

BENTLEY PHARMACEUTICALS INC

Form 10-K

March 15, 2007

**Table of Contents**

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549  
FORM 10-K**

(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, 2006**

**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.)

**Bentley Park**  
**2 Holland Way**  
**Exeter, New Hampshire**  
(Address of principal executive offices)

**03833**  
(Zip Code)

Registrant's telephone number, including area code: **(603) 658-6100**  
Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
<b>Common Stock, \$0.02 par value</b>	<b>New York Stock Exchange</b>
<b>Preferred Stock Purchase Rights</b>	<b>New York Stock Exchange</b>

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

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

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

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 a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):  
Large accelerated filer  Accelerated filer  Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (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 computed by reference to the price at which the common equity was last sold, or the average bid and asked prices of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter.

Title of Class	Aggregate Market Value *	As of Close of Business on
<b>Common Stock, \$0.02 par value</b>	<b>\$193,688,276</b>	<b>June 30, 2006</b>

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
<b>Common Stock, \$0.02 par value</b>	<b>22,268,358</b>	<b>March 9, 2007</b>

DOCUMENTS INCORPORATED BY REFERENCE

**Proxy Statement for the 2007 Annual Meeting of Stockholders Incorporated by Reference into Part III of this Annual Report on Form 10-K**

\* Excludes the Common Stock held by executive officers, directors and stockholders whose ownership exceeds 5% of the Common Stock outstanding at June 30, 2006. This calculation does not reflect a determination that such persons are affiliates for any other purposes. Calculation assumes no changes in ownership positions of institutional holders with ownership positions greater than 5% from positions reported on their Schedule 13 filings for the year ended December 31,

2005.

---

**TABLE OF CONTENTS**

Part I

Item 1. Business

Item 1A. Risk Factors

Item 1B. Unresolved Staff Comments

Item 2. Properties

Item 3. Legal Proceedings

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

Part II

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

Item 6. Selected Financial Data

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

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Item 8. Financial Statements and Supplementary Data

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

Item 9A. Controls and Procedures

Item 9B. Other Information

Part III

Item 10. Directors and Executive Officers of the Registrant and Corporate Governance

Item 11. Executive Compensation

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Item 13. Certain Relationships and Related Transactions and Director Independence

Item 14. Principal Accounting Fees and Services

Part IV

Item 15. Exhibits, Financial Statement Schedules

EXHIBIT INDEX

SIGNATURES

Ex-10.29 Settlement Term Sheet Agreement

Ex-21.1 Subsidiaries of the Registrant

Ex-23.1 Consent of Independent Registered Public Accounting firm

Ex-31.1 Section 302 Certification of the Chief Executive Officer

Ex-31.2 Section 302 Certification of the Chief Financial Officer

Ex-32.1 Section 906 Certification of the Chief Executive Officer

Ex-32.2 Section 906 Certification of the Chief Financial Officer

---

**Table of Contents**

**Part I**

**Item 1. Business**

**Overview**

We are an international specialty pharmaceutical company, headquartered in the U.S., that is focused on:  
Specialty Generics: development, licensing and sales of generic and branded generic pharmaceutical products and active pharmaceutical ingredients, or API, and the manufacturing of pharmaceuticals for others; and

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

Our pharmaceutical product sales and licensing activities are based primarily in Spain, where we have a significant commercial presence and manufacture and market approximately 118 products of various dosages and strengths through three wholly-owned Spanish subsidiaries: Laboratorios Belmac, Laboratorios Davur and Laboratorios Rimafar. Our products include approximately 167 product presentations, or SKUs, in four primary therapeutic areas: cardiovascular, gastrointestinal, central nervous system and infectious diseases. Although most of the sales of these products are currently in the Spanish market, we have recently focused on increasing sales in other European countries and other geographic regions through strategic alliances with companies in these territories. We continually add to our product portfolio in response to increasing market demand for generic and branded generic therapeutic agents and, when appropriate, divest portfolio products considered to be redundant or that have become non-strategic. We manufacture our finished dosage pharmaceutical products in our Spanish manufacturing facility which recently received approval from the U.S. Food and Drug Administration, or FDA, for the manufacture of our first U.S. generic product which was launched in the fourth quarter of 2006. Through our Spanish subsidiary Bentley A.P.I., we also own a manufacturing facility in Spain that specializes in the manufacturing of several APIs. This facility has also been approved by the FDA for the manufacture of one ingredient for marketing and sale in the U.S. We market our API products through our Spanish subsidiary, Bentley A.P.I. We also have an Irish subsidiary, Bentley Pharmaceuticals Ireland Limited, which received its first marketing approval by the Irish Medicines Board in 2005 and launched its first product in the fourth quarter of 2006.

We have U.S. and international patents and other proprietary rights to technologies that facilitate the absorption of drugs. We are developing products that incorporate our drug delivery technologies and have licensed applications of our proprietary CPE-215<sup>®</sup> drug delivery technology to Auxilium Pharmaceuticals, Inc., which launched Testim<sup>®</sup> in the U.S. market in February 2003. Testim, which incorporates our CPE-215 drug delivery technology, is a gel indicated for testosterone replacement therapy. We continue to seek other pharmaceutical and biotechnology companies to form additional strategic alliances to facilitate the development and commercialization of other products using our drug delivery technologies, including product candidates that deliver insulin to diabetic patients intranasally, deliver macromolecule therapeutics using a biodegradable Nanocaplet<sup>™</sup> technology and treat nail fungus infections topically.

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

**Table of Contents**

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

**Industry Overview**

*Pharmaceutical Industry in Europe*

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

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

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

Since Spain's entry into the European Union in 1986, the Spanish pharmaceutical market has been evolving steadily into a market that is increasingly similar to those of other countries in Western Europe and the U.S. With a population of approximately 44.7 million in 2006, Spain was ranked as the seventh largest pharmaceutical market in the world and fifth largest in the European Union. Pharmaceutical sales in Spain reached approximately \$11.6 billion in 2006, according to IMS Health.

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

Although comprising approximately 5.4% of sales in the Spanish pharmaceutical market (approximately 9.4% of the units of pharmaceutical products sold in Spain), generic pharmaceuticals are expected to significantly increase their market penetration due to increases in drug usage driven by an aging population and opportunities to launch new generic products as patents expire for blockbuster drugs. In response to the rise in healthcare costs, several initiatives are underway by the Spanish government to stimulate the use of generic pharmaceuticals, including education, financial incentives to prescribing

**Table of Contents**

physicians and public campaigns. Due to the structure of the Spanish market for pharmaceutical products, producers generally market their products to physicians and pharmacies to whom they emphasize a combination of quality and price.

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

*Drug Delivery Industry*

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

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

Pharmaceutical and biotechnology companies look to drug delivery enhancements as a way of improving treatment as well as gaining a competitive advantage. Alternative drug delivery technologies, which avoid first-pass metabolism and are less invasive, may also be sought by pharmaceutical and biotechnology companies for product line extensions for a branded drug and, in some cases, may possibly postpone competition from generic equivalents. In order to maintain the competitiveness of their proprietary drug candidates, large pharmaceutical companies seek delivery enhancements that will increase safety and efficacy, reduce side effects and make administration more convenient. Further, drug delivery companies can apply their technologies to off-patent products to formulate their own proprietary products, which they often commercialize by seeking marketing collaborations with larger pharmaceutical companies that have greater capabilities and resources.

Developing safer and more efficacious methods of delivering existing drugs generally is less risky than attempting to discover new drugs, because of lower development costs. On average, it takes 10 to 15 years for an experimental new drug to progress from the laboratory to commercialization in the U.S., with an average cost estimated to be approximately \$800 million to \$900 million. Typically, only one in 1,000 compounds entering preclinical testing advances into human testing and only one in five compounds tested in humans is approved for commercialization. By contrast, drug delivery companies typically target



**Table of Contents**

drugs that already have been approved, have a track record of safety and efficacy and have established markets for which there is a proven medical need. Consequently, clinical trials related to drug delivery technologies applied to previously-approved pharmaceuticals need only show that the new technologies deliver the drug without adverse side effects and with the same clinical efficacy.

**Our Strategy**

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

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

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

Our strategies to accomplish this objective include:

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

We plan to increase our generic and branded generic product sales by expanding the portfolio of products manufactured in Spain and by forming strategic alliances to increase our sales outside of Spain. We are expanding our product portfolio through the acquisition or licensing of currently marketed and late stage pharmaceutical products. We directly promote and sell these products in Spain through our own sales force of approximately 170 full-time personnel focused on major cities throughout Spain. Outside Spain we sell through alliances with partners in other countries in Europe and elsewhere.

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

Additionally, we have a strategic alliance with Teva Pharmaceutical Industries Limited, a worldwide leader in generic pharmaceutical products, granting us the right to register and market certain of Teva's pharmaceutical products in Spain through our sales force of approximately 170 full-time personnel who focus on major cities throughout Spain.

We are expanding the sales of products outside of Spain by developing alliances with strategic partners in targeted markets that offer compatible regulatory approval regimes and attractive margins. Most of these alliances relate to specific products that our partners have expertise in marketing. We have already developed alliances in Portugal, Greece, the United Kingdom, Germany, Austria, Morocco, Poland and the Czech Republic for targeted products in these and other countries. In certain European countries that have a

**Table of Contents**

highly developed competitive market for generics based primarily on price, we intend to sell either directly or through our alliances to distributors. In countries that require a sales force to market to physicians or consumers, we intend to continue to concentrate our efforts through alliances with entities that have sales and marketing forces already in place. We have made and will continue to make, as necessary, modifications to our finished pharmaceutical products manufacturing facility so that it will comply with Good Manufacturing Practices, or GMP, of the FDA. These modifications should enable us to submit our products for U.S. marketing approval by the FDA.

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

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

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

We believe these benefits include:

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

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;

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

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

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

## **Table of Contents**

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 therapeutic areas with high clinical need with compounds that have established market demand or that face limited market acceptance as a result of less efficient drug delivery methods. We are currently focusing intensively on applications of the CPE-215 technology to the intranasal delivery of insulin to diabetic patients.

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

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

faster relief of pain and inflammation; and

better taste.

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

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

## **Our Proprietary Drug Technologies**

### *Proprietary Drug Manufacturing Technologies*

We believe that there are several opportunities to enter into additional collaborations with pharmaceutical and biotechnology companies and expand our product lines using our proprietary drug technologies. For example, in November 2004, we entered into a collaboration agreement with Perrigo Company, the largest U.S. manufacturer of over-the-counter pharmaceutical and nutritional products for the store brand market, to co-develop and market generic simvastatin in the U.S. and potentially other markets. Our generic simvastatin was launched in December 2006 and marks our first U.S. generic product. Our agreement with Perrigo contains provisions which allow us to collaborate on additional products in the future when mutually agreed upon.

### *CPE-215 Permeation Platform Technology*

Our permeation platform technology consists of a series of related chemical compounds that enable the absorption of a wide variety of products across various biological membranes. Our primary compound and the foundation for our drug delivery platform technology is CPE-215 (pentadecalactone). CPE-215, when combined with certain drugs, has been shown to significantly increase the amount and rate of absorption of those drugs through various biological membranes. By controlling the formulation of CPE-215 that is combined with certain drugs, we have the ability to positively affect the quantity and rate at which the drug is absorbed through biological membranes. We believe that our CPE-215 technology is

**Table of Contents**

superior to certain other non-injection and non-oral drug delivery systems based on the following characteristics:  
broad applicability - works with a wide range of pharmaceutical compounds, including water soluble, 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 - approved by the FDA for long-term topical use in Testim.

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

*Solubility Enhancement Technology*

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

*Oral Formulation Technologies*

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

**Table of Contents**

*Nanocaplet Technology*

In May 2005 we announced the discovery and synthesis of a thermodynamically stable, biodegradable Nanocaplet technology for the delivery of macromolecule therapeutics. This proprietary technology was discovered as part of our four-year sponsored research program with the University of New Hampshire Nanostructured Polymers Research Center. We have successfully synthesized biodegradable nanovesicles, or nanocapsules, which are minute, chemical structures, that have the potential to encapsulate and deliver insulin systematically through the intestinal mucosa and reduce glucose levels.

**Licensed Product**

*Topical Testosterone Gel*

In February 2003, our licensee, Auxilium Pharmaceuticals launched Testim, a testosterone gel containing our CPE-215 drug delivery system, in the United States. Testim is marketed by Auxilium under a license of our drug delivery technology. Testim is approved for marketing in the U.S., Canada and 15 countries in Europe.

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

Testim resulted from our May 2000 research agreement with Auxilium, pursuant to which Auxilium agreed to develop and test various pharmaceutical compositions of topical testosterone using our CPE-215 technology. We licensed to Auxilium exclusive worldwide rights to develop, market and sell Testim, which rights became effective in September 2000. After Auxilium conducted clinical trials, a New Drug Application (NDA) was approved by the FDA on October 31, 2002. Testim was launched in the United States by Auxilium in February 2003. Auxilium uses its sales force to market Testim in the U.S. and has partnered with Paladin Labs Inc. to market the drug in Canada and Ipsen to market the drug in Europe.

**Manufactured and Marketed Products**

In Spain, we manufacture and market approximately 118 products of various dosages and strengths which include approximately 167 product presentations, or SKUs, in four primary therapeutic areas: cardiovascular, gastrointestinal, central nervous system and infectious diseases. We market these products primarily in Spain and have developed alliances with other companies that market our products, pursuant to license and supply agreements, in other countries, including Portugal, Greece, the United Kingdom, Germany, Austria, Morocco, Poland and the Czech Republic. In addition, we manufacture products that are marketed by other companies both in Spain and elsewhere. Our generic and branded generic products are marketed to physicians, pharmacists and hospitals by our three Spanish sales and marketing organizations,

**Table of Contents**

Laboratorios Belmac, Laboratorios Davur and Laboratorios Rimafar. We also market over-the-counter products through Laboratorios Rimafar. There are approximately 179,000 physicians and 21,000 pharmacies in Spain.

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

**Branded Generic Pharmaceutical Products**

Our branded generic pharmaceutical product line consists of 43 products of various dosages and strengths represented by approximately 20 trademarked brand names. Most of our branded generic products are known in the industry as branded generics because they are being marketed by us under a brand name even though we are not the innovator of the product. Sales of branded generic pharmaceuticals accounted for approximately 22% of our revenues in 2006, compared to 23% in 2005 and 25% in 2004. We market our branded generic products and, to a lesser extent, certain of our generic and over-the-counter products through our Laboratorios Belmac subsidiary, which has approximately 77 full-time sales personnel who focus on major cities throughout Spain. Several of our branded generic products are also marketed by the sales forces of Laboratorios Davur and Laboratorios Rimafar. We supplement our sales and marketing efforts for branded generic products through advertising in trade publications.

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

**Our Branded Generic**

<b>Product Name</b>	<b>Active Ingredient</b>	<b>Innovator Product (Company)</b>	<b>Used to Treat</b>
Belmalipâ	simvastatin	Zocorâ (Merck)	elevated cholesterol
Belmazolâ	omeprazole	PrilosecÒ (AstraZeneca)	gastroesophageal reflux disease
Cimascal D Forteâ	calcium carbonate and vitamin D3	Calcite-Dâ (Riva)	osteoporosis
Codeisanâ	codeine	Tricodeinâ (Solco)	cough and bronchitis
Enalapril Belmacâ	enalapril maleate	Vasotecâ (Merck)	cardiovascular disease and hypertension
IbumacÒ	ibuprofen	Motrinâ (McNeil)	rheumatoid arthritis
Lanzol®	lansoprazole	Prevacidâ (Tap)	gastroesophageal reflux disease
Mio RelaxÒ	carisoprodol	Somaâ (MedPointe)	muscle spasms

**Table of Contents****Our Branded Generic**

<b>Product Name</b>	<b>Active Ingredient</b>	<b>Innovator Product (Company)</b>	<b>Used to Treat</b>
Pentoxifilina Belmacâ	pentoxifylline	Trentalâ (Aventis)	peripheral arterial disease
Senioralâ	oxymetazoline and chlorpheniramine	Denoralâ (Aventis)	cold and sinus congestion
XetinÒ	paroxetine	Paxilâ (GlaxoSmithKline)	depression

**Generic Pharmaceutical Products**

Our generic pharmaceutical product line consists of 75 products of various dosages and strengths. We entered the generic pharmaceutical market in Spain in September 2000. Sales of generic pharmaceuticals accounted for approximately 36% of our revenues in 2006 and 2005, compared to 40% in 2004. Laboratorios Davur, our sales and marketing organization devoted primarily to generic products, markets pharmaceutical products to physicians and pharmacists through a sales force of approximately 68 full-time sales personnel who focus on major cities throughout Spain. Laboratorios Rimafar, our sales and marketing organization devoted primarily to generics and over-the-counter products, markets to pharmacists through a sales force of approximately 25 full-time sales personnel throughout Spain. Laboratorios Belmac, to a lesser extent, also sells selected generic products through its sales force. We supplement our sales and marketing efforts for generic products through advertising in trade publications.

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

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

<b>Our Generic Product Name</b>	<b>Active Ingredient</b>	<b>Innovator Product (Company)</b>	<b>Used to Treat</b>
Amlodapino Davurâ Amlodapino Rimafarâ	amlodapine	Norvasc® (Pfizer)	arterial hypertension
Amoxicilina Davurâ Amoxicilina Belmacâ	amoxicillin trihydrate	Amoxilâ (GlaxoSmithKline)	infections
Amox/Clavulanico Davurâ	amoxicillin/clavulanate potassium	Augmentinâ (GlaxoSmithKline)	infections
Azitromicina Davurâ	azithromycin	Zithromaxâ (Pfizer)	infections
Cardidopa/Levodopa Davurâ	cardidopa/levodopa	Sinemet® (Bristol-Myers Squibb)	Parkinson's disease
Ciprofloxacino Davurâ	ciprofloxacin hydrochloride	Ciproâ (Bayer)	microbial infections, including anthrax

**Table of Contents**

<b>Our Generic Product Name</b>	<b>Active Ingredient</b>	<b>Innovator Product (Company)</b>	<b>Used to Treat</b>
Ebastina Davurâ	ebastine	Ebastel®, Ebastle Forte® (Almirall)	seasonal allergic rhinitis
Enalapril Davurâ	enalapril maleate	Vasotecâ (Merck)	cardiovascular disease and hypertension
Finasterida Davurâ	finasteride	Proscar® (Merk)	enlarged prostate
Fluoxetina Davurâ Fluoxetina Rimafarâ Fluoxetina Belmacâ	fluoxetine hydrochloride	Prozacâ (Eli Lilly)	depression
Ibuprofeno Davurâ	ibuprofen	Motrinâ (McNeil)	pain, fever
Lansoprazol Davurâ Lansoprazol Rimafarâ	lanoprazole	Prevacidâ (TAP)	gastroesophageal reflux disease
Mirtazapina Davurâ	mirtazapine	Remeronâ (Organon)	depression
Omeprazol Davur â Omeprazol Rimafarâ	omeprazole	Prilosecâ (AstraZeneca)	gastroesophageal reflux disease
Paroxetina Davurâ Paroxetina Rimafarâ	paroxetine	Paxilâ (GlaxoSmithKline)	depression
Pentoxifilina Davurâ	pentoxifylline	Trentalâ (Aventis)	peripheral arterial disease
Pravastatina Davurâ Pravastatina Rimafarâ	pravastatin	Pravachol® (Bristol-Myers Squibb)	elevated cholesterol
Selegilina Davurâ	selegiline hydrochloride	Eldeprylâ (Somerset)	Parkinson s disease
Sertralina Davurâ	sertraline hydrochloride	Zoloftâ (Pfizer)	Depression
Simvastatina Davurâ Simvastatina Rimafarâ	simvastatin	Zocorâ (Merck)	elevated cholesterol
Trimetazidina Davurâ	trimetazedine	Idaptanâ (Servier)	coronary therapy

*Sales to Licensees and Others*

In addition to manufacturing and selling our own branded generic and generic products, we license the right to market products to others within and outside of Spain. These license agreements are usually accompanied by long-term exclusive supply agreements, whereby our licensees purchase the licensed products from our manufacturing facility. As of December 31, 2006, our Spanish operations have executed





**Table of Contents**

184 license agreements, of which 20 with customers in Spain and 95 with customers outside of Spain cover actively marketed products that are generating revenues. The remaining licenses, 9 with customers in Spain and 60 with customers outside of Spain, are for products that are awaiting regulatory approvals. Additionally, we have 16 contract manufacturing agreements in effect in Spain and 6 contract manufacturing agreements in effect for international customers. Our Irish operations have executed 9 license agreements which are for products that are awaiting regulatory approvals. Our clients market these products under their own names and with their own labeling. Many of the products we manufacture for others use the same active ingredients that are used in our own marketed products.

*Strategic Alliance with Perrigo Company*

We entered into a product development, license and manufacturing agreement with Perrigo Company in November 2004. Together, we have co-developed a generic version of simvastatin, which is currently being marketed and sold by Perrigo in the U.S. The finished dosage forms are produced by our manufacturing subsidiary, Laboratorios Belmac, which recently received approval from the FDA. Our generic simvastatin was launched in December 2006 and marks our first U.S. generic product. Although the highly competitive simvastatin market in the U.S. is not expected to yield any material profits to our generic business, this approval for the U.S. market has added to our capabilities and sharpened our focus on more profitable opportunities. Our agreement with Perrigo contains provisions which allow us to collaborate on additional products in the future when mutually agreed upon.

*Alliance with Teva*

In July 2000, we entered into a five year strategic alliance with Teva, pursuant to which we were granted a royalty-free, non-exclusive license to register and sell certain of Teva's pharmaceutical products. Under this license agreement, we register these products with Spain's Ministry of Health and, upon approval, sell these products in Spain. We have a non-exclusive obligation to purchase the products from Teva, allowing us to purchase any of the products from sources other than Teva if we can demonstrate that Teva's price for a product exceeds the current price from another qualified source and if Teva has not exercised its right to match the lower price. The original 5-year term of the collaboration with Teva expired in July 2005; however the collaboration agreement has automatically renewed for one-year terms since the expiration of the original term. The agreement will continually renew for additional one-year terms until terminated by either party. We have received marketing approval for 12 of these products, of which one was launched in 2004 and three were launched in 2006, and 27 other product registrations have been submitted to the Ministry of Health and are pending approval. While there can be no assurance that any future products will be co-developed and licensed from Teva beyond the existing term of July 2007, the existing licensed products (approved and pending) will remain the property of the Company and we expect Teva to continue to supply either raw materials or finished goods for those products for a period of at least five years from the launch of each product.

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

**Table of Contents***Manufacturing*

Our 108,000 square-foot pharmaceutical product manufacturing facility is located in Zaragoza, Spain. Our manufacturing facility complies with GMP in Europe and is capable of producing tablets, capsules, ointments, lotions, liquids and sachets, as well as microgranulated products. The facility also includes analytical chemistry, quality control, quality assurance and formulation research laboratories. We have also made modifications to this manufacturing facility so that it complies with U.S. GMPs. We recently received FDA approval at this facility for simvastatin, our first generic product in the U.S. Simvastatin is currently being marketed in the U.S. by our partner, Perrigo Company.

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

We have fully integrated manufacturing support systems, including quality assurance, quality control, regulatory compliance and inventory control. These support systems are designed to maintain high standards of quality for our products and deliver reliable products and services to our customers on a timely basis. We require a supply of quality raw materials and packaging materials to manufacture and package drug products. Historically we have not had difficulty obtaining raw materials and packaging materials from suppliers. Currently, we rely on over 100 suppliers to deliver our required raw materials and packaging materials, most of which are supplied by approximately one third of these entities. We have no reason to believe that we will be unable to procure adequate supplies of raw materials and packaging materials on a timely basis. Union Quimico Farmaceutica, S.A. is our primary supplier of omeprazole. We believe that alternative sources of omeprazole are available and we will obtain required governmental approval to source from them, if necessary.

**Products in Development**

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

<b>Product Candidate</b>	<b>Technology</b>	<b>Used to Treat</b>	<b>Status</b>
Generic products	Various	Various	Bioequivalence and/or submitted for approval in the U.S., Spain, Europe and other countries.
Intranasal insulin	CPE-215	Diabetes	Phase I/II
Oral peptide delivery	Nanocaplet	Various	Preclinical

*Generic Products*

We continually evaluate which pharmaceutical products are good candidates for us to develop, test and market as generic products in Spain, the U.S. and elsewhere. We select products based on factors

**Table of Contents**

including the timing of expiration of the patent on the innovator's product, the ability of our manufacturing facility to efficiently produce the product, the availability and cost of the raw materials to produce the product as well as the potential market size and pricing that can be obtained for the product. Once we select a product, our scientists develop a generic formulation of the product, which then must be tested to determine if it is bioequivalent to the innovator's product. Products are then submitted for marketing approval by the relevant regulatory authorities, generally starting with Spain's Ministry of Health.

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

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

*Nasulin<sup>TM</sup> (Intranasal Insulin)*

We are developing intranasal formulations of insulin to treat patients suffering from Type I and Type II diabetes. Based on preclinical studies and the results of our Phase I and Phase II studies, we believe our intranasal insulin formulation can potentially achieve higher levels of bioavailability compared to other drug delivery systems currently being developed. Our product is designed to deliver insulin through a small, discreet nasal spray that can be carried in a patient's pocket. Our formulation is designed to blunt the increase in glucose following meals. Our formulation may greatly reduce the number of insulin injections required to be taken by Type I diabetics (those required to take insulin) and it may reduce the number of medications currently required to be taken by Type II diabetics (those not required to take insulin).

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

Based on the results of this Phase I study, we proceeded with a Phase II protocol for evaluation in insulin-dependent diabetics, which was completed in late 2004. This study has shown that a Bentley formulation of insulin designed for intranasal administration shows preliminary evidence of efficacy, and appears to be well tolerated in patient volunteers with insulin dependent diabetes mellitus. Additional studies, both preclinical and clinical, were performed in 2005 and 2006. Additional Phase II studies were initiated in the U.S. in late 2006 and both studies will continue in the U.S. and India in 2007.

**Table of Contents**

Diabetes is a metabolic disorder affecting more than 200 million people worldwide. Diabetic patients who must endure frequent injections prefer less invasive methods of administering their medications. Alternative and more desirable methods of delivery would not only improve quality of life but also would contribute to patient compliance with prescribed therapy.

**Products Available for Licensing**

*Antifungal Nail Lacquer*

We have developed a topical nail lacquer for treating fingernail and toenail fungal infections (onychomycosis). We completed two Phase I/II clinical trials for the treatment of nail fungal infections at the University of Alabama at Birmingham in 2002 and 2003 utilizing a clotrimazole lacquer formulation containing CPE-215. According to the National Onychomycosis Society, nail fungus affects almost 30 million people in the U.S., primarily between the ages of 40 and 65. Patients electing to take oral therapy must undergo blood monitoring during the course of treatment to monitor for liver damage.

*Topical Hormonal Therapy*

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

*Intranasal Pain Management*

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

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

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

**Table of Contents**

**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. We have three U.S. patents and six foreign patents related to our CPE-215 technology. This includes a new patent issued in 2006 for our intranasal insulin and peptide delivery platform which is based on our CPE-215 technology. This is the first patent to issue of our comprehensive filings around the world designed to protect our intranasal delivery platform. The patents for our CPE-215 technology expire in the U.S. in 2008 and in foreign countries between 2010 and 2024.

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

In 2003, we acquired a U.S. patent regarding our antifungal nail lacquer product which expires in 2020. Patent applications for our antifungal nail lacquer are currently pending in Europe and other foreign countries.

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

**Research and Development**

Research and development expenses were \$10,459,000, \$5,800,000 and \$4,419,000 in the years ended December 31, 2006, 2005 and 2004, respectively. The steady increase in these expenses is attributed to continued investments in our research and development programs for our drug delivery technologies, primarily for Nasulin™, our intranasal insulin product candidate. We recently announced the expansion of our Nasulin Phase II studies to include clinical evaluations in Type II diabetic patients in the U.S and India. Research and development expenses in 2006 also include approximately \$664,000 of non-cash, share-based compensation expense for which there was no comparable expense recorded in prior years. We plan to incur increased research and development costs as we continue to conduct our clinical trials. Although cost estimates and timing of our trials are subject to change, we expect consolidated research and development expenses for 2007 to be approximately \$15,000,000 to \$16,000,000.

**Table of Contents**

**Competition**

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

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

**Customers**

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

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

In the past three years, only one of our customers, Cofares, accounted for more than ten percent of our consolidated total revenues. Sales to this customer accounted for approximately 11% of our consolidated total revenues in 2006, 12% in 2005 and 13% in 2004.

**Financial Information About Geographic Areas**

The majority of our revenues are generated from products sold in Spain. Spain revenues totaled \$77,228,000, \$69,845,000, and \$59,095,000 in the years ended December 31, 2006, 2005 and 2004, respectively. Long-lived assets in Spain at December 31, 2006, 2005 and 2004 were \$56,435,000, \$40,120,000 and \$39,160,000, respectively. See Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations and Note 14 of the Notes to Consolidated Financial Statements in Item 15 for additional financial information regarding geographic areas.

**Table of Contents**

**Seasonality**

See Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations for information regarding the impact of seasonality on our results of operations.

**Employees**

We employ approximately 442 people, 22 of whom are employed in the U.S. and 420 of whom are employed in Spain, as of March 1, 2007. Approximately 200 of these employees are principally engaged in manufacturing activities, 170 in sales and marketing, 26 in product development and 46 in management and administration. In general, we consider our relations with our employees to be good.

**Regulation**

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

*United States*

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

Preclinical testing;

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

Clinical trials;

Preparation and submission of the NDA; and

FDA's review and approval/disapproval of the NDA.

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

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

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

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



**Table of Contents**

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

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

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

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

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

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

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

**Table of Contents**

*Europe*

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

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

Spain, and many other European governments, have historically implemented reduced pricing strategies to mitigate rising healthcare costs. The most recent price reduction will be effective on March 1, 2007, which has required our sales force to begin marketing our products at lower prices as early as February. In addition, the impending price changes reduced our sales levels in the fourth quarter of 2006 as wholesalers and pharmacies reduced orders to minimum quantities until they were able to purchase at the new lower prices. We faced similar regulation in Spain in late October 2003 which reduced the prices of our top selling products. Since then we have continued to seek out new ways to improve the efficiency of our manufacturing operations, reduce our costs and increase sales volumes to help mitigate lower prices. We are also focused on increasing our sales in other countries and other geographic regions, including the U.S., through strategic alliances with distributors and collaborators in those territories. We also target markets that offer compatible regulatory approval regimes and attractive product margins. In August 2005, we formed an Irish subsidiary, Bentley Pharmaceuticals Ireland Limited, to assist in our European expansion strategy. Bentley Pharmaceuticals Ireland Limited received its first marketing approval by the Irish Medicines Board in November 2005 and launched its first product in the fourth quarter of 2006. (See Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations for more discussion of regulations in Spain.)

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

A manufacturing facility is required to obtain a general permit to operate a pharmaceutical business certifying that its facilities comply with European GMPs. These permits are granted by the national

**Table of Contents**

authorities in the country of manufacture and other European countries rely on regulation by the authority of the country of manufacture.

*Trends in Healthcare Regulation*

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

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

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

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

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

*Other Regulations*

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

**Table of Contents**

**Available Information**

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

**Item 1A. Risk Factors**

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

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

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

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

**Table of Contents**

and branded drug operations with greater financial, marketing and sales resources and experience in the geographic areas in which they operate. If we do not effectively identify generic and branded generic drugs and technologies and bring them to commercial success, then we will not be able to continue our growth and we will be adversely affected.

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

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

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

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

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

other pharmaceutical companies may market equivalent or superior products.

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

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

perceived efficacy of our products;

convenience and ease of administration;

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

availability of alternative treatments;

cost effectiveness;

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

publicity concerning our products or competing products; and

our ability to obtain third-party coverage or reimbursement.

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

the effectiveness of our sales force;

**Table of Contents**

the effectiveness of our production, distribution and marketing capabilities;

the success of competing products; and

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

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

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

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

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

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

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

We are a party to a number of agreements pursuant to which we are required to perform certain tasks in accordance with specified schedules such as manufacturing of products, timing and success of research and development goals, etc. Should we not meet these deadlines and requirements, our counterparties can take actions specified in these agreements which could substantially reduce the amount

**Table of Contents**

of revenues the Company would receive, or terminate the related agreements. Additionally, in accordance with the terms of these agreements, the Company may be forced to pay penalties or other damages to our counterparties for breaching these agreements.

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

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

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

Spanish sales from our omeprazole product line accounted for approximately 18% of our consolidated total revenues in 2006 and 2005. The active pharmaceutical ingredient for our omeprazole products is currently purchased from one supplier. If we lose and cannot effectively replace our supplier or are otherwise unable to continue the sales of our omeprazole products, our revenues would decline significantly.

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

Our revenues and profitability may be adversely affected by the continuing efforts of governmental and third-party payors to contain or reduce the costs of healthcare. A substantial portion of our operations consists of marketing and manufacturing, primarily in Spain and other parts of Europe, generic and branded generic pharmaceutical products. The use of generic drugs is regulated in Spain, the U.S. and many other countries, and is subject to many changing and competing public policy considerations. In addition, in certain markets, such as Spain, pricing or profitability of prescription pharmaceuticals is subject to government control through reimbursement limitations. Specifically, prices for prescription pharmaceutical products in Spain must be approved by Spain's Ministry of Health. In order to help control rising healthcare costs, the Ministry of Health, in recent years, has encouraged the substitution of generic-equivalent products. In further efforts to reduce healthcare costs, the Ministry of Health had been contemplating new laws and regulations that would significantly reduce the market prices of certain pharmaceutical products, including generic-equivalent drugs. For example, the Spanish government enacted a regulation effective March 1, 2007 that reduced the prices that the government reimburses for many prescription pharmaceutical products. This new regulation affects the majority of the products we sell in Spain. Had this regulation been effective for 2006, our consolidated revenues would have been reduced by approximately 10% to 12%.

Successful commercialization of many of our products, including those using our permeation technologies as well as our generic and branded generic 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

**Table of Contents**

managed care in the U.S. continues to increase the pressure on pharmaceutical pricing. Some governmental agencies, including those in Spain, can compel companies to continue to produce products that are not profitable for the company due to insufficient supply. In the U.S., there have been a number of federal and state proposals to implement similar government controls. We anticipate that there will continue to be a number of proposals in the U.S., as has been the case in many foreign markets. The announcement or adoption of such proposals could adversely affect us. Further, our ability to commercialize our products may be adversely affected to the extent that such proposals materially adversely affect the business, financial condition and profitability of companies that are prospective strategic partners.

The cost of healthcare in Spain, the U.S. and elsewhere continues to be a subject of investigation and action by various governmental agencies. Certain resulting legislative proposals may adversely affect us. For example, governmental actions to further reduce or eliminate reimbursement for drugs may directly diminish our markets. In addition, legislative safety and efficacy measures may be invoked that lengthen and increase the costs of drug approval processes. Further, social, economic and other broad policy legislation may induce unpredictable changes in the healthcare environment. If any of these measures are enacted in some form, they may have a material adverse effect on our results of operations.

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

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

- slow or insufficient patient enrollment;

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

- longer treatment time required to demonstrate efficacy;

- lack of sufficient supplies of the product candidate;

- adverse medical reactions or side effects in treated patients;

- lack of effectiveness of the product candidate being tested;

- regulatory requests for additional clinical trials; and

- instability of the pharmaceutical formulations.

A delay or termination of any of our clinical trials may have a material adverse effect on our results of operations.



**Table of Contents**

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

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

Competitors may interfere with our patent process in a variety of ways. Competitors may claim that they invented the claimed invention prior to us. Competitors also may claim that we are infringing their patents, interfering with or preventing the use of our technologies. Competitors also may contest our patents by showing the patent examiner that the invention was not original, was not novel or was obvious. A competitor could claim that our issued patents are not valid for a variety of other reasons as well.

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

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

Our generic and branded generic products may subject us to litigation and claims that we infringe the intellectual property of others.

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

**Table of Contents**

If a company claims we infringe its 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.

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

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

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

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

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

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

**Table of Contents**

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

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

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

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

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

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

**We are dependent on only one manufacturing facility that can be used to manufacture our pharmaceutical products and only one manufacturing facility that can be used to manufacture active pharmaceutical ingredients.**

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

**Table of Contents**

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

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

During the year ended December 31, 2006, 71% of our revenues were derived from sales made by our Spanish subsidiaries in Spain and 22% of our revenues were derived from sales made by our Spanish subsidiaries to customers in other foreign countries. We believe that the most substantial portion of our revenues will continue to be derived from sales in foreign countries. Conducting business internationally subjects us to a number of risks and uncertainties, including:

unexpected delays or changes in regulatory requirements;

difficulties and costs related to complying with a wide variety of complex foreign laws and treaties;

delays and expenses associated with tariffs and other trade barriers;

restrictions on and impediments to repatriation of our funds and our customers' ability to make payments to us;

political and economic instability;

acts of terrorism or war;

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

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

inadequate or uncertain protection of intellectual property in foreign countries;

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

adverse tax consequences or overlapping tax structures; and

limitations on the remittance of dividends by foreign subsidiaries.

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

Our revenues may be impacted by fluctuations in local currencies due to the fact that 92% of our revenues currently are generated by our Spanish subsidiaries, Laboratorios Belmac, Laboratorios Davur, Laboratorios Rimafar and Bentley API. Fluctuations in the value of the Euro, in relation to the U.S. Dollar, had a significant impact on our operations during the interim periods of 2006, but did not have a significant effect on our operations for the twelve months ended December 31, 2006. Our foreign operations also expose us to a number of currency related risks, including the following:

fluctuations in currency exchange rates;

limitations on the conversion of foreign currency; and

fluctuations of the carrying value of long lived assets.



**Table of Contents**

We do not currently engage in foreign exchange hedging transactions to manage our foreign currency exposure because much of our expenditures are in the same currency as our revenues. However, one of our subsidiaries has entered into a hedging arrangement to reduce the variability of future cash flows related to a foreign denominated liability recorded on its books.

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

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

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

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

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

We routinely consider acquisition and investment opportunities, although we have no current agreements or commitments with respect to any acquisitions or investments. Any future acquisitions or investments would further challenge our resources. If we do not properly meet the increasing expenses and demands on our resources from future growth, we will be adversely affected. To properly manage our growth, we must, among other things, improve and implement additional 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

**Table of Contents**

potential market opportunities. We plan to invest \$13.0 million to \$16.0 million in capital expenditures during the year ending December 31, 2007, including \$5.5 million that was budgeted in 2006, but now planned for 2007. We plan to expand our API manufacturing facility, expand our pharmaceutical product manufacturing facility and add new production lines in order to be able to accommodate the level of operations and growth that is anticipated as a result of the Company's expansion beyond the borders of Spain and the U.S. market. We plan to finance these expenditures from a combination of cash flow from operations, existing cash balances, and borrowings, if necessary. If we fail to generate additional revenue in excess of increased operating expenses in any fiscal period, we may incur losses.

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

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

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

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

One of our strategies for business expansion is the acquisition of additional technologies, products and product candidates. We may attempt to acquire these product candidates, or other potentially beneficial technologies, through the acquisition of businesses, services or products that we believe are a strategic fit with our business. Although we currently have no commitments or agreements with respect to any acquisitions, if we undertake an acquisition, the process of integrating the acquired business, technology, service or product may result in unforeseen operating difficulties and expenditures and may divert significant management attention from our ongoing business operations. Moreover, we may fail to realize the anticipated benefits of any acquisition for a variety of reasons such as an acquired technology or product candidate proving to not be safe or effective in later clinical trials. We may fund any future acquisition by issuing equity or debt securities, which could dilute your ownership percentage or limit our financial or operating flexibility as a result of restrictive covenants related to new debt. Acquisition efforts can consume significant management attention and require substantial expenditures, which could detract

**Table of Contents**

from our other programs. In addition, we may devote resources to potential acquisitions that are never completed.

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

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

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

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

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

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

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

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could inhibit or prevent the commercialization of pharmaceutical products we develop alone or with corporate collaborators. In Spain, we maintain product liability insurance in the amount of 3 million (approximately \$3.9 million U.S. Dollars) and clinical trial insurance in connection with our clinical testing activities in various amounts on a study-by-study basis. In the U.S. we maintain



**Table of Contents**

\$10.0 million in product liability and clinical trials insurance. While management believes that this insurance is reasonable, we cannot assure you that any of this coverage will be adequate to protect us in the event of a claim. We, or any corporate collaborators, may not be able to obtain or maintain insurance at a reasonable cost, if at all. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate if any claim arises.

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

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

demand and pricing for our products, including changes in wholesaler purchasing;

government or private healthcare reimbursement policies;

physician, pharmacy and patient acceptance of any of our current or future products;

patterns or cost structures for our products;

introduction of competing products, including generics;

any interruption in the manufacturing or distribution of Testim or any of our future products;

our operating expenses which fluctuate due to growth of our business;

timing and size of any new product or technology acquisitions we may complete; and

variations in our rates of product returns and allowances.

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

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

As of December 31, 2006, we had the following capital structure:

	<i>No. of Shares</i>
<i>Common stock outstanding</i>	22,262,413
<i>Common stock issuable upon:</i>	
<i>Exercise of options which are outstanding</i>	3,636,979
<i>Vesting of restricted stock units which are outstanding</i>	118,399
<i>Contingently issuable shares</i>	20,000
<i>Exercise/vesting of options and restricted stock units which are available for grant</i>	736,274
 <i>Total common stock outstanding assuming exercise of all of the above</i>	 26,774,065

**Table of Contents**

As of December 31, 2006, we had outstanding options to purchase 3,636,979 shares of common stock at exercise prices ranging from \$2.00 to \$15.83 (exercisable at a weighted average of \$9.80 per share), of which 2,834,644 were then vested and exercisable. We may conduct future offerings of our common stock or other securities with rights to convert the securities into shares of our common stock. Exercise of our outstanding options into shares of our common stock may significantly and negatively affect the market price for our common stock as well as decrease your percentage ownership and voting power.

**Our stock price is volatile.**

The market prices for our securities and for securities of emerging growth companies have historically been highly volatile. During the two years ended March 9, 2007, the price of our common stock has ranged from a high of \$22.90 to a low of \$6.50. Future announcements concerning us or our competitors may have a significant impact on the market price of our common stock. Factors which may affect our market price include:

- progress of our relationships with strategic partners;
- results of clinical studies and regulatory reviews;
- technological innovations by us or our competitors;
- market conditions in the pharmaceutical, drug delivery and biotechnology industries;
- effect of regulatory authorities on pricing of products;
- competitive products;
- financings;
- sales or the possibility of sales of our common stock;
- our results of operations and financial condition;
- proprietary rights and related litigation;
- public concern as to the safety or commercial value of our products; and
- general economic conditions.

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

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

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

**Table of Contents**

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

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

Our staggered board, the super-majority voting provisions, the potential issuance of preferred stock and our stockholder rights plan may have the effect of delaying, preventing or discouraging third parties or stockholders from attempting to replace our management.

**Item 1B. Unresolved Staff Comments**

None.

**Item 2. Properties**

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

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

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

We lease a 13,000 square foot facility in San Sebastian de los Reyes, Spain, an area northwest of Madrid, which houses the administrative offices for our Spanish and European operations. The lease for this facility expires in 2008.

**Table of Contents**

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

**Item 3. Legal Proceedings**

On September 27, 2004, we were served with a complaint in an action captioned Ethypharm S.A. France & Ethypharm S.A. Spain v. Bentley Pharmaceuticals, Inc., U.S. District Court for the District of Delaware, Civil Action No. 04-1300 (SLR). In this action, Ethypharm S.A. France and Ethypharm S.A. Spain, which are referred to individually and collectively as Ethypharm, alleged that since March 2002 our Spanish subsidiary Laboratorios Belmac, S.A. ( Belmac ) misappropriated unspecified Ethypharm trade secrets and confidential information and used that information in the manufacture of omeprazole, one of Belmac's pharmaceutical products. On April 11, 2005, Ethypharm S.A. Spain filed suit against Belmac S.A. in the Commercial Court No. 5 of Madrid, Spain. The complaint alleged that Belmac refused to renew its contract with Ethypharm for the manufacture of omeprazole which expired on March 22, 2002, and that after that date Belmac's continued manufacture of omeprazole pursuant to its own patented technology infringed Ethypharm's Spanish Patent No. ES9301319. In late 2006 Bentley and Belmac settled all outstanding litigation with Ethypharm. Under the settlement terms, Belmac paid Ethypharm \$4,000,000 in the fourth quarter of 2006 and will make four additional payments of \$1,000,000 each on the first four anniversaries of the first payment.

In December 2004, Belmac, jointly with three other Spanish manufacturers, initiated a legal proceeding in the 2nd Commercial Court of the City of Barcelona against Warner-Lambert Company requesting the partial revocation in Spain of European patent EP 409.281 concerning atorvastatin calcium. In turn, Warner-Lambert Company counterclaimed against the plaintiffs for alleged infringement of the patent in suit. The court ruled in favor of Belmac in a decision rendered on September 26, 2006, and Warner-Lambert Company has appealed the judgment. A decision on the appeal is expected by the second half of 2007.

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

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

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

None.

**Table of Contents****Part II****Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities**

Our common stock began trading on the New York Stock Exchange on May 12, 2004 and on NYSE Arca (formerly the Pacific Exchange) on March 27, 1996. We voluntarily withdrew our securities from listing with NYSE Arca in December of 2006. The withdrawal eliminates duplicative administrative requirements inherent in dual listings and avoids substantial new listing fees following the NYSE Group's recent merger with Archipelago Holdings, the parent company of NYSE Arca. The following table sets forth, for the periods indicated, the range of quarterly high and low sales prices for our common stock as reported on the New York Stock Exchange under the symbol BNT .

	<i>High</i>	<i>Low</i>
<b><i>Fiscal Year Ended December 31, 2005</i></b>		
<i>First Quarter</i>	<i>\$10.94</i>	<i>\$ 7.25</i>
<i>Second Quarter</i>	<i>12.10</i>	<i>6.50</i>
<i>Third Quarter</i>	<i>12.95</i>	<i>10.63</i>
<i>Fourth Quarter</i>	<i>20.80</i>	<i>11.27</i>
<b><i>Fiscal Year Ended December 31, 2006</i></b>		
<i>First Quarter</i>	<i>22.90</i>	<i>12.78</i>
<i>Second Quarter</i>	<i>14.19</i>	<i>9.43</i>
<i>Third Quarter</i>	<i>13.07</i>	<i>8.78</i>
<i>Fourth Quarter</i>	<i>12.90</i>	<i>8.82</i>
<b><i>Fiscal Year Ending December 31, 2007</i></b>		
<i>First Quarter (through March 9, 2007)</i>	<i>10.34</i>	<i>7.52</i>

As of March 9, 2007 there were 943 holders of record of our common stock, which does not reflect stockholders whose shares are held in street name.

**Dividends**

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

**Table of Contents****Issuer Purchases of Equity Securities**

	(a) Total Number of Shares (or Units) Purchased (1)	(b) Average Price Paid per Share (or Unit)(2)	(c) Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	(d) Maximum Number (or approximate dollar value) of Shares (or Units) that may yet be Purchased under the Plans or Programs
October 1, 2006 through October 31, 2006	19,015	\$12.035		
November 1, 2006 through November 30, 2006				
December 1, 2006 through December 31, 2006				
<b>Total</b>	<b>19,015</b>	<b>\$12.035</b>		

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

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

date of exercise.

**Item 6. Selected Financial Data**

The following sets forth the selected Consolidated Income Statement data for the years ended December 31, 2002, 2003, 2004, 2005 and 2006 and Consolidated Balance Sheet data as of December 31, 2002, 2003, 2004, 2005 and 2006, all of which are derived from our audited Consolidated Financial Statements and related notes. The following Consolidated Income Statement data for the years ended December 31, 2004, 2005 and 2006 and Consolidated Balance Sheet data as of December 31, 2005 and 2006 should be read together with our Consolidated Financial Statements and related notes appearing elsewhere in Item 15 and Management's Discussion and Analysis of Financial Condition and Results of Operations of this Annual Report on Form 10-K. The Consolidated Income Statement data for the years ended December 31, 2002 and 2003 and the Consolidated Balance Sheet data as of December 31, 2002, 2003 and 2004 are derived from our audited Consolidated Financial Statements and related notes not included in this Annual Report on Form 10-K.

**Table of Contents****Consolidated Income Statement Data**

<i>(in thousands, except per share data)</i>	<i>For the Year Ended December 31,</i>				
	<i>2002</i>	<i>2003</i>	<i>2004(a)</i>	<i>2005(b)</i>	<i>2006(c)(d)</i>
<i>Total revenues</i>	\$ 39,136	\$ 64,676	\$ 73,393	\$ 97,730	\$ 109,471
<i>Cost of net product sales</i>	16,477	26,399	34,893	46,161	49,850
<i>Gross profit</i>	22,659	38,277	38,500	51,569	59,621
<i>Operating expenses</i>	19,277	26,848	29,805	35,903	54,222
<i>Gain on sale of drug licenses</i>	650				38
<i>Other income (expenses)</i>	138	91	1,800	729	619
<i>Income before income taxes</i>	4,170	11,520	10,495	16,395	6,056
<i>Provision for income taxes</i>	2,534	5,423	4,805	5,476	5,082
<i>Net income</i>	\$ 1,636	\$ 6,097	\$ 5,690	\$ 10,919	\$ 974
<i>Net income per common share basic</i>	\$ 0.10	\$ 0.34	\$ 0.27	\$ 0.51	\$ 0.04
<i>Net income per common share diluted</i>	\$ 0.08	\$ 0.28	\$ 0.25	\$ 0.48	\$ 0.04
<i>Weighted average common shares outstanding basic</i>	16,569	17,997	20,901	21,558	22,141
<i>Weighted average common shares outstanding diluted</i>	19,798	21,637	22,627	22,929	23,068

(a) *Other income (expenses)* for the year ended December 31, 2004 includes the reversal of previously accrued tax assessments totaling \$1,467,000. These assessments had been accrued to be paid to the Spanish government as a



vehicle to help reduce the impact of the rising health care costs in Spain. Due to changes in the pharmaceutical industry in Spain and a change in the Spanish political environment, these liabilities no longer exist. Accordingly, these accruals were reversed during the second quarter of 2004. Additionally, a reclassification of approximately \$342,000 has been made between *Depreciation and amortization* and *Cost of net product sales* for depreciation on certain fixed assets to conform with the 2005 presentation format.

- (b) *Total revenues* for the year ended December 31, 2005 include a change in estimate of royalty revenues earned of approximately

\$1,092,000 recorded in the fourth quarter of 2005. This change in estimate of royalty revenues earned is based upon publicly available data determined to be more accurate than the source of data previously relied upon by management in estimating the sell-through of prescriptions dispensed.

(c) *Total revenues* for the year ended December 31, 2006 include an increase in royalty revenues of approximately \$479,000 recorded in the second quarter of 2006. This change in estimate was due to the Company's ability to reasonably estimate future product returns on sales of Testim based on actual historical data.

(d) *Operating expenses* for the year ended

December 31, 2006 include litigation settlement charges of approximately \$7,546,000 recorded in the third quarter of 2006 associated with the probable settlement of outstanding litigation claims. The Company recorded a tax benefit of \$2,746,000 in *provision for income taxes* upon finalization of the settlement in the fourth quarter of 2006. The Company also incurred related legal defense costs of approximately \$3,368,000 during the year ended December 31, 2006.

**Table of Contents****Consolidated Balance Sheet Data**

<i>(in thousands)</i>	<i>December 31,</i>				
	<i>2002</i>	<i>2003</i>	<i>2004</i>	<i>2005</i>	<i>2006(a)</i>
<i>Working capital</i>	<i>\$ 30,703</i>	<i>\$ 46,181</i>	<i>\$ 47,114</i>	<i>\$ 46,397</i>	<i>\$ 40,303</i>
<i>Current assets</i>	<i>\$ 43,972</i>	<i>\$ 66,899</i>	<i>\$ 74,710</i>	<i>\$ 75,077</i>	<i>\$ 67,690</i>
<i>Non-current assets</i>	<i>20,720</i>	<i>33,564</i>	<i>47,220</i>	<i>49,143</i>	<i>66,666</i>
<i>Total assets</i>	<i>\$ 64,692</i>	<i>\$ 100,463</i>	<i>\$ 121,930</i>	<i>\$ 124,220</i>	<i>\$ 134,356</i>
<i>Current liabilities</i>	<i>\$ 13,269</i>	<i>\$ 20,718</i>	<i>\$ 27,596</i>	<i>\$ 28,680</i>	<i>\$ 27,387</i>
<i>Long-term debt</i>	<i>345</i>	<i>369</i>	<i>349</i>		
<i>Other non-current liabilities</i>	<i>2,327</i>	<i>3,211</i>	<i>4,328</i>	<i>3,951</i>	<i>6,638</i>
<i>Total liabilities</i>	<i>\$ 15,941</i>	<i>\$ 24,298</i>	<i>\$ 32,273</i>	<i>\$ 32,631</i>	<i>\$ 34,025</i>
<i>Redeemable preferred stock</i>	<i>\$</i>	<i>\$</i>	<i>\$</i>	<i>\$</i>	<i>\$</i>
<i>Stockholders' equity</i>	<i>\$ 48,751</i>	<i>\$ 76,165</i>	<i>\$ 89,657</i>	<i>\$ 91,589</i>	<i>\$ 100,331</i>

(a) In the fourth quarter of the year ended December 31, 2006, the Company reclassified certain of its deferred tax items on its balance sheet to be consistent with the underlying transactions to which they relate. The reclassifications resulted in a \$1,244,000 decrease of its current deferred tax assets, an

increase of  
\$240,000 to its  
non-current  
deferred tax  
assets, a  
\$238,000  
increase in  
income taxes  
payable  
(included in  
*accrued*  
*expenses* on the  
Consolidated  
Balance Sheet)  
and a decrease  
of \$1,260,000 in  
its non-current  
deferred tax  
liabilities.

**Table of Contents****Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations**

The following discussion and analysis should be read in conjunction with the Financial Statements and related Notes included in Item 8 of this report. Except for the historical information contained herein the foregoing discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those projected in the forward-looking statements discussed herein.

Words such as expect, anticipate, intend, believe, will, may, could, should, project, estimate 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 Business, Legal Proceedings, Management's Discussion and Analysis of Financial Condition and Results of Operations, Risk Factors and other sections in this report, are not based on historical facts, but rather reflect our current expectations concerning future results and events. The forward-looking statements include statements about our strategy, the prospects of our technologies and research and development efforts, our plans to enter into more collaborative relationships, our prospects for revenue growth outside of Spain, anticipated financial results and the prospects for growth of our business. Although we believe that the expectations reflected in the forward-looking statements are reasonable, such statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be different from any future results, performance and achievements expressed or implied by these statements, including the risks outlined in the Risk Factors section and elsewhere in this report. You are cautioned not to place undue reliance on these forward-looking statements. We undertake no obligation to publicly update or revise any forward-looking statements, whether as the result of new information, future events or otherwise, except as may be required by law.

**Change in Estimate**

As discussed in Critical Accounting Policies and Estimates set forth below and explained in Note 1 to the Notes to Consolidated Financial Statements under Revenue recognition, during the quarter ended June 30, 2006, we recorded an increase in royalty revenues of approximately \$479,000, or \$0.02 per share, related to sales of Testim. In light of sufficient historical return experience on sales of Testim we were able to reasonably estimate future product returns and record those revenues upon shipment as opposed to when units were dispensed through patient prescriptions. This increase is reported in *Licensing and collaboration revenues* for the year ended December 31, 2006.

**Litigation Settlement**

We have settled all outstanding litigation with Ethypharm S.A. Spain and Ethypharm S.A. France (together, Ethypharm). As a result of the settlement, we recorded a \$7,546,000 charge in 2006 representing the present value of \$4,000,000 paid in the fourth quarter of 2006 and four payments of \$1,000,000 to be paid on the first four anniversaries of the first payment. We have incurred related litigation defense costs of approximately \$3,368,000, \$593,000 and \$241,000 in the years ended December 31, 2006, 2005 and 2004, respectively. The litigation and related charges incurred in the years ended December 31, 2006, 2005 and 2004 reduced our net income by approximately \$7,819,000 or \$0.34 per diluted share, \$499,000 or \$0.02 per diluted share, and \$237,000 or \$0.01 per diluted share, respectively. The litigation related charges are recorded in *litigation settlement expenses* on the Consolidated Income Statement.

**Table of Contents**

**Adoption of New Accounting Standard**

In the first quarter of 2006, we adopted Statement of Financial Accounting Standards ( SFAS ) No. 123 (Revised), Share-Based Payment, which requires us to record the expense associated with the fair value of share-based compensation within our financial statements. The adoption of this accounting standard resulted in incremental share-based compensation expense of approximately \$1,829,000, or \$0.08 per diluted share, in 2006. We expect to incur significant, ongoing share-based compensation expense resulting from equity grants that will reduce our overall net income in the future.

**Overview**

We are a specialty pharmaceutical company focused on:

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

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

*Specialty Generic Pharmaceuticals*

Our pharmaceutical product sales activities are based in Spain, where we have a significant commercial presence and we manufacture and market approximately 118 pharmaceutical products of various dosages and strengths. These products include approximately 167 product presentations or SKUs, in four primary therapeutic areas: cardiovascular, gastrointestinal, central nervous system and infectious diseases. In 2006, approximately 25% of our product revenues were derived from two of our product lines. We market our branded generic and generic products to physicians, pharmacists and hospitals through our three separate sales and marketing organizations based in Spain: Laboratorios Belmac, Laboratorios Davur and Laboratorios Rimafar. The Spanish government controls the price at which drugs can be sold in Spain. The government has historically implemented reduced pricing strategies to mitigate rising healthcare costs. The most recent price reduction, effective on March 1, 2007, caused our sales force to begin marketing our products at lower prices in Spain as early as February. The impending price changes reduced sales levels in the fourth quarter of 2006 as wholesalers and pharmacies reduced orders to minimum quantities until they were able to purchase at the new lower prices. We will continue to implement strategies to mitigate the impact of the lower prices, including the addition of new products to our portfolio. We launched eight generic products which added approximately \$1,600,000 to our revenues in 2006. We will also intend to continue to improve the efficiency of our manufacturing operations, reduce our costs and increase sales volumes. We are also focused on increasing our sales in other countries and other geographic regions, including the U.S., through strategic alliances with distributors and collaborators in those territories. We also target markets that offer compatible regulatory approval regimes and attractive product margins. In August 2005, we formed an Irish subsidiary, Bentley Pharmaceuticals Ireland Limited, to assist in our European expansion strategy. Bentley Pharmaceuticals Ireland Limited received its first marketing approval by the Irish Medicines Board in November 2005 and launched its first product in the fourth quarter of 2006.

In addition, we expect to grow our business by acquiring rights to market additional products to sell through our organization and our strategic alliances. We continually acquire rights to new products in response to increasing market demand for generic and branded generic therapeutic products. For example, in November 2004, we entered into a collaboration agreement with Perrigo Company, the largest U.S. manufacturer of over-the-counter pharmaceutical and nutritional products for the store brand market, to co-

**Table of Contents**

develop and market generic simvastatin in the U.S. and potentially other markets. Our generic simvastatin, which is manufactured at our FDA approved finish dosage facility in Spain, was launched in December of 2006. While we do not expect to see any material contribution from U.S. sales of our generic simvastatin, the entrance into the U.S. market marks a significant strategic milestone for us.

We also manufacture and market active pharmaceutical ingredients through our subsidiary, Bentley API. Our API facility has been approved by the FDA for the manufacture of one ingredient for marketing and sale in the U.S. In addition, our Spanish pharmaceutical product manufacturing facility produces pharmaceutical products that are marketed by other pharmaceutical companies both in Spain and in other international markets, including the U.S.

*Drug Delivery Technologies and Products*

We develop and co-develop products that incorporate our drug delivery technologies. We have licensed applications of our proprietary CPE-215 drug delivery technology to Auxilium Pharmaceuticals, Inc., which launched Testim the first product incorporating our CPE-215 drug delivery technology, in the United States in February 2003. Testim is a gel indicated for testosterone replacement therapy. Testim is also approved for marketing in 15 European countries and Canada. We are in discussions with other pharmaceutical and biotechnology companies to form additional strategic alliances to facilitate the development and commercialization of other products using our drug delivery technologies, including delivery of insulin to diabetic patients intranasally and delivery of macromolecule therapeutics using a biodegradable Nanocaplet technology.

*Research and Development Focus*

In 2004 we concluded our Phase II study for the intranasal delivery of insulin in Type I diabetes patients using our CPE-215 technology. We reported the results of that trial in an abstract titled *Intranasal Insulin Administration in Type I Diabetic Patients Utilizing CPE-215 Technology* at the American Diabetes Association 65th Scientific Sessions, September 10-14, 2005, in San Diego, California. The full results of that trial were published in 2006 in the journal *Diabetes Technology & Therapeutics*, Volume 8, Number 1. In 2006, we completed our Phase II intranasal insulin program studies in Ireland, advanced our Phase II studies in the U.S. and initiated Phase II studies in India. The U.S. development and clinical programs for intranasal insulin will continue and expand both outside and inside the U.S. We are continuing our clinical programs to support our strategy for the distribution of certain of our Spanish generic pharmaceutical products in other countries, including the U.S. through collaboration agreements similar to our agreement with Perrigo Company. We expect to continue to invest our resources to conduct clinical trials and support the required regulatory submissions for our clinical programs. We expect to incur increased costs for product formulation and testing efforts.

*Effect of Foreign Currency Fluctuations*

A substantial amount of our business is conducted in Europe and is therefore influenced by fluctuations in the U.S. Dollar's value in relation to other currencies, particularly the Euro. An increase in the weighted average value of the Euro in relation to the U.S. Dollar in 2006 compared to 2005, had the following impact on the results of our operations when reported in U.S. Dollars: (1) total revenues were increased by approximately \$1,142,000, (2) gross profit was increased by approximately \$531,000, (3) operating expenses increased by approximately \$677,000, (4) provision for income taxes was decreased by approximately \$259,000, which resulted in (5) a decrease to net income of approximately \$111,000.



**Table of Contents****Consolidated Results of Operations****Fiscal Year Ended December 31, 2006 Compared To Fiscal Year Ended December 31, 2005**Revenues

<i>(in thousands)</i>					<i>Change</i>	
	<i>2006</i>	<i>%</i>	<i>2005</i>	<i>%</i>	<i>\$</i>	<i>%</i>
<i>Specialty Generics</i>						
<i>Net product sales</i>	\$100,590	92%	\$91,308	93%	\$ 9,282	10%
<i>Licensing and collaboration revenues</i>	515	*	273	*	242	89%
	101,105	92%	91,581	93%	9,524	10%
<i>Drug Delivery</i>						
<i>Licensing and collaboration revenues</i>	8,366	8%	6,149	7%	2,217	36%
<i>Total revenues</i>	\$109,471	100%	\$97,730	100%	\$11,741	12%

\* *Less than 1%*

Total revenues for the year ended December 31, 2006 increased 12% from the year ended December 31, 2005. Our current year growth was driven primarily by increased net product sales in Spain, increased sales to licensees and others and increased Testim royalties. Testim royalties in 2005 included \$1,092,000 resulting from a revised estimate of sell-through of prescriptions dispensed.

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

For the year ended December 31, 2006:

<i>(in thousands)</i>	<i>Revenues Within Spain</i>			<i>Revenues</i>		<i>% of Total Revenues</i>
	<i>Branded Generics</i>	<i>Generics</i>	<i>Other</i>	<i>Outside of Spain</i>	<i>Total</i>	
<i>Omeprazole</i>	\$ 2,679	\$16,451	\$	\$	\$ 19,130	18%
<i>Simvastatin</i>	1,851	5,620			7,471	7%
<i>Enalapril</i>	4,826	1,824			6,650	6%
<i>Paroxetine</i>	1,449	3,045			4,494	4%
<i>Lansoprazole</i>	2,689	852			3,541	3%
<i>All other products</i>	10,628	11,263	795	1,763	24,449	22%
<i>Sales to licensees and others</i>			12,741	22,114	34,855	32%
<i>Licensing and collaborations</i>			515	8,366	8,881	8%

Edgar Filing: BENTLEY PHARMACEUTICALS INC - Form 10-K

<i>Total Revenues</i>	\$24,122	\$39,055	\$14,051	\$32,243	\$109,471	100%
<i>% of 2006 Revenues</i>	22%	36%	13%	29%	100%	

---

46

**Table of Contents**

For the year ended December 31, 2005:

<i>Product Line</i>	<i>Revenues Within Spain</i>			<i>Revenues Outside of Spain</i>		<i>% of Total Revenues</i>
	<i>Branded Generics</i>	<i>Generics</i>	<i>Other</i>	<i>Spain</i>	<i>Total</i>	
<i>Omeprazole</i>	\$ 2,779	\$15,394	\$	\$	\$18,173	18%
<i>Simvastatin</i>	1,666	5,080			6,746	7%
<i>Enalapril</i>	4,153	1,706			5,859	6%
<i>Paroxetine</i>	1,337	3,118			4,455	5%
<i>Lansoprazole</i>	1,856	530			2,386	2%
<i>All other products</i>	10,810	9,282	271	1,512	21,875	23%
<i>Sales to licensees and others</i>			11,589	20,225	31,814	32%
<i>Licensing and collaborations</i>			274	6,148	6,422	7%
<i>Total Revenues</i>	\$22,601	\$35,110	\$12,134	\$27,885	\$97,730	100%
<i>% of 2005 Revenues</i>	23%	36%	12%	29%	100%	

*Spanish Operations.* The increase in the net product sales for the year ended December 31, 2006 compared to the year ended December 31, 2005 is primarily due to: (1) an aggregate increase totaling \$2,473,000 in sales of our three top selling product lines (omeprazole, simvastatin and enalapril) and (2) an increase in sales to licensees and others totaling \$3,041,000 fueled primarily by sales outside of Spain.

**Branded Generic Pharmaceutical Products**

<i>(in thousands)</i>	<i>2006</i>		<i>2005</i>		<i>Change</i>	
	<i>\$</i>	<i>%</i>	<i>\$</i>	<i>%</i>	<i>\$</i>	<i>%</i>
<i>Branded Generic Product Sales:</i>						
<i>Enalapril</i>	\$ 4,826	20%	\$ 4,153	18%	\$ 673	16%
<i>Codeisan</i>	3,001	12%	3,441	16%	(440)	-13%
<i>Lansoprazole</i>	2,689	11%	1,856	8%	833	45%
<i>Omeprazole</i>	2,679	11%	2,779	12%	(100)	-4%
<i>Simvastatin</i>	1,851	8%	1,666	7%	185	11%
<i>All other branded products</i>	9,076	38%	8,706	39%	370	4%
<i>Total branded generic sales</i>	\$24,122	100%	\$22,601	100%	\$1,521	7%

\* *Not meaningful*

Sales of our branded generic pharmaceutical products accounted for 22% of total revenues during 2006 and increased 7%, or approximately \$1,521,000 over branded generic sales in 2005. Enalapril and lansoprazole, two of our top-selling branded generic products, accounted for the majority of the increase in our branded generic sales from the prior year and represent 31% of our 2006 branded generic sales.

Generic Pharmaceutical Products

<i>(in thousands)</i>					<i>Change</i>	
	<i>2006</i>	<i>%</i>	<i>2005</i>	<i>%</i>	<i>\$</i>	<i>%</i>
<i>Generic Product Sales:</i>						
<i>Omeprazole</i>	\$16,451	42%	\$15,394	44%	\$1,057	7%
<i>Simvastatin</i>	5,620	14%	5,080	14%	540	11%
<i>Paroxetine</i>	3,045	8%	3,118	9%	(73)	-2%
<i>Pentoxifylline</i>	2,571	7%	2,540	7%	31	1%
<i>Trimetazidine</i>	2,253	6%	2,214	6%	39	2%
<i>All other generic products</i>	9,115	23%	6,764	20%	2,351	35%
<i>Total generic sales</i>	\$39,055	100%	\$35,110	100%	\$3,945	11%

**Table of Contents**

Sales of our generic pharmaceutical products accounted for 36% of 2006 total revenues and increased 11%, or approximately \$3,945,000 over 2005 generic sales. Omeprazole and simvastatin remain our top-selling generic products and accounted for 40% of the generic pharmaceutical product growth. Additionally, eight generic product launches in 2006 (included in *All other generic products* above) contributed approximately \$1,663,000 to our 2006 generic sales and accounted for 42% of the generic sales growth from 2005.

**Sales to Licensees and Others**

<i>(in thousands)</i>			<b>Change</b>	
	<b>2006</b>	<b>2005</b>	<b>\$</b>	<b>%</b>
<i>Specialty generics</i>	\$34,855	\$31,814	\$3,041	10%

Sales to licensees and others increased by \$3,041,000 or 10% compared to 2005. The increased sales are due to our increased focus on geographic expansion and growth. Sales under our license agreements are generally larger order quantities which ship at less frequent intervals than our net product sales within Spain. As a result, a delay in the timing of such shipments could have a significant affect on recorded revenues from period to period.

**Licensing and Collaboration Revenues**

<i>(in thousands)</i>			<b>Change</b>	
	<b>2006</b>	<b>2005</b>	<b>\$</b>	<b>%</b>
<i>Specialty generics</i>	\$ 515	\$ 273	\$ 242	89%
<i>Drug delivery</i>	8,366	6,149	2,217	36%
<i>Total</i>	\$ 8,881	\$ 6,422	\$ 2,459	38%

*Licensing and collaboration revenues* now account for approximately 8% of total revenues and increased by approximately \$2,459,000, or approximately 38%, in 2006. These revenues include royalties totaling \$8,341,000 from sales of Testim. During the quarter ended June 30, 2006, we recorded an increase in royalty revenues of approximately \$479,000, or \$0.02 per share, due to a change in estimate which, based on historical experience, allowed it to reasonably estimate future product returns on sales of Testim. Testim is currently reported to have captured approximately 19% of all testosterone replacement prescriptions in the market. Also included in *licensing and collaboration revenues* are revenues of approximately \$515,000 related to product licensing activities in Europe in 2006 compared to \$274,000 in 2005.

**Gross Profit**

<i>(in thousands)</i>			<b>Change</b>	
	<b>2006</b>	<b>2005</b>	<b>\$</b>	<b>%</b>
<i>Specialty generics</i>	\$51,255	\$45,420	\$5,835	13%
<i>Drug delivery</i>	8,366	6,149	2,217	36%
<i>Total</i>	\$59,621	\$51,569	\$8,052	16%

Gross profit increased by approximately \$8,052,000, or 16%, in 2006, when compared to 2005. Gross margins on net product sales increased from 49% in 2005 to 50% in 2006. We expect to experience a decline in our future gross margins as a result of the new price regulations in Spain. However, we expect our margins to then gradually improve as we continue to implement our strategies to mitigate the price reductions.

**Table of Contents**Selling and Marketing Expenses

<i>(in thousands)</i>			<i>Change</i>	
	<i>2006</i>	<i>2005</i>	<i>\$</i>	<i>%</i>
<i>Specialty generics</i>	\$ 16,153	\$ 16,347	\$ (194)	-1%
<i>Drug delivery</i>				
<i>Total</i>	\$ 16,153	\$ 16,347	\$ (194)	-1%

Selling and marketing expenses decreased by approximately \$194,000, or 1% in 2006, when compared to 2005, partially through the efficient use of our selling and marketing resources. Selling and marketing expenses decreased as a percentage of net product sales to 16% in 2006, compared to 18% in 2005.

General and Administrative Expenses

<i>(in thousands)</i>			<i>Change</i>	
	<i>2006</i>	<i>2005</i>	<i>\$</i>	<i>%</i>
<i>Specialty generics</i>	\$ 7,391	\$ 8,930	\$ (1,539)	-17%
<i>Drug delivery</i>	7,410	2,475	4,935	199%
<i>Total</i>	\$ 14,801	\$ 11,405	\$ 3,396	30%

General and administrative expenses for 2006 increased by \$3,396,000 or 30% over the prior year. As a percentage of total revenues, general and administrative expenses were 14% in 2006, compared to 12% in 2005. The increase resulted in part from the recording of \$1,126,000 of share-based compensation in the current year which was not required to be recorded in prior years, of which we have allocated \$966,000 to our drug delivery segment. Drug delivery general and administrative expenses also include approximately \$600,000 of executive severance costs. General and administrative expenses also include intersegment allocations between the drug delivery and specialty generics businesses resulting from intercompany agreements. However, except in the presentation of our segment information, these allocations do not effect our consolidated results of operations.

Research and Development Expenses

<i>(in thousands)</i>			<i>Change</i>	
	<i>2006</i>	<i>2005</i>	<i>\$</i>	<i>%</i>
<i>Specialty generics</i>	\$ 1,777	\$ 1,378	\$ 399	29%
<i>Drug delivery</i>	8,682	4,422	4,260	96%
<i>Total</i>	\$ 10,459	\$ 5,800	\$ 4,659	80%

Research and development expenses increased 80% when compared to 2005. The increase resulted from continued investments in our research and development programs for our drug delivery technologies, primarily for Nasulin™, our intranasal insulin product. We recently announced the expansion of our Nasulin Phase II studies to include clinical evaluations in Type II diabetic patients in the U.S and India. Research and development expenses also include approximately \$664,000 of non-cash, share-based compensation expense for which there was no comparable expense recorded in the prior year. We plan to incur increased costs as we continue to conduct our clinical trials. Although cost estimates and timing of our trials are subject to change, we expect consolidated research and development expenses for 2007 to be approximately \$15,000,000 to \$16,000,000.



**Table of Contents**Litigation Settlement Expenses

<i>(in thousands)</i>			<i>Change</i>	
	<i>2006</i>	<i>2005</i>	<i>\$</i>	<i>%</i>
<i>Specialty generics</i>	\$10,914	\$593	\$10,321	*

\* *Not meaningful*

Litigation settlement expenses include a \$7,546,000 legal settlement and \$3,368,000 of related legal expenses in 2006. We recorded the present value of our legal settlement with Ethypharm S.A. France and Ethypharm S.A. Spain in September 2006. All claims related to the litigation were dismissed with prejudice in December 2006. See *Other liabilities* in Note 2 to the Consolidated Financial Statements for additional information. Related legal costs previously recorded in *general and administrative expenses* in 2006, 2005 and 2004 have been reclassified to *litigation settlement expenses* on the Consolidated Income Statements.

Other Income (Expenses)

<i>(in thousands)</i>			<i>Change</i>	
	<i>2006</i>	<i>2005</i>	<i>\$</i>	<i>%</i>
<i>Specialty generics</i>	\$ (64)	\$ (15)	\$ (49)	-327%
<i>Drug delivery</i>	683	744	(61)	-8%
<i>Total</i>	\$ 619	\$ 729	\$ (110)	-15%

Other income (expenses) in 2006 decreased by \$110,000 compared to 2005 primarily due to the reduction of interest income from reduced cash balances.

Provision for Income Taxes

<i>(in thousands)</i>	<i>Spain</i>	<i>Ireland</i>	<i>U.S.</i>	<i>Consolidated</i>
<i>Income (loss) before income taxes</i>				
<i>Specialty generics</i>	\$ 16,239	\$ 29	\$ (2,482)	\$ 13,786
<i>Drug delivery</i>		(10,447)	2,717	(7,730)
<i>Total income (loss) before income taxes</i>	16,239	(10,418)	235	6,056
<i>Provision (benefit) for income taxes</i>	5,082	(1,315)	1,982	5,749
<i>Valuation allowance</i>		1,315	(1,982)	(667)
<i>Net provision for income taxes</i>	5,082			5,082
<i>Net income (loss)</i>	\$ 11,157	\$ (10,418)	\$ 235	\$ 974
<i>Effective tax rate</i>	31%	0%	0%	84%



Effective October 2005, we executed intercompany agreements between Bentley Pharmaceuticals, Inc. and Bentley Pharmaceuticals Ireland Limited to license non-U.S. rights of certain technologies owned by Bentley Pharmaceuticals, Inc. and provide for cost-sharing of subsequent development efforts on those technologies. A net benefit of approximately \$10,376,000 has been recorded to the U.S. income from operations (and a corresponding reduction to Irish income from operations) in 2006 as a result of these agreements.

**Table of Contents**

In 2006, we generated U.S. income before income taxes of approximately \$235,000, compared to approximately \$1,042,000 in 2005. In both periods, we utilized U.S. federal net operating loss carry-forwards in order to offset the resulting income tax liability. During 2006, approximately \$6,232,000 of U.S. federal net operating loss carryforwards expired unutilized. As of December 31, 2006, the remaining U.S. federal net operating loss carry-forwards were approximately \$50,216,000. Bentley Pharmaceuticals Ireland Limited generated a net operating loss of approximately \$10,418,000 in 2006. As future operating profits cannot be reasonably assured, no tax benefit has been recorded for these losses. Accordingly, we have established a valuation allowance equal to the full amount of the deferred tax assets in Ireland.

Should we determine that it is more likely than not that we will realize certain of our net deferred tax assets for which we have previously provided a valuation allowance, an adjustment would be required to reduce the existing valuation allowance. In addition, we operate within multiple taxing jurisdictions and are subject to audit in those jurisdictions. These audits can involve complex issues, which may require an extended period of time for resolution. We have tax contingencies totaling \$530,000 at December 31, 2006, all of which have been recorded in prior years. No additional potential tax contingencies were considered to be probable and reasonably estimable as of December 31, 2006. However, there is the possibility that the ultimate resolution of such potential contingencies could have an adverse effect on our Consolidated Financial Statements in the future.

Net Income*(in thousands, except per share data)*

	<i>December 31,</i>		<i>Change</i>	
	<i>2006</i>	<i>2005</i>	<i>\$</i>	<i>%</i>
<i>Specialty Generics</i>	\$ 8,696	\$ 11,532	\$ (2,836)	-25%
<i>Drug Delivery</i>	(7,722)	(613)	(7,109)	-1160%
<i>Total net income</i>	\$ 974	\$ 10,919	\$ (9,945)	-91%
<i>Net income per common share:</i>				
<i>Basic</i>	\$ 0.04	\$ 0.51	\$ (0.47)	-92%
<i>Diluted</i>	\$ 0.04	\$ 0.48	\$ (0.44)	-92%
<i>Weighted average common shares outstanding:</i>				
<i>Basic</i>	22,141	21,558	583	3%
<i>Diluted</i>	23,068	22,929	139	1%

We reported 2006 income from operations of \$5,437,000, compared to 2005 income from operations of \$15,666,000. In 2006, the combination of income from operations of \$5,437,000 and the non-operating items, primarily the provision for income taxes of \$5,082,000, resulted in 2006 net income of \$974,000, or \$.04 per basic common share (\$.04 per diluted common share) on 22,141,000 weighted average basic common shares outstanding (23,068,000 weighted average diluted common shares outstanding), compared to 2005 net income of \$10,919,000, or \$.51 per basic common share (\$.48 per diluted common share) on 21,558,000 weighted average basic common shares outstanding (22,929,000 weighted average diluted common shares outstanding).

**Table of Contents****Fiscal Year Ended December 31, 2005 Compared To Fiscal Year Ended December 31, 2004****Revenues**

<i>(in thousands)</i>	2005		2004		Change	
		%		%	\$	%
<i>Specialty Generics</i>						
<i>Net product sales</i>	\$91,308	93%	\$69,942	95%	\$21,366	31%
<i>Licensing and collaboration revenues</i>	273	*	607	1%	(334)	-55%
	91,581	93%	70,549	96%	21,032	30%
<i>Drug Delivery</i>						
<i>Licensing and collaboration revenues</i>	6,149	7%	2,844	4%	3,305	116%
<i>Total revenues</i>	\$97,730	100%	\$73,393	100%	\$24,337	33%

\* Less than 1%

Total revenues for 2005 increased 33% from 2004. Growth was driven primarily by increased net product sales. The increase in licensing and collaboration revenues was due to increased royalty revenues from sales of Testim and included \$1,092,000 resulting from a revised estimate of sell-through of prescriptions dispensed that was recorded in the fourth quarter of 2005.

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

For the year ended December 31, 2005:

<i>(in thousands)</i>	<i>Revenues Within Spain</i>			<i>Revenues Outside of Spain</i>		<i>% of Total Revenues</i>
	<i>Branded</i>	<i>Generics</i>	<i>Other</i>	<i>Outside of Spain</i>	<i>Total</i>	
<i>Product Line</i>	<i>Generics</i>	<i>Generics</i>	<i>Other</i>	<i>Outside of Spain</i>	<i>Total</i>	
<i>Omeprazole</i>	\$ 2,779	\$15,394	\$	\$	\$18,173	18%
<i>Simvastatin</i>	1,666	5,080			6,746	7%
<i>Enalapril</i>	4,153	1,706			5,859	6%
<i>Paroxetine</i>	1,337	3,118			4,455	5%
<i>Codeisan</i>	3,441				3,441	4%
<i>All other products</i>	9,225	9,812	271	1,512	20,820	21%
<i>Sales to licensees and others</i>			11,589	20,225	31,814	32%
<i>Licensing and collaborations</i>			274	6,148	6,422	7%
<i>Total Revenues</i>	\$22,601	\$35,110	\$12,134	\$27,885	\$97,730	100%
<i>% of 2005 Revenues</i>	23%	36%	12%	29%	100%	



**Table of Contents**

For the year ended December 31, 2004:

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

*Spanish Operations.* The increase in net product sales for the year ended December 31, 2005 compared to the year ended December 31, 2004 was primarily due to: (1) increased sales to licensees and others totaling \$11,024,000 fueled primarily by sales outside of Spain; and (2) an aggregate increase totaling \$5,072,000 in sales of our three top selling product lines (omeprazole, simvastatin and enalapril). Sales of active pharmaceutical ingredients from our API manufacturing facility (included in All other products in the tables above) added \$1,783,000 to consolidated revenues in 2005.

**Branded Generic Pharmaceutical Products**

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

\* Not meaningful

Sales of our branded generic pharmaceutical products accounted for 23% of total revenues in 2005 and increased 23%, or approximately \$4,210,000 over branded generic sales in 2004. Enalapril, Codeisan and omeprazole were our

top-selling branded generic products in 2005 and accounted for approximately 46% of branded generic sales in 2005. Sales of lansoprazole, a branded generic pharmaceutical launched in December 2004, increased to \$1,856,000 in 2005 compared to approximately \$31,000 in 2004.

**Table of Contents**Generic Pharmaceutical Products

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

Sales of our generic pharmaceutical products accounted for 36% of total revenues during 2005 and increased 21%, or approximately \$6,091,000 over generic sales in 2004. Omeprazole, simvastatin and paroxetine were our top-selling generic products in 2005 and accounted for 58% of the generic pharmaceutical product growth from 2004.

Additionally, sales of our generic formulations of ibuprofen, enalapril, lansoprazole, and mirtazapine (included in *All other generic products* above) accounted for approximately 26% of the growth in 2005 generic pharmaceutical product sales.

Sales to Licensees and Others

(in thousands)	2005		2004		Change	
		%		%	\$	%
<i>Sales to licensees and others</i>	\$31,814		\$20,790		\$11,024	53%

Sales to licensees and others increased \$11,024,000 or 53% to \$31,814,000 in 2005. An increase in the weighted average value of the Euro, in relation to the U.S. Dollar, had the effect of decreasing 2005 revenues from sales to licensees and others by approximately \$223,000, or less than 1.0%.

Licensing and Collaboration Revenues

(in thousands)	2005		2004		Change	
		%		%	\$	%
<i>Specialty generics</i>	\$ 273		\$ 607		\$ (334)	-55%
<i>Drug delivery</i>	6,149		2,844		3,305	116%
<i>Total</i>	\$ 6,422		\$ 3,451		\$ 2,971	86%

Licensing and collaboration revenues accounted for approximately 7% of total revenues in 2005 and increased by approximately \$2,971,000, or approximately 86% from 2004. These revenues included royalties totaling \$6,132,000 from the commercialization and continued sales of Testim. *Licensing and collaboration revenues* in 2005 includes a change in our estimate of royalty revenues earned on Testim sales of approximately \$1,092,000, which was recorded in the fourth quarter of 2005. This change in our estimate of royalty revenues earned was based upon publicly available data determined to be more accurate than the source of data previously relied upon by management in recording estimated royalty revenues on Testim sales. Also included in *licensing and collaboration revenues* in 2005 were revenues of approximately \$274,000 related to product licensing activities in Europe.





**Table of Contents**Gross Profit

<i>(in thousands)</i>			<i>Change</i>	
	<i>2005</i>	<i>2004</i>	<i>\$</i>	<i>%</i>
<i>Specialty generics</i>	\$ 45,420	\$ 35,656	\$ 9,764	27%
<i>Drug delivery</i>	6,149	2,844	3,305	116%
<i>Total</i>	\$ 51,569	\$ 38,500	\$ 13,069	34%

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

Selling and Marketing Expenses

<i>(in thousands)</i>			<i>Change</i>	
	<i>2005</i>	<i>2004</i>	<i>\$</i>	<i>%</i>
<i>Specialty generics</i>	\$ 16,347	\$ 14,808	\$ 1,539	10%
<i>Drug delivery</i>				
<i>Total</i>	\$ 16,347	\$ 14,808	\$ 1,539	10%

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

General and Administrative Expenses

<i>(in thousands)</i>			<i>Change</i>	
	<i>2005</i>	<i>2004</i>	<i>\$</i>	<i>%</i>
<i>Specialty generics</i>	\$ 8,930	\$ 6,706	\$ 2,224	33%
<i>Drug delivery</i>	2,475	2,179	296	14%
<i>Total</i>	\$ 11,405	\$ 8,885	\$ 2,520	28%

General and administrative expenses for 2005 increased 28% over 2004. The \$2,520,000 increase was the result of increased general and administrative activities required to support our continuing growth and prepare for our anticipated growth. These expenditures included increased costs in 2005 for additional employees, outside services, insurance and other costs to support the growth of our organization and costs associated with our response to the requirements of the Sarbanes-Oxley Act of 2002. General and administrative expenses as a percent of total revenues were 12% in 2005, which is consistent with 2004. General and administrative expenses for 2005 and 2004 exclude \$593,000 and \$241,000 of legal expenses which have been reclassified to *litigation settlement* on the Consolidated Income Statements to conform with the 2006 presentation.

Research and Development Expenses

<i>(in thousands)</i>			<i>Change</i>	
	<i>2005</i>	<i>2004</i>	<i>\$</i>	<i>%</i>

<i>Specialty generics</i>	\$ 1,378	\$ 1,249	\$ 129	10%
<i>Drug delivery</i>	4,422	3,170	1,252	39%
<i>Total</i>	\$ 5,800	\$ 4,419	\$ 1,381	31%

**Table of Contents**

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

Other Income (Expenses)

<i>(in thousands)</i>			<i>Change</i>	
	<i>2005</i>	<i>2004</i>	<i>\$</i>	<i>%</i>
<i>Specialty generics</i>	\$ (15)	\$ 1,372	\$ (1,387)	-101%
<i>Drug delivery</i>	744	428	316	74%
<i>Total</i>	\$ 729	\$ 1,800	\$ (1,071)	-60%

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

Provision for Income Taxes

<i>(in thousands)</i>	<i>2005</i>			
	<i>Spain</i>	<i>Ireland</i>	<i>U.S.</i>	<i>Consolidated</i>
<i>Income (loss) before income taxes</i>				
<i>Specialty generics</i>	\$ 17,433	\$ (19)	\$ (406)	\$ 17,008
<i>Drug delivery</i>		(2,061)	1,448	(613)
<i>Total income ( loss) before income taxes</i>	17,433	(2,080)	1,042	16,395
<i>Provision (Benefit) for income taxes</i>	5,476	(260)	198	5,414
<i>Valuation allowance</i>		260	(198)	62
<i>Net provision for income taxes</i>	5,476			5,476
<i>Net income (loss)</i>	\$ 11,957	\$ (2,080)	\$ 1,042	\$ 10,919
<i>Effective tax rate</i>	31%	0%	0%	33%

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

In 2005, we generated U.S. income before income taxes of approximately \$1,042,000, compared to a loss before income taxes of approximately \$2,913,000 in 2004. We utilized U.S federal net operating loss carry-forwards in order to offset the resulting income tax liability. As of December 31, 2005, the remaining U.S federal net operating loss carry-forwards were approximately \$53,514,000. Bentley Pharmaceuticals Ireland Limited, which is reported in our European operations, generated a net operating loss of approximately \$2,080,000 in 2005. As future operating profits were not reasonably assured, no tax benefit was recorded for those losses in 2005. Accordingly, we established a valuation allowance equal to the full amount of the deferred tax assets in Ireland.



**Table of Contents***Net Income**(in thousands, except per share data)*

	<b>2005</b>	<b>2004</b>	<b>Change</b>	
			<b>\$</b>	<b>%</b>
<i>Specialty Generics</i>	\$ 11,532	\$ 8,292	\$ 3,240	39%
<i>Drug Delivery</i>	(613)	(2,602)	1,989	76%
<i>Total net income</i>	\$ 10,919	\$ 5,690	\$ 5,229	92%
<i>Net income per common share:</i>				
<i>Basic</i>	\$ 0.51	\$ 0.27	\$ 0.24	89%
<i>Diluted</i>	\$ 0.48	\$ 0.25	\$ 0.23	92%
<i>Weighted average common shares outstanding:</i>				
<i>Basic</i>	21,558	20,901	657	3%
<i>Diluted</i>	22,929	22,627	302	1%

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

**Table of Contents****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>Fiscal 2005</i>				<i>Fiscal 2006</i>			
	<i>3/31/05</i>	<i>6/30/05</i>	<i>9/30/05</i>	<i>Three Months Ended (Unaudited)</i>		<i>6/30/06</i>	<i>9/30/06(b)(c)</i>	<i>12/31/06(c)</i>
				<i>12/31/05(a)</i>	<i>3/31/06</i>			
	<i>(in thousands, except per share data)</i>							
<i>Total revenues</i>	\$ 24,244	\$ 24,764	\$ 23,512	\$ 25,210	28,278	28,983	25,156	27,054
<i>Cost of net product sales</i>	11,452	11,367	11,104	12,238	12,933	12,471	11,778	12,668
<i>Gross profit</i>	12,792	13,397	12,408	12,972	15,345	16,512	13,378	14,386
<i>Operating expenses</i>	9,145	9,408	8,730	8,620	11,991	11,580	19,085	11,566
<i>Gain on sale of license</i>								38
<i>Income (loss) from operations</i>	3,647	3,989	3,678	4,352	3,354	4,932	(5,707)	2,858
<i>Other income (expenses)</i>	113	173	184	259	193	187	208	31
<i>Provision (benefit) for income taxes</i>	1,590	1,554	1,377	955	2,393	2,484	1,730	(1,525)
<i>Net income(loss)</i>	\$ 2,170	\$ 2,608	\$ 2,485	\$ 3,656	1,154	2,635	(7,229)	4,414
<i>Net income(loss) per common share:</i>								
<i>Basic</i>	\$ 0.10	\$ 0.12	\$ 0.11	\$ 0.17	\$ 0.05	\$ 0.12	\$ (0.33)	\$ 0.20
<i>Diluted</i>	\$ 0.10	\$ 0.12	\$ 0.11	\$ 0.16	\$ 0.05	\$ 0.12	\$ (0.33)	\$ 0.19
<i>Weighted average common shares outstanding:</i>								
<i>Basic</i>	21,316	21,395	21,652	21,862	21,954	22,170	22,194	22,242
<i>Diluted</i>	22,531	22,603	22,970	23,564	23,807	22,876	22,194	22,735

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

(b) *Total revenues* for the year ended December 31, 2006 include an increase in royalty revenues of approximately \$479,000 recorded in the second quarter of 2006. This change in estimate was due to the Company's ability to

reasonably estimate future product returns on sales of Testim based on actual historical data.

(c) *Operating expenses* for the year ended December 31, 2006 include litigation settlement charges of approximately \$7,546,000 recorded in the third quarter of 2006 associated with the probable settlement of outstanding litigation claims. The Company recorded a tax benefit of \$2,746,000 in *provision for incomes taxes* upon finalization of the settlement in the fourth quarter of 2006. *Operating expenses* also include related legal defense costs of \$604,000, \$733,000, \$1,386,000 and \$645,000 in first, second, third and fourth quarters of 2006,



respectively.

**Table of Contents****Liquidity and Capital Resources**

Total assets increased 8% from \$124,220,000 at December 31, 2005 to \$134,356,000 at December 31, 2006 and stockholders' equity increased 10% from \$91,589,000 at December 31, 2005 to \$100,331,000 at December 31, 2006. The increase in stockholders' equity primarily reflects net income during the year of \$974,000 and the effect of fluctuations in the U.S. Dollar/Euro exchange rate, which resulted in a net increase of \$7,112,000 on our balance sheet.

Cash, cash equivalents and marketable securities decreased 53% from \$32,846,000 at December 31, 2005 to \$15,601,000 at December 31, 2006. Uses of cash primarily included additions to fixed assets totaling \$15,313,000, additions to drug licenses and related costs of \$2,772,000 and the net effect of financing activities as discussed below. Cash and cash equivalents at December 31, 2006 included approximately \$357,000 of short-term liquid investments considered to be cash equivalents.

Total receivables increased from \$26,916,000 at December 31, 2005 to \$32,963,000 at December 31, 2006. Receivables increased \$3,129,000, or 12% when expressed in constant currency.

Receivables from one international customer totaled \$2,579,000 at December 31, 2006; however, we owed the same customer approximately \$492,000 for co-marketing expenses at December 31, 2006. Revenues from this customer are recorded net of the related co-marketing costs. Receivables from our international customers generally have extended payment terms; however, we have not experienced any material delinquencies on any of our receivables that have had a material effect on our financial position, results of operations or cash flows.

Inventories increased approximately \$4,132,000 from \$12,147,000 at December 31, 2005 to \$16,279,000 at December 31, 2006. The increase was a result of recording \$1,338,000 of consigned inventory in the fourth quarter of 2006, an increase of \$1,440,000 due to changes in foreign currency exchange rates and increased raw materials purchases in anticipation of future orders.

The combined total of accounts payable and accrued expenses decreased \$620,000 from \$24,890,000 at December 31, 2005 to \$24,270,000 at December 31, 2006. This decrease was due to a \$1,527,000 decrease in purchases of fixed assets in accounts payable and accrued expenses and an \$827,000 decrease in co-marketing costs to one of our customers. Those decreases were partially offset by foreign currency fluctuations which increased accounts payable and accrued expenses by \$2,041,000.

Short-term borrowings and current portion of long-term debt decreased from \$2,995,000 at December 31, 2005 to \$554,000 at December 31, 2006. The decrease was primarily due to \$2,638,000 of net repayment of short-term borrowings in the year. The weighted average interest rate on our short-term borrowings and current portion of long-term debt at December 31, 2006 was 4.8%.

We recorded other liabilities totaling \$4,257,000 in 2006, of which \$1,518,000 was classified as current on the Consolidated Balance Sheet, primarily resulting from the settlement of litigation in the year. At December 31, 2006, we have recorded a liability of \$3,590,000, representing the net present value of the remaining settlement liability, of which \$1,000,000 is classified as current. Other current liabilities also included \$481,000 of payments received from our selling agent in anticipation of future sales of consigned inventories.

Operating activities in 2006 provided net cash of \$4,502,000 compared to \$12,596,000 in 2005. Net income, which decreased to \$974,000 in 2006, and changes in working capital accounted for the majority of the increase in cash flows from operations.

**Table of Contents**

Investing activities, primarily capital expenditures in Spain for land, improvements and equipment to upgrade the capacity of our manufacturing facilities in Spain and to increase our manufacturing and packaging capabilities with new high speed equipment, along with additions to drug licenses and related costs, used net cash of \$18,085,000 in 2006.

Financing activities during 2006 used net cash of \$4,136,000, and primarily represented the cash proceeds of approximately \$450,000 received from the exercise of stock options, offset by the following: (1) the remittance of employee tax withholding liabilities of approximately \$1,948,000 resulting from stock option exercises, and (2) net repayments of short-term borrowings totaling \$2,638,000.

Long-term debt, which totaled \$307,000 at December 31, 2006, is classified as current in anticipation of repayment during 2007.

*Contractual Obligations*

We have fixed contractual obligations under various agreements. Our contractual obligations were comprised of the following as of December 31, 2006:

<i>(in thousands)</i>	<i>Total</i>	<i>Less than 1 year</i>	<i>Payments Due By Period</i>		
			<i>1 3 years</i>	<i>3 5 years</i>	<i>More than 5 years</i>
<i>Long term debt</i>	\$ 307	\$ 307	\$	\$	\$
<i>Short-term borrowings</i>	247	247			
<i>Capital leases</i>					
<i>Operating leases</i>	2,052	1,177	841	34	
<i>Purchase obligations (1)</i>	6,570	6,570			
<i>Other current liabilities (2)</i>	1,518	1,518			
<i>Other long term liabilities (2)</i>	2,739		1,860	879	
<i>Total contractual cash obligations (3)(4)</i>	\$ 13,433	\$ 9,819	\$ 2,701	\$ 913	\$

(1) Included in purchase obligations are contractual obligations for the purchase of machinery, construction and engineering services and a new inventory management software application. The construction and engineering services and new inventory management

software application are associated with the expansion of our manufacturing facilities in Zaragoza, Spain. Purchase orders or contracts for the purchase of raw materials and other goods and services are not included in the table above as our purchase orders represent authorizations to purchase rather than binding agreements. For the purposes of this table, contractual obligations for purchase of goods or services are defined as agreements that are enforceable and legally binding and that specify all significant terms, including: fixed or minimum quantities to be purchased; fixed, minimum or variable price provisions; and the approximate timing of the transaction. Our purchase orders are based on our current

manufacturing needs and are fulfilled by our vendors within short time frame. We do not have agreements for the purchase of raw materials or other goods specifying minimum quantities. We also enter into contracts for outsourced services including payroll, information technology and maintenance; however, the obligations under these contracts are not significant and the contracts contain clauses allowing for cancellation at will, without significant penalty.

- (2) Included in other liabilities at December 31, 2006 are the present value of four annual payments of \$1,000,000 to be paid in connection with the settlement of litigation in 2006 and the value of a



**Table of Contents**

hedging instrument obtained to reduce the currency risk on the settlement obligation, of which \$2,739,000 is classified as long-term. There were no other contractual obligations included in other long-term liabilities in our Consolidated Balance Sheet as of December 31, 2006.

- (3) Not included in the chart above are key executive compensation agreements that have been renewed whereby we are currently obligated to pay approximately \$2,247,000 to our key executives in 2007. Such agreements renew annually unless terminated by any of the parties or amended by the Compensation Committee of the Board of Directors.
- (4) Also not included in the chart above is an aggregate of \$1,362,000 of deferred taxes due to be paid to the Spanish Ministry of Taxes over the next four years which resulted from the sale of certain drug licenses in prior years. These non-current deferred tax liabilities are netted against the Company's non-current deferred tax assets on the 2006 Consolidated Balance Sheet.

The expected timing of payments of the obligations discussed above are estimated based on current information. Timing of payments and actual amounts paid may be different depending on the time of receipt of goods or services or changes to agreed-upon amounts for obligations.

We paid \$4,000,000 in connection with our legal settlement with Ethypharm in 2006 and are obligated to make annual payments of \$1,000,000 in each of the next four years according to the terms of the settlement.

We plan to continue making improvements to our manufacturing facilities during 2007 that include the acquisition of additional manufacturing equipment and expansion of our active pharmaceutical ingredients manufacturing facility, in order to accommodate our expected growth. We plan to invest \$13.0 million to \$16.0 million in capital expenditures during 2007, including approximately \$5.5 budgeted in 2006, that is now planned for 2007. We plan to finance these expenditures from a combination of cash flow from operations, existing cash balances, and borrowings, if required. We also plan to continue our investments in research and development projects, primarily Nasulin, our intranasal insulin product candidate. Although cost estimates and timing of our trials are subject to change, we expect consolidated research and development expenses for 2007 to be approximately \$15,000,000 to \$16,000,000.

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

*Off-Balance Sheet Arrangements*

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

**Table of Contents****Critical Accounting Policies and Estimates**

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

*Revenue recognition and accounts receivable.*

- O Revenue on product sales is recognized when persuasive evidence of an arrangement exists, the price is fixed and final, delivery has occurred and there is a reasonable assurance of collection of the sales proceeds. We generally obtain purchase authorizations from our customers for a specified amount of product at a specified price and consider delivery to have occurred when the customer takes possession of the products and/or risk of loss has passed to the customer. We provide our customers with a limited right of return. Revenue is generally recognized upon delivery of products, at which time a reserve for sales returns is recorded. We have demonstrated the ability to make reasonable and reliable estimates of product returns in accordance with SFAS No. 48, *Revenue Recognition When Right of Return Exists*, and of allowances for doubtful accounts based on significant historical experience.
- O Revenue from service, research and development, and licensing and supply agreements is recognized when the service procedures have been completed or as revenue recognition criteria have been met for each separate unit of accounting (as defined in Emerging Issues Task Force ( EITF ) Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*).
- O We earn royalties from Auxilium sales of Testim, which incorporates our CPE-215 permeation enhancement technology. Since 2003, Auxilium has sold Testim to pharmaceutical wholesalers and chain drug stores, which have the right to return purchased product prior to the units being dispensed through patient prescriptions. Historically, customer returns were not able to be reasonably estimated. Therefore, in accordance with SFAS No. 48, we deferred the recognition of royalty revenues on product shipments of Testim, until the units were dispensed through patient prescriptions. During the quarter ended June 30, 2006, we recorded an increase in royalty revenues of approximately \$479,000, or \$0.02 per share, due to a change in estimate which, based on historical experience, allowed us to reasonably estimate future product returns on sales of Testim.
- O Accounts receivable are recorded at their net realizable value, generally as products are shipped or services are performed. Receivable balances are reported net of an estimated allowance for uncollectible accounts. Estimated uncollectible receivables are based on the amount and status of past due accounts, contractual terms with customers, the credit worthiness of customers and the history of our uncollectible accounts.



**Table of Contents**

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

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

*Share-based compensation.* Commencing January 1, 2006, we began accounting for share-based compensation in accordance with the fair value recognition provisions of SFAS No. 123 (Revised). Under the fair value recognition provisions of SFAS No. 123 (Revised), share-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as expense over the requisite service period. Determining the fair value of equity awards at the grant date requires judgment. We estimate the grant date fair value of stock options using the Black-Scholes option valuation model. This option valuation model requires the input of subjective assumptions including: (1) Expected life - the expected life (estimated period of time outstanding) of options granted is estimated based on historical exercise behaviors; (2) Volatility - the volatility of the Company's stock is calculated on the grant date of each equity award using daily price observations over a period of time commensurate with the related requisite service period; (3) Risk-free rate - the risk-free interest rate is based on the yield curve of U.S. Treasury securities in effect at the date of the grant, having a duration commensurate with the estimated life of the award; and (4) Dividends - as we have not declared dividends, and we do not expect to declare dividends in the future, we include an annual dividend rate of 0% when calculating the grant date fair value of equity awards. Because share-based compensation expense is based on awards ultimately expected to vest, it is reduced for estimated forfeitures. SFAS No. 123 (Revised) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures are estimated based on historical experience. While we recognize share-based compensation under the accelerated expense attribution method pursuant to FASB Interpretation No. 28 for all options previously accounted for under APB Opinion No. 25, we have elected to recognize share-based compensation attributable to equity awards granted subsequent to December 31, 2005 under the straight-line method which is an alternative allowed for under SFAS No. 123 (Revised). Had we elected to recognize compensation expense for new equity awards under the accelerated expense attribution method, recognition of the related compensation expense would be front-loaded in the requisite service period as opposed to being recognized evenly over the period.

SFAS No. 123 (Revised) requires a company to calculate the pool of excess tax benefits, or APIC Pool, available to absorb tax deficiencies recognized subsequent to adopting the accounting standard, as if the company had adopted SFAS No. 123, as originally issued, at its effective date in 1995. There are two allowable methods to calculate the hypothetical APIC Pool: (1) the long form method as set forth in SFAS No. 123 (Revised) or (2) the short form method as set forth in FASB Staff Position No. 123(R)-3. We have elected to use the long form method under which we track each award grant on an employee-by-employee basis and grant-by-grant basis to determine if there is a tax benefit or tax deficiency for such award. We then compared the fair value expense to the tax deduction received for each grant and aggregated the benefits and deficiencies to establish its hypothetical APIC Pool.

**Table of Contents**

Due to the adoption of SFAS No. 123 (Revised), some exercises result in tax deductions in excess of previously recorded benefits based on the option value at the time of grant, or windfalls. We recognize windfall tax benefits associated with the exercise of stock options directly to stockholders' equity only when realized. Accordingly, deferred tax assets are not recognized for net operating loss carryforwards resulting from windfall tax benefits occurring from January 1, 2006 onward. A windfall tax benefit occurs when the actual tax benefit realized by the company upon an employee's disposition of a share-based award exceeds the deferred tax asset, if any, associated with the award that the company had recorded.

*Provision for income taxes.* We have provided for current and deferred U.S. federal, state and foreign income taxes for the current and all prior periods presented. Current and deferred income taxes have been provided with respect to jurisdictions where certain of our subsidiaries produce taxable income. We have provided a valuation allowance with respect to the remainder of our deferred income taxes, consisting primarily of net operating loss carryforwards in the U.S. and Ireland, because of uncertainty regarding their realization.

Should we determine that it is more likely than not that we will realize certain of our net deferred tax assets for which we have previously provided a valuation allowance, an adjustment would be required to reduce the existing valuation allowance. In addition, we operate within multiple taxing jurisdictions and are subject to audit in those jurisdictions. These audits can involve complex issues, which may require an extended period of time for resolution. Although we believe that adequate consideration has been made for such issues, there is the possibility that the ultimate resolution of such issues could have an adverse effect on our financial position, results of operations or cash flows.

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

**New Accounting Standards**

In June 2006, the Financial Accounting Standards Board ( FASB ) issued Interpretation No. (FIN) 48, *Accounting for Uncertainty in Income Taxes*, which we adopted effective January 1, 2007. The purpose of FIN 48 is to clarify and set forth consistent rules for accounting for uncertain tax positions in accordance with SFAS 109, *Accounting for Income Taxes* by requiring the application of a more likely than not threshold for the recognition and derecognition of tax positions. Although we adopted FIN No. 48 effective January 1, 2007, we are still in the process of assessing what impact, if any, the adoption of this statement will have on our consolidated financial statements; however, based upon our initial assessment, we do not expect the adoption of FIN 48 to have a material impact on the Consolidated Balance Sheets or the Consolidated Statements of Cash Flows.

On September 13, 2006, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 108 *Considering the Effects of Prior Year Misstatements When Quantifying Misstatements in Current Year Financial Statements* ( SAB 108 ), which provides interpretive guidance on how the effects of the carryover or reversal of prior year misstatements should be considered in quantifying a current year misstatement. We adopted SAB No. 108 effective December 31, 2006. The adoption of SAB

**Table of Contents**

108 did not have an impact on our consolidated financial statements in the year ended December 31, 2006.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* ( SFAS 157 ), which provides guidance for measuring the fair value of assets and liabilities, and requires expanded disclosures about fair value measurements. SFAS 157 indicates that fair value should be determined based on the assumptions marketplace participants would use in pricing the asset or liability, and provides additional guidelines to consider in determining the market-based measurement. We adopted SFAS No. 157 effective January 1, 2007 and we do not expect this adoption to have a material impact on our consolidated financial statements.

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

*Foreign Currency.* A substantial amount of our business is conducted in Europe and is therefore influenced to the extent to which there are fluctuations in the U.S. Dollar's value against other currencies, specifically the Euro. 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. Exchange rates for periods ending and ended December 31, 2006, 2005 and 2004 are as follows:

<u>U.S. Dollars per Euro</u>	2006	2005	2004
Weighted average exchange rate	1.26	1.24	1.24
Exchange rate	1.31	1.19	1.36

The net effect of foreign currency translation on our Consolidated Balance Sheet during the year ended December 31, 2006 was an increase of \$7,112,000 and the cumulative historical effect was an increase of \$8,872,000, as reflected in our Consolidated Balance Sheets as *accumulated other comprehensive income*. The carrying value of assets and liabilities can be materially impacted by foreign currency translation, as can the translated amounts of revenues and expenses. Nonetheless, we do not plan to modify our business practices.

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

*Interest Rates.* The weighted average interest rate on our short-term borrowings and current portion of long-term debt was 4.8% and the balance outstanding was \$554,000 as of December 31, 2006. All amounts are due within one year and have been classified as current on the Consolidated Balance Sheets at December 31, 2006 and 2005. The effect of an increase in the interest rate of one percentage point (one hundred basis points) to 5.8% on short-term borrowings and current portion of long-term debt would have the effect of increasing interest expense by approximately \$6,000 annually.

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

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

**Table of Contents**

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

Not applicable.

**Item 9A. Controls and Procedures**

**Disclosure Controls and Procedures**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports that are filed or submitted under the under the Securities Exchange Act of 1934, as amended (the Exchange Act ) with the Securities and Exchange Commission is recorded, processed, summarized and reported within the time periods required for each report and that such information is reported to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management, with the participation of our principal executive officer and principal financial officer, carried out an evaluation of the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e)) under the Exchange Act as of the end of the period covered by this report. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of December 31, 2006.

**Internal Control over Financial Reporting**

*Management's Annual Report on Internal Control over Financial Reporting*

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2006. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control Integrated Framework*. Based on its assessment under the framework in *Internal Control Integrated Framework*, our management has concluded that, as of December 31, 2006, our internal control over financial reporting was effective.

*Attestation Report of the Independent Registered Public Accounting Firm*

Management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2006, has been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report which appears below.

*Changes in Internal Control Over Financial Reporting*

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

**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

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

We have audited management's assessment, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting, that Bentley Pharmaceuticals, Inc. and subsidiaries (the Company) maintained effective internal control over financial reporting as of December 31, 2006, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed by, or under the supervision of, the company's principal executive and principal financial officers, or persons performing similar functions, and effected by the company's board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that the Company maintained effective internal control over financial reporting as of December 31, 2006, is fairly stated, in all material respects, based on the criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2006, based on

**Table of Contents**

the criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's consolidated balance sheets as of December 31, 2006 and 2005, and the related consolidated income statements, statements of changes in stockholders' equity, and statements of cash flows for each of the three years in the period ended December 31, 2006, and our report dated March 15, 2007, expressed an unqualified opinion on those financial statements, and includes an explanatory paragraph regarding the Company's adoption of Statement of Financial Accounting Standards No. 123(Revised), *Share-Based Payment*.

/s/ Deloitte & Touche LLP

Boston, Massachusetts

March 15, 2007

**Table of Contents**

**Item 9B. Other Information**

Not applicable.

69

---

Table of Contents**Part III****Item 10. Directors and Executive Officers of the Registrant and Corporate Governance**

<b>Name</b>	<b>Age</b>	<b>Position</b>
James R. Murphy	57	Chairman, Chief Executive Officer and Director
Michael McGovern	63	Vice Chairman and Director
John A. Sedor	62	President
Richard P. Lindsay	45	Vice President, Chief Financial Officer, Treasurer and Secretary
Adolfo Herrera	47	Managing Director of European Subsidiaries
Miguel Fernandez	76	Director
F. Ross Johnson	75	Director
Edward J. Robinson	66	Director
John W. Spiegel	66	Lead Director

**James R. Murphy** has served as one of our directors since 1993. Mr. Murphy was President of Bentley from September 1994 until August 2005, was named Chief Executive Officer effective January 1995 and became Chairman of the Board in June 1995. Prior to rejoining Bentley, Mr. Murphy served as Vice President of Business Development at MacroChem Corporation, a publicly owned pharmaceutical and drug delivery company, from March 1993 through September 1994. From September 1992 until March 1993, Mr. Murphy served as a consultant in the pharmaceutical industry with his primary efforts directed toward product licensing. Prior thereto, Mr. Murphy served as Director - Worldwide Business Development and Strategic Planning of Bentley from December 1991 to September 1992. Mr. Murphy previously spent 14 years in pharmaceutical research and product development with SmithKline Corporation and in international business development with contract research and consulting laboratories. Mr. Murphy received a B.A. in Biology from Millersville University.

**Michael McGovern** has served as one of our directors since 1997 and was named Vice Chairman of Bentley in October 1999. Mr. McGovern serves as President of McGovern Enterprises, a provider of corporate and financial consulting services, which he founded in 1975. Mr. McGovern is Chairman of the Board of Training Solutions Interactive, Inc. and Vice Chairman of the Board of Employment Technologies, Inc. and is a Director on the corporate board of the Reynolds Development Company. Mr. McGovern received a B.S. and M.S. in accounting and his Juris Doctor from the University of Illinois. Mr. McGovern is a Certified Public Accountant.

**John A. Sedor** joined Bentley as President in August 2005. From 2001 to May 2005, he served as President and Chief Executive Officer for Sandoz Inc., based in Princeton, N.J. In this role, Mr. Sedor oversaw all aspects of Sandoz, the North American arm of Novartis Generics where his responsibilities included Sales and Marketing, Research and Development, Operations and Product Manufacturing, Business Development and Strategy. From 1998-2001, he served as President and Chief Executive



**Table of Contents**

Officer of Verion, Inc., a technology company, where he was responsible for the creation, launch and direction of the joint venture. Prior thereto, Mr. Sedor served as President and Chief Executive Officer of Centeon, a joint venture between two major multinational corporations, Rhône-Poulenc Rorer and Hoechst AG. Prior thereto, Mr. Sedor served as Executive Vice President at Rhône-Poulenc Rorer, Revlon Healthcare and Parke Davis. Mr. Sedor received his BS, Pharmacy/Chemistry from Duquesne University in 1970.

**Richard P. Lindsay**, joined Bentley as the Vice President of Finance and Chief Financial Officer of Bentley in September 2006. Previously, Mr. Lindsay was a self-employed independent consultant since October 2005. Mr. Lindsay served as Executive Vice President and Chief Financial Officer of StockerYale, Inc., a publicly traded photonics company, from August 2004 to October 2005 and was the Interim Controller of the University of Rhode Island from August 2003 to July 2004. Mr. Lindsay also served as Chief Financial Officer of Boston Beer Company, a publicly traded brewer of craft beers, from 1999 to 2003, where he was responsible for all finance, IT and business development functions for the company. Prior to his employment with Boston Beer Company, Mr. Lindsay served as a Senior Consultant for KPMG, LLP, an international accounting firm, after completing his service in the U.S. Navy, Submarine Service. Mr. Lindsay received his MBA (honors) from Northeastern University and a BS in Management with a concentration in Accounting and a minor in Economics from the University of Massachusetts. He is a Certified Public Accountant.

**Adolfo Herrera** serves as Managing Director of our European Subsidiaries, and has been employed as General Manager of Bentley's Spanish subsidiaries since 1999. Prior to joining Bentley in 1997, Mr. Herrera served as General Manager of Laboratorios Llorente-Juventus Group from 1993 to 1997, where he was employed since 1990. Prior thereto, Mr. Herrera was employed by the Public Health Ministry in Spain. Mr. Herrera received his degree in Veterinary Medicine from Complutense University in Madrid, Spain in 1982 and his MBA degree from Instituto de Empresas in Madrid, Spain in 1994.

**Miguel Fernandez** has served as one of our directors since 1999. Mr. Fernandez served from 1980 to 1996 as President of the International Division and corporate Vice President at Carter-Wallace, Inc., where he was responsible for all product lines outside of the United States. Prior thereto, Mr. Fernandez was employed for approximately eight years by SmithKline & French, where his last position was President of the division that included France, Portugal and Switzerland. Mr. Fernandez attended the University of British Columbia in Canada and received an M.B.A. from the Ivey School of Business at the University of Western Ontario in London, Ontario, Canada. Mr. Fernandez has been retired since 1996.

**F. Ross Johnson** has served as one of our directors since 2004. Mr. Johnson has been the Chairman and Chief Executive Officer of RJM Group, a management advisory and investment firm, since 1989. Prior to 1989, Mr. Johnson served as President and Chief Operating Officer of RJR/Nabisco, Inc., a public diversified holding company, having held various senior executive positions in RJR/Nabisco, Inc. and its predecessors, Standard Brands and Nabisco Brands since 1971. He received a Bachelor of Commerce from the University of Manitoba, Canada and a Master of Commerce from the University of Toronto, Canada. Mr. Johnson serves on the board of directors of AuthentiDate Holding Corporation, EdgeStone Capital Partners, and serves on the advisory boards of Wachovia Bank-Florida, Bennett Advisory Group - Palm Beach, Quebecor - Ontario, University of Toronto, and Black & McDonald Ltd.

**Edward J. Robinson** has served as one of our directors since 2004. Mr. Robinson served as Chief Operating Officer of Meditrust Operating Company, a healthcare REIT, in 1998. Previously he was the President and Chief Operating Officer of Avon Products, Inc., a public beauty products company, from 1993 to 1997, and Executive Vice President and Chief Financial Officer of Avon Products, Inc. from 1989 to 1992. Prior thereto, he held various positions with RJR Nabisco and its predecessor companies, Standard Brands and Nabisco Brands, including Executive Vice President, Chief Financial Officer, Vice President

## **Table of Contents**

Treasurer and Senior Vice President Controller. Mr. Robinson serves on the board of directors of Medical Staffing Network Holdings, Inc. and also serves on the Advisory Board of W.R. Capital Management L.P. He received a B.A. in Business Administration from Iona College. Mr. Robinson is a Certified Public Accountant licensed by the State of New York. Mr. Robinson has been retired since 1998.

**John W. Spiegel** has served as one of our directors since June 2002. Mr. Spiegel served as Vice Chairman and Chief Financial Officer of SunTrust Banks, Inc. from August 2000 until August 2004. Prior to August 2000, Mr. Spiegel was an Executive Vice President and Chief Financial Officer of SunTrust Banks since 1985. Mr. Spiegel also serves on the Board of Directors of HomeBanc Corp., Rock-Tenn Company, S1 Corporation and Colonial Properties Trust. Mr. Spiegel is also a trustee of Children's Healthcare of Atlanta, and is a member of the Dean's Advisory Council of the Goizueta Business School at Emory University. Mr. Spiegel received an MBA from Emory University.

### **Audit Committee**

The information called for by this item regarding Bentley's Audit Committee, including the Committee's financial expert, is incorporated by reference to our Proxy Statement for the 2007 Annual Meeting of Stockholders.

### **Section 16(a) Beneficial Ownership Reporting Compliance**

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our executive officers and directors, and any persons who own more than 10% of any class of our equity securities, to file certain reports relating to their ownership of such securities and changes in such ownership with the Securities and Exchange Commission and the New York Stock Exchange and to furnish us with copies of such reports. To the best of our knowledge during the year ended December 31, 2006, all Section 16(a) filing requirements have been satisfied.

### **Other Information**

As required by Section 303A.12(a) of the New York Stock Exchange Listed Company Manual, on June 19, 2006, our Chief Executive Officer submitted the Annual CEO Certification to the New York Stock Exchange, certifying that he was not aware of any violation by Bentley of the New York Stock Exchange's corporate governance listing standards, without qualification.

We filed with the SEC as exhibits to this Annual Report on Form 10-K for the year ended December 31, 2006 (which exhibits are identified as Exhibit 31.1 and Exhibit 31.2) certifications by our Chief Executive Officer and Chief Financial Officer regarding the quality of our public disclosures in accordance with Section 302 of the Sarbanes-Oxley Act of 2002.

Our Corporate Governance Guidelines, Code of Business Conduct and Ethics, Audit Committee Procedures for Handling Complaints, Nominating and Governance Committee Charter, Audit Committee Charter and Compensation Committee Charter are available on our website at [www.bentleypharm.com](http://www.bentleypharm.com). The information is also available in print to any shareholder who requests it. Additionally, copies of reports filed by us pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, including Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K may be accessed from our website, free of charge, as soon as reasonably practicable after we electronically file such reports with, or furnish such reports to, the Securities and Exchange Commission. Alternatively, these reports can be accessed through a query at the website of the Securities and Exchange Commission at [www.sec.gov](http://www.sec.gov).

**Table of Contents**

Our Board of Directors consists of six directors, four of whom (Messrs. John W. Spiegel, Miguel Fernandez, F. Ross Johnson and Edward J. Robinson) are considered to be independent in accordance with the listing standards of the New York Stock Exchange and Rule 10A-3 under the Securities Exchange Act of 1934, as amended. All four of the independent directors serve on our Audit Committee. Since his retirement in 2004 as the Chief Financial Officer of SunTrust Banks, Inc., John W. Spiegel has agreed to serve on a fourth public company audit committee, in addition to his service for Bentley and two others. The Board of Directors has determined that in Mr. Spiegel's current circumstances this simultaneous service does not impair his ability to serve on the Audit Committee of Bentley.

John W. Spiegel has been selected as the Lead Director (or Presiding Director) of our Board of Directors. Mr. Spiegel presides at executive sessions of meetings of our non-management and independent directors. Interested parties who wish to send communications on any topic to Mr. Spiegel, the presiding director and the Chairperson of the Nominating and Governance Committee or to Bentley's Board of Directors as a group, should address such communications to the Chairman of the Nominating and Governance Committee, c/o the Corporate Secretary, Bentley Pharmaceuticals, Inc., Bentley Park, 2 Holland Way, Exeter, New Hampshire, 03833.

**Code of Business Conduct and Ethics**

We have adopted a Code of Business Conduct and Ethics which applies to all of our employees and directors, including our principal executive officer, principal financial officer and principal accounting officer. The Code of Business Conduct and Ethics is available on our website at [www.bentleypharm.com](http://www.bentleypharm.com) and is also available in print to any shareholder who requests it.

**Item 11. Executive Compensation**

The information called for by this item is incorporated by reference to our Proxy Statement for the 2007 Annual Meeting of Stockholders.

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

The information called for by this item is incorporated by reference to our Proxy Statement for the 2007 Annual Meeting of Stockholders.

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

The information called for by this item is incorporated by reference to our Proxy Statement for the 2007 Annual Meeting of Stockholders.

**Item 14. Principal Accounting Fees and Services**

The information called for by this item is incorporated by reference to our Proxy Statement for the 2007 Annual Meeting of Stockholders.

**Table of Contents**

**Part IV**

**Item 15. Exhibits, Financial Statement Schedules**

	Page Herein
(a) The following documents are filed as a part of this report:	
(1) Financial Statements:	
Consolidated Financial Statements of Bentley Pharmaceuticals, Inc. and Subsidiaries	F-1 to F-36
(2) Financial Statement Schedules:	
None	
(3) Exhibits See index beginning on page 75	
(b) The exhibits filed as a part of this annual report on Form 10-K are listed on the Exhibit Index immediately preceding the signature page. The Exhibit Index is incorporated herein by reference.	

**Table of Contents**

**EXHIBIT INDEX**

Exhibit Number	Description
3.1	Articles of Incorporation of the Registrant, as amended and restated. (Reference is made to Appendix B to the Registrant's Definitive Proxy Statement for the Annual Meeting of Stockholders filed on May 18, 1999, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)
3.2	Amendment of Restated Articles of Incorporation of the Registrant. (Reference is made to Exhibit 3.1 to the Registrant's Form 10-Q for the quarter ended June 30, 2004, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)
3.3	Bylaws of the Registrant, as amended and restated. (Reference is made to Exhibit 3.1 to the Registrant's Form 10-Q for the quarter ended March 31, 2004, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)
4.1	Renewed Rights Agreement dated as of December 21, 2004 between Bentley Pharmaceuticals, Inc. and American Stock Transfer & Trust Company, as Rights Agent, including the form of Rights certificate as Exhibit B thereto and the Summary of Rights to Purchase Series A Junior Participating Preferred Stock as Exhibit C thereto. (Reference is made to Exhibit 4.1 to the Registrant's Form 8-K, filed on December 21, 2004, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)
10.1*	Registrant's Amended and Restated 1991 Stock Option Plan. (Reference is made to Appendix D to the Registrant's Definitive Proxy Statement for the Annual Meeting of Stockholders filed on May 18, 1999, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)
10.2*	Form of Non-qualified Stock Option Agreement under the Registrant's 1991 Stock Option Plan. (Reference is made to Exhibit 4.25 to the Registrant's Form 10-K for the year ended June 30, 1992, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)
10.3*	Registrant's 2001 Employee Stock Option Plan. (Reference is made to Appendix B to the Registrant's Definitive Proxy Statement for the Annual Meeting of Stockholders filed on April 9, 2001, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)
10.4*	Registrant's 2001 Directors' Stock Option Plan. (Reference is made to Appendix C to the Registrant's Definitive Proxy Statement for the Annual Meeting of Stockholders filed on April 9, 2001, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)

**Table of Contents**

Exhibit Number	Description
10.5*	Form of Stock Option contract under the Registrant's 2001 Employee Stock Option Plan. (Reference is made to Exhibit 4.8 to the Registrant's Form 10-K for the year ended December 31, 2001, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)
10.6*	Form of Stock Option contract under the Registrant's 2001 Directors' Stock Option Plan. (Reference is made to Exhibit 4.9 to the Registrant's Form 10-K for the year ended December 31, 2001, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)
10.7*	Amendment No. 1 to the Registrant's 2001 Employee Stock Option Plan. (Reference is made to Exhibit 4.10 to the Registrant's Form 10-K for the year ended December 31, 2003, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)
10.8*	Amendment No. 2 to the Registrant's 2001 Employee Stock Option Plan. (Reference is made to Exhibit 4.11 to the Registrant's Form 10-K for the year ended December 31, 2003, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)
10.9*	Amendment No. 1 to the Registrant's 2001 Directors' Stock Option Plan. (Reference is made to Exhibit 4.12 to the Registrant's Form 10-K for the year ended December 31, 2003, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)
10.10*	Amendment No. 2 to the Registrant's 2001 Directors' Stock Option Plan. (Reference is made to Exhibit 4.13 to the Registrant's Form 10-K for the year ended December 31, 2003, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)
10.11*	Form of Incentive Stock Option Certificate under the Registrant's Amended and Restated 2005 Equity and Incentive Plan. (Reference is made to Exhibit 10.2 to the Registrant's Form 10-Q for the quarter ended June 30, 2005, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)
10.12*	Form of Non-Statutory Stock Option Certificate under the Registrant's Amended and Restated 2005 Equity and Incentive Plan. (Reference is made to Exhibit 10.3 to the Registrant's Form 10-Q for the quarter ended June 30, 2005, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)
10.13	Bentley Pharmaceuticals, Inc. Amended and Restated 2005 Equity and Incentive Plan. (Reference is made to Exhibit 10.1 of the Registrant's Current Report on Form 8-K dated May 23, 2006, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)
10.14	Form of Restricted Stock Unit Certificate (Non-employee Directors) under the Registrant's Amended and Restated 2005 Equity and Incentive Plan. (Reference is made to Exhibit 10.2 of the Registrant's Form 10-Q for the quarter ended June 30, 2006, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)



**Table of Contents**

Exhibit Number	Description
10.15	Form of Restricted Stock Unit Certificate (Employees) under the Registrant's Amended and Restated 2005 Equity and Incentive Plan. (Reference is made to Exhibit 10.3 of the Registrant's Form 10-Q for the quarter ended June 30, 2006, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)
10.16*	Ordinary Labor Contract dated as of February 12, 1998 between the Registrant's wholly-owned subsidiary, Laboratorios Belmac, S.A. and Adolfo Herrera. (Reference is made to Exhibit 10.26 to the Registrant's Form 10-K for the year ended December 31, 2005, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)
10.17*	Employment Agreement dated as of January 1, 2002 between the Registrant and James R. Murphy. (Reference is made to Exhibit 10.1 to Amendment No. 1 to the Registrant's Form 10-K for the year ended December 31, 2001, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)
10.18*	Employment Agreement dated as of August 27, 2005 between the Registrant and John A. Sedor. (Reference is made to Exhibit 10.1 to the Registrant's Form 10-Q for the quarter ended September 30, 2005, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)
10.19*	Employment Agreement dated as of September 11, 2006 by and between the Registrant and Richard P. Lindsay. (Reference is made to Exhibit 10.1 of the Registrant's Current Report on Form 8-K dated September 11, 2006, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)
10.20*	Separation Agreement dated as of September 15, 2006 by and between the Registrant and Michael D. Price. (Reference is made to Exhibit 10.2 of the Registrant's Current Report on Form 8-K dated September 11, 2006, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)
10.21*	Information on remuneration of non-employee members of the Board of Directors. (Reference is made to Item 1.01 of the Registrant's Current Report on Form 8-K dated May 23, 2006, Commission File No. 1-10581, which item is incorporated herein by reference.)
10.22	Asset Purchase Agreement between the Registrant and Yungtai Hsu dated February 1, 1999, effective as of December 31, 1998. (Reference is made to Exhibit 7.1 to the Registrant's Form 8-K filed on February 26, 1999, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)
10.23	License Agreement between the Registrant and Auxilium A <sup>2</sup> , Inc. dated May 31, 2000, including Amendment No. 1 thereto dated October 2000 and Amendment No. 2 dated May 31, 2001. (Reference is made to Exhibit 10.10 to Amendment No. 2 to the Registrant's Form 10-K for the year ended December 31, 2001, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)





**Table of Contents**

Exhibit Number	Description
10.24	Supply Agreement, License Agreement and Rights Agreement between Laboratorios Belmac, S.A., Laboratorios Davur, S.L. and Teva Pharmaceutical Industries Ltd. dated July 18, 2000. (Reference is made to Exhibit 10.12 to Amendment No. 2 to the Registrant's Form 10-K for the year ended December 31, 2001, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)
10.25	Amendment No. 3 dated September 6, 2002 to License Agreement between the Registrant and Auxilium Pharmaceuticals, Inc. dated May 31, 2000. (Reference is made to Exhibit 10.10 to the Registrant's Form 10-K for the year ended December 31, 2002, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)
10.26	Amendment No. 4 dated March 25, 2004 to License Agreement between the Registrant and Auxilium Pharmaceuticals, Inc. dated May 31, 2000. (Reference is made to Exhibit 10.26 to the Registrant's Form 10-K for the year ended December 31, 2005, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)
10.27	License Agreement between the Registrant and Auxilium Pharmaceuticals, Inc. dated May 31, 2001 relating to products using Dihydrotestosterone. (Reference is made to Exhibit 10.12 to the Registrant's Form 10-K for the year ended December 31, 2002, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)
10.28	Amendment No. 1 dated September 6, 2002 to License Agreement between the Registrant and Auxilium Pharmaceuticals, Inc. dated May 31, 2001 related to products using Dihydrotestosterone. (Reference is made to Exhibit 10.13 to the Registrant's Form 10-K for the year ended December 31, 2002, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)
10.29	Settlement Term Sheet Agreement, dated September 29, 2006, between Ethypharm S.A. France, Ethypharm S.A. Spain, the Registrant and Laboratorios Belmac S. A.
21.1	Subsidiaries of the Registrant.
23.1	Consent of Independent Registered Public Accounting Firm.
31.1	Certification of the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

**Table of Contents**

Exhibit Number	Description
32.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

\* Indicates a management contract or compensatory plan or arrangement.

Filed herewith.

**Table of Contents**

**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 and Chief  
Executive Officer  
Date: March 15, 2007

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

Signature	Title	Date
/s/ James R. Murphy	Chairman, Chief	March 15, 2007
James R. Murphy	Executive Officer and Director (principal executive officer)	
/s/ Michael McGovern	Vice Chairman and Director	March 15, 2007
Michael McGovern		
/s/ Richard P. Lindsay	Vice-President,	March 15, 2007
Richard P. Lindsay	Chief Financial Officer, Treasurer and Secretary (principal financial officer)	
/s/ Robert P. Hebert	Controller, Assistant Treasurer	March 15, 2007
Robert P. Hebert	and Assistant Secretary (principal accounting officer)	
/s/ Miguel Fernandez	Director	March 15, 2007
Miguel Fernandez		
/s/ F. Ross Johnson	Director	March 15, 2007
F. Ross Johnson		
/s/ Edward J. Robinson	Director	March 15, 2007
Edward J. Robinson		

/s/ John W. Spiegel

Lead Director

March 15, 2007

John W. Spiegel

---

**Table of Contents**

**Index to Consolidated Financial Statements of  
Bentley Pharmaceuticals, Inc. and Subsidiaries**

	<b>Page</b>
Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets as of December 31, 2006 and 2005	F-3
Consolidated Income Statements for the years ended December 31, 2006, 2005 and 2004	F-4
Consolidated Statements of Changes in Stockholders' Equity for the years ended December 31, 2006, 2005 and 2004	F-5
Consolidated Statements of Cash Flows for the years ended December 31, 2006, 2005 and 2004	F-6
Notes to Consolidated Financial Statements	F-8
	F-1

---

**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

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

Exeter, New Hampshire

We have audited the accompanying consolidated balance sheets of Bentley Pharmaceuticals, Inc. and subsidiaries (the Company ) as of December 31, 2006 and 2005, and the related consolidated income statements, statements of changes in stockholders' equity, and statements of cash flows for each of the three years in the period ended December 31, 2006. 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 the standards of the Public Company Accounting Oversight Board (United States). 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 as of December 31, 2006 and 2005, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2006, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 2 to the consolidated financial statements, the Company adopted the provisions of Statement of Financial Accounting Standards ( SFAS ) No. 123 (Revised), *Share-Based Payment*, effective January 1, 2006.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the Company's internal control over financial reporting as of December 31, 2006, based on the criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 15, 2007 expressed an unqualified opinion on management's assessment of the effectiveness of the Company's internal control over financial reporting and an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ Deloitte & Touche LLP

Boston, Massachusetts

March 15, 2007

F-2

---

**Table of Contents****Bentley Pharmaceuticals, Inc. and Subsidiaries  
Consolidated Balance Sheets**

<i>(in thousands, except per share data)</i>	<b>December 31, 2006</b>	<b>December 31, 2005</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 12,424	\$ 32,384
Marketable securities	3,177	462
Receivables, net	32,963	26,916
Inventories	16,279	12,147
Deferred taxes	1,049	1,099
Prepaid expenses and other	1,798	2,069
Total current assets	67,690	75,077
Non-current assets:		
Fixed assets, net	48,556	33,366
Drug licenses and related costs, net	16,026	13,858
Restricted cash	1,000	1,000
Deferred taxes	240	
Other	844	919
Total non-current assets	66,666	49,143
	\$ 134,356	\$ 124,220
<b>Liabilities and Stockholders Equity</b>		
Current liabilities:		
Accounts payable	\$ 14,566	\$ 15,462
Accrued expenses	9,704	9,428
Short-term borrowings	247	2,608
Current portion of long-term debt	307	387
Deferred income	1,045	795
Other current liabilities	1,518	
Total current liabilities	27,387	28,680
Non-current liabilities:		
Deferred taxes		1,665
Deferred income	3,899	2,286
Other	2,739	



Edgar Filing: BENTLEY PHARMACEUTICALS INC - Form 10-K

Total non-current liabilities	6,638	3,951
Commitments and contingencies (Note 15)		
Stockholders' equity:		
Preferred stock, \$1.00 par value, authorized 2,000 shares, issued and outstanding, none		
Common stock, \$0.02 par value, authorized 100,000 shares, issued and outstanding, 22,262 and 21,923 shares	445	438
Additional paid-in capital	140,030	139,381
Accumulated deficit	(49,016)	(49,990)
Accumulated other comprehensive income	8,872	1,760
Total stockholders' equity	100,331	91,589
	\$ 134,356	\$ 124,220

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

F-3

---

**Table of Contents**

**Bentley Pharmaceuticals, Inc. and Subsidiaries**  
**Consolidated Income Statements**

*(in thousands, except per share data)*

	<b>For the Year Ended December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
Revenues:			
Net product sales	\$ 100,590	\$ 91,308	\$ 69,942
Licensing and collaboration revenues	8,881	6,422	3,451
Total revenues	109,471	97,730	73,393
Cost of net product sales	49,850	46,161	34,893
Gross profit	59,621	51,569	38,500
Operating expenses:			
Selling and marketing	16,153	16,347	14,808
General and administrative	14,801	11,405	8,885
Research and development	10,459	5,800	4,419
Litigation settlement	10,914	593	241
Depreciation and amortization	1,895	1,758	1,452
Total operating expenses	54,222	35,903	29,805
Gain on sale of drug license	38		
Income from operations	5,437	15,666	8,695
Other income (expenses):			
Interest income	820	928	548
Interest expense	(158)	(211)	(226)
Other, net	(43)	12	1,478
Income before income taxes	6,056	16,395	10,495
Provision for income taxes	5,082	5,476	4,805
Net income	\$ 974	\$ 10,919	\$ 5,690
Net income per common share:			
Basic	\$ 0.04	\$ 0.51	\$ 0.27

Edgar Filing: BENTLEY PHARMACEUTICALS INC - Form 10-K

Diluted	\$ 0.04	\$ 0.48	\$ 0.25
Weighted average common shares outstanding:			
Basic	22,141	21,558	20,901
Diluted	23,068	22,929	22,627

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

F-4

---

**Table of Contents**

**Bentley Pharmaceuticals, Inc. and Subsidiaries**  
**Consolidated Statements of Changes in Stockholders' Equity**

<i>(in thousands, except per share data)</i>	<b>\$0.02 Par</b>		<b>Stock</b>	<b>Additional</b>	<b>Accumulated</b>		
	<b>Value</b>	<b>Common</b>			<b>Other</b>	<b>Comprehensive</b>	
	<b>Shares</b>	<b>Amount</b>	<b>Warrants</b>	<b>Capital</b>	<b>Accumulated</b>	<b>Income</b>	<b>Total</b>
Balance at January 1, 2004	20,573	\$ 412	\$ 333	\$ 136,850	\$ (66,599)	\$ 5,169	\$ 76,165
Comprehensive income:							
Net income					5,690		5,690
Other comprehensive income:							
Foreign currency translation adjustment						4,553	4,553
Comprehensive income							10,243
Exercise of stock options/warrants	725		14	(333)	3,393		3,074
Equity-based compensation	14				175		175
Balance at December 31, 2004	21,312	426		140,418	(60,909)	9,722	89,657
Comprehensive income (loss):							
Net income					10,919		10,919
Other comprehensive loss:							
Foreign currency translation Adjustment						(7,962)	(7,962)
Comprehensive income							2,957
Exercise of stock options	1,021		20		4,055		4,075
Purchase of treasury shares	(430)		(8)		(5,313)		(5,321)
Equity-based compensation	20				221		221
Balance at December 31, 2005	21,923	438		139,381	(49,990)	1,760	91,589
Comprehensive income:							
Net income					974		974
Other comprehensive income:							
Foreign currency translation adjustment						7,112	7,112
Comprehensive income							8,086
Exercise of stock options	741		15		3,937		3,952
Purchase of treasury shares	(418)		(8)		(5,442)		(5,450)

Equity-based compensation	16			2,154			2,154
Balance at December 31, 2006	22,262	\$ 445	\$	\$ 140,030	\$ (49,016)	\$	8,872 \$ 100,331

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

F-5

---

**Table of Contents**

**Bentley Pharmaceuticals, Inc. and Subsidiaries**  
**Consolidated Statements of Cash Flows**

<i>(in thousands)</i>	<b>For the Year Ended December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
Cash flows from operating activities:			
Net income	\$ 974	\$ 10,919	\$ 5,690
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	5,570	5,096	3,918
Foreign currency gains	(133)		
Gain on sale of drug license	(38)		
Equity-based compensation expense	2,154	280	195
Change in fair value of derivative instrument	186		
Loss on disposal of assets	208	481	
Other non-cash items	12	38	(103)
(Increase) decrease in assets and increase (decrease) in liabilities:			
Receivables	(3,129)	(2,529)	(7,715)
Inventories	(2,691)	(3,701)	(2,083)
Deferred income taxes	(1,731)	(1,160)	(271)
Prepaid expenses and other current assets	343	(809)	(398)
Other assets	(31)	(681)	(153)
Accounts payable and accrued expenses	(2,663)	4,900	4,022
Deferred income	1,401	(173)	1,305
Other liabilities	4,070	(65)	(174)
Net cash provided by operating activities	4,502	12,596	4,233
Cash flows from investing activities:			
Additions to fixed assets	(15,313)	(11,018)	(10,049)
Additions to drug licenses and related costs	(2,772)	(2,045)	(1,204)
Proceeds from maturity of investments		461	150,352
Purchase of investments	(2,409)	(461)	(149,477)
Purchase of API manufacturing assets			(3,309)
Net cash used in investing activities	(20,494)	(13,063)	(13,687)

(Continued on following page)

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

F-6

**Table of Contents**

**Bentley Pharmaceuticals, Inc. and Subsidiaries**  
**Consolidated Statements of Cash Flows (Concluded)**

<i>(in thousands)</i>	<b>For the Year Ended December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
Cash flows from financing activities:			
Proceeds from the exercise of stock options/warrants	\$ 450	\$ 2,028	\$ 3,083
Remittance of employee tax liabilities in exchange for common stock tendered to the Company	(1,948)	(2,292)	
Purchases of treasury stock		(1,041)	
Proceeds from borrowings	1,643	1,938	5,759
Repayment of borrowings	(4,281)	(1,659)	(5,164)
Net cash (used in) provided by financing activities	(4,136)	(1,026)	3,678
Effect of exchange rate changes on cash	168	(353)	613
Net decrease in cash and cash equivalents	(19,960)	(1,846)	(5,163)
Cash and cash equivalents at beginning of year	32,384	34,230	39,393
Cash and cash equivalents at end of year	\$ 12,424	\$ 32,384	\$ 34,230

**Supplemental Disclosures of Cash Flow Information**

The Company paid cash during the year for:			
Interest	\$ 118	\$ 204	\$ 339
Foreign income taxes	\$ 4,555	\$ 4,231	\$ 4,283

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

The Company has issued Common Stock as equity-based compensation in lieu of cash during the year as follows:			
Shares	16	20	14
Amount	\$ 208	\$ 221	\$ 175
Amounts included in accounts payable at end of year for fixed asset and drug license purchases	\$ 1,869	\$ 2,675	\$ 3,986

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





**Table of Contents**

**Bentley Pharmaceuticals, Inc. and Subsidiaries**  
**Notes to Consolidated Financial Statements**

**NOTE 1 HISTORY AND OPERATIONS**

Bentley Pharmaceuticals, Inc. and Subsidiaries (which may be referred to as Bentley Pharmaceuticals, Bentley, or the Company), headquartered in the U.S., is an international specialty pharmaceutical company, incorporated in the State of Delaware, focused on:

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

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

Bentley's pharmaceutical product sales and licensing activities are based primarily in Spain, where it has a significant commercial presence and manufactures and markets approximately 118 products of various dosages and strengths through three wholly-owned Spanish subsidiaries: Laboratorios Belmac, Laboratorios Davur and Laboratorios Rimafar. Bentley's products include approximately 167 product presentations (stock keeping units, or SKUs) in four primary therapeutic areas: cardiovascular, gastrointestinal, central nervous system and infectious diseases. Although most of the Company's sales of these products are currently in the Spanish market, it has recently focused on increasing sales in other European countries and other geographic regions through strategic alliances with companies in these territories. The Company continually adds to its product portfolio in response to increasing market demand for generic and branded generic therapeutic agents and, when appropriate, divests portfolio products considered to be redundant or that have become non-strategic. The Company manufactures its finished dosage pharmaceutical products in its Spanish manufacturing facility which recently received approval from the U.S. Food and Drug Administration (FDA) for the manufacture of Company's first U.S. generic product which was launched in the fourth quarter of 2006. The Company owns a manufacturing facility in Spain that specializes in the manufacturing of several API. This facility has also been approved by the FDA for the manufacture of one ingredient for marketing and sale in the U.S. The Company markets its API products through its Spanish subsidiary, Bentley A.P.I. The Company also has an Irish subsidiary, Bentley Pharmaceuticals Ireland Limited, which received its first marketing approval by the Irish Medicines Board in 2005 and launched its first product in the fourth quarter of 2006.

The Company has U.S. and international patents and other proprietary rights to technologies that facilitate the absorption of drugs. Bentley is developing products that incorporate its drug delivery technologies and has licensed applications of its proprietary CPE-215<sup>®</sup> drug delivery technology to Auxilium Pharmaceuticals, Inc., which launched Testim<sup>®</sup> in the U.S. market in February 2003. Testim, which incorporates Bentley's CPE-215 drug delivery technology, is a gel indicated for testosterone replacement therapy. Bentley continues to seek other pharmaceutical and biotechnology companies to form additional strategic alliances to facilitate the development and commercialization of other products using its drug delivery technologies, including product candidates that deliver insulin to diabetic patients intranasally, deliver macromolecule therapeutics using a biodegradable Nanocaplet<sup>™</sup> technology and treat nail fungus infections topically.

**Table of Contents****Bentley Pharmaceuticals, Inc. and Subsidiaries****Notes to Consolidated Financial Statements (Continued)****NOTE 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES****Principles of consolidation and foreign currency translation**

The consolidated financial statements include the accounts of Bentley Pharmaceuticals, Inc. and its wholly-owned subsidiaries: Pharma de Espana, Inc. and its wholly-owned subsidiaries, Bentley A.P.I. S.L. and Laboratorios Belmac S.A. and its wholly-owned subsidiaries, Laboratorios Davur S.L. and Laboratorios Rimafar S.L.; Bentley Park, LLC; 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.; Belmac Jamaica, Ltd.; and Bentley Pharmaceuticals Ireland Limited. All intercompany 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 in the Consolidated Balance Sheets. Foreign currency gains and losses arising from cash transactions are credited to or charged against current earnings. Exchange rates as of, and for the years ended December 31, 2006, 2005 and 2004 are as follows:

<i>U.S. Dollars per Euro</i>	<b>2006</b>	<b>2005</b>	<b>2004</b>
Weighted average exchange rate	1.26	1.24	1.24
Exchange rate	1.31	1.19	1.36

The net effect of foreign currency translation on the Company's net assets during the years ended December 31, 2006, 2005 and 2004 was an increase of \$7,112,000, a decrease of \$7,962,000 and an increase of \$4,553,000, respectively, which have been included in *other comprehensive income*. The cumulative historical effect of foreign currency translation as of December 31, 2006 and 2005 was an increase of \$8,872,000 and \$1,760,000, respectively, as reflected in *accumulated other comprehensive income*.

**Use of estimates**

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

**Cash and cash equivalents and restricted cash**

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

Included in cash and cash equivalents at December 31, 2006 and 2005 are approximately \$357,000 and \$11,513,000, respectively, of short-term investments considered to be cash equivalents, as the original maturity dates of such investments were three months or less when purchased.

**Table of Contents**

**Bentley Pharmaceuticals, Inc. and Subsidiaries**  
**Notes to Consolidated Financial Statements (Continued)**

The Company acquired intellectual property during the year ended December 31, 2003 for \$1,000,000 plus future royalties on sales and licensing income. In connection with the acquisition, the Company obtained a renewable, irrevocable letter of credit in the amount of \$1,000,000 in favor of the assignor to guarantee future royalty payments. The \$1,000,000 used to secure the letter of credit has been classified as *restricted cash* in the Consolidated Balance Sheets as of December 31, 2006 and 2005.

**Marketable securities**

The Company has investments in Spanish government treasury bills, with maturities of greater than three months when purchased, totaling \$3,177,000 and \$462,000 as of December 31, 2006 and 2005, respectively, which are classified as available-for-sale. The Company's investments are carried at amortized cost, which approximates fair value due to the short-term nature of these investments. Accordingly, no unrealized gains or losses have been recognized with respect to these investments. Should the fair values differ significantly from the amortized costs, changes in fair market value resulting in unrealized gains or losses would be included as a component of *other comprehensive income*.

**Accounts receivable and allowances for doubtful accounts**

Accounts receivable are recorded at their net realizable value, generally as products are shipped or services are performed. Receivable balances are reported net of an estimated allowance for uncollectible accounts. Estimated uncollectible receivables are based on the amount and status of past due accounts, contractual terms with customers, the credit worthiness of customers and the Company's history of uncollectible accounts.

**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:

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

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. Leasehold improvements are amortized over the life of the respective lease. 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

**Table of Contents**

**Bentley Pharmaceuticals, Inc. and Subsidiaries**  
**Notes to Consolidated Financial Statements (Continued)**

drug licenses and related costs are amortized on a straight-line basis for periods not exceeding fifteen years from the dates of acquisition. In accordance with the guidelines in Statement of Financial Accounting Standards ( SFAS ) No. 142, *Goodwill and Other Intangible Assets*, the Company has reviewed its intangible assets for impairment in accordance with the recognition and measurement provisions of SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. Values of such assets are reviewed at least annually by the Company, by comparing the carrying amounts to their estimated future undiscounted cash flows, and adjustments are made for any diminution in value. The Company performed its annual 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 has determined that the estimated useful lives are appropriate for determining amortization expense.

**Other liabilities**

The Company and its subsidiary, Laboratorios Belmac, have settled all outstanding litigation with Ethypharm S.A. Spain and Ethypharm S.A. France (together, Ethypharm ). The Ethypharm claims alleged that the manufacture and sale by Laboratorios Belmac of omeprazole and other pharmaceutical products used Ethypharm s proprietary pellet technology or infringed Ethypharm s patents. As a result of the settlement the Company recorded a \$7,546,000 charge in 2006 representing the present value of the \$8,000,000 settlement, of which \$4,000,000 was paid in the fourth quarter of 2006 and four payments of \$1,000,000 will be paid on the first four anniversaries of the first payment, discounted at a rate of 4.72%. At December 31, 2006, the Company has recorded a liability of \$3,590,000 in the Consolidated Balance Sheet, representing the net present value of the remaining liability, of which \$1,000,000 is classified as current. The Company has incurred related litigation defense costs of approximately \$3,368,000, \$593,000 and \$241,000 in the years ended December 31, 2006, 2005 and 2004, respectively. The litigation related charges are recorded in *litigation settlement* expenses on the Company s Consolidated Income Statements.

**Derivative Instruments and Hedging Activity**

The Company accounts for derivative instruments in accordance with SFAS No. 133, *Accounting for Derivative Instruments and Certain Hedging Activities*, as amended by SFAS No. 138, *Accounting for Certain Derivative Instruments and Certain Hedging Activity, an Amendment of SFAS 133* and SFAS No. 149, *Amendment of Statement 133 on Derivative Instruments and Hedging Activities*. Under these standards, all derivative instruments are recorded as either assets or liabilities on the balance sheet at their respective fair values. Generally, if a derivative instrument is designated as a cash flow hedge, the change in the fair value of the derivative is recorded in other comprehensive income to the extent the derivative is effective, and the change recognized in the statement of operations when the hedged item affects earnings. If a derivative instrument is designated as a fair value hedge, the change in fair value of the derivative and of the hedged item attributable to the hedged risk are recognized in earnings in the current period.

In October of 2006 the Company entered into cash flow hedges designed to reduce the effect of fluctuations in foreign currency on scheduled litigation settlement payments. At December 31, 2006, there were four outstanding contracts, with an aggregate notional amount of \$4.0 million that are expected to mature over the next four years. These hedges are not expected to be highly effective in offsetting the change in cash flows attributed to the scheduled payments. Therefore, changes in the fair value of the hedges are recognized in earnings in the period of change. At December 31, 2006, the Company recorded a liability of \$186,000 related to these hedges, of which \$37,000 is reported as current in the Consolidated Balance Sheet. The Company recorded a corresponding loss in *other income (expenses)* in the Consolidated Income Statement.

**Table of Contents**

**Bentley Pharmaceuticals, Inc. and Subsidiaries**  
**Notes to Consolidated Financial Statements (Continued)**

**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 amounts of the Company's long-term obligations approximate fair value, when considering the amounts outstanding at December 31, 2006 and 2005. The fair value information presented herein is based on information available to management as of December 31, 2006.

**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 product. The Company provides its customers with a limited right of return. Revenue is recognized upon delivery and a reserve for sales returns is recorded when considered appropriate. The Company has demonstrated the ability to make reasonable and reliable estimates of product returns in accordance with SFAS No. 48, *Revenue Recognition When Right of Return Exists*, and of allowances for doubtful accounts based on significant historical experience.

Revenue from service, research and development, and licensing agreements is recognized when the service procedures have been completed or as revenue recognition criteria have been met for each separate unit of accounting as defined in Emerging Issues Task Force (EITF) Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*. The Company has deferred the recognition of approximately \$4,797,000 and \$2,594,000 of licensing revenues as of December 31, 2006 and 2005, respectively, for which the earnings process has not been completed.

The Company earns royalty revenues on Auxilium's sales of Testim, which incorporates the Company's CPE-215 permeation enhancement technology. Since 2003, Auxilium has sold Testim to pharmaceutical wholesalers and chain drug stores, which have the right to return purchased product prior to the units being dispensed through patient prescriptions. Historically, customer returns were not able to be reasonably estimated. Therefore, in accordance with SFAS No. 48, the Company deferred the recognition of royalty revenues on product shipments of Testim until the units were dispensed through patient prescriptions. During the quarter ended June 30, 2006, the Company recorded an increase in royalty revenues of approximately \$479,000 due to a change in estimate which, based on historical experience, allowed it to reasonably estimate future product returns on sales of Testim. As a result of the change in estimate, there were no deferred Testim royalties as of December 31, 2006. Deferred income from Testim royalties totaled \$348,000 as of December 31, 2005. Total royalty revenues recognized for the years ended December 31, 2006 and 2005 were \$8,341,000 and \$6,132,000, respectively.

**Research and development**

Research and development costs are expensed as incurred.

**Income taxes**

The Company accounts for income taxes in accordance with 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 Accounting Principles Board (APB) Opinion No. 23, *Accounting for Income*

**Table of Contents**

**Bentley Pharmaceuticals, Inc. and Subsidiaries**  
**Notes to Consolidated Financial Statements (Continued)**

*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. The cumulative amount of foreign earnings that have been permanently reinvested is approximately \$39,900,000.

**Basic and diluted net income per common share**

Basic and diluted net income per common share is based on the weighted average number of shares of Common Stock outstanding during each period in accordance with SFAS No. 128, *Earnings per Share*. 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, 2006, 2005 and 2004.

The following is a reconciliation between basic and diluted net income per common share for the years ended December 31, 2006, 2005 and 2004. There were approximately 927,000, 1,371,000 and 1,726,000 incremental shares issuable as a result of various stock options, restricted stock units, and/or warrants outstanding for the years ended December 31, 2006, 2005 and 2004, respectively.

	<b>Basic EPS</b>	<b>Effect of Dilutive Securities</b>	<b>Diluted EPS</b>
<b>For The Year Ended December 31, 2006</b>			
<b>(In Thousands, Except Per Share Data)</b>			
Net income	\$ 974	\$	\$ 974
Weighted average common shares outstanding	22,141	927	23,068
Net income per common share	\$ 0.04	\$	\$ 0.04

	<b>Basic EPS</b>	<b>Effect of Dilutive Securities</b>	<b>Diluted EPS</b>
<b>For The Year Ended December 31, 2005</b>			
<b>(In Thousands, Except Per Share Data)</b>			
Net income	\$10,919	\$	\$10,919
Weighted average common shares outstanding	21,558	1,371	22,929
Net income per common share	\$ 0.51	\$ (0.03)	\$ 0.48

	<b>Basic EPS</b>	<b>Effect of Dilutive Securities</b>	<b>Diluted EPS</b>
<b>For The Year Ended December 31, 2004</b>			
<b>(In Thousands, Except Per Share Data)</b>			
Net income	\$ 5,690	\$	\$ 5,690
Weighted average common shares outstanding	20,901	1,726	22,627
Net income per common share	\$ 0.27	\$ (0.02)	\$ 0.25

For the years ended December 31, 2006, 2005 and 2004, options and/or warrants to purchase 416,000, 736,000 and 672,000 shares of Common Stock, respectively, were excluded from the diluted EPS presentation as determined under the treasury stock method, because their exercise prices were greater than the average market value of the Common Stock during the period.

**Table of Contents**

**Bentley Pharmaceuticals, Inc. and Subsidiaries**  
**Notes to Consolidated Financial Statements (Continued)**

**Comprehensive income**

The Company applies SFAS No. 130, *Reporting Comprehensive Income*, which requires disclosure of all components of comprehensive income on an annual and interim basis. Comprehensive income is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. The Company's comprehensive income includes foreign currency translation gains (losses) and unrealized gains (losses). Should the fair values of the Company's marketable equity securities differ significantly from their amortized costs, unrealized gains or losses resulting from the change in fair market value would be included as a component of *other comprehensive income*.

**Share-based compensation plans**

The Company has share-based employee compensation plans that are described more fully in Note 11. In December 2004, the Financial Accounting Standards Board (the FASB) issued SFAS No. 123 (Revised), *Share-Based Payment*. This Statement is a revision of SFAS No. 123, *Accounting for Stock-Based Compensation*, and supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and its related implementation guidance. SFAS No. 123 (Revised) focuses primarily on accounting for transactions in which an entity obtains employee services in exchange for share-based payment transactions and requires that the cost resulting from those transactions be recognized in the financial statements. The Company adopted SFAS No. 123 (Revised) effective January 1, 2006 using the modified-prospective transition method. The Company uses the accelerated expense attribution method pursuant to FASB Interpretation No. (FIN) 28 for all options previously accounted for under APB Opinion No 25. Share-based compensation attributable to share-based awards granted subsequent to December 31, 2005 is recognized using the straight-line method pursuant to SFAS No. 123 (Revised). The adoption of SFAS No. 123 (Revised) in 2006 resulted in incremental share-based compensation expense of approximately \$1,829,000, or \$0.08 per basic and diluted share.

**Segments of an enterprise and related information**

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

**Recently issued accounting pronouncements**

In June 2006, the FASB issued FIN No. 48, *Accounting for Uncertainty in Income Taxes*, which the Company adopted effective January 1, 2007. The purpose of FIN No. 48 is to clarify and set forth consistent rules for accounting for uncertain tax positions in accordance with SFAS 109, "Accounting for Income Taxes" by requiring the application of a more likely than not threshold for the recognition and derecognition of tax positions. Although the Company adopted FIN No. 48 effective January 1, 2007, the Company is still in the process of assessing what impact, if any, the adoption of this statement will have on its consolidated financial statements; however, based upon its initial assessment, the Company does not expect the adoption of FIN No. 48 to have a material impact on its Consolidated Balance Sheets or the Consolidated Statements of Cash Flows.

On September 13, 2006, the Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin (SAB) No. 108 *Considering the Effects of Prior Year Misstatements When Quantifying Misstatements in Current Year Financial Statements*, which provides interpretive guidance

**Table of Contents**

**Bentley Pharmaceuticals, Inc. and Subsidiaries**  
**Notes to Consolidated Financial Statements (Continued)**

on how the effects of the carryover or reversal of prior year misstatements should be considered in quantifying a current year misstatement. The Company adopted SAB No. 108 effective December 31, 2006. The adoption of SAB 108 did not have an impact on the Company's consolidated financial statements in the year ended December 31, 2006.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*, which provides guidance for measuring the fair value of assets and liabilities, as well as requires expanded disclosures about fair value measurements. SFAS 157 indicates that fair value should be determined based on the assumptions marketplace participants would use in pricing the asset or liability, and provides additional guidelines to consider in determining the market-based measurement. The Company adopted SFAS No. 157 effective January 1, 2007 and does not expect this adoption to have a material impact on its consolidated financial statements.

**Reclassifications**

Certain costs incurred in *general and administrative expenses* in prior periods associated with litigation settlement in the current year have been reclassified from *general and administrative expenses* to *litigation settlement* to conform with the current period's presentation.

**NOTE 3 - RECEIVABLES**

Receivables consist of the following:

	<b>December 31,</b>	
	<b>2006</b>	<b>2005</b>
	<b>(In Thousands)</b>	
Trade receivables (of which \$247 and \$2,595, respectively, collateralize short-term borrowings with Spanish financial institutions)	\$ 27,880	\$ 21,293
VAT, income and social security taxes receivable	3,151	2,270
Royalties receivable	2,261	2,861
Other	82	694
	33,374	27,118
Less-allowance for doubtful accounts	(411)	(202)
	\$ 32,963	\$ 26,916

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

	<b>Year Ended December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
	<b>(In Thousands)</b>		
Balance at beginning of year	\$ 202	\$ 375	\$ 160
Net provisions charged to expenses	191	(122)	184
Write-offs reducing allowance	(10)	(9)	(1)
Effect of foreign currency	28	(42)	32
Balance at end of year	\$ 411	\$ 202	\$ 375



**Table of Contents**

**Bentley Pharmaceuticals, Inc. and Subsidiaries**  
**Notes to Consolidated Financial Statements (Continued)**

**NOTE 4 - INVENTORIES**

Inventories consist of the following:

	<b>December 31,</b>	
	<b>2006</b>	<b>2005</b>
	<b>(In Thousands)</b>	
Raw materials	\$ 8,669	\$ 6,414
Finished goods	7,621	5,869
	16,290	12,283
Less-allowance for slow moving inventory	(11)	(136)
	\$ 16,279	\$ 12,147

Included in the Company's inventories at December 31, 2006 are \$1,338,000 of consigned goods that have been shipped to the Company's collaborator in the fourth quarter of 2006. The Company has received payments of \$481,000 from its selling agent in anticipation of future sales of the products which have been recorded in *other current liabilities* on the Consolidated Balance Sheet.

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

	<b>Year Ended December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
	<b>(In Thousands)</b>		
Balance at beginning of year	\$ 136	\$ 75	\$ 74
Provisions charged to costs and expenses	11	70	
Write-offs reducing allowance	(144)		(5)
Effect of foreign currency	8	(9)	6
Balance at end of year	\$ 11	\$ 136	\$ 75

**NOTE 5 - FIXED ASSETS**

Fixed assets consist of the following:

	<b>December 31,</b>	
	<b>2006</b>	<b>2005</b>
	<b>(In Thousands)</b>	
Land	\$ 2,875	\$ 2,673
Buildings and improvements	17,538	14,151
Equipment	20,591	16,742
Furniture and fixtures	2,138	1,974
Other	394	148
	43,536	35,688
Capital in-progress	20,213	7,748
	63,749	43,436
Less-accumulated depreciation	(15,193)	(10,070)

\$ 48,556      \$ 33,366

In order to support the Company's growth in Europe, management is adding additional capacity to its manufacturing facilities through a series of improvements. During the years ended December 31, 2006 and 2005, the Company invested approximately \$10,321,000 and \$5,654,000, respectively, renovating and

F-16

---

**Table of Contents**

**Bentley Pharmaceuticals, Inc. and Subsidiaries**  
**Notes to Consolidated Financial Statements (Continued)**

expanding the Company's manufacturing and warehouse facilities and approximately \$4,628,000 and \$4,530,000, respectively, for related machinery and equipment.

In April 2004, the Company purchased a Spanish manufacturing facility, inventory and related machinery and equipment used to manufacture active pharmaceutical ingredients, for approximately \$3,309,000. The Company is manufacturing and marketing some of these products through its subsidiary, Bentley A.P.I. The 11,000 square foot facility is currently FDA approved for one product, which the Company sells to several customers, including customers in the United States.

Depreciation expense of approximately \$311,000, \$309,000 and \$288,000 has been charged to operations as a component of *depreciation and amortization expense* in the Consolidated Income Statements for the years ended December 31, 2006, 2005 and 2004, respectively. The Company has included depreciation totaling approximately \$3,675,000, \$3,338,000 and \$2,466,000 in *cost of net product sales* during the years ended December 31, 2006, 2005 and 2004, respectively.

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

Drug licenses and related costs consist of the following:

	<b>December 31,</b>	
	<b>2006</b>	<b>2005</b>
	<b>(In Thousands)</b>	
Drug licenses and related costs	\$ 23,069	\$ 19,443
Less-accumulated amortization	(7,043)	(5,585)
	\$ 16,026	\$ 13,858

Amortization expense for drug licenses and related costs was approximately \$1,584,000, \$1,403,000 and \$1,140,000 for the years ended December 31, 2006, 2005 and 2004, respectively, and has been recorded in *depreciation and amortization expense* in the accompanying Consolidated Income Statements.

Amortization expense for existing drug licenses and related costs for each of the next five years and for all remaining years thereafter is estimated to be as follows:

<b>Year Ending December 31,</b>	<b>Future Amortization Expense (In Thousands)</b>
2007	1,555
2008	1,533
2009	1,787
2010	1,543
2011	1,516
2012 and beyond	8,092

**NOTE 7 - RELATED PARTY AND SUPPLEMENTAL CASH FLOW DISCLOSURES**

During the year ended December 31, 2006, the Chief Executive Officer ( CEO ), the Chief Medical Officer ( CMO ) and the former Chief Financial Officer ( Former CFO ) of the Company exercised stock options to purchase an aggregate of 714,100 shares of the Company's Common Stock. In

**Table of Contents**

**Bentley Pharmaceuticals, Inc. and Subsidiaries**  
**Notes to Consolidated Financial Statements (Continued)**

satisfaction of the option exercise prices, the Company received approximately \$300,000 in cash proceeds and an aggregate of approximately 269,900 shares of previously acquired Bentley Common Stock, with a fair market value of approximately \$3,502,000. The Company also withheld a total of approximately 147,800 shares of Common Stock with a fair market value of approximately \$1,941,000 from the shares to be issued to these executives in connection with their exercises, in order to satisfy minimum federal and statutory tax withholding requirements. The shares of Common Stock acquired by the Company in connection with these stock option exercises were recorded at fair market value and are held by the Company as treasury shares. In addition, in accordance with the September 2006 separation agreement with the Former CFO, an additional 1,604 shares of Common Stock associated with a grant of restricted stock units were issued to the Former CFO. The Company withheld a total of 584 shares of Common Stock with a fair market value of approximately \$7,000 from the issuance of those shares in order to satisfy minimum federal and statutory tax withholding requirements.

As of December 31, 2006 and December 31, 2005, the Company has recorded approximately 849,100 and 430,800 shares, respectively, as treasury stock, with an historical cost of \$10,781,700 and \$5,321,000, respectively, which has been accounted for as a reduction of *common stock* and *additional paid in capital*.

During the year ended December 31, 2005, the CEO, the Former CFO and the CMO of the Company exercised stock options to purchase an aggregate of 925,700 shares of the Company's Common Stock. In satisfaction of the option exercise prices, the Company received approximately \$1,218,000 in cash proceeds and an aggregate of approximately 159,000 shares of previously acquired Bentley Common Stock, with a fair market value of approximately \$1,988,000. The Company also received a total of approximately 181,500 shares of Common Stock, with a fair market value of approximately \$2,292,000 from the three employees in order to satisfy minimum federal and statutory tax withholding requirements. The Company repurchased approximately 89,500 shares of Common Stock with a fair market value of approximately \$1,041,000 from the CEO and CMO in connection with these options exercises. The shares of Common Stock acquired by the Company in connection with these stock option exercises were recorded at fair market value and are held by the Company as treasury shares.

**NOTE 8 - ACCRUED EXPENSES**

Accrued expenses consist of the following:

	<b>December 31,</b>	
	<b>2006</b>	<b>2005</b>
	<b>(In Thousands)</b>	
Foreign income taxes payable	\$ 2,463	\$ 2,107
Allowance for sales returns	784	887
Accrued payroll and related taxes	3,288	2,268
Spanish pharmaceutical taxes payable	1,035	1,471
Other accrued expenses	2,134	2,695
	<b>\$ 9,704</b>	<b>\$ 9,428</b>

**Table of Contents**

**Bentley Pharmaceuticals, Inc. and Subsidiaries**  
**Notes to Consolidated Financial Statements (Continued)**

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

	Year Ended December 31,		
	2006	2005	2004
	(In Thousands)		
Balance at beginning of year	\$ 887	\$ 597	\$ 446
Provisions charged to costs and expenses (a)	1,939	898	721
Write-offs reducing allowance (a)	(2,138)	(652)	(618)
Effect of foreign currency	96	44	48
Balance at end of year	\$ 784	\$ 887	\$ 597

(a) The Company experienced an unforeseen level of product returns in 2004 as a result of government imposed price reductions in Spain. The product returns exceeded the Company's allowance for estimated sales returns, and were accounted for as a reduction in revenues of approximately \$2,705,000 in the year ended December 31, 2004.

**NOTE 9 - DEBT**

Short-term borrowings consist of the following:

	December 31,	
	2006	2005
	(In Thousands)	
Trade receivables discounted with Spanish financial institutions, with recourse, effective interest rate is 3.7% and 3.3%, respectively	\$ 247	\$ 2,595
		13

Revolving line of credit facilities payable to Spanish financial institutions, weighted average interest rate is 3.2%

\$ 247      \$ 2,608

The weighted average stated interest rate on short-term borrowings outstanding at December 31, 2006 and 2005 was 3.7% and 3.3%, respectively.

The revolving line of credit facilities with Spanish financial institutions, entitle the Company to borrow up to \$6,438,000 as of December 31, 2006 at interest rates ranging from 3.2% to 3.4%. The facilities are scheduled to mature on various dates through December 15, 2007 and are renewable.

Long-term debt consists of the following:

	<b>December 31,</b>	
	<b>2006</b>	<b>2005</b>
	<b>(In Thousands)</b>	
Loans payable to Spanish government	\$ 307	\$ 387
Less-current portion of long-term debt	(307)	(387)
 Total long-term debt	 \$	 \$

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 payable in seven equal annual installments of approximately \$17,000 beginning in 2006. Accordingly, the Company imputed interest at the market rate in Spain (5.2%) at the time of the borrowing, and recorded a discount on the obligation of \$33,000. Additionally, in December 2001, the Company entered into a loan agreement with the Spanish

**Table of Contents**

**Bentley Pharmaceuticals, Inc. and Subsidiaries**  
**Notes to Consolidated Financial Statements (Continued)**

government as part of a research-funding program. The loan is non-interest bearing and payable in seven equal annual installments of approximately \$31,000 which began in 2005. Accordingly, the Company imputed interest at the market rate in Spain (6%) at the time of the borrowing, and recorded a discount on the obligation of \$72,000. These obligations are classified as current in anticipation of repayment during the year ending December 31, 2007.

**NOTE 10 - PREFERRED STOCK**

The Company has 2,000,000 shares of Preferred Stock, \$1.00 par value, authorized for issuance. As of December 31, 2006 and 2005, no shares of Preferred Stock were outstanding.

**NOTE 11 - EQUITY AND SHARE-BASED COMPENSATION**

At December 31, 2006 the Company had the following shares of Common Stock reserved for issuance under various plans and agreements:

	<b>Common Shares (In Thousands)</b>
For exercise of outstanding stock options and restricted stock units	3,755
For future stock option and restricted stock unit grants	737
	4,492

**Common stock and restricted stock unit transactions**

During the year ended December 31, 2006, the Company issued approximately 739,500 shares of Common Stock upon exercise of stock purchase options, approximately 1,600 shares of Common Stock upon the vesting of restricted stock units and approximately 16,400 shares of Common Stock as share-based compensation in lieu of cash. The Company also received approximately 418,300 shares of treasury stock in connection with the exercise of stock purchase options during the year ended December 31, 2006 (See Note 7).

During the year ended December 31, 2005, the Company issued approximately 1,020,700 shares of Common Stock upon exercise of stock purchase options and approximately 20,100 shares of Common Stock as share-based compensation in lieu of cash. The Company also received approximately 430,000 shares of treasury stock in connection with the exercise of stock purchase options during the year ended December 31, 2005 (See Note 7).

During the year ended December 31, 2004, the Company issued approximately 400,000 shares of Common Stock upon exercise of Class B Warrants, approximately 325,600 shares of Common Stock upon exercise of stock purchase options, and approximately 14,400 shares of Common Stock as share-based compensation in lieu of cash.

The Company has never paid any cash dividends on its Common Stock. The current policy of the Board of Directors is to retain earnings to finance the operation and growth 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.

**Table of Contents**

**Bentley Pharmaceuticals, Inc. and Subsidiaries**  
**Notes to Consolidated Financial Statements (Continued)**

**Share-based compensation plans**

The Company has in effect equity incentive plans (the Plans), pursuant to which directors, officers, employees and consultants of the Company have been awarded grants of restricted stock units and options to purchase the Company's Common Stock. The Company's shareholders voted to increase the number of shares of Common Stock authorized for issuance pursuant to the Company's Amended and Restated 2005 Equity and Incentive Plan by 750,000 shares in May 2006. As of December 31, 2006, approximately 4,492,000 shares of Common Stock have been reserved for issuance under the Plans, of which approximately 2,786,000 are outstanding that were issued under the predecessor stock option plans. Approximately 969,000 shares are outstanding that were issued under the Amended and Restated 2005 Equity and Incentive Plan, excluding 20,000 shares underlying restricted stock units, contingently issuable to non-employee directors, that will be issued when the directors cease to serve on the Board of Directors of the Company. The balance of approximately 737,000 shares is available for future issuance under the Amended and Restated 2005 Equity and Incentive Plan, which is now the successor to all the other Plans. Of the shares available for future issuance, approximately 290,000 are available for future stock options only and the remainder are available for any type of award allowed under the plan.

A summary of stock option award activity under the Plans as of December 31, 2006 and changes during the year then ended are presented below (shares and aggregate intrinsic values in thousands):

	<b>For Year Ended December 31, 2006</b>			
	<b>Number of Options</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Term (Years)</b>	<b>Aggregate Intrinsic Value</b>
Options outstanding, December 31, 2003	3,920	\$ 6.75	5.74	
Granted	612	12.60		
Exercised	(326)	7.66		
Forfeited and expired	(119)	10.80		
Options outstanding, December 31, 2004	4,087	7.44	5.26	
Granted	870	9.11		
Exercised	(1,021)	3.93		
Forfeited and expired	(20)	8.87		
Options outstanding, December 31, 2005	3,916	8.72	6.28	
Granted	481	11.80		
Exercised	(739)	5.34		
Forfeited and expired	(21)	10.01		
Options outstanding, December 31, 2006	3,637	\$ 9.80	6.56	\$ 4,372
Vested or expected to vest, December 31, 2006	3,611	\$ 9.80	6.54	\$ 4,342
Options exercisable, December 31, 2006	2,835	\$ 9.66	5.87	\$ 3,613





**Table of Contents**

**Bentley Pharmaceuticals, Inc. and Subsidiaries**  
**Notes to Consolidated Financial Statements (Continued)**

The table below summarizes options outstanding and exercisable at December 31, 2006 (number of options in thousands):

Range of Exercise Prices	Options Outstanding			Options Currently Exercisable		
	Number Outstanding	Weighted Average Exercise Price	Weighted Average Life (Years) Remaining	Number Exercisable	Weighted Average Exercise Price	Weighted Average Exercise Price
\$ 2.00 - \$ 3.00	58	\$ 2.72	2.15	58	\$ 2.72	\$ 2.72
5.70 - 5.88	142	5.84	3.39	142	5.84	5.84
6.00 - 6.33	267	6.01	4.36	266	6.01	6.01
7.10 - 7.39	182	7.31	6.32	114	7.26	7.26
	320	7.50	8.25	107	7.50	7.50
8.00 - 8.93	310	8.28	5.79	310	8.28	8.28
9.00 - 9.80	448	9.68	5.04	448	9.68	9.68
	273	10.04	6.39	273	10.04	10.04
10.38 - 10.79	200	10.76	7.74	200	10.76	10.76
11.00 - 11.78	818	11.57	8.18	368	11.31	11.31
12.01 - 12.55	203	12.30	8.14	133	12.44	12.44
	373	13.30	6.17	373	13.30	13.30
13.48 - 15.83	43	14.07	6.90	43	14.07	14.07
<b>\$ 2.00 - \$ 15.83</b>	<b>3,637</b>	<b>\$ 9.80</b>	<b>6.56</b>	<b>2,835</b>	<b>\$ 9.66</b>	<b>\$ 9.66</b>

A summary of the activity for nonvested share awards as of December 31, 2006, 2005 and 2004 is provided below with changes during the years then ended (shares in thousands):

	For Year Ended December 31,					
	2006	2005		2004		
	Number of Options	Weighted Average Grant Date Fair Value	Number of Options	Weighted Average Grant Date Fair Value	Number of Options	Weighted Average Grant Date Fair Value
Nonvested options outstanding, beginning of the period	840	\$ 4.35	748	\$ 5.58	1,081	\$ 4.85
Granted	481	5.54	870	4.07	612	5.77
Vested	(499)	(4.82)	(763)	(4.41)	(868)	(5.01)
Forfeited	(20)	(4.62)	(15)	(4.24)	(77)	(4.94)
Nonvested options outstanding, end of the period	802	\$ 4.76	840	\$ 4.35	748	\$ 5.58

As of December 31, 2006, unrecognized compensation expense related to the unvested portion of the Company's stock options was approximately \$2,501,000 and is expected to be recognized over a weighted average period of approximately 1.8 years.

Options to purchase approximately 739,000, 1,021,000 and 326,000 shares of Common Stock were exercised during 2006, 2005 and 2004, respectively. Net cash proceeds to the Company from these option exercises totaled approximately \$450,000, \$2,028,000 and \$2,483,000, respectively, while the total intrinsic value (the excess of the market price over the exercise price) of those option exercises was

F-22

---

**Table of Contents**

**Bentley Pharmaceuticals, Inc. and Subsidiaries**  
**Notes to Consolidated Financial Statements (Continued)**

approximately \$5,586,000, \$8,583,000 and \$1,552,000, respectively. As future operating profits in the U.S. cannot be reasonably assured, no tax benefit resulting from the settlement of U.S. awards has been recorded. The total fair value of stock options that vested during the 2006, 2005 and 2004 was approximately \$2,405,000, \$3,365,000, and \$4,349,000, respectively.

The Company generally issues previously unissued shares for the exercise of stock options and to match eligible 401(k) Plan contributions; however, the Company may reissue previously acquired treasury shares to satisfy these issuances in the future. The Company does not have a policy of repurchasing shares on the open market to satisfy option exercises and matching contributions to the 401(k) Plan.

A summary of restricted stock units award activity under the Amended and Restated 2005 Equity and Incentive Plan as of December 31, 2006 and changes during the year then ended are presented below (shares and aggregate intrinsic values in thousands):

	For the Year Ended December 31, 2006			
	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Restricted stock units outstanding, December 31, 2005		\$		
Granted	146	11.47		
Vested	(22)	11.78		
Forfeited	(6)	11.78		
Restricted stock units outstanding, December 31, 2006	118	\$ 11.39	1.69	\$ 1,204
Vested and expected to vest, December 31, 2006	114	\$ 11.41	1.69	\$ 1,155

During 2006, the Company granted 106,000 restricted stock units to employees with a weighted average grant date fair value of \$11.35 and 40,000 restricted stock units to non-employee directors with a weighted average grant date fair value of \$11.78. Restricted stock units granted to employees were awarded in the second and fourth quarters of 2006 and the restricted stock units granted to non-employee directors were granted in the second quarter of 2006.

As of December 31, 2006, unrecognized compensation expense related to the unvested portion of the Company's restricted stock units was approximately \$1,153,000 and is expected to be recognized over a weighted average period of approximately 2.4 years. The Company's restricted stock units are outstanding until vested.

Included in the approximately 22,000 units that vested during the year are 20,000 shares contingently issuable to non-employee directors that, pursuant to the terms and conditions of the restricted stock unit agreements, will be issued when the directors cease to serve as directors of the Company. The balance of restricted stock units that vested in 2006 resulted in the issuance of 2,000 shares of Common Stock to one employee. The intrinsic value of these shares when they vested was approximately \$20,000. As future operating profits in the U.S. cannot be reasonably assured, the Company has not recorded any tax benefit resulting from the settlement of U.S. awards.

**Table of Contents**

**Bentley Pharmaceuticals, Inc. and Subsidiaries**  
**Notes to Consolidated Financial Statements (Continued)**

**Share-based compensation**

The 2006 share-based compensation expense recorded for stock option and restricted stock unit awards to employees and non-employee directors was approximately \$1,929,000, of which approximately \$26,000 is included in *cost of sales*, approximately \$13,000 is included in *selling and marketing expenses*, approximately \$1,226,000 (including approximately \$97,000 of share-based compensation expense recorded in the third quarter in accordance with the provisions of the Former CFO's separation agreement) is included in *general and administrative expenses* and approximately \$664,000 is included in *research and development expenses*. In addition, the Company reported \$17,000 of share-based compensation expense in *research and development expenses* related to a share-based award to a consultant. No related compensation expense was capitalized as the cost of an asset and there was no impact on net cash provided by operating activities or net cash used in financing activities as a result of these share-based transactions.

At the discretion of the Compensation Committee of the Board of Directors, the Company may grant shares of its Common Stock to employees in lieu of cash compensation. The Company also sponsors a 401(k) Plan for eligible employees and matches eligible contributions with shares of the Company's Common Stock. The Company issued approximately 16,400, 20,100 and 14,400 shares of Common Stock to its 401(k) Plan as matching contributions during the years ended December 31, 2006, 2005 and 2004, respectively. These shares are recorded at their fair value on the last day of each payroll period in which they are earned. All Company matching contributions vest 25% each year for the first four years of each employee's employment in which the employee works for the Company at least 1,000 hours.

Share-based compensation expense attributable to the Company's 401(k) Plan matching contributions and non-employee options represents the remainder of the Company's SFAS No. 123 (Revised) share-based compensation. *General and administrative expenses* include approximately \$102,000, \$113,000 and \$73,000 of such non-cash share-based compensation for the years ended December 31, 2006, 2005 and 2004, respectively. *Research and development expenses* include approximately \$122,000, \$167,000 and \$122,000 of such non-cash share-based compensation for the years ended December 31, 2006, 2005 and 2004, respectively.

The Company entered into a separation agreement with its Former CFO, pursuant to which certain share-based awards were modified during the quarter to allow for the acceleration of vesting and extension of the post-employment exercise period. These modifications resulted in the recognition of approximately \$97,000 of share-based compensation which has been recorded in *general and administrative expenses* in the year ended December 31, 2006.

As the Company previously adopted only the pro forma disclosure provisions of SFAS No. 123, compensation cost relating to the unvested portion of share-based awards granted prior to the date of adoption will continue to be recognized using the same estimate of the grant-date fair value and the same accelerated attribution method used to determine the pro forma disclosures under SFAS No. 123, except that the unamortized compensation expense related to those awards will be reduced for estimated forfeitures, as required by SFAS No. 123 (Revised).

The following table details the reported effect that share-based compensation expense had on net income and earnings per share for the year ended December 31, 2006 and the pro forma effect that share-based compensation expense would have had on net income and earnings per share for the years ended December 31, 2005 and 2004. The reported net income and earnings per share for the year ended December 31, 2006 in the table below includes the share-based compensation expense actually recorded in 2006 under the provisions of SFAS No. 123 (Revised). The amounts for 2005 and 2004 are included in the table below only to provide a comparative presentation to the prior year required disclosure (in

**Table of Contents**

**Bentley Pharmaceuticals, Inc. and Subsidiaries**  
**Notes to Consolidated Financial Statements (Continued)**

thousands, except per share data), which was prepared in accordance with SFAS No. 123, as originally issued.

	<b>Year Ended December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
	<b>(In Thousands, Except Per Share Data)</b>		
Net income, as reported	\$ 974	\$ 10,919	\$ 5,690
Add: Stock-based employee compensation expense included in reported net income	2,154	280	195
Deduct: Total stock-based employee compensation expense determined under fair value method for all awards	(2,154)	(3,452)	(2,978)
Pro forma net income	\$ 974	\$ 7,747	\$ 2,907
Net income per share:			
Basic as reported	\$ 0.04	\$ 0.51	\$ 0.27
Basic pro forma	\$ 0.04	\$ 0.36	\$ 0.14
Diluted as reported	\$ 0.04	\$ 0.48	\$ 0.25
Diluted pro forma	\$ 0.04	\$ 0.34	\$ 0.13

The fair value of each option award is estimated on the date of grant using the Black-Scholes option valuation model. Assumptions and the resulting fair value for option awards granted during the years ended December 31, 2006 and 2005 are provided below (results may vary depending on the assumptions applied within the model):

	<b>Year Ended December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
Risk free interest rate	4.95%	3.90%	2.94%
Dividend yield	0.00%	0.00%	0.00%
Expected life	5 years	5 years	5 years
Volatility	46.24%	45.28%	48.63%
Fair value of options granted	\$ 5.54	\$ 4.04	\$ 5.77

The risk-free interest rate is based on the yield curve of U.S. Treasury securities in effect at the date of the grant, having a duration commensurate with the estimated life of the award. The Company has not declared dividends, and does not expect to declare dividends in the future. Therefore, an annual dividend rate of 0% is used when calculating the grant date fair value of equity awards. The expected life (estimated period of time outstanding) of options granted is estimated based on historical exercise behaviors. The volatility of the Company's stock is calculated on the grant date of each equity award using daily price observations over a period of time commensurate with the related requisite service period. The maximum contractual term of the Company's share-based awards is 10 years.

As share-based compensation expense is based on awards ultimately expected to vest, it is reduced for estimated forfeitures. SFAS No. 123 (Revised) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures are estimated based on historical experience.

F-25

---

**Table of Contents**

**Bentley Pharmaceuticals, Inc. and Subsidiaries  
Notes to Consolidated Financial Statements (Continued)**

**Stock purchase warrants**

During the year ended December 31, 2004, approximately 400,000 stock purchase warrants with an exercise price of \$1.50 per share were exercised to acquire an aggregate of 400,000 shares of Common Stock. The Company received net cash proceeds of approximately \$600,000 from such exercises during the year ended December 31, 2004. Approximately 20,000 stock purchase warrants with an exercise price of \$20.00 per share expired unexercised during the year ended December 31, 2004. There were no stock purchase warrants issued subsequent to 2004 and there have not been any warrants outstanding since 2004.

**Stockholder Rights Plan**

Effective December 21, 2004, the Board of Directors of the Company adopted a new Stockholder Rights Plan that replaced the Company's previous Stockholder Rights Agreement that expired on December 21, 2004. Pursuant to the Renewed Rights Agreement, the Board of Directors declared a dividend of one Preferred Stock Purchase Right for each outstanding share of the Company's Common Stock, payable to stockholders of record at the close of business on December 21, 2004. Each right, when exercisable, entitles the registered holder to purchase from the Company one one-thousandth of a share of Series A Junior Participating Preferred Stock, par value \$1.00 per share, at a purchase price of \$72.55 per one one-thousandth of a share of Series A Preferred Stock, subject to adjustment. 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. 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.

In the event that an acquiring person becomes the beneficial owner of 15% or more of the then outstanding shares of Common Stock (except pursuant to a qualifying offer), each holder of a right will thereafter have the right to receive, upon payment of the purchase price, shares of Common Stock (or, in certain circumstances, cash, property or other securities of the Company) having a value (based on a formula set forth in the Renewed Rights Agreement) equal to two times the purchase price of the right. The rights are not exercisable until the distribution date and will expire at the close of business on December 19, 2014, unless earlier redeemed or exchanged by the Company.

F-26

---



**Table of Contents**

**Bentley Pharmaceuticals, Inc. and Subsidiaries**  
**Notes to Consolidated Financial Statements (Continued)**

**NOTE 12 - PROVISION FOR INCOME TAXES**

See Note 14 for information regarding the components of *income before income taxes*. The *provision for income taxes* consists of the following:

	<b>Year Ended December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
	<b>(In Thousands)</b>		
Current:			
Foreign	\$ 6,254	\$ 6,515	\$ 5,466
Deferred:			
State	(96)	120	(60)
Federal	2,134	134	(251)
Foreign	(1,171)	(1,039)	(661)
Tax effect of operating loss carryforwards:			
State	(56)	(56)	2,169
Federal			(1,041)
Foreign	(1,303)	(260)	
Change in valuation allowance	(680)	62	(817)
Total provision for income taxes	\$ 5,082	\$ 5,476	\$ 4,805

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

	<b>Year Ended December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
	<b>(In Thousands)</b>		
Statutory federal income taxes	\$ 4,555	\$ 6,198	\$ 3,695
Permanent differences from foreign subsidiary	346	311	492
Foreign tax audit settlement			604
State income taxes	(152)	63	(90)
Expiration/Reduction of loss carryforwards	2,119		2,199
Impact of foreign tax rate changes	(33)		
Tax credits	(1,044)	(1,124)	(971)
Other	(29)	(34)	(307)
Change in valuation allowance	(680)	62	(817)
	\$ 5,082	\$ 5,476	\$ 4,805

In November 2006, the Spanish government enacted legislation which reduces the Spanish statutory income tax rate from 35% in 2006 to 32.5% in 2007 and 30% in 2008. The Company has recorded a \$33,000 reduction in its deferred taxes and a corresponding reduction in its *provision for income taxes* in the year ended December 31, 2006 as a result of the change in tax rates.

**Table of Contents**

**Bentley Pharmaceuticals, Inc. and Subsidiaries**  
**Notes to Consolidated Financial Statements (Continued)**

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

	<b>December 31,</b>	
	<b>2006</b>	<b>2005</b>
	<b>(In Thousands)</b>	
Deferred tax assets:		
NOL carryforwards	\$ 20,010	\$ 18,665
Disposition of subsidiary	6,909	6,848
Foreign tax on deferred income	1,767	1,099
Tax credit carryforwards	1,303	744
Other, net	1,166	956
Total deferred tax assets	31,155	28,312
Foreign deferred tax liability	(2,074)	(1,665)
Other deferred tax liabilities	(217)	(215)
Valuation allowance	(27,575)	(26,998)
Deferred tax asset (liability), net	\$ 1,289	\$ (566)

The Company recorded provisions for foreign income taxes totaling \$5,082,000, \$5,476,000, and \$4,805,000 (\$4,201,000 plus a \$604,000 tax audit settlement recorded as a result of the 1998-2000 tax audit of its Spanish subsidiary), for the years ended December 31, 2006, 2005, and 2004 respectively. The 2006 effective tax rate was 84% compared to 33% in 2005 and 46% (40% excluding the \$604,000 tax audit settlement) in 2004. The 2006 effective tax rate on Spanish operations was 31% compared to 31% in 2005, and 36% (31% excluding the \$604,000 tax audit settlement) in 2004.

The Company generated U.S. federal net operating income of approximately \$235,000 in 2006 and \$1,042,000 in 2005, compared to a net operating loss of approximately \$2,913,000 in 2004. Bentley Pharmaceuticals Ireland Limited generated a net operating loss of approximately \$10,418,000 and \$2,080,000 in 2006 and 2005, respectively. As future operating profits cannot be reasonably assured, no tax benefit has been recorded for these losses. Accordingly, the Company has established a valuation allowance equal to the full amount of the deferred tax assets in Ireland. The Company's 2006 net current and non-current deferred tax assets of \$1,049,000 and \$240,000, respectively, result from temporary differences arising at the Company's Spanish subsidiaries. Net operating losses and taxes on deferred licensing and collaboration revenues represent the majority of the assets, which are partially offset by the deferral of a gain for Spanish statutory purposes on the sale of drug licenses in prior periods.

Should the Company determine that it is more likely than not that it will realize certain of its net deferred tax assets for which we have previously provided a valuation allowance, an adjustment would be required to reduce the existing valuation allowance. In addition, the Company operates within multiple taxing jurisdictions and is subject to audit in those jurisdictions. These audits can involve complex issues, which may require an extended period of time for resolution. The Company has tax contingencies totaling \$530,000 at December 31, 2006, all of which have been recorded in the *provision for income taxes* in prior years. No other potential tax contingencies were determined to be probable and reasonably estimable as of December 31, 2006. However, there is the possibility that the ultimate resolution of such potential contingencies could have an adverse effect on our Consolidated Financial Statements in the future.

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.



**Table of Contents**

**Bentley Pharmaceuticals, Inc. and Subsidiaries**  
**Notes to Consolidated Financial Statements (Continued)**

In October 2005, intercompany agreements were executed between Bentley Pharmaceuticals, Inc. and Bentley Pharmaceuticals Ireland Limited to license non-U.S. rights of certain technologies owned by Bentley Pharmaceuticals, Inc. and provide for cost-sharing of subsequent development efforts on those technologies. A net benefit of approximately \$10,376,000 has been recorded to the U.S. income from operations in 2006, which contributed to U.S. income before income taxes of \$235,000 in the current year. The Company utilized U.S. federal net operating loss carry-forwards in order to offset the resulting U.S. income tax liability. The NOL carryforwards include the benefit of 2006 compensation expense from nonqualified stock option dispositions and disqualifying dispositions of incentive stock options of approximately \$3,697,000, the tax effect of which \$(1,257,000) will be credited to additional paid-in capital if and when realized. The Company calculates that use of its NOL carryforwards may be limited each year as a result of stock option exercises resulting in an ownership change of more than 50% of the Company's outstanding equity. During 2006, approximately \$6,232,000 of U.S. federal net operating loss carryforwards expired unutilized. As of December 31, 2006, the remaining U.S. federal net operating loss carry-forwards were approximately \$50,216,000. If not offset against future taxable income, the NOL carryforwards will expire in tax years 2007 through 2025. During 2004, the Company determined that a portion of its State NOL carryforwards, generated during prior periods, were no longer available in the state jurisdictions in which the Company conducts business. The Company therefore reduced the deferred tax benefit related to its State NOL carryforwards by \$2,199,000.

The valuation allowance increased (decreased) by approximately \$577,000, \$2,920,000, and \$(817,000) in 2006, 2005 and 2004, respectively. The 2006 increase consists of approximately \$1,257,000 related to the loss carryforward attributable to the deduction for stock options. The loss carryforward attributable to the deductions for stock options in 2005 and 2004 was \$2,858,000 and \$375,000, respectively. The effect of the stock option deduction in 2004 was more than offset by other book to tax differences, resulting in valuation allowance changes that are only attributable to operating activities.

**NOTE 13 - SELECTED QUARTERLY FINANCIAL INFORMATION (Unaudited)**

The following tables contain condensed information from the Company's Consolidated Income Statements for each quarter of the years ended December 31, 2006, 2005 and 2004. The Company has derived this data from its unaudited quarterly financial statements. The Company believes that the following information reflects all normal recurring adjustments necessary for a fair presentation of the information for the periods presented. The operating results for any quarter are not necessarily indicative of results for any future period.

F-29

---

**Table of Contents**

**Bentley Pharmaceuticals, Inc. and Subsidiaries**  
**Notes to Consolidated Financial Statements (Continued)**

	<b>For the Three Months Ended</b>			
	<b>3/31/06(b)</b>	<b>6/30/06(a)(b)</b>	<b>9/30/06(b)</b>	<b>12/31/06(b)</b>
	<b>(In Thousands, Except Per Share Data)</b>			
Total revenues	\$ 28,278	\$ 28,983	\$ 25,156	\$ 27,054
Cost of net product sales	12,933	12,471	11,778	12,668
Gross profit	15,345	16,512	13,378	14,386
Operating expenses	11,991	11,580	19,085	11,566
Gain on sale of license				38
Income from operations	3,354	4,932	(5,707)	2,858
Other income (expenses)	193	187	208	31
Provision for income taxes	2,393	2,484	1,730	(1,525)
Net income	\$ 1,154	\$ 2,635	\$ (7,229)	\$ 4,414
Net income per common share:				
Basic	\$ 0.05	\$ 0.12	\$ (0.33)	\$ 0.20
Diluted	\$ 0.05	\$ 0.12	\$ (0.33)	\$ 0.19
Weighted average common shares outstanding:				
Basic	21,954	22,170	22,194	22,242
Diluted	23,807	22,876	22,194	22,735
	<b>For the Three Months Ended</b>			
	<b>3/31/05</b>	<b>6/30/05</b>	<b>9/30/05</b>	<b>12/31/05(c)</b>
	<b>(In Thousands, Except Per Share Data)</b>			
Total revenues	\$ 24,244	\$ 24,764	\$ 23,512	\$ 25,210
Cost of net product sales	11,452	11,367	11,104	12,238
Gross profit	12,792	13,397	12,408	12,972
Operating expenses	9,145	9,408	8,730	8,620
Income from operations	3,647	3,989	3,678	4,352
Other income (expenses)	113	173	184	259
Provision for income taxes	1,590	1,554	1,377	955
Net income	\$ 2,170	\$ 2,608	\$ 2,485	\$ 3,656
Net income per common share:				
Basic	\$ 0.10	\$ 0.12	\$ 0.11	\$ 0.17

Edgar Filing: BENTLEY PHARMACEUTICALS INC - Form 10-K

Diluted	\$ 0.10	\$ 0.12	\$ 0.11	\$ 0.16
Weighted average common shares outstanding:				
Basic	21,316	21,395	21,652	21,862
Diluted	22,531	22,603	22,970	23,564

F-30

---

**Table of Contents**

**Bentley Pharmaceuticals, Inc. and Subsidiaries**  
**Notes to Consolidated Financial Statements (Continued)**

	<b>For the Three Months Ended</b>			
	<b>3/31/04</b>	<b>6/30/04(d)</b>	<b>9/30/04</b>	<b>12/31/04</b>
	<b>(In Thousands, Except Per Share Data)</b>			
Total revenues	\$ 17,302	\$ 18,470	\$ 18,103	\$ 19,518
Cost of net product sales	8,255	8,465	8,662	9,511
Gross profit	9,047	10,005	9,441	10,007
Operating expenses	7,374	7,422	6,922	8,087
Income from operations	1,673	2,583	2,519	1,920
Other income (expenses)	57	1,348	238	157
Provision for income taxes	921	2,441	1,344	99
Net income	\$ 809	\$ 1,490	\$ 1,413	\$ 1,978
Net income per common share:				
Basic	\$ 0.04	\$ 0.07	\$ 0.07	\$ 0.09
Diluted	\$ 0.04	\$ 0.07	\$ 0.06	\$ 0.09
Weighted average common shares outstanding:				
Basic	20,597	20,644	21,049	21,308
Diluted	22,784	22,800	22,746	22,487

(a) *Total revenues* for the quarter ended June 30, 2006 includes an increase in royalty revenues of approximately \$479,000. This change in estimate was due to the Company's ability to reasonably estimate future product returns on sales of Testim based on actual historical

data.

- (b) *Operating expenses* for the quarter ended September 30, 2006 includes litigation settlement charges of approximately \$7,546,000. *Provision for income taxes* for the quarter ended December 31, 2006 includes a tax benefit of \$2,746,000 from the finalization of the related legal settlement. *Operating expenses* also include related legal defense costs of \$604,000, \$733,000, \$1,386,000 and \$645,000 in first, second, third and fourth quarters of 2006, respectively.
- (c) *Total revenues* for the quarter ended December 31, 2005 includes a change in estimate of royalty revenues earned of approximately \$1,092,000 recorded in the fourth quarter of



2005. This change in estimate of royalty revenues earned is based upon publicly available data determined to be more accurate than the source of data previously relied upon by management in estimating the sell-through of prescriptions dispensed.

- (d) *Other income (expenses)* for the quarter ended June 30, 2004 includes the reversal of previously accrued tax assessments totaling \$1,467,000. These assessments had been accrued to be paid to the Spanish government as a vehicle to help reduce the impact of the rising health care costs in Spain. Due to changes in the pharmaceutical industry in Spain and a change in the Spanish political environment, these liabilities no longer exist.

Accordingly,  
these accruals  
were reversed  
during the  
second quarter  
of 2004.

In the fourth quarter of the year ended December 31, 2006, the Company reclassified certain of its deferred tax items on its balance sheet to be consistent with the underlying transactions to which they relate. The reclassifications resulted in a \$1,244,000 decrease of its current deferred tax assets, an increase of \$240,000 to its non-current deferred tax assets, a \$238,000 increase in income taxes payable (included in *accrued expenses* on the Consolidated Balance Sheet) and a decrease of \$1,260,000 in its non-current deferred tax liabilities.

F-31

---

**Table of Contents****Bentley Pharmaceuticals, Inc. and Subsidiaries****Notes to Consolidated Financial Statements (Continued)****NOTE 14 - BUSINESS SEGMENT INFORMATION**

The Company, headquartered in the U.S., is an international specialty pharmaceutical company which operates in two business segments, specialty generics and drug delivery, and two geographical locations (Europe and the U.S.).

The Company's specialty generics segment is based in Europe and develops and manufactures a growing portfolio of generic and branded generic pharmaceuticals in Europe for the treatment of cardiovascular, gastrointestinal, infectious and central nervous system diseases through its subsidiary, Laboratorios Belmac, and markets these pharmaceutical products through its subsidiaries, Laboratorios Belmac, Laboratorios Davur, Laboratorios Rimafar and Bentley Pharmaceuticals Ireland. The U.S. operations of this segment include any sales of generic pharmaceuticals in the U.S. and continued research and development activities to bring additional generic pharmaceutical products into the U.S. This segment also manufactures and sells active pharmaceutical ingredients through its subsidiary, Bentley A.P.I.

The Company's drug delivery segment is based in both the U.S. and Europe and is focused on the advancement of proprietary drug delivery technologies that enhance or facilitate the absorption of pharmaceutical compounds across various membranes. In the U.S., the Company's activities consist primarily of licensing, product research and development, business development activities, corporate management and administration.

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, 2006 and 2005. The segments use the same accounting policies as those described in the summary of significant accounting policies in Note 2.

For the twelve months ended December 31, 2006 (in thousands):

	Specialty Generics		Drug Delivery		Consolidated
	Europe	U.S.	Europe	U.S.	
Net product sales	\$ 100,546	\$ 44	\$	\$	\$ 100,590
Licensing and collaboration revenues	515			8,366	8,881
Total revenues	101,061	44		8,366	109,471
Cost of net product sales	49,766	84			49,850
Gross profit	51,295	(40)		8,366	59,621
Selling and marketing expense	16,153				16,153
General and administrative expense	7,391		71	7,339	14,801
Research and development expense	1,777		4,341	4,341	10,459
Depreciation and amortization expense	1,129	87		679	1,895
Litigation settlement	8,543	2,371			10,914
Gain on sale of license	38				38
Income from operations	16,340	(2,498)	(4,412)	(3,993)	5,437
Interest income	139			681	820
Interest expense	(158)				(158)
Other income (expense), net	(61)	16		2	(43)
Income before income taxes	16,260	(2,482)	(4,412)	(3,310)	6,056
Provision for income taxes	5,082				5,082
Net income (loss)	11,178	(2,482)	(4,412)	(3,310)	974
Expenditures for fixed assets	14,487			826	15,313
Expenditures for drug licenses	1,856			916	2,772

F-32



**Table of Contents**

**Bentley Pharmaceuticals, Inc. and Subsidiaries**  
**Notes to Consolidated Financial Statements (Continued)**

As of December 31, 2006 (in thousands):

	<b>Specialty Generics</b>		<b>Drug Delivery</b>		<b>Consolidated</b>
	<b>Europe</b>	<b>U.S.</b>	<b>Europe</b>	<b>U.S.</b>	
Receivables, net	\$ 30,558	\$ 39	\$	\$ 2,366	\$ 32,963
Other current assets	21,758	1,338		11,631	34,727
Fixed assets	45,738			2,818	48,556
Drug licenses and related costs	10,697	1,833		3,496	16,026
Other non-current assets	885			1,199	2,084
Total assets	109,636	3,210		21,510	134,356
Current liabilities	24,651			2,736	27,387
Non-current liabilities	6,638				6,638
Total liabilities	31,289			2,736	34,025

For the twelve months ended December 31, 2005 (in thousands):

	<b>Specialty Generics</b>		<b>Drug Delivery</b>		<b>Consolidated</b>
	<b>Europe</b>	<b>U.S.</b>	<b>Europe</b>	<b>U.S.</b>	
Net product sales	\$91,308	\$	\$	\$	\$91,308
Licensing and collaboration revenues	273			6,149	6,422
Total revenues	91,581			6,149	97,730
Cost of net product sales	46,161				46,161
Gross profit	45,420			6,149	51,569
Selling and marketing expense	16,347				16,347
General and administrative expense	8,930		17	2,458	11,405
Research and development expense	1,378		2,044	2,378	5,800
Depreciation and amortization expense	1,068	81		609	1,758
Litigation settlement	268	325			593
Income from operations	17,429	(406)	(2,061)	704	15,666
Interest income	182			746	928
Interest expense	(211)				(211)
Other income (expense), net	14			(2)	12
Income before income taxes	17,414	(406)	(2,061)	1,448	16,395
Provision for income taxes	5,476				5,476
Net income (loss)	11,938	(406)	(2,061)	1,448	10,919
Expenditures for fixed assets	10,821			197	11,018
Expenditures for drug licenses	945			1,100	2,045

F-33

**Table of Contents**

**Bentley Pharmaceuticals, Inc. and Subsidiaries**  
**Notes to Consolidated Financial Statements (Continued)**

As of December 31, 2005 (in thousands):

	<b>Specialty Generics</b>		<b>Drug Delivery</b>		<b>Consolidated</b>
	<b>Europe</b>	<b>U.S.</b>	<b>Europe</b>	<b>U.S.</b>	
Receivables, net	\$23,469	\$	\$	\$ 3,447	\$ 26,916
Other current assets	26,443			21,718	48,161
Fixed assets	31,189			2,177	33,366
Drug licenses and related costs	8,931	1,581		3,346	13,858
Other non-current assets	615			1,304	1,919
Total assets	90,647	1,581		31,992	124,220
Current liabilities	25,639	97		2,944	28,680
Non-current liabilities	3,944			7	3,951
Total liabilities	29,583	97		2,951	32,631

Interest income and interest expense are based upon the actual results of each operating segment's assets and borrowings.

The majority of the Company's revenues are generated from products sold in Spain. Revenues from products sold in Spain totaled \$76,713,000, \$69,571,000, and \$58,488,000 in the years ended December 31, 2006, 2005 and 2004, respectively. Revenues from licensing and collaboration revenues in Spain totaled \$515,000, \$274,000 and \$607,000 in the years ended December 31, 2006, 2005 and 2004, respectively.

**NOTE 15 - COMMITMENTS, CONTINGENCIES AND CONCENTRATIONS**

The Company is obligated to pay certain royalty payments upon commercialization of products using its CPE-215 technology acquired in 1999 and its intellectual property acquired in 2003.

The Company has entered into renewable employment agreements with key executives and certain other personnel. These employment agreements provide for salaries, potential bonuses and other benefits in exchange for services provided. The employment agreements also provide for certain compensation in the event of termination or change in control of the Company. The Company is currently obligated to pay approximately \$2,247,000 in 2007 under such agreements, which are scheduled to expire on December 31, 2007. In addition, the Company is obligated to grant an aggregate of 100,000 stock options to executive officers in 2007.

During the year ended December 31, 2005, management of the Company identified certain tax contingencies that were determined to be probable and reasonably estimable. Consequently, the Company has included a charge totaling \$180,000 related to these contingencies in the *provision for income taxes* in the accompanying Consolidated Income Statements. No other potential tax contingencies were considered probable and reasonably estimable by the Company at December 31, 2005. However, there is the possibility that the ultimate resolution of such potential contingencies could have an adverse effect on the Company's Consolidated Financial Statements.

Revenues from one customer exceeded 10% of consolidated total revenues during the year ended December 31, 2006, accounting for 11% of 2006 consolidated total revenues and 4% of the consolidated receivables balance at December 31, 2006. Revenues from one customer exceeded 10% of consolidated total revenues during the year ended December 31, 2005, accounting for 12% of 2004 consolidated total revenues and 4% of the consolidated receivables balance at December 31, 2005. Revenues from one

**Table of Contents**

**Bentley Pharmaceuticals, Inc. and Subsidiaries**  
**Notes to Consolidated Financial Statements (Continued)**

customer exceeded 10% of consolidated total revenues during the year ended December 31, 2004, accounting for 13% of 2003 consolidated total revenues and 4% of the consolidated receivables balance at December 31, 2004.

Spanish sales from the Company's omeprazole product line accounted for approximately 18% in the years ended December 31, 2006 and 2005, respectively, and 22% of the consolidated total revenues in the year ended December 31, 2004. The active pharmaceutical ingredient for the Company's omeprazole products is currently purchased from one supplier.

The Company leases certain equipment and facilities under non-cancelable operating leases, which expire through the year 2008. Total charges to operations under operating leases were approximately \$1,236,000, \$1,059,000 and \$991,000 for the years ended December 31, 2005, 2004 and 2003, respectively. Future minimum lease payments under operating leases are as follows (in thousands):

Year Ending December 31,	Future Minimum Lease Payments
2007	1,177
2008	747
2009	94
2010	27
2011	7
2012 and beyond	0

The Company has committed approximately \$6,600,000 for capital expenditures as of December 31, 2006 for continued improvements to its manufacturing facilities, including the acquisition of additional manufacturing equipment and the expansion of its active pharmaceutical ingredients manufacturing facility.

On September 27, 2004, the Company was served with a complaint in an action captioned Ethypharm S.A. France & Ethypharm S.A. Spain v. Bentley Pharmaceuticals, Inc., U.S. District Court for the District of Delaware, Civil Action No. 04-1300 (SLR). In this action, Ethypharm S.A. France and Ethypharm S.A. Spain, which are referred to individually and collectively as Ethypharm, alleged that since March 2002 Bentley and its Spanish subsidiary Laboratorios Belmac, S.A. ( Belmac ) misappropriated unspecified Ethypharm trade secrets and confidential information and used that information in the manufacture of omeprazole, one of Belmac's pharmaceutical products. On April 11, 2005, Ethypharm S.A. Spain filed suit against Belmac S.A. in the Commercial Court No. 5 of Madrid, Spain. The complaint alleged that Belmac refused to renew its contract with Ethypharm for the manufacture of omeprazole which expired on March 22, 2002, and that after that date Belmac's continued manufacture of omeprazole pursuant to its own patented technology infringed Ethypharm's Spanish Patent No. ES9301319. In its complaint, Ethypharm sought an order from the court declaring Belmac to be in violation of Ethypharm's patent, preventing further sales of omeprazole by Belmac using processes that allegedly infringe Ethypharm's patent, and awarding monetary damages. In late 2006 Bentley and Belmac settled all outstanding litigation with Ethypharm. Under the settlement terms, Belmac paid Ethypharm \$4,000,000 in the fourth quarter of 2006 and will make four additional payments of \$1,000,000 each on the first four anniversaries of the first payment.

On December 2004, Belmac, jointly with three other Spanish manufacturers, initiated a legal proceeding in the 2<sup>nd</sup> Commercial Court of the City of Barcelona against Warner-Lambert Company requesting the partial revocation in Spain of European patent EP 409.281 concerning atorvastatin calcium. In turn, Warner-Lambert Company counterclaimed against the plaintiffs for alleged infringement of the patent in suit. The court ruled in favour of Belmac in a decision rendered on September 26, 2006,

**Table of Contents**

**Bentley Pharmaceuticals, Inc. and Subsidiaries  
Notes to Consolidated Financial Statements (Continued)**

and Warner-Lambert Company has appealed the judgment. A decision on the appeal is expected by the second half of 2007.

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

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

F-36