BENTLEY PHARMACEUTICALS INC
Form 10-K
March 16, 2006

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

for the fiscal year ended December 31, 2005

OR

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

for the transition period from to .

Commission file number 1-10581

Bentley Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**No. 59-1513162**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
Bentley Park **2 Holland Way** **Exeter, New Hampshire**	**03833**
(Address of principal executive offices)	(Zip Code)

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

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

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

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
YES o NO ý

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.
YES o NO ý

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o Accelerated filer ý Non-accelerated filer o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). YES o NO ý

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

Title of Class	Aggregate Market Value *	As of Close of Business on

Common Stock, $.02 par value	**$161,184,788**	**June 30, 2005**

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

Title of Class	Shares Outstanding	As of Close of Business on
Common Stock, $.02 par value	**21,926,191**	**March 8, 2006**

DOCUMENTS INCORPORATED BY REFERENCE

Proxy Statement for the 2006 Annual Meeting of Stockholders - Incorporated by

Reference into Part III of this Annual Report on Form 10-K

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* Excludes the Common Stock held by executive officers, directors and stockholders whose ownership exceeds 5% of the Common Stock outstanding at June 30, 2005. This calculation does not reflect a determination that such persons are affiliates for any other purposes. Calculation assumes no changes in ownership positions of institutional holders with ownership positions greater than 5% from positions reported on their Schedule 13 filings for the year ended December 31, 2004.

Part I

Item 1. Business

Overview

We are an international specialty pharmaceutical company, headquartered in the U.S., that is focused on:

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

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

Our pharmaceutical product sales and licensing activities are based primarily in Spain, where we have a significant commercial presence and manufacture and market approximately 100 products of various dosages and strengths through three wholly-owned Spanish subsidiaries: Laboratorios Belmac, Laboratorios Davur and Laboratorios Rimafar. Bentley s products include approximately 151 product presentations in four primary therapeutic areas: cardiovascular, gastrointestinal, central nervous system and infectious diseases. We continually add to our product portfolio in response to increasing market demand for generic and branded therapeutic agents, and when appropriate, divest portfolio products that we consider to be redundant or that have become non-strategic. Although most of our sales of these products are currently in the Spanish market, we have recently focused on increasing our sales in other European countries and other geographic regions through strategic alliances with companies in these territories.

In April 2004, we purchased a manufacturing facility located in Zaragoza, Spain that specializes in the manufacture of certain active pharmaceutical ingredients. The facility has been approved by the U.S. Food and Drug Administration (FDA) for the manufacture of one ingredient for marketing and sale in the U.S. We are manufacturing and marketing these products through our subsidiary, Bentley API. In November 2004, we entered into a collaboration agreement with Perrigo Company, the largest U.S. manufacturer of over-the-counter pharmaceutical and nutritional products for the store brand market, to co-develop and market a generic pharmaceutical product in the U.S. and potentially other markets. Our agreement with Perrigo contains provisions which allow us to collaborate on additional products in the future when mutually agreed upon. In August 2005, we formed an Irish subsidiary, Bentley Pharmaceuticals Ireland Limited, to assist in our European expansion strategy. Bentley Pharmaceuticals Ireland Limited received its first marketing approval by the Irish Medicines Board in November 2005.

In our research and development activities, we have U.S. and international patents and other proprietary rights to technologies that facilitate the absorption of drugs. We are developing products that incorporate our drug delivery technologies and have licensed applications of our proprietary CPE-215® drug delivery technology to Auxilium Pharmaceuticals, Inc., which launched Testim® in the U.S. market, in February 2003. Testim, which incorporates our CPE-215 drug delivery technology, is a gel indicated for testosterone replacement therapy, which restores serum testosterone levels in men and thereby improves symptoms of health problems associated with low testosterone levels

(hypogonadism). Testim is approved for marketing in Belgium, Denmark, Finland, Germany, Greece, Iceland, Ireland, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden and the United Kingdom and has also received scientific approval in Italy. In April 2005, Auxilium entered into a co-promotion agreement with Oscient Pharmaceuticals Corp. Under the terms of the agreement, Oscient promotes Testim to primary care physicians in the U.S. using its 300-person sales force, while Auxilium continues to promote Testim to urologists, endocrinologists and select primary care physicians. 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 delivery of insulin to diabetic patients intranasally, delivery of macromolecule therapeutics using a biodegradable Nanacaplet™ technology, and topical treatment of nail fungus infections.

Our Common Stock trades on the New York Stock Exchange (*NYSE)* under the trade symbol *BNT*.

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

Industry Overview

Pharmaceutical Industry in Europe

The European Union, with an increasingly affluent population of approximately 450 million people and approximately $144 billion in pharmaceutical sales in 2004, represents the second largest pharmaceutical market in the world, according to IMS Health.

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

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

Since Spain s entry into the European Union in 1986, the Spanish pharmaceutical market has been evolving steadily into a market that is increasingly similar to those of other countries in Western Europe and the U.S. With a population of approximately 40 million in 2005, Spain was ranked as the seventh largest pharmaceutical market in the world and fifth largest in the European Union. Pharmaceutical sales in Spain reached approximately $11 billion in 2005, according to IMS Health.

Over the last decade, there has been significant evolution of patent protections of pharmaceutical products in Spain. Prior to 1992, manufacturing processes for active pharmaceutical ingredients could be patented in Spain, but active pharmaceutical ingredients could not be patented as products. Commencing in

late 1992 active ingredients could be patented in Spain with protection running for 20 years from the date of application. This was followed by Spanish legislation in December 1996 that created a legal class of generic pharmaceuticals. In Spain, generic products are required to be therapeutically equivalent, have a similar composition to that of the original branded product and have demonstrated safety and efficacy. Safety and efficacy is presumed if the original reference product has been commercialized in Spain for 10 years. Generic products also must comply with product labeling requirements and be priced at a discount, which is typically at least 30% lower than the original branded product price.

Although comprising less than 5.4% of the Spanish pharmaceutical market (less than 9.4% 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. In response to the rise in healthcare costs, several initiatives are underway by the Spanish government to stimulate the use of generic pharmaceuticals, including education, financial incentives to prescribing physicians and public campaigns. Due to the structure of the Spanish market for pharmaceutical products, producers generally market their products to physicians and pharmacies to whom they emphasize a combination of quality and price.

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

Drug Delivery Industry

Drug delivery companies develop technologies to improve the administration of therapeutic compounds. These technologies are designed to enhance safety, efficacy, ease-of-use and patient compliance with prescribed therapy. Drug delivery technologies provide opportunities for pharmaceutical and biotechnology companies to extend their drug franchises as well as develop new and innovative products.

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

Pharmaceutical and biotechnology companies look to drug delivery enhancements as a way of gaining a competitive advantage. Alternative drug delivery technologies, which avoid first-pass metabolism and are less invasive, may also be sought by pharmaceutical and biotechnology companies for product line

extensions for a branded drug and, in some cases, may possibly postpone competition from generic equivalents. In order to maintain the competitiveness of their proprietary drug candidates, large pharmaceutical companies seek delivery enhancements that will increase safety and efficacy, reduce side effects and make administration more convenient. Further, drug delivery companies can apply their technologies to off-patent products to formulate their own proprietary products, which they often commercialize by seeking marketing collaborations with larger pharmaceutical companies that have greater capabilities and resources.

Developing safer and more efficacious methods of delivering existing drugs generally is less risky than attempting to discover new drugs, because of lower development costs. On average, it takes 10 to 15 years for an experimental new drug to progress from the laboratory to commercialization in the U.S., with an average cost of approximately $800 million to $900 million. Typically, only one in 5,000 compounds entering preclinical testing advances into human testing and only one in five compounds tested in humans is approved for commercialization. By contrast, drug delivery companies typically target drugs that already have been approved, have a track record of safety and efficacy and have established markets for which there is a proven medical need. Consequently, clinical trials related to drug delivery technologies applied to previously-approved pharmaceuticals need only show that the new technologies deliver the drug without adverse side effects and with the same clinical efficacy.

Our Strategy

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

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

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

Our strategies to accomplish this objective include:

Increase our product sales in Spain through targeted promotion and expansion of our product portfolio and increase international sales

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

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

and allow us to further leverage our sales force by providing them with more products to sell. We believe that we have developed particular expertise in marketing pharmaceutical products to physicians and pharmacies in Spain.

Additionally, we have a strategic alliance with Teva granting us the right to register and market certain of Teva s pharmaceutical products in Spain through our sales force of 156 full-time personnel who focus on major cities throughout Spain.

We are expanding the sales of products outside of Spain by developing alliances with strategic partners in targeted markets that offer compatible regulatory approval regimes and attractive margins. Most of these alliances relate to specific products that our partners have expertise in marketing. We have already developed alliances in Portugal, Greece, the United Kingdom, Germany, Austria, Morocco, Poland and the Czech Republic for targeted products in these and other countries. In certain European countries that have a highly developed competitive market for generics based primarily on price, we intend to sell either directly or through our alliances to distributors. In countries that require a sales force to market to physicians or consumers, we intend to continue to concentrate our efforts through alliances with entities that have sales and marketing forces already in place. We have made and will continue to make, as necessary, modifications to our finished pharmaceutical products manufacturing facility so that it will comply with Good Manufacturing Practices (GMP) of the FDA. These modifications should enable us to submit our products for U.S. marketing approval by the FDA.

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

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

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

We believe these benefits include:

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

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

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

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

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

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

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

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

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

faster relief of pain and inflammation; and

better taste.

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

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

Our Proprietary Drug Technologies

Proprietary Drug Manufacturing Technologies

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

CPE-215 Permeation Platform Technology

Our permeation platform technology consists of a series of related chemical compounds that enable the absorption of a wide variety of products across various biological membranes. Our primary compound and the foundation for our drug delivery platform technology is CPE-215 (pentadecalactone). CPE-215, when combined with certain drugs, has been shown to significantly increase the amount and rate of

absorption of those drugs through various biological membranes. By controlling the amount of CPE-215 that is combined with certain drugs, we have the ability to positively affect the quantity and rate at which the drug is absorbed through biological membranes. We believe that our CPE-215 technology is superior to certain other non-injection and non-oral drug delivery systems based on the following characteristics:

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

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

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

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

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

Solubility Enhancement Technology

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

Oral Formulation Technologies

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

Nanocaplet Technology

In May 2005 we announced the discovery and synthesis of a thermodynamically stable, biodegradable Nanocaplet technology for the delivery of macromolecule therapeutics. This proprietary technology was discovered as part of our four-year sponsored research program with the University of New Hampshire Nanostructured Polymers Research Center. We have successfully synthesized biodegradable nanovesicles, or nanocapsules, which are minute, chemical structures, that have been demonstrated in test animals to encapsulate and deliver insulin systematically through the intestinal mucosa and successfully reducing glucose levels. The insulin, which is stability-sensitive like many other peptides, was delivered intact in these animal studies. This discovery represents a significant advancement in drug delivery technology and could lead to reduced reliance on certain injected pharmaceuticals.

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 approved for marketing in Belgium, Denmark, Finland, Germany, Greece, Iceland, Ireland, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden and the United Kingdom and has received scientific approval in Italy.

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

Testim resulted from our May 2000 research agreement with Auxilium, a specialty pharmaceutical company that develops and markets products for urologic and sexual health, pursuant to which Auxilium agreed to develop and test various pharmaceutical compositions of topical testosterone using our CPE-215 technology. We licensed to Auxilium exclusive worldwide rights to develop, market and sell Testim, which rights became effective in September 2000. After Auxilium conducted clinical trials, a New Drug Application (NDA) was approved by the FDA on October 31, 2002. Testim was launched in the United States by Auxilium in February 2003. In June 2003, Testim was approved in the United Kingdom and in January 2004, Auxilium entered into an agreement with Bayer Inc., a division of Bayer AG, to market Testim in Canada upon approval of Testim by the Canadian authorities. Additionally, Testim was launched in Germany in January 2005 by Auxilium s partner, Ipsen.

Manufactured and Marketed Products

In Spain, we manufacture and market approximately 100 products of various dosages and strengths which include approximately 151 product presentations in four primary therapeutic areas: cardiovascular, gastrointestinal, central nervous system and infectious diseases. We market these products primarily in Spain and have developed alliances with other companies that market our products, pursuant to license and supply agreements, in other countries, including Portugal, Greece, the United Kingdom, Germany, Austria, Morocco, Poland and the Czech Republic. In addition, we manufacture products that are marketed by other companies both in Spain and elsewhere. Our generic and branded products are marketed to physicians, pharmacists and hospitals by our three Spanish sales and marketing organizations, Laboratorios Belmac, Laboratorios Davur and Laboratorios Rimafar. We also market over-the-counter products through Laboratorios Rimafar. There are approximately 179,000 physicians and 21,000 pharmacies in Spain.

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

Branded Pharmaceutical Products

Our branded pharmaceutical product line consists of 38 products of various dosages and strengths, represented by approximately 20 trademarked brand names. Sales of branded pharmaceuticals accounted for approximately 23% of our revenues in 2005, compared to 25% in 2004 and 29% in 2003. 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 71 full-time sales personnel who focus on major cities throughout Spain. Certain of our branded products are also marketed by the sales forces of Laboratorios Davur and Laboratorios Rimafar. We supplement our sales and marketing efforts for branded products through advertising in trade publications. Most of our branded products are known in the industry as branded generics as they are being marketed by us under a brand name even though we are not the innovator of the product.

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

Our Branded Product Name	Active Ingredient	Innovator Product	Used to Treat
Belmalip®	simvastatin	Zocor® (Merck)	elevated cholesterol
Belmazol®	omeprazole	Prilosec® (AstraZeneca)	gastroesophageal reflux disease
Cimascal D Forte®	calcium carbonate and vitamin D3	Calcite-D® (Riva)	osteoporosis
Codeisan®	codeine	Tricodein® (Solco)	cough and bronchitis
Enalapril Belmac®	enalapril maleate	Vasotec® (Merck)	cardiovascular disease and hypertension

10

Our Branded Product Name	Active Ingredient	Innovator Product	Used to Treat
Ibumac®	ibuprofen	Motrin® (McNeil)	rheumatoid arthritis
Lanzol®	lansoprazole	Prevacid® (Tap)	gastroesophageal reflux disease
Mio Relax®	carisoprodol	Soma® (MedPointe)	muscle spasms
Pentoxifilina Belmac®	pentoxifylline	Trental® (Aventis)	peripheral arterial disease
Senioral®	oxymetazoline and chlorpheniramine	Denoral® (Aventis)	cold and sinus congestion
Xetin®	paroxetine	Paxil® (GlaxoSmithKline)	depression

Generic Pharmaceutical Products

Our generic pharmaceutical product line consists of 62 products of various dosages and strengths. We entered the generic pharmaceutical market in Spain in September 2000. Laboratorios Davur, our sales and marketing organization devoted primarily to generic products, markets pharmaceutical products to physicians and pharmacists through a sales force of approximately 61 full-time sales personnel who focus on major cities throughout Spain. Laboratorios Rimafar, our sales and marketing organization devoted primarily to generics and over-the-counter products, markets to pharmacists through a sales force of approximately 23 full-time sales personnel throughout Spain. Laboratorios Belmac, to a lesser extent, also sells selected generic products through its sales force. We supplement our sales and marketing efforts for generic products through advertising in trade publications.

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

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

Our Generic Product Name	Active Ingredient	Innovator Product	Used to Treat
Amoxicilina Davur® Amoxicilina Belmac®	amoxicillin trihydrate	Amoxil® (GlaxoSmithKline)	infections
Azitromicina Davur®	azithromycin	Zithromax® (Pfizer)	infections
Ciprofloxacino Davur®	ciprofloxacin hydrochloride	Cipro® (Bayer)	microbial infections, including anthrax
Enalapril Davur®	enalapril maleate	Vasotec® (Merck)	cardiovascular disease and hypertension

Our Generic Product Name	Active Ingredient	Innovator Product	Used to Treat
Fluoxetina Davur® Fluoxetina Rimafar® Fluoxetina Belmac®	fluoxetine hydrochloride	Prozac® (Eli Lilly)	depression
Ibuprofeno Davur®	ibuprofen	Motrin® (McNeil)	pain, fever
Lansoprazol Davur® Lansoprazol Rimafar®	lanoprazole	Prevacid® (Tap)	gastroesophageal reflux disease
Mirtazapina Davur®	mirtazapine	Remeron® (Organon)	depression
Omeprazol Davur ® Omeprazol Rimafar®	omeprazole	Prilosec® (AstraZeneca)	gastroesophageal reflux disease
Paroxetina Davur® Paroxetina Rimafar®	paroxetine	Paxil® (GlaxoSmithKline)	depression
Pentoxifilina Davur®	pentoxifylline	Trental® (Aventis)	peripheral arterial disease
Selegilina Davur®	selegiline hydrochloride	Eldepryl® (Somerset)	Parkinson s disease
Sertralina Davur®	sertraline hydrochloride	Zoloft® (Pfizer)	depression
Simvastatina Davur® Simvastatina Rimafar®	simvastatin	Zocor® (Merck)	elevated cholesterol
Trimetazidina Davur®	trimetazedine	Idaptan® (Servier)	coronary therapy

Sales to Licensees and Others

In addition to manufacturing and selling our own branded and generic products, we license the right to market products to others within and outside of Spain. These license agreements are usually accompanied by long-term exclusive supply agreements, whereby our licensees purchase the licensed products from our manufacturing facility. As of December 31, 2005, the Company s Spanish operations have executed 142 license agreements, of which 17 with customers in Spain and 64 with customers outside of Spain, cover actively marketed products that are generating revenues. The remaining licenses, 2 with customers in Spain and 59 with customers outside of Spain, are for products that are awaiting regulatory approvals. Additionally, we have 16 contract manufacturing agreements in effect in Spain and 6 contract manufacturing agreements in effect for international customers. Our clients market these products under their own names and with their own labeling. Many of the products we manufacture for others use the same active ingredients that are used in our own marketed products.

Strategic Alliance with Perrigo Company

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

Under the agreement, Abbreviated New Drug Applications (ANDA) for the co-developed products will be submitted by Perrigo to the FDA. We, together with Perrigo, have identified a prescription drug for co-development and commercialization that will soon lose patent protection in the U.S. Under the agreement, we and Perrigo share undisclosed percentages of the cost of development for each ANDA. The specific products and percentage of development expenses have not been disclosed for competitive reasons. Our agreement with Perrigo contains provisions which allow us to collaborate on additional products in the future when mutually agreed upon.

Alliance with Teva

In July 2000, we entered into a five year strategic alliance with Teva, a world leader in generic pharmaceutical products, pursuant to which we were granted a royalty-free, non-exclusive license to register and sell certain of Teva s pharmaceutical products. Under this license agreement, we register these products with Spain s Ministry of Health and, upon approval, sell these products in Spain. We have a non-exclusive obligation to purchase the products from Teva, allowing us to purchase any of the products from sources other than Teva if we can demonstrate that Teva s price for a product exceeds the current price from another qualified source and if Teva has not exercised its right to match the lower price. The original 5-year term of the collaboration with Teva expired in July 2005; however the collaboration agreement automatically renewed for a one-year term. We expect the agreement to continually renew for additional one-year terms until or unless terminated by either party. We have received marketing approval for 12 of these products, of which, one was launched in 2004 and three were launched in 2006, and 27 other product registrations have been submitted to the Ministry of Health and are pending approval. While there can be no assurance that any future products will be co-developed and licensed from Teva beyond July 2006, the existing licensed products (approved and pending) will remain the property of the Company and Teva is expected to continue to supply either raw materials or finished goods for those products for a period of at least five years from the launch of each product.

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

Manufacturing

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

13

In April 2004, we purchased an 11,000 square foot manufacturing facility located in Zaragoza, Spain that specializes in the manufacture of certain active pharmaceutical ingredients. The facility has been approved by the U.S. Food and Drug Administration (FDA) for the manufacture of one ingredient for marketing and sale in the U.S. We are manufacturing and marketing these products through our subsidiary, Bentley API.

We have fully integrated manufacturing support systems, including quality assurance, quality control, regulatory compliance and inventory control. These support systems are designed to maintain high standards of quality for our products and deliver reliable products and services to our customers on a timely basis. We require a supply of quality raw materials and packaging materials to manufacture and package drug products. Historically we have not had difficulty obtaining raw materials and packaging materials from suppliers. Currently, we rely on approximately 61 suppliers to deliver our required raw materials and packaging materials, most of which are supplied by 24 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 primary supplier of omeprazole. We believe that alternative sources of omeprazole are available and we will obtain required governmental approval to source from them, if necessary.

Products in Development

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

Product Candidate	Technology	Used to Treat	Status
Generic products	Various	Various	Bioequivalence and/or submitted for approval in the U.S., Spain, Europe and other countries.
Intranasal insulin	CPE-215	Diabetes	Phase I/II
Oral peptide delivery	Nanocaplet	Various	Preclinical
Antifungal nail lacquer	CPE-215	Onychomycosis	Phase I/II
Topical hormonal therapy	CPE-215	Osteoporosis; Erectile dysfunction	Preclinical
Intranasal pain management	CPE-215	Pain	Preclinical

Generic Products

We continually evaluate which pharmaceutical products are good candidates for us to develop, test and market as generic products in Spain, the U.S. and elsewhere. We select products based on factors including the timing of expiration of the patent on the innovator s product, the ability of our manufacturing facility to efficiently produce the product, the availability and cost of the raw materials to produce the

14

product as well as the potential market size and pricing that can be obtained for the product. Once we select a product, our scientists develop a generic formulation of the product, which then must be tested to determine if it is bioequivalent to the innovator s product. Products are then submitted for marketing approval by the relevant regulatory authorities, generally starting with Spain s Ministry of Health.

In addition, under a strategic alliance, we and Perrigo have agreed to co-develop a generic pharmaceutical product that can be manufactured by our active pharmaceutical ingredients manufacturing subsidiary, Bentley API, and related finish dosage forms produced by our manufacturing subsidiary, Laboratorios Belmac. Through our alliance, Perrigo will market and sell this product in the U.S., and potentially other markets. Our agreement with Perrigo contains provisions which allow us to collaborate on additional products in the future when mutually agreed upon.

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

Intranasal Insulin

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

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

Based on the results of this Phase I study, we proceeded with a Phase II protocol for evaluation in insulin-dependent diabetics, which was completed in late 2004. This study has shown that a Bentley formulation of insulin designed for intranasal administration shows preliminary evidence of efficacy, and appears to be well tolerated in patient volunteers with insulin dependent diabetes mellitus. Additional work was performed in 2005 and is planned for the future, including continued formulation development and additional Phase II studies.

Diabetes is a metabolic disorder affecting more than 100 million people worldwide.

15

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 have developed a topical nail lacquer for treating fingernail and toenail fungal infections (onychomycosis). We completed two Phase I/II clinical trials for the treatment of nail fungal infections at the University of Alabama at Birmingham in 2002 and 2003 utilizing a clotrimazole lacquer formulation containing CPE-215. 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.

Topical Hormonal Therapy

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

Intranasal Pain Management

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

Orally delivered pain products may not provide rapid relief and typically demonstrate considerable patient-to-patient variability in absorption. Injectable formulations of pain products provide rapid and effective pain relief, but administration often requires professional assistance or hospitalization. We believe an intranasal pain product could provide significant medical benefits over oral and injectable formulations.

Under a research agreement with Auxilium, we formulated the intranasal delivery of a pain management chemical agent using our CPE-215 technology. Auxilium has the right to license this product application pursuant to our research agreement, but has not effected the license to date.

Intellectual Property

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

We have been granted a Spanish patent for our oral formulations of omeprazole and lansoprazole which expire in 2023.

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

Competition

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

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

Customers

In Spain, our sales representatives from Laboratorios Belmac, Laboratorios Davur and Laboratorios Rimafar actively promote our products to physicians and retail pharmacists. We sell our products directly to pharmaceutical distributors and indirectly to customers who purchase our products from distributors. Outside Spain, we currently sell our products to our strategic partners who then distribute our products directly or through distributors in their respective territories. We have begun to market certain products directly to distributors in selected markets outside of Spain. Our manufacturing facility also supplies branded and generic products to customers both within and outside of Spain, including the European Union, geographical Europe, Northern Africa and the Middle East, under licensing and supply agreements or contract manufacturing arrangements. The wholesale distributor network for pharmaceutical products in Europe and more specifically in Spain in recent years has been subject to increasing consolidation, which we expect will continue to increase our, and other industry participants , customer concentration.

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

In the past three years, only one of our customers, Cofares, accounted for more than ten percent of our consolidated total revenues. Sales to this customer accounted for approximately 12% of our consolidated total revenues in 2005, 13% in 2004 and 14% in 2003. See Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations and Note 14 of the Notes to the Consolidated Financial Statements in Item 15 for financial information regarding geographic areas.

Employees

We employ approximately 420 people, 22 of whom are employed in the U.S. and 398 of whom are employed in Spain, as of March 1, 2006. Approximately 173 of these employees are principally engaged in manufacturing activities, 156 in sales and marketing, 29 in product development and 62 in management and administration. In general, we consider our relations with our employees to be good.

Regulation

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

United States

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

Preclinical testing;

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

Clinical trials;

Preparation and submission of the NDA; and

FDA s review and approval/disapproval of the NDA.

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

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

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

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

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

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

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

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

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

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

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

Europe

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

Pharmaceutical manufacturers in Europe must obtain marketing approval from the regulatory authority of each country in which they intend to market a product. In Spain, that authority is the Spanish Ministry of Health. The development process in Europe is similar to that in the United States described above, with the same three clinical phases for branded drugs and bioequivalence studies for generic drugs to assure their safety and efficacy. A dossier must be prepared for each pharmaceutical product and, upon approval of the product, it may be marketed in that country. In Spain, generic products are generally approved approximately one year after submission, while branded products take considerably longer. Spain and several other European countries also regulate the price that can be charged to the patient for each product in addition to setting the amount that the public insurance programs will reimburse for each product, which directly affects 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 for more discussion of regulation in Spain.)

Spain s Council of Ministers has recently forwarded to Parliament a proposed medicines bill. The proposed bill states that when a doctor writes a prescription by active ingredient, rather than brand name, the pharmacist would dispense the lowest-priced product. If several products have equally low prices, the pharmacist should favor the generic product. If approved, all drugs which have been reimbursed for at least ten years, or eleven years if they have gained a new indication, would be placed into a reference-price group with products containing the same active pharmaceutical ingredients and delivery form. The reference price would be calculated as an average of the three lowest prices in the group. Where the reference price would result in price cuts of more than 30% to a product, companies would be able to reduce the price of that product gradually. Where a brand has held a marketing authorization for at least ten years, its current price

would be cut by 20%, providing an equivalent generic product is at a lower price in another European Union member state. Any product priced below 2.00 (or approximately $2.40) would be exempt from the reference price provisions. We cannot assure you whether this proposal may be enacted in some form, if at all, or the impact it may have if enacted.

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

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

Trends in Healthcare Regulation

The cost of healthcare continues to be a subject of investigation and action by governmental agencies, legislative bodies and private organizations. Many countries, in Europe and elsewhere, directly or indirectly through reimbursement limitations, control the selling prices and reimbursement prices of certain healthcare products. For example, in Spain, prices for prescription pharmaceutical products must be approved by Spain s Ministry of Health. In order to help control rising healthcare costs, the Ministry of Health, in recent years, has encouraged the substitution of generic-equivalent products, as described above. There can be no assurance that the government in Spain or in other countries will not implement additional price reductions in the future.

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

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

In the United States, most states have enacted generic substitution legislation requiring or permitting a dispensing pharmacist to substitute a generic version of a prescribed innovator drug. Federal and state governments continue their efforts to reduce costs of subsidized healthcare programs, including

21

restrictions on amounts agencies will reimburse for the use of products. Efforts to reduce healthcare costs are also being made in the private sector. Healthcare providers have responded by instituting various cost reduction and containment measures of their own. It is not possible to predict the extent to which we or the healthcare industry in general might be affected by these changes.

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

Other Regulations

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

Available Information

Copies of reports filed by us 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, Current Reports on Form 8-K and amendments to those reports may be accessed from our website at www.bentleypharm.com, 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.

Item 1A. Risk Factors

You should carefully consider the following discussion of risks and uncertainties that we face in our business. 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 below actually occurs, our business, financial condition, or results of operations could be materially adversely affected. In such case, the trading price of our common stock could decline and you may lose all, or part of your investment.

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

We believe that our growth depends on the identification of pharmaceutical products that are suitable for delivery using our proprietary technologies. Our principal drug delivery technology is our CPE-215 technology. This technology, like certain other drug delivery technologies, operates to increase the amount and rate of absorption of certain drugs across biological membranes. This technology does not operate independently and must be coupled with suitable pharmaceutical products in order to provide value. Consequently, our growth will depend to a great extent on identifying and commercializing these suitable drugs with respect to which we intend to expend significant resources and efforts. Identifying suitable

products is a lengthy and complex process that may not succeed. Even if identified, products may not be available to us or we may otherwise be unable to enter into licenses or other agreements for their use. In our efforts to identify suitable products, we compete with other drug delivery companies with greater research and development, financial, marketing and sales resources. If we do not effectively identify drugs to be used with our technologies, improve the delivery of drugs with our technologies and bring the improved drugs to commercial success, then we may not be able to continue our growth and we will be adversely affected.

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

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

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

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

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

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

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

other pharmaceutical companies may market equivalent or superior products.

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

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

perceived efficacy of our products;

convenience and ease of administration;

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

availability of alternative treatments;

cost effectiveness;

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

publicity concerning our products or competing products; and

our ability to obtain third-party coverage or reimbursement.

Even though regulatory approval has been received for Testim, and even if we receive regulatory approval and satisfy the above criteria for any other product candidates developed by us or incorporating our drug delivery technology, physicians may not prescribe these products if we do not promote the products effectively. Factors that could affect our success in marketing our products include:

the effectiveness of our sales force;

the effectiveness of our production, distribution and marketing capabilities;

the success of competing products; and

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

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

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

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

We must enter into agreements with strategic partners to conduct clinical trials, manufacturing, marketing and sales necessary to commercialize product candidates. In addition, our ability to apply our drug delivery technologies to any proprietary drugs will depend on our ability to establish and maintain strategic partnerships or other collaborative arrangements with the holders of proprietary rights to such

drugs. Arrangements with strategic partners may be established through a single comprehensive agreement or may evolve over time through a series of discrete agreements, such as letters of intent, research agreements and license agreements. We cannot assure you that we will be able to establish such strategic partnerships or collaborative arrangements on favorable terms or at all or that any agreement entered into with a strategic partner will lead to further agreements or ultimately result in commercialization of a product.

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

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

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

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

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

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

Spanish sales from our omeprazole product line accounted for approximately 18% and 22% of our consolidated total revenues in 2005 and 2004, respectively. The active pharmaceutical ingredient for our omeprazole products is currently purchased from one supplier. If we lose and cannot effectively replace our supplier or are otherwise unable to continue the sales of our omeprazole products, our revenues would decline significantly.

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

Our revenues and profitability may be adversely affected by the continuing efforts of governmental and third-party payors to contain or reduce the costs of healthcare. A substantial portion of our operations consists of marketing and manufacturing, primarily in Spain and other parts of Europe generic and branded pharmaceutical products. The use of generic drugs is regulated in Spain, the U.S. and many other countries, and is subject to many changing and competing public policy considerations. In addition, in certain markets, such as Spain, pricing or profitability of prescription pharmaceuticals is subject to government control through reimbursement limitations. Specifically, prices for prescription pharmaceutical products in Spain must be approved by Spain s Ministry of Health. In order to help control rising healthcare costs, the Ministry of Health, in recent years, has encouraged the substitution of generic-equivalent products. In further efforts to reduce healthcare costs, the Ministry of Health had been contemplating new laws and regulations that would significantly reduce the market prices of certain pharmaceutical products, including generic-equivalent drugs. For example, in late October 2003, the Spanish government enacted a regulation that reduced the prices that the government reimbursed for certain prescription pharmaceutical products. The regulation affected six of our chemical entities sold in Spain, including the chemical entities omeprazole, simvastatin and enalapril, which reduced our 2004 revenues by approximately $13.8 million.

Spain s Council of Ministers has recently forwarded to Parliament a proposed medicines bill. The proposed bill states that when a doctor writes a prescription by active ingredient, rather than brand name, the pharmacist would dispense the lowest-priced product. If several products have equally low prices, the pharmacist should favor the generic product. If approved, all drugs which have been reimbursed for at least ten years, or eleven years if they have gained a new indication, would be placed into a reference-price group with products containing the same active pharmaceutical ingredients and delivery form. The reference price would be calculated as an average of the three lowest prices in the group. Where the reference price would result in price cuts of more than 30% to a product, companies would be able to reduce the price of that product gradually. Where a brand has held a marketing authorization for at least ten years, its current price would be cut by 20%, providing an equivalent generic product is at a lower price in another European Union member state. Any product priced below 2.00 (or approximately $2.40) would be exempt from the reference price provisions. We cannot assure you whether this proposal may be enacted in some form, if at all, or the impact it may have if enacted.

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

The cost of healthcare in Spain, the U.S. and elsewhere continues to be a subject of investigation and action by various governmental agencies. Certain resulting legislative proposals may adversely affect

us. For example, governmental actions to further reduce or eliminate reimbursement for drugs may directly diminish our markets. In addition, legislative safety and efficacy measures may be invoked that lengthen and increase the costs of drug approval processes. Further, social, economic and other broad policy legislation may induce unpredictable changes in the healthcare environment. We cannot assure you whether any of these measures may be enacted in some form, if at all, or the impact they may have if enacted.

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

Any human pharmaceutical product developed by us would require clearance by the FDA for sales in the United States, by Spain s Ministry of Health for sales in Spain and by comparable regulatory agencies for sales in other countries. In the case of non-generic products, the process of conducting clinical trials and obtaining FDA and other regulatory approvals is lengthy and expensive and we cannot be assured of success. In order to obtain FDA approval of any new product candidates using our technologies, an NDA must be submitted to the FDA demonstrating that the product candidate, based on preclinical research, animal studies and human clinical trials, is safe for humans and effective for its intended use. Positive results from preclinical studies and early clinical trials do not ensure positive results in more advanced clinical trials designed to permit application for regulatory approval. We may suffer significant setbacks in clinical trials, even in cases where earlier clinical trials show promising results. Any of our new product candidates may produce undesirable side effects in humans that could cause us or regulatory authorities to interrupt, delay or halt clinical trials of a product candidate. We, the FDA or other regulatory authorities, may suspend our clinical trials at any time if we or they believe the trial participants face unacceptable health risks or if they find deficiencies in any of our regulatory submissions. Other factors that can cause delay or terminate our clinical trials include:

slow or insufficient patient enrollment;

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

longer treatment time required to demonstrate efficacy;

lack of sufficient supplies of the product candidate;

adverse medical reactions or side effects in treated patients;

lack of effectiveness of the product candidate being tested;

regulatory requests for additional clinical trials; and

instability of the pharmaceutical formulations.

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

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

Competitors may interfere with our patent process in a variety of ways. Competitors may claim that they invented the claimed invention prior to us. Competitors also may claim that we are infringing their

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

Examples of the risk of infringement claims are the different legal proceedings commenced against us in Madrid by Merck & Co. Inc. and its Spanish subsidiary, GlaxoSmithKline S.A. and its Spanish subsidiaries, and Ethypharm S.A. and its Spanish subsidiaries, in each case alleging that we violated their respective patents. As discussed in more detail in Item 3 Legal Proceedings we cannot assure you that similar actions will not be brought against us, or that these actions or any such similar actions will not have an adverse effect on us.

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

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

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

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

As a public company, we are subject to certain federal regulations and the rules and regulations of the Securities and Exchange Commission and the New York Stock Exchange. The Sarbanes-Oxley Act of 2002 required more stringent accounting, corporate fraud and securities laws. To implement this legislation,

the Securities and Exchange Commission has adopted new rules and may adopt additional rules pertaining to, among other things, additional disclosure and reporting requirements, including requirements relating to internal control procedures. The New York Stock Exchange has also adopted various rules relating to corporate governance. Our reputation and financial results could be materially harmed by any failure by us to comply with any current or future rules or regulations relating to the Sarbanes-Oxley Act or to any other federal corporate or stock exchange reform measures.

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

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

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

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

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

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

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

Any manufacturing facility for pharmaceutical products to be marketed in the United States is subject to FDA inspection and inspections by other government agencies both before and after approval of an

29

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

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

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

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

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

During the year ended December 31, 2005, 72% of our revenues were derived from sales made by our Spanish subsidiaries in Spain and 22% of our revenues were derived from sales made by our Spanish subsidiaries to customers in other foreign countries. We believe that the most substantial portion of our revenues will continue to be derived from sales in foreign countries. Conducting business internationally subjects us to a number of risks and uncertainties, including:

- unexpected delays or changes in regulatory requirements;
- difficulties and costs related to complying with a wide variety of complex foreign laws and treaties;
- delays and expenses associated with tariffs and other trade barriers;
- restrictions on and impediments to repatriation of our funds and our customers ability to make payments to us;

political and economic instability;

acts of terrorism or war;

difficulties and costs associated with staffing and managing international operations and implementing, maintaining and improving financial controls;

dependence upon independent sales representatives and other indirect resellers who may not be as effective and reliable as our employees;

inadequate or uncertain protection of intellectual property in foreign countries;

increased difficulty in collecting accounts receivable and longer accounts receivable cycles in certain foreign countries;

adverse tax consequences or overlapping tax structures; and

limitations on the remittance of dividends by foreign subsidiaries.

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

Our revenues may be impacted by fluctuations in local currencies due to the fact that 94% of our revenues currently are generated by our Spanish subsidiaries, Laboratorios Belmac, Laboratorios Davur, Laboratorios Rimafar and Bentley API. Fluctuations in the value of the Euro, in relation to the U.S. Dollar had a significant impact on our operations during the interim periods of 2005, but did not have a significant effect on our operations during the year ended December 31, 2005. We do not currently engage in foreign exchange hedging transactions to manage our foreign currency exposure because much of our expenditures are in the same currency as our revenues. Our foreign operations expose us to a number of currency related risks, including the following:

fluctuations in currency exchange rates;

limitations on the conversion of foreign currency; and

fluctuations of the carrying value of long lived assets.

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

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

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

The competitive position of our drug delivery technologies is subject to the possible development by others of superior technologies. Other drug delivery technologies, including oral and injection methods,

have wide acceptance, notwithstanding certain drawbacks, and are the subject of improvement efforts by other entities having greater resources. In addition, our drug delivery technologies are limited by the number and commercial magnitude of drugs with which they can successfully be combined.

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

We routinely consider acquisition and investment opportunities, although we have no current agreements or commitments with respect to any acquisitions or investments. Any future acquisitions or investments would further challenge our resources. If we do not properly meet the increasing expenses and demands on our resources from future growth, we will be adversely affected. To properly manage our growth, we must, among other things, implement additional and improve existing administrative, financial, marketing, operational and research and development systems, procedures and controls on a timely basis. We may also need to expand our staff in these and other areas. We may not be able to complete the improvements to our systems, procedures and controls necessary to support our future operations in a timely manner. We may not be able to hire, train, integrate, retain, motivate and manage required personnel, successfully integrate acquisitions or investments, nor successfully identify, manage and pursue existing and potential market opportunities. We plan to invest approximately $22.6 million in capital expenditures during the year ending December 31, 2006, including $10.0 million that was budgeted in 2005, but now planned for 2006. We plan to expand our API manufacturing facility, expand our pharmaceutical product manufacturing facility and add new production lines in order to be able to accommodate the level of operations and growth that is anticipated as a result of the Company s expansion beyond the borders of Spain and the U.S. market. We plan to finance these expenditures from a combination of cash flow from operations, borrowings, and existing cash balances. If we fail to generate additional revenue in excess of increased operating expenses in any fiscal period, we may incur losses.

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

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

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

take advantage of future opportunities, grow our business or respond to competitive pressures or unanticipated requirements.

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

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

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

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

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

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

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

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

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

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could inhibit or prevent the commercialization of pharmaceutical products we develop alone or with corporate collaborators. We maintain product liability insurance in the amount of 3 million (approximately $3.6 million U.S. Dollars) and clinical trial insurance in connection with our clinical testing activities in various amounts on a study-by-study basis. While management believes that this insurance is reasonable, we cannot assure you that any of this coverage will be adequate to protect us in the event of a claim. We, or any corporate collaborators, may not be able to obtain or maintain insurance at a reasonable cost, if at all. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate if any claim arises. Our agreement with Perrigo Company requires us to secure product liability insurance equal to $10 million upon commercialization of the product being developed. There can be no assurance that we will be able to secure such an amount of coverage at a reasonable cost or at all or that if secured, that it will be adequate to protect us in the event of a claim.

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

Variations in our quarterly and year-end operating results are difficult to predict and may fluctuate significantly from period to period. If our sales or operating results fall below the expectations

34

of investors or securities analysts, the price of our common stock could decline substantially. In addition to the other factors discussed under these Risk Factors, specific factors that may cause fluctuations in our operating results include:

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

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

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

As of December 31, 2005, we had the following capital structure:

	No. of Shares
Common Stock outstanding	*21,923,142*
Common stock issuable upon:	
Exercise of options which are outstanding	*3,916,378*
Exercise of options which are available for grant	*438,029*
Total common stock outstanding assuming exercise of all of the above	*26,277,549*

As of December 31, 2005, we had outstanding options to purchase 3,916,378 shares of common stock at exercise prices ranging from $2.00 to $15.83 (exercisable at a weighted average of $8.72 per share), of which 3,076,253 were then vested and exercisable. We may conduct future offerings of our common stock or other securities with rights to convert the securities into shares of our common stock. Exercise of our outstanding options into shares of our common stock may significantly and negatively affect the market price for our common stock as well as decrease your percentage ownership and voting power.

Our stock price is volatile.

The market prices for our securities and for securities of emerging growth companies have historically been highly volatile. During the two years ended March 10, 2006, the price of our common stock has ranged from a high of $22.90 to a low of $6.50. 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 may adversely affect the market price of our common stock. Furthermore, the stock market has experienced significant price and volume fluctuation unrelated to the operating performance of particular companies. These market fluctuations may also adversely affect the market price of our common stock.

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

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

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

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

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

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

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

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

We own an 11,000 square foot active pharmaceutical ingredients manufacturing facility in Zaragoza, Spain and during 2005 we purchased adjacent parcels of land totaling approximately four acres for expansion of our active pharmaceutical ingredients manufacturing operation. The API manufacturing facility is located in an industrial park and we have acquired sufficient acreage adjacent thereto to accommodate future expansion.

We lease a 13,000 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 2008.

We believe that each of our facilities has sufficient space for our current needs and our contemplated expansion in the near future. Our manufacturing facilities are currently operating at approximately 70% of capacity, if operating for two shifts per day, five days per week.

Item 3. **Legal Proceedings**

On February 4, 2002, we were notified that a legal proceeding had been commenced against us by Merck & Co. Inc. and its Spanish subsidiary, Merck Sharp & Dohme de España, S.A., alleging that we

violated their patents in our production of simvastatin products and requested an injunction ordering us to not manufacture or market the products. The case was brought against our Spanish subsidiaries in the 39th First Instance Court of the City of Madrid. After a hearing on February 18, 2002, the court refused to grant the requested injunction and dismissed the case on February 25, 2002, awarding us with court costs and legal fees. Merck appealed the award of fees, but the Madrid Court of Appeal rejected its allegations and upheld the First Instance decision in our favor.

Merck filed an infringement action against us in another proceeding brought in the 19th First Instance Court of the City of Madrid, of which we received notice on January 23, 2003. In this case, Merck also alleged violation of its patents in the production of simvastatin products, requested an order that we cease manufacturing the products and demanded damages during the period of manufacture. After a trial with respect to this matter held on February 19 and 20, 2004, the court, on April 8, 2004, ruled in our favor, again awarding us with court costs and legal fees. Merck appealed this ruling, but the Madrid Court of Appeal upheld the First Instance judgment on all grounds, rejecting Merck s appeal (judgment rendered on February 21, 2006, served to the parties on March 6, 2006). Merck has the ability to appeal this judgment before the Spanish Supreme Court.

On January 10, 2004, we were notified that a legal proceeding had been commenced against us by Smith Kline Beecham PLC, Smith Kline Beecham, S.A. and GlaxoSmithKline S.A. alleging that we violate their patents in our production of paroxetine products and requesting an order requiring us to not manufacture or market the products. The case was brought against our Spanish subsidiaries in the 50th First Instance Court of the City of Madrid. This proceeding followed a preliminary injunction that the same plaintiffs attempted to bring against us in 2003, which was dismissed. We filed a response to this suit in February 2004 that included a counterclaim requesting that the court declare the asserted patent invalid. On May 11, 2005, the Spanish Court terminated these judicial proceedings upon agreement among the parties to dismiss, without recourse, all paroxetine-related patent infringement claims in Spain.

On September 27, 2004, we were served with a complaint in an action captioned Ethypharm S.A. France & Ethypharm S.A. Spain v. Bentley Pharmaceuticals, Inc., U.S. District Court for the District of Delaware, Civil Action No. 04-1300 (SLR). In this action, Ethypharm S.A., a French-based drug delivery company, and its Spanish affiliate (collectively, Ethypharm), allege that since March 2002 we and our Spanish subsidiary Laboratorios Belmac, S.A. (Belmac) misappropriated unspecified Ethypharm trade secrets and confidential information and used that information in the manufacture of omeprazole, one of Belmac s pharmaceutical products. Based on Ethypharm s primary allegation of misappropriation of trade secrets, the complaint also asserted counts of fraud, unjust enrichment, and intentional interference with actual and prospective business relationships. Ethypharm s complaint seeks injunctive relief as well as damages. On September 26, 2005, the Court granted our motion to dismiss two counts, Count 1 (Fraud) and Count 3 (Unjust Enrichment), of Ethypharm s complaint but denied our motion to dismiss the complaint in its entirety without prejudice to its being renewed after the completion of discovery on the issue of agency. We intend to contest the case vigorously.

On April 11, 2005, Ethypharm s Spanish affiliate, Ethypharm S.A., filed suit against Belmac S.A. in the Commercial Court No. 5 of Madrid, Spain. The complaint alleges that Belmac refused to renew its contract with Ethypharm for the manufacture of omeprazole which expired on March 22, 2002, and that after that date Belmac s continued manufacture of omeprazole pursuant to its own patented technology has infringed Ethypharm s Spanish Patent No. ES9301319. In its complaint, Ethypharm seeks an order from the court declaring Belmac to be in violation of Ethypharm s patent, preventing further sales of omeprazole by Belmac using processes that allegedly infringe Ethypharm s patent, and awarding monetary damages. On July 5, 2005, Belmac filed an answer and counterclaim which denies Ethypharm s material allegations and seeks a declaration that Ethypharm s patent is invalid.

38

Ethypharm has responded to Belmac s counterclaim. No trial date has been set. Belmac intends to defend the case vigorously.

In January 2005, we were notified that a legal proceeding had been commenced against us by Pfizer Inc and its Spanish subsidiary Pfizer, S.A. requesting an order requiring us to not manufacture or market our amlodipine products. The case was brought against Laboratorios Davur S.L. in the 3rd Commercial Court of the City of Barcelona. After an initial hearing the court imposed an injunction, preventing us from launching our amlodipine products. However, upon appeal, the court lifted the requested injunction and awarded us with court costs and legal fees.

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**

None.

Part II

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

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

	High	Low
Fiscal Year Ended December 31, 2004		
First Quarter	*$ 14.76*	*$ 10.62*
Second Quarter	*14.10*	*11.20*
Third Quarter	*13.89*	*9.52*
Fourth Quarter	*11.40*	*8.35*
Fiscal Year Ended December 31, 2005		
First Quarter	*11.02*	*7.25*
Second Quarter	*12.10*	*6.50*
Third Quarter	*12.95*	*10.63*
Fourth Quarter	*20.80*	*11.27*
Fiscal Year Ending December 31, 2006		
First Quarter (through March 10, 2006)	*22.90*	*14.02*

As of March 10, 2006 there were 1,018 holders of record of our common stock, which does not reflect stockholders whose shares are held in street name.

Dividends

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

Issuer Purchases of Equity Securities

	(a) Total Number of Shares (or Units) Purchased (1)	(b) Average Price Paid per Share (or Unit)(2)	(c) Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	(d) Maximum Number (or approximate dollar value) of Shares (or Units) that may yet be Purchased under the Plans or Programs
October 1, 2005 through October 31, 2005		$		
November 1, 2005 through November 30, 2005				
December 1, 2005 through December 31, 2005	65,711	18.454		
Total	65,711	$ 18.454		

(1) Represents shares tendered to the Company at fair market value from option holders using mature stock to exercise vested stock options and satisfy minimum tax withholding liabilities.

(2) Weighted average of the high and low prices on the NYSE on the dates of exercise.

Item 6. Selected Financial Data

The following sets forth the selected Consolidated Income Statement data for the years ended December 31, 2001, 2002, 2003, 2004 and 2005 and Consolidated Balance Sheet data as of December 31, 2001, 2002, 2003, 2004 and 2005, all of which are derived from our audited Consolidated Financial Statements and related notes. The following Consolidated Income Statement data for the years ended December 31, 2003, 2004 and 2005 and Consolidated Balance Sheet data as of December 31, 2004 and 2005 should be read together with our Consolidated Financial Statements and related notes appearing elsewhere in Item 15 and Management s Discussion and Analysis of Financial Condition and Results of Operations of this Annual Report on Form 10-K. The Consolidated Income Statement data for the years ended December 31, 2001 and 2002 and the Consolidated Balance Sheet data as of December 31, 2001, 2002 and 2003 are derived from our audited Consolidated Financial Statements and related notes not included in this Annual Report on Form 10-K.

Consolidated Income Statement Data

(in thousands, except per share data)	For the Year Ended December 31, 2001	2002	2003	2004(a)	2005(b)
Total revenues	$ 26,411	$ 39,136	$ 64,676	$ 73,393	$ 97,730
Cost of net product sales	11,462	16,477	26,399	34,893	46,161
Gross profit	14,949	22,659	38,277	38,500	51,569
Operating expenses	16,137	19,277	26,848	29,805	35,903
Gain on sale of drug licenses	5,050	650			
Other income (expenses)	(49)	138	91	1,800	729
Income before income taxes	3,813	4,170	11,520	10,495	16,395
Provision for income taxes	2,452	2,534	5,423	4,805	5,476
Net income	$ 1,361	$ 1,636	$ 6,097	$ 5,690	$ 10,919
Net income per common share - basic	$ 0.10	$ 0.10	$ 0.34	$ 0.27	$ 0.51
Net income per common share - diluted	$ 0.08	$ 0.08	$ 0.28	$ 0.25	$ 0.48
Weighted average common shares outstanding - basic	14,196	16,569	17,997	20,901	21,558
Weighted average common shares outstanding - diluted	16,147	19,798	21,637	22,627	22,929

(a) *Other income (expenses)* for the year ended December 31, 2004 includes the reversal of previously accrued tax assessments totaling $1,467,000. These assessments had been accrued to be paid to the Spanish government as a vehicle to help reduce the impact of the rising health care costs in Spain. Due to changes in the pharmaceutical industry in Spain and a change in the Spanish political environment, these liabilities no longer exist. Accordingly, these accruals were reversed during the second quarter of 2004. Additionally, a reclass of approximately $342,000 has been made between *Depreciation and amortization* and *Cost of net product sales* for depreciation on certain fixed assets to conform with the 2005 presentation format.

(b) *Total revenues* for the year ended December 31, 2005 include a change in estimate of royalty revenues earned of approximately $1,092,000 recorded in the fourth quarter of 2005. This change in estimate of royalty revenues earned is based upon publicly available data determined to be more accurate than the source of data previously relied upon by management in estimating the sell-through of prescriptions dispensed.

Consolidated Balance Sheet Data

(in thousands)	December 31, 2001	2002	2003	2004	2005
Working capital	*$ 6,276*	*$ 30,703*	*$ 46,181*	*$ 47,114*	*$ 46,397*
Current assets	*$ 15,839*	*$ 43,972*	*$ 66,899*	*$ 74,710*	*$ 75,077*
Non-current assets	*16,280*	*20,720*	*33,564*	*47,220*	*49,143*
Total assets	*$ 32,119*	*$ 64,692*	*$ 100,463*	*$ 121,930*	*$ 124,220*
Current liabilities	*$ 9,563*	*$ 13,269*	*$ 20,718*	*$ 27,596*	*$ 28,680*
Long-term debt	*142*	*345*	*369*	*349*	
Other non-current liabilities	*1,990*	*2,327*	*3,211*	*4,328*	*3,951*
Total liabilities	*$ 11,695*	*$ 15,941*	*$ 24,298*	*$ 32,273*	*$ 32,631*
Redeemable preferred stock	*$*	*$*	*$*	*$*	*$*
Stockholders equity	*$ 20,424*	*$ 48,751*	*$ 76,165*	*$ 89,657*	*$ 91,589*

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 report. 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.

Words such as expect , anticipate , intend , believe , will , may , could , should , project , estimate and similar words are used to ide 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 Business Section, Management s Discussion and Analysis of Financial Condition and Results of Operations, Risk Factors and other sections in this report, are not based on historical facts, but rather reflect our current expectations concerning future results and events. The forward-looking statements include statements about our strategy, the prospects of our technologies and research and development efforts, our plans to enter into more collaborative relationships, our prospects for revenue growth outside of Spain, anticipated financial results and the prospects for growth of our business. 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 report. You are cautioned not to place undue reliance on these forward-looking statements. We undertake no obligation to publicly update or revise any forward-looking statements, whether as the result of new information, future events or otherwise.

Overview

We are a specialty pharmaceutical company focused on:

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

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

Branded and Generic Pharmaceuticals

Our pharmaceutical product sales activities are based in Spain, where we have a significant commercial presence and we manufacture and market approximately 100 pharmaceutical products of various dosages and strengths. These products include approximately 151 product presentations in four primary therapeutic areas: cardiovascular, gastrointestinal, central nervous system and infectious diseases. In 2005, approximately 25% of our product revenues were derived from two of our product lines. We market our branded and generic products to physicians, pharmacists and hospitals through our three separate sales and marketing organizations based in Spain: Laboratorios Belmac,

Laboratorios Davur and Laboratorios Rimafar. As prices for prescription pharmaceuticals have been lowered in Spain by action of the Ministry of Health, which has authority to approve pharmaceutical prices, we are working to improve the efficiency of our manufacturing operations to reduce our costs, while also increasing sales. We have recently focused

on increasing our sales in other European countries and other geographic regions through strategic alliances with distributors in these territories. We also target markets that offer compatible regulatory approval regimes and attractive product margins. In August 2005, we formed an Irish subsidiary, Bentley Pharmaceuticals Ireland Limited, to assist in our European expansion strategy. Bentley Pharmaceuticals Ireland Limited received its first marketing approval by the Irish Medicines Board in November 2005. There were no significant revenues in Bentley Pharmaceuticals Ireland in 2005.

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

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

Proprietary Drug Delivery Technologies and Products

We develop products that incorporate our drug delivery technologies that we have developed in the United States. We have licensed applications of our proprietary CPE-215 drug delivery technology to Auxilium Pharmaceuticals, Inc., which launched Testim the first product incorporating our CPE-215 drug delivery technology, in the United States in February 2003. Testim is a gel indicated for testosterone replacement therapy. Testim is approved for marketing in Belgium, Denmark, Finland, Germany, Greece, Iceland, Ireland, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden and the United Kingdom and has received scientific approval in Italy. 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 delivery of insulin to diabetic patients intranasally, delivery of macromolecule therapeutics using a biodegradable Nanacaplet technology and topical treatment of nail fungus.

Consolidated Results of Operations

Fiscal Year Ended December 31, 2005 Compared To Fiscal Year Ended December 31, 2004

Revenues

(in thousands)

	2005	%	2004	%	Change $	Change %
Revenues:						
Net product sales	*$ 91,308*	*93%*	*$ 69,942*	*95%*	*$ 21,366*	*31%*
Licensing and collaboration revenues	*6,422*	*7%*	*3,451*	*5%*	*2,971*	*86%*
Total revenues	*$ 97,730*	*100%*	*$ 73,393*	*100%*	*$ 24,337*	*33%*

Total revenues for the year ended December 31, 2005 increased 33% from the year ended December 31, 2004. Fluctuations in the weighted average value of the Euro, in relation to the U.S. Dollar had a significant impact on operations during the interim periods of 2005, but did not have a material impact on operations for the full year, as the quarterly fluctuations effectively neutralized each other. Our current year growth was driven primarily by increased net product sales. The increase in licensing and collaboration revenues was due to increased royalty revenues from sales of Testim and included $1,092,000 resulting from a revised estimate of sell-through of prescriptions dispensed that was recorded in the fourth quarter of 2005.

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

For the year ended December 31, 2005:

(in thousands)

	Revenues Within Spain			Revenues Outside of Spain		
Product Line	**Branded Products**	**Generic Products**	**Other**		**Total**	**% of Total Revenues**
Omeprazole	*$ 2,779*	*$ 15,394*	*$*	*$*	*$ 18,173*	*18%*
Simvastatin	*1,666*	*5,080*			*6,746*	*7%*
Enalapril	*4,153*	*1,706*			*5,859*	*6%*
Paroxetine	*1,337*	*3,118*			*4,455*	*5%*
Codesian	*3,441*				*3,441*	*4%*

All other products	*9,225*	*9,812*	*271*	*1,512*	*20,820*	*21%*
Sales to licensees and others			*11,589*	*20,225*	*31,814*	*32%*
Licensing and collaborations			*274*	*6,148*	*6,422*	*7%*
Total Revenues	*$ 22,601*	*$ 35,110*	*$ 12,134*	*$ 27,885*	*$ 97,730*	*100%*
% of 2005 Revenues	*23%*	*36%*	*12%*	*29%*	*100%*	

For the year ended December 31, 2004:

(in thousands)

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

Spanish Operations. The increase in the net product sales for the year ended December 31, 2005 compared to the year ended December 31, 2004 is due primarily to: (1) an increase in sales to licensees and others totaling $11,024,000 fueled primarily by sales outside of Spain; and (2) an aggregate increase totaling $5,072,000 in sales of our three top selling product lines (omeprazole, simvastatin and enalapril). Sales of active pharmaceutical ingredients from our API manufacturing facility (included in All other products in the tables above) added $1,783,000 to consolidated revenues in 2005. Fluctuations in the weighted average value of the Euro, in relation to the U.S. Dollar had a significant impact on operations during the interim periods of 2005, but did not have a material impact on operations for the year.

The Ministry of Health in Spain continues to encourage the substitution of generic-equivalent products in order to help control rising healthcare costs. In recent years, our business was negatively impacted by price reductions mandated by the Spanish government. We have furthered our expansion into markets outside of Spain, increased the number of drugs in our portfolio and purchased efficient high speed manufacturing equipment to help manage our business profitability. Additionally, in April 2004, we purchased a manufacturing facility, located in Zaragoza, Spain, which specializes in the manufacture of active pharmaceutical ingredients. The ability to manufacture active pharmaceutical ingredients has diversified our revenue base. We will continue to focus on acquiring, developing and launching new products that will improve our product mix. Four products were launched in 2005 and contributed approximately $588,000 to net product sales. We will also continue our efforts to increase sales outside of Spain through additional registration, marketing, and supply agreements. We will also continue to make significant investments in renovating and increasing capacity in manufacturing facilities and investments in new high speed, high volume equipment.

Branded Pharmaceutical Products

(in thousands)

	2005	%	2004	%	Change $	Change %
Branded Product Sales:						
Enalapril	$ 4,153	18%	$ 3,192	17%	$ 961	30%
Codesian	3,441	16%	3,131	17%	310	10%
Omeprazole	2,779	12%	2,721	15%	58	2%
Simvastatin	1,666	7%	1,392	8%	274	20%
Lansoprazole	1,856	8%	31	0%	1,825	*
All other branded products	8,706	39%	7,924	43%	782	10%
Total branded sales	$ 22,601	100%	$ 18,391	100%	$ 4,210	23%

** Not meaningful*

Sales of our branded pharmaceutical products accounted for 23% of total revenues during 2005 and increased 23%, or approximately $4,210,000 over branded sales in 2004. Enalapril, Codeisan and omeprazole remain our top-selling branded products and accounted for approximately 46% of branded sales in 2005. In addition to our focus on marketing existing products, we continue to develop and market new branded products. Sales of lansoprazole, a branded pharmaceutical that launched in December 2004, increased to $1,856,000 in 2005 compared to approximately $31,000 in 2004. Fluctuations in the weighted average value of the Euro, in relation to the U.S. Dollar had a significant impact on branded sales during the interim periods of 2005, but did not have a material impact on branded sales for the full year.

Generic Pharmaceutical Products

(in thousands)

	2005	%	2004	%	Change $	Change %
Generic Product Sales:						
Omeprazole	$ 15,394	44%	$ 13,520	47%	$ 1,874	14%
Simvastatin	5,080	14%	3,638	12%	1,442	40%
Paroxetine	3,118	9%	2,928	10%	190	6%
Pentoxifylline	2,540	7%	2,622	9%	(82)	-3%
Trimetazidine	2,214	6%	1,983	7%	231	12%
All other generic products	6,764	20%	4,328	15%	2,436	56%
Total generic sales	$ 35,110	100%	$ 29,019	100%	$ 6,091	21%

Sales of our generic pharmaceutical products accounted for 36% of total revenues during 2005 and increased 21%, or approximately $6,091,000 over generic sales in 2004. Omeprazole, simvastatin and paroxetine remain our top-selling generic products and accounted for 58% of the generic pharmaceutical product growth. Additionally, sales of our generic formulations of ibuprofen, enalapril, lansoprazole, and mirtazapine

(included in *All other generic products* above) accounted for approximately 26% of the growth in generic pharmaceutical product sales. Fluctuations in the weighted average value of the Euro, in relation to the U.S. Dollar had a significant impact on branded sales during the interim periods of 2005, but did not have a material impact on branded sales for the full year.

Sales to Licensees and Others

(in thousands)

	2005	2004	Change $	Change %
Sales to licensees and others	*$ 31,814*	*$ 20,790*	*$ 11,024*	*53%*

In addition to manufacturing and selling our own branded and generic products, we license the right to market products to others within and outside of Spain. These license agreements are usually accompanied by long-term exclusive supply agreements, whereby our licensees purchase the licensed products from our manufacturing company. As of December 31, 2005, our Spanish operations have executed 142 license agreements for product registrations, of which 17 with customers in Spain and 64 with customers outside of Spain, cover actively marketed products that are generating revenues. The remaining licenses, two with customers in Spain and 59 with customers outside of Spain, are for products that are awaiting regulatory approvals. Additionally, we have 16 contract manufacturing agreements in effect in Spain and 6 contract manufacturing agreements in effect for international customers. Our clients market these products under their own name and with their own labeling. Many of the products we manufacture for others use the same active ingredients that are used in our own marketed products. Sales under these agreements increased by 53% over the prior year, 54% in constant currency. An increase in the weighted average value of the Euro, in relation to the U.S. Dollar, had the effect of decreasing our revenues from sales to licensees and others by approximately $223,000, or less than 1.0%.

Licensing and Collaboration Revenues. Licensing and collaboration revenues now account for approximately 7% of total revenues and increased by approximately $2,971,000, or approximately 86%, in 2005. These revenues include royalties totaling $6,132,000 from the commercialization and continued sales of Testim, the first product incorporating our CPE-215 drug delivery technology, which was launched by our licensee, Auxilium, in February 2003. Testim is currently reported to have captured approximately 15% of all new testosterone replacement prescriptions in the market. *Licensing and collaboration revenues* in 2005 includes a change in our estimate of royalty revenues earned on Testim sales of approximately $1,092,000, which was recorded in the fourth quarter of 2005. This change in our estimate of royalty revenues earned is based upon publicly available data determined to be more accurate than the source of data previously relied upon by management in recording estimated royalty revenues on Testim sales. Also included in *licensing and collaboration revenues* in 2005 are revenues of approximately $274,000 related to product licensing activities in Europe.

Gross Profit. Gross profit increased by approximately $13,069,000, or 34%, in 2005, when compared to 2004. Gross margins on net product sales decreased from 50% in 2004 to 49% in 2005, primarily due to a Spanish pharmaceutical tax of approximately $1,555,000 charged to cost of sales.

Selling and Marketing Expenses

(in thousands)

	2005	2004	Change $	Change %
Selling and marketing	*$ 16,347*	*$ 14,808*	*$ 1,539*	*10%*

Selling and marketing expenses increased by approximately $1,539,000, or 10%, compared to last year. We realized an increase of $21,366,000 in net product sales in 2005 compared to 2004, or 31%, partially through the efficient use of our selling and marketing resources. Selling and marketing expenses decreased as a percentage of net product sales to 18% in 2005, compared to 21% in 2004.

General and Administrative Expenses

(in thousands)

	2005	2004	Change $	Change %
General and administrative	*$ 11,998*	*$ 9,126*	*$ 2,872*	*31%*

General and administrative expenses for 2005 increased 31% over the prior year. The $2,872,000 increase was the result of increased general and administrative activities required to support our continuing growth and prepare for our anticipated growth in the future. These expenditures include increased costs in the current year for additional employees, outside services, insurance and other costs to support the growth of our organization and costs associated with our response to the requirements of the Sarbanes-Oxley Act of 2002. General and administrative expenses as a percent of total revenues were 12% in 2005, which is consistent with 2004.

Research and Development Expenses

(in thousands)

	2005	2004	Change $	Change %
Research and development	*$ 5,800*	*$ 4,419*	*$ 1,381*	*31%*

Research and development expenses for 2005 increased approximately 31% compared to 2004. The increase is directly attributable to the advancement of our research and development programs.

In the first quarter of 2004, we completed and reported the results of a Phase I intranasal insulin trial, which incorporates our CPE-215 technology. Our Phase I trial demonstrated the effective delivery of insulin intranasally in healthy human subjects. In April 2005 we announced that we completed the data analysis stage of our Phase II study for the intranasal delivery of insulin, which we had concluded in December 2004. We reported the results of that trial in an abstract titled Intranasal Insulin Administration in Type I Diabetic Patients Utilizing CPE-215 Technology at the American Diabetes Association 65th Scientific Sessions, June 10-14, 2005, in San Diego, California. Additionally, we are continuing our clinical programs to support our strategy for the eventual distribution of certain of our Spanish generic pharmaceutical products in other countries, including the U.S. through our collaboration agreement with Perrigo Company to co-develop and market a generic pharmaceutical product in the U.S. and potentially other markets. We expect to continue to incur increased costs to conduct clinical trials and support the required regulatory submissions for our clinical programs. We expect to incur increased costs for product formulation and testing efforts. We also expect to incur costs associated with the acquisition and/or development of new or improved drug delivery technologies such as our May 2, 2005 announcement of the discovery and synthesis of a thermodynamically stable, biodegradable Nanocaplet technology

for the delivery of macromolecule therapeutics. 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 plan to increase our 2006 investments in research and development by 50% or more to help us build on the clinical progress of CPE-215 and advance the early-stage research on our Nanocaplet technology.

Other Income (Expenses)

(in thousands)

	2005	2004	Change $	Change %
Other income (expenses)	*$ 729*	*$ 1,800*	*$ (1,071)*	*-60%*

Other income (expenses) in 2005 decreased by $1,071,000 compared to 2004. The other income reported in 2004 included the reversal of previously accrued tax assessments totaling $1,467,000, partially offset by interest and penalties totaling $193,000 associated with the settlement of the tax audit of our Spanish subsidiary. Other income (expenses) in 2005 included interest income of approximately $928,000 compared to approximately $548,000 in 2004, which increase was due to rising interest rates.

Provision for Income Taxes

(in thousands)

	Europe	2005 U.S.	Consolidated
Income before income taxes	*$ 15,353*	*$ 1,042*	*$ 16,395*
Provision for income taxes	*5,216*	*198*	*5,414*
Valuation allowance	*260*	*(198)*	*62*
Net provision for income taxes	*5,476*		*5,476*
Net income	*$ 9,877*	*$ 1,042*	*$ 10,919*
Effective tax rate	*36%*	*0%*	*33%*

We have recorded provisions for foreign income taxes totaling $5,476,000 and $4,805,000 ($4,201,000 plus a $604,000 tax audit settlement recorded as a result of the tax audit by Spanish authorities of our Spanish subsidiary for the tax years 1998, 1999 and 2000) for the years ended December 31, 2005 and 2004, respectively.

Effective October 2005, we executed intercompany agreements between Bentley Pharmaceuticals, Inc. and Bentley Pharmaceuticals Ireland Limited to license non-U.S. rights of certain technologies owned by Bentley Pharmaceuticals, Inc. and provide for cost-sharing of subsequent development efforts on those technologies. A net benefit of approximately $2,045,000 has been recorded to the U.S. income from operations (and a corresponding reduction to European income from operations) in 2005 as a result of these agreements.

In 2005, we generated U.S. income before income taxes of approximately $1,042,000, compared to a loss before income taxes of approximately $2,913,000 in 2004. We utilized U.S federal net operating loss carry-forwards in order to offset the resulting income tax liability. As of December 31, 2005, the remaining U.S federal net operating loss carry-forwards were approximately $53,514,000. Bentley Pharmaceuticals Ireland Limited, which is reported in our European operations, generated a net operating loss of approximately $2,080,000 in 2005. As future operating profits cannot be reasonably assured, no

tax benefit has been recorded for these losses. Accordingly, we have established a valuation allowance equal to the full amount of the deferred tax assets in Ireland.

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. No additional potential tax contingencies were considered to be probable and reasonably estimable as of December 31, 2005. However, there is the possibility that the ultimate resolution of such potential contingencies could have an adverse effect on our Consolidated Financial Statements in the future.

Net Income

(in thousands, except per share data)

	2005	2004	Change Amount	Change %
Net income	*$ 10,919*	*$ 5,690*	*$ 5,229*	*92%*
Net income per common share:				
Basic	*$ 0.51*	*$ 0.27*	*$ 0.24*	*89%*
Diluted	*$ 0.48*	*$ 0.25*	*$ 0.23*	*92%*
Weighted average common shares outstanding:				
Basic	*21,558*	*20,901*	*657*	*3%*
Diluted	*22,929*	*22,627*	*302*	*1%*

We reported 2005 income from operations of $15,666,000, compared to 2004 income from operations of $8,695,000. In 2005, the combination of income from operations of $15,666,000 and the non-operating items, primarily the provision for income taxes of $5,476,000, resulted in 2005 net income of $10,919,000, or $.51 per basic common share ($.48 per diluted common share) on 21,558,000 weighted average basic common shares outstanding (22,929,000 weighted average diluted common shares outstanding), compared to 2004 net income of $5,690,000, or $.27 per basic common share ($.25 per diluted common share) on 20,901,000 weighted average basic common shares outstanding (22,627,000 weighted average diluted common shares outstanding).

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

Revenues

(in thousands)

	2004	%	2003	%	Change $	Change %
Revenues:						
Net product sales	$ 69,942	95%	$ 62,955	97%	$ 6,987	11%
Licensing and collaboration revenues	3,451	5%	1,721	3%	1,730	101%
Total revenues	$ 73,393	100%	$ 64,676	100%	$ 8,717	13%

Total revenues for 2004 increased 13% from 2003. However, our total revenues increased approximately 3% when expressed in constant currency. An increase in the weighted average value of the Euro, in relation to the U.S. Dollar, had the effect of increasing revenues by approximately $6,502,000, partially offsetting the impact of price reductions in Spain. Sales of active pharmaceutical ingredients from our new manufacturing facility (included in *All other products* in the table below) added $1,742,000 to our consolidated revenues in 2004. The advancement of our proprietary drug delivery programs in the U.S., evidenced by the growing royalty stream from sales of Testim, and other licensing revenues, increased our 2004 revenues by approximately $1,730,000, when compared to the prior year.

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

For the year ended December 31, 2004:

(in thousands)

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

53

For the year ended December 31, 2003:

(in thousands)

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

Spanish Operations. The core of our Spanish operations has been the efficient manufacturing and domestic marketing of branded and generic pharmaceutical products. The 11% increase in net product sales for the year ended December 31, 2004 over the prior year was primarily due to an increase in the weighted average value of the Euro in relation to the U.S. Dollar, increased sales outside of Spain, increased sales of our paroxetine product line, which was initially launched in May 2003, and increases in sales of other generic products, such as trimetazedine, pentoxifylline and increases in sales to licensees and others. Our paroxetine product line generated net sales of $3,973,000, representing 5% of our total revenues during 2004 and 37% of our total growth in 2004. These increases helped to offset or lessen the impact of price reductions in Spain, which are discussed below. Revenues from our omeprazole products in 2004 declined to 22% of our total revenues, compared to 31% in the prior year, due to reduced selling prices in Spain.

Branded Pharmaceutical Products

(in thousands)

	2004	%	2003	%	Change $	Change %
Branded Product Sales:						
Enalapril	*$ 3,192*	*17%*	*$ 2,610*	*14%*	*$ 582*	*22%*
Codeisan	*3,131*	*17%*	*2,713*	*14%*	*418*	*15%*
Omeprazole	*2,721*	*15%*	*6,099*	*32%*	*(3,378)*	*-55%*
Mio Relax	*1,485*	*8%*	*1,114*	*6%*	*371*	*33%*