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BENTLEY PHARMACEUTICALS



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## BENTLEY PHARMACEUTICALS, INC.



*is a specialty pharmaceutical company  
focused on advanced drug delivery  
technologies and pharmaceutical products.*

*Bentley's proprietary drug delivery  
technologies enhance or facilitate the  
absorption of pharmaceutical compounds  
across various membranes. Bentley also  
manufactures and markets a growing  
portfolio of generic and branded  
pharmaceuticals in Spain for the treatment  
of cardiovascular, gastrointestinal,  
infectious and neurological diseases  
through its subsidiaries Laboratorios  
Belmac and Laboratorios Davur.*

## *Dear Shareholders:*



*2001 was a year of solid accomplishments for Bentley marked by record revenue gains, substantial growth in our European market and continued advances in research and development. Progress made throughout 2001 and thus far in 2002 moves us closer to achieving our goal of becoming a leading worldwide specialty pharmaceutical company. Through our focus on commercialization and product diversification, Bentley is well positioned to continue its growth and enhance shareholder value.*

### **DRUG DELIVERY**

*Our drug delivery and oral drug formulation technologies improve the performance of existing pharmaceutical products by enhancing both delivery and effectiveness. We are focused on marketing our patented CPE-215 permeation enhancement platform technology, which improves the absorption of compounds across various biological membranes.*

*We are gaining interest in our drug delivery technology from the pharmaceutical industry, reflecting the need for improved drug performance. In fact, we entered into a research agreement with Pfizer Inc to formulate Pfizer compounds for enhanced delivery. As part of the agreement, Pfizer will have access to our drug delivery platform through a research license and will provide the funding necessary to conduct the compound enhancements using our patented technologies.*

We achieved a milestone in our licensing agreement with Auxilium by the successful completion of the Phase III clinical evaluation for the application of our CPE-215 technology to a topical gel formulation of testosterone.

The product is designed to treat low testosterone levels in men undergoing andropause, the male version of menopause. As a next step, Auxilium has filed a New Drug Application (NDA) with the FDA for approval to market the hormone replacement treatment in the United States and is in negotiations to market the product in Europe and Japan.

This is the first NDA that includes an application of our proprietary CPE-215 excipient technology. Moreover, if approved by the FDA, we stand to receive revenues based on worldwide sales of the drug, which will be marketed under the name Testim™. The rapidly growing market for male hormone replacement therapy is expected to reach \$2 billion over the next five years. Furthermore, we have initiated other exciting initiatives with Auxilium, including a research agreement for a new non-oral delivery formulation of a narcotic pain management product

and a new topical product for hormone replacement therapy, both in combination

with CPE-215.

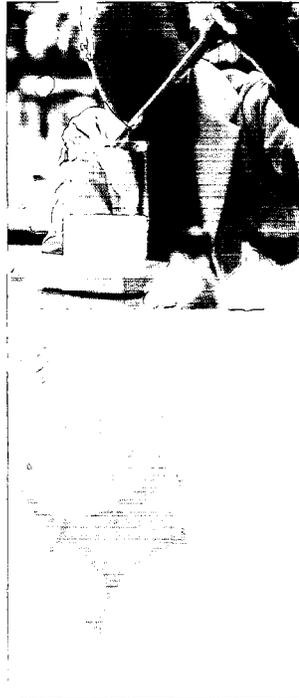
During the third quarter, we completed a clinical evaluation of our patented acetaminophen, which demonstrated that our formulations, in both tablet and sachet forms, achieve maximum blood concentration in approximately half the time as Tylenol® and Panadol®, the leading brands in the United States and Europe, respectively. Extremely encouraged by these successful

results, we decided to run further clinical evaluations in an effort to support the claim that our formulation is more effective than its popular brand named equivalents.

New uses for technology that we discover and develop will provide the foundation for our future growth; accordingly, we have strategically increased our investment in product development programs to ensure further technological



innovations and expansion of our clinical programs toward achieving commercialization. Clinical trials for evaluating our topical nail lacquer for treating nail-fungal infections are on track at the University of Alabama-Birmingham, and we expect to report positive results with respect to the finger-nail study in the very near future. Furthermore, we initiated a clinical study at Dartmouth Medical School for evaluating topical androgen therapy for women suffering from fibromyalgia syndrome, which is providing us with valuable information for the design of more advanced studies.



diseases, positions us to capture an even greater share of the overseas market where

generics continue to increase in popularity over higher priced reference drugs.

During the year, our two Spain-based subsidiaries, Laboratorios Belmac and Laboratorios Davur, were granted approval from the Spanish Ministry of Health to manufacture and market several new generic drugs, including two new dosage levels of enalapril, the generic version of Vasotec®,

#### EUROPEAN MANUFACTURING AND SALES

We are delighted with the performance of our European operations. Our significant commercial presence in Spain continues to grow with the marketing and manufacturing of more than 100 pharmaceutical dosage forms. Our diverse product line, consisting of both generic and branded products within the primary therapeutic areas of cardiovascular, gastrointestinal, infectious and neurological

three new dosage levels of simvastatin, the generic version of Zocor®, and a 10 mg tablet dosage of loratadine, the generic version of Claritin®. Sales generated from these drugs have already started to spark added revenue growth and will drive our momentum in the European market throughout 2002 and beyond.

We also hope to soon reap the benefits of our strategic alliance with Teva Pharmaceutical Industries.

We strategically review our product portfolio and periodically divest certain products to focus on newer generation products. In November 2000, we agreed to sell our registration rights and the related trademark to our branded version of enalapril (Controlvas). We received the balance of the purchase price upon completion of the transaction during the first quarter of 2001; consequently, we recognized a pre-tax gain of approximately \$5.0 million.

During 2001 we agreed to divest several other small products such as Amantadine and Lactiofil in order to concentrate on developing and promoting products that address larger markets.

#### FINANCIAL RESULTS

Our financial results continue to improve. Total revenue for the year increased 42% to

\$26.4 million from \$18.6 million the prior year. Net income for the year, which included pre-tax gains of approximately \$5.0 million on sales of drug licenses, reached \$1.4 million, compared to the prior year loss of \$745,000.



Our advances this year provide a record of solid achievement that we hope will lead to the future growth of Bentley. We expect 2002 and future years to be even better, as exciting new products employing our technologies

are launched and as we build on the revenue base we have established. We thank our employees and customers and especially you, our shareholders, for your continued support.

Very truly yours,

James R. Murphy  
Chairman, President and CEO

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

FORM 10-K\*

FOR ANNUAL AND TRANSITION REPORTS PURSUANT TO SECTIONS 13 OR 15(d) OF  
THE SECURITIES EXCHANGE ACT OF 1934

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT  
OF 1934 for the fiscal year ended December 31, 2001

OR

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

Commission File Number 1-10581

**BENTLEY PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of incorporation or organization)

No. 59-1513162  
(I.R.S. employer identification no.)

65 Lafayette Road, 3<sup>rd</sup> Floor, North Hampton, NH  
(Address of principal executive offices)

03862  
(Zip Code)

Registrant's telephone number, including area code: (603) 964-8006

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

Title of each class	Name of each exchange on which registered
Common Stock, \$.02 par value	American Stock Exchange and Pacific Exchange
Class B Redeemable Warrants	American Stock Exchange

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

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

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

State the aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant. The aggregate market value shall be computed by reference to the price at which the common equity was sold, or the average bid and asked prices of such common equity, as of a specified date within 60 days prior to the date of filing.

Title of Class	Aggregate Market Value	As of Close of Business on
Common Stock, \$.02 par value	\$123,008,607	March 19, 2002

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	14,708,228	March 19, 2002

DOCUMENTS INCORPORATED BY REFERENCE

Proxy Statement for the 2002 Annual Meeting of Stockholders - Incorporated by  
Reference into Part III of this Form 10-K

\*as amended

## Item 1. Business

### Overview

We are a specialty pharmaceutical company focused on advanced drug delivery technologies and pharmaceutical products. We have U.S. and international patent and other proprietary rights to technologies that enhance or facilitate the absorption of drugs across membranes of the skin, mouth, nose, vagina and eye. We are developing products incorporating these technologies and seek to form strategic alliances with major pharmaceutical and biotechnology companies to facilitate the development and commercialization of our products. We currently have strategic alliances regarding our drug delivery technologies with Pfizer Inc and Auxilium Pharmaceuticals, Inc. and are in preliminary discussions with a number of other pharmaceutical companies to form additional alliances.

We have a significant commercial presence in Spain, where we manufacture and market more than 100 pharmaceutical products, representing various dosage strengths and product formulations of more than 30 chemical entities. Our product line consists of generic and branded products within four primary therapeutic areas: cardiovascular, gastrointestinal, infectious and neurological diseases. Additionally, we have a strategic alliance with Teva Pharmaceutical Industries Ltd. granting us the right to register and market in Spain more than 75 of Teva's pharmaceutical products through our sales force of approximately 150 full-time personnel located in major cities throughout Spain.

### Industry Overview

#### *Drug Delivery Industry*

Drug delivery companies develop technologies to improve the administration of therapeutic compounds. These technologies are designed to enhance safety, efficacy, ease-of-use and patient compliance with prescribed therapy. Drug delivery technologies provide opportunities for pharmaceutical and biotechnology companies to extend their drug franchises as well as develop new and innovative products. The worldwide market for drug delivery systems was estimated to be \$35 billion in 2000 and is projected to increase to \$75 billion by 2005.

The vast majority of the drugs currently on the market are taken orally or are administered by injection. Oral drug delivery methods, while simple to use, typically subject drugs to first-pass metabolism in the body, which results in drug degradation in the stomach and further neutralization 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 body, also has major limitations, including pain, which can lead to decreased patient acceptance and compliance with prescribed therapy. A decline in patient compliance can increase the risk of medical complications and lead to higher healthcare costs. Also, the costs of injectable drugs typically are higher as a result of the additional costs associated with medical personnel to administer the injections and the costs associated with the purchase and disposal of syringes.

Pharmaceutical and biotechnology companies look to drug delivery enhancements as a way of gaining a competitive advantage. Alternative drug delivery technologies, which avoid first-pass metabolism and are less invasive, are often sought by pharmaceutical and biotechnology companies to extend the period of market exclusivity for a branded drug and thus postpone competition from generic drugs. 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 ways of delivering existing drugs generally is less risky than attempting to discover new drugs, because of the lower product development cost. On average, it takes 15 years for an experimental new drug to progress from the laboratory to commercialization in the U.S., with an average cost of approximately \$500 million. Typically, only one in 5,000 compounds entering preclinical testing advances into human testing and only one in five tested in humans is approved. 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 carrier technologies deliver the drug without harming the patient or changing the clinical attributes of the drug.

## *Market Overview of Europe and Spain*

The European Union, with an increasingly affluent population of approximately 375 million people, represents the second largest pharmaceutical market in the world with approximately \$75 billion in pharmaceutical sales in 2000, according to IMS Health. Healthcare expenditures in Western Europe, as in the U.S., are growing at a rate faster than the overall economy and drug expenditures as a percentage of total gross domestic product are lower than the 2.3% in the U.S., according to IMS Health.

With Spain's entry into the European Union in 1986, the Spanish pharmaceutical market has been evolving steadily into a market that is increasingly similar to those of other countries in Western Europe and the U.S. With a population of approximately 40 million, Spain was ranked in 1999 as the seventh largest pharmaceutical market in the world. Pharmaceutical sales in Spain reached approximately \$6.6 billion in 1999 and are expected to grow to more than \$10 billion by 2005, according to IMS Health.

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

Although comprising less than three percent of the Spanish pharmaceutical market, generic pharmaceuticals are expected to significantly increase their market penetration due to increases in drug usage driven by an aging population and opportunities to launch new generic products as patents expire for blockbuster drugs. Several initiatives are underway by the Spanish government, including education, financial incentives to prescribing physicians and public campaigns to stimulate the use of generic pharmaceuticals in response to the rise in healthcare costs.

### **Our Strategy**

Our primary objective is to be a leading specialty pharmaceutical company focused on advanced drug delivery and formulation technologies to improve the effectiveness of new and existing pharmaceuticals, while expanding our generic and branded operations in Spain and Europe. Our strategy to accomplish this objective includes the following:

#### *Focus on marketing and commercializing our CPE-215 permeation enhancement platform technology*

Our CPE-215 technology enhances the absorption of drugs across membranes of the skin, mouth, nose, vagina and eye. Our CPE-215 technology can be incorporated into a wide variety of pharmaceutical formats and products, including those formulated as creams, ointments, gels, solutions, lotions, sprays or patches. CPE-215 has a record of safety in humans as a food additive and fragrance. In addition, preclinical testing to date on CPE-215 as a drug delivery enhancement has further indicated its safety. We believe that this past experience with CPE-215 may result in reduced preclinical development time relating to its use in new formulations of previously approved compounds. We market our CPE-215 technology to major pharmaceutical and biotechnology companies whose products we believe would benefit from its permeation enhancement properties.

These benefits include:

- improving efficacy relative to oral administration, which subjects the drug to 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.

We currently have a research licensing agreement with Pfizer and a royalty-based license agreement with Auxilium and are in preliminary discussions with other pharmaceutical companies to commercialize our technologies across a wide range of pharmaceutical applications.

*Develop proprietary products based on our technologies*

We apply our drug delivery and oral drug formulation technologies to improve the performance of existing pharmaceutical products with respect to their method of delivery and effectiveness. We also may be able to reduce manufacturing costs for certain products as a result of our proprietary manufacturing process, which permits improved purity, stability and production yields.

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 inferior drug delivery methods. As an illustration of this strategy, we currently are completing Phase I/II clinical trials for the treatment of nail fungus infections and currently are engaged in preliminary negotiations with several pharmaceutical companies to continue the development of and to commercialize the product.

Also, as part of this strategy, we have developed and filed a patent for improved oral dosage forms of acetaminophen, and improved manufacturing 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 an improved method of manufacture, requiring less time and producing higher purity amid better stability.

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

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

We plan to expand our portfolio of products in Spain through the acquisition of currently marketed and late stage pharmaceutical products, as well as through strategic alliances with other pharmaceutical and biotechnology companies. We intend to directly promote and sell these products in Spain through our own sales force of approximately 150 full-time personnel located in major cities throughout Spain.

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 giving them more products to sell. We believe that we have developed particular expertise in marketing pharmaceutical products to physicians and pharmacies in Spain.

In July 2000, we entered into a strategic alliance with Teva, a world leader in generic pharmaceutical products, pursuant to which we were granted a royalty-free non-exclusive license to register and sell more than 75 finished pharmaceutical products representing more than 25 different chemical entities. Under this license agreement, we will register each product with Spain's Ministry of Health.

## Products in Development

The following are products that we are currently developing. Before they are commercialized, they must be approved by regulatory authorities, such as the FDA or Spanish Ministry of Health, in each jurisdiction where they will be marketed or sold.

<u>Product Candidate</u>	<u>Technology</u>	<u>Used to Treat</u>	<u>Status</u>
Topical testosterone gel	CPE-215	Hypogonadism	New Drug Application
Improved acetaminophen	Solubility Enhancement	Pain relief	Bioequivalence
Antifungal nail lacquer	CPE-215	Onychomycosis	Phase I/II
Androgenic steroid therapy	CPE-215	Chronic Fatigue Syndrome; Fibromyalgia	Pilot study
Intranasal insulin	CPE-215	Diabetes	Preclinical
Intranasal pain management	CPE-215	Pain relief	Preclinical
Topical hormonal therapy	CPE-215	Osteoporosis; Erectile Dysfunction	Preclinical

### *Topical Testosterone Gel*

Testosterone replacement therapy is used to treat men whose bodies produce insufficient amounts of testosterone (Hypogonadism), which can be a natural result of aging. Symptoms associated with low testosterone levels in men include depression, decreased libido, erectile dysfunction, muscular atrophy, loss of energy, mood alterations, increased body fat and reduced bone density. Currently marketed hormone replacement therapies involve delivery of hormones by injections, through transdermal patches and by gels. Injection therapy has major limitations, including pain, which can lead to decreased patient acceptance and compliance with prescribed therapy. Although patches have been able to alleviate many of the gastrointestinal side effects associated with oral delivery of hormones, patches, even in their smallest form, are often conspicuous and typically result in skin irritation or inaccurate dosing should the patch fall off. The transdermal delivery of hormones through gels, creams and lotions provides commercially attractive and efficacious alternatives to current methods of delivery. As more baby-boomers enter middle age and more attention is focused on male hormonal deficiencies, the worldwide testosterone replacement market is expected to reach \$1 billion by 2005.

In May 2000, we entered into a research services agreement with Auxilium to develop and test various pharmaceutical compositions of topical testosterone using our CPE-215 technology. A license of our technology to Auxilium became effective in September 2000. Phase III clinical trials performed by Auxilium for approval in the U.S. have been completed and a New Drug Application was submitted to the FDA in December 2001. Under the license, we granted to Auxilium a sole and exclusive, royalty-based license worldwide to develop, market and sell a topical testosterone product using our CPE-215 technology.

### *Improved Acetaminophen*

We have developed and patented improved oral formulations of acetaminophen, the active ingredient in such products as McNeil Consumer Healthcare's Tylenol® line of products commonly used for controlling pain, fever and inflammation. Our improved oral formulations of acetaminophen make it highly dispersible, rapidly soluble in water, better tasting and faster in reaching peak blood levels. These characteristics give our oral formulations superior properties over other currently marketed products, which do not dissolve easily in water and may cause bitter taste and flatulence. These improvements are particularly useful for treating children, the elderly, and those who have difficulty swallowing pills. Clinical studies in Europe documenting the product's improved dissolution and absorption were completed in 2001. We currently are conducting bioequivalency studies, which compare the rate and extent of absorption and levels of concentration in the blood stream of our improved oral formulations needed to produce a therapeutic effect, with other formulations of acetaminophen that previously have been approved by the FDA. We also are in preliminary discussions with potential collaborators in Europe, Asia and the United States to license and market this product.

### *Antifungal Nail Lacquer*

We have developed a new topical nail lacquer for treating fingernail and toenail fungal infections (Onychomycosis). We believe that our product is an improvement over oral therapies, which can cause liver damage, and other topical treatments that typically have low levels of efficacy. We currently are conducting Phase I/II clinical trials for the treatment of nail fungal infections in the hands and feet at the University of Alabama at Birmingham. According to the National Onychomycosis Society, nail fungus affects almost 30 million people, primarily between the ages of 40 and

65. Patients electing to take oral therapy must undergo blood monitoring during the course of treatment to monitor for liver damage. The cost of oral therapy is in excess of \$500 for a twelve-week treatment regimen, not including physician costs or other periodic monitoring costs.

#### *Androgenic Steroid Therapy*

We are developing a topical therapy utilizing androgenic steroids, which may incorporate our CPE-215 technology, for the treatment of Chronic Fatigue Syndrome and Fibromyalgia. The manifestations of Chronic Fatigue Syndrome are continuous exhaustion, muscle pain, cognitive disorientation and various other physical or psychological symptoms. Chronic Fatigue Syndrome has not received a high degree of publicity since it is often improperly diagnosed and lacks proven therapies. Chronic Fatigue Syndrome is recognized by the National Institutes of Health, the FDA and the Social Security Administration as a serious, disabling affliction. A study by DePaul University estimates that as many as 800,000 people in the U.S. suffer from this condition and that it is approximately three times more common in women than in men.

According to the National Census Bureau and Dartmouth Medical School, Fibromyalgia afflicts six to eight million people. Fibromyalgia primarily affects women between the ages of 40 and 60 with symptoms of muscle pain, fatigue, chronic headache and sleeplessness and has been estimated to strike as many as five percent of peri/postmenopausal women. A preliminary study conducted by Dartmouth scientists indicates that Fibromyalgia patients demonstrated improved muscle function, higher energy levels and restorative sleep in response to androgenic steroid therapy. We have licensed from Dartmouth College their exclusive U.S. patent rights covering the novel use of androgenic steroid therapy for treating Chronic Fatigue Syndrome and Fibromyalgia. In 2001, a pilot study of this therapy was initiated in female volunteers at the Dartmouth Medical Center.

#### *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, we believe our intranasal insulin formulation can achieve higher levels of bioavailability compared to other drug delivery systems currently being developed and of which we are aware. Our product is designed to deliver insulin through a small, discreet metered nasal spray that can be carried in a patient's pocket. We currently are in preclinical development in collaboration with an independent clinical research organization and the University of New Hampshire in preparation for a pilot study.

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

#### *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 a person is taking analgesic medications on a fixed schedule for pain control. A severe flare of pain is called breakthrough pain because the pain breaks through the regular pain medication. About one-half to two-thirds of patients with chronic cancer-related pain also experience episodes of breakthrough cancer pain. Generally, breakthrough pain occurs without prior onset symptoms and may last anywhere from seconds to minutes or hours. The U.S. prescription market for the treatment of moderate to severe pain, including breakthrough pain, is approximately \$2 billion annually.

We are developing an intranasal pain product using our CPE-215 technology with a chemical agent that is widely used for the relief of acute and chronic moderate to severe pain and that commonly is prescribed for pain associated with cancer. Orally delivered pain products may not provide rapid relief and typically demonstrate considerable patient-to-patient variability in absorption. Injectable formulations of pain products provide rapid and effective pain relief, but administration often requires professional assistance or hospitalization. Our intranasal pain product is in preclinical development for the treatment of chronic pain and acute episodes of chronic pain. We believe our intranasal pain product would provide significant medical benefits over oral and injectable formulations as it combines patient convenience and ease of use with the rapid onset of pain relief and the same potency as injectable delivery routes.

We have signed a research agreement with Auxilium pursuant to which we will develop and test the intranasal delivery of a pain management chemical agent using our CPE-215 technology. As part of our strategic alliance with Auxilium, upon Auxilium's acceptance of our preclinical studies, we will grant to them a worldwide license to develop, market and sell the products using our CPE-215 technology.

#### *Topical Hormonal Therapy*

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

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

Our topical hormonal therapy incorporates the use of metabolic steroids that regulate most of the hormonal action in adult males. Hormone replacement therapies using these metabolic steroids, including testosterone and dihydrotestosterone, may have significant benefits in treating a number of medical afflictions in men, including Osteoporosis and sexual dysfunction. We have signed a research agreement with Auxilium pursuant to which we will provide various topical formulations of the hormones incorporating our CPE-215 technology. Auxilium is evaluating our formulations and plans to perform appropriate preclinical studies. As part of our strategic alliance with Auxilium, upon Auxilium's acceptance of preclinical studies, we will grant to them a worldwide license to develop, market and sell topical hormonal therapies containing our CPE-215 technology to treat Osteoporosis in men and Erectile Dysfunction.

#### **Strategic Partners**

##### *Pfizer*

In October 2001, we entered into a research collaboration with Pfizer in which we were granted a non-exclusive worldwide royalty-free license to use Pfizer's compounds and technology to assess the performance of our CPE-215 technology with Pfizer's compounds. As part of the agreement, we granted to Pfizer the non-exclusive right to test the ability of our CPE-215 technology to enhance delivery of certain compounds proprietary to Pfizer. Pfizer is providing the funding necessary to conduct these studies using our CPE-215 technology and has agreed to provide additional funding for costs of further studies that are approved by a joint working committee consisting of designees of Pfizer and us. Pfizer has agreed to inform us if, following completion of the research, it is interested in further development of the formulations. The term of the agreement is the greater of one year or until work under the agreement has been completed. Pfizer would have to enter into a separate license agreement with us with respect to the manufacture, use, sale, offer for sale and import of the products using our CPE-215 technology before it could begin to distribute, market and sell these products.

##### *Auxilium*

In May 2000, we entered into a research agreement with Auxilium to develop and test the application of our CPE-215 technology with respect to the transdermal delivery of testosterone. Auxilium is an emerging therapeutic pharmaceutical company focused on diseases related to aging. In September 2000, a license to Auxilium of our CPE-215 technology became effective for a topical testosterone product. Phase III clinical trials performed by Auxilium for approval in the U.S. have been completed and a New Drug Application has been submitted to the FDA. In May 2001 we entered into research agreements with Auxilium to develop and test our CPE-215 technology with respect to delivery of a pain management compound and a topical hormonal therapy. Preclinical studies currently are underway regarding the application of our CPE-215 technology to a topical hormone therapy.

As part of our collaboration with Auxilium, we also entered into a perpetual license agreement whereby we granted to Auxilium an exclusive royalty-based worldwide license, to develop, market and sell topical testosterone gel containing our CPE-215 technology. This license also provides us with an opportunity to fulfill Auxilium's manufacturing

requirements for the sale of the products in the European market. Under the license agreement we would receive payments based upon Auxilium's completion of certain milestones in an aggregate of \$550,000 plus royalties based on net sales. Upon successful completion of preclinical studies for the intranasal pain management and topical hormone products, similar licenses would become effective.

#### *Teva*

In July 2000, we entered into a strategic alliance with Teva, a world leader in generic pharmaceutical products, in which we were granted a royalty-free non-exclusive license to register and sell more than 75 finished pharmaceutical products representing more than 25 different chemical entities. We are obligated under this license agreement to submit a registration file for each product to the relevant regulatory authorities in Spain in order to receive marketing authorizations in our name for that product. The marketing authorizations provide us with the requisite approvals, licenses and permits from the regulatory authorities to import, distribute, market and sell the products in Spain. In connection with this strategic alliance, Teva also entered into a supply agreement with us pursuant to which it would manufacture the products and supply them to us for marketing and sale in Spain. Our obligation to purchase the products from Teva is non-exclusive, allowing us to purchase any of the products from sources other than Teva if we can show that Teva's prices for the products exceed the current price from other qualified sources and if Teva has not exercised its right to match the lower price. The license agreement and the supply agreement have five year terms and both are renewed automatically for one-year terms for each product.

We have submitted registration applications to the Spanish Ministry of Health for 8 Teva products, none of which applications have been approved as of this date. Under a rights agreement entered into with Teva in July 2000, we granted Teva a right of first refusal to purchase Laboratorios Davur in the event that we decide to sell Laboratorios Davur or Laboratorios Belmac. We also granted Teva the right to bid for Laboratorios Belmac in the event we intend to sell Laboratorios Belmac.

#### *Our Proprietary Drug Technologies*

We believe that there are numerous opportunities to enter into additional collaborations with pharmaceutical and biotechnology companies and expand our product lines using our proprietary drug technologies.

#### *CPE-215 Permeation Enhancement Platform Technology*

Our permeation enhancement technology consists of a series of related chemical compounds that enhance 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 (cyclopentadecanolide). CPE-215, when combined with certain drugs, has been shown to significantly enhance 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 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 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 and eye; and
- well tolerated — no reported cases of irritation or toxicity.

CPE-215 has a long history of safe use in humans as a food additive and fragrance. In addition, our preclinical testing to date on CPE-215 as a drug delivery enhancement has further indicated its safety. We believe that this past experience with CPE-215 may result in reduced preclinical development activities required for new product formulations of previously approved pharmaceutical compounds.

### *Solubility Enhancement Technology*

Our solubility enhancement technology involves patent pending chemical and manufacturing procedures that enhance solubility without changing the compound's therapeutic properties. Although this technology can 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 the year 2001, 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. The use of our technology to increase solubility lessens undesirable side effects, such as flatulence and the bitter taste of pills, which commonly are associated with acetaminophen and many other oral medications.

### *Improved Oral Formulation Technologies*

Our oral formulation technologies involve the application of a new vacuum dry and desiccation manufacturing process as well as specialized equipment, each of which plays a role in producing pharmaceutical products that are more stable and pure, while reducing manufacturing time and costs. We have developed this technology to create new methods for manufacturing products such as omeprazole, lansoprazole and other similar products that are stability sensitive to humidity and temperature. We filed four new patents in 2000 and 2001 relating to these processes and equipment. The patents claim as innovative the manufacturing process that renders these products more stable, while protecting active substances from gastric degradation utilizing microgranulation and microencapsulation techniques. These patent pending technologies can contribute to our ability to compete against other companies whose manufacturing processes are more costly and time consuming.

### *Hydrogel Technology*

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

### **Product Sales and Marketing in Spain**

In Europe, primarily Spain, we manufacture and market more than 100 pharmaceutical products, representing various dosage strengths and product formulations of more than 30 chemical entities. Our product lines consist of generic and branded products within four primary therapeutic categories: cardiovascular, gastrointestinal, infectious and neurological diseases. Our generic and branded products are marketed to physicians and pharmacists by our two separate sales and marketing organizations, Laboratorios Davur and Laboratorios Belmac. To a lesser extent, we also market over-the-counter products through Laboratorios Belmac. There are approximately 90,000 physicians and 20,000 pharmacies in Spain. Revenues from products whose active ingredient is omeprazole accounted for approximately 56% of our net sales in 2001.

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

### *Generic Pharmaceuticals*

Our generic product line consists of 39 pharmaceutical products representing various dosage strengths and product formulations of ten chemical entities. We entered the generic pharmaceutical market in Spain in September 2000. Laboratorios Davur, our generic sales and marketing organization, markets generic pharmaceutical products to physicians and pharmacists through a sales force of approximately 60 full-time sales personnel located in major cities throughout Spain. In 2001, generic pharmaceuticals accounted for approximately 30% of our total product sales. We also supplement our sales and marketing efforts for generic products through advertising in trade publications.

We believe we can grow by providing to our generic products sales force a more extensive line of products to market to physician and pharmacy clients. To strengthen our entry into the generic market, in July 2000, we entered into a strategic alliance with Teva, one of the world's leaders in generic pharmaceuticals. Under this alliance, we have

licensed from Teva the right to register and market in Spain more than 75 of Teva's pharmaceutical products, representing more than 25 different chemical entities. Pursuant to the arrangement, Teva will supply the pharmaceutical products to us and we will register and, upon regulatory approval, market the products in Spain.

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

<u>Our Generic Product Name</u>	<u>Active Ingredient</u>	<u>Sold by Others as</u>	<u>Used to Treat</u>
Amoxicilina Davur	amoxicillin trihydrate	Amoxil® (GlaxoSmithKline)	infections
Ciprofloxacino Davur	ciprofloxacin hydrochloride	Cipro® (Bayer)	microbial infections, including anthrax
Enalapril Davur	enalapril maleate	Vasotec® (Merck)	cardiovascular disease and hypertension
Fluoxetina Davur	fluoxetine hydrochloride	Prozac® (Eli Lilly)	depression
Omeprazol Davur	omeprazole	Prilosec® (AstraZeneca)	gastroesophageal reflux disease
Simvastatina Davur	simvastatin	Zocor® (Merck)	high cholesterol

#### *Branded Pharmaceuticals*

Our branded product line consists of 62 pharmaceutical products representing various dosage strengths and product formulations of 22 chemical entities. Sales of branded pharmaceuticals accounted for 77% of our product sales in 2000 and 47% in 2001. We market our branded and, to a lesser extent, certain of our generic and over-the-counter products through our Laboratorios Belmac subsidiary, which has approximately 90 full-time sales personnel located in major cities throughout Spain. We supplement our sales and marketing efforts for branded products through advertising in trade publications.

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

<u>Our Branded Product Name</u>	<u>Active Ingredient</u>	<u>Sold by Others as</u>	<u>Used to Treat</u>
Amoxicilina Belmac®	amoxicillin trihydrate	Amoxil® (GlaxoSmithKline)	infections
Belmazol®	omeprazole	Prilosec® (AstraZeneca)	gastroesophageal reflux disease
Cimasal D Forte®	calcium carbonate and vitamin D3	Calcite-D® (Riva)	osteoporosis
Codeisan®	codeine	Tricodein® (Solco)	cough and bronchitis
Simvacol®	simvastatin	Zocor® (Merck)	high cholesterol
Enalapril Belmac®	enalapril maleate	Vasotec® (Merck)	cardiovascular disease and hypertension
Mio Relax®	carisoprodol	Soma® (MedPointe)	muscle spasms
Pentoxifilina®	pentoxifylline	Trental® (Aventis)	peripheral vascular ischemia
Senioral™	oxymetazoline and chlorpheniramine	Denoral® (Aventis)	cold and sinus congestion

#### *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. We also have three U.S. and four foreign patents pending regarding our CPE-215 technology. The patents for our CPE-215 technology expire in the U.S. in 2008 and in foreign countries between 2006 and 2014. We have one international patent application and one foreign patent application pending regarding our antifungal nail lacquer product. We also have two issued U.S. patents regarding our hydrogel technology that expire in 2008. In addition, we have one U.S. patent pending for an insulin composition. We licensed from Dartmouth College the exclusive rights to a patent covering the novel use of androgen therapy for treating Fibromyalgia and Chronic Fatigue Syndrome. In 2000 and 2001, we filed four new patents in Europe for improved oral formulations of pharmaceutical products, including omeprazole and lansoprazole.

We own approximately 50 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.

### **Research and Development**

Our research and product development efforts are focused on developing new product applications of our drug delivery and drug formulation technologies. We currently have ten scientists and technicians working on research and product development. For the years ended December 31, 1999, 2000 and 2001, our research and product development expenditures were \$685,000, \$1,102,000 and \$2,084,000, respectively.

### **Manufacturing**

Our 64,000 square-foot manufacturing facility is located in Zaragoza, Spain. Our manufacturing facility complies with European Good Manufacturing Practices and is capable of producing tablets, capsules, suppositories, creams, ointments, lotions, liquids and sachets, as well as microgranulated and microencapsulated products. The facility also includes analytical chemistry, quality control, quality assurance and formulation research laboratories.

Since we currently utilize less than 100% of our existing capacity to manufacture our own products, we have engaged in contract manufacturing of pharmaceuticals owned by other companies such as Antibioticos S.A., Laboratorios Cantabria S.A., and Shire Iberica S.A. We believe contract manufacturing provides a stable, recurring source of cash flow, a means of absorbing overhead costs, and experience in manufacturing a broad line of formulations that is advantageous to us in pursuing and integrating acquired products. Although the volume of our contract manufacturing continues to increase, contract manufacturing as a percentage of consolidated net sales declined from approximately 50% in 1994 to approximately 18% in 2001. We attribute this decline to the growth in sales of our own branded and generic pharmaceutical products over the period. We expect that contract manufacturing activities as a percentage of our overall sales will continue to decrease in the future.

We have fully integrated manufacturing support systems including quality assurance, quality control, regulatory compliance and inventory control. These support systems enable us to maintain high standards of quality for our products and deliver reliable products and services to our customers on a timely basis. We require a supply of quality raw materials and packaging materials to manufacture and package drug products. Historically we have not had difficulty obtaining raw materials and packaging materials from suppliers. Currently, we rely on approximately 70 suppliers to deliver our required raw materials and packaging materials. We have no reason to believe that we will be unable to procure adequate supplies of raw materials and packaging materials on a timely basis. Union Quimico Farmaceutica, S.A. is our sole supplier of omeprazole. Revenues from products whose active ingredient is omeprazole accounted for approximately 56% of our net sales in 2001. We believe that alternative sources of omeprazole are available and we will obtain required governmental approval to source from them, if necessary.

### **Competition**

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

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

## Customers

In Spain, our sales representatives from Laboratorios Belmac and Laboratorios Davur 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. The wholesale distributor network for pharmaceutical products in Europe and more specifically in Spain, in recent years has been subject to increasing consolidation, which has increased and we expect will continue to increase our, and other industry participants', customer concentration.

In 2001 and 2000, Cofares was our only customer accounting for more than ten percent of our consolidated net sales of approximately 15% and 14%, respectively. In 1999, Cofares and Antibioticos Farma, each of whose purchases accounted for approximately 13% of consolidated net sales, were the only customers which accounted for more than ten percent of consolidated net sales.

## Regulation

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

### *United States*

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

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

- Phase I — involves the initial introduction of the pharmaceutical into healthy human volunteers, the emphasis is on testing for safety (adverse effects), dosage tolerance, metabolism, excretion and clinical pharmacology.
- Phase II — involves studies in a limited patient population to determine the efficacy of the pharmaceutical for specific targeted indications, to determine dosage tolerance and optimal dosage and to identify possible adverse side effects and safety risks.
- Phase III — involves trials undertaken to evaluate clinical efficacy once a compound is found to be effective and to have an acceptable safety profile in Phase II evaluations, and to further test for safety within an expanded patient population at multiple clinical study sites.

The FDA reviews both the clinical plans and the trial results and may discontinue the trials at any time if there are significant safety issues. The results of preclinical and clinical trials are submitted to the FDA in the form of a New Drug Application for marketing approval. The approval process is affected by a number of factors, including the severity of the disease, the availability of alternative treatments and the risks and benefits demonstrated in clinical trials. Additional animal studies or clinical trials may be requested during the FDA review process and may delay marketing approval. After FDA approval for the initial indications, further clinical trials would be necessary to gain approval for the use of the product for any additional indications. The FDA may also require post-marketing testing to monitor for adverse effects, which can involve significant expense. Our products under development and future products to be developed must go through the approval process delineated above prior to gaining approval by the FDA for commercialization.

FDA approval is required for the marketing of generic equivalents or new dosage forms of an existing drug. An Abbreviated New Drug Application is required to be submitted to the FDA for approval. When processing an ANDA, the FDA waives the requirement of conducting complete clinical studies, although it normally requires bioavailability and/or bioequivalence studies. Bioavailability indicates the rate and extent of absorption and levels of concentration of a drug product in the blood stream. Bioequivalence compares the bioavailability of one drug product with another, and when established, indicates that the rate of absorption and levels of concentration of a generic drug in the body closely approximate those of the previously approved drug. An ANDA may be submitted for a drug on the basis that it is the equivalent to a previously approved drug.

In addition to obtaining FDA approval for each product, each manufacturer of drugs must be registered with the FDA. Domestic manufacturing establishments are subject to biennial inspections by the FDA and must comply with current Good Manufacturing Practices for drugs. To supply products for use in the U.S., foreign manufacturing establishments must comply with GMPs and are subject to periodic inspection by the FDA or by regulatory authorities in such countries under reciprocal agreements with the FDA.

#### *Spain and Europe*

As a pharmaceutical manufacturer in Spain, which is a member of the European Union, we are subject to the regulations enacted by the European Union. Prior to Spain's entry into the European Union in 1986, the pharmaceutical regulations in Spain were less stringent. Since that time, we, along with all Spanish pharmaceutical companies, must obtain manufacturing, marketing and pricing authorizations to commercialize pharmaceutical products in Spain. Pharmaceutical manufacturers in Spain must obtain from the Spanish Ministry of Health a general permit to operate a pharmaceutical business certifying that its facilities comply with European Good Manufacturing Practices. For marketing authorization of new products, the development process in Spain is comprised of three clinical phases for branded drugs and bioequivalent studies for generic drugs as in the U.S. to assure their safety and efficacy. A dossier must be prepared on each pharmaceutical product and, upon approval of the product by the Spanish Ministry of Health, it may be marketed in Spain. Finally, the Spanish Ministry of Health sets maximum prices and reimbursement rates for our products.

#### *Trends in Healthcare Regulation*

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

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

Many countries, directly or indirectly through reimbursement limitations, control the selling price of certain healthcare products. In addition, the prices for all prescription products in Spain are determined by the Spanish Ministry of Health. 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.

#### *Other Regulations*

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

#### **Employees**

We employ approximately 271 people, nine of whom are employed in the U.S. and 262 in Spain, as of February 28, 2002. Approximately 75 of these employees principally are engaged in manufacturing activities, 153 in sales and marketing, ten in product development and 33 in management and administration. In general, we consider our relations with our employees to be good.

## RISK FACTORS

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

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

Bentley's growth depends on the identification of pharmaceutical products that are suitable for delivery using our technologies. Our principal drug technology is our CPE-215 permeation enhancement platform technology. This technology, like other drug delivery enhancement technologies, operates to enhance the amount and rate of absorption of certain drugs across biological membranes. This technology does not operate independently and must be coupled with suitable pharmaceutical products in order to provide value. Consequently, our growth will depend to a great extent on identifying and commercializing these suitable drugs with respect to which we intend to expend significant resources and efforts. Identifying suitable products is a lengthy and complex process that may not succeed. Even if identified, products may not be available to us or we may otherwise be unable to enter into licenses or other agreements for their use. In our efforts to identify suitable products, we compete with other pharmaceutical delivery companies with greater research and development, financial, marketing and sales resources. If we do not effectively identify drugs to be used with our technologies, improve the delivery of drugs with our technologies and bring the improved drugs to commercial success, then we will 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. Although we already manufacture and market generic and branded drugs in Spain, the growth of these operations in particular and Bentley in general will depend to a great extent on identifying and commercializing additional such drugs for which we have existing capacity and infrastructure and, to a lesser extent, on increasing sales of existing products. Identifying and pursuing these new opportunities involves significant time and expense and we may not succeed. Even if identified, these products and technologies may not be commercially successful. Once identified, products to be manufactured and/or marketed by us under generic or branded names are subject to successful negotiation of acceptable economic and legal terms, and successful progress of the product through commercialization, as to which we cannot assure you. In these efforts, we compete with other pharmaceutical companies having generic and branded drug operations with greater financial, marketing and sales resources. If we do not effectively identify generic and branded drug products and technologies and bring them to commercial success, then we will not be able to continue our growth and we will be adversely affected.

The growth of our generic and branded operations may be adversely impacted by claims by others that our products infringe on the proprietary rights of their existing "brand-name" products. For example, in February 2002 we were notified that a legal proceeding seeking an injunction had been commenced in Madrid against us by Merck & Co. Inc. and its Spanish subsidiary alleging that we violated their patents in our production of the product simvastatin. Although the court in the same month dismissed the action, which could be brought in another proceeding, we cannot assure you that similar actions will not be brought nor that they will not have an adverse effect on us.

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

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

- any or all of the proposed products will be found to be ineffective;
- the proposed products will have adverse side effects or will otherwise fail to receive necessary regulatory clearances;

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

**We will rely on strategic partners to commercialize products that use our drug delivery technologies.**

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

We must enter into agreements with strategic partners to conduct clinical trials, manufacturing, marketing and sales necessary to commercialize product candidates. In addition, our ability to apply our drug delivery technologies to any proprietary drugs will depend on our ability to establish and maintain strategic partnerships or other collaborative arrangements with the holders of proprietary rights to such drugs. Arrangements with strategic partners may be established through a single comprehensive agreement or may evolve over time through a series of discrete agreements, such as letters of intent, research agreements and license agreements. We cannot assure you that we will be able to establish such strategic partnerships or collaborative arrangements on favorable terms or at all or that any agreement entered into with a strategic partner will lead to further agreements or ultimately result in commercialization of a product.

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

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

Revenues from products whose active ingredient is omeprazole accounted for approximately 56% of our net sales in 2001. We currently purchase omeprazole from a single supplier. If we lose and cannot effectively replace this supplier or are otherwise unable to continue the sales of products that contain this active ingredient, our revenues would decline significantly.

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

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

- slow or insufficient patient enrollment;
- slow recruitment and completion of necessary institutional approvals at clinical sites;
- longer treatment time required to demonstrate efficacy;
- lack of sufficient supplies of the product candidate;
- adverse medical reactions or side effects in treated patients;

- lack of effectiveness of the product candidate being tested;
- regulatory requests for additional clinical trials; and
- instability of the pharmaceutical formulations.

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

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

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

As an example of the risk of infringement claims, in February 2002 we were notified that a legal proceeding seeking an injunction had been commenced in Madrid against us by Merck & Co. Inc. and its Spanish subsidiary alleging that we violated their patents in our production of the product simvastatin. Although the court in the same month dismissed the action, which could be brought in another proceeding, we cannot assure you that similar such actions will not be brought nor that they will not have an adverse effect on us.

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

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

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

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

We cannot assure you that products that have obtained marketing approval in Spain will be approved for marketing elsewhere. If we are unable to obtain marketing approval for our products in countries other than Spain, we may not be able to obtain additional revenues from sales in those countries. If we are unable to obtain these marketing approvals, we would have to seek to enter into collaborative arrangements to sell or license our products to strategic partners that have marketing approval in those countries. We can not assure you that we would find or enter into acceptable arrangements with such strategic partners to market our products, nor can we assure you that any such arrangements would be successful.

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

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

**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.**

In the year ended December 31, 2001, substantially all of our revenues were derived from sales made by our Spanish subsidiaries in Spain and a small portion of those revenues (one to two percent) were derived from sales made by the subsidiaries to customers in other foreign countries. We believe that a significant portion of our revenues will continue to be derived from sales in foreign countries. Conducting business internationally subjects us to a number of risks and uncertainties, including:

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

**Currency fluctuations and the transition to the Euro could have a material adverse impact on our business.**

Our revenues may be impacted by fluctuations in local currencies due to the fact that substantially all of our revenues currently are generated by sales in Spain by our Spanish subsidiaries, Laboratorios Belmac S.A. and Laboratorios Davur S.L. Our Spanish subsidiaries reported an increase in net sales of 50% in local currency for the year ended December 31, 2001 compared to the prior year; this increase, however, was partially offset by a decline in the value

of the Spanish Peseta, when expressed in U.S. Dollars. We do not currently engage in foreign exchange hedging transactions to manage our foreign currency exposure. Our foreign operations expose us to a number of currency related risks, including the following:

- fluctuations in currency exchange rates;
- limitations on the conversion of foreign currency;
- fluctuations of the carrying value of long lived assets; and
- limitations on the remittance of dividends by foreign subsidiaries.

On January 1, 2002, European Union countries, which includes Spain, began operating with the Euro as their single currency. Uncertainty exists as to the effect the Euro will have on the marketplace. The currency conversion to the Euro exposes us to certain risks, including the following:

- the creation of suitable clearing and settlement payment schemes for the Euro;
- the legal treatment of outstanding financial contracts after the conversion date that refer to currencies other than the Euro; and
- whether the interest rate, tax and labor regimes of the European countries participating in the Euro will successfully converge over time, if at all.

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

Our success depends, in part, on achieving and maintaining a competitive position in the development of products and technologies in a rapidly evolving industry. If we cannot maintain competitive products and technologies, our current and potential strategic partners may choose to adopt the drug delivery technologies of our competitors. We also compete generally with other drug delivery, biotechnology and pharmaceutical companies engaged in the development of alternative drug delivery technologies or new drug research and testing. Many of these competitors have substantially greater financial, technological, manufacturing, marketing, managerial and research and development resources and experience than we do and represent significant competition for us. Our competitors may succeed in developing competing technologies or obtaining governmental approval for products before we achieve success, if at all. The products of our competitors may gain market acceptance more rapidly than our products. Developments by competitors may render our existing or proposed products noncompetitive or obsolete.

Our competitive positions in our generic and branded drug operations as well as with our drug delivery enhancement 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 in the bloodstream of our generic products are not statistically different from other pharmaceutical equivalents that have previously been approved by the regulatory authorities of the respective country, when administered at the same dosage level under similar clinical conditions.

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

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

Our revenues increased 42% and our research and development expenditures increased 89% from the year ended December 31, 2000 to the year ended December 31, 2001, challenging our management, administrative, financial, marketing, operational and research and development resources. In addition, we routinely consider acquisition and investment opportunities, although we have no current agreements or commitments with respect to any acquisitions or investments. Any future acquisitions or investments would further challenge our resources. If we do not properly meet the increasing expenses and demands on our resources from future growth, we will be adversely affected. To properly manage our growth, we must, among other things, implement additional and improve existing administrative, financial, marketing, operational and research and development systems, procedures and controls on a timely basis. We may also need to expand our staff in these and other areas. We may not be able to complete the improvements

to our systems, procedures and controls necessary to support our future operations in a timely manner. We may not be able to hire, train, integrate, retain, motivate and manage required personnel, successfully integrate acquisitions or investments, nor successfully identify, manage and pursue existing and potential market opportunities. If we fail to generate additional revenue in excess of increased operating expenses in any fiscal period, we may incur losses, or our losses may increase in that period.

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

Our revenues and profitability may be adversely affected by the continuing efforts of governmental and third party payors to contain or reduce the costs of healthcare. A substantial portion of our operations consists of marketing and manufacturing, primarily in Spain, generic and branded pharmaceutical products. The use of generic drugs is regulated in Spain, the U.S. and many other countries, subject to many changing and competing public policy considerations. In addition, in certain markets, such as Spain, pricing or profitability of prescription pharmaceuticals is subject to government control. Some governmental agencies, including those in Spain, can, due to insufficient supply, compel companies to continue to produce products that are not profitable for the company. In the U.S., there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar government controls.

Successful commercialization of many of our products, including those using our permeation enhancement 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.

We anticipate that there will continue to be a number of proposals in the U.S. to implement government control over the pricing or profitability of prescription pharmaceuticals, as is currently 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 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. As examples of pending legislative proposals that may adversely affect us, groups in Spain have urged the Spanish Parliament to consider proposals that would revise the pharmaceutical laws in response to social policy. One would change the pricing and availability of drugs in Spain and the other would conform Spanish drug exportation to international standards for certain purposes. We cannot assure you whether these proposals or others may be enacted in some form, if at all, or the impact they may have if enacted.

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

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

In addition to development and other costs, we expect to incur capital expenditures from time to time. These capital expenditures will be influenced by our regulatory compliance efforts, our success, if any, at developing collaborative arrangements with strategic partners, our needs for additional facilities and capital equipment and the growth, if any, of our business in general. We cannot assure you that we will receive additional funding on favorable terms if at all, or that we will be successful in attracting strategic partners. If we cannot raise funds or engage strategic partners on acceptable terms when needed, we may not be able to continue our research and development activities, develop or enhance our products and services, take advantage of future opportunities, grow our business or respond to competitive pressures or unanticipated requirements.

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

We have assigned many key responsibilities within our company to, and are dependent on, a relatively small number of individuals. If we lose the services of our Chief Executive Officer, Chief Science Officer or Vice President of Pharmaceutical Development, our ability to execute our business plan in the manner we currently anticipate would be adversely affected. The competition for qualified personnel is intense and the loss of key personnel could adversely affect our business. We maintain key person life insurance only for our Chief Executive Officer. We have an employment agreement with each of our executive officers.

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

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

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could inhibit or prevent the commercialization of pharmaceutical products we develop alone or with corporate collaborators. We maintain product liability insurance in the amount of \$3 million Euros (approximately \$2.6 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.

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, 2001, we had the following capital structure:

Common stock outstanding	14,585,200
Common stock issuable upon:	
Exercise of Class B Warrants	3,003,560
Exercise of other warrants	420,000
Exercise of options which are outstanding	2,937,256
Exercise of options which have not been granted	<u>1,006,000</u>
Total common stock outstanding assuming exercise of all of the above	<u>21,952,016</u>

As of December 31, 2001, we had outstanding options and warrants to purchase approximately 6,360,816 shares of common stock at exercise prices ranging from \$1.50 to \$45.00 (exercisable at a weighted average of \$4.83 per share), of which approximately 5,740,716 options and warrants were then exercisable. Since December 31, 2001 we have granted options to purchase 477,500 shares of common stock, exercisable at a weighted average of \$9.76 per share. In addition, we may conduct future offerings of our common stock or other securities with rights to convert the

securities into shares of our common stock. Exercise of our outstanding options and warrants into our common stock may significantly and negatively affect the market price for our common stock as well as decrease your percentage ownership and voting power.

**Our stock is volatile.**

The market prices for our securities and for securities of emerging growth companies have historically been highly volatile. During the last two years, the price of our common stock has ranged from a high of \$11.57 to a low of \$3.56. 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;
- competitive products;
- financings;
- sales or the possibility of sales of our common stock;
- our results of operations and financial condition;
- proprietary rights;
- public concern as to the safety or commercial value of our products; and
- general economic conditions.

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

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

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

Our certificate of incorporation and bylaws include provisions that also may have the effect of discouraging, delaying or preventing a change in control or an unsolicited acquisition proposal that a stockholder might consider favorable. Our board of directors is divided into three classes with staggered three-year terms, which makes it more difficult for an acquiror to change the overall composition of the board in a short period of time. The positive vote of at least two-thirds is required to approve a merger, a sale or lease of all or most of our assets, certain other business combinations or dissolution or liquidation, and an affirmative vote of two-thirds is required to amend any provision in our certificate of incorporation relating to our directors and officers or to amend any provision in our certificate of incorporation. Additionally, our certificate of incorporation authorizes our board of directors to issue preferred stock in one or more series with the rights, obligations and preferences of each series to be determined by our board without stockholder approval. Our staggered board, the super-majority voting provisions and the potential issuance of preferred stock may have the effect of delaying or preventing or discouraging third parties or stockholders from attempting to replace our management.

To the same potential effect, we have a stockholder rights plan designed to prevent a potential acquirer from gaining control of us and to protect us from coercive takeover attempts. The rights will become exercisable only if any person or group of affiliated persons beneficially acquires 15% or more of our common stock. Under certain circumstances, each holder of a right (other than the person or group who acquired 15% or more of our common stock) is entitled to purchase a defined number of shares of our common stock at 50% of its market price at the time that the right becomes exercisable.

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

### Item 2. Properties

We lease a 3,200 square foot facility in North Hampton, New Hampshire, which houses our corporate headquarters and research and development laboratory. We are located approximately 45 minutes north of Boston, Massachusetts. The lease for this facility expires in March 2004.

We own a 64,000 square foot facility in Zaragoza, Spain, which accommodates our manufacturing plant, warehouse, research and development laboratory and office space. The facility is located in an industrial park and is situated on sufficient acreage to accommodate future expansion.

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

### Item 3. Legal Proceedings

We were awarded a judgment of approximately \$2,130,000 in the Circuit Court of the Thirteenth Judicial Circuit, State of Florida, Hillsborough County Civil Division during the year ended December 31, 1998, relating to our claims of civil theft and breach of employment agreement filed against our former President and Chief Executive Officer, Michael M. Harshbarger. The judgment included treble damages totaling \$418,000 related to our civil theft claim and \$1,712,000 related to our breach of employment agreement claim. Harshbarger originally filed suit against us in November 1993, alleging wrongful termination, seeking monetary damages in excess of \$1,400,000. In addition to establishing a receivable on our books, we have established a reserve equal to the receivable, as we are of the opinion that Harshbarger does not have the financial resources to satisfy the judgment. Harshbarger filed a Motion for Relief From Judgment in September 1999, alleging among other things that he was not provided notice of the August 24, 1998 jury trial. A hearing was held on November 27, 2001 to determine the merits of Harshbarger's claims. The judge determined that the facts of the case did not warrant setting aside the default and judgment against Harshbarger and denied all of Harshbarger's motions. Harshbarger did not file a notice of appeal within the requisite time period, therefore, we consider that this matter has been concluded and expect no further action other than any action we may take to enforce our judgment.

On January 22, 2001, we settled a legal dispute, by paying \$140,000 to Creative Technologies, Inc. and Creative Technologies, Inc. agreed to the dismissal of the related suit with prejudice. Creative Technologies had asserted that it was due a brokerage or finder's fee with respect to our 1999 acquisition of permeation enhancement technology. We included the accrual for the \$140,000 charge in our Consolidated Balance Sheet as of December 31, 2000 and included the \$140,000 charge and related legal costs of approximately \$55,000 in operating expenses in our Consolidated Statement of Operations for the year ended December 31, 2000.

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 violate their patents in our production of the product simvastatin and requesting an injunction ordering us not to manufacture or market the product. The case was brought against our Spanish subsidiaries in the 39th First Instance Court of the City of Madrid. After a hearing on February 18, 2002, the court refused to grant the requested injunction and dismissed the case on February

25, 2002, awarding us court and legal fees. Merck has appealed the award of fees. Under Spanish law, Merck can reinstitute its claim against us in another proceeding. There were no sales of simvastatin in 2001, as the product was launched in late January 2002.

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

Not applicable.

**Part II**

**Item 5. Market for Registrant's Common Equity and Related Stockholder Matters**

The following table sets forth, for the periods indicated, the range of quarterly high and low sales prices for our common stock as reported on the American Stock Exchange under the symbol "BNT." Our common stock began trading on the American Stock Exchange on July 31, 1990 and on the Pacific Exchange on March 27, 1996.

	<u>High</u>	<u>Low</u>
<b>Fiscal 2000</b>		
First Quarter	\$12.50	\$5.88
Second Quarter	9.50	5.88
Third Quarter	11.00	6.88
Fourth Quarter	11.00	3.56
<b>Fiscal 2001</b>		
First Quarter	7.50	4.40
Second Quarter	6.35	4.40
Third Quarter	7.25	5.50
Fourth Quarter	10.50	6.25
<b>Fiscal 2002</b>		
First Quarter (through March 25, 2002)	11.57	7.60

As of March 25, 2002 there were 1,611 holders of record of our common stock, which does not reflect stockholders whose shares are held in street name.

**Dividends**

We have never paid cash dividends on our common stock. We intend to retain future earnings in order to finance the growth and development of our business.

**Item 6. Selected Financial Data**

The following sets forth the selected consolidated statement of operations data for each of the five years in the period ended December 31, 2001 and consolidated balance sheet data as of December 31, 2000 and 2001, all of which are derived from our audited consolidated financial statements and related notes. The following selected financial data for each of the three years in the period ended December 31, 2001 and as of December 31, 2000 and 2001 should be read together with our consolidated financial statements and related notes appearing elsewhere in Item 14 of this Annual Report on Form 10-K and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Our independent auditors have audited our consolidated financial statements for each of the five years in the period ended December 31, 2001. The consolidated statement of operations for each of the two years in the period ended December 31, 1998 are derived from our audited consolidated financial statements and related notes not included in Item 14 of this Annual Report on Form 10-K.

## Consolidated Statement of Operations Data

<i>(in thousands, except per share data)</i>	Year Ended December 31,				
	1997	1998	1999	2000	2001
Net sales	\$14,902	\$15,243	\$20,249	\$18,617	\$26,411
Cost of sales	8,010	6,601	8,445	7,189	11,462
Gross profit	6,892	8,642	11,804	11,428	14,949
Operating expenses	8,438	10,710	11,226	11,942	16,137
Gain on sale of drug licenses	-	-	-	-	5,050
Provision for income taxes	621	236	781	222	2,452
Net income (loss)	<u>\$ (3,815)</u>	<u>\$ (2,876)</u>	<u>\$ (1,090)</u>	<u>\$ (745)</u>	<u>\$ 1,361</u>
Income (loss) per common share – basic	<u>\$ (.97)</u>	<u>\$ (.35)</u>	<u>\$ (.12)</u>	<u>\$ (.06)</u>	<u>\$ .10</u>
Income (loss) per common share – diluted	<u>\$ (.97)</u>	<u>\$ (.35)</u>	<u>\$ (.12)</u>	<u>\$ (.06)</u>	<u>\$ .08</u>
Weighted average number of common shares outstanding – basic	<u>4,072</u>	<u>8,431</u>	<u>9,147</u>	<u>12,981</u>	<u>14,196</u>
Weighted average number of common shares outstanding – diluted	<u>4,072</u>	<u>8,431</u>	<u>9,147</u>	<u>12,981</u>	<u>16,147</u>

## Consolidated Balance Sheet Data

<i>(in thousands)</i>	December 31,	
	2000	2001
Working capital	\$ 3,742	\$ 6,276
Non-current assets	15,773	16,280
Total assets	28,877	32,119
Non-current liabilities	1,699	2,132
Redeemable preferred stock	-	-
Stockholders' equity	17,816	20,424

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

### GENERAL

We are a specialty pharmaceutical company focused on advanced drug delivery technologies and pharmaceutical products. A substantial part of our operations is in Spain, where we manufacture and market generic and branded pharmaceutical products and from which market we derive the majority of our sales.

Our primary objective is to be a leading specialty pharmaceutical company focused on advanced drug delivery and formulation technologies that improve the effectiveness of existing and new pharmaceuticals. We have patents and proprietary technologies that enhance or facilitate the absorption of drugs across membranes of the skin, mouth, nose, vagina and eye. We are developing products incorporating these technologies and seek to form strategic alliances with major pharmaceutical and biotechnology companies to facilitate the development and commercialization of our products. We currently have strategic alliances with Pfizer and Auxilium and are in preliminary discussions with a number of other pharmaceutical companies to form additional alliances.

We have entered into a research services agreement with Auxilium, an emerging therapeutic pharmaceutical company focused on diseases related to aging to develop and test various pharmaceutical compositions of a topical testosterone using our CPE-215 permeation enhancement technology. We have licensed our drug delivery technology to Auxilium for use in the development and commercialization of a topical testosterone product. Phase III clinical trials performed by Auxilium for the approval of this product in the U.S. have been completed and a New Drug Application has been submitted to the FDA.

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

We entered into a strategic alliance with Teva in July 2000 whereby we, through our Spanish subsidiaries, received the right to register and market in Spain more than 75 of Teva's products. The products are comprised of both branded and generic forms. Sales from the products are expected to begin gradually, but will progress over the next two to

three years. An investment in additional sales representatives has been and will continue to be required, along with an increase in regulatory activities, both of which may create a short-term decrease in our earnings. Through our subsidiary, Laboratorios Davur S.L., we also submitted registrations to the Spanish Ministry of Health for generic versions of various products in response to growing interest in generic drug products in Spain. We believe that gross margins may be lower on sales of these products.

We manufacture generic and branded pharmaceutical products in our Zaragoza, Spain facility and sell and market these products to physicians and pharmacists throughout Spain. In addition to manufacturing our own products, we utilize our excess capacity by acting as a contract manufacturer for other pharmaceutical companies.

We have not realized domestic taxable income to date. At December 31, 2001, net operating losses available to offset future domestic taxable income for federal income tax purposes were approximately \$36,047,000 million. Our U.S. federal net operating loss carryforwards, if not utilized, expire at various dates from 2007 to 2022. We have recorded a valuation allowance against our entire future tax benefit arising from our domestic net operating losses. The future utilization of our net operating loss carryforwards may be limited pursuant to U.S. tax regulations.

## **RESULTS OF OPERATIONS**

### **Fiscal Year Ended December 31, 2001 Compared To Fiscal Year Ended December 31, 2000**

*Net sales.* Net sales increased by 41.9% from \$18,617,000 in 2000 to \$26,411,000 in 2001. The \$7,794,000 increase was primarily the result of our continuing efforts in the generic drug market in Spain. We anticipated the opportunities in the emerging generic drug market in Spain and began taking measures over three years ago to enter the Spanish generic drug market. We began to register, market and distribute generic pharmaceutical products in Spain and began aligning our business model to be competitive in this arena, including hiring and training a new generic products sales force, submission of generic products to the Spanish Ministry of Health for approval and a marketing campaign designed to position ourselves as a leader in the Spanish generic drug market. Although in Spain we reported an increase in net sales of 50% in local currency in 2001 compared to the prior year, a three percent decline in the value of the Spanish Peseta and related Euro negatively impacted revenues by approximately \$579,000. Sales of the product Controlvas®, which accounted for approximately \$2,208,000 of net sales in 2000, declined to approximately \$60,000 in 2001 as a result of our divestiture of the related drug license during the first quarter of 2001, which resulted in a pre-tax gain of approximately \$4,977,000. Net sales in 2001 included sales of the product Arzimo1™ totaling approximately \$600,000, which will not continue in 2002 due to termination of our joint marketing agreement with Bristol-Myers Squibb for this product.

*Gross Profit.* Gross profit increased by 30.8% from \$11,428,000 in 2000 to \$14,949,000 in 2001. The \$3,521,000 increase was the direct result of the growth in our net sales from 2000 to 2001. However, our gross margins for 2001 decreased to 57% compared to gross margins of 61% in the prior year, primarily as a result of the mix of products sold, including the effects of the addition of our new generic product line and disposition of the Controlvas® drug license, as well as higher depreciation charges resulting from the recent renovations and improvements at our manufacturing facility. Net sales of Controlvas® products contributed approximately \$1,493,000 to gross profit during 2000; however, the divestiture of the Controlvas® drug license during the first quarter of 2001 reduced the gross profit contribution from sales of these products to approximately \$41,000, in 2001. Approximately 30% of our net sales during the year ended December 31, 2001 were generic product sales, which typically have lower sales prices and gross margins than branded products. In comparison, we sold no generic drug products during the first three quarters of the prior year. As generic product sales become more significant in the future, gross margins may continue to decrease. Additionally, the Ministry of Health in Spain levies on pharmaceutical companies a tax for the purposes of funding rising healthcare costs in Spain. In 2001, this tax had the effect of reducing gross profit by \$228,000, or one percentage point.

*Selling and Marketing Expenses.* Selling and marketing expenses increased by 39.5% from \$6,494,000 in 2000 to \$9,057,000 in 2001. The \$2,563,000 increase in 2001 was the result of our introduction and support of the launches of new generic drug products. Selling and marketing expenses as a percent of sales, however, declined slightly to 34.3% in 2001 compared to 34.9% in 2000. The three percent decline in the value of the Spanish Peseta and related Euro, in relation to the U.S. Dollar, during the year, had the effect of reducing selling and marketing expenses by \$221,000 in 2001.

*General and Administrative Expenses.* General and administrative expenses increased by 8.5% from \$3,766,000 in 2000 to \$4,085,000 in 2001. The \$319,000 increase in 2001 was the result of increased general and administrative activities required to support our revenue growth in 2001. General and administrative expenses as a percent of sales declined to 15.5% of net sales in 2001 compared to 20.2% of net sales in 2000. The three percent decline in the value of the Spanish Peseta and related Euro, in relation to the U.S. Dollar, during the period, had the effect of reducing general and administrative expenses by \$58,000 in 2001.

*Research and Development Expenses.* Research and development expenses increased by 89.1% from \$1,102,000 in 2000 to \$2,084,000 in 2001. The \$982,000 increase in 2001 was the result of an increase in our costs associated with Phase I Clinical Studies (treatment of nail fungal infections), preclinical programs underway in collaboration with universities and with product formulation and testing efforts being performed in the laboratory in our U.S. headquarters and at our facility in Zaragoza, Spain. We are using our U.S. laboratory to develop potential product applications using our drug delivery technologies. The expenditures in research and development, which totaled \$732,000 in the fourth quarter, reflect our focus on projects that are necessary for expansion of our portfolio of marketed products and clinical trials involving our technologies. We expect that our future expenditures for research and development activities will continue to increase as a result of programs that are necessary to advance new applications of our technologies.

*Depreciation and Amortization Expenses.* Depreciation and amortization expenses increased by 57.1% from \$580,000 in 2000 to \$911,000 in 2001. The \$331,000 increase in 2001 was the result of increased amortization charges related to our recent acquisition of drug licenses and technologies, including Codeisan<sup>®</sup>, (approximately \$289,000) and to a lesser extent, higher depreciation charges with respect to recent asset additions (approximately \$107,000), partially offset by the effect of fluctuations in foreign currency exchange rates (approximately \$13,000). Depreciation and amortization charges are expected to be higher than in 2001 as a result of these acquisitions.

*Interest Income.* Interest income decreased by 51.6% from \$347,000 in 2000 to \$168,000 in 2001. The \$179,000 decrease was the result of lower short-term interest bearing investment balances and lower interest rates on the existing investment balances during 2001 compared to 2000.

*Interest Expense.* Interest expense decreased by 44.4% from \$439,000 in 2000 to \$244,000 in 2001. The \$195,000 decrease was the result of the conversion of all outstanding debentures into shares of our common stock in the second quarter of 2000. Interest expense incurred during 2001 resulted primarily from the outstanding balances on lines of credit used for operating purposes and lines of credit and borrowings used to finance the purchase of the product Codeisan<sup>®</sup> and capital equipment and improvements in Spain.

*Provision for Income Taxes.* We generated additional U.S. federal net operating loss carryforwards in 2001. However, since we are not assured of future profitable domestic operations, we have recorded a valuation allowance for any future benefit of such losses. We recorded a provision for foreign income taxes totaling \$2,452,000 for 2001 as a result of reporting taxable income in Spain (approximately \$607,000) and capital gains tax (approximately \$1,845,000) primarily arising from the sale of Controlvas<sup>®</sup> and Amantadine<sup>®</sup>, compared to the provision for foreign income taxes of \$222,000 in the prior year as a result of taxable income earned in Spain. The provision for foreign income taxes would have been \$159,000 higher than reported, absent the three percent decline in the value of the Spanish Peseta and related Euro in relation to the U.S. Dollar during the year.

*Net Income.* We sold the trademarks, registration rights and dossiers for our branded pharmaceutical products, Controlvas<sup>®</sup> and Amantadine<sup>®</sup>, for approximately \$5,148,000 and \$114,000, respectively, during 2001, generating pre-tax gains of approximately \$4,977,000 and \$73,000, respectively. Including the \$5,050,000 pre-tax gains on sale of these drug licenses, we reported income from operations of \$3,862,000 for 2001 compared to a loss from operations of \$514,000 in the prior year. Excluding the \$5,050,000 pre-tax gain from the sale of the Controlvas<sup>®</sup> and Amantadine<sup>®</sup> drug licenses, the loss from operations for the year ended December 31, 2001 totaled \$1,188,000. The combination of income from operations of \$3,862,000 and the non-operating items, primarily the provision for income taxes of \$2,452,000, resulted in net income of \$1,361,000, or \$.10 per basic common share (\$.08 per diluted common share) on 14,196,000 weighted average basic common shares outstanding (16,147,000 weighted average diluted common shares outstanding) for 2001, compared to a net loss in the prior year of \$745,000, or \$.06 per basic and diluted common share on 12,981,000 weighted average common shares outstanding.

## Fiscal Year Ended December 31, 2000 Compared To Fiscal Year Ended December 31, 1999

*Net sales.* Net sales decreased by 8.1% from \$20,249,000 in 1999 to \$18,617,000 in 2000. The \$1,632,000 decrease was the result of increased generic drug competition that reduced sales of certain of our branded pharmaceutical products and a 16% decline in the value of the Spanish Peseta and related Euro in relation to the U.S. Dollar. The decline in the value of the local currency negatively impacted net sales by \$2,736,000 in 2000, resulting in net sales generated in Spain of \$18,487,000 when expressed in U.S. Dollars. Our Spanish subsidiaries reported an increase in net sales of 5% in local currency for 2000 compared to the prior year. Also impacting net sales was a decision by the Spanish Ministry of Health to suspend from commercialization a class of drugs that included Finedal, a product we previously marketed. Our net sales in 2000 included sales of Finedal totaling approximately \$230,000, while net sales in 1999 included Finedal sales of approximately \$880,000. We do not anticipate any future sales of this product nor do we anticipate incurring any future costs with respect to this product. Net sales in 2000 included \$130,000 related to research and licensing agreements and fees from research and product formulation activities in the U.S.

*Gross Profit.* Gross margins for 2000 increased to 61.4% compared to 58.3% in the prior year, primarily as a result of the mix of products sold and manufacturing efficiencies realized at our manufacturing facility during 2000 compared to the prior year. However, foreign currency fluctuations during 2000 had the effect of decreasing net sales and the related gross profit by \$376,000, or 3.2%, from \$11,804,000 in 1999 to \$11,428,000 in 2000.

*Selling and Marketing Expenses.* Selling and marketing expenses increased by 5.3% from \$6,166,000 in 1999 to \$6,494,000 in 2000. The \$328,000 increase in 2000 was the result of selling and marketing efforts to maintain and grow market share. Selling and marketing expenses, as a percent of net sales, increased to 34.9% in 2000 from 30.5% in 1999. Selling and marketing expenses, as reported in U.S. Dollars, were approximately \$1,012,000 lower than would have been reported as a result of the 16% decline in the value of the Spanish Peseta and related Euro in relation to the U.S. Dollar during the period.

*General and Administrative Expenses.* General and administrative expenses decreased by 1.3% from \$3,816,000 in 1999 to \$3,766,000 in 2000. The \$50,000 decrease was the result of a decline in the value of the Spanish Peseta and related Euro. General and administrative expenses, as reported in U.S. Dollars, were approximately \$274,000 lower than would have been reported as a result of the 16% decline in the value of the Spanish Peseta and related Euro in relation to the U.S. Dollar during the period. General and administrative expenses as a percent of net sales, increased from 18.8% in 1999 to 20.2% in 2000.

*Research and Development Expenses.* Research and development expenses increased by 60.9% from \$685,000 in 1999 to \$1,102,000 in 2000. The \$417,000 increase was the result of costs associated with conducting clinical trials, preclinical programs and product formulation and testing efforts.

*Depreciation and Amortization Expenses.* Depreciation and amortization expenses increased by 3.8% from \$559,000 in 1999 to \$580,000 in 2000. The \$21,000 increase was the result of higher depreciation charges related to renovations and improvements in our manufacturing facility and our U.S. laboratory and higher amortization charges for recently acquired drug licenses and technologies, partially offset by the effect of fluctuations in foreign currency exchange rates.

*Interest Income.* Interest income increased by 42.2% from \$244,000 in 1999 to \$347,000 in 2000. The \$103,000 increase was the result of higher short-term interest bearing investment balances and higher interest rates earned on the investment balances during 2000 as compared to 1999.

*Interest Expense.* Interest expense decreased by 62.4% from \$1,168,000 in 1999 to \$439,000 in 2000. The \$729,000 decrease was the result of the conversion into common stock of our 12% Senior Subordinated Debentures in the second quarter of 2000. Interest expense incurred during the nine months ended December 31, 2000 resulted primarily from the outstanding balances on lines of credit used for operating purposes and lines of credit and borrowings used to fund the purchase of the product Codeisan®, in Spain, during the third and fourth quarters of 2000. We financed approximately \$4,900,000 of the purchase, using short-term lines of credit and long-term borrowings. We used a portion of the deposit that we received from the sale of the trademark, registration rights and dossier for our branded pharmaceutical product, Controlvas®, to reduce short-term borrowings during the fourth quarter of 2000.

*Provision for Income Taxes.* We generated additional U.S. federal net operating loss carryforwards in 2000. However, since we are not assured of future profitable domestic operations, we have recorded a valuation allowance for any future benefit of such losses. We recorded a current provision for foreign income taxes totaling \$222,000 for 2000 as

a result of taxable income earned in Spain, compared to \$781,000 in the same period of the prior year. The provision for foreign income taxes would have been \$31,000 higher than reported, absent the 16% decline in the value of the Spanish Peseta and related Euro in relation to the U.S. Dollar during the period.

*Net Income.* We reported a loss from operations of \$514,000 for 2000 compared to income from operations of \$578,000 in the prior year. The impact of non-operating items, primarily interest income of \$347,000, interest expense of \$439,000 and the resulting provision for income taxes of \$222,000 resulted in a net loss of \$745,000, or \$.06 per basic and diluted common share (12,981,000 weighted average common shares outstanding) for 2000, compared to the net loss in the prior year, of \$1,090,000, or \$.12 per basic and diluted common share (9,147,000 weighted average common shares outstanding).

#### Selected Quarterly Financial Data

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

<i>(in thousands, except per share data)</i>	Three Months Ended (Unaudited)							
	Fiscal 2000				Fiscal 2001			
	3/31/00	6/30/00	9/30/00	12/31/00	3/31/01	6/30/01	9/30/01	12/31/01
Net sales	\$5,085	\$4,594	\$3,626	\$5,312	\$5,814	\$6,125	\$6,316	\$8,156
Gross profit	3,127	2,858	2,143	3,300	3,365	3,438	3,608	4,538
Income (loss) from operations	468	(101)	(476)	(405)	4,612(1)	(468)	120	(402)
Net income (loss)	41	(182)	(419)	(185)	2,642	(569)	(149)	(563)
Net income (loss) per common share:								
Basic	\$ -	\$ (.01)	\$ (.03)	\$ (.02)	\$ .19	\$ (.04)	\$ (.01)	\$ (.04)
Diluted	\$ -	\$ (.01)	\$ (.03)	\$ (.02)	\$ .17	\$ (.04)	\$ (.01)	\$ (.04)

(1) Includes pre-tax gain of approximately \$4,977,000 related to the sale of the Controlvas® drug license.

#### Liquidity and Capital Resources

Our total assets increased from \$28,877,000 at December 31, 2000 to \$32,119,000 at December 31, 2001, while stockholders' equity increased from \$17,816,000 at December 31, 2000 to \$20,424,000 at December 31, 2001. The increase in stockholders' equity reflects primarily the net income of \$1,361,000 in 2001, and net proceeds from the exercise of stock options and warrants totaling \$1,827,000, partially offset by the negative impact of the fluctuation of the Spanish Peseta and related Euro exchange rate of \$842,000 in 2001.

Our working capital increased from \$3,742,000 at December 31, 2000 to \$6,276,000 at December 31, 2001, primarily as a result of collection of the remainder of the cash due upon the sale of the product Controlvas® (approximately \$2,582,000), most of which was used to reduce short-term and long-term borrowings, the recognition of deferred income of approximately \$2,564,000 related to the sale of Controlvas®, and net proceeds received from the exercise of stock options and warrants totaling \$1,827,000 during 2001.

Cash and cash equivalents increased from \$4,816,000 at December 31, 2000 to \$5,736,000 at December 31, 2001, as a result of net cash generated by investing activities of \$744,000, which included proceeds received from the sale of the Controlvas® drug license (approximately \$2,582,000) partially offset by additions to fixed assets of approximately \$1,595,000 and additions to drug licenses of approximately \$437,000. Cash and cash equivalents also increased as a result of proceeds from the exercise of stock options and warrants (approximately \$1,827,000), which was partially offset by net repayments of borrowings (approximately \$1,704,000).

Receivables increased from \$5,135,000 at December 31, 2000 to \$6,937,000 at December 31, 2001 as a direct result of sales growth. Receivables increased by approximately \$2,222,000 in local currency, but fluctuations in foreign currency exchange rates offset the increase by approximately \$344,000. We have not experienced any material delinquencies on our receivables. Inventories increased from \$1,827,000 at December 31, 2000 to \$2,563,000 at December 31, 2001 primarily as a result of raw materials purchases in anticipation of demand for our generic products.

The combined total of accounts payable and accrued expenses increased from \$3,613,000 at December 31, 2000 to \$7,310,000 at December 31, 2001, primarily due to accruals for social security taxes payable, salaries payable and taxes payable (approximately \$866,000), as well as for inventory purchases (approximately \$1,445,000), additions to fixed assets (approximately \$322,000) and reserves for potential sales returns (approximately \$402,000), partially offset by the effect of fluctuations in foreign currency exchange rates (approximately \$472,000).

Short-term borrowings and current portion of long-term debt decreased from \$3,185,000 at December 31, 2000 to \$1,757,000 at December 31, 2001, as a result of utilizing proceeds from the sale of the product Controlvas® to reduce balances outstanding, combined with the effect of fluctuations in foreign currency exchange rates, partially offset by additional borrowings during the year ended December 31, 2001 to finance capital expenditures at our manufacturing plant in Spain and working capital needs. The weighted average interest rate on our short-term borrowings is 5.9%.

Long-term debt, which totaled \$623,000 at December 31, 2000, was reduced to zero during the year ended December 31, 2001 as a result of using proceeds from the sale of Controlvas® to reduce the outstanding balance and was subsequently increased to \$214,000 as of December 31, 2001 as a result of a Government-sponsored loan program in Spain, whereby a non-interest bearing loan has been provided for product development. We have recorded a discount on the obligation of \$72,000 using an imputed interest rate of 6%. The discount will be amortized to interest expense over the ten-year term of the loan.

In addition to our short-term borrowings and long-term debt, we have fixed contractual obligations under various lease agreements. Our contractual obligations were comprised of the following as of December 31, 2001:

(in thousands)	Total	Payments Due By Period			
		Less Than 1 Year	1-3 Years	4-6 Years	7-10 Years
<b>Contractual Obligations</b>					
Short-term borrowings	\$1,757	\$1,757	\$ -	\$ -	\$ -
Long-term debt, including imputed interest of \$72,000	214	-	30	92	92
Operating leases	2,945	736	2,117	92	-
Total contractual cash obligations	<u>\$4,916</u>	<u>\$2,493</u>	<u>\$2,147</u>	<u>\$184</u>	<u>\$92</u>

Operating activities for the year ended December 31, 2001 provided net cash of \$139,000. Investing activities, primarily the proceeds from the sale of drug licenses (\$2,698,000), partially offset by additions to machinery and equipment and capital improvements to our facilities in Spain and the U.S. (\$1,595,000) and the purchase of drug licenses (\$437,000) provided net cash of \$744,000 during the year ended December 31, 2001. Financing activities, primarily proceeds from the exercise of stock options and warrants (\$1,827,000), partially offset by net repayments of borrowings (\$1,704,000) provided net cash of \$122,000 during the year ended December 31, 2001.

*Seasonality, Effect of Inflation and Liquidity.* In the past, we have experienced lower sales in the third calendar quarter and higher sales in the fourth calendar quarter due to seasonality. As we market more pharmaceutical products whose sales are seasonal, seasonality of sales may become more significant. Neither inflation nor changing prices has materially impacted our net sales or income from operations for the periods presented. We expect to have sufficient liquidity to fund operations for at least the next twelve months. We continue to explore alternative sources for financing our business activities, including the possibility of public and/or private offerings of our securities. In appropriate situations, that will be strategically determined, we may seek financial assistance from other sources, including contribution by others to joint ventures and other collaborative or licensing arrangements for the development, testing, manufacturing and marketing of products under development.

### Critical Accounting Policies

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

- *Inventories.* Inventories are stated at the lower of cost or market, cost being determined on the first-in, first-out method. Reserves for slow moving and obsolete inventories are provided based on historical experience and current product demand. We evaluate the adequacy of these reserves quarterly.
- *Revenue recognition and accounts receivable.* Revenue on product sales is recognized when persuasive evidence of an arrangement exists, the price is fixed and final, delivery has occurred and there is a reasonable assurance of collection of the sales proceeds. We generally obtain oral or written purchase authorizations

from our customers for a specified amount of product at a specified price and consider delivery to have occurred at the time of shipment. We provide our customers with a limited right of return. Revenue is recognized at shipment and a reserve for sales returns is recorded. We have demonstrated the ability to make reasonable and reliable estimates of product returns in accordance with SFAS No. 48 and of allowances for doubtful accounts based on significant historical experience. Revenue from service sales is recognized when the service procedures have been completed or applicable milestones have been achieved. Revenue from research and development contracts is recognized over applicable contractual periods or as defined milestones are attained, as specified by each contract and as costs related to the contracts are incurred.

- *Foreign currency translation.* The financial position and results of operations of our foreign subsidiaries are measured using local currency as the functional currency. Assets and liabilities of each foreign subsidiary are translated at the rate of exchange in effect at the end of the period. Revenues and expenses are translated at the average exchange rate for the period. Foreign currency translation gains and losses not impacting cash flows are credited to or charged against other comprehensive income (loss). Foreign currency translation gains and losses arising from cash transactions are credited to or charged against current earnings.
- *Drug licenses and related costs.* Drug licenses and related costs incurred in connection with acquiring licenses, patents and other proprietary rights related to our commercially developed products are capitalized. Capitalized drug licenses and related costs are being amortized on a straight-line basis over fifteen years from the dates of acquisition. Carrying values of such assets are reviewed quarterly and are adjusted for any diminution in value.

#### New Accounting Standards

In June 1998, the Financial Accounting Standards Board issued SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities. The new standard, which was adopted on January 1, 2001, requires that all companies record derivatives on the balance sheet as assets or liabilities, measured at fair value. Gains or losses resulting from changes in the values of those derivatives are accounted for depending on the use of the derivative and whether it qualifies for hedge accounting. The adoption of this standard on January 1, 2001 had no impact on our financial position or results of operations.

In June 2001, the Financial Accounting Standards Board issued SFAS No. 141, Business Combinations, and SFAS No. 142, Goodwill and Other Intangible Assets. SFAS No. 141 supersedes APB No. 16, Business Combinations, and SFAS No. 38, Accounting for Preacquisition Contingencies of Purchased Enterprises and requires that all business combinations be accounted for by a single method — the purchase method. SFAS No. 141 also provides guidance on the recognition of intangible assets identified in a business combination and requires enhanced financial statement disclosures. SFAS No. 142 adopts a more aggregate view of goodwill and bases the accounting for goodwill on the units of the combined entity into which an acquired entity is integrated. In addition, SFAS No. 142 concludes that goodwill and intangible assets that have indefinite useful lives will not be amortized but rather will be tested at least annually for impairment. Intangible assets that have finite lives will continue to be amortized over their useful lives. SFAS No. 141 is effective for all business combinations initiated after June 30, 2001. The adoption of SFAS No. 142 is required for fiscal years beginning after December 15, 2001 (the year 2002 for us), except for the nonamortization and amortization provisions which are required for goodwill and intangible assets acquired after June 30, 2001. We believe that the adoption of SFAS No. 141 and SFAS No. 142 will not have a material impact on our financial position or results of operations.

In October 2001, the Financial Accounting Standards Board issued SFAS No. 144 Accounting for the Impairment or Disposal of Long-Lived Assets. SFAS No. 144 supersedes previous guidelines for financial accounting and reporting for the impairment or disposal of long-lived assets and for segments of a business to be disposed of. We believe that the adoption of SFAS No. 144 will not have a material impact on our financial position or results of operations.

#### Item 7A. Quantitative and Qualitative Disclosures About Market Risk

*Foreign Currency.* A substantial amount of our business is conducted in Europe and is therefore influenced to the extent to which there are fluctuations in the U.S. Dollar's value against other currencies, specifically the Euro and the Spanish Peseta. On January 1, 1999, the Euro became the official currency of European Union (EU) member states with a fixed conversion rate against their national currencies. The value of the Euro against the U.S. Dollar and all other currencies, including the EU member states that are not participating in the Euro zone, will fluctuate according to market conditions. The permanent value of one Euro in Spain was fixed at 166.386 Spanish Pesetas. The exchange

rate at December 31, 2001 and 2000 was 186.93 Spanish Pesetas (1.12 Euros) and 178.02 Spanish Pesetas (1.07 Euros) per U.S. Dollar, respectively. The weighted average exchange rate for the years ended December 31, 2001 and 2000 was 185.93 Spanish Pesetas (1.12 Euros) and 180.66 Spanish Pesetas (1.09 Euros) per U.S. Dollar, respectively. The effect of foreign currency fluctuations on long lived assets for the year ended December 31, 2001 was a decrease of \$842,000 and the cumulative historical effect was a decrease of \$3,470,000, as reflected in our Consolidated Balance Sheets as accumulated other comprehensive loss. Although exchange rates fluctuated significantly in recent years, including, the weakening of the Euro in relation to the U.S. Dollar in 1999, 2000 and the first six months of 2001, we do not believe that the effect of foreign currency fluctuation is material to our results of operations as the expenses related to much of our foreign currency revenues are in the same currency as such revenues. However, the carrying value of assets and reported values can be materially impacted by foreign currency translation, as can the translated amounts of net sales and expenses.

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

*Interest Rates.* The weighted average interest rate on our short-term borrowings is 5.9% and the balance outstanding is \$1,757,000 as of December 31, 2001. Our long-term borrowings are non-interest bearing and the balance outstanding at December 31, 2001 is \$214,000 including imputed interest (at 6.0%) of \$72,000. The effect of an increase in the interest rate of one hundred basis points (to 6.9% on short-term borrowings and to 7.0% on long-term borrowings) would have the effect of increasing interest expense by approximately \$20,000 annually.

**Item 8. Financial Statements and Supplementary Data**

See Item 14 of this Form 10-K.

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

Not applicable.

**Part III**

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

**Item 11. Executive Compensation**

The information called for by this item is incorporated by reference to our definitive Proxy Statement for the 2002 Annual Meeting of Stockholders to be filed pursuant to Regulation 14A.

**Item 12. Security Ownership of Certain Beneficial Owners and Management**

The information called for by this item is incorporated by reference to our definitive Proxy Statement for the 2002 Annual Meeting of Stockholders to be filed pursuant to Regulation 14A.

**Item 13. Certain Relationships and Related Transactions**

The information called for by this item is incorporated by reference to our definitive Proxy Statement for the 2002 Annual Meeting of Stockholders to be filed pursuant to Regulation 14A.

\* This information has been omitted from this 2001 Annual Report, but is included in our Annual Report on Form 10-K for the year ended December 31, 2001. See inside back cover for information about obtaining a copy of the complete Form 10-K.

Part IV

Item 14. Exhibits, Financial Statement Schedules and Reports on Form 8-K

	<u>Page Herein</u>
(a) The following documents are filed as a part of this report:	
(1) Financial Statements:	
Independent Auditors' Report	F-1
Consolidated Balance Sheets as of December 31, 2001 and 2000	F-2
Consolidated Statements of Operations and of Comprehensive Income (Loss) for the years ended December 31, 2001, 2000 and 1999	F-3
Consolidated Statements of Changes in Stockholders' Equity for the years ended December 31, 2001, 2000 and 1999	F-4
Consolidated Statements of Cash Flows for the years ended December 31, 2001, 2000 and 1999	F-5 to F-6
Notes to Consolidated Financial Statements	F-7 to F-20
(3) Exhibits*	
(b) Reports on Form 8-K filed during the fiscal quarter ended December 31, 2001:	
None.	

\* This information has been omitted from this 2001 Annual Report, but is included in our Annual Report on Form 10-K for the year ended December 31, 2001. See inside back cover for information about obtaining a copy of the complete Form 10-K.

SIGNATURES\*

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

BENTLEY PHARMACEUTICALS, INC.

By: /s/ James R. Murphy  
 James R. Murphy  
 Chairman, President and  
 Chief Executive Officer  
 Date: February 14, 2002

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ James R. Murphy</u> James R. Murphy	Chairman, President, Chief Executive Officer and Director (principal executive officer)	February 14, 2002
<u>/s/Michael McGovern</u> Michael McGovern	Vice Chairman and Director	February 14, 2002
<u>/s/ Robert M. Stote</u> Robert M. Stote, M.D.	Senior Vice President, Chief Science Officer and Director	February 14, 2002
<u>/s/ Michael D. Price</u> Michael D. Price	Vice-President, Chief Financial Officer, Treasurer, Secretary and Director (principal financial and accounting officer)	February 14, 2002
<u>/s/Robert J. Gyurik</u> Robert J. Gyurik	Vice President of Pharmaceutical Development and Director	February 14, 2002
<u>/s/Charles L. Bolling</u> Charles L. Bolling	Director	February 14, 2002
<u>/s/Miguel Fernandez</u> Miguel Fernandez	Director	February 14, 2002
<u>/s/William A. Packer</u> William A. Packer	Director	February 14, 2002

\* Signature page from initial filing of Annual Report on Form 10-K.

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

We have audited the accompanying consolidated balance sheets of Bentley Pharmaceuticals, Inc. and subsidiaries (the "Company") as of December 31, 2001 and 2000, and the related consolidated statements of operations and of comprehensive income (loss), changes in stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2001 and 2000, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2001 in conformity with accounting principles generally accepted in the United States of America.

*Deloitte & Touche LLP*

Boston, Massachusetts  
February 8, 2002

BENTLEY PHARMACEUTICALS, INC. AND SUBSIDIARIES  
CONSOLIDATED BALANCE SHEETS

(in thousands)

	December 31,	
	2001	2000
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 5,736	\$ 4,816
Receivables, net	6,937	5,135
Inventories, net	2,563	1,827
Deferred foreign taxes	141	851
Prepaid expenses and other	462	475
Total current assets	15,839	13,104
Non-current assets:		
Fixed assets, net	5,595	4,139
Drug licenses and related costs, net	10,276	10,979
Other	409	655
Total non-current assets	16,280	15,773
	\$ 32,119	\$ 28,877
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 4,820	\$ 2,645
Accrued expenses	2,490	968
Short-term borrowings	1,757	2,447
Current portion of long-term debt	-	738
Deferred income	496	2,564
Total current liabilities	9,563	9,362
Non-current liabilities:		
Foreign taxes payable	1,827	908
Long-term debt	142	623
Other	163	168
Total non-current liabilities	2,132	1,699
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$1.00 par value, authorized 2,000 shares, issued and outstanding, none	-	-
Common stock, \$.02 par value, authorized 35,000 shares, issued and outstanding, 14,585 and 13,914 shares	292	278
Stock purchase warrants (to purchase 3,424 and 4,038 shares of common stock)	433	632
Additional paid-in capital	97,501	95,227
Accumulated deficit	(74,332)	(75,693)
Accumulated other comprehensive loss	(3,470)	(2,628)
Total stockholders' equity	20,424	17,816
	\$ 32,119	\$ 28,877

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

**BENTLEY PHARMACEUTICALS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**AND OF COMPREHENSIVE INCOME (LOSS)**

*(in thousands except per share data)*

	<b>Year Ended December 31,</b>		
	<b>2001</b>	<b>2000</b>	<b>1999</b>
Net sales	\$26,411	\$18,617	\$20,249
Cost of sales	<u>11,462</u>	<u>7,189</u>	<u>8,445</u>
Gross profit	<u>14,949</u>	<u>11,428</u>	<u>11,804</u>
Operating expenses:			
Selling and marketing	9,057	6,494	6,166
General and administrative	4,085	3,766	3,816
Research and development	2,084	1,102	685
Depreciation and amortization	911	580	559
Total operating expenses	<u>16,137</u>	<u>11,942</u>	<u>11,226</u>
Gain on sale of drug licenses	<u>5,050</u>	-	-
Income (loss) from operations	<u>3,862</u>	<u>(514)</u>	<u>578</u>
Other income (expenses):			
Interest income	168	347	244
Interest expense	(244)	(439)	(1,168)
Other	<u>27</u>	<u>83</u>	<u>37</u>
Income (loss) before income taxes	<u>3,813</u>	<u>(523)</u>	<u>(309)</u>
Provision for foreign income taxes	<u>2,452</u>	<u>222</u>	<u>781</u>
Net income (loss)	<u>\$ 1,361</u>	<u>\$ (745)</u>	<u>\$ (1,090)</u>
Net income (loss) per common share:			
Basic	<u>\$ .10</u>	<u>\$ (.06)</u>	<u>\$ (.12)</u>
Diluted	<u>\$ .08</u>	<u>\$ (.06)</u>	<u>\$ (.12)</u>
Weighted average common shares outstanding:			
Basic	<u>14,196</u>	<u>12,981</u>	<u>9,147</u>
Diluted	<u>16,147</u>	<u>12,981</u>	<u>9,147</u>
Net income (loss)	\$ 1,361	\$ (745)	\$ (1,090)
Other comprehensive income (loss):			
Foreign currency translation losses, net	<u>(842)</u>	<u>(289)</u>	<u>(737)</u>
Comprehensive income (loss)	<u>\$ 519</u>	<u>\$ (1,034)</u>	<u>\$ (1,827)</u>

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

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

(in thousands)

	\$.02 Par Value Common Stock		Stock Purchase Warrants	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Shares	Amount					
Balance at December 31, 1998	8,443	\$168	\$ 556	\$83,728	\$(73,858)	\$(1,602)	\$ 8,992
Exercise of Class A Redeemable Warrants	859	18	(39)	2,584	-	-	2,563
Exercise of other stock warrants	50	1	(42)	116	-	-	75
Conversion of Debentures	77	1	-	132	-	-	133
Issuance of warrants to acquire technology	-	-	375	-	-	-	375
Common stock issued to acquire technology	585	12	-	838	-	-	850
Common stock issued as compensation	150	3	-	222	-	-	225
Common stock issued to consultants	66	1	-	187	-	-	188
Expiration of unexercised warrants	-	-	(51)	51	-	-	-
Foreign currency translation adjustment	-	-	-	-	-	(737)	(737)
Net loss	-	-	-	-	(1,090)	-	(1,090)
Balance at December 31, 1999	10,230	204	799	87,858	(74,948)	(2,339)	11,574
Exercise of Class B Redeemable Warrants	99	1	(2)	493	-	-	492
Conversion of Debentures	2,901	58	-	4,682	-	-	4,740
Exercise of stock options/warrants	684	15	(414)	2,197	-	-	1,798
Exercise of underwriter's warrants	-	-	249	(3)	-	-	246
Foreign currency translation adjustment	-	-	-	-	-	(289)	(289)
Net loss	-	-	-	-	(745)	-	(745)
Balance at December 31, 2000	13,914	278	632	95,227	(75,693)	(2,628)	17,816
Exercise of stock options/warrants	171	4	-	443	-	-	447
Exercise of underwriter's Class A Warrants	460	9	(199)	1,570	-	-	1,380
Equity based compensation	40	1	-	261	-	-	262
Foreign currency translation adjustment	-	-	-	-	-	(842)	(842)
Net income	-	-	-	-	1,361	-	1,361
Balance at December 31, 2001	<u>14,585</u>	<u>\$292</u>	<u>\$ 433</u>	<u>\$97,501</u>	<u>\$(74,332)</u>	<u>\$(3,470)</u>	<u>\$20,424</u>

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

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

(in thousands)

	For the Year Ended December 31,		
	<u>2001</u>	<u>2000</u>	<u>1999</u>
Cash flows from operating activities:			
Net income (loss)	\$ 1,361	\$ (745)	\$(1,090)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities			
Gain on sale of drug licenses	(5,050)	-	-
Depreciation and amortization	911	580	559
Equity-based compensation expense	262	69	225
Other non-cash items	136	262	904
(Increase) decrease in assets and increase (decrease) in liabilities			
Receivables	(2,060)	(1,385)	(1,495)
Inventories	(864)	(1,003)	85
Deferred taxes	1,629	-	-
Prepaid expenses and other current assets	100	(205)	504
Other assets	(11)	(97)	109
Accounts payable and accrued expenses	3,306	(171)	163
Deferred income	496	-	-
Other liabilities	(77)	(5)	(27)
Net cash provided by (used in) operating activities	<u>139</u>	<u>(2,700)</u>	<u>(63)</u>
Cash flows from investing activities:			
Proceeds from sale of drug licenses	2,698	2,564	-
Additions to fixed assets	(1,595)	(1,014)	(969)
Additions to drug licenses and related costs	(437)	(5,560)	(1,775)
Proceeds from sale of investments	31,645	17,193	-
Purchase of investments	(31,567)	(15,171)	(1,893)
Deferred compensation	-	(440)	-
Net cash provided by (used in) investing activities	<u>744</u>	<u>(2,428)</u>	<u>(4,637)</u>
Cash flows from financing activities:			
Proceeds from exercise of stock options/warrants	1,827	2,843	2,639
Proceeds from borrowings	2,515	5,009	1,418
Repayments of borrowings	(4,219)	(2,279)	(1,533)
Payments on capital leases	(1)	(5)	(5)
Net cash provided by financing activities	<u>122</u>	<u>5,568</u>	<u>2,519</u>
Effect of exchange rate changes on cash	<u>(85)</u>	<u>(46)</u>	<u>(100)</u>
Net increase (decrease) in cash and cash equivalents	920	394	(2,281)
Cash and cash equivalents at beginning of year	<u>4,816</u>	<u>4,422</u>	<u>6,703</u>
Cash and cash equivalents at end of year	<u>\$ 5,736</u>	<u>\$ 4,816</u>	<u>\$ 4,422</u>

(continued on following page)

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

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

<i>(in thousands)</i>	For the Year Ended December 31,		
	2001	2000	1999
<b>Supplemental Disclosures of Cash Flow Information</b>			
The Company paid cash during the year for:			
Interest	\$ 247	\$ 486	\$ 1,003
Taxes	<u>\$ 317</u>	<u>\$ 897</u>	<u>\$ 980</u>
<b>Supplemental Disclosures of Non-Cash Financing and Investing Activities</b>			
The Company has issued or is obligated to issue Common Stock in exchange for services and the purchase of drug delivery technology as follows:			
Shares	<u>40</u>	<u>8</u>	<u>801</u>
Amount	<u>\$ 233</u>	<u>\$ 69</u>	<u>\$ 1,263</u>
Deferred income	<u>\$ 41</u>	<u>\$ -</u>	<u>\$ -</u>
Fixed asset and drug license purchases included in accounts payable	<u>\$ 514</u>	<u>\$ 225</u>	<u>\$ 261</u>

During the year ended December 31, 2000, 7,254 of the Company's 12% Convertible Debentures with principal amount of \$7,254,000, net of discount of \$1,585,000 (and applicable unamortized debt issuance costs totaling \$929,000) were converted into approximately 2,901,000 shares of Common Stock.

During the year ended December 31, 1999, the Company issued Warrants to purchase 450,000 shares of Common Stock as partial consideration for the purchase of drug delivery technology, of which 50,000 were exercised during the year ended December 31, 1999. During the year ended December 31, 1999, 193 of the Company's 12% Convertible Debentures were converted into 77,200 shares of Common Stock. The Company recorded the assignment of patents and technology with an estimated value of \$553,000 during the year ended December 31, 1999.

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

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

**NOTE 1—HISTORY AND OPERATIONS**

Bentley Pharmaceuticals, Inc. and its Subsidiaries (the "Company") is a specialty pharmaceutical company focused on advanced drug delivery technologies and pharmaceutical products. The Company owns U.S. and international patent and other proprietary rights to technologies that enhance or facilitate the absorption of drugs across biological membranes. The Company is developing products incorporating these technologies and seeks to form strategic alliances with major pharmaceutical and biotechnology companies to facilitate the development and commercialization of its products. The Company currently has strategic alliances regarding its drug delivery technologies with Pfizer Inc and Auxilium Pharmaceuticals, Inc. and is in preliminary discussions with a number of large pharmaceutical companies to form additional alliances. The Company is incorporated in the State of Delaware.

The Company also has a commercial presence in Spain, where it manufactures and markets branded and generic pharmaceutical products within four therapeutic areas: cardiovascular, gastrointestinal, infectious and neurological diseases.

The Company anticipated the opportunities that the emerging generic drug market in Spain present and began taking measures over three years ago to enter the Spanish generic drug market. The Company created a wholly-owned subsidiary to register, market and distribute generic pharmaceutical products in Spain and began aligning its business model to be competitive in this arena, including hiring and training a new generic sales force, submission of generic-equivalent products to the Spanish Ministry of Health for approval and a marketing campaign designed to position the Company as a leader in the Spanish generic drug market. In July 2000, the Company entered into a strategic alliance with Teva Pharmaceutical Industries, Ltd. ("Teva"), whereby the Company has received the right to register and market in Spain more than 75 of Teva's products. Teva also entered into a supply agreement with the Company pursuant to which Teva will manufacture the products and supply them to us for marketing and sale in Spain. Teva was also granted a right of first refusal to acquire Laboratorios Davur in the event that the Company decides to sell that subsidiary or its direct parent, Laboratorios Belmac. The Company also granted Teva the right to bid for Laboratorios Belmac in the event the Company intends to sell that subsidiary.

Given the Company's current liquidity and cash balances and expectations with respect to the execution of its business model, management believes that it has sufficient resources to fund operations for the year 2002 and into the year 2003. However, there can be no assurance that changes in the Company's research and development plans or other events affecting the Company's revenues or operating expenses will not result in the earlier depletion of the Company's funds.

**NOTE 2—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Principles of consolidation and foreign currency translation**

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries: Pharma de Espana, Inc. and its wholly-owned subsidiary, Laboratorios Belmac S.A. and its wholly-owned subsidiaries, Laboratorios Davur S.L. and Laboratorios Rimafar S.L.; Bentley Healthcare Corporation and its wholly-owned subsidiary, Belmac Hygiene, Inc.; Belmac Health Corporation; Belmac Holdings, Inc. and its wholly-owned subsidiary, Belmac A.I., Inc.; B.O.G. International Finance, Inc.; and Belmac Jamaica, Ltd. All significant inter-company balances have been eliminated in consolidation. The financial position and results of operations of the Company's foreign subsidiaries are measured using local currency as the functional currency. Assets and liabilities of each foreign subsidiary are translated at the rate of exchange in effect at the end of the period. Revenues and expenses are translated at the average exchange rate for the period. Foreign currency translation gains and losses not impacting cash flows are credited to or charged against other comprehensive income (loss). Foreign currency translation gains and losses arising from cash transactions are credited to or charged against current earnings.

**Cash and cash equivalents**

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

## Marketable Securities

The Company had no marketable securities at December 31, 2001 or 2000.

## Inventories

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

## Fixed assets

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

	<u>Years</u>
Buildings and improvements	30
Equipment	3 - 7
Furniture and fixtures	5 - 7
Other	5

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

## Drug licenses and related costs

Drug licenses and related costs incurred in connection with acquiring licenses, patents, and other proprietary rights related to the Company's commercially developed products are capitalized. Capitalized drug licenses and related costs are being amortized on a straight-line basis over fifteen years from the dates of acquisition. Carrying values of such assets are reviewed quarterly by the Company and are adjusted for any diminution in value.

## Research and development

Research and development costs are expensed when incurred.

## Use of estimates

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

## Original issue discount/Debt issuance costs

Original issue discount related to the issuance of debt was amortized to interest expense using the effective interest method over the lives of the related debt. The costs related to the issuance of debt were capitalized and amortized to interest expense using the effective interest method over the lives of the related debt.

## Fair value of financial instruments

The carrying amounts of cash, cash equivalents, accounts payable, accrued expenses and short-term borrowings approximate fair value because of their short-term nature. The carrying amount of the Company's long-term obligations approximate fair value given the amounts outstanding at December 31, 2001 and 2000.

The fair value information presented herein is based on information available to management as of December 31, 2001. Although management is not aware of any factors that would significantly affect the estimated fair value amounts, such amounts have not been comprehensively revalued for purposes of these financial statements since that date and, therefore the current estimates of fair value may differ significantly from the amounts presented herein.

### Stock-based compensation plans

SFAS No. 123, *Accounting for Stock-Based Compensation*, addresses the financial accounting and reporting standards for stock or other equity-based compensation arrangements. The Company has elected to continue to use the intrinsic value-based method to account for employee stock option awards under the provisions of Accounting Principles Board Opinion No. 25 and provides disclosures based on the fair value method in the notes to the financial statements as permitted by SFAS No. 123. Stock or other equity-based compensation for non-employees must be accounted for under the fair value-based method as required by SFAS No. 123 and Emerging Issues Task Force (“EITF”) No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services* and other related interpretations. Under this method, the equity-based instrument is valued at either the fair value of the consideration received or the equity instrument issued on the date of grant. The resulting compensation cost is recognized and charged to operations over the service period, which is usually the vesting period.

### Revenue recognition

Revenue on product sales is recognized when persuasive evidence of an arrangement exists, the price is fixed and final, delivery has occurred and there is a reasonable assurance of collection of the sales proceeds. The Company generally obtains oral or written purchase authorizations from its customers for a specified amount of product at a specified price and considers delivery to have occurred at the time of shipment. The Company provides its customers with a limited right of return. Revenue is recognized at shipment and a reserve for sales returns is recorded. The Company has demonstrated the ability to make reasonable and reliable estimates of product returns in accordance with SFAS No. 48 based on significant historical experience.

Revenue from service sales is recognized when the service procedures have been completed or applicable milestones have been achieved. Revenue from research and development contracts is recognized over applicable contractual periods or as defined milestones are attained, as specified by each contract and as costs related to the contracts are incurred. Payments received under such arrangements prior to the completion of the related procedures or attainment of milestones are recorded as deferred income.

### Income taxes

The Company accounts for income taxes under SFAS No. 109, *Accounting for Income Taxes*, which requires the recognition of deferred tax assets and liabilities relating to the expected future tax consequences of events that have been recognized in the Company’s consolidated financial statements and tax returns. Unrecognized provisions for income taxes on undistributed earnings of foreign subsidiaries which are considered permanently invested are not material to the Company’s consolidated financial statements.

### Basic and diluted net income (loss) per common share

Basic and diluted net income (loss) per common share is based on the weighted average number of shares of Common Stock outstanding during each period. The effect of the Company’s outstanding stock options and stock purchase warrants were considered in the diluted net income per share calculation for the year ended December 31, 2001. The effect of outstanding stock options and stock purchase warrants were not considered for the years ended December 31, 2000 and 1999, because the results would have been anti-dilutive.

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

<i>(in thousands, except per share data)</i>	Basic EPS	Effect of Dilutive Securities	Diluted EPS
Net income	\$ 1,361	\$ -	\$ 1,361
Weighted average common shares outstanding	14,196	1,951	16,147
Net income per common share	\$ .10	\$ (.02)	\$ .08

Common Stock Equivalents totaling 3,013,000 and 3,025,000, representing the effect of potential exercises of options and warrants and the effect of potential conversion of Debentures into shares of Common Stock for each of the years ended December 31, 2000 and 1999, respectively, were not included in the computation of diluted net loss per common share because the effect would have been anti-dilutive.

## Segments of an enterprise and related information

SFAS No. 131 *Disclosures About Segments of an Enterprise and Related Information* redefines how operating segments are determined and requires disclosure of certain financial and descriptive information about a company's operating segments. The Company operates in one business segment, which is described in Note 2; however, see Note 13 for geographical data.

## Recently issued accounting pronouncements

In June 1998, the Financial Accounting Standards Board issued SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*. The new standard requires that all companies record derivatives on the balance sheet as assets or liabilities, measured at fair value. Gains or losses resulting from changes in the values of those derivatives are accounted for depending on the use of the derivative and whether it qualifies for hedge accounting. The adoption of this standard on January 1, 2001 had no impact on the Company's financial position or results of operations.

In June 2001, the Financial Accounting Standards Board issued SFAS No. 141, *Business Combinations*, and SFAS No. 142, *Goodwill and Other Intangible Assets*. SFAS No. 141 supersedes APB No. 16, *Business Combinations*, and SFAS No. 38, *Accounting for Preacquisition Contingencies of Purchased Enterprises* and requires that all business combinations be accounted for by a single method—the purchase method. SFAS No. 141 also provides guidance on the recognition of intangible assets identified in a business combination and requires enhanced financial statement disclosures. SFAS No. 142 adopts a more aggregate view of goodwill and bases the accounting for goodwill on the units of the combined entity into which an acquired entity is integrated. In addition, SFAS No. 142 concludes that goodwill and intangible assets that have indefinite useful lives will not be amortized but rather will be tested at least annually for impairment. Intangible assets that have finite lives will continue to be amortized over their useful lives. SFAS No. 141 is effective for all business combinations initiated after June 30, 2001. The adoption of SFAS No. 142 is required for fiscal years beginning after December 15, 2001 (the year 2002 for the Company), except for the nonamortization and amortization provisions which are required for goodwill and intangible assets acquired after June 30, 2001. The Company believes that the adoption of SFAS No. 141 and SFAS No. 142 will not have a material impact on the Company's financial position or results of operations.

In October 2001, the Financial Accounting Standards Board issued SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. SFAS No. 144 supersedes previous guidelines for financial accounting and reporting for the impairment or disposal of long-lived assets and for segments of a business to be disposed of. The adoption of SFAS No. 144 on January 1, 2002 did not have a material impact on the Company's financial position or results of operations.

## Reclassifications

Certain prior year amounts have been reclassified to conform with the current year's presentation format. Such reclassifications are not considered material to the consolidated financial statements.

## NOTE 3—RECEIVABLES

Receivables consist of the following (*in thousands*):

	December 31,	
	2001	2000
Trade receivables (of which \$1,747 and \$967, respectively, collateralize short-term borrowings with Spanish financial institutions)	\$6,397	\$4,807
VAT, income and social security taxes receivable	584	214
Other	<u>22</u>	<u>184</u>
	7,003	5,205
Less-allowance for doubtful accounts	<u>(66)</u>	<u>(70)</u>
	<u>\$6,937</u>	<u>\$5,135</u>

**NOTE 4—INVENTORIES**

Inventories consist of the following (*in thousands*):

	December 31,	
	2001	2000
Raw materials	\$1,387	\$ 692
Finished goods	1,230	1,196
	2,617	1,888
Less-allowance for slow moving inventory	(54)	(61)
	<u>\$2,563</u>	<u>\$1,827</u>

**NOTE 5—FIXED ASSETS**

Fixed assets consist of the following (*in thousands*):

	December 31.	
	2001	2000
Land	\$ 790	\$ 830
Buildings and improvements	3,008	2,607
Equipment	3,168	1,843
Furniture and fixtures	692	610
Leasehold improvements	44	44
Equipment under capital lease	-	27
	7,702	5,961
Less-accumulated depreciation	(2,107)	(1,822)
	<u>\$ 5,595</u>	<u>\$ 4,139</u>

Depreciation expense of approximately \$139,000, \$72,000 and \$43,000 has been charged to operations as a component of depreciation and amortization expense on the Consolidated Statements of Operations for the years ended December 31, 2001, 2000 and 1999, respectively. The Company has included depreciation totaling approximately \$324,000, \$260,000 and \$203,000 in cost of sales during the years ended December 31, 2001, 2000 and 1999, respectively.

Net book value of equipment under capital lease was \$0 and approximately \$1,000 at December 31, 2001 and 2000, respectively.

**NOTE 6—DRUG LICENSES AND RELATED COSTS**

Drug licenses and related costs consist of the following (*in thousands*):

	December 31,	
	2001	2000
Drug licenses and related costs	\$12,245	\$12,269
Less-accumulated amortization	(1,969)	(1,290)
	<u>\$10,276</u>	<u>\$10,979</u>

In November 2000, Laboratorios Belmac entered into an agreement to sell the trademark, registration rights and dossier for its branded pharmaceutical product, Controlvas®, for 950 million Spanish Pesetas (approximately \$5,148,000). Laboratorios Belmac received a 50% deposit from the purchaser in November 2000, which was reflected as deferred income in the Consolidated Balance Sheet as of December 31, 2000. The sale closed in February, 2001, resulting in a gain of approximately \$4,977,000 being recognized in the year ended December 31, 2001.

In June 2001, Laboratorios Belmac agreed to sell the trademark, registration rights and dossier for its pharmaceutical product, Amantadine®, to a third party for 30 million Spanish Pesetas (approximately \$153,000). A deposit of 11 million Spanish Pesetas (approximately \$56,000) was received from the purchaser in June 2001 and a second payment of 11 million Spanish Pesetas was received upon approval of the transfer of the rights to the purchaser by the Spanish Ministry of Health, which occurred during the quarter ended September 30, 2001, resulting in a recognized pre-tax gain of approximately \$73,000. The remaining 8 million Spanish Pesetas (approximately \$41,000) is payable over the next five years, in the form of a royalty arrangement.

The Company acquired the rights to market and manufacture in Spain, the product and trademark Codeisan® from Abello, a subsidiary of Merck & Co., Inc. during the year ended December 31, 2000 for 986 million Spanish Pesetas (approximately \$5,200,000). The brand line consists of tablet and liquid presentations, which is marketed and promoted by the Laboratorios Belmac sales force. Also acquired in the transaction was the associated manufacturing equipment.

On February 11, 1999, the Company acquired rights to certain U.S. and international patents and related technology (the "Assets") covering methods to enhance the absorption of drugs delivered to biological tissues. Consideration for the Assets was paid to Yungtai Hsu, an individual, in the form of a cash payment of approximately \$1.1 million, approximately 226,000 shares of Common Stock and ten-year warrants to purchase 450,000 shares of common stock. In addition, approximately 359,000 shares of Common Stock were conveyed to Conrex Pharmaceutical Corporation. The total of all consideration paid for the Assets was approximately \$2,600,000. Furthermore, terms of this transaction provide for certain royalty payments upon commercialization of products using the technologies.

Belmac Hygiene, Inc., a wholly owned subsidiary of the Company, entered into a 50/50 partnership in March 1994 with Maximed Corporation ("Maximed") to develop and market feminine healthcare products. Maximed contributed the hydrogel-based technology and the Company, through its subsidiary, was responsible for providing financing and funding of the partnership's activities. In December 1994, the Company commenced litigation against Maximed and was awarded a judgment in the amount of \$7.68 million in 1998, which was affirmed by the U.S. Court of Appeals. The Company attempted to collect the judgment, but was unable to obtain cash from Maximed to satisfy the judgment. Consequently, the Company decided to seek assignment of the technology and related patents in an effort to satisfy the judgment. As a result, the technology and patents were assigned to the Company in October 1999 and the Company treated such assignment as a distribution from the partnership. The Company estimated the value of the patents and technology to be approximately \$550,000 and recorded these assets as Drug licenses and related costs, net during the year ended December 31, 1999. The Company recorded no gain or loss as a result of this assignment. Management has determined that no reserve for impairment in value on these assets is necessary at December 31, 2001. The partnership is not currently engaged in business activities, nor does the Company anticipate that it will engage in any business activities in the future.

Amortization expense for drug licenses and related costs was approximately \$772,000, \$508,000 and \$516,000 for the years ended December 31, 2001, 2000 and 1999, respectively.

#### NOTE 7—RELATED PARTY NOTES

The Company provided loans to each of Messrs. Murphy, Price and Gyurik, who are executive officers of the Company, in the amounts of \$250,000, \$50,000 and \$140,000, respectively, in March 2000, which Messrs. Murphy, Price and Gyurik used to pay income taxes on equity-based compensation received in the prior year. In December 2001, the Compensation Committee of the Company's Board of Directors agreed to amend the loan agreements resulting in the forgiveness of principal and accrued interest totaling approximately \$56,000, \$11,000 and \$31,000, due from Messrs. Murphy, Price and Gyurik, respectively. The amounts forgiven were applied first to unpaid accrued interest and then to principal. These amounts were recorded as compensation expense during the year ended December 31, 2001 and treated as taxable income to the respective executives. The remaining loan balances, which bear interest at 2.37% annually, mature in March 2003 and are secured by 24,900, 5,400 and 14,200 shares of the Company's Common Stock owned by Messrs. Murphy, Price and Gyurik, respectively, as of December 31, 2001. Accrued interest on such loans totals approximately \$1,000 and \$23,000 at December 31, 2001 and 2000, respectively.

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

The Company has included the current portion of approximately \$98,000 in prepaid expenses and other current assets and the non-current portion of approximately \$294,000 in other non-current assets in the Consolidated Balance Sheet as of December 31, 2001. The balance outstanding at December 31, 2000 of approximately \$463,000 has been included in other non-current assets.

## NOTE 8—ACCRUED EXPENSES

Accrued expenses consist of the following (*in thousands*):

	December 31,	
	2001	2000
Foreign income taxes payable	\$ 596	\$ 13
Provision for sales returns	402	53
Accrued payroll	698	269
Other accrued expenses	794	633
	<u>\$2,490</u>	<u>\$968</u>

## NOTE 9—DEBT

Short-term borrowings consist of the following (*in thousands*):

	December 31,	
	2001	2000
Trade receivables discounted with a Spanish financial institution, with recourse, effective interest rate is 5.9% and 6.0%, respectively.	\$1,747	\$ 967
Revolving lines of credit payable to Spanish financial institutions, average interest rate is 5.3% and 6.0%, respectively.	10	1,480
	<u>\$1,757</u>	<u>\$2,447</u>

The weighted average stated interest rate on short-term borrowings outstanding at December 31, 2001 and 2000 was 5.9% and 6.0%, respectively.

The Company has revolving lines of credit with Spanish financial institutions, which lines total \$4,627,000 at December 31, 2001. The lines are scheduled to mature on various dates through November 30, 2002 and are renewable. At December 31, 2001, advances outstanding under the lines of credit were approximately \$10,000. The weighted average interest rate at December 31, 2001 and 2000 was 5.3% and 6.0%, respectively, and interest is payable quarterly.

Long-term debt consists of the following (*in thousands*):

	December 31,	
	2001	2000
Loan payable to Spanish government, net of unamortized discount of \$72,000	\$142	\$ -
Loans payable to Spanish financial institutions	-	1,360
Capitalized lease obligations relating to equipment	-	1
	142	1,361
Less-current portion	-	(738)
Total long-term debt	<u>\$142</u>	<u>\$ 623</u>

In December 2001, the Company entered into a loan agreement with the Spanish government as part of a research funding program. The loan is non-interest bearing and is payable in equal annual installments of approximately \$30,600 beginning in 2005. Accordingly, the Company has imputed interest at the market rate in Spain (6%) and recorded a discount on the obligation of \$72,000 and has classified the obligation at December 31, 2001 as non-current. The discount will be amortized over the ten-year term of the loan.

Loans payable to Spanish financial institutions were entered into in March 2000 to finance the acquisition of the Codeisan® drug license. The terms of the loans called for repayment over three years at an average interest rate of 6%. In September 2001 the loans were repaid using the proceeds from the sale of the Controlvas® drug license (see Note 6).

In February 1996, the Company publicly sold 6,900 Units at \$1,000 per Unit. Each Unit consisted of One Thousand Dollars (\$1,000) Principal Amount 12% Convertible Senior Subordinated Debenture due February 13, 2006 and 1,000 Class A Redeemable Warrants, each to purchase one share of Common Stock and one Class B Redeemable Warrant. Two Class B Redeemable Warrants entitle a holder to purchase one share of Common Stock at \$5.00 per share. During the year ended December 31, 2000, holders of the Company's 12% Debentures, converted all 7,254 of such Debentures, with a net carrying value of approximately \$5,669,000, into approximately 2,901,000 shares of Common Stock. Interest on the Debentures was payable quarterly.

For financial reporting purposes, the \$1,000 purchase price of each Unit was allocated as follows: \$722 to the Debenture, \$224 to the conversion discount feature of the Debenture and \$54 to the 1,000 Class A Warrants. None of the Unit purchase price was allocated to the Class B Warrants. Such allocation was based upon the relative fair value of each security on the date of issuance. Such allocation resulted in recording a discount on the Debentures of approximately \$1,900,000. The original issue discount and the costs related to the issuance of the Debentures was being amortized to interest expense using the effective interest method over the lives of the related Debentures until the date that such Debentures were converted into shares of Common Stock. The remaining unamortized original issue discount and related issuance costs were recorded an offset to Additional Paid-in Capital at the time of conversion. The effective interest rate on the Debentures was 18.1%.

On May 29, 1996, the Debentures and Class A Redeemable Warrants began trading separately. The expiration date of the Class A Warrants was extended to August 16, 1999. The expiration date of the underlying Class B Warrants was subsequently extended to December 31, 2002.

#### NOTE 10—PREFERRED STOCK

The Company has 2,000,000 shares of \$1.00 Preferred Stock authorized for issuance. As of December 31, 2001 and 2000, no shares of Preferred Stock were outstanding.

#### NOTE 11—STOCKHOLDERS' EQUITY

At December 31, 2001 the Company had the following Common Stock reserved for issuance under various plans and agreements (*in thousands*):

	<u>Common Shares</u>
For exercise of stock purchase warrants	3,424
For exercise of outstanding stock options	2,937
For future stock option grants	<u>1,006</u>
	<u>7,367</u>

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

#### Stock purchase warrants

At December 31, 2001, warrants to purchase an aggregate of approximately 3,424,000 shares of Common Stock were outstanding, which were exercisable at prices ranging from \$1.50 to \$20.00 per share, of which 400,000 warrants have an exercise price of \$1.50 per share, approximately 3,004,000 warrants have an exercise price of \$5.00 per share and 20,000 warrants have an exercise price of \$20.00 per share. The warrants expire on various dates from December 2002 through December 2009.

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

During the year ended December 31, 2000, approximately 197,000 Class B Warrants were exercised to acquire approximately 98,500 shares of Common Stock. Approximately 670,000 of other stock purchase warrants were also exercised to acquire approximately 670,000 shares of Common Stock, and Underwriter's Warrants were exercised to acquire 460 Debentures and 460,000 underwriter's Class A Warrants. The Company received net cash proceeds of approximately \$2,843,000 from all such exercises during the year ended December 31, 2000.

During the year ended December 31, 1999, the Company issued warrants to purchase an aggregate of 450,000 shares of Common Stock at \$1.50 per share as partial consideration for the purchase of permeation enhancement technology (see Note 6), of which 50,000 were exercised during 1999. During the year ended December 31, 1999, the Company also issued Class B Warrants to purchase 659,000 shares of Common Stock for \$5.00 per share. In addition, Class A Warrants were exercised during the year ended December 31, 1999 to acquire approximately 859,000 shares of

Common Stock and approximately 859,000 Class B Warrants, resulting in net cash proceeds to the Company of approximately \$2,600,000. Warrants to purchase approximately 1,322,000 shares of Common Stock (including approximately 1,252,000 Class A Warrants) expired unexercised during the year ended December 31, 1999.

In addition, the Company has granted warrants in connection with various services. These warrants have been granted for terms not exceeding ten years from the date of grant.

The table below summarizes warrant activity for the years ended December 31, 1999, 2000 and 2001.

<i>(in thousands, except per share data)</i>	<u>Number of Common Shares</u>	<u>Weighted Average Exercise Price Per Share</u>
Outstanding at December 31, 1998	5,928	\$3.84
Granted	1,109	\$3.58
Exercised	(909)	\$2.92
Canceled	(1,322)	\$3.05
Outstanding at December 31, 1999	4,806	\$4.17
Exercised	(768)	\$2.93
Outstanding at December 31, 2000	4,038	\$4.41
Exercised	(614)	\$2.89
Outstanding at December 31, 2001	<u>3,424</u>	\$4.68

#### **Common stock transactions**

During the year ended December 31, 2001, the Company issued approximately 460,000 shares of Common Stock as a result of the exercise of underwriter's Class A Warrants, approximately 4,200 shares of Common Stock upon exercise of Class B Warrants, approximately 150,000 shares of Common Stock upon exercise of 150,000 other stock purchase warrants, approximately 16,900 shares of Common Stock upon exercise of stock purchase options, and approximately 40,000 shares of Common Stock as compensation in lieu of cash. General and administrative expenses for the years ended December 31, 2001, 2000 and 1999 include \$160,000, \$39,000 and \$82,000, respectively, of non-cash equity-based compensation. Research and development expenses for the years ended December 31, 2001, 2000 and 1999 include \$102,000, \$30,000 and \$143,000, respectively, of non-cash equity-based compensation.

During the year ended December 31, 2000, the Company issued approximately 98,500 shares of Common Stock as a result of the exercise of approximately 197,000 Class B Warrants, approximately 670,000 shares of Common Stock upon exercise of other stock purchase warrants, approximately 14,000 shares of Common Stock upon exercise of stock purchase options and approximately 2,901,000 shares of Common Stock upon conversion of 7,254 of the Company's 12% Convertible Debentures.

During the year ended December 31, 1999, the Company issued approximately 585,000 shares of Common Stock as partial consideration for the acquisition of permeation enhancement technology, approximately 859,000 shares of Common Stock as a result of the exercise of approximately 859,000 Class A Warrants, approximately 77,000 shares of Common Stock upon conversion of 193 of the Company's 12% Convertible Debentures, 150,000 shares of Common Stock as compensation in lieu of cash, 66,000 shares of Common Stock for consulting fees earned in 1996, 1997 and 1998 and 50,000 shares of Common Stock upon exercise of other stock purchase warrants.

#### **Stock option plans**

The Company has in effect Stock Option Plans (the "Plans"), pursuant to which directors, officers, and employees of the Company are eligible to receive grants of options for the Company's Common Stock. Approximately 3,943,000 shares of Common Stock have been reserved for issuance under the Plans, of which approximately 943,000 are outstanding under the 1991 Plan, approximately 494,000 are outstanding under the 2001 Employee and Director Plans and 1,500,000 are outstanding under the Executive Plan as of December 31, 2001. Options may be granted for terms not exceeding ten years from the date of grant except for stock options which are granted to persons owning more than 10% of the total combined voting power of all classes of stock of the Company. For these individuals, options may be granted for terms not exceeding five years from the date of grant. Options may not be granted at a price which is less than 100% of the fair market value on the date the options are granted (110% in the case of persons owning more than 10% of the total combined voting power of the Company). Options granted under the Plans generally vest over one, two or three years. Options to purchase 16,900 and 14,000 shares of Common Stock were exercised during the years ended December 31, 2001 and 2000, respectively, resulting in net cash proceeds of approximately \$51,000 and \$35,000, respectively. No such options were exercised during the year ended December 31, 1999.

Had the compensation cost for the Plans been determined based on the fair value at the grant dates for awards under the Plans, consistent with the method described in SFAS 123, the Company's net income (loss) and basic and diluted net income (loss) per common share on a pro forma basis would have been *(in thousands, except per share data)*:

	Year Ended December 31,		
	2001	2000	1999
Net loss	\$(679)	\$(3,299)	\$(1,365)
Basic and diluted net loss per common share	\$ (.05)	\$ (.25)	\$ (.15)

The preceding pro forma results were calculated using the Black-Scholes option-pricing model. The following assumptions were used for the years ended December 31, 2001, 2000 and 1999, respectively: (1) risk-free interest rates of 5.2%, 6.6% and 5.8%, respectively; (2) dividend yields of 0.0%; (3) expected lives of 10 years; and (4) volatility of 140.8%, 126.9% and 90.0%, respectively. The weighted average fair value of options granted during the years ended December 31, 2001, 2000 and 1999 was \$3.72, \$4.48 and \$2.62, respectively. Results may vary depending on the assumptions applied within the model.

The table below summarizes activity in the Company's Plans for the years ended December 31, 1999, 2000 and 2001.

<i>(in thousands, except per share data):</i>	Number of Common Shares	Weighted Average Exercise Price
Outstanding at December 31, 1998	1,823	\$ 5.64
Granted	105	2.98
Canceled	(1)	2.75
Outstanding at December 31, 1999	1,927	5.50
Granted	570	7.56
Exercised	(14)	2.52
Canceled	(26)	113.96
Outstanding at December 31, 2000	2,457	4.87
Granted	553	6.04
Exercised	(17)	3.00
Canceled	(56)	9.66
Outstanding at December 31, 2001	<u>2,937</u>	\$ 5.00

The table below summarizes options outstanding and exercisable at December 31, 2001:

Range of Exercise Prices	Options Outstanding			Options Currently Exercisable	
	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)	Number of Options	Weighted Average Exercise Price
\$ 1.50 - 2.89	659,000	\$ 2.78	4.8	659,000	\$ 2.78
3.00 - 3.75	681,000	3.63	4.5	681,000	3.63
4.73	500,000	4.73	4.3	500,000	4.73
5.25 - 5.88	211,000	5.84	8.4	150,000	5.88
6.00 - 6.38	439,000	6.01	9.3	10,000	6.38
7.10 - 7.90	289,000	7.51	8.7	159,000	7.41
8.00 - 10.75	98,000	9.29	8.5	98,000	9.29
11.25 - 22.50	57,000	16.15	4.5	57,000	16.15
45.00	3,000	45.00	1.1	3,000	45.00
<u>\$ 1.50 - 45.00</u>	<u>2,937,000</u>	<u>\$ 5.00</u>	<u>6.1</u>	<u>2,317,000</u>	<u>\$ 4.64</u>

Options and warrants outstanding include approximately 3,424,000 warrants, all of which are exercisable, and approximately 2,937,000 options, of which approximately 2,317,000 are vested and exercisable at December 31, 2001.

#### 401(k) Retirement Plan

The Company sponsors a 401(k) retirement plan (the "401(k) Plan") under which eligible employees may contribute, on a pre-tax basis, between 1% and 15% of their respective total annual income from the Company, subject to maximum aggregate annual contribution imposed by the Internal Revenue Code of 1986, as amended. All full-time employees who work for the Company in the U.S. are eligible to participate in the 401(k) Plan. All employee contributions are allocated to the employee's individual account and are invested in various investment options as directed

by the employee. Employees' cash contributions are fully vested and nonforfeitable. The Company made matching contributions to the 401(k) Plan during the year ended December 31, 2001 in the form of approximately 13,658 shares of the Company's Common Stock valued at approximately \$83,000. The Company made matching cash contributions to the 401(k) Plan for the year ended December 31, 2000 of approximately \$2,500 and in the form of approximately 7,000 shares of the Company's Common Stock valued at approximately \$57,000. The Company made matching cash contributions to the 401(k) Plan for the year ended December 31, 1999 of approximately \$27,000. All Company matching contributions vest 25% each year for the first four years of each employee's employment.

### Stockholder Rights Plan

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

### NOTE 12—PROVISION FOR INCOME TAXES

For all periods presented the income (loss) before income taxes as shown in the consolidated statements of operations consists of losses generated in the United States and income derived from foreign operations.

The provision (benefit) for income taxes consists of the following (*in thousands*):

	<u>For the Year Ended December 31,</u>		
	<u>2001</u>	<u>2000</u>	<u>1999</u>
Foreign taxes	\$2,452	\$ 222	\$ 781
Tax benefit from US operating losses	(954)	(657)	(678)
Federal and state deferred taxes	(898)	1,162	(1,042)
Change in valuation allowance	<u>1,852</u>	<u>(505)</u>	<u>1,720</u>
Total provision for income taxes	<u>\$2,452</u>	<u>\$ 222</u>	<u>\$ 781</u>

A reconciliation between the federal statutory rate and the Company's effective income tax rate is as follows (*in thousands*):

	<u>For the Year Ended December 31</u>		
	<u>2001</u>	<u>2000</u>	<u>1999</u>
Statutory federal income tax (benefit)	\$1,296	\$(178)	\$(105)
Permanent differences from foreign subsidiary	202	(257)	208
Valuation allowance	<u>954</u>	<u>657</u>	<u>678</u>
	<u>\$2,452</u>	<u>\$ 222</u>	<u>\$ 781</u>

The components of the Company's deferred taxes are as follows (*in thousands*):

	<u>December 31,</u>	
	<u>2001</u>	<u>2000</u>
Deferred tax assets:		
NOL carryforwards	\$ 14,075	\$ 12,651
Capital loss carryforwards	10,799	10,641
Disposition of subsidiary	6,850	6,750
Foreign tax on deferred income	141	851
Tax credit carryforwards	415	415
Other, net	<u>603</u>	<u>428</u>
Total deferred tax assets	32,883	31,736
Deferred tax liabilities	(275)	(270)
Valuation allowance	<u>(32,467)</u>	<u>(30,615)</u>
Deferred tax asset, net	<u>\$ 141</u>	<u>\$ 851</u>

The Company has established a valuation allowance equal to the full amount of the domestic deferred tax asset, as future domestic operating profits cannot be assured. The Company has a current deferred tax asset of \$141,000 and a non-current tax liability of \$1,827,000 due to temporary differences arising as a result of the Company's Spanish subsidiary recording the gain on the sale of Controlvas® and the corresponding taxes for Spanish statutory purposes during the year ended December 31, 2000. The deferred tax asset is a result of taxes that related to deferred income and the tax liability results from taxes that will be payable in Spain beginning in 2004.

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

At December 31, 2001, the Company has NOL carryforwards of approximately \$36,047,000 available to offset U.S. taxable income. The Company calculates that its use of the NOL generated through December 31, 1997 may be limited to approximately \$1,000,000 each year as a result of stock option and warrant issuances resulting in an ownership change of more than 50% of the Company's outstanding equity. The NOL of approximately \$3,200,000 generated during the tax year ended December 31, 1998 is available to offset future taxable income along with the 1999, 2000 and 2001 losses without limitation. Additionally, approximately \$1,800,000 of the NOL generated in 1995 available to offset future U.S. taxable income will be limited to approximately \$300,000 per year over the subsequent six years due to the change in tax year end during 1995. If not offset against future taxable income, the NOL carryforwards will expire in tax years 2007 through 2022.

#### NOTE 13—BUSINESS SEGMENT INFORMATION

The Company is a U.S.-based specialty pharmaceutical company focused on advanced drug delivery technologies and pharmaceutical products. The Company also has a commercial presence in Europe. The Company's Spanish subsidiaries, Laboratorios Belmac S.A. and Laboratorios Davur S.L., manufacture and market branded and generic pharmaceutical products in Spain. In the U.S., the Company's activities consist primarily of limited product research and development, business development activities, corporate management, and administration.

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

Set forth in the tables below is certain financial information with respect to the Company's geographical segments for the years ended December 31, 2001, 2000 and 1999. The geographical segments use the same accounting policies as those described in the summary of significant accounting policies in Note 2.

	Year Ended December 31, 2001		
	Spain	Corporate/ Consolidation/ Elimination	Consolidated
<i>(in thousands)</i>			
Net sales	\$26,411	\$ -	\$26,411
Interest income	27	141	168
Interest expense	244	-	244
Depreciation and amortization expense	523	388	911
Income (loss) before income taxes	6,618	(2,805)	3,813
Income tax expense	2,452	-	2,452
Net income (loss)	4,166	(2,805)	1,361
Fixed assets	5,427	168	5,595
Drug licenses	6,663	3,613	10,276
Total assets	24,890	7,229	32,119
Total liabilities	10,974	721	11,695
Expenditures for drug licenses/delivery technology	412	72	484
Expenditures for fixed assets	2,029	40	2,069

	<u>Year Ended December 31, 2000</u>		
	<u>Spain</u>	<u>Corporate/ Consolidation/ Elimination</u>	<u>Consolidated</u>
<i>(in thousands)</i>			
Net sales	\$18,487	\$ 130	\$18,617
Interest income	16	331	347
Interest expense	205	234	439
Depreciation and amortization expense	235	345	580
Income (loss) before income taxes	1,408	(1,931)	(523)
Income tax expense	222	-	222
Net income (loss)	1,186	(1,931)	(745)
Fixed assets	3,959	180	4,139
Drug licenses	7,135	3,844	10,979
Total assets	19,896	8,981	28,877
Total liabilities	10,567	494	11,061
Expenditures for drug licenses/delivery technology	5,518	42	5,560
Expenditures for fixed assets	957	57	1,014

	<u>Year Ended December 31, 1999</u>		
	<u>Spain</u>	<u>Corporate/ Consolidation/ Elimination</u>	<u>Consolidated</u>
<i>(in thousands)</i>			
Net sales	\$20,249	\$ -	\$20,249
Interest income	-	244	244
Interest expense	147	1,021	1,168
Depreciation and amortization expense	289	270	559
Income (loss) before income taxes	1,686	(1,995)	(309)
Income tax expense	781	-	781
Net income (loss)	905	(1,995)	(1,090)
Fixed assets	3,512	172	3,684
Drug licenses	1,709	4,098	5,807
Total assets	11,739	10,498	22,237
Total liabilities	4,499	6,164	10,663
Expenditures for drug licenses/delivery technology	440	1,335	1,775
Expenditures for fixed assets	799	170	969

Interest income and interest expense are based upon the actual results of each operating segment's assets and borrowings. The consolidation/elimination column includes the elimination of all intersegment amounts as well as corporate segment amounts. The principal component of the inter-segment amounts related to inter-segment advances.

Revenues from one customer exceeded 10% of consolidated net sales during the year ended December 31, 2001, accounting for 15% of 2001 consolidated net sales and 7.5% of the consolidated receivables balance at December 31, 2001. Revenues from one customer exceeded 10% of consolidated net sales during the year ended December 31, 2000, accounting for 14% of 2000 consolidated net sales. Revenues from two customers exceeded 10% of consolidated net sales during the year ended December 31, 1999, each accounting for 13% of 1999 consolidated net sales.

#### **NOTE 14—COMMITMENTS AND CONTINGENCIES**

The Company is obligated to pay certain royalty payments upon commercialization of products using technologies acquired in a transaction, which it consummated during the year ended December 31, 1999 (see Note 6).

The Company has entered into various employment agreements with its executive officers, which agreements provide for salaries, potential bonuses and other benefits in exchange for services provided by the executive officers. The employment agreements also provide for certain compensation in the event of termination or change in control of the Company. Such agreements, which are renewable, are scheduled to expire on various dates through December 31, 2003.

The Company was awarded a judgment of approximately \$2,130,000 in the Circuit Court of the Thirteenth Judicial Circuit, State of Florida, Hillsborough County Civil Division during the year ended December 31, 1998, relating to its claims of civil theft and breach of employment agreement filed against its former President and Chief Executive

Officer, Michael M. Harshbarger. The judgment included treble damages totaling \$418,000 related to the civil theft claim and \$1,712,000 related to the breach of employment agreement claim. Harshbarger originally filed suit against the Company in November 1993, alleging wrongful termination, seeking monetary damages in excess of \$1,400,000. In addition to establishing a receivable on the Company's books, it has established a reserve equal to the receivable, as it is of the opinion that Harshbarger does not have the financial resources to satisfy the judgment. Harshbarger filed a Motion for Relief From Judgment in September 1999, alleging among other things that he was not provided notice of the August 24, 1998 jury trial. A hearing was held on November 27, 2001 to determine the merits of Harshbarger's claims. The judge determined that the facts of the case did not warrant setting aside the default and judgment against Harshbarger and denied all of Harshbarger's motions. Harshbarger did not file a notice of appeal within the requisite time period, therefore, the Company considers that this matter has been concluded and expects no further action other than any action it may take to enforce the judgment.

On January 22, 2001, the Company settled a legal dispute, by paying \$140,000 to Creative Technologies, Inc. and Creative Technologies, Inc. agreed to the dismissal of the related suit with prejudice. Creative Technologies had asserted that it was due a brokerage or finder's fee with respect to the Company's 1999 acquisition of permeation enhancement technology. The Company included the accrual for the \$140,000 charge in its Consolidated Balance Sheet as of December 31, 2000 and included the \$140,000 charge and related legal costs of approximately \$55,000 in operating expenses in the Consolidated Statement of Operations for the year ended December 31, 2000.

On February 4, 2002, the Company was notified that a legal proceeding had been commenced against it by Merck & Co. Inc. and its Spanish subsidiary, Merck Sharp & Dohme de España, S.A., (together "Merck") alleging that the Company violated Merck's patents in the production of the product simvastatin. The case was brought against the Company's Spanish subsidiaries in the 39th First Instance Court of the City of Madrid. Merck requested after a hearing that the court grant an injunction ordering the Company not to manufacture or market simvastatin. On February 18, 2002, the court refused to grant the requested injunction and dismissed the case on February 25, 2002, awarding the Company court and legal fees. There were no sales of simvastatin included in consolidated net sales for the year ended December 31, 2001, as the product was launched in late January 2002.

The Company leases certain equipment and facilities under non-cancelable operating leases, which expire through the year 2006. Total charges to operations under operating leases were approximately \$705,000, \$557,000 and \$442,000 for the years ended December 31, 2001, 2000 and 1999, respectively. Future minimum lease payments under operating leases are as follows (*in thousands*):

<u>Year Ending December 31,</u>	
2002	\$736
2003	737
2004	697
2005	683
2006 and beyond	92

## COMPANY PROFILE

### EXECUTIVE OFFICERS

James R. Murphy  
Chairman, President and Chief Executive Officer

Robert M. Stote, M.D., F.A.C.P.  
Senior Vice President and Chief Science Officer

Michael D. Price, CPA  
Vice President, Chief Financial Officer,  
Secretary and Treasurer

Robert J. Gyurik  
Vice President of Pharmaceutical Development

Jordan A. Horvath  
Vice President and General Counsel

### OPERATIONS EXECUTIVE-EUROPE

Adolfo Herrera Malaga, D.V.M.  
General Manager

### BOARD OF DIRECTORS

Charles L. Bolling  
Retired, Former Vice President  
Smith Kline and French Laboratories

Miguel Fernandez  
Retired, Former Vice President  
Carter-Wallace, Inc.

Robert J. Gyurik  
Vice President of Pharmaceutical Development  
Bentley Pharmaceuticals, Inc.

Michael McGovern, J.D.  
Vice Chairman, Bentley Pharmaceuticals, Inc.  
Chairman, Specialty Surgicenters, Inc.

James R. Murphy  
Chairman, President and Chief Executive Officer  
Bentley Pharmaceuticals, Inc.

William A. Packer  
Consultant - Biopharmaceutical Industry

Michael D. Price, CPA  
Vice President, Chief Financial Officer, Secretary  
and Treasurer, Bentley Pharmaceuticals, Inc.

Robert M. Stote, M.D., F.A.C.P.  
Senior Vice President and Chief Science Officer  
Bentley Pharmaceuticals, Inc.

### CORPORATE OFFICES

Bentley Pharmaceuticals, Inc.  
65 Lafayette Road, 3rd Floor  
North Hampton, NH 03862-2403  
Telephone: 603.964.8006  
Facsimile: 603.964.6889  
www.bentleypharm.com

### SUBSIDIARIES

Laboratorios Belmac S.A. - Madrid, Spain  
Laboratorios Davur S.L. - Madrid, Spain

### SECURITIES

The Company's securities are traded on the American and Pacific Stock Exchanges under the following trading symbols:

Common Stock: BNT  
Class B Redeemable Warrants: BNT.WS.B

### TRANSFER AGENT

Correspondence concerning Bentley Pharmaceuticals, Inc. stock certificates, changes in ownership, or changes of address should be directed to:

American Stock Transfer & Trust Company  
40 Wall Street  
New York, NY 10005  
Telephone: 800.937.5449  
Facsimile: 718.921.8323  
E-mail: info@amstock.com  
www.amstock.com

### LEGAL COUNSEL

Jenkins & Gilchrist Parker Chapin LLP  
405 Lexington Avenue  
New York, NY 10174

### INDEPENDENT AUDITORS

Deloitte & Touche LLP  
200 Berkeley Street  
Boston, MA 02116-5022

### AVAILABILITY OF FORM 10-K; INFORMATION REQUESTS

Shareholders may obtain, without charge, a copy of the Company's complete Annual Report on Form 10-K filed with the Securities and Exchange Commission, as well as other published documents, on the Company's website (www.bentleypharm.com) or by contacting the Company's corporate offices at:

Bentley Pharmaceuticals, Inc.  
65 Lafayette Road, 3rd Floor  
North Hampton, NH 03862-2403  
Attention: Celia Brown  
E-mail: invrel@bentleypharm.com

