

BENTLEY PHARMACEUTICALS

*INC*

2002

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ANNUAL  
REPORT



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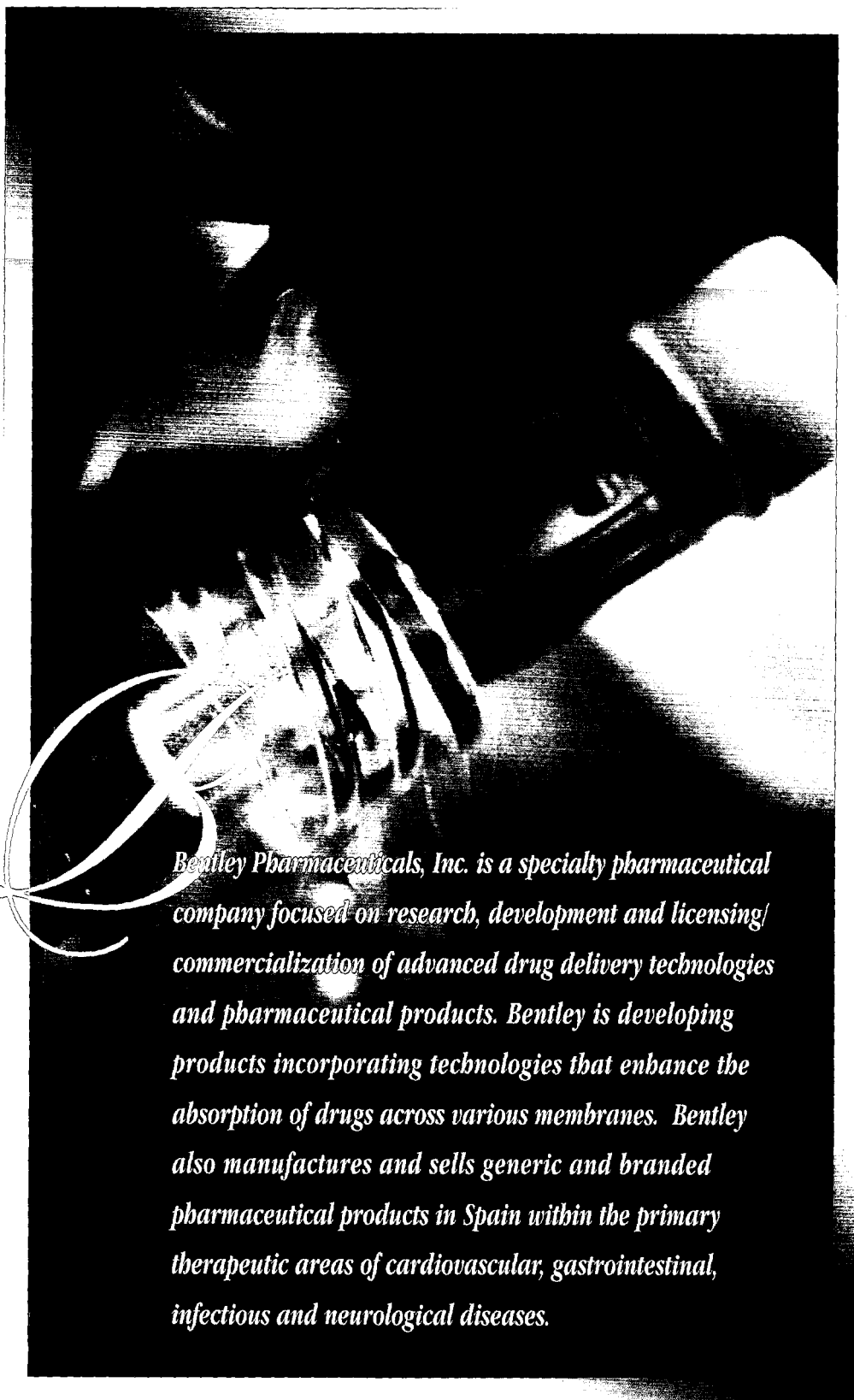
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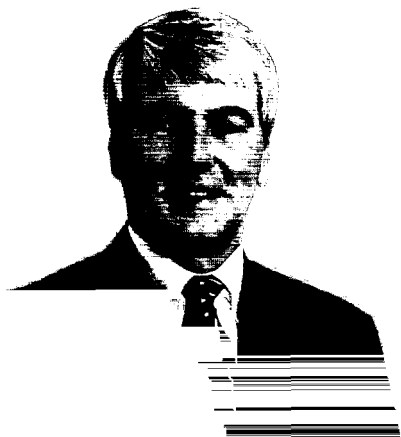
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# BENTLEY PHARMACEUTICALS



*Bentley Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on research, development and licensing/commercialization of advanced drug delivery technologies and pharmaceutical products. Bentley is developing products incorporating technologies that enhance the absorption of drugs across various membranes. Bentley also manufactures and sells generic and branded pharmaceutical products in Spain within the primary therapeutic areas of cardiovascular, gastrointestinal, infectious and neurological diseases.*

## TO OUR SHAREHOLDERS



It gives me great pleasure and pride to report to you the significant accomplishments Bentley Pharmaceuticals has made during the course of the past year in furthering every aspect of our business. We made solid progress with our drug delivery collaborations, European operations and financial performance as we build toward a promising future.

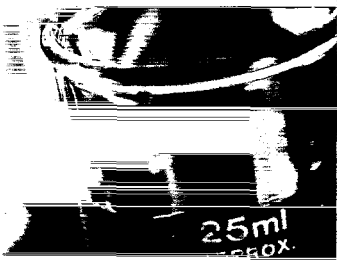
RESEARCH, DEVELOPMENT AND  
LICENSING/COMMERCIALIZATION OF  
ADVANCED DRUG DELIVERY TECHNOLOGIES

### *FDA Approval of First CPE-215™ Product.*

Our most significant accomplishment in validating our CPE-215™ drug delivery technology was the approval of the first product that incorporates our technology. Testim™, a topical testosterone replacement therapy, was approved by the U.S. Food and Drug Administration on October 31, 2002 and launched by our licensee, Auxilium Pharmaceuticals, in February 2003. This gel is used to treat men whose bodies produce insufficient amounts of testosterone (hypogonadism).

### *Anti-fungal Nail Lacquer.*

There are many other products in our pipeline that use our patented CPE-215 technology. We have received extremely encouraging results from the early phase trials of our anti-fungal nail lacquer for the treatment of fingernail and toenail fungal infections (onychomycosis). In August 2002 we announced that the University of Alabama – Birmingham pilot fingernail study showed varying degrees of improvement in more than 80% of patients who completed the study. In March 2003, we announced that our toenail study showed varying degrees of improvement in more than 94% of patients who completed the study.




*CPE-215 Pipeline.*

Other products in the CPE-215 pipeline include intranasal insulin for use by diabetic patients, intranasal pain management and topical hormonal therapy, all of which are in varying stages of development.



*Improved Acetaminophen.*

Another promising area of our development work is a patented improved oral formulation of acetaminophen, the active ingredient in products such as Tylenol® and Panadol®, which are used for controlling pain, fever and inflammation. Our powder sachets and tablets were evaluated



in two studies in which our product showed faster absorption and higher maximum blood concentrations. This product is working its way through the European regulatory process and we are in preliminary discussions with potential collaborators to commercialize it.

EUROPEAN MANUFACTURING AND SALES OF  
GENERIC AND BRANDED PHARMACEUTICAL  
PRODUCTS



***“We made solid progress with our drug delivery collaborations, European operations and financial performance as we build toward a promising future.”***

We have successfully expanded our sales of both generic and branded pharmaceutical products in Spain, which is reflected in the nearly 50% growth in our revenues in 2002 as compared to 2001. Our Spanish subsidiaries have successfully capitalized on the shift toward generic products in Spain's drug market by expanding our generic product line. In addition we have achieved our goals of expanding our product lines in

Spain in our four primary target areas of cardiovascular, gastrointestinal, infectious and neurological diseases. Among the products we either received regulatory approval for or launched in 2002 were: simvastatin, trimetazidine and zolpidem.

*Teva Collaboration.*

We continue to work with Teva Pharmaceutical, a strategic partner in Spain, to seek regulatory

approvals and introduce Teva's products into the Spanish market. We have the right to register and market 75 Teva products in Spain, a few of which will begin to impact our growth this year.

As we ramp up our sales and marketing initiatives in Spain and as our Teva relationship kicks into high gear, combined with the numerous products pending in our pipeline, we expect continued dynamic growth in Spain.

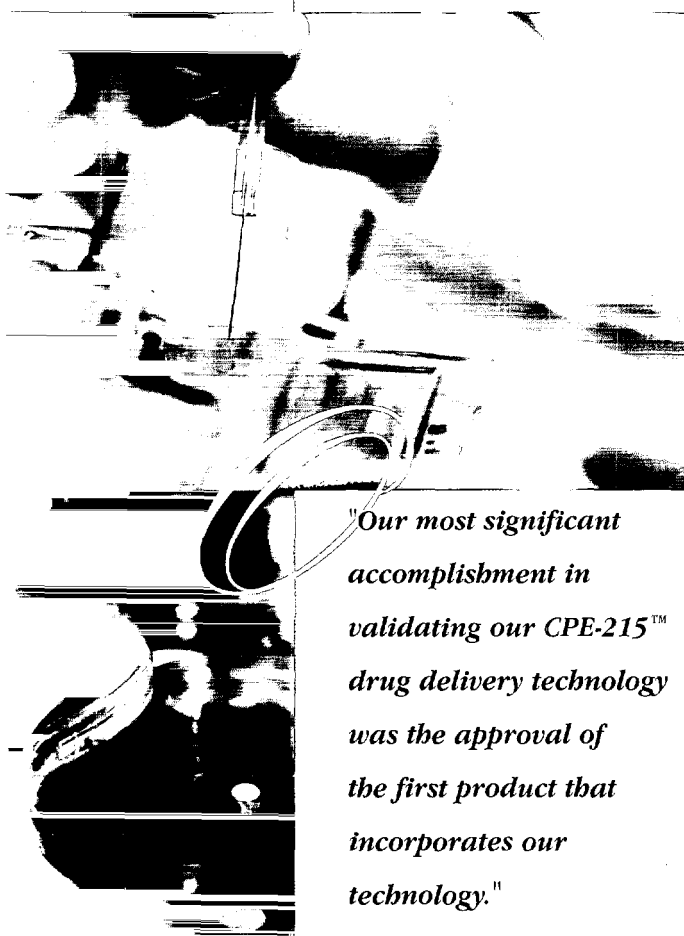
#### FINANCIAL CONDITION

We achieved record financial results in 2002. 2002 total revenues grew 48% to a record


\$39.1 million from \$26.4 million in 2001, primarily reflecting the rapid success of our generic products in Spain. Net income for 2002 reached \$1.6 million, or \$0.10 per basic common share and \$0.08 per diluted common share, compared with \$1.4 million, or \$0.10 per basic common share and \$0.08 per diluted common share, in 2001. It is important to note that the prior year included a gain of \$5.0 million from the sale of a cardiovascular product line, whereas 2002 net income includes gains of only \$650,000 from the sale of drug licenses. Our progress is much more apparent when these gains are excluded from the analysis. Income from operations before the gain on sale of product lines in 2002 totaled \$3.4 million, which is an improvement of \$4.6 million on 2001's loss of \$1.2 million.

Our balance sheet is also quite healthy, with over \$26 million in cash and cash equivalents as of year end,

primarily as a result of our stock offering in 2002. The stock offering of 2.5 million shares in April 2002, raised net proceeds of approximately \$22.1 million for general corporate purposes. We were pleased to work with Raymond James & Associates of St. Petersburg, Florida in placing these shares, many with institutions that had not previously invested in Bentley stock.



***"Our most significant accomplishment in validating our CPE-215™ drug delivery technology was the approval of the first product that incorporates our technology."***




COMMON STOCK AND CORPORATE MATTERS

*Russell 2000 Index.*

Most public companies have been challenged in the current economic environment to keep their business growing and their stock price stable. While we have had some volatility in the past year, we have been quite pleased to have remained relatively stable compared to many others. In July 2002, we joined the Russell 2000 index, which is an index widely used by fund managers as part of both passive and active investment strategies.

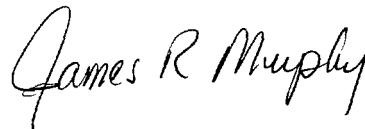
*New Laboratory and Headquarters.*



Early in 2003, we purchased a new corporate headquarters building in Exeter, New Hampshire, which will house our U.S. research and development laboratory as well as our corporate offices. We had clearly outgrown our current space and used the favorable real estate environment to purchase a facility that provides us with room to grow and expand.

As you can tell from this brief summary, we have had a busy and productive year. We have had many achievements that have poised us for even greater successes in the coming years. 2002 was a good year and 2003 is shaping up to be a great year. Thank you for your continued support.

Very truly yours,



James R. Murphy  
Chairman and CEO



***"We have successfully expanded our sales of both generic and branded pharmaceutical products in Spain, which is reflected in the nearly 50% growth in our revenues in 2002 as compared to 2001."***

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, 2002

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. [  ]

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

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

Title of Class	Aggregate Market Value	As of Close of Business on
Common Stock, \$.02 par value	\$177,974,776	June 30, 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	17,456,367	March 7, 2003

DOCUMENTS INCORPORATED BY REFERENCE

Proxy Statement for the 2003 Annual Meeting of Stockholders - Incorporated by  
Reference into Part III of this Form 10-K

\*see inside back cover for current address and phone number

## Part I

### Item 1. Business

#### Overview

We are a specialty pharmaceutical company focused on research, development and licensing/commercialization of advanced drug delivery technologies and pharmaceutical products; and manufacturing and selling of generic and branded pharmaceutical products. In our research and development activities based in the U.S., 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 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.

In our pharmaceutical product sales activities, 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 delivery 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 royalty-based license agreements 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 recently completed Phase I/II clinical trials for the treatment of nail fungus infections and currently are engaged in negotiations 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. See "Regulation" section of Item 1. for a more detailed discussion of the regulatory approval process.

<u>Product Candidate</u>	<u>Technology</u>	<u>Used to Treat</u>	<u>Status</u>
Topical testosterone gel	CPE-215	Hypogonadism	Product launched
Improved acetaminophen	Solubility Enhancement	Pain relief	Bioequivalence
Antifungal nail lacquer	CPE-215	Onychomycosis	Phase I/II
Androgenic steroid therapy	Proprietary	Chronic fatigue syndrome; Fibromyalgia	Pilot study completed
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. All clinical trials performed by Auxilium for approval in the U.S. have been completed and a New Drug Application was approved by the FDA on October 31, 2002. Under the license, we granted to Auxilium a sole and exclusive, royalty-based license worldwide to develop, market and sell Testim™, a topical testosterone product, using our CPE-215 technology, which was launched by Auxilium in February 2003.

### *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 have also completed 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 are in preliminary discussions with potential collaborators to license and market this product.

We evaluated our powder sachets and tablets in comparison to a European commercial market leader, Panadol® tablets, marketed by GlaxoSmithKline, and a U.S. market leader, Tylenol caplets, marketed by McNeil Consumer Healthcare. After a single oral dose of 1000 mg. in healthy volunteers, both our formulations tested in this study, powder sachets and solid tablets, were absorbed to maximum blood concentration significantly faster (approximately half the time) than the other market leading tablets, Panadol and Tylenol. Another study assessed the pharmacokinetic differences in the absorption rate of our new tablet formulation compared to another popular European tablet: Termalgin®, marketed by Laboratorios Novartis Farmacéutica. This study demonstrated that our product had a faster rate of

absorption and higher maximum blood concentration than Termalgin. The average time to reach the maximum blood concentration was 25 minutes for our tablets versus 45 minutes for Termalgin.

#### *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 recently completed Phase I/II clinical trials for the treatment of nail fungal infections at the University of Alabama at Birmingham. Trials for treatment of infections in fingernails have been completed and results have been reported. Trials in toenails were recently completed and results are scheduled to be presented in late March 2003. 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.

The results of the fingernail onychomycosis pilot study shows improvement in over 80% of patients who completed the study. The study, utilizing a clotrimazole lacquer formulation containing CPE-215, revealed that of 18 patients who completed the study, three months following treatment 16 showed improvement over their baseline condition, with five of those showing a complete cure (three or more millimeters of healthy nail growth and a negative culture for the fungus) and an additional ten showing a mycological cure (less than three millimeters of healthy nail growth and a negative culture for the fungus). Patients in the study applied the lacquer on a daily basis for 24 weeks. Most patients reported that they experienced cessation of their discomfort, more pliable nails and the onset of clear nail growth.

#### *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. This study was completed in 2002.

#### *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.

Diabetes is a metabolic disorder affecting approximately 100 million people worldwide that is projected to affect more than 300 million people worldwide in the next 25 years. The market for insulin treatment of diabetes in the United States is estimated at \$1.25 billion annually and Frost & Sullivan estimates that the worldwide market is approximately \$3 billion. Diabetic patients who must endure frequent injections prefer less invasive methods of administering their medications. Alternative and more desirable methods of delivery would not only improve 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 granted to Auxilium a worldwide license to develop, market and sell a topical hormonal therapy containing our CPE-215 technology.

#### **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 Testim, a topical testosterone product. Phase III clinical trials were performed by Auxilium for approval in the U.S. and a New Drug Application was approved by the FDA on October 31, 2002. Testim was launched by Auxilium in February 2003. 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. In September 2002 a license to Auxilium of our CPE-215 technology became effective for a topical hormone therapy product. Preclinical studies currently are underway regarding the application of our CPE-215 technology to a pain management compound.

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. In accordance with the terms of the license agreement, we have received payments, based upon Auxilium's completion of certain milestones, in the aggregate of \$550,000. Terms of the license agreement also entitle us to royalties based on net sales. A similar license agreement became effective in September 2002 for a topical hormone product, also specifying milestones in an aggregate of \$550,000 plus royalties based on net sales. Upon successful completion of preclinical studies for intranasal pain management, a similar license 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 in Spain 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.

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 areas: cardiovascular, gastrointestinal, infectious and neurological diseases. Our generic and branded products are marketed to physicians and pharmacists by our three separate sales and marketing organizations, Laboratorios Davur, Laboratorios Belmac and Laboratorios Rimafar. To a lesser extent, we also market over-the-counter products through Laboratorios Rimafar. There are approximately 90,000 physicians and 20,000 pharmacies in Spain. Revenues from products whose active ingredient is omeprazole accounted for approximately 49% of our net sales in 2002.

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, but increasing 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 2002, generic pharmaceuticals accounted for approximately 42% 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, 47% in 2001 and 39% in 2002. We market our branded and, to a lesser extent, certain of our generic and over-the-counter products through our Laboratorios Belmac subsidiary, which has approximately 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
Cimascal D Forte®	calcium carbonate and vitamin D3	Calcite-D® (Riva)	osteoporosis
Codeisan®	codeine	Tricodein® (Solco)	cough and bronchitis
Belmalip®	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 take place primarily in the United States and are focused on developing new product applications of our drug delivery and drug formulation technologies. We currently have 12 scientists and technicians working on research and product development. For the years ended December 31, 2002, 2001 and 2000, our research and product development expenditures were \$2,960,000, \$2,084,000 and \$1,102,000, respectively.

### **Manufacturing**

Our 65,000 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 Farma 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 product sales declined from approximately 50% in 1994 to approximately 19% in 2002. 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 revenues 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 49% of our net sales in 2002. 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, Laboratorios Davur and Laboratorios Rimafar actively promote our products to physicians and retail pharmacists. We sell our products directly to pharmaceutical distributors and indirectly to customers who purchase our products from distributors. 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 2002, 2001 and 2000, Cofares was our only customer accounting for more than ten percent of our consolidated net sales of approximately 14%, 15% and 14%, respectively.

In the United States, we have entered into research and license agreements with pharmaceutical companies, whereby we perform research activities and license product candidates in exchange for milestone payments and future royalties from product 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 prices and reimbursement prices of certain healthcare products. In addition, the prices for all prescription products in Spain are determined by the Spanish Ministry of Health. In order to control rising healthcare costs, substitution of generically equivalent products is often encouraged. In certain circumstances, the local governments in Spain require that prescriptions for generic medications be filled using one of the three cheapest products on the market unless the prescription specifies a particular manufacturer's product. 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 287 people, 10 of whom are employed in the U.S. and 277 in Spain, as of March 7, 2003. Approximately 88 of these employees principally are engaged in manufacturing activities, 149 in sales and marketing, 12 in product development and 38 in management and administration. In general, we consider our relations with our employees to be good.

## **Internet Information and SEC Documents**

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

## **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 may not be able to continue our growth and we will be adversely affected.

We intend to expend significant resources and efforts toward identifying and commercializing products and technologies to expand our generic and branded drug operations in Spain. 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, Merck brought the same claims in another proceeding in January 2003. 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 49% of our net sales in 2002. 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, Merck brought the same claims in another proceeding in January 2003. 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, 2002, 99% of our revenues were derived from sales made by our Spanish subsidiaries in Spain and a small portion of those revenues (six 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., Laboratorios Davur S.L. and Laboratorios Rimafar S.L. Our Spanish subsidiaries reported an increase in net sales of 42% in local currency for the year ended December 31, 2002 compared to the prior year; however, an increase in the value of the Euro, in relation to the U.S. Dollar, had the effect of increasing revenues by approximately \$2,145,000 during the year ended December 31, 2002. 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.

**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 48% and our research and development expenditures increased 42% from the year ended December 31, 2001 to the year ended December 31, 2002, 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. In order to control rising healthcare costs, substitution of generically equivalent products is often encouraged. In certain circumstances, the local governments in Spain require that prescriptions for generic medications be filled using one of the three cheapest products on the market unless the prescription specifies a particular manufacturer's product. 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 twenty-four months. However our revenues from operations and cash may not be sufficient over the next several years for commercializing all of the products we are currently developing. Consequently, we 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 \$3.25 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, 2002, we had the following capital structure:

Common stock outstanding	17,404,000
Common stock issuable upon:	
Exercise of Class B Warrants	2,872,000
Exercise of other warrants	420,000
Exercise of options which are outstanding	3,459,000
Exercise of options which have not been granted	<u>309,000</u>
Total common stock outstanding assuming exercise of all of the above	<u>24,464,000</u>

As of December 31, 2002, we had outstanding options and warrants to purchase approximately 6,751,000 shares of common stock at exercise prices ranging from \$1.50 to \$22.50 (exercisable at a weighted average of \$5.39 per share), of which approximately 6,002,000 options and warrants were then exercisable. Since December 31, 2002 we have granted options to purchase 250,000 shares of common stock, exercisable at a weighted average of \$8.07 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 \$12.08 to a low of \$4.40. Future announcements concerning us or our competitors may have a significant impact on the market price of our common stock. Factors which may affect our market price include:

- progress of our relationships with strategic partners;
- results of clinical studies and regulatory reviews;
- technological innovations by us or our competitors;
- market conditions in the pharmaceutical, drug delivery and biotechnology industries;
- 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 purchased a 15,700 square foot commercial building situated on approximately 14 acres of land in Exeter, New Hampshire in January 2003. We plan to move our corporate headquarters and research and development laboratory into this facility in April 2003. We are located approximately 45 minutes north of Boston, Massachusetts.

We also lease a 3,200 square foot facility in North Hampton, New Hampshire. The lease for this facility expires in March 2004.

We own a 65,000 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**

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. Merck re-instituted its claim against us in another proceeding brought in the 19<sup>th</sup> First Instance Court of the City of Madrid, which we received on January 23, 2003. This case also alleges violation of Merck's patents in the production of the product simvastatin, requests an order that we cease manufacturing the product and demands damages during the period of manufacture. We intend to vigorously oppose this claim as we believe it is without merit. Simvastatin was launched in January 2002 and sales of this product totaled approximately \$1,300,000 during the year ended December 31, 2002.

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

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

Not applicable.

## Part II

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

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

	<u>High</u>	<u>Low</u>
<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	11.57	7.60
Second Quarter	12.08	9.95
Third Quarter	11.60	8.35
Fourth Quarter	10.00	6.40
<b>Fiscal 2003</b>		
First Quarter (through March 7, 2003)	9.70	7.85

As of March 7, 2003 there were 1,125 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, 2002 and consolidated balance sheet data as of December 31, 2001 and 2002, 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, 2002 and as of December 31, 2001 and 2002 should be read together with our consolidated financial statements and related notes appearing elsewhere in Item 15 of this Annual Report on Form 10-K and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Our independent auditors have audited our consolidated financial statements for each of the five years in the period ended December 31, 2002. The consolidated statement of operations for each of the two years in the period ended December 31, 1999 are derived from our audited consolidated financial statements and related notes not included in Item 15 of this Annual Report on Form 10-K.

## Consolidated Statement of Operations Data

<i>(in thousands, except per share data)</i>	Year Ended December 31,				
	1998	1999	2000	2001	2002
Total revenues	\$15,243	\$20,249	\$18,617	\$26,411	\$39,136
Cost of sales	6,601	8,445	7,189	11,462	16,477
Gross profit	8,642	11,804	11,428	14,949	22,659
Operating expenses	10,710	11,226	11,942	16,137	19,277
Gain on sale of drug licenses	-	-	-	5,050	650
Provision for foreign income taxes	236	781	222	2,452	2,534
Net income (loss)	<u>\$ (2,876)</u>	<u>\$ (1,090)</u>	<u>\$ (745)</u>	<u>\$ 1,361</u>	<u>\$ 1,636</u>
Net income (loss) per common share – basic	<u>\$ (.35)</u>	<u>\$ (.12)</u>	<u>\$ (.06)</u>	<u>\$ .10</u>	<u>\$ .10</u>
Net income (loss) per common share – diluted	<u>\$ (.35)</u>	<u>\$ (.12)</u>	<u>\$ (.06)</u>	<u>\$ .08</u>	<u>\$ .08</u>
Weighted average common shares outstanding – basic	<u>8,431</u>	<u>9,147</u>	<u>12,981</u>	<u>14,196</u>	<u>16,569</u>
Weighted average common shares outstanding – diluted	<u>8,431</u>	<u>9,147</u>	<u>12,981</u>	<u>16,147</u>	<u>19,798</u>

## Consolidated Balance Sheet Data

<i>(in thousands)</i>	December 31,	
	2001	2002
Working capital	\$ 6,276	\$30,703
Non-current assets	16,280	20,720
Total assets	32,119	64,692
Non-current liabilities	2,132	2,672
Redeemable preferred stock	-	-
Stockholders' equity	20,424	48,751

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

### GENERAL

We are a specialty pharmaceutical company operating in two business segments: research, development and licensing/commercialization of advanced drug delivery technologies and pharmaceutical products; and manufacturing and selling of generic and branded 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 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 Testim, a topical testosterone product. Clinical trials performed by Auxilium for the approval of this product in the U.S. have been completed, a New Drug Application was approved by the FDA on October 31, 2002 and Testim was launched by Auxilium in February 2003.

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.

We entered into a strategic alliance with Teva in July 2000 whereby we, through our Spanish subsidiaries, received the right to register and sell 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, 2002, net operating losses available to offset future domestic taxable income for federal income tax purposes were approximately \$38,366,000 million. Our U.S. federal net operating loss carryforwards, if not utilized, expire at various dates from 2007 to 2023. 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, 2002 Compared To Fiscal Year Ended December 31, 2001

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

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

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

*Gross Profit.* Gross profit increased by 52% from \$14,949,000 in 2001 to \$22,659,000 in 2002. The \$7,710,000 increase was the direct result of the growth in our net product sales from 2001 to 2002. Our gross margins on net product sales in 2002 increased slightly to 57.4% compared to 56.6% in the prior year as result of economies of scale (allocation of fixed costs over a larger number of units, reducing the per-unit cost), partially offset by lower margins of generic products, which typically have lower prices. We experienced an increase in gross profit of 42% in local

currency in 2002 compared to the prior year. An increase in the weighted average value of the Euro, in relation to the U.S. Dollar over the past 12 months, had the effect of increasing gross profit by approximately \$1,218,000 during the year ended December 31, 2002. Sales of generic products accounted for approximately 42% of our net product sales during the year ended December 31, 2002, compared to 30% in the prior year. Although we expect to continue to benefit from economies of scale in the future as we grow, gross margins may decrease as sales of generic products, with lower margins, become more significant in the future. Additionally, the Ministry of Health in Spain levies a tax on pharmaceutical companies for the purpose of funding rising healthcare costs in Spain. In 2002, this tax had the effect of reducing gross profit by approximately \$551,000 and gross margins by approximately 1 percentage point.

*Selling and Marketing Expenses.* Selling and marketing expenses increased by 15% from \$9,057,000 in 2001 to \$10,400,000 in 2002. The \$1,343,000 increase was instrumental in achieving a 47% increase in net product sales during the period, as a result of our successful sales and marketing programs. The increase in the weighted average value of the Euro, in relation to the U.S. Dollar, over the past 12 months had the effect of increasing selling and marketing expenses by \$537,000 in 2002. Selling and marketing expenses as a percentage of net product sales decreased to 27% in 2002 compared to 34% of sales in 2001.

*General and Administrative Expenses.* General and administrative expenses increased by 20% from \$4,085,000 in 2001 to \$4,902,000 in 2002. The \$817,000 increase was the result of increased general and administrative activities required to support our revenue growth in 2002. General and administrative expenses as a percent of total revenues decreased to only 12.5% in 2002, compared to 15.5% of revenues in 2001. General and administrative expenses would have been approximately \$162,000 lower in 2002, absent the increase in the weighted average value of the Euro, in relation to the U.S. Dollar, over the past 12 months. We expect that our future expenditures for general and administrative expenses will continue to increase as we grow. Although we cannot reasonably estimate the costs associated with implementation of the internal control provisions of the Sarbanes-Oxley Act of 2002, we do expect to incur costs not previously experienced; however, we do not believe that these costs will be material to our financial position, results of operations or cash flows.

*Research and Development Expenses.* Research and development expenses increased by 42% from \$2,084,000 in 2001 to \$2,960,000 in 2002. The \$876,000 increase was the result of an increase in our costs associated with our research and development collaboration as well as our Phase I/II Clinical Studies (treatment of nail fungal infections), pre-clinical programs underway in collaboration with universities and with product formulation and testing efforts being performed in the laboratory in our U.S. headquarters and at our facility in Zaragoza, Spain. We are using our U.S. laboratory to develop potential product applications using our drug delivery technologies. The expenditures in research and development reflect our focus on projects that are necessary for expansion of our portfolio of marketed products and clinical trials involving our drug delivery technologies. We expect that our future expenditures for research and development activities will continue to increase as a result of programs that are necessary to advance new applications of our technologies.

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

*Interest Income.* Interest income increased by 66% from \$168,000 in 2001 to \$279,000 in 2002. The \$111,000 increase was the result of higher short-term interest bearing investment balances, partially offset by lower interest rates on the existing investment balances during 2002 compared to 2001.

*Interest Expense.* Interest expense decreased by 14% from \$244,000 in 2001 to \$209,000 in 2002. The \$35,000 decrease was the result of lower interest rates on lines of credit used for operating purposes and lines of credit and borrowings used to finance capital equipment and improvements in Spain.

*Provision for Income Taxes.* We generated additional U.S. federal net operating loss carry-forwards in 2002. However, since we are not assured of future profitable domestic operations, we have recorded a valuation allowance for any future tax benefit of such losses in the U.S. Therefore, no benefit has been recognized with respect to U.S. losses reported in 2002. We recorded a provision for foreign income taxes totaling \$2,534,000 (37% of Spanish pre-tax income) for the year ended December 31, 2002 compared to a provision for foreign income taxes of \$2,452,000 in the prior year. The provision for income taxes for 2002 included approximately \$2,304,000 as a result of reporting taxable income from operations in Spain and approximately \$230,000 as a result of capital gains taxes arising from the sale of Biolid®, Lactolifil® and other drug licenses, whereas the provision for income taxes in the prior year



included approximately \$607,000 as a result of reporting taxable income from operations in Spain and approximately \$1,845,000 as a result of capital gains taxes arising from the sale of drug licenses. The provision for foreign income taxes would have been approximately \$110,000 lower than reported, absent the increase in the weighted average value of the Euro, in relation to the U.S. Dollar, over the past 12 months.

*Net Income.* Including the \$650,000 pre-tax gain on sale of the Biolid, Lactiofil and other drug licenses, we reported income from operations of \$4,032,000 for 2002 compared to income from operations of \$3,862,000 (including \$4,977,000 of pre-tax gain on sale of the Controlvas® drug license) in the prior year. Excluding the \$650,000 pre-tax gain from the sale of drug licenses, income from operations for the year ended December 31, 2002 totaled \$3,382,000 compared to a loss of \$1,188,000 in the prior year. The combination of income from operations of \$4,032,000 and the non-operating items, primarily the provision for foreign income taxes of \$2,534,000, resulted in net income of \$1,636,000, or \$.10 per basic common share (\$.08 per diluted common share) on 16,569,000 weighted average basic common shares outstanding (19,798,000 weighted average diluted common shares outstanding) for 2002, compared to net income in the prior year of \$1,361,000, or \$.10 per basic common share (\$.08 per diluted common share) on 14,196,000 weighted average basic common shares outstanding (16,147,000 weighted average diluted common shares outstanding).

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

*Net Product Sales.* Net product sales increased by 42.9% from \$18,487,000 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 ArzimoI™ 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 revenues

declined to 15.5% of net sales in 2001 compared to 20.2% of net revenues 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.

*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®, (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).

*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 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 and Amantadine®, 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 and Amantadine, 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 and Amantadine 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.

## 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 2001				Fiscal 2002			
	3/31/01(1)	6/30/01	9/30/01	12/31/01	3/31/02(2)	6/30/02(2)	9/30/02(2)	12/31/02
Total revenues	\$5,814	\$6,125	\$6,316	\$8,156	\$9,174	\$9,867	\$8,571	\$11,524
Gross profit	3,365	3,438	3,608	4,538	5,398	5,618	4,992	6,651
Income (loss) from operations	4,612	(468)	120	(402)	755	1,395	692	1,190
Net income (loss)	2,642	(569)	(149)	(563)	135	519	291	691
Net income (loss) per common share:								
Basic	\$ .19	\$ (.04)	\$ (.01)	\$ (.04)	\$ .01	\$ .03	\$ .01	\$ .04
Diluted	\$ .17	\$ (.04)	\$ (.01)	\$ (.04)	\$ .01	\$ .03	\$ .02	\$ .03

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

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

## Liquidity and Capital Resources

Total assets increased from \$32,119,000 at December 31, 2001 to \$64,692,000 at December 31, 2002, while stockholders' equity increased from \$20,424,000 at December 31, 2001 to \$48,751,000 at December 31, 2002. The increase in stockholders' equity reflects primarily the net proceeds of \$22,108,000 from the April 2002 common stock offering, the exercise of stock options and warrants totaling \$1,375,000, the positive impact of the fluctuation of the Euro/US dollar exchange rate which totaled \$3,054,000 and net income of \$1,636,000.

Working capital increased from \$6,276,000 at December 31, 2001 to \$30,703,000 at December 31, 2002, primarily as a result of proceeds from the April 2002 common stock offering and exercises of stock options and warrants, partially offset by additions to fixed assets.

Cash, cash equivalents and marketable securities increased from \$5,736,000 at December 31, 2001 to \$26,977,000 at December 31, 2002, primarily as a result of net proceeds received from the April 2002 common stock offering, the net proceeds of which totaled \$22,108,000, proceeds received from exercises of stock options and warrants totaling \$1,375,000 and cash provided by operating activities of \$1,049,000, partially offset by net repayment of borrowings of \$198,000 and additions to fixed assets totaling \$3,432,000. Also included in cash and cash equivalents at December 31, 2002 are approximately \$23,360,000 of short-term liquid investments considered to be cash equivalents.

Receivables increased from \$6,937,000 at December 31, 2001 to \$10,874,000 at December 31, 2002 as a direct result of the increase in net product sales. Receivables increased by approximately \$2,302,000 in local currency, but fluctuations in foreign currency exchange rates increased receivables reported in U.S. dollars by approximately \$1,635,000. We have not experienced any material delinquencies on our receivables that have had a material effect on our financial position, results of operations or cash flows. Inventories increased from \$2,563,000 at December 31, 2001 to \$5,133,000 at December 31, 2002 primarily as a result of raw materials purchases and strategic increases in finished goods inventories in anticipation of continuing demand for our generic products. Inventories increased by approximately \$1,796,000 in local currency, but fluctuations in foreign currency exchange rates increased inventories reported in U.S. dollars by approximately \$774,000.

The combined total of accounts payable and accrued expenses increased from \$7,310,000 at December 31, 2001 to \$11,265,000 at December 31, 2002, primarily due to accruals for taxes payable (approximately \$1,342,000), as well as for inventory purchases (approximately \$1,463,000), additions to drug licenses (approximately \$166,000) and additions to fixed assets of \$245,000, as well as the effect of fluctuations in foreign currency exchange rates (approximately \$1,751,000), partially offset by a decrease in the reserves for potential sales returns (approximately \$53,000).

Short-term borrowings and current portion of long-term debt decreased from \$1,757,000 at December 31, 2001 to \$1,725,000 at December 31, 2002, as a result of net repayment of short-term borrowings, partially offset by the effect of fluctuations in foreign currency exchange rates. The weighted average interest rate on our short-term borrowings and current portion of long-term debt is 5.0%.

Long-term debt, which totaled \$142,000 at December 31, 2001, increased to \$345,000 during the year ended December 31, 2002 as a result of long-term equipment financing. The weighted average interest rate (including imputed interest) on our long-term debt is 5.2%.

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, 2002:

<i>(in thousands)</i>	Payments Due By Period				
	Total	Less Than 1 Year	1-3 Years	4-6 Years	7-10 Years
<b>Contractual Obligations</b>					
Short-term borrowings	\$1,598	\$1,598	\$ -	\$ -	\$ -
Long-term debt, including imputed interest of \$105	568	127	153	162	126
Operating leases	2,453	808	1,640	5	-
Total contractual cash obligations	<u>\$4,619</u>	<u>\$2,533</u>	<u>\$1,793</u>	<u>\$167</u>	<u>\$126</u>

Operating activities for the year ended December 31, 2002 provided net cash of \$1,049,000. Investing activities, primarily additions to machinery and equipment and capital improvements made to the manufacturing facility in Spain used net cash of \$3,696,000 during the year ended December 31, 2002. Financing activities, consisting primarily of net proceeds received from the April 2002 offering of common stock (approximately \$22,108,000) and the proceeds received from the exercise of stock options and warrants (approximately \$1,375,000), partially offset by net repayments of borrowings (approximately \$198,000) provided net cash of \$23,285,000 during the year ended December 31, 2002.

As discussed in Item 1., we also entered into a perpetual license agreement whereby we granted to Auxilium an exclusive royalty-based worldwide license, to develop, market and sell a topical testosterone gel containing our CPE-215 technology. In accordance with the terms of the license agreement, we have received payments, based upon Auxilium's completion of certain milestones, in the aggregate of \$550,000. Terms of the license agreement also entitle us to royalties based on net sales. Auxilium launched the product, named Testim, in February 2003 and we expect to receive royalty payments beginning in 2003. We are unable to estimate the amount or timing of these royalty payments at this time.

We plan to continue making improvements to our manufacturing facility during 2003 that include the acquisition of additional manufacturing equipment, in order to accommodate our expected growth. We have budgeted approximately \$2,340,000 for these capital expenditures related to these improvements and additions during 2003. Additionally, as discussed in Item 2., we purchased a 15,700 square foot commercial building situated on approximately 14 acres of land in Exeter, New Hampshire in January 2003. We plan to move our corporate headquarters and research and development laboratory into this facility in April 2003. We paid approximately \$1,776,000 cash for the property and expect to spend approximately \$450,000 in order to expand our research and development facility and add necessary research equipment.

*Seasonality, Effect of Inflation and Liquidity.* In the past, we have experienced lower sales in the third calendar quarter and higher sales in the fourth calendar quarter due to seasonality. As we market more pharmaceutical products whose sales are seasonal, seasonality of sales may become more significant. Neither inflation nor changing prices has materially impacted our revenues or income from operations for the periods presented. We expect to have sufficient liquidity to fund operations for at least the next twenty-four months. We continue to 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 purchase authorizations from our customers for a specified amount of product at a specified price and consider delivery to have occurred when the customer takes possession of the products. We provide our customers with a limited right of return. Revenue is recognized upon delivery of products 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 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 for periods not exceeding 15 years from the dates of acquisition. Carrying values of such assets are reviewed quarterly by comparing the carrying amounts to their estimated undiscounted cash flows and adjustments are made for any diminution in value.

### **New Accounting Standards**

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 Opinion 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 was required for fiscal years beginning after December 15, 2001, except for the nonamortization and amortization provisions which are required for goodwill and intangible assets acquired after June 30, 2001. The adoption of SFAS No. 141 and SFAS No. 142 did not have a material impact on our financial position, results of operations or cash flows.

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 our financial position, results of operations or cash flows.

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

No. 148's amendment of the transition and annual disclosure provisions of SFAS No. 123 are effective for fiscal years ending after December 15, 2002. The disclosure provisions for interim financial statements are effective for interim periods beginning after December 15, 2002. We currently account for stock-based compensation utilizing the intrinsic value method of accounting for stock-based employee compensation described by APB Opinion No. 25.

In December 2002, the Financial Accounting Standards Board issued Interpretation No. 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others* ("FIN 45"). FIN 45 elaborates on the disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under certain guarantees that it has issued. It also clarifies that a guarantor is required to recognize, at the inception of a guarantee, a liability for the fair value of the obligation undertaken in issuing the guarantee. We have adopted the disclosure requirements of FIN 45 as of December 31, 2002 and determined that no additional disclosures were required. In addition, we are required to adopt the initial recognition and measurement of the fair value of the obligation undertaken in issuing the guarantee on a prospective basis to guarantees issued or modified after December 31, 2002. We do not believe FIN 45 will have a material effect on our financial position, results of operations or cash flows.

In November 2002, the Emerging Issues Task Force ("EITF") issued EITF Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*. EITF Issue No. 00-21 addresses certain aspects of the accounting by a vendor for arrangements under which it will perform multiple revenue-generating activities. EITF Issue No. 00-21 establishes three principles: revenue arrangements with multiple deliverables should be divided into separate units of accounting, arrangement consideration should be allocated among the separate units of accounting based on their relative fair values, and revenue recognition criteria should be considered separately for separate units of accounting. EITF Issue No. 00-21 is effective for all revenue arrangements entered into in fiscal periods beginning after June 15, 2003, with early adoption permitted. We do not believe EITF Issue No. 00-21 will have a material effect on our financial position, results of operations or cash flows.

In November 2001, the EITF reached a consensus on EITF Issue No. 01-09, *Accounting for Consideration Given by a Vendor to a Customer or a Reseller of the Vendor's Products*, which is a codification of EITF Issues No. 00-14, 00-22 and 00-25. This issue presumes that consideration from a vendor to a customer or reseller of the vendor's products to be a reduction of the selling prices of the vendor's products and, therefore, should be characterized as a reduction of revenues under certain circumstances. Revenue reduction is required unless consideration relates to a separate identifiable benefit and the benefit's fair value can be established. EITF Issue No. 01-09 is effective for fiscal years beginning after December 15, 2001 and interim periods within those fiscal years. The adoption of EITF Issue No. 01-09 did not have a material effect on our financial position, results of operations or cash flows.

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

*Foreign Currency.* A substantial amount of our business is conducted in Europe and is therefore influenced to the extent to which there are fluctuations in the U.S. Dollar's value against other currencies, specifically the Euro. The exchange rate at December 31, 2002 and 2001 was .95 Euros and 1.12 Euros per U.S. Dollar, respectively. The weighted average exchange rate for the years ended December 31, 2002, 2001 and 2000 was 1.06 Euros, 1.12 Euros and 1.09 Euros per U.S. Dollar, respectively. The effect of foreign currency fluctuations on long lived assets for the year ended December 31, 2002 was an increase of \$3,054,000 and the cumulative historical effect was a decrease of \$416,000, as reflected in our Consolidated Balance Sheets as *accumulated other comprehensive loss*. Although exchange rates fluctuated significantly in recent years, we do not believe that the effect of foreign currency fluctuation is material to our results of operations as the expenses related to much of our foreign currency revenues are in the same 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 revenues and expenses. Nonetheless, we do not plan to modify our business practices.

We have relied primarily upon financing activities to fund our operations in the U.S. In the event that we are required to fund U.S. operations or cash needs with funds generated in 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 and current portion of long-term debt is 5.0% and the balance outstanding is \$1,725,000 as of December 31, 2002. A portion of our long-term borrowings is non-interest bearing and the balance outstanding on these borrowings at December 31, 2002 is \$378,000 including imputed interest (ranging from 4.8% to 6.0%) of \$105,000. The balance of our long-term borrowings of \$63,000 bears

interest at the rate of 2.9%. Consequently, the weighted average interest rate on our long-term borrowings is 5.2%. The effect of an increase in the interest rate of one percentage point (one hundred basis points) to 6.0% on short-term borrowings and to 6.2% on long-term borrowings would have the effect of increasing interest expense by approximately \$22,000 annually.

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

See Item 15 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 2003 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 2003 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 2003 Annual Meeting of Stockholders to be filed pursuant to Regulation 14A.

**Item 14. Controls and Procedures**

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

Within 90 days prior to the date of this report, Bentley carried out an evaluation, under the supervision and with the participation of Bentley's management, including the Company's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of Bentley's disclosure controls and procedures. Based on that evaluation, Bentley's Chief Executive Officer and Chief Financial Officer concluded that Bentley's disclosure controls and procedures are effective in timely alerting them to material information relating to Bentley (including its consolidated subsidiaries) which is required to be included in its publicly filed reports. There have been no significant changes in Bentley's internal controls or in other factors which could significantly affect internal controls since that evaluation.

\* This information has been omitted from this 2002 Annual Report, but is included in our Annual Report on Form 10-K for the year ended December 31, 2002. See inside back cover for information about obtaining a copy of the complete Form 10-K.

## Part IV

### Item 15. 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, 2002 and 2001	F-2
Consolidated Statements of Operations and of Comprehensive Income (Loss) for the years ended December 31, 2002, 2001 and 2000	F-3
Consolidated Statements of Changes in Stockholders' Equity for the years ended December 31, 2002, 2001 and 2000	F-4
Consolidated Statements of Cash Flows for the years ended December 31, 2002, 2001 and 2000	F-5 to F-6
Notes to Consolidated Financial Statements	F-7 to F-21
(3) Exhibits*	
(b) Reports on Form 8-K filed during the fiscal quarter ended December 31, 2002:	
None.	

\* This information has been omitted from this 2002 Annual Report, but is included in our Annual Report on Form 10-K for the year ended December 31, 2002. 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: March 13, 2003

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)	March 13, 2003
<u>/s/ Michael McGovern</u> Michael McGovern	Vice Chairman and Director	March 13, 2003
<u>/s/ Robert M. Stote</u> Robert M. Stote, M.D.	Senior Vice President, Chief Science Officer and Director	March 13, 2003
<u>/s/ Michael D. Price</u> Michael D. Price	Vice-President, Chief Financial Officer, Treasurer, Secretary and Director (principal financial and accounting officer)	March 13, 2003
<u>/s/ Robert J. Gyurik</u> Robert J. Gyurik	Vice President of Pharmaceutical Development and Director	March 13, 2003
<u>/s/ Charles L. Bolling</u> Charles L. Bolling	Director	March 13, 2003
<u>/s/ Miguel Fernandez</u> Miguel Fernandez	Director	March 13, 2003
<u>/s/ William A. Packer</u> William A. Packer	Director	March 13, 2003
<u>/s/ John W. Spiegel</u> John W. Spiegel	Director	March 13, 2003

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**INDEPENDENT AUDITORS' REPORT**

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, 2002 and 2001, 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, 2002. 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, 2002 and 2001, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2002 in conformity with accounting principles generally accepted in the United States of America.

*Deloitte & Touche LLP*

Boston, Massachusetts  
February 26, 2003

**BENTLEY PHARMACEUTICALS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS**

(in thousands)

	December 31,	
	2002	2001
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 26,581	\$ 5,736
Marketable securities	396	-
Receivables, net	10,874	6,937
Inventories, net	5,133	2,563
Deferred foreign taxes	123	141
Prepaid expenses and other	865	462
Total current assets	43,972	15,839
Non-current assets:		
Fixed assets, net	9,565	5,595
Drug licenses and related costs, net	10,975	10,276
Other	180	409
Total non-current assets	20,720	16,280
	\$ 64,692	\$ 32,119
 <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 7,206	\$ 4,820
Accrued expenses	4,059	2,490
Short-term borrowings	1,598	1,757
Current portion of long-term debt	127	-
Deferred income	279	496
Total current liabilities	13,269	9,563
Non-current liabilities:		
Foreign taxes payable	2,141	1,827
Long-term debt	345	142
Other	186	163
Total non-current liabilities	2,672	2,132
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$1.00 par value, authorized 2,000 shares, issued and outstanding, zero shares	-	-
Common stock, \$.02 par value, authorized 35,000 shares, issued and outstanding, 17,404 and 14,585 shares	348	292
Stock purchase warrants (to purchase 3,292 and 3,424 shares of common stock)	431	433
Additional paid-in capital	121,084	97,501
Accumulated deficit	(72,696)	(74,332)
Accumulated other comprehensive loss	(416)	(3,470)
Total stockholders' equity	48,751	20,424
	\$ 64,692	\$ 32,119

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)

	For the Year Ended December 31,		
	2002	2001	2000
Revenues:			
Net product sales	\$38,718	\$26,411	\$18,487
Licensing and collaboration revenue	418	-	130
Total revenues	39,136	26,411	18,617
Cost of net product sales	16,477	11,462	7,189
Gross profit	22,659	14,949	11,428
Operating expenses:			
Selling and marketing	10,400	9,057	6,494
General and administrative	4,902	4,085	3,766
Research and development	2,960	2,084	1,102
Depreciation and amortization	1,015	911	580
Total operating expenses	19,277	16,137	11,942
Income (loss) from operations before sale of drug licenses	3,382	(1,188)	(514)
Gain on sale of drug licenses	650	5,050	-
Income (loss) from operations	4,032	3,862	(514)
Other income (expenses):			
Interest income	279	168	347
Interest expense	(209)	(244)	(439)
Other	68	27	83
Income (loss) before income taxes	4,170	3,813	(523)
Provision for foreign income taxes	2,534	2,452	222
Net income (loss)	\$ 1,636	\$ 1,361	\$ (745)
Net income (loss) per common share:			
Basic	\$ .10	\$ .10	\$ (.06)
Diluted	\$ .08	\$ .08	\$ (.06)
Weighted average common shares outstanding:			
Basic	16,569	14,196	12,981
Diluted	19,798	16,147	12,981
Net income (loss)	\$ 1,636	\$ 1,361	\$ (745)
Other comprehensive income (loss):			
Foreign currency translation gains (losses)	3,054	(842)	(289)
Comprehensive income (loss)	\$ 4,690	\$ 519	\$ (1,034)

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

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

(in thousands)

	\$.02 Par Value Common Stock		Stock Purchase Warrants	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
	Shares	Amount					
Balance at December 31, 1999	10,230	\$204	\$ 799	\$ 87,858	\$(74,948)	\$(2,339)	\$11,574
Conversion of debentures	2,901	58	-	4,682	-	-	4,740
Exercise of stock options/warrants	684	15	(414)	2,197	-	-	1,798
Exercise of Class B redeemable warrants	99	1	(2)	493	-	-	492
Exercise of underwriter's warrants	-	-	249	(3)	-	-	246
Foreign currency translation adjustment	-	-	-	-	-	(289)	(289)
Net loss	-	-	-	-	(745)	-	(745)
Balance at December 31, 2000	<u>13,914</u>	<u>278</u>	<u>632</u>	<u>95,227</u>	<u>(75,693)</u>	<u>(2,628)</u>	<u>17,816</u>
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>
Offering of common stock, net	2,500	50	-	22,058	-	-	22,108
Exercise of stock options/warrants	304	6	(2)	1,369	-	-	1,373
Equity based compensation	15	-	-	156	-	-	156
Foreign currency translation adjustment	-	-	-	-	-	3,054	3,054
Net income	-	-	-	-	1,636	-	1,636
Balance at December 31, 2002	<u>17,404</u>	<u>\$348</u>	<u>\$ 431</u>	<u>\$121,084</u>	<u>\$(72,696)</u>	<u>\$ (416)</u>	<u>\$48,751</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,		
	2002	2001	2000
Cash flows from operating activities:			
Net income (loss)	\$ 1,636	\$ 1,361	\$ (745)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Gain on sale of drug licenses	(650)	(5,050)	-
Depreciation and amortization	1,584	1,235	840
Equity-based compensation expense	156	262	69
Other non-cash items	597	(188)	2
(Increase) decrease in assets and increase (decrease) in liabilities:			
Receivables	(1,949)	(2,060)	(1,385)
Inventories	(1,796)	(864)	(1,003)
Deferred foreign taxes	45	1,629	-
Prepaid expenses and other current assets	(259)	100	(205)
Other assets	24	(11)	(97)
Accounts payable and accrued expenses	1,855	3,306	(171)
Deferred income	(217)	496	-
Other liabilities	23	(77)	(5)
Net cash provided by (used in) operating activities	1,049	139	(2,700)
Cash flows from investing activities:			
Proceeds from sale of drug licenses	656	2,698	2,564
Proceeds from sale of investments	56,190	31,645	17,193
Purchase of investments	(56,314)	(31,567)	(15,171)
Additions to fixed assets	(3,432)	(1,595)	(1,014)
Additions to drug licenses and related costs	(796)	(437)	(5,560)
Deferred compensation	-	-	(440)
Net cash (used in) provided by investing activities	(3,696)	744	(2,428)
Cash flows from financing activities:			
Proceeds from offering of common stock, net	22,108	-	-
Proceeds from exercise of stock options/warrants	1,375	1,827	2,843
Proceeds from borrowings	2,841	2,514	5,004
Repayment of borrowings	(3,039)	(4,219)	(2,279)
Net cash provided by financing activities	23,285	122	5,568
Effect of exchange rate changes on cash	207	(85)	(46)
Net increase in cash and cash equivalents	20,845	920	394
Cash and cash equivalents at beginning of year	5,736	4,816	4,422
Cash and cash equivalents at end of year	\$ 26,581	\$ 5,736	\$ 4,816

(continued on following page)

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

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

(in thousands)

For the Year Ended December 31,  
2002                      2001                      2000

**Supplemental Disclosures of Cash Flow Information**

The Company paid cash during the year for (in thousands):

Interest	\$ 202	\$ 247	\$ 486
Taxes	<u>\$ 2,164</u>	<u>\$ 317</u>	<u>\$ 897</u>

**Supplemental Disclosures of Non-Cash Financing  
and Investing Activities**

The Company has issued or is obligated to issue Common Stock  
in exchange for services as follows (in thousands):

Shares	15	40	8
Amount	<u>\$ 151</u>	<u>\$ 233</u>	<u>\$ 69</u>

Included in year-end accounts payable are fixed asset  
and drug license purchases totaling (in thousands):

	<u>\$ 922</u>	<u>\$ 514</u>	<u>\$ 225</u>
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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.

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 operating in two business segments: research, development and licensing/commercialization of advanced drug delivery technologies and pharmaceutical products; and manufacturing and selling of generic and branded pharmaceutical products. In the research and development segment based in the U.S., the Company owns U.S. and international patent and other proprietary rights to technologies that enhance or facilitate the absorption of drugs across biological membranes. The Company is developing products incorporating these technologies and seeks to form strategic alliances with 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 other pharmaceutical companies to form additional alliances. The Company is incorporated in the State of Delaware.

In the pharmaceutical product sales segment based in Spain, the Company manufactures and markets branded and generic pharmaceutical products within four primary therapeutic areas: cardiovascular, gastrointestinal, infectious and neurological diseases.

The Company anticipated the opportunities that the emerging generic drug market in Spain present and began taking measures over four 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 the Company for marketing and sale in Spain. Teva was also granted a right of first refusal to acquire Laboratorios Davur in the event that the Company decides to sell that subsidiary or its direct parent, Laboratorios Belmac. The Company also granted Teva the right to bid for Laboratorios Belmac in the event the Company intends to sell that subsidiary.

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 at least the next twenty-four months. 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 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 classification in the Consolidated Balance Sheets and the Consolidated Statements of Cash Flows. Investments in securities that do not meet the definition of cash equivalents are classified as *marketable securities* in the Consolidated Balance Sheets.

### Marketable securities

The Company has investments in securities, with maturities of greater than three months when purchased, totaling \$396,000, which are classified as *marketable securities* as of December 31, 2002. The Company had no marketable securities as of December 31, 2001. These investments are considered available-for-sale and are carried at fair value. Unrealized gains or losses are treated as a component of *other comprehensive income (loss)*.

### Inventories

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

### Fixed assets

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

	<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 to operations as incurred. When assets are sold or retired, the cost of the asset and the related accumulated depreciation are removed from the accounts and any gain or loss is recognized currently.

### Drug licenses and related costs

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

### 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 is amortized to interest expense using the effective interest method over the lives of the related debt. The costs related to the issuance of debt is 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, marketable securities, receivables, accounts payable, accrued expenses and short-term borrowings approximate fair value because of their short-term nature. The carrying amount of the Company's long-term obligations approximate fair value given the amounts outstanding at December 31, 2002 and 2001.

The fair value information presented herein is based on information available to management as of December 31, 2002. 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

The Company has stock-based employee compensation plans that are described more fully in Note 11. The Company accounts for these plans under the recognition and measurement principles of APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and related Interpretations. No stock-based employee compensation cost is reflected in the Consolidated Statements of Operations, as all options granted under these plans had an exercise price equal to or greater than the market value of the underlying common stock on the dates of grant. The following table illustrates the effect on net income and earnings per share if the Company had applied the fair value recognition provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, to stock-based employee compensation.

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 No. 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,		
	2002	2001	2000
Net income (loss), as reported	\$ 1,636	\$ 1,361	\$ (745)
Total stock-based employee compensation expense determined under fair value method for all awards	<u>(3,673)</u>	<u>(2,040)</u>	<u>(2,554)</u>
Pro forma net loss	<u>\$(2,037)</u>	<u>\$ (679)</u>	<u>\$(3,299)</u>
Earnings (loss) per share:			
Basic — as reported	\$ 0.10	\$ 0.10	\$ (0.06)
Basic — pro forma	\$ (0.12)	\$ (0.05)	\$ (0.25)
Diluted — as reported	\$ 0.08	\$ 0.08	\$ (0.06)
Diluted — pro forma	\$ (0.12)	\$ (0.05)	\$ (0.25)

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, 2002, 2001 and 2000, respectively: (1) risk-free interest rates of 5.1%, 5.2% and 6.6%, respectively; (2) dividend yields of 0.0%; (3) expected lives of 5, 10 and 10 years, respectively; and (4) volatility of 57.6%, 140.8% and 126.9%, respectively. The weighted average fair value of options granted during the years ended December 31, 2002, 2001 and 2000 was \$5.58, \$3.72 and \$4.48, respectively. Results may vary depending on the assumptions applied within the model.

Stock or other equity-based compensation for non-employees is accounted for under the fair value method as required by SFAS No. 123 and Emerging Issues Task Force ("EITF") Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services* and other related interpretations. 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 purchase authorizations from its customers for a specified amount of product at a specified price and considers delivery to have occurred when the customer takes possession of the products. The Company provides its customers with a limited right of return. Revenue is recognized upon delivery and a reserve for sales returns is recorded. The Company has demonstrated the ability to make reasonable and reliable estimates of product returns in accordance with SFAS No. 48 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. 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. As permitted by APB Opinion No. 23, *Accounting for Income Taxes — Special Areas*, provisions for income taxes on undistributed earnings of foreign subsidiaries that are considered permanently invested are not recognized in the Company's consolidated financial statements.

### Basic and diluted net income (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 years ended December 31, 2002 and 2001. The effect of outstanding stock options and stock purchase warrants were not considered for the year ended December 31, 2000, because the results would have been anti-dilutive.

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

#### Year Ended December 31, 2002

<i>(in thousands, except per share data)</i>	<u>Basic EPS</u>	<u>Effect of Dilutive Securities</u>	<u>Diluted EPS</u>
Net income	\$ 1,636	\$ -	\$ 1,636
Weighted average common shares outstanding	16,569	3,229	19,798
Net income per common share	\$ .10	\$ (.02)	\$ .08

#### Year Ended December 31, 2001

<i>(in thousands, except per share data)</i>	<u>Basic EPS</u>	<u>Effect of Dilutive Securities</u>	<u>Diluted EPS</u>
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

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

Potential common Shares totaling 3,013,000, representing the effect of potential exercises of options and warrants and the effect of potential conversion of Debentures into shares of Common Stock were not included in the computation of diluted net loss per common share for the year ended December 31, 2000, 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 two business segments that are in two geographical locations. See Note 13 for the disclosures required by SFAS No. 131.

### Recently issued accounting pronouncements

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 Opinion 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 was required for fiscal years beginning after December 15, 2001, except for the nonamortization and amortization provisions that are required for goodwill and intangible assets acquired after June 30, 2001. The adoption of SFAS No. 141 and SFAS No. 142 did not have a material impact on the Company's financial position, results of operations or cash flows.

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, results of operations or cash flows.

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

In December 2002, the Financial Accounting Standards Board issued Interpretation No. 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others* ("FIN 45"). FIN 45 elaborates on the disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under certain guarantees that it has issued. It also clarifies that a guarantor is required to recognize, at the inception of a guarantee, a liability for the fair value of the obligation undertaken in issuing the guarantee. The Company has adopted the disclosure requirements of FIN 45 as of December 31, 2002 and determined that no additional disclosures were required. In addition, the Company is required to adopt the initial recognition and measurement of the fair value of the obligation undertaken in issuing the guarantee on a prospective basis to guarantees issued or modified after December 31, 2002. The Company does not believe the adoption of FIN 45 will have a material effect on the Company's financial position, results of operations or cash flows.

In November 2002, the EITF issued EITF Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*. EITF Issue No. 00-21 addresses certain aspects of the accounting by a vendor for arrangements under which it will perform multiple revenue-generating activities. EITF Issue No. 00-21 establishes three principles: revenue arrangements with multiple deliverables should be divided into separate units of accounting, arrangement consideration should be allocated among the separate units of accounting based on their relative fair values, and revenue recognition criteria should be considered separately for separate units of accounting. EITF Issue No. 00-21 is effective for all revenue arrangements entered into in fiscal periods beginning after June 15, 2003, with early adoption permitted. The Company does not believe the adoption of EITF Issue No. 00-21 will have a material effect on its financial position, results of operations or cash flows.

In November 2001, the EITF reached a consensus on EITF Issue No. 01-09, *Accounting for Consideration Given by a Vendor to a Customer or a Reseller of the Vendor's Products*, which is a codification of EITF Issues No. 00-14, 00-22 and 00-25. This issue presumes that consideration from a vendor to a customer or reseller of the vendor's products to be a reduction of the selling prices of the vendor's products and, therefore, should be characterized as a reduction of revenues under certain circumstances. Revenue reduction is required unless consideration relates to a separate identifiable benefit and the benefit's fair value can be established. EITF Issue No. 01-09 is effective for fiscal

years beginning after December 15, 2001 and interim periods within those fiscal years. The adoption of EITF Issue No. 01-09 did not have a material effect on the Company's financial position, results of operations or cash flows.

### 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,	
	2002	2001
Trade receivables (of which \$1,340 and \$1,747, respectively, collateralize short-term borrowings with Spanish financial institutions)	\$ 9,829	\$6,397
VAT, income and social security taxes receivable	1,033	584
Other	112	22
	<u>10,974</u>	<u>7,003</u>
Less-allowance for doubtful accounts	(100)	(66)
	<u>\$10,874</u>	<u>\$6,937</u>

### NOTE 4—INVENTORIES

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

	December 31,	
	2002	2001
Raw materials	\$3,518	\$1,387
Finished goods	1,677	1,230
	5,195	2,617
Less-allowance for slow moving inventory	(62)	(54)
	<u>\$5,133</u>	<u>\$2,563</u>

### NOTE 5—FIXED ASSETS

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

	December 31,	
	2002	2001
Land	\$ 930	\$ 790
Buildings and improvements	5,576	3,008
Equipment	5,197	3,168
Furniture and fixtures	1,006	692
Leasehold improvements	52	44
	<u>12,761</u>	<u>7,702</u>
Less-accumulated depreciation	(3,196)	(2,107)
	<u>\$ 9,565</u>	<u>\$ 5,595</u>

The Company entered into a purchase and sale agreement during the year ended December 31, 2002, whereby it agreed to purchase a 15,700 square foot commercial building located on approximately 14 acres of land in Exeter, NH for \$1,776,600. The Company paid a deposit of \$157,660 during the year ended December 31, 2002, which has been included in *other non-current assets* as of December 31, 2002. The Company completed the acquisition of the property subsequent to December 31, 2002.

Depreciation expense of approximately \$212,000, \$139,000 and \$72,000 has been charged to operations as a component of *depreciation and amortization expense* in the Consolidated Statements of Operations for the years ended December 31, 2002, 2001 and 2000, respectively. The Company has included depreciation totaling approximately

\$569,000, \$324,000 and \$260,000 in *cost of net product sales* during the years ended December 31, 2002, 2001 and 2000, respectively.

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

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

	<u>December 31,</u>	
	<u>2002</u>	<u>2001</u>
Drug licenses and related costs	\$13,908	\$12,245
Less-accumulated amortization	(2,933)	(1,969)
	<u>\$10,975</u>	<u>\$10,276</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 approximately \$5,148,000. Laboratorios Belmac received a 50% deposit from the purchaser in November 2000, which was reflected as *deferred income* in the Consolidated Balance Sheet as of December 31, 2000. The transaction was completed in February 2001, resulting in a gain of approximately \$4,977,000 being recognized in the year ended December 31, 2001.

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

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 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.

Amortization expense for drug licenses and related costs was approximately \$803,000, \$772,000 and \$508,000 for the years ended December 31, 2002, 2001 and 2000, respectively, and has been recorded in *depreciation and amortization expense* in the accompanying Consolidated Statements of Operations.

Amortization expense for drug licenses and related costs for each of the five years ending December 31, 2007 and for all remaining years thereafter is estimated to be approximately \$991,000 and \$6,020,000, 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.

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 remaining loan balances, which bear interest at 2.37% annually, mature in March 2003. Accrued interest on such loans totals approximately \$7,000 and \$1,000 at December 31, 2002 and 2001, respectively.

The balance outstanding at December 31, 2002 of approximately \$301,000 has been included in *prepaid expenses and other current assets* in the Consolidated Balance Sheet. As of December 31, 2001, the Company 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.

**NOTE 8—ACCRUED EXPENSES**

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

	December 31,	
	<u>2002</u>	<u>2001</u>
Foreign income taxes payable	\$1,177	\$ 596
Provision for sales returns	349	402
Accrued payroll	756	698
Other accrued expenses	<u>1,777</u>	<u>794</u>
	<u>\$4,059</u>	<u>\$2,490</u>

**NOTE 9—DEBT**

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

	December 31,	
	<u>2002</u>	<u>2001</u>
Trade receivables discounted with a Spanish financial institution, with recourse, effective interest rate is 5.2% and 5.9%, respectively	\$1,340	\$1,747
Revolving lines of credit payable to Spanish financial institutions, weighted average interest rate is 4.5% and 5.3%, respectively	<u>258</u>	<u>10</u>
	<u>\$1,598</u>	<u>\$1,757</u>

The weighted average stated interest rate on short-term borrowings outstanding at December 31, 2002 and 2001 was 5.1% and 5.9%, respectively.

The Company has revolving lines of credit with Spanish financial institutions, which entitle the Company to borrow up to \$5,537,000 at December 31, 2002. The lines are scheduled to mature on various dates through November 30, 2003 and are renewable. At December 31, 2002, advances outstanding under the lines of credit were approximately \$258,000. The weighted average interest rate at December 31, 2002 and 2001 was 4.5% and 5.3%, respectively, and interest is payable quarterly.

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

	December 31,	
	<u>2002</u>	<u>2001</u>
Loans payable to Spanish government, net of unamortized discount of \$105 and \$72, respectively	\$ 282	\$142
Loans payable for equipment financing	<u>190</u>	<u>-</u>
	472	142
Less-current portion	<u>(127)</u>	<u>-</u>
Total long-term debt	<u>\$ 345</u>	<u>\$142</u>

In March 2002, the Company entered into a loan agreement to finance the acquisition of manufacturing equipment. The terms of the loan require repayment over a two-year period at an average interest rate of 2.9%. As of December 31, 2002, approximately \$190,000 of the original balance remains outstanding.

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

In December 2001, the Company entered into a loan agreement with the Spanish government as part of a research-funding program. The loan is non-interest bearing and is payable in equal annual installments of approximately \$30,600



beginning in 2005. Accordingly, the Company imputed interest at the market rate in Spain (6%), recorded a discount on the obligation of \$72,000 and has classified the obligation at December 31, 2002 and 2001 as non-current. The discount is being amortized over the ten-year term of the loan.

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 as 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, 2003.

**NOTE 10—PREFERRED STOCK**

The Company has 2,000,000 shares of \$1.00 Preferred Stock authorized for issuance. As of December 31, 2002 and 2001, no shares of Preferred Stock were outstanding.

**NOTE 11—STOCKHOLDERS' EQUITY**

At December 31, 2002 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	3,292
For exercise of outstanding stock options	3,459
For future stock option grants	<u>309</u>
	<u>7,060</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, 2002, warrants to purchase an aggregate of approximately 3,292,000 shares of Common Stock were outstanding, which were exercisable at prices ranging from \$1.50 to \$20.00 per share, of which 400,000 warrants have an exercise price of \$1.50 per share, approximately 2,872,000 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 2003 through February 2009.

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

During the year ended December 31, 2001, underwriter's Class A Warrants were exercised to acquire 460,000 shares of Common Stock and 460,000 underwriter's Class B Warrants. Approximately 8,400 Class B Warrants and 150,000

other stock purchase warrants were exercised during 2001 to acquire an aggregate of 154,200 shares of Common Stock. The Company received net cash proceeds of approximately \$1,776,000 from all such exercises during the year ended December 31, 2001.

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.

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, 2000, 2001 and 2002.

<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, 1999	4,806	\$4.17
Exercised	<u>(768)</u>	\$2.93
Outstanding at December 31, 2000	4,038	\$4.41
Exercised	<u>(614)</u>	\$2.89
Outstanding at December 31, 2001	3,424	\$4.68
Exercised	<u>(132)</u>	\$5.00
Outstanding at December 31, 2002	<u>3,292</u>	\$4.67

#### **Common stock transactions**

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

During the year ended December 31, 2001, the Company issued approximately 460,000 shares of Common Stock as a result of the exercise of underwriter's Class A Warrants, approximately 4,200 shares of Common Stock upon exercise of Class B Warrants, approximately 150,000 shares of Common Stock upon exercise of 150,000 other stock purchase warrants, approximately 16,900 shares of Common Stock upon exercise of stock purchase options, and approximately 40,000 shares of Common Stock as equity-based compensation in lieu of cash.

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.

General and administrative expenses for the years ended December 31, 2002, 2001 and 2000 include \$100,000, \$160,000 and \$39,000, respectively, of non-cash equity-based compensation. Research and development expenses for the years ended December 31, 2002, 2001 and 2000 include \$56,000, \$102,000 and \$30,000, respectively, of non-cash equity-based compensation.

#### **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 3,768,000 shares of Common Stock have been reserved for issuance under the Plans, of which approximately 778,000 are outstanding under the 1991 Plan, approximately 1,181,000 are outstanding under the 2001 Employee and Director Plans and 1,500,000 are outstanding under the Executive Plan as of December 31, 2002. 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 that

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 172,300, 16,900 and 14,000 shares of Common Stock were exercised during the years ended December 31, 2002, 2001 and 2000, respectively, resulting in net cash proceeds of approximately \$715,000, \$51,000 and \$35,000, respectively.

The table below summarizes activity in the Company's Plans for the years ended December 31, 2000, 2001 and 2002.

<i>(in thousands, except per share data)</i>	<u>Number of Common Shares</u>	<u>Weighted Average Exercise Price</u>
Outstanding at December 31, 1999	1,927	\$ 5.50
Granted	570	7.56
Exercised	(14)	2.52
Canceled	<u>(26)</u>	113.96
Outstanding at December 31, 2000	2,457	4.87
Granted	553	6.04
Exercised	(17)	3.00
Canceled	<u>(56)</u>	9.66
Outstanding at December 31, 2001	2,937	5.00
Granted	699	10.28
Exercised	(172)	4.15
Canceled	<u>(5)</u>	29.40
Outstanding at December 31, 2002	<u>3,459</u>	\$ 6.07

The table below summarizes options outstanding and exercisable at December 31, 2002 (*number of options in thousands*):

<u>Options Outstanding</u>				<u>Options Currently Exercisable</u>	
Range of Exercise Prices	Number Of Options	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)	Number Of Options	Weighted Average Exercise Price
\$ 1.50 - 2.89	565	\$ 2.83	3.5	565	\$ 2.83
3.00 - 3.75	674	3.64	3.4	674	3.64
4.73	500	4.73	3.3	500	4.73
5.70 - 5.88	172	5.85	7.4	172	5.85
6.00 - 6.38	432	6.01	8.3	432	6.01
7.10 - 7.90	262	7.53	7.5	212	7.48
8.00 - 8.93	60	8.54	8.1	43	8.45
9.00 - 9.80	490	9.74	8.9	25	9.00
10.63 - 11.81	274	11.42	9.0	57	11.22
<u>20.00 - 22.50</u>	<u>30</u>	<u>20.08</u>	<u>0.6</u>	<u>30</u>	<u>20.08</u>
<u>\$ 1.50 - 22.50</u>	<u>3,459</u>	<u>\$ 6.07</u>	<u>5.8</u>	<u>2,710</u>	<u>\$ 4.96</u>

Options and warrants outstanding at December 31, 2002, include approximately 3,292,000 warrants, all of which are exercisable, and approximately 3,459,000 options, of which approximately 2,710,000 are vested and exercisable at December 31, 2002.

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

#### **401(k) Retirement Plan**

The Company sponsors a 401(k) retirement savings plan (the "401(k) Plan") under which eligible employees may contribute, on a pre-tax basis, 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 years ended December 31, 2002 and 2001 in the form of

approximately 9,300 and 13,700 shares, respectively, of the Company's Common Stock valued at approximately \$92,000 and \$83,000, respectively. 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. 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.

### Equity Transactions Subsequent to Year End

Subsequent to December 31, 2002, the Company issued a total of 41,000 shares of restricted Common Stock, which shares vest ratably over 12-months, to certain employees of the Company as equity-based compensation in lieu of cash and granted options to purchase an aggregate of 250,000 shares of Common Stock to certain employees of the Company.

### 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. See Note 13 for information regarding the components of income before taxes.

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

	Year Ended December 31,		
	2002	2001	2000
Foreign taxes	\$ 2,534	\$2,452	\$ 222
Tax benefit from US operating losses	(933)	(954)	(657)
Federal and state deferred taxes	10,453	(898)	1,162
Change in valuation allowance	(9,520)	1,852	(505)
Total provision for income taxes	<u>\$ 2,534</u>	<u>\$2,452</u>	<u>\$ 222</u>

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

	Year Ended December 31,		
	2002	2001	2000
Statutory federal income tax (benefit)	\$1,418	\$1,296	\$(178)
Permanent differences from foreign subsidiary	183	202	(257)
Valuation allowance	933	954	657
	<u>\$2,534</u>	<u>\$2,452</u>	<u>\$ 222</u>

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

	December 31,	
	2002	2001
Deferred tax assets:		
NOL carryforwards	\$ 15,118	\$ 14,075
Capital loss carryforwards	-	10,799
Disposition of subsidiary	6,912	6,850
Foreign tax on deferred income	123	141
Tax credit carryforwards	415	415
Other, net	719	603
Total deferred tax assets	<u>23,287</u>	<u>32,883</u>
Deferred tax liabilities	(217)	(275)
Valuation allowance	<u>(22,947)</u>	<u>(32,467)</u>
Deferred tax asset, net	<u>\$ 123</u>	<u>\$ 141</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 \$123,000 and a non-current tax liability of \$2,141,000 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 that could be utilized annually to offset future taxable income and income tax liabilities. The amount of any annual limitation is determined based upon the Company's value prior to an ownership change.

At December 31, 2002, the Company has NOL carryforwards of approximately \$38,366,000 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, 2001 and 2002 losses without limitation. Additionally, approximately \$1,800,000 of the NOL generated in 1995 available to offset future U.S. taxable income is 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 2023. Capital loss carryforwards totaling approximately \$10,799,000 expired unused during the year ended December 31, 2002.

The valuation allowance increased (decreased) by approximately (\$9,520,000), \$1,852,000 and (\$505,000) for each of the years ended December 31, 2002, 2001 and 2000, respectively.

#### **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., Laboratorios Davur S.L. and Laboratorios Rimafar 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 business and geographical segments for the years ended December 31, 2002, 2001 and 2000. The segments use the same accounting policies as those described in the summary of significant accounting policies in Note 2.

	Year Ended December 31, 2002		
	Product Sales/ Spain	R&D/ Collaborations/ U.S.	Consolidated
<i>(in thousands)</i>			
Total revenues	\$38,718	\$ 418	\$39,136
Interest income	-	279	279
Interest expense	200	9	209
Depreciation and amortization expense	655	360	1,015
Income (loss) before income taxes	6,913	(2,743)	4,170
Provision for income taxes	2,534	-	2,534
Net income (loss)	4,379	(2,743)	1,636
Fixed assets	9,417	148	9,565
Drug licenses and related costs	7,463	3,512	10,975
Total assets	38,199	26,493	64,692
Total liabilities	15,417	524	15,941
Expenditures for drug licenses/delivery technology	615	181	796
Expenditures for fixed assets	3,408	24	3,432

	Year Ended December 31, 2001		
	Product Sales/ Spain	R&D/ Collaborations/ U.S.	Consolidated
<i>(in thousands)</i>			
Total revenues	\$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
Provision for income taxes	2,452	-	2,452
Net income (loss)	4,166	(2,805)	1,361
Fixed assets	5,427	168	5,595
Drug licenses and related costs	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

	Year Ended December 31, 2000		
	Product Sales/ Spain	R&D/ Collaborations/ U.S.	Consolidated
<i>(in thousands)</i>			
Total revenues	\$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)
Provision for income taxes	222	-	222
Net income (loss)	1,186	(1,931)	(745)
Fixed assets	3,959	180	4,139
Drug licenses and related costs	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

Interest income and interest expense are based upon the actual results of each operating segment's assets and borrowings. The R & D/Collaborations/U.S. column includes the elimination of all inter-segment 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 total revenues during the year ended December 31, 2002, accounting for 14% of 2002 consolidated total revenues and 7.6% of the consolidated receivables balance at December 31, 2002. Revenues from one customer exceeded 10% of consolidated total revenues during the year ended December 31, 2001, accounting for 15% of 2001 consolidated total revenues 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.

#### **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 December 31, 2003.

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., alleging that the Company violates their patents in its production of the product simvastatin and requesting an injunction ordering the Company not to manufacture or market the product. The case was brought against the Company's Spanish subsidiaries in the 39th First Instance Court of the City of Madrid. After a hearing on February 18, 2002, the court refused to grant the requested injunction and dismissed the case on February 25, 2002, awarding the Company court and legal fees. Merck has appealed the award of fees. Simvastatin was launched in January 2002 and sales of this product totaled approximately \$1,300,000 during the year ended December 31, 2002. Merck re-instituted its claim against the Company in another proceeding brought in the 19th First Instance Court of the City of Madrid, which the Company received notice of on January 23, 2003. This case also alleges violation of Merck's patents in the production of the product simvastatin, requests an order that the Company cease manufacturing the product and demands damages during the period of manufacture. The Company intends to vigorously oppose this claim as management of the Company believes it is without merit. The Company believes that the resolution of this claim will not have a material adverse effect on its financial position, results of operations or cash flows.

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

The Company leases certain equipment and facilities under non-cancelable operating leases, which expire through the year 2007. Total charges to operations under operating leases were approximately \$785,000, \$705,000 and \$557,000 for the years ended December 31, 2002, 2001 and 2000, respectively. Future minimum lease payments under operating leases are as follows (*in thousands*):

<u>Year Ending December 31,</u>	
2003	\$808
2004	765
2005	755
2006	120
2007 and beyond	5

## 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,  
Treasurer and Secretary

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. CPA  
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,  
Treasurer and Secretary  
Bentley Pharmaceuticals, Inc.

John W. Spiegel  
Vice Chairman and Chief Financial Officer  
SunTrust Banks, Inc.

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

### CORPORATE OFFICES

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Facsimile: 603.658.6101  
www.bentleypharm.com

### SUBSIDIARIES

Laboratorios Belmac S.A. - Madrid, Spain  
Laboratorios Davur S.L. - Madrid, Spain  
Laboratorios Rimafar 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  
59 Maiden Lane, Plaza Level  
New York, NY 10038  
Telephone: 800.937.5449  
Facsimile: 718.236.2641  
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.  
Bentley Park  
2 Holland Way  
Exeter, NH 03833  
Attention: Celia Brown  
E-mail: invrel@bentleypharm.com





[www.bentleypharm.com](http://www.bentleypharm.com)