Product Line	Branded Products	Generic Products	Contract Manu-facturing	Other Revenues	Total
Omeprazole	$ 6,099	$13,863	$ -	$ -	$19,962
Simvastatin	2,176	4,412	-	-	6,588
Enalapril	2,610	1,878	-	-	4,488
Codeisan	2,713	-	-	-	2,713
Pentoxifylline	-	2,070	-	-	2,070
All other products	5,463	4,744	-	-	10,207
Contract manufacturing	-	-	9,536	-	9,536
Sales outside of Spain	-	-	-	7,391	7,391
Licensing and collaborations	-	-	-	1,721	1,721
Total Revenues	$19,061	$26,967	$ 9,536	$ 9,112	$64,676
% 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 Manu-facturing	Other Revenues	Total	
Omeprazole	$ 5,051	$ 9,813	$ -	$ -	$14,864	
Simvastatin	322	1,261	-	-	1,583	
Enalapril	955	1,515	-	-	2,470	
Codeisan	1,944	-	-	-	1,944	
Pentoxifylline	-	1,348	-	-	1,348	
All other products	4,103	2,738	-	-	6,841	
Contract manufacturing	-	-	7,406	-	7,406	
Sales outside of Spain	-	-	-	2,262	2,262	
Licensing and collaborations	-	-	-	418	418	
Total Revenues	$12,375	$16,675	$ 7,406	$ 2,680	$39,136	
% of 2002 Revenues	32%	43%	19%	6%	100%	

Branded Pharmaceutical Products

Our branded pharmaceutical product line consists of 43 pharmaceutical products representing various product presentations, formulations and dosage strengths of 32 chemical entities, which are represented by 18 trademarked brand names. Sales of branded pharmaceuticals accounted for 29% of our revenues in 2003, compared to 32% in 2002 and 47% in 2001. 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 73 full-time sales personnel located in 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 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	Sold by Others as	Us
Belmalip(R)	simvastatin	Zocor(R)(Merck)	h
Belmazol(R)	omeprazole	Prilosec(R)(AstraZeneca)	g d
Cimascal D Forte(R)	calcium carbonate and vitamin D3	Calcite-D(R)(Riva)	o
Codeisan(R)	codeine	Tricodein(R)(Solco)	c
Enalapril Belmac(R)	enalapril maleate	Vasotec(R)(Merck)	c a
Ibumac(R)	ibuprofen	Motrin(R)(McNeil)	r
Mio Relax(R)	carisoprodol	Soma(R)(MedPointe)	m
Pentoxifilina Belmac(R)	pentoxifylline	Trental(R)(Aventis)	p
Senioral(R)	oxymetazoline and chlorpheniramine	Denoral(R)(Aventis)	c
Xetin(R)	paroxetine	Paxil(R)(GlaxoSmithKline)	d

Generic Pharmaceutical Products

Our generic pharmaceutical product line consists of 50 pharmaceutical products representing various product presentations, formulations and dosage strengths of 12 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 61 full-time sales personnel located in 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 17 full-time sales personnel throughout Spain. Laboratorios Belmac also sells certain generic products. In 2003, generic pharmaceuticals accounted for approximately 42% of our total revenues. We also supplement our sales and marketing efforts for generic products through advertising in trade publications.

We believe we can grow by providing to our generic products sales force a more extensive line of products to market to physician and pharmacy clients. To strengthen our entry into the generic market, in July 2000, we entered into a strategic alliance with Teva, one of the world's leaders in generic pharmaceuticals. Under this alliance, we have licensed from Teva the right to register and market in Spain generic and/or branded versions of more than 75 of Teva's pharmaceutical products, representing more than 25 different chemical entities. Pursuant to the arrangement, Teva will supply the pharmaceutical products to us and we will register and, upon regulatory approval, market the products in Spain. We received marketing approval for certain of the Teva products in 2003 and intend to begin marketing these products in 2004.

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

Our Generic Product Name	Active Ingredient	Sold by Others as	Us
Amoxicilina Davur(R)	amoxicillin trihydrate	Amoxil(R)(GlaxoSmithKline)	i
Ciprofloxacino Davur(R)	ciprofloxacin hydrochloride	Cipro(R)(Bayer)	m i
Enalapril Davur(R)	enalapril maleate	Vasotec(R)(Merck)	c a
Fluoxetina Davur(R)	fluoxetine hydrochloride	Prozac(R)(Eli Lilly)	d
Omeprazol Davur(R) Omeprazol Rimafar(R)	omeprazole	Prilosec(R)(AstraZeneca)	g d
Paroxetene Davur(R)	paroxetine	Paxil(R)(GlaxoSmithKline)	d
Pentoxifilina Davur(R)	pentoxifylline	Trental(R)(Aventis)	p
Simvastatina Davur(R) Simvastatina Rimafar(R)	simvastatin	Zocor(R)(Merck)	h
Trimetazedine Davur(R)	trimetazedine	Idaptan(R)(Servier)	c

Strategic Alliance with Teva

In July 2000, we entered into a strategic alliance with Teva, a world leader in generic pharmaceutical products, in which we were granted a royalty-free non-exclusive license to register and

sell in Spain generic and/or branded versions of more than 75 pharmaceutical products representing more than 25 different chemical entities. We are obligated under this license agreement to submit a registration file for each product to the regulatory authorities in Spain in order to receive marketing authorizations in our name for that product. The marketing authorizations provide us with the requisite approvals, licenses and permits from the regulatory authorities to import, distribute, market and sell the products in Spain. We received marketing approval for certain of the Teva products in 2003 and intend to begin marketing these products in 2004.

In connection with this strategic alliance, Teva also entered into a supply agreement with us pursuant to which it would manufacture the products and supply them to us for marketing and sale in Spain. Our obligation to purchase the products from Teva is non-exclusive, 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 license agreement and the supply agreement have five year terms and both are renewed automatically for one-year terms for each product.

Under a rights agreement entered into with Teva in July 2000, we 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.

Contract Manufacturing and Sales Outside of Spain

In addition to manufacturing our own products, our Spanish manufacturing facility supplies branded and generic products to 14 entities in Spain and more than 15 entities in other European countries which market these products under their own name and with their own labeling. Typically we enter into a supply agreement with these entities for one or more products and license to the entity the registration dossiers we have prepared in order to assist them in obtaining regulatory approval of our product in the country of sale. All of the products we manufacture for others use the same active ingredients that are used in our own marketed products.

We believe contract manufacturing provides a stable, recurring source of cash flow, a means of absorbing overhead costs, and experience in manufacturing a broad line of formulations that is advantageous to us in pursuing and integrating acquired products. Although the volume of our contract manufacturing continues to increase, contract manufacturing as a percentage of consolidated revenues decreased from approximately 50% in 1994 to approximately 15% in 2003. We attribute this change in product mix to the growth in sales of our own branded and generic pharmaceutical products over this period. We expect that contract manufacturing activities as a percentage of our overall revenues will continue to decrease in the future.

We market our contract manufacturing services through contacts made by members of our senior management staff in Spain. Our contract manufacturing customers include entities such as Antibioticos Farma S.A., Laboratorios Edigen S.A. and Shire Iberica S.A. We compete for these sales on the basis of the price we can offer for our high quality products as a result of the efficiencies of our manufacturing facility.

Manufacturing Facility

Our 80,000 square-foot manufacturing facility is located in Zaragoza, Spain. Our manufacturing facility complies with European Good Manufacturing Practices (GMP) 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 our manufacturing facility in Spain so that it will comply with U.S. regulatory requirements. These modifications should enable us to perform additional clinical studies under U.S. regulatory standards so that we may 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 enable us 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 is 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 and Indukern, S.A. is our sole supplier of simvastatin. Spanish sales from two product lines, whose active ingredients are omeprazole and simvastatin, accounted for approximately 31% and 10% of our revenues in 2003, respectively. We believe that alternative sources of omeprazole and simvastatin 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 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
Generic products	Various	Various
Intranasal insulin	CPE-215	Diabetes
Antifungal nail lacquer	CPE-215	Onychomycosis
Improved acetaminophen	Solubility enhancement	Pain; fever
Topical hormonal therapy	CPE-215	Osteoporosis; Erectile dysfunction
Intranasal pain management	CPE-215	Pain

Generic Products

We are continually evaluating which pharmaceutical products are good candidates for us to develop, test and market in Spain 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 bio-equivalent 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.

We typically 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 a recently-completed Phase I study, we believe our intranasal insulin formulation can 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 metered 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 human 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 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 volunteer's 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 are proceeding with the design of a Phase II protocol for evaluation in diabetic patients. Work will continue on formulation development and to select an appropriate administration device for variable dosing.

Diabetes is a metabolic disorder affecting approximately 100 million people worldwide that 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 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 late February 2004, our leading candidate to license its topical Antifungal Nail Lacquer product line decided not to move forward with a collaboration following a change in their senior management. We have opened discussions with other potential licensees and continues to be encouraged with the level of commercial interest in this product line.

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 $500 for a twelve-week treatment regimen, not including physician costs or other periodic monitoring costs.

Improved Acetaminophen

We have developed and patented improved oral formulations of acetaminophen, the active ingredient in such products as McNeil Consumer Healthcare's Tylenol(R) line of products commonly used for controlling pain, fever and inflammation. Our improved oral formulations of acetaminophen make it highly dispersible, rapidly soluble in water, better tasting and faster in reaching peak blood levels. These characteristics give our oral formulations superior properties over most 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 bioequivalency studies, which compare the rate and extent of absorption and levels of concentration of our improved oral formulations needed to produce a therapeutic effect, with other formulations of acetaminophen that previously have been approved by the FDA. We have submitted this product for approval in Spain and are in preliminary discussions with potential collaborators to license and market this product outside of Spain.

Topical Hormonal Therapy

Osteoporosis is a disease characterized by low bone mass and structural deterioration of bone tissue, leading to bone fragility and increased susceptibility to fractures of the hip, spine and wrist. According to the National Osteoporosis Foundation, two million American men have osteoporosis, and another three million are at risk for this disease. We believe that our topical hormonal therapies, incorporating our CPE-215 technology, have the potential to effectively treat osteoporosis in men, without the gastrointestinal side effects of the leading oral treatments.

Erectile dysfunction is defined as the inability to achieve and/or maintain an erection adequate for satisfactory sexual function. Approximately 30 million men in the U.S. and 150 million men worldwide suffer from erectile dysfunction. The condition is correlated with increasing age, cardiovascular disease, hypertension, diabetes, hyperlipidemia and smoking. The leading treatments include oral preparations, which have been associated with a slow onset of action and drug interactions, as well as injections, which can cause pain when administered. We believe that our topical hormonal therapies, incorporating our CPE-215 technology, have the potential to effectively treat erectile dysfunction, without the side effects of the leading treatments.

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, such as testosterone and dihydrotestosterone, may have significant benefits in treating a number of medical afflictions in men, 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 is evaluating the formulations of this 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 anywhere from seconds to minutes or hours. The U.S. prescription market for the treatment of moderate to severe pain, including breakthrough pain, is approximately $2 billion annually.

We are developing an intranasal pain product using our CPE-215 technology with a chemical agent that is widely used for the relief of acute and chronic moderate-to-severe pain and that commonly is prescribed for pain associated with cancer. 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. Our intranasal pain product is in preclinical development for the treatment of chronic pain and acute episodes of chronic pain. We believe our intranasal pain product would provide significant medical benefits over oral and injectable formulations as it combines patient convenience and ease of use with the rapid onset of pain relief and the same potency as injectable delivery routes.

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.

Research Agreement with Pfizer

In October 2001, we entered into a research collaboration with Pfizer in which we were granted a non-exclusive worldwide royalty-free license to use Pfizer's compounds and technology to assess the performance of our CPE-215 technology with Pfizer's compounds. As part of the agreement, we granted to Pfizer the non-exclusive right to test the ability of our CPE-215 technology to enable delivery of

certain compounds proprietary to Pfizer. Pfizer provided the funding necessary to conduct these studies using our CPE-215 technology and agreed to provide additional funding for costs of further studies that are approved by a joint working committee consisting of designees of Pfizer and Bentley. Pfizer has agreed to inform us if, following completion of the research, it is interested in further development of the formulations. However, progress on this collaboration has been slow following Pfizer's merger with Pharmacia and the current agreement expires in April 2004. Pfizer would have to enter into a separate license agreement with us with respect to the manufacture, use, sale, offer for sale and import of the products using our CPE-215 technology before it could begin to distribute, market and sell these products.

Research and Development Resources and Expenditures

Our research and product development efforts take place in the United States and in Spain and are focused on developing new product applications of our drug delivery and drug formulation technologies. We currently have 16 scientists and technicians working on research and product development. For the years ended December 31, 2003, 2002 and 2001, our research and product development expenditures were $4,295,000, $2,960,000 and $2,084,000, respectively.

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 is pending in Europe and other foreign countries. This U.S. patent expires in 2020. We also have four international patents pending covering various applications of our CPE-215 technology, including testosterone and insulin compositions. We also have two issued U.S. patents relating to our hydrogel technology that expire in 2005 and 2007.

We were granted a patent in the United States for our improved oral formulation of acetaminophen, which continues to be pending in Europe and elsewhere. In 2003, we re-filed an international patent for improved oral formulations of omeprazole and lansoprazole, updating the initial applications which were filed in 2000 and 2001. This patent is also pending.

At the end of 2003 we terminated our license from Dartmouth College of the exclusive rights to a patent covering the novel use of androgen therapy for treating fibromyalgia and chronic fatigue syndrome due to the cost of future clinical trials for these indications and a re-evaluation of our clinical priorities.

We own approximately 108 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 reduce costs otherwise associated with contracting for the development, manufacture or marketing of our products by other companies. These reduced 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 most of the same products that we market and manufacture. In Spain, our principal competitors include companies such as Ratiopharm International GmbH, Merck Sharp & Dohme de Espana, S.A., Laboratorios Bayvit S.A. and Almirall Prodes Farma.

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 expect to begin to market certain products directly to distributors in selected markets. Our contract manufacturing customers are regional and multinational pharmaceutical companies. The wholesale distributor network for pharmaceutical products in Europe and more specifically in Spain in recent years has been subject to increasing consolidation, which has increased and we expect will continue to increase our, and other industry participants', customer concentration.

In 2003, 2002 and 2001, only one of our customers, Cofares, accounted for more than ten percent of our consolidated total revenues. Sales to this customer in each of the three years ended December 31, 2003, 2002 and 2001 accounted for approximately 14%, 14% and 15%, respectively, of our total revenues.

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

from product sales.

Employees

We employ approximately 309 people, 18 of whom are employed in the U.S. and 291 of whom are employed in Spain, as of March 1, 2003. Approximately 93 of these employees principally are engaged in manufacturing activities, 151 in sales and marketing, 16 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. 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 warning letters, fines, injunctions, product seizures or recalls, total or partial suspension of production, or refusal by governmental authorities to approve pending marketing approval applications or supplements to approved applications, as well as criminal prosecution.

United States

Prior to marketing a pharmaceutical product in the U.S., the product must be approved by the FDA. For new compounds, the regulatory approval process begins with preclinical laboratory and animal testing. Upon completion, an Investigational New Drug Application is submitted to the FDA, which must become effective before human clinical trials may be commenced. Sometimes, to minimize costs, we have chosen to conduct pilot studies. The data they produce can permit us to move directly into Phase II or III studies with the FDA.

Following completion of laboratory animal testing, human clinical trials typically are conducted in three sequential phases that may overlap.

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

- Phase II - involves studies in a limited patient population to determine the efficacy of the pharmaceutical for specific targeted indications, to determine dosage tolerance and optimal dosage and to identify possible adverse side effects and safety risks.

- Phase III - involves trials undertaken to evaluate clinical efficacy once a compound is found to be effective and to have an acceptable safety profile in Phase II evaluations, and to further test for safety within an expanded patient population at multiple clinical study sites.

The FDA reviews both the clinical plans and the trial results and may discontinue the trials at any time if there are significant safety issues. The results of preclinical and clinical trials are submitted to the FDA in the form of a New Drug Application for marketing approval. The approval process is affected by 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 would be 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, 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 required for the marketing of generic equivalents or new dosage forms of an existing drug. An Abbreviated New Drug Application is required to be submitted to the FDA for approval. When processing an ANDA, the FDA waives the requirement of conducting complete clinical studies, although it normally requires bioavailability and/or bioequivalence studies. Bioavailability indicates the rate and extent of absorption and levels of concentration of a drug product. Bioequivalence compares the bioavailability of one drug product with another, and when established, indicates that the rate of absorption and levels of concentration of a generic drug in the body closely approximate those of the previously approved drug. An ANDA may 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 be registered with the FDA. Domestic manufacturing establishments are subject to biennial inspections by the FDA and must comply with current Good Manufacturing Practices for drugs. To supply products for use in the U.S., foreign manufacturing establishments must comply with GMPs and are subject to periodic inspection by the FDA or by regulatory authorities in such countries under reciprocal agreements with the FDA.

Spain and 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. Prior to Spain's entry into the European Union in 1986, the pharmaceutical regulations in Spain were less stringent. Since that time, we, along with all Spanish pharmaceutical companies, must obtain manufacturing, marketing and pricing authorizations to commercialize pharmaceutical products in Spain.

Pharmaceutical manufacturers in Europe must obtain marketing approval from the regulatory authority in each country it intends 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 bioequivalent 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. (See Item 7 -- Management's Discussion and Analysis of Financial Condition and Results of Operations.)

In order to speed approvals within European Union countries, a mutual recognition procedure has been established. 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. If it does serve as a reference filing, 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, various aspects of the filing must comply with standards that vary by country. In addition, the process for initial evaluation of mutual recognition filings generally is significantly longer than for national filings and, as a result, companies often choose not to use this process for their first approval. Moreover, if the filing is rejected based on the standards of any of the countries selected, then the application will be rejected as a whole. 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 home authority.

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. In the United States, most states have enacted generic substitution legislation requiring or permitting a dispensing pharmacist to substitute a different manufacturer's version of a drug for the one prescribed. 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. We maintain product liability insurance for such potential claims; however, no such claims have ever been asserted against us. 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.

Many countries, directly or indirectly through reimbursement limitations, control the selling prices and reimbursement prices of certain healthcare products. In addition, 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, 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. (See Item 7 -- Management's Discussion and Analysis of Financial Condition and Results of Operations.) The regulation affected six of our chemical entities sold in Spain which currently account for approximately 65% to 70% of our revenues, including the chemical entities omeprazole, simvastatin and enalapril. However, we had been anticipating potential government regulations that could lead to lower selling prices and have developed, and continue to implement, a broad-based growth strategy that should mitigate the impact of the new prices. We cannot assure you 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 which 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 in Spain. Any change in this regulation may negatively affect our sales in Spain, as our products are often prescribed by name by doctors.

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.

Internet Information and SEC Documents

Our internet site is located at www.bentleypharm.com. Copies of our reports filed pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, including Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K may be accessed from our website, free of charge, as soon as reasonably practicable after we electronically file such reports with, or furnish such reports to, the Securities and Exchange Commission. Alternatively, these reports can be accessed through a query at the website of the Securities and Exchange Commission at www.sec.gov.

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 of part of your investment.

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

Bentley's 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 platform technology. This technology, like 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 pharmaceutical 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 Bentley 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 drug products 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.

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 clearances 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 clearances;
- the proposed products may be effective but uneconomical to market; or
- other pharmaceutical companies may market equivalent or superior products.

We will rely on strategic partners to 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 continue to pursue strategic partners for these purposes. We may not be successful in finding 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. 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.

A significant portion of our revenues are generated by the sale of products that are formulated from two active ingredients.

Spanish sales from two product lines whose active ingredients are omeprazole and simvastatin accounted for approximately 31% and 10% of our total revenues in 2003, respectively. The active pharmaceutical ingredient for our omeprazole products are currently purchased from one supplier. In addition, we only have one supplier for the active pharmaceutical ingredient for our simvastatin products. If we lose and cannot effectively replace either of these suppliers or are otherwise unable to continue the sales of products that contain these active ingredients, 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, 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. In addition, 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. (See Item 7 -- Management's Discussion and Analysis of Financial Condition and Results of Operations.) The regulation affected six of our chemical entities sold in Spain, which currently account for approximately 65% to 70% of our revenues, including the chemical entities omeprazole, simvastatin and enalapril.

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, due to insufficient supply, compel companies to continue to produce products that are not profitable for the company. 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. The process of conducting clinical trials and obtaining FDA and other regulatory approvals is lengthy and expensive and we cannot assure you of success. In order to obtain FDA approval of any 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 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.

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. In litigation, 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, courts outside the United States are sometimes 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 approvals 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.

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. If we are unable to obtain these marketing approvals, we would have to seek to enter into collaborative arrangements to sell or license our products to strategic partners that have marketing approval in those countries. We cannot assure you that we would find or enter into acceptable arrangements with such strategic partners to market our products, nor can we assure you that any such arrangements would be successful.

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 both before and after approval of a New Drug Application to determine compliance with the FDA's Good Manufacturing Practices 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.

All of our products are manufactured in one facility.

All of our manufactured products are produced 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.

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, 2003, 86% of our revenues were derived from sales made by our Spanish subsidiaries in Spain and 11% 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;
- 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; and
- adverse tax consequences or overlapping tax structures.

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 97% 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 36% in local currency for the year ended December 31, 2003 compared to the prior year; however, an increase in the value of the Euro, in relation to the U.S. Dollar, had the effect of increasing revenues by approximately $10,449,000 during the year ended December 31, 2003. 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;
- fluctuations of the carrying value of long lived assets; and
- limitations on the remittance of dividends by foreign subsidiaries.

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 cannot maintain 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 other pharmaceutical equivalents 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.

Our revenues increased 65% and our research and development expenditures increased 45% from the year ended December 31, 2002 to the year ended December 31, 2003, challenging our management, administrative, financial, marketing, operational and research and development resources. In addition, 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. 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.

We have used cash from outside financing to fund our operations. 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. We cannot assure you 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 cannot attract and retain key personnel, we may not be able to execute our business plan as anticipated.

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 Science Officer, Vice President of Pharmaceutical Development, 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. The competition for qualified personnel is intense and the loss of key personnel could adversely affect our business. We maintain key person life insurance only for our Chief Executive Officer. We have an employment agreement with each of our key executive officers.

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. 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 $3.8 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.

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, 2003, we had the following capital structure:

	No. of Shares
Common stock outstanding	20,573,000
Common stock issuable upon:	
Exercise of stock purchase warrants	420,000
Exercise of options which are outstanding	3,920,000
Exercise of options which have not been granted	1,578,000
Total common stock outstanding assuming exercise of all of the above	26,491,000

As of December 31, 2003, we had outstanding options and warrants to purchase approximately 4,340,000 shares of common stock at exercise prices ranging from $1.50 to $20.00 (exercisable at a weighted average of $6.33 per share), of which approximately 3,259,000 options and warrants were then vested and exercisable. Since December 31, 2003 we have granted options to purchase approximately 403,000 shares of common stock, exercisable at a weighted average exercise price of $13.27 per share. In addition, 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 and warrants 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 $6.40. 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.

Our business will suffer if we fail to comply with recent federal regulations and proposed rules of the Securities and Exchange Commission and American 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 American 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 American 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.

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 Bentley.

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 positive vote of at least two-thirds is required to approve a merger, a

sale or lease of all or most of our assets, certain other business combinations or dissolution or liquidation, and an affirmative vote of two-thirds is required to amend any provision in our certificate of incorporation relating to our directors and officers or to amend any provision 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 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.

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.

Item 2. Properties

We purchased a 15,700 square foot commercial building situated on approximately 14 acres of land in Exeter, New Hampshire in January 2003 and we moved our corporate headquarters and research and development laboratory into this facility in April 2003. We are located approximately 45 minutes north of Boston, Massachusetts.

We own an 80,000 square foot facility in Zaragoza, Spain, which accommodates our manufacturing plant, warehouse, research and development laboratory and office space. The facility is located in an industrial park and is situated on sufficient acreage 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 facility is currently operating at approximately 67% of its capacity, if it were operating for three 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 Espana, S.A., alleging that we violate their patents in our production of the product simvastatin and requesting an injunction ordering us not to manufacture or market the product. 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 us court costs and legal fees. 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, which we received notice of on January 23, 2003. This case also alleges violation of Merck's patents in the production of the product simvastatin, requests an order that we cease manufacturing the product and demands damages during the period of manufacture. A trial with respect to this matter was held on February 19 and 20, 2004, and we are waiting for the court's decision. We are vigorously opposing this claim as we believe it is without merit. We launched our simvastatin product line in January 2002.

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 the product paroxetine and requesting an order requiring us not to manufacture or market the product. 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 plaintiff attempted to bring against us in 2003, which was dismissed. We filed a response to this suit in February 2004 that includes a counterclaim requesting that the court declare the asserted

patent invalid. We intend to vigorously oppose this claim as we believe it is without merit. We launched our paroxetine product line in 2003.

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 and Related Stockholder Matters

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 American Stock Exchange under the symbol "BNT." Our common stock began trading on the American Stock Exchange on July 31, 1990 and on the Pacific Exchange on March 27, 1996.

	High	Low
Fiscal Year Ended December 31, 2002		
First Quarter	$ 11.57	$ 7.60
Second Quarter	12.08	9.91
Third Quarter	11.60	8.35
Fourth Quarter	10.00	6.40
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 Ending December 31, 2004		
First Quarter (through March 2, 2004)	14.76	10.62

As of March 2, 2004 there were 1,079 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. We intend to retain future earnings in order to finance the growth and development of our business.

Item 6. Selected Financial Data

The following sets forth the selected consolidated statement of

operations data for each of the five years in the period ended December 31, 2003 and consolidated balance sheet data as of December 31, 1999, 2000, 2001, 2002 and 2003, all of which are derived from our audited consolidated financial statements and related notes. The following selected financial data for each of the three years in the period ended December 31, 2003 and as of December 31, 2002 and 2003 should be read together with our consolidated financial statements and related notes appearing elsewhere in Item 15 of this Annual Report on Form 10-K and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The consolidated statement of operations data for the periods ended December 31, 1999 and 2000 and the consolidated balance sheet data as of December 31, 1999, 2000 and 2001 are derived from our audited consolidated financial statements and related notes not included in Item 15 of this Annual Report on Form 10-K.

Consolidated Statement of Operations Data

	For The Year Ended Decem		
(in thousands, except per share data)	1999	2000	2001
Total revenues	$ 20,249	$ 18,617	$ 26,411
Cost of sales	8,445	7,189	11,462
Gross profit	11,804	11,428	14,949
Operating expenses	11,226	11,942	16,137
Gain on sale of drug licenses	-	-	5,050
Other income (expenses), net	(887)	(9)	(49)
Provision for income taxes	781	222	2,452
Net income (loss)	$ (1,090)	$ (745)	$ 1,361
Net income (loss) per common share - basic	$ (0.12)	$ (0.06)	$ 0.10
Net income (loss) per common share - diluted	$ (0.12)	$ (0.06)	$ 0.08
Weighted average common shares outstanding - basic	9,147	12,981	14,196
Weighted average common shares outstanding - diluted	9,147	12,981	16,147

Consolidated Balance Sheet Data

	December 31,				
(in thousands)	1999	2000	2001	2002	2003

Working capital	$ 1,130	$ 3,742	$ 6,276	$ 30,703	$ 45,701
Currrent assets	$ 11,689	$ 13,104	$ 15,839	$ 43,972	$ 66,899
Non-current assets	10,548	15,773	16,280	20,720	33,564
Total assets	$ 22,237	$ 28,877	$ 32,119	$ 64,692	$100,463
Current liabilities	$ 10,559	$ 9,362	$ 9,563	$ 13,269	$ 21,198
Long-term debt	-	908	142	345	369
Other non-current liabilities	104	791	1,990	2,327	2,731
Total liabilities	$ 10,663	$ 11,061	$ 11,695	$ 15,941	$ 24,298
Redeemable preferred stock	$ -	$ -	$ -	$ -	$ -
Stockholders' equity	$ 11,574	$ 17,816	$ 20,424	$ 48,751	$ 76,165

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.

Business Environment

We are a specialty pharmaceutical company focused on:

- research, development and licensing/commercialization of advanced drug delivery technologies and pharmaceutical products; and
- development, licensing and sales of generic and branded pharmaceutical products and the manufacturing of pharmaceuticals for others.

In our research and development activities, we have patents and other proprietary rights to technologies that facilitate the absorption of drugs. Our pharmaceutical product sales activities are based in Spain, where we have a significant commercial presence and we manufacture and market approximately 100 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. We also manufacture pharmaceuticals for other drug companies.

We develop products which incorporate our drug delivery technologies

and have licensed applications of our proprietary CPE-215(R) drug delivery technology to Auxilium Pharmaceuticals, Inc., which launched Testim(TM), the first product incorporating our drug delivery technology, in February 2003. Testim 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), including loss of muscle mass and a decrease in sexual desire, sexual motivation and frequency of spontaneous erections. 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 generic and branded products are marketed to physicians, pharmacists and hospitals by our three separate sales and marketing organizations based in Spain: Laboratorios Belmac, Laboratorios Davur and Laboratorios Rimafar. We continually add to our product portfolio in response to increasing market demand for generic and branded therapeutic agents and 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 countries. We have a strategic alliance with Teva Pharmaceutical Industries Ltd. granting us the right to register and market in Spain more than 75 of Teva's pharmaceutical products through our sales force of approximately

151 full-time personnel located in major cities throughout Spain. In addition, our Spanish manufacturing facility produces pharmaceutical products which are marketed by pharmaceutical companies both in Spain and in other markets.

Consolidated Results of Operations

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

Revenues

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

Our total revenues increased 65% from the prior year. 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 first product incorporating our drug delivery technology, by our licensee in February 2003.

Our revenues are generated through our five primary sales channels (branded, generic, contract manufacturing, sales outside of Spain and licensing and collaborations). See a summary of our revenues by sales channel and top-selling product lines below:

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

	Sales Within Spain				
Product Line	Branded Products	Generic Products	Contract Manu-facturing	Other Revenues	Total
Omeprazole	$ 6,099	$13,863	$ -	$ -	$19,962
Simvastatin	2,176	4,412	-	-	6,588
Enalapril	2,610	1,878	-	-	4,488
Codeisan	2,713	-	-	-	2,713
Pentoxifylline	-	2,070	-	-	2,070
All other products	5,463	4,744	-	-	10,207
Contract manufacturing	-	-	9,536	-	9,536
Sales outside of Spain	-	-	-	7,391	7,391
Licensing and collaborations	-	-	-	1,721	1,721
Total Revenues	$19,061	$26,967	$ 9,536	$ 9,112	$64,676
% 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 Manu-facturing	Other Revenues	Total
Omeprazole	$ 5,051	$ 9,813	$ -	$ -	$14,864
Simvastatin	322	1,261	-	-	1,583
Enalapril	955	1,515	-	-	2,470
Codeisan	1,944	-	-	-	1,944
Pentoxifylline	-	1,348	-	-	1,348
All other products	4,103	2,738	-	-	6,841
Contract manufacturing	-	-	7,406	-	7,406
Sales outside of Spain	-	-	-	2,262	2,262
Licensing and collaborations	-	-	-	418	418
Total Revenues	$12,375	$16,675	$ 7,406	$ 2,680	$39,136
% of 2002 Revenues	32%	43%	19%	6%	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 over the past eight years 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 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 the prior year. 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 over the past 12 months, had the effect of increasing revenues by approximately $10,449,000, or 27%, during the year ended December 31, 2003.

Prices for prescription pharmaceutical products in Spain must be approved by the 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 six of our chemical entities, including the chemical entities omeprazole, simvastatin and enalapril, which accounted for approximately 65% to 70% of revenues in the year ended December 31, 2003. These new prices were required to take effect on December 26, 2003. However, we, and some other pharmaceutical companies in Spain, strategically implemented the new prices on December 1, 2003. Our strategy was to gain additional market share by selling to customers that wanted to buy the products at the new lower prices. We anticipated this opportunity as some of our customers delayed placing orders in November. November sales declined by approximately 19% percent from October

levels; however, December sales demand was very strong as we gained market share as a result of our pricing strategy. The increase in December unit volume offset the impact of the lower prices. While the adoption of the new prices did not have a material effect on our total sales in December, it did reduce our margins. Over the years, we had steadily improved our gross margins on net product sales from 57% in 2001 to 59% for the ten months ended October 31, 2003. The improved margins were the result of economies of scale. Our gross margins in November slipped to 55% as our fixed costs were absorbed by fewer units sold in that month. Upon reducing our prices in December of 2003, our gross margins remained constant at 55%, but unit volume increased by approximately 60% over November levels.

We have implemented several initiatives to mitigate the decline in margins. We expect to continue to increase our future sales volume through our pipeline of approximately 100 products, consisting of approximately 20 chemical entities that are not affected by the new pricing regulations. In addition, we have modified our pricing structure in efforts to increase our sales volume and market share throughout Spain. 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 have made significant investments in renovating and increasing capacity in our manufacturing facility, as well as investments in new high speed, high volume equipment. These investments will enable us to manufacture and package larger

quantities of products more efficiently and cost effectively. We anticipate that the current gross margins will continue until the existing inventory is depleted, near the end of the first quarter of 2004 and then we expect to see margins increase by about two percentage points. Thereafter, we expect margins to gradually improve, as they have in the past, as a result of increasing volumes and economies of scale.

Branded Pharmaceutical Products

(in thousands)					Increase	
	2003	%	2002	%	$	%
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 the prior year, 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 the prior year. Sales of our branded enalapril increased by approximately $1,655,000, or approximately 173% from the prior year. Sales of our branded omeprazole increased by approximately $1,048,000, or 21% from the prior year. Sales of our branded codeisan increased by approximately $769,000, or approximately 40% from the prior year. 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 over the past 12 months, 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

(in thousands)					Increase	
	2003	%	2002	%	$	%
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 the prior year. Sales of our generic omeprazole increased by approximately $4,050,000, or approximately 41% from the prior year. Sales of our generic simvastatin increased by approximately $3,151,000, or approximately 250% from the prior year. Sales of our generic pentoxifylline increased by approximately $722,000, or approximately 54% from the prior year. Generic products launched in 2003, such as trimetazedine and paroxetine, accounted for approximately $1,600,000 of our 2003 revenues. We expect to continue to increase our generic drug portfolio and increase our generic drug sales in Spain as products come off patent in the future. An increase in the weighted average value of the Euro, in relation to the U.S. Dollar over the past 12 months, had the effect of increasing generic net product sales by approximately $4,461,000, or 27%, during the year ended December 31, 2003.

Contract Manufacturing

(in thousands)			Increase	
	2003	2002	$	%
Contract manufacturing	$9,536	$7,406	$2,130	29%

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. Revenues generated from contract manufacturing have increased by approximately 29% from the prior year, but represented only 15% of total revenues in 2003, compared to 19% of total revenues in 2002. The increase is primarily attributable to increased demand for formulations of omeprazole, our largest contract manufactured product line. Our increased capacity and high speed, high volume equipment enable us to manufacture pharmaceutical products at low costs. This competitive advantage could lead to an increase in contract manufacturing agreements in 2004 as other pharmaceutical companies in Spain search to find low cost alternatives to mitigate the new lower selling prices. An increase in the weighted average value of the Euro, in relation to the U.S. Dollar over the past 12 months, had the effect of increasing contract manufacturing sales by approximately $1,577,000, or 21%, during the year ended December 31, 2003.

Sales Outside of Spain

(in thousands)			Increase	
	2003	2002	$	%
Sales outside of Spain	$7,391	$2,262	$5,129	227%

We have entered into license and supply agreements with more than 15 entities to sell our products outside of Spain. Sales under these supply agreements have increased 227% from 6% of total revenues in 2002 to 11% of total revenues in 2003. The $5,129,000 increase is primarily attributable to demand for formulations of omeprazole, our largest selling product outside of Spain. An increase in the weighted average value of the Euro, in relation to the U.S. Dollar over the past 12 months, had the effect of increasing sales outside of Spain by approximately $1,223,000, or 54%, 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, the first product incorporating our drug delivery technology, which was launched by our licensee, Auxilium, in February 2003. Testim is currently reported to capture approximately 10% of all new testosterone replacement prescriptions in the market. 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 the prior year. Approximately $14,315,000, or 92% of 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 the prior year as 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 at reduced selling prices. We experienced an increase in gross profit of 42% in local currency in 2003 compared to the prior year. An increase in the weighted average value of the Euro, in relation to the U.S. Dollar over the past 12 months, had the effect of increasing gross profit by approximately $6,065,000 during the year ended December 31, 2003.

Gross margins on certain of our products have decreased as a result of the recently reduced selling prices in Spain. Although we were not required to sell products at the new lower prices until December 26, 2003, we strategically implemented the new price structure beginning December 1, 2003. Our strategy was to gain additional market share by selling to customers that wanted to buy the products at the new lower prices. See discussion above in Spanish Operations.

As discussed above, we have implemented several initiatives to mitigate the decline in margins. We expect to continue to increase our future sales volume through our pipeline of approximately 100 products, consisting of approximately 20 chemical entities that are not affected by the new pricing

regulations. In addition, we have modified our pricing structure in efforts to increase our sales volume and market share throughout Spain. 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 have made significant investments in renovating and increasing capacity in our manufacturing facility, as well as investments in new high speed, high volume equipment. These investments will enable us to manufacture and package larger quantities of products more efficiently and cost effectively. We anticipate that

the current gross margin percentages will continue until the existing inventory is depleted near the end of the first quarter of 2004 and then we expect to see margins increase by about two percentage points. Thereafter, we expect margins to gradually improve, as they have in the past, as a result of increasing volumes and economies of scale.

Gross margins could decrease in the future if sales of higher priced products are replaced with sales of lower priced generic products, as a result of a change in our product mix or by additional governmental action. However, as previously discussed we have developed, and continue to implement, a broad-based growth strategy that should mitigate the impact on our margins over time.

Selling and Marketing Expenses

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

Selling and marketing expenses increased by approximately 37% from the prior year. 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, over the past 12 months 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

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

General and administrative expenses increased 43% from the prior year. 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, over the past 12 months. We expect that our future expenditures for general and administrative expenses will continue to increase as we grow. Although we cannot reasonably estimate the costs associated with

implementation of the internal control provisions of the Sarbanes-Oxley Act of 2002, we do expect to incur costs not previously experienced.

Research and Development Expenses

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

Research and development expenses increased approximately 45% from the prior year. 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. We are using our U.S. laboratory to develop potential product applications using our drug delivery technologies. 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.

We expect that our future expenditures for research and development activities will continue to increase as a result of programs that are necessary to advance new applications of our technologies. We are currently in the planning stages of clinical programs to support the eventual distribution of certain of our Spanish generic pharmaceutical products in other countries, including the U.S. We have also undertaken a clinical program for the intranasal delivery of insulin and have recently completed a successful Phase I study and are in the planning stages of additional clinical trials. We expect to incur costs to conduct clinical trials and support the required regulatory submissions for these programs. Although some of our cost estimates are preliminary, and the specific timing is not known, our research and development expenses in 2004 could be $2,000,000 higher than in the year ended December 31, 2003.

Provision for Income Taxes

	2003		
(in thousands)	Spain	U.S.	Consol-idated
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 the prior year. 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(R), Lactoliofil(R) 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, over the past 12 months.

Our U.S. Company recorded a provision for foreign incomes 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

(in thousands)	2003	2002	Increase $	Increase %
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). Net income in the future could be negatively impacted as a result of the lower selling prices in Spain and anticipated increases in research and development programs that are expected to benefit future periods. However, as previously discussed, our broad-based growth strategy should mitigate the impact of these developments over time.

Fiscal Year Ended December 31, 2002 Compared To Fiscal Year Ended December 31, 2001

Revenues

(in thousands)			Increase	
	2002	2001	$	%
Revenues:				
Net product sales	$38,718	$26,411	$12,307	47%
Licensing and collaboration revenues	418	-	418	*
Total revenues	$39,136	$26,411	$12,725	48%

* Not meaningful

Net Product Sales. Net product sales increased by 47% from $26,411,000 in 2001 to $38,718,000 in 2002. The $12,307,000 increase was primarily the result of our continuing efforts to increase sales in the generic drug market in Spain. We anticipated the opportunities in the emerging generic drug market in Spain and began taking measures over four years ago to enter the Spanish generic drug market. We began to register, manufacture and market generic pharmaceutical products in Spain and began aligning our business model to be competitive in this arena, including hiring and training a new generic products sales force, submission of generic-equivalent products to the Spanish Ministry of Health for approval and a marketing campaign designed to position ourselves as a leader in the Spanish generic drug market. We experienced an increase in net sales of 42% in local currency in Spain in 2002 compared to 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 revenues by approximately $2,145,000 during the year ended December 31, 2002.

Prices for prescription pharmaceuticals have been established in Spain by the Ministry of Health. In order to control rising healthcare costs, substitution of generically equivalent products is often encouraged. In certain circumstances, the local governments in Spain require that prescriptions for generic medications be filled using one of the three cheapest products on the market unless the prescription specifies a particular manufacturer's product. These policies may have the effect of eroding gross margins, as sales of higher priced branded products may be replaced with sales of lower priced generic products. We are striving to maintain product sales and gross margins by concentrating our efforts on increasing sales volume, being competitive in the generic drug market, developing new products and increasing exports outside Spain.

Licensing and Collaboration Revenues. Licensing and collaboration revenues totaled $418,000 in 2002. We entered into a research collaboration whereby our collaborator agreed to fund a research and development program to combine Bentley's patented CPE-215 drug delivery technologies with certain proprietary compounds. Our collaborator advanced to us $250,000 during the fourth quarter of 2001, which we recorded as deferred income as of December 31, 2001, and we recognized it as revenue as the related costs were incurred. We also recognized revenues totaling $150,000 during the year ended December 31, 2002, related to product licensing activities, which we included in the Consolidated Income Statements as licensing and collaboration revenues.

Gross Profit. Gross profit increased by 52% from $14,949,000 in 2001 to $22,659,000 in 2002. The $7,710,000 increase was the direct result of the growth in our net product sales from 2001 to 2002. Our gross margins on net product sales in 2002 increased slightly to 57.4% compared to 56.6% in the prior

year as 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. We experienced an increase in gross profit of 42% in local currency in 2002 compared to 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 gross profit by approximately $1,218,000 during the year ended December 31, 2002. Sales of generic products accounted for approximately 42% of our net product sales during the year ended December 31, 2002, compared to 30% in the prior year. Although we expect to continue to benefit from economies of scale in the future as we grow, gross margins may decrease as sales of generic products, with lower margins, become more significant in the future. Additionally, the Ministry of Health in Spain levies a tax on pharmaceutical companies for the purpose of funding rising healthcare costs in Spain. In 2002, this tax had the effect of reducing gross profit by approximately $551,000 and gross margins by approximately 1 percentage point.

Selling and Marketing Expenses

(in thousands)			Increase	
	2002	2001	$	%
Selling and marketing	$ 10,400	$ 9,057	$1,343	15%

Selling and marketing expenses increased by 15% from $9,057,000 in 2001 to $10,400,000 in 2002. The $1,343,000 increase was instrumental in achieving a 47% increase in net product sales during the period, as a result of our successful sales and marketing programs. 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 $537,000 in 2002. Selling and marketing expenses as a percentage of net product sales decreased to 27% in 2002 compared to 34% of sales in 2001.

General and Administrative Expenses

(in thousands)			Increase	
	2002	2001	$	%
General and administrative	$ 4,902	$ 4,085	$ 817	20%

General and administrative expenses increased by 20% from $4,085,000 in 2001 to $4,902,000 in 2002. The $817,000 increase was the result of increased general and administrative activities required to support our revenue growth in 2002. General and administrative expenses as a percent of total revenues decreased to only 12.5% in 2002, compared to 15.5% of revenues in 2001. General and administrative expenses would have been approximately $162,000 lower in 2002, absent the increase in the weighted average value of the Euro, in relation to the U.S. Dollar. We expect that our future expenditures for general and administrative expenses will continue to increase as we grow. Although we cannot reasonably estimate the costs associated with implementation of the internal control provisions of the Sarbanes-Oxley Act of 2002, we do expect to incur costs not previously experienced; however, we do not believe that these costs will be material to our financial position, results of operations or cash flows.

Research and Development Expenses

(in thousands)			Increase	
	2002	2001	$	%
Research and development	$ 2,960	$ 2,084	$ 876	42%

Research and development expenses increased by 42% from $2,084,000 in 2001 to $2,960,000 in 2002. The $876,000 increase was the result of an increase in our costs associated with our research and development collaboration as well as our Phase I/II Clinical Studies (treatment of nail fungal infections), 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. We are using our U.S. laboratory to develop potential product applications using our drug delivery technologies. 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. We expect that our future expenditures for research and development activities will continue to increase as a result of programs that are necessary to advance new applications of our technologies.

Depreciation and Amortization Expenses

(in thousands)	Increase

	2002	2001	$	%
Depreciation and amortization	$ 1,015	$ 911	$ 104	11%

Depreciation and amortization expenses increased by 11% from $911,000 in 2001 to $1,015,000 in 2002. The $104,000 increase in 2002 was primarily the result of higher depreciation charges with respect to recent asset additions and the effect of fluctuations in foreign currency exchange rates. Depreciation and amortization charges are expected to be higher in 2003 as a result of these additions.

Provision for Income Taxes

	2002		
(in thousands)	Spain	U.S.	Consoli
Income (loss) before income taxes	$ 6,913	$(2,743)	$ 4,1
Provision (benefit) for income taxes	2,534	(933)	1,6
Valuation allowance	-	933	9
Net provision for income taxes	2,534	-	2,5
Net income (loss)	$ 4,379	$(2,743)	$ 1,6
Effective tax rate	37%	0%	6

We generated additional U.S. federal net operating loss carry-forwards in 2002. 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 benefit has been recognized with respect to U.S. losses reported in 2002. We recorded a provision for foreign income taxes totaling $2,534,000 (37% of Spanish pre-tax income) for the year ended December 31, 2002 compared to a provision for foreign income taxes of $2,452,000 in the prior year. The provision for income taxes for 2002 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(R), Lactoliofil(R) and other drug licenses, whereas the provision for income taxes in the prior year included approximately $607,000 as a result of reporting taxable income from operations in Spain and approximately $1,845,000 as a result of capital gains taxes arising from the sale of drug licenses. The provision for income taxes would have been approximately $110,000 lower than reported, absent the increase in the weighted average value of the Euro, in relation to the U.S. Dollar.

Net Income

(in thousands)

	2002	2001	Increas $
Net income	$ 1,636	$ 1,361	$ 275
Net income per common share:			
Basic	$ 0.10	$ 0.10	$ -
Diluted	$ 0.08	$ 0.08	$ -
Weighted average common shares outstanding:			
Basic	16,569	14,196	2,373
Diluted	19,798	16,147	3,651

Including the $650,000 pre-tax gain on sale of the Biolid, Lactoliofil and other drug licenses, we reported income from operations of $4,032,000 for 2002 compared to income from operations of $3,862,000 (including $4,977,000 of pre-tax gain on sale of the Controlvas(R) drug license) in the prior year. Excluding the $650,000 pre-tax gain from the sale of drug licenses, income from operations for the year ended December 31, 2002 totaled $3,382,000 compared to a loss of $1,188,000 in the prior year. The combination of income from operations of $4,032,000 and the non-operating items, primarily the provision for income taxes of $2,534,000, resulted in 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) for 2002, compared to net income in the prior year of $1,361,000, or $.10 per basic common share ($.08 per diluted common share) on 14,196,000 weighted average basic common shares outstanding (16,147,000 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 2002				
	Three Months Ended (Unaudit				
	3/31/2002(a)	6/30/2002(a)	9/30/2002(a)	12/31/2002	3/31/2003
	(in thousands, except per s				
Total revenues	$ 9,174	$ 9,867	$ 8,571	$ 11,524	$ 14,988
Cost of sales	3,776	4,249	3,579	4,873	6,121
Gross profit	5,398	5,618	4,992	6,651	8,867

Operating expenses	4,715	4,743	4,300	5,519	6,213
Gain on sale of drug licenses	72	520	-	58	-
Income from operations	755	1,395	692	1,190	2,654
Other income/(expenses), net	(23)	10	67	84	29
Provision for income taxes	597	886	468	583	1,151
Net income	$ 135	$ 519	$ 291	$ 691	$ 1,532
Net income per common share:					
Basic	$ 0.01	$ 0.03	$ 0.02	$ 0.04	$ 0.09
Diluted	$ 0.01	$ 0.03	$ 0.01	$ 0.03	$ 0.08
Weighted average common shares outstanding:					
Basic	14,634	16,823	17,377	17,405	17,455
Diluted	17,922	20,484	20,706	20,121	20,350

(a) Certain prior period amounts previously reported as cost of sales have been reclassified as a reduction of revenues to conform with the current period's presentation format. Such reclassifications are not considered material to the consolidated financial statements.

Liquidity and Capital Resources

Total assets increased 55% from $64,692,000 at December 31, 2002 to $100,463,000 at December 31, 2003, while stockholders' equity increased 56% from $48,751,000 at December 31, 2002 to $76,165,000 at December 31, 2003. The increase in stockholders' equity reflects primarily the net proceeds from the exercise of stock options and warrants totaling $15,222,000, the positive impact of the fluctuation of the Euro/US dollar exchange rate which totaled $5,585,000 and net income of $6,097,000.

Working capital increased 49% from $30,703,000 at December 31, 2002 to $45,701,000 at December 31, 2003, primarily as a result of proceeds from exercises of stock options and warrants and positive cash flow from operations, which was partially offset by additions to fixed assets.

Cash, cash equivalents and marketable securities increased 51% from $26,977,000 at December 31, 2002 to $40,645,000 at December 31, 2003, primarily as a result of net proceeds received from exercises of stock options and warrants totaling $15,222,000 and cash provided by operating activities of $8,168,000, partially offset by additions to fixed assets totaling $8,076,000 and additions to drug licenses and related costs of $2,298,000. Also included in cash and cash equivalents at December

31, 2003 are approximately $29,156,000 of short-term liquid investments considered to be cash equivalents.

Receivables increased from $10,874,000 at December 31, 2002 to

$18,036,000 at December 31, 2003 as a direct result of the increase in net product sales. Trade receivables comprise 90% of total 2003 receivables, totaling $16,233,000. Receivables at December 31, 2003 also include royalties receivable totaling $884,000 and taxes receivable totaling $953,000. Receivables increased by approximately $4,119,000 in local currency, but fluctuations in foreign currency exchange rates increased receivables reported in U.S. dollars by approximately $3,043,000. We have not experienced any material delinquencies on our receivables that have had a material effect on our financial position, results of operations or cash flows. Inventories increased from $5,133,000 at December 31, 2002 to $7,106,000 at December 31, 2003 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 $801,000 in local currency, but fluctuations in foreign currency exchange rates increased inventories reported in U.S. dollars by approximately $1,172,000.

The combined total of accounts payable and accrued expenses increased from $11,265,000 at December 31, 2002 to $17,257,000 at December 31, 2003, primarily due to the effect of fluctuations in foreign currency exchange rates (approximately $2,864,000), accruals for taxes payable (approximately $1,784,000) and additions to fixed assets of $733,000.

Short-term borrowings and current portion of long-term debt increased from $1,725,000 at December 31, 2002 to $1,985,000 at December 31, 2003, as a result of the effect of fluctuations in foreign currency exchange rates partially offset by net repayment of short-term borrowings. The weighted average interest rate on our short-term borrowings and current portion of long-term debt is 3.8%.

Long-term debt, which totaled $345,000 at December 31, 2002, increased to $369,000 during the year ended December 31, 2003 as a result of imputed interest on certain interest-free loans in Spain. The weighted average interest rate (including imputed interest) on our long-term debt is 5.6%.

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, 2003 (in thousands):

		Payme	
	Total	Less than 1 year	1 - 3 years
Long-term debt, including imputed interest of $83	$ 522	$ 70	$ 107
Capital leases	-	-	-
Operating leases	1,405	708	686
Purchase obligations(1)	-	-	-
Other long-term liabilities(2)	2,731	15	1,134
Total contractual cash obligations(3)	$4,658	$ 793	$1,927

(1) 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, 2003. 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 which have been entered into subsequent to December 31, 2003 whereby the Company is currently obligated to pay approximately $1,490,000 to its key executives in 2004 and $350,000 in 2005. Such agreements are generally for one to two years in duration.

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.

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

Operating activities for the year ended December 31, 2003 provided net cash of $8,168,000. Investing activities, primarily additions to machinery and equipment and capital improvements made to the manufacturing facility in Spain, the purchase of a commercial building in the U.S. and additions to drug licenses used net cash of $10,843,000 during the year ended December 31, 2003. Financing activities, consisting primarily of the proceeds received from the exercise of stock options and warrants (approximately $15,222,000), partially offset by net repayments of borrowings (approximately $21,000) provided net cash of $14,201,000 during the year ended December 31, 2003.

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 facility during 2004 that include the acquisition of additional manufacturing equipment and expansion of our warehouse, in order to accommodate our expected growth. We

have budgeted approximately $4,600,000 for capital expenditures during 2004.

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. 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.

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, 2003. 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 for the remainder of our 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 (loss) in the Consolidated Balance Sheets. Foreign currency translation gains and losses arising from cash transactions are credited to or charged against current earnings.

New Accounting Standards

In December 2002, the Financial Accounting Standards Board issued SFAS No. 148, Accounting for Stock-Based Compensation - Transition and Disclosure. SFAS No. 148 amends SFAS No. 123, Accounting for Stock-Based Compensation, to provide alternative methods of transition for a voluntary change to the fair value method of accounting for stock-based employee compensation. SFAS No. 148 also amends the disclosure requirements of SFAS No. 123 to require disclosure in the summary of significant accounting policies, the effects of an entity's accounting policy with respect to stock-based employee compensation on reported net income and earnings per share in annual and interim financial statements. The disclosure provision is required for all companies with stock-based employee compensation, regardless of whether the company utilizes the fair value method of accounting described in SFAS No. 123 or the intrinsic value method described in APB Opinion No. 25, Accounting For Stock Issued to Employees. SFAS No. 148's amendment of the transition and annual disclosure provisions of SFAS No. 123 were effective for fiscal years ending after December 15, 2002 and have been incorporated in the Notes to the accompanying Consolidated Financial Statements. The disclosure

provisions for interim financial statements were effective for interim periods beginning after December 15, 2002. We have chosen not to adopt the fair value method of accounting for stock-based employee compensation at this time. Therefore, we continue to account for stock-based compensation utilizing the intrinsic value method of accounting for stock-based employee compensation described by APB Opinion No. 25.

In November 2002, the EITF issued EITF Issue No. 00-21, which addresses certain aspects of the accounting by a vendor for arrangements under which it will perform multiple revenue-generating activities. EITF Issue No. 00-21 establishes three principles: revenue arrangements with multiple deliverables should be divided into separate units of accounting; arrangement consideration should be allocated among the separate units of accounting based on their relative fair values; and revenue recognition criteria should be considered individually for each separate unit of accounting. EITF Issue No. 00-21 is effective for all revenue arrangements entered into in fiscal periods beginning after June 15, 2003, with early adoption permitted. The adoption of EITF Issue No. 00-21 in our third quarter of 2003 has not had a material effect on our financial position, results of operations or cash flows for the year ended December 31, 2003. However, the adoption of EITF Issue No. 00-21 may require the deferral and recognition over extended periods, of certain up-front fees

associated with our multiple element collaboration and license agreements and of our marketing, distribution and supply agreements.

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, 2003 and 2002 was .80 Euros and .95 Euros per U.S. Dollar, respectively. The weighted average exchange rate for the years ended December 31, 2003, 2002 and 2001 was .89 Euros, 1.06 Euros and 1.12 Euros per U.S. Dollar, respectively. The effect of foreign currency fluctuations on long lived assets for the year ended December 31, 2003 was an increase of $5,585,000 and the cumulative historical effect was an increase of $5,169,000, as reflected in our Consolidated Balance Sheets as accumulated other comprehensive income (loss). Although exchange rates fluctuated significantly in recent years, we do not believe that the effect of foreign currency fluctuation is material to our results of operations as the expenses related to much of our foreign currency revenues are in the same functional currency as those revenues, the Euro. However, 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, 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 3.8% and the balance outstanding is $1,915,000 as of December 31, 2003. A portion of our long-term borrowings is non-interest bearing and the balance outstanding on these borrowings at December 31, 2003 is $369,000 including imputed interest (ranging from 4.8% to 6.0%) of $83,000. The balance of our long-term borrowings of $70,000 bears interest at the rate of 2.9%. Consequently, the weighted average interest rate on our long-term borrowings is 5.6%. The effect of an increase in the interest rate of one percentage point (one hundred basis points) to 4.8% on short-term borrowings and to 6.6% on long-term borrowings would have the effect of increasing interest expense by approximately $24,000 annually.

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

Bentley maintains disclosure controls and procedures that are designed to ensure that information required to be disclosed in Bentley'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 Bentley's management, including its Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Bentley carried out an evaluation, under the supervision and with the participation of Bentley's management, including the Company's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of Bentley's disclosure controls and procedures. Based on that evaluation, Bentley's Chief Executive Officer and Chief Financial Officer concluded that (i) Bentley's disclosure controls and procedures were effective as of December 31, 2003 and (ii) no change in internal control over financial reporting occurred during the quarter ended December 31, 2003 that has materially affected, or is reasonably likely to materially affect, such internal control over financial reporting. Although Bentley's management continues to evaluate the internal control structure and strengthen Bentley's control procedures, particularly in connection with the requirements of Section 404 of the Sarbanes-Oxley Act of 2002, there have been no significant changes in Bentley's internal controls or in other factors which could significantly affect internal controls since that evaluation.

Part III

Item 10. Directors and Executive Officers of the Registrant

Name		Position
James R. Murphy	54	Chairman, President, Chief Executive Officer and Direct
Michael McGovern	60	Vice Chairman and Director
Robert M. Stote, M.D.	64	Senior Vice President, Chief Science Officer and Direct
Michael D. Price	46	Vice President, Chief Financial Officer, Treasurer, Sec
Robert J. Gyurik	57	Vice President of Pharmaceutical Development and Dire
Jordan A. Horvath	42	Vice President and General Counsel
Charles L. Bolling	80	Director
Miguel Fernandez	73	Director
William A. Packer	68	Director

John W. Spiegel	62	Director

James R. Murphy has served as one of our directors since 1993. Mr. Murphy became President of Bentley in September 1994, was named Chief Executive Officer effective January 1995 and became Chairman of the Board in June 1995. Prior to rejoining Bentley, 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 September 1992 until March 1993, Mr. Murphy served as a consultant in the pharmaceutical industry with his primary efforts directed toward product licensing. Prior thereto, Mr. Murphy served as Director - Worldwide Business Development and Strategic Planning of Bentley from December 1991 to September 1992. Mr. Murphy previously spent 14 years in pharmaceutical research and product development with SmithKline Corporation and in international business development with contract research and consulting laboratories. Mr. Murphy received a B.A. in Biology from Millersville University.

Michael McGovern has served as one of our directors since 1997 and was named Vice Chairman of Bentley in October 1999. Mr. McGovern serves as President of McGovern Enterprises, a provider of corporate and financial consulting services, which he founded in 1975. Mr. McGovern is Chairman of the Board of Specialty Surgicenters, Inc., is Vice Chairman of the Board of Employment Technologies, Inc. and is a Director on the corporate boards of Training Solutions Interactive, Inc. and the Reynolds

Development Company. Mr. McGovern received a B.S. and M.S. in accounting and his Juris Doctor from the University of Illinois. Mr. McGovern is a Certified Public Accountant.

Robert M. Stote, M.D. became Senior Vice President and Chief Science Officer of Bentley in March 1992 and has served as one of our directors since 1993. Prior to joining Bentley, Dr. Stote was employed for 20 years by SmithKline Beecham Corporation serving in a variety of executive clinical research positions. Dr. Stote was Chief of Nephrology at Presbyterian Medical Center of Philadelphia from 1972 to 1989 and was Clinical Professor of Medicine at the University of Pennsylvania. Dr. Stote also serves as a Director of Datatrak International, Inc. Dr. Stote received a B.S. in Pharmacy from the Albany College of Pharmacy, an M.D. from Albany Medical College and is Board Certified in Internal Medicine and Nephrology. He was a Fellow in Nephrology and Internal Medicine at the Mayo Clinic and is currently a Fellow of the American College of Physicians.

Michael D. Price became Chief Financial Officer, Vice President/Treasurer and Secretary of Bentley in October 1993, April 1993 and November 1992, respectively, and has served as one of our directors since 1995. He has served Bentley in other capacities since March 1992. Prior to joining Bentley, he was employed as a financial and management consultant with Carr Financial Group from March 1990 to March 1992. Prior thereto, he was employed as Vice President of Finance with Premiere Group, Inc. from June 1988 to February 1990. Prior thereto, Mr. Price was employed by Price Waterhouse (now PriceWaterhouseCoopers) from January 1982 to June 1988 where his last position with that firm was as an Audit Manager. Mr. Price received a B.S. in Business Administration with a concentration in Accounting from Auburn University and an M.B.A. from Florida State University. Mr. Price is a Certified Public Accountant licensed by the State of Florida.

Robert J. Gyurik has served as one of our directors since 1998 and became Vice President of Pharmaceutical Development of Bentley in March 1999. Before joining Bentley, Mr. Gyurik was Manager of Development and Quality Control at MacroChem Corporation, a position he held from May 1993 to February 1999. From 1971 to 1993 Mr. Gyurik worked in various research and development positions at SmithKline Beecham. Prior thereto, Mr. Gyurik worked at Schering as a Medicinal Chemist. Mr. Gyurik received a B.A. in Biology and Chemistry from Immaculata College. Mr. Gyurik is a member of the American Chemical Society, International Society for Chronobiology and the New York Academy of Sciences.

Jordan A. Horvath became Vice President and General Counsel of Bentley in August 2000. Prior to joining Bentley, he was a partner at Parker Chapin LLP, the Company's legal counsel in New York City (which has since merged to become Jenkens & Gilchrist Parker Chapin LLP), since 1996. He was an associate of that firm from 1991 to 1995. Mr. Horvath received an A.B. from Princeton University and a J.D. from the University of California, Berkeley.

Charles L. Bolling has served as one of our directors since 1991. Mr. Bolling served from 1968 to 1973 as Vice President of Product Management and Promotion (U.S.), from 1973 to 1977 as Vice President of Commercial Development and from 1977 to 1986 as Director of Business Development (International) at SmithKline & French Laboratories. Mr. Bolling received an A.B. from Princeton University. Mr. Bolling has been retired since 1986.

Miguel Fernandez has served as one of our directors since 1999. Mr. Fernandez served from 1980 to 1996 as President of the International Division and corporate Vice President at Carter-Wallace, Inc., where he was responsible for all product lines outside of the United States. Prior

thereto, Mr. Fernandez was employed for approximately eight years by SmithKline & French, where his last position was President of the division that included France, Portugal and Switzerland. Before SmithKline, Mr. Fernandez served as Managing Director of Warner Lambert in Argentina for two years. From 1962 to 1970, Mr. Fernandez was employed by Merck/Frost in Canada. Mr. Fernandez attended the University of British Columbia in Canada and received an M.B.A. from the Ivey School of Business at the University of Western Ontario in London, Ontario, Canada. Mr. Fernandez has been retired since 1996.

William A. Packer has served as one of our directors since 1999. Mr. Packer has been a business and industry consultant to a number of biopharmaceutical companies since 1998. From 1992 until 1998, Mr. Packer was President and Chief Financial Officer of Virus Research Institute, Inc., a publicly owned biotechnology company. Prior to this, Mr. Packer was employed by SmithKline Beecham Plc, where he held various senior management positions, the most recent as Senior Vice President, Biologicals, in which position he was responsible for the direction of SmithKline's global vaccine business. Mr. Packer is a Chartered Accountant.

John W. Spiegel has served as one of our directors since June 2002. Mr. Spiegel has served as Vice Chairman and Chief Financial Officer of SunTrust Banks, Inc. since August 2000. From 1985 to August 2000, Mr. Spiegel was an Executive Vice President and Chief Financial Officer of SunTrust Banks. Mr. Spiegel also serves as Chairman of the Board of the Bank Administration Institute and on the Board of Directors of Rock-Tenn Company (RKT), the Woodruff Arts Center, the High Museum of Art, the American Cardiovascular Research Institute, and the Children's Healthcare of Atlanta. Mr. Spiegel is also a member of the Dean's Advisory Council of the Goizueta Business School at Emory University. Mr. Spiegel received an MBA from Emory University.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our executive officers and directors, and any persons who own more than 10% of any class of our equity securities, to file certain reports relating to their ownership of such securities and changes in such ownership with the Securities and Exchange Commission and the American Stock Exchange and to furnish us with copies of such reports. To the best of our knowledge during the year ended December 31, 2003, all Section 16(a) filing requirements have been satisfied.

Item 11. Executive Compensation

The information called for by this item is incorporated by reference to our definitive Proxy Statement for the 2004 Annual Meeting of Stockholders to be filed pursuant to Regulation 14A.

Item 12. Security Ownership of Certain Beneficial Owners and Management

The information called for by this item is incorporated by reference to our definitive Proxy Statement for the 2004 Annual Meeting of Stockholders to be filed pursuant to Regulation 14A.

Item 13. Certain Relationships and Related Transactions

The information called for by this item is incorporated by reference to our definitive Proxy Statement for the 2004 Annual Meeting of Stockholders to be filed pursuant to Regulation 14A.

Item 14. Principal Accounting Fees and Services

The information called for by this item is incorporated by reference to our definitive Proxy Statement for the 2004 Annual Meeting of Stockholders to be filed pursuant to Regulation 14A.

Part IV

Item 15. Exhibits, Financial Statement Schedules and Reports on Form 8-K

	Page Herein
(a) The following documents are filed as a part of this report:	
(1) Financial Statements:	
Consolidated Financial Statements of Bentley Pharmaceuticals, Inc. and subsidiaries	F-1 to F-31

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EXHIBIT INDEX

(3) Exhibits filed as part of this report:

Exhibit Number	Description
3.1	Articles of Incorporation of the Registrant, as amended and restated. (Reference is made to Appendix B to the Registrant's Definitive Proxy Statement for the Annual Meeting of Stockholders filed with the Securities and Exchange Commission on May 18, 1999, Commission File No. 1-10581,which exhibit is incorporated herein by reference.)
3.2	Bylaws of the Registrant, as amended and restated. (Reference is made to Appendix C to the Registrant's Definitive Proxy Statement for the Annual Meeting of Stockholders filed with the Securities and Exchange Commission on May 18, 1999, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)
3.3	Rights Agreement, dated as of December 22, 1999, between the Registrant and American Stock Transfer and Trust Company, as Rights Agent, including the form of Rights Certificate as Exhibit B thereto. (Reference is made to Exhibit 4.1 to the Registrant's Form 8-K, filed December 27, 1999, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)
4.1	Registrant's Amended and Restated 1991 Stock Option Plan. (Reference is made to Appendix D to the Registrant's Definitive Proxy Statement for the Annual Meeting of Stockholders filed with the Securities and Exchange Commission on May 18, 1999, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)
4.2	Form of Non-qualified Stock Option Agreement under the Registrant's 1991 Stock Option Plan. (Reference is made to Exhibit 4.25 to the Registrant's Form 10-K for the period ended June 30, 1992, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)
4.3	Form of Warrant Agreement, including form of Class A and Class B Warrant. (Reference is made to Exhibit 4.29 to the Registrant's Registration Statement on Form S-1, Commission File No. 33-65125, which exhibit is incorporated herein by reference.)
4.4	Form of Underwriter Warrant. (Reference is made to Exhibit 4.30 to the Registrant's Registration Statement on Form S-1, Commission File No. 33-65125, which exhibit is incorporated herein by reference.)

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Exhibit Number	Description
4.5	Warrant issued by the Registrant for the benefit of Hsu, dated February

11, 1999. (Reference is made to exhibit 7.4 to the Registrant's Form 8-K filed February 26, 1999, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)

4.6 Registrant's 2001 Employee Stock Option Plan. (Reference is made to Appendix B to the Registrant's Definitive Proxy Statement for the Annual Meeting of Stockholders filed with the SEC on April 9, 2001, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)

4.7 Registrant's 2001 Directors' Stock Option Plan. (Reference is made to Appendix C to the Registrant's Definitive Proxy Statement for the Annual Meeting of Stockholders filed with the SEC on April 9, 2001, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)

4.8 Form of Stock Option contract under the Registrant's 2001 Employee Stock Option Plan. (Reference is made to Exhibit 4.8 to the Registrant's Form 10-K for the year ended December 31, 2001, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)

4.9 Form of Stock Option contract under the Registrant's 2001 Directors' Stock Option Plan. (Reference is made to Exhibit 4.9 to the Registrant's Form 10-K for the year ended December 31, 2001, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)

4.10* Amendment No. 1 to the Registrant's 2001 Employee Stock Option Plan.

4.11* Amendment No. 2 to the Registrant's 2001 Employee Stock Option Plan.

4.12* Amendment No. 1 to the Registrant's 2001 Directors' Stock Option Plan.

4.13* Amendment No. 2 to the Registrant's 2001 Directors' Stock Option Plan.

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* Filed herewith.

Exhibit Number	Description
10.1	Employment Agreement dated as of January 1, 2002 between the Registrant and James R. Murphy. (Reference is made to Exhibit 10.1 to the Registrant's Form 10-K for the year ended December 31, 2001, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)
10.2*	Employment Agreement dated as of January 1, 2004 between the Registrant and Robert M. Stote, M.D.
10.3	Employment Agreement dated as of January 1, 2002 between the Registrant and Michael D. Price. (Reference is made to Exhibit 10.3 to the Registrant's Form 10-K for the year ended December 31, 2001, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)
10.4	Employment Agreement dated as of January 1, 2002 between the Registrant and Robert J. Gyurik. (Reference is made to Exhibit 10.4 to the

Registrant's Form 10-K for the year ended December 31, 2001, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)

10.5 Agreement between the Registrant and Hsu dated February 1, 1999, effective as of December 31, 1998. (Reference is made to Exhibit 7.1 to the Registrant's Form 8-K filed February 26, 1999, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)

10.6 License Agreement between the Registrant and Auxilium A2, Inc. dated May 31, 2000, including Amendment No. 1 thereto dated October 2000 and Amendment No. 2 dated May 31, 2001. (Reference is made to Exhibit 10.10 to the Registrant's Form 10-K for the year ended December 31, 2001, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)

10.7 Agreement between the Registrant and Pfizer Inc dated October 25, 2001. (Reference is made to Exhibit 10.11 to the Registrant's Form 10-K for the year ended December 31, 2001, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)

10.8 Supply Agreement, License Agreement and Rights Agreement between Laboratorios Belmac, S.A., Laboratorios Davur, S.L. and Teva Pharmaceutical Industries Ltd. dated July 18, 2000. (Reference is made to Exhibit 10.12 to the Registrant's Form 10-K for the year ended December 31, 2001, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)

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* Filed herewith.

Exhibit Number	Description
10.9	Amendment No. 3 dated September 6, 2002 to License Agreement between the Registrant and Auxilium Pharmaceuticals, Inc. dated May 31, 2000. (Reference is made to Exhibit 10.10 to the Registrant's Form 10-K for the year ended December 31, 2002, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)
10.10	License Agreement between the Registrant and Auxilium Pharmaceuticals, Inc. dated May 31, 2001 relating to products using Dihydrotestosterone. (Reference is made to Exhibit 10.12 to the Registrant's Form 10-K for the year ended December 31, 2002, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)
10.11	Amendment No. 1 dated September 6, 2002 to License Agreement between the Registrant and Auxilium Pharmaceuticals, Inc. dated May 31, 2001 related to products using Dihydrotestosterone. (Reference is made to Exhibit 10.13 to the Registrant's Form 10-K for the year ended December 31, 2002, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)
10.12*	Amendment dated October 14, 2003 to the Agreement between the Registrant and Pfizer Inc dated October 25, 2001.

21.1* Subsidiaries of the Registrant.

23.1* Independent Auditors' Consent.

31.1* Certification of the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

31.2* Certification of the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

32.1* Certification of the Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

32.2* Certification of the Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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* Filed herewith.

(b) Reports on Form 8-K filed during the fiscal quarter ended December 31, 2003:

On October 29, 2003, a Report on Form 8-K was filed under Items 7 and 12 which disclosed the press release dated October 29, 2003 reporting financial results of the Registrant for the three and nine months ended September 30, 2003.

SIGNATURES

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

BENTLEY PHARMACEUTICALS, INC.
By: /s/ James R. Murphy

James R. Murphy
Chairman, President and
Chief Executive Officer
Date: March 4, 2004

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

Signature	Title	Date
/s/ James R. Murphy	Chairman, President, Chief Executive Officer	March 4, 2004

James R. Murphy	and Director (principal executive officer)	
/s/ Michael McGovern Michael McGovern	Vice Chairman and Director	March 4, 2004
/s/ Robert M. Stote Robert M. Stote, M.D.	Senior Vice President, Chief Science Officer and Director	March 4, 2004
/s/ Michael D. Price Michael D. Price	Vice-President, Chief Financial Officer, Treasurer, Secretary and Director (principal financial and accounting officer)	March 4, 2004
/s/ Robert J. Gyurik Robert J. Gyurik	Vice President of Pharmaceutical Development and Director	March 4, 2004
/s/ Charles L. Bolling Charles L. Bolling	Director	March 4, 2004
/s/ Miguel Fernandez Miguel Fernandez	Director	March 4, 2004
/s/ William A. Packer William A. Packer	Director	March 4, 2004
/s/ John W. Spiegel John W. Spiegel	Director	March 4, 2004

CONSOLIDATED FINANCIAL STATEMENTS OF
BENTLEY PHARMACEUTICALS, INC. AND SUBSIDIARIES

INDEPENDENT AUDITORS' REPORT

To the Board of Directors and Stockholders of
Bentley Pharmaceuticals, Inc.
Exeter, New Hampshire

We have audited the accompanying consolidated balance sheets of Bentley Pharmaceuticals, Inc. and subsidiaries (the "Company") as of December 31, 2003 and 2002, and the related consolidated income statements and statements of comprehensive income, changes in stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2003. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2003 and 2002, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2003 in conformity with accounting principles generally accepted in the United States of America.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
March 4, 2004

BENTLEY PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

(in thousands, except per share data)	December 31, 2003	December 31, 2002
ASSETS		
Current assets:		

Cash and cash equivalents	$ 39,393	$ 26,581
Marketable securities	1,252	396
Receivables, net	18,036	10,874
Inventories, net	7,106	5,133
Deferred taxes	213	123
Prepaid expenses and other	899	865
Total current assets	66,899	43,972
Non-current assets:		
Fixed assets, net	18,566	9,565
Drug licenses and related costs, net	13,818	10,975
Restricted cash	1,000	-
Other	180	180
Total non-current assets	33,564	20,720
	$ 100,463	$ 64,692
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 10,154	$ 7,206
Accrued expenses	7,103	4,059
Short-term borrowings	1,915	1,598
Current portion of long-term debt	70	127
Deferred income	1,956	279
Total current liabilities	21,198	13,269
Non-current liabilities:		
Deferred taxes	2,555	2,141
Long-term debt	369	345
Other	176	186
Total non-current liabilities	3,100	2,672
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $1.00 par value, authorized 2,000 shares, issued and outstanding, none	-	-
Common stock, $.02 par value, authorized 100,000 shares, issued and outstanding, 20,573 and 17,404 shares	412	348
Stock purchase warrants (to purchase 420 and 3,292 shares of common stock)	333	431
Additional paid-in capital	136,850	121,084
Accumulated deficit	(66,599)	(72,696)
Accumulated other comprehensive income (loss)	5,169	(416)
Total stockholders' equity	76,165	48,751
	$ 100,463	$ 64,692

The accompanying Notes to Consolidated Financial Statements are an integral part of these financial statements.

BENTLEY PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED INCOME STATEMENTS
AND STATEMENTS OF COMPREHENSIVE INCOME

(in thousands, except per share data)	For the Year Ended December 31,		
	2003	2002	2001
Revenues:			
Net product sales	$ 62,955	$ 38,718	$ 26,411
Licensing and collaboration revenues	1,721	418	-
Total revenues	64,676	39,136	26,411
Cost of net product sales	26,399	16,477	11,462
Gross profit	38,277	22,659	14,949
Operating expenses:			
Selling and marketing	14,212	10,400	9,057
General and administrative	7,001	4,902	4,085
Research and development	4,295	2,960	2,084
Depreciation and amortization	1,340	1,015	911
Total operating expenses	26,848	19,277	16,137
Income (loss) from operations before sale of drug licenses	11,429	3,382	(1,188)
Gain on sale of drug licenses	-	650	5,050
Income from operations	11,429	4,032	3,862
Other income (expenses):			
Interest income	332	279	168
Interest expense	(228)	(209)	(244)
Other, net	(13)	68	27
Income before income taxes	11,520	4,170	3,813
Provision for income taxes	5,423	2,534	2,452
Net income	$ 6,097	$ 1,636	$ 1,361
Net income per common share:			

Basic	$ 0.34	$ 0.10	$ 0.10
Diluted	$ 0.28	$ 0.08	$ 0.08
Weighted average common shares outstanding:			
Basic	17,997	16,569	14,196
Diluted	21,637	19,798	16,147
Net income	$ 6,097	$ 1,636	$ 1,361
Other comprehensive income (loss):			
Foreign currency translation gains (losses)	5,585	3,054	(842)
Comprehensive income	$ 11,682	$ 4,690	$ 519

The accompanying Notes to Consolidated Financial Statements are an integral part of these financial statements.

BENTLEY PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

(in thousands, except per share data)	$.02 Par Value Common Stock		Stock Purchase	Additional Paid-In	Accumu
	Shares	Amount	Warrants	Capital	Defi
Balance at December 31, 2000	13,914	$ 278	$ 632	$ 95,227	$(75
Exercise of stock options and warrants	171	4	-	443	
Exercise of underwriter's Class A warrants	460	9	(199)	1,570	
Equity based compensation	40	1	-	261	
Foreign currency translation adjustment	-	-	-	-	
Net income	-	-	-	-	1
Balance at December 31, 2001	14,585	292	433	97,501	(74
Offering of common stock, net	2,500	50	-	22,058	
Exercise of stock options and warrants	304	6	(2)	1,369	
Equity based compensation	15	-	-	156	
Foreign currency translation adjustment	-	-	-	-	
Net income	-	-	-	-	1
Balance at December 31, 2002	17,404	348	431	121,084	(72
Exercise of stock options and warrants	3,111	62	(98)	15,258	
Equity based compensation	58	2	-	508	
Foreign currency translation adjustment	-	-	-	-	
Net income	-	-	-	-	6

Balance at December 31, 2003	20,573	$ 412	$ 333	$136,850	$(66

The accompanying Notes to Consolidated Financial Statements are an integral part of these financial statements.

BENTLEY PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)	For the Year Ended December 31,		
	2003	2002	2001
Cash flows from operating activities:			
Net income	$ 6,097	$ 1,636	$ 1,361
Adjustments to reconcile net income to net cash provided by operating activities:			
Gain on sale of drug licenses	-	(650)	(5,050
Depreciation and amortization	2,479	1,584	1,235
Foregiveness of related party loans	302	98	98
Equity-based compensation expense	510	156	262
Other non-cash items	(163)	597	(286
(Increase) decrease in assets and increase (decrease) in liabilities:			
Receivables	(3,673)	(1,949)	(2,060
Inventories	(801)	(1,796)	(864
Deferred foreign taxes	(55)	45	1,629
Prepaid expenses and other current assets	(362)	(357)	100
Other assets	(18)	24	(11
Accounts payable and accrued expenses	2,682	1,855	3,306
Deferred income	1,180	(217)	496
Other liabilities	(10)	23	(77
Net cash provided by operating activities	8,168	1,049	139
Cash flows from investing activities:			
Proceeds from sale of investments	225,750	56,190	31,645
Purchase of investments	(226,219)	(56,314)	(31,567
Proceeds from sale of drug licenses	-	656	2,698
Additions to fixed assets	(8,076)	(3,432)	(1,595
Additions to drug licenses and related costs	(2,298)	(796)	(437
Net cash (used in) provided by investing activities	(10,843)	(3,696)	744

(Continued on following page)

The accompanying Notes to Consolidated Financial Statements are an integral part of these financial statements.

BENTLEY PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS (concluded)

(in thousands)	For the Year December	
	2003	2002
Cash flows from financing activities:		
Proceeds from exercise of stock options/warrants	$ 15,222	$ 1,37
Proceeds from offering of common stock, net	-	22,10
Repayment of borrowings	(3,577)	(3,03
Proceeds from borrowings	3,556	2,84
Increase in restricted cash	(1,000)	
Net cash provided by financing activities	14,201	23,28
Effect of exchange rate changes on cash	1,286	20
Net increase in cash and cash equivalents	12,812	20,84
Cash and cash equivalents at beginning of year	26,581	5,73
Cash and cash equivalents at end of year	$ 39,393	$ 26,58
Supplemental Disclosures of Cash Flow Information		
The Company paid cash during the year for:		
Interest	$ 203	$ 20
Taxes	$ 4,862	$ 2,16
Supplemental Disclosures of Non-Cash Financing and Investing Activities The Company has issued or is obligated to issue Common Stock in exchange for services as follows:		
Shares	58	1
Amount	$ 505	$ 15
Included in year-end accounts payable are fixed asset and drug license purchases totaling:	$ 1,721	$ 92

The accompanying Notes to Consolidated Financial Statements are an integral part

of these financial statements.

BENTLEY PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 - HISTORY AND OPERATIONS

Bentley Pharmaceuticals, Inc. and Subsidiaries (which may be referred to as Bentley Pharmaceuticals, Bentley or the Company) is a U.S.-based international specialty pharmaceutical company, incorporated in the State of Delaware, operating in two business segments: research, development and licensing/commercialization of advanced drug delivery technologies and pharmaceutical products; and development, licensing and sales of generic and branded pharmaceutical products and the manufacturing of pharmaceuticals for others. In the research and development segment based in the U.S., the Company owns U.S. and international patent and other proprietary rights to technologies that enhance or facilitate the absorption of drugs across biological membranes. The Company is developing products incorporating these technologies and seeks to form strategic alliances with other pharmaceutical and biotechnology companies to facilitate the development and commercialization of its products. The Company currently has strategic alliances with various companies in the pharmaceutical industry and is in preliminary discussions to form additional alliances with several others.

In the pharmaceutical product sales segment based in Spain, the Company manufactures and markets branded and generic pharmaceutical products within four primary therapeutic areas: cardiovascular, gastrointestinal, infectious and neurological diseases. In addition, the Company licenses the right to register and market its pharmaceutical products in other foreign countries. The Company also provides contract manufacturing services for pharmaceutical products to be sold both within Spain and in other foreign countries in connection with its international license agreements. The Company has also recently developed a strategy to introduce certain of its generic pharmaceutical products into the U.S. marketplace.

The Company anticipated the opportunities that the emerging generic drug market in Spain presented and began taking measures over four years ago to enter the Spanish generic drug market. The Company created Laboratorios Davur and Laboratorios Rimafar, wholly-owned subsidiaries of its Spanish entity, Laboratorios Belmac, to register, market and distribute generic pharmaceutical products in Spain and began aligning its business model to be competitive, including hiring and training a new generic sales force, submission of generic-equivalent products to the Spanish Ministry of Health for approval and a marketing campaign designed to position its Spanish generic subsidiaries as leaders in the Spanish generic drug market. In July 2000, the Company entered into a strategic alliance with Teva Pharmaceutical Industries, Ltd. (Teva), whereby the Company has received the right to register and market in Spain certain of Teva's pharmaceutical products, representing more than 25 different chemical entities. Teva also entered into a supply agreement with the Company pursuant to which Teva will manufacture the products and supply them to the Company for marketing and sale in Spain. Teva was also granted a right of first refusal to acquire Laboratorios Davur in the event that the Company decides to sell that subsidiary or its direct parent, Laboratorios Belmac. The Company also granted Teva the right to bid for Laboratorios Belmac in the event the Company intends to sell that subsidiary.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of consolidation and foreign currency translation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries: Pharma de Espana, Inc. and its wholly-owned subsidiary, Laboratorios Belmac S.A. and its wholly-owned subsidiaries, Laboratorios Davur S.L. and Laboratorios Rimafar S.L.;

Bentley Park, L.L.C.; Bentley Healthcare Corporation and its wholly-owned subsidiary, Belmac Hygiene, Inc.; Belmac Health Corporation; Belmac Holdings, Inc. and its wholly-owned subsidiary, Belmac A.I., Inc.; B.O.G. International Finance, Inc.; and Belmac Jamaica, Ltd. All inter-company balances have been eliminated in consolidation. The financial position and results of operations of the Company's 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 (loss) in the Consolidated Balance Sheets. Foreign currency translation gains and losses arising from cash transactions are credited to or charged against current earnings.

Use of estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and cash equivalents and restricted cash

The Company considers all highly liquid investments with remaining maturities of three months or less when purchased to be cash equivalents for purposes of classification in the Consolidated Balance Sheets and the Consolidated Statements of Cash Flows. Investments in securities that do not meet the definition of cash equivalents are classified as marketable securities in the Consolidated Balance Sheets.

Included in cash and cash equivalents at December 31, 2003 and 2002 are approximately $29,156,000 and $23,360,000, respectively, of short-term investments considered to be cash equivalents, as the remaining maturity dates of such investments were three months or less when purchased.

The Company acquired intellectual property during the year ended December 31, 2003 for $1,000,000 plus future royalties on sales and licensing income. In connection with the acquisition, the Company obtained a renewable, irrevocable letter of credit in the amount of $1,000,000 in favor of the assignor to guarantee future royalty payments. The $1,000,000 used to secure the letter of credit has been classified as restricted cash in the Consolidated Balance Sheets as of December 31, 2003.

Marketable securities

The Company has investments in securities, with maturities of greater than three months when purchased, totaling $1,252,000, which are classified as available-for-sale as of December 31, 2003, compared to $396,000 as of December 31, 2002. The Company's investments are carried at amortized cost which approximates fair value due to the short-term nature of these investments. Accordingly, no unrealized gains or losses have been recognized on these investments. Should the fair values differ significantly from the amortized costs, unrealized gains or losses would be included as a component of other comprehensive income (loss).

Inventories

Inventories are stated at the lower of cost or market, cost being determined on the first-in, first-out (FIFO) method. Reserves for slow moving and obsolete inventories are provided based on historical experience and current product demand.

Fixed assets

Fixed assets are stated at cost. Depreciation is computed using the straight-line method over the following estimated economic lives of the assets:

	Years
Buildings and improvements	30
Equipment	3-7
Furniture and fixtures	5-7
Other	5

Leasehold improvements are amortized over the life of the respective lease. Expenditures for replacements and improvements that significantly add to productive capacity or extend the useful life of an asset are capitalized, while expenditures for maintenance and repairs are charged to operations as incurred. When assets are sold or retired, the cost of the asset and the related accumulated depreciation are removed from the accounts and any gain or loss is recognized currently.

Drug licenses and related costs

Drug licenses and related costs incurred in connection with acquiring licenses, patents, and other proprietary rights related to the Company's commercially developed products are capitalized. Capitalized drug licenses and related costs are amortized on a straight-line basis for periods not exceeding fifteen years from the dates of acquisition. Carrying values of such assets are reviewed at least annually by the Company, by comparing the carrying amounts to their estimated undiscounted cash flows, and adjustments are made for any diminution in value. In accordance with the guidelines in Statement of Financial Accounting Standards ("SFAS") No. 142, Goodwill and Other Intangible Assets, the Company determined it has one reporting unit. The Company performed a review for diminution in value and has concluded that no diminution in value has occurred. The Company has also reassessed the useful lives of its drug licenses and related costs and determined the useful lives are appropriate in determining amortization expense.

Fair value of financial instruments

The carrying amounts of cash, cash equivalents, marketable securities, receivables, accounts payable, accrued expenses and short-term borrowings approximate fair value because of their short-term nature. The carrying amount of the Company's long-term obligations approximates fair value given the amounts outstanding at December 31, 2003 and 2002.

The fair value information presented herein is based on information available to management as of December 31, 2003. Although management is not aware of any factors that would significantly affect the estimated fair value amounts, such amounts have not been comprehensively revalued for purposes of these financial statements since that date and, therefore the current estimates of fair value may differ significantly from the amounts presented herein.

Revenue recognition

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. The Company generally obtains purchase authorizations from its customers for a specified amount of product at a specified price and considers delivery to have occurred when the customer takes possession of the products. The Company provides its customers with a limited right of return. Revenue is recognized upon delivery and a reserve for sales returns is recorded. The Company has demonstrated the ability to make reasonable and reliable estimates of product returns in accordance with 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. At December 31, 2003, the Company has deferred the recognition of approximately $634,000 in royalties and $1,322,000 of licensing, collaboration or other revenues which currently do not meet the requirements for revenue recognition.

Research and development

Research and development costs are expensed when incurred.

Income taxes

The Company accounts for income taxes under SFAS No. 109, Accounting for Income Taxes, which requires the recognition of deferred tax assets and liabilities relating to the expected future tax consequences of events that have been recognized in the Company's consolidated financial statements and tax returns. As permitted by APB Opinion No. 23, Accounting for Income Taxes - Special Areas, provisions for income taxes on undistributed earnings of foreign subsidiaries that are considered permanently invested are not recognized in the Company's consolidated financial statements.

Basic and diluted net income per common share

Basic and diluted net income per common share is based on the weighted average number of shares of Common Stock outstanding during each period. The effect of the Company's outstanding stock options and stock purchase warrants were considered in the diluted net income per share calculation for the years ended December 31, 2003, 2002 and 2001.

The following is a reconciliation between basic and diluted net income per common share for the years ended December 31, 2003, 2002 and 2001. Dilutive securities issuable for the years ended December 31, 2003, 2002 and 2001 include approximately 1,441,000, 1,309,000 and 663,000 shares, respectively, issuable as a result of Class B Warrants, and approximately 2,199,000, 1,920,000 and 1,288,000 shares, respectively, issuable as a result of various stock options and warrants outstanding.

For The Year Ended December 31, 2003

	Basic EPS	Ef D Se
	(In Thousands,	
Net income	$ 6,097	$
Weighted average common shares outstanding	17,997	
Net income per common share	$ 0.34	$

For The Year Ended December 31, 2002

	Basic EPS	Ef D Se
	(In Thousands,	
Net income	$ 1,636	$
Weighted average common shares outstanding	16,569	
Net income per common share	$ 0.10	$

For The Year Ended December 31, 2001

	Basic EPS	Ef D Se
	(In Thousands,	
Net income	$ 1,361	$
Weighted average common shares outstanding	14,196	
Net income per common share	$ 0.10	$

For the years ended December 31, 2003, 2002 and 2001, warrants and options to purchase 237,000, 324,000 and 467,000 shares of Common Stock, respectively, were excluded from the diluted EPS presentation because their exercise prices were greater than the average fair value of the Common Stock.

Comprehensive income

The Company applies SFAS No. 130, Reporting Comprehensive Income, which requires disclosure of all components of comprehensive income on an annual and interim basis. Comprehensive income is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. The Company's comprehensive income includes foreign currency translation gains (losses) and unrealized gains (losses) on its investments that are considered available-for-sale.

Stock-based compensation plans

The Company has stock-based employee compensation plans that are described more fully in Note 11. The Company accounts for these plans under the recognition and measurement principles of APB Opinion No. 25, Accounting for Stock Issued to Employees, and related Interpretations. Options granted under these plans have exercise prices equal to or greater than the market value of the underlying

common stock on the dates of grant, which is generally the date on which compensation is measured. In addition to these plans, the Company also sponsors a 401(k) Plan for eligible employees and matches eligible contributions with shares of the Company's Common Stock. From time to time, at the discretion of the Corporate Governance and Compensation Committee of the Board of Directors (the Compensation Committee), the Company grants shares of its Common Stock to employees in lieu of cash compensation. Related stock-based employee compensation costs are reflected in the Consolidated Income Statements and Statements of Cash Flows.

The following table illustrates the effect on net income and earnings per share as if the Company had applied the fair value recognition provisions of SFAS No. 123, Accounting for Stock-Based Compensation, to stock-based employee compensation:

	Year Ended Decembe	
	2003	2002
	(In Thousands, Except Per	
Net income, as reported	$ 6,097	$ 1,636
Add: Stock-based employee compensation expense included in reported net income	510	156

Deduct: Total stock-based employee compensation expense determined under fair value method for all awards.....	(3,232)	(3,829)
Pro forma net income (loss).....	$ 3,375	$ (2,037)
Net income (loss) per share:		
Basic - as reported.....	$ 0.34	$ 0.10
Basic - pro forma.....	$ 0.19	$ (0.12)
Diluted - as reported.....	$ 0.28	$ 0.08
Diluted - pro forma.....	$ 0.16	$ (0.12)

The preceding pro forma results were calculated using the Black-Scholes option pricing model with the following weighted average assumptions (results may vary depending on the assumptions applied within the model):

	Year Ended December 31,		
	2003	2002	2001
	(In Thousands, Except Per Share Data)		
Risk free interest rate.....	3.86%	5.08%	5.18%
Dividend yield.....	0.00%	0.00%	0.00%
Expected life.....	5 years	5 years	10 years
Volatility.....	54.12%	57.61%	140.81%
Fair value of options granted.....	$5.03	$5.58	$3.72

Stock or other equity-based compensation for non-employees is accounted for under the fair value method as required by SFAS No. 123 and EITF Issue No. 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services and other related interpretations.

Segments of an enterprise and related information

SFAS No. 131, Disclosures About Segments of an Enterprise and Related Information, redefines how operating segments are determined and requires disclosure of certain financial and descriptive information about a company's operating segments. The Company operates in two business segments that are in two geographical locations. See Note 14 for the disclosures required by SFAS No. 131.

Recently issued accounting pronouncements

In December 2002, the Financial Accounting Standards Board issued SFAS No. 148, Accounting for Stock-Based Compensation - Transition and Disclosure.

SFAS No. 148 amends SFAS No. 123, to provide alternative methods of transition for a voluntary change to the fair value method of accounting for stock-based employee compensation. SFAS No. 148 also amends the disclosure requirements of SFAS No. 123 to require disclosure in the summary of significant accounting policies, the effects of an entity's accounting policy with respect to stock-based employee compensation on reported net income and earnings per share in annual and interim financial statements. The disclosure provision is required for all companies with stock-based employee compensation, regardless of whether the company utilizes the fair value method of accounting described in SFAS No. 123 or the intrinsic value method described in APB Opinion No. 25. SFAS No. 148's amendment of the transition and annual disclosure provisions of SFAS No. 123 were effective for fiscal years ending after December 15, 2002 and have been incorporated in the Notes to the accompanying Consolidated Financial Statements. The disclosure provisions for interim financial statements were effective for interim periods beginning after December 15, 2002. We have chosen not to adopt the fair value method of accounting for stock-based employee compensation at this time. Accordingly, we continue to account for stock-based compensation utilizing the intrinsic value method of accounting for stock-based employee compensation described by APB Opinion No. 25.

In November 2002, the EITF released Issue No. 00-21, which addresses certain aspects of the accounting by a vendor for arrangements under which it will perform multiple revenue-generating activities. EITF Issue No. 00-21 establishes three principles: revenue arrangements with multiple deliverables should be divided into separate units of accounting; arrangement consideration should be allocated among the separate units of accounting based on their relative fair values; and revenue recognition criteria should be considered individually for each separate unit of accounting. EITF Issue No. 00-21 is effective for all revenue arrangements entered into in fiscal periods beginning after June 15, 2003, with early adoption permitted. The adoption of EITF Issue No. 00-21 in our third quarter of 2003 has not had a material effect on our financial position, results of operations or cash flows for the year ended December 31, 2003. However, the adoption of EITF Issue No. 00-21 may require the deferral and recognition over extended periods, of certain up-front fees associated with our multiple element collaboration and license agreements and of our marketing, distribution and supply agreements.

Reclassifications

Certain prior year amounts have been reclassified to conform with the current year's presentation format. Such reclassifications did not have a material effect on the Company's financial position, results of operations or cash flows.

NOTE 3 - RECEIVABLES

Receivables consist of the following:

Trade receivables (of which $1,914 and $1,340, respectively, collateralize short-term borrowings with Spanish financial institutions)	$ 16,
VAT, income and social security taxes receivable	
Royalties receivable	
Other	
	18,
Less-allowance for doubtful accounts	(
	$ 18,

The following is a summary of the activity related to our allowance for doubtful accounts:

	Year Ended December 31, 2003	Year Ended December 31, 2002	Year Ended December 31, 2
		(In Thousands)	
Balance at beginning of year	$ 100	$ 66	$ 13
Provisions charged to costs and expenses	102	64	54
Write-offs reducing provisions	(64)	(45)	-
Effect of foreign currency	22	15	(1)
Balance at end of year	$ 160	$ 100	$ 66

NOTE 4 - INVENTORIES

Inventories consist of the following:

	December 31, 2003	December 31, 2002
	(In Thousands)	
Raw materials	$ 5,351	$ 3,518
Finished goods	1,829	1,677
	7,180	5,195
Less-allowance for slow moving inventory	(74)	(62)
	$ 7,106	$ 5,133

The following is a summary of the activity related to our allowance for slow moving inventory:

	Year Ended December 31, 2003	Year Ended December 31, 20
		(In Thousands)
Balance at beginning of year	$ 62	$ 54
Provisions charged to costs and expenses	-	-
Write-offs reducing provisions	-	(1)
Effect of foreign currency	12	9
Balance at end of year	$ 74	$ 62

NOTE 5 - FIXED ASSETS

Fixed assets consist of the following:

	December 31,	
	2003	2002
	(In Thousands)	
Land	$ 1,900	$ 930
Buildings and improvements	9,085	5,576
Equipment	10,953	5,197
Furniture and fixtures	1,497	1,006
Leasehold improvements	43	52
	23,478	12,761
Less-accumulated depreciation	(4,912)	(3,196)
	$ 18,566	$ 9,565

In order to support the Company's growth in Europe, it is adding additional capacity to its manufacturing facility through a series of improvements. During the year ended December 31, 2003, the Company invested approximately $1,239,000 renovating the facility and approximately $4,136,000 for machinery and equipment including new high speed manufacturing and packaging equipment.

The Company also purchased a 15,700 square foot commercial building located on approximately 14 acres of land in Exeter, New Hampshire for approximately $1,800,000 in January 2003. The purchase included furniture and fixtures in the building and the purchase price was allocated to the following components in accordance with their relative fair market values: land - $786,000, buildings - $911,000, and furniture and fixtures - $103,000. The Company moved its corporate headquarters into the purchased building in April 2003. As a result of the move, the Company abandoned its former office space.

The remaining lease costs and costs for the abandonment of leasehold improvements totaling $44,000 were charged to general and administrative expenses in the Consolidated Income Statements for the year ended December 31, 2003. The lease agreement for the former office space ended in February 2004.

Depreciation expense of approximately $368,000, $212,000 and $139,000 has been charged to operations as a component of depreciation and amortization expense in the Consolidated Income Statements for the years ended December 31, 2003, 2002 and 2001, respectively. The Company has included depreciation totaling approximately $1,139,000, $569,000 and $324,000 in cost of net product sales during the years ended December 31, 2003, 2002 and 2001, respectively.

NOTE 6 - DRUG LICENSES AND RELATED COSTS

Drug licenses and related costs consist of the following:

	December 31,	
	2003	2002
	(In Thousands)	
Drug licenses and related costs	$ 18,102	$ 13,908
Less-accumulated amortization	(4,284)	(2,933)
	$ 13,818	$ 10,975

The Company acquired intellectual property during the year ended December 31, 2003 for $1,000,000 plus future royalties on sales and licensing income (See Notes 2 and 15).

In November 2000, Laboratorios Belmac entered into an agreement to sell the trademark, registration rights and dossier for its branded pharmaceutical product, Controlvas(R), for approximately $5,148,000. Laboratorios Belmac received a 50% deposit from the purchaser in November 2000, which was reflected as deferred income in the Consolidated Balance Sheet as of December 31, 2000. The transaction was completed in February 2001, resulting in a gain of approximately $4,977,000 being recognized in the year ended December 31, 2001.

In June 2001, Laboratorios Belmac agreed to sell the trademark, registration rights and dossier for its pharmaceutical product, Amantadine(R), to a third party for approximately $153,000. A deposit of approximately $56,000 was received from the purchaser in June 2001 and a second payment of the same amount was received upon approval of the transfer of the rights to the purchaser by the Spanish Ministry of Health, which occurred during the quarter ended September 30, 2001, resulting in recognition of a pre-tax gain of approximately $73,000. The remaining amount of approximately $41,000 is payable over the five subsequent years, in the form of a royalty arrangement.

Amortization expense for drug licenses and related costs was approximately $972,000, $803,000 and $772,000 for the years ended December 31, 2003, 2002 and 2001, respectively, and has been recorded in depreciation and amortization expense in the accompanying Consolidated Income Statements.

Amortization expense for existing drug licenses and related costs for each of the five years ending December 31, 2008 and for all remaining years thereafter is estimated to be approximately $1,047,000 and $8,583,000, respectively.

BENTLEY PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

NOTE 7 - RELATED PARTY NOTES

There are no Related Party Receivables from executive officers or directors at December 31, 2003. In March 2000, the Company provided loans to each of Messrs. Murphy, Price and Gyurik, who are executive officers of the Company, in the amounts of $250,000, $50,000 and $140,000, respectively, which Messrs. Murphy, Price and Gyurik used to pay income taxes on equity-based compensation received in the prior year. In December 2001, the Compensation Committee of the Company's Board of Directors agreed to amend the loan agreements resulting in the forgiveness of principal and accrued interest totaling approximately $56,000, $11,000 and $31,000, due from Messrs. Murphy, Price and Gyurik, respectively. The amounts forgiven were applied first to unpaid accrued interest and then to principal. These amounts were recorded as compensation expense during the year ended December 31, 2001 and treated as taxable income to the respective executives.

In January 2002, the Compensation Committee agreed to amend the loan agreements, resulting in the forgiveness of principal and accrued interest totaling approximately the same amounts as in December 2001 and the reduction in the number of shares collateralizing the remaining loan amounts to 18,700, 4,000 and 10,700 shares of the Company's Common Stock owned by Messrs. Murphy, Price and Gyurik, respectively. These amounts were recorded as compensation expense during the year ended December 31, 2002 and treated as taxable income to the respective executives.

In March 2003, the Compensation Committee agreed to amend the loan agreements, resulting in the forgiveness of the remaining aggregate principal of $294,000 and accrued interest on the loan balances of $8,000. As of March 31, 2003, the balance outstanding related to these loans was reduced to zero. These amounts were recorded as compensation expense during the year ended December 31, 2003 and treated as taxable income to the respective executives.

Of the balances outstanding at December 31, 2002 approximately $301,000 was included in prepaid expenses and other current assets in the Consolidated Balance Sheets. Accrued interest on such loans totaled approximately $7,000 at December 31, 2002.

NOTE 8 - ACCRUED EXPENSES

Accrued expenses consist of the following:

	December 31,	
	2003	2002
	(In Thousands)	
Foreign income taxes payable	$ 1,940	$ 1,177
Allowance for sales returns	446	349
Accrued payroll	952	756
Spanish pharmaceutical taxes payable	1,586	565
Other accrued expenses	2,179	1,212
	$ 7,103	$ 4,059

BENTLEY PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following is a summary of the activity related to our allowance for sales returns:

	Year Ended December 31, 2003	Year Ended December 31, 20
		(In Thousands)
Balance at beginning of year	$ 349	$ 402
Provisions charged to costs and expenses	640	311
Write-offs reducing provisions	(615)	(423)
Effect of foreign currency	72	59
Balance at end of year	$ 446	$ 349

NOTE 9 - DEBT

Short-term borrowings consist of the following:

Trade receivables discounted with a Spanish financial institution, with recourse, effective interest rate is 3.9% and 5.2%, respectively	
Revolving lines of credit payable to Spanish financial institutions, weighted average interest rate is 3.3% and 4.5%, respectively	

The weighted average stated interest rate on short-term borrowings outstanding at December 31, 2003 and 2002 was 3.8% and 5.1%, respectively.

The Company has revolving lines of credit with Spanish financial institutions, which entitle the Company to borrow up to $6,617,000 at December 31, 2003. The lines are scheduled to mature on various dates through November 30, 2004 and are renewable. At December 31, 2003, advances outstanding under the lines of credit totaled approximately $1,000. The weighted average interest rate at December 31, 2003 and 2002 was 3.3% and 4.5%, respectively, and interest is payable quarterly.

Long-term debt consists of the following:

	December 31,	
	2003	2002

	(In Thousands)	
Loans payable to Spanish government, net of unamortized discount of $83 and $105, respectively.....	$ 369	$ 282
Loans payable for equipment financing.....	70	190
	439	472
Less-current portion.....	(70)	(127)
Total long-term debt.....	$ 369	$ 345

In March 2002, the Company entered into a loan agreement to finance the acquisition of manufacturing equipment. The terms of the loan require repayment over a two-year period at an average interest rate of 2.9%. As of December 31, 2003, approximately $70,000 of the original balance remains outstanding.

In November 2002, the Company entered into a loan agreement with the Spanish government as part of a research-funding program. The loan is non-interest bearing and is payable in equal annual installments of approximately $17,000 beginning in 2006. Accordingly, the Company imputed interest at the market rate in Spain (4.8%), recorded a discount on the obligation of $33,000 and has classified the obligation at December 31, 2003 and 2002 as non-current. The discount is being amortized over the ten-year term of the loan.

In December 2001, the Company entered into a loan agreement with the Spanish government as part of a research-funding program. The loan is non-interest bearing and is payable in equal annual installments of approximately $31,000 beginning in 2005. Accordingly, the Company imputed interest at the market rate in Spain (6%), recorded a discount on the obligation of $72,000 and has classified the obligation at December 31, 2003 and 2002 as non-current. The discount is being amortized over the ten-year term of the loan.

NOTE 10 - PREFERRED STOCK

The Company has 2,000,000 shares of $1.00 Preferred Stock authorized for issuance. As of December 31, 2003 and 2002, no shares of Preferred Stock were outstanding.

NOTE 11 - STOCKHOLDERS' EQUITY

At December 31, 2003 the Company had the following Common Stock reserved for issuance under various plans and agreements (in thousands):

	Common Shares
For exercise of stock purchase warrants.....	420
For exercise of outstanding stock options.....	3,920
For future stock option grants.....	1,578
	5,918

The Company has never paid any dividends on its Common Stock. The current policy of the Board of Directors is to retain earnings to finance the operation of the Company's business. Accordingly, it is anticipated that no cash dividends will be paid to the holders of the Common Stock in the foreseeable future.

Common stock transactions

During the year ended December 31, 2003, the Company issued approximately 2,870,000 shares of Common Stock upon exercise of Class B Warrants, approximately 240,000 shares of Common Stock upon exercise of stock purchase options, and approximately 58,000 shares of Common Stock as equity-based compensation in lieu of cash.

During the year ended December 31, 2002, the Company issued approximately 2,500,000 shares of Common Stock in a Common Stock Offering which raised gross proceeds of $24,500,000, approximately 132,000 shares of Common Stock upon exercise of Class B Warrants, approximately 172,000 shares of Common Stock upon exercise of stock purchase options, and approximately 15,000 shares of Common Stock as equity-based compensation in lieu of cash.

During the year ended December 31, 2001, the Company issued approximately 460,000 shares of Common Stock as a result of the exercise of underwriter's Class A Warrants, approximately 4,200 shares of

Common Stock upon exercise of Class B Warrants, approximately 150,000 shares of Common Stock upon exercise of 150,000 other stock purchase warrants, approximately 16,900 shares of Common Stock upon exercise of stock purchase options, and approximately 40,000 shares of Common Stock as equity-based compensation in lieu of cash.

General and administrative expenses for the years ended December 31, 2003, 2002 and 2001 include $248,000, $100,000 and $160,000, respectively, of non-cash equity-based compensation. Research and development expenses for the years ended December 31, 2003, 2002 and 2001 include $262,000, $56,000 and $102,000, respectively, of non-cash equity-based compensation.

Stock purchase warrants

At December 31, 2003, warrants to purchase an aggregate of approximately 420,000 shares of Common Stock were outstanding, which were exercisable at prices ranging from $1.50 to $20.00 per share, of which 400,000 warrants have an exercise price of $1.50 per share and 20,000 warrants have an exercise price of $20.00 per share. The warrants expire on various dates from June 2004 through February 2009.

During the year ended December 31, 2003, approximately 5,740,000 Class B Warrants were exercised to acquire an aggregate of 2,870,000 shares of Common Stock. The Company received net cash proceeds of approximately $14,349,000 from all such exercises during the year ended December 31, 2003. Approximately 3,600 Class B Warrants which were not exercised by December 31, 2003 expired unexercised.

At December 31, 2002, warrants to purchase an aggregate of approximately 3,292,000 shares of Common Stock were outstanding, which were exercisable at prices ranging from $1.50 to $20.00 per share, of which 400,000 warrants had an exercise price of $1.50 per share, approximately 5,744,000 Class B Warrants to purchase approximately 2,872,000 shares of common stock had an exercise price of $5.00 per share and 20,000 warrants had an exercise price of $20.00 per share.

During the year ended December 31, 2002, approximately 263,800 Class B Warrants were exercised to acquire an aggregate of 131,900 shares of Common Stock. The Company received net cash proceeds of approximately $660,000 from all such exercises during the year ended December 31, 2002.

During the year ended December 31, 2001, underwriter's Class A Warrants were exercised to acquire 460,000 shares of Common Stock and 460,000 underwriter's Class B Warrants. Approximately 8,400 Class B Warrants and 150,000 other stock purchase warrants were exercised during 2001 to acquire an aggregate of 154,200 shares of Common Stock. The Company received net cash proceeds of approximately $1,776,000 from all such exercises during the year ended December 31, 2001.

The table below summarizes warrant activity for the years ended December 31, 2001, 2002 and 2003.

	Number of Common Shares
	(In Thousands, Ex
Outstanding at December 31, 2000	4,038
Exercised	(614)
Outstanding at December 31, 2001	3,424
Exercised	(132)
Outstanding at December 31, 2002	3,292
Exercised	(2,870)
Expired	(2)
Outstanding at December 31, 2003	420

Stock option plans

The Company has in effect Stock Option Plans (the "Plans"), pursuant to which directors, officers and employees of the Company are eligible to receive grants of options for the Company's Common Stock. Approximately 5,498,000 shares of Common Stock have been reserved for issuance under the Plans, of which approximately 605,000 are outstanding under the 1991 Plan, approximately

1,881,000 are outstanding under the 2001 Employee and Director Plans and 1,434,000 are outstanding under the Executive Plan as of December 31, 2003. Options may be granted for terms not exceeding ten years from the date of grant except for incentive stock options which are granted to persons owning more than 10% of the total combined voting power of all classes of stock of the Company. For these individuals, incentive stock options may be granted for terms not exceeding five years from the date of grant. Options may not be granted at a price that is less than 100% of the fair market value on the date the options are granted (110% in the case of incentive stock options for persons owning more than 10% of the total combined voting power of the Company). Options granted under the Plans generally vest over one or two years. Options to purchase 240,500, 172,300 and 16,900 shares of Common Stock were exercised during the years ended December 31, 2003, 2002 and 2001, respectively, resulting in net cash proceeds to the Company of approximately $962,000, $715,000 and $51,000, respectively.

The table below summarizes activity in the Company's Plans for the years ended December 31, 2001, 2002 and 2003.

	Number of Common Shares	Weighted Average Exercise Price
	(In Thousands, Except Per Share Data)	
Outstanding at December 31, 2000	2,457	$ 4.87
Granted	553	6.04
Exercised	(17)	3.00
Canceled	(56)	9.66
Outstanding at December 31, 2001	2,937	5.00
Granted	699	10.28
Exercised	(172)	4.15
Canceled	(5)	29.40
Outstanding at December 31, 2002	3,459	6.07
Granted	731	9.62
Exercised	(240)	4.00
Canceled	(30)	20.08
Outstanding at December 31, 2003	3,920	$ 6.75

The table below summarizes options outstanding and exercisable at December 31, 2003 (number of options in thousands):

Options Curren

	Options Outstanding			Exercisable	
Range of Exercise Prices	Number Of Options	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)	Number Of Options	We Av Ex P
$2.00-2.89	476	$ 2.86	2.5	476	$
3.00-3.75	579	3.62	2.5	579	
4.73	500	4.73	2.3	500	
5.70-5.88	147	5.84	6.4	147	
6.00-6.38	410	6.01	7.3	410	
7.10-7.90	262	7.53	6.7	262	
8.00-8.93	311	8.16	7.9	52	
9.00-9.80	534	9.68	8.0	250	
10.04-10.75	385	10.10	9.2	30	1
11.13-11.81	266	11.49	8.3	133	1
13.48-15.83	50	14.03	9.8	-	
$2.00-15.83	3,920	$ 6.75	5.8	2,839	$

Options and warrants outstanding at December 31, 2003 include approximately 420,000 warrants, all of which are exercisable, and approximately 3,920,000 options, of which approximately 2,839,000 are vested and exercisable at December 31, 2003.

Options and warrants outstanding at December 31, 2002 included warrants to purchase approximately 3,292,000 shares of common stock, all of which were exercisable, and approximately 3,459,000 options, of which approximately 2,710,000 were vested and exercisable at December 31, 2002.

Subsequent to December 31, 2003, the Company granted options to certain employees of the Company to purchase an aggregate of approximately 403,000 shares of Common Stock at a weighted average exercise price of $13.27, which options are scheduled to expire on various dates between January 1, 2014 and March 1, 2014.

401(k) Retirement Plan

The Company sponsors a 401(k) retirement savings plan (the "401(k) Plan") under which eligible employees may contribute, on a pre-tax basis, up to 100% of their respective total annual income from the Company, subject to a maximum aggregate annual contribution imposed by the Internal Revenue Code of 1986, as amended. All employees who work for the Company in the U.S. are eligible to participate in the 401(k) Plan. All employee contributions are allocated to the employee's individual account and are invested in various investment options as directed by the employee. Employees' cash contributions are fully vested and nonforfeitable. The Company made matching contributions to the 401(k) Plan during the years ended December 31, 2003, 2002 and 2001 in the

form of approximately 11,500, 9,300 and 13,700 shares, respectively, of the Company's Common Stock valued at approximately $117,000, $92,000 and $83,000, respectively. All Company matching contributions vest 25% each year for the first four years of each employee's employment, in which the employee works for the Company at least 1,000 hours.

Stockholder Rights Plan

On December 22, 1999, the Board of Directors of the Company adopted a stockholder rights plan pursuant to which a dividend of one right for each outstanding share of the Company's Common Stock on the record date of December 27, 1999 was declared. The plan is designed to prevent a potential acquirer from gaining control of the Company without fairly compensating all of the Company's stockholders and to protect the Company from coercive takeover attempts. Each of the rights, which are not currently exercisable, entitles the holder to purchase one one-thousandth of a share of Series A Junior Participating Preferred Stock at an exercise price of $16.50. The rights will become exercisable only if a person or group of affiliated persons beneficially acquire(s) 15% or more of the Company's Common Stock. Under certain circumstances, each holder of a right (other than the person or group who acquired 15% or more of the Company's Common Stock) is entitled to purchase a defined number of shares of the Company's Common Stock at 50% of the market price of the Common Stock at the time that the right becomes exercisable.

NOTE 12 - PROVISION FOR INCOME TAXES

For all periods presented the income before income taxes as shown in the Consolidated Income Statements consists of losses generated in the United States and income derived from foreign operations. See Note 14 for information regarding the components of income before taxes.

The provision for income taxes consists of the following:

	Year Ended December 31,		
	2003	2002	
	(In Thousands)		
Current:			
State	$ -	$ -	$
Federal	-	-	
Foreign	5,417	2,524	
Deferred:			
State	(54)	1,477	
Federal	(329)	9,073	
Foreign	6	8	
Effect of tax benefit from exercise of stock options:			
State	(61)	-	

Federal	(375)	-	
Tax benefit from operating loss carryforwards:			
State	(158)	(144)	
Federal	(973)	(884)	
Foreign	-	-	
Valuation allowance	1,950	(9,520)	
Total provision for income taxes	$ 5,423	$ 2,534	$

A reconciliation between the federal statutory rate and the Company's effective income tax rate is as follows:

	Year E
	2003
	(In
Statutory federal income tax	$ 3,917
Permanent differences from foreign subsidiary	489
Foreign withholding taxes	(331)
Valuation allowance	1,348
	$ 5,423

The components of the Company's deferred taxes are as follows:

Deferred tax assets:	
NOL carryforwards	$
Disposition of subsidiary	
Foreign tax on deferred income	
Tax credit carryforwards	
Other, net	
Total deferred tax assets	
Deferred tax liabilities	
Valuation allowance	(
Deferred tax asset, net	$

The Company has established a valuation allowance equal to the full amount of the domestic deferred tax asset, as future domestic operating profits cannot be assured. The Company has a current deferred tax asset of $213,000 and

a non-current tax liability of $2,555,000 due to temporary differences arising as a result of the Company's Spanish subsidiary recording the gain on the sale of drug licenses and the corresponding taxes for Spanish statutory purposes during the years ended December 31, 2001 and 2002. The deferred tax asset is a result of taxes that related to deferred income and the tax liability results from taxes that will be payable in Spain beginning in 2005.

Should the Company determine that it is more likely than not that it will realize certain of its net deferred tax assets for which it had previously provided a valuation allowance, an adjustment would be required to reduce the existing valuation allowance. In addition, the Company operates within multiple taxing jurisdictions and is subject to audit in those jurisdictions. These audits can involve complex issues, which may require an extended period of time for resolution. Although the Company believes 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 the Company's results of operations.

Under the provisions of the Internal Revenue Code, certain substantial changes in the Company's ownership may have limited, or may limit in the future, the amount of net operating loss (the "NOL") carryforwards that could be utilized annually to offset future taxable income and income tax liabilities. The amount of any annual limitation is determined based upon the Company's value prior to an ownership change.

At December 31, 2003, the Company has NOL carryforwards of approximately $42,331,000 available to offset U.S. taxable income. The NOL carryforwards include the benefit of disqualifying dispositions of $1,156,000, the tax effect of which $457,000 will be credited to additonal paid-in capital if and when realized. The Company calculates that use of its NOLs may be limited each year as a result of stock option and warrant issuances resulting in an ownership change of more than 50% of the Company's outstanding equity. If not offset against future taxable income, the NOL carryforwards will expire in tax years 2007 through 2023. Capital loss carryforwards totaling approximately $27,562,000 expired unused during the year ended December 31, 2002.

The valuation allowance increased (decreased) by approximately $1,950,000, ($9,520,000) and $1,852,000 for each of the years ended December 31, 2003, 2002 and 2001, respectively.

NOTE 13 - SELECTED QUARTERLY FINANCIAL INFORMATION (Unaudited)

The following tables contain condensed information from the Company's income statements for each quarter of the years ended December 31, 2003, 2002 and 2001. The Company believes that the following information reflects all normal recurring adjustments necessary for a fair presentation of the information for the periods presented. The operating results for any quarter are not necessarily indicative of results for any future period.

BENTLEY PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	Fiscal 2003			
	For the Three Months Ended			
	3/31/2003	6/30/2003	9/30/2003	12/31/2003
	(In Thousands, Except Per Share Data)			
Total revenues	$ 14,988	$ 16,754	$ 14,875	$ 18,059
Cost of sales	6,121	6,819	5,744	7,715
Gross profit	8,867	9,935	9,131	10,344
Operating expenses	6,213	6,619	6,290	7,726
Gain on sale of drug licenses	-	-	-	-
Income from operations	2,654	3,316	2,841	2,618
Other income/(expenses), net	29	18	20	24
Provision for income taxes	1,151	1,805	1,513	954
Net income	$ 1,532	$ 1,529	$ 1,348	$ 1,688
Net income per common share:				
Basic	$ 0.09	$ 0.09	$ 0.08	$ 0.09
Diluted	$ 0.08	$ 0.07	$ 0.06	$ 0.08
Weighted average common shares outstanding:				
Basic	17,455	17,534	17,911	19,071
Diluted	20,350	20,878	22,228	22,418

	Fiscal 2002			
	For the Three Months Ended			
	3/31/2002(a)	6/30/2002(a)	9/30/2002(a)	12/31/2002
	(In Thousands, Except Per Share Data)			
Total revenues	$ 9,174	$ 9,867	$ 8,571	$ 11,524
Cost of sales	3,776	4,249	3,579	4,873
Gross profit	5,398	5,618	4,992	6,651
Operating expenses	4,715	4,743	4,300	5,519
Gain on sale of drug licenses	72	520	-	58
Income from operations	755	1,395	692	1,190
Other income/(expenses), net	(23)	10	67	84
Provision for income taxes	597	886	468	583
Net income	$ 135	$ 519	$ 291	$ 691

Net income per common share:				
Basic	$ 0.01	$ 0.03	$ 0.02	$ 0.04
Diluted	$ 0.01	$ 0.03	$ 0.01	$ 0.03
Weighted average common shares outstanding:				
Basic	14,634	16,823	17,377	17,405
Diluted	17,922	20,484	20,706	20,121

(a) Certain prior period amounts previously reported as cost of sales have been reclassified as a reduction of revenues to conform with the current period's presentation format. Such reclassifications are not considered material to the consolidated financial statements.

	Fiscal 2001			
	For the Three Months Ended			
	3/31/2001	6/30/2001	9/30/2001	12/31/2001
	(In Thousands, Except Per Share Data)			
Total revenues	$ 5,814	$ 6,125	$ 6,316	$ 8,156
Cost of sales	2,449	2,687	2,708	3,618
Gross profit	3,365	3,438	3,608	4,538
Operating expenses	3,730	3,906	3,601	4,900
Gain on sale of drug licenses	4,977	-	113	(40)
Income from operations	4,612	(468)	120	(402)
Other income/(expenses), net	(11)	(7)	(24)	(7)
Provision for income taxes	1,959	94	245	154
Net income	$ 2,642	$ (569)	$ (149)	$ (563)
Net income per common share:				
Basic	$ 0.19	$ (0.04)	$ (0.01)	$ (0.04)
Diluted	$ 0.17	$ (0.04)	$ (0.01)	$ (0.04)
Weighted average common shares outstanding:				
Basic	13,915	13,952	14,308	14,585
Diluted	15,882	13,952	14,308	14,585

NOTE 14 - BUSINESS SEGMENT INFORMATION

The Company is a U.S.-based international specialty pharmaceutical company focused on advanced drug delivery technologies and pharmaceutical products. The Company also has a commercial presence in Europe. The Company's Spanish subsidiaries, Laboratorios Belmac, Laboratorios Davur and Laboratorios Rimafar, develop, license and sell generic and branded pharmaceutical products and manufacture pharmaceuticals for others. In the U.S., the Company's activities consist primarily of licensing, product research and development, business development activities, corporate management and administration.

Laboratorios Belmac and its subsidiaries derive its revenues from the development, licensing and sales of its own products as well as from product manufacturing for others, within four primary therapeutic categories of cardiovascular, gastrointestinal, infectious and neurological diseases.

Set forth in the tables below is certain financial information with respect to the Company's business and geographical segments for the years ended December 31, 2003, 2002 and 2001. The segments use the same accounting policies as those described in the summary of significant accounting policies in Note 2.

	Year Ended Decemb	
	(In thousand	
	Product Sales Spain	R/D/ Collaborati U.S.
Total revenues	$ 63,158	$ 1,518
Interest income	136	196
Interest expense	215	13
Depreciation and amortization expense	863	477
Income (loss) before income taxes	15,091	(3,571)
Provision for income taxes	5,092	331
Net income (loss)	9,999	(3,902)
Fixed assets	16,428	2,138
Drug licenses and related costs	9,441	4,377
Total assets	62,564	37,899
Total liabilities	22,619	1,679
Expenditures for drug licenses/delivery technology	1,075	1,223
Expenditures for fixed assets	5,970	2,106

	Year Ended Decemb	
	(In thousand	
	Product Sales Spain	R/D/ Collaborati U.S.

Total revenues	$ 38,718	$ 418
Interest income	-	279
Interest expense	200	9
Depreciation and amortization expense	655	360
Income (loss) before income taxes	6,913	(2,743)
Provision for income taxes	2,534	-
Net income (loss)	4,379	(2,743)
Fixed assets	9,417	148
Drug licenses and related costs	7,463	3,512
Total assets	38,199	26,493
Total liabilities	15,417	524
Expenditures for drug licenses/delivery technology	615	181
Expenditures for fixed assets	3,408	24

	Year Ended Decemb	
	Product Sales Spain	(In thousand R/D/ Collaborati U.S.
Total revenues	$ 26,411	$ -
Interest income	27	141
Interest expense	244	-
Depreciation and amortization expense	523	388
Income (loss) before income taxes	6,618	(2,805)
Provision for income taxes	2,452	-
Net income (loss)	4,166	(2,805)
Fixed assets	5,427	168
Drug licenses and related costs	6,663	3,613
Total assets	24,890	7,229
Total liabilities	10,974	721
Expenditures for drug licenses/delivery technology	412	72
Expenditures for fixed assets	2,029	40

Interest income and interest expense are based upon the actual results of each operating segment's assets and borrowings. The principal component of the inter-segment amounts is related to inter-segment advances.

Revenues from one customer exceeded 10% of consolidated total revenues during the year ended December 31, 2003, accounting for 14% of 2003 consolidated total revenues and 16% of the consolidated accounts receivable balance at December 31, 2003. Revenues from one customer exceeded 10% of consolidated total revenues during the year ended December 31, 2002, accounting for 14% of 2002 consolidated total revenues and 8% of the consolidated receivables balance at December 31, 2002. Revenues from one customer exceeded 10% of consolidated total revenues during the year ended December 31, 2001, accounting for 15% of 2001 consolidated total revenues.

NOTE 15 - COMMITMENTS AND CONTINGENCIES

The Company is obligated to pay certain royalty payments upon commercialization of products using its CPE-215 technology acquired in 1999 and on intellectual property acquired in 2003 (See Notes 2 and 6).

The Company has entered into various renewable, employment agreements with its key executive officers, which agreements provide for salaries, potential bonuses and other benefits in exchange for services provided by the key executive officers. The employment agreements also provide for certain compensation in the event of termination or change in control of the Company. The Company is currently obligated to pay approximately $1,490,000 to its key executives in 2004 and $350,000 in 2005 under such agreements, which are scheduled to expire on December 31, 2004 and 2005

The Company is currently undergoing a tax review of its Spanish subsidiary, Laboratorios, Belmac, S.A., by the Spanish tax authorities. Certain tax contingencies exist and when probable and reasonably estimable, are provided

for in the Consolidated Financial Statements. Accordingly, as of December 31, 2003, since these contingencies are not probable or reasonably estimable, no amounts have been provided for related to these contingencies.

The Company leases certain equipment and facilities under non-cancelable operating leases, which expire through the year 2008. Total charges to operations under operating leases were approximately $911,000, $785,000 and $705,000 for the years ended December 31, 2003, 2002 and 2001, respectively. Future minimum lease payments under operating leases are as follows:

	Year Ending December 31, (In Thousands)
2004	$ 708
2005	492
2006	175
2007	19
2008 and beyond	11

On February 4, 2002, the Company was notified that a legal proceeding had been commenced against it by Merck & Co. Inc. and its Spanish subsidiary, Merck Sharp & Dohme de Espana, S.A., alleging that the Company violates their patents in its production of the product simvastatin and requesting an injunction ordering the Company not to manufacture or market the product. The case was brought against the Company's 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 the Company. Merck has appealed the award of fees. Merck re-instituted its claim against the Company in another proceeding brought in the 19th First Instance Court of the City of Madrid, of which the Company received notice on January 23, 2003. This case also alleges violation of Merck's patents in the production of the product simvastatin, requests an order that the Company cease manufacturing the product

and demands damages during the period of manufacture. A trial with respect to this matter was held on February 19 and 20, 2004, and the Company is waiting for the court's decision. The Company is vigorously opposing this claim as the Company believes the claim is without merit. The Company's simvastatin product line was launched in January 2002.

On January 10, 2004, the Company was notified that a legal proceeding had been commenced against the Company by Smith Kline Beecham PLC, Smith Kline Beecham, S.A. and GlaxoSmithKline S.A. alleging that the Company violates their patents in the Company's production of the product paroxetine and requesting an order requiring that the Company not manufacture or market the product. The case was brought against the Company's 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 the Company in 2003, which was dismissed. The Company filed a response to this suit in February 2004 that includes a counterclaim requesting that the court declare the asserted patent invalid. The Company intends to vigorously oppose this claim as the Company believes the claim is without merit. The Company's paroxetine product line was launched in 2003.

The Company is a party to various other legal actions that arose in the ordinary course of business. The Company does not expect that resolution of these matters will have, individually or in the aggregate, a material adverse effect on the Company's financial position, results of operations or cash flows.