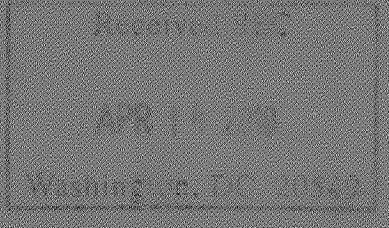
CPEX PHARMACEUTICALS INC.

2009 ANNUAL REPORT



CPEX
PHARMACEUTICALS, INC.

Dear Fellow Shareholders,

Looking back on our first full year as a stand-alone company, I am pleased by the accomplishments of our team during 2009. Total revenues grew from $15.6 million in 2008 to $18.7 million in 2009. We ended the year with $16.6 million in working capital and no debt. We believe we are well positioned to capitalize on the opportunities that lie ahead for CPEX and to deliver long-term value to our shareholders.

In 2009 we experienced record royalty revenues from the sales of Testim®, a testosterone replacement gel incorporating our drug delivery technology, licensed to and marketed by Auxilium Pharmaceuticals. Royalties from the sales of Testim increased 23% to $18.6 million in 2009 from $15.1 million the prior year. Also during 2009 we obtained six U.S. accelerated patents covering Testim, which were added to the currently listed Orange Book: Approved Drugs with Therapeutic Equivalence, which means that we now have a total of seven patents covering the Testim product. We believe the issuance of these patents strengthens our position in preventing generic competition, and the success and the expected further growth of Testim® give us continued confidence in the therapeutic applicability of our technology.

During 2009, we were encouraged by the progress being made by Serenity Pharmaceuticals, our licensing and development partner, as they continued to recruit patients in multiple Phase 3 clinical trials of Ser-120, their drug candidate for the treatment of nocturia, which uses our patented intranasal drug delivery technology. Recently, Serenity entered into a global agreement with Allergan, Inc. for the development and commercialization of Ser-120. In connection with that agreement, Allergan has assumed the existing exclusive license agreement between CPEX and Serenity. Under this agreement we are entitled to certain sales milestones as well as royalties on net sales once Ser-120 is marketed. We believe Allergan's interest in Ser-120 underscores the potential of the product in treating an important urologic disorder and more importantly provides further validation for our proprietary intranasal technology.

2009 and the early part of 2010 provided more clarity for our Nasulin development program. During 2009 we initiated and completed enrollment in a Phase 2a clinical trial of Nasulin which was designed to evaluate the efficacy and safety of Nasulin versus placebo over a 6-week treatment period in subjects with Type 2 diabetes being treated with basal insulin and oral anti-diabetes agents. Preliminary results showed that although subjects in the Nasulin group spent more time with normal glucose levels at the end of the study compared to subjects in the placebo group, the difference between the two groups was not statistically significant. At this time, we do not intend to continue to develop Nasulin, but we will continue to explore the possibility of selling or out-licensing the program.

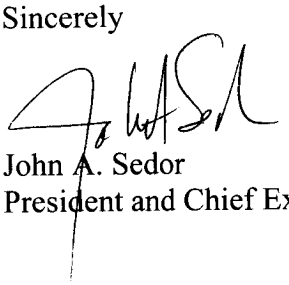
Overall we believe CPEX is well positioned and has numerous opportunities ahead to deliver shareholder value. In 2010, we plan to focus on the following strategic priorities:

- Capitalize on our recently announced partnership with Allergan regarding the development of Ser-120 for the treatment of nocturia;

- Continue to derive revenue from sales of Testim;
- Identify additional opportunities to out-license the CPE-215 technology to potential partners;
- Build our development pipeline, leveraging the expertise of our recently added Chief Scientific Officer, Nils Bergenhem, Ph.D., to develop and/or acquire new compounds; and
- Consider a variety of other strategic alternatives to enhance shareholder value.

In closing, I would like to thank our dedicated employees and you, our shareholders, for your continued support of CPEX and for playing an important role in our continued success.

Sincerely



John A. Sedor
President and Chief Executive Officer

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, 2009

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 1-33895

CPEX Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**No. 26-1172076**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
2 Holland Way Exeter, New Hampshire	**03833**
(Address of principal executive offices)	*(Zip Code)*

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

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

Title of Each Class	Name of Exchange on Which Registered
Common Stock, $0.01 par value	**The NASDAQ Stock Market LLC (NASDAQ Capital Market)**

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 whether the registrants have submitted electronically and posted on their corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrants were required to submit and post such files). 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 the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☐ (Do not check if a smaller reporting company) 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
Common Stock, $0.01 par value	**$20,279,080**	**June 30, 2009**

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

Title of Class	Shares Outstanding	As of Close of Business on
Common Stock, $0.01 par value	**2,540,728**	**March 24, 2010**

DOCUMENTS INCORPORATED BY REFERENCE

Definitive Proxy Statement for the 2010 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2009 — Incorporated by Reference into Part III of this Annual Report on Form 10-K

Part I

Item 1. *Business*

Overview

We are an emerging specialty pharmaceutical company in the business of research and development of pharmaceutical products utilizing our validated drug delivery platform technology. We have U.S. and international patents and other proprietary rights to technology that facilitates the absorption of drugs. Our platform drug delivery technology enhances permeation and absorption of pharmaceutical molecules across the skin, nasal mucosa and eye through development of proprietary formulations with molecules such as CPE-215. Our first product is Testim®, a gel for testosterone replacement therapy, which is a formulation of our technology with testosterone. Testim is licensed to Auxilium Pharmaceuticals, Inc. ("Auxilium") which is currently marketing it in the United States, Europe and other countries. We have an additional licensed application and 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 technology.

To date, our research and development programs for our drug delivery technology have been focused on the development of Nasulin, an intranasal formulation of insulin being developed to treat hyperglycemia in patients suffering from Type 1 and Type 2 diabetes. Our Nasulin development program includes 15 completed clinical trials in approximately 390 subjects. Eight of the studies were conducted in healthy volunteers, four in patients with Type 1 diabetes and three in patients with Type 2 diabetes. Of the 15 studies, 14 were Phase 1 trials and one was a Phase 2 trial. In 2009 we initiated and completed a Phase 1 Nasulin pharmacokinetic study designed to demonstrate dose proportionality of a second concentration strength. Also in 2009, we initiated and completed enrollment in a proof of concept Phase 2a study, designed to assess the glucose control of Nasulin versus placebo using continuous glucose monitoring in subjects with Type 2 diabetes. The primary objective of this study was to demonstrate that subjects receiving Nasulin would achieve a larger increase from baseline in the mean proportion of time spent with normal glucose levels (known as euglycemia) than those receiving placebo, as assessed by continuous glucose monitoring. In March 2010 the Company reported that preliminary results of this study showed that although subjects in the placebo group spent less time in euglycemia at the end of the study compared to subjects in the Nasulin group, the difference between the two groups was not statistically significant (p-value = 0.2). The secondary efficacy measurements of change from baseline in average glucose as measured by continuous glucose monitoring and the change from baseline in serum fructosamine were consistent with the primary endpoint analysis. We intend to conduct additional analyses on the data from the Phase 2a study and together with all other Nasulin data will determine the appropriate next steps for the Nasulin program. In the interim we have not commenced our planned Phase 2b trial or other Nasulin development initiatives.

In addition to our Nasulin program, Serenity Pharmaceuticals, Inc., our licensing and development partner, is recruiting patients in multiple Phase 3 clinical trials for an undisclosed urology drug delivered using CPEX's intranasal technology for the treatment of nocturia. These randomized, double blind, placebo controlled studies are being conducted at multiple sites in the United States.

We expect to incur increased costs from product pipeline development and testing efforts. Additional studies will be required should we continue to advance the Nasulin clinical program. Clinical and preclinical studies are subject to numerous risks and uncertainties. Many factors can delay or result in termination of future clinical studies. For example, patient enrollment delays or unexpected results from clinical studies could cause us to adjust our current clinical plans. See "Risk Factors" section, page 20.

We believe, based upon our experience with Testim and Nasulin, that our technology 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 technology, we are pursuing strategic alliances with partners including large pharmaceutical, specialty pharmaceutical and biotechnology companies. The alliance opportunities may include co-development of products, in-licensing of therapeutic molecules, out-licensing of delivery technology or partnering late-stage candidates for commercialization.

We were incorporated in the State of Delaware in 2007, and our principal executive offices are located in Exeter, New Hampshire.

Separation from Bentley Pharmaceuticals, Inc.

Our business was initially the drug delivery business of Bentley Pharmaceuticals, Inc. We were spun off in June 2008 in connection with the sale of Bentley's remaining business. Shares of our stock were distributed to Bentley stockholders after the close of business on June 30, 2008 (the "Separation Date") by means of a stock dividend, which was taxable to Bentley and Bentley's stockholders (the "Separation"). Each Bentley stockholder of record on June 20, 2008, the record date, received on the Separation Date one CPEX share for every ten shares of Bentley common stock. Bentley has no ownership interest in CPEX subsequent to the Separation.

Prior to our separation from Bentley, we entered into a Separation and Distribution Agreement, Tax Sharing Agreement, Employment Members Agreement and Transition Services Agreement (together referred to as the "Separation Agreements"), which have governed our relationship with Bentley since the Separation Date. The Transition Services Agreement, whereby Bentley agreed to provide us with certain executive and administrative services, expired under its terms in December 2008.

Our financial statements for the twelve months ended December 31, 2009 and the balance sheet as of December 31, 2008 represent stand-alone financial information for our Company. The statements of operations, statements of changes in stockholders' equity and statements of cash flows for the year ended December 31, 2008, which includes financial information for the six months before the Separation Date, and all of 2007 reflect the historical financial position, results of operations and cash flows of the business transferred to us from Bentley as part of the separation and distribution. Our financial statements have been prepared and are presented as if we had been operating as a separate entity using the historical cost basis of the assets and liabilities of Bentley and including the historical operations of the business transferred to us from Bentley as part of the separation. Prior to the Separation Date, we were fully integrated with Bentley and the accompanying financial statements reflect the application of certain estimates and allocations. Our statements of operations include all revenues and costs that are directly attributable to the business of CPEX. In addition, certain expenses of Bentley have been allocated to us using various assumptions that, in the opinion of management, are reasonable. These expenses include an allocated share of executive compensation, public company costs and other administrative costs. The allocated costs totaled $4.4 million and $4.2 million for the years ended December 31, 2008 and 2007, respectively. These amounts may differ from the costs associated with operating as an independent public company. Therefore, the results for the twelve months ended December 31, 2008 and 2007 are not indicative of the results that might have occurred if we had operated as an independent public company during those periods. There have been no allocations of expenses of Bentley charged to CPEX since the Separation Date.

Industry Overview

Specialty Pharmaceutical Companies Addressing Limitations of Current Therapies

Our goal is to become a leading specialty pharmaceutical company by creating a diverse and renewable pipeline of therapeutic compounds that address a wide variety of unmet medical needs. Specialty pharmaceutical companies like ours develop products to address the limitations of current therapies in selected established markets (endocrinology, urology, dermatology, neurology, etc.). These specialty markets can usually be addressed by smaller sales forces, but have the same market potential. Our pipeline products are designed to enhance safety, efficacy, ease-of-use and patient compliance. Our pipeline products also provide novel opportunities for pharmaceutical and biotechnology companies to partner with us to develop new and innovative products and extend their therapeutic franchises.

According to data obtained from Evaluate Pharma, the global specialty pharmaceutical market reached an overall value of approximately $85 billion in 2008 (an increase of 12.7% from 2007) and is projected to continue to grow for the foreseeable future.

Developing safer and more efficacious methods of delivering existing drugs is generally subject to less risk than attempting to discover new drugs, because of lower development costs. On average, it takes 10 to

15 years for an experimental new drug to progress from the laboratory to commercialization in the U.S., with an average cost of approximately $800 million to $900 million. Typically, only one in 5,000 compounds entering preclinical testing advances into human testing and only one in five compounds tested in humans is approved for commercialization. By contrast, we typically consider drugs for our pipeline that already have been approved and are commercially available, have a track record of safety and efficacy and have established markets for which there is an unmet medical need. In addition, we may be able to pursue an accelerated 505(b)(2) path to the market for some of our pipeline products that may translate into less time spent in the clinic and less money spent on clinical development. The 505(b)(2) development path in turn translates into a faster time to market launch and more overall patent life for the marketed drug.

The vast majority of the drugs currently on the market are administered orally or by injection. Oral drug delivery methods, while simple to use, typically subject drugs to degradation initially by the stomach and secondarily to first-pass metabolism in the liver before reaching the bloodstream. In order to achieve efficacy, higher drug dosages are often used, which can increase the risk of side effects.

Injectable pharmaceuticals, while avoiding first-pass metabolism in the liver, possess several disadvantages, which can lead to decreased patient acceptance and compliance with prescribed therapy. Injectable drugs are more painful for the patient and often require medical personnel to administer. In addition, injectable drugs are typically also more expensive due to the added cost associated with their manufacturing under sterile conditions and added costs for their administration, including medical personnel, syringes, needles and other supplies. A decline in patient acceptance and compliance due to any of these reasons can delay the initiation of treatment and increase the risk of medical complications and could lead to higher healthcare costs.

Alternative Drug Delivery Technologies

Pharmaceutical and biotechnology companies recognize the benefits of alternative delivery technologies as a way of gaining a competitive advantage. It has been reported that while pharmaceutical sales in the U.S. have risen steadily over the last several years to more than $720 billion in 2008, sales growth is expected to slow over the next several years due to an extraordinary number of patent expirations and to the poor global economy. At the same time, it is estimated that the global drug delivery market has tripled in value since 2000 to approximately $78 billion (Espicom Healthcare Intelligence, 2009). The growth in the drug delivery market has been driven by the recognition of pharmaceutical and biotechnology companies that provide alternative delivery technologies that avoid first-pass liver metabolism, that are less invasive than injectable options and that enable product line and patent position extension provide an attractive combination of advantages to companies and patients. Further, these pharmaceutical and biotechnology companies often benefit from specialty pharmaceutical companies that apply their technologies to off-patent products, formulating their own proprietary products, which are then typically commercialized by larger pharmaceutical companies capable of promoting the products.

Permeation Enhancement Technology — The Path to Improved Drug Benefits

Permeation enhancement with CPE-215 is the drug delivery technology of CPEX. It has been proven to enhance the absorption of drugs through the nasal mucosa, skin and eye. It can be adapted to products formulated as creams, ointments, gels, solutions, 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 U.S. Food and Drug Agency's inactive ingredient list for approved use in drug applications.

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

- Improved compliance and convenience to patients requiring ongoing injection therapies and the potential for earlier acceptance of prophylactic treatment for patients reluctant to use injections;
- Application to injectable peptides that could be administered intranasally with CPE-215;
- 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;
- Opportunities for allowing product differentiation based on benefits of administration.

Licensed Products

Testim, Licensed Topical Testosterone Gel

We earn royalty revenues on sales of Testim, a testosterone gel that incorporates our CPE-215 drug delivery technology. The product is licensed to Auxilium and was 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 $18.6 million, $15.1 million and $11.1 million for the years ended December 31, 2009, 2008 and 2007, 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 Ferring International S.A. to market the drug in Europe.

The testosterone replacement market has expanded as more baby-boomers enter middle age and more attention is focused on male hormonal deficiency and the benefits of replacement therapy. Hypogonadism, a condition in men where insufficient amounts of testosterone are produced, is thought to affect one out of every five men in the U.S. and Europe aged over 50. 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. This condition is currently significantly under-treated. Growing patient awareness together with education continue to spur demand for testosterone replacement therapy.

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

In October 2008, we and Auxilium received notice that Upsher-Smith Laboratories filed an Abbreviated New Drug Application, or ANDA, containing a paragraph IV certification in which it certified that it believes that its testosterone gel product does not infringe our patent covering Testim, U.S. Patent No. 7,320,968 ("the '968 Patent"). The '968 Patent covers a method for maintaining effective blood serum testosterone levels for treating a hypogonadal male using Testim and will expire in January 2025. The '968 patent is listed in Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book), published by the U.S. Food and Drug Administration. The paragraph IV certification sets forth allegations that the '968 Patent will not be infringed by Upsher-Smith's manufacture, use or sale of the product for which the ANDA was submitted. On December 4, 2008, we and Auxilium filed a lawsuit in the United States District Court for the District of Delaware against Upsher-Smith under the Hatch Waxman Act for infringement of our patent. In June 2009, Upsher-Smith amended its answer to the complaint to include a defense and counterclaim of invalidity of the '968 Patent, which we and Auxilium deny. We and Auxilium filed a reply to the counterclaim in July 2009 denying the invalidity of the '968 Patent. A patent issued by the Patent and Trademark Office, such as the '968 Patent, is presumed valid. As described more fully under Item 3 — "Legal Proceedings" in this report, any U.S. Food and Drug Agency (FDA) approval of Upsher-Smith's proposed generic product will be stayed until the earlier of 30 months beginning on the date of receipt of the paragraph IV certification (April 2011) or an adverse decision in our patent infringement lawsuit.

The primary competition for Testim is AndroGel®, marketed by Solvay Pharmaceuticals, Inc., and its potential generic competitors.

- Watson Pharmaceuticals Inc. and Par Pharmaceuticals Inc. have filed ANDAs against AndroGel but the timing of the entry of these generics is not expected until 2015.
- Perrigo Israel Pharmaceuticals, Ltd. has filed an ANDA against AndroGel but the timing of the entry of this generic is uncertain at this time.

There are several other compounds in various stages of clinical development which may compete with Testim.

- Endo Pharmaceuticals, Inc. signed an agreement with U.K. based ProStrakan Group plc for exclusive U.S. rights to commercialize FORTESTA™, a 2% testosterone gel. Endo filed a New Drug Application ("NDA") for FORTESTA™ in 2009 and has received a Complete Response Letter from the FDA. Endo has announced that it expects to respond to the FDA's questions in mid-2010. FORTESTA™ is approved in Europe and is sold by ProStrakan under the brand names Tostran™, Tostrex™ and Itnogen™.
- Bayer Schering Pharma discovered and developed NEBIDO™ a novel, long-acting injectable testosterone product sold in Europe. Bayer has licensed U.S. rights for this product to Endo, which filed an NDA with the FDA in 2009 using the brand name AVEED™. Endo has received and is evaluating a Complete Response Letter from the FDA regarding AVEED. The timing of the entry of FORTESTA™ and AVEED™ in the U.S. market is unknown.
- Acrux Limited, an Australian company, has developed AXIRON™, a 2% testosterone solution delivered in the armpit. Acrux has completed a Phase 3 clinical trial and is expected to file an NDA with the FDA in the near future.
- BioSante Pharmaceuticals, Inc. and Teva Pharmaceuticals USA, Inc. have developed Bio-T-Gel™, a once-daily transdermal testosterone gel currently in late stage human clinical trials.
- Clarus Therapeutics is developing an oral form of testosterone called OriTex™ which is currently in Phase 2 clinical trials.

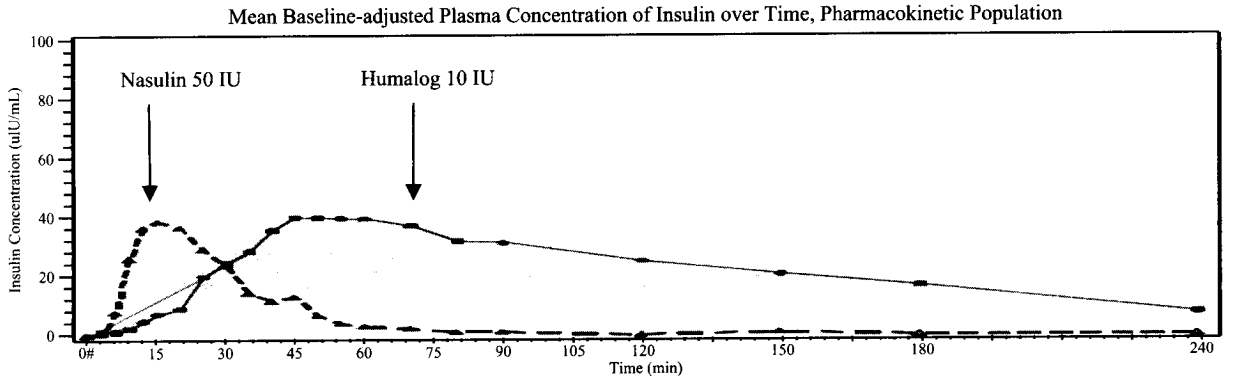
Other new treatments are being sought for testosterone replacement therapy; these products are in development and their future impact on the treatment of testosterone deficiency is unknown.

Product in Development

Nasulin™, Proprietary Intranasal Insulin Product

Nasulin is the patented intranasal insulin spray of CPEX which incorporates CPE-215 as a permeation enhancer. We are developing Nasulin to address the need for an insulin product that more closely resembles the body's normal physiological response and provides a more patient-friendly delivery method. These potential benefits could reshape the insulin market. Based on market reports and projections, we have estimated the global meal time injectable insulin market to be approximately $5.4 billion and the U.S. market to be approximately $3.1 billion. In general, drugs delivered via the nasal cavity have the potential to be readily absorbed across the highly vascularized nasal mucosa and directly into the circulatory system, thereby avoiding first-pass metabolism in the liver. When absorbed, 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.

Mean Baseline-adjusted Plasma Concentration of Insulin over Time, Pharmacokinetic Population



Study: BNT INS-US-0100-PK004: Randomized, Single-dose, 2-Way Crossover Glucose Clamp Study, T1 Subjects, n=6

According to 2007 prevalence data released by the United States Centers for Disease Control and Prevention, or CDC, the most recent year for which data is available, approximately 24 million people in the United States, or 8% of the population, suffer from diabetes. A study published by Diabetes Care in 2006 projects that the number of diagnosed diabetics in the U.S. could 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. Due to the time-action profiles of the rapid-acting mealtime injectable insulins, patients are at increased risk for hypoglycemic events and for gaining weight. The ultra-rapid time-action profile of Nasulin has the potential to reduce the risk of hypoglycemic events and of weight gain. In addition, because Nasulin delivers needle-free insulin, it has the potential to improve the acceptability of mealtime insulin among patients with diabetes and has the potential to improve adherence to insulin treatment regimens.

We believe an intranasal route of administration will yield an ultra-rapid time action profile which could provide better glucose control equivalent to meal time injectable insulins but with the potential for less hypoglycemia and weight gain. In addition, based on current data demonstrating that Nasulin does not enter the deep lung, this needle-free route of delivery potentially avoids the pulmonary disadvantages of competitive candidates that use an inhalation route of administration. As explained above, preliminary findings from our Phase 2a proof of concept study showed that although subjects in the placebo group spent less time in euglycemia at the end of the study compared to subjects in the Nasulin group, the difference between the two groups was not statistically significant (p-value = 0.2). Previously our development plan was to finish key efficacy Phase 2 trials in patients with Type 2 diabetes late in 2011 while simultaneously seeking a pharmaceutical partner to support Phase 3 clinical trials and product commercialization upon regulatory approval. As a result of the preliminary findings from the Phase 2a study, we intend to conduct additional analyses on the data together with all other Nasulin data and will determine the appropriate next steps for the Nasulin program. In the interim we have not commenced our planned Phase 2b trial or other Nasulin development initiatives.

Key Markets and Trends

Testosterone

Substantially all of our revenues are derived through royalty income from the only commercialized product licensed with our CPE-215 technology, Testim, which is sold by Auxilium.

Overview of Testosterone Replacement Market

The testosterone replacement market has expanded as more baby-boomers enter middle age and more attention is focused on male hormonal deficiency and the benefits of replacement therapy. 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. This condition is currently significantly under-treated and growing patient awareness together with education continue to spur demand for testosterone replacement therapy.

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

Diabetes

Our most advanced product in development, Nasulin, is an intranasal formulation of insulin being developed to treat hyperglycemia in patients suffering from Type 1 and Type 2 diabetes.

Overview of Diabetes

Diabetes is a major disease characterized by the body's inability to properly regulate levels of blood glucose, or blood sugar. The cells of the body use glucose as fuel, which is consumed 24 hours a day. Between meals, when glucose is not being supplied from food, the liver releases glucose into the blood to sustain adequate levels. Insulin is a hormone produced by the pancreas that regulates the body's blood glucose levels. Patients with diabetes develop abnormally high levels of glucose, a state known as hyperglycemia, either because they produce insufficient levels of insulin or because they fail to respond adequately to insulin produced by the body. Over time, poorly controlled levels of blood glucose can lead to major complications, including high blood pressure, blindness, amputations, kidney failure, heart attack, stroke and death.

According to 2007 prevalence data released by the United States Centers for Disease Control and Prevention, or CDC, approximately 24 million people in the United States, or 8% of the population, suffer from diabetes. This represents an increase of more than 3 million people in approximately two years. In addition to the 24 million people with diabetes, approximately 57 million people are estimated to have pre-diabetes, putting them at increased risk for developing diabetes. In addition, the incidence of diabetes is also increasing. A study published by Diabetes Care in 2006 projected that in 2050 there would be 48.3 million people with diagnosed diabetes in the United States. Diabetes extracts a heavy toll from those who suffer from it. The CDC reported that diabetes was the seventh leading cause of death listed on death certificates in 2006, but that diabetes was likely to be underreported as a cause of death. Overall, the CDC found that the risk of death among people with diabetes is about twice that of people without diabetes of similar age. The economic costs of diabetes are high as well. The American Diabetes Association estimates that in 2007, the total cost of diabetes in the United States was $174 billion. This amount includes $116 billion of direct medical costs and $58 billion for indirect medical costs including disability, work loss and premature mortality.

There are two major forms of diabetes, Type 1 and Type 2. Type 1 diabetes is an autoimmune disease characterized by a complete lack of insulin secretion by the pancreas, so insulin must be supplied from outside the body. In Type 2 diabetes, the pancreas continues to produce insulin; however, insulin-dependent cells become resistant to the effects of insulin. Over time, the pancreas becomes increasingly unable to secrete adequate amounts of insulin to support metabolism. According to the CDC, Type 2 diabetes is the more prevalent form of the disease, affecting approximately 90% to 95% of people diagnosed with diabetes.

Challenges of treating Type 2 Diabetes

Typically, the treatment of Type 2 diabetes starts with management of diet and exercise and progresses to treatment with various oral medications and then to treatment with insulin. Treatment with diet and exercise alone is not an effective long-term solution for most patients with Type 2 diabetes. Oral medications — which act predominantly by increasing the amount of insulin produced by the pancreas, by increasing the sensitivity of insulin-dependent cells or by reducing the glucose output of the liver — may have significant adverse effects and are limited in their ability to manage the disease effectively.

Insulin therapy usually involves administering several subcutaneous needle injections of insulin each day. Although this treatment regimen is accepted as an effective means to control glucose levels, it has limitations, including:

- the need for injections;
- the risk of abnormally low levels of blood glucose, known as hypoglycemia, that result from excessive insulin administration. Severe hypoglycemia can result in loss of mental acuity, confusion, increased heart rate, hunger, sweating and faintness and, at very low glucose levels, loss of consciousness, seizures, coma and death;
- the need for complex titration of insulin doses in connection with meals;
- inadequate post-meal glucose control;
- the need for frequent glucose monitoring with finger pricks; and

- the likelihood of weight gain.

Particularly because of the dislike of injections and finger pricks, patients delay the initiation of insulin therapy and may not adhere adequately to the prescribed treatment regimens once insulin therapy begins. Moreover, even when properly administered, current subcutaneous injections of insulin do not replicate the time-action profile of endogenous insulin. In a person without diabetes, blood insulin levels rise within several minutes of the entry into the bloodstream of glucose from a meal. By contrast, injected insulin enters the bloodstream more slowly, resulting in peak insulin levels in about 120 to 180 minutes for regular human insulin or 30-90 minutes for "rapid-acting" insulin analogs. The bioavailability profile of the currently available rapid-acting meal-time insulin products can cause patients with diabetes to have inadequate levels of insulin present at the initiation of a meal and to be over-insulinized between meals. This lag in insulin delivery results in hyperglycemia early after meal onset, followed by a tendency for hypoglycemia to develop during the period between meals. Physicians who treat patients with diabetes are concerned about the risks of hypoglycemia and, as a result, tend to under treat the chronic hyperglycemia that is associated with the disease. However, the resultant extensive hyperglycemia significantly contributes to many of the long-term cardiovascular and other serious complications of diabetes.

There are two components to the hyperglycemia concern. The first component is related to the duration and magnitude of the chronic sustained hyperglycemia associated with poorly controlled diabetes. This component is assessed by measuring HbA1c levels, which are a measure of the average blood glucose levels over the preceding three or four months. HbA1c levels are an indication of overall glucose control, and an important goal of all diabetes therapies is to lower HbA1c levels. The second component of hyperglycemia relates to the extent of acute glucose fluctuations above and below the average level. These fluctuations occur in response to meals and can be managed by diabetes medications, including insulin. In a clinical setting, this component is assessed by determining the mean amplitude of glucose fluctuations that occur following the ingestion of a meal.

There is evidence that acute glucose fluctuations may be the more significant factor contributing to the cardiovascular complications of diabetes, which are thought to stem from the activation of a mechanism known as oxidative stress that causes cellular damage. A recent study of patients with Type 2 diabetes reported in the Journal of the American Medical Association in April 2006 found that the urinary levels of a marker for oxidative stress were significantly correlated with the mean amplitude of glucose fluctuations during the post-meal period. This study concluded that acute glucose fluctuations may trigger oxidative stress, suggesting that doctors and patients should emphasize the management of acute glucose fluctuations as well as the goal of lowering HbA1c levels.

The results of the Diabetes Control and Complications Trial (DCCT), a long-term study conducted by the National Institutes of Health support the view that controlling acute glucose fluctuations contributes to a reduced risk for the cardiovascular complications of diabetes. In the study a group of patients treated using conventional insulin therapy (one-two insulin injections per day along with daily urine glucose tests) was compared to a group treated using intensive insulin therapy (either an insulin pump or at least three insulin injections and at least four blood glucose tests per day). In total, 1,441 patients were followed for an average of 6.5 years each. Intensive insulin therapy produced a significant reduction in HbA1c levels compared to conventional insulin therapy; the difference between treatment groups remained evident for the duration of the study. Moreover, the patients who had been intensively treated also showed significant decreases in risk for kidney and eye damage compared to the conventional treatment group. Although when these results were reported, the DCCT was discontinued, a group of 1,375 of these subjects (half from each of the original treatment groups) was subsequently followed in the Epidemiology of Diabetes Interventions and Complications (EDIC) study. After seven years in the EDIC study, the HbA1c levels of the former conventional therapy group did not differ from the HbA1c levels of the former intensive treatment group. The HbA1c levels of the former conventional therapy group had improved from the DCCT while those of the former intensive group had declined. However, the former conventional therapy group continued to show an elevated risk of kidney and eye damage compared to the former intensive therapy group, according to a report published in the Journal of the American Medical Association in May 2002. These findings led to the conclusion that intensive insulin therapy, which would be expected to reduce acute glucose fluctuations, can be beneficial for patients

with diabetes, even years after the therapy has been less intensified. However, the EDIC also demonstrates how intensive insulin therapy is difficult for many patients to implement in a home setting.

Even if intensive insulin therapy is implemented, the available insulin products are not able to enter the bloodstream fast enough to replicate the tight coupling between changes in blood glucose levels and the release of insulin by the pancreas that is seen in healthy individuals without diabetes. The early insulin response following glucose ingestion is an important part of maintaining control over glucose levels during the post-meal period. It is thought that the early surge of insulin levels shuts off glucose production by the liver, which otherwise would continue to release glucose into the bloodstream at the same time that glucose is being absorbed from the meal. This avoids hyperglycemia during mealtime and prevents the pancreas from having to secrete an excessive amount of insulin during the period between meals. Patients with diabetes, however, have little or no ability to secrete insulin rapidly in response to the onset of a meal. Without an adequate means to deliver insulin to the bloodstream rapidly enough to approximate the early insulin secretion seen in healthy individuals following a meal, patients with diabetes end up experiencing an endless series of glucose fluctuations, triggered by the meals and the sluggish insulin they take to control meal-time glucose. This shortcoming is a significant obstacle to the effectiveness of currently available insulin therapy for the treatment of diabetes and may be overcome by the rapid entry of Nasulin into the bloodstream seen consistently in CPEX's Phase 1 clinical trials to date.

Challenges of Treating Type 1 Diabetes

Type 1 diabetes is an autoimmune disease characterized by a complete lack of insulin secretion by the pancreas. In addition to diet, treatment for patients with Type 1 diabetes usually includes a regimen of a long-acting nightly dose of insulin supplemented by either very rapid or regular insulin before each meal. Type 1 diabetes usually begins early in life and, over time, these patients become better informed and more disciplined in their approach to their medical treatment.

Common side effects associated with the treatment of Type 1 diabetes include hypoglycemia and weight gain. Hypoglycemia is due to an excess of insulin at a time when glucose is either not being absorbed or produced by the body, usually experienced between the times when insulin enters the blood stream and just before the next meal is consumed. This results from the relatively long duration of action characteristic of most insulin preparations, including rapid acting insulin. We believe the rapid onset of Nasulin, peaking at around 15 minutes, and returning to baseline in less than 2 hours, resembles that of healthy subjects, which should lessen the risk of hypoglycemia.

Weight gain after insulin therapy initiation is caused by the anabolic effect of insulin. Commonly used injections tend to prolong this anabolic effect rather than allow the body to experience the alternating anabolic and catabolic activities found in healthy subjects. We believe the unique pharmacokinetic profile of Nasulin will allow a patient with Type 1 diabetes to experience the alternating anabolic and catabolic activity found in healthy subjects and potentially reduce weight gain. Additional analyses on the Phase 2a data needs to be completed before these potential benefits of Nasulin can be evaluated further.

Insulin Administration

Proteins and peptides such as insulin are typically delivered by injection because they cannot be delivered orally without being degraded in the stomach. Nasal administration of insulin could present a patient-friendly alternative to the multiple daily injections required to control diabetes. We believe, although there can be no assurance, that a rapid-acting insulin delivered via the nasal route could offer diabetics a new option for prandial, or meal-time, insulin. An ultra rapid-acting nasal insulin may have a unique value proposition compared with other insulin formulations on the market, especially in Type 2 patients who have adequate insulin reserves but a slow post-meal insulin response. In addition, a nasal dosage form of insulin would avoid the possible pulmonary side effects associated with inhalation of insulin while potentially broadening the applicable patient populations, increasing patient compliance and improving disease management.

Research and Development

Research and development expenses were $12.3 million, $9.1 million and $9.6 million for the years ended December 31, 2009, 2008 and 2007, respectively. These expenses are attributed to investments in our research and development programs, primarily for Nasulin, our intranasal insulin product candidate. We expect our research and development costs to decline in 2010 due to a reduction in activities related to Nasulin while we determine the appropriate next steps for the program.

Sources and Availability of Raw Materials

Our technology is dependent upon obtaining pharmaceutical grade CPE-215 from third-party suppliers. We do not manufacture our own CPE-215. Pharmaceutical grade CPE-215 is available from at least two major industrial manufacturers. The Company has obtained a secure supply from an independent manufacturer and has obtained sufficient inventory to take us through at least Phase 3 development of Nasulin. Other molecules and compounds used in our development process are often proprietary to our development partners and supplied directly by those partners.

Partners/Customers

We enter into research and license agreements with other companies under which 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.

License Agreement with Auxilium

We and Auxilium are parties to a License Agreement dated May 31, 2000 pursuant to which Auxilium obtained a sole and exclusive, worldwide, royalty-bearing license (including sub-license rights) to make, have made on their behalf, use and sell anywhere in the world any and all pharmaceutical compositions which contain (A) testosterone as the single active ingredient; and (B) CPE-215 and which are covered by a valid CPEX patent, all related patents and technology. Initially this license was based solely upon the issued U.S. Patent No. 5,023,252. Since this patent expired in June 2008, Auxilium's license is now based upon issued U.S. Patents, No. 7,320,968 and the recently obtained six U.S. patents (see "Intellectual Property"). In addition, Auxilium was granted the exclusive right to enter into another license agreement to acquire rights in these patents and technology for the development of combination products, which right expires upon the termination of the original License Agreement. The License Agreement continues for an indefinite term but it is terminable by us if Auxilium fails to make timely payments and may also be terminated by either party if (i) the other party becomes insolvent, (ii) the other party fails to cure a breach within 30 days or (iii) CPEX is dissolved.

Pursuant to the terms of the Agreement, we receive royalties of 12%, of Auxilium's annual net sales of Testim in the U.S. and Canada. In the event that we do not have, or do not maintain an enforceable patent in a country in which Auxilium products are sold, the royalty rate due to us from sales in that particular country reduces from the aforementioned rates to a rate in the low single-digits.

Development and License Agreement with Serenity Pharmaceuticals Corporation

On February 4, 2008 we entered into a Development and License Agreement with Serenity Pharmaceuticals Corporation, ("Serenity") to develop a nasal spray delivery product composition containing a molecule used in the treatment of nocturia, a condition causing an individual to wake one or more times at night to urinate. Serenity granted us a non-exclusive license to its technology and patents rights to conduct initial formulation activities under the Agreement. We granted Serenity an exclusive, sublicensable, worldwide license under United States Patent No. 7,244,703 and foreign equivalents and CPEX's proprietary CPE-215 drug delivery technology to conduct research activities related to the development of the Serenity product and to make and sell the product. Under the Agreement, Serenity will pay us certain milestone payments and a low single-digit royalty on Net Sales of the product. On a country-by-country basis, upon the later of ten years after the first commercial sale of the product or

the expiration of United States Patent No. 7,244,703 or its equivalent, Serenity will have a fully paid-up, royalty-free, non-exclusive license under our patent to make Serenity's product.

Growth Strategy

Our objective is to be a leading specialty pharmaceutical company focused on advanced drug delivery and formulation technologies to improve the delivery of new as well as existing pharmaceuticals. Our business strategy to accomplish this objective includes:

- evaluating the development and commercialization potential of our most advanced product candidate — Nasulin for intranasal insulin administration;
- identifying and implementing new product candidates for internal pipeline development that leverage our CPE-215 drug delivery technology and formulation expertise; and
- developing strong alliances for clinical research, product manufacturing and marketing.

Development and commercialization potential of Nasulin

We believe an intranasal route of administration will yield an ultra-rapid time action profile which could provide better glucose control equivalent to meal time injectable insulins but with the potential for less hypoglycemia and weight gain. In addition, based on current data demonstrating that Nasulin does not enter the deep lung, this needle-free route of delivery potentially avoids the pulmonary disadvantages of competitive candidates that use an inhalation route of administration. As explained above, preliminary findings from our Phase 2a proof of concept study showed that although subjects in the placebo group spent less time in euglycemia at the end of the study compared to subjects in the Nasulin group, the difference between the two groups was not statistically significant (p-value = 0.2). Previously our development plan was to finish key efficacy Phase 2 trials in patients with Type 2 diabetes late in 2011 while simultaneously seeking a pharmaceutical partner to support Phase 3 clinical trials and product commercialization upon regulatory approval. As a result of the preliminary findings from the Phase 2a study, we intend to conduct additional analyses on the data together with all other Nasulin data to determine the appropriate next steps for the Nasulin program. In the interim we have not commenced our planned Phase 2b trial or other Nasulin development initiatives.

The major issue that could hinder the development and commercialization potential of Nasulin would be an unacceptable level of variability in the pharmacokinetic profile of the drug. This could lead to inconsistent efficacy and/or a higher incidence of hypoglycemia in some patients. Other potential reasons might include (1) a higher maximum dose may be required to ensure adequate glucose lowering and developing a higher dose may not be technically and clinically feasible, and (2) the ultra rapid-on, rapid-off time action profile of the product may result in insulin levels in the blood that do not remain high enough for a sustained glucose lowering effect. Another issue which is being closely followed in clinical trials is nasal irritation. To date, three month toxicity studies in rats and dogs at maximum tolerated doses revealed no evidence of inflammation in the nose. The nature and pattern of these events will continue to be evaluated in all trials. While our clinical trials in healthy volunteers and in patients have reported adverse events associated with the nasal route of administration, to date only one serious adverse event has been reported associated with Nasulin. The event was described as a loss of sense of smell and was determined by the investigator to be mild in severity.

Our Nasulin development program includes 15 completed clinical trials in approximately 390 subjects. Eight of the studies were conducted in healthy volunteers, four in patients with Type 1 diabetes and three in patients with Type 2 diabetes. Of the 15 studies, 14 were Phase 1 trials and one was a Phase 2 trial.

The following is a list of completed studies for which clinical study reports are being finalized;

- BNT-INS-US-0100-PK007 — A Randomized, Single Site Open-Label, 5 Way Crossover Meal Challenge Study Comparing Time Action Profiles of Nasulin vs. Insulin Lispro, both in Combination with Insulin Glargine in male and Female Subjects with Type 1 Diabetes Mellitus. As previously reported, this study was intended to enroll up to 24 patients however due to slow and intermittent enrollment

rates the company completed an interim analysis and determined that it was not feasible to continuing to enroll in this trial. The Company believes the slow enrollment was due to the stringent inclusion criteria and was not product related.

- CPEX INS-US-0100-PK010 — A Single Site, Partially Randomized, 2 Cohort Study to Determine the Safety and Counter Regulatory Response of Nasulin™ (BNT-INS-0100) Compared to Insulin lispro after both Average and Diminished Sized Meals in Normal Non-Smoking Male and Female Subjects. All subjects have completed the study.

The following is a summary of the recently completed Phase 2a proof-of-concept study:

- Nasulin-US-0100-CPEX011 — The effect of Nasulin vs. Placebo on blood glucose control in patients with moderately controlled Type 2 diabetes mellitus currently treated with basal insulin and oral antidiabetic medications, excluding secretagogues, in a Phase 2a, randomized, parallel, double-blind, placebo-controlled, multi-center study. This study, which randomized 94 patients, was designed to assess the efficacy and safety of Nasulin versus a placebo over a 6-week treatment period and was conducted at multiple centers across the United States. Preliminary data became available in March 2010. The primary objective was to demonstrate that subjects receiving Nasulin would achieve a larger increase from baseline in the mean proportion of time spent with normal glucose levels (or in euglycemia) than those receiving placebo, as assessed by continuous glucose monitoring. Although subjects in the placebo group spent less time in euglycemia at the end of the study compared to subjects in the Nasulin group, the difference between the two groups was not statistically significant (p-value = 0.2). The secondary efficacy measurements of change from baseline in average glucose as measured by continuous glucose monitoring and the change from baseline in serum fructosamine were consistent with the primary endpoint analysis. No critical safety signals were detected with Nasulin in the study. The most common adverse events were those attributable to administration site reactions associated with the nasal route of delivery, the majority of which were mild. The percentage of subjects reporting hypoglycemia was similar between both the Nasulin and placebo groups. At the end of the trial, we conducted a meal challenge which demonstrated significant reductions in the maximum concentrations of serum glucose in the Nasulin group versus placebo, as well as significant reductions in the overall glucose load during 60, 90 and 240 minutes after dosing. These findings support the pharmacodynamic data demonstrated in previous Phase 1 clinical studies.

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

We intend to apply our CPE-215 drug delivery technology 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 will identify product candidates that we can bring to late stage development on our own.

Developing strong alliances to provide us scale advantages in clinical research, product manufacturing and marketing

In addition to pursuing our own proprietary compounds, we will continue to seek strategic collaborations with pharmaceutical and biotechnology companies to apply our CPE-215 technology to 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:

- 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.

Competition

Competition in the drug industry is intense. There are a number of competitors who possess capabilities relevant to the drug delivery field. In particular, we face substantial competition from companies pursuing the commercialization of products using nasal drug delivery technology. Established pharmaceutical companies, such as Archimedes Pharma Ltd, AstraZeneca PLC, Bayer Consumer Care, GlaxoSmithKline plc, and Pfizer, Inc. also have in-house nasal drug delivery research and development programs that have successfully developed non-insulin products that are being marketed using nasal drug delivery technology. We also face indirect competition from other companies with expertise in alternate drug delivery technologies, such as oral, injectable, patch-based and pulmonary administration. Competitors in these fields include AstraZeneca PLC and GlaxoSmithKline plc, Alkermes Inc., Unigene Inc., Generex Biotechnology Corporation, Emisphere Technologies, Inc. and Coremed Corporation. Many of our competitors have substantially greater capital resources, research and development resources and experience, manufacturing capabilities, regulatory expertise, sales and marketing resources and established collaborative relationships with pharmaceutical companies. Our competitors, either alone or with their collaboration partners, may succeed in developing drug delivery technologies that are similar or preferable in effectiveness, safety, cost and ease of commercialization and our competitors may obtain IP protection or commercialize competitive products sooner than we do.

Universities and public and private research institutions are also potential competitors. While these organizations primarily have educational objectives, they may develop proprietary technologies related to the drug delivery field or secure protection that we may need for development of our technologies and products. We may attempt to license these proprietary technologies, but these licenses may not be available to us on acceptable terms, if at all.

Even if we are able to develop products and then obtain the necessary regulatory approvals, our success will depend to a significant degree on the commercial success of the products developed by us and sold or distributed by our collaboration partners.

Testosterone Gels

We have described on page 5 the competition for Testim, the testosterone gel marketed and sold by Auxilium, including the ANDA filed by Upsher-Smith.

Diabetes

Inhaled and Oral Insulin

If our Nasulin product candidate obtains the necessary regulatory approvals and becomes commercialized, it will compete with products already in the market or currently in the development stage.

Companies known to be working on various versions of inhaled insulin products, in either liquid or dry form, include MannKind Corporation and Abbott Laboratories (through its acquisition of Kos Pharmaceuticals in 2006). MannKind completed Phase 3 clinical studies of their product, AFREZZA™ (formerly known as AFRESA®) in 2008 and submitted a New Drug Application (NDA) with the FDA in 2009. Other companies known to be working on similar programs include Emisphere and Coremed.

There are also several companies, including Generex Biotechnology Corporation, Biocon Pharmaceuticals, Inc., Diasome Pharmaceuticals, Oramed Pharmaceuticals, and Emisphere that are pursuing development of products involving the oral delivery of insulin. Oral-lyn™, Generex's oral insulin spray product has received regulatory approval in Ecuador, India, Lebanon and Algeria and approvals to market the product in Syria and Iraq (North) are expected in 2010. This product is also in Phase 3 clinical trials at several sites around the world. Biocon's product, IN-105, is a conjugated insulin molecule in tablet form that is currently in Phase 3 clinical trials. Diasome is developing Oral HDV-I, a low-dose, short-acting mealtime hepatic insulin in a pill or gel cap dose form. This product is currently in Phase 2 clinical trials. Oramed's product, ORMD-0801, is an oral insulin capsule is also in Phase 2 trials. We believe Emisphere's product is currently in early stage clinical development but the timeline to commercialization has not been made publicly available.

Non-insulin medications

We expect that Nasulin will compete with currently available non-insulin oral medications for Type 2 diabetes. These products include the following:

- Sulfonylureas (including Glucotrol®, Diabeta®, Glynase®, Micronase®, and Amaryl), also called oral hypoglycemic agents, prompt the pancreas to secrete insulin. This class of drugs is most effective in individuals whose pancreas still have some working beta cells.
- Meglitinides (including Prandin and Starlix®) are taken with meals and reduce the elevation in blood glucose that generally follows eating.
- Biguanides (including Glucophage®, Glucophage XR, and Fortamet®) lower blood glucose by improving the sensitivity of cells to insulin (i.e., by diminishing insulin resistance).
- Thiazolidinedione (including Avandia and Actos®) improves the uptake of glucose by cells in the body.
- Alpha-glucosidase inhibitors (including Prandase®, Precose and Glyset®) lower the amount of glucose absorbed from the intestines, thereby reducing the rise in blood glucose that occurs after a meal.
- Incretin mimetics (Byetta®) are a new class of drugs that work by several mechanisms including stimulating the pancreas to secrete insulin when blood glucose levels are high.
- Inhibitors of dipeptidyl peptidase IV (Januvia®) are another new class of drugs that work by blocking the degradation of GLP-1 (glucagon-like peptide-1), which is a naturally occurring incretin.

Injected insulin

In the subcutaneous insulin market, our competitors have made considerable efforts in promoting rapid acting injectable insulin formulations. Humalog®, which was developed by Eli Lilly and Company, and NovoLog®, which was developed by Novo Nordisk A/S, are the two principal injectable insulin formulations with which we expect to compete.

There are several companies, including Biodel Inc, and Halozyme Therapeutics, that are developing new injectable insulin products. Biodel recently submitted an NDA to the FDA seeking approval to market

VIAject®, an ultra-rapid-acting injectable human insulin for the treatment of diabetes. Halozyme's product, an injectable that combines their PH20 enzyme with insulin, is currently in Phase 2 clinical trials.

Insulin pumps

Insulin pumps are predominately used by patients with Type 1 diabetes but it has been reported that people with Type 2 diabetes have started to use them as well. The MiniMed Paradigm insulin pump, which is sold by Medtronic Inc., is currently the most prescribed and leading pump in the global market. Patients well controlled by insulin pumps may be reluctant to change insulin therapies.

Intellectual Property

We actively seek to protect our pharmaceutical formulations and proprietary information by means of U.S. and foreign patents, trademarks, trade secrets as well as various other contractual arrangements. We depend on our ability to protect our intellectual property and proprietary rights, but we may not be able to maintain the confidentiality, or assure the protection, of these assets in the United States or elsewhere.

Our success depends, in large part, on our ability to protect our current and future technologies and products and to defend our intellectual property rights. If we fail to protect our intellectual property adequately, competitors may manufacture and market products similar to ours. Patents covering our technologies have been issued to us, and we have filed, and expect to continue to file, patent applications seeking to protect newly developed technologies and products in various countries, including the United States. However, patents may not be issued with respect to any of our patent applications and existing or future patents issued to or licensed by us may not provide competitive advantages for our products. Patents that are issued may be challenged, invalidated or circumvented by our competitors. Furthermore, our patent rights may not prevent our competitors from developing, using or commercializing products that are similar or functionally equivalent to our products. Where trade secrets are our sole protection, we may not be able to prevent third parties from marketing generic equivalents to our products, reducing prices in the marketplace and reducing our profitability.

We have the following issued patents:

Patent/Technology	Jurisdiction	Expiration
Formulations and method of using macrocyclic enhancers, including CPE-215, with Testosterone, Testim® product	United States	2025(1)
Pharmaceutical formulations and methods of use patents relating to the use of nasal formulations of insulin ("Nasulin™")	United States	2024
Pharmaceutical formulations and methods of use patents relating to the combination of the macrocyclic enhancer with peptides, peptidomimetics or proteins	United States	2022

(1) Orange Book Listed Patents covering the Testim® formulation expire April 21, 2023 and January 18, 2025.

The use of our technology with various products such as insulin, testosterone as well as other peptides, is covered by both U.S. and foreign patents in many major market countries. The initial patent for use of our technology has expired in the United States in June 2008, will expire in Canada in 2010 and has expired in all other markets outside the United States. We have patent protection for the commercial formulations of testosterone (Testim) until 2025 and for the nasal insulin formulation under development (Nasulin) until 2024. We recently obtained six U.S. patents covering the testosterone formulation in the United States. These patents were added to the currently listed Orange Book: Approved Drugs with Therapeutic Equivalence ("Orange Book") patent for Testim, which means that there are a total of seven listed patents covering the Testim product. We have applied for and continue to file patent applications covering the use of our technology worldwide; however, we cannot provide any assurance that any patents will issue.

We also rely on trade secrets, non-patented proprietary expertise and continuing technological innovation that we seek to protect, in part, by entering into confidentiality agreements with licensees, suppliers, employees, consultants and others. To this end, we require our 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 all 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 our attention, or use, without proper authorization, any third party's proprietary technology. However, these agreements may be breached and there may not be adequate remedies in the event of a breach. Disputes may arise concerning the ownership of intellectual property or the applicability of confidentiality agreements. Moreover, our trade secrets and proprietary technology may otherwise become known or be independently developed by our competitors.

Third parties may claim that we infringe on their proprietary rights. There has been substantial litigation in the pharmaceutical industry with respect to the manufacture, use and sale of new products. These lawsuits relate to the validity and infringement of patents or proprietary rights of third parties. We may be required to commence or defend against charges relating to the infringement of patent or proprietary rights. Any such litigation could: (i) require us to incur substantial expenses, even if we are insured or successful in the litigation; (ii) require us to divert significant time and effort of our technical and management personnel; (iii) result in the loss of our rights to develop or make certain products; (iv) require us to pay substantial monetary damages or royalties in order to license proprietary rights from third parties; and (v) prevent us from launching a developed, tested and approved product.

Assignment Agreement with Access Pharmaceuticals, Inc.

Under an Assignment Agreement with MacroChem Corporation ("MacroChem"), dated June 24, 2003, which was assumed by Access Pharmaceuticals, Inc. ("Access") following their acquisition of MacroChem in February 2009, we own all of Access'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 "Access Patent Rights"). As a result of the assignment, Access retained no interest whatsoever in the Access Patent Rights. To date, we have not generated any revenue from the Access Patent Rights, which expire in 2020.

Government Regulation

Numerous governmental authorities in the U.S. and other countries extensively regulate the activities of pharmaceutical manufacturers. If we fail to comply with the applicable requirements of governmental authorities, we may be subject to administrative or judicial sanctions such as 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.

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 developing preclinical laboratory supporting data and animal safety testing. The approval process generally consists of the following five principal stages:

- preclinical testing (supporting safety and potential efficacy);
- submission and review by the FDA of an Investigational New Drug Exemption (IND) Application;
- clinical trials;
- preparation and submission of the New Drug Application (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 1 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 2 involves the first controlled clinical trial involving patients who have the targeted disease or condition and consists of safety and efficacy studies. The studies may be divided into early Phase 2 (or 2a), during which studies are performed to determine initial efficacy and late Phase 2 (or 2b) which may consist of placebo-controlled trials in a larger number of patients.
- Phase 3 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 Chemistry/Manufacturing/Controls data, clinical studies, statistical evaluation and all relevant supporting research data that has been collected over many years of development is submitted to the FDA in an NDA. Additionally, an NDA will contain complete information on the proposed manufacturing process including process, equipment and facilities validation demonstrating that the applicant is capable of consistently manufacturing a drug product of appropriate strength, quality and purity consistent with the product that was studied in the clinical trials. 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 Abbreviated New Drug Application, or 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 product under review) with another (usually the innovator product). When bioequivalence is established, the rate of absorption and levels of concentration of the 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 Good Manufacturing Practices or cGMPs for drugs. To supply products for use in the U.S., foreign manufacturing establishments must also comply with U.S. cGMPs 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.

Employees

We employ 17 people, as of March 24, 2010, all of which are full-time employees and are based in the United States. Approximately half of these employees are principally engaged in research, development, clinical and regulatory activities. In general, we consider our relations with our employees to be good.

Executive Officers

Our Executive Officers are listed below:

Name	Age	Position(s)
John A. Sedor	65	Chief Executive Officer, President and Director
Nils Bergenhem	51	Chief Scientific Officer and Vice President
Lance Berman	39	Chief Medical Officer and Senior Vice President
Robert P. Hebert	37	Chief Financial Officer and Vice President

John A. Sedor, CEO and President — Mr. Sedor has been our Chief Executive Officer and President since the spin-off from Bentley in 2008. Mr. Sedor was President of Bentley from 2005 until the spin-off. From 2001 to May 2005, he was President and CEO of Sandoz, Inc. (a division of Novartis AG). From 1998-2001 Mr. Sedor was President and Chief Executive Officer at Verion, Inc., a drug delivery company. Previously, Mr. Sedor served as President and Chief Executive Officer at Centeon, LLC, a joint venture between two major multinational corporations, Rhône-Poulenc Rorer and Hoechst AG. Previously, Mr. Sedor served as Executive Vice President at Rhône-Poulenc Rorer, Revlon Health Care and Parke-Davis. Mr. Sedor holds a Bachelor of Science degree in Pharmacy/Chemistry from Duquesne University, and has studied strategic marketing at both Northwestern University's Kellogg Graduate School of Management and Harvard Business School. He has also attended Harvard's Executive Forum.

Nils Bergenhem, Ph.D., Chief Scientific Officer — Dr. Berhgenhem joined us as Chief Scientific Officer in February 2010. From January 2008 until joining CPEX, Dr. Bergenhem served as Chief Scientific Officer at Escoublac, Inc., the first biotechnology company in the Biogen Idec Innovations Incubator. There, he was responsible for development and execution of the research plan for human osteocalcin in metabolic disease, Type 2 diabetes and obesity. From June 2005 until December 2007 he served as CSO at AdipoGenix where he oversaw internal drug discovery and development programs for obesity and related co-morbidities, as well as the AdipoGenix alliance with Johnson and Johnson. Previously, Dr. Bergenhem served as Vice President for Research at the Institute for Diabetes Discovery, as Director for Diabetes Research at OSI Pharmaceuticals Inc. and held positions of increasing importance at Novo Nordisk in Copenhagen. Dr. Bergenhem holds a BS degree in Chemistry from Linkoping University, Sweden, and a Ph.D. in Biochemistry from Umeå University, Sweden. He has completed postdoctoral work at University of Michigan in Molecular Biology and Human Genetics, where he also spent three years at the School of Medicine as Research Investigator at the Institute of Gerontology and at the Department of Biological Chemistry.

Lance Berman, M.D., Chief Medical Officer — Dr. Berman has been our Chief Medical Officer since February 2009. Previously, Dr. Berman served at Pfizer from 2003 until 2009. From December 2007 he served as Senior Medical Director and Global Medical Team Leader at Pfizer, responsible for the strategic medical development and evolution of products within the cardiovascular and diabetes portfolios. Previously, Dr. Berman held roles of increasing importance at Schering-Plough from 1999 to 2003 and Janssen Pharmaceuticals (Johnson & Johnson) from 1996 to 1999. Dr. Berman received his Bachelor of Medicine and Bachelor of Surgery at University of Cape Town in Cape Town, South Africa, and holds a Masters Degree in Pharmaceutical Medicine.

Robert P. Hebert, CFO and Vice President — Mr. Hebert has been in this role since the spin-off from Bentley in 2008. From June 2006 until the spin-off, Mr. Hebert was Controller and Principal Accounting Officer for Bentley. In this role, Mr. Hebert managed all of Bentley's accounting and reporting functions. From

May 2003 until June 2006, Mr. Hebert was Bentley's Director of SEC Reporting & Compliance, Assistant Secretary and Assistant Treasurer. His responsibilities in this role included Bentley's financial reporting and compliance with the requirements of the Sarbanes-Oxley Act of 2002. Prior to joining Bentley, Mr. Hebert worked as an auditor for Deloitte & Touche LLP from 1995 to 2003. Mr. Hebert received a B.S. in Business Administration with a concentration in accounting from Merrimack College in 1995.

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.cpexpharm.com, free of charge, as soon as reasonably practicable after we electronically file such reports with, or furnish such reports to, the Securities and Exchange Commission. Alternatively, these reports can be accessed through a query at the website of the Securities and Exchange Commission at www.sec.gov.

Item 1A. *Risk Factors*

You should carefully consider the following discussion of risks and uncertainties 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.

We anticipate that we will incur losses for the foreseeable future. We may never achieve or sustain profitability. If additional capital is not available, we may have to curtail or cease operations.

Our business currently is not expected to generate all of the cash that is necessary to finance our operations in the short-term. Subject to the success of our development programs, the continuance of our Testim® royalty payments, and potential future licensing transactions, we will need to raise additional capital to:

- fund our research and development programs;
- develop and commercialize our product candidates;
- enhance existing services;
- respond to competitive pressures; and
- acquire complementary businesses or technologies.

Our future capital needs depend on many factors, including:

- the scope, duration and expenditures associated with our research and development programs;
- continued scientific progress in these programs;
- the amount of royalties or other revenues we are able to earn and collect;
- the outcome of potential licensing transactions, if any;
- competing technological developments;
- our proprietary patent position, if any, in our products; and
- the regulatory approval process for our products.

We may seek to raise necessary funds through public or private equity offerings, debt financings or additional strategic alliances and licensing arrangements. We may not be able to obtain additional financing on terms favorable to us, if at all. General market conditions may make it very difficult for us to seek financing

from the capital markets. We may be required to relinquish rights to our technology or drug candidates, or grant licenses on terms that are not favorable to us, in order to raise additional funds through an alliance, a joint venture or a licensing arrangement. If adequate funds are not available, we may have to delay, reduce or eliminate one or more of our research or development programs and reduce overall overhead expenses. These actions would likely reduce the market price of our common stock.

Substantially all of our revenues to date have been generated from royalties on Auxilium's sales of Testim, which is subject to projected generic competition. Should the sales of Testim decline, we may be required to limit, scale back or cease operations.

Substantially all of our revenues are derived through royalty income from the only commercialized product utilizing our CPE-215 technology, Testim, which is sold by Auxilium. Testim royalties totaled $18.6 million, $15.1 million and $11.1 million in the years ended December 31, 2009, 2008 and 2007, respectively, and the only expenses regarding Testim® that we have incurred during that period have been patent maintenance costs, which have not been material. Though we believe that Auxilium intends to continue commercialization of Testim, sales of this product are subject to the following risks, among others:

- pressures from existing or new competing products, including generic products, that may provide therapeutic, convenience or pricing advantages over Testim or may garner a greater share of the market;
- growth of the overall androgen market where Testim competes; and
- commercialization priorities of Auxilium.

In October 2008, we and Auxilium received notice that Upsher-Smith Laboratories filed an Abbreviated New Drug Application, or ANDA, containing a paragraph IV certification in which it certified that it believes that its testosterone gel product does not infringe our '968 patent. The '968 Patent covers a method for maintaining effective blood serum testosterone levels for treating a hypogonadal male using Testim and will expire in January 2025. The '968 patent is listed in Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book), published by the U.S. Food and Drug Administration. The paragraph IV certification sets forth allegations that the '968 Patent will not be infringed by Upsher-Smith's manufacture, use or sale of the product for which the ANDA was submitted. On December 4, 2008, we and Auxilium filed a lawsuit in the United States District Court for the District of Delaware against Upsher-Smith under the Hatch Waxman Act for infringement of our patent. In June 2009, Upsher-Smith amended its answer to the complaint to include a defense and counterclaim of invalidity of the '968 Patent, which we and Auxilium deny. We and Auxilium filed a reply to the counterclaim in July 2009 denying the invalidity of the '968 Patent. A patent issued by the Patent and Trademark Office, such as the '968 Patent, is presumed valid. As described more fully under Item 3 — "Legal Proceedings" in this report, any FDA approval of Upsher-Smith's proposed generic product will be stayed until the earlier of 30 months beginning on the date of receipt of the paragraph IV certification (April 2011) or an adverse decision in our patent infringement lawsuit.

Should Testim sales be adversely impacted by any of the above risks, our revenues will be reduced, which may force us to delay our current plans to develop other product candidates.

In addition, our royalty income is dependent upon our ability to maintain our intellectual property claims for our CPE-215 technology that is used in the Testim product. Should we be unable to maintain our intellectual property position with regards to CPE-215, our royalty income would be impaired.

We cannot give any assurance that Nasulin will advance in clinical trials or will receive regulatory approval.

We are currently conducting additional analyses of the data from the Nasulin clinical studies to determine the appropriate next steps for the Nasulin program. We may decide not to conduct further trials of Nasulin. If we do conduct trials, the trials may not be successful and Nasulin may never receive regulatory approval or be successfully commercialized. Our clinical development program for Nasulin may not receive regulatory approval either if we fail to demonstrate that it is safe and effective in clinical trials and consequently fail to

obtain necessary approvals from the FDA, or similar non-U.S. regulatory agencies, or if we have inadequate financial or other resources to advance Nasulin through the clinical trial process.

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

Substantial time, 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.

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 technology. 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.

Our growth depends on identifying drugs suitable for our drug delivery technology.

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.

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

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

- the proposed products will have adverse side effects or will otherwise fail to receive necessary regulatory approvals;
- the proposed products may be effective but uneconomical to market; or
- other pharmaceutical companies may market equivalent or superior products.

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

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

- perceived efficacy of our products;
- convenience and ease of administration;
- prevalence and severity of adverse side effects in both clinical trials and commercial use;
- availability of alternative treatments;
- cost effectiveness;
- effectiveness of our marketing strategy and the pricing of our products;
- publicity concerning our products or competing products; and
- our ability to obtain third-party coverage or reimbursement.

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

- the effectiveness of our sales force;
- the effectiveness of our production, distribution and marketing capabilities;
- the success of competing products; and
- the availability and extent of reimbursement from third-party payors.

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

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

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

In collaborative arrangements, we will depend on the efforts of our strategic partners and will have limited participation in the development, manufacture, marketing and commercialization of the products subject to the collaboration. We cannot assure you that these strategic partnerships or collaborative arrangements will be successful, nor can we assure you that strategic partners or collaborators will not pursue alternative technologies or develop alternative products on their own or with others, including our competitors. In addition, our collaborators or contract manufacturers will 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.

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

We do not own or operate manufacturing facilities for clinical or commercial production of our product candidates. We lack the resources and the capability to manufacture any of our 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 product development or commercialization activity.

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.

The Company has a licensing agreement with Auxilium pursuant to which the Company licenses its CPE-215 with Testosterone formulation to Auxilium and receives royalties of 12% from Auxilium based upon Auxilium's sales of Testim. This royalty stream is the Company's major source of current revenue. If the Company does not maintain adequate patent protection for Testim, the royalty rate due to the Company would be reduced to 2%. To date the Company has not experienced a reduction in the royalty rate due to loss of patent protection and the Company recently obtained patents that cover the application of testosterone with CPE-215 in the U.S. and in foreign countries that continue through 2023.

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

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.

Successful commercialization of many of our 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 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 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 or are delayed for any product candidate, we will be unable to market it.

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

- slow or insufficient patient enrollment;

- slow recruitment and completion of necessary institutional approvals at clinical sites;
- longer treatment time required to demonstrate efficacy;
- lack of sufficient supplies of the product candidate;
- adverse medical reactions or side effects in treated patients;
- lack of effectiveness of the product candidate being tested;
- regulatory requests for additional clinical trials; and
- instability of the pharmaceutical formulations.

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

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 any of our product candidates. 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.

If our existing patents do not afford adequate protection to us, our competitors may be able to develop competing products.

The basic patent disclosing and claiming CPE-215 technology expired in the U.S. in June 2008 and most foreign markets in 2006. The patent will also expire in Canada in 2010. The Company has filed applications in many countries that cover the application of testosterone with CPE-215. Patents for the application of testosterone with CPE-215 have been issued to us in various countries, including the U.S., Canada and Europe that continue through 2023. As such, we do not anticipate a significant impact from the expiration of the basic CPE-215 patent on the current Testim royalty rates due to the Company or on our plan of operation or future business plans. The Company also has pending applications for other applications involving CPE-215 technology. If our pending applications covering various applications involving CPE-215 technology are not issued as patents or if our patents do not afford adequate protection to us or our licensees, our competitors may be able to use information from our expired and soon to expire patents to develop, manufacture and market products that compete with our products, as well as other products using CPE-215 that we otherwise might have developed.

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

We have filed a number of patent applications and have been granted licenses to, or have acquired, a number of patents. We cannot assure you, however, that any of our issued or licensed patents will afford adequate protection to us or our licensees. Furthermore, enforcing a claim that another person is infringing one or more of our patents is expensive and time consuming, and the outcome is unpredictable. 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.

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

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

Government regulations in the United States and other countries have a significant impact on our business and affect the research, development and marketing of products incorporating our technology. In the United States and other countries, governmental agencies have the authority to regulate the distribution, manufacture and sale of drugs. Failure to obtain or experiencing a delay in obtaining regulatory approval for our products could result in 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.

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.

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

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

We 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. While we currently do not have any plans to hire additional personnel, in the future, we may need to expand our staff in various areas of the business. 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. The Company has never been profitable and our revenues are currently insufficient to generate a profit; if we fail to generate additional revenue in excess of any increased operating expenses in any fiscal period, we will continue to incur losses.

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 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 from other pharmaceutical companies in recruiting competent personnel. The loss of key personnel, or the inability to attract and retain additional, competent employees, could adversely affect our business and financial results.

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

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. We maintain $5.0 million in product liability and clinical trials insurance in the U.S. at an approximate cost of $53,000 per policy year. While management believes this insurance is reasonable for conducting clinical trials, 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.

We have a history of operating losses, expect to continue to have losses in the future and may never achieve or maintain profitability.

We have incurred operating losses since the Separation date and we expect to continue to incur operating losses over the coming years as we continue to incur significant costs for research and development, clinical trials, sales and general and administrative functions. Our ability to achieve profitability depends upon our ability, alone or with others, to successfully complete the development of Nasulin, obtain the required regulatory clearances, and deliver Nasulin to market.

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 this "Risk Factors" section, specific factors that may cause fluctuations in our operating results include:

- demand and pricing for our products;
- 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;
- 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.

We could be negatively affected as a result of a threatened proxy fight and other actions of activist shareholders.

We received notice from Arcadia Opportunity Master Fund, Ltd. and its affiliates, Arcadia Capital Advisors, LLC and Richard Rofé, collectively referred as Arcadia, of their intention to nominate Mr. Rofé for election to our Board of Directors at our 2010 annual stockholders meeting. As of February 22, 2010, Arcadia owned beneficially 9.98% of our outstanding common stock. If Arcadia carries through with its intention and launches a proxy contest, our business could be adversely affected because:

- responding to proxy contests and other actions by activist stockholders can be costly and time-consuming, disrupting our operations and diverting the attention of management and our employees;
- perceived uncertainties as to our future direction may impact our existing or potential collaborations or strategic relationships; and
- if individuals are elected to our Board of Directors with a specific agenda, potentially including Mr. Rofé, it may adversely affect our ability to effectively and timely implement our strategic plan.

Our historical financial information is not necessarily representative of the results we would have achieved as a separate publicly traded company and may not be a reliable indicator of our future results.

The historical financial information we have included in this Form 10-K may not reflect what our results of operations, financial position and cash flows would have been had we been an independent publicly traded

company during the periods presented or what our results of operations, financial position and cash flows will be in the future when we are an independent company. This is primarily because:

- our historical financial information reflects allocations for services historically provided to us by Bentley, which allocations may not reflect the costs we will incur for similar services in the future as an independent company; and
- our historical financial information does not reflect changes that we expect to incur in the future as a result of our separation from Bentley, including changes in the cost structure, personnel needs, financing and operations of the contributed business as a result of the separation from Bentley and from reduced economies of scale.

Since the Separation date, we have been responsible for the additional costs associated with being an independent public company, including costs related to corporate governance and having listed and registered securities. Therefore, our financial statements may not be indicative of our future performance as an independent company. For additional information about our past financial performance and the basis of presentation of our financial statements, please see "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the notes thereto included elsewhere in this Form 10-K.

Risks Relating to Our Common Stock

Your percentage ownership in CPEX common stock may be diluted in the future.

Your percentage ownership in CPEX may be diluted in the future because of equity awards that have or we expect will be granted to our directors, officers and employees and the accelerated vesting of equity awards. Shareholders of CPEX have approved the Amended and Restated 2008 Equity Incentive Plan (the "2008 Equity Incentive Plan"), which provides for the grant of equity based awards, including restricted stock, restricted stock units, stock options, stock appreciation rights, unrestricted stock and stock equivalents and other equity-based awards to our directors, officers and other employees, advisors and consultants.

Provisions in our certificate of incorporation and by-laws and of Delaware law may prevent or delay an acquisition of our Company, which could decrease the trading price of our common stock.

Our certificate of incorporation, by-laws and Delaware law contain provisions that are intended to deter coercive takeover practices and inadequate takeover bids by making such practices or bids unacceptably expensive to the raider and to encourage prospective acquirors to negotiate with our Board of Directors rather than to attempt a hostile takeover. These provisions include, among others:

- a Board of Directors that is divided into three classes with staggered terms;
- elimination of the right of our stockholders to act by written consent;
- rules regarding how stockholders may present proposals or nominate directors for election at stockholder meetings;
- the right of our Board to issue preferred stock without stockholder approval; and
- limitations on the right of stockholders to remove directors.

Delaware law also imposes some restrictions on mergers and other business combinations between us and any holder of 15% or more of our outstanding common stock.

We also maintain a shareholder rights plan which may deter a potential acquiror from pursuing an offer for our company.

We believe these provisions protect our stockholders from coercive or otherwise unfair takeover tactics by requiring potential acquirors to negotiate with our Board and by providing our Board with more time to assess any acquisition proposal. These provisions are not intended to make our company immune from takeovers. However, these provisions apply even if the offer may be considered beneficial by some stockholders and

could delay or prevent an acquisition that our Board determines is not in the best interests of our company and our stockholders.

We do not expect to pay any dividends in the short term.

We do not expect to declare dividends in the short term. We currently intend to retain earnings to support our operations and to finance the growth and development of our business. There can be no assurance that we will have sufficient surplus under Delaware law to be able to pay any dividends. This may result from extraordinary cash expenses, actual expenses exceeding contemplated costs funding of capital expenditures, or increases in reserves. If we do not pay dividends, the price of our common stock must appreciate for you to receive a gain on your investment in CPEX. This appreciation may not occur.

Item 1B. *Unresolved Staff Comments*

Not applicable.

Item 2. *Properties*

We own a 15,700 square foot commercial building situated on approximately 14 acres of land in Exeter, New Hampshire which has sufficient space and fixtures to serve as our corporate headquarters and research and development laboratory. It is located approximately 50 miles north of Boston, Massachusetts.

Item 3. *Legal Proceedings*

In October 2008, we and Auxilium received notice that Upsher-Smith Laboratories filed an Abbreviated New Drug Application, or ANDA, containing a paragraph IV certification in which it certified that it believes that its testosterone gel product does not infringe our patent, U.S. Patent No. 7,320,968 ("the '968 Patent"). The '968 patent covers a method for maintaining effective blood serum testosterone levels for treating a hypogonadal male using Testim and will expire in January 2025. The '968 Patent is listed in Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book), published by the U.S. Food and Drug Administration. Upsher-Smith Laboratories' paragraph IV certification sets forth allegations that the '968 Patent will not be infringed by Upsher-Smith's manufacture, use or sale of the product for which the ANDA was submitted. On December 4, 2008, we and Auxilium filed a lawsuit in the United States District Court for the District of Delaware against Upsher-Smith under the Hatch Waxman Act for infringement of our patent. In June 2009, Upsher-Smith amended its answer to the complaint to include a defense and counterclaim of invalidity of the '968 Patent, which CPEX and Auxilium deny. A patent issued by the U.S. Patent and Trademark Office, such as the '968 Patent, is presumed valid. The lawsuit is currently ongoing. Any U.S. Food and Drug Administration (FDA) approval of Upsher-Smith's proposed generic product will be stayed until the earlier of 30 months from the date of receipt of the paragraph IV certification (April 2011) or an adverse decision in our patent infringement lawsuit.

CPEX has filed continuation and divisional applications with the USPTO relating to the '968 patent. Six patents issued from these applications on October 27, 2009, namely U.S. Patent Nos. 7,608,605, 7,608,606, 7,608,607, 7,608,608, 7,608,609 and 7,608,610, which may provide us with further market protection. Each of these six patents has been listed in listed in Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book) with respect to Testim.

We and Auxilium are committed to protecting our intellectual property rights and will vigorously pursue this lawsuit. However, if we are unsuccessful in defending the '968 Patent covering Testim, sales of Testim and our royalties relating to Testim sales will be materially reduced.

Item 4. *(Removed and Reserved)*

Part II

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

Our common stock has been trading on The NASDAQ Capital Market since July 1, 2008, under the trading symbol "CPEX". 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 NASDAQ Capital Market since the stock was first traded;

	High	Low
Fiscal Year Ended December 31, 2009		
First Quarter	*$12.58*	*$5.90*
Second Quarter	*11.54*	*6.76*
Third Quarter	*11.00*	*8.23*
Fourth Quarter	*12.75*	*8.00*
Fiscal Year Ended December 31, 2008		
Third Quarter	*$19.98*	*$9.17*
Fourth Quarter	*19.77*	*7.49*

As of March 24, 2010 the closing price of our Common Stock was $14.86 and there were 601 holders of record of our common stock, which does not reflect stockholders whose shares are held in street name.

Dividends

We did not pay dividends on our common stock during the years ended December 31, 2009 and 2008 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.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table summarizes the number of securities issuable under our Amended and Restated 2008 Equity Incentive Plan as of December 31, 2009.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in the First Column)
Equity compensation plans approved by security holders	509,925	$13.50	90,741
Equity compensation plans not approved by security holders	None	N/A	None
Total	509,925	$13.50	90,741

Item 6. *Selected Financial Data*

Not applicable.

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 to the Condensed Combined and Consolidated Financial Statements, or Notes, included in Item 15 of this Annual 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", "may", "could", "project", "estimate" and similar words are used to identify forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements, including, but not limited to, the statements in "Business", "Legal Proceedings", "Management's Discussion and Analysis of Financial Condition and Results of Operations", "Risk Factors" and other sections in this Annual 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, the prospects for clinical development of our product candidates, our prospects for revenue growth, 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.

Overview

We are an emerging specialty pharmaceutical company that employs 17 people as of March 24, 2010, at our principal executive offices in Exeter, New Hampshire. Our business is the research, development, licensing and commercialization of pharmaceutical products utilizing our validated drug delivery platform technology. We have U.S. and international patents and other proprietary rights to technology that facilitates the absorption of drugs. Our platform drug delivery technology enhances permeation and absorption of pharmaceutical molecules across the skin, nasal mucosa and eye through formulation development with proprietary molecules such as CPE-215. Our first product is Testim®, a gel for testosterone replacement therapy, which is a formulation of CPE-215 with testosterone. Testim is licensed to Auxilium Pharmaceuticals, Inc. who is currently marketing the product in the United States, Europe and other countries. Our second product, Nasulin™, currently in Phase 2, is an intranasal spray formulation of CPE-215 with insulin being developed to treat hyperglycemia in patients suffering from Type 1 and Type 2 diabetes.

We believe, based upon our experience with Testim and Nasulin, that our CPE-215 technology is a broad platform technology 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. The alliance opportunities may include co-development of products, in-licensing of therapeutic molecules, out-licensing of delivery technology or partnering late-stage candidates for commercialization.

Separation from Bentley

Our business was initially the drug delivery business of Bentley Pharmaceuticals, Inc. (referred to as "Bentley") which Bentley spun-off in June 2008 in connection with the sale of Bentley's remaining businesses. Shares of our stock were distributed to Bentley stockholders after the close of business on June 30, 2008 (the "Separation Date") by means of a stock dividend, a transaction that was taxable to Bentley and Bentley's stockholders (the "Separation"). Each Bentley stockholder of record on June 20, 2008, the record date, received on the Separation Date one CPEX share for every ten shares of Bentley common stock. Bentley has no ownership interest in CPEX subsequent to the Separation.

Our financial statements for the twelve months ended December 31, 2009 and the balance sheet as of December 31, 2008 represent stand-alone financial information for our Company. The statements of operations,

statements of changes in stockholders' equity and statements of cash flows for the years ended December 31, 2008, which include six months of financial data prior to the Separation Date, and all of 2007 reflect the historical financial position, results of operations and cash flows of the business transferred to us from Bentley as part of the Separation. Our financial statements have been prepared and are presented as if we had been operating as a separate entity using the historical cost basis of the assets and liabilities of Bentley and including the historical operations of the business transferred to us from Bentley as part of the Separation. Prior to the Separation Date, we were fully integrated with Bentley and the accompanying financial statements reflect the application of certain estimates and allocations. Our statements of operations include all revenues and costs that are directly attributable to our business. In addition, certain expenses of Bentley have been allocated to us using various assumptions that, in the opinion of management, are reasonable. These expenses include an allocated share of executive compensation, public company costs and other administrative costs. The allocated costs totaled $4.4 million and $4.2 million for the years ended December 31, 2008 and 2007, respectively. There have been no allocations of expenses charged to us since the Separation Date. The financial information included herein may not necessarily reflect our financial position, results of operations and cash flows in the future or what our financial position, results of operations and cash flows would have been had we been a stand-alone company during the periods presented.

Consolidated Results of Operations

The following is a discussion of the results of our operations for the years ended December 31, 2009, 2008 and 2007. Included in the financial disclosures are direct costs associated with our business and certain allocated costs from Bentley related to executive compensation, public company costs and other administrative costs for periods before June 30, 2008. As these costs only represent an allocation of the costs incurred by Bentley before the Separation, they are not necessarily indicative of the costs that would have been incurred if we were an independent public company in the periods presented. Inflation and changing prices have not had a material impact on our revenues or loss from operations in the three years ended December 31, 2009.

Fiscal Year Ended December 31, 2009 Compared To Fiscal Year Ended December 31, 2008

	Year Ended December 31,		Increase (Decrease)	
	2009	2008	$	%
	(In thousands)			
Royalties and other revenue	$18,658	$15,574	$ 3,084	20%
Operating expenses:				
General and administrative	8,867	6,493	2,374	37%
Research and development	12,291	9,119	3,172	35%
Separation costs	—	2,502	(2,502)	(100)%
Depreciation and amortization	699	682	17	2%
Total operating expenses	21,857	18,796	3,061	16%
Loss from operations	(3,199)	(3,222)	23	(1)%
Other, net	159	307	(148)	(48)%
Net loss	$(3,040)	$(2,915)	$ (125)	4%

Royalties and other revenue increased 20% to $18.7 million in 2009 from $15.6 million in 2008 due entirely to increased royalties earned on sales of Testim. For the year ended December 31, 2009, Testim prescriptions were reported to have grown approximately 15% compared to the same period in 2008. The long-term prospects for Testim sales are subject to resolution of our patent infringement suit against Upsher-Smith, which has made an ANDA filing for a generic version of Testim, as described above in "Legal Proceedings". Clinical and other revenue was $16,000 in 2009 compared to $513,000 in 2008 which includes revenue from our development and license agreement with Serenity Pharmaceuticals, Inc. which we signed in 2008.

General and administrative costs increased 37% to $8.9 million in 2009 compared to $6.5 million in 2008, primarily due to a $2.8 million increase in legal fees, mostly relating to the patent infringement suit against Upsher-Smith Laboratories, which were partially offset by a $674,000 decrease in share-based compensation expense. Included in general and administrative expenses for the year ended December 31, 2008 is a one-time, non-cash charge of approximately $980,000 resulting from the modification of equity awards associated with the spin-off from Bentley.

Research and development expenses consist primarily of costs associated with the development of Nasulin, our lead product candidate in development. These costs include costs of clinical trials, 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. Research and development costs increased to $12.3 million in 2009 compared to $9.1 million in 2008, mostly due to a $3.7 million increase in spending on clinical trials, which was partially offset by a reduction in non-cash share-based compensation expense of $494,000. The increase in clinical trials expense is primarily attributable to the Phase 2a study of Nasulin.

We expect our research and development costs in 2010 to be between $10 million and $12 million. We completed enrollment in a Phase 2a trial in the U.S. in 2009 and preliminary results from this trial were reported in March, 2010. Our expectation was to initiate a Phase 2b trial of Nasulin in the U.S. in 2010 while continuing the development of products in our pipeline. However, as explained above in "*Business — Overview*", we will not commence our planned Phase 2b trial or other Nasulin development initiatives while we conduct additional analyses on the data from the Phase 2a study together with all other Nasulin data to determine the appropriate next steps for the Nasulin program. Additional expenses for the full development of Nasulin cannot be estimated at this time. The risks and uncertainties associated with the planning and execution of a clinical development program includes, among other things, uncertainties about results that at any time could require us to abandon or greatly modify the program. Accordingly, we cannot estimate the period in which material net cash inflows from Nasulin might commence, if ever.

Separation costs, consisting of legal, tax and other strategic consulting costs specifically related to the separation from Bentley explained above, were $2.5 million in 2008. No additional separation costs have been incurred since the Separation Date and we do not expect to incur any additional separation costs in the future.

Fiscal Year Ended December 31, 2008 Compared To Fiscal Year Ended December 31, 2007

	Year Ended December 31,		Increase (Decrease)	
	2008	2007	$	%
	(In thousands)			
Royalties and other revenue	$15,574	$11,127	$4,447	40%
Operating expenses:				
General and administrative	6,493	5,206	1,287	25%
Research and development	9,119	9,646	(527)	(5)%
Separation costs	2,502	1,010	1,492	148%
Depreciation and amortization	682	752	(70)	(9)%
Total operating expenses:	18,796	16,614	2,182	13%
Loss from operations	(3,222)	(5,487)	2,265	(41)%
Other, net	307	559	(252)	(45)%
Net loss	$(2,915)	$(4,928)	$2,013	(41)%

Royalties and other revenue increased 40% to $15.6 million in 2008 from $11.1 million in 2007 due primarily to increased royalties earned on sales of Testim. For the year ended December 31, 2008, Testim prescriptions were reported to have grown approximately 27% compared to the same period in 2007. In addition, it is also reported that Testim's market share of the testosterone replacement gel market in December

2008 had increased to more than 22% versus approximately 21% in December 2007. Clinical and other revenue was $513,000 in 2008 which includes revenue from our development and license agreement with Serenity Pharmaceuticals, Inc. which we signed in 2008 and for which there is no comparable revenue in 2007.

General and administrative costs increased 25% to $6.5 million in 2008 compared to $5.2 million in 2007, primarily due to a non-cash charge of approximately $980,000 resulting from the modification of equity awards associated with the spin-off from Bentley.

Research and development expenses consist primarily of costs associated with the development of Nasulin, our lead product candidate. These costs include costs of clinical trials, 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. Research and development costs decreased to $9.1 million in 2008 compared to $9.6 million in 2007 due mostly to the timing of our pre-clinical and clinical activities. Spending on clinical trials was $1.5 million in 2008 compared to $2.1 million in 2007.

Separation costs, consisting of legal, tax and other strategic consulting costs specifically related to the separation from Bentley explained above, were $2.5 million in 2008 compared to $1.0 million in 2007.

Liquidity and Capital Resources

Overview

We had approximately $13.7 million in cash and cash equivalents at December 31, 2009, which, along with Testim royalties, we believe will be sufficient to fund our operations and our cash requirements for at least the next twelve months. Our cash includes balances maintained in commercial bank accounts, amounts invested in overnight sweep investments and cash deposits in money market accounts. Although cost estimates and timing of our activities are subject to change, we expect research and development expenses for 2010 to range between $10 million and $12 million. There can be no assurance that changes in our research and development plans or other events affecting our revenues or operating expenses will not result in the earlier depletion of our funds. However, we will continue to explore alternative sources for financing our business activities. In appropriate situations, which will be strategically determined, we may seek funding from other sources, including, but not limited to, contribution by others to joint ventures and other collaborative or licensing arrangements for the development, testing, manufacturing and marketing of Nasulin and other products currently under development or sales of debt or equity securities.

Summary Cash Flow Information

	December 31,		
	2009	2008	2007
		(In thousands)	
Summary Financial Position			
Cash and cash equivalents	$13,695	$15,211	$21,659
Accounts receivable	5,289	4,445	3,245
Total assets	26,043	26,473	32,397
Accounts payable and accrued expenses	3,007	2,630	3,221
Working capital	16,570	17,609	22,365
Total stockholders' equity	23,036	23,843	29,151

	December 31,		
	2009	2008	2007
Summary of Sources and (Uses) of Cash:			
Operating activities	$(598)	$ (553)	$(2,186)
Investing activities	(922)	(307)	(430)
Purchases of property, plant and equipment	(398)	(307)	(303)
Additions to intangible assets	(224)	—	(157)
Financing activities	4	(5,588)	13,523

Sources and Uses of Cash

Operating Activities

Net cash used in operating activities was $598,000 for the year ended December 31, 2009, largely resulting from the net loss of $3.0 million and an increase in accounts receivable of $844,000, which were partially offset by non-cash share-based compensation expense of $1.9 million, increases in accounts payable and accrued expenses of $670,000 and depreciation and amortization of $699,000. Net cash used in operating activities was $553,000 for the year ended December 31, 2008, largely resulting from the net loss of $2.9 million, an increase in accounts receivable of $1.2 million and a reduction in accounts payable and accrued expenses of $591,000, which were partially offset by non-cash share-based compensation of $3.2 million and depreciation and amortization of $682,000. Net cash used in 2007 was $2.2 million resulting from the net loss of $4.9 million and an increase in accounts receivable of $1.0 million, which were partially offset by non-cash share-based compensation expense of $1.5 million, an increase in accounts payable and accrued expenses of $1.1 million and depreciation and amortization expenses of $752,000.

Investing Activities

Net cash used in investing activities was $922,000 for the year ended December 31, 2009 which includes $398,000 for the purchase of manufacturing and laboratory equipment, $300,000 for the note receivable explained in the notes to our consolidated and combined financial statements under *Commitments, contingencies and concentrations,* and $224,000 for costs related to obtaining new patents. Net cash used in investing activities was $307,000 for the year ended December 31, 2008 due to the purchase of necessary equipment to scale-up our manufacturing capabilities. Net cash used in the twelve months ended December 31, 2007 was $430,000, which includes $303,000 for laboratory expansion and equipment and $157,000 for costs to acquire intellectual property rights. We expect to invest approximately $220,000 in capital expenditures in 2010, primarily for research and development equipment.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2009 includes proceeds from the exercise of stock options. Net cash used by financing activities was $5.6 million for the year ended December 31, 2008 due largely to the change in Bentley's net investment in our business of $7.3 million, which was partially offset by proceeds of $1.7 million from the exercise of stock options. Financing activities for 2007 reflect the net change in Bentley's net investment in our business, consisting primarily of the funding of our net loss and other operating and investing activities for CPEX. Additionally, the change in Bentley's net investment included a cash transfer of $5.5 million to us from Bentley.

Off-Balance Sheet Arrangements

We do not have any material 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, 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

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. We recognize revenue upon receiving sales reports from Auxilium which includes estimates for revenue deductions, including discounts, rebates and product returns. Estimates related to revenue deductions are predominately based on historical experience.

Accounts receivable are also recorded upon the receipt of sales reports from Auxilium at their net realizable value. 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.

Intellectual property costs

Costs incurred in connection with acquiring licenses, patents and other proprietary rights are capitalized. Capitalized costs are 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.

Research and development costs

Research and development expenses consist primarily of costs associated with our clinical trials, 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 Financial Accounting Standards Board (the "FASB") Accounting Standards Codification ("FASB ASC") 730-10-25-1 *(Prior authoritative literature: SFAS No. 2, Accounting for Research and Development Costs)*. Our clinical trial costs, which are reflected in research and development expenses, result from obligations under contracts with vendors, consultants, and clinical site agreements 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 is obtained through discussions with internal personnel as well as outside service providers. Determining the timing and level of services performed often requires judgment.

Share-based compensation

Certain former Bentley employees who became our employees following the separation from Bentley held equity compensation awards from Bentley. Share-based compensation expense for our business was allocated based on Bentley's consolidated expense related to our employees and certain allocated share-based compensation expense allocated from Bentley. Such expense was accounted for in accordance with the fair value recognition provisions of FASB ASC Topic 718 *(Prior authoritative literature: SFAS No. 123(R), Share-Based Payment)*. Under the fair value recognition provisions of FASB ASC 718, share-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as expense over the requisite service period. Determining the fair value of equity awards at the grant date requires judgment. We

estimate the grant date fair value of stock options using the Black-Scholes option valuation model. This option valuation model requires the input of subjective assumptions including: (1) Expected life — the expected life (estimated period of time outstanding) of options granted is estimated based on historical exercise behaviors, including the periods prior to the separation when we were the drug delivery business of Bentley; (2) Volatility — the volatility applied to grants is the average stock volatility of CPEX and a peer group of comparable life science companies using daily price observations for each company over a period of time commensurate with the expected life of the respective 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. FASB ASC 718 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.

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 our subsidiary produces 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. The provision for income taxes for 2007 has been determined on a pro-forma basis as if CPEX had filed separate tax returns under its current structure for the periods presented.

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 FASB ASC Topic 740 *(Prior authoritative literature: Financial Accounting Standards Board Interpretation No. 48, Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109, Accounting for Income Taxes).* The application of income tax law is inherently complex. 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.

Recently Issued Accounting Pronouncements

In September 2009, the Emerging Issues Task Force ("EITF") issued its final consensus for ASU 2009-13 (*Prior authoritative literature: EITF 08-1 Revenue Arrangements with Multiple Deliverables*), which will supersede the guidance in ASC 605-25 (*prior authoritative literature: EITF 00-21, Revenue Arrangements with Multiple Deliverables*). ASU 2009-13 retains the criteria from ASC 605-5 for when delivered items in a multiple-deliverable arrangement should be considered separate units of accounting, but modifies the previous separation criterion under ASC 605-25 that objective and reliable evidence of fair value of any undelivered items must exist for the delivered items to be considered a separate unit or separate units of accounting. ASU 2009-13 introduces a selling price hierarchy for multiple deliverable arrangements and allows for management selling price estimates in cases where no vendor specific objective evidence or third party evidence is

available. Additionally, this guidance eliminates the residual method of allocation. ASU 2009-13 will be applicable to the Company on January 1, 2011. The Company has not yet evaluated the impact, if any, that ASU 2009-13 will have on its financial statements.

In June 2009, the FASB issued ASC Topic 810 *(Prior authoritative literature: SFAS No. 167 Amendments to FASB Interpretation No. 46(R))*,which improves financial reporting by enterprises involved with variable interest entities. ASC 810 addresses (1) the effects on certain provisions of FASB Interpretation No. 46 (revised December 2003), Consolidation of Variable Interest Entities, as a result of the elimination of the qualifying special-purpose entity concept in SFAS 166 and (2) concerns about the application of certain key provisions of FIN 46(R), including those in which the accounting and disclosures under the Interpretation do not always provide timely and useful information about an enterprise's involvement in a variable interest entity. ASC 810 will be applicable to the Company on January 1, 2010. Earlier adoption is prohibited. The Company does not expect the adoption of this topic to have a material impact on its consolidated and combined financial statements.

In June 2009, the FASB issued ASC Topic 860 *(Prior authoritative literature: SFAS No. 166, Accounting for Transfers of Financial Assets, an amendment of FASB Statement No. 140)*. ASC Topic 860 prescribes the information that a reporting entity must provide in its financial reports about a transfer of financial assets; the effects of a transfer on its financial position, financial performance, and cash flows; and a transferor's continuing involvement in transferred financial assets. Specifically, among other aspects, ASC Topic 860 amends SFAS No. 140, *Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities*, or SFAS No. 140, by removing the concept of a qualifying special-purpose entity from SFAS No. 140 and removes the exception from applying FASB Interpretation No. 46, *Consolidation of Variable Interest Entities (revised)*, or FIN 46(R), to variable interest entities that are qualifying special-purpose entities. It also modifies the financial-components approach used in SFAS No. 140. ASC Topic 860 is effective for transfer of financial assets occurring on or after January 1, 2010. The Company does not expect the adoption of this topic to have a material impact on its consolidated and combined financial statements.

Effective July 1, 2009, the FASB issued ASC Topic 105 (*Prior authoritative literature: SFAS No. 168, The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles).* ASC Topic 105 identifies the FASB Accounting Standards Codification as the authoritative source of Accounting Principles Generally Accepted in the United States (" U.S. GAAP"). Rules and interpretive releases of the SEC under federal securities laws are also sources of authoritative U.S. GAAP for SEC registrants. ASC Topic 105 became effective for financial statements issued for interim reporting periods ending after September 15, 2009. Therefore, beginning with this Form 10-Q, all references made to U.S. GAAP in the notes to the Company's consolidated financial statements now use the new ASC numbering system. The ASC does not change or alter existing U.S. GAAP and, therefore, it does not have an impact on the Company's financial position, results of operations or cash flows.

In May 2009, FASB issued FASB ASC Topic 855 (*Prior authoritative literature: SFAS No. 165, Subsequent Events*). ASC Topic 855 establishes general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or available to be issued. ASC 855-10-25 requires an entity to recognize in the financial statements the effects of all subsequent events that provide additional evidence about conditions that existed at the date of the balance sheet. For unrecognized subsequent events that must be disclosed to keep the financial statements from being misleading, an entity will be required to disclose the nature of the event as well as an estimate of its financial effect, or a statement that such an estimate cannot be made. ASC 855 is effective for the interim or annual financial periods ending after June 15, 2009, and is required to be applied prospectively. This guidance does not impact the Company's current consolidated and combined financial statements.

In February 2008, the FASB issued ASC 820-10-65-1 (*Prior authoritative literature: FASB Staff Position 157-2, "Effective Date of FASB Statement No. 157")*, which delays the effective date of ASC Topic 820 for nonfinancial assets and nonfinancial liabilities, except for items that are recognized or disclosed at fair value in the financial statements on a reoccurring basis. The provisions of ASC 820 became effective for fiscal years

beginning after November 15, 2008. The adoption of this staff position did not have a material impact on the Company's consolidated and combined financial statements.

In April 2009, the FASB issued ASC 820-10-65-4 (*Prior authoritative literature*: *FASB Staff Position SFAS 157-4, "Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly"*). ASC 820-10-65-4 amends ASC 820-35-15A to provide additional guidance on estimating fair value when the volume and level of activity for an asset or liability have significantly decreased in relation to normal market activity for the asset or liability. ASC 820-10-65-4 is effective for interim reporting periods ending after June 15, 2009. The adoption of this staff position did not have a material impact on the Company's consolidated and combined financial statements.

In December 2007, the FASB issued ASC Topic 805 (*Prior authoritative literature:* SFAS *No. 141(R), Business Combinations ("SFAS No. 141(R)"*). ASC 805-20-25-2 and 25-3 establish principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any non-controlling interest in the acquiree and the goodwill acquired. ASC Topic 805 also establishes disclosure requirements which will enable users to evaluate the nature and financial effects of the business combination. The Company adopted this topic as of January 1, 2009 and determined that the adoption did not have a material impact on its consolidated and combined financial statements.

In December 2007, the FASB ratified the consensus reached by the EITF on ASC Topic 808 (*Prior authoritative literature*: *Issue No. 07-1, Accounting for Collaborative Agreements"*). ASC 808-10-20 provides the definition of a collaborative agreement and ASC 808-10-15 provides guidelines to assist an entity in determining whether or not it is a party in a collaborative agreement. ASC 808-10-45 states that costs incurred and revenues generated from transactions with third parties shall be reported in accordance with ASC 605-45 (*Prior authoritative* literature*: EITF Issue No. 99-19, Reporting Revenue Gross as a Principal versus Net as an Agent)*. ASC 808-10-50 also provides minimum disclosure requirements for an entity's collaboration agreements and transition guidance. The Company adopted ASC Topic 808 as of January 1, 2009 and determined that the adoption did not have a material impact on its consolidated and combined financial statements.

In April 2008, the FASB issued ASC Topic 350 *(Prior authoritative literature*: *FASB Staff Position ("FSP") 142-3, Determination of the Useful Life of Intangible Assets)*. ASC 350-30-35 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under Topic ASC 350. The Company adopted ASC 350-30-35 as of January 1, 2009 and determined that the adoption did not have a material impact on its consolidated and combined financial statements.

In June 2008, the FASB issued ASC Topic 260 (*Prior authoritative literature*: *EITF 03-6-1, Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities)*. ASC 260-10-45 clarified that all outstanding unvested share-based payment awards that contain rights to non-forfeitable dividends participate in undistributed earnings with common shareholders. Awards of this nature are considered participating securities and the two-class method of computing basic and diluted earnings per share must be applied. The Company adopted ASC Topic 260 as of January 1, 2009 and determined that the adoption did not have a material impact on its consolidated and combined financial statements.

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

Not applicable.

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

The financial statements required by this item are located beginning on page F-1 of this report.

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

Not applicable.

Item 9A. ***Controls and Procedures***

Not applicable.

Item 9A(T). ***Controls and Procedures***

Evaluation of Disclosure Controls and Procedures.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has 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 of 1934, as amended (the "Exchange Act")) as of the end of the period covered by this annual report (the "Evaluation Date"). Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the Evaluation Date, our disclosure controls and procedures were effective.

Management's 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 Rule 13a-15(f) of the Exchange Act. Under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, we conducted an assessment of the design and effectiveness of our internal control over financial reporting as of the Evaluation Date. In making its assessment of internal control over financial reporting, management used the criteria set forth by the Committee of Sponsoring Organizations ("COSO") of the Treadway Commission in *Internal Control — Integrated Framework.* Based on this assessment, our management concluded that, as of the Evaluation Date, our internal control over financial reporting was effective based on the criteria set forth by COSO in *Internal Control — Integrated Framework.*

This annual report does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit the Company to provide only management's report in this annual report.

Changes in Internal Control over Financial Reporting.

There have been no changes in our internal control over financial reporting (as defined in rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the fourth quarter of 2009 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. ***Other Information***

Not applicable.

Part III

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

The names, ages, titles and biographies of our executive officers are provided under "Executive Officers" in Part I of this Form 10-K, and are incorporated herein by reference. Additional information regarding our directors and executive officers is set forth in our Proxy Statement for the 2010 Annual Meeting of

Stockholders (the "2010 Proxy Statement") under the Sections "Election of Directors" and "Section 16(a) Beneficial Ownership Reporting Compliance" and is incorporated herein by reference.

Item 11. ***Executive Compensation***

The information regarding executive compensation is set forth under the Section entitled "Executive Compensation" in our 2010 Proxy Statement and is incorporated herein by reference.

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

The information regarding security ownership of certain beneficial owners, directors and executive officers is set forth under the Section entitled "Security Ownership of Certain Beneficial Owners and Management" in our 2010 Proxy Statement and is incorporated herein by reference.

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

The information regarding certain relationships and related transactions is set forth under the Section entitled "Transactions with Related Persons" in our 2010 Proxy Statement and is incorporated herein by reference.

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

The information regarding auditor fees and services is set forth under the Section entitled "Independent Registered Public Accounting Firm" in our 2010 Proxy Statement and is incorporated herein by reference.

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 CPEX Pharmaceuticals, Inc. and Subsidiary	F-1 to F-25
	(2) Financial Statement Schedules:	
	None	
	(3) Exhibits — See index beginning on page 46	
(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.	

Exhibit Index

to Form 10-K for the Year Ended December 31, 2009

Exhibit Number	Description of Exhibit
2.1	Form of Separation and Distribution Agreement by and between CPEX Pharmaceuticals, Inc. and Bentley Pharmaceuticals, Inc. Filed as Exhibit 2.1 to Amendment No. 2 of the CPEX Form 10 (File No. 001-33895) filed on May 8, 2008 and incorporated herein by this reference.
3.1	Amended and Restated Certificate of Incorporation of CPEX Pharmaceuticals, Inc. filed with the Office of the Secretary of State of the State of Delaware on September 28, 2007. Filed as Exhibit 3.1 to Amendment No. 4 of the CPEX Form 10 (File No. 001-33895) filed on May 30, 2008 and incorporated herein by this reference.
3.2	Amended and Restated By-laws of CPEX Pharmaceuticals, Inc. Filed as Exhibit 3.2 to Amendment No. 4 of the CPEX Form 10 (File No. 001-33895) filed on May 30, 2008 and incorporated herein by this reference.
4.1	Form of Rights Agreement between CPEX Pharmaceuticals, Inc. and American Stock Transfer and Trust Company. Filed as Exhibit 4.1 to Amendment No. 4 of the CPEX Form 10 (File No. 001-33895) filed on May 30, 2008 and incorporated herein by this reference.
4.2	Form of Certificate of Designation of Series A Preferred Stock. Filed as Exhibit A to the Form of Rights Agreement filed as Exhibit 4.1 to Amendment No. 4 of the CPEX Form 10 (File No. 001-33895) filed on May 30, 2008 and incorporated herein by this reference.
4.3	Form of Rights Certificate. Filed as Exhibit B to the Form of Rights Agreement filed as Exhibit 4.1 to Amendment No. 4 of the CPEX Form 10 (File No. 001-33895) filed on May 30, 2008 and incorporated herein by this reference.
10.1	Form of Transition Services Agreement by and between CPEX Pharmaceuticals, Inc. and Bentley Pharmaceuticals, Inc. Filed as Exhibit 10.1 to Amendment No. 1 of the CPEX Form 10 (File No. 001-33895) filed on April 11, 2008 and incorporated herein by this reference.
10.2	Form of Tax Sharing Agreement by and between CPEX Pharmaceuticals, Inc. and Bentley Pharmaceuticals, Inc. Filed as Exhibit 10.2 to Amendment No. 1 of the CPEX Form 10 (File No. 001-33895) filed on April 11, 2008 and incorporated herein by this reference.
10.3	Form of Employment Matters Agreement by and between CPEX Pharmaceuticals, Inc. and Bentley Pharmaceuticals, Inc. Filed as Exhibit 10.3 to Amendment No. 1 of the CPEX Form 10 (File No. 001-33895) filed on April 11, 2008 and incorporated herein by this reference.
10.4	Asset Purchase Agreement between Bentley Pharmaceuticals, Inc. and Yungtai Hsu dated February 1, 1999, including letter amendment effective as of December 31, 2007. Filed as Exhibit 10.4 to Amendment No. 1 of the CPEX Form 10 (File No. 001-33895) filed on April 11, 2008 and incorporated herein by this reference.
10.5	License Agreement between Bentley Pharmaceuticals, Inc. and Auxilium A2, Inc. dated May 31, 2000, including thereto Amendment No. 1 dated October 2000, Amendment No. 2 dated May 31, 2001, Amendment No. 3 dated September 6, 2002 and Amendment No. 4 dated March 25, 2004. Filed as Exhibit 10.5 to the CPEX Form 10-K for the fiscal year ended December 31, 2008 and incorporated herein by this reference.
10.6	Employment Agreement by and between CPEX Pharmaceuticals, Inc. and John Sedor dated April 11, 2007. Filed as Exhibit 10.6 to Amendment No. 1 of the CPEX Form 10 (File No. 001-33895) filed on April 11, 2008 and incorporated herein by this reference.
10.7	Employment Agreement by and between CPEX Pharmaceuticals, Inc. and Robert P. Hebert dated April 11, 2007 Filed as Exhibit 10.7 to Amendment No. 1 of the CPEX Form 10 (File No. 001-33895) filed on April 11, 2008 and incorporated herein by this reference.
10.8	CPEX Pharmaceuticals, Inc. Amended and Restated 2008 Equity Incentive Plan. Filed as Appendix A to the CPEX definitive proxy statement filed on May 8, 2009 and incorporated herein by this reference.
10.9	Employment Agreement by and between CPEX Pharmaceuticals, Inc. and Lance Berman dated February 2, 2009. Filed as Exhibit 10.1 to the CPEX Form 8-K filed on February 3, 2009 and incorporated herein by this reference.

Exhibit Number	Description of Exhibit
10.10	Employment Agreement by and between CPEX Pharmaceuticals, Inc. and Fred Feldman dated June 30, 2008. Filed as Exhibit 10.10 to the CPEX Form 10-K for the fiscal year ended December 31, 2008 and incorporated herein by this reference.
10.11*	Employment Agreement by and between CPEX Pharmaceuticals, Inc. and Nils Bergenhem dated February 1, 2010.
23.1*	Consent of BDO Seidman LLP, Independent Registered Public Accounting Firm.
23.2*	Consent of Deloitte & Touche LLP, 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.
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.

* Filed herewith.

Exhibits 10.3 and 10.6 through 10.11 above are management contracts or compensatory plans or arrangements in which executive officers or directors of CPEX Pharmaceuticals, Inc. participate.

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.

CPEX PHARMACEUTICALS, INC.

By: /s/ John A. Sedor
John A. Sedor
Chief Executive Officer and President

Date: March 29, 2010

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	Director and Chairman of the Board	March 29, 2010
/s/ Michael McGovern Michael McGovern	Director	March 29, 2010
/s/ Miguel Fernandez Miguel Fernandez	Director	March 29, 2010
/s/ John W. Spiegel John W. Spiegel	Director	March 29, 2010
/s/ John A. Sedor John A. Sedor	Chief Executive Officer, President and Director (Principal Executive Officer)	March 29, 2010
/s/ Robert P. Hebert Robert P. Hebert	Chief Financial Officer and Vice President (Principal Financial and Accounting Officer)	March 29, 2010

Index to Consolidated and Combined Financial Statements of CPEX Pharmaceuticals, Inc. and Subsidiary

Report of Independent Registered Public Accounting Firm

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

We have audited the accompanying consolidated balance sheet of CPEX Pharmaceuticals, Inc. and its subsidiary (the "Company") as of December 31, 2009, and the related consolidated statements of operations, changes in stockholders' equity and cash flows for the year then ended. 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 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 the financial statements are free of material misstatement. The Company is not required to have nor were we engaged to perform an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, such consolidated financial statements referred to above present fairly, in all material respects, the financial position of CPEX Pharmaceuticals, Inc. and its subsidiary as of December 31, 2009, and the results of its operations and their cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

/S/ BDO SEIDMAN, LLP

Boston, Massachusetts
March 29, 2010

Report of Independent Registered Public Accounting Firm

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

We have audited the accompanying consolidated balance sheet of CPEX Pharmaceuticals, Inc. and subsidiaries (the "Company") as of December 31, 2008, and the related consolidated and combined statements of operations, changes in stockholders' equity and Bentley Pharmaceuticals, Inc. net investment, and cash flows for each of the two years in the period ended December 31, 2008. 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. The Company is not required to have nor were we engaged to perform an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, 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 and combined financial statements present fairly, in all material respects, the financial position of CPEX Pharmaceuticals, Inc. and subsidiaries as of December 31, 2008, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2008, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 2 to the consolidated and combined financial statements, prior to the separation of the Company from Bentley Pharmaceuticals, Inc. ("Bentley") on June 30, 2008, CPEX Pharmaceuticals, Inc. was comprised of the assets, liabilities and operations of the drug delivery business of Bentley. The consolidated and combined financial statements also include allocations from Bentley in those periods. These allocations may not be reflective of the actual level of costs which would have been incurred had CPEX Pharmaceuticals, Inc. operated as a separate entity apart from Bentley.

/S/ Deloitte & Touche LLP

Boston, Massachusetts
March 24, 2009

CPEX Pharmaceuticals, Inc. and Subsidiary

Consolidated Balance Sheets

	December 31, 2009	December 31, 2008
	(In thousands, except per share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	$13,695	$15,211
Receivables	5,289	4,445
Prepaid expenses and other	593	583
Total current assets	19,577	20,239
Non-current assets:		
Fixed assets, net	2,938	2,832
Intangible assets, net	2,211	2,394
Restricted cash	1,000	1,000
Note receivable	300	—
Other	17	8
Total non-current assets	6,466	6,234
Total assets	$26,043	$26,473
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,374	$ 1,096
Accrued expenses	1,633	1,534
Total current liabilities	3,007	2,630
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Series A preferred stock, $1.00 par value, authorized 1,000 shares, issued and outstanding, none	—	—
Common stock, $0.01 par value, authorized 35,000 shares, issued and outstanding, 2,537 and 2,484 shares at December 31, 2009 and December 31, 2008, respectively	25	25
Additional paid-in capital	26,765	24,532
Accumulated deficit	(3,754)	(714)
Total stockholders' equity	23,036	23,843
Total liabilities and stockholders' equity	$26,043	$26,473

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

CPEX Pharmaceuticals, Inc. and Subsidiary

Consolidated and Combined Statements of Operations

	For the Year Ended December 31,		
	2009	2008	2007
	(In thousands, except per share data)		
Revenues:			
Royalties and other revenue	$18,658	$15,574	$11,127
Operating expenses:			
General and administrative	8,867	6,493	5,206
Research and development	12,291	9,119	9,646
Separation costs	—	2,502	1,010
Depreciation and amortization	699	682	752
Total operating expenses	21,857	18,796	16,614
Loss from operations	(3,199)	(3,222)	(5,487)
Other income (expenses):			
Interest income	162	312	591
Interest expense	(3)	(5)	(10)
Other, net	—	—	(22)
Net loss	$(3,040)	$(2,915)	$(4,928)
Net loss per common share:			
Basic and diluted	$ (1.21)	$ (1.25)	$ (2.17)
Weighted average common shares outstanding:			
Basic and diluted	2,511	2,338	2,274

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

CPEX Pharmaceuticals, Inc. and Subsidiary

Consolidated and Combined Statements of Changes in Stockholders' Equity and Bentley Pharmaceuticals, Inc. Net Investment

	$0.01 Par Value Common Stock		Additional Paid-In Capital	Accumulated Deficit	Bentley Pharmaceuticals, Inc. Net Investment	Total
	Shares	Amount		(In thousands)		
Balance at January 1, 2007	—	$—	$ —	$ —	$ 19,052	$19,052
Net loss	—	—	—	—	(4,928)	(4,928)
Net transfers from parent	—	—	—	—	15,027	15,027
Balance at December 31, 2007	—	—	—	—	29,151	29,151
Net loss	—	—	—	(714)	(2,201)	(2,915)
Net transfers to parent	—	—	—	—	(6,295)	(6,295)
Transfer of parent company investment	—	—	20,655	—	(20,655)	—
Issuance of common stock in connection with the spin-off	2,274	23	—	—	—	23
Exercise of stock options and vesting of restricted stock units	206	2	1,738	—	—	1,740
Share-based compensation	4	—	2,139	—	—	2,139
Balance at December 31, 2008	2,484	25	24,532	(714)	—	23,843
Net loss	—	—	—	(3,040)	—	(3,040)
Share-based compensation	18	—	1,936	—	—	1,936
Issuance of common stock in lieu of cash compensation	30	—	293	—	—	293
Exercise of stock options and vesting of restricted stock units	5	—	4	—	—	4
Balance at December 31, 2009	2,537	$25	$26,765	$(3,754)	—	$23,036

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

CPEX Pharmaceuticals, Inc. and Subsidiary

Consolidated and Combined Statements of Cash Flows

	For the Year Ended December 31,		
	2009	2008	2007
		(In thousands)	
Cash flows from operating activities:			
Net loss	$(3,040)	$(2,915)	$(4,928)
Adjustments to reconcile net loss to net cash used by operating activities:			
Depreciation and amortization	699	682	752
Non-cash charge for write-down of intangible assets	—	141	202
Share-based compensation expense	1,936	3,195	1,504
Loss on disposal of assets	—	—	28
Changes in operating assets and liabilities:			
Receivables	(844)	(1,200)	(983)
Prepaid expenses and other current assets	(10)	124	61
Other assets	(9)	36	106
Accounts payable and accrued expenses	670	(591)	1,081
Deferred income	—	(25)	(9)
Net cash used in operating activities	(598)	(553)	(2,186)
Cash flows from investing activities:			
Additions to fixed assets	(398)	(307)	(303)
Additions to intangible assets	(224)	—	(157)
Note receivable	(300)	—	—
Proceeds from the sale of fixed assets	—	—	30
Net cash used in investing activities	(922)	(307)	(430)
Cash flows from financing activities:			
Proceeds from the exercise of stock options	4	1,740	—
Net change in investment from Bentley Pharmaceuticals, Inc.	—	(7,328)	13,523
Net cash provided by (used in) financing activities	4	(5,588)	13,523
Net (decrease) increase in cash and cash equivalents	(1,516)	(6,448)	10,907
Cash and cash equivalents at beginning of year	15,211	21,659	10,752
Cash and cash equivalents at end of year	$13,695	$15,211	$21,659
Cash paid for interest	$ 3	$ 5	$ 10
Supplemental Disclosures of Non-Cash Financing and Investing Activities			
The Company has issued common stock in lieu of cash to its executive officers and other employees as a portion of their 2008 bonus during the year as follows:			
Shares	30	—	—
Amount	$ 293	$ —	$ —
The Company has issued common stock as share-based compensation in lieu of cash during the year as follows:			
Shares	18	4	19
Amount	172	52	200

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

NOTE 1 — DESCRIPTION OF BUSINESS

CPEX Pharmaceuticals, Inc. (which may be referred to as "CPEX" or the "Company") was incorporated on September 28, 2007 in the State of Delaware and has one wholly-owned subsidiary, CPEX Park, LLC. CPEX is an emerging specialty pharmaceutical company in the business of research and development of pharmaceutical products utilizing its validated drug delivery platform technology. The CPEX platform drug delivery technology is based upon CPE-215®, which enhances permeation and absorption of pharmaceutical molecules across biological membranes such as the skin, nasal mucosa and eye.

The first product of CPEX is Testim®, a gel for testosterone replacement therapy that is a formulation of CPE-215 with testosterone. Testim is licensed to Auxilium Pharmaceuticals, Inc. who is currently marketing the product in the United States, Europe and other countries.

Nasulin™, the Company's lead product candidate, is a patented intranasal insulin formulation which incorporates CPE-215 as a permeation facilitator that addresses the need for an improved delivery method for insulin. The Company has completed a series of Phase 1 and Phase 2 studies investigating Nasulin. The Company recently completed a Phase 2a study of Nasulin and is determining the appropriate next steps for the Nasulin program.

The Company's business was initially the drug delivery business of Bentley Pharmaceuticals, Inc. (referred to as "Bentley") which was spun-off in June 2008 in connection with the sale of Bentley's remaining businesses. Shares of our stock were distributed to Bentley stockholders after the close of business on June 30, 2008 (the "Separation Date") by means of a stock dividend, a transaction that was taxable to Bentley and Bentley's stockholders (the "Separation"). Each Bentley stockholder of record on June 20, 2008, the record date, received on the Separation Date one CPEX share for every ten shares of Bentley common stock. Bentley has no ownership interest in CPEX subsequent to the Separation.

In connection with the spin-off, CPEX and Bentley entered into a series of agreements, including a Separation and Distribution Agreement, a Transition Services Agreement, an Employee Matters Agreement and a Tax Sharing Agreement. See Note 6 for further discussion.

Separation costs, consisting of legal, tax and other strategic consulting costs specifically related to the separation from Bentley, were $2.5 million in 2008 and $1.0 million in 2007 and are reported as *Separation costs* within operating expenses in the accompanying Consolidated and Combined Statements of Operations. No additional separation costs have been incurred since the Separation Date and the Company does not expect to incur any additional separation costs in the future.

In December 2009, CPEX Pharma, Inc., a wholly-owned subsidiary, was merged with and into CPEX Pharmaceuticals, Inc. This merger was administrative in nature and had no impact on the Company's results of operations and financial condition.

The Company is subject to a number of risks common to emerging companies in the life sciences industry. Principal among these risks are the uncertainties of the drug development process, technological innovations, development of the same or similar technological innovations by the Company's competitors, protection of proprietary technology, compliance with government regulations and approval requirements, uncertainty of market acceptance of products, dependence on key individuals, product liability, and the need to obtain additional financing necessary to fund future operations. The Company's growth and ability to achieve profitability may be dependent upon the successful commercialization of new products and partnering arrangements.

NOTE 2 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of presentation

The consolidated and combined financial statements reflect the accounts of the Company and its subsidiary. All intercompany accounts and transactions have been eliminated.

Principles of consolidation

Prior to the Separation Date, the CPEX combined financial statements reflect the assets, liabilities and results of operations of the components of Bentley that constituted the drug delivery business to be separated into CPEX. The financial information for periods prior to July 1, 2008 is primarily comprised of Bentley's former U.S. drug delivery business and certain accounts of Bentley's wholly-owned subsidiaries, Bentley Pharmaceuticals Ireland Limited and Bentley Park, LLC. Financial information presented in periods subsequent to June 30, 2008 reflect the assets and liabilities of CPEX Pharmaceuticals, Inc. as an independent, publicly-traded company together with its wholly-owned subsidiaries, CPEX Pharma, Inc. (which merged with CPEX Pharmaceuticals, Inc. in December 2009) and CPEX Park, LLC. All intercompany balances have been eliminated in consolidation and combination. The drug delivery business of Bentley Pharmaceuticals Ireland Limited did not have any operations other than intercompany transactions with CPEX.

Management believes that the assumptions underlying the combined financial statements are reasonable. The financial information in the consolidated and combined financial statements for the years ended December 31, 2008 and 2007 do not include all the expenses that would have been incurred had CPEX been a separate, stand-alone entity. As such, the financial information herein does not reflect the results of operations and cash flows of what CPEX would have been, had CPEX been a separate, stand-alone entity during the years ended December 31, 2008 and 2007. Additionally, these historical combined financial statements include proportional cost allocations of certain common costs of Bentley and CPEX because specific identification of these expenses to each entity was not practicable.

Segment Data

The Company manages its operations on a consolidated, single segment basis for purposes of assessing performance and making operating decisions. Accordingly, the Company has only one reporting segment.

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 and Combined Statements of Cash Flows. The cash and cash equivalents of CPEX include cash balances maintained in commercial bank accounts, amounts invested in overnight sweep investments and cash deposits in money market accounts. The Company's cash balances exceed the limits of amounts insured by the Federal Deposit Insurance Corporation; however, because management believes deposits are maintained at highly rated financial institutions there is not a significant risk of loss of uninsured amounts. At December 31, 2009, the Company's cash and cash equivalents balance totaled $13.7 million.

In connection with intellectual property in-licensed in 2003, the Company obtained a renewable, irrevocable letter of credit in the amount of $1.0 million in favor of the assignor to guarantee future royalty payments by the Company. This letter of credit will expire on June 30, 2010, and the Company does not expect to renew it. The $1.0 million used to secure the letter of credit has been classified as *Restricted cash* in the Condensed Consolidated Balance Sheets as of December 31, 2009 and 2008.

Accounts receivable and allowances for doubtful accounts

The Company enters into collaboration and research agreements whereby the Company may receive milestone payments, research fees and/or royalties. Accounts receivable from these agreements are recorded at their net realizable value, generally as services are performed or as milestones and royalties are earned. When necessary, 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 uncollectible accounts. The Company's accounts receivable and revenues are primarily royalties due from its licensee, Auxilium for sales of Testim®. Testim royalties represented substantially all of the accounts receivable as of December 31, 2009 and 2008 and substantially all of the revenues in the years ended December 31, 2009, 2008 and 2007. All receivables are uncollateralized and therefore subject to credit risk.

The Company did not write-off any uncollectible receivables in the years ended December 31, 2009 and 2008. In addition, the Company reviewed all receivable balances and concluded that no allowance for doubtful accounts was necessary as of December 31, 2009.

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:

	Years
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.

Intangible assets

Costs incurred in connection with acquiring licenses, patents, and other proprietary rights related to the business of the Company are capitalized as intangible assets. These assets are amortized on a straight-line basis for periods not exceeding fifteen years from the dates of acquisition. Such assets are reviewed whenever events or changes in circumstances indicate that the assets may be impaired, by comparing the carrying amounts to their estimated future undiscounted cash flows, and adjustments are made for any diminution in value below the carrying value. During the year ended December 31, 2009 the Company capitalized approximately $224,000 relating to acquiring patents and did not record any impairment losses. During the year ended December 31, 2008 the Company recorded $141,000 related to the write-down of certain intangible assets related to the Company's anti-fungal nail lacquer. Impairment losses related to intangible assets are included in research and development expenses in the accompanying Consolidated and Combined Statements

of Operations. At December 31, 2009 the Company has also reassessed the useful lives of its remaining intangible assets and has determined that the estimated useful lives are appropriate for determining amortization expense.

Revenue recognition

The Company recognizes revenue from royalties on Auxilium's sales of Testim in accordance with the Financial Standards Accounting Board (the "FASB") Accounting Standards Codification ("FASB ASC") 605-10-S99-1 *(Prior authoritative literature: SAB No. 104, Revenue Recognition),* which requires sales to be recorded upon shipment, provided that there is evidence of a final arrangement, there are no uncertainties surrounding acceptance, title has passed, collectability is reasonably assured and the price is fixed or determinable. Since 2003, Auxilium has sold Testim to pharmaceutical wholesalers and chain drug stores, which have the right to return purchased products prior to the units being dispensed through patient prescriptions. Based on historical experience, the Company is able to reasonably estimate future product returns on sales of Testim and as a result, the Company did not defer Testim royalties for the years ended December 31, 2009, 2008 and 2007. Total royalty revenues recognized for the years ended December 31, 2009, 2008 and 2007 were $18.6 million, $15.1 million and $11.1 million, respectively.

Fair value measurements

On January 1, 2007, the Company adopted FASB ASC Topic 820 (*Prior authoritative literature: SFAS No. 157, "Fair Value Measurements")*, which provides guidance for measuring the fair value of assets and liabilities, and requires expanded disclosures about fair value measurements. FASB ASC 820-10-35-9 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 FASB ASC Topic 820 did not have a material impact on the Company's consolidated and combined financial statements. The carrying amounts of cash and cash equivalents, trade and note receivables, accounts payable and accrued expenses approximate fair value because of their short-term nature. FASB ASC 820-10-20 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). FASB ASC 820-10-35 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. FASB ASC 820-10-35 also 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 participant assumptions developed based on the best information available in the circumstances (unobservable inputs). FASB ASC 820-10-35-6 emphasizes that valuation techniques should maximize the use of observable inputs and minimize the use of unobservable inputs.

The additional disclosure requirements of FASB ASC 820-10-50 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, 2009 and the amounts as they correspond to the respective level within the fair value hierarchy established by FASB ASC 820-10-50.

		Fair Value Measurements at December 31, 2009 Using:		
	Total at December 31, 2009	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
		(In thousands)		
Assets:				
Money market funds(1)	$12,770	$12,770	—	—
Restricted Cash	1,000	1,000	—	—
Total assets at fair value . . .	$13,770	$13,770	—	—

(1) Included in cash and cash equivalents in the accompanying consolidated and combined balance sheet.

Research and development

Research and development expenses consist primarily of costs associated with the clinical trials of the Company's 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 FASB Topic ASC 730 *(Prior authoritative literature: 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. In accordance with FASB ASC 830-20-25-13 *(Prior authoritative literature: Emerging Issues Task Force Issue No. 07-3, Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities)*, these costs are capitalized upon payment and recognized as an expense 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 discussions with internal personnel as well as outside service providers.

Provision for income taxes

CPEX was not a separate taxable entity prior to its separation from Bentley. The CPEX operations were historically included in Bentley's consolidated U.S. federal and state income tax returns. On June 12, 2008, CPEX and Bentley entered into a Tax Sharing Agreement to facilitate CPEX in its separation from Bentley. Under the Tax Sharing Agreement, Bentley is responsible for all taxes arising from the CPEX operations up to the June 30, 2008 Separation Date. CPEX is responsible for all taxes arising from the CPEX operations following the Separation Date.

The provision for income taxes in 2009 has been determined based on the CPEX business operations as a separate, stand-alone entity. The provisions for income taxes in 2008 have been determined based on the CPEX business operations following its separation from Bentley. The provision for income taxes in 2007 has been determined on a pro-forma basis as if CPEX had filed a separate tax return under its current structure for the period presented. Accordingly, the effective tax rate of CPEX in future years could vary from its historical

effective tax rates depending on the future legal structure of CPEX and related tax elections. The historical net operating losses generated by CPEX through June 30, 2008 remained with Bentley subsequent to the spin-off transaction.

The Company adopted the provisions of FASB ASC Topic 740 *(Prior authoritative literature: Financial Accounting Standards Board Interpretation No. 48, Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109, Accounting for Income Taxes)* effective January 1, 2007. The purpose of ASC Topic 740 is to clarify and set forth consistent rules for accounting for uncertain tax positions by requiring the application of a "more likely than not" threshold for the recognition and derecognition of tax positions. The adoption of ASC Topic 740 did not have a material effect on the Company's financial statements. The Company recognizes interest and penalties related to uncertain tax positions as a component of the provision for income taxes. There were no unrecognized tax positions relating to the Company at the date of adoption.

Prior to the Separation Date, the Company had agreements with Bentley Pharmaceuticals, Inc. and its subsidiaries for allocation of various expenses of each company. Income and expenses resulting from these agreements were eliminated in combination; however, the related transactions affected the CPEX combined income tax provision. As future operating profits can not be reasonably assured both prior and subsequent to the Separation Date, no tax benefit has been recorded for the losses generated by CPEX in the years ended December 31, 2009, 2008 and 2007. Accordingly, CPEX has established valuation allowances equal to the full amount of its deferred tax assets. Should CPEX 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.

Comprehensive income (loss)

Comprehensive loss is defined as the change in net assets of the Company during a period from transactions generated from non-owner sources. It includes all changes in equity during a period except those resulting from investments by owners and distributions to owners. The Company had no components of comprehensive loss other than its net loss for all periods presented.

Net loss per common share

Basic net loss per common share is computed based on the weighted-average number of common shares outstanding during the period. Diluted net loss per common share is computed based upon the weighted-average number of common shares outstanding during the year, adjusted for the dilutive effect of the Company's common stock equivalents, including the exercise of common stock based upon average market price of the common stock for the period. Basic and diluted net loss per common share is computed the same for all periods presented, as the Company had losses for all periods presented and, consequently, the effect of the common stock equivalents is anti-dilutive.

Dilutive weighted average shares do not include 509,925 and 443,367 common stock equivalents, which includes stock options and restricted stock units, for the years ended December 31, 2009 and 2008, respectively, as their effect would have been anti-dilutive.

On June 30, 2008, the Company had approximately 2,274,000 common shares outstanding primarily as a result of the Separation on June 30, 2008, whereby Bentley stockholders of record on June 20, 2008 received one CPEX common share for every ten common shares of Bentley. The same number of shares is being used for the basic and diluted loss per share computation for all periods presented prior to June 30, 2008 because no CPEX equity awards were outstanding prior to the Separation Date. In addition, since the Company has been in a net loss position, any potential common shares would not be used to compute diluted loss per share because the effect would have been anti-dilutive.

In June 2009, in lieu of cash compensation, the Company awarded 29,624 shares of common stock to its executive officers and other employees as a portion of their 2008 bonuses. The total value of the awards, which were expensed in 2008, was approximately $293,000.

Share-based compensation

As of December 31, 2009 the Company had one share-based compensation plan, its Amended and Restated 2008 Equity Incentive Plan (the "Plan"). The Plan, which is stockholder approved, permits awards of unrestricted common stock, restricted stock, restricted stock units, options to purchase CPEX common stock, stock appreciation rights and stock equivalents for the Company's employees, directors and consultants. Equity awards are generally granted with an exercise price equal to the high and low trading prices of the Company's common stock on the grant date. Equity awards generally vest ratably over one to four year periods and expire 10 years from the grant date. Shares issued upon exercise of options or upon vesting of restricted stock units are generally issued from previously unissued shares of the Company.

Prior to the Separation, all equity awards were granted by Bentley. In accordance with the Employee Matters Agreement between the Company and Bentley, upon the Separation, outstanding Bentley awards held by U.S. employees, directors and consultants were converted into an adjusted Bentley award and a CPEX award. The number of common shares underlying the CPEX awards was calculated as one-tenth of the number of common shares underlying the original Bentley awards. The price of the CPEX awards was determined by multiplying the original exercise price of the Bentley awards by the when-issued trading price of CPEX common stock on the Separation Date and then dividing that number by the closing Bentley trading price on the Separation Date. These CPEX awards were granted under the Plan.

The Company follows the provisions of Statement of FASB ASC Topic 718 *(Prior authoritative literature: SFAS No. 123(R), Share-Based Payment).* Compensation expense is recognized, based on the requirements of ASC Topic 718, for all share-based payments.

The fair value of options granted was calculated using the Black-Sholes option valuation model. ASC Topic 718 also requires companies to use an estimated forfeiture rate when calculating the expense for the period. The Company has applied an estimated forfeiture rate to remaining unvested awards based on historical experience in determining the expense recorded in the Company's statement of operations. This estimate is periodically evaluated and adjusted as necessary. Ultimately, the actual expense recognized over the vesting period will only be for those shares that vest. See Note 8 for further discussion.

Recently issued accounting pronouncements

In September 2009, the Emerging Issues Task Force ("EITF") issued its final consensus for ASU 2009-13 (*Prior authoritative literature: EITF 08-1 Revenue Arrangements with Multiple Deliverables*), which will supersede the guidance in ASC 605-25 (*prior authoritative literature: EITF 00-21, Revenue Arrangements with Multiple Deliverables*). ASU 2009-13 retains the criteria from ASC 605-5 for when delivered items in a multiple-deliverable arrangement should be considered separate units of accounting, but modifies the previous separation criterion under ASC 605-25 that objective and reliable evidence of fair value of any undelivered items must exist for the delivered items to be considered a separate unit or separate units of accounting. ASU 2009-13 introduces a selling price hierarchy for multiple deliverable arrangements and allows for management selling price estimates in cases where no vendor specific objective evidence or third party evidence is available. Additionally, this guidance eliminates the residual method of allocation. ASU 2009-13 will be applicable to the Company on January 1, 2011. The Company has not yet evaluated the impact, if any, that ASU 2009-13 will have on its financial statements.

In June 2009, the FASB issued ASC Topic 810 *(Prior authoritative literature: SFAS No. 167 Amendments to FASB Interpretation No. 46(R))*,which improves financial reporting by enterprises involved with variable

interest entities. ASC 810 addresses (1) the effects on certain provisions of FASB Interpretation No. 46 (revised December 2003), Consolidation of Variable Interest Entities, as a result of the elimination of the qualifying special-purpose entity concept in SFAS 166 and (2) concerns about the application of certain key provisions of FIN 46(R), including those in which the accounting and disclosures under the Interpretation do not always provide timely and useful information about an enterprise's involvement in a variable interest entity. ASC 810 will be applicable to the Company on January 1, 2010. Earlier adoption is prohibited. The Company does not expect the adoption of this topic to have a material impact on its consolidated and combined financial statements.

In June 2009, the FASB issued ASC Topic 860 *(Prior authoritative literature: SFAS No. 166, Accounting for Transfers of Financial Assets, an amendment of FASB Statement No. 140).* ASC Topic 860 prescribes the information that a reporting entity must provide in its financial reports about a transfer of financial assets; the effects of a transfer on its financial position, financial performance, and cash flows; and a transferor's continuing involvement in transferred financial assets. Specifically, among other aspects, ASC Topic 860 amends SFAS No. 140, *Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities*, or SFAS No. 140, by removing the concept of a qualifying special-purpose entity from SFAS No. 140 and removes the exception from applying FASB Interpretation No. 46, *Consolidation of Variable Interest Entities (revised)*, or FIN 46(R), to variable interest entities that are qualifying special-purpose entities. It also modifies the financial-components approach used in SFAS No. 140. ASC Topic 860 is effective for transfer of financial assets occurring on or after January 1, 2010. The Company does not expect the adoption of this topic to have a material impact on its consolidated and combined financial statements.

Effective July 1, 2009, the FASB issued ASC Topic 105 (*Prior authoritative literature: SFAS No. 168, The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles).* ASC Topic 105 identifies the FASB Accounting Standards Codification as the authoritative source of accounting principles generally accepted in the United States ("U.S. GAAP"). Rules and interpretive releases of the SEC under federal securities laws are also sources of authoritative U.S. GAAP for SEC registrants. ASC Topic 105 became effective for financial statements issued for interim reporting periods ending after September 15, 2009. Therefore, beginning with this Form 10-Q, all references made to U.S. GAAP in the notes to the Company's consolidated financial statements now use the new ASC numbering system. The ASC does not change or alter existing U.S. GAAP and, therefore, it does not have an impact on the Company's financial position, results of operations or cash flows.

In May 2009, FASB issued FASB ASC Topic 855 (*Prior authoritative literature: SFAS No. 165, Subsequent Events*). ASC Topic 855 establishes general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or available to be issued. ASC 855-10-25 requires an entity to recognize in the financial statements the effects of all subsequent events that provide additional evidence about conditions that existed at the date of the balance sheet. For unrecognized subsequent events that must be disclosed to keep the financial statements from being misleading, an entity will be required to disclose the nature of the event as well as an estimate of its financial effect, or a statement that such an estimate cannot be made. ASC 855 is effective for the interim or annual financial periods ending after June 15, 2009, and is required to be applied prospectively. This guidance does not impact the Company's current consolidated and combined financial statements.

In February 2008, the FASB issued ASC 820-10-65-1 (*Prior authoritative literature: FASB Staff Position 157-2, "Effective Date of FASB Statement No. 157")*, which delays the effective date of ASC Topic 820 for nonfinancial assets and nonfinancial liabilities, except for items that are recognized or disclosed at fair value in the financial statements on a reoccurring basis. The provisions of ASC 820 became effective for fiscal years beginning after November 15, 2008. The adoption of this staff position did not have a material impact on the Company's consolidated and combined financial statements.

In April 2009, the FASB issued ASC 820-10-65-4 (*Prior authoritative literature: FASB Staff Position SFAS 157-4, "Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly"*). ASC 820-10-65-4 amends ASC 820-35-15A to provide additional guidance on estimating fair value when the volume and level of activity for an asset or liability have significantly decreased in relation to normal market activity for the asset or liability. ASC 820-10-65-4 is effective for interim reporting periods ending after June 15, 2009. The adoption of this staff position did not have a material impact on the Company's consolidated and combined financial statements.

In December 2007, the FASB issued ASC Topic 805 (*Prior authoritative literature:* SFAS *No. 141(R), Business Combinations ("SFAS No. 141(R)"*). ASC 805-20-25-2 and 25-3 establish principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any non-controlling interest in the acquiree and the goodwill acquired. ASC Topic 805 also establishes disclosure requirements which will enable users to evaluate the nature and financial effects of the business combination. The Company adopted this topic as of January 1, 2009 and determined that the adoption did not have a material impact on its consolidated and combined financial statements.

In December 2007, the FASB ratified the consensus reached by the EITF on ASC Topic 808 (*Prior authoritative literature: Issue No. 07-1, Accounting for Collaborative Agreements"*). ASC 808-10-20 provides the definition of a collaborative agreement and ASC 808-10-15 provides guidelines to assist an entity in determining whether or not it is a party in a collaborative agreement. ASC 808-10-45 states that costs incurred and revenues generated from transactions with third parties shall be reported in accordance with ASC 605-45 (*Prior authoritative* literature*: EITF Issue No. 99-19, Reporting Revenue Gross as a Principal versus Net as an Agent). ASC 808-10-50 also provides minimum disclosure requirements for an entity's collaboration agreements and transition guidance. The Company adopted ASC Topic 808 as of January 1, 2009 and determined that the adoption did not have a material impact on its consolidated and combined financial statements.*

In April 2008, the FASB issued ASC Topic 350 *(Prior authoritative literature: FASB Staff Position ("FSP") 142-3, Determination of the Useful Life of Intangible Assets).* ASC 350-30-35 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under Topic ASC 350. The Company adopted ASC 350-30-35 as of January 1, 2009 and determined that the adoption did not have a material impact on its consolidated and combined financial statements.

In June 2008, the FASB issued ASC Topic 260 (*Prior authoritative literature: EITF 03-6-1, Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities).* ASC 260-10-45 clarified that all outstanding unvested share-based payment awards that contain rights to non-forfeitable dividends participate in undistributed earnings with common shareholders. Awards of this nature are considered participating securities and the two-class method of computing basic and diluted earnings per share must be applied. The Company adopted ASC Topic 260 as of January 1, 2009 and determined that the adoption did not have a material impact on its consolidated and combined financial statements.

NOTE 3 — RECEIVABLES

Receivables consist of the following:

	December 31, 2009	December 31, 2008
	(In thousands)	
Royalties receivable	$5,206	$4,077
Other	83	368
	$5,289	$4,445

NOTE 4 — FIXED ASSETS

Fixed assets consist of the following:

	December 31, 2009	December 31, 2008
	(In thousands)	
Land	$ 787	$ 787
Buildings and improvements	1,183	1,183
Equipment	2,151	1,593
Furniture and fixtures	248	248
	4,369	3,811
Construction in-progress	—	160
	4,369	3,971
Less-accumulated depreciation	(1,431)	(1,139)
	$ 2,939	$ 2,832

Depreciation expense of approximately $292,000, $275,000 and $243,000 has been charged to operations as a component of *Depreciation and amortization expense* in the Consolidated and Combined Statements of Operations for the years ended December 31, 2009, 2008 and 2007, respectively.

NOTE 5 — INTANGIBLE ASSETS

Intangible assets consist of the following:

	December 31, 2009	December 31, 2008
	(In thousands)	
Patents and related patent costs	$ 5,204	$ 5,535
Less-accumulated amortization	(2,993)	(3,141)
	$ 2,211	$ 2,394

Amortization expense for drug licenses and related costs was approximately $407,000, $407,000 and $509,000 for the years ended December 31, 2009, 2008 and 2007, respectively, and has been recorded in *Depreciation and amortization expense* in the accompanying Consolidated and Combined Statements of Operations. During the year ended December 31, 2008 the Company recorded $141,000 related to the write-down of certain intangible assets related to the Company's anti-fungal nail lacquer. Impairment losses related to intangible assets are included in research and development expenses in the accompanying Consolidated and Combined Statements of Operations. There were no impairment losses for the year ended December 31, 2009.

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)
2010	$452
2011	452
2012	452
2013	452
2014	72
2015 and beyond	234

NOTE 6 — RELATED PARTY DISCLOSURES

Prior to the Separation Date, CPEX operations were fully integrated with Bentley, including executive services, finance, treasury, internal audit, corporate income tax, legal services and investor relations. The accompanying Consolidated and Combined Financial Statements reflect the application of certain estimates and allocations of operating expenses including stock-based compensation. Management believes the methods used to allocate these operating expenses are reasonable. The allocation methods include relative time devoted by executive management on CPEX business and related benefit received by CPEX for other services, such as public company costs and services. Allocations of expenses for these services totaled $4.4 million and $4.2 million for years ended December 31, 2008 and 2007, respectively, and are reflected in *Total operating expenses* in the Consolidated and Combined Statements of Operations. There have been no allocations of expenses charged to CPEX since the Separation Date.

On June 13, 2008, CPEX and Bentley entered into a series of agreements, — a Separation and Distribution Agreement, a Tax Sharing Agreement, a Transition Services Agreement and an Employee Matters Agreement — to facilitate CPEX in its separation from Bentley. The Transition Services Agreement had an initial term of six months and had an option to be extended for an additional six-month term. As a result of the Transition Services Agreement, CPEX and Bentley were able to provide services to the other as requested for a fee based upon the costs incurred in providing such services. As of the Separation Date, Bentley had prepaid $78,000 to CPEX for services expected to be provided to Bentley. Through December 31, 2008, CPEX recognized $78,000 for performance of those services which is included as an offset to operating expenses in *General and administrative* in the accompanying Consolidated and Combined Statements of Operations. The Transition Services Agreement expired and was not extended.

NOTE 7 — ACCRUED EXPENSES

Accrued expenses consist of the following:

	December 31,	
	2009	2008
	(In thousands)	
Accrued payroll and related taxes	$ 828	$ 715
Accrued clinical costs	183	92
Accrued professional fees	400	416
Other accrued expenses	222	311
	$1,633	$1,534

NOTE 8 — EQUITY AND SHARE-BASED COMPENSATION

As previously stated, as of December 31, 2009 the Company's one share-based compensation plan, which is stockholder approved, permits awards of unrestricted common stock, restricted stock, restricted stock units, options to purchase CPEX common stock, stock appreciation rights and stock equivalents for the Company's employees, directors and consultants. On June 18, 2009, the Company's stockholders approved, among other things, the addition of 100,000 shares of common stock to the reserve of shares available for issuance under the Plan. Prior to the Separation, all equity awards were granted by Bentley. In accordance with the Employee Matters Agreement between the Company and Bentley, outstanding Bentley awards held by U.S. employees, directors and consultants were converted into an adjusted Bentley award and a CPEX award on the Separation Date. The number of common shares underlying the CPEX awards was calculated as one-tenth of the number of common shares underlying the original Bentley awards. The price of the CPEX awards was determined by multiplying the original exercise price of the Bentley awards by the when-issued trading price of CPEX common stock on the Separation Date and then dividing that number by the closing Bentley trading price on the Separation Date. These CPEX awards were granted under the Plan. At December 31, 2009, approximately 601,000 shares of common stock were reserved for issuance under the Plan. Approximately 466,000 of these shares were subject to outstanding stock options and approximately 44,000 shares were subject to outstanding restricted stock units. The balance of approximately 91,000 shares were available for future issuance of awards under the Plan. The table below presents the Company's option activity for the year ended December 31, 2009:

	Number of Options (in 000's)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in 000's)
Options outstanding, January 1, 2009	430	$15.85		
Granted	61	7.81		
Exercised	(2)	2.69		
Forfeited and expired	(23)	17.21		
Options outstanding, December 31, 2009	466	$14.78	8.17	$278
Vested and expected to vest, December 31, 2009	457	$14.78	8.16	$272
Options exercisable, December 31, 2009	194	$14.63	7.48	$ 80

Options to purchase approximately 2,000 shares of CPEX common stock were exercised during the year ended December 31, 2009 for net cash proceeds to the Company of approximately $4,000, while the total intrinsic value of those option exercises was approximately $14,000. Since the future operating profits of CPEX cannot be reasonably assured, no tax benefit resulting from the settlement of awards has been recorded.

As of December 31, 2009, unrecognized compensation expense related to the unvested portion of the Company's stock options granted to CPEX employees was approximately $2.1 million and is expected to be recognized over a weighted average period of approximately 1.65 years.

The fair value of each option award granted to employees is estimated on the date of grant using the Black-Scholes option valuation model. Assumptions and the resulting fair value for option awards granted by CPEX during the years ended December 31, 2009 and 2008 are provided below:

	For the Year December 31, 2009	For the Year December 31, 2008
Weighted average risk free interest rate	2.45%	3.30%
Dividend yield	0%	0%
Expected life (years)	7	5 to 7
Volatility	85%-88%	65%-79%
Weighted average grant-date fair value of options granted	$ 5.98	$ 11.53

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. CPEX 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 of Bentley employees. Shares of CPEX common stock began trading on the NASDAQ Capital Market on July 1, 2008. Since this period of time is shorter than the expected term of the options granted, the volatility applied is the average volatility of CPEX and a peer group of comparable life science companies using daily price observations for each company over a period of time commensurate with the expected life of the respective award. CPEX share-based awards generally vest over three years and the maximum contractual term of the awards is 10 years.

In addition to the stock options described above, the Company has granted restricted stock units to its employees. The common shares subject to the restricted stock units are generally issued when they vest. The table below presents the Company's restricted stock unit activity for the twelve months ended December 31, 2009:

	Number of Restricted Stock Units (in 000's)	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in 000's)
Restricted stock units outstanding, January 1, 2009	14	$12.87		
Granted	35	9.03		
Vested(1)	(16)	10.44		
Forfeited	(1)	12.60		
Restricted stock units outstanding, December 31, 2009	32	$ 9.64	1.52	$347
Vested and expected to vest, December 31, 2009	30	$ 9.61	1.52	$334

(1) Includes approximately 13,000 restricted stock units that have vested but for which the underlying common shares are not settled or issued.

As of December 31, 2009, unrecognized compensation expense related to the unvested portion of the Company's restricted stock units granted to CPEX employees was approximately $204,000 and is expected to be recognized over a weighted average period of approximately 1.52 years.

Share-based compensation expense relative to grants of stock options and restricted stock units for the years ended December 31, 2009, 2008 and 2007 totaled approximately $1.8 million, $3.0 million and $1.2 million, respectively. For years ended December 31, 2008 and 2007 the Consolidated and Combined Statements of Operations include share-based compensation expense recorded for Bentley stock option awards

and Bentley restricted stock unit awards to CPEX employees prior to the Separation and an allocation of share-based compensation of executive officers, non-employee directors and consultants of Bentley. The expenses were recorded in the Condensed Consolidated and Combined Statements of Operations as follows:

	For Year Ended December 31,		
	2009	2008	2007
	(In thousands)		
General and administrative expenses	$1,351	$2,023	$ 630
Research and development expenses	413	968	612
	$1,764	$2,991	$1,242

No related compensation expense was capitalized as the cost of an asset and there was no impact on net cash provided by operating activities or net cash used in financing activities as a result of these share-based transactions.

The Company sponsors a 401(k) Plan for eligible employees (the "401k Plan") and matches eligible contributions with shares of the Company's common stock. In July 2008, the Company's Board of Directors authorized and reserved 50,000 shares of common stock for the Company's contribution to the 401(k) Plan. As of December 31, 2009 approximately 27,000 of these shares were available for contribution to the 401k Plan.

Share-based compensation expense includes matching contributions to the 401(k) Plan by the Company. Share-based compensation expense for periods prior to the Separation Date includes expense attributable to CPEX employees from Bentley's 401(k) matching contributions and the related allocated share-based compensation of executive officers. For the years ended December 31, 2009, 2008 and 2007 the related expenses were recorded in the Condensed Consolidated and Combined Statements of Operations as follows:

	For the Year Ended December 31,		
	2009	2008	2007
	(In thousands)		
General and administrative expenses	$ 76	$ 99	$ 91
Research and development expenses	96	105	171
	$172	$204	$262

Stockholder Rights Plan

Pursuant to the Rights Agreement that was adopted by the Board of Directors of the Company on June 12, 2008, the Board of Directors declared a dividend of one Right for each outstanding share of common stock payable to stockholders of record at the close of business on June 23, 2008. Each Right, when exercisable, entitles the registered holder to purchase one one-thousandth of a share of Series A preferred stock, par value $0.01 per share, at a purchase price of $100 per share, subject to adjustment. The Rights Agreement 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 acquires 15% or more of the Company's common stock (subject to certain exceptions).

In the event that an acquiring person became 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 a 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 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 June 12, 2018, unless earlier redeemed or exchanged by the Company.

NOTE 9 — PROVISION FOR INCOME TAXES

The provisions for income taxes in 2009, 2008 and 2007 have been determined based on the CPEX business operations as a separate, stand-alone entity. The provision for income taxes in 2008 has been determined based on the CPEX business operations following its separation from Bentley on the Separation Date (June 30, 2008). The separation was accomplished in a transaction by which Bentley's drug delivery business was contributed to CPEX, a wholly owned subsidiary of Bentley. CPEX was then spun out from Bentley in a taxable transaction by which Bentley shareholders received CPEX stock in a pro-rata distribution. Prior to the Separation Date, the CPEX operations were fully integrated with Bentley, which operated 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. CPEX and Bentley entered into a Tax Sharing Agreement under which Bentley is obligated on all taxes arising from the CPEX operations up to the Separation Date. CPEX is obligated on all taxes arising from the CPEX operations following the Separation Date.

Although results from operations were presented for the year ended December 31, 2008, net operating losses incurred through the Separation Date will be included in tax returns filed by Bentley and, accordingly, no tax benefits for these losses have been recorded in the income tax provision or deferred tax assets. The provision for income taxes for 2007 has been determined on a pro-forma basis as if CPEX had filed separate tax returns under its current structure for the periods presented.

	Year Ended December 31,		
	2009	2008	2007
	(In thousands)		
Current	$ —	$ —	$ —
Deferred:			
State	(158)	(40)	(24)
Federal	(1,505)	(396)	(4,082)
Tax effect of operating loss carryforwards:			
State	—	—	(56)
Federal	—	—	1,590
Change in valuation allowance	1,663	436	2,572
Total provision for income taxes	$ —	$ —	$ —

A reconciliation of the income tax provision using the federal statutory rate to the CPEX effective income tax rate is as follows:

	Year Ended December 31,		
	2009	2008	2007
	(In thousands)		
Income tax provision (benefits) at federal statutory rates	$(1,034)	$(242)	$(1,676)
Foreign income tax rate differential	—	—	(2,735)
State income taxes (net of federal benefit)	(158)	(40)	(80)
Expiration and utilization of operating loss carryforwards	—	—	2,316
Tax credits	(496)	(156)	(402)
Other	25	2	5
Change in valuation allowance	1,663	436	2,572
	$ —	$ —	$ —

The components of the CPEX deferred taxes follow. Under the terms of the Separation, the deferred tax assets at December 31, 2007 and through the Separation Date did not carryforward to CPEX and are therefore not included in the December 31, 2009 and 2008 balances.

	December 31, 2009	December 31, 2008
	(In thousands)	
Deferred tax assets:		
Net operating loss carryforwards	$ 656	$ 214
Book/tax basis difference in assets	309	308
Share-based compensation	1,024	344
Research and development tax credit carryforwards	652	156
Other, net	326	282
Total deferred tax assets	2,967	1,304
Valuation allowance	(2,967)	(1,304)
Deferred tax asset, net	$ —	$ —

As future operating profits cannot be reasonably assured, no tax benefit has been recorded for net operating losses. Accordingly, CPEX has established a valuation allowance equal to the full amount of the deferred tax assets. Should CPEX 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 valuation allowance for CPEX increased by $1,663,000 in 2009 and by $436,000 in 2008. The 2009 increase consists of $680,000 attributable to stock options, $496,000 in general business credits and $442,000 to NOL carryforwards. The valuation allowance of $1,304,000 in 2008 consists of $344,000 attributable to stock options, 214,000 to NOL carryforwards, and $156,000 in general business credits. The valuation allowance increased by approximately $2,572,000 in 2007, which is primarily attributed to $3,855,000 related to U.S. NOL carryforwards and $402,000 from general business credits. The general business credits are attributed to the Company's research and development activities.

The Company generated net operating losses ("NOLs") of approximately $3,040,000 in 2009 and $714,000 in 2008. As of December 31, 2009, the CPEX U.S. Federal NOL carryforwards were approximately $1,677,000. If not offset against future taxable income, the NOL carryforwards will expire in tax years 2028 through 2029. All NOLs generated through the Separation Date related to the CPEX business were retained by Bentley.

As of December 31, 2009, the CPEX U.S. Federal general business credit carryforwards were approximately $652,000. If not offset against future federal taxes, these general business credit carryforwards will expire in the tax years 2028 and 2029. All general business credits generated through the Separation Date related to the CPEX business were retained by Bentley. The Company did not experience any ownership changes during 2009 under Internal Revenue Code Section 382 that would further limit their NOLs or general business credit carryforwards.

In June 2006, the FASB issued ASC Topic 740 (*Prior authoritative literature: FIN 48, Accounting for Uncertainty in Income Taxes*), which CPEX adopted effective January 1, 2007. The adoption of FIN 48 did not have a material impact on the CPEX combined financial statements. CPEX recognizes interest and penalties related to uncertain tax positions as a component of the provision for income taxes. There were no unrecognized tax positions relating to CPEX at the date of adoption. As of December 31, 2009, the tax year

2008 is the only year that is open to examination due to the fact that it was the initial year in which CPEX filed as a taxpayer separate from the Bentley consolidated group.

NOTE 10 — SUBSEQUENT EVENTS

In accordance with ASC Topic 855 (as amended), the Company evaluated subsequent events through the date the audited consolidated and combined financial statements were issued. During this period the Company did not have any material recognizable subsequent events that require further disclosure in this filing.

NOTE 11 — 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 royalties are primarily calculated based upon net sales of certain products generated by the intellectual property. As of December 31, 2009, no royalties are due under the agreements.

Legal Proceedings

In October 2008, we and Auxilium received notice that Upsher-Smith Laboratories filed an Abbreviated New Drug Application, or ANDA, containing a paragraph IV certification in which it certified that it believes that its testosterone gel product does not infringe our patent, U.S. Patent No. 7,320,968 ("the '968 Patent"). The '968 patent covers a method for maintaining effective blood serum testosterone levels for treating a hypogonadal male using Testim and will expire in January 2025. The '968 Patent is listed in Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book), published by the U.S. Food and Drug Administration. Upsher-Smith Laboratories' paragraph IV certification sets forth allegations that the '968 Patent will not be infringed by Upsher-Smith's manufacture, use or sale of the product for which the ANDA was submitted. On December 4, 2008, we and Auxilium filed a lawsuit in the United States District Court for the District of Delaware against Upsher-Smith under the Hatch Waxman Act for infringement of our patent. In June 2009, Upsher-Smith amended its answer to the complaint to include a defense and counterclaim of invalidity of the '968 Patent, which CPEX and Auxilium deny. A patent issued by the U.S. Patent and Trademark Office, such as the '968 Patent, is presumed valid. The lawsuit is currently ongoing. Any U.S. Food and Drug Administration (FDA) approval of Upsher-Smith's proposed generic product will be stayed until the earlier of 30 months from the date of receipt of the paragraph IV certification (April 2011) or an adverse decision in our patent infringement lawsuit.

CPEX has filed continuation and divisional applications with the USPTO relating to the '968 patent. Six patents issued from these applications on October 27, 2009, namely U.S. Patent Nos. 7,608,605, 7,608,606, 7,608,607, 7,608,608, 7,608,609 and 7,608,610, which may provide us with further market protection. Each of these six patents has been listed in listed in Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book) with respect to Testim.

We and Auxilium are committed to protecting our intellectual property rights and will vigorously pursue this lawsuit. However, if we are unsuccessful in defending the '968 Patent covering Testim, sales of Testim and our royalties relating to Testim sales will be materially reduced.

Agreement for a Potential Joint Venture

As previously disclosed, on March 17, 2009, the Company signed an agreement with Heights Partners, LLC ("Heights") to evaluate the desirability for the Company and Heights to enter into a joint venture arrangement for the development of specified product candidates of Heights. Under the agreement, the parties evaluated several product candidates and on October 15, 2009, the Company advised Heights that it had selected two products for the collaboration. Under the terms of the agreement, the parties must execute a joint

venture or other contractual arrangement within 90 days, or by January 13, 2010, to conduct such collaboration. The parties agreed to extend this deadline until May 15, 2010. Under the agreement the Company paid $300,000 as an advance against its initial contribution to the potential joint venture. This advance was evidenced by a promissory note payable by Heights to CPEX and secured by a first priority security interest in Height's intellectual property, including, without limitation, patents, patent applications and know-how, covering any of the specified product development projects, all licenses and other agreements with respect to the foregoing and all proceeds the third party may receive from the sale or license of the intellectual property or products. Under the terms of the agreement as amended, the promissory note, which is included in non-current assets in the accompanying Consolidated Balance Sheet for the year ended December 31, 2009, together with interest, was due in October 2009. Upon execution of a joint venture or other contractual arrangement, Heights shall contribute the amounts payable under the note to the joint venture as the Company's initial investment. If the parties are unable to execute a joint venture agreement by May 15, 2010, and absent any further extension, all amounts advanced by the Company will become payable by Heights and either party may seek to terminate the obligation to form the joint venture.

Corporate Information

EXECUTIVE OFFICERS

John A. Sedor
Chief Executive Officer and President

Nils Bergenhem, Ph.D.
Chief Scientific Officer and Vice President

Robert P. Hebert
Chief Financial Officer and Vice President

Lance Berman, M.D.
Chief Medical Officer

BOARD OF DIRECTORS

James R. Murphy
Director and Non-Executive Chairman of the Board
CPEX Pharmaceuticals, Inc.

Michael McGovern *(1) (2)*
President, McGovern Enterprises

Miguel Fernandez *(1) (2) (3)*
Retired, Former Vice President
Carter-Wallace, Inc.

John W. Spiegel *(1) (2) (3)*
Retired, Former Chief Financial Officer
SunTrust Banks, Inc.

John A. Sedor
Chief Executive Officer and President
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SECURITIES

The Company's common stock is publicly traded on the Nasdaq Capital Market under the symbol "CPEX."

TRANSFER AGENT

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AVAILABILITY OF FORM 10-K; INFORMATION REQUESTS

Shareholders may obtain, without charge, a copy of the Company's complete Annual Report on Form 10-K filed with the Securities and Exchange Commission, as well as the Corporate Governance Guidelines, Nominating and Governance Committee Charter, Audit Committee Charter, Compensation Committee Charter, Code of Business Conduct and Ethics, Audit Committee Procedures for Handling Complaints and other published documents, on the Company's website (www.cpexpharm.com) or by contacting Investor Relations.

INVESTOR RELATIONS

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(1) Member of the Audit Committee (Chairman: John W. Spiegel)
(2) Member of the Compensation Committee (Chairman: Miguel Fernandez)
(3) Member of the Nominating and Governance Committee (Chairman: John W. Spiegel)

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