# RESPONDING
# RESHAPING
# RENEWING

Sepracor Inc.
2008 Annual Report

## Research and Development Pipeline

| PRODUCT CANDIDATE | TARGET INDICATION | Preclinical | Phase 1 | Phase 2 | Phase 3 | NDA prep |
|---|---|---|---|---|---|---|
| STEDESA™* | Epilepsy | | | | | |
| OMNARIS™ HFA Nasal Spray | Allergic Rhinitis | | | | | |
| XOPENEX® + ipratropium Inhalation Solution | COPD | | | | | |
| SEP-225289 | Depression | | | | | |
| SEP-0227018 (new LUNESTA formulation) | Insomnia | | | | | |
| SEP-227162 | Depression | | | | | |
| SEP-228432 | Depression/ADHD | | | | | |
| SEP-227900 | Neuropathic Pain | | | | | |
| Ciclesonide Inhalation Solution | Asthma | | | | | |
| BROVANA® + ciclesonide Inhalation Solution | COPD | | | | | |

* eslicarbazepine acetate, also referred to as BIA 2-093 under license from Bial-Portela & C$^{a}$, S.A.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This annual report to stockholders contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 concerning our business, operations and financial condition, including statements with respect to the safety, efficacy and potential benefits of our products and products under development, expectations with respect to the timing and success of regulatory filings, the development and commercialization of our products and product candidates and acquisitions of technologies, product candidates, approved products and/or businesses and other plans and strategies. All statements other than historical facts included in this report are forward-looking statements. When used in this report the words "expect," "anticipate," "intend," "plan," "believe," "seek," "will," "estimate," "goal," "should" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Because these forward-looking statements involve risks and uncertainties, actual results could differ materially from those expressed or implied by these forward-looking statements for a number of important reasons, including those discussed under "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this report. The forward-looking statements contained in this annual report represent our expectations as of the date of this report and should not be relied upon as representing our expectations as of any other date. Although subsequent events and developments will cause our expectations to change, we specifically disclaim any obligation to provide updates.

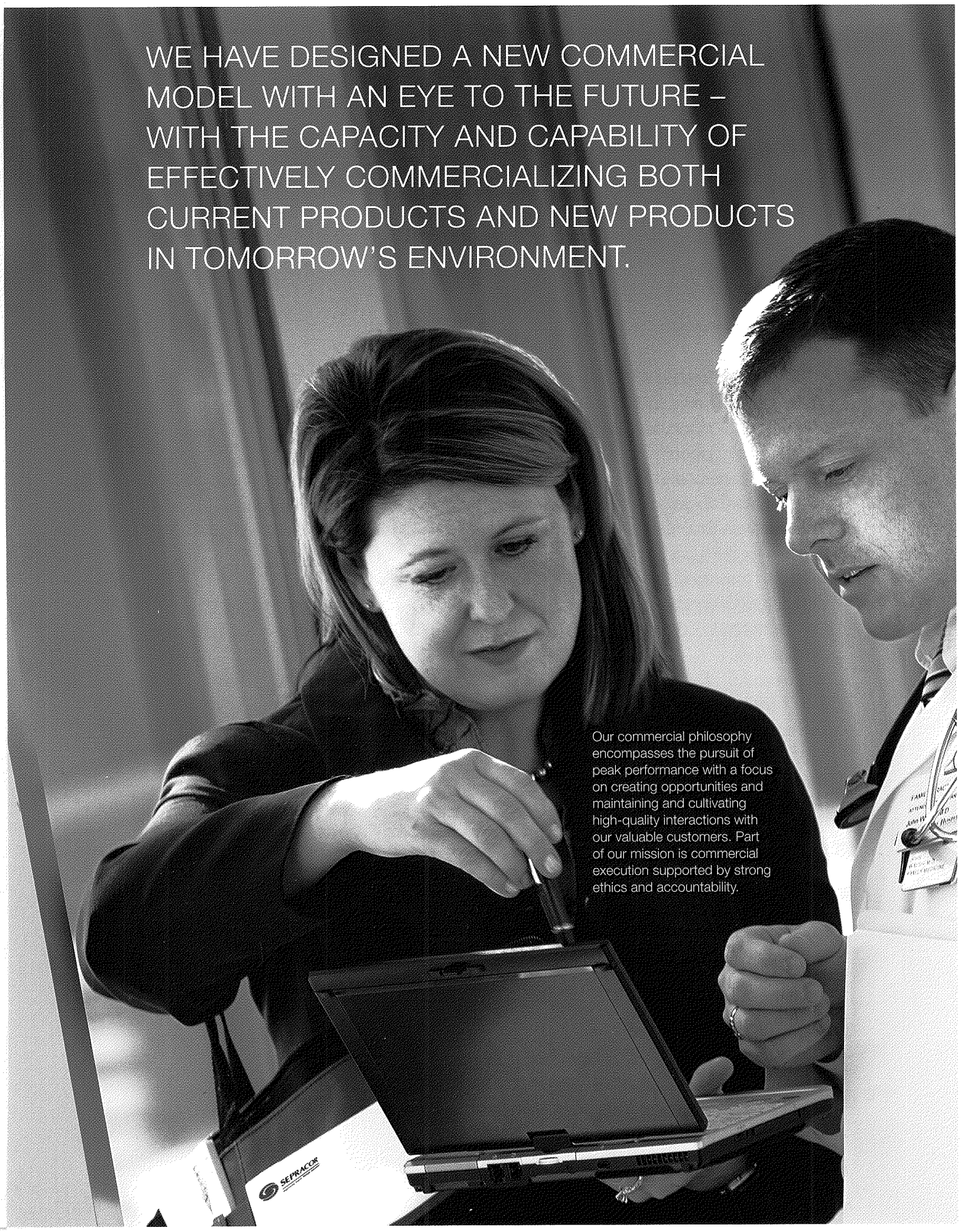
**Our Mission Statement:** Sepracor is dedicated to discovering, developing and commercializing innovative pharmaceutical products and services that improve health and quality of life. We understand our responsibility to ensure that decisions are guided first and foremost by what is in the best interests of patients. We are committed to the welfare of the patients we serve, the success of our employees and to increasing shareholder value.

# TO OUR SHAREHOLDERS

The year 2008 was particularly challenging for people and companies around the world. The economic turmoil that has roiled the markets has had a cascade effect on nearly every industry and individual in the U.S. and beyond. The global economic crisis that began to accelerate in the latter half of 2008 has also impacted the pharmaceutical industry, which had long been deemed to be more insulated from broader market downturns.

Today, we are increasingly seeing managed care organizations, state and federal health administrators and physicians responding to economic pressures to keep costs down, leading to a greater emphasis on utilization of generic medications and reduced reimbursement or higher co-payments for branded products. Further challenging growth in the industry is what we believe to be a more conservative regulatory environment. Recently, the U.S. Food and Drug Administration (FDA) has lengthened product review times, fueled in part by increased scrutiny on product safety. As a result, fewer novel pharmaceutical products reach the market. All of these factors have contributed to changing the face of pharmaceutical development and commercialization and have underscored the need for pharmaceutical companies to become more nimble and adaptive to the changing environment.

Despite all of these challenges, I am very pleased to be able to report that Sepracor delivered strong full-year 2008 results, achieved solid product performance with improvement in sales force productivity, leveraged both our existing and new product franchises, executed several important corporate development and licensing agreements and made steady progress in advancing our research and development pipeline.


WE HAVE DESIGNED A NEW COMMERCIAL MODEL WITH AN EYE TO THE FUTURE – WITH THE CAPACITY AND CAPABILITY OF EFFECTIVELY COMMERCIALIZING BOTH CURRENT PRODUCTS AND NEW PRODUCTS IN TOMORROW'S ENVIRONMENT.
Our commercial philosophy encompasses the pursuit of peak performance with a focus on creating opportunities and maintaining and cultivating high-quality interactions with our valuable customers. Part of our mission is commercial execution supported by strong ethics and accountability.
SEPRACOR

Sepracor is responding to an evolving pharmaceutical industry with a new commercial structure designed to maximize and enhance brand performance in an entrepreneurial, high-performance culture with a focus on our customers and profitability.

These accomplishments included:

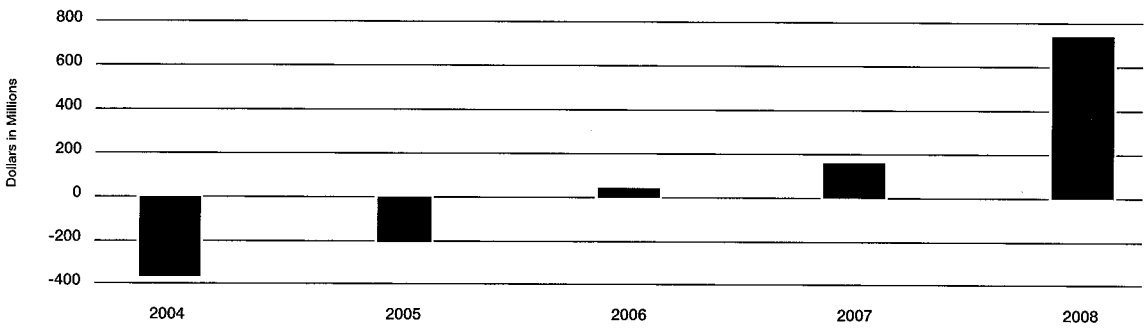
Fully Leveraging Existing and New Product Franchises
- Launched two new products: OMNARIS™ (ciclesonide) Nasal Spray and ALVESCO® (ciclesonide) HFA Inhalation Aerosol
- Delivered solid performance from LUNESTA® brand eszopiclone, XOPENEX® brand levalbuterol and BROVANA® brand arformoterol tartrate product franchises
- Settled patent litigation with Breath Limited for XOPENEX® brand levalbuterol HCl Inhalation Solution, which removed uncertainty and risk associated with this litigation for both parties

Synergistic Corporate Development and Licensing Opportunities
- Began 2008 having just completed a licensing agreement with Bial-Portela & C[a], S.A. for rights to commercialize STEDESA™ (eslicarbazepine acetate) in the U.S. and Canada
- Acquired U.S. distribution rights to OMNARIS Nasal Spray and ALVESCO HFA and obtained rights to ciclesonide development candidates from Nycomed GmbH
- Licensed XOPENEX/ipratropium combination product candidate from Arrow International Limited
- Licensed enabling technology from Arrow to enhance our BROVANA and ciclesonide franchises
- Acquired Oryx Pharmaceuticals, Inc. (renamed Sepracor Pharmaceuticals, Inc.), providing a Canadian commercial platform

Solid and Steady Progress in Building and Advancing Our Research & Development Pipeline
- Advanced and expanded our pipeline, which currently has ten candidates for the treatment of respiratory or central nervous system (CNS) disorders
- Substantially completed the New Drug Application (NDA) for STEDESA and anticipate submission to the FDA in the first half of 2009

Strong Financial Performance
- Full-year revenues reached $1.292 billion, an increase of 5.5% over 2007
- Demonstrated earnings momentum by increasing income from operations to $55.8 million from $22.5 million the preceding year

Progressively Increased Stockholders' Equity




– Initial steps taken in the fourth quarter of 2008 to decrease spending to improve our cost structure and provide increased efficiencies; in 2009, we will continue to seek opportunities to further improve our key expense ratios

Overall, our products either remained steady or grew in terms of prescription volume in 2008 versus 2007. The prescription sedative hypnotic market, in which LUNESTA competes, experienced some softening throughout the year with the prescription growth rate moderating to mid-single-digits by the end of the year versus what had been projected to be high single-digits at the beginning of 2008. Our XOPENEX Inhalation Solution product experienced relatively stable prescription volume in the retail sector over the course of the year. XOPENEX HFA® brand levalbuterol tartrate Inhalation Aerosol prescription volume grew by 9% over the preceding year in what is an increasingly competitive short-acting beta-agonist metered-dose inhaler market. BROVANA continued to achieve new highs in volume from month to month and quarter to quarter. Our two launch products, OMNARIS Nasal Spray and ALVESCO HFA, which we licensed in January 2008 from Nycomed and launched in April and September, respectively, are expected to become increasingly greater contributors to our overall revenues over time. We believe that both products were initially received favorably by health care providers, particularly among specialists. In early 2009, we commenced a broader roll-out to physicians for ALVESCO HFA, with positive early feedback.

When we began 2008, our objectives were to build a stronger, more productive commercial organization, to advance and expand our pharmaceutical pipeline, to energize and execute strategic commercial development and licensing initiatives and to provide strong financial performance. While these objectives were established in an economic environment vastly different from the one in which we currently find ourselves, they nonetheless remain very relevant today.

AS DEMONSTRATED BY OUR RESULTS IN 2008, WE HAVE BEEN VERY FOCUSED ON DELIVERING IMPROVEMENTS IN OUR COSTS-TO-REVENUES RATIOS, AND WE INTEND TO MAINTAIN THIS FOCUS IN 2009 AND BEYOND.

With a goal of delivering healthy financial performance through an improved cost structure, we expect to have greater capacity to develop and commercialize breakthrough medicines for those patients who need them, which in turn has the potential to provide greater shareholder value.

By reshaping our business model to create a more productive organization, we expect to optimize our ability to manage operating costs and enhance shareholder value over time.

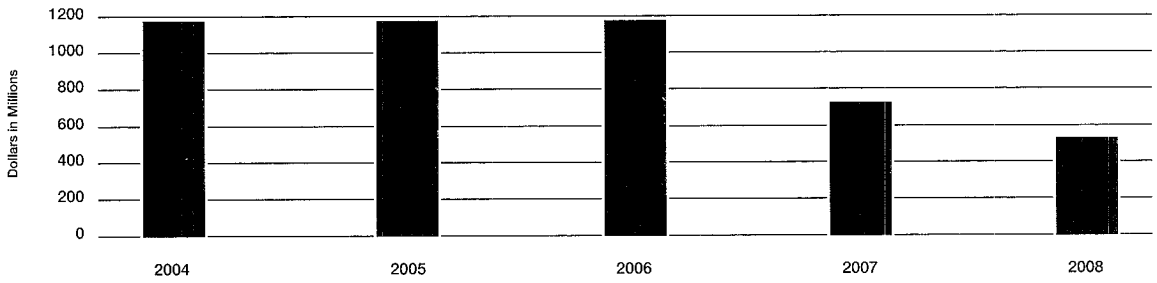
Our achievements in 2008 have given us just cause for optimism going into 2009. However, we recognize that it is a new world in the pharmaceutical industry – one that contains less predictability and greater risk. We believe that the ability of pharmaceutical companies to survive – and indeed, to flourish – in the future will be decided by how they respond to the new realities facing us today. By implementing our plan to reshape and renew our operations, we believe that Sepracor is well-positioned to adapt and succeed in 2009 and beyond and to continue improving health through innovation.

**Responding** – Sepracor's New Commercial Model

Today, the pharmaceutical industry is facing important new challenges from managed care, state and federal agencies, physicians and patients. Health care providers now are finding greater demands on their time. As a consequence, prescribers are limiting access by pharmaceutical industry sales representatives, making it more difficult for pharmaceutical companies to educate health care providers about the availability, safety and efficacy of new and existing drug therapies. As previously mentioned, federal and state governments and managed care organizations have increasingly sought ways to reduce costs, in part, by aggressively encouraging the use of generic medications – including putting in place measures that require trial of a generic medication prior to fulfillment of prescriptions for branded products. Patients, too, are altering their behavior to accommodate the new financial realities that they are facing, often by not filling prescriptions for medicines they need.

Over the course of 2008, we took steps to improve our productivity and began moving toward a more streamlined organization. We reassessed our commercial approach and put into place in early 2009 a new commercial structure and strategy aimed at optimizing product growth in 2009 and beyond. We believe that this new model was not only right for the company in terms of enabling improved operating leverage and productivity, but that it is also particularly well-suited to the changing dynamics within the industry. We believe that our new model, which incorporates significant reconfiguration and a reduction in the scale of our

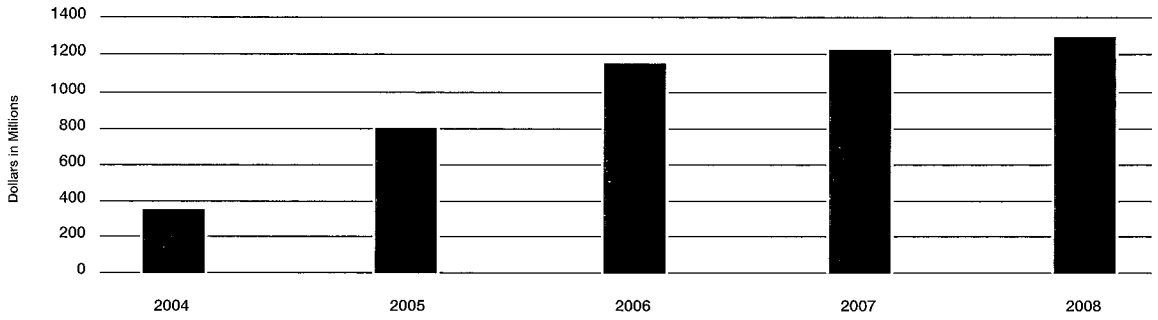
Progressively Reducing Outstanding Convertible Debt




field organization, along with a more closely aligned sales and marketing effort, will improve targeting and individual accountability, foster a renewed sense of entrepreneurship, emphasize a more customer-centric approach and enable us to be a more nimble, productive and cost-effective organization overall, leaving us well-positioned to leverage emerging opportunities from our product pipeline.

Responding with what we believe is a more efficient, accountable and competitive sales organization, our new model eliminates the traditional "mirrored territories" reach and frequency approach that has been common practice across the pharmaceutical industry. We believe that the mirrored territory sales method has become less effective over time, and more specifically, in the context of the changing health care environment that we have observed over the past year. Therefore, in early 2009, we adopted a new sales model that restructured our sales organization into two business units – one for primary care and another for specialty markets – with three sales teams segmented according to product focus. Our primary care unit will be accountable for LUNESTA, OMNARIS Nasal Spray, ALVESCO HFA and our XOPENEX franchise sales efforts. Our specialty markets business unit will focus on institutional and managed care markets sales efforts for all brands and specialized sales and marketing efforts for BROVANA. This approach provides our sales professionals significant opportunity for growth, with greater personal ownership for product profitability. The new structure also joins together our sales, marketing and managed care functions in a manner that should provide for significantly more collaboration and brand ownership. We expect this new model to promote and enable greater transparency and insight into brand performance and tactical successes in an expedient manner.

Revenues Have Grown Year Over Year




**Reshaping** – Improved Cost Structure Paves the Way for Enhanced Shareholder Value

Despite the pressures we saw on prescription growth, we completed 2008 in-line with mid-year projections at $1.292 billion in overall revenues. Cognizant of the changing paradigm in the pharmaceutical industry, and mindful of the need to maximize shareholder value, in the fourth quarter, we began improving operating expense ratios as part of our long-term plan to improve our overall cost structure and provide sustainable profitability. As a result, in the fourth quarter, we realized approximately $20 million in expense reductions. This effort to provide improved operating leverage in 2008 will continue into 2009 as we move forward in reshaping ourselves into a more productive organization aimed at providing safe and effective products for the welfare of the patients we serve and enhancing shareholder value.

As a result of restructuring and other non-personnel-related cost reductions, we anticipate achieving approximately $210 million in total cost savings between the fourth quarter of 2008 and year-end 2009, thereby significantly improving our cost ratios as compared to projected product revenues.

The anticipated improved leverage resulting from these initiatives and our expected product revenue performance for the year reflect what we believe will be a more streamlined and highly productive new business model.

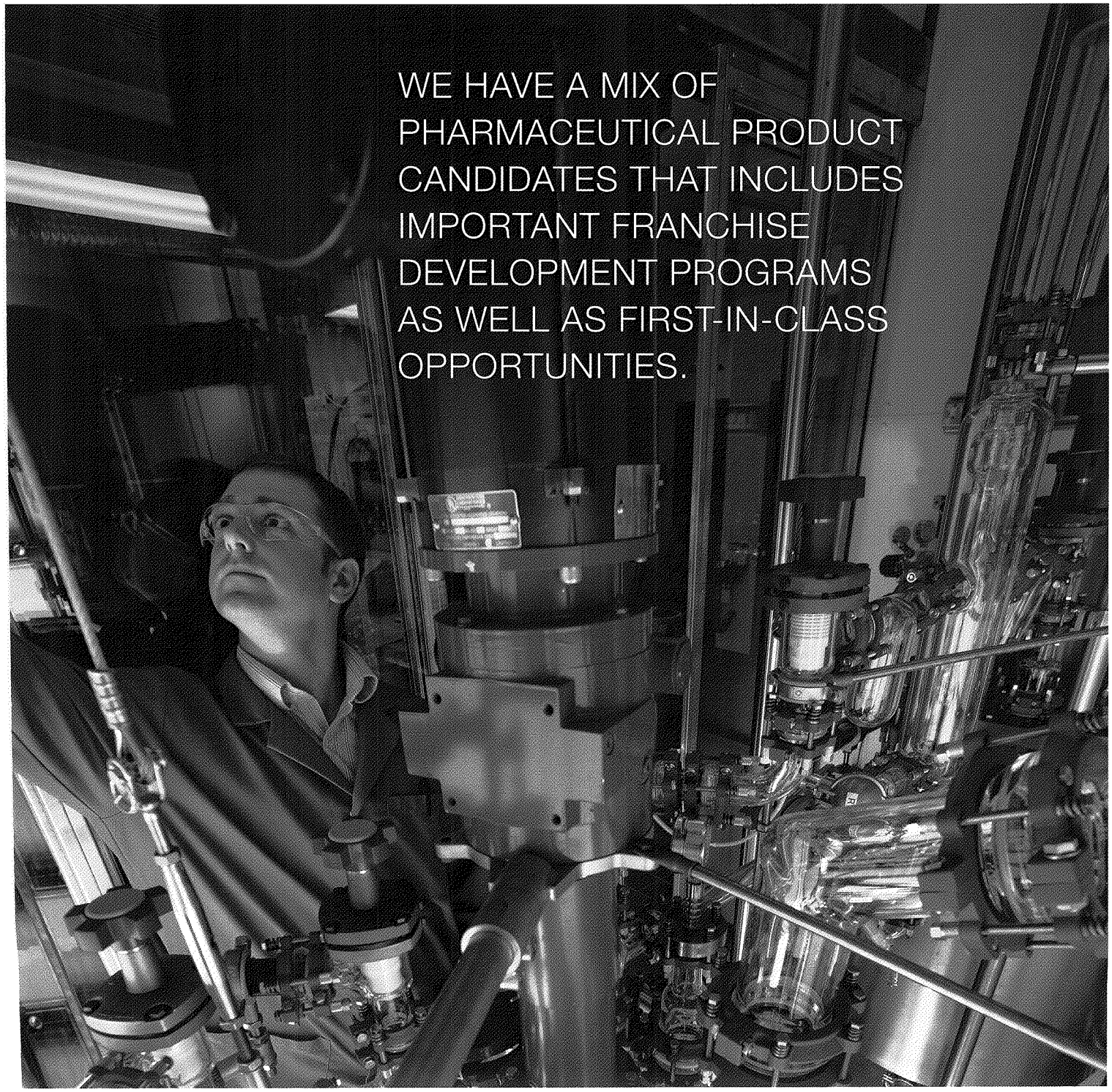
We are actively managing a deeper and broader research and development pipeline, which is a major component of our future growth strategy. Sepracor is renewing its commitment to meeting the needs of underserved markets.

**Renewing** – Expanding and Advancing Pipeline and Strategic Corporate Development and Licensing Initiatives are a Platform for Future Growth
In the pharmaceutical industry, innovation and intelligent collaborations are critical to ensuring future growth. Excellence in execution during the past year, both in research and development and strategic licensing, has put us in the enviable position of having a rapidly advancing development program of ten product candidates. These candidates have the potential to address therapeutic areas that we believe are underserved by currently available products and still others that we expect will enhance our current product franchises. As a result, we believe we have one of the strongest and deepest product pipelines in the specialty pharmaceutical industry.

Research and Development
As we progress through 2009, we anticipate several key milestones from our development programs. Our product candidates are focused on treating an array of respiratory and central nervous system disorders ranging from allergic rhinitis, chronic obstructive pulmonary disease (COPD) and asthma to epilepsy, depression, insomnia, neuropathic pain and attention deficit hyperactivity disorder. Among these milestones is the planned submission of an NDA to the FDA for STEDESA for the treatment of epilepsy; the anticipated results from several of our later-stage candidates; and the advancement of our early-, mid- and late-stage development programs.

The steady advancement of our robust portfolio of pipeline candidates will require strong support from our research and development organization, both in terms of expertise and judicious resource management, as well as appropriate and focused spending. As these candidates advance to later stages of development with demands for larger and longer clinical trials, we recognize that some candidates may be suited to cost-sharing development partnerships. We will also consider other opportunities for commercial development and licensing partnerships that will help sustain future growth. Mindful of our mandate to prudently manage our cash

In addition to advancing several early-, mid- and late-stage programs already in development, Sepracor continues to pursue synergistic opportunities for corporate development and licensing partnerships that could serve to broaden and deepen our therapeutic focus.



resources and appropriately balance expenditures with revenues, a significant aspect of our core strategic objectives for 2009 is the aggressive pursuit of partnerships that will enable us to more fully exploit our assets in development.

Corporate Development and Licensing

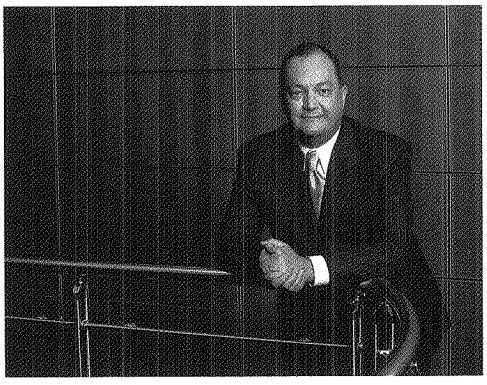
We were highly successful in securing key strategic corporate development and licensing collaborations during 2008 with four significant transactions. These included the acquisition of Canadian-based Oryx Pharmaceuticals, Inc. (renamed Sepracor Pharmaceuticals, Inc.), which provided us with a Canadian commercial platform, as well as the acquisition of the exclusive U.S. distribution rights for ALVESCO HFA, OMNARIS Nasal Spray and other ciclesonide development candidates, among others. Our corporate development and licensing efforts improved both our commercial and development portfolios during 2008. In the months ahead, we anticipate continuing to look for synergistic opportunities to fully leverage our new commercial model, complement our existing franchises and broaden our therapeutic focus.

The year 2009 promises to be one of great change as the nation adapts and reacts to the shifting economy. We believe that by ***responding*** and quickly adapting efficiencies in the challenging economic and health care environment through the ***reshaping*** of our organization in late 2008 and in early 2009, we have well-positioned Sepracor for ***renewed*** growth, innovation and success in the years to come. As we begin 2009, we consider ourselves to be a much more nimble and entrepreneurial organization that is ready to exploit emerging opportunities with speed and a focus on profitability.
I am confident in our prospects and look forward to reporting our progress to all of our stakeholders – patients, health care providers, employees and shareholders – throughout the year as we continue to focus on ***improving health through innovation***.

Sincerely,

Adrian Adams

Adrian Adams
President and Chief Executive Officer



Sepracor Inc.
2008 Form 10-K

# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549



# FORM 10-K

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

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the fiscal year ended December 31, 2008**

**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 0-19410**

# Sepracor Inc.

(Exact Name of Registrant as Specified in its Charter)

| **Delaware** | **22-2536587** |
|---|---|
| (State or Other Jurisdiction of Incorporation or Organization) | (IRS Employer Identification No.) |
| **84 Waterford Drive, Marlborough, Massachusetts** | **01752** |
| (Address of Principal Executive Offices) | (Zip Code) |

Registrant's telephone number, including area code: **(508) 481-6700**

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

| **Common Stock, $.10 par value** | **Nasdaq Global Select Market** |
|---|---|
| (Title of class) | (Name of Exchange on which Registered) |

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

| 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 Exchange Act). Yes ☐ No ☒

The aggregate market value of voting common stock held by nonaffiliates of the registrant based, on the last reported sale price of the common stock on the Nasdaq Global Select Market on June 30, 2008, was approximately $2,167,963,000.

The number of shares outstanding of the registrant's class of common stock as of February 20, 2009 was 109,170,980 shares.

## DOCUMENTS INCORPORATED BY REFERENCE

Proxy Statement for the 2009 Annual Meeting of Stockholders—Part III

**Sepracor Inc.**
**FORM 10-K**

## TABLE OF CONTENTS

## Cautionary Statement Regarding Forward-Looking Statements

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 concerning our business, operations and financial condition, including statements with respect to the safety, efficacy and potential benefits of our products and products under development, expectations with respect to the timing and success of the development and commercialization of our products and product candidates and acquisitions of technologies, product candidates, approved products and/or businesses, the timing and success of the submission, acceptance and approval of regulatory filings, the scope of patent protection with respect to our products and product candidates and information with respect to the other plans and strategies for our business and the business of our subsidiaries. All statements other than statements of historical facts included in this report regarding our strategy, future operations, timetables for product testing, development, regulatory approvals and commercialization, acquisitions, financial position, costs, prospects, plans and objectives of management are forward-looking statements. When used in this report the words "expect," "anticipate," "intend," "plan," "believe," "seek," "will," "estimate," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Because these forward-looking statements involve risks and uncertainties, actual results could differ materially from those expressed or implied by these forward-looking statements for a number of important reasons, including those discussed under "Risk Factors", "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this report.

You should read these forward-looking statements carefully because they discuss our expectations about our future performance, contain projections of our future operating results or our future financial condition, or state other "forward-looking" information. You should be aware that the occurrence of any of the events described under "Risk Factors" and elsewhere in this report could substantially harm our business, results of operations and financial condition and that upon the occurrence of any of these events, the trading price of our common stock could decline.

We cannot guarantee any future results, levels of activity, performance or achievements. The forward-looking statements contained in this Annual Report on Form 10-K represent our expectations as of the date of this Annual Report on Form 10-K and should not be relied upon as representing our expectations as of any other date. Subsequent events and developments will cause our expectations to change. However, while we may elect to update these forward-looking statements, we specifically disclaim any obligation to do so, even if our expectations change.

# PART I

## Item 1. Business.

### The Company

We are a research-based pharmaceutical company focused on discovering, developing and commercializing differentiated products that address large and growing markets and unmet medical needs and are prescribed principally by primary care physicians and certain specialists. Our drug discovery and development program, together with our corporate development and licensing activities, have yielded a portfolio of products and product candidates intended to treat a broad range of indications. We are currently concentrating our product development efforts in two therapeutic areas: respiratory diseases and central nervous system, or CNS, disorders.

In our isomer and metabolite development program, we identify existing drugs that might, in single-isomer or active-metabolite forms, provide significant advances over existing therapies within the indications of the existing drug or in new indications. We then develop isomers or metabolites designed to offer benefits over both the existing drug and competitive compounds, such as reduced side effects, improved therapeutic efficacy, effectiveness for new indications or improved dosage forms.

Our development program for new chemical entities encompasses a more traditional approach to drug development. In this program, we are seeking to discover novel compounds unrelated to existing commercial compounds that have the potential to provide benefits over existing treatments or provide new therapies for diseases currently lacking effective treatment.

In addition to our internal discovery and development programs, as part of our business strategy we plan to continue to consider and, as appropriate, make acquisitions of other businesses, approved products, product candidates and/or technologies.

Our currently marketed products in the United States are:

- LUNESTA® (eszopiclone), a non-benzodiazepine sedative hypnotic, for the treatment of insomnia in adults;
- XOPENEX® (levalbuterol HCl) Inhalation Solution, a short-acting bronchodilator, for the treatment or prevention of bronchospasm in patients six years of age and older with reversible obstructive airway disease;
- XOPENEX HFA® (levalbuterol tartrate) Inhalation Aerosol, a hydrofluoroalkane, or HFA, metered-dose inhaler, or MDI, for the treatment or prevention of bronchospasm in adults, adolescents and children four years of age and older with reversible obstructive airway disease;
- BROVANA® (arformoterol tartrate) Inhalation Solution, a long-acting, twice-daily (morning and evening), maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease, or COPD, including chronic bronchitis and emphysema;
- OMNARIS™ (ciclesonide) Nasal Spray, an intranasal formulation of ciclesonide for the treatment of nasal symptoms associated with seasonal allergic rhinitis in adults and children six years of age and older, and with perennial allergic rhinitis in adults and adolescents 12 years of age and older; and
- ALVESCO® (ciclesonide) HFA Inhalation Aerosol, an inhaled corticosteroid in an HFA MDI formulation for the maintenance treatment of asthma as prophylactic therapy in adult and adolescent patients 12 years of age and older.

In January 2008, we obtained from Nycomed GmbH, or Nycomed, the exclusive United States distribution rights to OMNARIS Nasal Spray and ALVESCO HFA Inhalation Aerosol. We commercially introduced OMNARIS Nasal Spray in April 2008. In September 2008 we commercially introduced ALVESCO HFA Inhalation Aerosol through a staged launch that was initially targeted primarily to specialists. In early 2009, we expanded our sales and marketing efforts to include a broader group of physicians. Because of the extended launch for ALVESCO HFA Inhalation Aerosol, we expect 2009 revenues for this product to take place in the latter part of the year as we reduce launch phase inventory.

Our sales force markets our products in the United States to primary care physicians, allergists, pulmonologists, pediatricians, hospitals, psychiatrists and sleep specialists, as appropriate. We expect to commercialize any additional products that we may successfully develop or acquire through our own or a contract sales force, co-promotion agreements and/or out-licensing partnerships.

In January 2009, we announced a corporate restructuring and workforce reduction plan pursuant to which we intend to reduce our workforce by approximately 20%, or approximately 530 positions, of which approximately 180 are corporate positions and approximately 350 are field-based positions. We expect to substantially complete the workforce reduction by the end of the second quarter of 2009. In addition, we eliminated approximately 410 contract sales organization sales representative positions. These representatives marketed OMNARIS Nasal Spray, ALVESCO HFA Inhalation Aerosol and our XOPENEX products from September 2008 through January 2009. In total, our sales positions were reduced to approximately 1,325 (although the actual number of sales positions varies from time to time due to attrition in the ordinary course of business).

In June 2008, in order to establish a Canadian commercial presence, we acquired the outstanding capital stock of Oryx Pharmaceuticals, Inc., or Oryx, a specialty pharmaceutical company that markets branded prescription pharmaceutical products to physician specialists and hospitals within Canada and is focused in the cardiovascular, CNS disorder, pain and infectious disease therapeutic areas. We subsequently changed Oryx's name to Sepracor Pharmaceuticals, Inc., or SPI. Following this acquisition, in accordance with Statement of Financial Accounting Standards, or SFAS, No. 131, *Disclosures about Segments of an Enterprise and Related Information,* or SFAS 131, we began operating in two segments distinguished by strategic business units that offer different products: (1) Sepracor Inc., which consists of Sepracor and our subsidiaries other than SPI and currently engages in the discovery, research and development and commercialization of pharmaceutical products, and (2) SPI, which currently engages in the licensing and commercialization of pharmaceutical products in Canada. However, since there are no differences among our operating segments that are material to an understanding of our business as a whole, we present the financial information of these two segments on a consolidated basis.

For the year ended December 31, 2008, our total revenues and net income were $1,292.3 million and $515.1 million, respectively. Fiscal year 2008 was our third profitable year since inception. We have historically funded our operations primarily through convertible debt financings, sales of our products, license agreements for our drug compounds, and the issuance of common stock, including the exercise of stock options. Although we may use one or more of these financing mechanisms in the future, we currently plan to finance our ongoing operations primarily with operating profits generated from product sales. In order to achieve continued profitability, we will need to continue to grow our product revenues and control our expenses. The rate of our future sales growth depends, in part, upon our ability to successfully develop or acquire and commercialize new products and/or product candidates.

In early 2009 and 2008, our key developments included the following:

**Corporate Development & Licensing**

- In June 2008, 1765800 Ontario Limited, a wholly-owned subsidiary of Sepracor incorporated under the laws of the Province of Ontario, Canada, which was subsequently renamed Sepracor Canada, Inc., completed the acquisition of 100% of the issued and outstanding common stock of Oryx pursuant to the share purchase agreement dated April 30, 2008, by and among Sepracor, 1765800 Ontario Limited, Oryx, Cobalt Pharmaceuticals, Inc., or Cobalt, and Melville Holdings Limited, which we refer to together with Cobalt as the Sellers, and Arrow Group A.p.S. Under the terms of the agreement, we paid the Sellers $50.0 million in cash upon closing the transaction and incurred an additional $2.1 million as a post-closing working capital adjustment. We are also required to pay the Sellers milestone payments of up to an aggregate of $20.0 million upon the accomplishment of various regulatory milestones. Oryx was subsequently renamed Sepracor Pharmaceuticals, Inc., and is now an indirect wholly-owned subsidiary of Sepracor.
- In April 2008, we entered into a license and development agreement with Arrow International Limited, or Arrow, for the development, commercialization, marketing, sale and distribution of Arrow's levalbuterol/ipratropium combination inhalation solution product in current and all future formulations and delivery modes, or the Levalbuterol/ipratropium Product, throughout the world. We paid Arrow an upfront payment of $500,000 upon execution of the agreement. We are also required to pay Arrow $25.0 million on December 15, 2009 and $25.0 million on December 15, 2010 as further consideration for the transfer of know-how and the grants of rights and licenses to the Arrow technology, provided Arrow is not in material breach of certain of its obligations under the agreement, as well as a milestone payment of $20.0 million upon receipt of marketing approval for the Levalbuterol/ipratropium Product in the United States. We will also pay single-digit royalties that escalate up to an agreed upon amount based on product sales, subject to Arrow's one-time option in the fourth quarter of 2009 to receive a lump sum

discounted amount of $23.5 million in lieu of ongoing royalty payments. Arrow has the right to manufacture and supply us with our requirements of the Levalbuterol/ipratropium Product. If Arrow elects not to manufacture and supply the Levalbuterol/ipratropium Product to us, we will have the right to manufacture or arrange for the manufacture of this product.

- In April 2008, we also entered into a license and development agreement with Arrow for know-how and intellectual property rights related to stable sterile suspension formulations, for use in the development, commercialization, marketing, sale and distribution of an inhalation pharmaceutical product containing ciclesonide as its only active ingredient and an inhalation pharmaceutical product containing both ciclesonide and arformoterol as its active ingredients, throughout the world, collectively referred to as the Ciclesonide Products. The agreement also includes rights to Arrow's "U-Bend" packaging technology, which allows increased accuracy in dosing through a novel U-Bend ampule design. We paid Arrow an upfront payment of $500,000 upon execution of the agreement. We are also required to pay Arrow $10.0 million on December 15, 2009 and $10.0 million on December 15, 2010, as further consideration for the transfer of know-how and the grants of rights and licenses to the Arrow technology, provided Arrow is not in material breach of certain of its obligations under the agreement, as well as milestone payments of up to an aggregate of $27.5 million upon the achievement of certain regulatory milestones relating to both of the Ciclesonide Products. We will also pay single-digit royalties on sales of the Ciclesonide Products, subject to Arrow's one-time options in the fourth quarter of 2009 to receive an aggregate lump sum discounted amount of up to $37.9 million in lieu of ongoing royalty payments.
- In January 2008, we entered into an agreement with Nycomed for the exclusive distribution, development and commercialization in the United States, its territories and possessions, of Nycomed's ciclesonide compound, and products incorporating such compound, including OMNARIS Nasal Spray and ALVESCO HFA Inhalation Aerosol. Under the agreement, we paid Nycomed an upfront payment of $150.0 million in February 2008 and may be required to make subsequent payments of up to $280.0 million over the life of the agreement upon accomplishment of various development and sales milestones. We will also compensate Nycomed for supplying finished products pursuant to the agreement, including a supply price for the products, which will be based on Nycomed's manufacturing costs plus a percentage of such costs, and make royalty payments to Nycomed based on our net sales of the products.
- In January 2008, we announced that we entered into a license agreement with Bial—Portela & C[a], S.A., or Bial, for the development and commercialization in the United States and Canada of eslicarbazepine acetate, Bial's anti-epileptic compound that Bial refers to as BIA 2-093 and we plan to market and sell under the brand name STEDESA™, if and when approved. Pursuant to the agreement, we paid Bial an upfront payment of $75.0 million, and we are required to make subsequent payments upon accomplishment of various development and regulatory milestones, including $10.0 million that we paid to Bial in May 2008 upon achievement of one such milestone, a $20.0 million milestone payment we expect to pay to Bial in 2009 upon acceptance of the New Drug Application, or NDA, for STEDESA by the United States Food and Drug Administration, or FDA, and which could include up to an additional $70.0 million if all other milestones are met. We will also compensate Bial for providing finished product pursuant to a supply agreement that is expected to be entered into by the parties, which will be calculated as a percentage of the average net selling price for finished tablets, and make milestone payments to Bial upon approval by the FDA of additional indications, if any.

**Litigation**

- Beginning February 9, 2009, we received notices from Teva Pharmaceuticals USA, Inc., or Teva, Cobalt Laboratories Inc., or Cobalt Laboratories, Dr. Reddy's Laboratories Ltd. and Dr. Reddy's

Laboratories, Inc., collectively referred to as Dr. Reddy's, Orchid Healthcare, a division of Orchid Chemicals & Pharmaceuticals Ltd., or Orchid, Glenmark Generics, Inc., or Glenmark Generics, Roxane Laboratories, Inc., or Roxane, Lupin Ltd, or Lupin, Wockhardt Limited, or Wockhardt, and Sun Pharma Global Inc., or Sun Global, that each has filed an Abbreviated New Drug Application, or ANDA, with the FDA for generic versions of eszopiclone tablets (1 mg, 2 mg and 3 mg). Each submission includes a Paragraph IV certification alleging that one or more of our patents listed in the FDA publication entitled *Approved Drug Products With Therapeutic Equivalence Evaluations*, commonly referred to as the "Orange Book", for LUNESTA is invalid, unenforceable or not infringed by their respective proposed generic products. We anticipate receipt of additional notices that other ANDAs with Paragraph IV certifications have been filed by different generic pharmaceutical companies. We are currently contemplating commencing civil actions against these parties for patent infringement and will consider commencing patent infringement litigation against any other company that files an ANDA that includes a Paragraph IV certification with respect to eszopiclone.

- In April 2008, we entered into a settlement and license agreement with Breath Limited, or Breath, to resolve the patent infringement litigation involving certain XOPENEX Inhalation Solution products (1.25 mg/3 mL, 0.63 mg/3 mL and 0.31 mg/3 mL). The agreement permits Breath to sell its generic versions of these products in the United States under the terms of an exclusive 180-day license from us commencing on August 20, 2012, and a non-exclusive license thereafter. Upon launch, Breath will pay us a double-digit royalty on gross profits generated from the sales of generic versions of these products. Under the agreement, Breath agrees not to sell any of the products covered by our patents that are the subject of the license before the date on which the license commences. On May 1, 2008, the parties submitted to the court an agreed order of dismissal without prejudice, which the court approved. The settlement and license agreement is a final settlement of the Breath litigation and the litigation is now concluded.

  In connection with the settlement and license agreement with Breath, in April 2008, we also entered into a supply agreement with Breath, whereby, effective August 20, 2012, we will exclusively supply certain levalbuterol products (1.25 mg/3 mL, 0.63 mg/3 mL and 0.31 mg/3 mL) to Breath, under our NDA for a period of 180 days, which we refer to as the Initial Term, and on a non-exclusive basis for up to an additional two and one-half year period thereafter. In addition to the royalties described above, Breath will pay us on a cost-plus-margin basis for supply of the XOPENEX Inhalation Solution products. The supply agreement contains provisions regarding termination for cause and convenience, including either party's right to terminate the agreement at any time after the Initial Term upon nine months written notice. Both the exclusive license under the settlement agreement and the exclusive supply obligations under the supply agreement could become effective prior to August 20, 2012, if a third-party launches a generic version of those dosages of our XOPENEX Inhalation Solution product or if the parties otherwise mutually agree.

**Directors & Officers**

- In August 2008, Richard Ranieri was elected to the newly-created position of Executive Vice President, Human Resources and Administration.
- In May 2008, our board of directors appointed Robert F. Scumaci to the position of Executive Vice President and Chief Financial Officer, effective May 20, 2008. Prior to his appointment to this position, Mr. Scumaci had served as our Executive Vice President, Corporate Finance and Administration since February 2001 and as our Treasurer since March 1996. Mr. Scumaci served as our Senior Vice President, Finance and Administration from March 1996 to February 2001 and as our Vice President and Controller from March 1995 until March 1996.

- In May 2008, we entered into a severance and consulting agreement with David P. Southwell pursuant to which Mr. Southwell resigned as our Chief Financial Officer and Executive Vice President, Corporate Planning, Development and Licensing on May 20, 2008. Mr. Southwell served as our consultant through December 31, 2008 to assist in the transition of his work and to provide such other advice and assistance on corporate projects requested by our Chief Executive Officer.
- In May 2008, Timothy J. Barberich retired as our Executive Chairman and has since served as Chairman of our board of directors. He has agreed to serve as our advisor through December 31, 2009 pursuant to the terms of the executive retirement agreement he entered into with us in December 2007. Mr. Barberich also intends to continue to serve as Chairman of our board of directors.

**Regulatory**

- In October 2008, we announced that the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMEA, issued a positive opinion recommending the European Commission, or EC, grant a marketing authorization for LUNIVIA® brand eszopiclone in the European Union, or EU, for the treatment of insomnia. The EU labeling provides for patients who require longer-term therapy to be treated for up to six months, with the usual course of therapy for typical patients being short-term. LUNIVIA is marketed in the United States under the brand name LUNESTA. We subsequently submitted an application for re-examination of the opinion relating to the CHMP's exclusion of a new active substance designation that we believe would enable more favorable commercialization of the product in the EU. In February 2009, the CHMP re-confirmed its initial opinion recommending LUNIVIA marketing approval in Europe, but without new active substance status. We intend to continue to pursue with the EC the circumstances surrounding LUNIVIA and our marketing application, and we anticipate the EC will be making a final decision in the near future.
- In January 2008, we notified the Centers for Medicare and Medicaid Services, or CMS, that we had identified potential errors in our determination of the best price used to calculate Medicaid rebate amounts in prior periods. We have been in regular contact with CMS regarding our process for addressing these potential errors. We have begun applying the processes and procedures resulting from our remediation efforts to our historical price reporting submissions and we plan to communicate the final results of our review in 2009 to CMS and, as necessary, the Health Resources and Services Administration and state Medicaid programs.

**Other Key Developments**

- On February 17, 2009, we announced that we commenced a tender offer to purchase for cash up to all $382.5 million aggregate principal amount of our outstanding 0% notes due 2024. The terms and conditions of the offer are set forth in the Schedule TO, Offer to Purchase and the related Letter of Transmittal filed with the Securities and Exchange Commission, or SEC, on February 17, 2009. We are offering to purchase the notes at a price of $970 for each $1,000 of principal amount of notes tendered. The tender offer will expire at midnight, New York City time, at the end of March 16, 2009, unless extended or earlier terminated pursuant to the terms of the tender offer. The tender offer will not be contingent upon any minimum number of notes being tendered but is subject to certain conditions described in the Offer to Purchase.
- In January 2009, we announced a corporate restructuring and workforce reduction plan pursuant to which we intend to reduce our workforce by approximately 20%, or approximately 530 positions, of which approximately 180 are corporate positions and approximately 350 are field-based positions. We expect to substantially complete the workforce reduction by the end of the second quarter of 2009. In addition, we eliminated approximately 410 contract sales organization

sales representative positions. These representatives marketed OMNARIS Nasal Spray, ALVESCO HFA Inhalation Aerosol and our XOPENEX products from September 2008 through January 2009. In total, our sales positions were reduced to approximately 1,325.

As a result of the reduction in workforce, we expect to record restructuring charges and make future payments of between approximately $33.0 million and $37.0 million, a substantial portion of which we anticipate will be recorded first quarter of 2009. We currently expect these charges to consist of approximately $23.0 million to $24.0 million relating to employee termination benefits and approximately $10.0 million to $13.0 million relating to other charges, including contract sales organization termination fees and lease termination fees associated with office locations, equipment and automobiles. The increase in the estimate of our restructuring charge from our previously announced range primarily relates to recent decisions to vacate two additional office locations and fees related to the termination of our contact sales organization earlier than previously anticipated. Our estimated restructuring charge is based on a number of assumptions. Actual results may differ materially and additional charges not currently expected may be incurred in connection with, or as a result of, these reductions.

- In December 2008, we repaid in full the entire $72.8 million principal amount of our 0% Series A notes due 2008.
- During the second half of 2008, we repurchased and retired, at our option in privately negotiated transactions, an aggregate of $117.6 million principal amount of our 0% notes due 2024. We paid a total of $106.9 million in cash to repurchase these notes.
- In September 2008, we introduced ALVESCO HFA Inhalation Aerosol, an inhaled corticosteroid in an HFA MDI formulation for the maintenance treatment of asthma as prophylactic therapy in adult and adolescent patients 12 years of age and older, through a specialist-only launch. In early 2009, we expanded our sales and marketing efforts for this product to include primary care physicians.
- In April 2008, we introduced OMNARIS Nasal Spray, an intranasal formulation of ciclesonide for the treatment of nasal symptoms associated with seasonal allergic rhinitis in adults and children six years of age and older, and with perennial allergic rhinitis in adults and adolescents 12 years of age and older.

**Marketed Products**

**LUNESTA**

*Overview*

LUNESTA brand eszopiclone is a non-benzodiazepine sedative hypnotic used for the treatment of insomnia. Symptoms of insomnia include difficulty falling asleep, awakening frequently during the night, waking up too early, an inability to fall back to sleep, or awakening feeling unrefreshed. LUNESTA is approved for long- or short-term treatment of sleep onset and sleep maintenance insomnia. LUNESTA is classified as a schedule IV controlled substance and is marketed in 1 mg, 2 mg and 3 mg film-coated tablets.

In December 2004, we received approval from the FDA for our NDA for LUNESTA. We commercially introduced LUNESTA in the United States in April 2005, and we currently market the product through our sales force. Our revenues from sales of LUNESTA declined slightly to $600.3 million in 2008 from $600.9 million in 2007 and were $565.4 million in 2006. LUNESTA accounted for approximately 46%, 49% and 48% of our total revenues in 2008, 2007 and 2006, respectively. We expect that LUNESTA will account for a substantial portion of our revenues in 2009.

Under our original license agreement with Rhone-Poulenc Rorer SA (the predecessor to Aventis) for eszopiclone, dated October 1999, we are obligated to pay a 5% royalty on sales of LUNESTA in the United States and, as part of the July 2004 amendment to this agreement, we permitted Aventis, now sanofi-aventis, to assign our royalty obligation to a third party in exchange for the right to read and reference sanofi-aventis' regulatory filings related to zopiclone outside of the United States for the purpose of development and regulatory registration of eszopiclone outside of the United States. Aventis has assigned to us the foreign counterparts to the U.S. patent covering eszopiclone and its therapeutic use.

In July 2007, we entered into an agreement with Eisai Co. Ltd., or Eisai, for the development and commercialization of our eszopiclone product in Japan. Under this agreement, Eisai will be responsible for completing remaining clinical trials necessary for attaining marketing approval from the Japanese regulatory authorities and, contingent on obtaining regulatory approval, commercialization of the product in Japan. We received an upfront milestone payment and will be entitled to receive subsequent payments upon accomplishment of various development, regulatory and pricing milestones, as well as royalties on product sales. We will also be responsible for, and will receive compensation in connection with, the manufacture and supply of bulk tablets and/or active ingredient.

In September 2007, we entered into an agreement with GSK Group Limited, or GSK, an affiliate of GlaxoSmithKline, for the development and commercialization of our eszopiclone product for all markets worldwide excluding the United States, Canada, Mexico and Japan. Our eszopiclone product will be marketed by GSK in its territories primarily as LUNIVIA brand eszopiclone for the treatment of insomnia. Under this agreement, we received an initial payment of $20.0 million and are entitled to receive additional payments upon accomplishment of various milestones. If all milestones are met, GSK will be obligated to pay us $155.0 million in aggregate license and milestone payments. We are also entitled to receive double-digit royalties up to an agreed upon amount upon increased product sales, and compensation for supplying the product to GSK pursuant to a supply agreement entered into by the parties.

In October 2008, we announced that the CHMP issued a positive opinion recommending the EC grant a marketing authorization for LUNIVIA in the EU. The EU labeling provides for patients who require longer-term therapy to be treated for up to six months, with the usual course of therapy for typical patients being short-term. We subsequently submitted an application for re-examination of the opinion relating to the CHMP's exclusion of a new active substance designation that we believe would enable more favorable commercialization of the product in the EU. In February 2009, the CHMP re-confirmed its initial opinion recommending LUNIVIA marketing approval in Europe, but without new active substance status. We intend to continue to pursue with the EC the circumstances surrounding LUNIVIA and our marketing application, and we anticipate the EC will be making a final decision in the near future.

During 2008, we devoted significant resources to the completion of Phase IIIb/IV post-marketing studies related to LUNESTA. We expect that we will continue to devote significant resources to Phase IIIb/IV post-marketing studies of LUNESTA during 2009.

*Intellectual Property Position*

We have two issued U.S. patents covering the therapeutic use of LUNESTA (eszopiclone) and two issued U.S. patents covering the compound eszopiclone and pharmaceutical formulations containing eszopiclone. The natural terms of the compound/formulation patents and one of the use patents expire in January 2012 while the natural term of the other use patent expires in August 2012. Under the Drug Price Competition and Patent Term Extension Act of 1984, known as the Hatch-Waxman Act, we have applied for a patent term extension of 760 days for one of the compound/formulation patents. If that extension is granted, it could extend the term of that compound/formulation patent to February 14, 2014. We cannot predict whether or not the patent term extension will be granted.

The Hatch-Waxman Act also provides for a five-year period of exclusivity, which began on the date the FDA approved LUNESTA, during which the FDA will not approve an ANDA for any product containing eszopiclone. The FDA can receive ANDAs after four years have elapsed from the date of approval if the ANDA contains a Paragraph IV patent challenge.

*Abbreviated New Drug Applications*

Beginning February 9, 2009, we received notices from Teva, Cobalt Laboratories, Dr. Reddy's, Orchid, Glenmark Generics, Roxane, Lupin, Wockhardt and Sun Global, that each has filed an ANDA with the FDA for generic versions of eszopiclone tablets (1 mg, 2 mg and 3 mg). Each submission includes a Paragraph IV certification alleging that one or more of our patents listed in the Orange Book for LUNESTA is invalid, unenforceable or not infringed by their respective proposed generic products. We anticipate receipt of additional notices that other ANDAs with Paragraph IV certifications have been filed by different generic pharmaceutical companies. We are currently contemplating commencing civil actions against these parties for patent infringement and will consider commencing patent infringement litigation against any other company that files an ANDA that includes a Paragraph IV certification with respect to eszopiclone.

If we commence patent infringement litigation against any of these ANDA filers and/or any others within 45 days of our receipt of their respective Paragraph IV notices, ANDA approval will be stayed until June 15, 2012, or potentially 6 months thereafter if we successfully obtain a pediatric exclusivity extension, or until a court decides that our patents are invalid, unenforceable or not infringed, whichever is earlier. Should we successfully enforce our patents, ANDA approval should not occur until expiration of the applicable patents, one of which may be extended by our outstanding patent term extension application.

*Manufacturing and Product Supply*

We manufacture the LUNESTA active pharmaceutical ingredient, or API, at our manufacturing facility in Windsor, Nova Scotia, Canada. We also have a qualified second source for API manufacturing at Dow Chemical Inc. in Michigan. Our final tablet manufacturing and packaging takes place at two Patheon, Inc., or Patheon, sites located outside Toronto, Ontario, Canada and Manati, Puerto Rico, and we anticipate entering into an agreement with another manufacturer for finished LUNESTA tablets during the first half of 2009. A third Patheon site, located in Cincinnati, Ohio, is currently used for packaging of LUNESTA. Any future change to manufacturers or the manufacturing process requires regulatory approval. We attempt to maintain sufficient inventories of API and finished products to protect against supply disruptions, but cannot guarantee we will not have product shortages.

**XOPENEX INHALATION SOLUTION**

*Overview*

XOPENEX (levalbuterol HCl) Inhalation Solution is a short-acting beta-agonist used to treat or prevent bronchospasm in children six years of age or older and adults with reversible obstructive airway disease. XOPENEX Inhalation Solution is used to relax the constricted or narrowed bronchial tubes and reduce bronchospasm in the lung. Bronchospasm occurs most commonly in patients with reversible obstructive airway disease, such as asthma, but can also occur in patients with COPD, including chronic bronchitis and emphysema, lung infections, acute bronchitis and other medical conditions. XOPENEX Inhalation Solution comes in a liquid form that is turned into a vapor-like mist in a nebulizer machine and is then inhaled. We market XOPENEX Inhalation Solution in 0.31 mg and 0.63 mg dosage strengths for routine treatment of children six to eleven years old, and 0.63 mg and 1.25 mg for patients twelve years of age and older. We currently sell XOPENEX Inhalation Solution in the United States through our sales force.

Our XOPENEX Inhalation Solution revenues tend to be greater during the colder weather months, when asthma symptoms are more prevalent, thus, our first quarter and fourth quarter revenues from XOPENEX Inhalation Solution historically have exceeded those of the second and third quarters. Our revenues from sales of XOPENEX Inhalation Solution declined to $441.0 million in 2008 from $487.2 million in 2007 and $543.0 million in 2006. XOPENEX Inhalation Solution accounted for approximately 34%, 40% and 46% of our total revenues in 2008, 2007 and 2006, respectively. We expect that XOPENEX Inhalation Solution will account for a substantial portion of our revenues in 2009.

In May 2007, CMS announced that, based on its interpretation of the statutory language of the Medicare Prescription Drug Improvement and Modernization Act of 2003, or MMA, it was required to discontinue the stand-alone reimbursement for XOPENEX Inhalation Solution and generic albuterol, which had been in place since January 2005, and instead calculate the reimbursement for XOPENEX Inhalation Solution and generic albuterol based on the blended weighted average selling price, or ASP, for the two products. This new reimbursement became effective on July 1, 2007. Using a blended weighted ASP for XOPENEX Inhalation Solution results in reimbursement for the product that is considerably lower than the published selling price for the product in the wholesaler distribution channel.

The reimbursement paid by CMS for XOPENEX Inhalation Solution has fallen significantly since July 1, 2007 as a result of the implementation of the blended Medicare Part B reimbursement rate. As a result, commencing January 1, 2009, we ceased contracting with home health care providers for XOPENEX Inhalation Solution. Accordingly, we expect that our sales to Medicare Part B providers will decrease and, as a result, our aggregate unit sales and revenues for this product will decrease. However, we expect the decrease in revenues will be proportionately less than the decrease in unit sales due to a commensurate reduction in the Medicaid rebate liability that has been incurred historically and that resulted from sales of XOPENEX Inhalation Solution at steeply discounted prices to home health care customers since the blended reimbursement rate went into effect.

*Intellectual Property Position*

We have five issued U.S. patents covering the approved therapeutic use of our XOPENEX products, which expire between January 2010 and August 2013. We also have an issued U.S. patent covering the formulation for our XOPENEX products, which expires in March 2021.

*Patent Infringement Litigation*

Breath, Dey, L.P., Barr Laboratories, Inc. or Barr, Teva, Watson Laboratories, Inc., or Watson, and Apotex Inc., or Apotex, have filed ANDAs, including Paragraph IV certifications, with the FDA seeking to market a generic version of levalbuterol hydrochloride inhalation solution before our patents expire. We brought an action against Breath for patent infringement, and in April 2008 we settled this matter and the litigation is now concluded. However, patent infringement litigation remains outstanding against Dey, L.P. and Barr. Our settlement with Breath and ongoing litigation with Dey, L.P. and Barr are described in detail in Part I, Item 3 "Legal Proceedings" of this Annual Report on Form 10-K. We have decided not to commence litigation against Watson, Teva and Apotex as their respective Paragraph IV certifications are limited to a single patent that expires in 2021.

The filing of a lawsuit for patent infringement under the Hatch-Waxman Act results in an automatic 30-month stay of the FDA's authority to grant marketing approval under an ANDA for XOPENEX Inhalation Solution. The 30-month stay against Breath's ANDA expired for our 1.25 mg/3 mL, 0.63 mg/3 mL and 0.31 mg/3 mL XOPENEX Inhalation Solution products on March 7, 2008. On April 9, 2008, the FDA granted final approval to Breath's ANDA for all three dosages. If the FDA determines that Breath has forfeited the 180-day semi-exclusivity period for those three dosages, other ANDA filers who have been granted final approval by the FDA could commence an "at risk" launch

upon expiration of the 30-month stay. For those three dosages, the 30-month stay against Dey, L.P. expired on July 9, 2008 and the 30-month stay against Barr expires on or about November 30, 2009. For our 1.25 mg/0.5 mL XOPENEX Inhalation Solution concentrate, we believe that Dey, L.P. is the sole first filer and potentially entitled to 180 days of semi-exclusivity for that concentration. The 30-month stay against Dey, L.P.'s ANDA for that concentration expired on February 14, 2009. Dey, L.P. may receive final approval to sell 1.25 mg/0.5 mL levalbuterol from the FDA at any time and could thereafter commence an "at risk" launch of this product.

If Dey, L.P. or Barr were to commence selling a generic alternative to any XOPENEX Inhalation Solution product prior to the resolution of our ongoing legal proceedings with these parties, or there is a court determination that the products these companies wish to market do not infringe our patents, or that our patents are invalid or unenforceable, it would have a material adverse effect on our business, financial condition and/or results of operations. In addition, our previously issued guidance regarding our projected financial results may no longer be accurate, and we would have to revise such guidance.

*Manufacturing and Product Supply*

We manufacture the API for XOPENEX Inhalation Solution at our manufacturing facility in Windsor, Nova Scotia, Canada. We also have a qualified second source for API manufacturing at Shasun Pharma Solutions, Ltd., formerly known as Rhodia-Chirex, Inc., in the United Kingdom. Catalent Pharma Solutions, LLC, or Catalent, formerly Cardinal Health, Inc., and Holopack International Corporation, or Holopack, are currently our only finished goods manufacturers of our XOPENEX Inhalation Solution. Any future change to manufacturers or the manufacturing process requires regulatory approval. We attempt to maintain sufficient inventories of API and finished products to protect against supply disruptions but cannot guarantee we will not have product shortages.

**XOPENEX HFA METERED-DOSE INHALER**

*Overview*

XOPENEX HFA (levalbuterol tartrate) Inhalation Aerosol, an HFA MDI, is indicated for the treatment or prevention of bronchospasm in adults, adolescents and children four years of age and older with reversible obstructive airway disease. MDIs are hand-held, pressurized canisters that deliver inhaled medications directly to the lungs. XOPENEX HFA combines levalbuterol with a propellant to produce a fine mist that delivers a specific amount of medication to a patient's lungs. XOPENEX HFA complements the XOPENEX Inhalation Solution product line and provides patients with a portable means of administering XOPENEX.

In March 2005, we received approval from the FDA for our NDA for XOPENEX HFA. We commercially introduced XOPENEX HFA in the United States in December 2005, and we currently market the product through our sales force. Revenues from sales of XOPENEX HFA declined slightly to $74.2 million in 2008 from $74.9 million in 2007 and were $41.0 million in 2006. XOPENEX HFA accounted for approximately 6%, 6% and 3% of our total revenues in 2008, 2007 and 2006, respectively. We expect XOPENEX HFA revenues to continue to be greater during the colder weather months, when asthma symptoms are more prevalent. As a result, we expect our first quarter and fourth quarter revenues for this product are expected to exceed those of the second and third quarters. In 2009, we expect that XOPENEX HFA will account for less than 6% of our overall revenues.

*Intellectual Property Position*

We have five issued U.S. patents covering the approved therapeutic use of our XOPENEX products, which expire between January 2010 and August 2013. We have an issued U.S. patent covering the active ingredient in XOPENEX HFA, which expires in October 2024. We also have a non-exclusive license under certain patents owned by 3M Corporation, or 3M, that relate to HFA inhalation aerosol technology. The 3M patents expire between 2009 and 2017.

*Manufacturing and Product Supply*

We manufacture the API for XOPENEX HFA at our facility in Windsor, Nova Scotia, Canada. We currently have one qualified manufacturer of finished commercial supplies of XOPENEX HFA, which is 3M. Under our supply agreement with 3M, we are obligated to pay to 3M a combination of a fixed price per unit of product purchased and a percentage royalty based on our net sales of XOPENEX HFA. Any future change to manufacturers or the manufacturing process requires regulatory approval. We attempt to maintain sufficient inventories of API and finished products to protect against supply disruptions but cannot guarantee we will not have product shortages.

**BROVANA**

*Overview*

BROVANA (arformoterol tartrate) Inhalation Solution is a long-acting, twice-daily (morning and evening), maintenance treatment of bronchoconstriction in patients with COPD, including chronic bronchitis and emphysema, and is approved for use with a nebulizer. COPD is a slowly progressive disease of the airways that is characterized by a gradual loss of lung function.

In October 2006, we received approval from the FDA for our NDA for BROVANA. The FDA granted us three-year new product exclusivity for BROVANA, which extends to October 2009. We commercially introduced BROVANA in the United States in April 2007, and we currently market the product through our sales force. Revenues from sales of BROVANA were $57.3 million in 2008 and $14.3 million in 2007 and accounted for approximately 4% and 1% of our total revenues in 2008 and 2007, respectively. In 2009, we expect that BROVANA will account for less than 7% of our overall revenues.

*Intellectual Property Position*

We have four issued U.S. patents covering the approved therapeutic use of BROVANA Inhalation Solution, all expiring in April 2012. We have applied for a patent term extension of 745 days for one of these patents. We also have four issued U.S. patents covering the active ingredient of BROVANA, one of which expires in November 2016, and the other three expire in November 2021.

*Patent Infringement Litigation*

In April 2007, we were served with a Complaint filed in the United States District Court for the Southern District of New York, C.A. No. 1:07-cv-2353, by Dey, L.P. and Dey, Inc., referred to collectively as Dey, alleging that the manufacture and sale of BROVANA infringes or will induce infringement of a single United States patent for which Dey owns all rights, title and interest. In April 2007, we filed an Answer and Counterclaims to this Complaint seeking to invalidate the originally asserted patent and a second related patent. In May 2007, Dey filed a reply asserting infringement of the second patent. In March 2008, United States Patent 7,348,362, or the '362 patent, entitled "Bronchodilation b-agonist compositions and Methods" issued and Dey, L.P. is the assignee of the patent. In August 2008, the court granted our Motion to Amend our Answer and Counterclaims to seek declaratory judgment that the '362 patent is invalid and unenforceable and to add Mylan Inc., Dey's parent corporation, as a party. Between December 2008 and January 2009, U.S. patents 7,462,645; 7,465,756; and 7,473,710 all entitled "Bronchodilation b-agonist compositions and Methods" issued. These three patents claim priority to the same parent patent application that issued as the '362 patent. In January 2009, Dey filed a motion to add these three patents to the case, which we did not oppose.

Under the current trial scheduling order, the trial will begin no earlier than October 2, 2009. It is too early to make a reasonable assessment as to the likely outcome or impact of this litigation. We are

unable to reasonably estimate any possible range of loss or liability related to this lawsuit due to its uncertain resolution.

*Manufacturing and Product Supply*

We manufacture the API for BROVANA at our manufacturing facility in Windsor, Nova Scotia, Canada. Catalent is currently our only qualified manufacturer of finished commercial supplies of BROVANA. Any future change to manufacturers or the manufacturing process requires regulatory approval. We attempt to maintain sufficient inventories of API and finished products to protect against supply disruptions but cannot guarantee we will not have product shortages.

**OMNARIS NASAL SPRAY**

OMNARIS Nasal Spray is an intranasal formulation of ciclesonide for the treatment of nasal symptoms associated with seasonal allergic rhinitis in adults and children six years of age and older, and with perennial allergic rhinitis in adults and adolescents 12 years of age and older. The nasal symptoms associated with seasonal and perennial allergic rhinitis include runny nose, itchy nose, congestion and sneezing. When used regularly, OMNARIS Nasal Spray helps to control the nasal symptoms associated with allergic rhinitis.

In January 2008, we obtained from Nycomed the exclusive U.S. distribution rights to OMNARIS Nasal Spray, which was approved by the FDA in October 2006. We commercially introduced OMNARIS Nasal Spray in the United States in April 2008, and we currently market the product through our sales force. Revenues from sales of OMNARIS Nasal Spray were $14.6 million in 2008 and accounted for approximately 1% of our total revenues. In 2009, we expect that OMNARIS Nasal Spray will account for less than 3% of our overall revenues.

Under our agreement with Nycomed, we are responsible for the technical and clinical development of OMNARIS HFA Nasal Spray. OMNARIS HFA Nasal Spray is an innovative intranasal steroid formulation being developed for therapeutic effects in seasonal as well as perennial allergic rhinitis. In late 2008, we initiated the OMNARIS HFA Nasal Spray Phase III clinical program.

We make quarterly royalty payments to Nycomed based on our net sales of OMNARIS Nasal Spray and compensate Nycomed for supplying OMNARIS Nasal Spray, including a supply price based on Nycomed's manufacturing costs plus a percentage of such costs. We attempt to maintain sufficient inventories of OMNARIS Nasal Spray to protect against supply disruptions, but cannot guarantee we will not have product shortages.

**ALVESCO HFA INHALATION AEROSOL**

ALVESCO HFA Inhalation Aerosol is an inhaled corticosteroid in an HFA MDI formulation for the maintenance treatment of asthma as prophylactic therapy in adult and adolescent patients 12 years of age and older. ALVESCO HFA Inhalation Aerosol combines ciclesonide with an HFA propellant to produce a fine mist that delivers a high proportion of the delivered dose into the lungs. When used regularly, ALVESCO helps reduce airway inflammation and helps to prevent and control symptoms of asthma.

In January 2008, we obtained from Nycomed the exclusive U.S. distribution rights for ALVESCO HFA Inhalation Aerosol, which was also approved by the FDA in January 2008. In September 2008, we commercially introduced ALVESCO HFA Inhalation Aerosol in the United States through a staged launch that was initially targeted primarily to specialists. In early 2009, we expanded our sales and marketing efforts to include a broader group of physicians and we currently market the product through our sales force. Revenues from sales of ALVESCO HFA Inhalation Aerosol were $16.8 million in 2008 and accounted for approximately 1% of our total revenues. In 2009, we expect that ALVESCO HFA Inhalation Aerosol will account for less than 2% of our overall revenues. Because of the extended

launch for ALVESCO HFA Inhalation Aerosol, we expect 2009 revenues for this product to take place in the latter part of the year as we reduce launch phase inventory.

We make quarterly royalty payments to Nycomed based on our net sales of ALVESCO HFA Inhalation Aerosol and compensate Nycomed for supplying ALVESCO HFA Inhalation Aerosol, including a supply price based on Nycomed's manufacturing costs plus a percentage of such costs. We attempt to maintain sufficient inventories of ALVESCO Inhalation Aerosol to protect against supply disruptions, but cannot guarantee we will not have product shortages.

## PRODUCTS MARKETED IN CANADA

*Overview*

SPI is a specialty pharmaceutical company that markets branded prescription products to physician specialists and hospitals within Canada and is focused in the cardiovascular, CNS disorders, pain and infectious disease therapeutic areas. SPI seeks to identify and in-license specialty pharmaceutical products within its area of therapeutic focus that have typically already been approved in the United States or in Europe. SPI's current product portfolio has 13 specialized pharmaceutical products in various stages of maturity.

Our revenues from sales of products in Canada were $11.1 million in 2008, and accounted for less than 1% of our total revenues. We acquired SPI, formerly Oryx Pharmaceuticals, Inc., in June 2008. SPI's revenues in 2008 from its two largest marketed products, NIASPAN® (niacin) for the treatment of cholesterol and ANGIOMAX® (bivalirudin) for use as an anticoagulant in patients undergoing percutaneous coronary intervention, were $4.3 million and $3.8 million, respectively, and accounted for approximately 73% of SPI's total revenues in 2008.

SPI's business strategy will also include the pursuit of regulatory approval of certain of our products and product candidates in Canada. If and when approved, SPI will commercialize these products in Canada.

*Manufacturing and Product Supply*

SPI's in-licensed products are mainly supplied by the licensor of such product in finished form, and the two products owned by SPI are manufactured by Patheon at its Whitby, Ontario, Canada facility. All of SPI's marketed products are warehoused and shipped through McKesson Logistics Solutions' Brampton, Canada location.

### Competition

We face intense competition in the sale of our current products, and expect to face intense competition in the sale of any future products we sell. If we are unable to compete effectively, our financial condition and results of operations could be materially adversely affected because we may not achieve our product revenue objectives and because we may use our financial resources to seek to differentiate ourselves from our competition. Large and small companies, academic institutions, governmental agencies and other public and private organizations conduct research, seek patent protection, develop and acquire products, establish collaboration arrangements for product development and sell or license products in competition with us. Many of our competitors and potential competitors have substantially greater resources, manufacturing and sales and marketing capabilities, research and development staff and production facilities than we have. Moreover, the therapeutic categories in which we compete are subject to rapid and substantial technological change. Our competitors may be able to respond more quickly to new or emerging technologies or to devote greater resources to the development, manufacture and marketing of new products and/or technologies than we can. As a result, any products and/or technologies that we develop may become obsolete or noncompetitive before we can recover expenses incurred in connection with their development.

For all of our marketed products, we need to demonstrate to physicians, patients and third-party payors the benefits of the products in terms of their safety, efficacy and cost, both on a stand-alone basis and, where appropriate, relative to competing products. The rate of growth of the overall market for branded pharmaceutical products, such as ours, has been decreasing, and we expect it will continue to decrease, due to increased generic competition, economic conditions and managed care trends. In addition, if competitors introduce new products or develop new processes or new information about existing products, then our marketed products, even those protected by patents, may be replaced in the marketplace or we may be required to lower our prices.

*Competition in the United States*

*LUNESTA*

For insomnia treatments, LUNESTA faces intense competition from established branded and generic products in several drug classes including benzodiazepines, non-benzodiazepines, melatonin agonists, select antidepressants and others. We estimate that our existing LUNESTA prescriptions account for less than 9% of the total annual prescriptions currently being written in the United States for insomnia pharmaceutical therapies. Furthermore, LUNESTA faces substantial competition from non-prescription, over-the-counter and dietary supplement insomnia product options. During 2008, partially as a result of increasing competition, LUNESTA unit sales and market share decreased. We expect that LUNESTA will face increasing competition from a generic version of AMBIEN® (zolpidem) that was introduced in April 2007, a generic version of AMBIEN CR® (zolpidem tartrate extended release), which we believe could be introduced as early as March 2009, and therapies in clinical development or under FDA review for the treatment of insomnia. We may also face additional competition in the event of commercial introduction of a generic version of LUNESTA. To be successful with LUNESTA, we must demonstrate to physicians, patients and payors the safety and efficacy benefits of the product, both on a stand-alone basis and, where appropriate, relative to competing products, both generic and branded.

*XOPENEX FRANCHISE*

For asthma and COPD treatments, XOPENEX Inhalation Solution and XOPENEX HFA face intense competition from a variety of products. Patients with asthma and COPD turn to numerous classes of drugs, including corticosteroids, long-acting beta-agonists, short-acting beta-agonists, leukotriene modifiers, anticholingerics, and others, as well as certain combinations thereof. XOPENEX Inhalation Solution and XOPENEX HFA together account for approximately 4% of the total annual prescriptions currently being written in the United States for asthma and COPD pharmaceutical therapies. XOPENEX Inhalation Solution and XOPENEX HFA also face intense competition specifically within the beta-agonist classes of asthma and COPD treatments. We estimate that our existing XOPENEX prescriptions account for approximately 11% of the total annual prescriptions currently being written in the United States for beta-agonist asthma and COPD pharmaceutical therapies.

Both monotherapy and combination therapy beta-agonist treatments compete directly with our XOPENEX products for the treatment of asthma and COPD. Albuterol, a short-acting beta-agonist, has been available generically for many years. Products containing albuterol as an active ingredient are well established and sell at prices substantially lower than XOPENEX Inhalation Solution and XOPENEX HFA. XOPENEX HFA also faces direct competition from branded HFA albuterol MDIs. Furthermore, as a consequence of our ongoing commercialization of BROVANA, prescription levels for XOPENEX Inhalation Solution may be adversely affected to the extent that a significant number of physicians prescribe BROVANA, which could reduce the concomitant need for XOPENEX products. We may also face additional competition in the event of the commercial introduction of generic versions of our XOPENEX products.

To be successful with our XOPENEX products, we must demonstrate that the efficacy and safety features of these drugs outweigh the higher price as compared to generic albuterol and other competing products and that these attributes differentiate these products from other asthma and COPD treatments, including beta-agonist asthma and COPD treatments.

*BROVANA*

For COPD treatments, BROVANA faces competition from a variety of products. Competitive products include all products used in the treatment of COPD. Patients with COPD turn to numerous classes of drugs including anticholingerics, corticosteroids, mukolytics, long-acting beta-agonists, short-acting beta-agonists, theophyllines, and others to treat their condition. We estimate that our existing BROVANA prescriptions account for less than 1% of the total annual prescriptions currently being written in the United States for COPD pharmaceutical therapies, and less than 1% of beta-agonist COPD pharmaceutical therapies, specifically. Even though BROVANA is a nebulized product, it also faces competition from long-acting beta-agonists and anticholinergics delivered by MDI and dry-powder inhaler. BROVANA also competes with combination therapy products used for COPD. To be successful with BROVANA, we must demonstrate to physicians, patients and payors the safety and efficacy benefits of the product, both on a stand-alone basis and, where appropriate, relative to competing products, both generic and branded.

*OMNARIS Nasal Spray*

OMNARIS Nasal Spray, a corticosteroid nasal spray, competes with perennial and seasonal allergic rhinitis treatments, and faces competition from oral antihistamines, intranasal antihistamines, intranasal decongestants, other intranasal corticosteroids, intranasal mast cell stabilizers, and antileukotrienes. We estimate that our existing OMNARIS Nasal Spray prescriptions account for less than 1% of the total annual prescriptions currently being written in the United States for allergic rhinitis pharmaceutical therapies, and less and 1% of inhaled nasal corticosteroid allergic rhinitis pharmaceutical therapies, specifically. To be successful with OMNARIS Nasal Spray, we must demonstrate to physicians, patients and payors the safety and efficacy benefits of the product, both on a stand-alone basis and, where appropriate, relative to competing branded and generic products, some of which may be less expensive than OMNARIS Nasal Spray and may be available without a prescription. We may also face additional competition in the event of commercial introduction of a generic version of OMNARIS Nasal Spray.

*ALVESCO HFA Inhalation Aerosol*

ALVESCO HFA Inhalation Aerosol, an inhaled corticosteroid in an MDI, competes with other asthma therapies, including asthma controller therapies, and faces competition from leukotriene receptor antagonists, inhaled corticosteroid/long-acting beta-agonist combinations, monotherapy long-acting beta-agonists and other monotherapy inhaled corticosteroids. In addition, several of these categories will have generic product entries in the future, which will likely result in competitive products that are less expensive than ALVESCO HFA Inhalation Aerosol. To be successful with ALVESCO HFA Inhalation Aerosol, we must demonstrate to physicians, patients and payors the safety and efficacy benefits of the product, both on a stand-alone basis and, where appropriate, relative to competing products, both generic and branded.

*Competition in Canada*

SPI faces competition from Canadian specialty pharmaceutical companies and large multi-national companies that commercialize competing products. Competition and innovation from these or other sources could potentially have a negative impact on sales of our products marketed in Canada, or make them obsolete. In addition, when seeking to license new products for distribution in Canada, we face competition from companies such as Paladin Labs Inc., Axcan Pharma Inc., Biovail Corporation, and

other small-to mid-tier pharmaceutical companies that have the same or similar in-licensing strategies. SPI may also be at a competitive marketing disadvantage against companies that have broader product lines and whose sales personnel are able to offer more complementary products than SPI. In addition, SPI could face competition in the event of commercial introduction of generic versions of one or more of its marketed products.

**Partnered Products and Revenue Related Agreements**

As part of our business strategy, we have entered into collaboration, license and distribution agreements with other pharmaceutical companies for the development and commercialization of various products. These agreements sometimes include the receipt or payment of nonrefundable upfront payments, payments on achieving significant milestones, and royalty payments on sales if and when the underlying product or product candidate is commercialized in the relevant jurisdiction. Our significant collaboration, license and distribution agreements are summarized below, and are described in more detail in Part II, Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Annual Report on Form 10-K.

*Out-Licensed Patents*

**sanofi-aventis for Fexofenadine HCl.** In August 1999, we licensed to Hoechst Marion Roussel, Inc., or HMR, now sanofi-aventis (formerly Aventis), our patent rights outside of the United States covering fexofenadine hydrochloride, or HCl, which is marketed by sanofi-aventis as ALLEGRA® (fexofenadine HCl).

**Schering-Plough Corporation for Desloratadine.** In December 1997, we licensed to Schering-Plough Corporation, or Schering-Plough, exclusive worldwide rights to our patents and patent applications relating to desloratadine, an active-metabolite of loratadine, which is marketed by Schering-Plough as CLARINEX® (desloratadine).

**UCB for Levocetirizine.** In February 2006, we entered into a license agreement with UCB S.A. pursuant to which we licensed all of our patents and patent applications in the United States regarding levocetirizine. In May 1999, we entered into a license agreement with UCB Farchim S.A. pursuant to which we licensed all of our patents and patent applications regarding levocetirizine outside of the United States. Levocetirizine is currently marketed by UCB S.A. and UCB Farchim S.A., which we refer to together as UCB, under the brand names XYZAL®/XUSAL™ (levocetirizine).

*Out-Licensed Products*

**Eisai for Eszopiclone.** In July 2007, we entered into an agreement with Eisai for the development and commercialization of our eszopiclone product in Japan. Under this agreement, Eisai will be responsible for completing the remaining clinical trials necessary for attaining marketing approval from the Japanese regulatory authorities and, contingent on obtaining regulatory approval, commercialization of the product in Japan.

**GSK for Eszopiclone.** In September 2007, we entered into an agreement with GSK for the development and commercialization of our eszopiclone product for all markets worldwide excluding the United States, Canada, Mexico and Japan. Our eszopiclone product will be marketed by GSK in its territories primarily as LUNIVIA brand eszopiclone for the treatment of insomnia, subject to receipt of regulatory approvals.

*In-Licenses and Exclusive Distributor Agreement*

**sanofi-aventis for Eszopiclone.** In September 1999, we entered into an agreement with sanofi-aventis' predecessor, Rhone-Poulenc Rorer SA, under which we exclusively licensed its preclinical,

clinical and post-marketing surveillance data package relating to zopiclone, its isomers and metabolites, to develop, make, use and sell eszopiclone in the United States.

**Bial for STEDESA.** In December 2007, we entered into a license agreement with Bial for the development and commercialization in the United States and Canada of Bial's anti-epileptic compound BIA 2-093, which we plan to market and sell under the brand name STEDESA, if and when approved.

**Nycomed for Ciclesonide Compound.** In January 2008, we entered into an agreement with Nycomed for the exclusive distribution, development and commercialization in the United States, its territories and possessions of Nycomed's ciclesonide compound, and products incorporating such compound, including ALVESCO HFA Inhalation Aerosol and OMNARIS Nasal Spray.

**Arrow for Levalbuterol/ipratropium Product.** In April 2008, we entered into a license and development agreement with Arrow for the development, commercialization, marketing, sale and distribution of Arrow's Levalbuterol/ipratropium Product in current and all future formulations and delivery modes, throughout the world.

**Arrow for Enabling Technology.** In April 2008, we also entered into a license and development agreement with Arrow for know-how and intellectual property rights related to stable sterile suspension formulations for use in the development, commercialization, marketing, sale and distribution of an inhalation pharmaceutical product containing ciclesonide as its only active ingredient and an inhalation pharmaceutical product containing both ciclesonide and arformoterol as its active ingredients, throughout the world.

*Partnered Products in Canada*

Prior to our acquisition of SPI in June 2008, its primary business strategy was to consider and, as appropriate, license approved products and product candidates for commercialization in Canada. SPI's licensing partners in Canada include multinational companies, regional pharmaceutical companies without a global presence, and U.S. and European companies with late-stage product candidates. Since its inception in 2001, SPI has entered into a number of in-licensing agreements resulting in its current portfolio of marketed products including its four main products ANGIOMAX, NIASPAN, CUBICIN® (daptomycin) and NAPRELAN® (controlled-release naproxen sodium).

SPI plans to expand its business strategy to include the pursuit of regulatory approval and commercialization of certain of our products and product candidates in Canada. SPI also plans to continue to pursue additional in-licensing arrangements with third parties to expand its Canadian product portfolio.

**Research and Development**

Our research and development activities are primarily directed toward discovering and developing new chemical entities unrelated to existing compounds and potentially improved versions of widely-prescribed drugs.

Our research and development expenses were $246.8 million, $263.8 million and $163.5 million for 2008, 2007 and 2006, respectively. Additionally, during 2008 we recognized a charge of approximately $90.0 million in connection with the write off acquired in-process research and development, or IPR&D, associated with the Nycomed and Arrow transactions. These expenses represent the cost of acquiring rights to branded pharmaceutical products in development from third parties, which we expense at the time of acquisition. Our spending during the past three years has been primarily focused on advancing our drug candidates through clinical trials. Over the three-year period ended December 31, 2008, our principal research and development programs were (1) post-NDA approval studies of LUNESTA, for which we received FDA approval in December 2004, and which we

commercially introduced in April 2005; (2) post-NDA approval studies of XOPENEX HFA, for which we received FDA approval in March 2005, and which we commercially introduced in December 2005; (3) post-NDA approval studies of BROVANA, for which we received FDA approval in October 2006, and which we commercially introduced in April 2007; (4) Phase I and Phase II studies of SEP-225289, a serotonin, norepinephrine and dopamine reuptake inhibitor, or SNDRI, for the treatment of major depressive disorder, or MDD; and (5) Phase I studies of SEP-227162, a serotonin, norepinephrine reuptake inhibitor, or SNRI, for the treatment of depression and/or anxiety.

In 2009, we intend to decrease our research and development expenditures as compared to 2008. We expect our principal research and development expenditures will relate to our drug discovery efforts and the following clinical programs, which are described in more detail below: (1) OMNARIS HFA Nasal Spray, (2) STEDESA, (3) LUNESTA Phase IIIb and Phase IV studies, (4) SEP-225289, (5) SEP-227162 and (6) post-NDA approval studies of BROVANA.

**Drug Development Programs**

All of our drug candidates require significant research, development, successful preclinical and/or clinical testing, regulatory approval and a commitment of significant additional resources prior to commercialization.

*Respiratory*

**XOPENEX HFA.** In late 2008, we commenced an FDA-required Phase IV pediatric study of XOPENEX HFA.

**BROVANA.** In October 2006, the FDA approved BROVANA, which we commercially introduced in April 2007, and mandated that we conduct a large Phase IV safety study and two pediatric Phase IV asthma studies. In late 2008, we clinically completed the first pediatric asthma study and are currently assessing the results, and we expect to commence the large safety study in 2009. During 2009, we also expect to discuss with the FDA next steps regarding the second potential pediatric asthma study.

**ALVESCO inhalation solution.** Under our agreement with Nycomed, we are responsible for the clinical development of ALVESCO inhalation solution. ALVESCO inhalation solution is an innovative inhaled corticosteroid for the treatment of asthma. ALVESCO inhalation solution is in the pre-Investigational New Drug Application, or IND, planning stage.

**OMNARIS HFA Nasal Spray.** Under our agreement with Nycomed, we are responsible for the technical and clinical development of OMNARIS HFA Nasal Spray. OMNARIS HFA Nasal Spray is an innovative intranasal steroid formulation being developed for therapeutic effects in seasonal as well as perennial allergic rhinitis. In late 2008, we initiated a Phase III clinical program for this product candidate.

**ALVESCO in combination with a long-acting beta-agonist.** Under our agreement with Nycomed, we are responsible for the clinical development of ALVESCO in combination with a long-acting beta-agonist, which we have determined will be arformoterol. Prior to entering into our agreement, Nycomed completed various preclinical and early-stage clinical studies. We are in the process of evaluating the next steps for the development of this combination product.

**Levalbuterol/ipratropium Product.** Under our agreement with Arrow, we are responsible for the clinical development and NDA submission of the Levalbuterol/ipratropium Product. Prior to entering into our agreement, Arrow completed various formulation development studies. During the first quarter of 2009, we met with the FDA to review our clinical program plan for this product candidate. Based on the outcome of this meeting, we anticipate submitting an IND in 2009 and commencing the clinical program, which will include an additional Phase II study requested by the FDA.

Nycomed has completed its United States study of ALVESCO HFA Inhalation Aerosol in patients between the ages of four and eleven with persistent (mild to severe) asthma. In this study, 528 patients were randomized to receive 40 mcg of ALVESCO HFA Inhalation Aerosol twice daily, 80 mcg of ALVESCO HFA Inhalation Aerosol twice daily or placebo twice daily. This study did not meet its primary efficacy endpoint.

*Central Nervous System*

**LUNESTA / LUNIVIA** (eszopiclone).

Together with our collaboration partners and SPI, we are currently seeking to develop and market our eszopiclone product outside the United States, and we are seeking to provide further clinical support of our LUNESTA marketing efforts in the United States.

***Eszopiclone—Europe***

In October 2008, we announced that the CHMP issued a positive opinion recommending the EC grant a marketing authorization for LUNIVIA in the EU for the treatment of insomnia. The EU labeling provides for patients who require longer-term therapy to be treated for up to six months, with the usual course of therapy for typical patients being short-term. We subsequently submitted an application for re-examination of the opinion relating to the CHMP's exclusion of a new active substance designation that we believe would enable more favorable commercialization of the product in the EU. In February 2009, the CHMP re-confirmed its initial opinion recommending LUNIVIA marketing approval in Europe, but without new active substance status. We intend to continue to pursue with the EC the circumstances surrounding LUNIVIA and our marketing application, and we anticipate the EC will be making a final decision in the near future.

We also have an ongoing European clinical study of eszopiclone in combination with venlafaxine for the treatment of patients with depression. This study finished enrollment in 2008, and we anticipate study completion in late 2009.

***Eszopiclone—Japan***

In the United States, we have completed a Phase I pharmacokinetic study of eszopiclone for the treatment of insomnia for use in connection with the registration we initiated with the Japanese regulatory authorities in 2006. In 2006, we conducted successful regulatory meetings in Japan with regard to our plans for further study and development of eszopiclone and filed a Clinical Trial Notification, or CTN, in Japan, which is equivalent to an IND in the United States. During 2007, we completed a Phase I pharmacokinetic study for the treatment of insomnia in the elderly in Japan. In the third quarter of 2007, we established a joint development committee with Eisai, our eszopiclone collaboration partner in Japan. This committee has developed plans, committed resources and caused the initiation of clinical studies required to complete the remaining development necessary in connection with the filing of the Japanese NDA equivalent. Based on the current development plan, the major outstanding component of the Japanese development program is the completion of two clinical studies in Japan. We transferred the CTN to Eisai in the third quarter of 2008, and Eisai initiated the two clinical trials in Japan in the fourth quarter of 2008.

***LUNESTA—United States***

During 2008 and early 2009, we completed two pediatric studies of LUNESTA in response to an FDA Written Request letter, in addition to completing a Phase IV study on the use of LUNESTA for the treatment of insomnia in the elderly. In the first half of 2009, we plan to initiate two additional pediatric studies in accordance with the FDA's Written Request letter.

**LUNESTA franchise development program.** Our LUNESTA franchise development program is progressing. We are in the process of completing studies of LUNESTA with an improved film coat and, assuming successful completion of these studies and receipt of required regulatory approvals, we anticipate launching LUNESTA with this new coating in 2010. In addition, we are developing SEP-0227018, a new LUNESTA formulation being studied for potentially reduced side effects and other potential benefits. SEP-0227018 is currently in Phase II clinical development.

**STEDESA (eslicarbazepine acetate)** is an anti-epileptic compound that we licensed from Bial in late 2007. Under our agreement with Bial, we are responsible for further developing STEDESA, which is referred to by Bial as BIA 2-093, filing an NDA with the FDA for adjunct treatment of epilepsy in adults and seeking regulatory approval in Canada. STEDESA is a new chemical entity that is intended to offer patients suffering with partial epilepsy additional control of their seizures and improved quality of life. Bial has completed a Phase III program in Europe for the adjunctive treatment of epilepsy. Bial and Sepracor representatives attended a pre-NDA meeting with the FDA in January 2008. We also met with the FDA during the fourth quarter of 2008 to further define the NDA content requirements, and we anticipate submitting the NDA to the FDA in the first half of 2009. We also plan to initiate a Phase III adult monotherapy program and a pediatric adjunct Phase IIIb program in the United States in 2009.

**SEP-225441,** a modified-release formulation of eszopiclone, is a $GABA_A$ (gamma-aminobutyric acid) agonist and potent anxiolytic in preclinical models. We initiated clinical Phase I studies in Europe in 2007. In the fourth quarter of 2007, we submitted an IND to the FDA and initiated a Phase II generalized anxiety disorder study in the United States. Patient enrollment and treatment for the Phase II study is complete and clinical results are anticipated during the first quarter of 2009.

**SEP-225289** is an SNDRI for the treatment of MDD. SEP-225289 has been shown in preclinical studies to be a potent and balanced reuptake inhibitor of serotonin, norepinephrine and dopamine, which are three neurotransmitters associated with depression. While there are currently no triple reuptake inhibitors on the market, preclinical studies suggest that a triple mechanism of action may provide a profile superior to those of currently marketed antidepressants. In 2006, we completed a Phase I, single-blind, randomized, placebo-controlled safety, tolerability and pharmacokinetic clinical study. In late 2007, we initiated a Phase II proof-of-concept study for the use of SEP-225289 in patients with depression, which we anticipate completing in mid-year 2009.

**SEP-227162** is an SNRI for the treatment of depression and/or anxiety. In the fourth quarter of 2008, we submitted a briefing package to the FDA regarding our Phase III program for SEP-227162 and anticipate a response during the first half of 2009. Following the FDA's response, we will determine the next steps in the development program for this product candidate.

**SEP-225432** is an SNDRI for the treatment of MDD and has been shown in preclinical studies to be a potent and balanced reuptake inhibitor of serotonin, norepinephrine and dopamine, which are three neurotransmitters associated with depression. While there are currently no triple reuptake inhibitors on the market, preclinical studies suggest that a triple mechanism of action may provide a profile superior to those of currently marketed antidepressants. We submitted an IND in December 2007 and completed a first human Phase I clinical study during 2008. We are also considering studying SEP-225432 for the treatment of attention deficit hyperactivity disorder, or ADHD.

**SEP-227900** is a D-amino acid oxidase inhibitor for the treatment of various CNS disorders. We submitted an IND and initiated a first-in-man Phase I clinical study for this product candidate in 2008. We anticipate initiating a Phase II clinical trial in late 2009.

We have elected not to continue development of SEP-225425, an SNDRI that was under development in 2008 for MDD, due to specific drug characteristics discovered during Phase I testing.

**Drug Discovery and Early Research Programs**

Our drug discovery efforts represent an investment in the long-term success of the company. However, drug discovery and clinical studies are high risk endeavors and all of our clinical drug candidates will require significant resources for clinical development, safety testing and regulatory approval prior to commercialization.

Our discovery and early clinical research group seeks to discover novel compounds for the treatment of neurological and neuropsychiatric disorders and then execute proof-of-concept human trials to establish benefits over existing treatments or address unmet medical needs. As part of an integrated portfolio strategy, this group also explores opportunities to in-license compounds, and use existing and late-stage development compounds, for new therapeutic indications or as drug combinations. We balance three types of discovery and early research portfolio projects: (1) first-in class molecules that modify the activity of novel drug targets, (2) best-in-class molecules that modify the activity of recently validated drug targets and could prove superior to competitor molecules, and (3) disease pathway molecules that modify important cellular pathways involved in disease processes but for which the precise drug targets may not be known.

Blocking the reuptake of certain brain neurotransmitters has been demonstrated to lead to effective treatments for mood and anxiety disorders as well as pain. Current drugs are mainly focused on modulating the serotonin and norepinephrine transmitter systems, but do not modulate the dopamine system even though this transmitter is known to also be involved in the regulation of mood and attention. Molecules that are finely tuned to modulate the activity of all three systems are termed triple reuptake inhibitors and we believe they have the potential to address a variety of disorders including mood, anxiety, cognition, ADHD and obesity. We have continued to expand our triple reuptake franchise by advancing SEP-225432 to the human clinical study phase and developing additional back-up molecules for other indications.

We have recently identified sub-type selective potentiators that bind to $GABA_A$ receptors, including those that demonstrate anxiolytic but not sedation effects in non-human primates. We believe these molecules may have utility in treating anxiety or psychosis without the sedation typically associated with the $GABA_A$ complex.

Inhibitors of D-amino acid oxidase may offer therapeutic potential for treatment of cognitive disorders, schizophrenia and pain. Although this target has been of great interest to pharmaceutical companies, historically, it has been challenging to identify antagonists. Our discovery program has identified SEP-227900 and advanced this molecule to the IND stage, where efforts are now focused on conducting human trials for efficacy in treating pain and cognitive disorders. In addition, we have identified a variety of structurally distinct back-up molecules for this target.

**Marketing and Sales**

*United States*

We currently market and sell our products through our sales force, and we out-license certain of our intellectual property rights in exchange for royalties. We believe that in certain situations, partnering arrangements allow us to use the partner's development and marketing expertise to market our drug candidates more quickly than we otherwise could. We currently have partnering and out-licensing agreements for our products and intellectual property with Schering-Plough, sanofi-aventis, UCB, Eisai and GSK. In each of these partnering arrangements, we are dependent upon the efforts, including marketing and sales efforts for approved products, of our partners, and these efforts may not be successful.

In January 2009, we announced a corporate restructuring and workforce reduction plan pursuant to which we reduced our field-based positions by approximately 350. In addition, we eliminated

approximately 410 contract sales organization sales representative positions. In total, our sales positions were reduced to approximately 1,325.

Our products are primarily sold directly to pharmaceutical wholesalers, retail pharmacy chains and home health care organizations. There are a limited number of major wholesalers and retail chains as a result of significant consolidation among companies in the industry. Therefore, as is typical in the pharmaceutical industry, a few customers provide a significant portion of our overall revenues. Also, our terms of sale typically allow for the return of unused products, up to one year after the products' expiration.

Product sales of LUNESTA, XOPENEX Inhalation Solution, XOPENEX HFA, BROVANA, OMNARIS Nasal Spray and ALVESCO HFA Inhalation Aerosol to McKesson Corp, Cardinal Health, Inc. and AmerisourceBergen Corp. represented approximately 35%, 27% and 16%, respectively, of our revenues in 2008. No other customer accounted for more than 10% of our revenues in 2008.

We currently warehouse and ship all of our products through UPS Supply Chain Solutions, a division of United Parcel Services, Inc., through locations in Louisville, Kentucky and outside of Reno, Nevada. Our expectation for 2009 and beyond is to continue to distribute all of our products through one third-party vendor with at least two locations.

In 2009, we expect sales and marketing expenses to decrease as compared with 2008 as a result of our corporate restructuring and workforce reduction plan, together with other anticipated cost savings initiatives.

*Canada*

SPI seeks to position its products through focused direct marketing efforts and through its internal sales organization comprised of approximately 20 sales professionals. SPI's marketed products are sold directly to pharmaceutical wholesalers, retail pharmacy chains and hospitals. All of SPI's products are warehoused and shipped through McKesson Logistics Solutions' Brampton, Ontario, Canada location.

**Manufacturing**

We prepare certain of our drug compounds for research purposes primarily at our laboratories in Marlborough, Massachusetts. We also own and operate a current Good Manufacturing Practices, or cGMP, compliant 50,000 square foot fine chemical manufacturing facility in Windsor, Nova Scotia, Canada, which we believe has sufficient capacity to support the production of our internally developed product candidates in quantities required for our clinical trials. If we successfully develop and receive regulatory approval for additional product candidates, we will need to either manufacture the drugs ourselves or rely on third parties for manufacturing. While we believe that we have the capability to scale up our manufacturing process to support the production in commercial quantities of our internally developed drugs, we may contract out to third-party manufacturers the production of a substantial portion of those drugs. See the discussions above for specific information on the manufacture of our marketed products.

We have a quality assurance/quality control program to ensure that our products and product candidates are manufactured in accordance with applicable regulations. We require that our contract manufacturers and collaboration partners adhere to cGMP. The facilities of our contract manufacturers and collaboration partners must pass regular post-approval FDA inspections. The FDA or other regulatory agencies must approve the processes and the facilities that may be used for the manufacture of any of our potential products.

**Government Regulation**

*Government Approval Process*

We, our collaboration partners and our customers are required to obtain the approval of the FDA and similar health authorities in foreign countries, to test clinically and sell commercially, pharmaceuticals and biopharmaceuticals for human use.

Human therapeutics are generally subject to rigorous preclinical and clinical testing. The standard process required by the FDA before a drug may be marketed in the United States includes:

- preclinical laboratory tests and animal studies of toxicity and, often, carcinogenicity;
- submission to the FDA of an IND application, which must be accepted before human clinical trials may commence;
- adequate and well-controlled human clinical trials to establish safety and efficacy of the drug for its intended indication;
- submission to the FDA of an NDA; and
- FDA acceptance and approval of the NDA prior to any commercial sale or shipment of the drug.

We sometimes attempt to shorten the regulatory approval process of our drug candidates by relying on preclinical and clinical toxicology data with respect to a parent drug.

Typically, clinical evaluation involves a three-phase process. In Phase I, the initial introduction of the drug to humans, the drug is tested for safety, or adverse effects, dosage tolerance, absorption, distribution, metabolism and excretion. Phase II involves studies in a limited patient population to:

- determine the efficacy of the drug for specific targeted indications;
- determine dosage tolerance and optimal dosage; and
- identify possible adverse effects and safety risks.

When a compound is found to be effective and to have an acceptable safety profile in Phase II evaluations, Phase III trials are undertaken to further evaluate clinical efficacy and to test further for safety within an expanded patient population at geographically dispersed clinical study sites. The process of completing clinical testing, obtaining FDA regulatory approval and commencing commercial marketing takes a number of years. We may not successfully complete Phase I, Phase II or Phase III testing within any specified time period, if at all, with respect to any of our products subject to this testing. Even if we successfully complete clinical testing and the FDA accepts an NDA for filing, the FDA may not approve an NDA. Furthermore, even if an NDA is approved, the FDA may not accept our evidence that a particular product meets our claims of superiority.

*Other Regulations Relating to the Sale of Pharmaceuticals*

FDA regulations pertain not only to health care products, but also to the processes and production facilities used to produce such products. Although we have designed the required areas of our facilities in the United States and Canada to conform to cGMP, the FDA will not review the facilities for compliance until we produce a product for which we are seeking marketing approval. Environmental legislation provides for restrictions and prohibitions on releases or emissions of various substances produced in, and waste by-products from, our operations.

The Controlled Substances Act imposes various registration, record-keeping and reporting requirements, procurement and manufacturing quotas, labeling and packaging requirements, security controls and a restriction on prescription refills on certain pharmaceutical products. A principal factor

in determining the particular requirements of this Act, if any, applicable to a product is its actual or potential abuse profile. A pharmaceutical product may be listed as a Schedule II, III, IV or V substance, with Schedule II substances considered to present the highest risk of substance abuse and Schedule V substances the lowest. Eszopiclone, the active drug substance in LUNESTA, has been scheduled under the Controlled Substances Act as a Schedule IV substance. Prescriptions for Schedule IV substances may not be filled or refilled more than six months after they are written and they may not be refilled more than five times unless they are renewed. Schedule IV substances are also subject to special handling procedures relating to storage, shipment, inventory control and disposal. In addition to Federal scheduling, LUNESTA is subject to state controlled substance regulation, and may be placed in more restrictive state schedules than those determined by the U.S. Drug Enforcement Agency and FDA. To date, LUNESTA has not been placed in a more restrictive schedule by any state.

The FDA also imposes requirements relating to the marketing of drug products after approval, including requirements relating to the advertising and promotion of drug products to health care professionals and consumers and the reporting to the FDA of adverse drug experiences known to companies holding approved applications. Our failure to adhere to these requirements could lead to regulatory or enforcement action by the FDA or other government agencies. Information reported to the FDA in compliance with these requirements could cause the FDA to withdraw drug approval or to require modification of labeling, for example, to add warnings or contraindications. The FDA has the statutory authority to seek judicial remedies and sanctions and to take administrative corrective action for violation of these and other FDA requirements and standards.

We are also subject to various Federal and state laws pertaining to health care fraud, including anti-kickback laws and false claims laws. Anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive, or pay any remuneration in exchange for, or to induce, the utilization of products or services reimbursed by a Federal or state health care program, including the purchase or prescribing of a particular drug. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment to third-party payors, including Medicare and Medicaid, false or fraudulent claims for reimbursed drugs or services, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Penalties for violations of health care fraud or false claims laws can include disgorgement of profits, fines and exclusion from Federal health care programs such as Medicare.

The cost of pharmaceutical products is continually being investigated and reviewed by various government agencies, legislative bodies and private organizations in the United States and throughout the world. In the United States, most states have enacted legislation permitting, or even requiring, a dispensing pharmacist to substitute a different manufacturer's generic version of a pharmaceutical product for the one prescribed.

*Reimbursement*

In the United States and other countries in which we sell products, sales of drug products are dependent in part on the availability of reimbursement by third-party payors, such as government and private insurance plans. Third-party payors are increasingly challenging the reimbursements paid for drugs and other medical products and services. We cannot provide assurance that any of our marketed products will be considered cost effective by payors or that reimbursement will be available or will be sufficient to allow us to sell these products on a competitive and profitable basis.

Two principal payors in the United States are Medicaid and Medicare. Medicaid is a Federal and state entitlement program that pays for medical assistance for certain individuals and families with low incomes and resources and who meet other eligibility requirements. Medicaid became law in 1965 and is jointly funded by the Federal and state governments (including the District of Columbia and the territories) to assist states in furnishing medical assistance to eligible needy persons. Medicaid is the

largest source of funding for medical and health-related services for the indigent population in the United States.

Our marketed products are generally eligible for reimbursement under Medicaid and are, therefore, subject to rebates under the Medicaid Drug Rebate Program established by the Omnibus Budget Reconciliation Act of 1990. Under the Medicaid Drug Rebate Program, we pay a rebate to each participating state agency for each unit of our product reimbursed by Medicaid. The basic amount of the rebate for each product is the greater of 15.1% of the Average Manufacturer's Price, or AMP, of that product, or the difference between AMP and the best price available from us to any non-excluded customer. The rebate amount also includes an inflation adjustment if AMP increases faster than a specified inflation index. The rules related to determining AMP and best price are complicated. We compute best price and the required rebate payments each quarter based on our knowledge of the statutory requirements, the current CMS guidance and our understanding of which customers are properly excluded from best price consideration. AMP and best price may be recalculated after they are initially submitted based on the availability of additional data or because of additional analysis of prices that have been reported.

In January 2008, we notified CMS that we had identified potential errors in our determination of the best price used to calculate Medicaid rebate amounts in prior periods. As a result of these potential errors, in the first quarter of 2008 we reduced and restated revenues for periods prior to 2008 for contingent rebates based on management's best estimates and assumptions made prior to any concurrence by CMS. We have been in regular contact with CMS regarding our process for addressing these potential errors. As more fully described in Part II, Item 9A, "Controls and Procedures" of this Annual Report on Form 10-K, we recently remediated a material weakness in our internal controls over the process to identify transactions with the potential to establish a new Medicaid best price, which resulted in these potential errors in our best price calculations. We have begun applying the processes and procedures resulting from our remediation efforts to our historical price reporting submissions and we plan to communicate the final results of our review in 2009 to CMS and, as necessary, the Health Resources and Services Administration and state Medicaid programs.

Several state Medicaid programs have implemented Preferred Drug Lists, or PDLs, and more states may adopt this practice. Products placed on a state Medicaid program's PDL are not subject to restrictions on their utilization by Medicaid patients, such as the need to obtain authorization prior to prescribing. If our drugs are not included on Medicaid PDLs, use of our drugs in the Medicaid program may be adversely affected. In some states that have adopted PDLs, we have been, and may continue to be, required to provide substantial supplemental rebates to state Medicaid authorities in order for our drugs to be included on the PDL.

Pharmaceutical manufacturers, as a condition of participation in the Medicaid Drug Rebate Programs, must enter into an agreement with the Secretary of the Department of Health and Human Services to participate in the 340B program, enacted by the Public Health Service, or PHS, Act. Under the 340B program, pharmaceutical manufacturers are required to extend discounts based on the Medicaid rebate to a variety of health care entities referred to as covered entities. These covered entities include health care providers that receive health services grants from the PHS as well as certain hospitals that serve a disproportionate share of low-income patients.

Section 603 of the Veteran's Health Care Act of 1992 requires manufacturers of covered drugs to enter into a master agreement with the Secretary of the Department of Veteran Affairs, or VA, in order to have its drugs covered under Medicaid. The master agreement requires the manufacturer to make its products available for federal procurement by listing them on the Federal Supply Schedule. In addition, the master agreement requires the manufacturer to enter into a Pharmaceutical Pricing Agreement, or PPA, with the VA. Under the PPA, the manufacturer agrees to sell its drugs to the "Big Four" federal agencies—the VA, the Department of Defense, the PHS and the Coast Guard—at or

below a Federal Ceiling Price, which is set at 76% of a calculation called the Non-Federal Average Manufacturer Price.

Another source of reimbursement for drug products is state Pharmaceutical Assistance Programs, or SPAPs. Many of these programs were created by states to aid low-income elderly or persons with disabilities who do not qualify for Medicaid. We pay rebates to some SPAPs and, if they are considered qualified programs by CMS, the prices we provide these entities are excluded from our Medicaid best price.

The Medicare program was enacted in 1965 under the Social Security Act and provides health care coverage to aged and disabled eligible consumers. The Medicare program is comprised of several parts. In general, Medicare Part B covers physician services and many other forms of outpatient care, including some outpatient drugs. Drugs covered under Part B include those furnished incident to a physician's service and those furnished under the durable medical equipment benefit. XOPENEX Inhalation Solution and BROVANA are eligible for coverage under Medicare Part B because each is administered via a nebulizer, which is a piece of durable medical equipment covered under Part B. We established a Medicare Part B rebate program in order to increase the access by Medicare Part B beneficiaries to our BROVANA product through Medicare Part B pharmacy providers.

Effective January 1, 2006, Congress enacted a prescription drug benefit known as Medicare Part D. CMS contracted with numerous Medicare Advantage Prescription Drug, or MA-PD, managed care plans and Medicare Prescription Drug Plans, or PDPs, which offer only prescription drug coverage, to deliver the drug benefit. MA-PDs and PDPs develop formularies that determine which products are covered and at what co-pay level. We pay rebates to certain Medicare Part D plans on the sale of LUNESTA, XOPENEX Inhalation Solution, XOPENEX HFA, BROVANA, OMNARIS Nasal Spray and ALVESCO HFA Inhalation Aerosol.

Federal and state government agencies continue to promote efforts to reduce health care costs, including those associated with the Medicare and Medicaid programs. These efforts may include supplemental rebates and restrictions on the amounts that agencies will reimburse for the use of products.

*Availability and Delivery of Pharmaceutical Products*

We expect debate to continue during 2009 at the Federal and state levels over the availability, delivery of, and payment for, pharmaceutical products. We believe that if certain legislation is enacted, it could have the effect of reducing prices or limiting price increases of pharmaceutical products.

At this time it is not possible to predict the extent to which we, or the pharmaceutical industry in general, might be affected by the reimbursement and pricing issues discussed above.

*Hazardous Materials*

Our research and development activities involve the controlled use of hazardous materials, chemicals, biological materials and various radioactive compounds. We believe that our procedures comply with the standards prescribed by state and Federal regulations; however, the risk of injury or accidental contamination cannot be completely eliminated.

**Government Regulation in Canada**

*Government Approval Process*

The process for approval to market a prescription drug in Canada is substantially similar to that in the United States. A New Drug Submission is filed with Health Canada and contains substantially the same information and data that is provided in an NDA filed in the United States with the FDA.

However, approval of a product by the FDA does not necessarily mean that Health Canada will approve the product for marketing in Canada. Furthermore, the terms of the marketing authorization, including product claims, approved by Health Canada may differ from those approved by the FDA.

*Reimbursement*

After Canadian regulatory approval is received for a prescription drug, it can be sold in Canada to the public in accordance with prescription pharmaceutical regulations. Payment for prescription drugs in Canada is made by one of three sources: cash, private insurance or government drug plans. For patients reimbursed by third-party private insurers, these plans are generally provided by their employers. Patients may be reimbursed a percentage of the cost of covered drugs minus deductibles or co-pays. The availability for reimbursement of drugs varies according to the type of reimbursement plan designed by the patients' insurance company.

Provincial and Federal drug plans in Canada generally serve patients over the age of 65 and patients to whom the cost of medications represents a significant financial burden. Each provincial government covers the cost of drugs listed on an individual formulary. For new products, there is a Common Drug Review, or CDR, of available clinical evidence including a review of the pharmacoeconomic data for the drug. The Canadian Expert Drug Advisory Committee makes a listing recommendation to the provinces.

At the provincial level, products are reviewed on the basis of their cost-effectiveness, comparable utility to other similar products, projected utilization and cost implications to the publicly-funded drug budget. Each submission is reviewed but there is wide variance in the formulary decisions and the time taken to make such decisions. Provinces may utilize the recommendations of the CDR, or perform their own analysis. Presently, all provinces except Quebec use the CDR recommendations in their assessment, but make their formulary decisions independently from the CDR. In many provinces, the formulary committee may grant "restricted or limited use approvals" for a drug as a means of regulating the size of the patient population eligible for reimbursement for the cost of the drug.

Until provincial and private reimbursement is approved, a product is sold only in cash transactions. Decisions on reimbursement under private plans are typically made shortly after SPI makes a request for reimbursement. Decisions on approval for provincial government reimbursement may take in excess of 12 months.

SPI's ability to sell its current and future products will be affected by its ability to obtain and maintain coverage on private and government drug plans and any changes implemented by such drug plans.

*Patented Medicine Prices Review Board*

The Patented Medicine Prices Review Board, or PMPRB, is an independent body created under the Canadian Patent Act to protect consumer interests in light of increased patent protection for pharmaceuticals. Its primary mandate is to ensure that the prices charged by manufacturers of "patented" medicines in Canada are not excessive. The mandate of the PMPRB does not include reviewing the prices of non-patented medicines. The PMPRB determines the price of a given pharmaceutical through comparison to the prices of other medicines that are clinically equivalent and to the publicly available ex-factory prices of the same medicine sold in other specified industrialized countries.

The PMPRB review is conducted after the product has been introduced to the marketplace and does not delay a product launch. The determination by the PMPRB that the price of the product is "not excessive" can take up to 24 months. After approval of the price by the PMPRB, future price increases are restricted by PMPRB and cannot exceed the annual Canadian Consumer Price Index.

**Patents and Proprietary Technology**

We and our affiliates, subsidiaries and collaboration partners have obtained patents and filed patent applications in the United States and selected other countries relating to compositions of, formulations of, methods of making, and methods of using our drugs and drug candidates (and those for which we have rights to develop and commercialize), and for related synthesis and separations. In addition, we have licensed from third parties certain rights under various patents and patent applications. We are currently considering, and to a large extent seeking, all available forms of patent protection for our drugs, drug candidates and discovery programs.

We have a significant number of other U.S. and foreign patents and patent applications covering composition of, methods of making and methods of using our product candidates. Patents may not be issued based on patent applications we have already filed or that we file in the future, and if patents are issued, they may be insufficient in scope. Patents and/or patent applications covering our product candidates would become increasingly material to our business if and when we seek to commercialize these candidates. Our ability to commercialize any drug successfully will largely depend on our ability to obtain, maintain and enforce patents of sufficient strength and scope to prevent third parties from developing and commercializing similar or competitive products.

Many of the compounds that we are investigating or developing may be subject to patents held by third parties. There may be foreign equivalents to these third-party patents, the scope and expiration of which may vary from country to country. Even if we are issued a patent for the use of a molecular entity that is currently covered by one or more third-party patents, products incorporating any such molecular entity may not be sold until all of such third-party patents expire unless a license is obtained to such third-party patents or such third-party patents are determined to be invalid, unenforceable, or not infringed by a court of proper jurisdiction. In addition, there may be pending additional third-party patent applications covering our drugs in development, which, if issued, may preclude the sale of our drugs. If we conclude that it is necessary and advisable to take a license from a third party in connection with a product we are developing, such a license may not be available to us on terms that we find acceptable, or at all, and could burden the product with significant royalty obligations.

**Related Party**

*BioSphere Medical, Inc.*

In 1994, we established and independently financed BioSepra Inc. as a subsidiary through an initial public offering of its common stock. From 1994 to 1999, the company operated as BioSepra Inc., developing proprietary microsphere beads used as chromatography media in the production of pharmaceuticals.

In February 1999, BioSepra determined that it would refocus on embolotherapy, which is the occlusion of the blood supply to fibroids and vascular defects. BioSepra acquired a 51% interest in French-based BioSphere Medical, S.A., referred to as BioSphere France, with an option to purchase the remaining 49% interest in BioSphere France, and changed its corporate name to BioSphere Medical, Inc., or BioSphere. The acquisition enabled BioSphere to gain ownership of technology know-how and European regulatory approval of Embosphere® Microspheres. Between February 1999 and October 2001, BioSphere acquired the remaining 49% interest in BioSphere France.

In November 2004, we purchased, in a private placement, 4,000 shares of BioSphere Series A Convertible Preferred Stock and warrants to purchase 200,000 shares of BioSphere common stock from BioSphere for an aggregate purchase price of $4.0 million. Each share of BioSphere Series A Convertible Preferred Stock is convertible into 250 shares of BioSphere common stock. In addition, quarterly dividends of 6% per annum are paid on the shares in either cash or additional shares of Series A Convertible Preferred Stock, at BioSphere's election.

At December 31, 2008, we owned 3,224,333 shares, or approximately 18%, of BioSphere's outstanding common stock, 4,820 shares of Series A Convertible Preferred Stock and warrants to purchase an additional 200,000 shares of common stock. Assuming conversion of our of Series A Convertible Preferred Stock of BioSphere and the exercise of our warrants, we would own approximately 23% of the outstanding common stock of BioSphere. We account for our investment in BioSphere under the equity method.

**Employees**

At December 31, 2008, we employed approximately 2,400 persons throughout the world, including approximately 2,300 in the United States. Our employees are not unionized or affiliated with any internal or external labor organizations. We believe our future success largely depends upon our continued ability to attract and retain highly skilled employees.

In January 2009, we announced a corporate restructuring and workforce reduction plan pursuant to which we intend to reduce our workforce by approximately 20%. We expect to substantially complete the workforce reduction by the end of the second quarter of 2009.

**Investor Information**

We are a Delaware corporation and were founded in 1984. Our principal executive offices are located at 84 Waterford Drive, Marlborough, Massachusetts 01752. Our telephone number is (508) 481-6700.

We maintain a web site with the address www.sepracor.com. We are not including the information contained on our web site as part of, or incorporating by reference into, this Annual Report. We make available free of charge on or through our web site our Annual Reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports as soon as practicable after such material is electronically filed with, or furnished to, the SEC. In addition, we intend to disclose on our web site any amendments to, or waivers from, our code of business conduct and ethics that are required to be disclosed pursuant to rules of the SEC.

We file annual, quarterly and special reports, proxy statements and other information with the SEC. You may read and copy materials that we have filed with the SEC at the SEC public reference room located at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room.

Our SEC filings are also available to the public on the SEC's Internet website at www.sec.gov.

## Item 1A. Risk Factors

You should carefully consider the risks described below in addition to the other information contained in this report, before making an investment decision. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not currently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations, financial condition or results from operations.

**Risks Related to Our Financial Results and Our Common Stock**

***We have a history of net losses and we may not be able to generate revenues sufficient to achieve and maintain profitability on a quarterly and annual basis.***

Until the year ended December 31, 2006, we had incurred net losses each year since our inception. It is possible we will not be able to maintain profitability on a quarterly or annual basis. We expect to

continue to incur significant operating expenditures to further develop and commercialize our products and product candidates and in order to allow us to otherwise expand our product portfolio through drug discovery and business development efforts. As a result, we will need to generate significant revenues in future periods to achieve and maintain profitability. We cannot provide assurance that we will be able to maintain profitability for any substantial period of time. If revenues grow more slowly than we anticipate or if operating expenses exceed our expectations or cannot be adjusted accordingly, our business, results of operations and financial condition will be materially and adversely affected. In addition, if we are unable to achieve, maintain or increase profitability on a quarterly or annual basis, the market price of our common stock may decline.

***Almost all of our revenues are derived from sales of LUNESTA and XOPENEX Inhalation Solution, and our future success depends on the continued commercial success of these products as well as our other products.***

Approximately 81% of our total revenues for the year ended December 31, 2008 resulted from sales of LUNESTA and XOPENEX Inhalation Solution, and we expect that sales from these two products will continue to represent a significant majority of our revenues for the coming year. However, unit sales for both LUNESTA and XOPENEX Inhalation Solution decreased during the year ended December 31, 2008, as compared to the same period during the prior year, and may continue to decrease. LUNESTA's market share and unit sales may continue to decrease as a result of the introduction of zolpidem tartrate, the generic equivalent to AMBIEN, in 2007, other competitive products being marketed or developed by others, such as a generic equivalent to AMBIEN CR, which we believe could be introduced as early as March 2009, and potential disruption to our business as we implement our corporate restructuring and workforce reduction plan. Moreover, the growth of the overall non-generic pharmaceutical market, which includes branded drugs such as LUNESTA and XOPENEX Inhalation Solution, has been declining, and may continue to decline, as a result of economic conditions and managed care trends. If we do not maintain sales of LUNESTA and if sales of XOPENEX Inhalation Solution in other markets do not offset the reduction in revenues resulting from our decision to no longer contract with home health providers for XOPENEX Inhalation Solution beginning January 1, 2009, we may not have sufficient revenues to achieve our business plan or repay our outstanding debt, and our business will not be successful.

We do not have long-term sales contracts with our customers, and we rely primarily on purchase orders for sales of LUNESTA, XOPENEX Inhalation Solution and our other marketed products. Reductions, delays or cancellations of orders for LUNESTA, XOPENEX Inhalation Solution or our other marketed products could adversely affect our operating results. Any other adverse developments with respect to the sale of LUNESTA or XOPENEX Inhalation Solution could significantly reduce revenues and have a material adverse effect on our ability to maintain profitability and achieve our business plan.

We cannot be certain that we will be able to successfully market and sell LUNESTA and/or XOPENEX Inhalation Solution, that we will be able to successfully market and sell BROVANA, XOPENEX HFA, OMNARIS Nasal Spray and ALVESCO HFA Inhalation Aerosol, or that any of our marketed products will be accepted in their markets. Specifically, the following factors, among others, could affect the level of success and market acceptance of our products:

- a change in the perception of the health care community of their safety and/or efficacy, both in an absolute sense and relative to that of competing products;
- the introduction of new products into the sleep or respiratory markets;
- the level and effectiveness of our sales and marketing efforts;
- any unfavorable publicity regarding these products or similar products;
- litigation or threats of litigation with respect to these products;

- a finding that our patents are invalid or unenforceable or that generic versions of our marketed products do not infringe our patents or the "at risk" launch of generic versions of our products;
- the price of the product relative to other competing drugs or treatments;
- private insurers, such as managed care organizations, or MCOs, adopting their own coverage restrictions or demanding price concessions in response to state, Federal or administrative action;
- any adverse impact on revenues as a result of our corporate restructuring and workforce reduction plan;
- any changes in government and other third-party payor reimbursement policies and practices; and
- regulatory developments or other factors affecting the manufacture, marketing or use of these products.

In addition, a number of the patents we own and/or license to third parties and for which we receive sales revenues or royalties are the subject of patent invalidation or revocation claims by companies seeking to introduce generic equivalents of the products covered by such patents. We can provide no assurance concerning the duration or outcome of any patent-related lawsuits. If we, or third parties from whom we receive royalties, are not successful in enforcing our respective patents, the companies seeking to market generic versions will not be excluded from marketing their generic versions of these products. Introduction of generic equivalents of any of these products before the expiration of our patents or the patents of our licensees could have a material adverse effect on our business.

***We have significant debt and we may not be able to make principal payments when due.***

As of December 31, 2008, our total convertible debt was approximately $530.5 million. None of our 0% Series B notes due December 2010 or our 0% notes due October 2024 restricts us or our subsidiaries' ability to incur additional indebtedness, including debt that ranks senior to the notes. The 0% notes due 2024 are senior to the Series B notes due 2010. Additional indebtedness that we incur may in certain circumstances rank senior to or on parity with this debt. Our ability to satisfy our obligations will depend upon our future performance, which is subject to many factors, including factors beyond our control. Our 0% Series B notes due 2010 are convertible into our common stock at the option of the holders and the conversion price is $29.84. If the market price for our common stock does not exceed the conversion price, the holders of our 0% Series B notes due 2010 may decide not to convert their securities into common stock. For example, the holders of our 0% Series A notes due 2008 did not convert such notes into common stock, and on December 15, 2008, the maturity date for the 0% Series A notes due 2008, we repaid in cash the entire principal amount of $72.8 million.

As of December 31, 2008, our total cash, cash equivalents and short- and long-term investments totaled $765.8 million. Our 0% notes due 2024 are convertible into cash and, if applicable, shares of our common stock under a conversion formula that becomes applicable if and when our common stock price exceeds $67.20 per share on the NASDAQ Global Select Market. Prior to our stock exceeding such price, the notes are convertible at the option of the holders in October 2009, 2014, 2019 and 2024, as well as under certain circumstances. On February 17, 2009, we announced that we commenced a tender offer to purchase for cash up to all $382.5 million aggregate principal amount of our outstanding 0% notes due 2024. We are offering to purchase the notes at a price of $970 for each $1,000 of principal amount of notes tendered, or a total of $371.0 million if all outstanding 0% notes due 2024 are tendered and repurchased. If holders do not trade and/or we do not repurchase all of the 0% notes due 2024, and if some or all of our significant contingent payments become due and payable

under our collaboration agreements, we may not be able to make the required payment upon future conversion of the notes.

Historically, we have had negative cash flow from operations, and since 2006 we have experienced positive cash flow from operating activities. Unless we have sufficient cash or are able to generate sufficient operating cash flow to pay off the principal of our outstanding debt, we will be required to raise additional funds or default on our obligations under the notes. If operating profits generated from sales of our products does not meet expected levels, it is unlikely that we would have sufficient cash flow to repay our outstanding convertible debt and/or make cash payments upon maturity of the 0% Series B notes due 2010. There can be no assurance that, if required, we would be able to raise the additional funds on favorable terms, if at all.

***If we exchange debt for shares of common stock, there will be additional dilution to holders of our common stock.***

As of December 31, 2008, we had approximately $148.0 million of outstanding debt that could be converted into shares of our common stock and an additional $382.5 million of outstanding debt that could be converted into cash and, if applicable, shares of our common stock. In order to reduce future payments due at maturity, we have in the past and may, from time to time, depending on market conditions, repurchase additional outstanding convertible debt for cash, such as our outstanding tender offer for the repurchase of our 0% notes due 2024; exchange debt for shares of our common stock, warrants, preferred stock, debt or other consideration; or a combination of any of the foregoing. The amounts involved in any such transactions, individually or in the aggregate, could be material. If we exchange shares of our capital stock, or securities convertible into or exercisable for our capital stock, for outstanding convertible debt or use proceeds from the issuance of convertible debt to fund redemption of outstanding convertible debt with a higher conversion ratio, the number of shares that we might issue as a result of such exchanges would significantly exceed the number of shares originally issuable upon conversion of such debt and, accordingly, such exchanges would result in material dilution to holders of our common stock. Repurchase of the notes, including any repurchase of our 0% notes due 2024 pursuant to our outstanding tender offer, could also adversely affect the trading market for such notes if the public float in such notes is materially reduced. We cannot provide assurance that all or any portion of the holders of our 0% notes due 2024 will tender their notes, that we will repurchase any notes that are tendered or that we will repurchase or exchange any additional outstanding convertible debt.

***If we identify a material weakness in our internal control over financial reporting it could adversely affect our ability to meet reporting obligations and negatively affect the trading price of our stock.***

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. Accordingly, a material weakness increases the risk that the financial information we report contains material errors. As more fully described in Part II, Item 9A, "Controls and Procedures" of this Annual Report on Form 10-K, we recently remediated a material weakness in our internal control over the process to identify transactions with the potential to establish a new Medicaid best price, which affected the accuracy of our net revenues and product sales allowance and return accounts. However, we may identify additional control deficiencies in the future that individually or in the aggregate constitute a material weakness. If there are other undetected or uncorrected deficiencies in our internal controls, we could fail to meet our reporting obligations, we could have material misstatements in our financial statements and, under certain circumstances, could be subject to legal liability. In addition, inferior controls could cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

***If the estimates we make, or the assumptions on which we rely, in preparing our financial statements prove inaccurate, our actual results may vary from those reflected in our projections and accruals.***

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, net revenues and expenses, the amounts of charges accrued by us and related disclosure of contingent assets and liabilities. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. We cannot provide assurance, however, that our estimates, or the assumptions underlying them, will not be materially different from actual results. For example, our royalty revenues are recognized based upon our estimates of our collaboration partners' sales during the period and, if these sales estimates are greater than the actual sales that occur during the period, our net income would be reduced. In addition, we estimate product sales allowances, including payment term discounts, government and commercial rebates and returns and other discounts. If actual amounts differ from these estimates, net income could be adversely affected. Each, in turn, could adversely affect our financial condition, results from operations and stock price.

***If sufficient funds to finance our business are not available to us when needed or on acceptable terms, then we may be required to delay, scale back, eliminate or alter our business strategy.***

We may require additional funds for our research and product development programs, operating expenses, repayment of debt, the pursuit of regulatory approvals, license or acquisition opportunities and the expansion of our production, sales and marketing capabilities. Historically, we have satisfied our funding needs through collaboration arrangements with corporate partners, sales of products and equity and debt financings. These funding sources may not be available to us when needed in the future. In addition, the current economic crisis has severely diminished the availability of capital. The cost and terms of any such future financing is unclear, and we can provide no assurance that we will be able to raise additional funds on terms acceptable to us, if at all. We may also need to issue equity securities with rights, preferences and privileges senior to our common stock or issue debt securities containing limitations or restrictions on our ability to engage in certain transactions in the future.

Insufficient funds could require us to delay, scale back, eliminate or alter certain of our research and product development programs and/or commercialization efforts or to enter into license agreements with third parties to commercialize products or technologies that we would otherwise develop or commercialize ourselves. Our cash requirements may vary materially from those now planned because of factors including:

- patent developments;
- licensing or acquisition opportunities;
- drug discovery and development efforts;
- relationships with collaboration partners;
- the FDA regulatory process;
- expansion into foreign markets;
- litigation and government inquiries and investigations;
- whether our 0% Series B notes due 2010 will be paid in cash rather than converted into common stock pursuant to the terms of such debt;
- our ability to achieve anticipated cost reductions as a result of our corporate restructuring or an adverse impact on revenues as a result of the restructuring;
- our capital requirements; and

- selling, marketing and manufacturing expenses in connection with commercialization of products.

***Our effective tax rate may increase or fluctuate, which could increase our income tax expense and reduce our net income.***

Our effective tax rate could be adversely affected by several factors, many of which are outside of our control, including:

- material differences between forecasted and actual tax rates as a result of a shift in the mix of pretax profits and losses in different tax jurisdictions, our ability to use tax credits, or effective tax rates by tax jurisdiction being different than our estimates;
- changing tax laws, accounting standards, such as occurred with the introduction of SFAS No. 123(R), *Shared-Based Payment,* (revised 2004), or SFAS 123(R) and Financial Accounting Standards Board, or FASB, Interpretation No. 48, *Accounting for Uncertainity in Income Taxes,* or FIN 48, regulations, and interpretations in multiple tax jurisdictions in which we operate, as well as the requirements of certain tax rulings;
- an increase in expenses not deductible for tax purposes, including certain stock-based compensation expense, write-offs of acquired IPR&D and impairment of goodwill;
- the tax effects of purchase accounting for acquisitions and restructuring charges that may cause fluctuations between reporting periods;
- changes in the valuation of our deferred tax assets and liabilities;
- changes in tax laws or the interpretation of such tax laws; and
- tax assessments resulting from income tax audits or any related tax interest or penalties.

***Our long-term investments include auction-rate securities that may not be accessible within the next 12 months and may experience a decline in value, which may adversely affect our liquidity and income.***

At December 31, 2008, $70.9 million of our investment portfolio was invested in AAA rated auction-rate securities. These investments were rated AAA by one or more rating agency. Auction-rate securities are long-term variable rate bonds tied to short-term interest rates. After the initial issuance of the securities, the interest rate on the securities is reset periodically, at intervals established at the time of issuance (primarily every 28 days), based on market demand for a reset period. Auction-rate securities are bought and sold in the marketplace through a competitive bidding process often referred to as an auction. If there is insufficient interest in the securities at the time of an auction, the auction may not be completed and the rates may be reset to predetermined "penalty" or "maximum" rates.

Substantially all of our auction-rate securities are backed by pools of student loans guaranteed by Federal Family Education Loan Program, or FFELP, and we continue to believe that the credit quality of these securities is high based on this guarantee and other collateral. Auctions for these securities began failing in the first quarter of 2008 and continued to fail throughout the remainder of 2008, which we believe is a result of the recent uncertainties in the credit markets. Consequently, the investments are not currently liquid, and we will not be able to access these funds until a future auction of these investments is successful, a buyer is found outside of the auction process, the security is called or the underlying securities have matured. At the time of our initial investment and through the date of this report, all of our auction-rate securities remain AAA rated by one or more rating agency. We believe we have the ability to hold these investments until the lack of liquidity in these markets is resolved. As a result, we continue to classify the entire balance of auction-rate securities as non-current available-for-sale investments at fair value on our consolidated balance sheets.

Typically, the fair value of auction-rate securities investments approximates par value due to the frequent resets through the auction process. While we continue to earn interest on our auction-rate securities investments at the contractual rate, these investments are not currently trading and therefore do not have a readily determinable market value. Accordingly, the estimated fair value of the auction-rate securities no longer approximates par value.

At December 31, 2008, because of the temporary declines in fair value for the auction-rate securities, which we attribute to liquidity matters rather than credit issues as discussed above, we have classified our auction-rate securities at Level 3, as defined under the SFAS 157, *Fair Value Measurements,* or SFAS 157, framework and described in Note E "Fair Value Measurements" of our consolidated financial statements included in this Annual Report on Form 10-K, with a fair value of $70.9 million. The fair value of these auction-rate securities are estimated utilizing a trinomial discounted cash flow analysis, which was compared, when possible, to other observable market data or inputs with similar characteristics. The assumptions used in preparing the discounted cash flow analysis include estimates for the maximum interest rate, the probability of passing, failing or default at each auction, the severity of default and the discount rate. Based on this assessment of fair value, as of December 31, 2008, we determined there was a decline in fair value of our auction-rate securities investments of $8.7 million, which we deem temporary. If current market conditions deteriorate further, we may be required to record additional unrealized losses in other comprehensive income. If the credit ratings of the security issuers deteriorate, the anticipated recovery in market values does not occur, or we need funds from the auction-rate securities to meet working capital needs, we may be required to adjust the carrying value of these investments through impairment charges recorded to earnings, as appropriate, which could be material.

***Fluctuations in the demand for our products, the success and timing of clinical trials, regulatory approvals, product introductions, collaboration and licensing arrangements, any termination of development efforts and other material events will cause fluctuations in our quarterly operating results, which could cause volatility in our stock price.***

Our quarterly operating results are likely to fluctuate significantly, which could cause our stock price to be volatile. These fluctuations will depend on many factors, including:

- timing and extent of product sales and market penetration;
- timing and extent of operating expenses, including selling and marketing expenses and the costs of reducing, expanding and/or maintaining a direct sales force or attaining the services of a co-promotion partner or contract sales force;
- success and timing of regulatory filings and approvals for products developed by us or our licensing or collaborative partners;
- timing of product introductions;
- success of product introductions, including OMNARIS Nasal Spray and ALVESCO HFA Inhalation Aerosol;
- changes in third-party reimbursement policies;
- introduction of competitive products into the market;
- results of clinical trials with respect to products under development;
- a finding that our patents are invalid or unenforceable or that generic versions of our products do not infringe our patents or the "at risk" launch of generic versions of our products;
- a finding that our products infringe the patents of a third party;

- the initiation of, or adverse developments in, any judicial litigation proceedings or governmental investigations in which we are involved;
- a change in the perception of the health care and/or investor communities with respect to our products;
- success and timing of collaboration agreements for development of our pharmaceutical candidates and development costs for those pharmaceuticals;
- timing of receipt or payment of upfront, milestone or royalty payments under collaboration or licensing agreements;
- unfavorable publicity regarding our company or our products or competitive products;
- timing and success of any business and/or product acquisitions;
- timing and success of expansion into foreign markets;
- termination of development efforts of any product under development or any collaboration agreement; and
- timing of expenses we may incur with respect to any license or acquisition of products or technologies.

***We have various mechanisms in place to discourage takeover attempts, which may reduce or eliminate our stockholders' ability to sell their shares for a premium in a change of control transaction.***

Various provisions of our certificate of incorporation and by-laws and of Delaware corporate law may discourage, delay or prevent a change of control or takeover attempt of our company by a third-party that is opposed by our management and board of directors. Public stockholders who might desire to participate in such a transaction may not have the opportunity to do so. These anti-takeover provisions could substantially impede the ability of public stockholders to benefit from a change of control or change in our management and board of directors. These provisions include:

- preferred stock that could be issued by our board of directors to make it more difficult for a third-party to acquire, or to discourage a third-party from acquiring, a majority of our outstanding voting stock;
- classification of our directors into three classes with respect to the time for which they hold office;
- non-cumulative voting for directors;
- control by our board of directors of the size of our board of directors;
- limitations on the ability of stockholders to call special meetings of stockholders;
- inability of our stockholders to take any action by written consent; and
- advance notice requirements for nominations of candidates for election to our board of directors or for proposing matters that can be acted upon by our stockholders at stockholder meetings.

In addition, in June 2002, our board of directors adopted a shareholder rights plan, the provisions of which could make it more difficult for a potential acquirer of Sepracor to consummate an acquisition transaction.

***The price of our common stock historically has been volatile, which could cause the loss of part or all of an investment in Sepracor.***

The market price of our common stock, like that of the common stock of many other pharmaceutical and biotechnology companies, has been highly volatile. In addition, the stock market has experienced extreme price and volume fluctuations. The volatility and market prices of securities of many pharmaceutical and biotechnology companies have been significantly affected for reasons frequently unrelated to, or disproportionate to, the operating performance of the specific companies. These broad market fluctuations may adversely affect the market price of our common stock. Prices for our common stock are determined in the marketplace and may be influenced by many factors, including variations in our financial results and investors' perceptions of us, and changes in recommendations by securities analysts as well as their perceptions of general economic, industry and market conditions.

**Risks Related to Commercialization, Marketing and Sales**

***We face intense competition and many of our competitors have greater resources and capabilities than we have.***

We face intense competition in the sale of our current products, and expect to face intense competition in the sale of any future products we sell. If we are unable to compete effectively, our financial condition and results of operations could be materially adversely affected because we may not achieve our product revenue objectives and because we may use our financial resources to seek to differentiate ourselves from our competition. Large and small companies, academic institutions, governmental agencies and other public and private organizations conduct research, seek patent protection, develop and acquire products, establish collaborative arrangements for product development and sell or license products in competition with us. Many of our competitors and potential competitors have substantially greater resources, manufacturing and sales and marketing capabilities, research and development staff and production facilities than we have. Moreover, the therapeutic categories in which we compete are subject to rapid and substantial technological change. Our competitors may be able to respond more quickly to new or emerging technologies or to devote greater resources to the development, manufacture and marketing of new products and/or technologies than we can. As a result, any products and/or technologies that we develop may become obsolete or noncompetitive before we can recover expenses incurred in connection with their development.

For all of our marketed products, we need to demonstrate to physicians, patients and third-party payors the benefits of the products in terms of their safety, efficacy and cost, both on a stand-alone basis and, where appropriate, relative to competing products. The growth of the overall market for branded pharmaceutical products, such as ours, has been decreasing, and we expect it will continue to decrease, due to increased generic competition, economic conditions and managed care trends. In addition, if competitors introduce new products or develop new processes or new information about existing products, then our marketed products, even those protected by patents, may be replaced in the marketplace or we may be required to lower our prices.

*Competition in the United States*

*LUNESTA*

For insomnia treatments, LUNESTA faces intense competition from established branded and generic products in several drug classes including benzodiazepines, non-benzodiazepines, melatonin agonists, select antidepressants and others. We estimate that our existing LUNESTA prescriptions account for less than 9% of the total annual prescriptions currently being written in the United States for insomnia pharmaceutical therapies. Furthermore, LUNESTA faces substantial competition from non-prescription, over-the-counter and dietary supplement insomnia product options. During 2008,

partially as a result of increasing competition, LUNESTA unit sales and market share decreased. We expect that LUNESTA will face increasing competition from a generic version of AMBIEN that was introduced in April 2007, a generic version of AMBIEN CR, which we believe could be introduced as early as March 2009, and therapies in clinical development or under FDA review for the treatment of insomnia. We may also face additional competition in the event of commercial introduction of a generic version of LUNESTA. To be successful with LUNESTA, we must demonstrate to physicians, patients and payors the safety and efficacy benefits of the product, both on a stand-alone basis and, where appropriate, relative to competing products, both generic and branded.

*XOPENEX FRANCHISE*

For asthma and COPD treatments, XOPENEX Inhalation Solution and XOPENEX HFA face intense competition from a variety of products. Patients with asthma and COPD turn to numerous classes of drugs, including corticosteroids, long-acting beta-agonists, short-acting beta-agonists, leukotriene modifiers, anticholingerics, and others, as well as certain combinations thereof. XOPENEX Inhalation Solution and XOPENEX HFA together account for approximately 4% of the total annual prescriptions currently being written in the United States for asthma and COPD pharmaceutical therapies. XOPENEX Inhalation Solution and XOPENEX HFA also face intense competition specifically within the beta-agonist classes of asthma and COPD treatments. We estimate that our existing XOPENEX prescriptions account for approximately 11% of the total annual prescriptions currently being written in the United States for beta-agonist asthma and COPD pharmaceutical therapies.

Both monotherapy and combination therapy beta-agonist treatments compete directly with our XOPENEX products for the treatment of asthma and COPD. Albuterol, a short-acting beta-agonist, has been available generically for many years. Products containing albuterol as an active ingredient are well established and sell at prices substantially lower than XOPENEX Inhalation Solution and XOPENEX HFA. XOPENEX HFA also faces direct competition from branded HFA albuterol MDIs. Furthermore, as a consequence of our ongoing commercialization of BROVANA, prescription levels for XOPENEX Inhalation Solution may be adversely affected to the extent that a significant number of physicians prescribe BROVANA, which could reduce the concomitant need for XOPENEX products. We may also face additional competition in the event of the commercial introduction of generic versions of our XOPENEX products.

To be successful with our XOPENEX products, we must demonstrate that the efficacy and safety features of these drugs outweigh the higher price as compared to generic albuterol and other competing products and that these attributes differentiate these products from other asthma and COPD treatments, including beta-agonist asthma and COPD treatments.

*BROVANA*

For COPD treatments, BROVANA faces competition from a variety of products. Competitive products include all products used in the treatment of COPD. Patients with COPD turn to numerous classes of drugs including anticholingerics, corticosteroids, mukolytics, long-acting beta-agonists, short-acting beta-agonists, theophyllines, and others to treat their condition. We estimate that our existing BROVANA prescriptions account for less than 1% of the total annual prescriptions currently being written in the United States for COPD pharmaceutical therapies, and less than 1% of beta-agonist COPD pharmaceutical therapies, specifically. Even though BROVANA is a nebulized product, it also faces competition from long-acting beta-agonists and anticholinergics delivered by MDI and dry-powder inhaler. BROVANA also competes with combination therapy products used for COPD. To be successful with BROVANA, we must demonstrate to physicians, patients and payors the safety and efficacy benefits of the product, both on a stand-alone basis and, where appropriate, relative to competing products, both generic and branded.

*OMNARIS Nasal Spray*

OMNARIS Nasal Spray, a corticosteroid nasal spray, competes with perennial and seasonal allergic rhinitis treatments, and faces competition from oral antihistamines, intranasal antihistamines, intranasal decongestants, other intranasal corticosteroids, intranasal mast cell stabilizers, and antileukotrienes. We estimate that our existing OMNARIS Nasal Spray prescriptions account for less than 1% of the total annual prescriptions currently being written in the United States for allergic rhinitis pharmaceutical therapies, and less and 1% of inhaled nasal corticosteroid allergic rhinitis pharmaceutical therapies, specifically. To be successful with OMNARIS Nasal Spray, we must demonstrate to physicians, patients and payors the safety and efficacy benefits of the product, both on a stand-alone basis and, where appropriate, relative to competing branded and generic products, some of which may be less expensive than OMNARIS Nasal Spray and may be available without a prescription. We may also face additional competition in the event of commercial introduction of a generic version of OMNARIS Nasal Spray.

*ALVESCO HFA Inhalation Aerosol*

ALVESCO HFA Inhalation Aerosol, an inhaled corticosteroid in an MDI, competes with other asthma therapies, including asthma controller therapies, and faces competition from leukotriene receptor antagonists, inhaled corticosteroid/long-acting beta-agonist combinations, monotherapy long-acting beta-agonists and other monotherapy inhaled corticosteroids. In addition, several of these categories will have generic product entries in the future, which will likely result in competitive products that are less expensive than ALVESCO HFA Inhalation Aerosol. To be successful with ALVESCO HFA Inhalation Aerosol, we must demonstrate to physicians, patients and payors the safety and efficacy benefits of the product, both on a stand-alone basis and, where appropriate, relative to competing products, both generic and branded.

*Competition in Canada*

SPI faces competition from Canadian specialty pharmaceutical companies and large multi-national companies that commercialize competing products. Competition and innovation from these or other sources could potentially have a negative impact on sales of our products marketed in Canada, or make them obsolete. In addition, when seeking to license new products for distribution in Canada, we face competition from companies such as Paladin Labs Inc., Axcan Pharma Inc., Biovail Corporation, and other small-to mid-tier pharmaceutical companies that have the same or similar in-licensing strategies. SPI may also be at a competitive marketing disadvantage against companies that have broader product lines and whose sales personnel are able to offer more complementary products than SPI. In addition, SPI could face competition in the event of commercial introduction of generic versions of one or more of its marketed products.

***We may be unable to successfully commercialize products for which we receive approval from the FDA or similar foreign agencies.***

Commercialization of a product for which we have received an approval letter from the FDA or similar foreign agency could be delayed for a number of reasons, some of which are outside of our control, including delays in delivery of the product due to importation regulations and/or problems with our distribution channels or delays in the issuance of approvals from, or the completion of, required procedures by agencies other than the FDA, such as the United States Drug Enforcement Administration. In addition, commercialization of approved products may be delayed by our failure to timely finalize distribution arrangements, manufacturing processes and arrangements, produce sufficient inventory and/or properly prepare our sales force. If we are unable to successfully commercialize a product promptly after receipt of an approval letter, our business and financial position may be materially adversely affected due to reduced revenues from product sales during the period or periods that commercialization is delayed and the shortening of any lead time to market we may have had over

our competitors. In addition, the exclusivity period, which is the time during which the FDA or similar foreign agency will prevent generic pharmaceutical companies from introducing a generic copy of the product, begins to run upon approval and, therefore, to the extent we are unable to successfully commercialize a product promptly after receipt of an approval letter, our long-term product sales and revenues could be adversely affected.

Even if the FDA or similar foreign agencies grant us regulatory approval of a product, if we fail to comply with the applicable regulatory requirements, we may be forced to suspend and/or cease commercialization of the product due to suspension or withdrawal of regulatory approvals, product recalls, seizures of products and/or operating restrictions and may be subject to fines and criminal prosecution. In any such event, our ability to successfully commercialize the product would be impaired and sales and revenues could be materially adversely affected.

***We sell our products primarily through a direct sales force, and if we are not successful in attracting and retaining qualified sales personnel, we may not be successful in commercializing our products. In addition, our recent decision to significantly reduce the number of our sales positions could impair our ability to maintain or increase sales levels or successfully commercialize new products.***

We have established a sales force to market our products. Our ability to realize significant revenues from direct marketing and sales activities depends on our ability to attract and retain qualified sales personnel. Competition for qualified sales personnel is intense. In January 2009, we decided to reduce the number of our sales force positions, which included the reduction of approximately 350 field-based positions and the elimination of approximately 410 contract sales organization sales representative positions. This sales force reduction could harm our ability to attract and retain qualified sales personnel. Any failure to attract or retain qualified sales personnel could prevent us from successfully commercializing our products, impair our ability to maintain sales levels and/or support potential sales growth and sales of additional products we may commercialize in the future. The recently announced sales force reduction could also result in lack of focus and reduced productivity among our sales personnel and could result in an adverse impact on our revenues. If our sales organization does not devote the time and resources necessary to attain sales projections, we may not be able to achieve anticipated revenues and our financial condition and operating results could be harmed.

We may increase or decrease the size of our sales force in the future based on assumptions that prove inaccurate. For example, such increases may be done in anticipation of approvals and/or expected sales growth that are not realized. Any future expansion of the direct sales force will require us to incur significant expenses. To the extent we expand our direct sales force in anticipation of receiving marketing approval for products under development, commercially introducing newly developed or acquired products and/or expected sales growth, we may again be forced to reduce our sales force if our expectations are not realized. In addition, our recently announced sales force reduction, and any future sales force reduction, may make it more difficult for us to attract the qualified sales people necessary to implement necessary sales force expansion. We may also need to enter into additional co-promotion, contract sales force or other such arrangements with third parties, for example, where our own direct sales force is not large enough or sufficiently well aligned to achieve maximum penetration in the market. We may not be successful in entering into any co-promotion, contract sales force or other such arrangements, and the terms of any co-promotion, contract sales force or other such arrangements may not be favorable to us.

***Our corporate restructuring and workforce reduction plan may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business.***

In January 2009, we announced a corporate restructuring and workforce reduction plan pursuant to which we intend to reduce our workforce by approximately 20%. In addition, we eliminated

approximately 410 contract sales organization sales representative positions. These representatives marketed OMNARIS Nasal Spray, ALVESCO HFA Inhalation Aerosol and our XOPENEX products from September 2008 through January 2009. We are taking these actions in order to reduce costs, streamline operations and improve our cost structure, and we expect that this restructuring plan will result in a significant reduction in operating expenses. The workforce reduction is expected to be substantially completed by the end of the second quarter of 2009.

As a result of the reduction in workforce, we expect to record restructuring charges and make future payments of between $33.0 million and $37.0 million, a substantial portion of which we anticipate will be recorded in the first quarter of 2009. These estimated restructuring charges are based on a number of assumptions. Actual results may differ materially and additional charges not currently expected may be incurred in connection with, or as a result of, these reductions. In addition, we may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to achieve the anticipated benefits, savings or improvements in our cost structure in the expected time frame or other unforeseen events occur, our business and results of operations may be adversely affected.

Our restructuring plan may be disruptive to our operations. For example, cost savings measures may distract management from our core business, harm our reputation, yield unanticipated consequences, such as attrition beyond planned reductions in workforce, or increased difficulties in our day-to-day operations, and may adversely affect employee morale. Our workforce reductions could also harm our ability to attract and retain qualified management, scientific, manufacturing and sales and marketing personnel who are critical to our business. Any failure to attract or retain qualified personnel could prevent us from successfully developing and commercializing our products and product candidates, impair our ability to maintain sales levels and/or support potential sales growth and sales of additional products we may commercialize in the future. Moreover, although we believe it is necessary to reduce the cost of our operations to improve our performance, these initiatives may preclude us from making potentially significant expenditures that could improve our product offerings and competitiveness over the longer term.

***We may not be able to meet the unique operational, legal and financial challenges that we will encounter in our international operations, which may limit the growth of our business.***

Our success will depend in part on our ability to obtain approval for, and market and sell, our products in foreign markets. We undertake these activities both on our own and in conjunction with strategic partners. Expanding sales of our products and operations internationally could impose substantial burdens on our resources, divert management's attention from domestic operations and otherwise adversely affect our business. Furthermore, international operations are subject to several inherent risks including:

- failure of local laws to provide adequate protection against infringement of our intellectual property;
- protectionist laws and business practices that favor local competitors, which could slow or prohibit our growth in international markets;
- difficulties in terminating or modifying business arrangements because of restrictions in markets outside the United States;
- delays in regulatory approval of our products outside of the United States;
- manufacturing, import, export or other similar inspection or regulatory requirements imposed by non-U.S. authorities;

- our ability to avoid the re-importation of our products into the United States at prices that are lower than those maintained by us in the United States;
- currency conversion issues arising from sales denominated in currencies other than the United States dollar;
- foreign currency exchange rate fluctuations;
- longer accounts receivable payment cycles and difficulties in collecting accounts receivable; and
- governmental activities related to pricing for products outside of the United States.

If we are unable to meet and overcome these challenges, our international operations may not be successful, which would limit the growth of our business and could adversely impact our results of operations.

***If we, our collaboration partners or our third-party manufacturers, do not comply with cGMP regulations, then the FDA or other regulatory authorities could refuse to approve marketing applications or force us to recall or withdraw our marketed products.***

The FDA and other regulatory authorities require that our marketed products be manufactured according to their cGMP regulations. The failure by us, our collaborative partners or our third-party manufacturers to comply with cGMP regulations could lead to delay in our development programs or refusal by the FDA or other regulatory authorities to approve marketing applications. Following marketing approval of a product, failure in either respect could also impede commercial introduction or ongoing distribution of the product and/or be the basis for action by the FDA or other regulatory authorities to withdraw approvals previously granted, to recall products and for other regulatory action.

***We could be exposed to significant liability claims that could prevent or interfere with our product commercialization efforts.***

We may be subject to product liability claims that arise through clinical testing, manufacturing, marketing, sale and use of pharmaceutical products. Product liability claims could distract our management and key personnel from our core business, require us to spend significant time and money in litigation or to pay significant damages, which could prevent or interfere with our product commercialization efforts and could adversely affect our business. Claims of this nature could also subject us to product recalls or adversely affect our reputation, which could damage our position in the market. Although we maintain product liability insurance coverage for our clinical trials and products we commercialize, it is possible that we will not be able to obtain further product liability insurance on acceptable terms, if at all, and that our insurance coverage may not provide adequate coverage against all potential claims.

***Buying patterns of our wholesalers may vary from time to time, which could have a material impact on our financial condition, cash flows and results of operations.***

Sales of our products to wholesalers represent a substantial portion of our total sales. Buying patterns of our wholesalers may vary from time to time, in part as a result of pricing, seasonality or stage of a product in its life cycle. Wholesalers, or direct customers of wholesalers, may accumulate inventory in one quarter and limit product purchases in subsequent quarters, which could have a material impact on our financial condition, cash flows and results of operations.

We have entered into wholesaler fee-for-service agreements, or FFSAs, with several of our customers. Under the FFSAs, we pay a fee to maintain certain minimum inventory levels. We believe it is beneficial to enter into FFSAs to establish specified levels of product inventory to be maintained and to obtain more precise information as to the level of our product inventory available throughout the

product distribution channel. We record the cost associated with the FFSAs as revenue deductions. We cannot be certain that the FFSAs will be effective in limiting speculative purchasing activity, that there will not be a future drawdown of inventory as a result of minimum inventory requirements, or otherwise, or that the inventory level data provided through our FFSAs are accurate. If speculative purchasing does occur, if these customers significantly decrease their inventory levels, or if inventory level data provided through FFSAs is inaccurate, our business, financial condition, cash flows and results of operations may also be adversely affected.

**Risks Related to the Regulatory Environment**

***If our product candidates do not receive government approval, we will not be able to commercialize them.***

The FDA and similar foreign agencies must approve for commercialization in the relevant jurisdiction any pharmaceutical products developed by us or our development partners. These agencies impose substantial requirements on drug manufacturing and marketing. Any unanticipated preclinical and clinical studies we or our collaboration development partners are required to undertake, could result in a significant increase in the cost of advancing our products to commercialization. In addition, failure by us or our collaborative development partners to obtain regulatory approval on a timely basis, or at all, or the attempt by us or our collaborative development partners to receive regulatory approval to achieve labeling objectives, could prevent or adversely affect the timing of commercial introduction of, or our ability to market and sell, our products.

***If we fail to successfully develop and receive regulatory approval for product candidates, we will be unable to commercialize the product candidates and future sales and earnings growth will be substantially hampered.***

Our ability to maintain profitability will depend in large part on successful development and commercialization of additional products. Most of our product candidates are in the early stages of development. We cannot assure you that we will be able to develop or acquire and commercially introduce new products in a timely manner or that new products, if developed or acquired, will be approved for the indications and/or with the labeling we expect, or that they will achieve market acceptance. Before we commercialize any other product candidate in the United States, we will need to successfully develop the product candidate by completing successful clinical trials, submitting an NDA for the product candidate that is accepted for filing by the FDA and receiving FDA approval to market the candidate. We must comply with similar requirements in foreign jurisdictions before commercializing any products in the jurisdiction. If we fail to successfully develop a product candidate and/or the FDA or similar foreign agency delays or denies approval of any NDA, or foreign equivalent, that we have submitted or submit in the future, then commercialization of our products under development may be delayed or terminated, which could have a material adverse effect on our business.

A number of problems may arise during the development of our product candidates, including the following:

- results of clinical trials may not be consistent with preclinical study results;
- results from later phases of clinical trials may not be consistent with results from earlier phases;
- results from clinical trials may not demonstrate that the product candidate is safe and efficacious;
- the product candidate may not offer therapeutic or other improvements over comparable drugs;
- we may not receive regulatory approval for our product candidates;
- we may elect not to continue funding the development of our product candidates; or
- funds may not be available to develop all of our product candidates.

Even if the FDA or similar foreign agencies grant us regulatory approval of a product, the approval may take longer than we anticipate and may be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for costly post-marketing follow up studies. Moreover, if we fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

In addition, our growth is dependent on our continued ability to penetrate new markets where we have limited experience and competition is intense. We cannot be certain that the markets we serve will grow in the future, that our existing and new products will meet the requirements of these markets, that our products will achieve customer acceptance in these markets, that competitors or regulators will not force prices to an unacceptably low level or take market share from us, or that we can achieve or maintain profits in these markets.

***Our sales depend on payment and reimbursement from third-party payors, and limitations on coverage availability or a reduction in payment rate or reimbursement could result in decreased use or sales of our products.***

Sales of our products are dependent, in part, on the availability of reimbursement from third-party payors such as Federal, state and foreign government agencies under programs such as Medicare and Medicaid, and private insurance plans. Third-party payors continually attempt to contain or reduce the cost of health care by challenging the prices charged for medical products and services. We may not be able to sell our products profitably if reimbursement is unavailable or coverage is limited in scope or amount.

There have been, there are, and we expect there will continue to be, state and Federal legislative and/or administrative proposals that could limit the amount that state or Federal governments will pay to reimburse the cost of pharmaceutical products. Legislative or administrative acts including, but not limited to, bundling multiple products into the same reimbursement code, imposing least costly alternatives that reference the reimbursement for our products to that of lower priced alternative therapies, conducting comparative effectiveness evaluations, and changing the manner in which reimbursement is calculated for prescription drugs, can reduce reimbursement for our products and could adversely affect our business. In addition, private insurers, such as MCOs, may adopt their own coverage restrictions or demand price concessions in response to legislation or administrative action. Reduction in reimbursement for our products could have a material adverse effect on our results of operations. Also, the increasing emphasis on managed care in the United States may put increasing pressure on the price and usage of our products, which may adversely affect product sales. Further, when a new drug product is approved, governmental and/or private reimbursement for that product is uncertain, as is the amount for which that product will be reimbursed and the extent of coverage for the product. We cannot predict future availability or amount of reimbursement for our approved products or product candidates and current reimbursement policies for our marketed products may change at any time.

The MMA established a prescription drug benefit beginning in 2006 for all Medicare beneficiaries. We do not know the extent to which our marketed products that are included in the Medicare prescription drug benefit will continue to be included, and we may be required to provide significant discounts or rebates to drug plans participating in the Medicare drug benefit. Moreover, Congress may enact legislation that permits the Federal government to directly negotiate price and demand discounts on pharmaceutical products that may implicitly create price controls on prescription drugs. In addition, MCOs, Health Maintenance Organizations, or HMOs, Preferred Provider Organizations, or PPOs, health care institutions and other government agencies continue to seek price discounts. MCOs, HMOs, PPOs and private health plans administer the Medicare drug benefit, leading to managed care and private health plans influencing prescription decisions for a larger segment of the population. In

addition, certain states have proposed, and certain other states have adopted, various programs to control prices for their seniors' and low-income drug programs, including price or patient reimbursement constraints, restrictions on access to certain products, importation from other countries, such as Canada, and bulk purchasing of drugs.

As we enter into agreements to license our products for commercialization outside of the United States, we may be subject to pricing decisions made by regulatory bodies and private insurers around the world. Such pricing decisions may affect royalty rates and payments made to us under those agreements, or decisions whether or not to commercialize our products in the applicable jurisdiction. Efforts to obtain pricing decisions are often the responsibility of our third-party licensees, and we cannot predict the success of any third-party in obtaining desirable pricing, or how the actions of such third-party or any regulatory body or private insurer will affect the ultimate commercial benefits of those transactions.

If reimbursement for our marketed products changes adversely or if we fail to obtain adequate reimbursement for our other current or future products, health care providers may limit how much or under what circumstances they will prescribe or administer them, which could reduce use of our products or cause us to reduce the price of our products.

***We will spend considerable time and money complying with Federal, state and foreign laws and regulations and, if we are unable to fully comply with such laws and regulations, we could face substantial penalties.***

We are subject to extensive regulation by Federal, state and foreign governments. The laws that directly or indirectly affect our business include, but are not limited to, the following:

- Federal Medicare and Medicaid Anti-Kickback laws, which prohibit persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either referral of an individual, or furnishing or arranging for a good or service, for which payment may be made under Federal health care programs such as the Medicare and Medicaid programs;
- other Medicare and Medicaid laws and regulations that establish requirements for coverage and payment for marketing our products, including the amount of such payments;
- the Federal False Claims Act, which imposes civil and criminal liability on individuals and entities who submit, or cause to be submitted, false or fraudulent claims for payment to the government;
- the Federal Health Insurance Portability and Accountability Act of 1996, which prohibits executing a scheme to defraud any health care benefit program, including private payors and, further, requires us to comply with standards regarding privacy and security of individually identifiable health information and conduct certain electronic transactions using standardized code sets;
- the Federal False Statements Statute, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of, or payment for, health care benefits, items or services;
- the Federal Food, Drug and Cosmetic Act, which regulates manufacturing, labeling, marketing, distribution and sale of prescription drugs and medical devices;
- the Hatch-Waxman Act, and amendments thereto, including the MMA, which regulate pharmaceutical patent litigation;
- the Controlled Substances Act, which regulates handling of controlled substances such as LUNESTA;

- the Prescription Drug User Fee Act, which governs the filing of applications for marketing approval of new prescription drug products;
- the FDA Amendments Act of 2007;
- the Deficit Reduction Act of 2005;
- state and foreign law equivalents of the foregoing; and
- state food and drug laws, pharmacy acts and state pharmacy board regulations, which govern the sale, distribution, use, administration and prescribing of prescription drugs.

If our past, present or future operations are found to be in violation of any of the laws described above or other governmental regulations to which we or our customers are subject, we may be subject to the applicable penalty associated with the violation, including civil and criminal penalties, damages, fines, exclusion from Medicare and Medicaid programs and curtailment or restructuring of our operations. Similarly, if our customers are found non-compliant with applicable laws, they may be subject to sanctions, which could also have a negative impact on us. In addition, if we are required to obtain permits or licenses under these laws that we do not already possess, we may become subject to substantial additional regulation or incur significant expense. Any penalties, damages, fines, exclusion from Medicare and Medicaid programs or curtailment or restructuring of our operations would adversely affect our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from operating our business and damage our reputation.

Federal and state government agencies also continue to promote efforts to reduce health care costs, including those associated with the Medicare and Medicaid programs. These efforts may include supplemental rebates and restrictions on the amounts that agencies will reimburse for the use of products. In addition, both the Federal and state governments have initiated investigations and lawsuits concerning the Medicaid price reporting practices of many pharmaceutical companies to ensure compliance with the Medicaid rebate program. For example, in November 2008, along with approximately 15 other pharmaceutical companies, we were sued by the State of Kansas in state court for allegedly inducing fraudulent payments for our products by Kansas Medicaid through our alleged manipulation of the average wholesale prices for our products. We have joined other branded product defendants in filing a motion to dismiss this cause of action and we expect the court to decide on this motion in March 2009. No trial date has been set and no answer has been filed by us pending the state court's action on the motion to dismiss. While we are prepared to defend against these allegations, it is too early to make a reasonable assessment as to the likely outcome of this litigation. We could be subject to damages and penalties as a consequence of this lawsuit, if we are found liable.

***The approval of the sale of certain medications without a prescription may adversely affect our business.***

In May 2001, an advisory panel to the FDA recommended that the FDA allow certain popular allergy medications to be sold without a prescription. In November 2002 and November 2007, the FDA approved CLARITIN® and ZYRTEC®, respectively, both allergy medications, to be sold without a prescription. In the future, the FDA may allow the sale of additional allergy medications without a prescription. The sale of CLARITIN, ZYRTEC and/or, if allowed, other allergy medications without a prescription, may have a material adverse effect on our business because the market for prescription drugs, including CLARINEX and XYZAL/XUSAL for which we receive royalties on sales, has been and may continue to be, adversely affected.

***We provided PHS discounts to entities we have determined are ineligible for such pricing in periods prior to 2008. This circumstance creates uncertainty as to whether a new Medicaid best price was set in prior periods. If a new best price was set, we will be required to pay additional Medicaid rebates. In addition, we may face an increased risk of investigation or litigation concerning our Medicaid price reporting or other price reporting obligations.***

Under the Medicaid rebate program, we are obligated to pay a rebate to each participating state Medicaid program for each unit of our product reimbursed by that program. The amount of the rebate for each product is set by law as the greater of (a) 15.1% of AMP or (b) the difference between AMP and the Medicaid best price, which is the lowest price available from us to any customer not excluded by law from that determination. The rules related to determining AMP and best price are complicated. We compute best price and the required rebate payments each quarter based on our knowledge of the statutory requirements, the current CMS guidance and our understanding of which customers are properly excluded from best price consideration.

In January 2008, we notified CMS that we had identified potential errors in our determination of the best price used to calculate Medicaid rebate amounts in prior periods. As a result of these potential errors, in the first quarter of 2008 we reduced and restated revenues for periods prior to 2008 for contingent rebates based on management's best estimates and assumptions made prior to any concurrence by CMS. We have been in regular contact with CMS regarding our process for addressing these potential errors. We have begun applying the processes and procedures resulting from our remediation efforts to our historical price reporting submissions and we plan to communicate the final results of our review in 2009 to CMS and, as necessary, the Health Resources and Services Administration and state Medicaid programs. The extent to which we reduced our revenues in prior periods due to contingent rebates may change as a result of our continued review and future communications with CMS, and we are uncertain whether we have overestimated the amount of additional rebates we may be required to pay, or whether we will be subject to fines, penalties or interest.

Both the federal government and state governments have initiated investigations and lawsuits concerning the Medicaid price reporting practices of many pharmaceutical companies to ensure compliance with the requirements of the Medicaid rebate program legislation. As a result of the errors that we identified in our calculation of Medicaid rebate reserve amounts, we may face an increased risk of a government investigation or lawsuits concerning our Medicaid or other price reporting. If any such investigation or lawsuit is initiated, we may be required to pay additional rebates or other amounts related to sales made in prior periods, and we may be subject to fines, penalties or interest. In addition, an investigation or lawsuit concerning our Medicaid price reporting could be costly, could divert the attention of our management from our core business and could damage our reputation.

***If our drugs are not included on state Preferred Drug Lists, use of our drugs may be negatively affected.***

Several state Medicaid programs have implemented PDLs and more states may adopt this practice. Products placed on a state Medicaid program's PDL are not subject to restrictions on their utilization by Medicaid patients, such as the need to obtain authorization prior to prescribing. If our drugs are not included on Medicaid PDLs, use of our drugs in the Medicaid program may be adversely affected. In some states that have adopted PDLs, we have been, and may continue to be, required to provide substantial supplemental rebates to state Medicaid authorities in order for our drugs to be included on the PDL.

***Failure to comply with existing and future environmental, safety and health laws and regulations could adversely affect our results of operations and financial condition.***

We are subject to numerous environmental, safety and health laws and regulations. These laws and regulations govern, among other things, the generation, use and storage of hazardous materials as well

as the health and safety of our employees. Our operations can involve the handling of hazardous and other highly regulated materials which, if not properly handled or disposed of, could subject us to civil and criminal liabilities under these laws and regulations. We may have not been, and we may not at all times in the future be, in compliance with such environmental, safety and health laws and regulations.

The costs of complying with existing and future environmental, safety and health laws and regulations may be significant. In addition to these costs, the costs and expenses associated with any future claims for personal injury or the clean-up of hazardous materials could adversely affect our results of operations and financial condition.

**Risks Related to Our Intellectual Property**

***If we or our collaboration partners fail to adequately protect or enforce our respective intellectual property rights, then we could lose revenue under our licensing agreements or lose sales to generic equivalents of our marketed products.***

Our success depends in large part on our ability, and the ability of our collaboration partners, to obtain, maintain and successfully enforce patents, and protect trade secrets. Our ability to commercialize any drug successfully will largely depend upon our ability, and the ability of our collaboration partners, to obtain and maintain patents, including successful enforcement of those patents, of sufficient scope to prevent third parties from developing the same or substantially equivalent products. Our revenues under collaboration agreements with pharmaceutical companies also depend in part on the existence and scope of issued patents. In the absence of patent and trade secret protection, competitors may adversely affect our business by independently developing and marketing the same or substantially equivalent products. It is also possible that we could incur substantial costs if we are required to initiate litigation against others to protect or enforce our intellectual property rights.

We have filed patent applications covering composition of, methods of making, and/or methods of using, our products and product candidates. We may not be issued patents based on patent applications already filed or that we file in the future and if patents are issued, they may be insufficient in scope to cover the products licensed under these collaboration agreements. Generally, we do not receive royalty revenues from sales of products licensed under collaboration agreements in countries where we do not have a patent for such products. The issuance of a patent in one country does not ensure the issuance of a patent in any other country. Furthermore, the patent position of companies in the pharmaceutical industry generally involves complex legal and factual questions, and has been, and remains the subject of, much litigation. Legal standards relating to scope and validity of patent claims are evolving. Any patents we have obtained, or obtain in the future, may be challenged, invalidated or circumvented. Moreover, the United States Patent and Trademark Office may commence interference proceedings involving our patents or patent applications. Any challenge to, or invalidation or circumvention of, our patents or patent applications would be costly, would require significant time and attention of our management and could have a material adverse effect on our business. In addition, if we are not successful in obtaining patents of sufficient scope and enforcing our patents, we will not be able to prevent others from introducing generic versions of our products.

***If we or our licensees do not prevail against those parties seeking to market generic versions of our products or products for which we receive royalties, our business will be adversely affected and we may not have sufficient revenues to achieve our business plan or repay our outstanding debt.***

With respect to XOPENEX Inhalation Solution, Breath, Dey, L.P., Barr, Teva, Watson and Apotex, have filed ANDAs including Paragraph IV certifications with the FDA seeking to market a generic version of levalbuterol hydrochloride inhalation solution before our patents expire. We brought an action against Breath for patent infringement, and in April 2008 we settled this matter and the litigation is now concluded. However, patent infringement litigation remains outstanding against

Dey, L.P. and Barr. Our settlement with Breath and on going litigation with Dey, L.P. and Barr are described in detail in Part I, Item 3 "Legal Proceedings" of this Annual Report on Form 10-K. We have decided not to commence litigation against Watson, Teva and Apotex as their respective Paragraph IV certifications are limited to a single patent that expires in 2021.

In May 2008, we provided to the Federal Trade Commission and Department of Justice Antitrust Division the notifications of the settlement with Breath as required under Section 1112(a) of the MMA. The settlement with Breath and the other agreements with Breath and its affiliates, including the supply agreement, the agreement for the acquisition of Oryx and license agreements with Arrow, may be reviewed by antitrust enforcement agencies, such as the Federal Trade Commission and Department of Justice Antitrust Division. There can be no assurances that governmental authorities will not seek to challenge the settlement with Breath or that a competitor, customer or other third-party will not initiate a private action under antitrust or other laws challenging the settlement with Breath. We may not prevail in any such challenges or litigation and, in any event, may incur significant costs in the event of an investigation or in defending any action under antitrust laws.

Beginning February 9, 2009, we received notices from Teva, Cobalt Laboratories, Dr. Reddy's, Orchid, Glenmark Generics, Roxane, Lupin, Wockhardt and Sun Global, that each has filed an ANDA with the FDA for generic versions of eszopiclone tablets (1 mg, 2 mg and 3 mg). Each submission includes a Paragraph IV certification alleging that one or more of our patents listed in the Orange Book for LUNESTA is invalid, unenforceable or not infringed by their respective proposed generic products. We anticipate receipt of additional notices that other ANDAs with Paragraph IV certifications have been filed by different generic pharmaceutical companies. We are currently contemplating commencing civil actions against these parties for patent infringement and will consider commencing patent infringement litigation against any other company that files an ANDA that includes a Paragraph IV certification with respect to eszopiclone.

Certain of Schering-Plough's CLARINEX products for which we receive sales royalties are currently the subject of patent infringement litigation. Since June 2007, the FDA has received ANDAs relating to various dosage forms of CLARINEX from eleven different generic pharmaceutical companies. These ANDA submissions include Paragraph IV certifications alleging that our patents, which Schering-Plough (as exclusive licensee of such patents) listed in the Orange Book for these products, are invalid, unenforceable and/or not infringed by the submitter's proposed product. We and the University of Massachusetts, co-owners of certain patents listed in the Orange Book, filed civil actions against these parties for patent infringement in the United States District Court for the District of New Jersey. In April 2008, the trial judge consolidated these cases for all purposes including discovery and trial. The court has not set a trial date. We believe that all of these ANDAs are subject to a statutory stay of approval until at least December 21, 2009 based on previous litigation commenced by Schering-Plough against these parties in separate civil actions involving another patent.

We entered into a consent agreement with one of these ANDA filers whereby the ANDA filer agreed not to pursue its case or market its CLARINEX product until the expiration of our patents listed by Schering-Plough in the Orange Book or until our patents for the product are found invalid or unenforceable. In addition, as a result of separate formal settlement agreements that Schering-Plough entered into with several ANDA filers involved in litigation with Schering-Plough, or Schering-Plough Settlement Agreements, we and the University of Massachusetts submitted, and the court approved, stipulations of dismissal without prejudice against five of the ANDA filers that we sued. In addition, we and the University of Massachusetts, submitted one additional stipulation of dismissal without prejudice that is awaiting approval by the court and have actions remaining against four additional ANDA filers. The Schering-Plough Settlement Agreements entered to date permit generic entry of CLARINEX-D®-12 Hour, CLARINEX-D® – 24 Hour and CLARINEX® REDITABS® on January 1, 2012 and CLARINEX® 5 mg tablet on July 1, 2012. Upon generic entry of each product by a party to

a Schering-Plough Settlement Agreement, our right to receive royalties on sales of such product will be significantly reduced.

UCB S.A.'s XYZAL 5 mg product, for which we receive royalties, is currently the subject of patent infringement litigation. The FDA has received ANDAs from four generic pharmaceutical companies that include Paragraph IV certifications alleging that one of our patents, which UCB S.A. (as NDA holder and licensee of the patent) listed in the Orange Book for this product, is invalid and/or not infringed by the ANDA filer's product. UCB S.A., on its own and on our behalf, commenced patent infringement litigation against all of these parties. We believe that these ANDAs are subject to a statutory stay of approval until at least on or about August 29, 2010.

In addition, a number of our foreign patents that we have out-licensed to Schering-Plough, sanofi-aventis and the UCB Farchim S.A. in connection with the sale of CLARINEX, ALLEGRA and XYZAL/XUSAL, respectively, are subject to patent invalidity claims. If patent-based exclusivity is lost for one or more of these products in any foreign jurisdiction, our rights to receive royalty revenue with respect to such product in the relevant jurisdiction will terminate, which may have a material adverse effect on our business, financial condition and results of operations. Should the courts uphold our foreign patents, companies seeking to market generic versions of our drugs and the drugs of our licensees should be deterred from market entry until the expiration of the applicable patent(s).

Patent litigation involves complex legal and factual questions. We can provide no assurance concerning the duration or outcome of any patent-related lawsuits. If we, third parties from whom we receive royalties, or third parties from whom we have licensed products or received other rights to commercialize products, are not successful in enforcing relevant patents, the companies seeking to market generic versions of our marketed drugs and the drugs of our licensees will not be excluded, for the full term of our patents, from marketing their generic versions of our marketed products or third-party products for which we have licensed rights to our patents. Introduction of generic equivalents of any of our marketed products or third-party products for which we have licensed rights to our patents before the expiration of our patents would have a material adverse effect on our business.

Additionally, the costs to us of these proceedings, even if resolved in our favor, could be substantial. Such litigation could also substantially divert the attention of our management and other key personnel from our core business and our resources in general. Uncertainties resulting from the initiation and continuation of these and any other litigation proceedings could harm our ability to compete in the marketplace.

***If we face a claim of intellectual property infringement by a third party, we could be liable for significant damages or be prevented from commercializing our products.***

Our success depends in part on our ability to operate without infringing the proprietary rights of others, including patent and trademark rights. Third parties, typically pharmaceutical companies, may hold patents or patent applications covering compositions, methods of making and uses, covering the composition of matter for some of our drug candidates. Third parties may also hold patents relating to drug delivery technology that may be necessary for development or commercialization of some of our drug candidates. In each of these cases, unless we have or obtain a license agreement, or unless we are able to prove that the third party's patents are invalid or unenforceable, we generally may not commercialize the drug candidates until these third-party patents expire or are declared invalid or unenforceable by the courts. Licenses may not be available to us on acceptable terms, if at all.

Others may file suit against us alleging that our marketed products or product candidates infringe patents they hold. Even if resolved in our favor, any patent infringement litigation would be costly, would require significant time and attention of our management, could prevent us from commercializing our marketed products for a period of time, could require us to pay significant damages and could have a material adverse effect on our business. If the matter is not resolved in our favor, we could be required to pay significant damages and/or be prevented from commercializing the product and our business could be materially adversely affected. In April 2007, we were served with a Complaint filed by Dey, alleging that the manufacture and sale of BROVANA infringes or will induce infringement of a single United States patent for which Dey owns all rights, title and interest. In April 2007, we filed an Answer and Counterclaims to this Complaint seeking to invalidate the originally asserted patent and a second related patent. In May 2007, Dey filed a reply asserting infringement of the second patent. In March 2008, United States Patent 7,348,362 entitled "Bronchodilation b-agonist compositions and Methods" issued and Dey, L.P. is the assignee of the patent. In August 2008, the court granted our Motion to Amend our Answer and Counterclaims to seek declaratory judgment that the '362 patent is invalid and unenforceable and to add Mylan Inc., Dey's parent corporation, as a party. Between December 2008 and January 2009, U.S. patents 7,462,645; 7,465,756; and 7,473,710 all entitled "Bronchodilation b-agonist compositions and Methods" issued. These three patents claim priority to the same parent patent application that issued as the '362 patent. In January 2009, Dey filed a motion to add these three patents to the case, which we did not oppose.

Under the current trial scheduling order, the trial will begin no earlier than October 2, 2009. It is too early to make a reasonable assessment as to the likely outcome or impact of this litigation. We are unable to reasonably estimate any possible range of loss or liability related to this lawsuit due to its uncertain resolution.

If any of our trademarks or the trademarks we license from our third-party collaborators, or our use of any of these trademarks in connection with products we commercialize, is challenged, we or our third-party collaborators may be forced to rename the affected product or product candidate, which could be costly and time consuming, and would result in the loss of any brand equity associated with the product name.

**Risks Related to Our Dependence on Third Parties**

***If any third-party collaborator is not successful in development or commercialization of our products and product candidates, we may not realize the potential commercial benefits of the arrangement and our results of operations could be adversely affected.***

We have entered into a collaboration agreement with 3M for the manufacturing of XOPENEX HFA. Under this agreement, we license certain proprietary technology from 3M, and it is responsible for manufacturing the MDI formulation of XOPENEX. We have also entered into agreements with Eisai and GSK for development and commercialization of our eszopiclone product, marketed as LUNESTA in the United States. Under the Eisai agreement, Eisai will be responsible for completing remaining clinical trials necessary for obtaining marketing approval from the Japanese regulatory authorities and, contingent on regulatory approval, commercialization of the product in Japan. Under the GSK agreement, GSK is responsible for the development and commercialization of the product for all markets worldwide, excluding the United States, Canada, Mexico and Japan. In addition, we have entered into a license agreement with Bial for the development and commercialization in the United States and Canada of STEDESA. Under this agreement, Bial is responsible for certain development activities and prosecuting all patents and patent applications it licensed to us. We have also entered into a distribution and development agreement with Nycomed for the development, commercialization and distribution in the United States, its territories and possessions of Nycomed's ciclesonide compound, and certain products incorporating such compound, including ALVESCO HFA Inhalation Aerosol and OMNARIS Nasal Spray. Under this agreement, Nycomed is responsible for prosecuting all

patents and patent applications with respect to these products. Most recently, we entered into two license and development agreements with Arrow for the development and commercialization of Arrow's Levalbuterol/ipratropium Product candidate and for the development and commercialization of a ciclesonide standalone product and a ciclesonide/arformoterol combination product utilizing Arrow's know-how and intellectual property rights related to stable sterile suspension formulations and other technology.

If 3M, Eisai, GSK, Bial, Nycomed, Arrow or any future development or commercialization collaborator does not devote sufficient time and resources to its collaboration arrangement with us, breaches or terminates its agreement with us, fails to perform its obligations to us in a timely manner, is unsuccessful in its development and/or commercialization efforts, or is unsuccessful in obtaining, maintaining or enforcing patents, and/or protecting trade secrets we license to or from such collaborator, we may not realize the potential commercial benefits of the arrangement and our results of operations may be adversely affected. In addition, if regulatory approval or commercialization of any product candidate under development by, or in collaboration with, a partner is delayed or limited, we may not realize, or may be delayed in realizing, the potential commercial benefits of the arrangement. For example, in October 2008, the CHMP of the EMEA issued an opinion recommending the EC grant a marketing authorization for LUNIVIA brand eszopiclone in the EU for the treatment of insomnia; however, the opinion did not include a new active substance designation, which we believe would enable more favorable commercialization of the product in the EU. In February 2009, the CHMP re-confirmed its initial opinion recommending LUNIVIA marketing approval in Europe, but without new active substance status. We intend to continue to pursue with the EC the circumstances surrounding LUNIVIA and our marketing application, and we anticipate the EC will be making a final decision in the near future.

***The royalties and other payments we receive under licensing arrangements could be delayed, reduced or terminated if our licensing partners terminate, or fail to perform their obligations under, their agreements with us, or if our licensing partners are unsuccessful in their sales efforts.***

We have entered into licensing arrangements pursuant to which we license patents to pharmaceutical companies and our revenues under these licensing arrangements consist primarily of milestone payments, royalties on sales of products and supply payments. Payments and royalties under these arrangements depend in large part on the efforts of our licensing partners in countries where we hold patents, including development and sales efforts and enforcement of patents, which we cannot control. If any of our licensing partners does not devote sufficient time and resources to its licensing arrangement with us or focuses its efforts in countries where we do not hold patents, we may not realize the potential commercial benefits of the arrangement, our revenues under these arrangements may be less than anticipated and our results of operations may be adversely affected. If any of our licensing partners was to breach or terminate its agreement with us or fail to perform its obligations to us in a timely manner, the royalties and other payments we receive under the licensing agreement could decrease or cease. If we are unable or fail to perform, or are in breach of our obligations under a licensing agreement, the royalties and other payments and benefits to which we are otherwise entitled under the agreement could be reduced or eliminated. Any delay or termination of this type could have a material adverse effect on our financial condition and results of operations because we may lose technology rights and milestone, royalty or supply payments from licensing partners and/or revenues from product sales, if any, could be delayed, reduced or terminated.

***We rely on third-party manufacturers, and this reliance could adversely affect our ability to meet our customers' demands.***

We currently operate a manufacturing plant that we believe can meet our commercial requirements of the API for XOPENEX Inhalation Solution, XOPENEX HFA and BROVANA,

partially fulfill our commercial requirements of the API for LUNESTA, and support production of our internally developed product candidates in amounts needed for our clinical trials. However, we do not have facilities for manufacturing pharmaceutical dosage forms or finished drug products. Developing and obtaining this capability would be time consuming and expensive. Unless and until we develop this capability, we will rely substantially, and in some cases, entirely, on third-party manufacturers. Catalent and Holopack are currently our only finished goods manufacturers of our XOPENEX Inhalation Solution, and Catalent is currently the sole finished goods manufacturer of BROVANA. Patheon is the sole manufacturer of LUNESTA, although we plan to enter into an agreement with a second manufacturer of LUNESTA during the first half of 2009, and 3M is the sole manufacturer and supplier of XOPENEX HFA. Certain components of XOPENEX HFA are available from only a single source. If Catalent, Holopack, Patheon, 3M, or any of our sole-source component suppliers experiences delays or difficulties in producing, packaging or delivering XOPENEX Inhalation Solution, XOPENEX HFA or its components, BROVANA or LUNESTA, as the case may be, we could be unable to meet our customers' demands for such products, which could lead to lost sales, customer dissatisfaction and damage to our reputation. Moreover, if we experience delays or difficulties meeting our supply obligations to GSK and Eisai as a result of our third-party suppliers and manufacturers not meeting our demands, or for any other reason, we may not realize the potential commercial benefits of our supply and/or licensing arrangements with these parties and our results of operations may be adversely affected. If we are required to change manufacturers, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines, including FDA guidelines. The delays associated with the verification of a new manufacturer for XOPENEX Inhalation Solution, XOPENEX HFA or its components, BROVANA or LUNESTA could adversely affect our ability to produce such products in a timely manner or within budget.

Pursuant to our distribution, development and commercialization agreement with Nycomed, Nycomed will be responsible for exclusively manufacturing and supplying us with our requirements of ALVESCO HFA Inhalation Aerosol and OMNARIS Nasal Spray. Furthermore, in the event that we develop and commercialize any additional products containing the ciclesonide compound, including OMNARIS HFA Nasal Spray, we will rely on Nycomed and/or other third parties for the manufacture and supply of such products. If the manufacturer of a ciclesonide product experiences delays or difficulties in producing, packaging or delivering such product, we could be unable to meet our customers' demands for the product, which could lead to lost sales, customer dissatisfaction and damage to our reputation.

We license certain proprietary technology required to manufacture our XOPENEX HFA from 3M. If 3M is unable or unwilling to fulfill its obligations to us under our agreement, we may be unable to manufacture XOPENEX HFA on terms that are acceptable to us, if at all. Our other current contract manufacturers, as well as any future contract manufacturers, may also independently own technology related to manufacturing of our products. If so, we would be heavily dependent on such manufacturer and such manufacturer could require us to obtain a license in order to have another party manufacture our products.

**Risks Related to Growth of Our Business**

***If we fail to acquire and develop additional product candidates or approved products, our ability to grow will be impaired.***

We are currently commercializing six products. In addition, OMNARIS HFA Nasal Spray is in Phase III clinical development and we plan to file an NDA for STEDESA in the first half of 2009. However, all of our other product candidates are in the early stages of development. In order to increase the likelihood that we will be able to successfully develop and/or commercialize additional drugs, we intend to acquire and develop additional product candidates and/or approved products. The

success of this growth strategy depends upon our ability to correctly establish criteria for such acquisitions and successfully identify, select and acquire product candidates and/or products that meet such criteria. We will be required to integrate any acquired product candidates, including the product candidates we licensed from Bial and Arrow and product candidates we are developing pursuant to our agreement with Nycomed, into our research and development operations and any acquired products, including ALVESCO HFA Inhalation Aerosol and OMNARIS Nasal Spray, into our sales and marketing operations. Managing the development and/or commercialization of a new product involves numerous other financial and operational risks, including difficulties allocating resources between existing and acquired assets and attracting and retaining qualified employees to develop and/or sell the product.

Any product candidate we acquire may require additional research and development efforts prior to commercial sale, including extensive preclinical and/or clinical testing and approval by the FDA or foreign regulatory authorities. All product candidates are prone to the risks of failure inherent in pharmaceutical product development, including the possibility that the product candidate will not be safe and effective or approved by regulatory authorities.

In addition, we cannot be certain that any products that we develop or acquire will be:

- manufactured or produced economically;
- successfully commercialized or reimbursed at rates sufficient for us to achieve or maintain profitability with respect to such products;
- complementary to our existing product portfolio; or
- widely accepted in the marketplace.

Proposing, negotiating and implementing an economically viable acquisition is a lengthy and complex process. Other companies, including those with substantially greater financial, marketing and sales resources, may compete with us for the acquisition of product candidates and approved products. We may not be able to acquire the rights to additional product candidates and approved products on terms that we find acceptable, or at all.

***We may undertake strategic acquisitions in the future and any difficulties from integrating acquired businesses, products and product candidates could adversely affect our stock price, business operations, financial condition or results from operations.***

We may acquire additional businesses, products or product candidates that complement or augment our existing business. We have limited acquisition experience and may not be able to integrate any acquired business, product or product candidate successfully or operate any acquired business profitably. Integrating any newly acquired business, product or product candidate could be expensive and time-consuming. Integration efforts often place a significant strain on managerial, operational and financial resources and could prove to be more difficult or expensive than we predict. The diversion of our management's attention and any delay or difficulties encountered in connection with any future acquisitions we may consummate could result in the disruption of our ongoing business or inconsistencies in standards, controls, procedures and policies that could adversely affect our ability to maintain relationships with customers, suppliers, collaborators, employees and others with whom we have business dealings. Moreover, we may need to raise additional funds through public or private debt or equity financing to acquire any businesses, products or product candidates, which may result in dilution for stockholders or the incurrence of indebtedness.

As part of our efforts to acquire businesses, products and product candidates or to enter into other significant transactions, we conduct business, legal and financial due diligence with the goal of identifying and evaluating material risks involved in the transaction. Despite our efforts, we ultimately

may be unsuccessful in ascertaining or evaluating all such risks and, as a result, might not realize the intended advantages of the transaction. If we fail to realize the expected benefits from acquisitions we have consummated or may consummate in the future, whether as a result of unidentified risks, integration difficulties, regulatory setbacks or other events, our business, results of operations and financial condition could be adversely affected. We will also need to make certain assumptions regarding acquired product candidates, including, among other things, development costs, the likelihood of receiving regulatory approval and the market for such product candidates. Our assumptions may prove to be incorrect, which could cause us to fail to realize the anticipated benefits of these transactions.

In addition, we will likely experience significant charges to earnings in connection with our efforts, if any, to consummate acquisitions. These charges may include fees and expenses for investment bankers, attorneys, accountants and other advisers in connection with our efforts, and may be incurred whether or not an acquisition is consummated. Even if our efforts are successful, we may incur as part of a transaction substantial charges for closure costs associated with elimination of duplicate operations and facilities and acquired IPR&D charges. In either case, the incurrence of these charges could adversely affect our results of operations for particular quarterly or annual periods.

***Development and commercialization of our product candidates could be delayed or terminated if we are unable to enter into collaboration agreements in the future or if any future collaboration agreement is subject to lengthy government review.***

Development and commercialization of some of our product candidates may depend on our ability to enter into additional collaboration agreements with pharmaceutical companies to fund all or part of the costs of development and commercialization of these product candidates. We may not be able to enter into collaboration agreements and the terms of the collaboration agreements, if any, may not be favorable to us. Inability to enter into collaboration agreements could delay or preclude development, manufacture and/or commercialization of some of our drugs and could have a material adverse effect on our financial condition and results of operations because:

- we may be required to expend additional funds to advance the drugs to commercialization;
- revenue from product sales could be delayed; or
- we may elect not to commercialize the drugs.

We are required to file a notice under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, or the HSR Act, for certain agreements containing exclusive license grants and to delay the effectiveness of any such exclusive license until expiration or earlier termination of the notice and waiting period under the HSR Act. If expiration or termination of the notice and waiting period under the HSR Act is delayed because of lengthy government review, or if the Federal Trade Commission or Department of Justice successfully challenges such a license, development and commercialization could be delayed or precluded and our business could be adversely affected.

**Item 1B. Unresolved Staff Comments.**

None.

**Item 2. Properties.**

Our main facility at 84 Waterford Drive, Marlborough, Massachusetts, consists of approximately 58 acres and a 192,600 square foot research and development and corporate office building, which we purchased in November 2002. In November 2007, we entered into an agreement with a commercial builder for the construction of a 143,000 square foot building to be used by us as additional office space. We anticipate construction of this building will be completed in the first quarter of 2009.

We lease space in three additional facilities in Marlborough, Massachusetts. We lease 57,477 square feet of office and laboratory space at 33 Locke Drive. This is comprised of two leases, one of which is 25,000 square feet and will expire in April 2009 and will not be renewed, and the other of which is 32,477 and will expire in June 2012. We lease 68,815 square feet of office space at 111 Locke Drive under a lease that will expire in June 2012. The 111 Locke Drive facility serves as our regional sales office for the northeast region, a sales training facility and additional office space. In 2008, we entered into a lease for an additional 14,211 square feet at 100 Locke Drive to accommodate our needs until our new building at Waterford Drive is complete, which will expire in April 2009 and not be renewed.

Our primary manufacturing location is a cGMP-compliant 50,000 square-foot fine chemical manufacturing facility located on a four-acre site in Windsor, Nova Scotia, Canada, which we acquired in March 1994. Production at the Nova Scotia facility began in February 1995. In 2008, we entered into a lease for 8,764 square feet of office space in Mississagua, Canada, to serve as SPI's corporate headquarters, which will expire in November 2013.

## Item 3. Legal Proceedings.

***Litigation Related to Generic Competition and Patent Infringement***

Patent litigation involves complex legal and factual questions. We can provide no assurance concerning the duration or outcome of any patent-related lawsuits. If we, third parties from whom we receive royalties, or third parties from whom we have licensed products or received other rights to commercialize products, are not successful in enforcing our respective patents, the companies seeking to market generic versions of our marketed drugs and the drugs of our licensees will not be excluded, for the full term of the respective patents, from marketing their generic versions of our marketed products or third-party products for which we have licensed rights to our patents. Introduction of generic equivalents of any of our marketed products or third-party products for which we have licensed rights to our patents before the expiration of our or our collaborators' patents would have a material adverse effect on our business, financial condition and results of operations.

**Levalbuterol Hydrochloride Inhalation Solution Abbreviated New Drug Applications**

In September 2005, we received notification that the FDA had received an ANDA from Breath, seeking approval of a generic version of our 1.25 mg/3 mL, 0.63 mg/3 mL and 0.31 mg/3 mL XOPENEX Inhalation Solution. Breath's submission includes a Paragraph IV certification alleging that our patents listed in the Orange Book for these three dosages of XOPENEX Inhalation Solution are invalid, unenforceable or not infringed by the generic version for which Breath sought approval. In October 2005, we filed a civil action against Breath for patent infringement in the United States District Court for the District of Massachusetts, No. 1:06-CV-10043.

In April 2008, we entered into a settlement and license agreement with Breath to resolve this litigation. The agreement permits Breath to sell its generic versions of these XOPENEX Inhalation Solution products in the United States under the terms of an exclusive 180-day license commencing on August 20, 2012 and a non-exclusive license thereafter. Upon launch, Breath will pay us a double-digit royalty on gross profits generated from the sales of generic versions of these XOPENEX Inhalation Solution products. Under the agreement, Breath agrees not to sell any of the products covered by our patents that are the subject of the license before the date on which the license commences. On May 1, 2008, the parties submitted to the court an agreed order of dismissal without prejudice, which the court approved. The litigation is now concluded.

In connection with the settlement and license agreement with Breath, in April 2008 we also entered into a supply agreement with Breath whereby, effective August 20, 2012, we will exclusively supply levalbuterol products (1.25 mg/3 mL, 0.63 mg/3 mL and 0.31 mg/3 mL) to Breath, under our

NDA for a period of 180 days, which we refer to as the Initial Term, and on a non-exclusive basis for two and one-half years thereafter. In addition to the royalties described above, Breath will pay us on a cost plus margin basis for supply of these levalbuterol products. The supply agreement contains provisions regarding termination for cause and convenience, including either party's right to terminate the agreement at any time after the Initial Term upon nine months written notice. Both the exclusive license under the settlement and license agreement and the exclusive supply obligations under the supply agreement could become effective prior to August 20, 2012 if a third-party launches a generic version of those dosages of XOPENEX Inhalation Solution or if the parties otherwise mutually agree.

In May 2008, we provided to the Federal Trade Commission and Department of Justice Antitrust Division the notifications of the settlement with Breath as required under Section 1112(a) of the MMA. The settlement with Breath and the other agreements with Breath and its affiliates, including the supply agreement, the agreement for the acquisition of Oryx and license agreements with Arrow, may be reviewed by antitrust enforcement agencies, such as the Federal Trade Commission and Department of Justice Antitrust Division. There can be no assurances that governmental authorities will not seek to challenge the settlement with Breath or that a competitor, customer or other third-party will not initiate a private action under antitrust or other laws challenging the settlement with Breath. We may not prevail in any such challenges or litigation and, in any event, may incur significant costs in the event of an investigation or in defending any action under antitrust laws.

In January 2006, we received notification that the FDA had received an ANDA from Dey, L.P., seeking approval of a generic version of our 1.25 mg/3 mL, 0.63 mg/3 mL, and 0.31 mg/3 mL XOPENEX Inhalation Solution. Dey, L.P.'s submission includes a Paragraph IV certification alleging that our patents listed in the Orange Book for these three dosages of XOPENEX Inhalation Solution are invalid, unenforceable, or not infringed by the generic version for which Dey, L.P. has sought approval. In February 2006, we filed a civil action against Dey, L.P. for patent infringement and the case is pending in the United States District Court for the District of Delaware, C.A. No. 06-113.

In August 2006, we received notification that the FDA had received an ANDA from Dey, L.P. seeking approval of a generic version of our 1.25 mg/0.5 mL XOPENEX Inhalation Solution concentrate. Dey, L.P.'s submission includes a Paragraph IV certification alleging that our patents listed in the Orange Book for 1.25 mg/0.5 mL XOPENEX Inhalation Solution concentrate are invalid, unenforceable, or not infringed by the generic version for which Dey, L.P. is seeking approval. In September 2006, we filed a civil action against Dey, L.P. for patent infringement in the United States District Court for the District of Delaware, C.A. No. 06-604. In September 2006, both civil actions we filed against Dey, L.P. were consolidated into a single suit.

In May 2007, we received notification that the FDA had received an ANDA from Barr seeking approval of a generic version of our 1.25 mg/3 mL, 0.63 mg/3 mL and 0.31 mg/3 mL XOPENEX Inhalation Solution. Barr's submission includes a Paragraph IV certification alleging that our patents listed in the Orange Book for these three dosages of XOPENEX Inhalation Solution are invalid, unenforceable or not infringed by the generic version for which Barr has sought approval. In July 2007, we filed a civil action against Barr for patent infringement and the case is pending in the United States District Court for the District of Delaware.

In March 2008, the trial judge consolidated the Dey, L.P. and Barr cases for all purposes, including discovery and trial, and the consolidated case is pending as C.A. No. 06-113. The court held a Markman hearing in July 2008, to address the parties' disputed issues of patent claim interpretation and issued its written decision and ruling on these matters in December 2008. A pretrial conference is scheduled for September 2009 and trial is currently scheduled to begin within 120 days of the pretrial conference.

In June 2008, Dey, L.P. filed a Complaint against us in the United States District Court for the District of Delaware, C.A. No. 08-372. The Complaint is a declaratory judgment action in which

Dey, L.P. seeks a declaration of non-infringement and invalidity of United States Patent 6,451,289 owned by us. Dey, L.P. had previously sent us notice that its ANDA contained a Paragraph IV certification against the 6,451,289 patent, and we did not commence litigation in response. We filed a Motion to Dismiss for lack of subject matter jurisdiction in response to the Complaint. In January 2009, the court entered an order denying our Motion to Dismiss and issued a corresponding opinion shortly thereafter. In February 2009, we filed a Motion for Certification of the court's order denying our Motion to Dismiss and to stay the proceedings pending resolution of appeal. The court subsequently issued an order staying this case pending its decision on our Motion for Certification and to stay the proceedings pending resolution of appeal.

The filing of an action for patent infringement under the Hatch-Waxman Act results in an automatic 30-month stay of the FDA's authority to grant final marketing approval to those companies that filed an ANDA containing a Paragraph IV certification against one or more of our XOPENEX Inhalation Solution patents. If an ANDA submission that includes a Paragraph IV certification is filed against a patent for a drug that has been granted five year new chemical entity data exclusivity, and that ANDA is filed between years four and five of the date the data exclusivity was awarded, such as in the case of the recently filed ANDAs with Paragraph IV certifications regarding LUNESTA, the statutory stay will run for 7.5 years from the NDA approval date. The first filer of an ANDA with a Paragraph IV certification is potentially entitled to a 180-day period of semi-exclusivity during which the FDA cannot approve subsequently filed ANDAs. The 180-day semi-exclusivity period would begin to run only upon first commercial marketing by the first filer. There are, however, also certain events that could cause the first filer to forfeit the 180-day semi-exclusivity period, which we refer to as a forfeiture event.

For our 1.25 mg/3 mL, 0.63 mg/3 mL, and 0.31 mg/3 mL dosages of XOPENEX Inhalation Solution, we believe that Breath is the sole first filer and potentially entitled to 180 days of semi-exclusivity against subsequent ANDA filers for those three dosages. The 30-month stay against Breath's ANDA expired on March 7, 2008. On April 9, 2008, the FDA granted final approval to Breath's ANDA for all three dosages. However, if a forfeiture event occurs and the FDA determines that Breath has forfeited the 180-day semi-exclusivity period for those three dosages, other ANDA filers who have been granted final approval by the FDA could commence an "at risk" launch upon expiration of the 30-month stay. For those three dosages, the 30-month stay against Dey, L.P. expired on July 9, 2008 and the 30-month stay against Barr expires on or about November 30, 2009.

For our 1.25 mg/0.5 mL XOPENEX Inhalation Solution concentrate, we believe that Dey, L.P. is the sole first filer and potentially entitled to 180 days of semi-exclusivity for that concentration. The 30-month stay against Dey, L.P.'s ANDA for that concentration expired on February 14, 2009. Dey, L.P. may receive final approval to sell 1.25mg/0.5 mL levalbuterol from the FDA at any time and could thereafter commence an "at risk" launch of this product.

Although we could seek recovery of any damages sustained in connection with any activities conducted by a party that infringes a valid and enforceable claim in our patents, whether we are ultimately entitled to such damages would be determined by the court in connection with our ongoing legal proceedings with each party desiring to launch generic levalbuterol hydrochloride products. If any of these parties were to commence selling a generic alternative to our XOPENEX Inhalation Solution products prior to the resolution of these ongoing legal proceedings, or there is a court determination that the products these companies wish to market do not infringe our patents, or that our patents are invalid or unenforceable, it would have a material adverse effect on our business, financial condition and results of operations. In addition, our previously issued guidance regarding our projected financial results may no longer be accurate, and we would have to revise such guidance.

**Eszopiclone Abbreviated New Drug Applications**

Beginning February 9, 2009, we received notices from Teva, Cobalt Laboratories, Dr. Reddy's, Orchid, Glenmark Generics, Roxane, Lupin, Wockhardt and Sun Global, that each has filed an ANDA with the FDA for generic versions of eszopiclone tablets (1 mg, 2 mg and 3 mg). Each submission includes a Paragraph IV certification alleging that one or more of our patents listed in the Orange Book for LUNESTA is invalid, unenforceable or not infringed by their respective proposed generic products. We anticipate receipt of additional notices that other ANDAs with Paragraph IV certifications have been filed by different generic pharmaceutical companies. We are currently contemplating commencing civil actions against these parties for patent infringement and will consider commencing patent infringement litigation against any other company that files an ANDA that includes a Paragraph IV certification with respect to eszopiclone.

If we commence patent infringement litigation against any of these ANDA filers and/or any others within 45 days of our receipt of their respective Paragraph IV notices, ANDA approval will be stayed until June 15, 2012, or potentially 6 months thereafter if we successfully obtain a pediatric exclusivity extension, or until a court decides that our patents are invalid, unenforceable or not infringed, whichever is earlier. Should we successfully enforce our patents, ANDA approval should not occur until expiration of the applicable patents, one of which may be extended by our outstanding patent term extension application.

**Desloratadine Abbreviated New Drug Applications**

Certain of Schering-Plough's CLARINEX products for which we receive sales royalties are currently the subject of patent infringement litigation. Since June 2007, the FDA has received ANDAs relating to various dosage forms of CLARINEX from eleven different generic pharmaceutical companies. These ANDA submissions include Paragraph IV certifications alleging that our patents, which Schering-Plough (as exclusive licensee of such patents) listed in the Orange Book for these products, are invalid, unenforceable and/or not infringed by the submitter's proposed product. We and the University of Massachusetts, co-owners of certain patents listed in the Orange Book, filed civil actions against these parties for patent infringement in the United States District Court for the District of New Jersey. In April 2008, the trial judge consolidated these cases for all purposes including discovery and trial. The court has not set a trial date. We believe that all of these ANDAs are subject to a statutory stay of approval until at least December 21, 2009 based on previous litigation commenced by Schering-Plough against these parties in separate civil actions involving another patent.

In March 2008, we entered into a consent agreement with Glenmark Pharmaceuticals, Inc., or Glenmark, one of the eleven generic pharmaceutical companies that filed a Paragraph IV certification against our patents, whereby Glenmark agreed not to pursue its case and to not market CLARINEX 5 mg tablets until the expiration of our patents listed by Schering-Plough in the Orange Book or until these patents are found invalid or unenforceable.

As a result of separate formal settlement agreements that Schering-Plough entered into with several ANDA filers involved in litigation with Schering-Plough, or Schering-Plough Settlement Agreements, we and the University of Massachusetts submitted, and the court approved, stipulations of dismissal without prejudice against five of the ANDA filers that we sued. In addition, we and the University of Massachusetts submitted one additional stipulation of dismissal without prejudice that is awaiting approval by the court and have actions remaining against four additional ANDA filers. The Schering-Plough Settlement Agreements entered to date permit generic entry of CLARINEX-D-12 Hour, CLARINEX-D -24 Hour and CLARINEX REDITABS on January 1, 2012 and CLARINEX 5 mg tablet on July 1, 2012. Upon generic entry of each product by a party to a Schering-Plough Settlement Agreement, our right to receive royalties on sales of such product will be significantly reduced.

**Levocetirizine Abbreviated New Drug Applications**

Beginning in February 2008, we and UCB S.A. received notices from Synthon Pharmaceuticals, Inc., or Synthon, Sun Pharmaceutical Industries Limited of Andheri (East), or Sun, Sandoz Inc., or Sandoz, and Pliva Hrvatska D.O.O. and Barr, or Pliva/Barr, that each has filed an ANDA seeking approval to market a generic version of XYZAL 5 mg tablets, and that each ANDA contained a Paragraph IV certification alleging that United States Patent 5,698,558, owned by us and exclusively licensed to UCB S.A., is invalid, unenforceable or not infringed. Beginning in April 2008, UCB S.A. filed in its name and on our behalf civil actions for patent infringement in the United States District Court for the Eastern District of North Carolina against Synthon, Sun, Sandoz, Pliva/Barr. We believe that all of these ANDAs are subject to a 30-month statutory stay of approval, resulting from the filing of lawsuits for patent infringement, the earliest of which, against Synthon, is scheduled to expire on or about August 29, 2010. In August 2008, the trial judge consolidated these cases for all purposes including discovery and trial. The court has not set a trial date.

***BROVANA Patent Infringement Claim***

In April 2007, we were served with a Complaint filed in the United States District Court for the Southern District of New York, C.A. No. 1:07-cv-2353, by Dey alleging that the manufacture and sale of BROVANA infringes or will induce infringement of a single United States patent for which Dey owns all rights, title and interest. In April 2007, we filed an Answer and Counterclaims to this Complaint seeking to invalidate the originally asserted patent and a second related patent. In May 2007, Dey filed a reply asserting infringement of the second patent. In March 2008, United States Patent 7,348,362, or the '362 patent, entitled "Bronchodilation b-agonist compositions and Methods" issued and Dey, L.P. is the assignee of the patent. In August 2008, the court granted our Motion to Amend our Answer and Counterclaims to seek declaratory judgment that the '362 patent is invalid and unenforceable and to add Mylan Inc., Dey, L.P.'s parent corporation, as a party. Between December 2008 and January 2009, U.S. patents 7,462,645; 7,465,756; and 7,473,710 all entitled "Bronchodilation b-agonist compositions and Methods" issued. These three patents claim priority to the same parent patent application that issued as the '362 patent. In January 2009, Dey filed a motion to add these three patents to the case, which we did not oppose.

Under the current trial scheduling order, the trial will begin no earlier than October 2, 2009. It is too early to make a reasonable assessment as to the likely outcome or impact of this litigation. We are unable to reasonably estimate any possible range of loss or liability related to this lawsuit due to its uncertain resolution.

***Class Action Litigation Settlement***

In June 2007, we filed in the United States District Court for the District of Massachusetts, or the Court, a Stipulation of Settlement regarding two securities class action lawsuits, or class actions, then pending in the Court naming Sepracor and certain of our current and former officers and one director as defendants. The class actions, which were filed on behalf of certain purchasers of our equity and debt securities, or the plaintiffs, alleged that the defendants violated the Federal securities laws by making false and misleading statements relating to the testing, safety and likelihood of approval of tecastemizole by the FDA. Under the terms of the Stipulation of Settlement, in June 2007 we paid into escrow $52.5 million in settlement of the class actions and, in July 2007, received an $18.5 million reimbursement from our insurance carriers. We recorded the litigation settlement expense of $34.0 million, relating to this matter, during the quarter ended March 31, 2007. In September 2007, the Court granted final approval of the Stipulation of Settlement and entered a final judgment consistent with the Stipulation of Settlement. The settlement is now final and the total settlement amount has been released from escrow.

*Other Legal Proceedings*

We have been named as the defendant in two separate lawsuits filed in the United States District Court for the Middle District of Florida (Sharp, et al., filed July 17, 2008) and the United States District Court for the District of Arizona (Greeves, et al., served September 9, 2008) claiming that our pharmaceutical sales representatives should have been categorized as "non-exempt" rather than "exempt" employees under the Fair Labor Standards Act. Both lawsuits claim that we owe damages, overtime wages, interest, costs and attorneys' fees for periods preceding the filing of the respective actions. Other companies in the pharmaceutical industry face substantially similar lawsuits. We filed an Answer to the Complaint in each of the Sharp and Greeves litigation on October 10, 2008 and October 15, 2008, respectively. Discovery in each case is proceeding and no trial dates have been set. Based upon the facts as presently known, we do not believe that it is likely that either collective action will result in liability that would be material to our financial position. We believe these lawsuits are without merit and we are prepared to defend against them vigorously.

From time to time we are party to other legal proceedings in the course of our business. We do not, however, expect such other legal proceedings to have a material adverse effect on our business, financial condition or results of operations.

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

No matters were submitted to a vote of our security holders, through solicitation of proxies or otherwise, during the last quarter of the year ended December 31, 2008.

## EXECUTIVE OFFICERS OF THE REGISTRANT

The following table sets forth the names, ages and positions of our current executive officers.

| Name | Age | Position |
|---|---|---|
| Adrian Adams | 58 | President and Chief Executive Officer |
| Mark H. N. Corrigan, M.D. | 51 | Executive Vice President, Research and Development |
| Mark Iwicki | 42 | Executive Vice President and Chief Commercial Officer |
| Andrew I. Koven | 51 | Executive Vice President, General Counsel and Corporate Secretary |
| Richard Ranieri | 57 | Executive Vice President, Human Resources and Administration |
| Robert F. Scumaci | 49 | Executive Vice President and Chief Financial Officer |

*Mr. Adams* has served as our President and Chief Executive Officer since May 2007. From March 2007 to May 2007, Mr. Adams served as our President and Chief Operating Officer. From 2002 until March 2007, Mr. Adams served as the President and Chief Executive Officer of Kos Pharmaceuticals, Inc., or Kos, and from 2001 until 2002 as its President and Chief Operating Officer. Prior to joining Kos, Mr. Adams served as President and Chief Executive Officer of Novartis Pharmaceuticals in Europe. Mr. Adams also served SmithKline Beecham Pharmaceuticals from 1992 to 1999 in various national and international capacities, last serving as President of its Canadian subsidiaries. Mr. Adams has served as a director of Amylin Pharmaceuticals, Inc. since October 2007.

*Dr. Corrigan* has served as our Executive Vice President, Research and Development since April 2003. Prior to joining Sepracor, Dr. Corrigan was Group Vice President of Global Clinical Research and Experimental Medicine at Pharmacia, a pharmaceutical company, from 1998 to 2003. After spending seven years in academic research, Dr. Corrigan joined Upjohn in 1993 and served in several senior management positions in clinical research and development for Upjohn and Pharmacia Upjohn. Dr. Corrigan is board certified in psychiatry and neurology and has served as a board member of Cubist Pharmaceuticals since June 2008.

*Mr. Iwicki* has served as our Executive Vice President and Chief Commercial Officer since October 2007. Prior to joining Sepracor, Mr. Iwicki was Vice President, Cardiovascular Business Franchise Head at Novartis Pharmaceuticals, or Novartis, from 1998 until October 2007. Prior to his tenure with Novartis, Mr. Iwicki served in sales, marketing and management positions at Merck & Co. and Astra Merck Inc. and began his career at Merck & Co. in 1989.

*Mr. Koven* has served as our Executive Vice President, General Counsel and Corporate Secretary since March 2007. Prior to joining Sepracor, Mr. Koven served as Executive Vice President, General Counsel and Corporate Secretary of Kos from August 2003 to March 2007. Mr. Koven served as Senior Vice President, General Counsel and Corporate Secretary at Lavipharm Laboratories Inc. from 2000 to August 2003, and he served as Assistant General Counsel of both the Pharmaceutical and Consumer Health divisions of Warner Lambert Company from 1993 to 2000, and earlier practiced law at Cahill, Gordon and Reindel in New York.

*Mr. Ranieri* has served as our Executive Vice President, Human Resources and Administration since August 2008. Prior to joining Sepracor, Mr. Ranieri was Senior Vice President and Chief Administrative Officer at Neurocrine Biosciences, Inc., or Neurocrine, from June 2005 until August 2008. Prior to his tenure with Neurocrine, Mr. Ranieri served as Senior Vice President, Human Resources at Genencor International Inc., or Genencor, from 1993 until June 2005. Prior to joining Genencor, Mr. Ranieri spent over 13 years with GlaxoSmithKline where he held a variety of human resources and sales management positions.

*Mr. Scumaci* has served as our Executive Vice President and Chief Financial Officer since May 2008. From February 2001 to May 2008, Mr. Scumaci served as our Executive Vice President, Corporate Finance and Administration, and as our Treasurer from March 1996 through October 2008. In May 2007, Mr. Scumaci assumed the additional responsibility for our commercial technical operations. Mr. Scumaci served as our Senior Vice President, Finance and Administration from March 1996 to February 2001 and as our Vice President and Controller from March 1995 until March 1996. From 1987 to 1994, Mr. Scumaci was employed by Ares-Serono Group, a multinational pharmaceutical company, most recently as Vice President, Finance and Administration of North American Operations. Previously, he was associated with Revlon Inc. and Coopers & Lybrand in various finance and accounting capacities.

## PART II

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

#### (a) Market for Registrant's Common Equity

Our common stock is traded on the NASDAQ Global Select Market under the symbol SEPR. On February 20, 2009, the closing price of our common stock, as reported on the NASDAQ Global Select Market, was $15.49 per share. The following table sets forth for the periods indicated the high and low sales prices per share of our common stock as reported by the NASDAQ Global Select Market.

| | High | Low |
|---|---|---|
| **2009** | | |
| First Quarter (through February 20, 2009) | $17.49 | $10.85 |

| | High | Low |
|---|---|---|
| **2008** | | |
| First Quarter | $30.60 | $16.85 |
| Second Quarter | $24.40 | $18.76 |
| Third Quarter | $22.25 | $16.03 |
| Fourth Quarter | $18.49 | $ 9.83 |

| | High | Low |
|---|---|---|
| **2007** | | |
| First Quarter | $63.24 | $45.84 |
| Second Quarter | $57.11 | $40.26 |
| Third Quarter | $43.31 | $25.88 |
| Fourth Quarter | $28.62 | $22.25 |

On February 20, 2009, we had approximately 352 stockholders of record.

#### (b) Dividend Policy

We have never paid cash dividends on our common stock. We currently intend to reinvest our future earnings, if any, for use in the business and do not expect to pay cash dividends.

#### (c) Issuer Purchases of Equity Securities

None.

**Item 6. Selected Financial Data.**

The selected consolidated financial data set forth below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Financial Statements and Supplementary Data" and the related notes thereto. The historical results presented are not necessarily indicative of future results.

**SEPRACOR SELECTED FINANCIAL DATA**

| | Year Ended December 31, | | | | |
|---|---|---|---|---|---|
| | 2008 | 2007 | 2006 | 2005 | 2004 |
| | (In Thousands, Except Per Share Data) | | | | |
| STATEMENT OF OPERATIONS DATA: | | | | | |
| Revenues: | | | | | |
| Product sales, net | $1,215,239 | $1,177,256 | $1,149,374 | $749,865 | $ 311,945 |
| Royalties and license fees | 77,050 | 47,974 | 33,759 | 51,243 | 61,096 |
| Total revenues | 1,292,289 | 1,225,230 | 1,183,133 | 801,108 | 373,041 |
| Costs and expenses: | | | | | |
| Cost of revenue | 132,441 | 117,155 | 104,736 | 67,431 | 35,427 |
| Research and development(1) | 246,813 | 263,756 | 163,488 | 144,504 | 159,974 |
| Research and development—in process upon acquisition(2) | 89,995 | — | — | — | — |
| Selling, general and administrative and patent costs | 760,511 | 780,711 | 763,563 | 626,075 | 388,750 |
| Amortization of intangibles | 7,368 | 154 | 230 | 535 | 667 |
| Litigation settlement, net | — | 34,000 | — | — | — |
| Restructuring expense | (566) | 6,921 | — | — | — |
| Total costs and expenses | 1,236,562 | 1,202,697 | 1,032,017 | 838,545 | 584,818 |
| Income (loss) from operations | 55,727 | 22,533 | 151,116 | (37,437) | (211,777) |
| Other income (expense): | | | | | |
| Interest income | 24,124 | 46,599 | 46,589 | 27,462 | 8,470 |
| Interest expense | (8,506) | (3,020) | (22,166) | (23,368) | (23,646) |
| Debt conversion expense(3) | — | — | — | — | (69,768) |
| Gain (loss) on early extinguishment of debt(4) | 10,082 | — | — | — | (7,022) |
| Equity in investee losses(5) | (1,103) | (507) | (422) | (665) | (1,485) |
| Other(6) | (11,960) | (1,002) | (300) | (79) | 482 |
| Gain on sale of affiliate stock(7) | — | — | — | 18,345 | — |
| Income (loss) before income taxes | 68,364 | 64,603 | 174,817 | (15,742) | (304,746) |
| (Benefit from) provision for income taxes(8) | (446,746) | 6,270 | 3,656 | 151 | — |
| Net income (loss) | $ 515,110 | $ 58,333 | $ 171,161 | $(15,893) | $(304,746) |
| Basic net income (loss) per common share | $ 4.79 | $ 0.55 | $ 1.63 | $ (0.15) | $ (3.31) |
| Diluted net income (loss) per common share | $ 4.47 | $ 0.50 | $ 1.48 | $ (0.15) | $ (3.31) |
| Shares used in computing basic and diluted net income (loss) per common share: | | | | | |
| Basic | 107,527 | 106,847 | 104,943 | 104,839 | 92,017 |
| Diluted | 115,260 | 116,364 | 115,508 | 104,839 | 92,017 |

| | December 31, | | | | |
|---|---|---|---|---|---|
| | 2008 | 2007 | 2006 | 2005 | 2004 |
| BALANCE SHEET DATA: | | | | | |
| Cash and short and long-term investments | $ 765,830 | $1,065,619 | $1,166,324 | $ 976,201 | $ 833,912 |
| Total assets | 1,815,075 | 1,404,726 | 1,493,793 | 1,274,497 | 1,039,118 |
| Short- and long-term debt | 531,938 | 723,425 | 1,161,898 | 1,164,110 | 1,165,275 |
| Stockholders' equity (deficit) | $ 708,622 | $ 176,413 | $ 40,184 | $ (204,072) | $ (349,878) |

(1) Research and development costs for 2007 include the $75.0 million upfront payment to Bial.

(2) Represents costs associated with our Nycomed and Arrow transactions in 2008.

(3) Represents inducement costs associated with our conversion of $177.2 million of our 0% Series A notes due 2008 and $352.0 million of our 0% Series B notes due 2010, which was completed in 2004.

(4) Represents a gain on our redemption in 2008 of the then outstanding $117.6 million principal amount of our 0% convertible subordinated notes due 2024 and a loss on our redemption in 2004 of the then remaining outstanding $430.0 million principal amount of our 5.75% convertible subordinated notes due 2006.

(5) Represents our portion of BioSphere losses.

(6) This amount includes an other-than-temporary impairment loss of $14.4 million on our investment in ACADIA Pharmaceuticals Inc., or ACADIA, in 2008.

(7) Represents a gain on the sale of approximately 688,000 shares of Vicuron Pharmaceuticals Inc. common stock in 2005.

(8) This amount includes the release of our valuation allowance in 2008.

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

### Executive Overview

We are a research-based pharmaceutical company focused on discovering, developing and commercializing differentiated products that address large and growing markets and unmet medical needs and that are prescribed principally by primary care physicians and certain specialists. Our drug research and development program, together with our corporate development and licensing activities, have yielded a portfolio of products and product candidates intended to treat a broad range of indications. We are currently concentrating our product development efforts in two therapeutic areas: respiratory diseases and CNS disorders.

Our currently marketed products in the United States are:

- LUNESTA® (eszopiclone), a non-benzodiazepine sedative hypnotic, for the treatment of insomnia in adults;
- XOPENEX® (levalbuterol HCl) Inhalation Solution, a short-acting bronchodilator, for the treatment or prevention of bronchospasm in patients six years of age and older with reversible obstructive airway disease;
- XOPENEX HFA® (levalbuterol tartrate) Inhalation Aerosol, an MDI for the treatment or prevention of bronchospasm in adults, adolescents and children four years of age and older with reversible obstructive airway disease;

- BROVANA® (arformoterol tartrate) Inhalation Solution, a long-acting, twice-daily (morning and evening), maintenance treatment of bronchoconstriction in patients with COPD, including chronic bronchitis and emphysema;
- OMNARIS™ (ciclesonide) Nasal Spray, an intranasal formulation of ciclesonide for the treatment of nasal symptoms associated with seasonal allergic rhinitis in adults and children six years of age and older, and with perennial allergic rhinitis in adults and adolescents 12 years of age and older; and
- ALVESCO® (ciclesonide) HFA Inhalation Aerosol, an inhaled corticosteroid in an HFA MDI formulation for the maintenance treatment of asthma as prophylactic therapy in adult and adolescent patients 12 years of age and older.

In January 2008, we obtained from Nycomed the exclusive United States distribution rights to OMNARIS Nasal Spray and ALVESCO HFA Inhalation Aerosol. We commercially introduced OMNARIS Nasal Spray in April 2008. In September 2008, we commercially introduced ALVESCO HFA Inhalation Aerosol through an extended, staged launch that initially was targeted primarily to specialists. In early 2009, we expanded our sales and marketing efforts to include a broader group of physicians. Because of the extended, staged launch for ALVESCO HFA Inhalation Aerosol, we expect 2009 revenues for this product to take place in the latter part of the year as we reduce launch phase inventory.

Our sales force markets our products in the United States to primary care physicians, allergists, pulmonologists, pediatricians, hospitals, psychiatrists and sleep specialists, as appropriate. We expect to commercialize any additional products that we may successfully develop or acquire through our own or a contract sales force, co-promotion agreements and/or out-licensing partnerships.

In January 2009, we announced a corporate restructuring and workforce reduction plan pursuant to which we intend to reduce our workforce by approximately 20%, or approximately 530 positions, of which approximately 180 are corporate positions and approximately 350 are field-based positions. We expect to substantially complete the workforce reduction by the end of the second quarter of 2009. In addition, we eliminated approximately 410 contract sales organization sales representative positions. These representatives marketed OMNARIS Nasal Spray, ALVESCO HFA Inhalation Aerosol and our XOPENEX products from September 2008 through January 2009. In total, our sales positions were reduced to approximately 1,325 (although the actual number of sales positions varies from time to time due to attrition in the ordinary course of business).

These reductions, together with other anticipated cost-saving initiatives across the organization, have resulted in a projected reduction in operating expenses of approximately $190 million in 2009, which is in addition to approximately $20 million of expense reductions realized during the fourth quarter of 2008. We are taking these actions in order to reduce costs, streamline operations and improve our cost structure. However, if we are unable to achieve the anticipated benefits, savings or improvements in our cost structure in the expected timeframe or other unforeseen events occur, our business and results of operations may be adversely affected. In addition, our restructuring plan may be disruptive to our business and could impair our ability to maintain sales levels and/or support potential sales growth and sales of additional products we may commercialize in the future.

As a result of the reduction in workforce, we expect to record restructuring charges and make future payments of between approximately $33.0 million and $37.0 million, a substantial portion of which we anticipate will be recorded in the first quarter of 2009. We currently expect these charges to consist of approximately $23.0 million to $24.0 million relating to employee termination benefits and approximately $10.0 million to $13.0 million relating to other charges, including contract sales organization termination fees and lease termination fees associated with office locations, equipment and automobiles. The increase in the estimate of our restructuring charge from our previously announced

range primarily relates to recent decisions to vacate two additional office locations and fees related to the termination of our contact sales organization earlier than previously anticipated. Our estimated restructuring charge is based on a number of assumptions. Actual results may differ materially and additional charges not currently expected may be incurred in connection with, or as a result of, these reductions.

In June 2008, in order to establish a Canadian commercial presence, we acquired the outstanding capital stock of Oryx Pharmaceuticals, Inc., or Oryx, a specialty pharmaceutical company that markets branded prescription pharmaceutical products to physician specialists and hospitals within Canada and is focused in the cardiovascular, CNS disorder, pain and infectious disease therapeutic areas. We subsequently changed Oryx's name to Sepracor Pharmaceuticals, Inc., or SPI. Following this acquisition, in accordance with SFAS 131, we began operating in two segments distinguished by strategic business units that offer different products: (1) Sepracor Inc., which consists of Sepracor and our subsidiaries other than SPI and currently engages in the discovery, research and development and commercialization of pharmaceutical products, and (2) SPI, which currently engages in the licensing and commercialization of pharmaceutical products in Canada. However, since there are no differences among our operating segments that are material to an understanding of our business as a whole, we present the discussion in this Management's Discussion and Analysis of Financial Condition and Results of Operations on a consolidated basis. The accounting policies of both segments are the same.

Factors that will be critical for us in achieving near-term success include our ability to:

- increase our LUNESTA revenues, despite increasing competition;
- grow XOPENEX Inhalation Solution revenues outside of the Medicare market by maintaining targeted sales and marketing efforts aimed at the retail and hospital market segments;
- continue to increase our XOPENEX HFA revenues;
- successfully market and sell BROVANA, particularly in the home health care market segment, which could be adversely affected by potential restrictions on Medicare Part B reimbursement or changes in the Medicare Part B reimbursement amount for BROVANA;
- successfully commercialize OMNARIS Nasal Spray and ALVESCO HFA Inhalation Aerosol;
- successfully implement our corporate restructuring and workforce reduction plan and manage the impact of the restructuring on our revenues;
- reduce and manage expenses effectively to help preserve profitability and positive cash flow from operations; and
- maintain patent protection for our products, including successful enforcement of our patents, particularly for XOPENEX Inhalation Solution and LUNESTA for which a number of ANDAs have been submitted to the FDA.

We believe that success in each of these areas should allow us to continue to be profitable in the near term and provide us the ability to repay our outstanding convertible debt of $530.5 million if and when it comes due. If not converted, repurchased at the holders' or our option, or otherwise refinanced earlier, the principal amount of this debt becomes due as follows:

| Principal Amount of Convertible Debt | Maturity Date |
|---|---|
| $148,020,000 | October 2010 |
| $382,450,000(1) | 2024(2) |

(1) During the year ended December 31, 2008, we repurchased and retired, at our option in privately negotiated transactions, an aggregate of $117.6 million principal amount of our

0% notes due 2024. We paid a total of $106.9 million in cash to repurchase these notes. On February 17, 2009, we announced that we commenced a tender offer to purchase for cash up to all $382.5 million aggregate principal amount of our outstanding 0% notes due 2024.

(2) These notes may be converted into cash, and if applicable, shares of our common stock under a conversion formula that becomes applicable, if and when, our common stock price exceeds $67.20 per share on the NASDAQ Global Select Market. Prior to our common stock exceeding such price, the notes are convertible to cash at the option of the holders in October 2009, 2014, 2019 and 2024, as well as under certain other conditions.

Our long-term success depends in part on our ability to continue to sell our commercialized products, build upon our current business, successfully develop or acquire and commercialize new products and successfully implement our corporate restructuring and workforce reduction plan. Our long-term success also depends in part on our ability to maintain patent protection for our products, including successful enforcement of our patents, particularly for XOPENEX Inhalation Solution and LUNESTA for which a number of ANDAs have been submitted to the FDA.

We expect that sales of LUNESTA and XOPENEX Inhalation Solution will represent the majority of our total revenues in 2009. We do not have long-term sales contracts with our customers, and we rely on purchase orders for sales of our products. Reductions, delays or cancellations of orders for our marketed products could adversely affect our operating results. If sales of our marketed products do not meet our expectations, we may not have sufficient revenues to achieve our business plan and our business will not be successful.

In 2009, we expect to be profitable for the year on an operating and net income basis. We expect research and development expenses, sales, marketing and distribution expenses and general and administrative expense to decrease compared to 2008 as a result of our corporate restructuring and workforce reduction plan, together with other anticipated cost savings initiatives. As part of our business strategy, we have and expect to continue considering and, as appropriate, consummating acquisitions of other technologies, product candidates, approved products and/or businesses. We can provide no assurance that we will be successful in completing any such future acquisitions.

**Recent Developments**

In February 2009, the CHMP re-confirmed its initial opinion recommending the EC grant LUNIVIA marketing approval in Europe, but without a new active substance status designation that we believe would enable more favorable commercialization of the product in the EU. We intend to continue to pursue with the EC the circumstances surrounding LUNIVIA and our marketing application, and we anticipate the EC will be making a final decision in near future.

On February 17, 2009, we announced that we commenced a tender offer to purchase for cash up to all $382.5 million aggregate principal amount of our outstanding 0% notes due 2024. The terms and conditions of the offer are set forth in the Schedule TO, Offer to Purchase and the related Letter of Transmittal filed with the SEC on February 17, 2009. We are offering to purchase the notes at a price of $970 for each $1,000 of principal amount of notes tendered. The tender offer will expire at midnight, New York City time, at the end of March 16, 2009, unless extended or earlier terminated pursuant to the terms of the tender offer. The tender offer will not be contingent upon any minimum number of notes being tendered but is subject to certain conditions described in the Offer to Purchase.

Beginning February 9, 2009, we received notices from Teva, Cobalt Laboratories, Dr. Reddy's, Orchid, Glenmark Generics, Roxane, Lupin, Wockhardt and Sun Global, that each has filed an ANDA with the FDA for generic versions of eszopiclone tablets (1 mg, 2 mg and 3 mg). Each submission includes a Paragraph IV certification alleging that one or more of our patents listed in the Orange

Book for LUNESTA is invalid, unenforceable or not infringed by their respective proposed generic products. We anticipate receipt of additional notices that other ANDAs with Paragraph IV certifications have been filed by different generic pharmaceutical companies. We are currently contemplating commencing civil actions against these parties for patent infringement and will consider commencing patent infringement litigation against any other company that files an ANDA that includes a Paragraph IV certification with respect to eszopiclone.

**Partnered Products and Revenue Related Agreements**

As part of our business strategy, we have entered into collaboration, license and distribution agreements with other pharmaceutical companies for the development and commercialization of various products. These agreements sometimes include the receipt or payment of nonrefundable upfront payments, payments on achieving significant milestones, and royalty payments on sales if and when the underlying product or product candidate is commercialized in the relevant jurisdiction.

*Out-Licensed Patents*

Royalty revenues from our out-licensing agreements for certain patents we own were $70.3 million, $47.7 million and $33.8 million for the years ended December 31, 2008, 2007 and 2006, respectively. Our royalty revenues currently come primarily from sales in the antihistamine market. The antihistamine products for which we receive royalties face intense competition from over-the-counter products, such as CLARITIN and ZYRTEC, and generic prescription antihistamine products. This competition has a direct impact on our ability to earn royalties in this market. Additionally, there is uncertainty relating to possible changes in the market with much discussion about other prescription allergy products possibly being sold without a prescription. Finally, there is a possibility that companies that produce generic drugs may succeed in their patent challenges relating to drugs for which we receive royalties and other branded drugs with large market share. This could result in the introduction of other generic equivalents, which may increase price competition among antihistamines and lower market share for the branded drugs.

**sanofi-aventis for Fexofenadine HCl.** In July 1993, we licensed to HMR, now sanofi-aventis (formerly Aventis), our U.S. patent rights covering fexofenadine HCl, which is marketed by sanofi-aventis as ALLEGRA. However, since the introduction of a generic version of ALLEGRA in the United States during the third quarter of 2005, we have ceased to earn royalties on sales in the United States of ALLEGRA. Since August 1999, we have been entitled to receive royalties on fexofenadine product sales in countries outside of the United States where we have patents related to fexofenadine. We are currently receiving royalties from sanofi-aventis for sales of ALLEGRA in Japan, Canada and Australia and in certain EU member states. We recorded approximately $26.6 million, $25.2 million and $16.6 million of royalty revenues under these agreements in 2008, 2007 and 2006, respectively.

**Schering-Plough Corporation for Desloratadine.** In December 1997, we licensed to Schering-Plough exclusive worldwide rights to our patents and patent applications relating to desloratadine, an active-metabolite of loratadine, which is marketed by Schering-Plough as CLARITIN. In January 2002, Schering-Plough commercially introduced CLARINEX brand desloratadine 5 mg tablets for the treatment of seasonal allergic rhinitis, in adults and children twelve years of age and older. In February 2002, Schering-Plough received FDA approval to market CLARINEX tablets for the treatment of chronic idiopathic urticaria, or CIU, in adults and children twelve years of age and older. Under the terms of our license agreement with Schering-Plough, we are currently receiving royalties on sales of CLARINEX in countries in which we hold patents. We recorded approximately $24.1 million, $16.5 million and $12.2 million of royalty revenue under this agreement in 2008, 2007 and 2006, respectively. Beginning in October 2007, the contractual royalty rate increased with respect to sales in the United States.

Schering-Plough has entered into settlement agreements with several ANDA filers involved in litigation with Schering-Plough that permit generic entry of CLARINEX-D-12 Hour, CLARINEX-D-24 Hour and CLARINEX REDITABS on January 1, 2012 and CLARINEX 5 mg tablet on July 1, 2012. Upon generic entry of each product by a party to any such settlement agreement, our right to receive royalties on sales of such product will be significantly reduced.

**UCB for Levocetirizine.** In February 2006, we entered into a license agreement with UCB S.A. relating to levocetirizine. Under this agreement, we have exclusively licensed to UCB S.A. all of our patents and patent applications in the United States regarding levocetirizine and royalties are payable to us on United States sales of levocetirizine products. Pursuant to our agreement with UCB Farchim S.A., we also earn royalties on sales of levocetirizine outside of the United States. Levocetirizine is currently marketed by UCB Farchim S.A. under the brand names XYZAL and XUSAL in the EU for treatment of symptoms of seasonal and perennial allergic rhinitis, persistent allergic rhinitis and CIU in adults and children six years of age and older. We recorded approximately $19.6 million, $6.0 million and $5.0 million of royalty revenue under the agreements with the UCB entities in 2008, 2007 and 2006, respectively.

*Out-Licensed Products*

**Eisai for Eszopiclone.** In July 2007, we entered into an agreement with Eisai for the development and commercialization of our eszopiclone product in Japan. Under this agreement, Eisai will be responsible for completing remaining clinical trials necessary for obtaining marketing approval from the Japanese regulatory authorities and, contingent on obtaining regulatory approval, commercialization of the product in Japan. We received an initial milestone payment and will be entitled to receive subsequent payments upon accomplishment of various development, regulatory and pricing milestones, as well as royalties on product sales. We will also be responsible for, and will receive compensation in connection with, the manufacture and supply of bulk tablets and/or active ingredient.

**GSK for Eszopiclone.** In September 2007, we entered into an agreement with GSK for the development and commercialization of our eszopiclone product for all markets worldwide excluding the United States, Canada, Mexico and Japan. Our eszopiclone product will be marketed by GSK in its territories primarily as LUNIVIA brand eszopiclone for the treatment of insomnia, contingent upon receipt of applicable regulatory approvals. Under this agreement, we received an initial payment of $20.0 million and are entitled to receive additional payments upon accomplishment of various milestones. If all milestones are met, GSK will be obligated to pay us $155.0 million in aggregate license and milestone payments. We are also entitled to receive double-digit royalties, which escalate up to an agreed upon amount, upon increased product sales, and compensation for supplying the product to GSK pursuant to a supply agreement entered into by the parties.

*In-Licenses and Exclusive Distributor Agreement*

**sanofi-aventis for Eszopiclone.** In September 1999, we entered into an agreement with sanofi-aventis' predecessor, Rhone-Poulenc Rorer SA, under which we exclusively licensed preclinical, clinical and post-marketing surveillance data package relating to zopiclone, its isomers and metabolites, to develop, make, use and sell eszopiclone in the United States. Zopiclone is marketed by sanofi-aventis in approximately 80 countries worldwide under the brand names of IMOVANE® and AMOBAN®. Under this agreement, Rhone-Poulenc Rorer assigned all U.S. patent applications relating to (S)-zopiclone to us. Under an amended agreement, we have the right to read and reference sanofi-aventis' regulatory filings related to zopiclone outside of the United States for the purpose of development and regulatory registration of eszopiclone outside of the United States, and sanofi-aventis has assigned to us the foreign counterparts to the U.S. patent covering eszopiclone and its therapeutic use. Also as part of the amendment, we permitted sanofi-aventis to assign our obligation to pay a royalty on sales of LUNESTA in the United States to a third party.

**Bial for STEDESA.** In December 2007, we entered into a license agreement with Bial for the development and commercialization in the United States and Canada of Bial's anti-epileptic compound, BIA 2-093, which we plan to market and sell under the brand name STEDESA, if and when approved. Pursuant to the agreement, we paid Bial an upfront payment of $75.0 million and are required to make subsequent payments upon accomplishment of various development and regulatory milestones, including $10.0 million we paid to Bial in May 2008 upon achievement of one such milestone, a $20 million milestone payment we expect to pay Bial in 2009 upon acceptance of the NDA for STEDESA by the FDA and which could include up to an additional $70.0 million if all milestones are met. We will also compensate Bial for providing finished product pursuant to a supply agreement that is expected to be entered into by the parties, which will be calculated as a percentage of the average net selling price for finished tablets, and milestone payments upon FDA approval of additional indications, if any.

**Nycomed for Ciclesonide Compound.** In January 2008, we entered into an agreement with Nycomed for the exclusive distribution, development and commercialization in the United States, its territories and possessions of Nycomed's ciclesonide compound, and products incorporating such compound, including ALVESCO HFA Inhalation Aerosol, for use in the treatment of asthma, and OMNARIS Nasal Spray for use in the treatment of allergic rhinitis. Under the agreement, we paid Nycomed an upfront payment of $150.0 million in February 2008 and may be required to make subsequent payments of up to $280.0 million over the life of the agreement upon accomplishment of various development and sales milestones. We also compensate Nycomed for supplying finished product pursuant to the agreement, including a supply price for the products, which will be based on Nycomed's manufacturing costs plus a percentage of such costs, and make quarterly royalty payments based on our net sales of the products.

**Arrow for Levalbuterol/ipratropium Product.** In April 2008, we entered into a license and development agreement with Arrow for the development, commercialization, marketing, sale and distribution of Arrow's Levalbuterol/ipratropium Product in current and all future formulations and delivery modes, throughout the world. We paid Arrow an upfront payment of $500,000 upon execution of the agreement. We are also required to pay Arrow $25.0 million on December 15, 2009 and $25.0 million on December 15, 2010 as further consideration for the transfer of know-how and the grants of rights and licenses to the Arrow technology, provided Arrow is not in material breach of certain of its obligations under the agreement, as well as a milestone payment of $20.0 million upon receipt of marketing approval for the Levalbuterol/ipratropium Product in the United States. We will also pay single-digit royalties that escalate up to an agreed upon amount based on product sales, subject to Arrow's one-time option in the fourth quarter of 2009 to receive a lump sum discounted amount of $23.5 million in lieu of ongoing royalty payments, which if incurred will result in an IPR&D charge in the fourth quarter of 2009. Arrow has the right to manufacture and supply us with our requirements of the Levalbuterol/ipratropium Product. If Arrow elects not to manufacture and supply the Levalbuterol/ipratropium Product to us, we will have the right to manufacture or arrange for the manufacture of the Levalbuterol/ipratropium Product.

**Arrow for Ciclesonide Enabling Technology.** In April 2008, we also entered into a license and development agreement with Arrow for know-how and intellectual property rights related to stable sterile suspension formulations, for use in the development, commercialization, marketing, sale and distribution of an inhalation pharmaceutical product containing ciclesonide as its only active ingredient and an inhalation pharmaceutical product containing both ciclesonide and arformoterol as its active ingredients, throughout the world, collectively referred to as the Ciclesonide Products. The agreement also includes rights to Arrow's "U-Bend" packaging technology, which allows increased accuracy in dosing through a novel U-Bend ampule design. We paid Arrow an upfront payment of $500,000 upon execution of the agreement. We are also required to pay Arrow $10.0 million on December 15, 2009 and $10.0 million on December 15, 2010, as further consideration for the transfer of know-how and the

grants of rights and licenses to the Arrow technology, provided Arrow is not in material breach of certain of its obligations under the agreement, as well as milestone payments of up to an aggregate of $27.5 million upon the achievement of certain regulatory milestones relating to both of the Ciclesonside Products. We will also pay single-digit royalties on sales of the Ciclesonide Products, subject to Arrow's one-time options in the fourth quarter of 2009 to receive an aggregate lump sum discounted amount of up to $37.9 million in lieu of ongoing royalty payments, which if incurred will result in an IPR&D charge in the fourth quarter of 2009.

*Partnered Products in Canada*

Prior to our acquisition of SPI in June 2008, its primary business strategy was to consider and, as appropriate, license approved products and product candidates for commercialization in Canada. SPI's partners in Canada include multinational companies, regional pharmaceutical companies without a global presence, and U.S. and European companies with biotech late-stage product candidates. Since its inception in 2001, SPI has entered into a number of in-licensing agreements resulting in its current portfolio of marketed products including its four main products ANGIOMAX, NIASPAN, CUBICIN and NAPRELAN.

Since our acquisition of SPI, it has expanded its business strategy to include the pursuit of regulatory approval and commercialization of certain of our products and product candidates in Canada. SPI also plans to continue to pursue additional in-licensing arrangements with third parties to expand its Canadian product portfolio.

**Results of Operations**

**Year Ended December 31, 2008 Compared to 2007**

***Revenues***

*Product Sales Revenues*

Product sales were $1,215.3 million and $1,177.3 million in 2008 and 2007, respectively, an increase of approximately 3%.

Sales of LUNESTA were $600.3 million and $600.9 million in 2008 and 2007, respectively, a decrease of less than 1%. The decrease was primarily the result of an approximately 8% decrease in the number of units sold, which we believe is primarily the result of the April 2007 commercial introduction of zolpidem tartrate, the generic equivalent to AMBIEN, and a decline in the overall market growth for insomnia products. Partially offsetting the decrease in the number of units sold was a net selling price increase of approximately 9%. The net selling price increase consisted of a gross selling price increase of approximately 20% offset by an increase in product sales allowances. Adjustments recorded to gross sales are disclosed below under the heading "Analysis of gross sales to net sales".

Sales of XOPENEX Inhalation Solution were $441.0 million and $487.2 million in 2008 and 2007, respectively, a decrease of approximately 10%. The decrease was primarily due to a decrease in number of units sold of approximately 17%, which we believe is primarily the result of a decline in units sold in the home health care market, which are subject to reimbursement under Medicare Part B. The reimbursement paid by CMS for XOPENEX Inhalation Solution has fallen significantly since July 1, 2007 as a result of the implementation of the blended Medicare Part B reimbursement rate for XOPENEX Inhalation Solution and generic albuterol. As a result, commencing January 1, 2009, we ceased contracting with home health care providers for XOPENEX Inhalation Solution. Accordingly, we expect that our sales to Medicare Part B providers will decrease and, as a result, our aggregate unit sales and revenues for this product will decrease. However, we expect the decrease in revenues will be proportionately less than the decrease in unit sales due to a commensurate reduction in Medicaid

rebate liability that has been incurred historically and that resulted from sales of XOPENEX Inhalation Solution at steeply discounted prices to home health care providers since the blended reimbursement rate went into effect. We also believe that the re-allocation of our sales resources in an effort to support the commercial introductions of OMNARIS Nasal Spray and ALVESCO HFA Inhalation Aerosol may have contributed to the decrease in the number of units sold. Partially offsetting the decrease in the number of units sold was a net selling price increase of approximately 9%. The net selling price increase consisted of a gross selling price increase of approximately 18% offset by an increase in product sales allowances. Adjustments recorded to gross sales are disclosed below under the heading "Analysis of gross sales to net sales".

Sales of XOPENEX HFA were $74.2 million and $74.9 million in 2008 and 2007, respectively, a decrease of less than 1%. The decrease was primarily the result of an approximately 8% decrease in the number of units sold. Partially offsetting the decrease in the number of units sold was a net selling price increase of approximately 8%. The net selling price increase consisted of a gross selling price increase of approximately 10% offset by an increase in product sales allowances. Adjustments recorded to gross sales are disclosed below under the heading "Analysis of gross sales to net sales".

Sales of BROVANA were $57.3 million and $14.3 million in 2008 and 2007, respectively, an increase of 301%. We commercially introduced BROVANA in April 2007. The increase is primarily the result of an increase in the number of units sold of approximately 305%. Partially offsetting the increase in the number of units sold was a net selling price decrease of approximately 1%. The net selling price decrease consisted of a gross selling price increase of approximately 9% offset by an increase in product sales allowances. Adjustments recorded to gross sales are disclosed below under the heading "Analysis of gross sales to net sales".

Sales of OMNARIS Nasal Spray were $14.6 million and $0 in 2008 and 2007, respectively. We commercially introduced OMNARIS Nasal Spray in April 2008. Adjustments recorded to gross sales are disclosed below under the heading "Analysis of gross sales to net sales".

Sales of ALVESCO HFA Inhalation Aerosol were $16.8 million and $0 in 2008 and 2007, respectively. We commercially introduced ALVESCO HFA Inhalation Aerosol in September 2008. Adjustments recorded to gross sales are disclosed below under the heading "Analysis of gross sales to net sales".

*Analysis of gross sales to net sales*—The following table presents the adjustments deducted from total gross sales to arrive at total net sales:

| | For the Years Ended December 31, | | | | | |
|---|---|---|---|---|---|---|
| | 2008 | % of Sales | 2007 | % of Sales | Change | % Change |
| | (Dollars in Thousands) | | | | | |
| Gross sales | $1,762,561 | 100.0% | $1,594,467 | 100.0% | $168,094 | 11% |
| Adjustments to gross sales: | | | | | | |
| Payment term discounts | 34,639 | 2.0% | 31,939 | 2.0% | 2,700 | 8% |
| Wholesaler fee-for-service | 24,897 | 1.4% | 28,629 | 1.8% | (3,732) | (13)% |
| Government and commercial rebates and discounts | 457,417 | 26.0% | 312,686 | 19.6% | 144,731 | 46% |
| Returns | 19,213 | 1.1% | 29,606 | 1.9% | (10,393) | (35)% |
| Other (includes product introduction discounts) | 11,156 | 0.6% | 14,351 | 0.9% | (3,195) | (22)% |
| Sub-total adjustments | 547,322 | 31.1% | 417,211 | 26.2% | 130,111 | 31% |
| Net sales | $1,215,239 | 68.9% | $1,177,256 | 73.8% | $ 37,983 | 3% |

The increase in adjustments to gross sales as a percentage of gross sales in 2008, as compared to 2007, primarily reflects an increase in government and commercial rebates and discounts as a result of:

- an increase in discounts given through managed care programs on the sales of LUNESTA, XOPENEX HFA and XOPENEX Inhalation Solution;
- an increase in Medicare Part D discounts given on the sales of LUNESTA and XOPENEX HFA;
- an increase in discounts under a program with the VA on the sales of LUNESTA and XOPENEX Inhalation Solution;
- an increase in Medicare Part B discounts given on the sales of XOPENEX Inhalation Solution and BROVANA;
- a net increase in Medicaid discounts primarily given on the sales of XOPENEX Inhalation Solution and XOPENEX HFA, partially off-set by a decrease in Medicaid discounts given on the sales of LUNESTA; and
- a slight increase in discounts given to hospitals in the form of chargebacks given primarily on the sales of XOPENEX Inhalation Solution and LUNESTA, largely offset by a decrease in chargebacks given on the sales of XOPENEX HFA.

In addition, the increase in government rebates and contractual discounts was partially offset by:

- a net decrease in product returns reserves primarily related XOPENEX Inhalation Solution, XOPENEX HFA and LUNESTA as we experienced a lower rate of actual returns for these products in 2008; and
- a net decrease in wholesaler fee-for-service discounts primarily related to credits earned in 2008 due to XOPENEX Inhalation Solution, LUNESTA and XOPENEX HFA gross price increases in that period; and
- a net decrease in other discounts primarily related to the timing and reduction of XOPENEX HFA vouchers and coupons distributed.

*Royalties and License Fees Revenue*

Royalties and license fees were $77.0 million and $48.0 million for the twelve months ended December 31, 2008 and 2007, respectively, an increase of approximately 61%.

Royalties earned on the sales of ALLEGRA under our agreements with sanofi-aventis were $26.6 million and $25.2 million in 2008 and 2007, respectively, an increase of approximately 6%. The increase is primarily the result of increased sales in Japan.

Royalties earned on sales of CLARINEX under our agreement with Schering-Plough were $24.1 million and $16.5 million in 2008 and 2007, respectively, an increase of approximately 46%. The increase is primarily the result of a contractual royalty rate increase that took effect in October 2007.

Royalties received on sales of XYZAL/XUSAL under our agreements with UCB were $19.6 million and $6.0 million in 2008 and 2007, respectively, an increase of approximately 226%. The increase is the result of the commercialization of XYZAL in the United States beginning in the fourth quarter of 2007.

License fees recognized on our GSK and Eisai agreements for the development and commercialization of our eszopiclone product, which we entered into in the second half 2007, were $5.8 million and $264,000 in 2008 and 2007, respectively. The increase primarily relates to an additional

Eisai milestone achieved in 2008 as well as reimbursed product development services provided to both GSK and Eisai during 2008.

A number of the patents we own and license to third parties for which we receive these royalties are the subject of patent invalidation or revocation claims by companies seeking to introduce generic equivalents of the products covered by such patents. We can provide no assurance concerning the duration or outcome of any patent related lawsuits. If we, or third parties from whom we receive royalties, are not successful in enforcing our respective patents, the companies seeking to market generic versions will not be excluded from marketing their generic versions of these products. Introduction of generic equivalents of any of these products before the expiration of our patents or the patents of our licensees could have a material adverse effect on our business.

***Costs of Revenues***

*Cost of Products Sold*

Cost of products sold was $130.3 million in 2008 and $115.8 million in 2007, respectively, an increase of approximately 13%.

Cost of LUNESTA sold as a percentage of LUNESTA gross sales was approximately 5% and 6% in 2008 and 2007, respectively. The decrease in the cost as a percentage of gross sales is primarily due to an increase in our gross selling price.

Cost of XOPENEX Inhalation Solution sold as a percentage of XOPENEX Inhalation Solution gross sales was approximately 6% and 7% in 2008 and 2007, respectively. The decrease in the cost as a percentage of gross sales is primarily due to an increase in our gross selling price.

Cost of XOPENEX HFA sold as a percentage of XOPENEX HFA gross sales was approximately 15% in 2008 and 2007.

Cost of BROVANA sold as a percentage of BROVANA gross sales was approximately 11% and 15% in 2008 and 2007, respectively. We commercially introduced BROVANA in April 2007. The decrease in the cost as a percentage of gross sales is primarily due to lower manufacturing costs during 2008 as compared to 2007, in addition to an increase in our gross selling price. The decrease in the cost to manufacture BROVANA is the result of increased production of the 60-count package, which has a lower manufacturing cost than the 30-count package, during 2008 as compared to 2007.

Cost of OMNARIS Nasal Spray sold as a percentage of OMNARIS Nasal Spray gross sales was approximately 33% in 2008. We commercially introduced OMNARIS Nasal Spray in April 2008.

Cost of ALVESCO HFA Inhalation Aerosol sold as a percentage of ALVESCO HFA Inhalation Aerosol gross sales was approximately 25% in 2008. We commercially introduced ALVESCO HFA Inhalation Aerosol in September 2008.

*Cost of Royalty Revenue*

Cost of royalties earned was $2.1 million and $1.3 million for 2008 and 2007, respectively. The cost of royalties in both periods relates to an obligation to a third party as a result of royalties we earn from Schering-Plough based on its sales of CLARINEX. This increase in obligations to the third party is due to the increase in royalties earned in 2008 as compared to 2007.

***Research and Development***

Research and development expenses were $246.8 million and $263.8 million in 2008 and 2007, respectively, a decrease of approximately 6%. The decrease is primarily due to the $75.0 million fee we paid in 2007 to Bial pursuant to the license agreement for STEDESA, offset by a $10.0 million

milestone payment we paid to Bial in 2008, increased spending on the new ciclesonide pipeline, increased spending on four of our early-stage programs, SEP-225441, SEP-228432, SEP-225289 and SEP-227900, and increased drug discovery efforts.

In 2009, we intend to decrease our research and development expenditures as compared to 2008. We expect our principal research and development expenditures will relate to our drug discovery efforts and the following clinical programs: (1) OMNARIS HFA Nasal Spray, (2) STEDESA, (3) LUNESTA Phase IIIb and Phase IV Studies, (4) SEP-225289, (5) SEP-227162 and (6) post-NDA approval studies of BROVANA.

Drug development and approval in the United States is a multi-step process regulated by the FDA. The process begins with the filing of IND which, if successful, allows the opportunity for study in humans, or clinical study, of the potential new drug. Clinical development typically involves three phases of study: Phase I, II and III. The most significant costs in clinical development are in Phase III clinical trials, as they tend to be the longest and largest studies in the drug development process. Following successful completion of Phase III clinical trials, an NDA must be submitted to, and accepted by, the FDA, and the FDA must approve the NDA, prior to commercialization of the drug. We may elect either on our own, or at the request of the FDA, to conduct further studies that are referred to as Phase IIIb and IV studies, which if conducted, could cause us to incur substantial costs. Phase IIIb studies are initiated while the NDA is under FDA review. These studies are conducted under an IND. Phase IV studies, also referred to as post-marketing studies, are studies that are initiated and conducted after the FDA has approved a product for marketing. Phase IV studies may be requested by the FDA either before or after the FDA has approved an NDA. These studies may also be independently initiated by the company for which an NDA has been approved. The FDA and companies conducting post-marketing studies use them to gather additional information about a product's safety, efficacy or optimal use.

Successful development of our product candidates is highly uncertain. Completion dates and completion costs can vary significantly for each product candidate and are difficult to predict. The lengthy process of seeking FDA approvals, and subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or delay in obtaining, regulatory approvals could materially adversely affect our business. We cannot provide assurance that we will obtain any approval required by the FDA on a timely basis, if at all.

For additional discussion of the risks and uncertainties associated with completing development of potential product candidates, see "Risk Factors."

Below is a summary of development for our products and product candidates that represent approximately 10% or more of our direct project research and development spending for the year ended December 31, 2008. The "Estimate of Completion of Phase" column contains forward-looking statements regarding expected timing of completion of product development phases. Completion of product development, if successful, culminates in the submission of an NDA to the FDA; however, there can be no assurance that the FDA will accept for filing, or approve, any NDA. The actual timing of completion of phases could differ materially from the estimates provided in the table. The FDA approved product and the three product candidates listed in the table below accounted for approximately 63% of our direct project research and development spending for the year ended

December 31, 2008. No other product candidate accounted for more than 6% of our direct research and development spending in this period.

| Product or Product Candidate | Indication | Phase of Development | Estimate of Completion of Phase |
|---|---|---|---|
| LUNESTA (eszopiclone) | Insomnia | * | * |
| SEP-225441 | Anxiety | Phase II | 2009 |
| SEP-227162 | Depression | Phase I | 2009 |
| SEP-225289 | Depression | Phase II | 2009 |

* Spending relates to post-marketing studies. We commercially introduced LUNESTA in April 2005.

Below is a summary of expenditure information related to our products and product candidates representing approximately 10% or more of our direct project research and development spending during the year ended December 31, 2008 or 2007, as well as the costs incurred on these projects through December 31, 2008. The costs in this analysis include only direct costs and do not include certain indirect labor, overhead, share-based compensation or other costs that benefit multiple projects. As a result, fully-loaded research and development cost summaries by project are not presented.

| | Project costs for the year ended December 31, 2008 | Project costs to date through December 31, 2008 | Project costs for the year ended December 31, 2007 | Project costs to date through December 31, 2007 |
|---|---|---|---|---|
| | | (In Thousands) | | |
| LUNESTA (eszopiclone) | $26,235 | $271,332 | $25,074 | $245,097 |
| BROVANA (arformoterol tartrate) | $ 5,443 | $194,211 | $14,837 | $188,768 |
| SEP-225289 | $14,841 | $ 39,034 | $11,083 | $ 24,193 |
| SEP-225441 | $15,686 | $ 22,931 | $ 7,245 | $ 7,245 |
| SEP-227162 | $11,763 | $ 32,747 | $12,844 | $ 20,984 |

Due to the length of time necessary to develop a product, uncertainties related to the ability to obtain governmental approval for commercialization, and difficulty in estimating costs of projects, we do not believe it is possible to make accurate and meaningful estimates, with any degree of accuracy, of the ultimate cost to bring our product candidates that have not entered into Phase III clinical trials to FDA approved status. We recently commenced a Phase III clinical trial for OMNARIS HFA Nasal Spray. As of December 31, 2008, the costs associated with this project were approximately $4.1 million. We estimate that it will cost an additional $40.0 million to $50.0 million to advance OMNARIS HFA Nasal Spray from its current stage of development through an NDA submission is an additional $40.0 million to $50.0 million based on a targeted NDA submission during 2011, provided that no significant delays are imposed by internal resource constraints or unanticipated FDA requirements.

***Research and Development in-process upon acquisition***

In 2008, we recorded approximately $90.0 million of IPR&D including $50.8 million associated with Arrow as well as $39.2 million associated with the Nycomed transaction. These expenses represent the cost of acquiring rights to branded pharmaceutical products in development from third parties, which we expensed at the time of acquisition.

The $50.8 million of IPR&D associated with the Arrow transactions relates to the following:

- rights to Arrow's Levalbuterol/ipratropium Product for the potential treatment of COPD, which we have targeted for commercial introduction in 2013;

- know-how and intellectual property rights related to stable sterile suspension formulations, which we refer to as Enabling Technology, for use in connection with an inhalation solution pharmaceutical product containing ciclesonide as its only active ingredient, intended for the potential treatment of asthma symptoms regardless of asthma severity, which we have targeted commercial introduction at the end of 2013 or early 2014; and
- Enabling Technology for use in connection with an inhalation solution pharmaceutical product containing both ciclesonide and arformoterol as its active ingredients, intended as a long-acting maintenance treatment of bronchoconstriction in patients suffering from COPD, which we have targeted for commercial introduction in 2015/2016.

The $39.2 million of IPR&D associated with the Nycomed transaction relates to an OMNARIS HFA Nasal Spray and two other respiratory-related candidates. We have targeted commercial introduction of OMNARIS HFA Nasal Spray for 2012. One of the respiratory candidates is a combination therapy that is comprised of ciclesonide and a long-acting beta-agonist (we have selected arformoterol), which we have targeted for commercial introduction for 2014. The second respiratory candidate is an inhalation solution for which we have targeted commercial introduction at the end of 2013 or early 2014.

***Selling, Marketing and Distribution***

Selling, marketing and distribution expenses were $654.1 million and $699.3 million in 2008 and 2007, respectively, a decrease of approximately 6%. The decrease was largely due to a $110.0 million reduction in advertising and promotional expenses related to LUNESTA, XOPENEX and BROVANA and in salary and other compensation expenses associated with field sales positions. Amounts are partially offset by a $44.0 million increase in marketing and promotional expenses related to OMNARIS Nasal Spray and ALVESCO HFA Inhalation Aerosol, both commercially introduced in 2008, as well as $19.4 million associated with the addition of our former contract sales organization in 2008.

***General and Administrative***

General and administrative costs were $106.4 million and $81.4 million in 2008 and 2007, respectively, an increase of approximately 31%. The increase is primarily the result of a $14.1 million increase in salary and other compensation related expenses, a $5.2 million increase in legal fees largely related to patent litigation, and a $6.8 million increase in costs related to the additional work required for our remediation plan to address a material weakness in internal control and financial reporting as discussed in Part II, Item 9A "Controls and Procedures" of this Annual Report on Form 10-K as well as an increase in audit fees and other internal company initiatives.

***Amortization of Intangible Assets***

Amortization of intangible assets was $7.4 million and $154,000 in 2008 and 2007, respectively. The increase primarily relates to the amortization of the intangible assets acquired from Nycomed and Arrow in the first and second quarters of 2008, respectively.

***Litigation Settlement***

Litigation settlement expense was $0 and $34.0 million in 2008 and 2007, respectively. In June 2007, we filed in the Court a Stipulation of Settlement regarding two class actions pending in the Court naming Sepracor and certain of our current and former officers and one director as defendants. As previously disclosed, the class actions alleged that the defendants violated the Federal securities laws by making false and misleading statements relating to the testing, safety and likelihood of approval of tecastemizole by the FDA. Under the terms of the Stipulation of Settlement, in June 2007 we paid into

escrow $52.5 million in settlement of the class actions and, in July 2007, received an $18.5 million reimbursement from our insurance carriers. In September 2007, the Court granted final approval of the Stipulation of Settlement and entered a final judgment consistent with the Stipulation of Settlement. The settlement is now final and the total settlement amount has been released from escrow. We recorded the litigation settlement expense of $34.0 million relating to this matter during the quarter ended March 31, 2007.

***Restructuring***

Restructuring in 2008 was an expense reversal of $566,000 as compared to restructuring expense of $6.9 million in 2007. In December 2007, we recorded a $6.9 million restructure reserve related to a restructuring and re-alignment of our sales force. The restructuring program was completed by December 31, 2007 and the charge was primarily comprised of severance costs for terminated employees and contract termination costs for excess leased computer equipment and company cars. The $566,000 expense reversal in 2008 was primarily the result of a change in estimate associated with employee severance costs and contract terminations.

***Other Income (Expense)***

Interest income was $24.1 million and $46.6 million in 2008 and 2007, respectively. Our monthly average cash and investment balances were approximately $851.2 million and $918.0 million for 2008 and 2007, respectively. For 2008 and 2007, the average annualized interest rate that we earned on our investments was 2.8% and 5.1%, respectively. The decrease in interest income was a result of a decrease in cash balances and lower interest rates in 2008.

Gain on extinguishment of debt was $10.1 million and $0 in 2008 and 2007, respectively. During the second half of 2008, we repurchased and retired, at our option in privately negotiated transactions, an aggregate of $117.6 million principal amount of our 0% notes due 2024. We paid a total of $106.9 million in cash to repurchase these notes. In connection with these transactions, we recorded a gain on the extinguishment of $10.7 million offset by non-cash charges of approximately $600,000 resulting from the write-off of debt issuance costs associated with the retired debt.

Interest expense was $8.5 million and $3.0 million in 2008 and 2007, respectively. The expense for 2008 is primarily related to imputed interest on the contingent liabilities associated with the assets we licensed from Arrow. The expense in 2007 is primarily related to the interest we paid on our 5% convertible subordinated debentures, which we repaid in full upon their maturity on February 15, 2007.

Our ownership interest in BioSphere at December 31, 2008 was approximately 18% and we account for the investment under the equity method of accounting. Our share of equity losses was $1.1 million and $507,000 in 2008 and 2007, respectively. The increase in equity losses is attributable to higher losses at BioSphere.

Other expense was $12.0 million and $1.0 million in 2008 and 2007, respectively. The expense in 2008 primarily represents a $14.4 million other-than-temporary impairment recorded in connection with our investment in ACADIA, partially offset by a $2.6 million insurance settlement.

***Income Taxes***

The benefit from income tax was $446.7 million in 2008 as compared to an expense of $6.3 million in 2007. The net tax benefit recorded for the year ended December 31, 2008 was principally due to a tax benefit of $452.0 million recorded upon our decision to release a valuation allowance recorded against net deferred tax assets in the United States and a foreign jurisdiction. Excluding the effect of these tax benefits, our income tax provisions for the year ended December 31, 2008 consisted primarily

of certain state income taxes. The tax provision for the year ended December 31, 2007 is primarily due to foreign income taxes as well as United States Federal and state alternative minimum tax, or AMT.

As of the end of the first quarter of 2008, a full valuation allowance was recorded against our net deferred tax assets in the United States and foreign jurisdictions. Based upon our settlement of patent litigation with Breath during the second quarter of 2008, our operating results over recent years and through June 30, 2008 and an assessment of our expected future results of operations, we determined that it is more likely than not that we will realize a substantial portion of our deferred tax assets in the United States and a foreign jurisdiction. As a result, during the second quarter of 2008, we released a total of $452.0 million of our valuation allowance, which was recorded as an income tax benefit.

We have a remaining valuation allowance recorded against United States net deferred tax assets of $182.8 million, which consists of $145.1 million for stock-based compensation deductions and $6.9 million of stock-based compensation research and development credits that will be credited to additional paid-in-capital when realized; and $1.9 million for certain state operating loss carryforwards, $9.0 million for capital losses, and $19.9 million of research and development credits that will likely expire without being utilized. Additionally, there is a non-U.S. valuation allowance of $1.1 million for non-U.S. operating loss and tax credit carryforwards that will likely expire without being utilized.

**Year Ended December 31, 2007 Compared to 2006**

***Revenues***

*Product Sales Revenues*

Product sales were $1,177.3 million and $1,149.4 million in 2007 and 2006, respectively, an increase of approximately 2%.

Sales of LUNESTA were $600.9 million and $565.4 million in 2007 and 2006, respectively, an increase of approximately 6%. The increase was primarily due to a 7% increase in net selling price, which resulted from a gross price increase of approximately 13%, offset by an increase in sales discounts and allowance of approximately 5%. Units sold decreased by just under 1%. Adjustments recorded to gross sales are disclosed below under the heading "Analysis of gross sales to net sales".

Sales of XOPENEX Inhalation Solution were $487.2 million and $543.0 million in 2007 and 2006, respectively, a decrease of approximately 10%. The decrease was primarily due to units sold decreasing by approximately 4% and a decrease in net selling price of 6%. The net selling price decrease resulted from a realized gross price increase of approximately 7%, offset by an increase in sales discounts and allowances of approximately 10%. Adjustments recorded to gross sales are disclosed below under the heading "Analysis of gross sales to net sales".

Sales of XOPENEX HFA were $74.9 million and $41.0 million in 2007 and 2006, respectively, an increase of approximately 83%. The increase was primarily due to a 30% increase in net selling price, which resulted from a decrease in sales discounts and allowances and a 40% increase in units sold. Adjustments recorded to gross sales are disclosed below under the heading "Analysis of gross sales to net sales".

Sales of BROVANA were $14.3 million and $0 in 2007 and 2006, respectively. We commercially introduced BROVANA in April 2007. Adjustments recorded to gross sales are disclosed below under the heading "Analysis of gross sales to net sales".

*Analysis of gross sales to net sales*—The following table presents the adjustments deducted from total gross sales to arrive at total net sales:

| | For the Years Ended December 31, | | | | | |
|---|---|---|---|---|---|---|
| | 2007 | % of Sales | 2006 | % of Sales | Change | % Change |
| | (Dollars in Thousands) | | | | | |
| Gross sales | $1,594,467 | 100.0% | $1,435,363 | 100.0% | $159,104 | 11% |
| Adjustments to gross sales: | | | | | | |
| Payment term discounts | 31,939 | 2.0% | 29,264 | 2.0% | 2,675 | 9% |
| Wholesaler fee-for-service | 28,629 | 1.8% | 42,048 | 2.9% | (13,419) | (32)% |
| Government and commercial rebates and discounts | 312,686 | 19.6% | 190,206 | 13.3% | 122,480 | 64% |
| Returns | 29,606 | 1.9% | 20,255 | 1.4% | 9,351 | 46% |
| Other (includes product introduction discounts) | 14,351 | 0.9% | 4,216 | 0.3% | 10,135 | 240% |
| Sub-total adjustments | 417,211 | 26.2% | 285,989 | 19.9% | 131,222 | 46% |
| Net sales | $1,177,256 | 73.8% | $1,149,374 | 80.1% | $ 27,882 | 2% |

The increase in adjustments to gross sales as a percentage of gross sales in 2007 as compared to 2006 primarily reflects an overall increase in government and commercial rebates and discounts as a result of:

- an increase in Medicaid discounts that we offered on the sales of XOPENEX Inhalation Solution, LUNESTA and XOPENEX HFA;
- an increase in discounts given through Medicare Part B program that we offered on the sales of XOPENEX Inhalation Solution as a result of CMS' decision to discontinue the stand-alone reimbursement for the product, which created a new reimbursement rate for XOPENEX Inhalation Solution;
- an increase in managed care commercial discounts we offered on the sales of LUNESTA and XOPENEX HFA;
- an increase in discounts given through the Medicare Part D program that we offered on the sales of LUNESTA; and
- a decrease in XOPENEX HFA units sold under a government contract with the VA in 2007 as compared to 2006.

Returns also increased in 2007 as compared to 2006, which is primarily due to a higher rate of return of XOPENEX Inhalation Solution as a result of CMS' decision to discontinue the stand-alone reimbursement for the product and also higher returns of LUNESTA, primarily in the 1 mg tablets and all hospital unit doses. In addition, other discounts increased as we increased the utilization of coupon programs, primarily related to XOPENEX HFA. Partially offsetting these increases in adjustments to gross sales as a percentage of gross sales was a net decrease in wholesaler fee-for-service charges primarily related to credits earned due to LUNESTA and XOPENEX Inhalation Solution gross price increases during 2007.

*Royalties and License Fees Revenue*

Royalties and license fees were $48.0 million and $33.8 million in 2007 and 2006, respectively, an increase of approximately 42%.

Royalties earned on the sales of ALLEGRA under our agreement with sanofi-aventis were $25.2 million and $16.6 million in 2007 and 2006, respectively, an increase of approximately 52%. The increase was primarily the result of increased sales in Japan and sanofi-aventis' product commercialization of a 180 mg dosage strength of ALLEGRA.

Royalties earned on sales of CLARINEX under our agreement with Schering-Plough were $16.5 million and $12.2 million in 2007 and 2006, respectively, an increase of approximately 35%. The increase was primarily the result of a contractual royalty rate increase that took effect in October 2007.

Royalties received on sales of XYZAL/XUSAL under our agreement with UCB were $6.0 million and $5.0 million in 2007 and 2006, respectively, an increase of approximately 21%.

License fees recognized on our GSK and Eisai agreements for the development and commercialization of our eszopiclone product, which we entered into in the second half 2007, were $264,000 and $0 in 2007 and 2006, respectively.

***Costs of Revenues***

*Cost of Products Sold*

Cost of products sold was $115.8 million and $103.8 million in 2007 and 2006, respectively, an increase of approximately 12%.

Cost of LUNESTA sold as a percentage of LUNESTA gross sales was approximately 6% in 2007 and 2006, principally due to royalties we pay to a third party on net sales of LUNESTA.

Cost of XOPENEX Inhalation Solution sold as a percentage of XOPENEX Inhalation Solution gross sales was approximately 7% in 2007 and 2006.

Cost of XOPENEX HFA sold as a percentage of XOPENEX HFA gross sales was approximately 15% in 2007 and 2006. Included in the costs of XOPENEX HFA sold is a royalty paid on net sales of XOPENEX HFA to 3M, our third-party finished goods manufacturer of the product.

Cost of BROVANA sold as a percentage of BROVANA gross sales was approximately 15% in 2007. We commercially introduced BROVANA in April 2007.

*Cost of Royalty Revenue*

Cost of royalties earned was $1.3 million and $1.0 million for 2007 and 2006, respectively. The cost of royalties in both periods relates to an obligation to a third party as a result of royalties we earn from Schering-Plough based on its sales of CLARINEX. This increase in obligations to the third party is due to the increase in royalties earned in 2007 as compared to 2006.

***Research and Development***

Research and development expenses were $263.8 million and $163.5 million in 2007 and 2006, respectively, an increase of approximately 61%. The increase is primarily due to the $75.0 million fee we paid to Bial pursuant to the license agreement for Bial's anti-epileptic compound, increased spending on two of our early-stage programs, SEP-227162 and SEP-225441, the LUNESTA Phase IIIb/IV and pediatric studies and increased drug discovery efforts.

Below is a summary of development of our products and product candidates that represent 10% or more of our direct project research and development spending for the year ended December 31, 2007. The three FDA-approved products and two product candidates listed in the table below accounted for

approximately 81% of our direct project research and development spending in 2007. No other product candidate accounted for more than 9% of our direct research and development spending in 2007.

| Product or Product Candidate | Indication | Phase of Development in 2007 |
|---|---|---|
| LUNESTA (eszopiclone) | Insomnia | * |
| XOPENEX HFA (levalbuterol tartrate) | Respiratory—Asthma | ** |
| BROVANA (arformoterol tartrate) | Respiratory—COPD | *** |
| SEP-225289 | Depression | Phase II |
| SEP-227162 | Depression | Phase I |

* Spending relates to post-NDA approval studies. We commercially introduced LUNESTA in April 2005.

** We commercially introduced XOPENEX HFA in December 2005.

*** We commercially introduced BROVANA in April 2007.

Below is a summary of expenditure information related to our products and product candidates representing 10% or more of our direct project research and development spending during the years ended December 31, 2007 and 2006, as well as the costs incurred as of December 31, 2007 on these projects. The costs in this analysis include only direct costs and do not include certain indirect labor, overhead, share-based compensation, up-front license fees, milestone payments, or other costs that benefit multiple projects. As a result, fully-loaded research and development cost summaries by project are not presented.

| | Project costs for the year ended December 31, 2007 | Project costs through December 31, 2007 | Project costs for the year ended December 31, 2006 | Project costs through December 31, 2006 |
|---|---|---|---|---|
| | | (In Thousands) | | |
| LUNESTA (eszopiclone) | $25,074 | $245,097 | $20,301 | $220,023 |
| XOPENEX HFA (levalbuterol tartrate) | $ 6,209 | $175,507 | $12,507 | $169,298 |
| BROVANA (arformoterol tartrate) | $14,837 | $188,768 | $12,353 | $173,931 |
| SEP-225289 | $11,083 | $ 24,193 | $ 9,041 | $ 13,110 |
| SEP-227162 | $12,844 | $ 20,984 | $ 6,394 | $ 8,140 |

***Selling, Marketing and Distribution***

Selling, marketing and distribution expenses were $699.3 million and $691.7 million in 2007 and 2006, respectively, an increase of approximately 1%. The increase was primarily attributable to an increase in salary and other compensation related expense as a result of hiring additional sales representatives and management in the second quarter of 2006 to support our marketed products, in addition to increased costs associated with our April 2007 commercialization of BROVANA. These increases were partially offset by a decrease in marketing, advertising and promotional expenses primarily related to costs to support LUNESTA.

***General and Administrative***

General and administrative costs were $81.5 million and $72.1 million in 2007 and 2006, respectively, an increase of approximately 13%. The increase was largely due to an increase in legal fees of approximately $8.7 million related to patent support and litigation costs.

*Litigation Settlement*

Litigation settlement expense was $34.0 million and $0 in 2007 and 2006, respectively. In June 2007, we filed a Stipulation of Settlement regarding two class actions pending naming Sepracor and certain of our current and former officers and one director as defendants. As previously disclosed, the class actions alleged that the defendants violated the Federal securities laws by making false and misleading statements relating to the testing, safety and likelihood of approval of tecastemizole by the FDA. Under the terms of the Stipulation of Settlement, in June 2007, we paid into escrow $52.5 million in settlement of the class actions and, in July 2007, received an $18.5 million reimbursement from our insurance carriers. In September 2007, the Court granted final approval of the Stipulation of Settlement and entered a final judgment consistent with the Stipulation of Settlement. The settlement is now final and the total settlement amount has been released from escrow. We recorded the litigation settlement expense of $34.0 million relating to this matter during the quarter ended March 31, 2007.

*Restructuring*

Restructuring expense was $6.9 million and $0 in 2007 and 2006, respectively. During the quarter ended December 31, 2007, we decided to restructure and re-align our sales force. The costs associated with the restructuring were employee-related items, primarily resulting from severance costs of $6.5 million and contract terminations on excess leased computer equipment and company cars for $428,000. All associated costs were paid by the end of the second quarter of 2008.

*Other Income (Expense)*

Interest income was $46.6 million in both 2007 and 2006. Our monthly average cash and investment balance was approximately $918.0 million and $990.2 million in 2007 and 2006, respectively. For 2007 and 2006, the average annualized interest rate that we earned on our investments was 5.1% and 4.7%, respectively.

Interest expense was $3.0 million and $22.2 million in 2007 and 2006, respectively. The expense in both periods is primarily related to the interest we paid on our 5% convertible subordinated debentures due 2007, which we repaid in full upon their maturity in February 2007.

Our ownership interest in BioSphere at December 31, 2007 was approximately 18% and we account for the investment under the equity method of accounting. Our share of equity loss was $507,000 and $422,000 in 2007 and 2006, respectively. The increase in equity losses is attributable to greater losses at BioSphere.

*Income Taxes*

Income tax expense was $6.3 million and $3.7 million in 2007 and 2006, respectively. Income tax expense in 2007 and 2006 includes Federal and state AMT, state income taxes and foreign income tax in 2007. Although we had Federal and state tax net operating loss carryforwards as of December 31, 2007 and 2006, the utilization of these loss carryforwards was limited in the calculation of AMT.

**Critical Accounting Policies**

A critical accounting policy is one that is both important to the portrayal of our financial condition and results of operations and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. While our significant accounting policies are more fully described in Note B "Summary of

Significant Accounting Policies" to the consolidated financial statements included in this Annual Report on Form 10-K, we believe the following accounting policies to be critical:

***Product Revenue Recognition:*** We recognize revenues from product sales, upon delivery, when title to product and associated risk of loss has passed to the customer and collectability is reasonably assured. We record revenues from product sales net of applicable allowances for returns, rebates and other applicable discounts and allowances.

The timing of product shipments and receipts can have a significant impact on the amount of revenues recognized in a period. Also, the majority of our products are sold through distributors. Revenue could be adversely affected if distributor inventories increased to an excessive level. If this were to happen, we could experience reduced purchases in subsequent periods, or product returns from the distribution channel due to overstocking, low end-user demand or product expiration. We have invested in resources to track channel inventories in order to prevent distributor inventories from increasing to excessive levels. If we determine that distributor inventories are at excessive levels, we do not recognize revenue for those shipments that we believe represent excessive inventory.

***Product Sales Allowances and Reserves:*** We record product sales net of the following significant categories of product sales allowances: payment term discounts, wholesaler fee-for-service discounts, government and commercial rebates and discounts (includes Medicaid discounts, Medicare discounts, managed care discounts, chargebacks and group purchasing organization, or GPO, contract discounts), returns and other discounts. Calculating each of these items involves significant estimates and judgments and requires us to use information from external sources. Based on known market events and trends, internal and external historical trends, third party data, customer buying patterns and up-to-date knowledge of contractual and statutory requirements, we believe we are able to make reasonable estimates of sales discounts.

1) *Payment Term Discounts*—We offer our direct purchase customers a 2% prompt-pay cash discount as an incentive to remit payment within the first 30 days after the date of the invoice. Prompt-pay discount calculations are based on the gross amount of each invoice. We account for these discounts by reducing sales by the 2% discount amount when product is sold, and apply earned cash discounts at the time of payment. Since we began selling our products commercially in 1999, our customers have routinely taken advantage of this discount. Based on common industry practices and our customers' overall payment performance, we accrue for cash discounts on product sales recorded during the period. We adjust the accrual to reflect actual experience as necessary, and historical adjustments have not been material. Based on our history of estimating payment term discounts and the low dollar exposure, we do not anticipate that changes to estimates will have a material impact on net sales.

2) *Wholesaler Fee- for-Service Discounts*—In both 2008 and 2007, we had agreements with certain wholesaler customers that provide these wholesalers with the opportunity to earn discounts in exchange for the performance of certain services. Our effective rate of wholesaler fee-for-service discounts applied across all product gross sales was approximately 1.4% and 1.8% in 2008 and 2007, respectively. The net decrease in the wholesaler fee-for service discounts is primarily related to credits earned in 2008 due to XOPENEX Inhalation Solution, LUNESTA and XOPENEX HFA gross price increases in that period. Our accruals for wholesaler fee-for-service discounts are based on actual data of product sales made to wholesale customers with agreements and not on estimates. If the percentage of gross sales sold to wholesalers with agreements increases, our liability related to these discounts could increase materially.

3) *Government Rebates and Contractual Discounts—*

*Medicaid Discounts*—We record accruals for rebates to be provided through the Medicaid Drug Rebate Program as a reduction of sales when the product is sold. We rebate individual states for all

eligible units purchased under the Medicaid program based on a rebate per unit calculation, which is driven off of our AMP. We estimate the expected rebate per unit to be used and adjust our rebate accruals based on expected changes in rebate pricing. We also examine the historical rebate trends and the trend of sales that become eligible for Medicaid programs and any changes expected to these trends. In addition, certain states have supplemental rebate programs, which provide such states with an additional rebate. Supplemental rebates, like rebates under the Medicaid Drug Rebate Program, are recorded as a reduction of sales when the product is sold. Rebate amounts are generally invoiced quarterly in arrears and paid thirty days after they are invoiced. As a result, our accrual consists of: (i) an estimate of the amount expected to be incurred for the current quarter's prescriptions; (ii) an accrual for prior quarters' unpaid rebates; and (iii) an accrual for estimated inventory in the distribution channel.

We recorded a provision for Medicaid rebates of 9.4% and 9.1% of gross sales in 2008 and 2007, respectively. The increase in Medicaid discounts primarily relates to discounts given on the sales of XOPENEX Inhalation Solution and XOPENEX HFA, partially off-set by a decrease in Medicaid discounts given on the sales of LUNESTA. The most significant estimate we make in connection with this accrual is the estimate of the number of Medicaid-eligible units in the distribution channel. With the exception of the potential errors in our determination of best price used to calculate Medicaid rebate amounts in periods prior to 2008, as described in more detail in Part I, Item 1 "Business—Government Regulation—Reimbursement", our estimates have been approximately 94% accurate in recent quarters. Although the actual Medicaid rebate may vary by more than 6% of the estimated eligible Medicaid units in future periods, we believe, based on prior experience, a 6% variation in our estimate is reasonably likely. A 6% understatement of Medicaid-eligible units at December 31, 2008 would have resulted in an additional provision of approximately $3.5 million.

*Medicare Discounts—Part B*—We record accruals for rebates to be provided through Medicare Part B programs as a reduction of sales when the product is sold. We established a Medicare Part B rebate program in order to increase the access by Medicare Part B beneficiaries to our XOPENEX Inhalation Solution product through Medicare Part B pharmacy providers, or MPPs. We estimate the expected rebate using historical data and by examining trends and expected changes in Medicare Part B codes. Medicare Part B payments are paid to MPPs primarily on a monthly basis. Accordingly, the provision typically relates to the activity over a one-month period and, as a result, the total provision consists of: (i) an estimate of the amount expected to be incurred for the current month's prescriptions; (ii) an accrual for prior months' unpaid rebates; and (iii) an accrual for estimated inventory in the distribution channel.

*Medicare Discounts—Part D*—Effective January 1, 2006, Medicare created a prescription drug benefit for its beneficiaries known as Medicare Part D. The CMS contracted with numerous health plans and prescription drug benefit plans to design and administer the drug benefit, including the development of a formulary that defines which products are covered and at what co-pay level. We pay rebates to certain Medicare Part D health plans and prescription drug plans on the utilization of LUNESTA, XOPENEX Inhalation Solution, XOPENEX HFA and BROVANA. XOPENEX Inhalation Solution and BROVANA have been, and we expect they will remain, subject to reimbursement under Medicare Part B resulting in minimal Medicare Part D utilization. Our accruals for Medicare Part D are estimated based on projected sales volumes through the contracted health and drug plans.

The provision for both Medicare rebates was 6.9% and 4.9% of gross sales in 2008 and 2007, respectively. The increase in both Medicare rebates is primarily due to an increase in discounts given on the sales of LUNESTA, XOPENEX HFA, XOPENEX Inhalation Solution and BROVANA. Actual Medicare discounts could change significantly in the future based on future Medicare reimbursement classifications. Based on the accuracy of our historic estimates we do not expect changes in estimates to have a material impact on net sales.

*Managed Care Discounts*—We have entered into agreements with certain MCOs whereby we provide agreed upon discounts to such entities based on the achievement of sales volume and/or market share purchasing targets. We record accruals for these discounts as a reduction of sales when product is sold based on discount rates and expected levels of sales volumes of these MCOs during a period. We estimate eligible sales based on historical amounts and sales trends and expected changes to these trends. Discounts are generally invoiced and paid quarterly in arrears. Accordingly, our accrual consists of: (i) the amount expected to be incurred for the current quarter's prescriptions, (ii) an accrual for prior quarters unpaid discounts; and (iii) an accrual for estimated inventory in the distribution channel.

The provision for MCO rebates was approximately 6.3% and 3.3% of gross sales in 2008 and 2007, respectively. The increase in MCO rebates is primarily related to an increase in discounts given through managed care programs on the sales of LUNESTA, XOPENEX HFA and XOPENEX Inhalation Solution.

Actual MCO discounts could exceed historical experience and our estimates of expected future participation in these programs. However, in part due to the fact that only a few organizations currently account for approximately 90% of our MCO discounts, our MCO discount estimates have historically been very similar to the actual MCO discounts. We expect that a small number of organizations will continue to account for substantially all of our MCO discounts for the foreseeable future and, therefore, do not expect significant changes to our MCO discount estimates in future periods.

*Chargebacks and GPO Contract Discounts*—We have entered into agreements with certain GPOs in which their members can purchase product from our wholesalers at a specified price. GPOs are organizations that represent a group of end buyers in the purchase of goods. These agreements involve the wholesalers who receive a stated margin on sales to GPOs. When the difference between the wholesaler's purchase price and the GPO's price creates a margin less than the amount agreed between us and the wholesaler, the wholesaler requests a credit, which is referred to as a chargeback. We record accruals for these discounts as a reduction of sales when product is sold. We estimate eligible sales based on a history of the average actual chargebacks and an average of the chargeback cycle time, which is the time from when a wholesaler sells to a GPO until we issue a credit to the wholesaler. We examine the history of sales which qualify for chargebacks and monitor sales trends and contractual changes. Our accrual consists of the amount expected to be incurred for the current sales in the calculated chargeback cycle, plus an accrual for estimated inventory in the distribution channel.

The provision for chargebacks and GPO contract credits was approximately 2.4% of gross sales in 2008 and 2007. Actual chargeback and GPO contract credits could exceed historical experience and our estimates of future participation in these programs. However, over the past few years, chargeback activity has been fairly stable with the exception of XOPENEX HFA, which currently has a limited number of chargeback contracts. Therefore, we do not expect significant variation between actual chargeback and GPO credits and our estimates.

4) *Returns*—Customers can return short-dated or expired product that meets the guidelines set forth in our returned goods policy. Product shelf-life from the date of manufacture for XOPENEX Inhalation Solution is 18 to 24 months, XOPENEX HFA is 24 months, LUNESTA is 24 to 36 months, BROVANA is 18 months, OMNARIS Nasal Spray is 24 months and ALVESCO HFA is 24 months. Returns are accepted from wholesalers and retail pharmacies. Customers can receive credit for returned product with six months or less of shelf life remaining and expired product within 12 months following the expiration date. We record an estimate for returns as reductions of revenue at the time product sales are recorded. We base our estimates of product returns on the percentage of returns that we have experienced historically, on a historical aging of the average time a return occurs from the time the product was sold and on key analytical measures such as the percentage of the outstanding pipeline covered by the returns reserve. For products with insufficient return history, we estimate by

examining data of similar drugs. For example, we utilized the return history of XOPENEX HFA in estimating a returns reserve for ALVESCO HFA. We may adjust our estimate of product returns if we are aware of other factors that we believe could significantly impact our expected return percentages. These factors include our estimate of inventory levels of our products in the distribution channel, the product shelf-life of the product we have shipped, competitive issues such as new product entrants and other known changes in sales trends.

The provision for returns was approximately 1.1% and 1.9% in 2008 and 2007, respectively. The decrease in our provision for returns is primarily attributable to lower actual returns related to XOPENEX Inhalation Solution, XOPENEX HFA and LUNESTA. Actual returns could exceed historical experience and our estimates of expected future returns due to factors such as wholesaler and retailer stocking patterns and inventory levels and/or competitive changes. Based on these factors, and as a result of fluctuations observed in prior periods, we believe it is reasonably likely that the actual returns provision percentage could vary from the estimated percentage within a range of up to 0.25%. If the returns provision percentage for each of these products had increased by 0.25% of gross sales in 2008, an additional provision of approximately $4.4 million would have been necessary.

Many of our accruals include an estimate of inventory in the distribution pipeline. At December 31, 2008, we believe a reasonable estimate of the value of our pipeline inventory in gross sales dollars is approximately $104.1 million for XOPENEX Inhalation Solution, $22.1 million for XOPENEX HFA, $126.3 million for LUNESTA, $7.4 million for BROVANA, $6.7 million for OMNARIS Nasal Spray and $20.7 million for ALVESCO HFA Inhalation Aerosol.

5) *Other Discounts*—At times we offer special programs and discounts to support the goal of making our products widely available. In 2008 and 2007, we utilized discount programs related to LUNESTA and XOPENEX HFA, and in 2008 we added programs related to OMNARIS Nasal Spray and ALVESCO HFA Inhalation Aerosol. These programs include, free product sample voucher programs under the LUNESTA 7-Night Challenge and the XOPENEX HFA voucher programs, as well as reduced co-pay coupon programs under the LUNESTA—Sleep and Save program, XOPENEX HFA, OMNARIS Nasal Spray and ALVESCO HFA Inhalation Aerosol coupon programs. Under the free product voucher programs, physicians give patients vouchers to obtain free samples of the prescribed drug from any retail pharmacy. We reimburse retail pharmacies for the cost of these products through a third-party administrator. We use the voucher program primarily in states where samples cannot be shipped directly to physicians. Under the reduced co-pay coupon programs, patients are given coupons to purchase the prescribed drug at a discount from any retail pharmacy. We reimburse retail pharmacies for these discounts through a third-party administrator. In 2007, we implemented a patient assistance program that was in place through the end of 2008, which provided LUNESTA, XOPENEX Inhalation Solution, XOPENEX HFA and BROVANA at no cost to those eligible patients who lacked prescription drug coverage and were unable to afford them. In 2008, our other discounts decreased as compared to 2007, which is largely the result of a decrease in our voucher and coupon programs related to XOPENEX HFA.

In each case mentioned above, we estimate the cost of reimbursement as a reduction of gross sales when the product is sold. In addition, we maintain an accrual for unused coupons and vouchers based on outstanding total coupons and vouchers and their historical usage rates and adjust this accrual whenever changes in such historical usage rate occurs. Each of these programs has a defined expiration date.

The following table summarizes activity in each of the above product sales allowances and reserve categories for the years ended December 31, 2008 and 2007:

| | Payment Terms Discount | Wholesaler Fee for Service | Government Rebates and Contractual Discounts | Returns | Other Discounts | Total |
|---|---|---|---|---|---|---|
| | | | (In Thousands) | | | |
| Balance at December 31, 2006 . . . | $ (4,351) | $(16,669) | $(126,233) | $(23,218) | $ (1,511) | $(171,982) |
| Current provision: | | | | | | |
| Current year . . . . . | (31,939) | (29,086) | (312,049) | (29,606) | (14,791) | (417,471) |
| Prior year . . . . . | — | 457 | (637) | — | 440 | 260 |
| Total . . . . . | (31,939) | (28,629) | (312,686) | (29,606) | (14,351) | (417,211) |
| Actual: | | | | | | |
| Current year . . . . . | 27,773 | 19,063 | 175,373 | 2,142 | 12,629 | 236,980 |
| Prior year . . . . . | 4,378 | 14,123 | 56,813 | 26,331 | 590 | 102,235 |
| Total . . . . . | 32,151 | 33,186 | 232,186 | 28,473 | 13,219 | 339,215 |
| Balance at December 31, 2007 . . . | $ (4,139) | $(12,112) | $(206,733) | $(24,351) | $ (2,643) | $(249,978) |
| Current provision: | | | | | | |
| Current year . . . . . | (34,639) | (24,897) | (447,973) | (19,213) | (11,156) | (537,878) |
| Prior year . . . . . | — | — | (9,444) | — | — | (9,444) |
| Total . . . . . | (34,639) | (24,897) | (457,417) | (19,213) | (11,156) | (547,322) |
| Actual: | | | | | | |
| Current year . . . . . | 31,116 | 14,484 | 307,684 | 6,968 | 9,657 | 369,909 |
| Prior year . . . . . | 3,912 | 11,046 | 116,557 | 13,369 | 2,168 | 147,052 |
| Total . . . . . | 35,028 | 25,530 | 424,241 | 20,337 | 11,825 | 516,961 |
| Balance at December 31, 2008 . . . | $ (3,750) | $(11,479) | $(239,909) | $(23,227) | $ (1,974) | $(280,339) |

***Royalty Revenue Recognition:*** Royalty revenue is recognized based upon estimates of sales of products including our licensed intellectual property in licensed territories in the period in which the sales occur or at the time we received the royalty payment. Royalty revenue estimates are derived when possible from information from the company paying the royalty, or from historical data and third-party prescription data. Changes in market conditions, such as the introduction of competitive products, can lead to significant deviations from historical patterns and therefore cause estimates to be inaccurate. When estimates differ from actual results, the difference is recognized in the following quarter, provided the difference is not material to the results of either quarter. Historically, our estimates have not materially differed from our actual results.

***License Fee Revenue Recognition:*** We have entered into collaborative agreements with other pharmaceutical companies for the development and commercialization of our eszopiclone product outside of the United States, Canada and Mexico. The terms of these agreements involve multiple deliverables by us, such as license rights, development services and clinical and commercial supply, in exchange for consideration to us in the form of non-refundable license fees, non-refundable contingent milestones, out-of-pocket cost reimbursements, and royalties on net product sales. Our revenue recognition policy for all multiple revenue-generating arrangements are in accordance with the guidance provided in the SEC's Staff Accounting Bulletin, or SAB, No. 101, *Revenue Recognition in Financial Statements*, as amended by SAB No. 104, *Revenue Recognition*, and Emerging Issues Task Force, or EITF, Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables,* or SAB, No. 101.

***Accounts Receivable and Bad Debt:*** Our trade receivables in 2008 and 2007 primarily represent amounts due to us from wholesalers, distributors and retailers of our pharmaceutical products. We perform ongoing credit evaluations of our customers and generally do not require collateral. Bad debt write-offs were not significant in 2008, 2007 and 2006; however, they could be significant in the future and we monitor our receivables closely because a few customers make up a large portion of our overall revenues. In 2008 and 2007, our top four customers accounted for approximately 84% and 87%, respectively, of our total revenues.

***Impairment of Goodwill and Intangible Assets:*** SFAS No. 142, *Goodwill and Other Intangible Assets*, or SFAS 142, requires that we annually review goodwill and other intangible assets that have indefinite lives for impairment and when events or changes in circumstances indicate the carrying value of these assets might exceed their current fair values. The fair value of our reporting units has been determined by the income approach using the excess cash flow method and a discount rate of 13%, which requires us to make certain assumptions and estimates regarding industry economic factors and future profitability of acquired businesses. It is our policy to allocate goodwill and conduct impairment testing based on our most current business plans, which reflect changes we anticipate in the economy and the pharmaceutical industry. If actual results are not consistent with our assumptions and judgments, we could be exposed to a material impairment charge.

***Impairment of Long-Lived Assets:*** We review our long-lived assets for impairment in accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, or SFAS 144, whenever events or changes in circumstances indicate the undiscounted cash flow estimated to be generated by those assets is less than the assets' carrying amount. Any change in the carrying amount of an asset as a result of our evaluation is separately identified in the consolidated statements of operations in the period that the impairment occurs.

***Other-Than-Temporary Impairments of Available-For-Sale Investments:*** A decline in the market value of any available-for-sale investments below its cost that is deemed to be other-than-temporary results in a reduction in carrying amount to fair value. The impairment is charged to operations and a new cost basis for the security established. The determination of whether an available-for-sale marketable security is other-than-temporarily impaired requires significant judgment and requires consideration of available quantitative and qualitative evidence in evaluating the potential impairment. Factors evaluated to determine whether the investment is other-than-temporarily impaired include: significant deterioration in the issuer's earnings performance, credit rating, asset quality, business prospects of the issuer, adverse changes in the general market conditions in which the issuer operates, length of time that the fair value has been below our cost, our expected future cash flows from the security and our intent and ability to retain the investment for a sufficient period of time to allow for recovery in the market value of the investment. Assumptions associated with these factors are subject to future market and economic conditions, which could differ from our assessment. During 2008, we determined that our investment in ACADIA had sustained other-than-temporary impairments and, as a result, we recognized impairment losses of $14.4 million, which were recorded as other expense in the consolidated statement of operations.

***Fair Value Measurement:*** Effective January 1, 2008, we partially adopted SFAS 157. SFAS 157 defines fair value, establishes a framework and gives guidance regarding the methods used for measuring fair value and expands disclosures about fair value measurements. In February 2008, the FASB released a FASB Staff Position, or FSP, No. 157-2, *Effective Date of FASB Statement No. 157*, or FSP 157-2, which delays the effective date of SFAS 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually).

We have not adopted SFAS 157 as it relates to goodwill and other intangible assets due to the delay allowed by FSP 157-2. We do not expect that the adoption of this standard for non-financial

assets and liabilities will have a significant impact on our consolidated financial position, results of operations or cash flows. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability, in an orderly transaction between market participants at the measurement date. Fair value is based upon quoted market prices, where available. Where quoted market prices or other observable inputs are not available, we apply valuation techniques to estimate fair value. SFAS 157 establishes a three-level valuation hierarchy for disclosure of fair value measurements. The three levels of the hierarchy are defined as follows:

Level 1—Inputs to the valuation methodology are quoted market prices for identical assets or liabilities in active markets. The types of assets measured at fair value using Level 1 inputs include our publicly traded equity investments with quoted market prices and money market funds.

Level 2—Inputs include quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability (i.e., interest rates, yield curves, etc.) and inputs that are derived principally from or corroborated by observable market data by correlation or other means (market corroborated inputs). The types of assets measured at fair value using Level 2 inputs include our publicly traded debt securities and other marketable securities with quoted market prices, which are in markets that are considered less active.

Level 3—Inputs to the valuation methodology are unobservable inputs based on management's best estimate of inputs market participants would use in pricing the asset or liability at the measurement date, including assumptions about risk. The types of assets measured at fair value using Level 3 inputs include auction-rate securities where the auctions have failed.

***Inventory Write-Downs:*** Inventory represents bulk material, work-in-process and finished goods relating to our commercial products on hand, valued at lower of cost or market value. Inventories are reviewed periodically for slow-moving or obsolete status based on sales activity, both projected and historical, and through a review of the expiration dates. Our current sales projections provide for full utilization of the inventory balance. If product sales levels differ from projections, inventory may not be fully utilized and could be subject to impairment, at which point we would write down the value of the inventory to its net realizable value.

We expense costs relating to inventory as research and development expense until such time as we receive an approval letter from the FDA for a new product, and then we begin to capitalize the inventory costs relating to that product.

***Share-Based Compensation:*** On January 1, 2006, we adopted SFAS 123(R), which requires measurement and recognition of compensation expense for all share-based payment awards made to employees and directors. Under SFAS 123(R), the fair value of share-based payment awards is estimated at the grant date using an option pricing model, and the portion that is ultimately expected to vest is recognized as compensation cost over the requisite service period. We use the Black-Scholes option-pricing model, which uses both historical and current market data to estimate the fair value. This method incorporates various assumptions such as the risk-free interest rate, expected volatility, expected dividend yield and expected life of the options.

***Research and Development Expenses:*** We expense internal and external research and development costs, including costs of funded research and development arrangements, in the period incurred. We also expense the cost of purchased technology in the period of purchase if we believe that the technology has not demonstrated technological feasibility and that it does not have an alternative future use.

***Purchased In-Process Research and Development Expenses:*** Purchased IPR&D represents the estimated fair value assigned to research and development projects acquired in a purchase business

combination or asset acquisition that have not been completed at the date of acquisition and which have no alternative future use. Accordingly, these costs are charged to expense as of the acquisition date.

**Recent Accounting Pronouncements**

See Note B "Summary of Significant Accounting Policies" to the consolidated financial statements for a description of recent accounting pronouncements including the expected dates of adoption and effects on our results of operations, financial position and cash flows.

**Liquidity and Capital Resources**

Our liquidity requirements have historically consisted of research and development expenses, sales and marketing expenses, in-licensing fees, capital expenditures, working capital, debt service and general corporate expenses. Historically, we have funded these requirements and the growth of our business primarily through convertible subordinated debt offerings, the issuance of common stock, including the exercise of stock options, sales of our products and license agreements for our drug compounds. Although we may use one or more of these financing mechanisms in the future, we now expect to fund our liquidity requirements primarily with operating profits generated from product sales. We also believe we have the ability to meet our short-term liquidity needs through the use of our cash and short-term investments on hand at December 31, 2008.

As of December 31, 2008, our total convertible debt was approximately $530.5 million: $148.0 million of outstanding 0% Series B notes due December 2010 and $382.5 million of outstanding 0% notes due 2024.

During the second half of 2008, we repurchased and retired, at our option in privately negotiated transactions, an aggregate of $117.6 million principal amount of our 0% notes due 2024. We paid a total of $106.9 million in cash to repurchase these notes. In December 2008, we repaid in full the entire $72.8 million principal amount of our 0% Series A notes due 2008.

On February 17, 2009, we announced that we commenced a tender offer to purchase for cash up to all $382.5 million aggregate principal amount of our outstanding 0% notes due 2024. We are offering to purchase the notes at a price of $970 for each $1,000 of principal amount of notes tendered, or a total of $371.0 million if all outstanding 0% notes due 2024 are repurchased. The tender offer will expire at midnight, New York City time, at the end of March 16, 2009, unless extended or earlier terminated pursuant to the terms of the tender offer. The tender offer will not be contingent upon any minimum number of notes being tendered but will be subject to certain conditions described in the Offer to Purchase. Our 0% notes due 2024 that are not repurchased by us pursuant to the tender offer may be converted into cash at the option of the noteholders in October 2009, 2014, 2019 and 2024, as well as under certain conditions.

At December 31, 2008, $70.9 million of our investment portfolio was invested in AAA rated auction-rate securities. These investments were rated AAA by one or more rating agency. Auction-rate securities are long-term variable rate bonds tied to short-term interest rates. After the initial issuance of the securities, the interest rate on the securities is reset periodically, at intervals established at the time of issuance (primarily every 28 days), based on market demand for a reset period. Auction-rate securities are bought and sold in the marketplace through a competitive bidding process often referred to as an auction. If there is insufficient interest in the securities at the time of an auction, the auction may not be completed and the rates may be reset to predetermined "penalty" or "maximum" rates.

Substantially all of our auction-rate securities are backed by pools of student loans guaranteed by the FFELP and we continue to believe that the credit quality of these securities is high based on this guarantee and other collateral. Auctions for these securities began failing in the first quarter of 2008

and continued to fail throughout the remainder of the year, which we believe is a result of the recent uncertainties in the credit markets. Consequently, the investments are not currently liquid, and we will not be able to access these funds until a future auction of these investments is successful, a buyer is found outside of the auction process, the security is called, or the underlying securities have matured. At the time of our initial investment and through the date of this report, all of our auction-rate securities remain AAA rated by one or more rating agency. We believe we have the ability to hold these investments until the lack of liquidity in these markets is resolved. As a result, we continue to classify the entire balance of auction-rate securities as non-current available-for-sale investments at fair value on our consolidated balance sheets.

Typically, the fair value of auction-rate securities investments approximates par value due to the frequent resets through the auction process. While we continue to earn interest on our auction-rate securities investments at the contractual rate, these investments are not currently trading and therefore do not have a readily determinable market value. Accordingly, the estimated fair value of the auction-rate securities no longer approximates par value.

At December 31, 2008, because of the temporary declines in fair value for the auction-rate securities, which we attribute to liquidity matters rather than credit issues as discussed above, we have classified our auction-rate securities at Level 3, as defined under the SFAS 157 framework and described in Note E "Fair Value Measurements", of our consolidated financial statements included in this Annual Report on Form 10-K, with a fair value of $70.9 million. The fair value of these auction-rate securities is estimated utilizing a trinomial discounted cash flow analysis, which was compared, when possible, to other observable market data or inputs with similar characteristics. The assumptions used in preparing the discounted cash flow analysis include estimates for the maximum interest rate, the probability of passing, failing or default at each auction, the severity of default and the discount rate. Based on this assessment of fair value, as of December 31, 2008, we determined there was a decline in fair value of our auction-rate securities investments of $8.7 million, which was deemed temporary on the basis that substantially all of our auction-rate securities are backed by pools of student loans guaranteed by FFELP, and we continue to believe that the credit quality of these securities is high based on this guarantee and other collateral. The decline in the fair value of our auction-rate securities investments was primarily the result of the assumed delay in the return of liquidity to this investment market-sector. If current market conditions deteriorate further, we may be required to record additional unrealized losses in other comprehensive income. If the credit ratings of the security issuers deteriorate or the anticipated recovery in market values does not occur, we may be required to adjust the carrying value of these investments through impairment charges recorded to earnings, as appropriate, which could be material.

Cash, cash equivalents and short- and long-term investments totaled $765.8 million, or 42% of total assets, at December 31, 2008, compared to $1.1 billion, or 76% of total assets, at December 31, 2007.

Net cash provided by operating activities for the year ended December 31, 2008 was $162.8 million, which includes net income of $515.1 million. Our net income includes non-cash adjustments of $280.9 million, consisting primarily of the release of the tax valuation allowance, research and development in-process upon acquisition, share-based compensation, impairment on investments, gain on extinguishment of debt, interest accretion on license fee liabilities and depreciation and amortization expense. Accounts receivable increased by $16.2 million primarily due to the timing of our sales. Inventory on hand increased by $14.2 million primarily due to the replenishment of depleted XOPENEX Inhalation Solution inventory, in addition to inventory recorded in connection with the SPI acquisition. Other assets increased by $17.1 million, which is primarily a result of an increase in prepaid expenses and a change in our other receivables. Accrued expenses decreased by $58.6 million primarily due to the $75.0 million upfront payment we paid to Bial in January 2008. Product sales allowances and

reserves increased by $30.8 million primarily due to rebates related to LUNESTA, XOPENEX HFA and BROVANA product sales.

Net cash provided by investing activities for the year ended December 31, 2008 was $44.2 million, which is primarily attributable to the net purchase, sale and maturities of short- and long-term investments of $299.7 million offset by the purchase of intangible assets from Nycomed for $150.0 million, the acquisition and related costs associated with Oryx for $55.0 million, and the purchases of property and equipment of $49.6 million.

Net cash used in financing activities for the year ended December 31, 2008 was $173.1 million. We used $179.7 million to repurchase and retire an aggregate of $117.6 million and $72.8 million principal amount of our 0% notes due 2024 and 0% notes due 2008, respectively, as well as $1.1 million for capital lease obligations. These amounts were partially offset by receipts of $6.9 million from issuing common stock upon the exercise of stock options issued under our stock option plans.

We believe our existing cash and the cash flow that we anticipate from operations will be sufficient to support existing operations through at least the next twelve months. In the longer term, we expect to continue to fund our existing operations with operating profits generated from product sales. Our actual future cash requirements and our ability to generate revenue, however, will depend on many factors, including:

- LUNESTA sales;
- XOPENEX Inhalation Solution and XOPENEX HFA sales;
- BROVANA sales;
- successful commercialization of OMNARIS Nasal Spray and ALVESCO HFA Inhalation Aerosol;
- successful acquisition of technologies, product candidates, approved products and/or businesses;
- successful expansion into foreign markets;
- our ability to establish and maintain additional strategic alliances and licensing arrangements;
- whether our debt due in 2010 will be paid in cash rather than converted into common stock pursuant to the terms of such debt;
- the amount, if any, of 0% notes due 2024 that are repurchased pursuant to our outstanding tender offer or, if not repurchased by us, are converted into cash by the holders in October 2009;
- progress of our preclinical and clinical research programs and the number and breadth of these programs;
- progress of our development efforts and the development efforts of our strategic partners;
- achievement of milestones under our strategic alliance arrangements;
- royalties from agreements with parties to which we have licensed our technology;
- the outcome of pending litigation, including patent infringement litigation, litigation related to generic competition and/or any possible future litigation; and
- the possible future "at risk" launch of generic versions of our products.

If our assumptions underlying our beliefs regarding future revenues and expenses change, or if opportunities or needs arise, we may seek to raise additional cash by selling debt or equity securities or

otherwise borrowing money. However, we may not be able to raise such funds on favorable terms, if at all.

Based on our current operating plan, we believe that we will not be required to raise additional capital to fund the repayments of our outstanding convertible debt when due, although we may choose to do so. However, if holders of our 0% notes due 2024 do not trade and/or we do not repurchase all of these notes pursuant to our outstanding tender offer and if some or all of our significant contingent payments become due and payable under our collaboration agreements, we may not be able to make the required payment upon future conversion of the notes. In addition, if we are not able to successfully continue to grow our revenues and properly manage our expenses, it is likely that our business would be materially and adversely affected and that we would be required to raise additional funds in order to repay our outstanding convertible debt. The current economic crisis has severely diminished the availability of capital. The cost and terms of any such future financing is unclear and we can provide no assurance that we will be able to raise additional funds on terms acceptable to us, if at all.

*Acquisition Strategy*

In 2008, we utilized an aggregate of $281.0 million in cash to make upfront payments in connection with our transactions with Bial, Nycomed, Arrow and the former shareholders of Oryx. In addition to these upfront payments we have committed to make future payments to these parties, which are described below under the heading "Contractual Obligations."

As part of our business strategy, we plan to continue to consider and, as appropriate, make acquisitions of other businesses, approved products, product candidates and/or technologies. Our cash reserves and other liquid assets may be inadequate to consummate these acquisitions and it may be necessary for us to raise substantial additional funds and/or issue shares of our capital stock in the future to consummate these transactions. In addition, as a result of our acquisition efforts, we are likely to experience significant charges to earnings for acquisitions and related expenses (whether or not our efforts are successful) that may include transaction costs and closing costs.

**Contractual Obligations**

Contractual obligations represent future cash commitments and liabilities under agreements with third parties and exclude contingent liabilities for which we cannot reasonably predict future payment, including contingencies related to potential future development, financing and/or commercial milestone payments under collaboration agreements. The following chart summarizes our material contractual obligations as of December 31, 2008:

| Contractual Obligations | Total | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 and beyond |
|---|---|---|---|---|---|---|---|
| | | | (In Thousands) | | | | |
| Convertible subordinated debt—principal(1) | $530,470 | $382,450 | $148,020 | $ — | $ — | $ — | $ — |
| Arrow—Levalbuterol/ipratropium(2) | 70,000 | 25,000 | 25,000 | — | 20,000 | — | — |
| Arrow—Ciclesonide(3) | 47,500 | 12,500 | 15,000 | — | — | 2,500 | 17,500 |
| Capital lease obligations | 1,553 | 1,242 | 311 | — | — | — | — |
| Operating leases(4) | 5,780 | 1,988 | 1,524 | 1,394 | 674 | 200 | — |
| Purchase obligations(5) | 116,629 | 104,579 | 7,668 | 3,622 | 760 | — | — |
| Total material contractual cash obligations(6) | $771,932 | $527,759 | $197,523 | $5,016 | $21,434 | $2,700 | $17,500 |

(1) $148.0 million of the 0% notes due 2010 may be converted into common stock. To the extent it is converted, such amounts would no longer be a contractual cash obligation. On February 17, 2009,

we announced that we commenced a tender offer to purchase for cash up to all $382.5 million aggregate principal amount of our outstanding 0% notes due 2024. We are offering to purchase the notes at a price of $970 for each $1,000 of principal amount of notes tendered. The tender offer will expire at midnight, New York City time, at the end of March 16, 2009, unless extended or earlier terminated pursuant to the terms of the tender offer. Our 0% notes due 2024 that are not repurchased by us pursuant to the tender offer may be converted into cash at the option of the noteholders in October 2009, 2014, 2019 and 2024, as well as under certain conditions. Our 0% notes due 2024 are classified as current liabilities and presented as a 2009 contractual obligation because holders have a right to require us to repurchase the notes beginning in 2009.

(2) See Note H "Goodwill and Intangible Assets" to our consolidated financial statements included with this report relating to future payments to Arrow under the Levalbuterol/ipratropium Product agreement. The 2012 amount represents $20.0 million in future payments, the timing of which is based upon management's best estimate and assumptions and could shift from period to period. The amounts in the table do not include a potential $23.5 million payment in the fourth quarter of 2009 in the event Arrow exercises its option to receive a lump sum discounted amount in lieu of ongoing royalty payments.

(3) See Note H "Goodwill and Intangible Assets" to our consolidated financial statements included with this report relating to future payments under the agreement with Arrow regarding the Ciclesonide Products. The 2009, 2010, 2013 and 2014 and beyond amounts include $2.5 million, $5.0 million, $2.5 million and $17.5 million, respectively, in future payments, the timing of which is based upon management's best estimate and assumptions and could shift from period to period. The amounts in the table do not include a potential aggregate payment of up $37.9 million in the fourth quarter of 2009 in the event Arrow exercises its options to receive a lump sum discounted amount in lieu of ongoing royalty payments.

(4) Operating leases include our leased facilities obligations.

(5) Purchase obligations relate to research and development commitments for new and existing products and open purchase orders for the acquisition of goods and services in the ordinary course of business. Our obligation to pay certain of these amounts may be reduced or eliminated based on certain future events.

(6) In addition to the material contractual cash obligations included in this chart, we have committed to make potential future milestone payments to third parties as part of licensing, distribution and development agreements. Payments under these agreements generally become due and payable only upon achievement of certain development, regulatory and/or commercial milestones. For example, Nycomed, Bial and the former shareholders of Oryx may become entitled to receive subsequent payments of up to $280.0 million, $90.0 million and $20.0 million, respectively, if all milestones are met. Because the achievement of these milestones is neither probable nor reasonably estimable, such contingent payments have not been recorded on our consolidated balance sheets and have not been included in this chart.

This table also excludes approximately $24.7 million pertaining to uncertain tax positions as we cannot make a reliable estimate of the period of cash settlement with the respective taxing authorities.

**Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements, other than operating leases in the normal course of business, or variable interest entities or activities that include non-exchange-traded contracts accounted for at fair value.

**Item 7A. Quantitative and Qualitative Disclosure about Market Risk.**

We are exposed to market risk from changes in interest rates and equity prices, which could affect our future results of operations and financial condition. We manage our exposure to these risks through our regular operating and financing activities.

*Interest Rates:* Our cash and cash equivalents consist of cash, money market funds, and short-term investments with original maturities of three months or less. Our short-term investments consist of U.S. government securities, certificates of deposits, corporate commercial paper, corporate bonds, and asset-backed securities. As of December 31, 2008 the carrying value of our cash and cash equivalents and short-term investments of $629.3 million and $62.4 million, respectively, approximated fair value. Due to the conservative nature and relatively short duration of these investments, interest rate risk is mitigated. Our interest income, however, is sensitive to changes in the general level of interest rates and would decrease in a declining interest rate environment.

Our long-term investments consist of equity securities and auction rate securities with carrying values of $3.3 million and $70.9 million, respectively, which approximate fair value. Auction rate securities are long-term variable rate bonds tied to short-term interest rates. After the initial issuance of the securities, the interest rate on the securities is reset periodically, at intervals established at the time of issuance (primarily every 28 days), based on market demand for a reset period. Auction-rate securities are bought and sold in the marketplace through a competitive bidding process referred to as an auction. If there is insufficient interest in the securities at the time of an auction, the auction may not be completed and the rates may be reset to predetermined "penalty" or "maximum" rates.

Substantially all of our auction rate securities are backed by pools of student loans guaranteed by the FFELP and we continue to believe the credit quality of these securities is high based on this guarantee and other collateral. Auctions for these securities began failing in the first quarter of 2008 and continued to fail throughout the remainder of 2008, which we believe is a result of the recent uncertainties in the credit markets. Consequently, the investments are not currently liquid, and we will not be able to access these funds until a future auction of these investments is successful, a buyer is found outside of the auction process, the security is called, or the underlying securities have matured. If the credit ratings of the security issuers deteriorate, the anticipated recovery in market values does not occur or we need funds from the auction-rate securities to meet working capital needs, we may be required to adjust the carrying value of these investments through impairment charges recorded to earnings.

Our investment policy specifies credit quality standards for our investments, and our investment portfolio is monitored for compliance with our investment policy. The primary objective of the investment policy is the preservation of capital. Due to the conservative nature and relatively short duration of our overall investments portfolio, credit and interest rate risk is mitigated.

The interest rates on our convertible senior subordinated notes due 2010 and 2024 are fixed at 0%. Hence, these instruments are not exposed to significant interest rate risk. The aggregate fair value of these convertible notes of $468.8 million is less than the corresponding carrying value of $530.5 million as of December 31, 2008. Declining interest rates would increase the fair value of these convertible notes.

*Equity Prices:* Our convertible subordinated debt is sensitive to fluctuations in the price of our common stock into which the debt is convertible. Changes in equity prices could result in changes in the fair value of our convertible subordinated debt due to the difference between the current market price of the debt and the market price at the date of issuance of the debt. Based on the historical volatility of our common stock and the excess of the conversion prices over the current price of our common stock, however, a change in the price of our common stock of 10% would not have a material effect on the fair value of our convertible notes.

## Item 8. Financial Statements and Supplementary Data.

The financial statements and schedules required by this item are filed as Appendix A hereto and are listed under Item 15 below.

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

There have been no disagreements with our independent registered public accounting firm on accounting and financial disclosure matters.

## Item 9A. Controls and Procedures.

### Disclosure Controls and Procedures

Our management has carried out an evaluation, under the supervision and with the participation of our President and Chief Executive Officer and Executive Vice President and Chief Financial Officer of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2008. The term "disclosure controls and procedures," as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 means controls and other procedures of a company that are designed to ensure that information required to be disclosed in the reports that the company files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal financial officers, as appropriate, to allow timely decisions regarding required disclosure. There are inherent limitations to the effectiveness of any system of disclosure controls and procedures, including the possibility of human error and the circumvention or overriding of the controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based upon our management's evaluation, the President and Chief Executive Officer and Executive Vice President and Chief Financial Officer have concluded that, as of December 31, 2008, our disclosure controls and procedures were effective at the reasonable assurance level.

### Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting as defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Exchange Act, is a process designed under the supervision of our President and Chief Executive Officer and Executive Vice President and Chief Financial Officer to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external reporting purposes in accordance with generally accepted accounting principles.

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

Our management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2008. In making its assessment, management has utilized the criteria set forth by the Committee of Sponsoring Organizations (COSO) of the Treadway Commission in *Internal Control—Integrated Framework.* Management concluded that, based on its assessment, our internal control over financial reporting was effective as of December 31, 2008 based on those criteria.

The effectiveness of our internal control over financial reporting as of December 31, 2008 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which appears on page F-2 of Appendix A to this Annual Report on Form 10-K.

**Remediation of Material Weakness**

During the quarter ended December 31, 2008, we completed the evaluation of the design and tested the operating effectiveness of the policies and procedures and related controls that we implemented to remediate the material weakness described below. Based on this review and testing, we believe the material weakness is now remediated.

During the twelve months ended December 31, 2008, we engaged in substantial efforts to implement new controls and enhance existing controls to remediate the material weakness related to the process we used to identify transactions with the potential to establish a new Medicaid best price, which affected the accuracy of our net revenue and product sales allowances and reserve accounts. Specifically, our controls over the calculation of Medicaid rebates were not designed to effectively monitor whether certain entities were appropriately exempt from the Medicaid best price calculation.

**Changes in Internal Control Over Financial Reporting**

During the three months ended December 31, 2008, we finalized the implementation and enhancement of the controls we use to identify transactions with the potential to establish a new Medicaid best price. We also completed our evaluation of the design and tested the operating effectiveness of those controls. The culmination of these changes, which are summarized as follows, were the only material changes in our internal control over financial reporting during the quarter ended December 31, 2008 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting:

- polices and procedures related to the accurate determination of the lowest commercial price that is not excludable from Medicaid rebate best price liability and the final review and approval of these determinations by senior management;
- manual and automated procedures for determining the eligibility of entities seeking access to PHS pricing;
- quarterly communications to CMS on our methodology used to determine best price and our best price results;
- monthly meetings between our contracting group and the accounting/finance group to ensure that appropriate and collaborative communications occur around the determination of best price and other price reporting and related contracting issues; and
- reconciliations of chargeback and rebate information maintained in our sub-ledgers to our Oracle enterprise resource planning system.

**Item 9B. Other Information.**

None.

## PART III

**Items 10-14.**

We have included information about our executive officers in Part I of this report under the caption "Executive Officers of the Registrant."

The information required by Part III, Items 10-14 of this report is incorporated by reference from our definitive proxy statement for our 2009 Annual Meeting of Stockholders. Such information will be contained in the sections of such proxy statement captioned "Stock Ownership of Certain Beneficial Owners and Management," "Proposal 1—Election of Directors," "Directors, Executive Officers and Corporate Governance," "Information about Executive Officer and Director Compensation," "Certain Relationships and Related Transactions, and Director Independence," "Other Matters—Section 16(a) Beneficial Ownership Reporting Compliance."

In December 2008, our board of directors approved a code of conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer and controller, and persons performing similar functions. The new code of conduct and ethics encompasses and supersedes the code of conduct and ethics previously adopted by our board of directors in March 2004 and now includes, among other things, adherence to the revised pharmaceutical research manufacturers association, or PhRMA, code on interactions with healthcare professionals. We have posted our code of business conduct and ethics, and intend to disclose any amendments to, or waivers from, the code, on our web site, which is located at *www.sepracor.com* in the corporate governance section.

## PART IV

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

The following documents are included in this Annual Report on Form 10-K.

1. The following financial statements (and related notes) of the Company are included as Appendix A hereto and are filed as part of this Annual Report on Form 10-K:



2. The schedule listed below is filed as part of this report:



All other schedules are omitted as the information required is inapplicable or the information is presented in the consolidated financial statements or the related notes.

3. The Exhibits listed in the Exhibit Index immediately preceding the Exhibits are filed as a part of this Annual Report on Form 10-K.

The following trademarks are mentioned in this report:

Sepracor, LUNESTA, XOPENEX, XOPENEX HFA and BROVANA are registered trademarks of Sepracor. OMNARIS is a trademark and ALVESCO is a registered trademark of Nycomed GmbH. This report also contains trademarks of other companies.

## 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.

SEPRACOR INC.

By: /s/ ADRIAN ADAMS
Adrian Adams
*President and Chief Executive Officer*

Date: February 27, 2008

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

| Name | Title | Date |
|---|---|---|
| /s/ ADRIAN ADAMS<br>Adrian Adams | President, Chief Executive Officer and Director (Principal Executive Officer) | February 27, 2008 |
| /s/ ROBERT F. SCUMACI<br>Robert F. Scumaci | Executive Vice President and Chief Financial Officer (Principal Financial Officer) | February 27, 2008 |
| /s/ TIMOTHY J. BARBERICH<br>Timothy J. Barberich | Chairman and Director | February 27, 2008 |
| /s/ DIGBY W. BARRIOS<br>Digby W. Barrios | Director | February 27, 2008 |
| /s/ ROBERT J. CRESCI<br>Robert J. Cresci | Director | February 27, 2008 |
| _____<br>James F. Mrazek | Director | February 27, 2008 |
| /s/ LISA RICCIARDI<br>Lisa Ricciardi | Director | February 27, 2008 |
| /s/ TIMOTHY J. RINK<br>Timothy J. Rink | Director | February 27, 2008 |
| /s/ ALAN A. STEIGROD<br>Alan A. Steigrod | Director | February 27, 2008 |

## APPENDIX A

## INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

## Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Sepracor Inc.:

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, stockholders' equity (deficit) and comprehensive income, and of cash flows present fairly, in all material respects, the financial position of Sepracor Inc. and its subsidiaries (collectively, the "Company") at December 31, 2008 and 2007, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2008 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the accompanying index, Appendix A, presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements and financial statement schedule, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express opinions on these financial statements, on the financial statement schedule, and on the Company's internal control over financial reporting based on our integrated 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 audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included 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, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

As disclosed in Note B to the consolidated financial statements, the Company changed the manner in which it accounts for uncertain income tax positions in 2007.

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

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

/s/ PricewaterhouseCoopers LLP
Boston, MA
February 27, 2009

## SEPRACOR INC.
## CONSOLIDATED BALANCE SHEETS

| | December 31, 2008 | December 31, 2007 |
|---|---|---|
| | (In Thousands, Except Par Value Amounts) | |
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 629,255 | $ 598,929 |
| Short-term investments | 62,376 | 292,659 |
| Accounts receivable, net of allowances of $4,619 and $4,599 at December 31, 2008 and 2007, respectively | 177,457 | 159,644 |
| Inventories | 69,003 | 53,125 |
| Deferred tax asset | 126,965 | — |
| Other current assets | 34,254 | 26,948 |
| Total current assets | 1,099,310 | 1,131,305 |
| Long-term investments | 74,199 | 174,031 |
| Property and equipment, net | 117,072 | 87,308 |
| Intangible assets, net | 154,936 | 501 |
| Goodwill | 19,898 | — |
| Deferred tax asset | 343,518 | — |
| Other assets | 6,142 | 11,581 |
| Total assets | $1,815,075 | $ 1,404,726 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 20,429 | $ 17,317 |
| Accrued expenses | 146,109 | 210,109 |
| Current portion of long-term debt | 383,612 | 73,962 |
| Product sales allowances and reserves | 276,589 | 245,839 |
| Other current liabilities | 37,903 | 6,887 |
| Total current liabilities | 864,642 | 554,114 |
| Long-term debt | 148,326 | 649,463 |
| Deferred tax liabilities | 5,577 | — |
| Other liabilities | 87,908 | 24,736 |
| Total liabilities | 1,106,453 | 1,228,313 |
| Commitments and contingencies (Notes J, K and L) | | |
| Stockholders' equity (deficit): | | |
| Preferred stock, $1.00 par value, 1,000 shares authorized, none outstanding at December 31, 2008 and 2007 | — | — |
| Common stock, $.10 par value, 240,000 shares authorized at December 31, 2008 and 2007; 113,357 and 111,955 shares issued; 109,096 and 107,694 shares outstanding, at December 31, 2008 and 2007, respectively | 11,335 | 11,195 |
| Treasury stock, at cost (4,261 shares at December 31, 2008 and 2007) | (232,028) | (232,028) |
| Additional paid-in capital | 1,905,627 | 1,858,775 |
| Accumulated deficit | (956,606) | (1,471,716) |
| Accumulated other comprehensive (loss) income | (19,706) | 10,187 |
| Total stockholders' equity | 708,622 | 176,413 |
| Total liabilities and stockholders' equity | $1,815,075 | $ 1,404,726 |

The accompanying notes are an integral part of the consolidated financial statements.

## SEPRACOR INC.

## CONSOLIDATED STATEMENTS OF OPERATIONS

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2008 | 2007 | 2006 |
| | (In Thousands, Except Per Share Amounts) | | |
| Revenues: | | | |
| Product sales, net | $1,215,239 | $1,177,256 | $1,149,374 |
| Royalties and license fees | 77,050 | 47,974 | 33,759 |
| Total revenues | 1,292,289 | 1,225,230 | 1,183,133 |
| Costs and expenses: | | | |
| Cost of products sold | 130,323 | 115,835 | 103,760 |
| Cost of royalties earned | 2,118 | 1,320 | 976 |
| Research and development | 246,813 | 263,756 | 163,488 |
| Research and development—in-process upon acquisition | 89,995 | — | — |
| Selling, marketing and distribution | 654,074 | 699,336 | 691,650 |
| General and administrative | 106,437 | 81,375 | 71,913 |
| Amortization of intangible assets | 7,368 | 154 | 230 |
| Litigation settlement, net | — | 34,000 | — |
| Restructuring | (566) | 6,921 | — |
| Total costs and expenses | 1,236,562 | 1,202,697 | 1,032,017 |
| Income from operations | 55,727 | 22,533 | 151,116 |
| Other income (expense): | | | |
| Interest income | 24,124 | 46,599 | 46,589 |
| Gain on extinguishment of debt | 10,082 | — | — |
| Interest expense | (8,506) | (3,020) | (22,166) |
| Equity in investee losses | (1,103) | (507) | (422) |
| Other expense | (11,960) | (1,002) | (300) |
| Income before income taxes | 68,364 | 64,603 | 174,817 |
| (Benefit from) provision for income taxes | (446,746) | 6,270 | 3,656 |
| Net income | $ 515,110 | $ 58,333 | $ 171,161 |
| Basic net income per common share | $ 4.79 | $ 0.55 | $ 1.63 |
| Diluted net income per common share | $ 4.47 | $ 0.50 | $ 1.48 |
| Shares used in computing basic and diluted net income per common share: | | | |
| Basic | 107,527 | 106,847 | 104,943 |
| Diluted | 115,260 | 116,364 | 115,508 |

The accompanying notes are an integral part of the consolidated financial statements.

## SEPRACOR INC.

## CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT) AND COMPREHENSIVE INCOME

### (In Thousands)

| | Common Stock | | Treasury Stock | Additional Paid-in Capital | Accumulated Deficit | Accumulated Other Comprehensive Income (Loss) | Total Stockholders' Equity (Deficit) |
|---|---|---|---|---|---|---|---|
| | Shares | Amount | | | | | |
| **BALANCE AT DECEMBER 31, 2005** | 108,354 | $10,835 | $(232,028) | $1,711,653 | $(1,701,210) | $ 6,678 | $(204,072) |
| Comprehensive income (loss): | | | | | | | |
| Net income | | | | | 171,161 | | 171,161 |
| Foreign currency translation | | | | | | (48) | (48) |
| Unrealized loss on marketable equity securities | | | | | | (3,790) | (3,790) |
| Total comprehensive income | | | | | | | $ 167,323 |
| Issuance of common stock to employees under stock plans | 1,686 | 169 | | 31,564 | | | 31,733 |
| Stock compensation | | | | 45,200 | | | 45,200 |
| **BALANCE AT DECEMBER 31, 2006** | 110,040 | $11,004 | $(232,028) | $1,788,417 | $(1,530,049) | $ 2,840 | $ 40,184 |
| Comprehensive income (loss): | | | | | | | |
| Net income | | | | | 58,333 | | 58,333 |
| Foreign currency translation | | | | | | 3,566 | 3,566 |
| Unrealized gain on marketable equity securities | | | | | | 3,781 | 3,781 |
| Total comprehensive income | | | | | | | $ 65,680 |
| Issuance of common stock to employees under stock plans | 1,915 | 191 | | 35,895 | | | 36,086 |
| Stock compensation | | | | 34,278 | | | 34,278 |
| Tax benefit for stock compensation | | | | 185 | | | 185 |
| **BALANCE AT DECEMBER 31, 2007** | 111,955 | $11,195 | $(232,028) | $1,858,775 | $(1,471,716) | $ 10,187 | $ 176,413 |
| Comprehensive income (loss): | | | | | | | |
| Net income | | | | | 515,110 | | 515,110 |
| Foreign currency translation | | | | | | (15,480) | (15,480) |
| Unrealized loss on marketable equity securities | | | | | | (14,413) | (14,413) |
| Total comprehensive income | | | | | | | $ 485,217 |
| Issuance of common stock to employees under stock plans | 1,402 | 140 | | 6,787 | | | 6,927 |
| Stock compensation | | | | 39,265 | | | 39,265 |
| Tax benefit for stock compensation | | | | 800 | | | 800 |
| **BALANCE AT DECEMBER 31, 2008** | 113,357 | $11,335 | $(232,028) | $1,905,627 | $ (956,606) | $(19,706) | $ 708,622 |

The accompanying notes are an integral part of the consolidated financial statements.

## SEPRACOR INC.

## CONSOLIDATED STATEMENTS OF CASH FLOWS

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2008 | 2007 | 2006 |
| | (In Thousands) | | |
| Cash flows from operating activities: | | | |
| Net income | $ 515,110 | $ 58,333 | $ 171,161 |
| Adjustments to reconcile net income to net cash used in operating activities: | | | |
| Depreciation and amortization | 34,710 | 18,664 | 20,724 |
| Research and development—in-process upon acquisition | 89,995 | — | — |
| Interest accretion on license fee liabilities | 8,264 | — | — |
| Gain on extinguishment of debt | (10,082) | — | — |
| Impairment on investments | 14,380 | — | — |
| Equity in investee losses | 1,103 | 507 | 422 |
| Stock compensation | 39,265 | 34,278 | 45,200 |
| Benefit from deferred income taxes | (459,350) | (17,120) | — |
| Loss (gain) on disposal of patents and property and equipment | 796 | (5) | 53 |
| Changes in operating assets and liabilities, net of acquisition: | | | |
| Accounts receivable | (16,177) | 15,458 | (34,638) |
| Inventories | (14,169) | (14,699) | 1,900 |
| Other assets | (17,091) | 15,624 | (3,033) |
| Accounts payable | 2,952 | 6,515 | (850) |
| Accrued expenses | (58,596) | 96,843 | (74,364) |
| Product sales allowances and reserves | 30,793 | 78,209 | 55,262 |
| Other liabilities | 854 | 31,393 | (2,949) |
| Net cash provided by operating activities | 162,757 | 324,000 | 178,888 |
| Cash flows from investing activities: | | | |
| Purchases of available-for-sale investments | (38,478) | (179,148) | (96,931) |
| Sales of available-for-sale investments | 64,163 | 57,878 | 56,808 |
| Maturities of available-for-sale investments | 34,820 | 43,860 | 62,700 |
| Purchases of held-to-maturity investments | (319,564) | (671,979) | (980,060) |
| Maturities of held-to-maturity investments | 558,801 | 1,038,349 | 1,010,786 |
| Additions to property and equipment | (49,615) | (25,450) | (15,896) |
| Payments for purchased intangibles | (151,000) | 273 | 150 |
| Investment in non-affiliate | — | — | (8,939) |
| Change in other assets | — | — | 28 |
| Business acquisition, net of cash acquired | (54,953) | — | — |
| Net cash provided by investing activities | 44,174 | 263,783 | 28,646 |
| Cash flows from financing activities: | | | |
| Net proceeds from issuance of common stock | 6,927 | 36,086 | 31,733 |
| Tax benefit for stock compensation | 800 | 185 | — |
| Repayments of long-term debt and capital leases | (180,804) | (441,164) | (2,015) |
| Net cash (used in) provided by financing activities | (173,077) | (404,893) | 29,718 |
| Effect of exchange rate changes on cash and cash equivalents | (3,528) | 628 | 15 |
| Net increase in cash and cash equivalents | 30,326 | 183,518 | 237,267 |
| Cash and cash equivalents at beginning of year | 598,929 | 415,411 | 178,144 |
| Cash and cash equivalents at end of year | $ 629,255 | $ 598,929 | $ 415,411 |
| Supplemental cash flow data: | | | |
| Cash paid during the year for interest | $ 182 | $ 11,210 | $ 22,048 |
| Cash paid during the year for income taxes | $ 8,615 | $ 4,066 | $ 3,656 |
| Supplemental schedule of noncash investing and financing activities: | | | |
| Fair value of assets acquired under acquisition and license and development agreement | $ 148,122 | $ — | $ — |
| Fair value of liabilities assumed under acquisition and license and development agreement | $ (92,169) | $ — | $ — |
| Net cash paid upon execution of acquisition and license and development agreement | $ 55,953 | $ — | $ — |
| Additions to capital leases | $ — | $ 3,260 | $ — |

The accompanying notes are an integral part of the consolidated financial statements.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

### A) Nature of the Business

Sepracor Inc. was incorporated in 1984 to research, develop and commercialize products for the synthesis and separation of pharmaceutical and biopharmaceutical compounds. We are now a research-based pharmaceutical company focused on the discovery, development and commercialization of differentiated products that address large and growing markets and unmet medical needs which can be marketed to primary care doctors and specialists through our sales force. Our corporate headquarters are located in Marlborough, Massachusetts.

Our consolidated financial statements include the accounts of Sepracor Inc. and all of our wholly-owned subsidiaries. Our consolidated financial statements include our investment in BioSphere Medical, Inc., or BioSphere, which is recorded under the equity method and our investments in ACADIA Pharmaceuticals Inc., or ACADIA, which we account for as marketable equity securities. Certain prior period amounts have been reclassified to conform to the current period presentation.

We and our subsidiaries are subject to risks common to companies in the industry including, but not limited to, the safety, efficacy and successful development and regulatory approval of product candidates, fluctuations in operating results, protection of proprietary technology, dependence on third-party collaboration partners and third-party sales efforts, limited manufacturing capacity, risk of product liability, compliance with government regulations and dependence on key personnel.

### B) Summary of Significant Accounting Policies

*Principles of Consolidation:* Our consolidated financial statements include our accounts and all of our wholly-owned subsidiaries accounts. All material intercompany transactions have been eliminated. Investments in affiliated companies, which are 20% to 50% owned, and over which we do not exercise control, are accounted for using the equity method. Investments in affiliated companies, which are less than 20% owned, and over which we do not exercise significant influence, are accounted for using the cost method.

*Use of Estimates and Assumptions in the Preparation of Financial Statements:* The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the following: (i) the reported amounts of assets, including our intangible assets, and liabilities, (ii) the disclosure of contingent assets and liabilities at the dates of the financial statements and (iii) the reported amounts of revenues, including our product sales allowances and returns, and expenses during the reporting periods. Actual results could differ materially from those estimates.

*Translation of Foreign Currencies:* The assets and liabilities of our international subsidiaries are translated into United States dollars using current exchange rates as of the balance sheet date and revenues and expenses are translated at average exchange rates prevailing during the period. The resulting translation adjustment is recorded in accumulated other comprehensive income (loss). Foreign exchange transaction gains and losses are included in net income in the consolidated statements of operations and were not material for the years presented.

*Cash and Cash Equivalents:* Investments that are highly liquid with maturities of three months or less are classified as cash and cash equivalents, which primarily consist of cash, money market funds, and short-term investments with original maturities of three months or less. Cash and cash equivalents are stated at cost, which approximates market value.

*Investments:* Investments with maturities of greater than three months from the date of purchase but less than one year from the balance sheet date are classified as short-term investments, while

investments with maturities beyond one year from the balance sheet date are classified as long-term investments. Short- and long-term investments are classified as either available-for-sale or held-to-maturity. Available-for-sale investments are carried at fair value with unrealized gains and losses recorded as a component of accumulated other comprehensive income. Realized gains and losses on our available-for-sale investments are recognized in results of operations and we recorded losses of $14.6 million, which includes an other-than-temporary impairment loss of $14.4 million on our investment in ACADIA, in 2008 as compared to $0 in 2007. See Note E "Fair Value Measurements" included herein for year end balances. Held-to-maturity investments are recorded at cost plus accrued amortization, which approximates fair value. Held-to-maturity investments were $63.4 million at December 31, 2008, all of which was due within one year. Held-to-maturity investments were $309.5 million at December 31, 2007, of which $271.7 million was due within one year and $37.8 million was due in greater than one year. Realized gains and losses on held-to-maturity securities were insignificant in 2008 and 2007.

We evaluate our investments for possible other-than-temporary impairment by reviewing factors such as the investment rating for the securities, the length of time and extent to which fair value has been below cost basis, the financial condition of the issuer and our ability and intent to hold the investment for a period of time that may be sufficient for anticipated recovery of market value. If it is determined that a decline in value is other-than-temporary an impairment charge is recorded to the extent that the carrying value of the security exceeds the estimated fair market value.

*Concentration of Credit Risk:* We have no significant off balance sheet concentration of credit risk. Financial instruments that potentially subject us to concentrations of credit risk primarily consist of the cash and cash equivalents, short- and long-term investments and trade accounts receivable.

The percentage of total revenues from significant customers is as follows:

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2008 | 2007 | 2006 |
| Customer A | 35% | 31% | 35% |
| Customer B | 27% | 29% | 26% |
| Customer C | 16% | 17% | 17% |
| Customer D | 6% | 10% | 9% |

Certain prior year percentages have been reclassified to give effect for a merger of certain of our customers.

*Fair Value of Financial Instruments:* The carrying value of cash, short-term investments, accounts receivable, accounts payable and accrued expenses approximate fair value due to their short-term, highly liquid characteristics.

*Accounts Receivable and Bad Debt:* Our trade receivables in 2008 and 2007 primarily represent amounts due from wholesalers, distributors and retailers of our pharmaceutical products. We perform ongoing credit evaluations of our customers and we generally do not require collateral. Our allowance for doubtful accounts was $867,000 and $459,000 at December 31, 2008 and 2007, respectively, and our allowance for payment term discounts related to accounts receivable was $3.7 million and $4.1 million at December 31, 2008 and 2007, respectively.

Bad debt write-offs were not significant in 2008, 2007 and 2006; however, we monitor our receivables closely because a few customers provide a large portion of our overall revenues. Customers

with amounts due that represent greater than 10% of our accounts receivable balance are as follows at December 31:

| | 2008 | 2007 |
|---|---|---|
| Customer A | 41% | 29% |
| Customer B | 25% | 33% |
| Customer C | 19% | 12% |
| Customer D | 2% | 15% |

*Inventories:* Inventories are stated at the lower of cost (first-in, first-out) or market using a standard cost method. We expense costs relating to inventory until such time as we receive approval from the U.S. Food and Drug Administration, or FDA, for a new product, and then we begin to capitalize the costs relating to that product. We write down our inventory for expiration and probable quality assurance and quality control issues identified in the manufacturing process.

*Property and Equipment:* Property and equipment are recorded at cost. Expenditures for maintenance and repairs are charged to expense while the costs of significant improvements are capitalized. Upon retirement or sale, the cost of the assets disposed of and the related accumulated depreciation are removed from the balance sheet and any resulting gain or loss is included in the statement of operations. Depreciation is computed using the straight-line method over the following useful lives: three years for computer equipment and software; 3 to 10 years for laboratory, manufacturing and office equipment; and 30 years for buildings. Leasehold improvements are amortized over the shorter of the estimated useful lives of the improvements or the remaining term of the lease.

*Deferred Financing Costs:* Deferred financing costs relating to expenses incurred to complete convertible subordinated debt offerings are amortized evenly over the earlier of the term of the debt, or the date on which we can first be obligated to repurchase all, or part, of the debt.

*Impairment of Long-Lived Assets:* Long-lived assets, which includes property and equipment, intangible assets and other long-term assets, are assessed for impairment in accordance with Statement of Financial Accounting Standard, or SFAS, No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, or SFAS 144, whenever events or changes in circumstances indicate the undiscounted cash flow estimated to be generated by those assets is less than the assets' carrying amount. Any change in the carrying amount of an asset as a result of our evaluation is separately identified in the consolidated statements of operations in the period that the impairment occurs.

*Goodwill:* Goodwill, which represents the excess of purchase price over the fair value of net assets acquired, is carried at cost. In accordance with SFAS No. 142, *Accounting for Goodwill and Other Intangible Assets*, or SFAS 142, goodwill is not amortized; rather, it is subject to a periodic assessment for impairment by applying a fair-value based test. Goodwill is assessed annually in the third fiscal quarter of each year for impairment or more frequently if impairment indicators arise. SFAS 142 prescribes a two-step method for determining goodwill impairments. In the first step, we determine the fair value of our reporting units. If the net book value of our reporting units exceeds the fair value, we would then perform the second step of the impairment test, which requires allocation of our reporting unit's fair value to all of its assets and liabilities in a manner similar to a purchase price allocation, with any residual fair value being allocated to goodwill. An impairment charge will be recognized only when the implied fair value of our reporting unit's goodwill is less than its carrying amount. In the third quarter of 2008, our goodwill was evaluated for impairment and, based on the fair value of our reporting units, no impairments were identified. As a result of the significance of our goodwill, our

results of operations and financial position in a future period could be negatively impacted should an impairment of goodwill occur.

*Product Revenue Recognition:* We recognize revenue from product sales, upon delivery, when title to product and associated risk of loss has passed to our customer and collectability is reasonably assured. All revenues from product sales are recorded net of applicable allowances for returns, rebates and other applicable discounts and allowances.

*Rebate and Return Reserves:* Certain product sales qualify for rebates from standard list pricing due to government sponsored programs or other contractual agreements. We also issue credit for the return of our products for up to one year after the products' expiration. We record an estimate for these allowances as reductions of revenue at the time product sales are recorded. We derive reserves for product returns and rebates through an analysis of historical experience updated for changes in facts and circumstances as appropriate and by utilizing reports obtained from external, independent sources. Reserves for rebate programs are shown as product sales allowances and reserves on our balance sheet and were $253.4 million and $221.5 million at December 31, 2008 and 2007, respectively. Reserves for returns are recorded as product sales allowances and reserves on our balance sheet and were $23.2 million and $24.4 million at December 31, 2008 and 2007, respectively.

*Royalty Revenue Recognition:* Royalty revenue is recognized based upon estimates of sales of products including our licensed intellectual property in licensed territories in the period in which the sales occur or at the time we received the royalty payment. Royalty revenue estimates are derived when possible from information from the company paying the royalty, or from historical data and third-party prescription data. Changes in market conditions, such as the introduction of competitive products, can lead to significant deviations from historical patterns and therefore cause estimates to be inaccurate. When estimates differ from actual results, the difference is recognized in the following quarter, provided the difference is not material to the results of either quarter. Historically, our estimates have not materially differed from our actual results.

*License Fee Revenue Recognition:* We have entered into collaborative agreements with other pharmaceutical companies for the development and commercialization of our eszopiclone product outside of the United States, Canada and Mexico. The terms of these agreements involve multiple deliverables by us, such as license rights, development services, and clinical and commercial supply, in exchange for consideration to us in the form of non-refundable license fees, non-refundable contingent milestones, out-of-pocket cost reimbursements, and royalties on net product sales. Our revenue recognition policy for all multiple revenue-generating arrangements are in accordance with the guidance provided in the Securities and Exchange Commission, or SEC's, Staff Accounting Bulletin, or SAB, No. 101, *Revenue Recognition in Financial Statements*, as amended by SAB No. 104, *Revenue Recognition*, and Emerging Issues Task Force, or EITF, Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*, or SAB No. 101.

*Research and Development Expenses:* We expense research and development costs in the period incurred. Upfront and milestone payments made to third parties in connection with our collaborative license and development arrangements are expensed as incurred up to the point of regulatory approval. Milestone payments made to third parties, upon or subsequent to, regulatory approval are capitalized and amortized over the remaining useful life of the acquired intangible asset. Advance payments for future research and development activities are capitalized until the goods have been delivered or services have been performed.

*In-Process Research and Development Expenses:* Purchased in-process research and development, or IPR&D, represents the estimated fair value assigned to research and development projects acquired

in a purchase business combination or asset acquisition that have not been completed at the date of acquisition and which have no alternative future use. Accordingly, these costs are charged to expense as of the acquisition date.

*Advertising Costs:* Advertising costs are expensed as incurred. These costs are comprised of media, agency and production expenses and are included in selling, marketing and distribution expense on the consolidated statements of operations. Advertising expense was $148.2 million, $216.4 million and $234.5 million for fiscal years 2008, 2007 and 2006, respectively.

*Income Taxes:* Our income tax expense includes United States and foreign income taxes. Certain items of income and expense are not reported in tax returns and financial statements in the same year. The tax effects of these differences are reported as deferred tax assets and liabilities. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to tax benefit carryforwards and to differences between the financial statement amounts of assets and liabilities and their respective tax basis. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. Deferred tax assets and liabilities are measured using enacted tax rates in effect for the year in which the differences are expected to reverse. A valuation allowance is established if, based on management's review of both positive and negative evidence, it is more likely than not that all or a portion of the deferred tax asset will not be realized.

*Derivatives:* We record all derivative instruments as either assets or liabilities in our consolidated balance sheets and measure those instruments at fair value and subsequent changes in fair value are reflected in current earnings or in accumulated other comprehensive income. In November 2004, we acquired warrants to purchase 200,000 shares of BioSphere common stock. Based on the application of the Black-Scholes option pricing model which incorporates current stock price, expected stock price volatility, expected interest rates and the expected holding period of the warrants, we determined the estimated fair value of the warrants to be $35,000 and $372,000 at December 31, 2008 and 2007, respectively.

*Basic and Diluted Net Income Per Common Share:* Basic earnings per share, or EPS, excludes dilution and is computed by dividing net income by the weighted-average number of common shares outstanding for the period. Unvested restricted shares, although legally issued and outstanding, are not considered outstanding for purposes of calculating basic EPS. Diluted EPS is calculated by dividing net income by the weighted-average number of common shares outstanding plus the dilutive effect, if any, of outstanding stock options, restricted shares and restricted stock units. Potential common shares result from the assumed conversion of convertible subordinated debt and the assumed exercise of outstanding stock options, the proceeds of which are then assumed to have been used to repurchase outstanding stock options using the treasury stock method. Potential common shares are not included in the per share calculation when the effect of their inclusion would be anti-dilutive.

For the years ended December 31, 2008, 2007 and 2006, the following options to purchase shares of common stock were excluded from the computation of diluted EPS because they would have had an anti-dilutive effect:

| | 2008 | 2007 | 2006 |
|---|---|---|---|
| | (In Thousands, Except Per Share Data) | | |
| Number of options | 9,051 | 6,751 | 3,184 |
| Price range per share | $11.09 to $87.50 | $18.45 to $87.50 | $52.08 to $87.50 |

There were 4.8 million shares of common stock reserved for issuance upon conversion of convertible subordinated debt in 2006. There have been no additional shares reserved in 2007 or 2008.

We have issued 0% convertible subordinated notes due 2024, which were not convertible into equity as of December 31, 2008. Once these notes become convertible into equity, shares of common stock will be reserved under the conversion formula for issuance upon conversion if and when our common stock price exceeds $67.20 per share on the NASDAQ Global Select Market. Prior to such occurrence, the notes are only convertible into cash.

*Stock-Based Compensation:* Effective January 1, 2006, we adopted the provisions of SFAS No. 123(R), *Share-Based Payment*, (revised 2004), or SFAS 123(R), which establishes accounting for equity instruments exchanged for employee services. Under the provisions of SFAS 123(R), share-based compensation cost is measured at the grant date, based on the fair value of the award, and is recognized as an expense over the employee's requisite service period (generally the vesting period of the equity award).

In accordance with SFAS 123(R), SFAS 109, *Accounting for Income Taxes*, and EITF of the Financial Accounting Standards Board, or FASB, Topic D-32, *Intraperiod Tax Allocation of the Tax Effect of Pretax Income from Continuing Operations*, we have elected to recognize any excess income tax benefits from stock option exercises in additional paid-in capital only if an incremental income tax benefit would be realized after considering all other tax attributes presently available to us. We measure the tax benefit associated with excess tax deductions related to stock-based compensation expense by multiplying the excess tax deductions by the statutory tax rates. We use the incremental tax benefit approach for utilization of tax attributes.

**Recent Accounting Pronouncements:**

In October 2008, the FASB issued FASB Staff Position, or FSP, No. 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active,* or FSP 157-3, to clarify the application of the provisions of SFAS No. 157, *Fair Value Measurements,* or SFAS 157, in an inactive market and how an entity would determine fair value in an inactive market. FSP 157-3 was effective upon issuance and applies to our current financial statements. The application of the provisions of FSP 157-3 did not materially affect our results of operations or financial condition as of and for the year ended December 31, 2008.

In September 2008, the EITF issued EITF No. 08-6, *Equity Method Investment Accounting Considerations,* or EITF 08-6. EITF 08-6 addresses the effect of SFAS No. 141(R) and SFAS No. 160 on the equity method of accounting. This statement is effective for financial statements issued for fiscal years and interim periods beginning after December 15, 2008. We do not expect the adoption of EITF 08-6 to have a material impact on our consolidated financial statements.

In June 2008, the EITF issued FSP No. EITF 03-6-1, *Determining Whether Instruments Granted in Share-Based Payment Transactions are Participating Securities,* or EITF 03-6-1, which states that unvested share-based payment awards that contain nonforfeitable rights to dividends or dividend equivalents (whether paid or unpaid) are participating securities and shall be included in the computation of EPS under the two-class method. This statement is effective for financial statements issued for fiscal years and interim periods beginning after December 15, 2008. Upon adoption, we anticipate basic and diluted EPS will decrease as follows:

| | 2008 | 2007 |
|---|---|---|
| Basic | $(.06) | $(.01) |
| Diluted | $(.04) | $ — |

In May 2008, the FASB issued FSP No. APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)*, or FSP 14-1, which

clarifies the accounting for convertible debt instruments that may be settled in cash (including partial cash settlement) upon conversion. FSP 14-1 requires issuers to account separately for the liability and equity components of certain convertible debt instruments in a manner that reflects the issuer's nonconvertible debt (unsecured debt) borrowing rate when interest cost is recognized. FSP 14-1 requires bifurcation of a component of the debt, classification of that component in equity and the accretion of the resulting discount on the debt to be recognized as part of interest expense in our consolidated statement of operations. FSP 14-1 requires retrospective application to the terms of instruments as they existed for all periods presented. Accordingly, prior periods will be adjusted as if the new rule had been in effect in these prior periods. This statement is effective for financial statements issued for fiscal years and interim periods beginning after December 15, 2008 and early adoption is not permitted. Although we are currently evaluating the impact that this FSP will have on our consolidated financial statements, we believe that the retrospective application of the FSP will have a significant effect in reducing reported net income and diluted EPS for the years ended December 31, 2007 and 2008. In addition, net income and diluted EPS will be materially reduced in 2009 in which our $500.0 million convertible senior subordinated notes due 2024 are included in our consolidated financial statements. After adopting FSP 14-1, we currently estimate that our convertible debt liability will decrease by approximately $125.7 million (with a corresponding increase to equity), and we will record additional non-cash interest expense, net of capitalized interest, of approximately $16.4 million in 2009.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities—an amendment of FASB Statement No. 133*, or SFAS 161. SFAS 161 requires enhanced disclosures about an entity's derivative and hedging activities to make transparent the effect of those activities on the entity's financial position, financial performance and cash flows. This statement is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008, with early application encouraged. This statement encourages, but does not require, comparative disclosures for earlier periods at initial adoption. We do not expect the adoption of SFAS 161 to have a material impact on our consolidated financial statements.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements—an amendment of ARB No. 51*, or SFAS 160. SFAS 160 establishes accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. It clarifies that a noncontrolling interest in a subsidiary is an ownership interest in the consolidated entity that should be reported as equity in the consolidated financial statements. This pronouncement will be effective for fiscal years beginning on or after December 15, 2008. SFAS 160 requires retroactive adoption of the presentation and disclosure requirements for existing minority interests. All other requirements of SFAS 160 shall be applied prospectively. We do not expect the adoption of SFAS 160 to have a material impact on our consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations*, or SFAS 141(R), which will require an acquiring company to measure all assets acquired and liabilities assumed, including contingent considerations and all contractual contingencies, at fair value as of the acquisition date. In addition, an acquiring company is required to capitalize IPR&D and either amortize it over the life of the product, or write it off if the project is abandoned or impaired. This statement applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. We expect this statement will have an impact on our accounting for future business combinations once adopted.

In November 2007, the EITF reached a final consensus on Issue No. 07-1, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property,* or EITF 07-1. This statement is effective for financial statements issued for fiscal years beginning after

December 15, 2008, and interim periods within those fiscal years, and is to be applied retrospectively to all periods presented for all collaborative arrangements existing as of the effective date. We do not expect the adoption of EITF 07-1 to have a material impact on our consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities—including an amendment of FASB Statement No. 115,* or SFAS 159. SFAS 159 expands the use of fair value accounting but does not affect existing standards which require assets or liabilities to be carried at fair value. The objective of SFAS 159 is to improve financial reporting by providing companies with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. Under SFAS 159, a company may elect to use fair value to measure eligible items at specified election dates and report unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting date. This election is irrevocable. Eligible items include, but are not limited to, accounts and loans receivable, available-for-sale and held-to-maturity securities, equity method investments, accounts payable, guarantees, issued debt and firm commitments. This statement is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2007, with early adoption permitted. Currently, we have not expanded our eligible items subject to the fair value option under SFAS 159. Accordingly, adoption of this statement has had no impact on our financial results.

**C) Acquisitions**

In June 2008, in order to establish a Canadian commercial presence, we acquired the outstanding capital stock of Oryx Pharmaceuticals, Inc., or Oryx, a specialty pharmaceutical company that markets branded prescription pharmaceutical products to physician specialists and hospitals within Canada and is focused in the cardiovascular, central nervous system, or CNS, disorders, pain and infectious diseases therapeutic areas, for approximately $55.0 million, including $3.0 million of acquisition-related transaction costs and $2.1 million as a post-closing working capital adjustment. We subsequently changed Oryx's name to Sepracor Pharmaceuticals, Inc., or SPI. In addition, the selling shareholders are entitled to receive milestone payments of up to an aggregate of $20.0 million upon the accomplishment of various regulatory milestones. This acquisition was accounted for under the purchase method of accounting and the results of operations of SPI have been included in our consolidated results from June 1, 2008, the acquisition date. The purchase price of the acquisition was allocated to tangible and intangible assets and assumed liabilities based on their estimated fair values. We have allocated $34.1 million of the purchase price to intangible assets primarily comprised of acquired technology. We are amortizing the acquired technology over estimated average useful lives of 3 to 13 years. The excess purchase price of $24.5 million after this allocation has been accounted for as goodwill.

The following table presents the fair values of assets and liabilities recorded in connection with the SPI acquisition:

| | Total (In Thousands) |
|---|---|
| Accounts receivable | $ 1,982 |
| Inventory | 4,568 |
| Other current assets | 3,457 |
| Goodwill | 24,516 |
| Intangible assets | 34,070 |
| Fixed assets | 40 |
| Total assets acquired | 68,633 |
| Accrued expenses and other current liabilities | 3,853 |
| Deferred tax liability | 9,827 |
| Cash consideration paid, net of cash acquired | $54,953 |

The SPI acquisition is not material to our consolidated statements of operations, and therefore, pro forma information is not presented.

**D) Business Investments**

*ACADIA*

In January 2005, we entered into a collaboration agreement with ACADIA for the development of new drug candidates targeted toward the treatment of CNS disorders. This agreement expired pursuant to its terms in January 2008, and we are no longer pursuing the development of the drug candidates subject to this agreement.

In 2005 and 2006, under the terms of the collaboration agreement with ACADIA, we purchased a total of 1,890,422 shares of ACADIA's common stock for $16.1 million. These publicly traded securities, which are classified as available-for-sale, are accounted for under SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities.* We adjust the carrying value of our available-for-sale securities to fair value and report the related temporary unrealized gains and losses as a separate component in other comprehensive income. Declines in the fair value of an available-for-sale security that are estimated to be "other-than-temporary" are recognized as other expense in the consolidated statements of operations, thus establishing a new cost basis for such investments. We evaluate our investment securities portfolio on a quarterly basis to determine whether declines in the fair value of these securities are other-than-temporary. This quarterly evaluation consists of reviewing, among other things, the fair value of our investment securities compared to their carrying amount, the historical volatility of the price of each security and any market and company-specific factors related to each security.

During 2008, based on a significant decline in the value of ACADIA's common stock, which we believe was the result of adverse clinical results announced in June 2008, we recorded other-than-temporary impairment charges totaling $14.4 million related to this security. These amounts were recognized as other expense in the consolidated statements of operations, thus establishing a new cost basis for the ACADIA investment. As of December 31, 2008, the fair market value of our investment in ACADIA was approximately $1.7 million, which is recorded in long-term investments on the accompanying consolidated balance sheet.

*BIOSPHERE*

BioSphere was a consolidated subsidiary from 1994 through July 2, 2001. As a result of a public offering of BioSphere common stock in 2001, our ownership of BioSphere was reduced from approximately 55% to 26%. Therefore, effective July 3, 2001, we changed the method of accounting for our investment in BioSphere from consolidating the results of BioSphere operations to the equity method. On November 10, 2004, we purchased from BioSphere, in a private placement, 4,000 shares of BioSphere Series A Convertible Preferred Stock and warrants to purchase an additional 200,000 shares of BioSphere common stock for an aggregate purchase price of $4.0 million. Each share of BioSphere Series A Convertible Preferred Stock is convertible into 250 shares of BioSphere common stock at a conversion price of $4.00 per share. In addition, quarterly dividends of 6% per annum are paid on the shares either in cash or additional shares of Series A Convertible Preferred Stock at BioSphere's election and as of December 31, 2008, we have received an additional 820 shares of Series A Convertible Preferred Stock in connection with dividend payments.

At December 31, 2008 and 2007, we owned 3,224,333 shares, or approximately 18% of BioSphere's outstanding common stock. The cost basis of those shares is $4.4 million, and the fair market value of those shares was approximately $6.2 million and $16.5 million as of December 31, 2008 and 2007, respectively. In addition, as of December 31, 2008 and 2007, we owned 4,820 and 4,749 shares of Series A Convertible Preferred Stock, respectively, and warrants to purchase an additional 200,000 shares of common stock. Based on the application of the Black-Scholes option pricing model, we determined the estimated fair value of these warrants to be $35,000 and $372,000 at December 31, 2008 and 2007, respectively, which was recorded as an investment in affiliate. Assuming conversion of our Series A Convertible Preferred Stock and the exercise of our warrants, we would own approximately 23% of BioSphere's common stock as of December 31, 2008 and 2007. We recorded $1.1 million, $507,000 and $422,000 as our share of BioSphere's losses for the years ended December 31, 2008, 2007 and 2006, respectively.

**E) Fair Value Measurements**

In September 2006, the FASB issued SFAS 157. SFAS 157 defines fair value, establishes a framework and gives guidance regarding the methods used for measuring fair value and expands disclosures about fair value measurements. We partially adopted this statement effective January 1, 2008. In February 2008, the FASB released FSP No. 157-2, *Effective Date of FASB Statement No. 157,* or FSP 157-2, which delays the effective date of SFAS 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually).

We have not adopted SFAS 157 as it relates to goodwill and other intangible assets due to the delay allowed by FSP 157-2. We do not expect that the adoption of this standard for non-financial assets and liabilities will have a significant impact on our consolidated financial position, results of operations or cash flows. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability, in an orderly transaction between market participants at the measurement date. Fair value is based upon quoted market prices, where available. Where quoted market prices or other observable inputs are not available, we apply valuation techniques to estimate fair value. SFAS 157 establishes a three-level valuation hierarchy for disclosure of fair value measurements. The three levels of the hierarchy are defined as follows:

Level 1—Inputs to the valuation methodology are quoted market prices for identical assets or liabilities in active markets. The types of assets measured at fair value using Level 1 inputs include our publicly traded equity investments with quoted market prices and money market funds.

Level 2—Inputs include quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability (i.e., interest rates, yield curves, etc.) and inputs that are derived principally from, or corroborated by, observable market data by correlation or other means (market corroborated inputs). The types of assets measured at fair value using Level 2 inputs include our publicly traded debt securities and other marketable securities with quoted market prices, which are in markets that are considered less active.

Level 3—Inputs to the valuation methodology are unobservable inputs based on management's best estimate of inputs market participants would use in pricing the asset or liability at the measurement date, including assumptions about risk. The types of assets measured at fair value using Level 3 inputs include auction-rate securities where the auctions have failed.

In accordance with the fair value hierarchy described above, the following table shows the fair value of our financial assets and liabilities that are measured at fair value on a recurring basis as of December 31, 2008:

| | Quoted Prices in Active Markets | Significant Other Observable Inputs | Significant Unobservable Inputs | Carrying Value at December 31, 2008 |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| | | (In Thousands) | | |
| Money market funds | $595,750 | $ — | $ — | $595,750 |
| Asset-backed securities | — | 681 | — | 681 |
| Equity securities(1) | 4,539 | — | — | 4,539 |
| Auction-rate securities | — | — | 70,912 | 70,912 |
| Total | $600,289 | $681 | $70,912 | $671,882 |

(1) Included within equity securities is our investment in ACADIA. See Note D "Business Investments" regarding the other-than-temporary impairment taken on this investment during 2008.

Auction-rate securities are long-term variable rate bonds tied to short-term interest rates. After the initial issuance of the securities, the interest rate on the securities is reset periodically, at intervals established at the time of issuance (primarily every twenty-eight days), based on market demand for a reset period. Auction-rate securities are bought and sold in the marketplace through a competitive bidding process referred to as an auction. If there is insufficient interest in the securities at the time of an auction, the auction may not be completed and the rates may be reset to predetermined "penalty" or "maximum" rates.

Substantially all of our auction-rate investments, approximately $70.9 million at December 31, 2008, are backed by pools of student loans guaranteed by the Federal Family Education Loan Program, or FFELP, and we continue to believe that the credit quality of these securities is high based on this guarantee and other collateral. Auctions for these securities began failing in the first quarter of 2008 and continued to fail throughout the remainder of 2008, which we believe is a result of the recent uncertainties in the credit markets. Consequently, the investments are not currently liquid, and we will not be able to access these funds until a future auction of these investments is successful, a buyer is found outside of the auction process, the security is called, or the underlying securities have matured. At the time of the initial investment and through the date of this report, all of these auction-rate securities remain AAA rated by one or more rating agency. We believe we have the ability to hold

these investments until the lack of liquidity in these markets is resolved. As a result, we continue to classify the entire balance of our auction-rate securities as non-current available-for-sale investments at fair value on our consolidated balance sheets.

Because of the temporary declines in fair value for the auction-rate securities, which we attribute to liquidity matters rather than credit issues as discussed above, we have recorded an unrealized loss of $8.7 million to other comprehensive income as of December 31, 2008. The decline in the fair value of our auction-rate securities investments was primarily the result of the assumed delay in the return of liquidity to this investment market-sector. Any future fluctuation in fair value related to these instruments that we deem to be temporary, including any recoveries of previous write-downs, would be recorded to other comprehensive income. If current market conditions deteriorate further, we may be required to record additional unrealized losses in other comprehensive income. If the credit ratings of the security issuers deteriorate, the anticipated recovery in market values does not occur or we need funds from the auction-rate securities to meet working capital needs, we may be required to adjust the carrying value of these investments through impairment charges recorded to earnings.

The fair values of these auction-rate securities are estimated utilizing a trinomial discounted cash flow valuation model as of December 31, 2008. This analysis considers, among other items, the maximum interest rate, the probability of passing, failing or default at each auction, the severity of default and the discount rate. These securities were also compared, when possible, to other observable market data or inputs with similar characteristics to the securities that we held, including credit default swaps spreads on securities with similar credit, implied volatility rates on exchange traded options and spreads on corporate credit. The analysis assumes that a successful auction would occur, at par, at some point in time for each security.

All of our assets measured at fair value on a recurring basis using significant Level 3 inputs as of December 31, 2008 were auction-rate securities. The following table summarizes the change in balances for the twelve month period ended December 31, 2008:

| | Level 3 Auction-Rate Securities |
|---|---|
| | (In Thousands) |
| Balance at December 31, 2007 | $ 99,900 |
| Unrealized loss included in other comprehensive income | (3,509) |
| Net settlements | (16,150) |
| Balance at March 31, 2008 | $ 80,241 |
| Unrealized loss included in other comprehensive income | (447) |
| Net settlements | (1,600) |
| Balance at June 30, 2008 | $ 78,194 |
| Unrealized gain included in other comprehensive income | 110 |
| Net settlements | (1,250) |
| Balance at September 30, 2008 | $ 77,054 |
| Unrealized loss included in other comprehensive income | (4,892) |
| Net settlements | (1,250) |
| Balance at December 31, 2008 | $ 70,912 |

**F) Inventories**

Inventories consist of the following at December 31:

| | 2008 | 2007 |
|---|---|---|
| | (In Thousands) | |
| Raw materials | $28,306 | $26,811 |
| Finished goods | 40,697 | 26,314 |
| | $69,003 | $53,125 |

**G) Property and Equipment**

Property and equipment consist of the following at December 31:

| | 2008 | 2007 |
|---|---|---|
| | (In Thousands) | |
| Land | $ 4,150 | $ 4,181 |
| Building | 85,174 | 50,927 |
| Laboratory and manufacturing equipment | 46,792 | 50,233 |
| Office equipment | 70,181 | 61,683 |
| Leasehold improvements | 3,156 | 3,064 |
| | 209,453 | 170,088 |
| Accumulated depreciation and amortization | (92,381) | (82,780) |
| | $117,072 | $ 87,308 |

Property and equipment under capital leases at December 31, 2008 and 2007 was $3.3 million and $3.7 million, respectively. Accumulated amortization related to property and equipment under capital leases at December 31, 2008 and 2007 was $1.9 million and $1.2 million, respectively. Depreciation expense was $16.6 million, $15.4 million and $15.6 million including amortization on capital leases of $1.3 million, $1.0 million and $1.6 million, respectively, for the years ended December 31, 2008, 2007 and 2006, respectively.

**H) Goodwill and Intangible Assets**

In accordance with SFAS No. 142, *Goodwill and Other Intangible Assets*, or SFAS 142, goodwill is tested for impairment at least annually, or on an interim basis if an event occurs or circumstances change that would, more likely than not, reduce the fair value of the reporting unit below its carrying value. We completed our annual impairment review as of the third quarter and concluded that no impairment charge was required as of that date.

The carrying value of goodwill was $19.9 million at December 31, 2008, which is attributed to the SPI acquisition (See Note C "Acquisitions"). Currency translation adjustments of approximately $4.6 million were recorded for the year ended December 31, 2008.

Intangible assets subject to amortization are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable in accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, or SFAS 144. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset group to the estimated undiscounted future cash flows expected to be generated by the asset group. If the carrying amount of an asset group exceeds its estimated future cash flows, an impairment

charge is recognized in the amount by which the carrying amount of the asset group exceeds the fair value of the asset group. No impairment charges were required for the year ended December 31, 2008.

In April 2008, we entered into a worldwide license and development agreement with Arrow International Limited, or Arrow, for the development, commercialization, marketing, sale and distribution of Arrow's levalbuterol/ipratropium combination inhalation solution product, which we refer to as the Levalbuterol/ipratropium Product, in current and all future formulations and delivery modes. We refer to this agreement as the Levalbuterol/ipratropium Product Agreement. We paid Arrow $500,000 upon execution of this agreement and we are also required to pay Arrow an additional $70.0 million as further consideration under the agreement, provided Arrow is not in material breach of certain of its obligations under the agreement. Although these future payments are subject to Arrow's continued compliance with the agreement, they have been recorded because we believe it is probable that Arrow will be entitled to these future payments. Arrow will also receive single-digit royalties on our sales of the Levalbuterol/ipratropium Product, subject to Arrow's one-time option exercisable in the fourth quarter of 2009 to receive a lump sum discounted amount of $23.5 million in lieu of ongoing royalty payments.

In April 2008, we also entered into a worldwide license and development agreement with Arrow, which we refer to as the Ciclesonide Agreement, for know-how and intellectual property rights related to stable sterile suspension formulations, for use in the development, commercialization, marketing, sale and distribution of an inhalation solution pharmaceutical product containing ciclesonide as its only active ingredient, or the Nebule Ciclesonide Product, and an inhalation solution pharmaceutical product containing both ciclesonide and arformoterol as its active ingredients, or the Ciclesonide/arformoterol Combination Product. The agreement also includes rights to Arrow's "U-Bend" packaging technology, which allows increased accuracy in dosing through a novel U-Bend ampule design. We paid Arrow $500,000 upon execution of this agreement, and we are also required to pay Arrow an additional $47.5 million as further consideration under the agreement, provided Arrow is not in material breach of certain of its obligations under the agreement. Although these future payments are subject to Arrow's continued compliance with the agreement, they have been recorded because we believe it is probable that Arrow will be entitled to these future payments. Arrow will also receive single-digit royalties on our sales of the Nebule Ciclesonide Product and Ciclesonide/arformoterol Combination Product, subject to Arrow's one-time options exercisable in the fourth quarter of 2009 to receive an aggregate lump sum discounted amount of up to $37.9 million in lieu of ongoing royalty payments.

The total of $117.5 million of future payments due to Arrow, pursuant to the Levalbuterol/ipratropium Product Agreement ($70 million) and the Ciclesonide Agreement ($47.5 million), which we refer to collectively as the Future Payments to Arrow, were recorded at their present value of $78.0 million as other current and long-term liabilities on our consolidated balance sheets as of December 31, 2008. We impute interest expense associated with these liabilities using a 13% interest rate, which are amortized over the expected term of the payments and are recorded as interest expense in our consolidated statements of operations.

Of the $78.0 million of Future Payments to Arrow initially recorded, and the $1.0 million previously paid to Arrow pursuant to the two agreements, $50.8 million was assigned to IPR&D. IPR&D is defined by FASB Interpretation No. 4, *Applicability of SFAS Statement No. 2 to Business Combinations Accounted for by the Purchase Method*, or FIN 4, as being a development project that has been initiated and achieved material progress but: (i) has not yet reached technological feasibility or has not yet reached the appropriate regulatory approval; (ii) has no alternative future use; and (iii) the fair value is estimable with reasonable certainty. As required by FIN 4, the portion of the purchase price under the Levalbuterol/ipratropium Product Agreement and the Ciclesonide Agreement allocated

to IPR&D was immediately charged to operations following the consummation of the transaction and is reflected in our consolidated statements of operations.

A project-by-project valuation using the guidance in SFAS No. 141, *Business Combinations*, or SFAS 141, has been conducted to determine the fair value of our research and development projects that were in-process, but not yet completed, as of the date we entered into the Levalbuterol/ipratropium Product Agreement and the Ciclesonide Agreement. The Levalbuterol/ipratropium Product candidate, an inhalation solution with the potential to treat chronic obstructive pulmonary disease, or COPD, was the only project in development under the Levalbuterol/ipratropium Product Agreement as of the valuation date. We have targeted commercial introduction of this product for 2013. The two projects in development pursuant to the Ciclesonide Agreement as of the valuation date were the (i) Nebule Ciclesonide Product candidate and (ii) Ciclesonide/arformoterol Combination Product candidate. The Nebule Ciclesonide Product candidate is an inhalation solution formulation of ciclesonide, which is an inhaled corticosteroid that is intended for the treatment of asthma symptoms, regardless of asthma severity. We have targeted commercial introduction of this product for 2013 or early 2014. The Ciclesonide/arformoterol Combination Product candidate will be comprised of a nebulized version of ciclesonide with arformoterol inhalation solution, which is a long-acting maintenance treatment of bronchoconstriction in patients suffering from COPD. The Ciclesonide/arformoterol Combination Product is targeted for commercial introduction in 2015/2016. Successful development of our products is highly uncertain. Completion costs can be significant, vary for each product and are difficult to predict.

The fair value of IPR&D has been determined by the income approach using the excess cash flow method. The value of the projects has been based on the present value of probability adjusted incremental cash flows, after the deduction of contributory asset charges for other assets employed (including working capital, trade names and acquired workforce). The probability weightings used to determine IPR&D cash flows ranged from 25% to 80%. The discount rates used to determine the present value of IPR&D cash flows ranged from 15% to 25%.

The remaining $28.2 million of acquired intangible assets represent core technology product rights.

During the first quarter of 2008, we entered into an agreement with Nycomed GmbH, or Nycomed, for the exclusive distribution, development and commercialization in the United States, its territories and possessions, of Nycomed's ciclesonide compound, and products incorporating such compound, including ALVESCO® (ciclesonide) HFA Inhalation Aerosol metered-dose inhaler, or MDI, for use in the treatment of asthma, OMNARIS™ (ciclesonide) Nasal Spray for use in the treatment of allergic rhinitis and three development projects for line extensions. Under the agreement, we paid Nycomed an upfront payment of $150.0 million in February 2008 and may be required to make subsequent payments of up to $280.0 million over the life of the agreement upon accomplishment of various development and sales milestones. The transaction was accounted for under the purchase method of accounting and the purchase price was allocated to identifiable intangible assets based on their estimated fair values.

Of the $150.0 million of intangible assets related to the Nycomed transaction, $39.2 million was assigned to IPR&D. As required by FIN 4, the portion of the purchase price allocated to IPR&D was immediately charged to operations following the consummation of the transaction and is reflected in our consolidated statements of operations.

A project-by-project valuation using the guidance in SFAS 141 has been conducted to determine the fair value of Nycomed's research and development projects that were in-process, but not yet completed, as of the consummation of the Nycomed transaction. The three projects in development as of the valuation date were a hydrofluoroalkane, or HFA, MDI and two other respiratory-related

candidates. We have targeted commercial introduction of the HFA MDI for 2012. One of the respiratory candidates is a combination therapy that is comprised of ciclesonide and a long-acting beta-agonist (we have selected arformoterol), which we have targeted for commercial introduction for 2014. The second respiratory candidate is an inhalation solution for which we have targeted commercial introduction at the end of 2013 or early 2014.

The fair value of IPR&D has been determined by the income approach using the excess cash flow method. The value of the Nycomed projects has been based on the present value of probability adjusted incremental cash flows, after the deduction of contributory asset charges for other assets employed (including working capital, trade names and acquired workforce). The probability weightings used to determine IPR&D cash flows ranged from 65% to 86%. The discount rate used to determine the present value of IPR&D cash flows was approximately 25%.

The remaining $110.8 million of acquired intangible assets related to the Nycomed transaction include: OMNARIS Nasal Spray product rights for $21.2 million, ALVESCO HFA Inhalation Aerosol product rights for $30.0 million, and core technology product rights for $59.6 million.

Our intangible assets included in the consolidated balance sheets are detailed as follows:

| | December 31, 2008 | | | December 31, 2007 | | |
|---|---|---|---|---|---|---|
| | Gross Carrying Amount | Accumulated Amortization | Net Carrying Amounts | Gross Carrying Amount | Accumulated Amortization | Net Carrying Amounts |
| | | | (In Thousands) | | | |
| SPI's intangible assets | $ 27,839 | $ (2,094) | $ 25,745 | $ — | $ — | $ — |
| Arrow's intangible assets | 28,238 | (1,255) | 26,983 | — | — | — |
| Nycomed's intangible assets | 110,763 | (8,925) | 101,838 | — | — | — |
| Patents and other intangible assets | 2,259 | (1,889) | 370 | 2,259 | (1,758) | 501 |
| Total intangible assets | $169,099 | $(14,163) | $154,936 | $2,259 | $(1,758) | $501 |

SPI intangible assets are being amortized over 3 to 13 years; Arrow intangible assets are being amortized over 15 years; Nycomed intangible assets are being amortized over 8 to 15 years; and patents are being amortized over 10 years.

The gross carrying value of intangible assets decreased by approximately $6.2 million for the year ended December 31, 2008 due to the effect of foreign currency translation.

The estimated aggregate amortization expense for each of the next five years is $12.1 million, $10.5 million, $9.4 million, $8.5 million and $8.3 million in 2009, 2010, 2011, 2012 and 2013, respectively.

## I) Accrued Expenses

Accrued expenses consist of the following at December 31:

| | 2008 | 2007 |
|---|---|---|
| | (In Thousands) | |
| Research and development costs | $ 30,120 | $ 19,437 |
| Sales and marketing costs | 14,202 | 30,969 |
| Compensation costs | 43,716 | 37,084 |
| Manufacturing costs | 20,536 | 19,206 |
| Royalties | 14,485 | 10,006 |
| Licensing fee | — | 67,500 |
| Other | 23,050 | 25,907 |
| Total accrued expenses | $146,109 | $210,109 |

## J) Debt and Lease Obligations

Convertible subordinated debt and capital lease obligations consist of the following at December 31:

| | 2008 | 2007 |
|---|---|---|
| | (In Thousands) | |
| 0% Series A convertible senior subordinated notes due 2008 | $ — | $ 72,800 |
| 0% Series B convertible senior subordinated notes due 2010 | 148,020 | 148,020 |
| 0% convertible senior subordinated notes due 2024 | 382,450 | 500,000 |
| Capital lease obligations | 1,468 | 2,605 |
| Total debt | 531,938 | 723,425 |
| Less current portion | (383,612) | (73,962) |
| Total long-term debt | $ 148,326 | $649,463 |

*0% Series A Convertible Subordinated Notes due 2008*

In December 2008, we paid in full $72.8 million in principal amount of outstanding 0% Series A convertible subordinated notes, which matured on December 15, 2008.

*0% Series B Convertible Senior Subordinated Notes due 2010*

In December 2003, we issued $400.0 million in principal amount of 0% Series B convertible senior subordinated notes due 2010, or 0% notes due 2010. In January 2004, pursuant to an option granted to the initial purchasers of our 0% notes due 2010, we issued an additional $100.0 million of 0% notes due 2010. Net of issuance costs, our proceeds were approximately $97.2 million. The 0% notes due 2010 are convertible into common stock, at the option of the holder, at a price of $29.84 per share. The 0% notes due 2010 do not bear interest and are not redeemable. We may be required to repurchase the 0% notes due 2010 at the option of the holders if there is a change in control of Sepracor or upon the termination of trading of our common stock on NASDAQ or similar markets. Upon the satisfaction of any of the previously mentioned conditions as of the last day of the reporting period, or during the twelve months prior to the maturity date, we would classify the then principal balance of the 0% notes due 2010 as a current liability on our consolidated balance sheets. As part of the sale of the 0% notes due 2010, we incurred offering costs of $11.3 million, which have been recorded as deferred financing costs and are being amortized over the term of the notes.

During September 2004, certain holders of our 0% notes due 2010 agreed to convert $352.0 million in principal amount of their 0% notes due 2010 into an aggregate of 11,797,483 shares of our common stock. As an inducement to convert their notes, we paid the holders of the 0% notes due 2010 cash payments of $45.9 million. These amounts were recorded as a loss on conversion of convertible notes. Deferred financing costs related to the converted 0% notes due 2010 of $8.8 million were netted against the amount of debt converted into equity. At December 31, 2008 and 2007, $148.0 million of our 0% notes due 2010 remained outstanding.

*0% Convertible Senior Subordinated Notes due 2024*

In September 2004, we issued $500.0 million in principal amount of 0% convertible senior subordinated notes due 2024, or 0% notes due 2024. Holders may convert the notes into cash and, if applicable, shares of our common stock at a conversion rate of 14.8816 shares of common stock per $1,000 principal amount of notes (which is equal to a conversion price of approximately $67.20 per share), subject to adjustment, before the close of business on the business day immediately preceding October 15, 2024 only under the following circumstances:

- during any fiscal quarter beginning after December 31, 2004, if the closing sale price of our common stock for at least 20 trading days in the 30 consecutive trading days ending on the last day of the preceding fiscal quarter is more than 130% of the conversion price per share of common stock on the last day of such preceding quarter;
- during the five business day period following any five consecutive trading day period, or the measurement period, in which the trading price per note on each day of that measurement period is less than 98% of the closing sale price of our common stock multiplied by the conversion rate on each such day;
- if the notes have been called for redemption;
- upon the occurrence and continuance of specified corporate transactions; and
- in connection with a transaction or event constituting a fundamental change occurring on or prior to October 20, 2009.

Upon conversion of the 0% notes due 2024, if the adjusted conversion value of the notes, which is defined as the product of (i) the conversion rate in effect on the conversion date; and (ii) the average of the daily volume weighted average price of our common stock for each of the five consecutive trading days beginning on the second trading day immediately following the day the notes are tendered for conversion, is less than or equal to the principal amount of the notes, then we will convert the notes for an amount in cash equal to the adjusted conversion value of the notes. If the adjusted conversion value of the 0% notes due 2024 is greater than the principal amount of the notes, then we will convert the notes into whole shares of our common stock for an amount equal to the adjusted conversion value of the notes less the principal amount of the notes, plus an amount in cash equal to the principal amount of the notes plus the cash value of any fractional shares of our common stock. During 2008, none of the listed circumstances occurred and there was no conversion of debt.

The 0% notes due 2024 do not bear interest. On or after October 20, 2009, we have the option to redeem for cash all or part of the 0% notes due 2024 at any time at a redemption price equal to 100% of the principal amount of the notes to be redeemed. We may be required by the note holders to repurchase for cash all or part of the 0% notes due 2024 on October 15 of 2009, 2014 and 2019 at a repurchase price equal to 100% of the principal amount of the notes to be repurchased. We may be required to repurchase for cash all or part of the 0% notes due 2024 upon a change in control of Sepracor or a termination of trading of our common stock on the NASDAQ or similar markets at a

repurchase price equal to 100% of the principal amount of the notes to be repurchased, plus in certain change in control circumstances, an additional make-whole payment. Our 0% notes due 2024 will be classified as current liabilities and presented in the current portion of long-term debt on our consolidated balance sheets upon satisfaction of any of the previously mentioned conditions or if the reporting period is within twelve months of the first putable date of October 15, 2009. At December 31, 2008, our 0% notes due 2024 are classified as current liabilities on our consolidated balance sheets as a result of the October 2009 put date. In connection with the sale of the 0% notes due 2024, we incurred offering costs of approximately $14.2 million, which have been recorded as deferred financing costs and are being amortized over 5 years, the note holders first potential redemption date.

During the second half of 2008, we repurchased and retired, at our option in privately negotiated transactions, an aggregate of $117.6 million principal amount of our 0% notes due 2024. We paid a total of $106.9 million in cash to repurchase these notes. In connection with these transactions, we recorded a gain on the extinguishment of $10.7 million offset by non-cash charges of approximately $600,000 resulting from the write-off of debt issuance costs associated with the retired debt. The net gain of $10.1 million was recorded as a gain on extinguishment of debt on our consolidated statements of operations. At December 31, 2008 and 2007, $382.5 million and $500.0 million of the 0% notes due 2024 remained outstanding, respectively.

The aggregate maturities of short- and long-term debt, excluding capital lease obligations, are $382.5 million in 2009 and $148.0 million in 2010. The estimated fair value of our debt, which is estimated based on quoted market prices, was approximately $468.8 million and $683.2 million, compared to its carrying value of $530.5 million and $720.8 million at December 31, 2008 and 2007, respectively.

We lease certain buildings and laboratory facilities under non-cancelable operating lease agreements that expire through 2014. Estimated future minimum lease payments with a term of more than one year as of December 31, 2008 are as follows: $2.0 million in 2009; $1.5 million in 2010; $1.4 million in 2011, $674,000 in 2012 and $200,000 in 2013. Rental expense was $2.1 million, $1.5 million and $1.3 million for the years ended December 31, 2008, 2007 and 2006, respectively.

**K) Commitments and Contingencies**

**Collaboration Agreements**

See Note H "Goodwill and Intangible Assets" regarding commitments for future payments under the Arrow Levalbuterol/ipratoropium Product Agreement, Arrow Ciclesonide Agreement and Nycomed agreement.

We have committed to make potential future milestone payments to third parties as part of licensing, distribution and development agreements. Payments under these agreements generally become due and payable only upon achievement of certain development, regulatory and/or commercial milestones. We may also be required to make additional payments to Nycomed, Bial—Portela & C[a], S.A. and the former shareholders of SPI, of up to $280.0 million, $90.0 million and $20.0 million, respectively, if all milestones under the agreements with these parties are met. Because the achievement of these milestones is neither probable nor reasonably estimable, such contingent payments have not been recorded on our consolidated balance sheets.

**Indemnification Obligations**

We enter into indemnification agreements under which we indemnify and hold harmless certain parties, including customers such as wholesalers, collaboration partners and parties conducting research on our behalf against claims, liabilities and losses brought by third parties to the extent that the claims arise out of (i) injury or death to person or property caused by defect in our marketed products or clinical trial product candidates, (ii) negligence in the manufacture or distribution of the product or clinical trial product candidate, or (iii) a material breach by Sepracor. We have no liabilities recorded for these guarantees at December 31, 2008 and 2007 and, if liabilities were incurred, we have insurance policies covering products, clinical trials and general liabilities, which could mitigate any losses. Although we maintain product liability insurance coverage for our clinical trials and products we commercialize, it is possible that we will not be able to obtain further liability insurance on acceptable terms, if at all, and that our insurance coverage may not provide adequate coverage against all potential claims.

Under our certificate of incorporation we indemnify our officers and directors for certain events or occurrences while the officer or director is, or was, serving at our request in such capacity. The term of the indemnification period is for the officer's or director's lifetime. The maximum potential amount of future payments we could be required to make under the terms of our certificate of incorporation is unlimited, however, we believe the fair value of this indemnification is minimal.

**L) Litigation**

***Litigation Related to Generic Competition and Patent Infringement***

Patent litigation involves complex legal and factual questions. We can provide no assurance concerning the duration or outcome of any patent-related lawsuits. If we, third parties from whom we receive royalties, or third parties from whom we have licensed products or received other rights to commercialize products, are not successful in enforcing our respective patents, the companies seeking to market generic versions of our marketed drugs and the drugs of our licensees will not be excluded, for the full term of the respective patents, from marketing their generic versions of our marketed products or third-party products for which we have licensed rights to our patents. Introduction of generic equivalents of any of our marketed products or third-party products for which we have licensed rights to our patents before the expiration of our or our collaborators' patents would have a material adverse effect on our business, financial condition and results of operations.

**Levalbuterol Hydrochloride Inhalation Solution Abbreviated New Drug Applications**

In September 2005, we received notification that the FDA had received an Abbreviated New Drug Application, or ANDA, from Breath Limited, or Breath, seeking approval of a generic version of our 1.25 mg/3 mL, 0.63 mg/3 mL and 0.31 mg/3 mL XOPENEX Inhalation Solution. Breath's submission includes a Paragraph IV certification alleging that our patents listed in FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly referred to as the "Orange Book," for these three dosages of XOPENEX Inhalation Solution are invalid, unenforceable or not infringed by the generic version for which Breath sought approval. In October 2005, we filed a civil action against Breath for patent infringement in the United States District Court for the District of Massachusetts, No. 1:06-CV-10043.

In April 2008, we entered into a settlement and license agreement with Breath to resolve this litigation. The agreement permits Breath to sell its generic versions of these XOPENEX Inhalation Solution products in the United States under the terms of an exclusive 180-day license commencing on August 20, 2012 and a non-exclusive license thereafter. Upon launch, Breath will pay us a double-digit

royalty on gross profits generated from the sales of generic versions of these XOPENEX Inhalation Solution products. Under the agreement, Breath agrees not to sell any of the products covered by our patents that are the subject of the license before the date on which the license commences. On May 1, 2008, the parties submitted to the court an agreed order of dismissal without prejudice, which the court approved. The litigation is now concluded.

In connection with the settlement and license agreement with Breath, in April 2008 we also entered into a supply agreement with Breath whereby, effective August 20, 2012, we will exclusively supply levalbuterol products (1.25 mg/3 mL, 0.63 mg/3 mL and 0.31 mg/3 mL) to Breath, under our New Drug Application, or NDA, for a period of 180 days, which we refer to as the Initial Term, and on a non-exclusive basis for two and one-half years thereafter. In addition to the royalties described above, Breath will pay us on a cost plus margin basis for supply of these levalbuterol products. The supply agreement contains provisions regarding termination for cause and convenience, including either party's right to terminate the agreement at any time after the Initial Term upon nine months written notice. Both the exclusive license under the settlement and license agreement and the exclusive supply obligations under the supply agreement could become effective prior to August 20, 2012 if a third-party launches a generic version of those dosages of XOPENEX Inhalation Solution or if the parties otherwise mutually agree.

In May 2008, we provided to the Federal Trade Commission and Department of Justice Antitrust Division the notifications of the settlement with Breath as required under Section 1112(a) of the Medicare Prescription Drug Improvement and Modernization Act of 2003. The settlement with Breath and the other agreements with Breath and its affiliates, including the supply agreement, the agreement for the acquisition of Oryx and license agreements with Arrow, may be reviewed by antitrust enforcement agencies, such as the Federal Trade Commission and Department of Justice Antitrust Division. There can be no assurances that governmental authorities will not seek to challenge the settlement with Breath or that a competitor, customer or other third-party will not initiate a private action under antitrust or other laws challenging the settlement with Breath. We may not prevail in any such challenges or litigation and, in any event, may incur significant costs in the event of an investigation or in defending any action under antitrust laws.

In January 2006, we received notification that the FDA had received an ANDA from Dey, L.P., seeking approval of a generic version of our 1.25 mg/3 mL, 0.63 mg/3 mL, and 0.31 mg/3 mL XOPENEX Inhalation Solution. Dey, L.P.'s submission includes a Paragraph IV certification alleging that our patents listed in the Orange Book for these three dosages of XOPENEX Inhalation Solution are invalid, unenforceable, or not infringed by the generic version for which Dey, L.P. has sought approval. In February 2006, we filed a civil action against Dey, L.P. for patent infringement and the case is pending in the United States District Court for the District of Delaware, C.A. No. 06-113.

In August 2006, we received notification that the FDA had received an ANDA from Dey, L.P. seeking approval of a generic version of our 1.25 mg/0.5 mL XOPENEX Inhalation Solution concentrate. Dey, L.P.'s submission includes a Paragraph IV certification alleging that our patents listed in the Orange Book for 1.25 mg/0.5 mL XOPENEX Inhalation Solution concentrate are invalid, unenforceable, or not infringed by the generic version for which Dey, L.P. is seeking approval. In September 2006, we filed a civil action against Dey, L.P. for patent infringement in the United States District Court for the District of Delaware, C.A. No. 06-604. In September 2006, both civil actions we filed against Dey, L.P. were consolidated into a single suit.

In May 2007, we received notification that the FDA had received an ANDA from Barr Laboratories, Inc., or Barr, seeking approval of a generic version of our 1.25 mg/3 mL, 0.63 mg/3 mL and 0.31 mg/3 mL XOPENEX Inhalation Solution. Barr's submission includes a Paragraph IV

certification alleging that our patents listed in the Orange Book for these three dosages of XOPENEX Inhalation Solution are invalid, unenforceable or not infringed by the generic version for which Barr has sought approval. In July 2007, we filed a civil action against Barr for patent infringement and the case is pending in the United States District Court for the District of Delaware.

In March 2008, the trial judge consolidated the Dey, L.P. and Barr cases for all purposes, including discovery and trial, and the consolidated case is pending as C.A. No. 06-113. The court held a Markman hearing in July 2008, to address the parties' disputed issues of patent claim interpretation and issued its written decision and ruling on these matters in December 2008. A pretrial conference is scheduled for September 2009 and trial is currently scheduled to begin within 120 days of the pretrial conference.

In June 2008, Dey, L.P. filed a Complaint against us in the United States District Court for the District of Delaware, C.A. No. 08-372. The Complaint is a declaratory judgment action in which Dey, L.P. seeks a declaration of non-infringement and invalidity of United States Patent 6,451,289 owned by us. Dey, L.P. had previously sent us notice that its ANDA contained a Paragraph IV certification against the 6,451,289 patent, and we did not commence litigation in response. We filed a Motion to Dismiss for lack of subject matter jurisdiction in response to the Complaint. In January 2009, the court entered an order denying our Motion to Dismiss and issued a corresponding opinion shortly thereafter. In February 2009, we filed a Motion for Certification of the court's order denying our Motion to Dismiss and to stay the proceedings pending resolution of appeal. The court subsequently issued an order staying this case pending its decision on our Motion for Certification and to stay the proceedings pending resolution of appeal.

The filing of an action for patent infringement under the Hatch-Waxman Act results in an automatic 30-month stay of the FDA's authority to grant final marketing approval to those companies that filed an ANDA containing a Paragraph IV certification against one or more of our XOPENEX Inhalation Solution patents. If an ANDA submission that includes a Paragraph IV certification is filed against a patent for a drug that has been granted five year new chemical entity data exclusivity, and that ANDA is filed between years four and five of the date the data exclusivity was awarded, such as in the case of the recently filed ANDAs with Paragraph IV certifications regarding LUNESTA, the statutory stay will run for 7.5 years from the NDA approval date. The first filer of an ANDA with a Paragraph IV certification is potentially entitled to a 180-day period of semi-exclusivity during which the FDA cannot approve subsequently filed ANDAs. The 180-day semi-exclusivity period would begin to run only upon first commercial marketing by the first filer. There are, however, also certain events that could cause the first filer to forfeit the 180-day semi-exclusivity period, which we refer to as a forfeiture event.

For our 1.25 mg/3 mL, 0.63 mg/3 mL, and 0.31 mg/3 mL dosages of XOPENEX Inhalation Solution, we believe that Breath is the sole first filer and potentially entitled to 180 days of semi-exclusivity against subsequent ANDA filers for those three dosages. The 30-month stay against Breath's ANDA expired on March 7, 2008. On April 9, 2008, the FDA granted final approval to Breath's ANDA for all three dosages. However, if a forfeiture event occurs and the FDA determines that Breath has forfeited the 180-day semi-exclusivity period for those three dosages, other ANDA filers who have been granted final approval by the FDA could commence an "at risk" launch upon expiration of the 30-month stay. For those three dosages, the 30-month stay against Dey, L.P. expired on July 9, 2008 and the 30-month stay against Barr expires on or about November 30, 2009.

For our 1.25 mg/0.5 mL XOPENEX Inhalation Solution concentrate, we believe that Dey, L.P. is the sole first filer and potentially entitled to 180 days of semi-exclusivity for that concentration. The 30-month stay against Dey, L.P.'s ANDA for that concentration expired on February 14, 2009. Dey, L.P.

may receive final approval to sell 1.25mg/0.5 mL levalbuterol from the FDA at any time and could thereafter commence an "at risk" launch.

Although we could seek recovery of any damages sustained in connection with any activities conducted by a party that infringes a valid and enforceable claim in our patents, whether we are ultimately entitled to such damages would be determined by the court in connection with our ongoing legal proceedings with each party desiring to launch generic levalbuterol hydrochloride products. If any of these parties were to commence selling a generic alternative to our XOPENEX Inhalation Solution products prior to the resolution of these ongoing legal proceedings, or there is a court determination that the products these companies wish to market do not infringe our patents, or that our patents are invalid or unenforceable, it would have a material adverse effect on our business, financial condition and results of operations. In addition, our previously issued guidance regarding our projected financial results may no longer be accurate, and we would have to revise such guidance.

**Eszopiclone Abbreviated New Drug Applications**

Beginning February 9, 2009, we received notices from Teva Pharmaceuticals USA, Inc., Cobalt Laboratories Inc., Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories, Inc., Orchid Healthcare, a division of Orchid Chemicals & Pharmaceuticals Ltd., Glenmark Generics, Inc., Roxane Laboratories, Inc., Lupin Ltd, Wockhardt Limited and Sun Pharma Global Inc., that each has filed an ANDA with the FDA for generic versions of eszopiclone tablets (1 mg, 2 mg and 3 mg). Each submission includes a Paragraph IV certification alleging that one or more of our patents listed in the Orange Book for LUNESTA is invalid, unenforceable or not infringed by their respective proposed generic products. We anticipate receipt of additional notices that other ANDAs with Paragraph IV certifications have been filed by different generic pharmaceutical companies. We are currently contemplating commencing civil actions against these parties for patent infringement and will consider commencing patent infringement litigation against any other company that files an ANDA that includes a Paragraph IV certification with respect to eszopiclone.

If we commence patent infringement litigation against any of these ANDA filers and/or any others within 45 days of our receipt of their respective Paragraph IV notices, ANDA approval will be stayed until June 15, 2012, or potentially 6 months thereafter if we successfully obtain a pediatric exclusivity extension, or until a court decides that our patents are invalid, unenforceable or not infringed, whichever is earlier. Should we successfully enforce our patents, ANDA approval should not occur until expiration of the applicable patents, one of which may be extended by our outstanding patent term extension application.

**Desloratadine Abbreviated New Drug Applications**

Certain of Schering-Plough Corporation's, or Schering-Plough, CLARINEX products for which we receive sales royalties are currently the subject of patent infringement litigation. Since June 2007, the FDA has received ANDAs relating to various dosage forms of CLARINEX from eleven different generic pharmaceutical companies. These ANDA submissions include Paragraph IV certifications alleging that our patents, which Schering-Plough (as exclusive licensee of such patents) listed in the Orange Book for these products, are invalid, unenforceable and/or not infringed by the submitter's proposed product. We and the University of Massachusetts, co-owners of certain patents listed in the Orange Book, filed civil actions against these parties for patent infringement in the United States District Court for the District of New Jersey. In April 2008, the trial judge consolidated these cases for all purposes including discovery and trial. The court has not set a trial date. We believe that all of these ANDAs are subject to a statutory stay of approval until at least December 21, 2009 based on previous

litigation commenced by Schering-Plough against these parties in separate civil actions involving another patent.

In March 2008, we entered into a consent agreement with Glenmark Pharmaceuticals, Inc., or Glenmark, one of the eleven generic pharmaceutical companies that filed a Paragraph IV certification against our patents, whereby Glenmark agreed not to pursue its case and to not market CLARINEX 5 mg tablets until the expiration of our patents listed by Schering-Plough in the Orange Book or until these patents are found invalid or unenforceable.

As a result of separate formal settlement agreements that Schering-Plough entered into with several ANDA filers involved in litigation with Schering-Plough, or Schering-Plough Settlement Agreements, we and the University of Massachusetts submitted, and the court approved, stipulations of dismissal without prejudice against five of the ANDA filers that we sued. In addition, we and the University of Massachusetts submitted one additional stipulation of dismissal without prejudice that is awaiting approval by the court and have actions remaining against four additional ANDA filers. The Schering-Plough Settlement Agreements entered to date permit generic entry of CLARINEX-D-12 Hour, CLARINEX-D -24 Hour and CLARINEX REDITABS on January 1, 2012 and CLARINEX 5 mg tablet on July 1, 2012. Upon generic entry of each product by a party to a Schering-Plough Settlement Agreement, our right to receive royalties on sales of such product will be significantly reduced.

**Levocetirizine Abbreviated New Drug Applications**

Beginning in February 2008, we and UCB S.A. received notices from Synthon Pharmaceuticals, Inc., or Synthon, Sun Pharmaceutical Industries Limited of Andheri (East), or Sun, Sandoz Inc., or Sandoz, and Pliva Hrvatska D.O.O. and Barr, or Pliva/Barr, that each has filed an ANDA seeking approval to market a generic version of XYZAL 5 mg tablets, and that each ANDA contained a Paragraph IV certification alleging that United States Patent 5,698,558, owned by us and exclusively licensed to UCB S.A., is invalid, unenforceable or not infringed. Beginning in April 2008, UCB S.A. filed in its name and on our behalf civil actions for patent infringement in the United States District Court for the Eastern District of North Carolina against Synthon, Sun, Sandoz, Pliva/Barr. We believe that all of these ANDAs are subject to a 30-month statutory stay of approval, resulting from the filing of lawsuits for patent infringement, the earliest of which, against Synthon, is scheduled to expire on or about August 29, 2010. In August 2008, the trial judge consolidated these cases for all purposes including discovery and trial. The court has not set a trial date.

***BROVANA Patent Infringement Claim***

In April 2007, we were served with a Complaint filed in the United States District Court for the Southern District of New York, C.A. No. 1:07-cv-2353, by Dey, L.P. and Dey, Inc., referred to collectively as Dey, alleging that the manufacture and sale of BROVANA infringes or will induce infringement of a single United States patent for which Dey owns all rights, title and interest. In April 2007, we filed an Answer and Counterclaims to this Complaint seeking to invalidate the originally asserted patent and a second related patent. In May 2007, Dey filed a reply asserting infringement of the second patent. In March 2008, United States Patent 7,348,362, or the '362 patent, entitled "Bronchodilation b-agonist compositions and Methods" issued and Dey, L.P. is the assignee of the patent. In August 2008, the court granted our Motion to Amend our Answer and Counterclaims to seek declaratory judgment that the '362 patent is invalid and unenforceable and to add Mylan Inc., Dey, L.P.'s parent corporation, as a party. Between December 2008 and January 2009, U.S. patents 7,462,645; 7,465,756; and 7,473,710 all entitled "Bronchodilation b-agonist compositions and Methods" issued. These three patents claim priority to the same parent patent application that issued as the '362

patent. In January 2009, Dey filed a motion to add these three patents to the case, which we did not oppose.

Under the current trial scheduling order, the trial will begin no earlier than October 2, 2009. It is too early to make a reasonable assessment as to the likely outcome or impact of this litigation. We are unable to reasonably estimate any possible range of loss or liability related to this lawsuit due to its uncertain resolution.

*Class Action Litigation Settlement*

In June 2007, we filed in the United States District Court for the District of Massachusetts, or the Court, a Stipulation of Settlement regarding two securities class action lawsuits, or class actions, then pending in the Court naming Sepracor and certain of our current and former officers and one director as defendants. The class actions, which were filed on behalf of certain purchasers of our equity and debt securities, or the plaintiffs, alleged that the defendants violated the Federal securities laws by making false and misleading statements relating to the testing, safety and likelihood of approval of tecastemizole by the FDA. Under the terms of the Stipulation of Settlement, in June 2007 we paid into escrow $52.5 million in settlement of the class actions and, in July 2007, received an $18.5 million reimbursement from our insurance carriers. We recorded the litigation settlement expense of $34.0 million, relating to this matter, during the quarter ended March 31, 2007. In September 2007, the Court granted final approval of the Stipulation of Settlement and entered a final judgment consistent with the Stipulation of Settlement. The settlement is now final and the total settlement amount has been released from escrow.

*Other Legal Proceedings*

We have been named as the defendant in two separate lawsuits filed in the United States District Court for the Middle District of Florida (Sharp, et al., filed July 17, 2008) and the United States District Court for the District of Arizona (Greeves, et al., served September 9, 2008) claiming that our pharmaceutical sales representatives should have been categorized as "non-exempt" rather than "exempt" employees under the Fair Labor Standards Act. Both lawsuits claim that we owe damages, overtime wages, interest, costs and attorneys' fees for periods preceding the filing of the respective actions. Other companies in the pharmaceutical industry face substantially similar lawsuits. We filed an Answer to the Complaint in each of the Sharp and Greeves litigation on October 10, 2008 and October 15, 2008, respectively. Discovery in each case is proceeding and no trial dates have been set. Based upon the facts as presently known, we do not believe that it is likely that either collective action will result in liability that would be material to our financial position. We believe these lawsuits are without merit and we are prepared to defend against them vigorously.

From time to time we are party to other legal proceedings in the course of our business. We do not, however, expect such other legal proceedings to have a material adverse effect on our business, financial condition or results of operations.

**M) Stockholders' Equity**

**Preferred Stock**

Our board of directors is authorized, without stockholder approval, but subject to any limitations prescribed by law, to issue up to 1,000,000 shares of preferred stock, in one or more series. Each such series will have such rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, as will be determined by the board of directors.

**Other Comprehensive Income**

The changes in the components of other comprehensive income at December 31, 2008 and 2007 were as follows:

| | 2008 | 2007 |
|---|---|---|
| | (In Thousands) | |
| Net income | $515,110 | $58,333 |
| Net unrealized (loss) gain on available-for-sale securities | (14,413) | 3,781 |
| Net foreign currency translation adjustments | (15,480) | 3,566 |
| Other comprehensive (loss) income | (29,893) | 7,347 |
| Comprehensive income | $485,217 | $65,680 |

Accumulated balances within other comprehensive income (loss) were as follows:

| | 2008 | 2007 |
|---|---|---|
| | (In Thousands) | |
| Net unrealized (loss) gain on available-for-sale securities | $ (9,642) | $ 4,771 |
| Net foreign currency translation adjustments | (10,064) | 5,416 |
| Accumulated other comprehensive (loss) income | $(19,706) | $10,187 |

The net unrealized loss on available-for-sale securities for the year ended December 31, 2008 primarily reflects the market loss on our auction-rate securities.

**N) Stock Plans**

The 1997 Stock Option Plan, or 1997 Plan, permitted us to grant non-qualified stock options, or NSOs, to purchase up to 1.0 million shares of common stock to our employees and consultants. Executive officers were not entitled to receive stock options under the 1997 Plan. NSOs granted under the 1997 Plan have an exercise price equal to the fair market value at the date of grant, a maximum term of ten years from the date of grant and generally vest over five years. The 1997 Plan expired in the fourth quarter of 2007.

The 1999 Director Stock Option Plan, or 1999 Director Plan, permitted us to grant NSOs to purchase up to 1.8 million shares of common stock to our non-employee directors. The 1999 Director Plan will no longer be used for further equity award grants.

The 2000 Stock Incentive Plan, as amended, or 2000 Plan, permits us to grant incentive stock options, or ISOs, NSOs and restricted stock awards to purchase up to 15.0 million shares of common stock to our employees, officers, directors and consultants. Stock options granted under the 2000 Plan have an exercise price equal to the fair market value at the date of grant, a maximum term of ten years from the date of grant and generally vest over five years.

The 2002 Stock Incentive Plan, as amended, or 2002 Plan, permits us to grant NSOs and restricted stock awards to purchase up to 4.0 million shares of common stock to our employees, other than executive officers. Stock options granted under the 2002 Plan have an exercise price equal to the fair market value at the date of grant, a maximum term of ten years from the date of grant and generally vest over five years.

The 2008 Director Stock Incentive Plan, or 2008 Director Plan, permits us to grant NSOs and restricted stock awards to purchase up to 500,000 shares of common stock to our non-employee

directors. Stock options granted under this plan have a maximum term of ten years and an exercise price equal to the fair market value at the date of grant. Stock options granted to new directors vest in equal annual installments over five years and the annual grants to directors vest in full on the day prior to the first annual meeting following the date of grant.

On January 1, 2006, we adopted the provisions of SFAS 123(R), which establishes accounting for equity instruments exchanged for employee services. Under the provisions of SFAS 123(R), share-based compensation cost is measured at the grant date, based on the fair value of the award, and is recognized as an expense over the employee's requisite service period (generally the vesting period of the equity award). We adopted SFAS 123(R) using the modified prospective application method, under which prior periods are not retrospectively revised for comparative purposes. Accordingly, no compensation expense for stock options was recognized for the periods prior to January 1, 2006.

The following table presents stock-based compensation expense by award type for the years ended December 31, 2008, 2007 and 2006, respectively:

| | 2008 | 2007 | 2006 |
|---|---|---|---|
| | (In Thousands) | | |
| Employee stock options | $27,375 | $27,695 | $41,385 |
| Restricted stock | 10,413 | 5,104 | 1,930 |
| Employee stock purchase plan | 1,477 | 1,479 | 1,885 |
| Stock-based compensation expense | $39,265 | $34,278 | $45,200 |

The following table presents stock-based compensation expense included in our consolidated statements of operations for the years ended December 31, 2008, 2007 and 2006, respectively:

| | 2008 | 2007 | 2006 |
|---|---|---|---|
| | (In Thousands) | | |
| Cost of products sold | $ 665 | $ 496 | $ 454 |
| Research and development | 9,124 | 9,470 | 10,984 |
| Selling, marketing and distribution | 10,961 | 11,425 | 15,386 |
| General and administrative | 18,515 | 12,887 | 18,376 |
| Stock-based compensation expense | $39,265 | $34,278 | $45,200 |

We estimate the fair value of stock options using the Black-Scholes valuation model. This valuation model takes into account the exercise price of the award, as well as a variety of assumptions. The assumptions we use to estimate the fair value of stock options include the expected term, the expected volatility of our stock over the expected term, the risk-free interest rate over the expected term, and our expected annual dividend yield. We believe that the valuation technique and the approach we utilized to develop the underlying assumptions are appropriate in calculating the fair values of the stock options granted in the years ended December 31, 2008, 2007 and 2006. Estimates of fair value are not intended to predict actual future events or the value ultimately realized by persons who receive equity awards.

The following table presents the weighted average assumptions used in the Black-Scholes valuation model to determine the fair value of stock options granted for the years ended December 31, 2008, 2007 and 2006, respectively:

| | 2008 | 2007 | 2006 |
|---|---|---|---|
| Expected term | 6.0 years | 5.6 years | 5.5 years |
| Expected volatility factor | 50% | 28% | 30% |
| Risk-free interest rate | 3.0% | 4.45% | 4.70% |
| Expected annual dividend yield | — | — | — |

The following tables summarize information about the number of outstanding and exercisable options as of December 31, 2008 segregated by price range (in thousands, except for per share amounts and contractual life):

| | Options Outstanding | | | Options Exercisable | |
|---|---|---|---|---|---|
| Exercise Price Range | Number of Options Outstanding | Weighted-Average Remaining Contractual Life (Years) | Weighted-Average Exercise Price Per Share | Number of Options Exercisable | Weighted-Average Exercise Price Per Share |
| $ 6.24 - $11.09 | 577 | 3.8 | $ 6.40 | 561 | $ 6.27 |
| $11.57 - $18.06 | 863 | 4.3 | $13.50 | 682 | $13.10 |
| $18.45 - $27.70 | 3,339 | 7.6 | $22.76 | 1,072 | $24.42 |
| $28.01 - $44.15 | 524 | 5.6 | $36.27 | 309 | $39.15 |
| $44.78 - $71.88 | 4,998 | 6.4 | $53.08 | 2,654 | $53.81 |
| $87.31 - $87.50 | 112 | 1.4 | $87.48 | 112 | $87.48 |
| | 10,413 | 6.4 | $37.02 | 5,390 | $37.72 |

The following tables summarize stock option activity for the plans (in thousands, except for per share amounts and contractual life):

| | 2008 | | | |
|---|---|---|---|---|
| | Number of Options | Weighted-Average Exercise Price Per Share | Weighted-Average Remaining Contractual Terms (In Years) | Aggregate Intrinsic Value |
| Outstanding at January 1, 2007 | 10,799 | $36.99(1) | | |
| Granted | 2,586 | 45.34 | | |
| Exercised | (1,360) | 22.09 | | |
| Cancelled | (1,001) | 48.86 | | |
| Expired | (593) | 39.74 | | |
| Outstanding at December 31, 2007 | 10,431 | $39.73 | | |
| Granted | 2,304 | 21.21 | | |
| Exercised | (164) | 14.29 | | |
| Cancelled | (694) | 25.75 | | |
| Expired | (1,464) | 29.99 | | |
| Outstanding at December 31, 2008 | 10,413 | $37.02 | 6.4 | $2,345 |
| Exercisable at December 31, 2008 | 5,390 | $37.72 | 4.5 | $2,345 |
| Expected to vest at December 31, 2008 | 10,025 | $37.74 | 6.2 | $2,345 |

(1) In March 2007, the exercise price of certain stock options was increased at the election of the officers holding such options.

The total intrinsic value of stock options exercised during the year ended December 31, 2008 and 2007 was $1.6 million and $33.6 million, respectively.

At December 31, 2008, unrecognized compensation expense related to non-vested stock options and restricted stock was $63.4 million and $27.4 million, respectively, which is expected to be recognized over weighted average periods of 3.1 years and 2.3 years, respectively.

*Restricted Stock and Restricted Stock Units*

Under the equity incentive plans, in addition to stock options, we granted certain employees restricted stock and restricted stock units, which we refer to collectively as restricted shares. Such awards generally vest annually over a one to five year period from the date of grant. Ownership of restricted shares typically cannot be transferred until the shares have vested. In connection with restricted share grants, we record compensation expense based on the fair value of the shares granted amortized on a straight-line basis over the vesting period.

The following tables summarize non-vested share activity for our plans (in thousands, except for per share amounts):

| | Stock Options | | Restricted Stock | |
|---|---|---|---|---|
| | Number of Shares (In Thousands) | Weighted Average Fair Value | Number of Shares (In Thousands) | Weighted Average Fair Value |
| Non-vested at December 31, 2006 | 4,544 | $22.65 | 174 | $55.34 |
| Granted | 2,586 | 15.84 | 418 | 41.03 |
| Vested | (1,424) | 19.33 | (46) | 55.24 |
| Forfeited | (1,001) | 23.22 | (44) | 53.53 |
| Non-vested at December 31, 2007 | 4,705 | $18.91 | 502 | $41.94 |
| Granted | 2,304 | 10.52 | 1,074 | 20.65 |
| Vested | (1,292) | 19.66 | (169) | 41.05 |
| Forfeited | (694) | 10.97 | (38) | 25.00 |
| Non-vested at December 31, 2008 | 5,023 | $15.06 | 1,369 | $25.52 |

*Employee Stock Purchase Plan*

The 1998 Employee Stock Purchase Plan, as amended, or 1998 ESPP, permits an aggregate of 1,900,000 shares of common stock to be purchased by employees at 85% of market value on the first or last day of each six-month offering period, whichever is lower, through accumulation of payroll deductions ranging from 1% to 10% of compensation subject to certain limitations. Employees purchased approximately 346,000, 207,000 and 167,000 shares for a total of $4.6 million, $6.0 million and $7.3 million, respectively, during the years ended December 31, 2008, 2007 and 2006, respectively. At December 31, 2008, there were approximately 386,000 shares of common stock authorized for future issuance under the 1998 ESPP.

At December 31, 2008, the estimated unrecognized compensation expense related to the December 1, 2008 offering period of the 1998 ESPP, which concludes on May 31, 2009, was $804,000. The associated expense is amortized on a straight-line basis over the offering period.

**O) Income Taxes**

The components of income tax expense consist of the following at December 31:

| | 2008 | 2007 | 2006 |
|---|---|---|---|
| | | (In Thousands) | |
| Current income tax expense | | | |
| Federal | $ 6,000 | $ 19,764 | $3,530 |
| State | 6,466 | 2,940 | 126 |
| Foreign | 138 | 686 | — |
| Total current income tax expense | $ 12,604 | $ 23,390 | $3,656 |
| Deferred income tax expense | | | |
| Federal | $(440,215) | $(15,376) | $ — |
| State | (15,446) | (1,744) | — |
| Foreign | (3,689) | — | — |
| Total deferred income tax benefit | $(459,350) | $(17,120) | $ — |
| Total current and deferred income tax expense | $(446,746) | $ 6,270 | $3,656 |

For each of the years ended December 31, 2008, 2007 and 2006, our United States Federal statutory tax rate was 35%, 35% and 34% and our effective tax rate was a credit of 653.5% and an expense of 9.7% and 2.1%, respectively. Our effective tax rate varies from our statutory tax rate for the years ended December 31 principally due to the following:

| | 2008 | 2007 | 2006 |
|---|---|---|---|
| United States Federal statutory tax rate | 35.0% | 35.0% | 34.0% |
| State income taxes, net of U.S. Federal tax expense | 5.5 | 4.9 | 5.9 |
| Tax rate and tax law differential of foreign operations | 6.5 | 0.9 | — |
| Research and development credits | (8.2) | (11.4) | (4.4) |
| Change in valuation allowance | (711.2) | (24.5) | (35.3) |
| Other | 4.8 | 0.3 | 0.4 |
| Deferred compensation amortization | — | 4.5 | 1.5 |
| Stock based compensation | 14.1 | — | — |
| | (653.5)% | 9.7% | 2.1% |

Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to tax benefit carryforwards and to differences between the financial statement amounts of assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using enacted tax rates in effect for the year in which the differences are expected to reverse. A valuation allowance is established if, based on management's review of both positive and negative evidence, it is more likely than not that all or a portion of the deferred tax asset will not be realized. To the extent we establish a valuation allowance or increase this allowance in a period, we include an expense within the tax provision in the statement of operations.

As of the end of the first quarter of 2008, a full valuation allowance was recorded against our net deferred tax assets in the United States and foreign jurisdictions. Based upon our settlement with Breath during the second quarter of 2008, our operating results over recent years and through June 30, 2008 and an assessment of our expected future results of operations, we determined that it is more likely than not that we will realize a substantial portion of our deferred tax assets in the United States

and a foreign jurisdiction. As a result, during the second quarter of 2008, we released a total of $452.0 million of our valuation allowance, which was recorded as an income tax benefit.

As of December 31, 2008, we had a remaining valuation allowance recorded against United States net deferred tax assets of $182.8 million which consists of $145.1 million for stock based compensation deductions and $6.9 million of stock based compensation research and development credits that will be credited to additional paid-in-capital when realized; $1.9 million for certain state operating loss carryforwards, $9.0 million for capital losses and $19.9 million of research and development credits that will likely expire without being utilized. Additionally, there is a non-U.S. valuation allowance of $1.1 million for non-U.S. operating loss and tax credit carryforwards that will likely expire without being utilized.

At December 31, 2008, we had Federal tax net operating loss carryforwards of approximately $866.1 million, which expire in the years 2021 through 2025 and state tax net operating loss carryforwards of approximately $158.0 million, which expire in the years 2009 through 2025. Based upon the Internal Revenue Code and changes in company ownership, utilization of the net operating losses and tax credit carryforwards may be subject to an annual limitation. At December 31, 2008, we had non-U.S. net operating loss carryforwards of approximately $6.3 million, which will expire in the years 2009 through 2026. At December 31, 2008, we had Federal and state research and experimentation credit carryforwards of approximately $56.4 million and $31.4 million, respectively, which will expire from 2009 through 2028 and 2023, respectively, Canadian federal investment tax credits of $3.8 million, which expire in the years 2009 through 2028 and federal alternative minimum tax credits of $12.0 million which do not expire.

The components of net deferred taxes were as follows at December 31:

| | 2008 | 2007 |
|---|---|---|
| | (In Thousands) | |
| Assets | | |
| Net operating loss carryforwards | $ 311,731 | $ 379,516 |
| Research and development capitalization | 16,321 | 24,161 |
| Tax credit carryforwards | 93,142 | 93,984 |
| Accrued expenses | 19,714 | 10,968 |
| Reserves | 100,394 | 92,472 |
| Depreciation | 2,528 | 2,592 |
| Intangibles | 28,770 | 1,664 |
| Other | 9,438 | 8,112 |
| License fee | 39,396 | 29,227 |
| Stock based compensation | 16,413 | 15,351 |
| Basis difference of subsidiaries | 13,231 | 4,118 |
| Liabilities | | |
| Deferred revenue on license fees | (2,275) | (103) |
| Valuation allowance | (183,897) | (662,062) |
| Net deferred taxes | $ 464,906 | $ — |

The United States and foreign components of income before income taxes were as follows for the years ended December 31:

| | 2008 | 2007 | 2006 |
|---|---|---|---|
| | | (In Thousands) | |
| United States | $76,061 | $69,463 | $178,617 |
| Foreign | (7,697) | (4,860) | (3,800) |
| Total | $68,364 | $64,603 | $174,817 |

We file tax returns in the United States Federal jurisdiction and in various state, local and foreign jurisdictions. During the third quarter of 2007, the Internal Revenue Service, or IRS, formally concluded its examination of our 2004 and 2005 federal income tax returns, and no payment was due as a result of the audit. We are no longer subject to IRS examination for years prior to 2005, although carryforward attributes that were generated prior to 2005 may still be adjusted upon examination by the tax authorities if they either have been or will be used in a future period. Our foreign income tax returns are not currently under examination. In 2008, the Canada Revenue Agency completed its examination of our Scientific Research and Experimental Development claims for the years ended December 31, 2006, 2005, 2004 and 2003, and no payment was due as a result of the audit. With limited exceptions, our foreign income tax returns are no longer subject to examination for years prior to 2004, although carryforward attributes that were generated prior to these periods may still be adjusted upon examination if they either have been or will be used in a future period. Undistributed earnings of non-U.S. subsidiaries approximated $7.6 million at December 31, 2008. We intend to reinvest these earnings indefinitely in operations outside the United States. The estimate of additional income tax if such earnings were remitted to the U.S. approximates $2.9 million.

Effective January 1, 2007, we adopted the provisions of FIN 48, *Accounting for Uncertainty in Income Taxes,* or FIN 48. The implementation of FIN 48 did not have a material impact on our consolidated financial statements or results of operations. A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in thousands):

| | |
|---|---|
| Balance at January 1, 2007 | $ — |
| Additions based on tax positions related to the current year | — |
| Additions for tax positions of prior years | 18,438 |
| Balance at December 31, 2007 | $ 18,438 |
| Additions based on tax positions related to the current year | 1,098 |
| Additions for tax positions of prior years | 18,316 |
| Reductions for tax positions of prior years | (13,185) |
| Balance at December 31, 2008 | $ 24,667 |

The $24.7 million of unrecognized tax benefits represents approximately $10.6 million of tax positions for which the ultimate deductibility is highly certain but for which there is uncertainty about the timing of such deduction. Because of the impact of deferred income tax accounting, other than for interest and penalties, the disallowance of the shorter deductibility period would not change the effective income tax rate but would accelerate the payment of cash to the taxing authority to an earlier period by approximately $900,000. Approximately $13.2 million of tax positions relate to certain tax credits which have not been utilized as of December 31, 2008. We expect the liability for unrecognized tax benefits to change by an insignificant amount during the next 12 months.

We recognize accrued interest and penalties related to unrecognized tax benefits as a component of income tax expense. This policy did not change as a result of the adoption of FIN 48. We have accrued approximately $183,000, $210,000 and $0 of interest as of December 31, 2008, 2007 and 2006, respectively, and $0 of penalties.

We completed a research tax credit study in 2008. The results of the study are included in the unrecognized tax benefits balance as of December 31, 2008.

**P) Employees' Savings Plan**

We have a 401(k) savings plan for all domestic employees. Under the provisions of our 401(k) savings plan, employees may voluntarily contribute up to 60% of their compensation, up to the statutory limit. In addition, we can make a matching contribution at our discretion. We matched 50% of the first $7,000, $7,000 and $5,000 contributed by employees up to $3,500, $3,500 and $2,500 maximum per employee during 2008, 2007 and 2006, respectively. We incurred expenses of $5.2 million, $5.4 million and $3.9 million in 2008, 2007 and 2006, respectively, as a result of our matching contribution.

**Q) Restructuring Charges**

During the year ended December 31, 2007, we completed an evaluation of our sales force structure, size and allocation in an attempt to maximize efficiency of our sales force. This evaluation resulted in a decision to restructure and re-align our sales force. The restructuring program was completed by December 31, 2007, approximately 300 positions were eliminated and we recorded a charge of $6.9 million. This charge was primarily comprised of severance costs for terminated employees and contract termination costs for excess leased computer equipment and company cars.

During 2008, we reversed $566,000 of our restructure reserve primarily as a result of a change in estimate associated with employee severance costs and contract terminations.

The following table sets forth the restructuring accrual activity during the years ended December 31, 2008 and 2007:

| | Employee Related Items and Benefits | Contract Terminations | Total |
|---|---|---|---|
| | (In Thousands) | | |
| Restructuring charges accrual at December 31, 2006 | $ — | $ — | $ — |
| Initial provision | 6,493 | 428 | 6,921 |
| Cash payments | (187) | — | (187) |
| Restructuring charges accrual at December 31, 2007 | $ 6,306 | $ 428 | $ 6,734 |
| Adjustments to the initial provision | (239) | (327) | (566) |
| Cash payments | (6,067) | (101) | (6,168) |
| Restructuring charges accrual at December 31, 2008 | $ — | $ — | $ — |

**R) Business Segment Reporting**

With the addition of SPI, we now report and operate in two segments distinguished by strategic business units that offer different products: (i) Sepracor Inc., which consists of Sepracor and our subsidiaries other than SPI and currently engages in the discovery, research and development and commercialization of pharmaceutical products and (ii) SPI, which currently engages in the licensing and commercialization of pharmaceutical products in Canada.

Following the acquisition of SPI in June 2008, in accordance with SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information,* we began to separately report information for the SPI segment. The accounting policies of both segments are the same as those described in the summary of significant accounting policies, which are contained in Note B "Summary of Significant Accounting Policies".

The tables below represent segment information for the periods identified and provides a reconciliation of segment information to total consolidated information. Reconciliations of segment information for the years ended December 31, 2007 and 2006 are not presented as Sepracor had only one segment during those periods. For the Sepracor segment and SPI, segment income (loss) from operations represents segment gross profit less direct research and development expenses, acquired IPR&D, direct selling, general and administrative expenses and amortization of intangible assets. There are no inter-segment revenues and we do not report capital expenditures by segment as such information is not used by our chief operating decision-maker.

| | December 31, 2008 | | |
|---|---|---|---|
| | Sepracor | SPI | Consolidated |
| | (In Thousands) | | |
| Product revenues | $1,204,187 | $11,052 | $1,215,239 |
| Royalties and license fees | 76,152 | 898 | 77,050 |
| Total revenues | $1,280,339 | $11,950 | $1,292,289 |
| Income (loss) from operations | $ 56,981 | $(1,254) | $ 55,727 |
| Total assets | $1,759,148 | $55,927 | $1,815,075 |
| Depreciation and amortization | $ 33,019 | $ 2,117 | $ 35,136 |

Reconciling information between reportable segments and consolidated totals is shown in the following table:

| | December 31, 2008 |
|---|---|
| | (In Thousands) |
| Income (loss) from operations | $ 55,727 |
| Interest income | 24,124 |
| Interest expense | (8,506) |
| Gain on extinguishment of debt | 10,082 |
| Equity in investee losses | (1,103) |
| Other income (expense) | (11,960) |
| Income (loss) before income taxes | $ 68,364 |

All of our revenues in 2008, 2007 and 2006 were received from unaffiliated customers located in the United States and Canada. Product revenue by product is presented below, and since revenue for SPI is less than 1% of total revenue we have only presented this information on a consolidated basis for SPI:

| | 2008 | 2007 | 2006 |
|---|---|---|---|
| | | (In Thousands) | |
| Product sales: | | | |
| XOPENEX Inhalation Solution | $ 441,011 | $ 487,189 | $ 542,944 |
| LUNESTA | 600,283 | 600,904 | 565,436 |
| XOPENEX HFA | 74,213 | 74,883 | 40,994 |
| BROVANA | 57,239 | 14,280 | — |
| OMNARIS Nasal Spray | 14,632 | — | — |
| ALVESCO HFA Inhalation Aerosol | 16,809 | — | — |
| SPI | 11,052 | — | — |
| Total product sales | $1,215,239 | $1,177,256 | $1,149,374 |

Long-lived asset information, which is comprised of property and equipment, by geographic area is presented below:

| | 2008 | 2007 | 2006 |
|---|---|---|---|
| | | (In Thousands) | |
| Long-lived assets: | | | |
| United States | $105,415 | $75,151 | $64,156 |
| Canada | 11,657 | 12,157 | 8,655 |
| Total long-lived assets | $117,072 | $87,308 | $72,811 |

## S) Quarterly Consolidated Financial Data (Unaudited)

| | First Quarter | Second Quarter(1) | Third Quarter | Fourth Quarter |
|---|---|---|---|---|
| | | (In Thousands, Except Per Share Data) | | |
| **2008** | | | | |
| Net revenues | $320,779 | $294,145 | $307,673 | $369,692 |
| Gross profit | $290,955 | $266,264 | $272,096 | $330,533 |
| Net income applicable to common shares | $ 12,192 | $395,080 | $ 19,438 | $ 88,400 |
| Basic net income per common share | $ 0.11 | $ 3.66 | $ 0.18 | $ 0.82 |
| Diluted net income per common share | $ 0.11 | $ 3.41 | $ 0.17 | $ 0.77 |
| **2007** | | | | |
| Net revenues | $327,700 | $276,792 | $280,758 | $339,980 |
| Gross profit | $296,082 | $251,262 | $254,338 | $306,393 |
| Net income (loss) applicable to common shares | $ 18,815 | $ 4,811 | $ 39,708 | $ (5,001) |
| Basic net income (loss) per common share | $ 0.18 | $ 0.05 | $ 0.37 | $ (0.05) |
| Diluted net income (loss) per common share | $ 0.16 | $ 0.04 | $ 0.34 | $ (0.05) |

(1) The three months ended June 30, 2008 includes the release of our valuation allowance.

**T) Subsequent Events**

In January 2009, we announced a corporate restructuring and workforce reduction plan pursuant to which we intend to reduce our workforce by approximately 20%, or approximately 530 positions, of which approximately 180 are corporate positions and approximately 350 are field-based positions. We expect to substantially complete the workforce reduction by the end of the second quarter of 2009. In addition, we eliminated approximately 410 contract sales organization sales representative positions. In total, our sales positions were reduced to approximately 1,325.

As a result of the reduction in workforce, we expect to record charges and make future payments of between $33.0 million and $37.0 million, a substantial portion of which we anticipate will be recorded in the first quarter of 2009. We currently expect these charges to consist of approximately $23.0 million to $24.0 million relating to employee termination benefits and approximately $10.0 million to $13.0 million relating to other charges, including contract sales organization termination fees and lease termination fees associated with office locations, equipment and automobiles. The increase in the estimate of our restructuring charge from our previously announced range primarily relates to recent decisions to vacate two additional office locations and fees related to the termination of our contact sales organization earlier than previously anticipated. Our estimated restructuring charge is based on a number of assumptions. Actual results may differ materially and additional charges not currently expected may be incurred in connection with, or as a result of, these reductions.

On February 17, 2009, we announced that we commenced a tender offer to purchase for cash up to all $382.5 million aggregate principal amount of our outstanding 0% notes due 2024. The terms and conditions of the offer are set forth in the Schedule TO, Offer to Purchase and the related Letter of Transmittal filed with the SEC on February 17, 2009. We are offering to purchase the notes at a price of $970 for each $1,000 of principal amount of notes tendered. The tender offer will expire at midnight, New York City time, at the end of March 16, 2009, unless extended or earlier terminated pursuant to the terms of the tender offer. The tender offer will not be contingent upon any minimum number of notes being tendered but is subject to certain conditions described in the Offer to Purchase.

**SEPRACOR INC.**
**Schedule II**
**Valuation and Qualifying Accounts and Reserves**
**Years Ended December 31, 2008, 2007 and 2006**
**(In Thousands)**

| Description | Balance at Beginning of Period | Additions | Deductions | Balance at End of Period |
|---|---|---|---|---|
| Allowance for Doubtful Accounts(1) | | | | |
| Year Ended December 31, 2008 | $ 459 | $ 450 | $ 42 | $ 867 |
| Year Ended December 31, 2007 | $ 470 | $ — | $ 11 | $ 459 |
| Year Ended December 31, 2006 | $ 470 | $ — | $ — | $ 470 |
| Sales Rebates, Chargebacks & Allowances(2) | | | | |
| Year Ended December 31, 2008 | $221,488 | $493,470 | $461,596 | $253,362 |
| Year Ended December 31, 2007 | $144,413 | $355,666 | $278,591 | $221,488 |
| Year Ended December 31, 2006 | $ 96,099 | $236,470 | $188,156 | $144,413 |
| Sales Return Reserves(3) | | | | |
| Year Ended December 31, 2008 | $ 24,351 | $ 19,213 | $ 20,337 | $ 23,227 |
| Year Ended December 31, 2007 | $ 23,218 | $ 29,606 | $ 28,473 | $ 24,351 |
| Year Ended December 31, 2006 | $ 16,269 | $ 20,253 | $ 13,304 | $ 23,218 |
| Deferred Tax Asset Valuation Allowance(4) | | | | |
| Year Ended December 31, 2008 | $662,062 | $ 10,942 | $489,108 | $183,896 |
| Year Ended December 31, 2007 | $695,513 | $135,223 | $168,674 | $662,062 |
| Year Ended December 31, 2006 | $737,983 | $ 5,442 | $ 47,912 | $695,513 |

(1) Additions to Allowance for Doubtful Accounts are recorded as an expense.

(2) Additions to Sales Rebates, Chargebacks and Allowances are recorded as a reduction of revenue.

(3) Additions to Sales Return Reserves are recorded as a reduction of revenue.

(4) Additions to Deferred Tax Asset Valuation Allowance are recorded as expense.

## EXHIBIT INDEX

| Exhibit Number | Description | Form or Schedule | Incorporated by Reference to | | |
|---|---|---|---|---|---|
| | | | Exhibit No. | Filing Date with SEC | SEC File Number |
| 3.1 | Restated Certificate of Incorporation | Form 10-K for 12/31/2002 | 3.1 | 3/31/2003 | 000-19410 |
| 3.2 | Amended and Restated By-Laws of the Registrant | Form 10-K for 12/31/2000 | 3.2 | 3/28/2001 | 000-19410 |
| 4.1 | Specimen Certificate for shares of common stock, $0.10 par value, of the Registrant | Form S-1 | 4.1 | 9/20/1991 | 333-41653 |
| 4.2 | Rights Agreement, dated June 30, 2002, between the Registrant and EquiServe Trust Company, N.A., as Rights Agent | Form 8-K | 4.1 | 6/4/2002 | 000-19410 |
| 4.4 | Form of 0% Series B Convertible Subordinated Notes due 2010 | Form 10-K for 12/31/2003 | 4.6 | 3/15/2004 | 000-19410 |
| 4.5 | Form of 0% Convertible Senior Subordinated Notes due 2024 | Form 10-K for 12/31/2004 | 4.7 | 3/15/2004 | 000-19410 |
| 10.1# | The Registrant's 1991 Amended and Restated Stock Option Plan | Form 10-Q for 9/30/1999 | 10.1 | 11/12/1999 | 000-19410 |
| 10.2# | The Registrant's 1991 Director Stock Option Plan, as amended and restated | Form 10-K for 12/31/1998 | 10.3 | 3/31/1999 | 000-19410 |
| 10.3# | The Registrant's 1997 Stock Option Plan | Form 10-K for 12/31/1997 | 10.36 | 3/31/1998 | 000-19410 |
| 10.4# | The Registrant's 1998 Employee Stock Purchase Plan, as amended | Form 10-K for 12/31/2003 | 10.5 | 3/15/2004 | 000-19410 |
| 10.5# | The Registrant's 1999 Director Stock Option Plan | Form 10-Q for 9/30/1999 | 10.2 | 11/12/1999 | 000-19410 |
| 10.6# | The Registrant's 2000 Stock Incentive Plan, as amended | Form 10-Q for 6/30/2008 | 10.9 | 8/8/2008 | 000-19410 |
| 10.7# | The Registrant's 2002 Stock Incentive Plan, as amended | Form 10-Q for 6/30/2002 | 10.1 | 8/14/2004 | 000-19410 |
| 10.8# | The Registrant's 2008 Director Stock Incentive Plan | Form 10-Q for 6/30/2008 | 10.10 | 8/8/2008 | |
| 10.9 | The Registrant's Severance Benefit Program | * | | | |
| 10.10 | Form of Incentive Stock Option Agreement Granted under the Registrant's 2000 Stock Incentive Plan | Form 10-K for 12/31/2004 | 10.42 | 3/16/2005 | 000-19410 |
| 10.11 | Form of Nonstatutory Stock Option Agreement Granted under the Registrant's 2000 Stock Incentive Plan | Form 10-K for 12/31/2004 | 10.43 | 3/16/2005 | 000-19410 |
| 10.12 | Form of Restricted Stock Agreement Granted under the Registrant's 2000 Stock Incentive Plan | Form 10-K for 12/31/2006 | 10.35 | 3/1/2007 | 000-19410 |

| Exhibit Number | Description | Form or Schedule | Incorporated by Reference to | | |
|---|---|---|---|---|---|
| | | | Exhibit No. | Filing Date with SEC | SEC File Number |
| 10.13# | Summary of Plan regarding "Parachute Payments" and Section 280G Gross-Up Payments | Form 10-K for 12/31/1999 | 10.35 | 3/30/2000 | 000-19410 |
| 10.14# | Form of Executive Retention Agreement by and between the Registrant and each of Robert F. Scumaci, and Mark H.N. Corrigan, as amended | * | | | |
| 10.15# | Form of Executive Retention Agreement by and between the Registrant and each of Andrew I. Koven, Mark Iwicki and Richard Ranieri, as amended | * | | | |
| 10.16# | Amended and Restated Employment Agreement by and between the Registrant and Adrian Adams dated November 6, 2008, as amended by letter agreement dated December 23, 2008 | * | | | |
| 10.17# | Executive Retention Agreement by and between the Registrant and Adrian Adams dated March 1, 2007, as amended by letter agreement dated December 23, 2008 | * | | | |
| 10.18# | Amended and Restated Employment Agreement by and between the Registrant and Mark H.N. Corrigan, M.D. dated November 6, 2008, as amended by letter agreement dated December 23, 2008 | * | | | |
| 10.19# | Amended and Restated Employment Agreement by and between the Registrant and Andrew I. Koven dated November 6, 2008, as amended by letter agreement dated December 23, 2008 | * | | | |
| 10.20# | Amended and Restated Employment Agreement by and between the Registrant and Mark Iwicki dated November 6, 2008, as amended by letter agreement dated December 23, 2008 | * | | | |
| 10.21# | Amended and Restated Employment Agreement by and between the Registrant and Richard Ranieri dated November 6, 2008, as amended by letter agreement dated December 23, 2008 | * | | | |
| 10.22# | Amended and Restated Employment Agreement by and between the Registrant and Robert F. Scumaci dated November 6, 2008, as amended by letter agreement dated December 23, 2008 | * | | | |

| Exhibit Number | Description | Form or Schedule | Incorporated by Reference to | | |
|---|---|---|---|---|---|
| | | | Exhibit No. | Filing Date with SEC | SEC File Number |
| 10.23# | Executive Retirement Agreement by and between Sepracor Inc. and Timothy Barberich dated December 27, 2007 | Form 8-K for 12/27/2007 | 10.1 | 12/31/2007 | 000-19410 |
| 10.24# | Severance and Consulting Agreement by and between the Registrant and David Southwell dated May 14, 2008. | Form 10-Q for 6/30/2008 | 10.6 | 8/8/2008 | 000-19410 |
| 10.25 | Technology Transfer and License Agreement, dated as of January 1, 1994, between the Registrant and BioSepra Inc. | Form 10-K for 12/31/1998 | 10.10 | 3/31/1999 | 000-19410 |
| 10.26 | Technology Transfer and License Agreement, dated as of January 1, 1994, between the Registrant and HemaSure Inc. | Form 10-K for 12/31/1998 | 10.11 | 3/31/1999 | 000-19410 |
| 10.27† | Agreement, dated as of December 5, 1997, by and between the Registrant and Schering-Plough Ltd. | Form 10-K for 12/31/1997 | 10.31 | 3/31/1998 | 000-19410 |
| 10.28† | Amendment to December 5, 1997 Exclusive License Agreement between Registrant and Schering-Plough Ltd. dated November 10, 2008 | * | | | |
| 10.29 | Assignment Agreement, dated as of August 25, 1999, by and between the Registrant and Georgetown University | Form 10-Q for 9/30/1999 | 10.3 | 11/12/1999 | 000-19410 |
| 10.30† | License Agreement, dated August 31, 1999, by and between the Registrant and Hoechst Marion Roussel, Inc. | Form 10-K for 12/31/1999 | 10.30 | 3/30/2000 | 000-19410 |
| 10.31† | EX-US License Agreement, dated August 31, 1999, by and between the Registrant and Hoechst Marion Roussel, Inc. | Form 10-K for 12/31/1999 | 10.31 | 3/30/2000 | 000-19410 |
| 10.32† | License and Assignment Agreement, dated September 30, 1999, by and between the Registrant and Rhone-Poulenc Rorer SA | Form 10-K for 12/31/1999 | 10.32 | 3/30/2000 | 000-19410 |
| 10.33† | License Agreement, dated May 27, 1999, by and between UCB Farchim S.A. and the Registrant | Form 10-K for 12/31/1999 | 10.33 | 3/30/2000 | 000-19410 |
| 10.34† | Agreement, dated December 20, 2001, between Minnesota Mining and Manufacture Company, 3M Innovative Properties Company and the Registrant | Form 10-K for 12/31/2001 | 10.43 | 4/1/2002 | 000-19410 |
| 10.35 | Indenture, dated as of December 12, 2003, by and between the Registrant and the JPMorgan Chase Bank, as Trustee | Form 8-K | 4.1 | 12/19/2003 | 000-19410 |

| Exhibit Number | Description | Form or Schedule | Incorporated by Reference to | | |
|---|---|---|---|---|---|
| | | | Exhibit No. | Filing Date with SEC | SEC File Number |
| 10.36 | Indenture, dated September 22, 2004, between the Registrant and JPMorgan Chase Bank, as trustee | Form 8-K | 4.1 | 9/24/2004 | 000-19410 |
| 10.37† | Manufacturing Services Agreement, dated March 1, 2004, between Patheon and the Registrant | Form 8-K | 99.1 | 12/21/2004 | 000-19410 |
| 10.38† | Amendments No. 1, 2 and 3 to the Manufacturing Services Agreement, dated March 1, 2004, between Patheon and the Registrant | Form 10-K for 12/31/2006 | 10.30 | 3/1/2007 | 000-19410 |
| 10.39† | Amended and Restated Manufacturing Services Agreement dated November 6, 2007 among the Registrant and Patheon Inc., Patheon Pharmaceuticals Inc. & MOVA Pharmaceutical Corporation | Form 10-K for 12/31/2007 | 10.40 | 2/29/2008 | 000-19418 |
| 10.40† | Exclusive Supply and Distribution Agreement, dated as of November 16, 2004, by and among 3M Company, through its 3M Drug Delivery Systems Division, 3M Innovative Properties Company and the Registrant | Form 10-K for 12/31/2004 | 10.46 | 3/16/2005 | 000-19410 |
| 10.41† | U.S. License Agreement for Levoceterizine, dated as of February 17, 2006, by and between UCB S.A. and the Registrant | Form 10-K for 12/31/2005 | 10.43 | 3/16/2006 | 000-19410 |
| 10.42† | Letter Agreement dated December 31, 2007, between the Registrant and Bial—Portela & C[a], S.A. | Form 10-K for 12/31/2007 | 10.43 | 2/29/2008 | 000-19410 |
| 10.43† | License Agreement dated December 31, 2007, between the Registrant and Bial—Portela & C[a], S.A. | Form 10-K for 12/31/2007 | 10.44 | 2/29/2008 | 000-19410 |
| 10.44† | Distribution and Development Agreement for Ciclesonide in the USA dated January 25, 2008 between the Registrant and Nycomed GmbH | Form 10-K for 12/31/2007 | 10.45 | 2/29/2008 | 000-19410 |
| 10.45† | Development, License and Commercialization Agreement dated September 11, 2007 by and between the Registrant and Glaxo Group Limited, an affiliate of GlaxoSmithKline | Form 10-Q for 9/30/2007 | 10.4 | 11/09/2007 | 000-19410 |
| 10.46† | Share Purchase Agreement, dated April 30, 2008, between the Registrant, 1765800 Ontario Limited, Cobalt Pharmaceuticals Inc., Melville Holdings Limited, Oryx Pharmaceuticals, Inc. and Arrow Group A.p.S. | Form 10-Q for 6/30/2008 | 10.1 | 8/8/2008 | 000-19410 |

| Exhibit Number | Description | Form or Schedule | Incorporated by Reference to | | |
|---|---|---|---|---|---|
| | | | Exhibit No. | Filing Date with SEC | SEC File Number |
| 10.47† | License and Development Agreement, dated April 30, 2008, between the Registrant and Arrow International Limited for Levalbuterol/ipratropium Product. | Form 10-Q for 6/30/2008 | 10.2 | 8/8/2008 | 000-19410 |
| 10.48† | License and Development Agreement, dated April 30, 2008, between the Registrant and Arrow International Limited for ciclesonide products. | Form 10-Q for 6/30/2008 | 10.3 | 8/8/2008 | 000-19410 |
| 10.49† | Settlement and License Agreement, dated April 30, 2008, between the Registrant and Breath Limited | Form 10-Q for 6/30/2008 | 10.4 | 8/8/2008 | 000-19410 |
| 10.50† | Supply Agreement, dated April 30, 2008, between the Registrant and Breath Limited. | Form 10-Q for 6/30/2008 | 10.5 | 8/8/2008 | 000-19410 |
| 10.51# | Summary of Executive Officer Compensation for 2008 | * | | | |
| 10.52# | Summary of Non-Employee Director Compensation for 2008 | * | | | |
| 21 | Subsidiaries of the Registrant | * | | | |
| 23 | Consent of PricewaterhouseCoopers LLP, an Independent Registered Public Accounting Firm | * | | | |
| 31.1 | Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/ Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended | * | | | |
| 31.2 | Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/ Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended | * | | | |
| 32.1 | Certification of 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 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.

(#) Management contract or compensatory plan or arrangement filed as an exhibit to this Form pursuant to Item 14(c) of Form 10-K.

(†) Confidential treatment has been requested as to certain portions, which portions have been filed separately with the Securities and Exchange Commission.

(This page has been left blank intentionally.)

**Exhibit 21**

## LIST OF SUBSIDIARIES

| Name | Jurisdiction of Incorporation |
|---|---|
| Sepracor Canada (Nova Scotia) Limited (100% owned subsidiary of Sepracor Canada, Inc.) | Nova Scotia, Canada |
| Sepracor N.V. (100% owned subsidiary of Sepracor) | Netherland Antilles |
| Sepracor Research and Development Trust (100% owned subsidiary of Sepracor) | Delaware |
| Sepracor Pharmaceuticals (Ireland) Ltd. (100% owned subsidiary of Sepracor N.V.) | Ireland |
| Sepracor Canada, Inc. (100% owned subsidiary of Sepracor) | Ontario, Canada |
| Sepracor RM, Inc. (100% owned subsidiary of Sepracor) | Delaware |
| Sepracor Pharmaceuticals, Inc. (100% owned subsidiary of Sepracor Canada, Inc.) | Ontario, Canada |

**Exhibit 23**

## CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 33-43460, 33-44808, 33-48428, 333-05217, 333-05219, 333-94774, 333-48719, 333-05221, 333-58557, 333-58559, 333-58563, 33-48427, 33-63710, 33-79724, 333-85003, 333-84983, 333-58368, 333-100888, 333-100887, 333-112748, 333-130368, 333-138815, 333-145323, 333-152436, 333-152437 and 333-152438) of Sepracor Inc. of our report dated February 27, 2009 relating to the financial statements, financial statement schedule and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PRICEWATERHOUSECOOPERS LLP

Boston, Massachusetts
February 27, 2009

**Exhibit 31.1**

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Adrian Adams, certify that:

1. I have reviewed this Annual Report on Form 10-K of Sepracor Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this Annual Report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this Annual Report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this Annual Report is being prepared;
   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an Annual Report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2009

/s/ ADRIAN ADAMS

Adrian Adams
*President and Chief Executive Officer*

**Exhibit 31.2**

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Robert F. Scumaci, certify that:

1. I have reviewed this Annual Report on Form 10-K of Sepracor Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this Annual Report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this Annual Report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this Annual Report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an Annual Report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2009

/s/ ROBERT F. SCUMACI

Robert F. Scumaci
*Executive Vice President and Chief Financial Officer*

**Exhibit 32.1**

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report on Form 10-K of Sepracor Inc. (the "Company") for the period ended December 31, 2008 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Adrian Adams, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 27, 2009

/s/ ADRIAN ADAMS

Adrian Adams
*Chief Executive Officer*

A signed original of this written statement required by Section 906 has been provided to Sepracor Inc. and will be retained by Sepracor Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

**Exhibit 32.2**

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report on Form 10-K of Sepracor Inc. (the "Company") for the period ended December 31, 2008 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Robert F. Scumaci, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 27, 2009

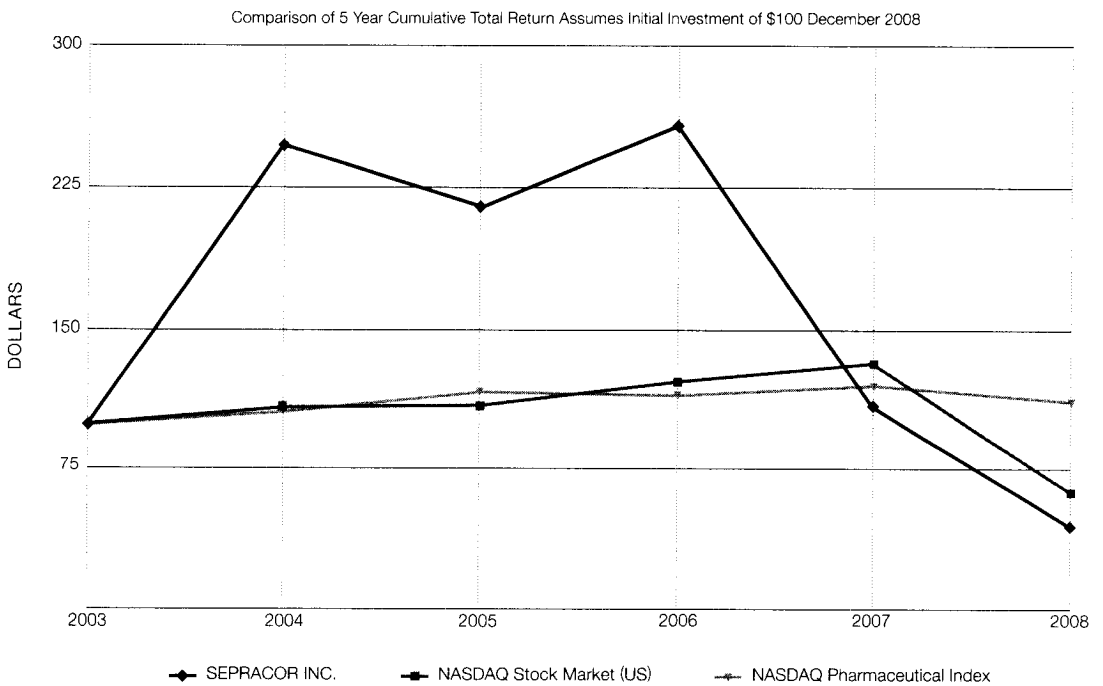
/s/ ROBERT F. SCUMACI

Robert F. Scumaci
*Chief Financial Officer*

A signed original of this written statement required by Section 906 has been provided to Sepracor Inc. and will be retained by Sepracor Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

## Comparative Stock Performance Graph

The comparative total return performance graph below compares the cumulative stockholder return on our common stock for the period from December 31, 2003 through the year ended December 31, 2008 with the cumulative Total Return Index for (I) the NASDAQ Stock Market (U.S. companies), which we refer to as the NASDAQ Composite Index, and (II) the NASDAQ Pharmaceutical Index. This graph assumes the investment of $100 on December 31, 2003 in our common stock, the NASDAQ Composite Index, and the NASDAQ Pharmaceutical Index and assumes all dividends are reinvested. Measurement points are the last trading days of each of the years ended December 31, 2003, 2004, 2005, 2006, 2007, and 2008.




| | | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 |
|---|---|---|---|---|---|---|---|
| SEPRACOR INC. | Return % | – | 148.13 | -13.08 | 19.33 | -57.37 | -58.17 |
| | Cum $ | 100.00 | 248.13 | 215.66 | 257.35 | 109.70 | 45.89 |
| NASDAQ Stock Market (US) | Return % | – | 8.83 | 2.12 | 9.85 | 8.43 | -51.82 |
| | Cum $ | 100.00 | 108.83 | 111.14 | 122.09 | 132.39 | 63.78 |
| NASDAQ Pharmaceutical Index | Return % | – | 6.50 | 10.13 | -2.13 | 5.17 | -6.97 |
| | Cum $ | 100.00 | 106.50 | 117.29 | 114.79 | 120.73 | 112.32 |

NOTES:

Data complete through last fiscal year.

Corporate Performance Graph with peer group uses peer group only performance (excludes only company).

Peer group indices use beginning of period market capitalization weighting.

Calculated (or Derived) based from CRSP NASDAQ Stock Market (US Companies), CRSP NASDAQ Pharmaceuticals, Center for Research in Security Prices (CRSP®), Booth School of Business, The University of Chicago. Copyright 2009 Zacks Investment Research, Inc. Used with permission. All rights reserved.

## CORPORATE INFORMATION

Our Annual Meeting of Stockholders will be held at 9:00 a.m. on May 14, 2009 at Sepracor's Corporate Headquarters, 158 Waterford Drive, Marlborough, MA.

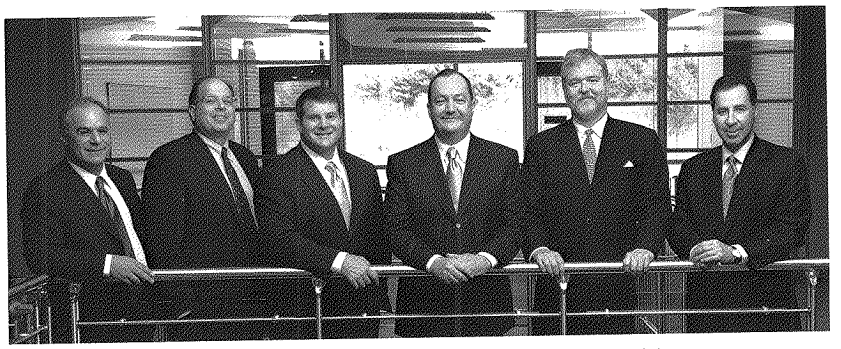
**Common Stock**
Our common stock is traded on the NASDAQ Global Select Market under the symbol SEPR.

**Primary Outside Legal Counsel**
WilmerHale, Boston, MA

**Independent Registered Public Accounting Firm**
PricewaterhouseCoopers LLP, Boston, MA

**Corporate Headquarters**
Sepracor Inc.
84 Waterford Drive
Marlborough, MA 01752
Telephone: (508) 481-6700
Facsimile: (508) 357-7499

**Transfer Agent and Registrar**
Questions regarding accounts, address changes, stock transfers and lost certificates should be directed to:
Computershare
P.O. Box 43010
Providence, RI 02940-3010
Phone: (781) 575-2879



Pictured left to right: Andrew I. Koven, Robert F. Scumaci, Mark Iwicki, Adrian Adams, Mark H.N. Corrigan, M.D., Richard Ranieri

## EXECUTIVE MANAGEMENT

Adrian Adams
President and Chief Executive Officer

Mark H.N. Corrigan, M.D.
Executive Vice President,
Research and Development

Mark Iwicki
Executive Vice President and
Chief Commercial Officer

Andrew I. Koven
Executive Vice President, General
Counsel and Corporate Secretary

Richard Ranieri
Executive Vice President,
Human Resources and Administration

Robert F. Scumaci
Executive Vice President
and Chief Financial Officer



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## BOARD OF DIRECTORS

Adrian Adams
President and Chief Executive Officer,
Sepracor Inc.

Timothy J. Barberich
Former Chief Executive Officer
and current Chairman of the
Board, Sepracor Inc.

Digby W. Barrios
Former President and CEO,
Boehringer Ingelheim Corporation

Robert J. Cresci
Managing Director, Pecks
Management Partners Ltd.

James F. Mrazek
Former Vice President and General
Manager, Healthcare Division of
Johnson & Johnson Products Inc.

Lisa Ricciardi
Adjunct Partner,
Essex Woodlands Health Ventures

Timothy J. Rink, M.A., M.D., Sc.D.
Former Chairman and
Chief Executive Officer,
Aurora Biosciences, Inc.

Alan A. Steigrod
Former Executive Vice President,
Glaxo Holdings plc


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