

BENTLEY PHARMACEUTICALS INC

Form 10-K

March 17, 2008

**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, 2007**

**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  
**Common Stock, \$0.02 par value**  
**Preferred Stock Purchase Rights**

Name of each exchange on which registered  
**New York Stock Exchange**  
**New York Stock Exchange**

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.  
YES  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, a non-accelerated filer, or a smaller reporting company. See definitions of "accelerated filer," "large accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company

Edgar Filing: BENTLEY PHARMACEUTICALS INC - Form 10-K

(Do not check if a smaller reporting company)

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>\$183,234,580</b>	<b>June 30, 2007</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>22,449,814</b>	<b>March 15, 2008</b>

DOCUMENTS INCORPORATED BY REFERENCE

**Proxy Statement for the 2008 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, 2007. 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,  
2006.

---

**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 Accountant Fees and Services

Part IV

Item 15. Exhibits, Financial Statement Schedules

EXHIBIT INDEX

SIGNATURES

EX-10.17 Letter Agreement, dated December 13, 2007 (Adolfo Herrera Malaga)

EX-10.21 Letter Agreement dated March 17, 2008 (Richard P. Lindsay)

EX-21.1 Subsidiaries

EX-23.1 Consent of Independent Registered Public Accounting Firm

EX-31.1 Section 302 Certification of CEO

EX-31.2 Section 302 Certification of CFO

EX-32.1 Section 906 Certification of CEO

EX-32.2 Section 906 Certification of CFO

---

**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 (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 200 product presentations (also known as stock keeping units, or SKUs) through three wholly-owned Spanish subsidiaries: Laboratorios Belmac, Laboratorios Davur and Laboratorios Rimafar. Our products are in four primary therapeutic areas: cardiovascular, gastrointestinal, central nervous system and infectious diseases. Although the majority of our 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 received approval from the U.S. Food and Drug Administration ( FDA ) in late 2006 for the manufacture of our first U.S. generic product. We own a manufacturing facility in Spain that specializes in the manufacturing of several API products. 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 launched its first product in late 2006.

We are also in the business of development, licensing and commercialization of pharmaceutical products utilizing our validated drug delivery technology. We have U.S. and international patents and other proprietary rights to technologies that facilitate the absorption of drugs. We develop and co-develop products that incorporate our drug delivery technologies. Our platform drug delivery technology utilizes CPE-215 to enhance permeation and absorption of pharmaceutical molecules across biological membranes such as the skin, nasal mucosa and eye. We have licensed applications of our proprietary CPE-215 drug delivery technology to Auxilium Pharmaceuticals, Inc. ( Auxilium ), which launched Testim, the first product incorporating our CPE-215 drug delivery technology, in the United States in February 2003.

Our development activities are primarily focused on the development of Nasulin, our intranasal insulin product candidate, which is based on our CPE-215 technology. In 2004 we concluded a Phase IIA study for Nasulin in Type 1 diabetic patients using our CPE-215 technology. In 2006, we completed an additional Phase I study in Ireland and advanced our Phase IIA studies in the U.S. in Type 1 diabetic patients. In the first quarter of 2007 we completed preparations for a Phase II study in India in Type 2 diabetic patients, which began in the second quarter of 2007. We expect the U.S. development and clinical programs for Nasulin to continue and expand both outside and inside the U.S.

## **Table of Contents**

We believe, based upon our experience with Testim and Nasulin, that our CPE-215 formulation technology constitutes a broad platform that has the ability to significantly enhance the permeation of a wide range of therapeutic molecules. To expand the development and commercialization of products using our CPE-215 drug delivery technology, we are pursuing strategic alliances with partners including large pharmaceutical, specialty pharmaceutical and biotechnology companies.

Bentley Pharmaceuticals, Inc., is incorporated in the State of Delaware. References in this report to the Company, we, us, our or Bentley refer to our parent company and its subsidiaries as a group, without regard to the separate operations and obligations of each entity in the group, unless the context clearly indicates otherwise. Our Common Stock trades on the New York Stock Exchange (*NYSE*) under the trade symbol *BNT*.

### **Proposed Spin-Off Transaction**

On October 23, 2007 we announced a plan to spin-off our drug delivery business. This transaction is subject to a number of conditions. Management expects that shares of the new specialty pharmaceutical drug delivery company, CPEX Pharmaceuticals, Inc. (which may be referred to as CPEX), will be distributed to Bentley stockholders by means of a stock dividend. On the record date, which has not yet been set, each Bentley stockholder will be entitled to receive shares of CPEX in connection with the spin-off of the drug delivery business. The spin-off would result in CPEX operating as an independent entity with publicly traded common stock. Bentley would not have any ownership interest in CPEX subsequent to the spin-off.

In connection with the spin-off, CPEX and Bentley expect to enter into a series of agreements, including a separation and distribution agreement, a transition services agreement, an employee matters agreement and a tax allocation agreement. Consummation of the spin-off is subject to several conditions, including final approval by the Bentley Board of Directors, approval for listing of CPEX common stock on a national securities exchange, and the effectiveness of the Form 10 filed with the Securities and Exchange Commission for the registration of the securities of CPEX. Approval by Bentley's stockholders is not required as a condition to the consummation of the proposed spin-off.

### **Industry Overview**

#### *Pharmaceutical Industry in Europe*

The European Union, with an increasingly affluent population of approximately half a billion people and approximately \$161 billion in pharmaceutical sales in 2005, 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 price 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

**Table of Contents**

manufacturers whose costs 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 2007, 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 \$13.7 billion in 2007, according to IMS Health.

Over the past 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 6.6% of sales in the Spanish pharmaceutical market (approximately 13.2% of the units of pharmaceutical products sold in Spain), generic pharmaceuticals are expected to significantly increase their market penetration due to increases in drug usage driven by an aging population and opportunities to launch new generic products as patents expire for blockbuster drugs. In response to the rise in healthcare costs, several initiatives are underway by the Spanish government to stimulate the use of generic pharmaceuticals, including education, financial incentives to prescribing physicians and public campaigns. Due to the structure of the Spanish market for pharmaceutical products, producers generally market their products to physicians and pharmacies to whom they emphasize a combination of quality and price.

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

*Drug Delivery Industry*

The drug delivery technology industry is experiencing increasing demand from biotechnology, genomics and pharmaceuticals companies. Advanced therapies created by recent advances in biotechnology and genomics are requiring complex delivery technologies. Pharmaceutical companies are looking for solutions to offset anticipated revenue losses as their products lose patent protection and experience competition from generic pharmaceutical introductions. Drug delivery technologies provide a potential path to extend the life cycle of these products that are losing their patent protection.

Drug delivery technology companies typically form a partnership or licensing relationship with the company owning the intellectual property rights to a compound. However there has been a recent



**Table of Contents**

trend where a number of drug delivery companies have started to develop their own formulations to use in combination with their proprietary drug delivery platforms.

Targeted routes of administration are trending towards non-invasive technologies rather than injections initially used for many biotherapeutics. These non-invasive delivery systems are often easier to administer, have less severe side effects, and potentially could allow for reduced dosing frequency. These benefits to the patient could improve patient compliance and provide sufficient value to the patient to support stronger pricing to the manufacturer. While the oral delivery route is expected to be the most popular, inhalable, buccal, lingual and nasal routes are considered essential for effective delivery of biological therapies.

**Our Strategy**

Our objective is to be a leading international specialty pharmaceutical company 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.

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.

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

**Table of Contents**

Czech Republic for targeted products in these and other countries. In certain European countries that have a highly developed competitive market for generics based primarily on price, we intend to sell either directly or through our alliances to distributors. In countries that require a sales force to market to physicians or consumers, we intend to continue to concentrate our efforts through alliances with entities that have sales and marketing forces already in place. We have made and will continue to make, as necessary, modifications to our finished pharmaceutical products manufacturing facility so that it will comply with Good Manufacturing Practices, 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*

Our strategy is focused on developing a portfolio of products utilizing our proprietary CPE-215 drug delivery technology. Our development program will identify potential molecules that address a commercially viable market, an unmet clinical need, and are compatible with our proprietary drug delivery technology. Initially we expect to form partnerships through collaboration with pharmaceutical and biotechnology companies to develop and finance product candidates. These partnerships, in addition to funding, provide access to product candidates and a sharing of the risks associated with development. We plan to expand our pipeline with our own product candidates by applying our drug delivery technologies to products that have come off patent or others that we may in-license.

Our immediate focus is on completing Phase II clinical trials for Nasulin and establishing a partnership with a large pharmaceutical company for Phase III clinical trials and commercialization.

**Key Drivers of Our Drug Delivery Businesses**

The key drivers of our drug delivery business include:

Continuing growth of Testim royalty revenues,

Establishing a partnership to further develop and commercialize Nasulin,

Identifying and developing new product candidates for our internal pipeline, and

Developing strong alliances providing us scale advantages in clinical research, product manufacturing and marketing.

*Continued growth of Testim royalty revenues*

Royalty income from Testim is our only source of current revenue in our drug delivery business. Continuation of this income stream is needed, and expected, to fund further development and defray other administrative and operating costs.

*Development and commercialization of Nasulin*

Nasulin is currently in Phase II clinical trials in the United States and India for the treatment of Type 1 and Type 2 diabetes. We believe an intranasal route of administration will yield significant improvements in patient compliance and avoid the potential pulmonary disadvantages of competitive candidates that use an inhalation route of administration. Our expectation is to substantially complete Phase II trials in Type 2 diabetics in 2009 while simultaneously seeking a pharmaceutical partner to support Phase III clinical trials and product commercialization upon regulatory approval.

**Table of Contents**

*Identifying new product candidates that leverage our CPE-215 technology and formulation expertise*

We intend to apply our CPE-215 drug delivery technologies in an effort to improve the performance of existing pharmaceutical products and advanced research candidates with respect to their method of delivery and effectiveness. Candidates will be prioritized for selection based on compatibility with CPE-215, clinical need, market size, and potential for the associated intellectual property to be protected through patents. We are targeting 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.

Once we bring our products to an advanced stage of development, we intend to develop collaboration relationships that leverage the clinical development, marketing and sales capabilities of strategic partners. We hope to collaborate with partners to commercialize our internal product candidates by utilizing their late stage clinical development, regulatory, marketing and sales capabilities. 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. As we succeed with this strategy, we expect to identify product candidates that we can bring to late stage development for ourselves.

*Developing strong alliances providing us scale advantages in clinical research, product manufacturing and marketing*

In addition to pursuing our own proprietary compounds, we will continue to establish strategic collaborations with pharmaceutical and biotechnology companies marketing our CPE-215 technology for application with their branded or generic products. We will assist our collaboration partners in developing more effective drug delivery methods for their product candidates that have already completed early stage clinical trials, or are even currently marketed. We believe pharmaceutical and biotechnology companies will be motivated to co-develop products utilizing CPE-215 technology to achieve these benefits through:

- 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;

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

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

- reducing the high capital investment needed to introduce and manufacture injectable drugs.

We generally structure our collaborative arrangements to receive research and development funding and milestone payments during the development phase and upon commercialization, and patent-based royalties on future sales of products.

**Table of Contents**

**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.

*CPE-215, Proprietary Permeation Enhancement Platform Technology*

Permeation enhancement with CPE-215 is our patented drug delivery technology. CPE-215 enhances the absorption of drugs across a variety of biological membranes including the skin, mouth, nose and eye. The technology can be adapted to products formulated as creams, ointments, gels, solutions, lotions, sprays or patches. CPE-215 also has maintained a record of safety as a direct and indirect food additive and fragrance, and is listed on the FDA's inactive ingredient list for approved use in drug applications.

We believe that key benefits of the patented drug permeation technology using CPE-215 may include the following therapeutic and commercial opportunities and advantages:

Improve compliance and convenience to patients requiring ongoing injection therapies and provide earlier entry into prophylactic treatment for patients reluctant to injections;

Application to other injectable peptides that can be administered intranasally;

Application to therapeutic molecules that are degraded by passage through the liver or would benefit from intra-nasal administration to eliminate first-pass metabolism;

Application to a variety of metabolic, neurological, and other serious medical conditions;

Opportunities for life-cycle extension strategies for existing marketed products; and

Opportunities for allowing product differentiation based on benefits of administration.

*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

**Table of Contents**

temperature. We have been granted a Spanish patent relating to these processes. The patent claims as innovative the manufacturing process that renders these products more stable, while protecting active substances from gastric degradation utilizing microgranulation and microencapsulation techniques. These patented technologies can contribute to our ability to compete against other companies whose manufacturing processes are more costly and time consuming.

*Nanocaplet Technology*

In May 2005 we announced the discovery and synthesis of a thermodynamically stable, biodegradable Nanocaplet technology for the delivery of macromolecule therapeutics. This proprietary technology was discovered as part of our four-year sponsored research program with the University of New Hampshire Nanostructured Polymers Research Center. We discontinued our early research stage nanocaplet project in December 2007 to focus on advancing Nasulin through clinical trials while working on a pipeline of other projects that could be advanced into Product Development.

**Licensed Product**

***Testim, Licensed Topical Testosterone Gel***

We earn royalty revenues on sales of Testim, a testosterone gel that incorporates the CPE-215 drug delivery technology. The product is licensed to Auxilium and was successfully launched in the U.S. in early 2003 as a testosterone replacement therapy. Testim has been approved for marketing in Canada and 15 countries in Europe. Royalties received from Testim sales were \$11.1 million, \$8.3 million and \$6.1 million for the years ended December 31, 2007, 2006 and 2005, respectively. 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 with Ipsen to market the drug in Europe.

The testosterone replacement market has increased as more baby-boomers enter middle age and more attention is focused on male hormonal deficiency and the benefits of replacement therapy. A recent study published in the July 2006 International Journal of Clinical Practice indicates that 39% of U.S. males over 45 years have hypogonadism, a condition in men where insufficient amounts of testosterone are produced. 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. The condition is significantly under-treated. Growing patient awareness and education continue to spur demand for testosterone replacement therapy.

Currently marketed testosterone replacement therapies deliver hormones through injections, transdermal patches or gels. The transdermal delivery from gels provide commercially attractive and efficacious alternatives to other current methods of delivery by providing a more steady state of absorption rather than the bolus surge of injection or the irritation caused by patches resulting in a less desirable dosing regimen.

The primary competition for Testim is AndroGel<sup>®</sup>, marketed by Solvay Pharmaceuticals, Inc., and others. In addition to Solvay Pharmaceuticals, Inc., MacroChem Corp. has developed a testosterone gel that is currently in Phase I studies. Ardane plc., has announced plans to develop a testosterone cream for the U.S. market. Indevus Pharmaceuticals, Inc. has licensed a long acting testosterone injection that is currently marketed in Europe and we believe that this product could be launched in the U.S. in 2008 if approved by the FDA. Another potential introduction into the marketplace is an oral therapy called Androxal. Other new treatments are being sought for testosterone replacement therapy; these products are in development and their future impact on the treatment of testosterone deficiency is unknown.

**Table of Contents**

**Manufactured and Marketed Products**

In Spain, we manufacture and market approximately 200 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, 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 46 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 21% of our revenues in 2007, compared to 22% in 2006 and 23% in 2005. 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.

**Table of Contents**

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
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 95 products of various dosages and strengths. We entered the generic pharmaceutical market in Spain in September 2000. Sales of generic pharmaceuticals accounted for approximately 32% of our revenues in 2007, compared to 36% in 2006 and 2005. 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 66 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 24 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.

**Table of Contents**

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
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





**Table of Contents**

<b>Our Generic Product Name</b>	<b>Active Ingredient</b>	<b>Innovator Product (Company)</b>	<b>Used to Treat</b>
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	trimetazidine	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, 2007, our Spanish operations have executed 251 license agreements, of which 29 with customers in Spain and 124 with customers outside of Spain cover actively marketed products that are generating revenues. The remaining licenses, 2 with customers in Spain and 68 with customers outside of Spain, are for products that are awaiting regulatory approvals. Our Irish subsidiary has executed 10 license agreements that have been approved to actively market products and 2 licenses agreements which are for products that are awaiting regulatory approvals. Additionally, we have 16 contract manufacturing agreements in effect in Spain. 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 co-developed a generic version of simvastatin. The finish dosage forms were produced by our manufacturing subsidiary, Laboratorios Belmac, which received approval from the FDA in 2006. We have not been able to yield any material profits as a result of the highly competitive simvastatin market in the U.S. We have not received any additional orders for our U.S. generic simvastatin and do not expect to generate any profits from this product for the foreseeable future.

*Alliance with Teva*

After terminating our strategic alliance and rights agreement with Teva earlier in 2007, we entered into a series of new agreements whereby we will be providing Teva with the right to use certain of our products in several territories. Product supply will be provided by our finish dose manufacturing plant in Spain.

*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

**Table of Contents**

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. In 2006 we received FDA approval of this facility for simvastatin, our first generic product in the U.S.

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 <i>Generic Products</i>	CPE-215	Diabetes	Phase I/II

We continually evaluate which pharmaceutical products are good candidates for us to develop, test and market as generic products in Spain, the U.S. and elsewhere. We select products based on factors including the timing of expiration of the patent on the innovator's product, the ability of our manufacturing facility to efficiently produce the product, the availability and cost of the raw materials to produce the 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 have the capability to co-develop generic pharmaceutical products for sale in the U.S. that can be manufactured by our active pharmaceutical ingredients

**Table of Contents**

manufacturing subsidiary, Bentley API, and related finish dosage forms produced by our manufacturing subsidiary, Laboratorios Belmac.

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, Proprietary Intranasal Insulin Product***

Nasulin is the patented intranasal insulin spray of Bentley which incorporates CPE-215 as a permeation facilitator that addresses the need for an improved delivery method for insulin, which we believe could potentially reshape the insulin market. Based on market reports and projections, we have estimated the insulin market to be approximately \$8.0 billion. In general, drugs entering the nasal cavity are readily absorbed across the highly vascularized nasal mucosa directly into the circulatory system, thereby avoiding first-pass metabolism in the liver. The speed of absorption affords a faster onset of action compared to the most rapid-acting, injectable insulin formulations. A series of studies have confirmed that Nasulin delivers insulin quickly through the nasal mucosa, even more rapidly than subcutaneous injection.

The U.S. Center for Disease Control and Prevention ( CDC ) estimates there were approximately 14.6 million diagnosed diabetics in the United States in 2005. A study published by Diabetes Care in 2006 projects that the number of diagnosed diabetics in the U.S. will reach 48.3 million by 2050 due to an aging population, rising obesity rates and poor health habits. Prescription trends show a preference for combining rapid-acting injections during mealtimes with a once daily basal insulin injection. Injectable insulin treatments create a general level of patient dissatisfaction and, as a result, compliance can be a challenge. Poor patient compliance or under-treatment causes serious diabetic complications. Nasulin is specifically designed to facilitate compliance, provide a very rapid effect, and avoid long-term consequences brought on by inconsistent treatments.

Nasulin is currently in Phase II clinical trials for the treatment of Type 1 and Type 2 diabetes. We believe an intranasal route of administration will yield significant improvements in patient compliance and avoid the potential pulmonary disadvantages of competitive candidates that use an inhalation route of administration. Our expectation is to complete all Phase II trials in 2009 while simultaneously seeking a pharmaceutical partner to support Phase III clinical trials and product commercialization upon regulatory approval. While the terms of any future alliance will be determined through negotiation, we would look to license the product in return for upfront payments, milestones and royalties that reflect our research investment, innovation and potential market size.

The primary competition for Nasulin is from injectable and oral insulin currently on the market, pulmonary insulin in development, another early stage intranasal insulin product in development from Nasteck, and other oral insulin in development.

**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

**Table of Contents**

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. There have been no clinical developments with respect to this product since 2003, but the Company is actively pursuing licensing opportunities for this product.

*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 an exclusive worldwide license to develop, market and sell a topical hormonal therapy containing our CPE-215 technology. Since 2004, we have earned approximately \$28,000 in revenues under this agreement. Our expenses during this period, generally consisting of patent maintenance costs, have not been material.

*Intranasal Pain Management*

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 exclusive right to license this product application pursuant to our research agreement, but has not activated the license to date. We have received immaterial revenues and incurred some nominal expenses under this license.

**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.

*Material patents related to our CPE-215 technology*

<b>Patent/Technology</b>	<b>Jurisdiction</b>	<b>Expiration</b>
Hsieh patents entitled Lactone/cyclic ketone delivery enhancer relate to the CPE-215 technology platform	United States	2008
	Canada	2010
	Italy, Luxembourg	2011
Testosterone gel-macrocyclic enhancer patents relate to the Testim product	Australia, Bulgaria, Europe, Greece, Lebanon, Mexico, New Zealand, Saudi Arabia, South Africa and Singapore	2023
	United States	2025
Pharmaceutical Compositions and Methods patent entitled for Insulin Treatment relates to the Nasulin product	United States	2024
Pharmaceutical Compositions and Methods patent entitled for Peptide Treatment covers potential products slated for further development	United States	2024

**Table of Contents**

Our CPE-215 technology is covered by U.S. and foreign patents covering many major market countries. Although the initial patent for our CPE-215 technology expires in the U.S. in June 2008 and expires in Canada in 2010, Italy and Luxembourg in 2011, and expired in all markets outside the U.S. in 2006, patent extensions of our technology to other drugs continue for specific medical uses through 2025. For example, patents that cover intranasal delivery utilizing CPE-215 technology for insulin and other peptides continue through 2025. Recently issued patents that also cover the application of testosterone with CPE-215 in the U.S. and in foreign countries continue through 2023. Additional patents, using both CPE-215 and other technologies have been applied for and are pending although we cannot be certain that a patent will issue from any of those applications.

*Other patents and intellectual property*

Bentley entered into an Assignment Agreement with MacroChem Corporation ( MacroChem ), dated June 24, 2003, pursuant to which Bentley purchased from MacroChem all of MacroChem's right, title and interest to U.S. Patent Number 6,495,124 B1 and any and all related patents and patent applications which are divisions, continuations, continuations-in-part, reissues, renewals, extensions and supplementary protection certificates (the MacroChem Patent Rights ). As a result of the assignment, MacroChem retained no interest whatsoever in the MacroChem Patent Rights. To date, the Company has not generated any revenue from the MacroChem Patent Rights, which expire in 2020.

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

We own approximately 110 trademarks for pharmaceutical products in Spain. In addition, we also rely on unpatented proprietary technologies in the development and commercialization of our products.

We also rely on unpatented proprietary technologies in the development and commercialization of our products. We also depend upon the 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 may not be patentable, and our 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 \$13,600,000, \$10,459,000 and \$5,800,000 in the years ended December 31, 2007, 2006 and 2005, 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. We plan to incur increased research and development costs as we continue to conduct our clinical trials.

**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 9% of our consolidated total revenues in 2007, 11% in 2006 and 12% in 2005.

**Financial Information About Geographic Areas**

The majority of our revenues are generated from products sold in Spain. Spain revenues totaled \$81,206,000, \$77,228,000, and \$69,845,000 in the years ended December 31, 2007, 2006 and 2005, respectively. Long-lived assets in Spain at December 31, 2007, 2006 and 2005 were \$69,598,000, \$56,435,000 and \$40,120,000, 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 470 people, 22 of whom are employed in the U.S. and 448 of whom are employed in Spain, as of December 31, 2007. Approximately 229 of these employees are principally engaged in manufacturing activities, 167 in sales and marketing, 26 in product development and 48 in management and administration. In general, we consider our relations with our employees to be good.

**Regulation**

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

*United States*

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

Preclinical testing;

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

Clinical trials;

Preparation and submission of the NDA; and

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

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

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

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

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

Phase II involves the first controlled clinical trial involving patients who have the targeted disease or condition and consists of safety and efficacy studies. The studies may be divided into early



**Table of Contents**

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, longer-term, well controlled efficacy and safety studies within an expanded patient population, frequently at multiple clinical study sites.

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

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

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

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

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

*Europe*

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

**Table of Contents**

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 was effective on March 1, 2007, and has required our sales force to begin marketing our products at lower prices. 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 late 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 expedite approvals within European Union countries, the European Union has established a mutual recognition procedure. When a manufacturer submits a pharmaceutical product for marketing approval, it must designate whether the filing will serve as a reference authorization for other European Union countries and, if so, which specific European countries. If the filing is not designated as a mutual recognition reference filing, then other applications must be made individually to other countries for approval to be granted in those other countries. If the filing is designated as a reference authorization, then the authority in the initial country is required to evaluate the submission on the basis of its own domestic standards as well as the standards of each of the countries listed by the manufacturer. As the standards for pharmaceutical approvals have not been harmonized among the various European Union members, certain aspects of the filing must comply with standards that vary by country. In addition, the process for initial evaluation of mutual recognition filings is generally significantly longer than that for national filings and, as a result, companies often choose not to use this process for their first approval. However, if the filing is approved for the reference and the mutual recognition countries, the manufacturer would be permitted to market the product in all of the jurisdictions selected.

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

*Trends in Healthcare Regulation*

The cost of healthcare continues to be a subject of investigation and action by governmental agencies, legislative bodies and private organizations. Many countries, in Europe and elsewhere, directly or

## **Table of Contents**

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.

### **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).

**Table of Contents**

**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 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

**Table of Contents**

regulatory review process required before marketing clearance can be obtained, the time periods before commercialization of any of these products are long and uncertain. Risks during development include the possibility that:

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

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

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

other pharmaceutical companies may market equivalent or superior products.

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

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

perceived efficacy of our products;

convenience and ease of administration;

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

availability of alternative treatments;

cost effectiveness;

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

publicity concerning our products or competing products; and

our ability to obtain third-party coverage or reimbursement.

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

the effectiveness of our sales force;

the effectiveness of our production, distribution and marketing capabilities;

the success of competing products; and

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

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

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

In light of our limited development resources and the significant time, expense, expertise and infrastructure necessary to bring new drugs and formulations from inception to market, we are particularly dependent on resources from third parties to commercialize products incorporating our technologies. Our strategy involves forming alliances to develop, manufacture, market and sell our products in the United States and other countries. We may not be

successful in finding strategic partners or in otherwise obtaining financing, in which case the development of our products would be delayed or curtailed.

We must enter into agreements with strategic partners to conduct clinical trials, manufacturing, marketing and sales necessary to commercialize product candidates. In addition, our ability to apply our drug delivery technologies to any proprietary drugs will depend on our ability to establish and maintain

**Table of Contents**

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

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

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

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

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

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

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

Spanish sales from our omeprazole product line accounted for approximately 14% and 18% of our consolidated total revenues in 2007 and 2006, respectively. The active pharmaceutical ingredient for our omeprazole products is currently purchased from one supplier. If we lose and cannot effectively replace our supplier or are otherwise unable to continue the sales of our omeprazole products, our revenues would decline significantly.

**Table of Contents**

**An interruption in the sourcing and availability of the active ingredient used in our CPE-215 technology could cause our drug delivery technology product development and commercialization to slow or stop.**

We do not own or operate manufacturing facilities for clinical or commercial production of our drug delivery product candidates. We lack the resources and the capability to manufacture any of our drug delivery product candidates on a clinical or commercial scale. We also lack the resources to manufacture the excipient CPE-215, which is the major component of our CPE-215 technology. Our technology is dependent upon obtaining pharmaceutical grade CPE-215 which is available from at least two major industrial manufacturers. If a third party supplier is unable to provide us with required quantities of pharmaceutical grade CPE-215 on commercially favorable terms, we may be unable to continue our drug delivery product development or commercialization activity.

**If any of our product candidates for which we receive regulatory approval do not achieve broad market acceptance, the revenues that we generate from their sales will be limited.**

The commercial success of our product candidates for which we obtain marketing approval from the FDA or other regulatory authorities will depend upon the acceptance of these products by the medical community and coverage and reimbursement of them by third-party payors, including government payors. The degree of market acceptance of any of our approved products will depend on a number of factors, including:

limitations or warnings contained in a product's FDA-approved labeling;

changes in the standard of care for the targeted indications for either of our product candidates could reduce the marketing impact of any superiority claims that we could make following FDA approval;

limitations inherent in the approved indication for either of our product candidates compared to more commonly-understood or addressed conditions; and

potential advantages over, and availability of, alternative treatments, including, in the case of Nasulin, a number of products already used to treat diabetes.

Our ability to effectively promote and sell our product candidates will also depend on pricing and cost effectiveness, including our ability to produce a product at a competitive price and our ability to obtain sufficient third-party coverage or reimbursement. We will also need to demonstrate acceptable evidence of safety and efficacy as well as relative convenience and ease of administration. Market acceptance could be further limited depending on the prevalence and severity of any expected or unexpected adverse side effects associated with our product candidates. If our product candidates are approved but do not achieve an adequate level of acceptance by physicians, health care payors and patients, we may not generate sufficient revenue from these products, and we may not become or remain profitable. In addition, our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

**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



**Table of Contents**

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 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:

**Table of Contents**

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. **We rely on third parties to conduct clinical trials for our product candidates and plan to rely on third parties to conduct future clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize our current and future product candidates.**

We do not have the ability to conduct clinical trials for Nasulin or any other product candidate. We rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories, to conduct all of our clinical trials for our product candidates. Although we rely on these third parties to conduct our clinical trials, we are responsible for ensuring that each of our clinical trials is conducted in accordance with its investigational plan and protocol. Moreover, the FDA and other non-U.S. regulatory authorities require us to comply with regulations and standards, commonly referred to as Good Clinical Practices ( GCPs ), for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. Our reliance on third parties does not relieve us of these responsibilities and requirements. If the third parties do not perform their contractual duties or obligations, do not meet expected deadlines or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to GCPs or for any other reason, we may need to enter into new arrangements with alternative third parties and our clinical trials may be extended, delayed or terminated. In addition, failure by such third parties to perform their obligations in compliance with GCPs may cause our clinical trials to fail to meet regulatory requirements, which may require us to repeat our clinical trials.

**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.



**Table of Contents**

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.

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 obtain or delay in obtaining regulatory approval for our products could result in a reduction of our expected revenues. 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.

**Table of Contents**

**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.

**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.

**Table of Contents**

**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.

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, 2007, 65% of our revenues were derived from sales made by our Spanish subsidiaries in Spain and 26% 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

31

---

**Table of Contents**

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 91% 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 2007. 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.

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 innovator 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.



**Table of Contents**

**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 potential market opportunities. We plan to invest \$11.0 million to \$13.0 million in capital expenditures during the year ending December 31, 2008, including \$3.9 million that was budgeted in 2007, but now planned for 2008. We plan to complete the expansion of our API manufacturing facility and of 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.

**Table of Contents**

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

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

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

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

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

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

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

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

The testing and marketing of medical products entails an inherent risk of product liability. We may be held liable to the extent that there are any adverse reactions from the use of our products. Some of our products involve new methods of delivery for drugs, some of which may require precautions to prevent

**Table of Contents**

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.

Regardless of merit or eventual outcome, liability claims may result in:

- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- decreased demand for our product candidates;
- impairment of our business reputation;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- loss of revenues; and

the inability to commercialize our product candidates.

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 \$4.4 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 \$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.

**The discovery of any new side effects or negative efficacy findings for our products could significantly harm our business.**

While the safety of our products has been, is being, and will be extensively studied in clinical trials there can be no assurance that new or more serious side effects or negative efficacy findings may not be discovered based on long term safety and efficacy studies or required reporting of adverse events regarding any of our products after each such product has been marketed, any of which could severely harm our business and result in one or more of the following regulatory events:

- a voluntary or involuntary recall or market withdrawal of the applicable product;
- labeling changes such as restriction on intended uses, additional contraindications, warnings, precautions, or adverse reactions that would limit the applicable product's market potential;
- a boxed warning on the label;
- imposition of post-marketing surveillance studies or risk management programs;
- distribution restrictions; and

adverse publicity.

In addition, one or more of the above factors would also have the potential to negatively impact regulatory registrations for the applicable product in other countries.

**Table of Contents****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, 2007, we had the following capital structure (in thousands):

	<i>No. of Shares</i>
<i>Common stock outstanding</i>	22,377
<i>Common stock issuable upon:</i>	
<i>Exercise of options which are outstanding</i>	3,838
<i>Vesting of restricted stock units which are outstanding</i>	197
<i>Contingently issuable shares</i>	60
<i>Exercise/vesting of options and restricted stock units which are available for grant</i>	323
 <i>Total common stock outstanding assuming exercise of all of the above</i>	 26,795

As of December 31, 2007, we had outstanding options to purchase approximately 3,838,000 shares of common stock at exercise prices ranging from \$2.00 to \$15.83 (exercisable at a weighted average of \$9.97 per share), of which approximately 3,014,000 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.



**Table of Contents**

**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 4, 2008, the price of our common stock has ranged from a high of \$17.50 to a low of \$7.51. 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.

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



**Table of Contents**

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.

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**

In October 2007, we were notified that a legal proceeding had been commenced against our subsidiaries, Laboratorios Belmac, S.A., Laboratorios Davur, S.L. and Laboratorios Rimafar, S.L. by Wyeth requesting an order requiring our subsidiaries to not manufacture or launch their venlafaxine products. The case was brought in the 4th Commercial Court of the City of Madrid. After an initial hearing the court rejected Wyeth's request for an interim injunction. The underlying proceedings are still pending.

In September 2007, we were notified that a legal proceeding had been commenced against our subsidiaries, Laboratorios Davur, S.L. and Laboratorios Rimafar, S.L., jointly with other manufacturers,

**Table of Contents**

by Merck & Co. Inc. and its Spanish subsidiary Merck Sharp & Dohme de España, S.A. requesting an order requiring our subsidiaries to not manufacture or launch certain of their alendronate products (70mg weekly). In October 2007, we filed a counterclaim against Merck seeking the revocation in Spain of European Patent 1.175.904. The case was brought in the 6th Commercial Court of the City of Barcelona and is currently pending.

In June 2007, we were notified that a legal proceeding had been commenced against our subsidiary, Laboratorios Belmac S.A., jointly with three other Spanish manufacturers, by Warner-Lambert Company requesting an order requiring Belmac not to manufacture or launch their atorvastatin products. This patent infringement action is based on the Spanish counterpart of European patent EP 247.633 which expired on May 29, 2007. In January 2008, the court rejected the action filed by Warner-Lambert and awarded legal costs to Belmac.

In January 2005, we were notified that a legal proceeding had been commenced against our subsidiary, Laboratorios Davur S.L., by Pfizer Inc. and its Spanish subsidiary Pfizer, S.A. requesting an order requiring Davur to not manufacture or market its amlodipine products. The case was brought against Davur in the 3rd Commercial Court of the City of Barcelona. After an initial hearing the court imposed an interim injunction, preventing Davur from launching its amlodipine products. However, upon appeal, the court lifted the requested injunction and awarded Davur with court costs and legal fees. Pfizer has appealed the judgment. A decision on the appeal is expected in mid 2008.

In December 2004, our subsidiary, Laboratorios Belmac, S.A., 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 favour 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 in the beginning of 2008.

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, 2006</i></b>		
<i>First Quarter</i>	\$22.90	\$12.78
<i>Second Quarter</i>	14.19	9.43
<i>Third Quarter</i>	13.07	8.78
<i>Fourth Quarter</i>	12.90	8.82
<b><i>Fiscal Year Ended December 31, 2007</i></b>		
<i>First Quarter</i>	10.34	7.51
<i>Second Quarter</i>	13.54	8.10
<i>Third Quarter</i>	13.00	9.05
<i>Fourth Quarter</i>	15.70	11.99
<b><i>Fiscal Year Ending December 31, 2008</i></b>		
<i>First Quarter (through March 4, 2008)</i>	15.89	13.17

As of March 4, 2008 there were 948 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.

**Item 6. Selected Financial Data**

The following sets forth the selected Consolidated Income Statement data for the years ended December 31, 2003, 2004, 2005, 2006 and 2007 and Consolidated Balance Sheet data as of December 31, 2003, 2004, 2005, 2006 and 2007, 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, 2005, 2006 and 2007 and Consolidated Balance Sheet data as of December 31, 2006 and 2007 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, 2003 and 2004 and the Consolidated Balance Sheet data as of December 31, 2003,

**Table of Contents**

2004 and 2005 are derived from our audited Consolidated Financial Statements and related notes not included in this Annual Report on Form 10-K.

**Consolidated Income Statement Data**

<i>(in thousands, except per share data)</i>	<i>For the Year Ended December 31,</i>				
	<i>2003</i>	<i>2004(a)</i>	<i>2005(b)</i>	<i>2006(c)(d)</i>	<i>2007(e)</i>
<i>Total revenues</i>	\$ 64,676	\$ 73,393	\$ 97,730	\$ 109,471	\$ 124,687
<i>Cost of net product sales</i>	26,399	34,893	46,161	49,850	64,010
<i>Gross profit</i>	38,277	38,500	51,569	59,621	60,677
<i>Operating expenses</i>	26,848	29,805	35,903	54,222	53,275
<i>Gain (loss) on sale of drug licenses</i>				38	(111)
<i>Other income (expenses)</i>	91	1,800	729	619	928
<i>Income before income taxes</i>	11,520	10,495	16,395	6,056	8,219
<i>Provision for income taxes</i>	5,423	4,805	5,476	5,082	5,534
<i>Net income</i>	\$ 6,097	\$ 5,690	\$ 10,919	\$ 974	\$ 2,685
<i>Net income per common share basic</i>	\$ 0.34	\$ 0.27	\$ 0.51	\$ 0.04	\$ 0.12
<i>Net income per common share diluted</i>	\$ 0.28	\$ 0.25	\$ 0.48	\$ 0.04	\$ 0.12
<i>Weighted average common shares outstanding basic</i>	17,997	20,901	21,558	22,141	22,339
<i>Weighted average common shares outstanding diluted</i>	21,637	22,627	22,929	23,068	22,957

(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.

- (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.

**Table of Contents**

- (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.
- (e) *Operating expenses* for the year ended December 31, 2007 included impairment charges of \$1,443,000

related to the write-down of its U.S. generic simvastatin drug license and certain other U.S. generic drug projects.

### Consolidated Balance Sheet Data

<i>(in thousands)</i>	<i>December 31,</i>				
	<i>2003</i>	<i>2004</i>	<i>2005</i>	<i>2006</i>	<i>2007(a)</i>
<i>Working capital</i>	\$ 46,181	\$ 47,114	\$ 46,397	\$ 40,303	\$ 61,597
<i>Current assets</i>	\$ 66,899	\$ 74,710	\$ 75,077	\$ 67,690	\$ 94,680
<i>Non-current assets</i>	33,564	47,220	49,143	66,666	78,416
<i>Total assets</i>	\$ 100,463	\$ 121,930	\$ 124,220	\$ 134,356	\$ 173,096
<i>Current liabilities</i>	\$ 20,718	\$ 27,596	\$ 28,680	\$ 27,387	\$ 33,083
<i>Long-term debt</i>	369	349			15,595
<i>Other non-current liabilities</i>	3,211	4,328	3,951	6,638	8,446
<i>Total liabilities</i>	\$ 24,298	\$ 32,273	\$ 32,631	\$ 34,025	\$ 57,124
<i>Stockholders equity</i>	\$ 76,165	\$ 89,657	\$ 91,589	\$ 100,331	\$ 115,972

(a) In the fourth quarter of the year ended December 31, 2007, the Company recorded impairment charges of \$1,443,000 related to the write-down of its U.S. generic simvastatin drug license and certain other U.S. generic drug projects (included in *non-current*



*assets*).

**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 and 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.

**Planned Spin-off**

On October 23, 2007 the Company announced a plan to spin-off its drug delivery business. This transaction is subject to a number of conditions. Management expects that shares of the new specialty pharmaceutical drug delivery company, CPEX Pharmaceuticals, Inc. will be distributed to Bentley stockholders by means of a stock dividend. On the record date, which has not yet been set, each Bentley stockholder will be entitled to receive shares of CPEX in connection with the spin-off of the drug delivery business. The spin-off would result in CPEX operating as an independent entity with publicly traded common stock. Bentley would not have any ownership interest in CPEX subsequent to the spin-off.

In connection with the spin-off, CPEX and Bentley expect to enter into a series of agreements, including a separation and distribution agreement, a transition services agreement, an employee matters agreement and a tax allocation agreement. Consummation of the spin-off is subject to several conditions, including final approval by the Bentley Board of Directors, approval for listing of CPEX common stock on a national securities exchange, and the effectiveness of the Form 10 filed with the Securities and Exchange Commission for the registration of the securities of CPEX. Approval by Bentley's stockholders is not required as a condition to the consummation of the proposed spin-off.

The Company has incurred and is expected to continue to incur legal, tax and other strategic consulting costs specifically associated with the planned spin-off. These costs totaled \$2,020,000 for the year ended December 31, 2007 and have been reported as *separation costs* within operating expenses in the Company's Consolidated Income Statements.

**Table of Contents****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**

In 2006, we settled all outstanding litigation with Etypharm S.A. Spain and Etypharm S.A. France (together, Etypharm). As a result of the settlement, we recorded a \$7,546,000 charge in 2006 representing the present value of the \$8,000,000 settlement, discounted at a rate of 4.72%. In accordance with the payment terms of the settlement, \$4,000,000 was paid in the fourth quarter of 2006, \$1,000,000 was paid in the fourth quarter of 2007 and the three remaining annual payments of \$1,000,000 will be paid in each of the fourth quarters of 2008, 2009 and 2010. We incurred defense costs of approximately \$3,368,000 and \$593,000 related to this litigation in the years ended December 31, 2006 and 2005, respectively. The litigation related charges are recorded in *litigation settlement* expenses on the Company's Consolidated Income Statements.

**Overview**

We are an international specialty pharmaceutical company, headquartered in the U.S., 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.

***Specialty Generic Pharmaceuticals***

Our pharmaceutical product sales and licensing activities are based primarily in Spain, where we have a significant commercial presence and manufacture and market approximately 200 product presentations (stock keeping units or SKUs) in four primary therapeutic areas: cardiovascular, gastrointestinal, central nervous system and infectious diseases. In 2007, approximately 24% of our product revenues were derived from three of our top 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. In past years we expanded our geographic sales to countries outside of Spain including several countries in the European Union. As of December 31, 2007 approximately 29% of our net product sales were derived from sales outside of Spain. Our generic simvastatin product, which is manufactured at our FDA approved finished dosage facility in Spain, was launched in the U.S. in December of 2006. The launch of our first U.S. generic product marked a significant strategic milestone for us; however, due to market price conditions and limited demand, sales of our generic simvastatin have been determined to be less favorable than our initial projections. As a result, we have recorded net charges of approximately \$425,000 to *cost of net product sales* for inventory write-downs and obsolescence reserves, which reduced the carrying value of these inventories to zero at December 31, 2007. As a result of these market conditions and adjustments, we

**Table of Contents**

have also reassessed the carrying value of our U.S. simvastatin drug license at December 31, 2007. Due to the inability to generate net profits on these products and the lack of additional orders, we have recorded an impairment charge of \$949,000 to *research and development expenses* to reduce the carrying value of this drug license to zero at December 31, 2007.

While the pricing of our pharmaceutical products is influenced by market forces (size of the market, number of competitors, etc.), our pricing in Spain and other countries is also subject to governmental price controls. The majority of our products are subject to price controls set in place by the Spanish government. The Spanish government enacted legislation effective March 1, 2007 which reduced the amount it reimburses for pharmaceutical products. As a result of the legislation our sales force began marketing our products at lower selling prices in Spain as early as February 2007. We also experienced reduced sales levels in the beginning of the first quarter of 2007 as Spanish wholesalers and pharmacies minimized order quantities until they were able to purchase our products at the new lower prices. Once we began selling at the new prices we experienced an increase in the number of our units sold. While the increased unit volume has substantially offset the impact of the reduced selling prices on our net product sales, our gross margins have decreased from 54% in the year ended December 31, 2006 to 49% in the year ended December 31, 2007 (excluding inventory write-downs associated with our U.S. generic simvastatin discussed above). The products most impacted by the price reductions are two of our top selling product lines, omeprazole and simvastatin. Despite increased sales volumes, our simvastatin and omeprazole revenues decreased by 21% and 7%, respectively, when compared to the prior year. We have implemented strategies to mitigate lower selling prices, including strategies to reduce manufacturing costs and increase sales volumes.

We are seeking to continue expanding our product sales in other geographic regions, including the U.S., through strategic alliances. We are targeting markets that offer compatible regulatory approval regimes and attractive product margins. In addition, we expect to grow our business by developing and acquiring rights to market additional products to sell through our sales organization and our strategic alliances. We launched six generic products in 2007 which added approximately \$614,000 to our revenues in 2007. We continually acquire rights to new products in response to increasing market demand for generic and branded generic therapeutic products.

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.

**Table of Contents***Research and Development Focus*

In 2004, we concluded a Phase IIA study for Nasulin in Type 1 diabetic patients using our CPE-215 technology. We reported the results of that trial in an abstract titled *Intranasal Insulin Administration in Type 1 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 an additional Phase I study in Ireland in healthy non-diabetic volunteers, diabetic patients and advanced our Phase IIA studies in the U.S. in Type 1 diabetic patients. In the first quarter of 2007, we completed preparations for a Phase II study in India in Type 2 diabetic patients, which began in the second quarter of 2007. Portions of the results from our U.S. and Irish studies were presented at the American Diabetes Association 67th Scientific Sessions in Chicago, Illinois in June 2007. We expect the U.S. development and clinical programs for Nasulin to continue and expand domestically and internationally. We expect to incur increased costs from the advancement of our clinical programs and from continued 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 2007 compared to 2006, had the following impact on the results of our operations when reported in U.S. Dollars: (1) total revenues were increased by approximately \$9,533,000, (2) gross profit was increased by approximately \$4,247,000, (3) operating expenses increased by approximately \$2,799,000, (4) provision for income taxes was increased by approximately \$470,000, which resulted in (5) an increase to net income of approximately \$978,000.

**Consolidated Results of Operations***Fiscal Year Ended December 31, 2007 Compared To Fiscal Year Ended December 31, 2006*Revenues

<i>(in thousands)</i>	<b>2007</b>	<b>%</b>	<b>2006</b>	<b>%</b>	<b>Change</b>	
					<b>\$</b>	<b>%</b>
<i>Specialty Generics</i>						
<i>Net product sales</i>	\$112,999	91%	\$100,590	92%	\$12,409	12%
<i>Licensing and collaboration revenues</i>	561	*	515	*	46	9%
	113,560	91%	101,105	92%	12,455	12%
<i>Drug Delivery</i>						
<i>Licensing and collaboration revenues</i>	11,127	9%	8,366	8%	2,761	33%
<i>Total revenues</i>	\$124,687	100%	\$109,471	100%	\$15,216	14%

\* *Less than 1%*

Total revenues for the year ended December 31, 2007 increased 14% from the year ended December 31, 2006. Our current year growth was driven primarily by increased net product sales in Spain, increased sales to licensees and others and increased Testim royalties.

**Table of Contents**

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, 2007:

<i>(in thousands)</i> <b>Product Line</b>	<b>Revenues Within Spain</b>			<b>Revenues</b>		<b>% of Total Revenues</b>
	<b>Branded Generics</b>	<b>Generics</b>	<b>Other</b>	<b>Outside of Spain</b>	<b>Total</b>	
<i>Omeprazole</i>	\$ 1,912	\$15,818	\$	\$	\$ 17,730	14%
<i>Enalapril</i>	5,176	1,522			6,698	5%
<i>Simvastatin</i>	1,022	4,866			5,888	5%
<i>Paroxetine</i>	1,521	3,424			4,945	4%
<i>Lansoprazole</i>	3,610	1,265			4,875	4%
<i>All other products</i>	12,788	13,330	466	3,409	29,993	24%
<i>Sales to licensees and others</i>			13,925	28,945	42,870	35%
<i>Licensing and collaborations</i>			561	11,127	11,688	9%
<b>Total Revenues</b>	<b>\$26,029</b>	<b>\$40,225</b>	<b>\$14,952</b>	<b>\$43,481</b>	<b>\$124,687</b>	<b>100%</b>
<i>% of 2007 Revenues</i>	21%	32%	12%	35%	100%	

For the year ended December 31, 2006:

<i>(in thousands)</i> <b>Product Line</b>	<b>Revenues Within Spain</b>			<b>Revenues</b>		<b>% of Total Revenues</b>
	<b>Branded Generics</b>	<b>Generics</b>	<b>Other</b>	<b>Outside of Spain</b>	<b>Total</b>	
<i>Omeprazole</i>	\$ 2,679	\$16,451	\$	\$	\$ 19,130	18%
<i>Enalapril</i>	4,826	1,824			6,650	6%
<i>Simvastatin</i>	1,851	5,620			7,471	7%
<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%
<b>Total Revenues</b>	<b>\$24,122</b>	<b>\$39,055</b>	<b>\$14,051</b>	<b>\$32,243</b>	<b>\$109,471</b>	<b>100%</b>
<i>% of 2006 Revenues</i>	22%	36%	13%	29%	100%	

*Spanish Operations.* Net product sales increased by \$12,409,000, or 12%, compared to the prior year. Net product sales increased by 3% when expressed in constant currency. In addition to fluctuations in foreign currency rates, we experienced a 23% increase in our sales to licensees and others compared to the prior year. Additionally, all other products combined to contribute an additional \$5,544,000 to 2007 revenues over 2006.

Branded Generic Pharmaceutical Products

<i>(in thousands)</i>	<i>2007</i>	<i>%</i>	<i>2006</i>	<i>%</i>	<i>Change</i>	
					<i>\$</i>	<i>%</i>
<i>Branded Generic Product</i>						
<i>Sales:</i>						
<i>Enalapril</i>	\$ 5,176	20%	\$ 4,826	20%	\$ 350	7%
<i>Codeisan</i>	3,921	15%	3,001	12%	920	31%
<i>Lansoprazole</i>	3,610	14%	2,689	11%	921	34%
<i>Ibuprofen</i>	2,386	9%	1,492	6%	894	60%
<i>Omeprazole</i>	1,912	7%	2,679	11%	(767)	(29)%
<i>All other branded products</i>	9,024	35%	9,435	40%	(411)	(4)%
<i>Total branded generic sales</i>	\$26,029	100%	\$24,122	100%	\$1,907	8%

**Table of Contents**

Sales of our branded generic pharmaceutical products accounted for 21% of total revenues during 2007 and increased 8%, or approximately \$1,907,000 over 2006. Codeisan 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 29% of our 2007 branded generic sales. Included in all other branded generic products are sales of our simvastatin which decreased 45% or approximately \$830,000 as a result of the price reductions in the current year.

**Generic Pharmaceutical Products**

<i>(in thousands)</i>	2007	%	2006	%	Change	
					\$	%
<i>Generic Product Sales:</i>						
<i>Omeprazole</i>	\$15,818	39%	\$16,451	42%	\$ (633)	(4)%
<i>Simvastatin</i>	4,866	12%	5,620	14%	(754)	(13)%
<i>Paroxetine</i>	3,424	9%	3,045	8%	379	12%
<i>Trimetazidine</i>	2,804	7%	2,253	6%	551	24%
<i>Pentoxifylline</i>	2,799	7%	2,571	7%	228	9%
<i>All other generic products</i>	10,514	26%	9,115	23%	1,399	15%
<i>Total generic sales</i>	\$40,225	100%	\$39,055	100%	\$1,170	3%

Sales of our generic pharmaceutical products accounted for 32% of 2007 total revenues and increased 3%, or approximately \$1,170,000 over 2006 generic sales. Six generic product launches in 2007 (included in *All other generic products* above) contributed approximately \$614,000 to our 2007 generic sales and accounted for 52% of the generic sales growth from 2006.

**Sales to Licensees and Others**

<i>(in thousands)</i>	2007	2006	Change	
			\$	%
<i>Specialty generics</i>	\$42,870	\$34,855	\$8,015	23%

Sales to licensees and others increased by \$8,015,000 or 23% compared to 2006. 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>	2007	2006	Change	
			\$	%
<i>Specialty generics</i>	\$ 561	\$ 515	\$ 46	9%
<i>Drug delivery</i>	11,127	8,366	2,761	33%
<i>Total</i>	\$11,688	\$8,881	\$2,807	32%

*Licensing and collaboration revenues* now account for approximately 9% of total revenues and increased by approximately \$2,807,000, or approximately 32%, in 2007. These revenues in 2007 included royalties totaling \$11,121,000 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 22% of all testosterone





**Table of Contents**

replacement prescriptions in the market. Also included in *licensing and collaboration revenues* are revenues of approximately \$561,000 related to specialty generic product licensing activities in Europe in 2007 compared to \$515,000 in 2006.

Gross Profit

<i>(in thousands)</i>	2007	2006	Change	
			\$	%
Specialty generics	\$ 49,550	\$ 51,255	\$ (1,705)	(3)%
Drug delivery	11,127	8,366	2,761	33%
Total	\$ 60,677	\$ 59,621	\$ 1,056	2%

Gross profit increased by approximately \$1,056,000, or 2%, in 2007, when compared to 2006. Gross profit decreased \$3,191,000 or 5.4% when expressed in constant currency. Gross margins on net product sales decreased from 50% in 2006 to 43% in 2007 primarily resulting from the 2007 price reductions. We expect our margins to gradually improve as we continue to implement our strategies to mitigate the price reductions.

Selling and Marketing Expenses

<i>(in thousands)</i>	2007	2006	Change	
			\$	%
Specialty generics	\$ 18,523	\$ 16,153	\$ 2,370	15%
Drug delivery				
Total	\$ 18,523	\$ 16,153	\$ 2,370	15%

Selling and marketing expenses increased by approximately \$2,370,000, or 15% in 2007, when compared to 2006 primarily due to fluctuations in foreign currency rates. Selling and marketing expenses remain consistent as a percentage of net product sales at 16% for 2007 and 2006. Selling and marketing expenses, such as commissions, increased as a result of increased sales volume in the year.

General and Administrative Expenses

<i>(in thousands)</i>	2007	2006	Change	
			\$	%
Specialty generics	\$ 9,558	\$ 7,391	\$ 2,167	29%
Drug delivery	7,515	7,410	105	1%
Total	\$ 17,073	\$ 14,801	\$ 2,272	15%

General and administrative expenses for 2007 increased by \$2,272,000 or 15% over the prior year. As a percentage of total revenues, general and administrative expenses were consistent at 14% for 2007 and 2006. 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. General and administrative expenses in 2007 also include approximately \$1,547,000 of non-cash, stock-based compensation expense compared to \$1,126,000 of such expense recorded in 2006, primarily related to our drug delivery business.

**Table of Contents**Research and Development Expenses

<i>(in thousands)</i>	<b>2007</b>	<b>2006</b>	<b>Change</b>	
			<b>\$</b>	<b>%</b>
Specialty generics	\$ 3,026	\$ 1,777	\$ 1,249	70%
Drug delivery	10,574	8,682	1,892	22%
<b>Total</b>	<b>\$ 13,600</b>	<b>\$ 10,459</b>	<b>\$ 3,141</b>	<b>30%</b>

Research and development expenses increased 30% when compared to 2006. The increase related to our specialty generics business includes impairment charges totaling \$1,433,000 associated with our U.S. simvastatin drug license and other U.S. generic drug projects. The increase related to our drug delivery business resulted from continued investments and advancements in our research and development programs for our drug delivery technologies, primarily Nasulin™, our intranasal insulin product. We plan to incur increased costs as we continue to conduct our clinical trials. Research and development expenses in 2007 also included approximately \$1,075,000 of non-cash, stock-based compensation expense compared to \$664,000 of such expense recorded in 2006, primarily related to our drug delivery business.

Litigation Settlement Expenses

<i>(in thousands)</i>	<b>2007</b>	<b>2006</b>	<b>Change</b>	
			<b>\$</b>	<b>%</b>
Specialty generics	\$	\$10,914	\$(10,914)	*

\* *Not meaningful*

Litigation settlement expenses in 2006 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.

Separation Costs

<i>(in thousands)</i>	<b>2007</b>	<b>2006</b>	<b>Change</b>	
			<b>\$</b>	<b>%</b>
Drug Delivery	\$2,020	\$	\$2,020	*

\* *Not meaningful*

As noted above, we have incurred legal, tax and other strategic consulting costs specifically associated with a planned spin-off of the drug delivery business. These costs include the services of lawyers, accountants, tax and compensation consultants needed to effectively complete the spin-off.

**Table of Contents**Provision for Income Taxes

<i>(in thousands)</i>	<b>2007</b>			
	<i>Spain</i>	<i>Ireland</i>	<i>U.S.</i>	<i>Consolidated</i>
<i>Income (loss) before income taxes</i>				
<i>Specialty generics</i>	\$ 19,710	\$ (250)	\$ (2,066)	\$ 17,394
<i>Drug delivery</i>		12,509	(21,684)	(9,175)
<i>Total income (loss) before income taxes</i>	19,710	12,259	(23,750)	8,219
<i>Provision (benefit) for income taxes</i>	5,534	1,563	(4,765)	2,332
<i>Valuation allowance</i>		(1,563)	4,765	3,202
<i>Net provision for income taxes</i>	5,534			5,534
<i>Net income (loss)</i>	\$ 14,176	\$ 12,259	\$ (23,750)	\$ 2,685
<i>Effective tax rate</i>	28%	0%	0%	67%

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. In 2007, these agreements were cancelled and all charges from Bentley Pharmaceuticals, Inc. to Bentley Pharmaceuticals Ireland Ltd in connection with these agreements were subsequently credited. As a result of these adjustments, Bentley Pharmaceuticals Ireland generated net operating income of approximately \$12,259,000 in 2007. Bentley Pharmaceuticals Ireland generated net operating losses of \$10,418,000 and \$2,080,000 in 2006 and 2005, respectively, which have been utilized against the 2007 income in determining the provision.

In 2007, we generated a U.S. loss before income taxes of approximately \$23,750,000, compared to income of approximately \$235,000 in 2006. During 2007, approximately \$6,812,000 of U.S. federal net operating loss carryforwards expired unutilized. As of December 31, 2007, the remaining U.S. federal net operating loss carry-forwards were approximately \$44,704,000.

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 total unrecognized tax benefits of \$763,000 at December 31, 2007,

**Table of Contents**Net Income

<i>(in thousands, except per share data)</i>	<b>2007</b>	<b>2006</b>	<b>Change</b>	
			<b>\$</b>	<b>%</b>
<i>Specialty Generics</i>	\$ 11,860	\$ 8,696	\$ 3,164	36%
<i>Drug Delivery</i>	(9,175)	(7,722)	(1,453)	(19)%
<i>Total net income</i>	\$ 2,685	\$ 974	\$ 1,711	176%
<i>Net income per common share:</i>				
<i>Basic</i>	\$ 0.12	\$ 0.04	\$ 0.08	200%
<i>Diluted</i>	\$ 0.12	\$ 0.04	\$ 0.08	200%
<i>Weighted average common shares outstanding:</i>				
<i>Basic</i>	22,339	22,141	198	1%
<i>Diluted</i>	22,957	23,068	(111)	*

\* *Less than 1%*

We reported 2007 income from operations of \$7,291,000, compared to 2006 income from operations of \$5,437,000. In 2007, the combination of income from operations of \$7,291,000 and the non-operating items of \$928,000, net of the provision for income taxes of \$5,534,000, resulted in 2007 net income of \$2,685,000, or \$0.12 per basic common share (\$0.12 per diluted common share) on 22,339,000 weighted average basic common shares outstanding (22,957,000 weighted average diluted common shares outstanding), compared to 2006 net income of \$974,000, or \$0.04 per basic common share (\$0.04 per diluted common share) on 22,141,000 weighted average basic common shares outstanding (23,068,000 weighted average diluted common shares outstanding).

**Table of Contents****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 2006 increased 12% from 2005. The 2006 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.

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</i>	<i>Generics</i>	<i>Other</i>	<i>Outside of Spain</i>	<i>Total</i>	
<i>Product Line</i>	<i>Generics</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%
<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%	

For the year ended December 31, 2005:

<i>(in thousands)</i> <i>Product Line</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>	\$ 2,779	\$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%	

**Table of Contents**

*Spanish Operations.* The increase in the net product sales for 2006 compared 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>	<b>2006</b>	<b>%</b>	<b>2005</b>	<b>%</b>	<b>Change</b>	
					<b>\$</b>	<b>%</b>
<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 2005 and represent 31% of our 2006 branded generic sales.

**Generic Pharmaceutical Products**

<i>(in thousands)</i>	<b>2006</b>	<b>%</b>	<b>2005</b>	<b>%</b>	<b>Change</b>	
					<b>\$</b>	<b>%</b>
<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%

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.



**Table of Contents**Sales to Licensees and Others

<i>(in thousands)</i>	<b>2006</b>	<b>2005</b>	<b>Change</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.

Licensing and Collaboration Revenues

<i>(in thousands)</i>	<b>2006</b>	<b>2005</b>	<b>Change</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 accounted for approximately 8% of total revenues at December 31, 2006 and increased by approximately \$2,459,000, or approximately 38%, compared to 2005. These revenues include royalties totaling \$8,341,000 from sales of Testim. 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>2006</b>	<b>2005</b>	<b>Change</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.

Selling and Marketing Expenses

<i>(in thousands)</i>	<b>2006</b>	<b>2005</b>	<b>Change</b>	
			<b>\$</b>	<b>%</b>
<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.

**Table of Contents**General and Administrative Expenses

<i>(in thousands)</i>	<b>2006</b>	<b>2005</b>	<b>Change</b>	
			<b>\$</b>	<b>%</b>
<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 2005. 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>	<b>2006</b>	<b>2005</b>	<b>Change</b>	
			<b>\$</b>	<b>%</b>
<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. 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 2005.

Litigation Settlement Expenses

<i>(in thousands)</i>	<b>2006</b>	<b>2005</b>	<b>Change</b>	
			<b>\$</b>	<b>%</b>
<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. Legal costs related to that litigation, which were previously recorded in *general and administrative expenses* in 2006, 2005 and 2004, have been reclassified to *litigation settlement expenses* on the Consolidated Income Statements.

**Table of Contents**Provision for Income Taxes

<i>(in thousands)</i>	2006			<i>Consolidated</i>
	<i>Spain</i>	<i>Ireland</i>	<i>U.S.</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.

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.

We had tax contingencies totaling \$530,000 at December 31, 2006, all of which were 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

<i>(in thousands, except per share data)</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%

Edgar Filing: BENTLEY PHARMACEUTICALS INC - Form 10-K

*Net income per common share:*

<i>Basic</i>	\$ 0.04	\$ 0.51	\$ (0.47)	-92%
--------------	---------	---------	-----------	------

<i>Diluted</i>	\$ 0.04	\$ 0.48	\$ (0.44)	-92%
----------------	---------	---------	-----------	------

*Weighted average common shares outstanding:*

<i>Basic</i>	22,141	21,558	583	3%
--------------	--------	--------	-----	----

<i>Diluted</i>	23,068	22,929	139	1%
----------------	--------	--------	-----	----

**Table of Contents**

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).

**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 2006</i>				<i>Fiscal 2007</i>			
	<i>3/31/06</i>	<i>6/30/06</i>	<i>9/30/06(a)(b)</i>	<i>12/31/06(b)</i>	<i>3/31/07</i>	<i>6/30/07</i>	<i>9/30/07</i>	<i>12/31/07(c)(d)</i>
	<i>(in thousands, except per share data)</i>							
<i>Total revenues</i>	\$ 28,278	\$ 28,983	\$ 25,156	\$ 27,054	\$ 31,391	\$ 31,179	\$ 27,348	\$ 34,769
<i>Cost of net product sales</i>	12,933	12,471	11,778	12,668	15,897	15,790	14,451	17,872
<i>Gross profit</i>	15,345	16,512	13,378	14,386	15,494	15,389	12,897	16,897
<i>Operating expenses</i>	11,991	11,580	19,085	11,566	11,274	13,440	12,530	16,031
<i>Gain (loss) on sale of drug license</i>				38				(111)
<i>Income (loss) from operations</i>	3,354	4,932	(5,707)	2,858	4,220	1,949	367	755
<i>Other income (expenses)</i>	193	187	208	31	221	278	(57)	486
<i>Provision (benefit) for income taxes</i>	2,393	2,484	1,730	(1,525)	2,081	1,517	911	1,025
<i>Net income(loss)</i>	\$ 1,154	\$ 2,635	\$ (7,229)	\$ 4,414	\$ 2,360	\$ 710	\$ (601)	\$ 216
<i>Net income(loss) per common share:</i>								
<i>Basic</i>	\$ 0.05	\$ 0.12	\$ (0.33)	\$ 0.20	\$ 0.11	\$ 0.03	\$ (0.03)	\$ 0.01
<i>Diluted</i>	\$ 0.05	\$ 0.12	\$ (0.33)	\$ 0.19	\$ 0.10	\$ 0.03	\$ (0.03)	\$ 0.01

*Weighted average  
common shares  
outstanding:*

<i>Basic</i>	21,954	22,170	22,194	22,242	22,293	22,318	22,354	22,391
<i>Diluted</i>	23,807	22,876	22,194	22,735	22,534	22,892	22,354	23,322

(a) *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.

(b) *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

**Table of Contents**

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.

- (c) *Operating expenses* for the fourth quarter ended December 31, 2007 include impairment charges of \$1,225,000 related to the write-down of the Company's U.S. generic simvastatin drug license and certain other U.S. generic drug projects.

(d) *Cost of net product sales and net income* for the fourth quarter ended December 31, 2007 includes \$378,000 and \$255,000 net of tax, respectively, related to intercompany profits included in inventory which were not properly eliminated in prior quarters. The intercompany profit eliminations were not considered to be material to the prior quarters.

#### **Liquidity and Capital Resources**

Total assets increased 29% from \$134,356,000 at December 31, 2006 to \$173,096,000 at December 31, 2007 and stockholders' equity increased 16% from \$100,331,000 at December 31, 2006 to \$115,972,000 at December 31, 2007. The increase in stockholders' equity primarily reflects net income during the year of \$2,685,000 and the effect of fluctuations in the U.S. Dollar/Euro exchange rate, which resulted in a net increase of \$10,120,000 on our balance sheet.

Cash, cash equivalents and marketable securities increased 123% from \$15,601,000 at December 31, 2006 to \$34,716,000 at December 31, 2007. Uses of cash primarily included additions to fixed assets totaling \$9,989,000, additions to drug licenses and related costs of \$2,662,000 and the net effect of financing activities as discussed below. Cash and cash equivalents at December 31, 2007 included approximately \$9,704,000 of short-term liquid investments considered to be cash equivalents.

Total receivables increased from \$32,963,000 at December 31, 2006 to \$39,324,000 at December 31, 2007. Receivables increased \$2,445,000, or 7% when expressed in constant currency. Receivables from one international customer totaled \$2,864,000 at December 31, 2007; however, we owed the same customer approximately \$264,000 for co-marketing expenses at December 31, 2007. 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 \$1,379,000 from \$16,279,000 at December 31, 2006 to \$17,658,000 at December 31, 2007. The increase of \$1,379,000 was primarily a result of changes in foreign currency exchange rates which increased inventory by \$1,907,000 and an increase in raw materials of \$1,430,000, partially offset by the \$1,100,000 write down of consigned inventories to their net realizable value and a decrease in finished goods inventories of \$500,000.



The combined total of accounts payable and accrued expenses increased \$5,766,000 from \$24,270,000 at December 31, 2006 to \$30,036,000 at December 31, 2007. This increase was due to a \$3,353,000 increase in purchases of inventory offset by a decrease of \$557,000 of fixed assets and drug licenses in accounts payable and accrued expenses. In addition, foreign currency fluctuations increased accounts payable and accrued expenses by \$2,747,000.

Short-term borrowings and current portion of long-term debt increased from \$554,000 at December 31, 2006 to \$724,000 at December 31, 2007. The increase was primarily due to \$116,000 drawn against the credit line as well as an increase in the portion of debt that became classified as short-term debt during the year ended December 31, 2007 of \$608,000. The weighted average interest rate on our short-term borrowings and current portion of long-term debt at December 31, 2007 was 5.05%.

**Table of Contents**

Other liabilities totaled \$3,607,000 in 2007, of which \$1,137,000 was classified as current on the Consolidated Balance Sheet, primarily related to the settlement of litigation in 2006. At December 31, 2007, we have recorded a liability of \$2,754,000, representing the net present value of the remaining settlement liability, of which \$1,000,000 is classified as current.

Operating activities in 2007 provided net cash of \$14,749,000 compared to \$4,502,000 in 2006. Net income, which increased to \$2,685,000 in 2007, and changes in working capital accounted for the majority of the increase in cash flows from operations.

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 \$12,651,000 in 2007.

Financing activities during 2007 provided net cash of \$14,914,000, and primarily represented the cash proceeds of approximately \$14,901,000 received from borrowings, \$619,000 from the exercise of stock options, offset by the following: (1) the remittance of employee tax withholding liabilities of approximately \$52,000 resulting from stock option exercises, and (2) net repayments of short-term borrowings totaling \$554,000.

Long-term debt, net of current portion of \$608,000, totaled \$15,595,000 at December 31, 2007. On June 29, 2007, the Company's subsidiary, Laboratorios Belmac (Belmac), entered into a loan agreement with a Spanish financial institution, pursuant to which Belmac borrowed 11,000,000 Euros (approximately \$16,203,000 at December 31, 2007). In accordance with the loan agreement, Belmac will be charged interest on the loan at a variable rate, reset quarterly, equal to the Euro Interbank Offered Rate, plus 0.5%, plus a single, up-front fee of 0.2%. The interest rate under the loan at December 31, 2007 was 5.2%. The principal of the loan will be repaid in quarterly installments of 412,500 Euros (approximately \$608,000) beginning December 31, 2008, with the balance due on December 31, 2013.

Pursuant to financial covenants in the loan agreement, Belmac must (i) maintain a net financial debt to net equity ratio of less than 0.33 to 1; (ii) maintain a net financial debt to operating profit ratio of less than 2.75 to 1; and (iii) not have either such ratio increase in any fiscal year by more than 20% over the respective ratio from the prior fiscal year. In addition, Belmac's obligations under the loan agreement have been guaranteed by Bentley and Bentley's other subsidiaries in Spain. Belmac has agreed to pledge assets at the request of the financial institution if Belmac fails to comply with these financial covenants and Belmac has also agreed to not pledge any assets to any other party. The loan may be prepaid at any time without a fee. At December 31, 2007, the Company is in compliance with all financial and non-financial debt covenants.

Long-term debt which totaled \$307,000 at December 31, 2006 and was classified as current in the Consolidated Balance Sheet was repaid during 2007.

**Table of Contents***Contractual Obligations*

We have fixed contractual obligations under various agreements. Our contractual obligations were comprised of the following as of December 31, 2007:

<i>(in thousands)</i>	<i>Total</i>	<i>Payments Due By Period</i>			
		<i>Less than 1 year</i>	<i>1 - 3 years</i>	<i>3 - 5 years</i>	<i>More than 5 years</i>
<i>Long-term debt</i>	\$ 16,203	\$ 608	\$ 4,860	\$ 4,860	\$ 5,875
<i>Short-term borrowings</i>	116	116			
<i>Capital leases</i>					
<i>Operating leases</i>	3,070	1,754	1,237	79	
<i>Purchase obligations (1)</i>	8,087	7,501	586		
<i>Other current liabilities (2)</i>	1,137	1,137			
<i>Other long-term liabilities (2)</i>	2,016		2,016		
<i>Total contractual cash obligations (3)(4)</i>	\$ 30,629	\$ 11,116	\$ 8,699	\$ 4,939	\$ 5,875

(1) 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 obligations primarily consist of

\$2.8 million for capital expenditures, \$2.7 million for preclinical and clinical projects and \$1.8 million related to compensation agreements with key management. Contractual obligations related to capital expenditures represent commitments made by the Company for the purchase of machinery, construction and engineering services. Purchase obligations related to preclinical and clinical projects have been estimated by management using the most recent project plans. Purchase obligations related to compensation to key management personnel under employment agreements are expected to be renewed annually unless terminated by any of the parties or amended by the

Compensation  
Committee of  
the Board of  
Directors.

- (2) Included in other liabilities at December 31, 2007 are the present value of three annual payments of \$1,000,000 to be paid in connection with the settlement of litigation in 2006 and the value of a hedging instrument obtained to reduce the currency risk on the settlement obligation, of which \$1,991,000 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, 2007.
- (3) Not included in the chart above is an aggregate of \$1,081,000, of which approximately \$360,000 is current, of

deferred taxes due to be paid to the Spanish Ministry of Taxes over the next three years which resulted from the sale of certain drug licenses in prior years. These deferred tax liabilities are netted against the Company's deferred tax assets on the 2007 Consolidated Balance Sheet.

- (4) Not included in the table above are unrecognized tax benefits totaling \$763,000, of which \$309,000 is classified as current in the Consolidated Balance Sheet as of December 31, 2007. None of our uncertain tax positions are currently subject to ongoing examinations by taxing authorities. Additionally, we expect our unrecognized tax benefits to expire due to statute of limitations without examination by

such taxing  
authorities.

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, \$1,000,000 in the fourth quarter of 2007 and are obligated to make three additional payments of \$1,000,000 in each of the fourth quarters of 2008, 2009 and 2010.

## **Table of Contents**

We plan to continue making improvements to our manufacturing facilities during 2008 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 \$11.0 million to \$13.0 million in capital expenditures during 2008, including approximately \$2.8 million budgeted in 2007, that is now planned for 2008. 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.

*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.

### **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. We provide our customers with a limited right of return. Revenue is recognized upon delivery of products and a reserve for sales returns is recorded when considered appropriate. 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.



**Table of Contents**

- o We earn royalty revenues on Auxilium's 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 due to a change in estimate, which, based upon historical experience, allowed us to reasonably estimate future product returns on sales of Testim.
  
- o We enter into licensing and supply agreements with certain customers that provide for the supply of specified products at specified prices. Our two deliverables in these agreements (the license and the product sales) do not meet the criteria for separation under Emerging Issues Task Force (EITF) Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*, and are therefore accounted for as one unit of account in accordance with EITF 00-21. Specifically, the license agreements contain contractual restrictions whereby the licensees are obligated to purchase the licensed products exclusively from us for the entire term of the related supply agreement. Additionally, our licensees are precluded from being able to sell, sub-lease or transfer their rights or from being able to manufacture the product in-house. Our product sales under the agreements are recognized in the same manner as our normal product sales. The license fees, which are due and payable upfront, are refundable to the customer until the customer has received marketing authorization to sell the licensed product. Accordingly, we defer the revenue recognition of the license fees until the customer obtains marketing authorization. We then recognize the license fees as revenue on a straight line basis over the term of the related supply agreement.

- 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.

*Inventories.* Inventories are stated at the lower of cost or market, cost being determined on the first-in, first-out method. We analyze our inventory on a quarterly basis and write-down inventory that has a cost basis in excess of its expected net realizable value. The determination of whether or not inventory costs will be realized requires management estimates. Actual results may differ from those estimates and require inventory to be written-down, resulting in a new cost basis until sold. Reserves for slow moving or obsolete inventories are provided based on historical experience and forecasted demand. We recorded adjustments totaling \$1,090,000 to write-down inventories to their net realizable value and reserve for slow moving inventories with respect to our U.S. simvastatin products in the year ended December 31, 2007.

*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. We recorded impairment changes totaling \$1,433,000 to research and development expenses in the year ended December 31, 2007 as a result of such reviews.

*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



**Table of Contents**

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 expected life of the award; (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.

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.

*Clinical trial expenses.* Clinical trial expenses, which are reflected in research and development expenses, result from obligations under contract with vendors, consultants, and clinical sites in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations which vary from contract to contract and may result in cash flows which are not consistent with the periods in which materials or services are provided. These costs are capitalized upon payment and expensed according to the progress of each trial as measured by patient progression and the timing of various aspects of the trial. The progress of the trials, including the level of services performed, is determined for financial reporting purposes based upon judgments made after discussions with internal personnel as well as outside service providers.

*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.

**Table of Contents**

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.

Effective January 1, 2007, we account for uncertain tax positions in accordance with Financial Accounting Standards Board Interpretation No. 48, *Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109, Accounting for Income Taxes* ( FIN No. 48 ). As a result of the implementation of FIN No. 48, we recorded a \$405,000 increase in our non-current liabilities for uncertain tax positions which was accounted for as an increase to the January 1, 2007 accumulated deficit. The application of income tax law is inherently complex. Income tax laws and regulations are voluminous and often ambiguous. As such, we are required to make many subjective assumptions and judgments regarding our income tax exposures. Interpretations and guidance surrounding income tax laws and regulations change frequently. Changes in our subjective assumptions and judgments could have a material effect on our financial position, results of operations or cash flows. In addition, as we operate within multiple taxing jurisdictions, we are subject to audit in those jurisdictions. The ultimate resolution of tax audits may require an extended period of time. Although we believe an adequate provision has been made for uncertain tax positions, there is the possibility that the ultimate resolution of such positions 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**

On January 1, 2007, we adopted the provisions of Financial Accounting Standards Board Interpretation No. 48, *Accounting for Uncertainty in Income Taxes – an interpretation of FASB Statement No. 109* ( FIN 48 ). The purpose of FIN 48 is to clarify and set forth consistent rules for accounting for uncertain tax positions in accordance with Statement of Financial Accounting Standards No. 109, *Accounting for Income Taxes* ( SFAS No. 109 ) by requiring the application of a more likely than not threshold for the recognition and derecognition of tax positions. As a result of the implementation of FIN 48, we recorded a \$405,000 increase in our non-current liabilities on January 1, 2007 for uncertain tax positions, which was accounted for as an increase to accumulated deficit. In order to conform with the balance sheet disclosure requirements of FIN 48, we also reclassified our previously recorded liabilities of \$546,000 for uncertain tax positions from accrued expenses to other non-current liabilities on January 1, 2007. We had \$935,000 of unrecognized tax benefits at the adoption date, all of which would affect our effective tax rate if recognized.

On January 1, 2007, we adopted Statement of Financial Accounting Standards ( SFAS ) No. 157, *Fair Value Measurements* ( SFAS No. 157 ), which provides guidance for measuring the fair value of assets and liabilities, and requires expanded disclosures about fair value measurements. SFAS No. 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 adoption of SFAS No. 157 did not have a material impact on our Consolidated Financial Statements.

In February 2007, the Financial Accounting Standards Board ( FASB ) issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities – including an amendment of FASB Statement No. 115*, ( SFAS

No. 159 ). SFAS No. 159 permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. SFAS No. 159 also establishes presentation and disclosure requirements designed to facilitate comparisons between entities that choose different measurement attributes for similar types of assets and liabilities. SFAS No. 159 becomes effective for us as of January 1, 2008. We are currently evaluating the impact SFAS No. 159 will have on our consolidated financial statements.

**Table of Contents**

In June 2007, the FASB ratified the consensus reached by the EITF on Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities* ( EITF Issue No. 07-3 ). EITF Issue No. 07-3 states that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. Such amounts should be recognized as an expense as the related goods are delivered or the related services performed. If an entity does not expect the goods to be delivered or services to be rendered, the capitalized advance payment should be charged to expense. EITF Issue No. 07-3 is effective for fiscal years beginning after December 15, 2007 and earlier application is not permitted. We often enter into agreements for research and development goods and service. As such, we are evaluating the impact that the adoption of EITF Issue No. 07-3 will have on our consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations* ( SFAS No. 141(R) ), which replaces SFAS No. 141. SFAS No. 141(R) establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any noncontrolling interest in the acquiree and the goodwill acquired. The Statement also establishes disclosure requirements which will enable users to evaluate the nature and financial effects of the business combination. SFAS No. 141(R) is effective for fiscal years beginning after December 15, 2008. We have not determined the effect that the application of SFAS No. 141(R) will have on our consolidated financial statements.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements – an amendment of Accounting Research Bulletin No. 51* ( SFAS No. 160 ) which establishes accounting and reporting standards for ownership interests in subsidiaries held by parties other than the parent, the amount of consolidated net income attributable to the parent and to the noncontrolling interest, changes in a parent's ownership interest and the valuation of retained noncontrolling equity investments when a subsidiary is deconsolidated. The Statement also establishes reporting requirements that provide sufficient disclosures that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. SFAS No. 160 is effective for fiscal years beginning after December 15, 2008. We have not determined the effect that the application of SFAS No. 160 will have on our consolidated financial statements.

In December 2007, the FASB ratified the consensus reached by the EITF on Issue No. 07-1, *Accounting for Collaborative Agreements* ( EITF Issue No. 07-1 ). EITF Issue No. 07-1 provides the definition of a collaborative agreement and guidelines to assist an entity in determining whether or not it is a party in a collaborative agreement. EITF Issue No. 07-1 states that costs incurred and revenues generated from transactions with third parties shall be reported in accordance with EITF Issue No. 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent*. EITF Issue No. 07-1 also provides minimum disclosure requirements for an entity's collaboration agreements and transition guidance. EITF Issue No. 07-1 is effective for fiscal years beginning after December 15, 2008. We are evaluating the impact that the adoption of EITF Issue No. 07-1 will have 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, 2007, 2006 and 2005 are as follows:

**Table of Contents**

<b>U.S. Dollars per Euro</b>	<b>2007</b>	<b>2006</b>	<b>2005</b>
Weighted average exchange rate	1.37	1.26	1.24
Exchange rate	1.47	1.31	1.19

After we concluded our settlement of intellectual property litigation in 2006, we entered into forward contracts designed to reduce the effect of fluctuations in foreign currency on the litigation settlement payments scheduled to be made annually through 2010. These contracts are subject to foreign currency risk. Additionally, we have short-term foreign currency denominated debt. We applied a sensitivity analysis to reflect the impact that a 10% hypothetical change in the foreign currency rates would have on the value of our forward contracts and foreign currency denominated debt.

<b>Financial instrument:</b>	<b>Favorable (Unfavorable)</b>		<b>Impact on</b>
	<b>Assuming a 10% Increase</b>	<b>Assuming a 10% Decrease</b>	
	<b>in FX Rates</b>	<b>in FX Rates</b>	
Forward contracts (Euro)	\$ (254,351)	\$ 309,136	Fair value
Foreign currency denominated debt	\$(1,617,000)	\$1,617,000	Fair value

There are many economic factors that can affect volatility in foreign exchange rates. As such factors cannot be predicted, the actual impact on earnings due to a change in the respective rates could vary substantially from the amounts calculated above.

The net effect of foreign currency translation on our Consolidated Balance Sheet during the year ended December 31, 2007 was an increase of \$10,120,000 and the cumulative historical effect was an increase of \$18,992,000, 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 interest rate on our long-term debt of \$15,595,000 at December 31, 2007 was 5.02%. The interest rate on our long-term debt is variable and resets quarterly. The effect of an increase in interest rates of one percentage point (one hundred basis points) to an average of 6.02% on our long-term debt would have the effect of increasing interest expense by approximately \$156,000 annually; however, no payments are due under the loan agreement until December 31, 2008. The weighted average interest rate on our short-term borrowings totaling \$724,000 at December 31, 2007 was 5.05%. The effect of an increase in the interest rate of one percentage point (one hundred basis points) to 6.05% on our short-term borrowings would have the effect of increasing interest expense by approximately \$7,000 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**

*(a) Evaluation of Disclosure Controls and Procedures.*

Our management, with the participation of our Chief Executive Officer, or CEO, and Chief Financial Officer, or CFO, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act) as of December 31, 2007. In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and our management necessarily applied its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Management has concluded that the controls over the consolidation process for one of the Company's subsidiaries were not effective as of December 31, 2007 and represented a material weakness, as described below in management's report on internal control over financial reporting. Based on this evaluation and the material weakness described below, our CEO and CFO concluded that our disclosure controls and procedures were not effective as of December 31, 2007.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Notwithstanding the existence of the material weakness described below in management's report on internal control over financial reporting, the consolidated financial statements included in this Annual Report on Form 10-K fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented.

*(b) 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 Securities Exchange Act. Under the supervision and with the participation of our management, including our CEO and CFO, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ( COSO ).

Our internal control over financial reporting includes policies and procedures that pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect transactions and dispositions of assets, provide reasonable assurances that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that receipts and expenditures are being made in accordance with authorizations of our management and Directors; and provide reasonable assurance regarding prevention or timely detection of unauthorized acquisitions, use or disposition of our assets that could have a material effect on our financial statements.

A material weakness is defined as a deficiency, or a combination of deficiencies, in internal controls over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

**Material Weakness in consolidation process for one of the Company's subsidiaries**

Based on our evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2007, management identified a material weakness related to the inadequate design of our controls related to our ability to apply generally accepted accounting principles as they relate to identifying, reconciling, and appropriately eliminating intercompany balances for one of our subsidiaries. This material weakness resulted in a post-closing adjustment proposed to and recorded in the Company's consolidated financial statements affecting inventory and cost of sales. This adjustment is reflected in the accompanying consolidated financial statements for the year ended December 31, 2007, and was not material; however there is a reasonable possibility that a material misstatement of the annual or interim financial statements could have occurred and not be prevented or detected on a timely basis.

Because of the material weakness described above, management has concluded that we did not maintain effective internal control over financial reporting as of December 31, 2007, based on criteria in Internal Control – Integrated

Framework issued by the COSO.

Deloitte & Touche LLP, our independent registered public accounting firm which also audited our consolidated financial statements, has issued an attestation report on our internal control over financial reporting, which appears below.

**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 Bentley Pharmaceuticals, Inc. and subsidiaries (the Company's) internal control over financial reporting as of December 31, 2007, 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, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on 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, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on that risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weakness has been identified and included in management's assessment:

The Company did not design effective controls over the consolidation process for one of the Company's subsidiaries with respect to identifying, reconciling, and appropriately eliminating certain intercompany balances in the appropriate accounting period.

This material weakness was considered in determining the nature, timing, and extent of audit tests applied in our audit of the consolidated financial statements of the Company as of and for the year ended December 31, 2007, and this report does not affect our report on such financial statements.

**Table of Contents**

In our opinion, because of the effect of the material weakness identified above on the achievement of the objectives of the control criteria, the Company has not maintained effective internal control over financial reporting as of December 31, 2007, based on 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 consolidated financial statements as of and for the year ended December 31, 2007, of the Company and our report dated March 17, 2008, expressed an unqualified opinion on those financial statements, and includes an explanatory paragraph regarding the Company's adoption of Financial Accounting Standards Board Interpretation No. 48, *Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 109*, effective January 1, 2007.

/s/ Deloitte & Touche LLP

Boston, Massachusetts

March 17, 2008

**Table of Contents**

*(c) 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.

**Management remediation plan**

During the first quarter of 2008, management added to its internal control over financial reporting a specific control procedure designed to remediate the material weakness described above.

**Item 9B. Other Information**

Not applicable.

**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	58	Chairman, Chief Executive Officer and Director
Michael McGovern	64	Vice Chairman and Director
John A. Sedor	63	President
Richard P. Lindsay	46	Vice President, Chief Financial Officer, Treasurer and Secretary
Adolfo Herrera	48	Managing Director of European Subsidiaries
Miguel Fernandez	77	Director
F. Ross Johnson	76	Director
Edward J. Robinson	67	Director
John W. Spiegel	67	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 drug delivery company. 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 international 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 Executive Officer of RJR/Nabisco, Inc. He received a Bachelor of Commerce from the University of Manitoba, Canada and an MBA from the University of Toronto and has received several honorary degrees. Mr. Johnson has served on the board of 27 public companies over the past 35 years. He currently serves on the board of directors of AuthentiDate Holding Corporation, Bennett Advisory Group Palm Beach, Quebec 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 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

## **Table of Contents**

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 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 2008 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, 2007, 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 26, 2007, 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, 2007 (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).

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



**Table of Contents**

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 2008 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 2008 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 2008 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 2008 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-40
(2) Financial Statement Schedules:	
None	
(3) Exhibits See index beginning on page 77	
(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*	Letter Agreement dated December 13, 2007 by and between Laboratorios Belmac, S.A. and Adolfo Herrera Málaga.
10.18*	Amended and Restated Employment Agreement dated as of August 20, 2007 between the Registrant and James R. Murphy. (Reference is made to Exhibit 10.1 to the Registrant's Form 10-Q for the quarter ended September 30, 2007, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)
10.19*	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.)
10.20*	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.)
10.21*	Letter Agreement dated March 17, 2008 amending the Employment Agreement between the Registrant and Richard P. Lindsay.
10.22*	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.)
10.23	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.)
10.24	Letter Amendment dated February 8, 2008 between the Registrant and Yungtai Hsu effective December 31, 2007. (Reference is made to Exhibit 10.1 to the Registrant's Form 8-K filed on February 13, 2008, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)

**Table of Contents**

Exhibit Number	Description
10.25	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.)
10.26	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.)
10.27	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.)
10.28	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.)
10.29	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.)
10.30	Settlement Term Sheet Agreement, dated September 29, 2006, between Ethypharm S.A. France, Ethypharm S.A. Spain, the Registrant and Laboratorios Belmac S. A. (Reference is made to Exhibit 10.29 to the Registrant's Form 10-K for the year ended December 31, 2006, Commission File No. 1-10581, which exhibit is incorporated herein by reference.)
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 17, 2008

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 James R. Murphy	Chairman, Chief Executive Officer and Director (principal executive officer)	March 17, 2008
/s/ Michael McGovern Michael McGovern	Vice Chairman and Director	March 17, 2008
/s/ Richard P. Lindsay Richard P. Lindsay	Vice-President, Chief Financial Officer, Treasurer and Secretary (principal financial officer)	March 17, 2008
/s/ Robert P. Hebert Robert P. Hebert	Controller, Assistant Treasurer and Assistant Secretary (principal accounting officer)	March 17, 2008
/s/ Miguel Fernandez Miguel Fernandez	Director	March 17, 2008
/s/ F. Ross Johnson F. Ross Johnson	Director	March 17, 2008
/s/ Edward J. Robinson Edward J. Robinson	Director	March 17, 2008
/s/ John W. Spiegel John W. Spiegel	Lead Director	March 17, 2008





**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, 2007 and 2006	F-3
Consolidated Income Statements for the years ended December 31, 2007, 2006 and 2005	F-4
Consolidated Statements of Changes in Stockholders' Equity for the years ended December 31, 2007, 2006 and 2005	F-5
Consolidated Statements of Cash Flows for the years ended December 31, 2007, 2006 and 2005	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, 2007 and 2006, 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, 2007. 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 Bentley Pharmaceuticals, Inc. and subsidiaries as of December 31, 2007 and 2006, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2007, 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 Financial Accounting Standards Board ( FASB ) Interpretation No. 48, *Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 109*, effective January 1, 2007 and 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 Company's internal control over financial reporting as of December 31, 2007, 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 17, 2008 expressed an adverse opinion on the Company's internal control over financial reporting because of a material weakness.

/s/ Deloitte & Touche LLP

Boston, Massachusetts

March 17, 2008

F -2

---

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

<i>(in thousands, except per share data)</i>	<b>December 31, 2007</b>	<b>December 31, 2006</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 33,706	\$ 12,424
Marketable securities	1,010	3,177
Receivables, net	39,324	32,963
Inventories	17,658	16,279
Deferred taxes	1,067	1,049
Prepaid expenses and other	1,915	1,798
Total current assets	94,680	67,690
Non-current assets:		
Fixed assets, net	59,191	48,556
Drug licenses and related costs, net	16,624	16,026
Restricted cash	1,000	1,000
Deferred taxes	676	240
Other	925	844
Total non-current assets	78,416	66,666
Total assets	\$ 173,096	\$ 134,356
<b>Liabilities and Stockholders Equity</b>		
Current liabilities:		
Accounts payable	\$ 19,413	\$ 14,566
Accrued expenses	10,623	9,704
Short-term borrowings	116	247
Current portion of long-term debt	608	307
Deferred income	1,186	1,045
Other current liabilities	1,137	1,518
Total current liabilities	33,083	27,387
Non-current liabilities:		
Long-term debt	15,595	
Deferred income	5,976	3,899
Other	2,470	2,739

Edgar Filing: BENTLEY PHARMACEUTICALS INC - Form 10-K

Total non-current liabilities	24,041	6,638
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, 22,376 and 22,262 shares	447	445
Additional paid-in capital	143,269	140,030
Accumulated deficit	(46,736)	(49,016)
Accumulated other comprehensive income	18,992	8,872
Total stockholders' equity	115,972	100,331
Total liabilities and stockholders' equity	\$ 173,096	\$ 134,356

*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>2007</b>	<b>2006</b>	<b>2005</b>
Revenues:			
Net product sales	\$ 112,999	\$ 100,590	\$ 91,308
Licensing and collaboration revenues	11,688	8,881	6,422
Total revenues	124,687	109,471	97,730
Cost of net product sales	64,010	49,850	46,161
Gross profit	60,677	59,621	51,569
Operating expenses:			
Selling and marketing	18,523	16,153	16,347
General and administrative	17,073	14,801	11,405
Research and development	13,600	10,459	5,800
Litigation settlement		10,914	593
Separation costs	2,020		
Depreciation and amortization	2,059	1,895	1,758
Total operating expenses	53,275	54,222	35,903
(Loss) gain on sale of drug license	(111)	38	
Income from operations	7,291	5,437	15,666
Other income (expenses):			
Interest income	1,092	820	928
Interest expense	(598)	(158)	(211)
Other, net	434	(43)	12
Income before income taxes	8,219	6,056	16,395
Provision for income taxes	5,534	5,082	5,476
Net income	\$ 2,685	\$ 974	\$ 10,919
Net income per common share:			
Basic	\$ 0.12	\$ 0.04	\$ 0.51

Diluted	\$ 0.12	\$ 0.04	\$ 0.48
Weighted average common shares outstanding:			
Basic	22,339	22,141	21,558
Diluted	22,957	23,068	22,929

*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**

*(in thousands)*

	<b>\$0.02 Par Value Common Stock</b>		<b>Additional Paid-In Capital</b>	<b>Accumulated Deficit</b>	<b>Accumulated Other Comprehensive Income</b>	<b>Total</b>
	<b>Shares</b>	<b>Amount</b>				
Balance at January 1, 2005	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)
Stock-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)
Stock-based compensation	16		2,154			2,154
Balance at December 31, 2006	22,262	445	140,030	(49,016)	8,872	100,331
Comprehensive income:						



Edgar Filing: BENTLEY PHARMACEUTICALS INC - Form 10-K

Net income				2,685			2,685
Other comprehensive income:							
Foreign currency translation adjustment					10,120		10,120
Comprehensive income							\$ 12,805
Cumulative effect of change in accounting from the implementation of FIN48				(405)			(405)
Exercise of stock options and vesting of restricted stock units	97	2		617			619
Purchase of treasury shares	(4)			(52)			(52)
Stock-based compensation	21			2,674			2,674
Balance at December 31, 2007	22,376	\$ 447	\$ 143,269	\$ (46,736)	\$ 18,992		\$ 115,972

*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>2007</b>	<b>2006</b>	<b>2005</b>
Cash flows from operating activities:			
Net income	\$ 2,685	\$ 974	\$ 10,919
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	6,712	5,570	5,096
Non-cash charge for inventory write-down and reserves	425		
Non-cash charge for write-down of intangible assets	1,433		
Foreign currency gains	(200)	(133)	
Loss (gain) on sale of drug license	111	(38)	
Stock-based compensation expense	2,674	2,154	280
Change in fair value of derivative instrument	105	186	
Loss on disposal of assets	317	208	481
Other non-cash items	12	12	38
(Increase) decrease in assets and increase (decrease) in liabilities:			
Receivables, net	(2,445)	(3,129)	(2,529)
Inventories	106	(2,691)	(3,701)
Deferred income taxes	(265)	(1,731)	(1,160)
Prepaid expenses and other current assets	(4)	343	(809)
Other assets	(26)	(31)	(681)
Accounts payable and accrued expenses	3,017	(2,663)	4,900
Deferred income	1,441	1,401	(173)
Other liabilities	(1,349)	4,070	(65)
Net cash provided by operating activities	14,749	4,502	12,596
Cash flows from investing activities:			
Additions to fixed assets	(9,989)	(15,313)	(11,018)
Additions to drug licenses and related costs	(2,662)	(2,772)	(2,045)
Proceeds from the sale of fixed assets	30		
Proceeds from sale of drug license	43		
Proceeds from maturity of investments	3,177		461
Purchase of investments	(901)	(2,409)	(461)
Net cash used in investing activities	(10,302)	(20,494)	(13,063)

(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>2007</b>	<b>2006</b>	<b>2005</b>
Cash flows from financing activities:			
Proceeds from the exercise of stock options	\$ 619	\$ 450	\$ 2,028
Remittance of employee tax liabilities in exchange for common stock tendered to the Company	(52)	(1,948)	(2,292)
Purchases of treasury stock			(1,041)
Proceeds from borrowings	14,901	1,643	1,938
Repayment of borrowings	(554)	(4,281)	(1,659)
Net cash provided by (used in) financing activities	14,914	(4,136)	(1,026)
Effect of exchange rate changes on cash	1,921	168	(353)
Net increase (decrease) in cash and cash equivalents	21,282	(19,960)	(1,846)
Cash and cash equivalents at beginning of year	12,424	32,384	34,230
Cash and cash equivalents at end of year	\$ 33,706	\$ 12,424	\$ 32,384

**Supplemental Disclosures of Cash Flow Information**

The Company paid cash during the year for:			
Interest	\$ 226	\$ 118	\$ 204
Foreign income taxes	\$ 4,650	\$ 4,555	\$ 4,231

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

The Company has issued Common Stock as stock-based compensation in lieu of cash during the year as follows:

Shares	21	16	20
Amount	\$ 223	\$ 208	\$ 221
Amounts included in accounts payable at end of year for fixed asset and drug license purchases	\$ 1,404	\$ 1,869	\$ 2,675

*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 200 product presentations (stock keeping units, or SKUs) through three wholly-owned Spanish subsidiaries: Laboratorios Belmac, Laboratorios Davur and Laboratorios Rimafar. Bentley's products are 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 received approval from the U.S. Food and Drug Administration (FDA) in late 2006 for the manufacture of its first U.S. generic product. The Company, through its Spanish subsidiary, Bentley A.P.I., owns a manufacturing facility in Spain that specializes in the manufacturing of several API products. 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 launched its first product in late 2006.

Bentley is also in the business of development, licensing and commercialization of pharmaceutical products utilizing its validated drug delivery technology. Bentley has U.S. and international patents and other proprietary rights to technologies that facilitate the absorption of drugs. Bentley develops and co-develops products that incorporate its drug delivery technologies. Bentley's platform drug delivery technology utilizes CPE-215 to enhance permeation and absorption of pharmaceutical molecules across biological membranes such as the skin, nasal mucosa and eye. Bentley has licensed applications of its proprietary CPE-215 drug delivery technology to Auxilium Pharmaceuticals, Inc. (Auxilium), which launched Testim, the first product incorporating its CPE-215 drug delivery technology, in the United States in February 2003.

On October 23, 2007 the Company announced a plan to spin-off its drug delivery business in a transaction that is subject to a number of conditions. Management expects that shares of the new specialty pharmaceutical drug delivery company, CPEX Pharmaceuticals, Inc., will be distributed to Bentley stockholders by means of a stock dividend. On the record date, which has not yet been set, each Bentley stockholder will be entitled to receive shares of CPEX in connection with the spin-off of the drug delivery

**Table of Contents**

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

business. The spin-off would result in CPEX operating as an independent entity with publicly traded common stock. Bentley would not have any ownership interest in CPEX subsequent to the spin-off.

In connection with the spin-off, CPEX and Bentley expect to enter into a series of agreements, including a separation and distribution agreement, a transition services agreement, an employee matters agreement and a tax allocation agreement. Consummation of the spin-off is subject to several conditions, including final approval by the Bentley Board of Directors, approval for listing of CPEX common stock on a national securities exchange, and the effectiveness of the Form 10 filed with the Securities and Exchange Commission for the registration of the securities of CPEX. Approval by Bentley's stockholders is not required as a condition to the consummation of the proposed spin-off.

The Company has incurred and is expected to continue to incur legal, tax and other strategic consulting costs specifically associated with the planned spin-off. These costs totaled \$2,020,000 for the year ended December 31, 2007 and have been reported as *separation costs* within operating expenses in the Company's Consolidated Income Statements.

**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; Belmac Jamaica, Ltd.; Bentley Pharmaceuticals Ireland Limited; and CPEX Pharmaceuticals, Inc. and its wholly-owned subsidiary, CPEX Pharma, Inc. During fiscal 2007, the Company dissolved the following inactive wholly-owned subsidiaries: 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.; and B.O.G. International Finance, Inc. 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, 2007, 2006 and 2005 are as follows:

<b>U.S. Dollars per Euro</b>	<b>2007</b>	<b>2006</b>	<b>2005</b>
Weighted average exchange rate	1.37	1.26	1.24
Exchange rate	1.47	1.31	1.19

The net effect of foreign currency translation on the Company's net assets during the years ended December 31, 2007, 2006 and 2005 was an increase of \$10,120,000, an increase of \$7,112,000 and a decrease of \$7,962,000, respectively, which have been included in *other comprehensive income*. The cumulative historical effect of foreign currency translation as of December 31, 2007 and 2006 was \$18,992,000 and \$8,872,000, respectively, as reflected in *accumulated other comprehensive income*.

**Table of Contents**

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

**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, 2007 and 2006 are approximately \$9,704,000 and \$357,000, 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.

The Company acquired intellectual property during the year ended December 31, 2003 for \$1,000,000 plus future royalties on sales and licensing income received through February 14, 2020. 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, 2007 and 2006.

**Marketable securities**

The Company has investments in Spanish government treasury bills, with maturities of greater than three months when purchased, totaling \$1,010,000 and \$3,177,000 as of December 31, 2007 and 2006, 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.

**Table of Contents**

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

**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 lesser of the useful life of the assets or 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 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, or more frequently if events or changes in circumstances indicate that the assets may be impaired, comparing the carrying amounts to their estimated future undiscounted cash flows and adjusting for any diminution in value. The Company recorded impairment losses of \$1,433,000 in the year ended December 31, 2007 related to the write-down of its U.S. generic simvastatin drug license and certain other U.S. generic drug projects. At December 31, 2007, the Company also reassessed the useful lives of its remaining drug licenses and related costs and has determined that the estimated useful lives are appropriate for determining amortization expense.

**Other liabilities**

In 2006, the Company and its subsidiary, Laboratorios Belmac, 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, discounted at a rate of 4.72%. In accordance with the payment terms of the settlement, \$4,000,000 was paid in the fourth quarter of 2006, \$1,000,000 was paid in the fourth quarter of 2007 and the three remaining annual payments of \$1,000,000 will be paid in each of the fourth quarters of 2008, 2009 and 2010. At December 31, 2007 and December 31, 2006, the Company had \$2,754,000 and \$3,590,000, respectively recorded in the Consolidated Balance Sheets, representing the net present value of the remaining liability on those dates, of which \$1,000,000 is classified as *other current liabilities* in both years. The Company incurred related litigation defense costs of approximately \$3,368,000 and \$593,000 in the years ended December 31, 2006 and 2005, respectively. The litigation related charges are

F-11



**Table of Contents**

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

recorded in *litigation settlement* expenses on the Company's Consolidated Income Statements. The Company amortized \$175,000 and \$43,000 of the net present value discount to interest expense in the years ended December 31, 2007 and 2006, respectively.

**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 four cash flow hedges designed to reduce the effect of fluctuations in foreign currency on scheduled litigation settlement payments. At December 31, 2007, there were three outstanding contracts remaining, with an aggregate notional amount of \$3.0 million that are expected to mature over the next three 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. The fair value of the cash flow hedges are determined based upon an independent fair value assessment performed by a bank using a market approach valuation technique. At December 31, 2007 and December 31, 2006, the Company had liabilities recorded of \$374,000 and \$186,000, respectively related to these hedges of which \$137,000 and \$37,000, respectively are classified as current in the Consolidated Balance Sheets. The Company recorded corresponding losses of \$148,000 and \$186,000 for the years ended December 31, 2007 and 2006, respectively in *other income (expenses)* in the Consolidated Income Statements.

**Fair value measurements**

On January 1, 2007, the Company adopted Statement of Financial Accounting Standards (SFAS) No. 157, *Fair Value Measurements* (SFAS No. 157), which provides guidance for measuring the fair value of assets and liabilities, and requires expanded disclosures about fair value measurements. SFAS No. 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 adoption of SFAS No. 157 did not have a material impact on the Company's Consolidated Financial Statements for the year ended December 31, 2007.

SFAS No. 157 clarifies that the definition of fair value retains the exchange price notion and focuses on the price that would be received to sell the asset or paid to transfer the liability (an exit price), not the price that would be paid to acquire the asset or received to assume the liability (an entry price). SFAS No. 157 also emphasizes that fair value is a market-based measurement, not an entity-specific measurement, therefore a fair value measurement should be determined based on the assumptions that market participants would use in pricing the asset or liability including assumptions about risk, the effect of sale or use restrictions on an asset and non-performance risk including an entity's own credit risk relative to a liability. SFAS No. 157 establishes a fair value hierarchy that distinguishes between (1) market participant assumptions developed based on market data obtained from sources independent of the reporting entity (observable inputs) and (2) the reporting entity's own assumptions about market

**Table of Contents**

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

participant assumptions developed based on the best information available in the circumstances (unobservable inputs). SFAS No. 157 emphasizes that valuation techniques should maximize the use of observable inputs and minimize the use of unobservable inputs.

The additional disclosure requirements of SFAS No. 157 focus on the inputs used to measure fair value and for recurring fair value measurements using significant unobservable inputs and the effect of the measurement on earnings (or changes in net assets) for the reporting period. Inputs are categorized by a fair value hierarchy, Level 1 through Level 3, the highest priority being given to Level 1 and the lowest priority to Level 3. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date. Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly. Level 3 inputs are unobservable inputs for the asset or liability. Unobservable inputs shall be used to measure fair value to the extent that observable inputs are not available.

The following tables present the Company's assets and liabilities measured at fair value on a recurring basis as of December 31, 2007 and the amounts as they correspond to the respective level within the fair value hierarchy established by SFAS No. 157.

<b>(In Thousands)</b>	<b>Fair Value Measurements at December 31, 2007</b>			
	<b>Total at December 31, 2007</b>	<b>Quoted Prices in Active Markets for Identical Assets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>
<b>Assets:</b>				
Marketable Securities	\$ 1,010	\$ 1,010	\$	\$
<b>Liabilities:</b>				
Cash flow hedges	\$ 374	\$	\$	\$ 374

<b>(In Thousands)</b>	<b>Fair Value Measurements at December 31, 2007 Using Significant Unobservable Inputs (Level 3) Cash Flow Hedges</b>	
Beginning Balance at January 1, 2007	\$	186
Total gains or losses (realized/unrealized):		
Included in earnings (or changes in net assets)		404
Included in other comprehensive income		
Purchases, issuances, and settlements		(216)
Transfers in and/or out of Level 3		
Ending balance at December 31, 2007	\$	374

The amount of total gains or losses for the period included in earnings (or changes in net assets) attributable to the change in unrealized gains or losses relating to assets still held at December 31, 2007 \$

Gains and losses (realized and unrealized) included in earnings (or changes in net assets) for the year ended December 31, 2007 are reported in *Other income (expenses)* in the Company's Consolidated Income Statement.

		<b>Other income (expenses)</b>
Total gains or losses included in earnings (or changes in net assets) for the year ended December 31, 2007	\$	404
Changes in unrealized gains or losses relating to assets held at December 31, 2007	\$	

F-13

---

**Table of Contents**

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

The following table presents the Company's assets measured at fair value on a nonrecurring basis as of December 31, 2007 and the amounts as they correspond to the respective level within the fair value hierarchy established by SFAS No. 157.

(In Thousands)	Total at December 31, 2007	Fair Value Measurements at December 31, 2007 Using:				Total Gains (Losses)
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)		
Assets:	\$ 16,624	\$	\$	\$ 16,624	\$ (1,433)	
Drug licenses and related costs, net						

**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* ( SFAS No. 48 ), and of allowances for doubtful accounts based on significant historical experience.

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. Customer returns were not able to be reasonably estimated prior to April 1, 2006. 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, 2007 and 2006. Total royalty revenues recognized for the years ended December 31, 2007, 2006 and 2005 were \$11,121,000, \$8,341,000 and \$6,132,000, respectively.

The Company enters into licensing and supply agreements with certain customers that provide for the supply of specified products at specified prices. The Company's two deliverables in these agreements (the license and the product sales) do not meet the criteria for separation under EITF 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*, and are therefore accounted for as one unit of account in accordance with EITF 00-21. Specifically, the license agreements contain contractual restrictions whereby the licensees are obligated to purchase the licensed products exclusively from the Company for the entire term of the related supply agreement. Additionally, licensees are precluded from being able to sell, sub-lease or transfer their rights or from being able to manufacture the product in-house. The Company's product sales under the agreements are recognized in the same manner as its normal product sales. The license fees, which are due and payable upfront, are refundable to the customer until the customer

has received marketing authorization to sell the licensed product. Accordingly, the Company defers the revenue recognition of the license fees until the customer obtains marketing authorization. The Company then recognizes the license fees as revenue on a straight line basis over the term of the related supply agreement.

F-14

---

**Table of Contents**

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

The Company has deferred recognition of approximately \$5,424,000 and \$4,797,000 of license fees as of December 31, 2007 and 2006, respectively.

**Research and development**

Research and development expenses consist primarily of costs associated with the clinical trials of product candidates, manufacturing supplies and other development materials, compensation and related benefits for research and development personnel, costs for consultants, and various overhead costs. Research and development costs are expensed as incurred consistent with SFAS No. 2, *Accounting for Research and Development Costs*.

**Clinical trial expenses**

Clinical trial expenses, which are reflected in research and development expenses, result from obligations under contracts with vendors, consultants, and clinical sites in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations which vary from contract to contract and may result in cash flows which are not consistent with the periods in which materials or services are provided. These costs are capitalized upon payment and expensed according to the progress of each trial as measured by patient progression and the timing of various aspects of the trial. The progress of the trials, including the level of services performed, is determined based upon judgments made after discussions with internal personnel as well as outside service providers.

**Provision for income taxes**

On January 1, 2007, the Company adopted the provisions of Financial Standards Accounting Board Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* ( FIN 48 ), an interpretation of FASB Statement No. 109, *Accounting for Income Taxes*, ( SFAS No. 109 ). The purpose of FIN 48 is to clarify and set forth consistent rules for accounting for uncertain tax positions in accordance with SFAS No. 109 by requiring the application of a more likely than not threshold for the recognition and derecognition of tax positions. As a result of the implementation of FIN 48, the Company recorded a \$405,000 increase in its non-current liabilities as of January 1, 2007 for uncertain tax positions, which was accounted for as an increase to accumulated deficit. In order to conform with the balance sheet disclosure requirements of FIN 48, the Company also reclassified its previously recorded liabilities of \$530,000 for uncertain tax positions from accrued expenses to other non-current liabilities as of January 1, 2007.

The following table summarizes the activity related to the Company's unrecognized tax benefits for the year ended December 31, 2007 (in thousands):

Balance at January 1, 2007	\$ 626
Increases related to current year tax positions	78
Expirations due to the lapse of statute of limitations	(234)
Other (primarily impact of fluctuations in foreign currency rates)	44
Balance at December 31, 2007	\$ 514

The Company had \$935,000 of unrecognized tax benefits at the adoption date and \$763,000 as of December 31, 2007, all of which would affect its effective tax rate if recognized. The Company expects a decrease of approximately \$309,000 in its unrecognized tax benefits during the year ended December 31, 2008 as a result of the expiration of certain foreign tax contingencies resulting from the lapse of statute of limitations. The Company recognizes interest and penalties related to uncertain tax positions as a

**Table of Contents**

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

component of the provision for income taxes. As of the date of adoption, the Company had approximately \$249,000 of accrued penalties and \$51,000 of accrued interest related to its uncertain tax positions. As of December 31, 2007, the Company had approximately \$171,000 of accrued penalties and \$78,000 of accrued interest related to its uncertain tax positions. Tax years ranging from 2003 to 2007 remain open to examination by the major taxing authorities in jurisdictions where the Company is subject to taxation, principally the U.S. and Spain.

As a result of reporting taxable income in Spain, the Company recorded provisions for foreign income taxes totaling \$5,534,000 and \$5,082,000 for the years ended December 31, 2007 and 2006, respectively. The provisions represented 28% and 31% of the pre-tax income reported in Spain for the years ended December 31, 2007 and 2006, respectively. The provisions represented 67% and 84% of consolidated pre-tax income for the years ended December 31, 2007 and 2006, respectively.

The Company maintains various agreements by and between Bentley Pharmaceuticals, Inc. and its subsidiaries. Income and expenses resulting from these agreements are eliminated in consolidation; however, the related transactions affect the Company's consolidated income tax provision.

The Company generated a U.S. federal net operating loss of approximately \$23,750,000 in 2007 and net operating income of approximately \$235,000 and \$1,042,000 in 2006 and 2005, respectively. As future operating profits cannot be reasonably assured, no tax benefit has been recorded for these losses. The Company has established valuation allowances equal to the full amount of the U.S. deferred tax assets. Should the Company determine that it is more likely than not that it will realize certain of its net deferred tax assets for which it has previously provided a valuation allowance, an adjustment would be required to reduce the existing valuation allowance.

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 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 \$68,300,000.

**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 were considered in the diluted net income per share calculation for the years ended December 31, 2007, 2006 and 2005.

The following is a reconciliation between basic and diluted net income per common share for the years ended December 31, 2007, 2006 and 2005. Dilutive securities issuable for the years ended December 31, 2007, 2006 and 2005 include approximately 618,000, 927,000 and 1,371,000 dilutive incremental shares issuable as a result of various stock options and unvested restricted stock units that are outstanding.

<b>For The Year Ended December 31, 2007</b>	<b>Basic EPS</b>	<b>Effect of Dilutive Securities</b>	<b>Diluted EPS</b>
	<b>(In Thousands, Except Per Share Data)</b>		
Net income	\$ 2,685	\$	\$ 2,685
Weighted average common shares outstanding	22,339	618	22,957
Net income per common share	\$ 0.12	\$	\$ 0.12

**Table of Contents**

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

<b>For The Year Ended December 31, 2006</b>	<b>Basic EPS</b>	<b>Effect of Dilutive Securities</b>	<b>Diluted EPS</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>For The Year Ended December 31, 2005</b>	<b>Basic EPS</b>	<b>Effect of Dilutive Securities</b>	<b>Diluted EPS</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

For the years ended December 31, 2007, 2006 and 2005, options to purchase 1,485,000, 416,000 and 736,000 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.

**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).

**Stock-based compensation plans**

The Company has stock-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. Stock-based compensation attributable to stock-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 stock-based compensation expense of approximately \$1,829,000, or \$0.08 per basic and diluted share.



**Table of Contents**

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

**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 February 2007, the Financial Accounting Standards Board ( FASB ) issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities – including an amendment of FASB Statement No. 115*, ( SFAS No. 159 ). SFAS No. 159 permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. SFAS No. 159 also establishes presentation and disclosure requirements designed to facilitate comparisons between entities that choose different measurement attributes for similar types of assets and liabilities. SFAS No. 159 becomes effective for the Company as of January 1, 2008. The Company has not elected to measure any of its financial instruments or other items at fair value that are not currently required to be measured at fair value.

In June 2007, the FASB ratified the consensus reached by the EITF on Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities* ( EITF Issue No. 07-3 ). EITF Issue No. 07-3 states that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. Such amounts should be recognized as an expense as the related goods are delivered or the related services performed. If an entity does not expect the goods to be delivered or services to be rendered, the capitalized advance payment should be charged to expense. EITF Issue No. 07-3 is effective for fiscal years beginning after December 15, 2007 and earlier application is not permitted. The Company often enters into agreements for research and

**Table of Contents**

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

development goods and service. As such, the Company is evaluating the impact that the adoption of EITF Issue No. 07-3 will have on its consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations* ( SFAS No. 141(R) ), which replaces SFAS No. 141. SFAS No. 141(R) establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any noncontrolling interest in the acquiree and the goodwill acquired. The Statement also establishes disclosure requirements which will enable users to evaluate the nature and financial effects of the business combination. SFAS No. 141(R) is effective for fiscal years beginning after December 15, 2008. The Company has not determined the effect that the application of SFAS No. 141(R) will have on its consolidated financial statements.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements - an amendment of Accounting Research Bulletin No. 51* ( SFAS No. 160 ) which establishes accounting and reporting standards for ownership interests in subsidiaries held by parties other than the parent, the amount of consolidated net income attributable to the parent and to the noncontrolling interest, changes in a parent's ownership interest and the valuation of retained noncontrolling equity investments when a subsidiary is deconsolidated. The Statement also establishes reporting requirements that provide sufficient disclosures that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. SFAS No. 160 is effective for fiscal years beginning after December 15, 2008. The Company has not determined the effect that the application of SFAS No. 160 will have on its consolidated financial statements.

In December 2007, the FASB ratified the consensus reached by the EITF on Issue No. 07-1, *Accounting for Collaborative Agreements* ( EITF Issue No. 07-1 ). EITF Issue No. 07-1 provides the definition of a collaborative agreement and guidelines to assist an entity in determining whether or not it is a party in a collaborative agreement. EITF Issue No. 07-1 states that costs incurred and revenues generated from transactions with third parties shall be reported in accordance with EITF Issue No. 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent*. EITF Issue No. 07-1 also provides minimum disclosure requirements for an entity's collaboration agreements and transition guidance. EITF Issue No. 07-1 is effective for fiscal years beginning after December 15, 2008. The Company is evaluating the impact that the adoption of EITF Issue No. 07-1 will have on its consolidated financial statements.

**NOTE 3 RECEIVABLES**

Receivables consist of the following (in thousands):

	<b>December 31,</b>	
	<b>2007</b>	<b>2006</b>
Trade receivables (of which \$0 and \$247, respectively, collateralize short-term borrowings with Spanish financial institutions)	\$ 32,279	\$ 27,880
VAT, income and social security taxes receivable	4,333	3,151
Royalties receivable	3,237	2,261
Other	161	82
	40,010	33,374
Less-allowance for doubtful accounts	(686)	(411)
	\$ 39,324	\$ 32,963

**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 doubtful accounts:

	Year Ended December 31,		
	2007	2006	2005
	(In Thousands)		
Balance at beginning of year	\$ 411	\$ 202	\$ 375
Net provisions charged to expenses	212	191	(122)
Write-offs reducing allowance	(29)	(10)	(9)
Effect of foreign currency	92	28	(42)
Balance at end of year	\$ 686	\$ 411	\$ 202

**NOTE 4 INVENTORIES**

Inventories consist of the following:

	December 31,	
	2007	2006
	(In Thousands)	
Raw materials	\$ 11,802	\$ 8,669
Finished goods	6,798	7,621
	18,600	16,290
Less-allowance for slow moving inventory	(942)	(11)
	\$ 17,658	\$ 16,279

Included in the Company's inventories are consigned inventories that have been shipped to the Company's collaborator related to the Company's first U.S. generic product launched in late December 2006. Market price conditions and demand for this product are less favorable than originally estimated. As a result, in 2007, the Company recorded net adjustments totaling \$1,090,000 to write down these inventories to their net realizable value and reserve for slow moving inventories. In accordance with its collaboration agreement, the Company is liable for a portion of these adjustments and has therefore recorded a net charge of approximately \$425,000 to *cost of net product sales* in the Consolidated Income Statement, reflecting its share of these adjustments. These inventories totaled \$1,338,000 at December 31, 2006. These inventories, which have a gross value of \$321,000, have been fully reserved as of December 31, 2007.

As of December 31, 2006, the Company has recorded \$481,000 as payments from its collaborator net of adjustments, which have been recorded in *other current liabilities* on the Consolidated Balance Sheets.

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

	Year Ended December 31,		
	2007	2006	2005
	(In Thousands)		
Balance at beginning of year	\$ 11	\$ 136	\$ 75
Provisions charged to costs and expenses	938	11	70
Write-offs reducing allowance	(11)	(144)	
Effect of foreign currency	4	8	(9)

Balance at end of year	\$ 942	\$ 11	\$ 136
------------------------	--------	-------	--------

F-20

---

**Table of Contents**

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

**NOTE 5 FIXED ASSETS**

Fixed assets consist of the following:

	<b>December 31,</b>	
	<b>2007</b>	<b>2006</b>
	<b>(In Thousands)</b>	
Land	\$ 3,128	\$ 2,875
Buildings and improvements	26,185	17,538
Equipment	26,813	20,591
Furniture and fixtures	2,537	2,138
Other	350	394
	59,013	43,536
Capital in-progress	22,314	20,213
	81,327	63,749
Less-accumulated depreciation	(22,136)	(15,193)
	\$ 59,191	\$ 48,556

In order to support the Company's growth in Europe, management is adding capacity to its manufacturing facilities through a series of improvements. During the years ended December 31, 2007 and 2006, the Company invested approximately \$7,778,000 and \$10,321,000, respectively, renovating and expanding the Company's manufacturing and warehouse facilities and approximately \$1,503,000 and \$4,628,000, respectively, for related machinery and equipment.

Depreciation expense of approximately \$343,000, \$311,000 and \$309,000 has been charged to operations as a component of *depreciation and amortization expense* in the Consolidated Income Statements for the years ended December 31, 2007, 2006 and 2005, respectively. The Company has included depreciation totaling approximately \$4,653,000, \$3,675,000 and \$3,338,000 in *cost of net product sales* during the years ended December 31, 2007, 2006 and 2005, respectively.

**NOTE 6 DRUG LICENSES AND RELATED COSTS**

Drug licenses and related costs consist of the following:

	<b>December 31,</b>	
	<b>2007</b>	<b>2006</b>
	<b>(In Thousands)</b>	
Drug licenses and related costs	\$ 25,667	\$ 23,069
Less-accumulated amortization	(9,043)	(7,043)
	\$ 16,624	\$ 16,026

Amortization expense for drug licenses and related costs was approximately \$1,716,000, \$1,584,000 and \$1,403,000 for the years ended December 31, 2007, 2006 and 2005, respectively, and has been recorded in *depreciation and amortization expense* in the accompanying Consolidated Income Statements.

**Table of Contents**

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

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:

Year Ending December 31,	Future Amortization Expense (In Thousands)
2008	\$1,622
2009	1,670
2010	1,698
2011	1,672
2012	1,660
2013 and beyond	8,302

**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 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, 2007 and December 31, 2006, the Company has recorded approximately 853,400 and 849,100 shares, respectively, as treasury stock, with an historical cost of \$10,833,000 and \$10,781,700, respectively, which has been accounted for as a reduction of *common stock* and *additional paid in capital* in the Consolidated Financial Statements.

**NOTE 8 ACCRUED EXPENSES**

Accrued expenses consist of the following:

	December 31,	
	2007	2006
	(In Thousands)	
Foreign income taxes payable	\$ 1,634	\$ 2,463
Allowance for sales returns	691	784
Accrued payroll and related taxes	5,209	3,288
Spanish pharmaceutical taxes payable	1,443	1,035
Other accrued expenses	1,646	2,134
	\$ 10,623	\$ 9,704

**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:

	<b>Year Ended December 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
	<b>(In Thousands)</b>		
Balance at beginning of year	\$ 784	\$ 887	\$ 597
Provisions charged to costs and expenses	3,154	1,939	898
Write-offs reducing allowance	(3,323)	(2,138)	(652)
Effect of foreign currency	76	96	44
Balance at end of year	\$ 691	\$ 784	\$ 887

**NOTE 9 DEBT**

Short-term borrowings consist of the following:

	<b>December 31,</b>	
	<b>2007</b>	<b>2006</b>
	<b>(In Thousands)</b>	
Trade receivables discounted with Spanish financial institutions, with recourse, effective interest rate is 3.7%	\$	\$ 247
Revolving lines of credit payable to Spanish financial institutions, weighted average interest rate is 5.05%	116	
	\$ 116	\$ 247

The weighted average stated interest rate on short-term borrowings outstanding was 5.05% and 3.7% at December 31, 2007 and 2006, respectively. The Company also maintains revolving line of credit facilities with Spanish financial institutions, which entitled the Company to borrow up to \$7,218,000 at December 31, 2007 at interest rates ranging from 4.92% to 5.12%. The facilities are scheduled to mature on various dates through December 15, 2008 and are renewable.

Long-term debt consists of the following:

	<b>December 31,</b>	
	<b>2007</b>	<b>2006</b>
	<b>(In Thousands)</b>	
Loans payable	\$ 16,203	\$ 307
Less-current portion of long-term debt	(608)	(307)
Total long-term debt	\$ 15,595	\$

**Table of Contents**

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

On June 29, 2007, the Company's subsidiary, Laboratorios Belmac ( Belmac ), entered into a loan agreement with a Spanish financial institution, pursuant to which Belmac borrowed 11,000,000 Euros (equal to approximately \$16,203,000 at December 31, 2007). In accordance with the loan agreement, Belmac will be charged interest on the loan at a variable rate, reset quarterly, equal to the Euro Interbank Offered Rate, plus 0.5%, plus a single, up-front fee of 0.2%. The interest rate under the loan at December 31, 2007 was 5.2%. The principal of the loan will be repaid in quarterly installments of 412,500 Euros (equal to approximately \$608,000 at December 31, 2007) beginning December 31, 2008, with the balance due on December 31, 2013. Maturities on the long-term debt, as expressed in U.S. dollars as of December 31, 2007 are as follows (in thousands):

<b>Year</b>	<b>Principal Payment</b>
2008	\$ 608
2009	2,430
2010	2,430
2011	2,430
2012	2,430
2013	5,875
<b>Total</b>	<b>\$ 16,203</b>

Pursuant to financial covenants in the loan agreement, Belmac must (i) maintain a net financial debt to net equity ratio of less than 0.33 to 1; (ii) maintain a net financial debt to operating profit ratio of less than 2.75 to 1; and (iii) not have either such ratio increase in any fiscal year by more than 20% over the respective ratio from the prior fiscal year. In addition, Belmac's obligations under the loan agreement have been guaranteed by Bentley and Bentley's other subsidiaries in Spain. Belmac has agreed to pledge assets at the request of the financial institution if Belmac fails to comply with these financial covenants and Belmac has also agreed to not pledge any assets to any other party. The loan may be prepaid at any time without a fee.

In previous years, the Company entered into loan agreements with the Spanish government as a part of government-sponsored research-funding programs. The loans were non-interest bearing and payable in annual installments beginning in 2005. These loans were repaid in full in 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, 2007 and 2006, no shares of Preferred Stock were outstanding.

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

At December 31, 2007 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	4,035
For future stock option and restricted stock unit grants	323
	4,358



**Table of Contents**

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

**Common stock and restricted stock unit transactions**

During the year ended December 31, 2007, the Company issued approximately 72,750 shares of Common Stock upon exercise of stock purchase options, approximately 24,500 shares of Common Stock upon the vesting of restricted stock units and approximately 21,300 shares of Common Stock as share-based compensation in lieu of cash. The Company also received approximately 4,300 shares of treasury stock in connection with the exercise of stock purchase options during the year ended December 31, 2007 (See Note 7).

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).

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.

**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. As of December 31, 2007, approximately 4,358,000 shares of Common Stock have been reserved for issuance under the Plans, of which approximately 3,838,000 shares are subject to outstanding stock options and approximately 197,000 shares are subject to outstanding restricted stock units. The balance of approximately 323,000 shares is available for future issuance under the Amended and Restated 2005 Equity and Incentive Plan (the Amended Plan), which is the successor to all the Company's other equity Plans. Of the shares available for future issuance, approximately 1,800 are available only for future grants of stock options, while the remainder are available for any type of award allowed under the Amended Plan. In May 2006, the Company's shareholders had voted to increase the number of shares of Common Stock authorized for issuance pursuant to the Amended Plan by 750,000 shares, but those shares were approved only for grants of stock options.

F-25

---

**Table of Contents**

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

A summary of stock option award activity under the Plans for the three years ended December 31, 2007 are presented below (shares and aggregate intrinsic values in thousands):

	<b>For Year Ended December 31, 2007</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, January 1, 2005	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	
Granted	331	11.97		
Exercised	(73)	8.48		
Forfeited and expired	(57)	12.72		
Options outstanding, December 31, 2007	3,838	\$ 9.97	6.00	\$ 19,658
Vested or expected to vest, December 31, 2007	3,612	\$ 9.97	6.32	\$ 19,550
Options exercisable, December 31, 2007	3,014	\$ 9.64	5.29	\$ 16,417

**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, 2007 (number of options in thousands):

Range of Exercise Prices	Options Outstanding			Options Currently Exercisable	
	Number Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)	Number Exercisable	Weighted Average Exercise Price
\$2.00-\$3.00	54	\$ 2.72	1.16	54	\$ 2.72
5.70 - 5.88	142	5.84	2.39	142	5.84
6.00 - 6.33	262	6.01	3.36	262	6.01
7.10 - 7.39	164	7.30	5.12	136	7.28
7.50	320	7.50	7.25	213	7.50
8.00 - 8.93	298	8.29	5.00	298	8.29
9.00 - 9.80	408	9.67	4.05	408	9.67
10.04	273	10.04	5.39	273	10.04
10.38 - 10.79	200	10.76	6.74	200	10.76
11.00 - 11.98	1,148	11.69	7.83	502	11.44
12.01 - 12.55	203	12.30	7.14	160	12.37
13.30	323	13.30	6.01	323	13.30
13.48 - 15.83	43	14.07	5.90	43	14.07
\$2.00-\$15.83	3,838	\$ 9.97	6.00	3,014	\$ 9.64

A summary of the activity for nonvested share awards for the years ended December 31, 2007, 2006 and 2005 is provided below (shares in thousands):

	For Year Ended December 31,					
	2007		2006		2005	
	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	802	\$ 4.76	840	\$ 4.35	748	\$ 5.58
Granted	331	12.20	481	5.54	870	4.07
Vested	(303)	(4.51)	(499)	(4.82)	(763)	(4.41)
Forfeited	(5)	(7.38)	(20)	(4.62)	(15)	(4.24)
Nonvested options outstanding, end of the period	825	\$ 7.85	802	\$ 4.76	840	\$ 4.35

As of December 31, 2007, unrecognized compensation expense related to the unvested portion of the Company's stock options was approximately \$2,860,000 and is expected to be recognized over a weighted average period of approximately 4.4 years.

Options to purchase approximately 73,000, 739,000 and 1,021,000 shares of Common Stock were exercised during 2007, 2006 and 2005, respectively. Net cash proceeds to the Company from these option exercises totaled approximately \$619,000, \$450,000 and \$2,028,000, respectively, while the total intrinsic value (the excess of the market price over the exercise price) of those option exercises was approximately

F-27

---

**Table of Contents**

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

\$481,000, \$5,586,000 and \$8,583,000, 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 2007, 2006 and 2005 was approximately \$1,367,000, \$2,405,000, and \$3,365,000, 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 unit award activity under the Amended and Restated 2005 Equity and Incentive Plan for the two years ended December 31, 2007 are presented below (shares and aggregate intrinsic values in thousands):

	For the Years Ended December 31, 2007 and 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, January 1, 2006		\$		
	Granted	146	11.47		
Vested	(22)	11.78			
Forfeited	(6)	11.78			
Restricted stock units outstanding, December 31, 2006	118	\$ 11.39	1.69		
Granted	151	12.10			
Vested	(65)	12.71			
Forfeited	(7)	11.66			
Restricted stock units outstanding, December 31, 2007	197	\$ 11.81	1.58	\$ 2,976	
Vested and expected to vest, December 31, 2007	189	\$ 11.82	1.58	\$ 2,855	

During 2007, the Company granted 111,000 restricted stock units to employees with a weighted average grant date fair value of \$12.06 and 40,000 restricted stock units to non-employee directors with a weighted average grant date fair value of \$12.20. These restricted stock units were granted in the second quarter of 2007.

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, 2007, unrecognized compensation expense related to the unvested portion of the Company's restricted stock units was approximately \$1,936,000 and is expected to be recognized over a weighted average period of approximately 2.8 years. The Company's restricted stock units issued to its employees are outstanding until vested, at which time they are settled by the issuance of the underlying shares.



**Table of Contents**

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

At December 31, 2007, 60,000 units of vested restricted stock are contingently issuable to non-employee directors that, pursuant to the terms and conditions of the restricted stock unit agreements, will be issued on the earlier of the date the respective director ceases to serve as a director of the Company or the date the director has otherwise designated by a proper election filed with the Company. The balance of restricted stock units that vested in 2007 and 2006 resulted in the issuance of 25,000 shares of Common Stock to employees and the issuance of approximately 2,000 shares of Common Stock to one employee, respectively. The intrinsic value of these shares when they vested was approximately \$370,000 and \$20,000 in 2007 and 2006, respectively. 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.

**Stock-based compensation**

Share-based compensation expense recorded for stock option and restricted stock unit awards to employees, non-employee directors and one consultant for the years ended December 31, 2007 and 2006 was approximately \$2,329,000 and \$1,929,000, respectively. The related expenses were recorded in the Company's Consolidated Income Statements as follows (in thousands):

	<b>For the Year Ended</b>	
	<b>December 31,</b>	
	<b>2007</b>	<b>2006</b>
<i>Cost of net product sales</i>	\$ 35	\$ 26
<i>Selling and marketing expenses</i>	18	13
<i>General and administrative expenses</i>	1,440	1,226
<i>Research and development expenses</i>	836	664
	<b>\$ 2,329</b>	<b>\$ 1,929</b>

During 2006, the Company entered into a separation agreement with its Former CFO, pursuant to which certain stock-based awards were modified 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 stock-based compensation expense in *general and administrative expenses* in the year ended December 31, 2006.

No related compensation cost 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 stock-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 21,300, 16,400 and 20,100 shares of Common Stock to its 401(k) Plan as matching contributions during the years ended December 31, 2007, 2006 and 2005, 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.

Stock-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. The related expenses were recorded in the Company's Consolidated Income Statements as follows (in thousands):

F-29

**Table of Contents**

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

	<b>For the Year Ended December 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
<i>General and administrative expenses</i>	\$ 107	\$ 102	\$ 113
<i>Research and development expenses</i>	238	122	167
	\$ 345	\$ 224	\$ 280

As the Company previously adopted only the pro forma disclosure provisions of SFAS No. 123, compensation cost relating to the unvested portion of stock-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 pro forma effect that stock-based compensation expense would have had on net income and earnings per share for the year ended December 31, 2005.

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

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, 2007, 2006 and 2005 are provided below (results may vary depending on the assumptions applied within the model):



**Table of Contents**

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

	Year Ended December 31,		
	2007	2006	2005
Risk free interest rate	4.79%	4.95%	3.90%
Dividend yield	0.00%	0.00%	0.00%
Expected life	5 years	5 years	5 years
Volatility	44.57%	46.24%	45.28%
Fair value of options granted	12.20	\$ 5.54	\$ 4.04

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 expected life of the respective award. The maximum contractual term of the Company's stock-based awards is 10 years.

As stock-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.

**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.

**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>2007</b>	<b>2006</b>	<b>2005</b>
	<b>(In Thousands)</b>		
Current:			
Foreign	\$ 5,962	\$ 6,254	\$ 6,515
Deferred:			
State	(38)	(96)	120
Federal	(4,671)	2,134	134
Foreign	(428)	(1,171)	(1,039)
Tax effect of operating loss carryforwards:			
State	(56)	(56)	(56)
Foreign	1,563	(1,303)	(260)
Change in valuation allowance	3,202	(680)	62
Total provision for income taxes	\$ 5,534	\$ 5,082	\$ 5,476

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>2007</b>	<b>2006</b>	<b>2005</b>
	<b>(In Thousands)</b>		
Statutory federal income taxes	\$ 2,794	\$ 2,059	\$ 6,230
Foreign income tax rate differential	(2,933)	2,405	7
Permanent differences from foreign subsidiary	205	346	311
Foreign dividend	7,259		
State income taxes	(93)	(152)	63
Expiration/Reduction of loss carryforwards	2,316	2,119	
Impact of foreign tax rate changes	128	(33)	
Tax credits	(7,252)	(1,044)	(1,124)
Other	(92)	62	(73)
Change in valuation allowance	3,202	(680)	62
	\$ 5,534	\$ 5,082	\$ 5,476

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.

**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>2007</b>	<b>2006</b>
	<b>(In Thousands)</b>	
Deferred tax assets:		
NOL carryforwards	\$ 16,361	\$ 20,010
Disposition of subsidiary	6,845	6,909
Foreign tax on deferred income	2,556	1,767
Tax credit carryforwards	7,305	1,303
Other, net	1,975	1,166
Total deferred tax assets	35,042	31,155
Foreign deferred tax liability	(2,307)	(2,074)
Other deferred tax liabilities	(215)	(217)
Valuation allowance	(30,777)	(27,575)
Deferred tax asset (liability), net	\$ 1,743	\$ 1,289

The Company recorded provisions for foreign income taxes totaling \$5,534,000, \$5,082,000 and \$5,476,000, for the years ended December 31, 2007, 2006, and 2005, respectively. The effective tax rate in 2007 was 67% compared to 84% in 2006 and 33% in 2005. The effective tax rate in 2007 on Spanish operations was 28% compared to 31% in both 2006 and 2005.

The Company generated a U.S. net operating loss of approximately \$23,750,000 in 2007, compared to net operating income of approximately \$235,000 and \$1,042,000 in 2006 and 2005, respectively.

The Company's 2007 net current and non-current deferred tax assets of \$1,067,000 and \$676,000, 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. The Company has recorded a full valuation for its net deferred tax assets in the U.S.

Should the Company determine that it is more likely than not that it will realize certain of its net deferred tax assets for which it has 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 had unrecognized tax benefits totaling \$514,000 at December 31, 2007, of which \$78,000 has been recorded in the *provision for income taxes* in the current year and \$436,000 relates to the prior year. The Company recognizes interest and penalties related to uncertain tax positions as a component of the provision for income taxes. As of December 31, 2007, the Company had approximately \$171,000 of accrued penalties and \$78,000 of accrued interest related to its uncertain tax positions.

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. In 2007, these agreements were cancelled and all charges from Bentley Pharmaceuticals, Inc. to Bentley Pharmaceuticals Ireland Ltd. in connection with these agreements were subsequently credited. As a result of these adjustments, Bentley Pharmaceuticals Ireland generated net operating income of approximately \$12,259,000 in 2007. Bentley Pharmaceuticals Ireland generated net operating losses of \$10,418,000 and \$2,080,000 in 2006 and 2005, respectively.

The Company calculates that the 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. Approximately \$6,812,000 of U.S. federal net operating loss carryforwards expired unutilized during the year ended December 31, 2007. The remaining U.S. federal net operating loss carry-forwards as of December 31, 2007 were approximately \$44,704,000. If not offset against future taxable income, the NOL carryforwards will expire in tax years 2008 through 2027.

The valuation allowance increased by approximately \$3,202,000, \$577,000, and \$2,920,000 in the years ended December 31, 2007, 2006 and 2005, respectively. The increase in the year ended December 31, 2007 is primarily attributed to \$5,293,000 from foreign tax credits and \$532,000 from general business credits, and is partially offset by \$1,879,000 of expired U.S. federal NOLs and the utilization of \$1,563,000 of Irish NOLs. The increase in the year ended December 31, 2006 consists of approximately \$1,257,000 related to the loss carryforward attributable to the deduction for stock options. The increase in the year ended December 31, 2005 primarily consists of approximately \$2,858,000 related to the loss carryforward.

**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, 2007 and 2006. 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.

	<b>For the Three Months Ended</b>			
	<b>3/31/07</b>	<b>6/30/07</b>	<b>9/30/07</b>	<b>12/31/07(a)(d)</b>
	<b>(In Thousands, Except Per Share Data)</b>			
Total revenues	\$ 31,391	\$ 31,179	\$ 27,348	\$ 34,769
Cost of net product sales	15,897	15,790	14,451	17,872
Gross profit	15,494	15,389	12,897	16,897
Operating expenses	11,274	13,440	12,530	16,031
Loss on sale of license				(111)
Income from operations	4,220	1,949	367	755
Other income (expenses)	221	278	(57)	486
Provision for income taxes	2,081	1,517	911	1,025
Net income (loss)	\$ 2,360	\$ 710	\$ (601)	\$ 216
Net income (loss) per common share:				
Basic	\$ 0.11	\$ 0.03	\$ (0.03)	\$ 0.01
Diluted	\$ 0.10	\$ 0.03	\$ (0.03)	\$ 0.01

Weighted average common shares outstanding:

Basic	22,293	22,318	22,354	22,391
Diluted	22,534	22,892	22,354	23,322

F-34

---

**Table of Contents**

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

	For the Three Months Ended			
	3/31/06(b)	6/30/06(b)(c)	9/30/06(b)	12/31/06(b)
	(In Thousands, Except Per Share Data)			
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 (loss) from operations	3,354	4,932	(5,707)	2,858
Other income	193	187	208	31
Provision (benefit) for income taxes	2,393	2,484	1,730	(1,525)
Net income (loss)	\$ 1,154	\$ 2,635	\$ (7,229)	\$ 4,414
Net income (loss) 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

(a) *Operating expenses* for the fourth quarter ended December 31, 2007 included impairment charges of \$1,225,000 related to the write-down of its U.S. generic simvastatin drug license and certain other U.S. generic drug projects.

(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 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.

- (d) *Cost of net  
product sales  
and net income  
(loss)* for the  
fourth quarter  
ended  
December 31,  
2007 includes  
\$378,000 and  
\$255,000 net of  
tax,  
respectively,  
related to  
intercompany  
profits included  
in inventory  
which were not  
properly  
eliminated in  
prior quarters.  
The  
intercompany  
profit  
eliminations  
were not  
considered to be  
material to the  
prior quarters.

**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.).

F-35

---



**Table of Contents**

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

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 was 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. The Company ceased its European drug delivery activities effective December 31, 2007. As such, the Company's drug delivery activities are now solely based in the U.S. and 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, 2007 and 2006. The segments use the same accounting policies as those described in the summary of significant accounting policies in Note 2.

For the year ended December 31, 2007 (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	\$ 112,329	\$ 670	\$	\$	\$ 112,999
Licensing and collaboration revenues	561			11,127	11,688
Total revenues	112,890	670		11,127	124,687
Cost of net product sales	62,809	1,201			64,010
Gross profit	50,081	(531)		11,127	60,677
Selling and marketing expense	18,523				18,523
General and administrative expense	9,613	(55)		7,515	17,073
Research and development expense	1,801	1,225	3,926	6,648	13,600
Depreciation and amortization expense	1,158	149		752	2,059
Separation costs				2,020	2,020
Loss on sale of drug license	(111)				(111)
Income from operations	18,875	(1,850)	(3,926)	(5,808)	7,291
Interest income	501			591	1,092
Interest expense	(588)			(10)	(598)
Other income (expense), net	672	(216)	16,435	(16,457)	434
Income before income taxes	19,460	(2,066)	12,509	(21,684)	8,219
Provision for income taxes	5,534				5,534
Net income (loss)	13,926	(2,066)	12,509	(21,684)	2,685
Expenditures for fixed assets	9,686			303	9,989
Expenditures for drug licenses	2,473	32		157	2,662

F-36

**Table of Contents**

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

As of December 31, 2007 (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	\$ 36,071	\$	\$	\$ 3,253	\$ 39,324
Other current assets	32,707	274		22,375	55,356
Fixed assets, net	56,391			2,800	59,191
Drug licenses and related costs, net	13,206	476		2,942	16,624
Other non-current assets	1,514			1,087	2,601
Total assets	139,889	750		32,457	173,096
Current liabilities	28,282	315		4,486	33,083
Long term debt	15,595				15,595
Non-current liabilities	8,446				8,446
Total liabilities	52,323	315		4,486	57,124

For the year ended 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>	
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-37

**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, net	45,738			2,818	48,556
Drug licenses and related costs, net	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

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

Edgar Filing: BENTLEY PHARMACEUTICALS INC - Form 10-K

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 \$80,645,000, \$76,713,000 and \$69,571,000 in the years ended December 31, 2007, 2006 and 2005, respectively. Revenues from licensing and collaboration revenues in Spain totaled \$561,000, \$515,000 and \$274,000 in the years ended December 31, 2007, 2006 and 2005, respectively.

Set forth in the table below is a summary of our revenues from external customers including a breakout of our revenues for our major product lines for the years ended December 31, 2007 and 2006 (in thousands):

Revenue source	2007	% of Total Revenues	2006	% of Total Revenues	2005	% of Total Revenues
Omeprazole	\$ 17,730	14%	\$ 19,130	18%	\$ 18,173	18%
Enalapril	6,698	5%	6,650	6%	5,859	6%
Simvastatin	5,888	5%	7,471	7%	6,746	7%
Paroxetine	4,945	4%	4,494	4%	4,455	5%
Lansoprazole	4,875	4%	3,541	3%	2,386	2%
All other products	29,993	24%	24,449	22%	21,875	23%
Sales to licensees and others	42,870	35%	34,855	32%	31,814	32%
Total net product sales	112,999	91%	100,590	92%	91,308	93%
Licensing and collaborations	11,688	9%	8,881	8%	6,422	7%
Total Revenues	\$ 124,687	100%	\$ 109,471	100%	\$ 97,730	100%

**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

**Table of Contents**

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

event of termination or change in control of the Company. The Company is currently obligated to pay approximately \$1,829,000 in 2008 under such agreements, which are scheduled to expire on December 31, 2008. In addition, the Company is obligated to grant an aggregate of 100,000 stock options to executive officers in 2008.

Revenues from one customer accounted for 9% of 2007 consolidated total revenues and 3% of the consolidated receivables balance at December 31, 2007. 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 2005 consolidated total revenues and 4% of the consolidated receivables balance at December 31, 2005.

Spanish sales from the Company's omeprazole product line accounted for approximately 14% in the year ended December 31, 2007 and 18% in both years ended December 31, 2006 and 2005. 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 2012. Total charges to operations under operating leases were approximately \$1,817,000, \$1,236,000 and \$1,059,000 for the years ended December 31, 2007, 2006 and 2005, respectively. Future minimum lease payments under operating leases are as follows (in thousands):

<b>Year Ending December 31,</b>	<b>Future Minimum Lease Payments</b>
2008	\$ 1,754
2009	893
2010	344
2011	56
2012	23
thereafter	

The Company has purchase orders totaling approximately \$2,796,000 for capital expenditures as of December 31, 2007 for continued improvements to its manufacturing facilities, including the acquisition of additional manufacturing equipment and the expansion of its active pharmaceutical ingredients manufacturing facility in Spain.

In October 2007, the Company was notified that a legal proceeding had been commenced against its subsidiaries, Laboratorios Belmac, S.A., Laboratorios Davur, S.L. and Laboratorios Rimafar, S.L. by Wyeth requesting an order requiring the Company to not manufacture or launch its venlafaxine products. The case was brought in the 4th Commercial Court of the City of Madrid. After an initial hearing the court rejected Wyeth's request for an interim injunction. The underlying proceedings are still pending.

In September 2007, the Company was notified that a legal proceeding had been commenced against its subsidiaries, Laboratorios Davur, S.L. and Laboratorios Rimafar, S.L., jointly with other manufacturers, by Merck & Co. Inc. and its Spanish subsidiary Merck Sharp & Dohme de España, S.A. requesting an order requiring the Company to not manufacture or launch certain of its alendronate products (70mg weekly). In October 2007, the Company filed a counterclaim against Merck seeking the revocation in Spain of European Patent 1.175.904. The case was brought in the 6th Commercial Court of the City of Barcelona and is currently pending.

**Table of Contents**

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

In June 2007, the Company was notified that a legal proceeding had been commenced against its subsidiary, Laboratorios Belmac S.A., jointly with three other Spanish manufacturers, by Warner-Lambert Company requesting an order requiring Belmac not to manufacture or launch their atorvastatin products. This patent infringement action is based on the Spanish counterpart of European patent EP 247.633 which expired on May 29, 2007. In January 2008, the court rejected the action filed by Warner-Lambert and awarded legal costs to Belmac.

In January 2005, the Company was notified that a legal proceeding had been commenced against its subsidiary, Laboratorios Davur S.L., 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 Davur in the 3rd Commercial Court of the City of Barcelona. After an initial hearing the court imposed an interim injunction, preventing Davur from launching its amlodipine products. However, upon appeal, the court lifted the requested injunction and awarded Davur with court costs and legal fees. Pfizer has appealed the judgment. A decision on the appeal is expected in mid 2008.

In December 2004, the Company's subsidiary, Laboratorios Belmac, S.A., 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 favour 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 in the beginning of 2008.

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-40