UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

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

(Mark One)

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

For the 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: 000-50651

SANTARUS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**33-0734433**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
3721 Valley Centre Drive, Suite 400 San Diego, California	**92130**
(Address of Principal Executive Offices)	*(Zip Code)*

(858) 314-5700

(Registrant's telephone number, including area code)

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

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, par value $0.0001 per share	Nasdaq Global Market
Series A Junior Participating Preferred Stock Purchase Rights	Nasdaq Global Market

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

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act of 1933. Yes ☐ No ☑

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. 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 Exchange Act 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 the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☑

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):
Large accelerated filer ☐ Accelerated filer ☑ Non-accelerated filer ☐ Smaller reporting company ☐
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

As of June 30, 2008, the last business day of the registrant's most recently completed second quarter, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $85.6 million, based on the closing price of the registrant's common stock on the Nasdaq Global Market on June 30, 2008 of $2.01 per share.*

The number of outstanding shares of the registrant's common stock, par value $0.0001 per share, as of February 15, 2009 was 57,799,588.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement to be filed with the Securities and Exchange Commission within 120 days after registrant's fiscal year end December 31, 2008 are incorporated by reference into Part III of this report.

* Excludes the common stock held by executive officers, directors and stockholders whose ownership exceeded 10% of the registrant's common stock outstanding at June 30, 2008. This calculation does not reflect a determination that such persons are affiliates for any other purposes.

SANTARUS, INC.

FORM 10-K — ANNUAL REPORT
For the Year Ended December 31, 2008

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PART I

Forward-Looking Statements

Any statements in this report and the information incorporated herein by reference about our expectations, beliefs, plans, objectives, assumptions or future events or performance that are not historical facts are forward-looking statements. You can identify these forward-looking statements by the use of words or phrases such as "believe," "may," "could," "will," "estimate," "continue," "anticipate," "intend," "seek," "plan," "expect," "should," or "would." Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties inherent in our business including, without limitation: our ability to increase market demand for, and sales of, our Zegerid® and Glumetza® products; the scope and validity of patent protection for our products, including the outcome and duration of our patent infringement lawsuit against Par Pharmaceutical, Inc., and our ability to commercialize products without infringing the patent rights of others; whether we are successful in generating revenue under our strategic alliances, including our over-the-counter, or OTC, license agreement with Schering-Plough Healthcare Products, Inc., or Schering-Plough, and our license and distribution agreements with Glaxo Group Limited, an affiliate of GlaxoSmithKline plc; Schering-Plough's ability to address issues in the U.S. Food and Drug Administration's, or FDA's, complete response letter for its Zegerid brand OTC product and whether the FDA ultimately approves Schering-Plough's new drug application, or NDA, in a timely manner or at all; our ability to successfully develop (including successful completion of the ongoing and planned phase III clinical trials) and obtain regulatory approval for our budesonide MMX® and rifamycin SV MMX product candidates in a timely manner or at all; whether the FDA accepts the NDA for the new tablet formulation of our Zegerid products for filing or ultimately approves the NDA in a timely manner or at all; adverse side effects or inadequate therapeutic efficacy of our products or products we promote that could result in product recalls, market withdrawals or product liability claims; competition from other pharmaceutical or biotechnology companies and evolving market dynamics, including the impact of currently available generic prescription and OTC proton pump inhibitor, or PPI, products and the introduction of additional generic or branded PPI products; our ability to further diversify our sources of revenue and product portfolio; other difficulties or delays relating to the development, testing, manufacturing and marketing of, and obtaining and maintaining regulatory approvals for, our and our strategic partners' products; fluctuations in quarterly and annual results; our ability to obtain additional financing as needed to support our operations or future product acquisitions; the impact of the recent turmoil in the financial markets; and other risks detailed below under Part I — Item 1A — Risk Factors.

Although we believe that the expectations reflected in our forward-looking statements are reasonable, we cannot guarantee future results, events, levels of activity, performance or achievement. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.

Corporate Information

We were incorporated in California in December 1996 and reincorporated in Delaware in July 2002. Our principal executive offices are located at 3721 Valley Centre Drive, Suite 400, San Diego, California 92130 and our telephone number is (858) 314-5700. Our web site address is www.santarus.com. The information contained in, or that can be accessed through, our web site is not part of this report. Unless the context requires otherwise, in this report the terms "Santarus," "we," "us" and "our" refer to Santarus, Inc., a Delaware corporation.

We have received U.S. and European Union, or EU, trademark registration for our corporate name, Santarus®. We also have received trademark registration in the U.S., EU, Canada and Japan for our brand name, Zegerid®, and we have applied for trademark registration for various other names and logos. All other trademarks, service marks or trade names appearing in this report are the property of their respective owners. Use or display by us of other parties' trademarks, trade dress or products is not intended to and does not imply a relationship with, or endorsements or sponsorship of, us by the trademark or trade dress owners.

Item 1. Business

Overview

We are a specialty pharmaceutical company focused on acquiring, developing and commercializing proprietary products that address the needs of patients treated by gastroenterologists and other targeted physicians. Our commercial organization currently promotes Zegerid® (omeprazole/sodium bicarbonate) immediate-release proton pump inhibitor, or PPI, prescription products for the treatment of upper gastrointestinal, or GI, conditions, including gastroesophageal reflux disease, or GERD. Our commercial organization also currently promotes Glumetza® (metformin hydrochloride extended release tablets) prescription products as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. In addition to our commercial efforts, we are also focused on expanding our portfolio of products for the U.S. prescription market to support our long-term growth strategy, and we are currently in late-stage clinical development with budesonide MMX® and rifamycin SV MMX, which are product candidates designed to treat lower GI conditions. To further leverage our proprietary PPI technology and diversify our sources of revenue, we have entered into strategic alliances with Schering-Plough Consumer Healthcare Products, Inc., or Schering-Plough, for the U.S. and Canadian over-the-counter, or OTC, markets and with Glaxo Group Limited, an affiliate of GlaxoSmithKline, plc, or GSK, for selected prescription and OTC markets outside the U.S. and for prescription markets in Puerto Rico and the U.S. Virgin Islands. Our goal is to become a premier specialty pharmaceutical company with a diversified portfolio of commercial and development products.

Santarus Portfolio			
Marketed Products			
Drug	**Partner**	**Approved Indications**	**Status**
Zegerid® Capsules and Powder for Oral Suspension (Rx – U.S.)		Heartburn/GERD, Erosive Esophagitis, Duodenal and Gastric Ulcers, Upper GI Bleeding	Marketed
Glumetza® Extended Release Tablets (Rx – U.S.)	Depomed	Type 2 Diabetes	Marketed
Development Product Candidates			
Drug	**Partner**	**Potential Indications***	**Status**
OTC Zegerid® (U.S.)	Schering-Plough	Heartburn	NDA submitted March 2008
Zegerid® Tablet Formulation (Rx – U.S.)		Heartburn/GERD, Erosive Esophagitis, Duodenal and Gastric Ulcers	NDA submitted January 2009
Zegerid® Rx and OTC (Ex – U.S.)**	GSK	Heartburn/GERD, Erosive Esophagitis, Duodenal and Gastric Ulcers	Preparation of regulatory filings ongoing
Budesonide MMX® (U.S.)	Cosmo	Mild or Moderate Active Ulcerative Colitis	Two phase III clinical trials ongoing
Rifamycin SV MMX® (U.S.)	Cosmo	Traveler's Diarrhea	Initiation of phase III program planned for first half of 2010

* These potential indications will be subject to completion of any applicable product development and clinical programs and to approval by the FDA or applicable foreign regulatory authorities.

** GSK is also currently distributing and promoting Zegerid prescription products in Puerto Rico and the U.S. Virgin Islands.

Currently Marketed Products

Our commercial organization is currently promoting Zegerid (omeprazole/sodium bicarbonate) Capsules and Powder for Oral Suspension, which are proprietary formulations that combine omeprazole, which is a PPI, and an antacid. We developed these products as the first immediate-release oral PPIs for the U.S. prescription market, and they have been approved by the U.S. Food and Drug Administration, or FDA, to treat or reduce the risk of a variety of upper GI diseases and disorders, including GERD. Our Zegerid products are based on patented technology and utilize antacids, which raise the gastric pH and thus protect the PPI, omeprazole, from acid degradation in the stomach, allowing the omeprazole to be quickly absorbed into the bloodstream. We commercially launched Zegerid Capsules in early 2006 and Zegerid Powder for Oral Suspension in late 2004 and early 2005. In 2008, we reported $101.2 million in net product sales of our Zegerid prescription products, which reflects an increase of approximately 27% over the net product sales reported in 2007.

Our commercial organization also promotes Glumetza (metformin hydrochloride extended release tablets) prescription products in the U.S., under the terms of an exclusive promotion agreement that we entered into with Depomed, Inc., or Depomed, in July 2008. Glumetza is a once-daily, extended-release formulation of metformin that incorporates patented drug delivery technology and is indicated as an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 diabetes. The extended-release delivery system is designed to offer patients with diabetes an ability to reach their optimal dose of metformin with fewer GI side effects. We began our promotion of the Glumetza products in October 2008. In 2008, we reported $4.7 million in promotion revenue associated with Glumetza, which reflects the amount earned under the Glumetza promotion agreement for the fourth quarter.

Development Product Candidates

We are developing two product candidates targeting lower GI conditions under the terms of a strategic collaboration that we entered into with Cosmo Technologies Limited, or Cosmo, in December 2008. The product candidates utilize Cosmo's patented MMX technology, which is a proprietary multi-matrix system that is designed to result in the controlled release and homogeneous distribution of a drug substance throughout the length of the colon. The goal of the MMX technology is to improve efficacy while reducing side effects typically associated with systemic absorption. Budesonide MMX is an oral corticosteroid and is currently being investigated in two phase III clinical trials for the induction of remission of mild or moderate active ulcerative colitis. Rifamycin SV MMX is a broad spectrum, semi-synthetic antibiotic and has been investigated in a phase II clinical program for traveler's diarrhea. Under the strategic collaboration, we were granted exclusive rights to develop and commercialize these product candidates in the U.S.

In addition, in January 2009, we submitted a new drug application, or NDA, to the FDA for a new tablet formulation to add to our Zegerid family of prescription products. The new formulation is an immediate-release tablet that combines omeprazole with a mix of buffers.

Additional Strategic Alliances

To further leverage our proprietary PPI technology and diversify our sources of revenue, we licensed exclusive rights to Schering-Plough under our patented PPI technology to develop, manufacture and sell Zegerid brand OTC products in the lower dosage strength of 20 mg of omeprazole in the U.S. and Canada. We have also entered into a license agreement and a distribution agreement granting exclusive rights to GSK under our patented PPI technology to develop, manufacture and commercialize prescription and OTC products in up to 114 specified countries outside of the U.S., Europe, Australia, Japan and Canada (including markets within Africa, Asia, the Middle-East, and Central and South America), and to distribute and sell Zegerid brand prescription products in Puerto Rico and the U.S. Virgin Islands.

Strategy

Our goal is to become a premier specialty pharmaceutical company with a diversified portfolio of commercial and development products. Our business strategy for achieving this goal is focused on increasing sales of Zegerid and Glumetza brand products in the U.S. prescription pharmaceutical market, advancing our lower GI development

products, maximizing the value of our proprietary PPI technology in other pharmaceutical markets, and expanding our product portfolio to further leverage our existing commercial capabilities through internal development or co-promotion, in-licensing or acquisition of marketed or late-stage proprietary products. Key elements of our business strategy include the following:

- ***Increasing Sales of Zegerid and Glumetza Brand Prescription Products.*** Our commercial resources are focused on increasing market demand for, and sales of, Zegerid and Glumetza brand prescription products. Our field sales organization currently promotes Zegerid products to targeted gastroenterologists and primary care physicians. To leverage our commercial capabilities and increase revenues, we entered into a promotion agreement for the Glumetza products in July 2008, and our field sales organization began promoting these products to targeted endocrinologists and primary care physicians in October 2008. We believe that both the Zegerid and Glumetza brand products offer differentiated treatment options for physicians and their patients and continue to represent an attractive market opportunity.

- ***Advancing Our Lower GI Development Products.*** We are also focused on advancing the development of the budesonide MMX and rifamycin SV MMX product candidates, which utilize the patented MMX delivery technology developed by Cosmo. Budesonide MMX is an oral corticosteroid and is currently being investigated in two phase III clinical trials for the induction of remission of mild or moderate active ulcerative colitis. Rifamycin SV MMX is a broad spectrum, semi-synthetic antibiotic, and has been investigated in a phase II clinical program for traveler's diarrhea. The MMX technology is designed to deliver a drug substance directly to the colon. We believe the utilization of the MMX technology with these product candidates may result in improved efficacy, while also reducing side effects typically associated with systemic absorption. We were granted exclusive rights to continue the development of these product candidates and, assuming regulatory approval, to commercialize them in the U.S. under a strategic collaboration that we entered into with Cosmo in December 2008.

- ***Maximizing the Value of Our Proprietary PPI Technology.*** In addition to our efforts related to our Zegerid prescription products in the U.S., we are focused on maximizing the value of our patented PPI technology in other pharmaceutical markets. We have licensed exclusive rights to Schering-Plough to develop, manufacture and sell Zegerid brand OTC products with the lower dosage strength of 20 mg of omeprazole in the U.S. and Canada. We have also granted exclusive rights to GSK to commercialize prescription and OTC omeprazole products in up to 114 specified countries within Africa, Asia, the Middle-East, and Central and South America and to distribute Zegerid brand prescription products in Puerto Rico and the U.S. Virgin Islands. We believe these arrangements and revenue sources have the potential to add significant value to our company. In addition, we submitted an NDA to the FDA in January 2009 for a new tablet formulation to add to our family of Zegerid prescription products. We plan to continue to evaluate additional opportunities to expand the commercialization of our PPI technology both within and outside the U.S.

- ***Expanding our Product Portfolio to Further Leverage our Commercial Capabilities through Internal Development or Co-promotion, In-licensing or Acquisition of Marketed or Late-Stage Proprietary Products.*** In the future, we also plan to expand our product portfolio to further leverage our commercial capabilities, and we may explore arrangements for additional marketed or late-stage products. We will concentrate our efforts on proprietary products that would be complementary to our existing products and have attractive commercial potential.

Currently Marketed Products

Zegerid Capsules and Zegerid Powder for Oral Suspension

Our Zegerid brand prescription products are proprietary immediate-release formulations that combine omeprazole, which is a PPI, and antacids. Zegerid (omeprazole/sodium bicarbonate) Capsules is an immediate-release formulation that contains omeprazole and sodium bicarbonate in a capsule dosage form and is available in 20 mg/1100 mg and 40 mg/1100 mg dosage strengths. Zegerid (omeprazole/sodium bicarbonate) Powder for Oral Suspension is an immediate-release formulation that contains omeprazole and sodium bicarbonate in a powder for oral suspension dosage form and is available in 20 mg/1680 mg and 40 mg/1680 mg dosage strengths. These

products are indicated for the treatment of heartburn and other symptoms associated with GERD, short-term treatment (4-8 weeks) of erosive esophagitis which has been diagnosed by endoscopy, maintenance of healing of erosive esophagitis, short-term treatment (4-8 weeks) of active duodenal ulcers, and short-term treatment (4-8 weeks) of active benign gastric ulcers. Zegerid Powder for Oral Suspension is also indicated for the reduction of risk of upper GI bleeding in critically ill patients. Currently, there are six issued U.S. patents that provide coverage for our Zegerid products, all of which patents expire in July 2016. Additional information about the intellectual property for our Zegerid products is set forth below under the heading "Business – Intellectual Property – Zegerid Products and Related PPI Technology."

We received FDA approval of each of our NDAs for these Zegerid products within the initial 10-month period for FDA review under the policies of the Prescription Drug User Fee Act, or PDUFA. We commercially launched Zegerid Capsules in early 2006 and Zegerid Powder for Oral Suspension in late 2004 and early 2005. Since launching these products, we have reported net product sales of our Zegerid products of $13.7 million, $46.0 million, $79.4 million and $101.2 million in each of 2005, 2006, 2007 and 2008, respectively.

We have developed our Zegerid family of prescription products to provide the following distinct features:

- *Immediate Release* — All currently marketed PPIs in the U.S., other than Zegerid, are available for oral use only in delayed-release, enteric-coated formulations. Our Zegerid products utilize one or more antacids, instead of delayed-release, enteric coatings, to protect the omeprazole from acid degradation. The antacids neutralize gastric acid, protect the omeprazole from acid degradation and enable rapid absorption of the omeprazole, which, in turn, allows the omeprazole to begin to inhibit acid production. For example, in our pivotal pharmacokinetic/pharmacodynamic, or PK/PD, clinical trials evaluating Zegerid Capsules and Zegerid Powder for Oral Suspension, maximal plasma levels of omeprazole were attained in approximately 30 minutes, as compared with 1.5 hours or longer to reach peak plasma levels for delayed-release omeprazole in the same trials.

- *Duration of Acid Control* — While providing for immediate release, our Zegerid products are also designed to provide a duration of acid control similar to delayed-release PPIs and, thus, allow for once-daily dosing. For example, in our pivotal PK/PD clinical trials evaluating Zegerid Capsules and Zegerid Powder for Oral Suspension, the products maintained a median gastric pH above 4 ranging from 12.2 to 18.6 hours per day, depending on the dosage strength and formulation, after repeated once-daily dosing.

- *Nighttime and Daytime Acid Control* — Zegerid Powder for Oral Suspension has also demonstrated effective acid control during the night when dosed at bedtime. For example, in a PD clinical trial evaluating Zegerid Powder for Oral Suspension and delayed-release PPI brands, Nexium® and Prevacid®, significantly fewer patients treated with Zegerid experienced nocturnal acid breakthrough than when treated with the comparator drugs. Nocturnal acid breakthrough was defined as gastric pH less than 4 for more than one continuous hour between 10:00 pm and 6:00 am with once-daily PPI therapy. Zegerid Capsules have also demonstrated significantly longer control of gastric acidity over a 24-hour period, when dosed in the morning before breakfast. For example, in a PD clinical trial evaluating the effects of morning dosing of each of Zegerid Capsules and delayed-release PPI brands, Protonix® and Prevacid, on 24-hour gastric acid control in patients with symptoms of GERD, the time that gastric pH was greater than 4 for patients taking Zegerid was 14.3 hours compared with 10 hours for patients treated with Protonix and 11.7 hours for patients treated with Prevacid.

- *Variety of Formulations* — Our Zegerid products are currently marketed in capsule and powder for oral suspension dosage forms. We have also recently submitted an NDA to the FDA for a new tablet formulation of our Zegerid products, utilizing our patented PPI technology. In addition to providing alternative formulations for use in the general adult population, our powder for oral suspension formulation may address the needs of specific patient populations, such as those who have difficulty swallowing capsules or tablets.

Upper Gastrointestinal Diseases and Disorders

Our Zegerid products have been approved by the FDA to treat or reduce the risk of a variety of upper GI diseases and disorders. Upper GI diseases and disorders, such as heartburn, GERD, erosive esophagitis and gastric and duodenal ulcers, are generally caused by or aggravated by acid secretion in the stomach or gastric acid that refluxes into the esophagus. Prolonged exposure to excess acid may result in ulcers or other serious damage to the tissue of the esophagus, stomach or small intestine.

Heartburn is pain or a burning sensation in the throat or chest area resulting from the reflux of acid from the stomach into the esophagus. An individual consistently experiencing heartburn at least twice per week is generally diagnosed as having GERD. According to the National Heartburn Alliance, an estimated 54 million American adults experience heartburn two or more days per week. In addition, GERD symptoms frequently occur during the nighttime hours, and it is estimated that nearly 80% of frequent heartburn sufferers experience symptoms at night.

Erosive esophagitis is characterized by erosions and ulcers from the repeated exposure of the esophagus to acid and digestive enzymes. It is estimated that as many as 30% of GERD patients, or approximately 16 million patients, have erosive esophagitis in the U.S. Erosive esophagitis may or may not be accompanied by heartburn, and is typically diagnosed by a gastroenterologist through a procedure known as an endoscopy.

Gastric and duodenal ulcers are ulcers or erosions in the stomach or duodenum, respectively. These ulcers may be caused by a combination of gastric acid and bacterial infection or may result from the use of other medications such as nonsteroidal anti-inflammatory drugs, or NSAIDs. It is estimated that there are approximately 14 million patients who suffer from gastric and duodenal ulcers in the U.S. Most patients with these ulcers are referred to a gastroenterologist who will perform an endoscopy to determine the extent and severity of the ulcers.

According to IMS Health, an independent market research firm, the U.S. market for prescription PPI products had total sales of more than $14.0 billion during 2008.

Glumetza Extended Release Tablets

Glumetza (metformin hydrochloride extended release tablets) is a once-daily, extended-release formulation of metformin in 500 mg and 1000 mg dosage strengths that incorporates patented drug delivery technology and is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. We began promoting the Glumetza products in October 2008 under a promotion agreement entered into with Depomed, as further described below. In 2008, we reported $4.7 million in promotion revenue associated with Glumetza, which reflects the amount earned under the Glumetza promotion agreement for the fourth quarter.

Metformin is one of the most commonly prescribed oral medications for the treatment of type 2 diabetes, and it is used to improve glycemic control in diabetes patients. However, the efficacy of immediate-release metformin as a single-agent therapy may be limited due primarily to the inability to titrate patients up to the maximum daily recommended dose of 2000 mg per day due to the occurrence of GI side effects, such as nausea. It is estimated that dose-related GI side effects may occur in up to 50 percent of metformin-treated patients. Many patients who are unable to tolerate the GI side effects of immediate-release metformin at 2000 mg per day do not achieve adequate glycemic control. Patient compliance is also a concern with immediate-release metformin, which is dosed twice per day and recommended three times per day for doses greater than 2000 mg.

Glumetza is formulated with patented extended-release drug delivery technology designed to address these limitations of metformin therapy. Glumetza's delivery system has the potential to allow physicians to titrate dosing to reach up to 2000 mg per day, depending on patient response, without a significant increase in GI side effects compared with 1500 mg per day of immediate-release metformin. Glumetza may offer patients with diabetes an ability to reach their optimal dose of metformin with fewer adverse events. In addition, Glumetza is dosed once daily, which may help to improve patient compliance. Currently, there are four issued U.S. patents that provide coverage for one or both of the Glumetza products, with expiration dates ranging from September 2016 to October 2021. Additional information about the intellectual property for the Glumetza products is set forth below under the heading "Business – Intellectual Property – Glumetza Extended Release Tablets."

Type 2 Diabetes

Type 2 diabetes is the most common form of diabetes, accounting for 90% to 95% of all diagnosed diabetes cases, according to the National Institute of Diabetes and Digestive and Kidney Diseases of the National Institutes of Health, or the NIDDK. Diabetes is a disease in which levels of glucose, a type of sugar found in the blood, are above normal. Diabetic patients do not produce sufficient levels of insulin, a hormone produced in the pancreas, or do not properly utilize the insulin, making it difficult for the body to convert food into energy. The body breaks down food into glucose, and delivers glucose to cells through the bloodstream. Cells use insulin to help process blood glucose into energy. In the case of type 2 diabetes, cells fail to use insulin properly or the pancreas cannot make as much insulin as the body requires. That causes the amount of glucose in the blood to increase, while starving cells of energy. Over time, high blood glucose levels damage nerves and blood vessels, which can lead to complications such as heart disease, stroke, blindness, kidney disease and nerve problems.

According to the American Diabetes Association, approximately 24 million people in the United States have diabetes. Of those, approximately 18 million have been diagnosed. The number of people who have been diagnosed with diabetes is increasing, and according to the Centers for Disease Control and Prevention, or CDC, approximately 1.6 million new cases of diabetes were diagnosed in 2007. Among adults with diagnosed diabetes, it is estimated that 57% take oral medication only and 13% take both insulin and oral medication, according to the CDC.

According to IMS Health, the U.S. market for prescription diabetes products had total sales of approximately $13.6 billion during 2008. Prescription metformin products account for approximately 31% of the total prescription diabetes market. Branded prescription metformin products (including Fortamet®, Glucophage®, Glucophage XR® and Glumetza and excluding metformin combination products) had total sales of more than $144 million during 2008.

Promotion Agreement with Depomed

In July 2008, we entered into a promotion agreement with Depomed granting us exclusive rights to promote the Glumetza prescription products in the U.S. Under the promotion agreement, we are required to meet certain minimum promotion obligations during the term of the agreement. For a period of one year from the date we began promoting the Glumetza products, we are required to deliver a minimum number of sales calls to potential Glumetza prescribers. Thereafter, on an annual basis, we are required to make "sales force expenditures" at least equal to an agreed-upon percentage of the prior year's net sales, where sales force expenditures for purposes of the promotion agreement are sales calls with specified assigned values (indexed to inflation in future years) depending on the relative position of the call and the number of other products promoted by the sales representatives promoting Glumetza. In addition, during the term of the agreement, we are required to make certain minimum marketing, advertising, medical affairs and other commercial support expenditures.

We paid Depomed a $12.0 million upfront fee, and based on the achievement of specified levels of annual Glumetza net product sales, we may be required to pay Depomed one-time sales milestones, totaling up to $16.0 million in aggregate. Depomed records revenue from the sales of Glumetza products, and pays us a fee ranging from 75% to 80% of the gross margin earned from all net sales of Glumetza products in the U.S., with gross margin defined as net sales less cost of goods including product-related fees paid by Depomed to Biovail Laboratories International SRL.

We are responsible for all costs associated with our sales force and for all other sales and marketing-related expenses associated with our promotion of Glumetza products, including an initial commitment of $5 million in promotional costs from signing through March 31, 2009. Depomed is responsible for overseeing product manufacturing and supply. A joint commercialization committee has been formed to oversee and guide the strategic direction of the Glumetza alliance.

Under the promotion agreement, Depomed retains the option to co-promote Glumetza products in the future to obstetricians and gynecologists. During the term of the promotion agreement, neither party is permitted to, directly or indirectly, promote, market, or sell in the U.S. any single agent metformin products for human use, other than the Glumetza products covered by the promotion agreement.

Under the promotion agreement, we have a right of first negotiation in the event that Depomed desires to divest its rights in the Glumetza products to a third party or wishes to grant rights to a third party to develop or commercialize a pharmaceutical product containing Depomed's proprietary AcuForm™ drug delivery technology in combination with metformin and any other generic active pharmaceutical ingredient.

The promotion agreement will continue in effect until the expiration of the last-to-expire patent or patent application with a valid claim in the U.S. covering a Glumetza product, unless terminated sooner. Subject to 90 days prior written notice to Depomed, we may terminate the promotion agreement at any time following the 18-month anniversary of the effective date of the agreement. Subject to notice to Depomed, we may also terminate the agreement immediately in other circumstances, such as loss of market exclusivity or in the event of certain regulatory or governmental actions or if Depomed fails to supply the Glumetza product as reasonably necessary to meet trade demand for a period of three months or longer. Subject to 60 days prior written notice to us, Depomed may terminate the agreement if we fail to meet our obligations with respect to minimum promotion obligations and fail to cure such breach within a specified time period. Depomed may also terminate the agreement on 180 days prior written notice if we fail to deliver certain required information related to forecasted sales force expenditures. Either party may terminate the agreement under certain specified circumstances relating to a significant recall or withdrawal of the Glumetza product. Either party may also terminate the agreement if the other party fails to perform any material term of the agreement and fails to cure such breach, subject to prior written notice within a specified time period. In addition, either party may terminate the agreement if a force majeure event prevents the other party from carrying out its material obligations under the agreement for a period of at least six months. Finally, either party may terminate the agreement if the other party becomes insolvent, files or consents to the filing of a petition under any bankruptcy or insolvency law or has any such petition filed against it, and within a specified time period, such filing has not been dismissed.

Development Product Candidates

Budesonide MMX

Budesonide MMX is a corticosteroid in a novel oral tablet formulation, which utilizes Cosmo's proprietary MMX multi-matrix system delivery technology and is being developed for the treatment of ulcerative colitis. The MMX technology is designed to result in the controlled release and even distribution of a drug substance throughout the length of the colon and to minimize systemic absorption of the drug substance, potentially offering an opportunity for improved efficacy and reduced side effects. We believe there is a need for a locally-acting steroid, such as budesonide, for the treatment of ulcerative colitis, and that the utilization of the MMX technology with budesonide may result in reduced side effects versus standard oral corticosteroid therapy, such as prednisone, and potentially allow for longer periods of treatment.

A pilot phase II clinical trial evaluated 32 patients with ulcerative colitis who received either budesonide MMX at 9 mg once daily or placebo. The patients in the trial were required to have active ulcerative colitis and to have been on stable doses of an oral 5-aminosalicylic acid, or 5-ASA, product for at least two months prior to trial entry. The primary endpoint of the phase II trial was the number of patients achieving either at least a 50% reduction from the baseline clinical activity index, or CAI, score or remission (defined as a CAI score less than or equal to 4) after four weeks of treatment. The CAI is a measure based on patient, investigator and laboratory findings with regard to several clinical criteria. The primary endpoint was reached by 8 out of 17 patients in the budesonide MMX group (47.1%) and 5 out of 15 patients in the placebo group (33.3%). There was not a statistically significant difference between the budesonide MMX and placebo groups based on the primary endpoint. Additional supportive data from the trial indicated that the mean CAI score decreased significantly from baseline to week four in the budesonide MMX patients ($p<0.0001$) but not with placebo ($p=0.1$). From a safety perspective, neither significant suppression of adrenocortical function nor significant side effects were observed. The pilot phase II clinical trial provided safety and efficacy data sufficient for budesonide MMX to progress into further clinical testing.

Budesonide MMX is currently being evaluated for the first-line treatment of ulcerative colitis in phase III clinical trials. Two multicenter, double-blind phase III clinical trials to evaluate budesonide MMX for the induction of remission in patients with mild or moderate active ulcerative colitis are currently underway in North America and Europe, both of which are intended to support U.S. regulatory approval. The protocols for the phase III clinical

trials have been reviewed and approved by the FDA under Special Protocol Assessments. We are responsible for overseeing the phase III U.S. registration trial, which is being conducted by Cosmo, and Cosmo is conducting the European trial in connection with a licensing arrangement with its European partner, Ferring Pharmaceuticals.

The phase III clinical trials are expected to enroll a total of approximately 900 patients. In each trial patients are dosed with budesonide MMX at either 6 mg or 9 mg once daily, and the results will be compared to a placebo control group over an eight week course of treatment. Patients are required to discontinue current therapy and will undergo a washout period prior to initiation of treatment. The primary endpoint in each of the trials is the percentage of patients achieving clinical remission versus placebo as measured by the ulcerative colitis disease activity index, or UCDAI, after eight weeks of treatment. A reference arm with an active comparator is also included in each trial. In the U.S. registration trial, patients in the reference arm will be dosed with two 400 mg Asacol® (mesalamine) delayed-release tablets three times daily for a total of 2400 mg. In the European trial, patients in the reference arm will be dosed with one 3 mg Entocort® EC (budesonide) capsule three times daily for a total of 9 mg. The reference arms are not powered to show statistically significant differences versus budesonide MMX. Additionally, up to approximately 150 patients are expected to continue in a 12-month extended use trial.

Assuming timely enrollment, we currently anticipate that we will have preliminary results from the phase III clinical program, excluding the extension trial, during the first half of 2010. Assuming successful and timely completion of the phase III clinical program and extension trial, we plan to submit an NDA for budesonide MMX to the FDA in 2011.

Currently, there are two issued U.S. patents that provide coverage for the budesonide MMX product candidate, which patents expire in June 2020. Additional information about the intellectual property for the budesonide MMX product candidate is set forth below under the heading "Business – Intellectual Property – Budesonide MMX and Rifamycin SV MMX Product Candidates."

Inflammatory Bowel Disease and Ulcerative Colitis

According to the prevalence statistics provided by the NIDDK, inflammatory bowel disease, or IBD, affects an estimated 1.2 million Americans, including more than 730,000 patients with ulcerative colitis and more than 480,000 patients with Crohn's disease. Ulcerative colitis is a chronic form of inflammatory bowel disease characterized by inflammation of the lining of the colon. Symptoms of active ulcerative colitis include rectal bleeding, abdominal pain, increased stool frequency, loss of appetite, fever and weight loss. Crohn's disease is also a chronic form of inflammatory bowel disease, however, it is not limited to the colon and may affect any area of the GI tract. The cause of ulcerative colitis and Crohn's disease is unknown and no known cure exists.

Treatments for ulcerative colitis are aimed at inducing remission of inflammation and its symptoms and maintaining remission. Currently, the first line pharmaceutical therapy for ulcerative colitis is treatment with a systemic or topical 5-ASA drug. However, many patients taking 5-ASAs may continue to experience intermittent flares of inflammation causing them to seek further treatment. In addition, a significant number of patients taking 5-ASAs may experience adverse events such as nausea, vomiting and diarrhea. Corticosteroids, such as prednisone, are often used as a second line treatment when 5-ASA drugs are not adequately controlling inflammation. It has been reported in the clinical literature that up to 30% of ulcerative colitis patients required treatment with corticosteroids. The use of steroids to treat ulcerative colitis, however, has been limited to date to short term treatment due to systemic side effects associated with steroid use. However, steroids with newer delivery mechanisms have been successfully used in treating patients with IBD. For example, Entocort® EC, a delayed-release formulation of budesonide, which targets release in the small intestine and ascending colon, has been approved for induction and maintenance of clinical remission in mild to moderate Crohn's disease.

According to IMS Health, the U.S. market for prescription products (excluding anti-TNF products) for the treatment of IBD, including ulcerative colitis and Crohn's disease, had total sales of more than $1.2 billion during 2008.

Rifamycin SV MMX

Rifamycin SV MMX is a broad spectrum, semi-synthetic antibiotic, which is being developed for the treatment of bacterial infections of the colon. The utilization of the MMX technology with rifamycin SV MMX allows the antibiotic to be delivered directly into the colon, with the goal of improving efficacy while minimizing unwanted effects on the bacterial flora in the small intestine. In addition, due to low systemic absorption of rifamycin SV MMX, we hope to be able to reduce the development of antibiotic-resistant strains of bacteria, a major concern with systemically-delivered antibiotics.

Cosmo has completed a phase II clinical program with rifamycin SV MMX in traveler's diarrhea. The results from these studies indicated that rifamycin SV MMX was well tolerated and effective at doses of 800 mg to 1200 mg per day. We will be responsible for the design and execution of a phase III U.S. registration trial for traveler's diarrhea, while it is anticipated that the European phase III clinical trial in the same indication will be conducted by Cosmo's European partner, Dr. Falk Pharma. Both of these phase III trials are intended to support U.S. regulatory approval.

Based on input received from the FDA during a pre-investigational new drug meeting held in January 2009, Cosmo has committed to conduct various activities, including a multiple-dose PK clinical study and a single dose food effect clinical study in healthy volunteers, as well as a genotoxicity study in an appropriate animal species and a reproductive toxicity study. Assuming successful and timely completion of those activities, we would then expect to file an investigational new drug, or IND, application and initiate the planned phase III U.S. registration trial in traveler's diarrhea in the first half of 2010.

Currently, there is one issued U.S. patent that provides coverage for the rifamycin SV MMX product candidate, which patent expires in June 2020. Additional information about the intellectual property for the rifamycin SV MMX product candidate is set forth below under the heading "Business – Intellectual Property – Budesonide MMX and Rifamycin SV MMX Product Candidates."

Infections of the Colon and Traveler's Diarrhea

Infections of the colon are generally caused by bacteria, viruses or parasites. A common colon infection is traveler's diarrhea, and according to the CDC, each year between 20% and 50% of international travelers, an estimated 10 million people, develop diarrhea, with approximately 80% of the cases caused by bacteria. The onset of traveler's diarrhea usually occurs within the first week of travel, but may occur at any time while traveling, and even after returning home. Typically, a traveler experiences multiple loose or watery bowel movements each day. Other commonly associated symptoms are nausea, vomiting, abdominal cramping, bloating, fever, urgency and malaise. Antibiotics, such as Cipro® (ciprofloxacin), Xifaxan® (rifaxamin) and Zithromax® (azithromycin), are primarily used to treat traveler's diarrhea. In some cases, increasing bacterial resistance to existing antibiotics may limit their usefulness.

Other colonic diseases that may have an infectious component include infectious diarrhea, Crohn's disease, ulcerative colitis, irritable bowel syndrome, Clostridium difficile-associated diarrhea, pouchitis and diverticular disease.

Strategic Collaboration with Cosmo

In December 2008, we entered into a strategic collaboration with Cosmo, including a license agreement, stock issuance agreement and registration rights agreement, under which we were granted exclusive rights to develop and commercialize the budesonide MMX and rifamycin SV MMX product candidates in the U.S.

License Agreement

Under the license agreement, Cosmo granted us the exclusive right to develop, market and commercialize the budesonide MMX and rifamycin SV MMX product candidates in the U.S. As upfront consideration, we issued 6,000,000 shares of our common stock and made a cash payment of $2.5 million to Cosmo. We may also pay Cosmo up to a total of $9.0 million in clinical and regulatory milestones for the initial indications for the licensed

products, up to $6.0 million in clinical and regulatory milestones for a second indication for rifamycin SV MMX and up to $57.5 million in commercial milestones. The milestones may be paid in cash or through issuance of additional shares of our common stock, at Cosmo's option, subject to certain limitations.

We will pay tiered royalties to Cosmo ranging from 12% to 14% on net sales of any licensed products we sell. The royalties are subject to reduction in certain circumstances, including in the event of market launch in the U.S. of a generic version of a licensed product. Our obligation to pay the specified royalties under the license agreement will continue for the life of the relevant patents (including certain patent applications) covering each licensed product. Following that period, the parties have agreed to negotiate in good faith a reduced royalty arrangement for the continued use of Cosmo's know-how and trademarks related to the licensed products.

We will be responsible for one-half of the total out-of-pocket costs associated with the two ongoing budesonide MMX multi-center phase III clinical trials and for all of the out-of-pocket costs for the planned rifamycin SV MMX phase III U.S. registration trial. In the event that additional clinical work is required to obtain U.S. regulatory approval for either of the licensed products, the parties will agree on cost sharing. Cosmo is responsible for any additional pre-clinical costs for rifamycin SV MMX and for any product development and scale-up costs for either of the licensed products.

We have agreed to use commercially reasonable efforts to market, promote and sell each of the licensed products, including launching such product within 12 months following receipt of U.S. regulatory approval, utilizing a minimum number of field sales representatives during the first year following launch and spending specified minimum amounts on our sales and marketing efforts during the first three years following launch.

During the term of the license agreement, we and Cosmo have each agreed not to market or sell any product which contains as an active ingredient, with respect to budesonide MMX, anti-inflammatory corticosteroids for ulcerative colitis and other approved indications for such product, and with respect to rifamycin SV MMX, antibiotics belonging to the ansamycin family for traveler's diarrhea and other approved indications for such product.

Cosmo will manufacture and supply all of our drug product requirements during the term of the license agreement. The parties have agreed to enter into a supply agreement prior to the submission of the first NDA for a licensed product.

The term of the license agreement will continue until 50 years following the expiration of the patent rights. We may withdraw from the license agreement for one or both licensed products upon 60 days prior written notice to Cosmo in the event that either such product fails to achieve the primary endpoints in the applicable phase III clinical trials within five years following the date of the license agreement or the clinical trials with respect to such product are not sufficient to obtain U.S. regulatory approval within five years following the date of the license agreement. In addition, either party may terminate the license agreement in the event of the other party's uncured material breach.

Stock Issuance Agreement/Registration Rights Agreement

As described above, we issued to Cosmo 6,000,000 shares of our common stock as upfront consideration under the license agreement. In addition, we will also make payments to Cosmo upon the achievement of certain development and commercial milestones, which milestones may be paid in cash or through issuance of additional shares of common stock, at Cosmo's option. Our obligation to issue additional shares of common stock to Cosmo upon the achievement of one or more milestones is subject to certain limitations, including that the total number of shares of common stock issued to Cosmo, including the initial 6,000,000 shares, shall not exceed 10,300,000 shares. Any such additional shares to be issued will be valued at the average daily closing price of the common stock as reported on the Nasdaq Global Market for the 30 consecutive trading days ending on the day immediately prior to the achievement of the applicable milestone.

Cosmo has agreed that for the 15 months following the date of issuance of the initial 6,000,000 shares of common stock and for the six months following the issuance of any shares of common stock upon achievement of milestones, it will not transfer or dispose of any such issued shares. In addition, Cosmo has agreed through

December 15, 2011 that neither it nor its affiliates will acquire beneficial ownership of additional shares of our common stock, other than under the stock issuance agreement, subject to certain exceptions.

Under the terms of the registration rights agreement, we filed a resale registration statement on Form S-3 with the Securities and Exchange Commission, or SEC, in January 2009, to register the resale of the shares issuable to Cosmo under the stock issuance agreement. We are obligated to use best efforts to have such registration statement declared effective by the SEC.

Zegerid Tablet

In January 2009, we submitted a 505(b)(2) NDA to the FDA for a new tablet formulation to add to our Zegerid family of prescription products. The new formulation is an immediate-release tablet that combines omeprazole with a mix of buffers. Our objective is to have the new Zegerid tablet product commercially available in the fourth quarter of 2009.

Additional Strategic Alliances

To further leverage our proprietary PPI technology and diversify our sources of revenue, we have entered into strategic alliances with Schering-Plough for the U.S. and Canadian OTC markets and with GSK for selected prescription and OTC markets outside the U.S. and for prescription markets in Puerto Rico and the U.S. Virgin Islands.

OTC License Agreement with Schering-Plough

In October 2006, we licensed exclusive rights to Schering-Plough under our patented PPI technology to develop, manufacture, market and sell Zegerid brand OTC products in the lower dosage strength of 20 mg of omeprazole in the U.S. and Canada. We estimate that the U.S. market for OTC heartburn products had sales in excess of $1.5 billion in 2008. Schering-Plough is responsible for all activities related to product and clinical development, manufacturing, regulatory matters, marketing and sales of products under the license agreement and is required to use diligent efforts to conduct and complete such activities in a timely manner. Schering-Plough's diligence requirements include minimum marketing spending commitments and the utilization of the Zegerid name in any OTC product marks, as more specifically described in the license agreement. We and Schering-Plough have formed a joint steering committee to oversee Schering-Plough's activities under the license agreement and to facilitate communications between the parties.

Schering-Plough submitted an NDA for its first product under the license agreement in March 2008. In January 2009, Schering-Plough received a complete response letter from the FDA, which outlined questions that the FDA identified during its review of the NDA. We are in regular communications with Schering-Plough, who continues to work closely with the FDA to define the nature and content of the response to the FDA. We believe that the response will be based on further analysis of existing data.

Under the license agreement, we received a $15.0 million upfront license fee in November 2006, a $5.0 million milestone payment in August 2007 and a $2.5 million milestone payment in May 2008. We may receive an additional $20.0 million payment upon the achievement of a specified regulatory milestone and up to an additional $37.5 million in aggregate milestone payments upon the achievement of specified sales milestones. We are also entitled to receive low double-digit royalties, subject to adjustment in certain circumstances, on net sales of any OTC products sold by Schering-Plough under the license agreement. In turn, we will be obligated to pay royalties to the University of Missouri based on net sales of any OTC products sold by Schering-Plough.

During the term of the license agreement, Schering-Plough and its affiliates have agreed not to develop, market or sell other OTC PPI products in the U.S. or Canada, and also agreed to certain other limitations on Schering-Plough's activities related to PPI products. In addition, we agreed not to, and also agreed not to grant any license to any other third party to, develop, market or sell OTC products in the U.S. or Canada utilizing our patented PPI technology.

The license agreement remains in effect as long as Schering-Plough is marketing products under the license agreement. Schering-Plough may terminate the agreement at any time on 180 days prior written notice to us. In addition, either party may terminate the license agreement in the event of uncured material breach of a material obligation, subject to certain limitations, or in the event of bankruptcy or insolvency.

License Agreement and Distribution Agreement with GSK

In November 2007, we entered into a license agreement and a distribution agreement granting exclusive rights to GSK under our patented PPI technology to commercialize prescription and OTC immediate-release omeprazole products in a number of international markets and to distribute and sell Zegerid brand immediate-release omeprazole prescription products in Puerto Rico and the U.S. Virgin Islands, as further described below.

License Agreement

Under the license agreement, we granted GSK the exclusive right to develop, manufacture and commercialize prescription and OTC immediate-release omeprazole products for sale in up to 114 countries outside of the U.S., Europe, Australia, Japan and Canada, including specified countries in Africa, Asia, the Middle-East and Central and South America. We estimate that sales of PPI products in the covered international markets are approximately $2.6 billion annually. GSK is required to use commercially reasonable efforts to seek regulatory approval for, and to launch, market and sell licensed products in the licensed territories and is required to do so within specified time frames in certain "major countries," defined in the license agreement as Brazil, China, Mexico, South Africa, South Korea, Taiwan and Turkey. GSK will be responsible for all costs associated with its activities related to the license agreement.

Currently, GSK is working to prepare the regulatory filings necessary to obtain marketing approval authorization in various countries covered by the license agreement. We believe that GSK will begin to make regulatory filings in selected countries in 2009 or 2010. Assuming these filings result in marketing authorizations and commercial launch, we believe that we may begin to receive royalty revenue under the GSK license agreement in 2010 or 2011.

Under the license agreement, we received an $11.5 million upfront fee. We will also receive tiered royalties equal to a percentage, ranging from the mid-teens to mid-twenties, of net sales of any licensed products sold by GSK under the license agreement. The royalties are subject to reduction on a country-by-country basis in the event that sales of any generic products achieve a specific level of market share, referred to as "generic competition" in such country. In turn, we will be obligated under our license agreement with the University of Missouri to pay royalties to the University of Missouri based on net sales of any licensed products sold by GSK. When determining the applicable royalty tier, net sales under both the license agreement and the distribution agreement are combined. GSK's obligation to pay royalties under the license agreement will continue as long as GSK is selling licensed products, unless the license agreement is terminated earlier or in the event GSK exercises its option to make a buy-out payment at the 20th anniversary of the license agreement. To support GSK's initial launch costs, we agreed to waive the initial $2.5 million of aggregate royalties payable under the license agreement and the distribution agreement.

During the term of the license agreement and until the later of the fifth anniversary of the effective date of the license agreement or the second anniversary of the termination of the license agreement, GSK has agreed not to market or sell other immediate-release PPI products in the licensed territories. Until the fifth anniversary of the effective date of the license agreement, we have agreed not to market or sell other immediate-release PPI products in the licensed territories.

The license agreement will remain in effect as long as GSK is obligated to pay royalties under the license agreement for one or more licensed territories. GSK may terminate the license agreement on six months prior written notice to us at any time. We may terminate the license agreement on a country-by-country basis in the event that GSK fails to satisfy its diligence obligations applicable to such country. In addition, either party may terminate the license agreement in the event of the other party's uncured material breach or bankruptcy or insolvency. Following termination, the rights associated with licensed products revert to us.

Distribution Agreement

Under the distribution agreement, we granted GSK the exclusive right to distribute and sell Zegerid brand immediate-release omeprazole prescription products in Puerto Rico and the U.S. Virgin Islands. GSK commenced distributing our Zegerid products in these territories in February 2008, and GSK is obligated to use commercially reasonable efforts to continue to distribute and sell the distribution products during the term of the distribution agreement. GSK is responsible for all costs associated with its activities related to the distribution agreement. The distribution products are sold under the Zegerid brand name.

Under the distribution agreement, we are entitled to receive tiered royalties ranging from the mid-teens to the mid-twenties on net sales of any distribution products sold by GSK. The royalties are subject to reduction in the event of generic competition in the territories covered by the distribution agreement. In turn, we are obligated under our license agreement with the University of Missouri to pay royalties to the University of Missouri based on net sales of any distribution products sold by GSK. When determining the applicable royalty tier, net sales under both the license agreement and the distribution agreement are combined. GSK's obligation to pay royalties under the distribution agreement will continue as long as GSK is selling distribution products, unless the distribution agreement is terminated earlier or in the event that GSK exercises its option to make a buy-out payment at the 20th anniversary of the distribution agreement. To support GSK's initial launch costs, we agreed to waive the initial $2.5 million of aggregate royalties payable under the license agreement and the distribution agreement.

During an initial period following the execution of the distribution agreement, we are obligated to supply distribution products to GSK for sale in Puerto Rico and the U.S. Virgin Islands, and GSK pays a specified transfer price for such distribution products covering our fully burdened costs.

During the term of the distribution agreement and until the later of the fifth anniversary of the distribution agreement or the second anniversary of the termination of the distribution agreement, GSK has agreed not to market or sell other immediate-release PPI products in Puerto Rico or the U.S. Virgin Islands. Until the third anniversary of the effective date of the distribution agreement, we have agreed not to market or sell other immediate-release PPI products in the territories covered by the distribution agreement.

The distribution agreement will remain in effect as long as GSK is selling products under the distribution agreement in Puerto Rico or the U.S. Virgin Islands. GSK may terminate the distribution agreement on six months prior written notice to us at any time. In addition, either party may terminate the distribution agreement in the event of the other party's uncured material breach or bankruptcy or insolvency or if the distribution products are withdrawn from the U.S. market. Following termination, the rights associated with distribution products revert to us.

Sales and Marketing

We have established a commercial organization that is focused on the promotion of our currently marketed Zegerid and Glumetza prescription products. The commercial organization targets high prescribing physicians in the U.S., including gastroenterologists, endocrinologists and primary care physicians.

Our commercial organization is comprised of approximately 380 sales and marketing personnel, including in-house staff, our field sales representatives, fully-dedicated field sales representatives under our contract sales organization agreement with inVentiv Commercial Services, LLC, or inVentiv, sales managers and account managers. Our field sales representatives are positioned in major metropolitan areas across the U.S. and have an average of more than five years of pharmaceutical sales experience. The efforts of our field sales representatives are supplemented by the efforts of the inVentiv sales representatives, who are also positioned across the U.S.

These field sales representatives communicate the features and benefits of our Zegerid and Glumetza products to our targeted physicians. The field sales representatives each undergo a rigorous training program focused on our product offerings, disease background, competitive products and our sales techniques, as well as compliance with applicable laws. Our program includes significant field-based learning to provide a comprehensive understanding and perspective as to the applicable markets and disease states and the needs of both physicians and patients.

In addition, we utilize field-based district sales managers and regional sales directors to oversee the activities of our field sales representatives and national and regional account managers to work with managed care organizations and the government to obtain formulary and reimbursement coverage for our products. We also use a variety of marketing programs to promote our products, including promotional materials, speaker programs, journal advertising, industry publications, electronic media and product sampling.

Our account managers contact third-party payors, seeking reimbursement coverage for our products. Although the process for obtaining coverage can be lengthy and time-consuming, we have entered into numerous contracts with private health insurers, managed care organizations, government entities and other third-party payors that provide coverage for our products at a level that we believe is generally similar to the current level of coverage for the branded delayed-release PPI products.

Contract Sales Organization Agreement with inVentiv

To support our sales and marketing efforts, we have entered into a contract sales organization agreement with inVentiv under which inVentiv is committed to provide contract sales representatives to promote our products, as well as additional management and administrative support. We are currently utilizing approximately 100 inVentiv sales representatives, who are located throughout the U.S., to promote our Zegerid and Glumetza products.

In consideration for inVentiv's services under the agreement, we pay to inVentiv a monthly fee, subject to adjustment based on actual staffing levels. In addition, under the agreement, we are obligated to reimburse inVentiv for approved pass-through costs, which are anticipated to primarily include bonus, meeting and travel costs, as well as other promotional costs.

The current term of the agreement expires in November 2010. We may terminate the agreement at any time without paying a termination fee. Moreover, either party may terminate the agreement upon an uncured material breach by the other party or upon bankruptcy or insolvency of the other party, and inVentiv may also terminate the agreement if we fail to make timely payments under the agreement.

Manufacturing and Distribution

We rely on third parties for the manufacture of both clinical and commercial quantities of our products and for product distribution, and we do not currently have any of our own manufacturing or distribution facilities. Our third-party manufacturers are subject to extensive governmental regulation. The FDA mandates that drugs be manufactured, packaged and labeled in conformity with current good manufacturing practices, or cGMP. In complying with cGMP regulations, manufacturers must continue to expend time, money and effort in production, record keeping and quality control to ensure that their services and products meet applicable specifications and other requirements. We intend to continue to outsource the manufacture and distribution of our products for the foreseeable future, and we believe this manufacturing strategy will enable us to direct our financial resources to commercialization without devoting the resources and capital required to build cGMP compliant manufacturing facilities.

Although there are potential sources of supply other than our existing suppliers, any new supplier would be required to qualify under applicable regulatory requirements and would need to have sufficient rights under applicable intellectual property laws to the method of manufacture of such products or ingredients.

Zegerid Prescription Products

We currently rely on Norwich Pharmaceuticals, Inc., or Norwich, as our only supplier of Zegerid Capsules, and we have entered into an agreement with Norwich that provides for the commercial supply of this product. The agreement provides for an initial four-year term, which expires in January 2010, and thereafter continues in force indefinitely unless terminated with 18 months written notice. We can also terminate the agreement, effective immediately, at any time if we decide to no longer market the product, in the event any governmental agency takes any action that prevents us from importing, exporting, purchasing or selling the product or in the event of certain regulatory proceedings involving the manufacturer. Either party may terminate the agreement if the other party fails to perform any material term of the agreement and fails to cure such breach within a specified time period, subject to

prior written notice.

In addition, we currently rely on Patheon Inc. as our only supplier of Zegerid Powder for Oral Suspension, and we have entered into an agreement with Patheon that provides for the commercial supply of this product. The commercial supply agreement requires that we purchase a significant percentage of our requirements of this product from Patheon and also obligated us to fund certain equipment purchases. The initial term of the agreement expires in August 2009. Thereafter, the agreement continues in force indefinitely, except that either party may terminate the agreement at any time beginning in August 2009 by providing the other party with 18 months prior written notice. In addition, we may terminate the agreement at any time if we decide to no longer market the powder for oral suspension product by providing six months prior written notice. We may also terminate the agreement with 30 days written notice in the event any governmental agency takes any action that prevents us from purchasing or selling the product for a certain period of time. Either party may terminate the agreement if the other party fails to perform any material term of the agreement or in the event of the other party's insolvency or bankruptcy, subject to prior written notice within a specified time period.

We also currently rely on Union Quimico Farmaceutica, S.A., or Uquifa, as our exclusive supplier of the omeprazole active ingredient in each of our Zegerid prescription products. Under our supply agreement with Uquifa, we must purchase all of our requirements of omeprazole from Uquifa. The current term of the agreement expires in September 2011. The agreement provides for automatic two-year renewal terms. We can terminate the agreement upon at least 12 months notice prior to the expiration of the term. In addition, we can terminate this agreement with 30 days written notice in the event any governmental agency takes any action that prevents us from purchasing or selling either omeprazole or the finished product for a certain period of time. Either party may terminate the agreement if the other party fails to perform any material term of the agreement subject to prior written notice and an opportunity to cure.

We currently have two approved suppliers for sodium bicarbonate, which is a component in our marketed powder for oral suspension and capsule products, and we rely on our third-party manufacturers to purchase the sodium bicarbonate. Additionally, we rely on single suppliers for certain excipients in our powder for oral suspension and capsule products.

We are in the process of establishing a commercial supplier for the new tablet formulation of our Zegerid family of products, for which an NDA was submitted to the FDA in January 2009.

Glumetza Extended Release Tablets

Under our promotion agreement for the Glumetza products, Depomed is responsible for overseeing product manufacturing and supply.

Budesonide MMX and Rifamycin SV MMX

Cosmo will manufacture and supply our requirements of the budesonide MMX and rifamycin SV MMX product candidates, and we have agreed to purchase such requirements exclusively from Cosmo during the term of our license agreement with Cosmo. We and Cosmo have agreed to enter into a separate supply agreement prior to the submission of the first NDA for each product candidate.

Distribution

We sell our Zegerid products primarily to pharmaceutical wholesalers, who in turn seek to distribute the products to retail pharmacies, mail order pharmacies, hospitals and other institutional customers. We have retained third-party service providers to perform a variety of functions related to the distribution of our approved products, including logistics management, sample accountability, storage and transportation. We have also entered into channel services agreements with some wholesalers under which we receive certain distribution management services and data reporting from the wholesalers, in exchange for a fee. Sales to our three largest wholesalers in 2008, Cardinal Health, Inc., McKesson Corporation and AmerisourceBergen Corporation, accounted for approximately 30%, 27% and 16%, respectively, of our annual revenues. The loss of any of these wholesalers as customers could materially and adversely affect our business, results of operations, financial condition and cash flows.

Under our promotion agreement for the Glumetza products, Depomed is responsible for sale and distribution of the Glumetza products to pharmaceutical wholesalers and other customers.

Intellectual Property

Our goal is to obtain, maintain and enforce patent protection for our products, compounds, formulations, processes, methods and other proprietary technologies invented, developed, licensed or acquired by us, preserve our trade secrets, and operate without infringing on the proprietary rights of other parties, both in the U.S. and in other countries. Our policy is to actively seek to obtain, where appropriate, intellectual property protection for our products, proprietary information and proprietary technology through a combination of contractual arrangements and laws, including patents, both in the U.S. and elsewhere in the world.

Due to the length of time and expense associated with bringing new pharmaceutical products to market, we recognize that there are considerable benefits associated with developing, licensing or acquiring products that are protected by existing patents or for which patent protection can be obtained. In addition, we have applied and intend to continue to apply for patent protection for new technology we develop whenever we determine that the benefit of patent protection outweighs the cost of obtaining patent protection.

We also depend upon the skills, knowledge and experience of our scientific and technical personnel, as well as that of our advisors, consultants and other contractors. To help protect our proprietary know-how that is not patentable, and for inventions for which patents may be difficult to enforce, we rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we require our employees, consultants, advisors and certain other contractors to enter into confidentiality agreements which prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business. Additionally, these confidentiality agreements require that our employees, consultants and advisors do not bring to us, or use without proper authorization, any third party's proprietary technology.

Zegerid Products and Related PPI Technology

We have entered into an exclusive, worldwide license agreement with the University of Missouri for patents and pending patent applications relating to specific formulations of PPIs with antacids and other buffering agents and methods of using these formulations, the terms of which are described further below. Currently, there are six issued U.S. patents that provide coverage for our Zegerid products (U.S. Patent Nos. 5,840,737; 6,489,346; 6,645,988; 6,699,885; 6,780,882; and 7,399,772), all of which are subject to the University of Missouri license agreement. There are also several pending U.S. patent applications relating to our Zegerid products and technology, some of which are subject to the University of Missouri license agreement and some of which we own. The issued patents generally cover pharmaceutical compositions combining PPIs with buffering agents, such as antacids, and methods of treating GI disorders by administering solid or liquid forms of such compositions, and each of the patents expires in July 2016. In addition to the U.S. patent coverage, several international patents have been issued, including in Australia, Austria, Belgium, Canada, Cyprus, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Mexico, Monaco, Netherlands, New Zealand, Portugal, Russia, Singapore, South Africa, South Korea, Spain, Sweden, Switzerland, Turkey and the United Kingdom, and several international patent applications are pending, all of which are subject to the University of Missouri license agreement. The issued claims in these international patents vary between the different countries and include claims covering pharmaceutical compositions combining PPIs with buffering agents and the use of these compositions in the manufacture of drug products for the treatment of GI disorders.

In December 2007, the University of Missouri filed an Application for Reissue of U.S. Patent No. 5,840,737, or the '737 patent, with the U.S. Patent and Trademark Office, or PTO. The '737 patent is one of six issued patents listed in the Approved Drug Products with Therapeutic Equivalence Evaluations, or the Orange Book, for Zegerid Powder for Oral Suspension. The '737 patent is not one of the four patents listed in the Orange Book for Zegerid Capsules. It is not feasible to predict the impact that the reissue proceeding may have on the scope and validity of the '737 patent claims. If the claims of the '737 patent ultimately are narrowed substantially or invalidated by the

PTO, the extent of the patent coverage afforded to our Zegerid family of products could be impaired, which could potentially harm our business and operating results.

In August 2006, an Indian company filed a pre-grant opposition to a pending Indian patent application that is licensed to us under our license agreement with the University of Missouri. A hearing was conducted in October 2007. In September 2008, the Indian Patent Office declined to grant a patent on the claims presented. As a result of the recent Indian Patent Office decision, we may not be able to obtain patent coverage for one or more of our Zegerid products in India.

Litigation with Par Pharmaceutical, Inc.

In September 2007, we filed a lawsuit in the United States District Court for the District of Delaware against Par Pharmaceutical, Inc., or Par, for infringement of U.S. Patent Nos. 6,645,988; 6,489,346; and 6,699,885, each of which is listed in the Orange Book for Zegerid Capsules. In December 2007, we filed a second lawsuit in the United States District Court for the District of Delaware against Par for infringement of U.S. Patent Nos. 6,645,988; 6,489,346; 6,699,885; and 6,780,882, each of which is listed in the Orange Book for Zegerid Powder for Oral Suspension. The University of Missouri, licensor of the patents, is a co-plaintiff in the litigation, and both lawsuits have been consolidated for all purposes. The lawsuits are in response to abbreviated new drug applications, or ANDAs, filed by Par with the FDA regarding Par's intent to market generic versions of our Zegerid Capsules and Zegerid Powder for Oral Suspension products prior to the July 2016 expiration of the asserted patents. Each complaint seeks a judgment that Par has infringed the asserted patents and that the effective date of approval of Par's ANDA shall not be earlier than the expiration date of the asserted patents. Par has filed answers in each case, primarily asserting non-infringement, invalidity and/or unenforceability. Par has also filed counterclaims seeking a declaration in its favor on those issues. On July 15, 2008, the PTO issued U.S. Patent No. 7,399,772, or the '772 patent, which is now listed in the Orange Book for both Zegerid Capsules and Zegerid Powder for Oral Suspension. In October 2008, we amended our complaint to add the '772 patent to the pending litigation with Par. A claim construction, or "Markman," hearing was held in November 2008. Following the hearing, the court adopted all of the claim constructions we and the University of Missouri proposed. The discovery phase of the lawsuits is continuing. Trial is currently scheduled for July 2009.

In addition, as part of this litigation, Par initially filed counterclaims seeking a declaration that the '737 patent is not infringed, is invalid and/or is unenforceable. We moved to dismiss, or in the alternative, stay these claims due to a reissue proceeding involving the '737 patent currently pending before the PTO, and we and the University of Missouri also granted Par a covenant not to sue on the original '737 patent. In November 2008, Par dismissed its counterclaims relating to the '737 patent.

We commenced each of the lawsuits against Par within the applicable 45 day period required to automatically stay, or bar, the FDA from approving Par's ANDAs for 30 months or until a district court decision that is adverse to the asserted patents, whichever may occur earlier. If the litigation is still ongoing after 30 months, the termination of the stay could result in the introduction of one or more products generic to Zegerid Capsules and/or Zegerid Powder for Oral Suspension prior to resolution of the litigation.

Although we intend to vigorously defend and enforce our patent rights, we are not able to predict the outcome of the litigation. Any adverse outcome in this litigation could result in one or more generic versions of Zegerid Capsules and/or Zegerid Powder for Oral Suspension being launched before the expiration of the listed patents in July 2016, which could adversely affect our ability to successfully execute our business strategy to maximize the value of Zegerid Capsules and Zegerid Powder for Oral Suspension and would negatively impact our financial condition and results of operations, including causing a significant decrease in our revenues and cash flows. An adverse outcome may also impact the patent protection for the products being commercialized pursuant to our strategic alliances with GSK and Schering-Plough, which in turn may impact the amount of, or our ability to receive, milestone payments and royalties under those agreements. In addition, even if we prevail, the litigation will be costly, time-consuming and distracting to management, which could have a material adverse effect on our business.

Exclusive License Agreement with the University of Missouri

In January 2001, we entered into an exclusive, worldwide license agreement with the University of Missouri for patents and pending patent applications relating to specific formulations of PPIs with antacids and other buffering agents and methods of using these formulations. Pursuant to the terms of the license agreement, we paid the University of Missouri an upfront licensing fee of $1.0 million in 2001, a one-time $1.0 million milestone fee in 2003 following the filing of our first NDA and a one-time $5.0 million milestone fee in July 2004 following the FDA's approval of Zegerid Powder for Oral Suspension 20 mg. We are required to make additional milestone payments to the University of Missouri upon initial commercial sale in specified territories outside the U.S., which may total up to $3.5 million in the aggregate. We are also required to make milestone payments based on first-time achievement of significant sales thresholds, up to a maximum of $86.3 million, the first of which is a one-time $2.5 million milestone payment upon initial achievement of $100.0 million in annual calendar year net product sales, which includes sales by us, GSK and Schering-Plough. The $2.5 million sales milestone was earned in 2008 and is payable to the University of Missouri in the first quarter of 2009. We are also obligated to pay royalties to the University of Missouri on net sales of our products and any products commercialized by GSK under our license and distribution agreements and Schering-Plough under our OTC license agreement. Under the license agreement, we are permitted to sublicense our rights to third parties. We are obligated to make payments to the University of Missouri in connection with any sublicense, the nature of which depends on the specific sublicense structure. In addition, we are required to bear the costs of prosecuting and maintaining the licensed patents, but the University of Missouri remains responsible for prosecution of any applications. Under the license agreement, we are also required to carry occurrence-based liability insurance with policy limits of at least $5.0 million per occurrence and a $10.0 million annual aggregate.

The license from the University of Missouri expires in each country when the last patent for licensed technology expires in that country and the last patent application for licensed technology in that country is abandoned, provided that our obligation to pay certain minimum royalties in countries in which there are no pending patent applications or existing patents terminates on a country-by-country basis on the 15th anniversary of our first commercial sale in such country. If we fail to meet certain diligence obligations following commercialization in specified countries, the University of Missouri can terminate our license or render it non-exclusive with respect to those countries. Our rights under this license are also generally subject to early termination under specified circumstances, including our material and uncured breach or our bankruptcy or insolvency. To date, we believe we have met all of our obligations under the license. We can terminate the license at any time, in whole or in part, with 60 days written notice.

Glumetza Extended Release Tablets

We have exclusive rights to promote the Glumetza products in the U.S. under our promotion agreement with Depomed. Currently, there are 4 issued U.S. patents that provide coverage for the Glumetza 500 mg dose product (U.S. Patent Nos. 6,340,475 (expires in September 2016); 6,635,280 (expires in September 2016); 6,488,962 (expires in June 2020); and 6,723,340 (expires in October 2021)). There is one issued U.S. patent that provides coverage for the Glumetza 1000 mg dose product (U.S. Patent No. 6,488,962 (expires in June 2020)). The issued patents generally cover various aspects of the delivery technology utilized in each of the Glumetza products. In addition, there is one pending U.S. patent application that covers the Glumetza 1000 mg dose product.

The terms of the promotion agreement with Depomed are described further above, under the heading "Business – Marketed Products – Glumetza – Promotion Agreement with Depomed, Inc."

Budesonide MMX and Rifamycin SV MMX Product Candidates

We have exclusive rights to develop and commercialize the budesonide MMX and rifamycin SV MMX product candidates in the U.S. under our strategic collaboration with Cosmo. Currently, there are two issued U.S. patents that provide coverage for the budesonide MMX product candidate (U.S. Patent Nos. 7,431,943 and 7,410,651), as well as one pending U.S. patent application. The issued patents cover the MMX technology generally and the MMX technology with budesonide, and each of these patents expires in June 2020. There is one issued U.S. patent that provides coverage for the rifamycin SV MMX product candidate (U.S. Patent No. 7,431,943), which expires in June 2020, and two pending U.S. patent applications. The issued patent covers the MMX technology generally.

The terms of the strategic collaboration with Cosmo are described further above, under the heading "Business – Development Products – Strategic Collaboration with Cosmo Technologies Ltd."

Trademarks

We have received U.S. and European Union, or EU, trademark registration for our corporate name, Santarus®. We also have received trademark registration in the U.S., EU, Canada and Japan for our brand name, Zegerid®, and we have applied for trademark registration for various other names and logos. Over time, we intend to maintain registrations on trademarks that remain valuable to our business.

We have licensed from Depomed the right to use the Glumetza® registered trademark in the U.S. in connection with our activities under the promotion agreement with Depomed.

We have licensed from Cosmo the right to use the MMX® and MMX Multi-Matrix System® registered trademarks in the U.S. in connection with our development and commercialization of the budesonide MMX and rifamycin SV MMX product candidates.

Competition

The pharmaceutical industry is subject to intense competition. Our success will depend, in part, upon our ability to achieve market share at the expense of existing, established and future products in the relevant target markets. We face, and will continue to face, competition in the development and commercialization of our products primarily from pharmaceutical and biotechnology companies, many of which have significantly greater financial and other resources than we do, as well as from academic institutions, government agencies and research institutions.

Our competitors have addressed the market for our Zegerid prescription products through the development and marketing of many products, including:

- branded PPI prescription products (such as Nexium®, Prevacid®, Aciphex® and Protonix®);
- generic PPI prescription products (such as delayed-release omeprazole and delayed-release pantoprazole);
- OTC PPI products (such as Prilosec OTC® and store-brand versions); and
- other prescription and/or OTC acid-reducing agents (such as histamine-2 receptor antagonists and antacids).

In addition, various companies are developing new products that may compete with our Zegerid prescription and OTC products in the future, including new PPIs, motility agents, reversible acid inhibitors, cytoprotective compounds and products that act on the lower esophageal sphincter, or LES. For example, Takeda Pharmaceutical Company Limited, or Takeda, recently received FDA approval to market and began selling its Kapidex™ (dexlansoprazole) prescription PPI product, which is an enantiomer of lansoprazole, the active ingredient in Takeda's Prevacid product. In addition, Novartis AG has announced that it is developing an OTC version of Takeda's Prevacid prescription PPI product.

Similarly, our competitors have addressed the market for the Glumetza products through the development and marketing of many products, including other branded immediate-release and extended-release metformin products (such as Fortamet, Glucophage and Glucophage XR), generic immediate-release and extended-release metformin products and other prescription diabetes treatments.

We will be required to compete with these or other new products that may have greater efficacy or other benefits relative to our marketed products.

Research and Development

Our research and development expenses were $11.8 million for 2008, $6.8 million for 2007 and $7.6 million for 2006. Research and development expenses have historically consisted primarily of costs associated with clinical

trials of our products under development as well as clinical studies designed to further differentiate our Zegerid products from those of our competitors, development of and preparation for commercial manufacturing of our products, compensation and other expenses related to research and development personnel and facilities expenses. Our research and development efforts are currently focused primarily on development of the budesonide MMX and rifamycin SV MMX product candidates and advancing our Zegerid family of products, including our new tablet formulation.

In the future, we plan to continue to advance the development of the budesonide MMX and rifamycin SV MMX product candidates, and we may conduct additional clinical trials to further differentiate our Zegerid family of products, as well as conduct research and development related to any future products that we may in-license or otherwise acquire. We are unable to estimate with any certainty the research and development costs that we may incur in the future. We anticipate that we will make determinations as to which development projects to pursue and how much funding to direct to each project on an ongoing basis in response to the scientific, clinical and commercial merits of each project.

Government Regulation

Governmental authorities in the U.S. and other countries extensively regulate the testing, manufacturing, labeling, storage, recordkeeping, advertising, promotion, export, marketing and distribution, among other things, of pharmaceutical products. In the U.S., the FDA, under the Federal Food, Drug, and Cosmetic Act and other federal statutes and regulations, subjects pharmaceutical products to rigorous review. If we do not comply with applicable requirements, we may be fined, the government may refuse to approve our marketing applications or allow us to manufacture or market our products, and we may be criminally prosecuted.

We and our third-party manufacturers, distributors, clinical research organizations and contract sales organization may also be subject to regulations under other federal, state, and local laws, including the Occupational Safety and Health Act, the Environmental Protection Act, the Clean Air Act and import, export and customs regulations as well as the laws and regulations of other countries.

Clinical Testing and the FDA Approval Process

To obtain approval of a new product from the FDA, we must, among other requirements, submit data supporting safety and efficacy as well as detailed information on the manufacture, quality control and composition of the product and proposed labeling. The testing and collection of data and the preparation of necessary applications are expensive and time-consuming. The FDA may not act quickly or favorably in reviewing these applications, and we may encounter significant difficulties or costs in our efforts to obtain FDA approvals that could delay or preclude us from marketing our products.

The process required by the FDA before a new drug may be marketed in the U.S. generally involves the following: completion of preclinical laboratory and animal testing in compliance with FDA regulations; submission of an IND which must become effective before human clinical trials may begin; performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use; and submission and approval of an NDA by the FDA. The sponsor typically conducts human clinical trials in three sequential phases, but the phases may overlap. In phase I clinical trials, the product is tested in a small number of patients or healthy volunteers, primarily for safety at one or more doses. In phase II, in addition to safety, the sponsor evaluates the efficacy of the product on targeted indications, and identifies possible adverse effects and safety risks, in a patient population somewhat larger than phase I clinical trials. Phase III clinical trials typically involve additional clinical evaluation of safety and clinical efficacy in an expanded population at geographically-dispersed test sites.

Clinical trials must be conducted in accordance with the FDA's good clinical practices requirements. The FDA may order the temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. An institutional review board, or IRB, generally must approve the clinical trial design and patient informed consent at each clinical site and may also require the clinical trial at that site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may

impose other conditions.

The applicant must submit to the FDA the results of the preclinical and clinical trials, together with, among other things, detailed information on the manufacture, quality control and composition of the product and proposed labeling, in the form of an NDA, including payment of a user fee. The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the PDUFA policies adopted by the FDA, the FDA sets a goal of 10 months in which to complete its initial review of a standard NDA and issue an action letter. The review process and the target action date under PDUFA may be extended if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the submission. Following completion of the FDA's review of the NDA and the clinical and manufacturing procedures and facilities, the FDA will issue an action letter, which will either be an "approval" authorizing commercial marketing of the drug for certain indications or a "complete response letter" containing the conditions that must be met in order to secure approval of the NDA. These conditions may include deficiencies identified in connection with the FDA's evaluation of the NDA submission or the clinical and manufacturing procedures and facilities. Until any such conditions or deficiencies have been resolved, the FDA may refuse to approve the NDA.

Section 505(b)(2) NDAs

As an alternate path to FDA approval for new or improved formulations of previously approved products, a company may file a Section 505(b)(2) NDA. Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Amendments. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The Hatch-Waxman Amendments permit the applicant to rely upon certain preclinical or clinical studies conducted for an approved product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the 505(b)(2) applicant.

To the extent that the 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid is called a "paragraph iv certification." If the applicant does not challenge the listed patents, the 505(b)(2) application will not be approved until all the listed patents claiming the referenced product have expired. The 505(b)(2) application also will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical or molecular entity, listed in the Orange Book for the referenced product has expired.

If the applicant has provided a paragraph iv certification to the FDA, the applicant must also send notice of the paragraph iv certification to the NDA and patent holders for the referenced product once the applicant's NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a legal challenge to the paragraph iv certification. The filing of a patent infringement lawsuit within 45 days of their receipt of a paragraph iv certification automatically prevents the FDA from approving the 505(b)(2) NDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the 505(b)(2) applicant. Thus, the 505(b)(2) applicant may invest a significant amount of time and expense in the development of its products only to be subject to significant delay and patent litigation before its products may be commercialized. Alternatively, if the listed patent holder does not file a patent infringement lawsuit within the required 45-day period, the applicant's NDA will not be subject to the 30-month stay.

In January 2009, we submitted a 505(b)(2) NDA to the FDA for our new tablet formulation as part of our Zegerid family of prescription products, which NDA referenced certain preclinical and clinical studies conducted for Prilosec® (delayed-release omeprazole capsules). If the NDA is accepted for filing by the FDA, we will provide

notice and a paragraph iv certification to AstraZeneca, the holder of the Prilosec NDA, and related affiliated patent holders that we believe the tablet product does not infringe the unexpired patents listed in the Orange Book for Prilosec or that those patents are invalid. We provided similar notices in connection with each of our NDAs for Zegerid Capsules and Zegerid Powder for Oral Suspension, and AstraZeneca did not file any lawsuits against us within the required 45-day period. Although we believe we continue to have meritorious non-infringement and/or invalidity positions with regard to the listed patents, we cannot be certain as to whether or not AstraZeneca will elect to file a lawsuit against us with regard to the NDA for the new tablet product. The outcome of any such litigation would be uncertain and defending such litigation would be expensive, time-consuming and distracting to management.

Other Regulatory Requirements

Following FDA approval, marketed prescription products continue to be subject to a number of post-approval regulatory requirements. If we seek to make certain changes to an approved product, such as the addition of a new labeled indication or making certain manufacturing changes or product enhancements, we will need FDA review and approval before the change can be implemented. While physicians may use products for indications that have not been approved by the FDA, we may not label or promote the product for an indication that has not been approved. Securing FDA approval for new indications or product enhancements and, in some cases, for labeling claims or changes in manufacturing, is generally a time-consuming and expensive process that may require us to conduct clinical studies under the FDA's investigational new drug regulations. Even if such studies are conducted, the FDA may not approve any change in a timely fashion, or at all. In addition, adverse experiences associated with use of the products must be reported to the FDA, and FDA rules govern how we can label, advertise or otherwise commercialize our products.

The FDA also may, in its discretion, require post-marketing testing and surveillance to monitor the effects of approved products or place conditions on any approvals that could restrict the commercial applications of these products. For example, in connection with the approval of our NDAs for Zegerid Powder for Oral Suspension, we committed to commence clinical studies to evaluate the product in pediatric populations in 2005. We have not yet commenced any of the studies and, prior to doing so, will need to finalize study designs, including receiving FDA input on one of the proposed study designs, engage clinical research organizations and undertake other related activities.

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback statutes and false claims statutes. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Violations of the anti-kickback statute are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal healthcare programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn are used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

In addition, we and the third-party manufacturers on which we rely for the manufacture of our products are subject to requirements that drugs be manufactured, packaged and labeled in conformity with cGMP. To comply with cGMP requirements, manufacturers must continue to spend time, money and effort to meet requirements relating to personnel, facilities, equipment, production and process, labeling and packaging, quality control, recordkeeping and other requirements. The FDA periodically inspects drug manufacturing facilities to evaluate compliance with cGMP requirements.

Also, as part of the sales and marketing process, pharmaceutical companies frequently provide samples of approved drugs to physicians. This practice is regulated by the FDA and other governmental authorities, including, in particular, requirements concerning recordkeeping and control procedures.

Outside of the U.S., our ability or that of our partners to market our products will also depend on receiving marketing authorizations from the appropriate regulatory authorities. The foreign regulatory approval process includes all of the risks associated with the FDA approval described above. In addition, the requirements governing the conduct of clinical trials and marketing authorization vary widely from country to country.

Employees

As of January 31, 2009, we had 345 employees. A total of 41 employees were engaged in clinical research, regulatory, quality assurance, product development and manufacturing, and medical affairs, 279 were in sales, marketing, commercial operations and business development, and 25 were in administration and finance.

Available Information

We make available free of charge on or through our Internet 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 reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission. Our Internet address is www.santarus.com. Information is also available through the SEC's website at www.sec.gov or is available at the SEC's Public Reference Room located at 100 F Street, NE, Washington DC, 20549. Information on the operation of the Public Reference Room is available by calling the SEC at 800-SEC-0330.

Item 1A. Risk Factors

Certain factors may have a material adverse effect on our business, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors in its entirety, in addition to other information contained in this report as well as our other public filings with the Securities and Exchange Commission, or SEC.

In the near-term, the success of our business will depend on many factors, including:

- whether we are able to increase market demand for, and sales of, our currently marketed prescription products – Zegerid® (omeprazole/sodium bicarbonate) Capsules and Powder for Oral Suspension and Glumetza® (metformin hydrochloride extended release tablets);

- whether we are able to maintain patent protection for our products, including whether we are successful in our litigation against Par Pharmaceutical, Inc., or Par, for infringement of patents covering Zegerid Capsules and Zegerid Powder for Oral Suspension;

- whether we are successful in generating revenue under our strategic alliances, including our over-the-counter, or OTC, license agreement with Schering-Plough Healthcare Products, Inc., or Schering-Plough, and our license and distribution agreements with Glaxo Group Limited, an affiliate of GlaxoSmithKline plc, or GSK; and

- whether we are successful in progressing the development and commercialization of our development products, including the budesonide MMX® and rifamycin SV MMX product candidates and the new tablet formulation of our Zegerid prescription products, in a timely manner.

Each of these factors, as well as other factors that may impact our business, are described in more detail in the following discussion. Although the factors highlighted above are among the most significant, any of the following factors could materially adversely affect our business or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time, and you should consider all of the factors described when evaluating our business.

Risks Related to Our Business and Industry

We depend on the commercial success of the Zegerid and Glumetza prescription products, and we cannot be certain that we will be able to continue to increase sales of these products.

We anticipate that in the near term our ability to generate revenues will depend in large part on the commercial success of our currently marketed Zegerid and Glumetza prescription products, which in turn, will depend on several factors, including our ability to:

- successfully increase market demand for, and sales of, these products through the promotional efforts of our own sales force, the contract sales representatives under our agreement with inVentiv Commercial Services, LLC, or inVentiv, and any other promotional arrangements that we may later establish;
- successfully maintain patent protection for these products, including whether we are successful in the lawsuits we filed against Par for infringement of patents covering our Zegerid Capsules and Zegerid Powder for Oral Suspension products;
- obtain greater acceptance of the products by physicians and patients and obtain and maintain distribution at the retail level;
- maintain adequate levels of reimbursement coverage for our products from third-party payors, particularly in light of the availability of other branded and generic competitive products;
- establish and maintain agreements with wholesalers and distributors on commercially reasonable terms; and
- maintain commercial manufacturing arrangements with third-party manufacturers as necessary to meet commercial demand for the products.

In addition, the occurrence of adverse side effects or inadequate therapeutic efficacy of the Zegerid or Glumetza products, and any resulting product liability claims or product recalls, could impact our ability to increase sales of these products.

We cannot be certain that our continued marketing of the Zegerid and Glumetza products will result in increased demand for, and sales of, those products. If we fail to successfully commercialize our prescription products, we may be unable to generate sufficient revenues to grow our business and attain and sustain profitability, and our business, financial condition and results of operations will be materially adversely affected.

We may not generate adequate revenues under our promotion agreement for Glumetza products to justify our level of promotional effort and expense under the agreement.

In July 2008, we entered into a promotion agreement with Depomed, Inc., or Depomed, pursuant to which we agreed to promote Depomed's Glumetza prescription products in the U.S. Under the terms of the promotion agreement, Depomed pays us a fee ranging from 75% to 80% of the gross margin earned from all net sales of Glumetza products in the U.S., with gross margin defined as net sales less cost of goods including product-related fees paid by Depomed to Biovail Laboratories International SRL. We paid Depomed a $12.0 million upfront fee, and based on the achievement of specified levels of annual Glumetza net product sales, we may be required to pay Depomed one-time sales milestones, totaling up to $16.0 million in aggregate. We are also responsible for all costs associated with our

sales force and for all other sales and marketing-related expenses associated with our promotion of Glumetza products, including an initial commitment of $5.0 million in non-sales force advertising and promotional costs from signing through March 31, 2009. We began promotion of Glumetza products in October 2008.

Our ability to generate adequate revenues under the promotion agreement to justify the resources and the level of promotional effort we will have to expend is subject to a number of risks and uncertainties, including those described in the previous risk factor relating to our ability to increase sales of the Glumetza products, as well as the potential for termination of the promotion arrangement and Depomed's ability to maintain commercial supply and patent protection for the Glumetza products. In addition, the promotion of the Glumetza products could detract from our sales representatives' efforts to promote our Zegerid products and have an adverse impact on Zegerid sales. If our promotion efforts are not successful, our ability to generate sufficient revenues to grow our business and attain and sustain profitability may be adversely affected.

Our ability to generate revenues also depends on the success of our strategic alliances with GSK and Schering-Plough, many aspects of which are out of our control.

Our ability to generate revenues in the longer term will also depend on whether our strategic alliances with GSK and Schering-Plough lead to the successful commercialization of additional omeprazole products using our patented proton pump inhibitor, or PPI, technology, and we cannot be certain that we will receive any additional milestone payments or sales-based royalties from these alliances. In November 2007, we entered into a license agreement and a distribution agreement granting exclusive rights to GSK under our patented PPI technology to develop, manufacture and commercialize prescription and OTC products in up to 114 specified countries within Africa, Asia, the Middle-East, and Central and South America, and to distribute and sell Zegerid brand prescription products in Puerto Rico and the U.S. Virgin Islands. In October 2006, we entered into an OTC license agreement with Schering-Plough, pursuant to which we granted exclusive rights under our patented PPI technology to develop, manufacture, market and sell omeprazole products for the OTC market in the U.S. and Canada.

Under these agreements, we depend on the efforts of GSK and Schering-Plough, and we have limited control over their commercialization efforts. For example, GSK and Schering-Plough may not commercialize products as fast as we would like or as fast as the market may expect and may not generate the level of sales that we would like. GSK is currently distributing and selling our Zegerid prescription products in Puerto Rico and the U.S. Virgin Islands and is working to prepare the filings necessary to obtain marketing approval authorization in various countries covered by the license agreement, and we cannot be certain that GSK will be successful in those efforts. In January 2009, Schering-Plough received a complete response letter from the U.S. Food and Drug Administration, or FDA, which outlined questions that the FDA identified during its review of Schering-Plough's new drug application, or NDA, for its first product under the license agreement. We are in regular communications with Schering-Plough, who continues to work closely with the FDA to define the nature and content of the response to the FDA. We believe that the response will be based on further analysis of existing data. We cannot be certain that Schering-Plough will ultimately receive FDA approval for a licensed product in a timely manner or at all. In addition, in December 2008, a Citizen Petition raising certain concerns, including concerns related to the potential approval and labeling of Schering-Plough's proposed Zegerid brand OTC product, was submitted to the FDA by The Proctor & Gamble Company. The Citizen Petition is currently being reviewed by the FDA and we cannot be certain about the impact, if any, that the Citizen Petition will have on Schering-Plough's development efforts.

Any failures by GSK or Schering-Plough could have a negative impact on physician and patient impressions of our prescription products in the U.S. Even if GSK's and Schering-Plough's efforts are successful, we will only receive specified milestone payments and royalties on net sales and may not enjoy the same financial rewards as we would have had we developed and launched the products ourselves. Furthermore, the availability of products developed by Schering-Plough using our patented PPI technology for the U.S. OTC market could decrease demand or negatively impact reimbursement coverage for our prescription products in the U.S.

We are also subject to risks associated with termination of our agreements with GSK and Schering-Plough. The GSK license and distribution agreements may be terminated by either party in the event of the other party's uncured material breach or bankruptcy or insolvency. In addition, GSK may terminate the license and distribution agreements on six months prior written notice to us at any time. The Schering-Plough license agreement may be terminated by either party if the other party is in material breach of its material obligations, subject to certain

limitations. In addition, Schering-Plough may terminate the agreement in its entirety on 180 days prior written notice to us at any time.

If GSK and Schering-Plough fail to successfully commercialize products using our patented PPI technology or are significantly delayed in doing so, we may be unable to generate sufficient revenues to grow our business and attain and sustain profitability, and our business, financial condition and results of operations will be materially adversely affected.

Our budesonide MMX and rifamycin SV MMX product candidates will require significant development activities and ultimately may not be approved by the FDA, and any failure or delays associated with these activities or the FDA's approval of such products would increase our costs and time to market.

We are currently developing our budesonide MMX and rifamycin SV MMX product candidates under a strategic collaboration with Cosmo Technologies Limited, or Cosmo, and in connection with those development programs we face substantial risks of failure that are inherent in developing pharmaceutical products. The pharmaceutical industry is subject to stringent regulation by many different agencies at the federal, state and international levels. For example, our product candidates must satisfy rigorous standards of safety and efficacy before the FDA will approve them for commercial use.

Product development is generally a long, expensive and uncertain process. Successful development of product formulations depends on many factors, including our ability to select key components, establish a stable formulation (for both development and commercial use), develop a product that demonstrates our intended safety and efficacy profile, and transfer from development stage to commercial-scale operations. Any delays we encounter during our product development activities would in turn adversely affect our ability to commercialize the product under development.

Once we have manufactured formulations of our product candidates that we believe will be suitable for clinical testing, we then must complete our clinical testing, and failure can occur at any stage of testing. These clinical tests must comply with FDA and other applicable regulations. We may encounter delays based on our inability to timely enroll enough patients to complete our clinical trials. We may suffer significant setbacks in advanced clinical trials, even after showing promising results in earlier trials. The results of later clinical trials may not replicate the results of prior clinical trials. Based on results at any stage of clinical trials, we may decide to discontinue development of a product candidate. We or the FDA may suspend clinical trials at any time if the patients participating in the trials are exposed to unacceptable health risks or if the FDA finds deficiencies in our applications to conduct the clinical trials or in the conduct of our trials. Moreover, not all product candidates in clinical trials will receive timely, or any, regulatory approval.

Even if clinical trials are completed as planned, their results may not support our assumptions or our product claims. The clinical trial process may fail to demonstrate that our products are safe for humans or effective for their intended uses. Our product development costs will increase and our product revenues will be delayed if we experience delays in testing or regulatory approvals or if we need to perform more or larger clinical trials than planned. In addition, such failures could cause us to abandon a product entirely. If we fail to take any current or future product from the development stage to market, we will have incurred significant expenses without the possibility of generating revenues, and our business will be adversely affected.

With regard to budesonide MMX, Cosmo is conducting two multicenter phase III clinical trials to evaluate the product candidate for the induction of remission in patients with mild or moderate active ulcerative colitis are currently underway in North America and Europe, both of which are intended to support U.S. regulatory approval. We are responsible for overseeing the phase III U.S. registration trial. Assuming timely enrollment, we currently anticipate that we will have preliminary results from the phase III clinical program, excluding the safety extension trial, during the first half of 2010. Assuming successful and timely completion of the phase III clinical program and safety extension trial, we plan to submit an NDA for budesonide MMX to the FDA in 2011.

With regard to rifamycin SV MMX, Cosmo is currently conducting various pre-IND activities, including a multiple-dose PK clinical study and a single dose food effect clinical study in healthy volunteers, as well as a genotoxicity study in an appropriate animal species and a reproductive toxicity study. Assuming successful and

timely completion of those activities, we would then expect to file an IND and initiate the planned phase III U.S. registration trial in traveler's diarrhea in the first half of 2010. It is anticipated that a European phase III clinical trial in the same indication will be conducted by Cosmo's European partner Dr. Falk Pharma. Both of the phase III trials are intended to support U.S. regulatory approval.

We cannot be certain that the ongoing and planned clinical and development programs will proceed in a timely manner. We also cannot be certain that the budesonide MMX and rifamycin SV MMX product candidates will achieve the desired safety and efficacy profile in one or more of the ongoing or future clinical trials or that the other development activities will be completed in a successful and timely manner. For example, the phase II clinical trial for the budesonide MMX product candidate was pilot in nature and involved a different design than the currently ongoing phase III clinical trials. As a result, there may be a higher degree of uncertainty regarding the potential outcome of the phase III clinical trials. Moreover, it is anticipated that U.S. regulatory approval for each of the product candidates will be supported in part by clinical trials being conducted by Cosmo or its European partners, in addition to the clinical trials that we will oversee or conduct. As a result, certain of the clinical activities for these product candidates are not within our direct control.

Any failures or delays in the product development or clinical programs relating to our product candidates could adversely affect our ability to commercialize one or more of our development products and the timing for commercial availability, which in turn could adversely affect our business.

Our pending NDA for the tablet formulation of our Zegerid prescription products may not be approved by the FDA in a timely manner, or at all, which would adversely impact our ability to commercialize this product.

In January 2009, we submitted a 505(b)(2) NDA for a new tablet formulation of our Zegerid prescription products. If the FDA determines that the NDA fails to contain information sufficient to support approval, the FDA may request additional information from us, including data from additional clinical trials. Ultimately, the FDA may not approve the tablet product in a timely manner or at all. Any failure to obtain FDA approval or delay associated with the FDA's review process would adversely impact our ability to commercialize this product, which in turn could adversely impact our business, financial condition and results of operations.

The markets in which we compete are intensely competitive and many of our competitors have significantly more resources and experience, which may limit our commercial opportunity.

The pharmaceutical industry is intensely competitive, particularly in the gastrointestinal, or GI, and diabetes fields in which our currently marketed products compete and our development products may compete, and there are many other currently marketed products that are well-established and successful, as well as development programs underway. In addition, many of our competitors are large, well-established companies in the pharmaceutical field. Given our relatively small size and the nature of the GI and diabetes markets, we may not be able to compete effectively.

In addition, many of our competitors, either alone or together with their collaborative partners, may have significantly greater experience in:

- developing prescription and OTC drugs;
- undertaking preclinical testing and human clinical trials;
- formulating and manufacturing drugs;
- obtaining FDA and other regulatory approvals of drugs; and
- launching, marketing, distributing and selling drugs.

As a result, they may have a greater ability to undertake more extensive research and development, manufacturing, marketing and other programs. Many of these companies may succeed in developing products earlier than we do, completing the regulatory process and showing safety and efficacy of products more rapidly than we do

or developing products that are more effective than our products. Additionally, many of our competitors have greater resources to conduct clinical studies differentiating their products, as compared to our limited resources. Further, the products they develop may be based on new and different technology and may exhibit benefits relative to our products.

Many of these companies with which we compete also have significantly greater financial and other resources than we do. Larger pharmaceutical companies typically have significantly larger field sales force organizations and invest significant amounts in advertising and marketing their products, including through the purchase of television advertisements and the use of other direct-to-consumer methods. As a result, these larger companies are able to reach a greater number of physicians and consumers and reach them more frequently than we can with our smaller sales organization.

If we are unable to compete successfully, our business, financial condition and results of operations will be materially adversely affected.

Our currently marketed products compete with many other drug products, which could put downward pressure on pricing and market share and limit our ability to generate revenues.

Our Zegerid prescription products compete with many other products, including:

- branded PPI prescription products (such as Nexium®, Prevacid®, Aciphex® and Protonix®);
- generic PPI prescription products (such as delayed-release omeprazole and delayed-release pantoprazole);
- OTC PPI products (such as Prilosec OTC® and store-brand versions); and
- other prescription and/or OTC acid-reducing agents (such as histamine-2 receptor antagonists and antacids).

In addition, various companies are developing new products that may compete with our Zegerid prescription and OTC products in the future, including new PPIs, motility agents, reversible acid inhibitors, cytoprotective compounds and products that act on the lower esophageal sphincter, or LES. For example, Takeda Pharmaceutical Company Limited, or Takeda, recently received FDA approval to market and began selling its Kapidex™ (dexlansoprazole) prescription PPI product, which is an enantiomer of lansoprazole, the active ingredient in Takeda's Prevacid product. In addition, Novartis AG has announced that it is developing an OTC version of Takeda's Prevacid prescription PPI product.

Similarly, the Glumetza prescription products compete with many other products, including:

- other branded immediate-release and extended-release metformin products (such as Fortamet®, Glucophage® and Glucophage XR®);
- generic immediate-release and extended-release metformin products; and
- other prescription diabetes treatments.

We or our strategic partners may also face competition for our products from lower priced products from foreign countries that have placed price controls on pharmaceutical products. Proposed federal legislative changes may expand consumers' ability to import lower priced versions of our products and competing products from Canada. Further, several states and local governments have implemented importation schemes for their citizens, and, in the absence of federal action to curtail such activities, we expect other states and local governments to launch importation efforts. The importation of foreign products that compete with our own products could negatively impact our business and prospects.

The existence of numerous competitive products may put downward pressure on pricing and market share, which in turn may adversely affect our business, financial condition and results of operations.

Our reliance on third-party clinical investigators and clinical research organizations may result in delays in completing, or a failure to complete, clinical trials or we may be unable to use the clinical data gathered if they fail to comply with regulatory requirements or perform under our agreements with them.

As an integral component of our clinical development programs, we engage clinical investigators and clinical research organizations, or CROs, to enroll patients and conduct and manage our clinical studies. As a result, many key aspects of this process have been and will be out of our direct control. If the CROs and other third parties that we rely on for patient enrollment and other portions of our clinical trials fail to perform the clinical trials in a timely and satisfactory manner and in compliance with applicable U.S. and foreign regulations, we could face significant delays in completing our clinical trials or we may be unable to rely in the future on the clinical data generated. If these clinical investigators and CROs do not carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, we may be required to repeat one or more of our clinical trials and we may be unable to obtain or maintain regulatory approval for or successfully commercialize our products.

We depend on a limited number of wholesaler customers for retail distribution of our Zegerid products, and if we lose any of our significant wholesaler customers, our business could be harmed.

Our wholesaler customers for our Zegerid products include some of the nation's leading wholesale pharmaceutical distributors, such as Cardinal Health, Inc., McKesson Corporation and AmerisourceBergen Corporation, and major drug chains. Sales to Cardinal, McKesson and AmerisourceBergen accounted for approximately 30%, 27% and 16%, respectively, of our annual revenues during 2008. The loss of any of these wholesaler customers' accounts or a material reduction in their purchases could harm our business, financial condition or results of operations. In addition, we may face pricing pressure from our wholesaler customers.

We do not currently have any manufacturing facilities and instead rely on third-party manufacturers.

We rely on third-party manufacturers to provide us with an adequate and reliable supply of our products on a timely basis, and we do not currently have any of our own manufacturing or distribution facilities. Our manufacturers must comply with U.S. regulations, including the FDA's current good manufacturing practices, applicable to the manufacturing processes related to pharmaceutical products, and their facilities must be inspected and approved by the FDA and other regulatory agencies on an ongoing basis as part of their business. In addition, because several of our key manufacturers are located outside of the U.S., they must also comply with applicable foreign laws and regulations.

We have limited control over our third-party manufacturers, including with respect to regulatory compliance and quality assurance matters. Any delay or interruption of supply related to a third-party manufacturer's failure to comply with regulatory or other requirements would limit our ability to make sales of our products. Any manufacturing defect or error discovered after products have been produced and distributed could result in even more significant consequences, including costly recall procedures, re-stocking costs, damage to our reputation and potential for product liability claims. With respect to any future products under development, if the FDA finds significant issues with any of our manufacturers during the pre-approval inspection process, the approval of those products could be delayed while the manufacturer addresses the FDA's concerns, or we may be required to identify and obtain the FDA's approval of a new supplier. This could result in significant delays before manufacturing of our products can begin, which in turn would delay commercialization of our products. In addition, the importation of pharmaceutical products into the U.S. is subject to regulation by the FDA, and the FDA can refuse to allow an imported product into the U.S. if it is not satisfied that the product complies with applicable laws or regulations.

For our Zegerid prescription products, we rely on Norwich Pharmaceuticals, Inc., located in New York, as the current sole third-party manufacturer of Zegerid Capsules. In addition, we rely on a single third-party manufacturer located outside of the U.S., Patheon Inc., for the supply of Zegerid Powder for Oral Suspension, and we are obligated under our supply agreement to purchase a significant portion of our requirements of this product from Patheon. We also currently rely on a single third-party supplier located outside of the U.S., Union Quimico Farmaceutica, S.A., or Uquifa, for the supply of omeprazole, which is an active pharmaceutical ingredient in each of

our current Zegerid products. We are obligated under our supply agreement with Uquifa to purchase all of our requirements of omeprazole from this supplier.

For the Glumetza products, we rely on Depomed to oversee product manufacturing and supply. Similarly, for our budesonide MMX and rifamycin SV MMX product candidates, we rely on Cosmo to manufacture and supply all of our drug product requirements.

Any significant problem that our sole source manufacturers or suppliers experience could result in a delay or interruption in the supply to us until the manufacturer or supplier cures the problem or until we locate an alternative source of supply. In addition, because our sole source manufacturers and suppliers provide services to a number of other pharmaceutical companies, they may experience capacity constraints or choose to prioritize one or more of their other customers over us. In addition, to the extent GSK or Schering-Plough utilizes our suppliers for our Zegerid prescription products, capacity at those suppliers may become further constrained.

Although alternative sources of supply exist, the number of third-party manufacturers with the manufacturing and regulatory expertise and facilities necessary to manufacture the finished forms of our pharmaceutical products or the key ingredients in our products is limited, and it would take a significant amount of time to arrange for alternative manufacturers. Any new supplier of products or key ingredients would be required to qualify under applicable regulatory requirements and would need to have sufficient rights under applicable intellectual property laws to the method of manufacturing such products or ingredients. The FDA may require us to conduct additional clinical trials, collect stability data and provide additional information concerning any new supplier before we could distribute products from that supplier. Obtaining the necessary FDA approvals or other qualifications under applicable regulatory requirements and ensuring non-infringement of third-party intellectual property rights could result in a significant interruption of supply and could require the new supplier to bear significant additional costs which may be passed on to us.

Our reporting and payment obligations under the Medicaid rebate program and other governmental purchasing and rebate programs are complex and may involve subjective decisions, and any failure to comply with those obligations could subject us to penalties and sanctions, which in turn could have a material adverse effect on our business and financial condition.

As a condition of reimbursement by various federal and state healthcare programs, we must calculate and report certain pricing information to federal and state healthcare agencies. The regulations regarding reporting and payment obligations with respect to Medicaid reimbursement and rebates and other governmental programs are complex. Our calculations and methodologies are subject to review and challenge by the applicable governmental agencies, and it is possible that such reviews could result in material changes. In addition, because our processes for these calculations and the judgments involved in making these calculations involve subjective decisions and complex methodologies, these calculations are subject to the risk of errors. Any failure to comply with the government reporting and payment obligations could result in civil and/or criminal sanctions.

Regulatory approval for our currently marketed products is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated.

Any regulatory approval is limited to those specific diseases and indications for which our products are deemed to be safe and effective by the FDA. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. If we are not able to obtain FDA approval for any desired future indications for our products, our ability to effectively market and sell our products may be reduced and our business may be adversely affected.

While physicians may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical studies and approved by the regulatory authorities, our ability to promote the products is limited to those indications that are specifically approved by the FDA. These "off-label" uses are common across medical specialties and may constitute an appropriate treatment for many patients in varied circumstances. Regulatory authorities in the U.S. generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off-label use. If our promotional activities fail to comply with these regulations or guidelines, we may be

subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines relating to promotion and advertising may cause the FDA to delay its approval or refuse to approve a product, the suspension or withdrawal of an approved product from the market, recalls, fines, disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could harm our business.

We are subject to ongoing regulatory review of our currently marketed products.

Following receipt of regulatory approval, any products that we market continue to be subject to extensive regulation. These regulations impact many aspects of our operations, including the manufacture, labeling, packaging, adverse event reporting, storage, distribution, advertising, promotion and record keeping related to the products. The FDA also frequently requires post-marketing testing and surveillance to monitor the effects of approved products or place conditions on any approvals that could restrict the commercial applications of these products. For example, in connection with the approval of our NDAs for Zegerid Powder for Oral Suspension, we committed to commence clinical studies to evaluate the product in pediatric populations in 2005. We have not yet commenced any of the studies and, prior to doing so, will need to finalize study designs, including receiving FDA input on one of the proposed study designs, engage clinical research organizations and undertake other related activities. In addition, the subsequent discovery of previously unknown problems with the product may result in restrictions on the product, including withdrawal of the product from the market. 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, disgorgement of money, operating restrictions and criminal prosecution.

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback statutes and false claims statutes. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Violations of the anti-kickback statute are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal healthcare programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn are used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines and imprisonment.

Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Such a challenge could have a material adverse effect on our business, financial condition and results of operations.

In addition, as part of the sales and marketing process, pharmaceutical companies frequently provide samples of approved drugs to physicians. This practice is regulated by the FDA and other governmental authorities, including, in particular, requirements concerning record keeping and control procedures. Any failure to comply with the regulations may result in significant criminal and civil penalties as well as damage to our credibility in the

marketplace.

We are subject to new legislation, regulatory proposals and managed care initiatives that may increase our costs of compliance and adversely affect our ability to market our products, obtain collaborators and raise capital.

There have been a number of legislative and regulatory proposals aimed at changing the healthcare system and pharmaceutical industry, including reductions in the cost of prescription products, changes in the levels at which consumers and healthcare providers are reimbursed for purchases of pharmaceutical products, proposals concerning reimportation of pharmaceutical products and proposals concerning safety matters. For example, in an attempt to protect against counterfeit drugs, the federal government and numerous states have enacted pedigree legislation. In particular, California has enacted legislation that requires development of an electronic pedigree to track and trace each prescription drug at the saleable unit level through the distribution system. California's electronic pedigree requirement is scheduled to take effect in January 2011. Compliance with California and future federal or state electronic pedigree requirements will likely require an increase in our operational expenses and will likely be administratively burdensome. It is also possible that other proposals will be adopted, particularly in light of the 2008 presidential and congressional elections and the potential agenda of the new administration. For example, the new presidential administration has proposed a budget that would include significant amounts to finance the reform of the U.S. healthcare system with an objective of ultimately reducing healthcare costs by, among other things, limiting the level of reimbursement for pharmaceuticals. The enactment of any cost containment measures could result in decreased net revenues from our pharmaceutical products and decrease potential returns from our research and development efforts. It has also been reported that the new presidential administration may be seeking to curb practices that could result in the extension of the term of patent protection for pharmaceuticals, which may include applications for new indications or product enhancements. As a result of these and other new proposals, we may determine to change our current manner of operation, provide additional benefits or change our contract arrangements, any of which could have a material adverse effect on our business, financial condition and results of operations.

We face a risk of product liability claims and may not be able to obtain adequate insurance.

Our business exposes us to potential liability risks that may arise from the clinical testing, manufacture and sale of our products and product candidates. These risks exist even if a product is approved for commercial sale by the FDA and manufactured in facilities licensed and regulated by the FDA. Any product liability claim or series of claims brought against us could significantly harm our business by, among other things, reducing demand for our products, injuring our reputation and creating significant adverse media attention and costly litigation. Plaintiffs have received substantial damage awards in some jurisdictions against pharmaceutical companies based upon claims for injuries allegedly caused by the use of their products. Any judgment against us that is in excess of our insurance policy limits would have to be paid from our cash reserves, which would reduce our capital resources. Although we have product and clinical trials liability insurance with a coverage limit of $15.0 million, this coverage may prove to be inadequate. Furthermore, we cannot be certain that our current insurance coverage will continue to be available for our commercial or clinical trial activities on reasonable terms, if at all. Further, we may not have sufficient capital resources to pay a judgment, in which case our creditors could levy against our assets, including our intellectual property.

We rely on third parties to perform many necessary services for our commercial products, including services related to the distribution, storage and transportation of our products.

We have retained third-party service providers to perform a variety of functions related to the sale and distribution of our products, key aspects of which are out of our direct control. For example, we rely on one third-party service provider to provide key services related to warehousing and inventory management, distribution, contract administration and chargeback processing, accounts receivable management and call center management, and, as a result, most of our inventory is stored at a single warehouse maintained by the service provider. We place substantial reliance on this provider as well as other third-party providers that perform services for us, including entrusting our inventories of products to their care and handling. If these third-party service providers fail to comply with applicable laws and regulations, fail to meet expected deadlines, or otherwise do not carry out their contractual duties to us, or encounter physical or natural damage at their facilities, our ability to deliver product to meet commercial demand would be significantly impaired. In addition, we utilize third parties to perform various other

services for us relating to sample accountability and regulatory monitoring, including adverse event reporting, safety database management and other product maintenance services. If the quality or accuracy of the data maintained by these service providers is insufficient, our ability to continue to market our products could be jeopardized or we could be subject to regulatory sanctions. We do not currently have the internal capacity to perform these important commercial functions, and we may not be able to maintain commercial arrangements for these services on reasonable terms.

If we are unable to attract and retain key personnel, our business will suffer.

We are a small company and, as of January 31, 2009, had 345 employees. Our success depends on our continued ability to attract, retain and motivate highly qualified management, clinical, manufacturing, product development, business development and sales and marketing personnel. We, as well as inVentiv, our contract sales provider, may not be able to recruit and retain qualified personnel in the future, due to competition for personnel among pharmaceutical businesses, and the failure to do so could have a significant negative impact on our future product revenues and business results.

Our success depends on a number of key senior management personnel, particularly Gerald T. Proehl, our President and Chief Executive Officer. Although we have employment agreements with our executive officers, these agreements are terminable at will at any time with or without notice and, therefore, we cannot be certain that we will be able to retain their services. In addition, although we have a "key person" insurance policy on Mr. Proehl, we do not have "key person" insurance policies on any of our other employees that would compensate us for the loss of their services. If we lose the services of one or more of these individuals, replacement could be difficult and may take an extended period of time and could impede significantly the achievement of our business objectives.

Risks Related to Our Intellectual Property

The protection of our intellectual property rights is critical to our success and any failure on our part to adequately maintain such rights would materially affect our business.

We regard the protection of patents, trademarks and other proprietary rights that we own or license as critical to our success and competitive position. Laws and contractual restrictions, however, may not be sufficient to prevent unauthorized use or misappropriation of our technology or deter others from independently developing products that are substantially equivalent or superior to our products.

Patents

Our commercial success will depend in part on the patent rights we have licensed or will license and on patent protection for our own inventions related to the products that we market and intend to market. Our success also depends on maintaining these patent rights against third-party challenges to their validity, scope or enforceability. Our patent position is subject to uncertainties similar to other biotechnology and pharmaceutical companies. For example, the U.S. Patent and Trademark Office, or PTO, or the courts may deny, narrow or invalidate patent claims, particularly those that concern biotechnology and pharmaceutical inventions.

We may not be successful in securing or maintaining proprietary or patent protection for our products, and protection that we have and do secure may be challenged and possibly lost. Our competitors may develop products similar to ours using methods and technologies that are beyond the scope of our intellectual property rights. Other drug companies may challenge the scope, validity and enforceability of our patent claims and may be able to develop generic versions of our products if we are unable to maintain our proprietary rights. For example, although we believe that we have valid patent protection in the U.S. for our Zegerid products until at least 2016, depending on the outcome of our patent infringement suits against Par, described below, a generic version of Zegerid could be launched prior to the expiration of our patents. It is also possible that other generic drug makers will attempt to introduce generic versions of our Zegerid products, or that the Glumetza products will face similar challenges, prior to the expiration of the applicable patents. We also may not be able to protect our intellectual property rights against third-party infringement, which may be difficult to detect.

Zegerid Products and Related PPI Technology

We have entered into an exclusive, worldwide license agreement with the University of Missouri for patents and pending patent applications relating to specific formulations of PPIs with antacids and other buffering agents and methods of using these formulations, the terms of which are described under the heading "Business – Intellectual Property – Zegerid Products and Related PPI Technology – Exclusive License Agreement with the University of Missouri." Currently, there are six issued U.S. patents that provide coverage for our Zegerid products (U.S. Patent Nos. 5,840,737; 6,489,346; 6,645,988; 6,699,885; 6,780,882; and 7,399,772), all of which are subject to the University of Missouri license agreement. There are also several pending U.S. patent applications relating to our Zegerid products and technology, some of which are subject to the University of Missouri license agreement and some of which we own. The issued patents generally cover pharmaceutical compositions combining PPIs with buffering agents, such as antacids, and methods of treating GI disorders by administering solid or liquid forms of such compositions, and each of the patents expires in July 2016. In addition to the U.S. patent coverage, several international patents have been issued, including in Australia, Austria, Belgium, Canada, Cyprus, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Mexico, Monaco, Netherlands, New Zealand, Portugal, Russia, Singapore, South Africa, South Korea, Spain, Sweden, Switzerland, Turkey and the United Kingdom, and several international patent applications are pending, all of which are subject to the University of Missouri license agreement. The issued claims in these international patents vary between the different countries and include claims covering pharmaceutical compositions combining PPIs with buffering agents and the use of these compositions in the manufacture of drug products for the treatment of GI disorders.

We consult with the University of Missouri in its pursuit of the patent applications that we have licensed, but the University of Missouri remains primarily responsible for prosecution of the applications. We cannot control the amount or timing of resources that the University of Missouri devotes on our behalf. It may not assign as great a priority to prosecution of patent applications relating to technology we license as we would if we were undertaking such prosecution ourselves. As a result of this lack of control and general uncertainties in the patent prosecution process, we cannot be sure that any additional patents will ever be issued. Issued patents generally require the payment of maintenance or similar fees to continue their validity. We rely on the University of Missouri to do this, subject to our obligation to provide reimbursement, and the University's failure to do so could result in the forfeiture of patents not maintained. In addition, the initial U.S. patent from the University of Missouri does not have corresponding international or foreign counterpart applications and there can be no assurance that we will be able to obtain foreign patent rights to protect each of our products in all foreign countries of interest.

In December 2007, the University of Missouri filed an Application for Reissue of U.S. Patent No. 5,840,737, or the '737 patent, with the PTO. The '737 patent is one of six issued patents listed in the Approved Drug Products with Therapeutic Equivalence Evaluations, or the Orange Book, for Zegerid Powder for Oral Suspension. The '737 patent is not one of the four patents listed in the Orange Book for Zegerid Capsules. It is not feasible to predict the impact that the reissue proceeding may have on the scope and validity of the '737 patent claims. If the claims of the '737 patent ultimately are narrowed substantially or invalidated by the PTO, the extent of the patent coverage afforded to our Zegerid family of products could be impaired, which could potentially harm our business and operating results.

In August 2006, an Indian company filed a pre-grant opposition to a pending Indian patent application that is licensed to us under our license agreement with the University of Missouri. A hearing was conducted in October 2007. In September 2008, the Indian Patent Office declined to grant a patent on the claims presented. As a result of the recent Indian Patent Office decision, we may not be able to obtain patent coverage for one or more of our Zegerid products in India.

Glumetza Extended Release Tablets

We have exclusive rights to promote the Glumetza products in the U.S. under our promotion agreement with Depomed. Currently, there are 4 issued U.S. patents that provide coverage for the Glumetza 500 mg dose product (U.S. Patent Nos. 6,340,475 (expires in September 2016); 6,635,280 (expires in September 2016); 6,488,962 (expires in June 2020); and 6,723,340 (expires in October 2021)). There is one issued U.S. patent that provides coverage for the Glumetza 1000 mg dose product (U.S. Patent No. 6,488,962 (expires in June 2020)). The issued

patents generally cover various aspects of the delivery technology utilized in each of the Glumetza products. In addition, there is one pending U.S. patent application that covers the Glumetza 1000 mg dose product.

We consult with Depomed concerning the patent rights relating to the Glumetza products, but Depomed remains primarily responsible for prosecution of the applications. We cannot control the amount or timing of resources that Depomed devotes to these activities. It may not assign as great a priority to prosecution of patent applications as we would if we were undertaking such prosecution ourselves. As a result of this lack of control and general uncertainties in the patent prosecution process, we cannot be sure that any additional patents will ever be issued. Issued patents generally require the payment of maintenance or similar fees to continue their validity. We rely on Depomed to do this, and Depomed's failure to do so could result in the forfeiture of patents not maintained.

Budesonide MMX and Rifamycin SV MMX

We have exclusive rights to develop and commercialize the budesonide MMX and rifamycin SV MMX product candidates in the U.S. under our strategic collaboration with Cosmo. Currently, there are two issued U.S. patents that provide coverage for the budesonide MMX product candidate (U.S. Patent Nos. 7,431,943 and 7,410,651), as well as one pending U.S. patent application. The issued patents cover the MMX technology generally and the MMX technology with budesonide, and each of these patents expires in June 2020. There is one issued U.S. patent that provides coverage for the rifamycin SV MMX product candidate (U.S. Patent No. 7,431,943), which expires in June 2020, and two pending U.S. patent applications. The issued patent covers the MMX technology generally.

We consult with Cosmo concerning the patent rights relating to the budesonide MMX and rifamycin SV MMX product candidates, but Cosmo remains primarily responsible for prosecution of the applications. We cannot control the amount or timing of resources that Cosmo devotes to these activities. It may not assign as great a priority to prosecution of patent applications as we would if we were undertaking such prosecution ourselves. As a result of this lack of control and general uncertainties in the patent prosecution process, we cannot be sure that any additional patents will ever be issued. Issued patents generally require the payment of maintenance or similar fees to continue their validity. We rely on Cosmo to do this, and Cosmo's failure to do so could result in the forfeiture of patents not maintained.

Trade Secrets and Proprietary Know-how

We also rely upon unpatented proprietary know-how and continuing technological innovation in developing our products. Although we require our employees, consultants, advisors and current and prospective business partners to enter into confidentiality agreements prohibiting them from disclosing or taking our proprietary information and technology, these agreements may not provide meaningful protection for our trade secrets and proprietary know-how. Further, people who are not parties to confidentiality agreements may obtain access to our trade secrets or know-how. Others may independently develop similar or equivalent trade secrets or know-how. If our confidential, proprietary information is divulged to third parties, including our competitors, our competitive position in the marketplace will be harmed and our ability to successfully penetrate our target markets could be severely compromised.

Trademarks

Our trademarks are important to our success and competitive position. We have received U.S. and European Union, or EU, trademark registration for our corporate name, Santarus®. We also have received trademark registration in the U.S., EU, Canada and Japan for our brand name, Zegerid®, and have applied for trademark registration for various other names and logos. Any objections we receive from the PTO, foreign trademark authorities or third parties relating to our registered trademarks and pending applications could require us to incur significant expense in defending the objections or establishing alternative names. There is no guarantee we will be able to secure any of our pending trademark applications with the PTO or comparable foreign authorities.

If we do not adequately protect our rights in our various trademarks from infringement, any goodwill that has been developed in those marks would be lost or impaired. We could also be forced to cease using any of our trademarks that are found to infringe upon or otherwise violate the trademark or service mark rights of another company, and, as a result, we could lose all the goodwill which has been developed in those marks and could be

liable for damages caused by any such infringement or violation.

The duration and any potential negative outcome in the ongoing patent litigation with Par could adversely affect our financial condition and results of operations as it could result in the introduction of generic products prior to the expiration of the patents for Zegerid Capsules and Zegerid Powder for Oral Suspension, as well as in significant legal expenses and diversion of management time.

In September 2007, we filed a lawsuit in the United States District Court for the District of Delaware against Par for infringement of U.S. Patent Nos. 6,645,988; 6,489,346; and 6,699,885, each of which is listed in the Orange Book for Zegerid Capsules. In December 2007, we filed a second lawsuit in the United States District Court for the District of Delaware against Par for infringement of U.S. Patent Nos. 6,645,988; 6,489,346; 6,699,885; and 6,780,882, each of which is listed in the Orange Book for Zegerid Powder for Oral Suspension. The University of Missouri, licensor of the patents, is a co-plaintiff in the litigation, and both lawsuits have been consolidated for all purposes. The lawsuits are in response to abbreviated new drug applications, or ANDAs, filed by Par with the FDA regarding Par's intent to market generic versions of our Zegerid Capsules and Zegerid Powder for Oral Suspension products prior to the July 2016 expiration of the asserted patents. Each complaint seeks a judgment that Par has infringed the asserted patents and that the effective date of approval of Par's ANDA shall not be earlier than the expiration date of the asserted patents. Par has filed answers in each case, primarily asserting non-infringement, invalidity and/or unenforceability. Par has also filed counterclaims seeking a declaration in its favor on those issues. On July 15, 2008, the PTO issued U.S. Patent No. 7,399,772, or the '772 patent, which is now listed in the Orange Book for both Zegerid Capsules and Zegerid Powder for Oral Suspension. In October 2008, we amended our complaint to add the '772 patent to the pending litigation with Par. A claim construction, or "Markman," hearing was held in November 2008. Following the hearing, the court adopted all of the claim constructions we and the University of Missouri proposed. The discovery phase of the lawsuits is continuing. Trial is currently scheduled for July 2009.

In addition, as part of this litigation, Par initially filed counterclaims seeking a declaration that the '737 patent is not infringed, is invalid and/or is unenforceable. We moved to dismiss, or in the alternative, stay these claims due to a reissue proceeding involving the '737 patent currently pending before the PTO, and we and the University of Missouri also granted Par a covenant not to sue on the original '737 patent. In November 2008, Par dismissed its counterclaims relating to the '737 patent.

We commenced each of the lawsuits against Par within the applicable 45 day period required to automatically stay, or bar, the FDA from approving Par's ANDAs for 30 months or until a district court decision that is adverse to the asserted patents, whichever may occur earlier. If the litigation is still ongoing after 30 months, the termination of the stay could result in the introduction of one or more products generic to Zegerid Capsules and/or Zegerid Powder for Oral Suspension prior to resolution of the litigation.

Although we intend to vigorously defend and enforce our patent rights, we are not able to predict the outcome of the litigation. Any adverse outcome in this litigation could result in one or more generic versions of Zegerid Capsules and/or Zegerid Powder for Oral Suspension being launched before the expiration of the listed patents in July 2016, which could adversely affect our ability to successfully execute our business strategy to maximize the value of Zegerid Capsules and Zegerid Powder for Oral Suspension and would negatively impact our financial condition and results of operations, including causing a significant decrease in our revenues and cash flows. An adverse outcome may also impact the patent protection for the products being commercialized pursuant to our strategic alliances with GSK and Schering-Plough, which in turn may impact the amount of, or our ability to receive, milestone payments and royalties under those agreements. In addition, even if we prevail, the litigation will be costly, time-consuming and distracting to management, which could have a material adverse effect on our business.

Third parties may choose to file patent infringement claims against us, which litigation would be costly, time-consuming and distracting to management and could be materially adverse to our business.

The products we currently market, and those we may market in the future, may infringe patent and other rights of third parties. In addition, our competitors, many of which have substantially greater resources than us and have made significant investments in competing technologies or products, may seek to apply for and obtain patents that will prevent, limit or interfere with our ability to make, use and sell products either in the U.S. or international

markets. Intellectual property litigation in the pharmaceutical industry is common, and we expect this to continue.

If we or our third-party manufacturers or suppliers are unsuccessful in any challenge to our rights to manufacture, market and sell our products, we may be required to license the disputed rights, if the holder of those rights is willing, or to cease manufacturing and marketing the challenged products, or, if possible, to modify our products to avoid infringing upon those rights. If we or our third-party manufacturers or suppliers are unsuccessful in defending our rights, we could be liable for royalties on past sales or more significant damages, and we could be required to obtain and pay for licenses if we are to continue to manufacture and sell our products. These licenses may not be available and, if available, could require us to pay substantial upfront fees and future royalty payments. Any patent owner may seek preliminary injunctive relief in connection with an infringement claim, as well as a permanent injunction, and, if successful in the claim, may be entitled to lost profits from infringing sales, attorneys' fees and interest and other amounts. Any damages could be increased if there is a finding of willful infringement. Even if we and our third-party manufacturers and suppliers are successful in defending an infringement claim, the expense, time delay and burden on management of litigation could have a material adverse effect on our business.

For example, in January 2009, we submitted a 505(b)(2) NDA for our new tablet formulation as part of our Zegerid family of prescription products, which NDA referenced certain preclinical and clinical studies conducted for Prilosec® (delayed-release omeprazole capsules). If the NDA is accepted for filing by the FDA, we will provide notice and a paragraph iv certification to AstraZeneca, the holder of the Prilosec NDA, and related affiliated patent holders that the tablet product does not infringe the unexpired patents listed in the Orange Book for Prilosec or that those patents are invalid. We provided similar notices in connection with each of our NDAs for Zegerid Capsules and Zegerid Powder for Oral Suspension, and AstraZeneca did not file any lawsuits against us within the required 45-day period. Although we believe we continue to have meritorious non-infringement and/or invalidity positions with regard to the listed patents, we cannot be certain as to whether or not AstraZeneca will elect to file a lawsuit against us with regard to the NDA for the new tablet product. The outcome of any such litigation would be uncertain and defending such litigation would be expensive, time-consuming and distracting to management.

Our Zegerid products depend on technology licensed from the University of Missouri and any loss of our license rights would harm our business and seriously affect our ability to market our products.

Our Zegerid products are based on patented technology and technology for which patent applications are pending that we have exclusively licensed from the University of Missouri. A loss or adverse modification of our technology license from the University of Missouri would materially harm our ability to develop and commercialize our current Zegerid products and other products based on that licensed technology that we may attempt to develop or commercialize in the future. The University of Missouri may claim that new patents or new patent applications that result from new research performed by the University of Missouri are not part of the licensed technology.

The licenses from the University of Missouri expire in each country when the last patent for licensed technology expires in that country and the last patent application for licensed technology in that country is abandoned. In addition, our rights under the University of Missouri license are subject to early termination under specified circumstances, including our material and uncured breach of the license agreement or our bankruptcy or insolvency. Further, we are required to use commercially reasonable efforts to develop and sell products based on the technology we licensed from the University of Missouri to meet market demand. If we fail to meet these obligations in specified countries, after giving us an opportunity to cure the failure, the University of Missouri can terminate our license or render it nonexclusive with respect to those countries. To date, we believe we have met all of our obligations under the University of Missouri agreement. However, in the event that the University of Missouri is able to terminate the license agreement for one of the reasons specified in the license agreement, we would lose our rights to develop, market and sell our current Zegerid products and we would not be able to develop, market and sell future products based on those licensed technologies.

Risks Related to Our Financial Results and Need for Financing

We have incurred significant operating losses since our inception, and we expect to incur significant additional operating losses and may not attain and sustain profitability.

The extent of our future operating losses and our ability to attain and sustain profitability are highly uncertain.

We have been engaged in developing and commercializing drugs and have generated significant operating losses since our inception in December 1996. Our commercial activities and continued product development and clinical activities will require significant expenditures. For the year ended December 31, 2008, we recognized $130.2 million in total revenues, and, as of December 31, 2008, we had an accumulated deficit of $322.5 million. We expect to incur additional operating losses and capital expenditures as we support the continued marketing of the Zegerid and Glumetza products and any other products we commercialize, and continue our product development and clinical research programs.

To the extent we need to raise additional funds in connection with the licensing or acquisition of new products or to continue our operations, we may be unable to raise capital when needed.

We believe that our current cash, cash equivalents and short-term investments will be sufficient to fund our current operations for at least the next 12 months; however, our projected revenue may decrease or our expenses may increase and that would lead to our cash resources being consumed earlier than we expect. Although we do not believe that we will need to raise additional funds to finance our current operations over the next 12 months, we may pursue raising additional funds in connection with licensing or acquisition of new products. Sources of additional funds may include funds generated through strategic collaborations or licensing agreements, or through equity, debt and/or royalty financing.

In November 2008, we filed a universal shelf registration statement on Form S-3 with the SEC, which was declared effective in December 2008. The universal shelf registration statement replaced our previous universal shelf registration statement that expired in December 2008. The universal shelf registration statement may permit us, from time to time, to offer and sell up to approximately $75.0 million of equity or debt securities. However, there can be no assurance that we will be able to complete any such offerings of securities. Factors influencing the availability of additional financing include the progress of our commercial and development activities, investor perception of our prospects and the general condition of the financial markets, among others.

In July 2006, we entered into a loan agreement with Comerica Bank, or Comerica, which we subsequently amended in July 2008, pursuant to which we may request advances in an aggregate outstanding amount not to exceed $25.0 million. Amounts borrowed under the loan agreement may be repaid and re-borrowed at any time prior to July 11, 2011. In December 2008, we borrowed $10.0 million under the loan agreement. Our ability to borrow additional amounts under the loan agreement depends upon a number of conditions and restrictions, and we cannot be certain that we will satisfy all borrowing conditions at a time when we desire to borrow such amounts under the loan agreement. For example, we have made comprehensive representations and warranties to Comerica as our lender, and all of these representations and warranties generally must be true and correct at the time of any proposed borrowing. Furthermore, we are subject to a number of affirmative and negative covenants, each of which must be satisfied at the time of any proposed borrowing. If we have not satisfied these various conditions, or an event of default otherwise has occurred, we may be unable to borrow additional amounts under the loan agreement, and may be required to repay any amounts previously borrowed. In addition, given the current financial market conditions, our continued ability to borrow under the loan agreement may be dependent on the financial solvency of banks in general, including Comerica.

We cannot be certain that our existing cash and marketable securities resources will be adequate to sustain our current operations. To the extent we require additional funding, we cannot be certain that such funding will be available to us on acceptable terms, or at all. If adequate funds are not available on terms acceptable to us at that time, our ability to continue our current operations or pursue new product opportunities would be significantly limited.

Our quarterly financial results are likely to fluctuate significantly due to uncertainties about future sales levels for our currently marketed products and future costs associated with our development products.

Our quarterly operating results are difficult to predict and may fluctuate significantly from period to period, particularly because the commercial success of, and demand for currently marketed products, as well as the success and costs of our development programs are uncertain and therefore our future prospects are uncertain. The level of our revenues, if any, and results of operations at any given time will be based primarily on the following factors:

- commercial success of the Zegerid and Glumetza prescription products;

- the outcome of, or other developments related to, our patent infringement suit against Par involving Zegerid Capsules and Zegerid Powder for Oral Suspension;

- progress under the strategic alliances with GSK and Schering-Plough, including Schering-Plough's ability to obtain regulatory approval for a licensed OTC product;

- our ability to obtain regulatory approval for any future products we develop, including the new tablet formulation of our Zegerid prescription products, for which an NDA was submitted in January 2009;

- results of clinical trials and other development programs, including the ongoing and planned clinical trials for the budesonide MMX and rifamycin SV MMX product candidates, and our ability to establish safety and efficacy for our development products;

- interruption in the manufacturing or distribution of our products;

- timing of new product offerings, acquisitions, licenses or other significant events by us, GSK, Schering-Plough or our competitors;

- legislative changes affecting the products we may offer or those of our competitors; and

- the effect of competing technological and market developments.

It will continue to be difficult for us to forecast demand for our products with any degree of certainty. In addition, we expect to incur significant operating expenses as we continue to support the marketing of the Zegerid and Glumetza products and continue our product development and clinical research programs. Accordingly, we may experience significant, unanticipated quarterly losses. Because of these factors, our operating results in one or more future quarters may fail to meet the expectations of securities analysts or investors, which could cause our stock price to decline significantly.

Our current and any future indebtedness under our loan agreement with Comerica could adversely affect our financial health.

Under our loan agreement with Comerica, we may incur a significant amount of indebtedness. Such indebtedness could have important consequences. For example, it could:

- impair our ability to obtain additional financing in the future for working capital needs, capital expenditures and general corporate purposes;

- increase our vulnerability to general adverse economic and industry conditions;

- make it more difficult for us to satisfy other debt obligations we may incur in the future;

- require us to dedicate a substantial portion of our cash flows from operations to the payment of principal and interest on our indebtedness, thereby reducing the availability of our cash flows to fund working capital needs, capital expenditures and other general corporate purposes;

- limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate;

- place us at a disadvantage compared to our competitors that have less indebtedness; and

- expose us to higher interest expense in the event of increases in interest rates because our indebtedness under the loan agreement with Comerica bears interest at a variable rate.

For a description of the loan agreement, see Management's Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources.

Covenants in our loan agreement with Comerica may limit our ability to operate our business.

Under our loan agreement with Comerica, we are subject to specified affirmative and negative covenants, including limitations on our ability: to undergo certain change of control events; to convey, sell, lease, license, transfer or otherwise dispose of assets; to create, incur, assume, guarantee or be liable with respect to certain indebtedness; to grant liens; to pay dividends and make certain other restricted payments; and to make investments. In addition, under the loan agreement we are required to maintain a balance of cash with Comerica in an amount of not less than $4.0 million and to maintain any other cash balances with either Comerica or another financial institution covered by a control agreement for the benefit of Comerica. We are also subject to specified financial covenants with respect to a minimum liquidity ratio and, in specified limited circumstances, minimum EBITDA requirements, as defined in the loan agreement.

If we default under the loan agreement because of a covenant breach or otherwise, all outstanding amounts could become immediately due and payable, which would negatively impact our liquidity and reduce the availability of our cash flows to fund working capital needs, capital expenditures and other general corporate purposes.

Our results of operations and liquidity needs could be materially negatively affected by market fluctuations and economic downturn.

Our results of operations could be materially negatively affected by economic conditions generally, both in the U.S. and elsewhere around the world. Continuing concerns over inflation, energy costs, geopolitical issues, the availability and cost of credit, the U.S. mortgage market and a declining residential real estate market in the U.S. have contributed to increased volatility and diminished expectations for the economy and the markets going forward. These factors, combined with volatile oil prices, declining business and consumer confidence and increased unemployment, have precipitated an economic recession. Domestic and international equity markets continue to experience heightened volatility and turmoil. These events and the continuing market upheavals may have an adverse effect on us. In the event of a continuing market downturn, our results of operations could be adversely affected by those factors in many ways, including making it more difficult for us to raise funds if necessary, and our stock price may further decline. In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits. Given the current instability of financial institutions, we cannot be assured that we will not experience losses on these deposits.

In addition, concern about the stability of markets generally and the strength of counterparties specifically has led many lenders and institutional investors to reduce, and in some cases, cease to provide credit to businesses and consumers.

Negative conditions in the global credit markets may impair the liquidity of a portion of our investment portfolio.

As of December 31, 2008, our long-term investments included AAA-rated auction rate securities, or ARS, issued by state municipalities. Our ARS are debt instruments with a long-term maturity and an interest rate that is reset in short-term intervals through auctions. The conditions in the global credit markets have prevented many investors from liquidating their holdings of ARS because the amount of securities submitted for sale has exceeded the amount of purchase orders for such securities. If there is insufficient demand for the securities at the time of an auction, the auction may not be completed and the interest rates may be reset to predetermined higher rates. When auctions for these securities fail, the investments may not be readily convertible to cash until a future auction of these investments is successful or they are redeemed or mature.

Due to conditions in the global credit markets, in 2008, our ARS, representing a par value of approximately $4.3 million, had insufficient demand resulting in multiple failed auctions. As a result, these affected securities are currently not liquid and the interest rates have been reset to predetermined higher rates.

In October 2008, we received an offer of Auction Rate Securities Rights, or ARS Rights, from our investment provider, UBS Financial Services, Inc., a subsidiary of UBS AG, or UBS. In November 2008, we accepted the ARS Rights offer. The ARS Rights permit us to require UBS to purchase our ARS at par value at any time during the period of June 30, 2010 through July 2, 2012. If we do not exercise our ARS Rights, the ARS will continue to accrue interest as determined by the auction process or the terms of the ARS if the auction fails. If the ARS Rights are not exercised before July 2, 2012 they will expire and UBS will have no further obligation to buy our ARS. UBS has the discretion to purchase or sell our ARS at any time without prior notice so long as we receive a payment at par upon any sale or disposition. UBS will only exercise its discretion to purchase or sell our ARS for the purpose of restructurings, dispositions or other solutions that will provide us with par value for our ARS. As a condition to accepting the offer of ARS Rights, we released UBS from all claims except claims for consequential damages relating to its marketing and sales of ARS. We also agreed not to serve as a class representative or receive benefits under any class action settlement or investor fund.

In the event we need to access the funds that are in an illiquid state, we will not be able to do so without the likely loss of principal, until a future auction for these investments is successful or they are redeemed by the issuer or they mature. If we are unable to sell these securities in the market or they are not redeemed, then we may be required to hold them to maturity.

In connection with the reporting of our financial condition and results of operations, we are required to make estimates and judgments which involve uncertainties, and any significant differences between our estimates and actual results could have an adverse impact on our financial position, results of operations and cash flows.

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. In particular, as part of our revenue recognition policy, our estimates of product returns, rebates and chargebacks require our most subjective and complex judgment due to the need to make estimates about matters that are inherently uncertain. Any significant differences between our actual results and our estimates under different assumptions or conditions could negatively impact our financial position, results of operations and cash flows.

Risks Related to the Securities Markets and Ownership of Our Common Stock

Our stock price has been and may continue to be volatile, and our stockholders may not be able to sell their shares at attractive prices.

The market prices for securities of specialty pharmaceutical companies in general have been highly volatile and may continue to be highly volatile in the future. For example, during the year ended December 31, 2008, the trading prices for our common stock ranged from a high of $3.24 to a low of $1.23. In addition, we have not paid cash dividends since our inception and do not intend to pay cash dividends in the foreseeable future. Furthermore, our loan agreement with Comerica prohibits us from paying dividends. Therefore, investors will have to rely on appreciation in our stock price and a liquid trading market in order to achieve a gain on their investment.

The trading price of our common stock may continue to fluctuate substantially as a result of one or more of the following factors:

- announcements concerning our commercial progress and activities, including sales trends, or concerning our product development programs, results of our clinical trials or status of our regulatory submissions;
- developments in our pending patent infringement suit against Par involving Zegerid Capsules and Zegerid Powder for Oral Suspension;
- regulatory developments and related announcements in the U.S., including announcements by the FDA, and foreign countries;
- other disputes or developments concerning proprietary rights, including patents and trade secrets, litigation

matters, and our ability to patent or otherwise protect our products and technologies;

- developments, including progress or delays, pursuant to our strategic alliances with GSK and Schering-Plough;
- conditions or trends in the pharmaceutical and biotechnology industries;
- fluctuations in stock market prices and trading volumes of similar companies or of the markets generally;
- changes in, or our failure to meet or exceed, investors' and securities analysts' expectations;
- announcements of technological innovations or new commercial products by us or our competitors;
- actual or anticipated fluctuations in our or our competitors' quarterly or annual operating results;
- announcements concerning borrowings under our loan agreement, takedowns under our existing universal shelf registration statement or other developments relating to the loan agreement, universal shelf registration statement or our other financing activities;
- our entering into licenses, strategic partnerships and similar arrangements, or the termination of such arrangements;
- acquisition of products or businesses by us or our competitors;
- announcements made by, or events affecting, our strategic partners, our contract sales force provider, our suppliers or other third parties that provide services to us;
- litigation and government inquiries; or
- economic and political factors, including wars, terrorism and political unrest.

Our stock price could decline and our stockholders may suffer dilution in connection with future issuances of equity or debt securities.

We believe that our current cash, cash equivalents and short-term investments will be sufficient to fund our current operations for at least the next 12 months; however, our projected revenue may decrease or our expenses may increase and that would lead to our cash resources being consumed earlier than we expect. Although we do not believe that we will need to raise additional funds to finance our current operations over the next 12 months, we may pursue raising additional funds in connection with licensing or acquisition of new products. Sources of additional funds may include funds generated through strategic collaborations or licensing agreements, or through equity, debt and/or royalty financing. To the extent we conduct substantial future offerings of equity or debt securities, such offerings could cause our stock price to decline. For example, we may issue securities under our existing universal shelf registration statement or we may pursue alternative financing arrangements.

The exercise of outstanding options and warrants and future equity issuances, including future public offerings or future private placements of equity securities and any additional shares issued in connection with acquisitions, will also result in dilution to investors. The market price of our common stock could fall as a result of resales of any of these shares of common stock due to an increased number of shares available for sale in the market.

Future sales of our common stock by our stockholders may depress our stock price.

A concentrated number of stockholders hold significant blocks of our outstanding common stock. Sales by our current stockholders of a substantial number of shares, or the expectation that such sales may occur, could significantly reduce the market price of our common stock. For example, sales by Cosmo of any shares that we have issued or may issue to it in connection with our strategic collaboration (following expiration of the applicable lock-

up period), or the expectation that sales may occur, could significantly reduce the market price of our common stock. In addition, the holders of a substantial number of shares of common stock may have rights, subject to certain conditions, to require us to file registration statements to permit the resale of their shares in the public market or to include their shares in registration statements that we may file for ourselves or other stockholders. Moreover, certain of our executive officers have from time to time established programmed selling plans under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended, for the purpose of effecting sales of common stock, and other employees and affiliates, including our directors and executive officers, may choose to establish similar plans in the future. If any of our stockholders cause securities to be sold in the public market, the sales could reduce the trading price of our common stock. These sales also could impede our ability to raise future capital.

We may become involved in securities or other class action litigation that could divert management's attention and harm our business.

The stock market has from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of pharmaceutical and biotechnology companies. These broad market fluctuations may cause the market price of our common stock to decline. In the past, following periods of volatility in the market price of a particular company's securities, securities class action litigation has often been brought against that company. In addition, over the last few years, several class action lawsuits have been filed against pharmaceutical companies alleging that the companies' sales representatives have been misclassified as exempt employees under the Federal Fair Labor Standards Act and applicable state laws. Summary judgment has been granted in favor of the pharmaceutical companies in several of the cases, however, they remain subject to appeal. We cannot be certain as to how the lawsuits will ultimately be resolved. Although we have not been the subject of these types of lawsuits, we may be targeted in the future. Litigation often is expensive and diverts management's attention and resources, which could adversely affect our business.

Anti-takeover provisions in our organizational documents and Delaware law may discourage or prevent a change in control, even if an acquisition would be beneficial to our stockholders, which could adversely affect our stock price and prevent attempts by our stockholders to replace or remove our current management.

Our certificate of incorporation and bylaws contain provisions that may delay or prevent a change in control, discourage bids at a premium over the market price of our common stock and adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock.

These provisions include:

- dividing our board of directors into three classes serving staggered three-year terms;
- prohibiting our stockholders from calling a special meeting of stockholders;
- permitting the issuance of additional shares of our common stock or preferred stock without stockholder approval;
- prohibiting our stockholders from making certain changes to our certificate of incorporation or bylaws except with 66 2/3% stockholder approval; and
- requiring advance notice for raising business matters or nominating directors at stockholders' meetings.

We are also subject to provisions of the Delaware corporation law that, in general, prohibit any business combination with a beneficial owner of 15% or more of our common stock for five years unless the holder's acquisition of our stock was approved in advance by our board of directors. Together, these charter and statutory provisions could make the removal of management more difficult and may discourage transactions that otherwise could involve payment of a premium over prevailing market prices for our common stock.

In addition, in November 2004, we adopted a stockholder rights plan, which was subsequently amended in April 2006 and December 2008. Although the rights plan will not prevent a takeover, it is intended to encourage anyone seeking to acquire our company to negotiate with our board prior to attempting a takeover by potentially

significantly diluting an acquirer's ownership interest in our outstanding capital stock. The existence of the rights plan may also discourage transactions that otherwise could involve payment of a premium over prevailing market prices for our common stock.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

Our primary office facility consists of approximately 24,500 square feet in San Diego, California. We sublease our primary office facility pursuant to a sublease agreement that expires in February 2013.

Item 3. Legal Proceedings

In September 2007, we filed a lawsuit in the United States District Court for the District of Delaware against Par Pharmaceutical, Inc., or Par, for infringement of U.S. Patent Nos. 6,645,988; 6,489,346; and 6,699,885, each of which is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations, or the Orange Book, for Zegerid Capsules. In December 2007, we filed a second lawsuit in the United States District Court for the District of Delaware against Par for infringement of U.S. Patent Nos. 6,645,988; 6,489,346; 6,699,885; and 6,780,882, each of which is listed in the Orange Book for Zegerid Powder for Oral Suspension. The University of Missouri, licensor of the patents, is a co-plaintiff in the litigation, and both lawsuits have been consolidated for all purposes. The lawsuits are in response to abbreviated new drug applications, or ANDAs, filed by Par with the U.S. Food and Drug Administration, or FDA, regarding Par's intent to market generic versions of our Zegerid Capsules and Zegerid Powder for Oral Suspension products prior to the July 2016 expiration of the asserted patents. Each complaint seeks a judgment that Par has infringed the asserted patents and that the effective date of approval of Par's ANDA shall not be earlier than the expiration date of the asserted patents. Par has filed answers in each case, primarily asserting non-infringement, invalidity and/or unenforceability. Par has also filed counterclaims seeking a declaration in its favor on those issues. On July 15, 2008, the U.S. Patent and Trademark Office, or PTO, issued U.S. Patent No. 7,399,772, or the '772 patent, which is now listed in the Orange Book for both Zegerid Capsules and Zegerid Powder for Oral Suspension. In October 2008, we amended our complaint to add the '772 patent to the pending litigation with Par. A claim construction, or "Markman," hearing was held in November 2008. Following the hearing, the court adopted all of the claim constructions we and the University of Missouri proposed. The discovery phase of the lawsuits is continuing. Trial is currently scheduled for July 2009.

In addition, as part of this litigation, Par initially filed counterclaims seeking a declaration that U.S. Patent No. 5,840,737, the '737 patent, is not infringed, is invalid and/or is unenforceable. We moved to dismiss, or in the alternative, stay these claims due to a reissue proceeding involving the '737 patent currently pending before the PTO, and we and the University of Missouri also granted Par a covenant not to sue on the original '737 patent. In November 2008, Par dismissed its counterclaims relating to the '737 patent.

We commenced each of the lawsuits against Par within the applicable 45 day period required to automatically stay, or bar, the FDA from approving Par's ANDAs for 30 months or until a district court decision that is adverse to the asserted patents, whichever may occur earlier. If the litigation is still ongoing after 30 months, the termination of the stay could result in the introduction of one or more products generic to Zegerid Capsules and/or Zegerid Powder for Oral Suspension prior to resolution of the litigation.

Although we intend to vigorously defend and enforce our patent rights, we are not able to predict the outcome of the litigation. Any adverse outcome in this litigation could result in one or more generic versions of Zegerid Capsules and/or Zegerid Powder for Oral Suspension being launched before the expiration of the listed patents in July 2016, which could adversely affect our ability to successfully execute our business strategy to maximize the value of Zegerid Capsules and Zegerid Powder for Oral Suspension and would negatively impact our financial condition and results of operations, including causing a significant decrease in our revenues and cash flows. An adverse outcome may also impact the patent protection for the products being commercialized pursuant to our strategic alliances with Glaxo Group Limited, an affiliate of GlaxoSmithKline, plc, and Schering-Plough Consumer Healthcare Products, Inc., which in turn may impact the amount of, or our ability to receive, milestone payments and

royalties under those agreements. In addition, even if we prevail, the litigation will be costly, time-consuming and distracting to management, which could have a material adverse effect on our business.

In December 2007, the University of Missouri filed an Application for Reissue of the '737 patent with the PTO. The '737 patent is one of six issued patents listed in the Orange Book for Zegerid Powder for Oral Suspension. The '737 patent is not one of the four patents listed in the Orange Book for Zegerid Capsules. It is not feasible to predict the impact that the reissue proceeding may have on the scope and validity of the '737 patent claims. If the claims of the '737 patent ultimately are narrowed substantially or invalidated by the PTO, the extent of the patent coverage afforded to our Zegerid family of products could be impaired, which could potentially harm our business and operating results.

In August 2006, an Indian company filed a pre-grant opposition to a pending Indian patent application that is licensed to us under our license agreement with the University of Missouri. A hearing was conducted in October 2007. In September 2008, the Indian Patent Office declined to grant a patent on the claims presented. As a result of the recent Indian Patent Office decision, we may not be able to obtain patent coverage for one or more of our Zegerid products in India.

Santaris Pharma A/S has filed a Request for Revocation against our European Union registration for the mark Santarus® on the basis of non-use. This Request for Revocation was filed in response to our filing of an opposition against the EU application for the mark Santaris Pharma™. These proceedings are pending and any adverse decision may negatively impact our right to use our Santarus® mark in the EU.

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

Not applicable.

PART II

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

Market Information

Our common stock has been traded on the Nasdaq Global Market since April 1, 2004 under the symbol SNTS. Prior to such time, there was no public market for our common stock. The following table sets forth the high and low sales prices for our common stock as reported on the Nasdaq Global Market for the periods indicated.

	High	Low
Year Ended December 31, 2007		
First Quarter	$8.15	$6.11
Second Quarter	$7.96	$4.82
Third Quarter	$5.83	$1.93
Fourth Quarter	$2.80	$1.90
Year Ended December 31, 2008		
First Quarter	$3.14	$1.78
Second Quarter	$3.24	$1.98
Third Quarter	$2.93	$1.91
Fourth Quarter	$2.68	$1.23

As of February 15, 2009, there were approximately 91 holders of record of our common stock.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support operations and finance the growth and development of our business and do not intend to pay cash dividends on our common stock for the foreseeable future. Furthermore, our loan agreement with Comerica prohibits us from paying dividends. Any future determination related to our dividend policy will be made at the discretion of our board of directors.

Recent Sales of Unregistered Securities

As previously disclosed in our Current Report on Form 8-K filed on December 15, 2008, we have entered into a strategic collaboration with Cosmo Technologies Limited, an affiliate of Cosmo Pharmaceuticals S.p.A., or Cosmo, pursuant to which we were granted certain exclusive rights to develop and commercialize selected proprietary pharmaceutical products of Cosmo in the U.S. In partial consideration of the licenses granted, on December 15, 2008, we issued 6,000,000 shares of our common stock to Cosmo and agreed to issue up to an additional 4,300,000 shares of common stock upon the achievement of development and commercial milestones, subject to certain limitations. The strategic collaboration is described in more detail in Note 4 to the financial statements included with this report. In connection with the issuance of shares of our common stock to Cosmo, we relied on the exemption from registration contained in Section 4(2) of the Securities Act as a transaction by an issuer not involving a public offering. Cosmo represented to us that it was an accredited investor within the meaning of Rule 501 of Regulation D under the Securities Act and that it was acquiring the securities for investment only and not with a view to or for sale in connection with any distribution thereof.

Issuer Purchases of Equity Securities

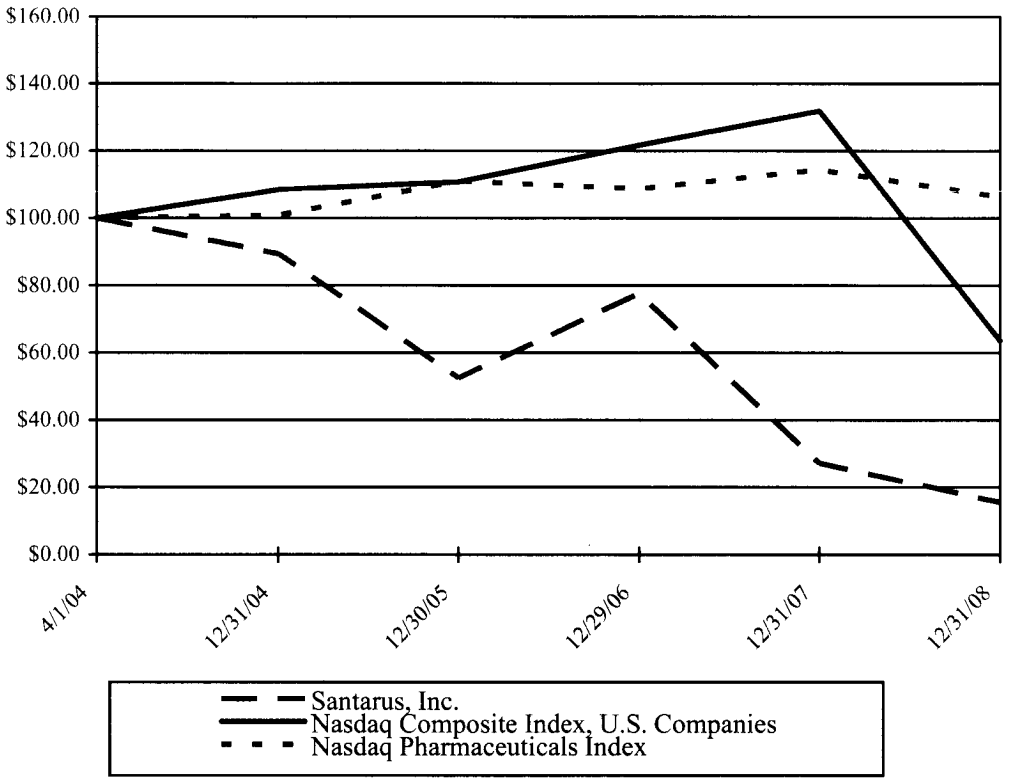
Not applicable.

Performance Graph

The following graph illustrates a comparison of the total cumulative stockholder return on our common stock since April 1, 2004, which is the date our common stock first began trading on the Nasdaq Global Market, to two indices: the Nasdaq Composite Index, U.S. Companies, and the Nasdaq Pharmaceuticals Index. The graph assumes an initial investment of $100 on April 1, 2004. The comparisons in the graph are required by the Securities and Exchange Commission and are not intended to forecast or be indicative of possible future performance of our common stock.

Comparison of Cumulative Total Return on Investment

Since April 1, 2004



	4/1/04	12/31/04	12/30/05	12/29/06	12/31/07	12/31/08
Santarus, Inc.	$100.00	$89.50	$52.48	$77.53	$27.23	$15.54
Nasdaq Composite Index, U.S. Companies	$100.00	$108.50	$110.77	$121.70	$131.97	$63.58
Nasdaq Pharmaceuticals Index	$100.00	$100.90	$111.11	$108.76	$114.36	$106.42

Item 6. Selected Financial Data

The selected statement of operations data for the years ended December 31, 2005 and 2004, and the selected balance sheet data as of December 31, 2006, 2005 and 2004, are derived from our audited financial statements not included in this Form 10-K. The selected statement of operations data for the years ended December 31, 2008, 2007 and 2006 and the selected balance sheet data as of December 31, 2008 and 2007, are derived from the audited financial statements for such years and as of such dates, which are included elsewhere in this Form 10-K. You should read these selected financial data together with "Management's Discussion and Analysis of Financial

Condition and Results of Operations" and our financial statements and related notes included elsewhere in this Form 10-K.

	Years Ended December 31,				
	2008	2007	2006	2005	2004
	(in thousands, except per share amounts)				
Statement of Operations Data:					
Revenues:					
Product sales, net	$ 101,220	$ 79,403	$ 45,980	$ 13,667	$ 634
Promotion revenue	9,837	1,803	—	—	—
License and royalty revenue	19,144	13,222	3,263	12,857	714
Total revenues	130,201	94,428	49,243	26,524	1,348
Costs and expenses:					
Cost of product sales	7,345	7,301	4,927	2,129	1,968
License fees and royalties	22,257	11,117	6,437	3,414	5,089
Research and development	11,760	6,849	7,572	11,292	24,823
Selling, general and administrative	108,012	116,503	89,828	79,391	52,354
Total costs and expenses	149,374	141,770	108,764	96,226	84,234
Loss from operations	(19,173)	(47,342)	(59,521)	(69,702)	(82,886)
Interest and other income, net	1,190	3,077	3,055	4,716	1,391
Loss before income taxes	(17,983)	(44,265)	(56,466)	(64,986)	(81,495)
Income tax expense	534	—	—	—	—
Net loss	(18,517)	(44,265)	(56,466)	(64,986)	(81,495)
Accretion to redemption value of redeemable convertible preferred stock	—	—	—	—	(1,124)
Net loss attributable to common stockholders	$ (18,517)	$ (44,265)	$ (56,466)	$ (64,986)	$ (82,619)
Basic and diluted net loss per share	$ (0.36)	$ (0.87)	$ (1.19)	$ (1.66)	$ (3.30)
Weighted average shares outstanding used to calculate basic and diluted net loss per share	51,835	51,061	47,355	39,188	25,017

	As of December 31,				
	2008	2007	2006	2005	2004
	(in thousands)				
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 52,037	$ 64,678	$ 75,534	$ 69,367	$ 114,008
Working capital	3,734	25,582	59,010	59,572	94,346
Total assets	92,484	85,344	93,628	79,935	122,216
Deferred revenue, less current portion	2,436	12,722	15,444	8,571	11,429
Long-term debt, less current portion	10,000	—	—	—	38
Total stockholders' equity	9,323	15,348	46,305	54,520	85,843

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	(in thousands, except per share amounts)			
Selected Quarterly Financial Data (unaudited):				
2008:				
Product sales, net	$ 19,415	$ 23,954	$ 28,106	$ 29,745
Total revenues	24,466	36,005	32,209	37,521
Cost of product sales	1,695	1,701	1,924	2,025
Total costs and expenses	32,646	33,062	36,338	47,328
Net income (loss)	(7,619)	3,205	(3,952)	(10,151)
Basic and diluted net income (loss) per share	(0.15)	0.06	(0.08)	(0.19)
2007:				
Product sales, net	$ 17,027	$ 18,800	$ 19,527	$ 24,049
Total revenues	18,958	20,730	26,458	28,282
Cost of product sales	1,647	1,663	1,782	2,209
Total costs and expenses	36,312	34,427	34,065	36,966
Net income (loss)	(16,436)	(12,936)	(6,902)	(7,991)
Basic and diluted net loss per share	(0.32)	(0.25)	(0.13)	(0.16)

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

You should read the following discussion and analysis together with "Selected Financial Data" and the financial statements and related notes included elsewhere in this Form 10-K. This discussion may contain forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in any forward-looking statements as a result of many factors, including those set forth in our filings with the Securities and Exchange Commission.

Overview

We are a specialty pharmaceutical company focused on acquiring, developing and commercializing proprietary products that address the needs of patients treated by gastroenterologists and other targeted physicians.

Our commercial organization is currently promoting Zegerid® (omeprazole/sodium bicarbonate) Capsules and Powder for Oral Suspension, which are proprietary formulations that combine omeprazole, which is a proton pump inhibitor, or PPI, and an antacid. We developed these products as the first immediate-release oral PPIs for the U.S. prescription market, and they have been approved by the U.S. Food and Drug Administration, or FDA, to treat or reduce the risk of a variety of upper gastrointestinal, or GI, diseases and disorders, including gastroesophageal reflux disease, or GERD. Our Zegerid products are based on patented technology and utilize antacids, which raise the gastric pH and thus protect the PPI, omeprazole, from acid degradation in the stomach, allowing the omeprazole to be quickly absorbed into the bloodstream. We commercially launched Zegerid Capsules in early 2006 and Zegerid Powder for Oral Suspension in late 2004 and early 2005.

Our commercial organization also promotes Glumetza® (metformin hydrochloride extended release tablets) prescription products in the U.S., under the terms of an exclusive promotion agreement that we entered into with Depomed, Inc., or Depomed, in July 2008. Glumetza is a once-daily, extended-release formulation of metformin that incorporates patented drug delivery technology and is indicated as an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 diabetes. The extended-release delivery system is designed to offer patients with diabetes an ability to reach their optimal dose of metformin with fewer GI side effects. We began our promotion of the Glumetza products in October 2008.

We are developing two product candidates targeting lower GI conditions under the terms of a strategic collaboration that we entered into with Cosmo Technologies Limited, or Cosmo, in December 2008. The product candidates utilize Cosmo's patented MMX® technology, which is a proprietary multi-matrix system that is designed to result in the controlled release and homogeneous distribution of a drug substance throughout the length of the colon. The goal of the MMX technology is to improve efficacy while reducing side effects by minimizing systemic absorption. Budesonide MMX is an oral corticosteroid and is currently being investigated in two phase III clinical trials for the induction of remission of mild or moderate active ulcerative colitis. Rifamycin SV MMX is a broad

spectrum, semi-synthetic antibiotic and has been investigated in a phase II clinical program for traveler's diarrhea. Under the strategic collaboration, we were granted exclusive rights to develop and commercialize these product candidates in the U.S.

In addition, in January 2009, we submitted a new drug application, or NDA, to the FDA for a new tablet formulation to add to our Zegerid family of prescription products. The new formulation is an immediate-release tablet that combines omeprazole with a mix of buffers.

To further leverage our proprietary PPI technology and diversify our sources of revenue, we licensed exclusive rights to Schering-Plough Consumer Healthcare Products, Inc., or Schering-Plough, under our patented PPI technology to develop, manufacture and sell Zegerid brand over-the-counter, or OTC, products in the lower dosage strength of 20 mg of omeprazole in the U.S. and Canada. We have also entered into a license agreement and a distribution agreement granting exclusive rights to Glaxo Group Limited, an affiliate of GlaxoSmithKline, plc, or GSK, under our patented PPI technology to develop, manufacture and commercialize prescription and OTC products in up to 114 specified countries outside of the U.S., Europe, Australia, Japan and Canada (including markets within Africa, Asia, the Middle-East, and Central and South America), and to distribute and sell Zegerid brand prescription products in Puerto Rico and the U.S. Virgin Islands.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. We review our estimates on an on-going basis. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions. While our significant accounting policies are described in more detail in Note 1 to our financial statements included in this Form 10-K, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

We follow Staff Accounting Bulletin, or SAB, No. 104, *Revenue Recognition*, and recognize revenue when there is persuasive evidence that an arrangement exists, title has passed, the price is fixed or determinable, and collectibility is reasonably assured.

Product Sales, Net. We sell our Zegerid products primarily to pharmaceutical wholesale distributors. We are obligated to accept from customers the return of products that are within six months of their expiration date or up to 12 months beyond their expiration date. We authorize returns for damaged products and exchanges for expired products in accordance with our return goods policy and procedures, and have established allowances for such amounts at the time of sale.

We recognize revenue from product sales in accordance with SAB No. 104 and Statement of Financial Accounting Standards, or SFAS, No. 48, *Revenue Recognition When Right of Return Exists.* Among its criteria for revenue recognition from sale transactions where a buyer has a right of return, SFAS No. 48 requires the amount of future returns to be reasonably estimable. We recognize product sales net of estimated allowances for product returns, estimated rebates in connection with contracts relating to managed care, Medicaid, Medicare, and patient coupons, and estimated chargebacks from distributors, wholesaler fees and prompt payment and other discounts.

We establish allowances for estimated product returns, rebates and chargebacks based primarily on the following qualitative and quantitative factors:

- the number of and specific contractual terms of agreements with customers;
- estimated levels of inventory in the distribution channel;
- estimated remaining shelf life of products;

- analysis of prescription data gathered by a third-party prescription data provider;
- direct communication with customers;
- historical product returns, rebates and chargebacks;
- anticipated introduction of competitive products or generics;
- anticipated pricing strategy changes by us and/or our competitors; and
- the impact of state and federal regulations.

In our analyses, we utilize prescription data purchased from a third-party data provider to develop estimates of historical inventory channel pull-through. We utilize a separate analysis which compares historical product shipments less returns to estimated historical prescriptions written. Based on that analysis, we develop an estimate of the quantity of product in the distribution channel which may be subject to various product return, rebate and chargeback exposures.

Our estimates of product returns, rebates and chargebacks require our most subjective and complex judgment due to the need to make estimates about matters that are inherently uncertain. If actual future payments for returns, rebates, chargebacks and other discounts exceed the estimates we made at the time of sale, our financial position, results of operations and cash flows would be negatively impacted.

Our allowance for product returns was $10.3 million as of December 31, 2008 and $5.9 million as of December 31, 2007. In order to provide a basis for estimating future product returns on sales to our customers at the time title transfers, we have been tracking our Zegerid products return history from the time of our first commercial product launch of Zegerid Powder for Oral Suspension 20 mg in late 2004, taking into consideration product expiration dating and estimated inventory levels in the distribution channel. We recognize product sales at the time title passes to our customers, and we provide for an estimate of future product returns at that time based upon our historical product returns trends, our analysis of product expiration dating and estimated inventory levels in the distribution channel, and the other factors discussed above. There may be a significant time lag between the date we determine the estimated allowance and when we receive the product return and issue credit to a customer. Due to this time lag, we record adjustments to our estimated allowance over several periods, which can result in a net increase or a net decrease in our operating results in those periods. In 2007, based upon our review of additional product returns history gathered through the end of 2007 and analysis of product expiration dating and inventory in the distribution channel, we increased our estimate for product returns to reflect actual experience accordingly. This change in estimate provided for potential product returns related to sales in prior periods and resulted in an increase to our net loss of approximately $1.9 million in 2007.

Our allowance for rebates, chargebacks and other discounts was $29.3 million as of December 31, 2008 and $21.0 million as of December 31, 2007. These allowances reflect an estimate of our liability for rebates due to managed care organizations under specific contracts, rebates due to various governmental organizations under Medicaid and Medicare contracts and regulations, chargebacks due to various organizations purchasing our products through federal contracts and/or group purchasing agreements, and other rebates and customer discounts due in connection with wholesaler fees and prompt payment and other discounts. We estimate our liability for rebates and chargebacks at each reporting period based on a combination of the qualitative and quantitative assumptions listed above. In each reporting period, we evaluate our outstanding contracts and apply the contractual discounts to the invoiced price of wholesaler shipments recognized. Although the total invoiced price of shipments to wholesalers for the reporting period and the contractual terms are known during the reporting period, we project the ultimate disposition of the sale (e.g. future utilization rates of cash payors, managed care, Medicaid, Medicare or other contracted organizations). This estimate is based on historical trends adjusted for anticipated changes based on specific contractual terms of new agreements with customers, anticipated pricing strategy changes by us and/or our competitors and the other qualitative and quantitative factors described above. There may be a significant time lag between the date we determine the estimated allowance and when we make the contractual payment or issue credit to a customer. Due to this time lag, we record adjustments to our estimated allowance over several periods, which can result in a net increase or a net decrease in our operating results in those periods. To date, actual results have not materially differed from our estimates.

Promotion Revenue and License and Royalty Revenue. We recognize promotion revenue and license and royalty revenue consistent with the provisions of SAB No. 104 and Emerging Issues Task Force, or EITF, Issue No. 00-21,

Revenue Arrangements with Multiple Deliverables. We analyze each element of our promotion and licensing agreements to determine the appropriate revenue recognition. We recognize revenue on upfront payments over the period of significant involvement under the related agreements unless the fee is in exchange for products delivered or services rendered that represent the culmination of a separate earnings process and no further performance obligation exists under the contract. We recognize milestone payments upon the achievement of specified milestones if (1) the milestone is substantive in nature, and the achievement of the milestone was not reasonably assured at the inception of the agreement and (2) the fees are nonrefundable. Any milestone payments received prior to satisfying these revenue recognition criteria are recognized as deferred revenue. Sales milestones, royalties and promotion fees are recognized as revenue when earned under the agreements.

Inventories and Related Reserves

Inventories are stated at the lower of cost (FIFO) or market and consist of finished goods and raw materials used in the manufacture of our Zegerid Capsules and Zegerid Powder for Oral Suspension products. Also included in inventories are product samples of the Glumetza products which we purchase from Depomed under our promotion agreement. Inventories as of December 31, 2007 also included product samples of Naprelan® (naproxen sodium) Controlled Release Tablets which we purchased from Victory Pharma, Inc., or Victory, under our co-promotion agreement, which was terminated effective as of October 1, 2008. We provide reserves for potentially excess, dated or obsolete inventories based on an analysis of inventory on hand and on firm purchase commitments compared to forecasts of future sales.

Stock-Based Compensation

Effective January 1, 2006, we adopted the fair value recognition provisions of SFAS No. 123 (revised 2004), *Share-Based Payment*, which is a revision of SFAS No. 123, *Accounting for Stock-Based Compensation,* or SFAS No. 123(R), using the modified prospective transition method. Under this transition method, compensation cost recognized for 2008, 2007 and 2006 included (a) compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123, and (b) compensation cost for all share-based payments granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS No. 123(R). Results for prior periods have not been restated.

We estimate the fair value of stock options and employee stock purchase plan rights granted using the Black-Scholes valuation model. This estimate is affected by our stock price, as well as assumptions regarding a number of complex and subjective variables. These variables include the expected volatility of our stock price, the expected term of the stock option, the risk-free interest rate and expected dividends. As the length of time our shares have been publicly traded is generally shorter than the expected life of the option, we consider the expected volatility of similar entities as well as our historical volatility since our initial public offering in April 2004 in determining our volatility factor. In evaluating similar entities, we consider factors such as industry, stage of development, size and financial leverage. In determining the expected life of the options, we use the "short-cut" method described in SAB No. 110. Under this method, the expected life is presumed to be the mid-point between the vesting date and the end of the contractual term. We will continue to use the "short-cut" method until we have sufficient historical exercise data to estimate the expected life of the options.

For options granted prior to January 1, 2006, we amortized the fair value on an accelerated basis. For options granted after January 1, 2006, we amortize the fair value on a straight-line basis. All options are amortized over the requisite service period of the awards, which is generally the vesting period ranging from one to four years. Pre-vesting forfeitures were estimated to be approximately 0% for 2008, 2007 and 2006 as the majority of options granted contain monthly vesting terms. In 2008, certain stock options were granted to employees at or above the vice president level that vest upon the attainment of specific financial performance targets. The measurement date of stock options containing performance-based vesting is the date the stock option grant is authorized and the specific performance goals are communicated. Compensation expense is recognized based on the probability that the performance criteria will be met. The recognition of compensation expense associated with performance-based vesting requires judgment in assessing the probability of meeting the performance goals, as well as defined criteria for assessing achievement of the performance-related goals. The continued assessment of probability may result in additional expense recognition or expense reversal depending on the level of achievement of the performance goals.

We account for options issued to non-employees under SFAS No. 123(R) and EITF Issue No. 96-18, *Accounting for Equity Investments that are Issued to Other than Employees for Acquiring or in Conjunction with Selling Goods or Services*. As such, the value of options issued to non-employees is periodically remeasured as the underlying options vest.

The following table includes stock-based compensation recognized in accordance with SFAS No. 123(R) and EITF Issue No. 96-18 in our statement of operations (in thousands):

	Years Ended December 31,		
	2008	2007	2006
Cost of product sales	$ 95	$ 207	$ 124
Research and development	478	899	1,163
Selling, general and administrative	3,638	10,644	8,038
Total	$ 4,211	$ 11,750	$ 9,325

In 2007, we accelerated the vesting of certain out-of-the-money stock options with per share exercise prices of $5.00 or greater for employees below the vice president level. We recognized $5.7 million in stock-based compensation expense associated with the stock option vesting acceleration on November 6, 2007. As of December 31, 2008, total unrecognized compensation cost related to stock options was approximately $7.2 million, and the weighted average period over which it was expected to be recognized was 2.2 years.

The above listing is not intended to be a comprehensive list of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by GAAP. There are also areas in which our management's judgment in selecting any available alternative would not produce a materially different result. Please see our audited financial statements and notes thereto included elsewhere in this Form 10-K, which contain accounting policies and other disclosures required by GAAP.

Results of Operations

Comparison of Years Ended December 31, 2008, 2007 and 2006

Product Sales, Net. Product sales, net were $101.2 million for 2008, $79.4 million for 2007 and $46.0 million for 2006 and consisted of sales of Zegerid Capsules and Zegerid Powder for Oral Suspension. The $21.8 million increase in product sales, net from 2007 to 2008 was primarily attributable to an increase in the sales volume of Zegerid Capsules as well as increased average selling prices. The $33.4 million increase in product sales, net from 2006 to 2007 was primarily attributable to an increase in sales of Zegerid Capsules, which we commercially launched in early 2006. For 2008 as compared to 2007 and 2007 as compared to 2006, the amount of rebates, chargebacks and other discounts has grown primarily as a result of increased sales of our Zegerid products and increased utilization under contracts with various managed care organizations and governmental organizations relating to Medicaid and Medicare. Additionally, based upon our review of additional product returns history gathered through the end of 2007 and analysis of product expiration dating and estimated inventory in the distribution channel, we increased our estimate for product returns in 2007 to reflect actual experience accordingly. This change in estimate provided for potential product returns related to sales in prior periods and resulted in an increase to our net loss of approximately $1.9 million in 2007.

Promotion Revenue. Promotion revenue was $9.8 million for 2008 and $1.8 million for 2007. There was no promotion revenue in 2006. In 2008 and 2007, promotion revenue was comprised of co-promotion fees earned under our agreements with Victory pursuant to which we co-promoted the Naprelan products and with C.B. Fleet Company, Incorporated, or Fleet, pursuant to which we co-promoted the Fleet® Phospho-soda® EZ-Prep™ Bowel Cleansing System. In July 2008, we and Victory mutually agreed to terminate our co-promotion agreement previously entered into in June 2007. We ended all promotional efforts under the agreement as of September 30, 2008. We entered into our co-promotion agreement with Fleet in August 2007, which was subsequently amended in May 2008. Effective as of October 1, 2008, our co-promotion agreement expired in accordance with its terms. We received co-promotion fees of approximately $4.8 million over the term of the co-promotion agreement with Fleet.

Promotion revenue for 2008 also included fees earned under our promotion agreement with Depomed of approximately $4.7 million for the three months ended December 31, 2008.

License and Royalty Revenue. License and royalty revenue was $19.2 million for 2008, $13.2 million for 2007, and $3.2 million for 2006. Significant components of our license and royalty revenue are described below:

- In June 2008, we received a $2.5 million nonrefundable regulatory milestone relating to FDA acceptance for filing of an NDA submitted by Schering-Plough for a Zegerid branded omeprazole/sodium bicarbonate OTC product in a 20 mg dosage strength of omeprazole. In August 2007, we received a nonrefundable $5.0 million milestone payment from Schering-Plough relating to progress on clinical development strategy. We recognized the payments of $2.5 million and $5.0 million in license and royalty revenue in 2008 and 2007, respectively, due to the substantive nature of the milestones achieved. In November 2006, we received a nonrefundable $15.0 million upfront license fee in connection with our license agreement with Schering-Plough. The $15.0 million upfront payment is being amortized to revenue on a straight-line basis over a 37-month period through the end of 2009, which represents the estimated period during which we have significant responsibilities under the agreement.

- In December 2007, we received a nonrefundable $11.5 million upfront payment in connection with our license and distribution agreements with GSK. To support GSK's initial launch costs, we agreed to waive the first $2.5 million of aggregate royalties payable under the agreements. Of the total $11.5 million upfront payment, the $2.5 million in waived royalty obligations was recorded as deferred revenue and is being recognized as revenue as the royalties are earned. The remaining $9.0 million was also recorded as deferred revenue and is being amortized to revenue on a straight-line basis over an 18-month period, which represents the estimated period we are obligated to supply Zegerid products to GSK for sale in Puerto Rico and the U.S. Virgin Islands under the distribution agreement.

- In October 2004, we received a nonrefundable $15.0 million upfront payment in connection with our non-exclusive agreement with Otsuka America Pharmaceutical Inc., or Otsuka America, under which Otsuka America had been co-promoting Zegerid Capsules and Zegerid Powder for Oral Suspension. The $15.0 million upfront payment was being amortized to revenue on a straight-line basis over the 63-month contractual term through the end of 2009. On May 28, 2008, we agreed to terminate the co-promotion agreement effective as of June 30, 2008. In connection with the termination, we amortized the remaining balance of the $15.0 million up-front payment previously received from Otsuka America in October 2004 and recognized approximately $5.7 million in license and royalty revenue in 2008 associated with this amortization.

Cost of Product Sales. Cost of product sales was $7.3 million for 2008, $7.3 million for 2007 and $4.9 million for 2006, or approximately 7%, 9% and 11% of net product sales, respectively. Cost of product sales consists primarily of raw materials, third-party manufacturing costs, freight and indirect personnel and other overhead costs associated with the sales of our Zegerid products. Cost of product sales also includes reserves for excess, dated or obsolete commercial inventories based on an analysis of inventory on hand and on firm purchase commitments compared to forecasts of future sales. The decrease in our cost of product sales as a percentage of net product sales from 2007 to 2008 was primarily attributable to increased average selling prices. Additionally, the decrease in our cost of product sales as a percentage of net product sales from 2007 to 2008 and from 2006 to 2007 was attributable to lower manufacturing costs associated with our capsule product and certain fixed costs being applied to increased sales volumes.

License Fees and Royalties. License fees and royalties were $22.3 million for 2008, $11.1 million for 2007 and $6.4 million for 2006. License fees and royalties consisted of royalties due to the University of Missouri and Otsuka America based upon our net product sales as well as royalties due to the University of Missouri based upon products sold by GSK under our license and distribution agreements. Following the termination of our co-promotion agreement effective as of June 30, 2008, we are no longer obligated to pay royalties to Otsuka America. In 2008, license fees and royalties also included $2.5 million related to an accrual of a one-time sales milestone due to the University of Missouri under our license agreement upon initial achievement of $100.0 million in annual calendar year net product sales. In addition, in 2008, license fees and royalties included license fee amortization from the $12.0 million upfront fee paid to Depomed under our promotion agreement entered into in July 2008. The $12.0

million upfront fee has been capitalized and is being amortized to license fee expense over the estimated useful life of the asset on a straight-line basis through mid-2016.

In December 2008, we entered into a strategic collaboration with Cosmo including a license agreement, stock issuance agreement and registration rights agreement, under which we were granted exclusive rights to develop and commercialize the budesonide MMX and rifamycin SV MMX product candidates in the U.S. As upfront consideration, we issued 6,000,000 shares of our common stock and made a cash payment of $2.5 million to Cosmo. We may also pay Cosmo up to a total of $9.0 million in clinical and regulatory milestones for the initial indications for the licensed products, up to $6.0 million in clinical and regulatory milestones for a second indication for rifamycin SV MMX and up to $57.5 million in commercial milestones. The milestones may be paid in cash or through issuance of additional shares of our common stock, at Cosmo's option, subject to certain limitations. We will pay tiered royalties to Cosmo ranging from 12% to 14% on net sales of any licensed products we sell. The royalties are subject to reduction in certain circumstances, including in the event of market launch in the U.S. of a generic version of a licensed product. The cash payment of $2.5 million and the fair value of the 6,000,000 shares of our common stock issued to Cosmo of approximately $7.5 million were included in license fees and royalties in 2008.

Under the stock issuance agreement, Cosmo has agreed that for the 15 months following the date of issuance of the initial 6,000,000 shares of common stock and for the six months following the issuance of any shares of common stock upon achievement of milestones, it will not transfer or dispose of any such issued shares. In addition, Cosmo has agreed through December 15, 2011 that neither it nor its affiliates will acquire beneficial ownership of additional shares of our common stock, other than under the stock issuance agreement, subject to certain exceptions. Our obligation to issue additional shares of common stock to Cosmo upon the achievement of one or more milestones is subject to certain limitations, including that the total number of shares of common stock issued to Cosmo, including the initial 6,000,000 shares, shall not exceed 10,300,000 shares. Any such additional shares to be issued will be valued at the average daily closing price of the common stock as reported on the Nasdaq Global Market for the 30 consecutive trading days ending on the day immediately prior to the achievement of the applicable milestone.

We estimated a fair value of $1.24 per share for the initial 6,000,000 shares of our common stock issued to Cosmo in 2008, which reflected a discount of approximately 38% on the $2.00 per share closing price of our common stock on the issuance date. For a publicly traded stock, the fair value of a single unrestricted share of common stock is assumed to be equivalent to the quoted market price on the valuation date. However, since the 6,000,000 shares issued to Cosmo have a 15-month trading restriction pursuant to the stock issuance agreement, we calculated a discount for lack of marketability, or DLOM, applicable to the quoted market price. We calculated the DLOM associated with the contractual restriction using the Black-Scholes valuation model for a hypothetical put option with the following assumptions: life of the option of 1.25 years; risk-free interest rate of 0.58%; volatility of 90%; and dividend rate of 0%.

Under the terms of the registration rights agreement, we filed a resale registration statement on Form S-3 with the SEC in January 2009, to register the resale of shares issuable to Cosmo under the stock issuance agreement. We are obligated to use best efforts to have such registration statement declared effective by the Securities and Exchange Commission, or SEC.

Research and Development. Research and development expenses were $11.8 million for 2008, $6.8 million for 2007 and $7.6 million for 2006. The $5.0 million increase in our research and development expenses from 2007 to 2008 was primarily attributable to our strategic collaboration with Cosmo entered into in December 2008. We will be responsible for one-half of the total out-of-pocket costs associated with the two ongoing multi-center budesonide MMX phase III clinical trials and for all of the out-of-pocket costs for the planned rifamycin SV MMX phase III U.S. registration trial. Included in our research and development expenses for 2008 was approximately $3.9 million representing one-half of the out-of-pocket costs incurred in connection with the ongoing budesonide MMX phase III clinical trials which are reimbursable to Cosmo through December 31, 2008. In addition to the costs associated with our strategic collaboration with Cosmo, the increase in our research and development expenses from 2007 to 2008 was attributable to development costs associated with a new tablet formulation we intend to add to our Zegerid family of branded prescription pharmaceutical products. In January 2009, we submitted a 505(b)(2) NDA to the FDA for this new tablet formulation. This increase in research and development expenses was offset in part by a decrease in spending associated with Zegerid Capsules. Included in 2007 was spending associated with our clinical

trial evaluating the effects of morning dosing of each of Zegerid Capsules and delayed-release PPI brands, Protonix® and Prevacid®, on 24-hour gastric acid control in patients with symptoms of GERD. There were no expenses associated with this clinical trial in 2008. The $723,000 decrease in our research and development expenses from 2006 to 2007 was primarily attributable to a decrease in manufacturing development activities associated with the capsule and chewable tablet products and a decrease in stock-based compensation, offset in part by spending associated with our clinical trial evaluating the effects of morning dosing of each of Zegerid Capsules and delayed-release PPI brands, Protonix and Prevacid, on 24-hour gastric acid control in patients with symptoms of GERD.

Research and development expenses have historically consisted primarily of costs associated with clinical trials of our products under development as well as clinical studies designed to further differentiate our Zegerid products from those of our competitors, development of and preparation for commercial manufacturing of our products, compensation and other expenses related to research and development personnel and facilities expenses. In connection with our strategic collaboration with Cosmo entered into in December 2008, we are developing two product candidates targeting lower GI conditions. Budesonide MMX is an oral corticosteroid and is currently being investigated in two multi-center phase III clinical trials for the induction of remission of mild or moderate active ulcerative colitis. Assuming successful and timely completion of the clinical program, we plan to submit an NDA for budesonide MMX to the FDA in 2011. Rifamycin SV MMX is a broad spectrum, semi-synthetic antibiotic and has been investigated in a phase II clinical program for traveler's diarrhea. Assuming successful and timely completion of certain non-clinical and pharmacokinetic clinical activities, we would then expect to file an investigational new drug application with the FDA and initiate the planned phase III U.S. registration trial in traveler's diarrhea in the first half of 2010. We are unable to estimate with any certainty the research and development costs that we may incur in the future. We have also committed, in connection with the approval of our NDAs for Zegerid Powder for Oral Suspension, to evaluate the product in pediatric populations, including pharmacokinetic/pharmacodynamic, or PK/PD, and safety studies. In the future, we may conduct additional clinical trials to further differentiate our Zegerid family of products, as well as conduct research and development related to any future products that we may in-license or otherwise acquire. Although we are currently focused primarily on advancing our Zegerid family of products and development of the budesonide MMX and rifamycin SV MMX product candidates, we anticipate that we will make determinations as to which development projects to pursue and how much funding to direct to each project on an ongoing basis in response to the scientific, clinical and commercial merits of each project.

Selling, General and Administrative. Selling, general and administrative expenses were $108.0 million for 2008, $116.5 million for 2007 and $89.8 million for 2006. The $8.5 million decrease in our selling, general and administrative expenses from 2007 to 2008 was primarily attributable to a decrease in costs associated with our advertising and promotional activities related to our Zegerid products, a decrease in the number of sales representatives under our contract sales organization agreement with inVentiv and a decrease in stock-based compensation. These decreases in expenses were offset in part by an increase in legal fees primarily due to the patent infringement litigation against Par Pharmaceutical, Inc., or Par, and costs associated with sales training and advertising and promotional activities associated with the commencement of promotion of the Glumetza products under our promotion agreement with Depomed. The $26.7 million increase in our selling, general and administrative expenses from 2006 to 2007 was primarily attributable to the expansion of our commercial presence, including expenses associated with our contract sales organization agreement with inVentiv entered into in late 2006 and costs related to our sales and marketing personnel resulting from an increase in headcount. The increase in selling, general and administrative expenses was also attributable to increased stock-based compensation expense associated with the stock option vesting acceleration on November 6, 2007. Additionally, an increase in costs associated with advertising and promotional activities including product samples contributed to the increase in our selling, general and administrative expenses.

Interest and Other Income, Net. Interest and other income, net was $1.2 million in 2008, $3.1 million in 2007 and $3.1 million in 2006. The $1.9 million decrease from 2007 to 2008 was primarily attributable to lower interest income resulting from lower average cash balances and a lower rate of return on our cash, cash equivalents and short-term investments.

Liquidity and Capital Resources

As of December 31, 2008, cash, cash equivalents and short-term investments were $52.0 million, compared to $64.7 million as of December 31, 2007, a decrease of $12.7 million. This decrease resulted primarily from our net loss for 2008, adjusted for non-cash stock-based compensation and changes in operating assets and liabilities, as well as our $12.0 million upfront payment to Depomed in July 2008. In addition, due to the illiquid state of our auction rate securities, or ARS, we reclassified the fair value of these securities from short-term to long-term investments in 2008. These decreases in cash, cash equivalents and short-term investments were offset in part by the $10.0 million draw down on our revolving credit facility with Comerica Bank, or Comerica, in December 2008.

Our ARS are AAA-rated municipal debt obligations with a long-term maturity and an interest rate that is reset in short-term intervals (every 28 days) through auctions. Due to conditions in the global credit markets, in 2008, these securities, representing a par value of $4.3 million, had insufficient demand resulting in multiple failed auctions. As a result, these affected securities are currently not liquid and the interest rates have been reset to predetermined higher rates.

In October 2008, we received an offer of Auction Rate Securities Rights, or ARS Rights, from our investment provider, UBS Financial Services, Inc., a subsidiary of UBS AG, or UBS. In November 2008, we accepted the ARS Rights offer. The ARS Rights permit us to require UBS to purchase our ARS at par value at any time during the period of June 30, 2010 through July 2, 2012. If we do not exercise our ARS Rights, the ARS will continue to accrue interest as determined by the auction process or the terms of the ARS if the auction fails. If the ARS Rights are not exercised before July 2, 2012 they will expire and UBS will have no further obligation to buy our ARS. UBS has the discretion to purchase or sell our ARS at any time without prior notice so long as we receive a payment at par upon any sale or disposition. UBS will only exercise its discretion to purchase or sell our ARS for the purpose of restructurings, dispositions or other solutions that will provide us with par value for our ARS. As a condition to accepting the offer of ARS Rights, we released UBS from all claims except claims for consequential damages relating to its marketing and sales of ARS. We also agreed not to serve as a class representative or receive benefits under any class action settlement or investor fund.

Typically the fair value of ARS approximates par value due to the frequent resets through the auction process. While we continue to earn interest on our ARS at the maximum contractual rates, these investments are not currently trading and therefore do not currently have a readily determinable market value. Accordingly, the estimated fair value of the ARS no longer approximates par value. We have used a discounted cash flow model to determine the estimated fair value of our investment in ARS and our ARS Rights as of December 31, 2008. The assumptions used in preparing the discounted cash flow model include estimates for interest rates, timing and amount of cash flows and expected holding period of the ARS and ARS Rights.

We elected to measure the ARS Rights under the fair value option of SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities – Including an amendment to FASB Statement No. 115,* and recognized a gain of approximately $1.5 million and recorded a corresponding long-term investment. Reflecting our intent to exercise the ARS Rights during the period of June 30, 2010 through July 2, 2012, we transferred our ARS from investments available-for-sale to trading securities. As a result of this transfer and as we no longer intend to hold the ARS until the fair value recovers, we recognized an other-than-temporary impairment loss of approximately $1.5 million, representing a reversal of the related temporary valuation allowance that was previously recorded in other comprehensive loss. We believe this loss is primarily attributable to the limited liquidity of these investments and have no reason to believe that any of the underlying issuers are presently at risk of default. The recording of the fair value of the ARS Rights and the recognition of the other-than-temporary impairment loss resulted in a net impact to the statement of operations for the year ended December 31, 2008 of approximately $50,000, which was recorded as a reduction to interest income.

Net cash used in operating activities was $6.5 million for 2008, $12.1 million for 2007 and $32.9 million for 2006. The primary use of cash was to fund our net losses for these periods, adjusted for non-cash expenses, including $7.5 million related to the issuance of common stock to Cosmo in connection with our strategic collaboration entered into in 2008, $4.2 million for 2008, $11.7 million for 2007 and $9.3 million for 2006 in stock-based compensation, $1.4 million for 2008, $587,000 for 2007 and $592,000 in depreciation and amortization and changes in operating assets and liabilities. Significant working capital uses of cash for 2008 included decreases in

deferred revenue and increases in accounts receivable and other current assets. These working capital uses of cash were offset in part by increases in the allowance for product returns and increases in accounts payable and accrued liabilities primarily driven by an increase in accrued rebates and accrued research and development expenses associated with our strategic collaboration with Cosmo. Significant working capital sources of cash for 2007 included increases in accounts payable and accrued liabilities primarily driven by an increase in accrued rebates, and increases in the allowance for product returns and deferred revenue. These working capital sources of cash were offset in part by increases in accounts receivable. Significant working capital sources of cash for 2006 included increases in accounts payable and accrued liabilities and an increase in deferred revenue related to the $15.0 million upfront license fee we received in connection with our license agreement with Schering-Plough. These working capital sources of cash were offset in part by increases in accounts receivable and inventories, which resulted from our overall increase in net product sales due to the launch of Zegerid Capsules in 2006, and decreases in the allowance for product returns.

Net cash used in investing activities was $12.9 million for 2008 and $2.0 million for 2007, and net cash provided by investing activities was $5.0 million for 2006. These activities consisted of purchases and sales and maturities of short-term investments and purchases of property and equipment. Additionally, in 2008, net cash used in investing activities consisted of the $12.0 million upfront payment to Depomed in connection with our promotion agreement.

Net cash provided by financing activities was $10.8 million for 2008, $1.6 million for 2007 and $38.9 million for 2006. In 2008, net cash provided by financing activities included the $10.0 million draw down on our revolving credit facility with Comerica. In 2006, net cash provided by financing activities consisted primarily of the issuance of common stock in connection with draw downs under our committed equity financing facility with Kingsbridge Capital Limited. Additionally, net cash provided by financing activities included proceeds received from the exercise of stock options and through the issuance of common stock under our employee stock purchase plan in 2008, 2007 and 2006.

While we support the commercialization of our Zegerid products, promote Glumetza under our promotion agreement with Depomed, develop and manufacture our Zegerid products and our budesonide MMX and rifamycin SV MMX product candidates under our strategic collaboration with Cosmo and pursue new product opportunities, we anticipate significant cash requirements for personnel costs for our own organization, as well as in connection with our contract sales agreement with inVentiv, advertising and promotional activities, clinical trial costs, capital expenditures, and investment in additional office space, internal systems and infrastructure.

We currently rely on Norwich Pharmaceuticals, Inc. as our manufacturer of Zegerid Capsules and Patheon, Inc. as our manufacturer of Zegerid Powder for Oral Suspension. We also purchase commercial quantities of omeprazole, an active ingredient in our Zegerid products, from Union Quimico Farmaceutica, S.A. At December 31, 2008, we had finished goods and raw materials inventory purchase commitments of approximately $3.3 million.

The following summarizes our long-term contractual obligations as of December 31, 2008, excluding potential sales-based royalty obligations and milestone payments under our agreements with the University of Missouri, Depomed and Cosmo which are described below:

	Payments Due by Period				
Contractual Obligations	Total	Less than One Year	One to Three Years	Four to Five Years	Thereafter
			(in thousands)		
Operating leases	$ 6,071	$ 2,054	$ 3,937	$ 80	$ —
Other long-term contractual obligations	244	74	170	—	—
Total	$ 6,315	$ 2,128	$ 4,107	$ 80	$ —

Under our exclusive worldwide license agreement with the University of Missouri entered into in January 2001, we are required to make milestone payments to the University of Missouri upon initial commercial sale in specified territories outside the U.S., which may total up to $3.5 million in the aggregate. We are also required to make milestone payments based on first-time achievement of significant sales thresholds, up to a maximum of $86.3 million, the first of which is a $2.5 million milestone payment upon initial achievement of $100.0 million in annual calendar year sales, which includes sales by us, GSK and Schering-Plough. This initial $2.5 million sales

milestone was earned in 2008 and is payable to the University of Missouri in the first quarter of 2009. We are also obligated to pay royalties on net sales of our products and any products commercialized by GSK under our license and distribution agreements and Schering-Plough under our OTC license agreement.

Under our promotion agreement with Depomed entered into in July 2008, we may be required to pay Depomed one-time sales milestones totaling up to $16.0 million in aggregate. Under the promotion agreement, we are required to meet certain minimum promotion obligations during the term of the agreement. We began promoting the Glumetza products in October 2008. For a period of one year from the date we began promoting the Glumetza products, we are required to deliver a minimum number of sales calls to potential Glumetza prescribers. Following the end of that one-year period, for a period of three years, we are required to make specified minimum sales force expenditures. In addition, during the term of the agreement, we are required to make certain minimum marketing, advertising, medical affairs and other commercial support expenditures, including an initial commitment of $5.0 million in promotional costs from signing through March 31, 2009.

Under our license agreement, stock issuance agreement and registration rights agreement with Cosmo entered into in December 2008, we may pay Cosmo up to a total of $9.0 million in clinical and regulatory milestones for the initial indications for the licensed products, up to $6.0 million in clinical and regulatory milestones for a second indication for rifamycin SV MMX and up to $57.5 million in commercial milestones. The milestones may be paid in cash or through issuance of additional shares of our common stock, at Cosmo's option, subject to certain limitations. We will pay tiered royalties to Cosmo ranging from 12% to 14% on net sales of any licensed products we sell. We will be responsible for one-half of the total out-of-pocket costs associated with the two ongoing budesonide MMX multi-center phase III clinical trials and for all of the out-of-pocket costs for the planned rifamycin SV MMX phase III U.S. registration trial.

The amount and timing of cash requirements will depend on market acceptance of Zegerid Capsules and Zegerid Powder for Oral Suspension, the Glumetza products and any other products that we may market in the future, the resources we devote to researching, developing, formulating, manufacturing, commercializing and supporting our products, and our ability to enter into third-party collaborations.

Any adverse outcome in the litigation against Par could result in one or more generic versions of Zegerid Capsules and/or Zegerid Powder for Oral Suspension being launched before the expiration of the listed patents in July 2016, which could adversely affect our ability to successfully execute our business strategy to maximize the value of Zegerid Capsules and Zegerid Powder for Oral Suspension and would negatively impact our financial condition and results of operations, including causing a significant decrease in our revenues and cash flows. An adverse outcome may also impact the patent protection for the products being commercialized pursuant to our strategic alliances with GSK and Schering-Plough, which in turn may impact the amount of, or our ability to receive, milestone payments and royalties under those agreements. Although we intend to vigorously defend and enforce our patent rights, we are not able to predict the outcome of the litigation. In addition, even if we prevail, the litigation will be costly, time-consuming and distracting to management, which could have a material adverse effect on our business.

We believe that our current cash, cash equivalents and short-term investments will be sufficient to fund our current operations for at least the next 12 months; however, our projected revenue may decrease or our expenses may increase and that would lead to our cash resources being consumed earlier than we expect. Although we do not believe that we will need to raise additional funds to finance our current operations over the next 12 months, we may pursue raising additional funds in connection with licensing or acquisition of new products. Sources of additional funds may include funds generated through strategic collaborations or licensing agreements, or through equity, debt and/or royalty financing.

In November 2008, we filed a universal shelf registration statement on Form S-3 with the SEC, which was declared effective in December 2008. The universal shelf registration statement replaced our previous universal shelf registration statement that expired in December 2008. The universal shelf registration statement may permit us, from time to time, to offer and sell up to an additional approximately $75.0 million of equity or debt securities. However, there can be no assurance that we will be able to complete any such offerings of securities. Factors influencing the availability of additional financing include the progress of our commercial and development activities, investor perception of our prospects and the general condition of the financial markets, among others.

In July 2006, we entered into our loan agreement with Comerica, which was subsequently amended in July 2008, pursuant to which we may request advances in an aggregate outstanding amount not to exceed $25.0 million. In December 2008, we drew down $10.0 million under the loan agreement. The revolving loan bears interest at a variable rate of interest, per annum, most recently announced by Comerica as its "prime rate" plus 0.50%, which as of December 31, 2008 was 3.75%. Interest payments on advances made under the loan agreement are due and payable in arrears on the first calendar day of each month during the term of the loan agreement. Amounts borrowed under the loan agreement may be repaid and re-borrowed at any time prior to July 11, 2011. There is a non-refundable unused commitment fee equal to 0.50% per annum on the difference between the amount of the revolving line and the average daily balance outstanding thereunder during the term of the loan agreement, payable quarterly in arrears. The loan agreement will remain in full force and effect for so long as any obligations remain outstanding or Comerica has any obligation to make credit extensions under the loan agreement.

Amounts borrowed under the loan agreement are secured by substantially all of our personal property, excluding intellectual property. Under the loan agreement, we are subject to certain affirmative and negative covenants, including limitations on our ability: to undergo certain change of control events; to convey, sell, lease, license, transfer or otherwise dispose of assets; to create, incur, assume, guarantee or be liable with respect to certain indebtedness; to grant liens; to pay dividends and make certain other restricted payments; and to make investments. In addition, under the loan agreement, we are required to maintain a balance of cash with Comerica in an amount of not less than $4.0 million and to maintain any other cash balances with either Comerica or another financial institution covered by a control agreement for the benefit of Comerica. We are also subject to specified financial covenants with respect to a minimum liquidity ratio and, in specified limited circumstances, minimum EBITDA requirements. We have currently met all of our obligations under the loan agreement.

We cannot be certain that our existing cash and marketable securities resources will be adequate to sustain our current operations. To the extent we require additional funding, we cannot be certain that such funding will be available to us on acceptable terms, or at all. For example, we may not be successful in obtaining collaboration agreements, or in receiving milestone or royalty payments under those agreements. In addition, if we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish potentially valuable rights to our products or proprietary technologies, or grant licenses on terms that are not favorable to us. To the extent that we raise additional capital by issuing equity or convertible securities, our stockholders' ownership will be diluted. Any debt financing we enter into may involve covenants that restrict our operations. If adequate funds are not available on terms acceptable to us at that time, our ability to continue our current operations or pursue new product opportunities would be significantly limited.

In addition, our results of operations could be materially affected by economic conditions generally, both in the U.S. and elsewhere around the world. Continuing concerns over inflation, energy costs, geopolitical issues, the availability and cost of credit, the U.S. mortgage market and a declining residential real estate market in the U.S. have contributed to increased volatility and diminished expectations for the economy and the markets going forward. These factors, combined with volatile oil prices, declining business and consumer confidence and increased unemployment, have precipitated an economic recession. Domestic and international equity markets continue to experience heightened volatility and turmoil. These events and the continuing market upheavals may have an adverse effect on us. In the event of a continuing market downturn, our results of operations could be adversely affected by those factors in many negative ways, including making it more difficult for us to raise funds if necessary, and our stock price may further decline. In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits. Given the current instability of financial institutions, we cannot be assured that we will not experience losses on these deposits.

As of December 31, 2008, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts. As such, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships.

Accounting Pronouncements

Adoption of Recent Accounting Pronouncements

In September 2006, the Financial Accounting Standards Board, or FASB, issued SFAS No. 157, *Fair Value Measurements*. SFAS No. 157 establishes a framework for measuring fair value in accordance with GAAP, clarifies the definition of fair value within that framework, and expands disclosures about the use of fair value measurements. It also responds to investors' requests for expanded information about the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value and the effect of fair value measurements on earnings. SFAS No. 157 applies whenever other standards require (or permit) assets or liabilities to be measured at fair value, and does not expand the use of fair value in any new circumstances. SFAS No. 157 was effective for us on January 1, 2008. The adoption of SFAS No. 157 did not have a material impact on our financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities — Including an amendment to FASB Statement No. 115*. SFAS No. 159 allows certain financial assets and liabilities to be recognized, at our election, at fair market value, with any gains or losses for the period recorded in the statement of operations. SFAS No. 159 includes available-for-sale securities in the assets eligible for this treatment. Currently, we record the unrealized gains or losses for the period in comprehensive income (loss) and in the equity section of the balance sheet. SFAS No. 159 was effective for us on January 1, 2008. We did not elect to adopt the fair value option under SFAS No. 159 on any assets or liabilities not previously carried at fair value, except for the ARS Rights that were recorded in connection with our acceptance of the offer of ARS Rights from UBS as more fully described above.

In June 2007, the EITF issued EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to be Used in Future Research and Development Activities*. The consensus requires companies to defer and capitalize prepaid, nonrefundable research and development payments to third parties over the period that the research and development activities are performed or the services are provided, subject to an assessment of recoverability. EITF Issue No. 07-3 is effective for new contracts entered into beginning on January 1, 2008. The adoption of EITF Issue No. 07-3 did not have a material impact on our financial statements.

Pending Adoption of Recent Accounting Pronouncements

In November 2007, the EITF issued EITF Issue No. 07-1, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property.* Companies may enter into arrangements with other companies to jointly develop, manufacture, distribute, and market a product. Often the activities associated with these arrangements are conducted by the collaborators without the creation of a separate legal entity (that is, the arrangement is operated as a "virtual joint venture"). The arrangements generally provide that the collaborators will share, based on contractually defined calculations, the profits or losses from the associated activities. Periodically, the collaborators share financial information related to product revenues generated (if any) and costs incurred that may trigger a sharing payment for the combined profits or losses. The consensus requires collaborators in such an arrangement to present the result of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable GAAP or, in the absence of other applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. EITF Issue No. 07-1 is effective for collaborative arrangements in place at the beginning of the annual period beginning after December 15, 2008. We do not expect the adoption of EITF Issue No. 07-1 to have a material impact on our financial statements.

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations*. SFAS No. 141(R) changes the requirements for an acquirer's recognition and measurement of the assets acquired and liabilities assumed in a business combination, including the treatment of contingent consideration, pre-acquisition contingencies, transaction costs, in-process research and development and restructuring costs. In addition, under SFAS No. 141(R), changes in an acquired entity's deferred tax assets and uncertain tax positions after the measurement period will impact income tax expense. This statement is effective for us with respect to business combination transactions for which the acquisition date is after December 31, 2008.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements (an amendment of Accounting Research Bulletin, or ARB, No. 51).* SFAS No. 160 requires that noncontrolling (minority) interests be reported as a component of equity, that net income attributable to the parent and to the noncontrolling interest be separately identified in the income statement, that changes in a parent's ownership interest while the parent retains its controlling interest be accounted for as equity transactions, and that any retained noncontrolling equity investment upon the deconsolidation of a subsidiary be initially measured at fair value. This statement is effective for fiscal years beginning after December 31, 2008, and shall be applied prospectively. However, the presentation and disclosure requirements of SFAS No. 160 are required to be applied retrospectively for all periods presented. The retrospective presentation and disclosure requirements of this statement will be applied to any prior periods presented in financial statements for the fiscal year ending December 31, 2009, and later periods during which we have a consolidated subsidiary with a noncontrolling interest. As of December 31, 2008, we do not have any consolidated subsidiaries in which there is a noncontrolling interest.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Under the terms of our loan agreement with Comerica Bank, or Comerica, the interest rate applicable to any amounts borrowed by us under the credit facility will be, at our election, indexed to either Comerica's prime rate or the LIBOR rate. If we elect Comerica's prime rate for all or any portion of our borrowings, the interest rate will be variable, which would expose us to the risk of increased interest expense if interest rates rise. If we elect the LIBOR rate for all or any portion of our borrowings, such LIBOR rate will remain fixed only for a specified, limited period of time after the date of our election, after which we will be required to repay the borrowed amount, or elect a new interest rate indexed to either Comerica's prime rate or the LIBOR rate. The new rate may be higher than the earlier interest rate applicable under the loan agreement. As of December 31, 2008, the balance outstanding under the credit facility was $10.0 million, and we had elected the "prime rate" plus 0.50% interest rate option, which was 3.75% as of December 31, 2008. Under our current policies, we do not use interest rate derivative instruments to manage our exposure to interest rate changes. A hypothetical 1% increase or decrease in the interest rate under the loan agreement would not materially affect our interest expense at our current level of borrowing.

In addition to market risk related to our loan agreement with Comerica, we are exposed to market risk primarily in the area of changes in U.S. interest rates and conditions in the credit markets, particularly because the majority of our investments are in short-term marketable securities. We do not have any material foreign currency or other derivative financial instruments. Our short-term investment securities consist of high-grade corporate debt securities and government agency securities which are classified as available-for-sale and therefore reported on the balance sheet at estimated market value. As of December 31, 2008, our long-term investments included AAA-rated auction rate securities, or ARS, issued by state municipalities. Our ARS are debt instruments with a long-term maturity and an interest rate that is reset in short-term intervals through auctions. The conditions in the global credit markets have prevented many investors from liquidating their holdings of ARS because the amount of securities submitted for sale has exceeded the amount of purchase orders for such securities. If there is insufficient demand for the securities at the time of an auction, the auction may not be completed and the interest rates may be reset to predetermined higher rates. When auctions for these securities fail, the investments may not be readily convertible to cash until a future auction of these investments is successful or they are redeemed or mature.

Due to conditions in the global credit markets, in 2008, our ARS, representing a par value of approximately $4.3 million, had insufficient demand resulting in multiple failed auctions. As a result, these affected securities are currently not liquid and the interest rates have been reset to predetermined higher rates.

In October 2008, we received an offer of Auction Rate Securities Rights, or ARS Rights, from our investment provider, UBS Financial Services, Inc., a subsidiary of UBS AG, or UBS. In November 2008, we accepted the ARS Rights offer. The ARS Rights permit us to require UBS to purchase our ARS at par value at any time during the period of June 30, 2010 through July 2, 2012. If we do not exercise our ARS Rights, the ARS will continue to accrue interest as determined by the auction process or the terms of the ARS if the auction fails. If the ARS Rights are not exercised before July 2, 2012 they will expire and UBS will have no further obligation to buy our ARS. UBS has the discretion to purchase or sell our ARS at any time without prior notice so long as we receive a payment at par upon any sale or disposition. UBS will only exercise its discretion to purchase or sell our ARS for the purpose of restructurings, dispositions or other solutions that will provide us with par value for our ARS. As a condition to accepting the offer of ARS Rights, we released UBS from all claims except claims for consequential damages

relating to its marketing and sales of ARS. We also agreed not to serve as a class representative or receive benefits under any class action settlement or investor fund.

In the event we need to access the funds that are in an illiquid state, we will not be able to do so without the likely loss of principal, until a future auction for these investments is successful or they are redeemed by the issuer or they mature. If we are unable to sell these securities in the market or they are not redeemed, then we may be required to hold them to maturity. We do not believe we have a need to access these funds for operational purposes for the foreseeable future. We will continue to monitor and evaluate these investments on an ongoing basis for impairment. Based on our ability to access our cash, cash equivalents and other short-term investments, our expected operating cash flows, and our other sources of cash, we do not anticipate that the potential illiquidity of these investments will affect our ability to execute our current business plan.

Our results of operations could be materially affected by economic conditions generally, both in the U.S. and elsewhere around the world. Continuing concerns over inflation, energy costs, geopolitical issues, the availability and cost of credit, the U.S. mortgage market and a declining residential real estate market in the U.S. have contributed to increased volatility and diminished expectations for the economy and the markets going forward. These factors, combined with volatile oil prices, declining business and consumer confidence and increased unemployment, have precipitated an economic recession. Domestic and international equity markets continue to experience heightened volatility and turmoil. These events and the continuing market upheavals may have an adverse effect on us. In the event of a continuing market downturn, our results of operations could be adversely affected by those factors in many negative ways, including making it more difficult for us to raise funds if necessary, and our stock price may further decline. In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits. Given the current instability of financial institutions, we cannot be assured that we will not experience losses on these deposits.

Item 8. Financial Statements and Supplementary Data

See the list of financial statements filed with this report under Part IV — Item 15 below.

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

Not applicable.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Securities Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Securities and Exchange Commission Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the foregoing, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control Over Financial Reporting

Internal control over financial reporting refers to the process designed by, or under the supervision of, our chief

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

Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Management is responsible for establishing and maintaining adequate internal control over our financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting. Management has used the framework set forth in the report entitled "Internal Control—Integrated Framework" published by the Committee of Sponsoring Organizations of the Treadway Commission to evaluate the effectiveness of our internal control over financial reporting. Based on its evaluation, management has concluded that our internal control over financial reporting was effective as of December 31, 2008, the end of our most recent fiscal year. Ernst & Young LLP, our independent registered public accounting firm, has issued a report on the effectiveness of our internal control over financial reporting, which is included herein.

There has been no change in our internal control over financial reporting during the last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Santarus, Inc.

We have audited Santarus, Inc.'s 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 (the COSO criteria). Santarus, Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

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

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

Because of 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.

In our opinion, Santarus, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of Santarus, Inc. as of December 31, 2008 and 2007, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2008 of Santarus, Inc. and our report dated March 2, 2009, expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
March 2, 2009

Item 9B. Other Information

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item will be contained in our definitive proxy statement, or Proxy Statement, to be filed with the Securities and Exchange Commission in connection with the Annual Meeting of our Stockholders, which is expected to be filed not later than 120 days after the end of our fiscal year ended December 31, 2008, and is incorporated in this report by reference.

We have adopted a Code of Business Conduct and Ethics that applies to our chief executive officer, chief financial officer, and to all of our other officers, directors and employees. The Code of Business Conduct and Ethics is available at the Corporate Governance section of the Investor Relations page on our website at www.santarus.com. We intend to disclose future amendments to, or waivers from, certain provisions of our Code of Business Conduct and Ethics on the above website promptly following the date of such amendment or waiver.

Item 11. Executive Compensation

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

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

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

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

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

Item 14. Principal Accountant Fees and Services

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) *Documents filed as part of this report.*

1. The following financial statements of Santarus, Inc. and Report of Independent Registered Public Accounting Firm, are included in this report:

Report of Independent Registered Public Accounting Firm

Balance Sheets as of December 31, 2008 and 2007

Statements of Operations for each of the years ended December 31, 2008, 2007 and 2006

Statements of Stockholders' Equity for each of the years ended December 31, 2008, 2007 and 2006

Statements of Cash Flows for each of the years ended December 31, 2008, 2007 and 2006

Notes to Financial Statements

2. List of financial statement schedules:

Schedule II – Valuation and Qualifying Accounts

Schedules not listed above have been omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

3. List of exhibits required by Item 601 of Regulation S-K. See part (b) below.

(b) *Exhibits.* The following exhibits are filed as a part of this report:

Exhibit Number	Description
3.1(1)	Amended and Restated Certificate of Incorporation
3.2(2)	Amended and Restated Bylaws
3.3(3)	Certificate of Designations for Series A Junior Participating Preferred Stock
4.1(3)	Form of Common Stock Certificate
4.2(4)	Amended and Restated Investors' Rights Agreement, dated April 30, 2003, among us and the parties named therein
4.3(4)	Amendment No. 1 to Amended and Restated Investors' Rights Agreement, dated May 19, 2003, among us and the parties named therein
4.4(4)†	Stock Restriction and Registration Rights Agreement, dated January 26, 2001, between us and The Curators of the University of Missouri
4.5(4)	Form of Common Stock Purchase Warrant
4.6(3)	Rights Agreement, dated as of November 12, 2004, between us and American Stock Transfer & Trust Company, which includes the form of Certificate of Designations of the Series A Junior Participating Preferred Stock of Santarus, Inc. as Exhibit A, the form of Right Certificate as Exhibit B and the Summary of Rights to Purchase Preferred Shares as Exhibit C
4.7(5)	First Amendment to Rights Agreement, dated April 19, 2006, between us and American Stock Transfer & Trust Company
4.8(6)	Second Amendment to Rights Agreement, dated December 10, 2008, between us and American Stock Transfer and Trust Company

Exhibit Number	Description
4.9(7)	Warrant to Purchase Shares of Common Stock, dated February 3, 2006, issued by us to Kingsbridge Capital Limited
4.10(7)	Registration Rights Agreement, dated February 3, 2006, between us and Kingsbridge Capital Limited
4.11(8)	Registration Rights Agreement, dated December 10, 2008, between us and Cosmo Technologies Limited
10.1(4)†	Stock Purchase Agreement, dated January 26, 2001, between us and The Curators of the University of Missouri
10.2(4)†	Exclusive License Agreement, dated January 26, 2001, between us and The Curators of the University of Missouri
10.3(4)†	Amendment No. 1 to Exclusive License Agreement, dated February 21, 2003, between us and The Curators of the University of Missouri
10.4(9) †	Amendment No. 2 to Exclusive License Agreement, dated August 20, 2007, between us and The Curators of the University of Missouri
10.5(4)†	Omeprazole Supply Agreement, dated September 25, 2003, among us, InterChem Trading Corporation and Union Quimico Farmaceutica, S.A.
10.6(10) †	Amendment No. 1 to Omeprazole Supply Agreement, dated November 1, 2004, among us, InterChem Trading Corporation and Union Quimico Farmaceutica, S.A.
10.7(10) †	Amendment No. 2 to Omeprazole Supply Agreement, dated July 11, 2007, among us, InterChem Trading Corporation and Union Quimico Farmaceutica, S.A.
10.8+	Amendment No. 3 to Omeprazole Supply Agreement, dated December 17, 2008, among us, InterChem Trading Corporation and Union Quimico Farmaceutica, S.A.
10.9(11)†	Amended and Restated Manufacturing and Supply Agreement, dated December 19, 2006, between us and Patheon Inc.
10.10(12)†	Manufacturing and Supply Agreement, dated September 27, 2004, between us and OSG Norwich Pharmaceuticals, Inc.
10.11(12)†	Co-Promotion Agreement, dated October 4, 2004, between us and Otsuka America Pharmaceutical, Inc.
10.12(13)†	Amendment No. 1 to Co-Promotion Agreement, dated January 6, 2006, between us and Otsuka America Pharmaceutical, Inc.
10.13(7)	Common Stock Purchase Agreement, dated February 3, 2006, between us and Kingsbridge Capital Limited
10.14(14)	Amended and Restated Loan and Security Agreement, dated as of July 11, 2008, between us and Comerica Bank
10.15(14)	Amended and Restated LIBOR Addendum to Loan and Security Agreement, dated as of July 11, 2008, between us and Comerica Bank
10.16(15)†	OTC License Agreement, dated October 17, 2006, between us and Schering-Plough Healthcare Products, Inc.
10.17(16)†	Service Agreement, dated November 3, 2006, between us and Ventiv Commercial Services, LLC (d/b/a inVentiv Commercial Services, LLC)
10.18(10) †	Amendment No. 1 to Service Agreement, dated June 15, 2007, between us and Ventiv Commercial Services, LLC (d/b/a inVentiv Commercial Services, LLC)
10.19(17)†	Amendment No. 2 to Service Agreement, dated October 6, 2008, between us and Ventiv Commercial Services, LLC (d/b/a inVentiv Commercial Services, LLC)
10.20(18)†	Co-Promotion Agreement, dated as of June 28, 2007, by and between us and Victory Pharma, Inc.
10.21(9) †	Co-Promotion Agreement, dated August 24, 2007, between us and C.B. Fleet Company, Incorporated
10.22(19)†	Amendment No. 1 to Co-Promotion Agreement, dated May 6, 2008, between us and C.B. Fleet Company, Incorporated
10.23(20)†	License Agreement, dated November 30, 2007, between us and Glaxo Group Limited, an affiliate of GlaxoSmithKline plc

Exhibit Number	Description
10.24(20)†	Distribution Agreement, dated November 30, 2007, between us and Glaxo Group Limited, an affiliate of GlaxoSmithKline plc
10.25+	License Agreement, dated December 10, 2008, between us and Cosmo Technologies Limited
10.26+	Stock Issuance Agreement, dated December 10, 2008, between us and Cosmo Technologies Limited
10.27(21)†	Promotion Agreement, dated July 21, 2008, between us and Depomed, Inc.
10.28(4)	Office Building Lease, dated August 24, 2001, between us and Torrey View Associates LP
10.29(4)	Irrevocable Stand-by Letter of Credit, dated August 24, 2001, issued by UBS Paine Webber Inc.
10.30(22)	Sublease, dated December 11, 2007, between us and Avnet, Inc.
10.31(4)#	Form of Indemnification Agreement between us and each of our directors and officers
10.32(4)#	1998 Stock Option Plan
10.33(23)#	Amendment to 1998 Stock Option Plan
10.34(24)#	Amended and Restated 2004 Equity Incentive Award Plan
10.35(23)#	Amendment No. 1 to Amended and Restated 2004 Equity Incentive Award Plan
10.36(25)#	Amendment No. 2 to Amended and Restated 2004 Equity Incentive Award Plan
10.37(26)#	Form of Stock Option Agreement under Amended and Restated 2004 Equity Incentive Award Plan
10.38(27)#	Form of Immediately Exerciseable Stock Option Agreement under Amended and Restated 2004 Equity Incentive Award Plan
10.39(28)#	Amended and Restated Employee Stock Purchase Plan
10.40(20)#	Amended and Restated Employment Agreement, dated December 5, 2007, between us and Gerald T. Proehl
10.41(20)#	Amended and Restated Employment Agreement, dated December 5, 2007, between us and Debra P. Crawford
10.42(20)#	Amended and Restated Employment Agreement, dated December 5, 2007, between us and Julie A. DeMeules
10.43(20)#	Amended and Restated Employment Agreement, dated December 5, 2007, between us and William C. Denby, III
10.44(20)#	Amended and Restated Employment Agreement, dated December 5, 2007, between us and Warren E. Hall
10.45(20)#	Amended and Restated Employment Agreement, dated December 5, 2007, between us and Michael D. Step
10.46(20)#	Amended and Restated Employment Agreement, dated December 5, 2007, between us and E. David Ballard, II, M.D.
10.47(20)#	Amended and Restated Employment Agreement, dated December 5, 2007, between us and Maria Bedoya-Toro
10.48(20)#	Amended and Restated Employment Agreement, dated December 5, 2007, between us and Carey J. Fox
10.49(29)#	2007 Bonus Plan
10.50(30)#	2008 Bonus Plan
10.51(31)#	2009 Bonus Plan
23.1	Consent of Independent Registered Public Accounting Firm
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
32.1*	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(1) Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2004, filed with the Securities and Exchange Commission on May 13, 2004.

(2) Incorporated by reference to our Current Report on Form 8-K, filed with the Securities and Exchange Commission on December 5, 2008.

(3) Incorporated by reference to our Current Report on Form 8-K, filed with the Securities and Exchange Commission on November 17, 2004.

(4) Incorporated by reference to our Registration Statement on Form S-1, filed with the Securities and Exchange Commission on December 23, 2003, as amended (File No. 333-111515).

(5) Incorporated by reference to our Current Report on Form 8-K, filed with the Securities and Exchange Commission on April 21, 2006.

(6) Incorporated by reference to our Current Report on Form 8-K, filed with the Securities and Exchange Commission on December 15, 2008.

(7) Incorporated by reference to our Current Report on Form 8-K, filed with the Securities and Exchange Commission on February 3, 2006.

(8) Incorporated by reference to our Registration Statement on Form S-3, filed with the Securities and Exchange Commission on January 20, 2009 (File No. 333-156806).

(9) Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended September 30, 2007, filed with the Securities and Exchange Commission on November 2, 2007.

(10)Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2007, filed with the Securities and Exchange Commission on August 6, 2007.

(11)Incorporated by reference to our Current Report on Form 8-K, filed with the Securities and Exchange Commission on December 21, 2006.

(12)Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended September 30, 2004, filed with the Securities and Exchange Commission on November 12, 2004.

(13)Incorporated by reference to our Current Report on Form 8-K, filed with the Securities and Exchange Commission on January 6, 2006.

(14)Incorporated by reference to our Current Report on Form 8-K, filed with the Securities and Exchange Commission on July 14, 2008.

(15)Incorporated by reference to our Current Report on Form 8-K, filed with the Securities and Exchange Commission on October 18, 2006.

(16)Incorporated by reference to our Current Report on Form 8-K, filed with the Securities and Exchange Commission on November 7, 2006.

(17)Incorporated by reference to our Current Report on Form 8-K, filed with the Securities and Exchange Commission on October 7, 2008.

(18)Incorporated by reference to our Current Report on Form 8-K, filed with the Securities and Exchange Commission on June 28, 2007.

(19)Incorporated by reference to our Current Report on Form 8-K, filed with the Securities and Exchange Commission on May 7, 2008.

(20)Incorporated by reference to our Annual Report on Form 10-K for the year ended December 31, 2007, filed with the Securities and Exchange Commission on March 4, 2008.

(21)Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2008, filed with the Securities and Exchange Commission on August 5, 2008.

(22)Incorporated by reference to our Current Report on Form 8-K, filed with the Securities and Exchange Commission on December 13, 2007.

(23)Incorporated by reference to our Annual Report on Form 10-K for the year ended December 31, 2005, filed with the Securities and Exchange Commission on March 7, 2006.

(24)Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, filed with the Securities and Exchange Commission on August 13, 2004.

(25)Incorporated by reference to our Registration Statement on Form S-8, filed with the Securities and Exchange Commission on December 21, 2006.

(26)Incorporated by reference to our Current Report on Form 8-K, filed with the Securities and Exchange Commission on February 8, 2005.

(27)Incorporated by reference to our Current Report on Form 8-K, filed with the Securities and Exchange Commission on February 16, 2005.

(28)Incorporated by reference to our Registration Statement on Form S-8, filed with the Securities and Exchange Commission on December 18, 2007.

(29)Incorporated by reference to our applicable Current Report on Form 8-K, filed with the Securities and Exchange Commission on December 21, 2006.

(30)Incorporated by reference to our applicable Current Report on Form 8-K, filed with the Securities and Exchange Commission on February 22, 2008.

(31)Incorporated by reference to our applicable Current Report on Form 8-K, filed with the Securities and Exchange Commission on February 24, 2009.

† Confidential treatment has been granted as to certain portions, which portions have been omitted and filed separately with the Securities and Exchange Commission.

+ Application has been made to the Securities and Exchange Commission to seek confidential treatment of certain provisions. Omitted material for which confidential treatment has been requested has been filed separately with the Securities and Exchange Commission.

# Indicates management contract or compensatory plan.

* These certifications are being furnished solely to accompany this annual report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of Santarus, Inc., whether made before or after the date hereof, regardless of any general incorporation language in such filing.

(c) *Financial Statement Schedule.*

See Item 15(a)(2) above.

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.

SANTARUS, INC.

Dated: March 5, 2009

By: /s/ GERALD T. PROEHL

Gerald T. Proehl
President and Chief Executive Officer

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/ GERALD T. PROEHL Gerald T. Proehl	President, Chief Executive Officer and Director *(Principal Executive Officer)*	March 5, 2009
/s/ DEBRA P. CRAWFORD Debra P. Crawford	Senior Vice President and Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 5, 2009
/s/ DAVID F. HALE David F. Hale	Director *(Chairman of the Board of Directors)*	March 5, 2009
/s/ DANIEL D. BURGESS Daniel D. Burgess	Director	March 5, 2009
/s/ MICHAEL G. CARTER, M.B., CH.B., F.R.C.P. (U.K.) Michael G. Carter, M.B., Ch.B., F.R.C.P. (U.K.)	Director	March 5, 2009
/s/ MICHAEL E. HERMAN Michael E. Herman	Director	March 5, 2009
/s/ TED W. LOVE, M.D. Ted W. Love, M.D.	Director	March 5, 2009
/s/ KENT SNYDER Kent Snyder	Director	March 5, 2009

SANTARUS, INC.

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Santarus, Inc.

We have audited the accompanying balance sheets of Santarus, Inc. as of December 31, 2008 and 2007, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2008. Our audits also included the financial schedule listed in the Index at Item 15(a). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Santarus, Inc. at December 31, 2008 and 2007, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2008, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Santarus, Inc.'s 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 and our report dated March 2, 2009, expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
March 2, 2009

Santarus, Inc.
Balance Sheets
(in thousands, except share and per share amounts)

	December 31, 2008	December 31, 2007
Assets		
Current assets:		
Cash and cash equivalents	$ 49,886	$ 58,382
Short-term investments	2,151	6,296
Accounts receivable, net	13,366	9,681
Inventories, net	5,230	6,157
Other current assets	3,826	2,340
Total current assets	74,459	82,856
Long-term restricted cash	1,400	1,400
Long-term investments	4,250	—
Property and equipment, net	988	667
Intangible assets, net	11,250	—
Other assets	137	421
Total assets	$ 92,484	$ 85,344
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities	$ 53,109	$ 37,355
Allowance for product returns	10,251	5,947
Current portion of deferred revenue	7,365	13,972
Total current liabilities	70,725	57,274
Deferred revenue, less current portion	2,436	12,722
Long-term debt	10,000	—
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at December 31, 2008 and 2007; no shares issued and outstanding at December 31, 2008 and 2007	—	—
Common stock, $0.0001 par value; 100,000,000 shares authorized at December 31, 2008 and 2007; 57,799,588 and 51,315,485 shares issued and outstanding at December 31, 2008 and 2007, respectively	6	5
Additional paid-in capital	331,831	319,342
Accumulated other comprehensive income	2	—
Accumulated deficit	(322,516)	(303,999)
Total stockholders' equity	9,323	15,348
Total liabilities and stockholders' equity	$ 92,484	$ 85,344

See accompanying notes.

Santarus, Inc.
Statements of Operations
(in thousands, except share and per share amounts)

	Years Ended December 31,		
	2008	2007	2006
Revenues:			
Product sales, net	$ 101,220	$ 79,403	$ 45,980
Promotion revenue	9,837	1,803	—
License and royalty revenue	19,144	13,222	3,263
Total revenues	130,201	94,428	49,243
Costs and expenses:			
Cost of product sales	7,345	7,301	4,927
License fees and royalties	22,257	11,117	6,437
Research and development	11,760	6,849	7,572
Selling, general and administrative	108,012	116,503	89,828
Total costs and expenses	149,374	141,770	108,764
Loss from operations	(19,173)	(47,342)	(59,521)
Interest and other income, net	1,190	3,077	3,055
Loss before income taxes	(17,983)	(44,265)	(56,466)
Income tax expense	534	—	—
Net loss	$ (18,517)	$ (44,265)	$ (56,466)
Basic and diluted net loss per share	$ (0.36)	$ (0.87)	$ (1.19)
Weighted average shares outstanding used to calculate basic and diluted net loss per share	51,835,482	51,060,650	47,355,050

See accompanying notes.

Santarus, Inc.
Statements of Stockholders' Equity
(in thousands, except share amounts)

	Common stock		Additional paid-in capital	Deferred compensation	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders' equity
	Shares	Amount					
Balance at December 31, 2005	44,467,087	$ 4	$ 259,487	$ (1,699)	$ (4)	$ (203,268)	$ 54,520
Issuance of common stock upon exercise of stock options, net of 10,187 unvested shares repurchased	402,221	—	1,523	—	—	—	1,523
Issuance of common stock under Committed Equity Financing Facility, net of issuance costs	5,401,787	1	36,259	—	—	—	36,260
Financing cost of warrant issued in connection with Committed Equity Financing Facility	—	—	(1,282)	—	—	—	(1,282)
Issuance of warrant in connection with Committed Equity Financing Facility	—	—	1,282	—	—	—	1,282
Issuance of common stock upon exercise of warrants	14,832	—	—	—	—	—	—
Issuance of common stock under employee stock purchase plan	444,695	—	1,139	—	—	—	1,139
Stock-based compensation	—	—	9,325	—	—	—	9,325
Reclassification of deferred compensation due to adoption of SFAS No. 123(R)	—	—	(1,699)	1,699	—	—	—
Net loss	—	—	—	—	—	(56,466)	(56,466)
Unrealized gain on investments	—	—	—	—	4	—	4
Comprehensive loss	—	—	—	—	—	—	(56,462)
Balance at December 31, 2006	50,730,622	5	306,034	—	—	(259,734)	46,305

	Common stock		Additional paid-in capital	Deferred compensation	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders' equity
	Shares	Amount					
Balance at December 31, 2006	50,730,622	5	306,034	—	—	(259,734)	46,305
Issuance of common stock upon exercise of stock options, net of 12,001 unvested shares repurchased	84,851	—	265	—	—	—	265
Issuance of common stock under employee stock purchase plan	500,012	—	1,293	—	—	—	1,293
Stock-based compensation	—	—	11,750	—	—	—	11,750
Net loss	—	—	—	—	—	(44,265)	(44,265)
Unrealized gain on investments	—	—	—	—	—	—	—
Comprehensive loss	—	—	—	—	—	—	(44,265)
Balance at December 31, 2007	51,315,485	5	319,342	—	—	(303,999)	15,348
Issuance of common stock upon exercise of stock options	101,158	—	77	—	—	—	77
Issuance of common stock under employee stock purchase plan	382,945	—	762	—	—	—	762
Issuance of common stock at $1.24 per share for technology license agreement	6,000,000	1	7,439	—	—	—	7,440
Stock-based compensation	—	—	4,211	—	—	—	4,211
Net loss	—	—	—	—	—	(18,517)	(18,517)
Unrealized gain on investments	—	—	—	—	2	—	2
Comprehensive loss	—	—	—	—	—	—	(18,515)
Balance at December 31, 2008	57,799,588	$ 6	$ 331,831	$ —	$ 2	$ (322,516)	$ 9,323

See accompanying notes.

Santarus, Inc.
Statements of Cash Flows
(in thousands)

	Years Ended December 31,		
	2008	2007	2006
Operating activities			
Net loss	$ (18,517)	$ (44,265)	$ (56,466)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,355	587	592
Recognition of auction rate securities rights	(1,457)	—	—
Unrealized loss on trading securities	1,507	—	—
Stock-based compensation	4,211	11,750	9,325
Issuance of common stock for technology license agreement	7,440	—	—
Changes in operating assets and liabilities:			
Accounts receivable, net	(3,686)	(2,547)	(4,471)
Inventories, net	928	822	(3,846)
Other current assets	(1,486)	(1,096)	9
Other assets	61	(4)	—
Accounts payable and accrued liabilities	15,754	14,820	13,049
Allowance for product returns	4,304	4,324	(2,841)
Deferred revenue	(16,894)	3,528	11,737
Net cash used in operating activities	(6,480)	(12,081)	(32,912)
Investing activities			
Purchases of short-term investments	(4,488)	(4,723)	(4,384)
Maturities of short-term investments	2,929	3,095	9,189
Long-term restricted cash	1,400	300	250
Purchases of property and equipment	(696)	(651)	(59)
Acquisition of intangible assets	(12,000)	—	—
Net cash (used in) provided by investing activities	(12,855)	(1,979)	4,996
Financing activities			
Proceeds from draw down on credit facility	10,000	—	—
Exercise of stock options	77	265	1,523
Issuance of common stock, net	762	1,293	37,399
Payments on equipment notes payable	—	—	(38)
Net cash provided by financing activities	10,839	1,558	38,884
(Decrease) increase in cash and cash equivalents	(8,496)	(12,502)	10,968
Cash and cash equivalents at beginning of the year	58,382	70,884	59,916
Cash and cash equivalents at end of the year	$ 49,886	$ 58,382	$ 70,884
Supplemental disclosure of cash flow information:			
Interest paid	$ 95	$ 11	$ 14
Supplemental schedule of noncash investing and financing activities:			
Issuance of warrant in connection with Committed Equity Financing Facility	$ —	$ —	$ 1,282

See accompanying notes.

1. Organization and Summary of Significant Accounting Policies

Organization and Business

Santarus, Inc. ("Santarus" or the "Company") is a specialty pharmaceutical company focused on acquiring, developing and commercializing proprietary products that address the needs of patients treated by gastroenterologists or other targeted physicians. Santarus was incorporated on December 6, 1996 as a California corporation and did not commence significant business activities until late 1998. On July 9, 2002, the Company reincorporated in the State of Delaware.

Use of Estimates in the Preparation of Financial Statements

The preparation of financial statements in conformity with U.S. generally accepted accounting principles ("GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities as well as disclosures of contingent assets and liabilities at the date of the financial statements. Estimates also affect the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

Cash and cash equivalents consist of highly liquid investments with a remaining maturity of three months or less when purchased.

Short-Term Investments

The Company has classified its debt securities as available-for-sale and, accordingly, carries its short-term investments at fair value, and unrealized holding gains or losses on these securities are carried as a separate component of stockholders' equity. The cost of debt securities is adjusted for amortization of premiums or accretion of discounts to maturity, and such amortization is included in interest income. Realized gains and losses and declines in value judged to be other-than-temporary (of which there have been none to date) on available-for-sale securities are included in interest income. The cost of securities sold is based on the specific identification method.

Fair Value Measurements

The carrying value of the Company's financial instruments, including cash, cash equivalents, accounts payable and accrued liabilities and the Company's revolving credit facility approximates fair value due to the relative short-term nature of these instruments.

In February 2007, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standard ("SFAS") No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities — Including an amendment to FASB Statement No. 115.* SFAS No. 159 allows certain financial assets and liabilities to be recognized, at the Company's election, at fair market value, with any gains or losses for the period recorded in the statement of operations. SFAS No. 159 includes available-for-sale securities in the assets eligible for this treatment. Currently, the Company records the unrealized gains or losses on available-for-sale securities for the period in comprehensive income (loss) and in the equity section of the balance sheet. SFAS No. 159 was effective for the Company on January 1, 2008. The Company did not elect to adopt the fair value option under SFAS No. 159 on any assets or liabilities not previously carried at fair value, except for the Auction Rate Securities Rights ("ARS Rights") that were recorded in connection with the Company's acceptance of the offer of ARS Rights from its investment provider, UBS Financial Services, Inc., a subsidiary of UBS AG ("UBS"), as more fully described below.

Effective January 1, 2008, the Company adopted SFAS No. 157, *Fair Value Measurements*. SFAS No. 157 establishes a framework for measuring fair value in accordance with GAAP, clarifies the definition of fair value within that framework, and expands disclosures about the use of fair value measurements. It also responds to investors' requests for expanded information about the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value and the effect of fair value measurements on earnings. SFAS No. 157 applies whenever other standards require (or permit) assets or liabilities to be measured at fair value, and does not expand the use of fair value in any new circumstances. The adoption of SFAS No. 157 did not have a material impact on the Company's financial statements.

SFAS No. 157 establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include: Level 1, defined as observable inputs such as quoted prices in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions.

The Company's financial assets measured at fair value on a recurring basis subject to the disclosure requirements of SFAS No. 157 at December 31, 2008 are as follows (in thousands):

	Fair Value Measurements at Reporting Date Using			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**	**Total**
Money market funds	$ 39,468	$ —	$ —	$ 39,468
U.S. government sponsored enterprise securities	—	12,206	—	12,206
Commercial paper	—	1,763	—	1,763
Municipal debt obligations – auction rate securities	—	—	2,793	2,793
Auction rate securities rights	—	—	1,457	1,457
	$ 39,468	$ 13,969	$ 4,250	$ 57,687

Level 3 assets held as of December 31, 2008 include municipal debt obligations with an auction rate reset mechanism issued by state municipalities. These auction rate securities ("ARS") are AAA-rated debt instruments with long-term maturity dates ranging from 2034 to 2042 and interest rates that are reset at short-term intervals (every 28 days) through auctions. Due to conditions in the global credit markets, in 2008, these securities, representing a par value of $4.3 million, had insufficient demand resulting in multiple failed auctions. As a result, these affected securities are currently not liquid and the interest rates have been reset to predetermined higher rates. Due to the illiquid state of these investments, the Company has classified the balance of its ARS as long-term investments in the balance sheet as of December 31, 2008.

In October 2008, the Company received an offer of ARS Rights from UBS, and in November 2008, the Company accepted the ARS Rights offer. The ARS Rights permit the Company to require UBS to purchase the Company's ARS at par value at any time during the period of June 30, 2010 through July 2, 2012. If the Company does not exercise its ARS Rights, the ARS will continue to accrue interest as determined by the auction process or the terms of the ARS if the auction fails. If the ARS Rights are not exercised before July 2, 2012 they will expire and UBS will have no further obligation to buy the Company's ARS. UBS has the discretion to purchase or sell the Company's ARS at any time without prior notice so long as the Company receives a payment at par upon any sale or disposition. UBS will only exercise its discretion to purchase or sell the Company's ARS for the purpose of restructurings, dispositions or other solutions that will provide the Company with par value for its ARS. As a condition to accepting the offer of ARS Rights, the Company released UBS from all claims except claims for consequential damages relating to its marketing and sales of ARS. The Company also agreed not to serve as a class representative or receive benefits under any class action settlement or investor fund.

Typically the fair value of ARS approximates par value due to the frequent resets through the auction process. While the Company continues to earn interest on its ARS at the maximum contractual rates, these investments are not currently trading and therefore do not currently have a readily determinable market value. Accordingly, the estimated fair value of the ARS no longer approximates par value. The Company has used a discounted cash flow model to determine the estimated fair value of its investment in ARS and its ARS Rights as of December 31, 2008. The assumptions used in preparing the discounted cash flow model include estimates for interest rates, timing and amount of cash flows and expected holding period of the ARS and ARS Rights.

The Company elected to measure the ARS Rights under the fair value option of SFAS No. 159 and recognized a gain of approximately $1.5 million and recorded a corresponding long-term investment. Reflecting management's intent to exercise its ARS Rights during the period of June 30, 2010 through July 2, 2012, the Company transferred its ARS from investments available-for-sale to trading securities. As a result of this transfer and as the Company no longer intends to hold the ARS until the fair value recovers, the Company recognized an other-than-temporary impairment loss of approximately $1.5 million, representing a reversal of the related temporary valuation allowance that was previously recorded in other comprehensive loss. Management believes this loss is primarily attributable to the limited liquidity of these investments and has no reason to believe that any of the underlying issuers are presently at risk of default. The recording of the fair value of the ARS Rights and the recognition of the other-than-temporary impairment loss resulted in a net impact to the statement of operations for the year ended December 31, 2008 of approximately $50,000, which was recorded as a reduction to interest income. The ARS Rights will continue to be measured at fair value utilizing Level 3 inputs until the earlier of their maturity or exercise.

The following table provides a summary of changes in fair value of the Company's Level 3 financial assets as of December 31, 2008 (in thousands):

	Year Ended December 31, 2008
Long-term investments:	
Beginning balance	$ —
Transfers in	4,300
Unrealized loss included in net loss	(1,507)
Recognition of auction rate securities rights	1,457
Ending balance as of December 31, 2008	$ 4,250

Concentration of Credit Risk and Sources of Supply

The Company invests its excess cash in highly liquid debt instruments of financial institutions, U.S. government sponsored enterprises, government municipalities, and corporations with strong credit ratings. The Company has established guidelines relative to diversification of its cash investments and their maturities that are intended to maintain safety and liquidity. These guidelines are periodically reviewed and modified to take advantage of trends in yields and interest rates and changes in the Company's operations and financial position. To date, the Company has not experienced any material realized losses on its cash and cash equivalents and short-term investments.

The Company sells its products to established wholesale distributors in the pharmaceutical industry. Credit is extended based on an evaluation of the customer's financial condition, and collateral is not required. Approximately 95% of the accounts receivable balance as of December 31, 2008 represents amounts due from three customers. The Company evaluates the collectibility of its accounts receivable based on a variety of factors including the length of time the receivables are past due, the financial health of the customer and historical experience. Based upon the review of these factors, the Company did not record an allowance for doubtful accounts at December 31, 2008.

The Company relies on Norwich Pharmaceuticals, Inc., located in New York, as the current sole third-party manufacturer of Zegerid® (omeprazole/sodium bicarbonate) Capsules. In addition, the Company relies on a single third-party manufacturer located outside of the U.S., Patheon Inc., for the supply of Zegerid (omeprazole/sodium bicarbonate) Powder for Oral Suspension, and the Company is obligated under its supply agreement to purchase a significant portion of its requirements of this product from Patheon. The Company also currently relies on a single

third-party supplier located outside of the U.S., Union Quimico Farmaceutica, S.A., or Uquifa, for the supply of omeprazole, which is an active pharmaceutical ingredient in each of its Zegerid products. The Company is obligated under its supply agreement with Uquifa to purchase all of its requirements of omeprazole from this supplier. The Company also currently has two approved suppliers for sodium bicarbonate, which is a component in the marketed powder for oral suspension and capsule products, and the Company relies on its third-party manufacturers to purchase the sodium bicarbonate. Additionally, the Company relies on single suppliers for certain excipients in the powder for oral suspension and capsule products.

Inventories, Net

Inventories are stated at the lower of cost (FIFO) or market and consist of finished goods and raw materials used in the manufacture of the Company's Zegerid Capsules and Zegerid Powder for Oral Suspension products. Also included in inventories as of December 31, 2008 are product samples of Glumetza® (metformin hydrochloride extended release tablets) which the Company purchases from Depomed, Inc. ("Depomed") under its promotion agreement. Inventories as of December 31, 2007 also included product samples of Naprelan® (naproxen sodium) Controlled Release Tablets which the Company purchased from Victory Pharma, Inc. ("Victory") under its co-promotion agreement, which was terminated effective as of October 1, 2008. The Company provides reserves for potentially excess, dated or obsolete inventories based on an analysis of inventory on hand and on firm purchase commitments, compared to forecasts of future sales.

Property and Equipment

Property and equipment are carried at cost less accumulated depreciation and amortized over the estimated useful lives of the assets, ranging from three to five years or the term of the related lease using the straight-line method.

Intangible Assets, Net

Intangible assets are recorded at cost, less accumulated amortization. These costs are capitalized and amortized on a straight-line basis over the estimated periods benefited by the asset. The Company's intangible assets consist of license rights associated with its promotion agreement with Depomed entered into in July 2008. The Company paid Depomed a $12.0 million upfront fee, which has been capitalized and is being amortized to license fee expense over the estimated useful life of the asset through mid-2016. Total amortization expense for the year ended December 31, 2008 was $750,000, and the total unamortized cost as of December 31, 2008 was approximately $11.3 million.

In accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, the Company assesses the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If impairment is indicated, the Company measures the amount of such impairment by comparing the fair value to the carrying value. There have been no indicators of impairment through December 31, 2008.

Revenue Recognition

The Company follows Staff Accounting Bulletin ("SAB") No. 104, *Revenue Recognition*, and recognizes revenue when there is persuasive evidence that an arrangement exists, title has passed, the price is fixed or determinable, and collectibility is reasonably assured.

Product Sales, Net. The Company received approval from the U.S. Food and Drug Administration ("FDA") to market Zegerid Capsules in 2006 for the treatment of heartburn and other symptoms associated with gastroesophageal reflux disease ("GERD"), treatment and maintenance of healing of erosive esophagitis and treatment of duodenal and gastric ulcers. The Company received approval from the FDA to market Zegerid Powder for Oral Suspension for these same indications in 2004. In addition, Zegerid Powder for Oral Suspension is approved for the reduction of risk of upper gastrointestinal bleeding in critically ill patients, and is currently the only proton pump inhibitor ("PPI") product approved for this indication. The Company commercially launched Zegerid Capsules in early 2006 and launched Zegerid Powder for Oral Suspension 20 mg in late 2004 and the 40 mg dosage strength in early 2005.

The Company sells its Zegerid products primarily to pharmaceutical wholesale distributors. The Company is obligated to accept from customers the return of products that are within six months of their expiration date or up to 12 months beyond their expiration date. The Company authorizes returns for damaged products and exchanges for expired products in accordance with its return goods policy and procedures, and has established allowances for such amounts at the time of sale.

The Company recognizes revenue from product sales in accordance with SAB No. 104 and SFAS No. 48, *Revenue Recognition When Right of Return Exists.* Among its criteria for revenue recognition from sale transactions where a buyer has a right of return, SFAS No. 48 requires the amount of future returns to be reasonably estimable. The Company recognizes product sales net of estimated allowances for product returns, estimated rebates in connection with contracts relating to managed care, Medicaid, Medicare, and patient coupons, and estimated chargebacks from distributors, wholesaler fees and prompt payment and other discounts.

The Company establishes allowances for estimated product returns, rebates and chargebacks based primarily on the following qualitative and quantitative factors:

- the number of and specific contractual terms of agreements with customers;
- estimated levels of inventory in the distribution channel;
- estimated remaining shelf life of products;
- analysis of prescription data gathered by a third-party prescription data provider;
- direct communication with customers;
- historical product returns, rebates and chargebacks;
- anticipated introduction of competitive products or generics;
- anticipated pricing strategy changes by the Company and/or its competitors; and
- the impact of state and federal regulations.

In its analyses, the Company utilizes prescription data purchased from a third-party data provider to develop estimates of historical inventory channel pull-through. The Company utilizes a separate analysis which compares historical product shipments less returns to estimated historical prescriptions written. Based on that analysis, the Company develops an estimate of the quantity of product in the distribution channel which may be subject to various product return, rebate and chargeback exposures.

The Company's estimates of product returns, rebates and chargebacks require management's most subjective and complex judgment due to the need to make estimates about matters that are inherently uncertain. If actual future payments for returns, rebates, chargebacks and other discounts exceed the estimates the Company made at the time of sale, its financial position, results of operations and cash flows would be negatively impacted.

The Company's allowance for product returns was $10.3 million as of December 31, 2008 and $5.9 million as of December 31, 2007. In order to provide a basis for estimating future product returns on sales to its customers at the time title transfers, the Company has been tracking its Zegerid products return history from the time of its first commercial product launch of Zegerid Powder for Oral Suspension 20 mg in late 2004, taking into consideration product expiration dating and estimated inventory levels in the distribution channel. The Company recognizes product sales at the time title passes to its customers, and the Company provides for an estimate of future product returns at that time based upon its historical product returns trends, analysis of product expiration dating and inventory levels in the distribution channel, and the other factors discussed above. There may be a significant time lag between the date the Company determines the estimated allowance and when it receives the product return and issues credit to a customer. Due to this time lag, the Company records adjustments to its estimated allowance over several periods, which can result in a net increase or a net decrease in its operating results in those periods. In 2007, based upon the Company's review of additional product returns history gathered through the end of 2007 and analysis of product expiration dating and estimated inventory in the distribution channel, the Company increased its estimate for product returns to reflect actual experience accordingly. This change in estimate provided for potential product returns related to sales in prior periods and resulted in an increase to net loss of approximately $1.9 million in 2007.

The Company's allowance for rebates, chargebacks and other discounts was $29.3 million as of December 31, 2008 and $21.0 million as of December 31, 2007. These allowances reflect an estimate of the Company's liability for rebates due to managed care organizations under specific contracts, rebates due to various governmental organizations under Medicaid and Medicare contracts and regulations, chargebacks due to various organizations purchasing the Company's products through federal contracts and/or group purchasing agreements, and other rebates and customer discounts due in connection with wholesaler fees and prompt payment and other discounts. The Company estimates its liability for rebates and chargebacks at each reporting period based on a combination of the qualitative and quantitative assumptions listed above. In each reporting period, the Company evaluates its outstanding contracts and applies the contractual discounts to the invoiced price of wholesaler shipments recognized. Although the total invoiced price of shipments to wholesalers for the reporting period and the contractual terms are known during the reporting period, the Company projects the ultimate disposition of the sale (e.g. future utilization rates of cash payors, managed care, Medicaid, Medicare or other contracted organizations). This estimate is based on historical trends adjusted for anticipated changes based on specific contractual terms of new agreements with customers, anticipated pricing strategy changes by the Company and/or its competitors and the other qualitative and quantitative factors described above. There may be a significant time lag between the date the Company determines the estimated allowance and when the Company makes the contractual payment or issues credit to a customer. Due to this time lag, the Company records adjustments to its estimated allowance over several periods, which can result in a net increase or a net decrease in its operating results in those periods. To date, actual results have not materially differed from the Company's estimates.

Promotion Revenue and License and Royalty Revenue. The Company recognizes promotion revenue and license and royalty revenue consistent with the provisions of SAB No. 104 and Emerging Issues Task Force ("EITF") Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*. The Company analyzes each element of its promotion and licensing agreements to determine the appropriate revenue recognition. The Company recognizes revenue on upfront payments over the period of significant involvement under the related agreements unless the fee is in exchange for products delivered or services rendered that represent the culmination of a separate earnings process and no further performance obligation exists under the contract. The Company recognizes milestone payments upon the achievement of specified milestones if (1) the milestone is substantive in nature, and the achievement of the milestone was not reasonably assured at the inception of the agreement and (2) the fees are nonrefundable. Any milestone payments received prior to satisfying these revenue recognition criteria are recognized as deferred revenue. Sales milestones, royalties and promotion fees are recognized as revenue when earned under the agreements.

Research and Development Expenses and License Fees

Research and development expenses have consisted primarily of costs associated with clinical trials of the Company's products under development as well as clinical studies designed to further differentiate its products from those of its competitors, development of and preparation for commercial manufacturing of the Company's products, compensation and other expenses related to research and development personnel and facilities expenses. Clinical trial costs include fees paid to clinical research organizations, research institutions, collaborative partners and other service providers, which conduct certain research and development activities on behalf of the Company.

Research and development expenditures are charged to expense as incurred. Expenses related to clinical trials are generally accrued based on contracted amounts applied to the level of patient enrollment and activity according to the protocol. If timelines or contracts are modified based on changes in the clinical trial protocol or scope of work to be performed, the Company modifies its estimates accordingly on a prospective basis.

The Company expenses amounts paid to obtain patents or acquire licenses associated with products under development when the ultimate recoverability of the amounts paid is uncertain and the technology has no alternative future use when acquired. Future acquisitions of patents and technology licenses will be charged to expense or capitalized based upon management's assessment regarding the ultimate recoverability of the amounts paid and the potential for alternative future use.

Patent Costs

Costs related to filing and pursuing patent applications are expensed as incurred as recoverability of such expenditures is uncertain.

Shipping and Handling Costs

The Company does not charge its customers for freight. The amounts of such costs are included in selling, general and administrative expenses and are not material.

Advertising Expense

The Company records the cost of its advertising efforts when services are performed or goods are delivered. The Company recorded approximately $3.5 million, $5.8 million and $5.7 million in advertising expense for the years ended December 31, 2008, 2007 and 2006, respectively.

Stock-Based Compensation

Effective January 1, 2006, the Company adopted the fair value recognition provisions of SFAS No. 123 (revised 2004), *Share-Based Payment*, which is a revision of SFAS No. 123, *Accounting for Stock-Based Compensation* ("SFAS No. 123(R)") using the modified prospective transition method. Under this transition method, compensation cost recognized for the years ended December 31, 2008, 2007 and 2006 included (1) compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123, and (2) compensation cost for all share-based payments granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS No. 123(R). Results for prior periods have not been restated.

The Company estimates the fair value of stock options and employee stock purchase plan rights granted using the Black-Scholes valuation model. For options granted prior to January 1, 2006, the Company amortizes the fair value on an accelerated basis. For options granted after January 1, 2006, the Company amortizes the fair value on a straight-line basis. All options are amortized over the requisite service period of the awards, which is generally the vesting period of one to four years. Pre-vesting forfeitures were estimated to be approximately 0% for the years ended December 31, 2008, 2007 and 2006 as the majority of options granted contain monthly vesting terms. In 2008, certain stock options were granted to employees at or above the vice president level that vest upon the attainment of specific financial performance targets. The measurement date of stock options containing performance-based vesting is the date the stock option grant is authorized and the specific performance goals are communicated. Compensation expense is recognized based on the probability that the performance criteria will be met. The recognition of compensation expense associated with performance-based vesting requires judgment in assessing the probability of meeting the performance goals, as well as defined criteria for assessing achievement of the performance-related goals. The continued assessment of probability may result in additional expense recognition or expense reversal depending on the level of achievement of the performance goals. The Company has not recorded any compensation expense related to performance-based awards for the year ended December 31, 2008.

The fair value of each option is estimated on the date of grant using the Black-Scholes valuation model. The following assumptions were used during these periods:

	Years Ended December 31,		
	2008	2007	2006
Stock Options:			
Risk-free interest rate	1.5% – 3.4%	3.6% – 4.9%	4.6% – 5.0%
Expected volatility	64% – 68%	60%	60%
Expected life of options (years)	5.27 – 6.58	5.27 – 6.08	5.27 – 6.08
Expected dividend yield	—	—	—
Employee Stock Purchase Plan:			
Risk-free interest rate	0.1% – 2.0%	3.3% – 5.0%	4.8% – 5.1%
Expected volatility	64% – 68%	60%	60%
Expected life of options (years)	0.50	0.50 – 2.00	0.50 – 2.00
Expected dividend yield	—	—	—

Risk-Free Interest Rate. The risk-free interest rate is based on the implied yield available on U.S. Treasury zero-coupon issues with a remaining term equal to the expected term of the option.

Expected Volatility. As the length of time the Company's shares have been publicly traded is generally shorter than the expected life of the option, the Company's considers the expected volatility of similar entities as well as the Company's historical volatility since its initial public offering in April 2004 in determining its volatility factor. In evaluating similar entities, the Company considers factors such as industry, stage of development, size and financial leverage.

Expected Life of Options. In determining the expected life of the options, the Company uses the "short-cut" method described in SAB No. 110. Under this method, the expected life is presumed to be the mid-point between the vesting date and the end of the contractual term. The Company will continue to use the "short-cut" method until it has sufficient historical exercise data to estimate the expected life of the options.

Expected Dividend Yield. The Company has never paid any dividends and does not intend to in the near future.

The weighted average per share fair value of stock options granted in the years ended December 31, 2008, 2007 and 2006 was $1.41, $2.91 and $4.10, respectively. The weighted average per share fair value of employee stock purchase plan rights granted in the years ended December 31, 2008, 2007 and 2006 was $0.78, $1.70 and $3.34, respectively. As of December 31, 2008, total unrecognized compensation cost related to stock options and employee stock purchase plan rights was approximately $7.2 million, and the weighted average period over which it is expected to be recognized is 2.2 years.

Comprehensive Income (Loss)

Comprehensive income (loss) consists of net income (loss) and other comprehensive income (loss). Other comprehensive income (loss) includes certain changes in stockholders' equity that are excluded from net income (loss), specifically unrealized gains and losses on securities available-for-sale. Comprehensive loss consists of the following (in thousands):

	Years Ended December 31,		
	2008	2007	2006
Net loss	$ (18,517)	$ (44,265)	$ (56,466)
Unrealized gain on investments	2	—	4
Comprehensive loss	$ (18,515)	$ (44,265)	$ (56,462)

Net Loss Per Share

The Company calculates net loss per share in accordance with SFAS No. 128, *Earnings Per Share*. Basic loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted loss per share is computed by dividing the net loss by the weighted average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, common stock subject to repurchase by the Company, preferred stock, options, and warrants are considered to be common stock equivalents and are only included in the calculation of diluted loss per share when their effect is dilutive.

	Years Ended December 31,		
	2008	2007	2006
Historical:			
Numerator:			
Net loss (in thousands)	$ (18,517)	$ (44,265)	$ (56,466)
Denominator:			
Weighted average common shares outstanding	51,836,524	51,064,953	47,399,739
Weighted average unvested common shares subject to repurchase	(1,042)	(4,303)	(44,689)
Denominator for basic and diluted net loss per share	51,835,482	51,060,650	47,355,050
Basic and diluted net loss per share	$ (0.36)	$ (0.87)	$ (1.19)
Historical outstanding antidilutive securities not included in diluted net loss per share calculation:			
Common stock subject to repurchase	—	3,939	29,208
Options to purchase common stock	11,915,568	9,948,464	6,543,006
Stock warrants	366,284	366,284	366,284
	12,281,852	10,318,687	6,938,498

Segment Reporting

Management has determined that the Company operates in one business segment which is the development and commercialization of pharmaceutical products.

Recent Accounting Pronouncements

Adoption of Recent Accounting Pronouncements

In June 2007, the EITF issued EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to be Used in Future Research and Development Activities*. The consensus requires companies to defer and capitalize prepaid, nonrefundable research and development payments to third parties over the period that the research and development activities are performed or the services are provided, subject to an assessment of recoverability. EITF Issue No. 07-3 is effective for new contracts entered into beginning on January 1, 2008. The adoption of EITF Issue No. 07-3 did not have a material impact on the Company's financial statements.

Pending Adoption of Recent Accounting Pronouncements

In November 2007, the EITF issued EITF Issue No. 07-1, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property*. Companies may enter into arrangements with other companies to jointly develop, manufacture, distribute, and market a product. Often the activities associated with these arrangements are conducted by the collaborators without the creation of a separate legal entity (that is, the arrangement is operated as a "virtual joint venture"). The arrangements generally provide that the collaborators will share, based on contractually defined calculations, the profits or losses from the associated activities. Periodically, the collaborators share financial information related to product revenues generated (if any) and costs incurred that may trigger a sharing payment for the combined profits or losses. The consensus requires collaborators in such an arrangement to present the result of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable GAAP or, in the absence of other

applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. EITF Issue No. 07-1 is effective for collaborative arrangements in place at the beginning of the annual period beginning after December 15, 2008. The Company does not expect the adoption of EITF Issue No. 07-1 to have a material impact on its financial statements.

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations*. SFAS No. 141(R) changes the requirements for an acquirer's recognition and measurement of the assets acquired and liabilities assumed in a business combination, including the treatment of contingent consideration, pre-acquisition contingencies, transaction costs, in-process research and development and restructuring costs. In addition, under SFAS No. 141(R), changes in an acquired entity's deferred tax assets and uncertain tax positions after the measurement period will impact income tax expense. This statement is effective for the Company with respect to business combination transactions for which the acquisition date is after December 31, 2008.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements (an amendment of Accounting Research Bulletin, or ARB, No. 51)*. SFAS No. 160 requires that noncontrolling (minority) interests be reported as a component of equity, that net income attributable to the parent and to the noncontrolling interest be separately identified in the income statement, that changes in a parent's ownership interest while the parent retains its controlling interest be accounted for as equity transactions, and that any retained noncontrolling equity investment upon the deconsolidation of a subsidiary be initially measured at fair value. This statement is effective for fiscal years beginning after December 31, 2008, and shall be applied prospectively. However, the presentation and disclosure requirements of SFAS No. 160 are required to be applied retrospectively for all periods presented. The retrospective presentation and disclosure requirements of this statement will be applied to any prior periods presented in financial statements for the fiscal year ending December 31, 2009, and later periods during which we have a consolidated subsidiary with a noncontrolling interest. As of December 31, 2008, the Company does not have any consolidated subsidiaries in which there is a noncontrolling interest.

2. Short-Term Investments

The following is a summary of short-term investment securities available-for-sale as of December 31, 2008 and 2007 (in thousands). All short-term investment securities available-for-sale held as of December 31, 2008 and all corporate debt securities held as of December 31, 2007 have contractual maturities within one year. All municipal debt obligations held as of December 31, 2007 consisted of ARS issued by state municipalities. These ARS are debt instruments with a long-term maturity and an interest rate that is reset in short-term intervals (every 28 days) through auctions. As discussed in Note 1, due to conditions in the global credit markets in 2008 and the illiquid state of these investments, the Company has classified the balance of its ARS as long-term investments in the balance sheet as of December 31, 2008.

	Amortized Cost	Market Value	Unrealized Gain
December 31, 2008:			
U.S. government sponsored enterprise securities	$ 2,149	$ 2,151	$ 2
December 31, 2007:			
Municipal debt obligations	$ 4,300	$ 4,300	$ —
Corporate debt securities	1,996	1,996	—
Total	$ 6,296	$ 6,296	$ —

There were no gross realized gains or losses on sales of available-for-sale securities for the years ended December 31, 2008 and 2007.

3. Balance Sheet Details

Inventories, net consist of the following (in thousands):

	December 31,	
	2008	2007
Raw materials	$ 977	$ 1,511
Finished goods	4,561	4,812
	5,538	6,323
Allowance for excess and obsolete inventory	(308)	(166)
	$ 5,230	$ 6,157

Property and equipment, net consist of the following (in thousands):

	December 31,	
	2008	2007
Computer equipment and software	$ 1,258	$ 1,295
Office equipment and furniture	1,154	1,074
Leasehold improvements	446	346
	2,858	2,715
Less accumulated depreciation and amortization	(1,870)	(2,048)
	$ 988	$ 667

For the years ended December 31, 2008, 2007 and 2006, depreciation expense was approximately $374,000, $314,000 and $343,000, respectively.

Accounts payable and accrued liabilities consist of the following (in thousands):

	December 31,	
	2008	2007
Accounts payable	$ 6,102	$ 5,180
Accrued compensation and benefits	6,862	5,360
Accrued rebates	26,034	19,479
Accrued license fees and royalties	4,038	3,364
Accrued research and development expenses	4,126	83
Other accrued liabilities	5,947	3,889
	$ 53,109	$ 37,355

4. License Agreements

University of Missouri

In January 2001, the Company entered into a technology license agreement with the University of Missouri. Under the technology license agreement, the University of Missouri granted the Company an exclusive, worldwide license to patents and patent applications relating to specific formulations of immediate-release PPIs with antacids for treating upper GI diseases and disorders. Pursuant to the terms of the license agreement, the Company issued to the University of Missouri 164,284 shares of the Company's common stock and paid an upfront licensing fee of $1.0 million, a one-time $1.0 million milestone fee upon the filing of the Company's first new drug application ("NDA") in 2003 and a one-time $5.0 million milestone fee upon the FDA's approval of Zegerid Powder for Oral Suspension 20 mg in 2004. The Company is required to make additional milestone payments to the University of Missouri upon initial commercial sale in specified territories outside the U.S., which may total up to $3.5 million in the aggregate. The Company is also required to make milestone payments based on first-time achievement of significant sales thresholds, up to a maximum of $86.3 million, the first of which is a one-time $2.5 million milestone payment upon initial achievement of $100.0 million in annual calendar year net product sales of immediate-release omeprazole products, which includes sales by the Company, Glaxo Group Limited, an affiliate of GlaxoSmithKline plc ("GSK") and Schering-Plough Healthcare Products, Inc. ("Schering-Plough"). Based upon the achievement of the initial sales milestone, the Company has accrued for the $2.5 million payment in license fee expenses in the year ended December 31, 2008. The Company is also obligated to pay royalties on net sales of the

Company's products and any products commercialized by GSK under the license and distribution agreements and Schering-Plough under the over-the-counter ("OTC") license agreement. The license agreement with the University of Missouri is valid through the last to expire patent issued pursuant to the license agreement, or in countries in which there are no pending patent applications or existing patents, terminates on a country-by-country basis on the fifteenth anniversary of the Company's first commercial sale in such country. The rights under the University of Missouri license are subject to early termination under specified circumstances.

Schering-Plough Healthcare Products, Inc.

In October 2006, the Company entered into a license agreement with Schering-Plough, pursuant to which the Company granted Schering-Plough rights to develop, manufacture, market and sell Zegerid brand omeprazole products using the Company's patented PPI technology for the OTC market in the U.S. and Canada. Schering-Plough is responsible, at its sole expense, for all activities related to product and clinical development, manufacturing, regulatory matters, marketing and sales of products under the license agreement and is required to use diligent efforts to conduct and complete such activities in a timely manner.

In November 2006, the Company received a nonrefundable $15.0 million upfront license fee from Schering-Plough. The $15.0 million upfront payment is being amortized to revenue on a straight-line basis over a 37-month period through the end of 2009 which represents the estimated period over which the Company has significant responsibilities under the agreement. In August 2007, the Company received a $5.0 million milestone payment relating to progress on clinical product development strategy. In June 2008, the Company received a $2.5 million regulatory milestone relating to FDA acceptance for filing of an NDA submitted by Schering-Plough for a Zegerid branded omeprazole/sodium bicarbonate OTC product in a 20 mg dosage strength of omeprazole. The Company recognized the $5.0 million milestone payment and the $2.5 million milestone payment as revenue in 2007 and 2008, respectively, due to the substantive nature of the milestones achieved and since the Company has no ongoing obligations associated with the milestones. The Company may receive an additional milestone payment of $20.0 million upon the achievement of a specified regulatory milestone and up to an additional $37.5 million in milestone payments upon the achievement of specified sales milestones. The Company will also receive low double-digit royalties, subject to adjustment in certain circumstances, on net sales of any OTC products sold by Schering-Plough under the license agreement. In turn, the Company will be obligated to pay royalties to the University of Missouri based on net sales of any OTC products sold by Schering-Plough.

The license agreement will remain in effect as long as Schering-Plough is marketing products under the license agreement in the U.S. or Canada. Schering-Plough may terminate the agreement at any time on 180 days prior written notice to the Company. In addition, either party may terminate the agreement in the event of uncured material breach of a material obligation, subject to certain limitations, or in the event of bankruptcy or insolvency.

Glaxo Group Limited

In November 2007, the Company entered into a license agreement and a distribution agreement with GSK, granting GSK certain exclusive rights to commercialize prescription and OTC immediate-release omeprazole products in a number of international markets and to distribute and sell Zegerid brand immediate-release omeprazole prescription products in Puerto Rico and the U.S. Virgin Islands.

Under the license agreement, GSK is responsible for the development, manufacture and commercialization of prescription and OTC immediate-release omeprazole products for sale in up to 114 countries, outside of the U.S., Europe, Australia, Japan and Canada (including markets within Africa, Asia, the Middle-East and Central and South America). Under the distribution agreement, GSK began distributing, marketing and selling Zegerid brand prescription products in Puerto Rico and the U.S. Virgin Islands in February 2008. During an initial period following the execution of the distribution agreement, the Company is obligated to supply Zegerid products to GSK for sale in Puerto Rico and the U.S. Virgin Islands, and GSK will pay a specified transfer price covering the Company's fully burdened costs. GSK bears all costs for its activities under the license and distribution agreements.

Under the license agreement, in December 2007, the Company received an $11.5 million upfront fee, and the Company receives tiered royalties, subject to reduction in certain circumstances, on net sales of any products sold under the license and distribution agreements. In turn, the Company is obligated to pay royalties to the University of

Missouri based on net sales of any licensed products sold by GSK. GSK has an option to make a buy-out payment 20 years after the effective date of the agreements, after which time, GSK's royalty obligations generally would end. To support GSK's initial launch costs, the Company agreed to waive the first $2.5 million of aggregate royalties payable under the license and distribution agreements. Of the total $11.5 million upfront payment, the $2.5 million in waived royalty obligations was recorded as deferred revenue and will be recognized as revenue when the royalties are earned. The remaining $9.0 million was also recorded as deferred revenue and is being amortized to revenue on a straight-line basis over an 18-month period, which represents the estimated period the Company is obligated to supply Zegerid products to GSK for sale in Puerto Rico and the U.S. Virgin Islands under the distribution agreement.

The term of the license agreement continues so long as GSK is obligated to pay royalties, and the term of the distribution agreement continues as long as GSK sells the products, unless the agreements are terminated earlier by either GSK or the Company under specified circumstances. GSK may terminate the license agreement or the distribution agreement on six months prior written notice at any time. The Company may terminate the license agreement on a country-by-country basis in the event that GSK fails to satisfy certain diligence obligations. In addition, either party may terminate the license agreement or the distribution agreement in the event of the other party's uncured material breach or bankruptcy or insolvency.

Cosmo Technologies Limited

In December 2008, the Company entered into a strategic collaboration with Cosmo Technologies, Limited, an affiliate of Cosmo Pharmaceuticals S.p.A. ("Cosmo") including a license agreement, stock issuance agreement and registration rights agreement, under which the Company was granted exclusive rights to develop and commercialize the budesonide MMX® and rifamycin SV MMX product candidates in the U.S. As upfront consideration, the Company issued 6,000,000 shares of its common stock and made a cash payment of $2.5 million to Cosmo. The Company may also pay Cosmo up to a total of $9.0 million in clinical and regulatory milestones for the initial indications for the licensed products, up to $6.0 million in clinical and regulatory milestones for a second indication for rifamycin SV MMX and up to $57.5 million in commercial milestones. The milestones may be paid in cash or through issuance of additional shares of the Company's common stock, at Cosmo's option, subject to certain limitations. The Company will pay tiered royalties to Cosmo ranging from 12% to 14% on net sales of any licensed products the Company sells. The royalties are subject to reduction in certain circumstances, including in the event of market launch in the U.S. of a generic version of a licensed product. The Company will be responsible for one-half of the total out-of-pocket costs associated with the two ongoing budesonide MMX phase III clinical trials and for all of the out-of-pocket costs for the planned rifamycin SV MMX multi-center phase III U.S. registration trial. Included in research and development expenses in 2008 was approximately $3.9 million of out-of-pocket costs incurred in connection with the ongoing budesonide MMX phase III clinical trials reimbursable to Cosmo through December 31, 2008. In the event that additional clinical work is required to obtain U.S. regulatory approval for either of the licensed products, the parties will agree on cost sharing. Cosmo is responsible for any additional pre-clinical costs for rifamycin SV MMX and for any product development and scale-up costs for either of the licensed products.

The Company has agreed to use commercially reasonable efforts to market, promote and sell each of the licensed products, including launching such product within 12 months following receipt of U.S. regulatory approval, utilizing a minimum number of field sales representatives during the first year following launch and spending specified minimum amounts on its sales and marketing efforts during the first three years following launch. Cosmo will manufacture and supply all of the Company's requirements of licensed products during the term of the license agreement. The parties have agreed to enter into a supply agreement prior to the submission of the first NDA for a licensed product.

The term of the license agreement will continue until 50 years following the expiration of the patent rights. The Company may withdraw from the license agreement for one or both licensed products upon 60 days prior written notice to Cosmo in the event that either such product fails to achieve the primary endpoints in the applicable phase III clinical trial within five years following the date of the license agreement or the clinical trials with respect to such product are not sufficient to obtain U.S. regulatory approval within five years following the date of the license agreement. In addition, either party may terminate the license agreement in the event of the other party's uncured material breach.

Under the stock issuance agreement, Cosmo has agreed that for the 15 months following the date of issuance of the initial 6,000,000 shares of common stock and for the six months following the issuance of any shares of common stock upon achievement of milestones, it will not transfer or dispose of any such issued shares. In addition, Cosmo has agreed through December 15, 2011 that neither it nor its affiliates will acquire beneficial ownership of additional shares of our common stock, other than under the stock issuance agreement, subject to certain exceptions. The Company's obligation to issue additional shares of common stock to Cosmo upon the achievement of one or more milestones is subject to certain limitations, including that the total number of shares of common stock issued to Cosmo, including the initial 6,000,000 shares, shall not exceed 10,300,000 shares. Any such additional shares to be issued will be valued at the average daily closing price of the common stock as reported on the Nasdaq Global Market for the 30 consecutive trading days ending on the day immediately prior to the achievement of the applicable milestone.

The Company recorded the upfront cash payment of $2.5 million and the fair value of the 6,000,000 shares of its common stock issued to Cosmo of approximately $7.5 million in license fees and royalties expense in 2008. The Company estimated a fair value of $1.24 per share for the initial 6,000,000 shares of its common stock issued to Cosmo, which reflected a discount of approximately 38% on the $2.00 per share closing price of its common stock on the issuance date. For a publicly traded stock, the fair value of a single unrestricted share of common stock is assumed to be equivalent to the quoted market price on the valuation date. However, since the 6,000,000 shares issued to Cosmo have a 15-month trading restriction pursuant to the stock issuance agreement, the Company calculated a discount for lack of marketability ("DLOM") applicable to the quoted market price. The Company calculated the DLOM associated with the contractual restriction using the Black-Scholes valuation model for a hypothetical put option with the following assumptions: life of the option of 1.25 years; risk-free interest rate of 0.58%; volatility of 90%; and dividend rate of 0%.

Under the terms of the registration rights agreement, the Company filed a resale registration statement on Form S-3 with the Securities and Exchange Commission ("SEC") in January 2009, to register the resale of the shares issuable to Cosmo under the stock issuance agreement. The Company is obligated to use best efforts to have such registration statement declared effective by the SEC.

5. Promotion Agreement with Depomed, Inc.

On July 21, 2008, the Company entered into a promotion agreement with Depomed granting the Company exclusive rights to promote Depomed's Glumetza products in the U.S., including its territories and possessions and Puerto Rico (collectively, the "Territory"). Glumetza is a once-daily, extended-release formulation of metformin that incorporates patented drug delivery technology and is indicated as an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 diabetes.

Under the promotion agreement, the Company is required to meet certain minimum promotion obligations during the term of the agreement. The Company began promoting the Glumetza products in October 2008, and for a period of one year from the promotion commencement date, the Company is required to deliver a minimum number of sales calls to potential Glumetza prescribers. Following the end of that one-year period, for a period of three years, the Company is required to make specified minimum sales force expenditures. In addition, during the term of the agreement, the Company is required to make certain minimum marketing, advertising, medical affairs and other commercial support expenditures.

Under the terms of the promotion agreement, the Company paid Depomed a $12.0 million upfront fee, and based on the achievement of specified levels of annual Glumetza net product sales, the Company may pay Depomed one-time sales milestones, totaling up to $16.0 million in aggregate. The $12.0 million upfront fee has been capitalized and included in intangible assets and is being amortized to license fee expense over the estimated useful life of the asset on a straight-line basis through mid-2016. Total amortization expense for the year ended December 31, 2008 was $750,000. Depomed pays the Company a fee ranging from 75% to 80% of the gross margin earned from all net sales of Glumetza products in the Territory, with gross margin defined as net sales less cost of goods including product-related fees paid by Depomed to Biovail Laboratories International SRL. Depomed is responsible for overseeing product manufacturing and supply and will continue to record revenue from the sales of Glumetza products. The Company is responsible for all costs associated with its sales force and for all other sales and

marketing-related expenses associated with its promotion of Glumetza products, including an initial commitment of $5.0 million in non-sales force advertising and promotional costs from signing through March 31, 2009. A joint commercialization committee has been formed to oversee and guide the strategic direction of the Glumetza alliance. The promotion agreement will continue in effect until the expiration of the last-to-expire patent or patent application with a valid claim in the Territory covering a Glumetza product, unless terminated sooner. Subject to 90 days prior written notice to Depomed, the Company may terminate the promotion agreement at any time following the 18-month anniversary of the effective date of the agreement. Subject to notice to Depomed, the Company may also terminate the agreement immediately in other circumstances, such as loss of market exclusivity or in the event of certain regulatory or governmental actions or if Depomed fails to supply the Glumetza product as reasonably necessary to meet trade demand for a period of three months or longer. Subject to 60 days prior written notice to the Company, Depomed may terminate the agreement if the Company fails to meet its obligations with respect to minimum promotion obligations and fails to cure such breach within a specified time period. Depomed may also terminate the agreement on 180 days prior written notice if the Company fails to deliver certain required information related to forecasted sales force expenditures. Either party may terminate the agreement under certain other limited circumstances.

6. Co-Promotion Agreements

Otsuka America Pharmaceutical, Inc.

On April 15, 2008, the Company provided notice to Otsuka America Pharmaceutical, Inc. ("Otsuka America") of the Company's intent to terminate their co-promotion agreement for Zegerid Capsules and Powder for Oral Suspension effective August 13, 2008, or earlier as the parties may mutually agree. On May 28, 2008, the Company and Otsuka America agreed to terminate the co-promotion agreement effective as of June 30, 2008. The Company and Otsuka America entered into the co-promotion agreement in October 2004 to co-promote Zegerid products in the U.S. through December 31, 2009, unless terminated earlier under amended terms agreed to in January 2006. Following the effective date of termination, there are no continuing financial commitments for either company, and the Company is no longer obligated to pay a high single-digit royalty on Zegerid net sales to Otsuka America. In addition, the Company amortized the remaining balance of the $15.0 million up-front payment previously received from Otsuka America in October 2004 and recognized approximately $5.7 million in license and royalty revenue in the year ended December 31, 2008 associated with this amortization.

Victory Pharma, Inc.

On July 18, 2008, the Company and Victory mutually agreed to terminate their co-promotion agreement for Victory's Naprelan prescription pharmaceutical products effective as of October 1, 2008. The Company and Victory entered into the co-promotion agreement in June 2007 to co-promote the Naprelan products in the U.S. through June 10, 2014, unless terminated earlier. The Company ended all promotional efforts under the agreement as of September 30, 2008, and Victory paid to the Company all co-promotion fees due to the Company under the agreement through such period.

C.B. Fleet Company, Incorporated

On May 6, 2008, the Company and C.B. Fleet Company, Incorporated ("Fleet") entered into an amendment to their co-promotion agreement dated August 24, 2007 regarding the co-promotion by the Company of the Fleet® Phospho-soda® EZ-Prep™ Bowel Cleansing System to gastroenterologists in the U.S. The amendment increased the maximum number of sales calls for which the Company was eligible to receive co-promotion fees from Fleet and specified the maximum number of sales calls on a monthly basis. The increase in the maximum number of sales calls increased the maximum amount of co-promotion fees that the Company was eligible to receive from approximately $3.0 million to approximately $4.8 million over the one-year term of the agreement. The co-promotion agreement expired in accordance with its terms on October 1, 2008.

7. Long-Term Debt

On July 11, 2008, the Company entered into an Amended and Restated Loan and Security Agreement (the "Amended Loan Agreement") with Comerica Bank ("Comerica"). The Amended Loan Agreement amends and

restates the terms of the original Loan and Security Agreement entered into between the Company and Comerica in July 2006. In December 2008, the Company drew down $10.0 million under the Amended Loan Agreement. The credit facility under the Amended Loan Agreement consists of a revolving line of credit, pursuant to which the Company may request advances in an aggregate outstanding amount not to exceed $25.0 million. Under the Amended Loan Agreement, the revolving loan bears interest, as selected by the Company, at either the variable rate of interest, per annum, most recently announced by Comerica as its "prime rate" plus 0.50% or the LIBOR rate (as computed in the Amended and Restated LIBOR Addendum to the Amended Loan Agreement) plus 3.00%. The Company has selected the "prime rate" plus 0.50% interest rate option, which as of December 31, 2008 was 3.75%. Interest payments on advances made under the Amended Loan Agreement are due and payable in arrears on the first calendar day of each month during the term of the Amended Loan Agreement. Amounts borrowed under the Amended Loan Agreement may be repaid and re-borrowed at any time prior to July 11, 2011. There is a non-refundable unused commitment fee equal to 0.50% per annum on the difference between the amount of the revolving line and the average daily balance outstanding thereunder during the term of the Amended Loan Agreement, payable quarterly in arrears. The Amended Loan Agreement will remain in full force and effect for so long as any obligations remain outstanding or Comerica has any obligation to make credit extensions under the Amended Loan Agreement.

Amounts borrowed under the Amended Loan Agreement are secured by substantially all of the Company's personal property, excluding intellectual property. Under the Amended Loan Agreement, the Company is subject to certain affirmative and negative covenants, including limitations on the Company's ability: to undergo certain change of control events; to convey, sell, lease, license, transfer or otherwise dispose of assets; to create, incur, assume, guarantee or be liable with respect to certain indebtedness; to grant liens; to pay dividends and make certain other restricted payments; and to make investments. In addition, under the Amended Loan Agreement the Company is required to maintain a balance of cash with Comerica in an amount of not less than $4.0 million and to maintain any other cash balances with either Comerica or another financial institution covered by a control agreement for the benefit of Comerica. The Company is also subject to specified financial covenants with respect to a minimum liquidity ratio and, in specified limited circumstances, minimum EBITDA requirements as defined in the Amended Loan Agreement. The Company has currently met all of its obligations under the Amended Loan Agreement.

8. Commitments and Contingencies

Leases

The Company leases its primary office facility and certain equipment under various operating leases. In December 2007, the Company entered into a sublease agreement for the Company's primary office facility. The sublease expires on February 27, 2013. The sublease provides for an initial annual base rent from the commencement date until March 31, 2009 payable in monthly installments. The annual base rent is subject to 3.5% annual increases on April 1 of each calendar year throughout the term. The Company is also required to pay its pro rata share of any building and project operating costs that may exceed those operating costs incurred during the 2008 calendar year. The Company received an allowance of approximately $559,000 to cover the cost of the Company's tenant improvements, which was provided in the form of an offset against the monthly installments of basic rent initially payable under the sublease. The cumulative rent to be paid under the sublease, net of the tenant allowance of approximately $559,000, is being amortized on a straight-line basis over the term of the sublease. In conjunction with the sublease, in January 2008, the Company established a letter of credit in the amount of $150,000 naming the sublessor as beneficiary. The amount of the letter of credit automatically increased to $400,000 on January 15, 2008. As long as the Company is not in default of any of the material terms of the sublease, the amount of the letter of credit will be reduced to $300,000 on October 1, 2010 and $200,000 on February 28, 2012.

In November 2004, the Company entered into a master lease agreement giving the Company the ability to lease vehicles under operating leases. In connection with the Company accepting delivery of vehicles and entering into lease obligations in January 2005, the Company established a letter of credit for $1.0 million naming the lessor as beneficiary. The letter of credit is fully secured by restricted cash and has automatic annual extensions. Each lease schedule has an initial term of 12 months from the date of delivery with successive 12-month renewal terms. The Company intends to lease each vehicle, on average, approximately 36 months. The Company guarantees a certain residual value at the lease termination date. If the Company determines that it is probable that a loss will be incurred upon disposition of a vehicle resulting from the remaining book value of the lease exceeding the current fair market

value of the vehicle, the Company accrues for the potential loss at the time of such determination.

At December 31, 2008, estimated annual future minimum payments under the Company's operating leases are as follows (in thousands):

2009	$ 2,054
2010	1,737
2011	1,243
2012	957
2013	80
Thereafter	—
Total minimum lease payments	$ 6,071

Rent expense on facilities and equipment was approximately $2.6 million, $2.5 million and $3.0 million for the years ended December 31, 2008, 2007 and 2006, respectively.

Other Long-Term Commitments

The Company has entered into other long-term commitments for services requiring the Company to make payments of approximately $74,000 and $62,000 in 2009 and 2010, respectively, and $54,000 in each year from 2011 to 2012.

In November 2006, the Company entered into a service agreement with inVentiv Commercial Services, LLC ("inVentiv"), a commercialization services organization, which was subsequently amended in June 2007 and October 2008, under which inVentiv provides contract sales representatives to promote the Company's Zegerid and Glumetza products in the U.S. The Company recognizes the revenue generated by the promotional efforts of inVentiv and pays inVentiv a fee for providing the contract sales personnel.

In consideration for inVentiv's services under the agreement, the Company pays to inVentiv a monthly fee, subject to adjustment based on actual staffing levels. In addition, under the agreement, the Company is obligated to reimburse inVentiv for approved pass-through costs, which are anticipated to primarily include bonus, meeting and travel costs, as well as other promotional costs.

The current term of the agreement expires in November 2010. The Company may terminate the agreement at any time without paying a termination fee. Moreover, either party may terminate the agreement upon an uncured material breach by the other party or upon bankruptcy or insolvency of the other party, and inVentiv may also terminate the agreement if the Company fails to make timely payments under the agreement.

Legal Proceedings

In September 2007, the Company filed a lawsuit in the United States District Court for the District of Delaware against Par Pharmaceutical, Inc. ("Par") for infringement of U.S. Patent Nos. 6,645,988; 6,489,346; and 6,699,885, each of which is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for Zegerid Capsules. In December 2007, the Company filed a second lawsuit in the United States District Court for the District of Delaware against Par for infringement of U.S. Patent Nos. 6,645,988; 6,489,346; 6,699,885; and 6,780,882, each of which is listed in the Orange Book for Zegerid Powder for Oral Suspension. The University of Missouri, licensor of the patents, is a co-plaintiff in the litigation, and both lawsuits have been consolidated for all purposes. The lawsuits are in response to Abbreviated New Drug Applications ("ANDAs") filed by Par with the FDA regarding Par's intent to market generic versions of the Company's Zegerid Capsules and Zegerid Powder for Oral Suspension products prior to the July 2016 expiration of the asserted patents. Each complaint seeks a judgment that Par has infringed the asserted patents and that the effective date of approval of Par's ANDA shall not be earlier than the expiration date of the asserted patents. Par has filed answers in each case, primarily asserting non-infringement, invalidity and/or unenforceability. Par has also filed counterclaims seeking a declaration in its favor on those issues. On July 15, 2008, the U.S. Patent and Trademark Office ("PTO") issued U.S. Patent No. 7,399,772 (the "'772 patent"), which is now listed in the Orange Book for both Zegerid Capsules and Zegerid Powder for Oral Suspension. In October 2008, the Company amended its complaint to add the '772 patent to the pending litigation

with Par. A claim construction ("Markman") hearing was held in November 2008. Following the hearing, the court adopted all of the claim constructions the Company and the University of Missouri proposed. The discovery phase of the lawsuits is continuing. Trial is currently scheduled for July 2009.

In addition, as part of this litigation, Par initially filed counterclaims seeking a declaration that U.S. Patent No. 5,840,737 (the "'737 patent") is not infringed, is invalid and/or is unenforceable. The Company moved to dismiss, or in the alternative, stay these claims due to a reissue proceeding involving the '737 patent currently pending before the PTO, and the Company and the University of Missouri also granted Par a covenant not to sue on the original '737 patent. In November 2008, Par dismissed its counterclaims relating to the '737 patent.

The Company commenced each of the lawsuits within the applicable 45 day period required to automatically stay, or bar, the FDA from approving Par's ANDAs for 30 months or until a district court decision that is adverse to the asserted patents, whichever may occur earlier. If the litigation is still ongoing after 30 months, the termination of the stay could result in the introduction of one or more products generic to Zegerid Capsules and/or Zegerid Powder for Oral Suspension prior to resolution of the litigation.

Although the Company intends to vigorously defend and enforce its patent rights, the Company is not able to predict the outcome of the litigation. Any adverse outcome in this litigation could result in one or more generic versions of Zegerid Capsules and/or Zegerid Powder for Oral Suspension being launched before the expiration of the listed patents in July 2016, which could adversely affect the Company's ability to successfully execute its business strategy to maximize the value of Zegerid Capsules and Zegerid Powder for Oral Suspension and would negatively impact the Company's financial condition and results of operations, including causing a significant decrease in our revenues and cash flows. An adverse outcome may also impact the patent protection for the products being commercialized pursuant to the Company's strategic alliances with GlaxoSmithKline plc ("GSK") and Schering-Plough, which in turn may impact the amount of, or the Company's ability to receive, milestone payments and royalties under those agreements. In addition, even if the Company prevails, the litigation will be costly, time-consuming and distracting to management, which could have a material adverse effect on the Company's business.

In December 2007, the University of Missouri filed an Application for Reissue of the '737 patent with the PTO. It is not feasible to predict the impact that the reissue proceeding may have on the scope and validity of the '737 patent claims. If the claims of the '737 patent ultimately are narrowed substantially or invalidated by the PTO, the extent of the patent coverage afforded to the Company's Zegerid family of products could be impaired, which could potentially harm the Company's business and operating results.

9. Stockholders' Equity

Authorized Shares

Effective with the Company's initial public offering in April 2004, the Company's certificate of incorporation was amended and restated to provide for authorized capital stock of 100,000,000 shares of common stock and 10,000,000 shares of undesignated preferred stock. In November 2004, in connection with the Company's adoption of the Stockholder Rights Plan, the Company designated 100,000 shares of preferred stock as Series A Junior Participating Preferred Stock.

Common Stock Offerings

In February 2006, the Company entered into a committed equity financing facility ("CEFF") with Kingsbridge Capital Limited ("Kingsbridge"), which entitled the Company to sell and obligated Kingsbridge to purchase, from time to time over a period of three years, shares of the Company's common stock for cash consideration up to the lesser of $75.0 million or 8,853,165 shares, subject to certain conditions and restrictions. In connection with the CEFF, the Company entered into a common stock purchase agreement and registration rights agreement, and the Company also issued a warrant to Kingsbridge to purchase 365,000 shares of the Company's common stock at a price of $8.2836 per share. The warrant is fully exercisable beginning after the six month anniversary of the agreement for a period of five years thereafter. The warrant was valued on the date of grant using the Black-Scholes method using the following assumptions: a risk-free interest rate of 4.5%, a volatility factor of 60%, a life of

5.5 years and a dividend yield of zero. The estimated value of the warrant was approximately $1.3 million and was recorded as a component of stockholders' equity in the year ended December 31, 2006. In 2006, the Company completed four draw downs under the CEFF and issued a total of 5,401,787 shares in exchange for aggregate gross proceeds of $36.5 million. The CEFF expired in February 2009.

On November 26, 2008, the Company filed a universal shelf registration statement on Form S-3 covering equity or debt securities with the SEC which was declared effective in December 2008. The universal shelf registration statement replaced our previous universal shelf registration statement that expired in December 2008. The universal shelf registration statement may permit us, from time to time, to offer and sell up to approximately $75.0 million of equity or debt securities. As of December 31, 2008, the Company has not issued securities under the universal shelf registration statement.

Stockholder Rights Plan

In November 2004, the Company adopted a Stockholder Rights Plan, which was subsequently amended in April 2006 and December 2008 (the "Rights Plan"). The Rights Plan provides for a dividend distribution of one Preferred Share Purchase Right (a "Right") on each outstanding share of the Company's common stock held on November 22, 2004. Subject to limited exceptions, the Rights will be exercisable if a person or group acquires 15% or more of the Company's common stock or announces a tender offer for 15% or more of the common stock. Under certain circumstances, each Right will entitle stockholders to buy one one-thousandth of a share of newly created Series A Junior Participating Preferred Stock of the Company at an exercise price of $100. The Company's Board of Directors will be entitled to redeem the Rights at $0.01 per Right at any time before a person has acquired 15% or more of the outstanding common stock.

Warrants

In 2002 and 2003, the Company issued warrants to purchase an aggregate of 1,284 shares of its common stock in connection with certain consulting services. The warrants are exercisable for a period of approximately 10 years with exercise prices ranging from $1.05 to $2.10 per share. In February 2006, in connection with the CEFF with Kingsbridge, the Company issued a warrant to Kingsbridge to purchase 365,000 shares of the Company's common stock at a price of $8.2836 per share. The warrant is fully exercisable beginning after the six month anniversary of the agreement for a period of five years thereafter. As of December 31, 2008, warrants to purchase 366,284 shares of common stock were outstanding.

Stock Option Plans

The Company has two stock option plans for the benefit of its eligible employees, consultants and independent directors. In October 1998, the Company adopted the Santarus, Inc. 1998 Stock Option Plan (the "1998 Plan"). The 1998 Plan was initially approved by the Company's stockholders in November 1998. The 1998 Plan, as amended, authorized the Company to issue options to purchase up to 4,171,428 shares of its common stock. Under the terms of the 1998 Plan, nonqualified and incentive options were granted at prices not less than 85% and 100% of the fair value on the date of grant, respectively. With the completion of the Company's initial public offering in April 2004, no additional options have been or will be granted under the 1998 Plan, and all options that are repurchased, forfeited, cancelled or expire will become available for grant under the 2004 Plan.

In January 2004, the Company adopted the 2004 Equity Incentive Award Plan (the "2004 Plan"). The 2004 Plan was approved by the Company's stockholders in February 2004, became effective with the Company's initial public offering in April 2004 and was subsequently amended and restated in July 2004. As of December 31, 2008, the Company was authorized to issue options to purchase 13,233,287 shares of its common stock under the 2004 Plan and had 2,801,979 shares available for future issuance. In addition, the 2004 Plan contains an "evergreen provision" that allows for an annual increase in the number of shares available for issuance on the first day of the fiscal year, equal to the lesser of 5% of the outstanding capital stock on each January 1, 2,500,000 shares, or an amount determined by the Company's board of directors. Effective January 1, 2009, the number of shares available for issuance was increased by 2,500,000 shares through the "evergreen provision." The number of shares of common stock available for issuance will be further increased by any options that are repurchased, forfeited, cancelled or expire under the 1998 Plan.

Options generally vest over periods ranging from one to four years and expire ten years from the date of grant. In 2008, certain stock options were granted to employees at or above the vice president level that vest upon the attainment of specific financial performance targets. Certain options are immediately exercisable, and unvested common shares obtained upon early exercise of options are subject to repurchase by the Company at the original issue price. As of December 31, 2008, there were no unvested common shares outstanding subject to repurchase by the Company.

A summary of stock option activity is as follows:

Options	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2008	9,948,464	$ 5.57		
Granted	2,930,927	2.32		
Exercised	(101,158)	0.76		
Forfeited	(319,927)	2.50		
Expired	(542,738)	7.32		
Outstanding at December 31, 2008	11,915,568	$ 4.82	7.45	$ 662
Exercisable at December 31, 2008	8,396,620	$ 5.51	6.84	$ 662

The aggregate intrinsic value of options outstanding and options exercisable at December 31, 2008 is calculated as the difference between the exercise price of the underlying options and the market price of the Company's common stock for the shares that had exercise prices that were lower than the $1.57 closing price of the Company's common stock on December 31, 2008. The total intrinsic value of options exercised in the years ended December 31, 2008, 2007 and 2006 was approximately $93,000, $228,000 and $1.5 million, respectively, determined as of the date of exercise. The Company received approximately $77,000, $276,000 and $1.5 million in cash from options exercised in the years ended December 31, 2008, 2007 and 2006, respectively.

The Company accounts for options issued to non-employees under SFAS No. 123(R) and EITF Issue No. 96-18, *Accounting for Equity Investments that are Issued to Other than Employees for Acquiring or in Conjunction with Selling Goods or Services*. As such, the value of options issued to non-employees is periodically remeasured as the underlying options vest. For the years ended December 31, 2007 and 2006, stock-based compensation related to stock options issued to non-employees was approximately $46,000 and $505,000 respectively. There was no stock-based compensation in 2008 related to stock options issued to non-employees.

For the years ended December 31, 2008, 2007 and 2006, the Company recognized approximately $4.2 million, $11.8 million and $9.3 million, respectively, of total stock-based compensation in accordance with SFAS No. 123(R) and EITF Issue No. 96-18.

Employee Stock Purchase Plan

In April 2004, the Company implemented the employee stock purchase plan, which was approved by the Company's stockholders in February 2004 and subsequently amended and restated in July 2004 and November 2007. Under the Amended and Restated Employee Stock Purchase Plan (the "ESPP"), employees may contribute up to 20%, subject to certain maximums, of their cash earnings through payroll deductions, to be used to purchase shares of the Company's common stock on each semi-annual purchase date. The purchase price will be equal to 85% of the market value per share on the employee's entry date into the offering period, or if lower, 85% of the fair market value on the specified purchase date. The Company initially reserved 400,000 shares of common stock for issuance under the ESPP. In addition, the ESPP contains an "evergreen provision" that allows for an annual increase in the number of shares available for issuance on the first day of the fiscal year, equal to the lesser of 1% of the outstanding capital stock on each January 1, 500,000 shares, or an amount determined by the Company's board of directors. As of December 31, 2008, the Company had issued 2,090,785 shares of common stock under the ESPP and had 117,169 shares available for future issuance. Effective January 1, 2009, the number of shares available for

issuance was increased by 500,000 shares through the "evergreen provision."

Shares Reserved for Future Issuance

Common stock reserved for future issuance as of December 31, 2008 and 2007 are as follows:

	December 31,	
	2008	2007
Stock options issued and outstanding	11,915,568	9,948,464
Authorized for future issuance under equity compensation plans	2,919,148	2,370,355
Stock warrants outstanding	366,284	366,284
	15,201,000	12,685,103

10. 401(k) Plan

The Company maintains a defined contribution 401(k) plan available to eligible employees. Employee contributions are voluntary and are determined on an individual basis, limited to the maximum amount allowable under federal tax regulations. Effective in January 2007, the Company matches 25% of employee contributions up to 6% of eligible compensation, with cliff vesting over five years from the date of hire. Employer contributions were approximately $416,000 in 2008 and $376,000 in 2007.

11. Income Taxes

On July 13, 2006, the FASB issued Financial Interpretation ("FIN") No. 48, *Accounting for Uncertainty in Income Taxes – An Interpretation of FASB Statement No. 109*. FIN No. 48 clarifies the accounting for uncertainty in income taxes recognized in an entity's financial statements in accordance with SFAS No. 109, *Accounting for Income Taxes,* and prescribes a recognition threshold and measurement attributes for financial statement disclosure of tax positions taken or expected to be taken on a tax return. Under FIN No. 48, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, FIN No. 48 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN No. 48 is effective for fiscal years beginning after December 15, 2006.

The Company adopted the provisions of FIN No. 48 on January 1, 2007. There were no unrecognized tax benefits as of the date of adoption and there are no unrecognized tax benefits included in the balance sheet at December 31, 2008 that would, if recognized, affect the effective tax rate.

The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no interest and/or penalties accrued on the Company's balance sheets at December 31, 2008 and 2007, and has not recognized any interest and/or penalties in the statement of operations for the years ended December 31, 2008 and 2007.

The following is a reconciliation of the unrecognized tax benefits during 2008 (in thousands):

Unrecognized tax benefits at January 1, 2008	$	—
Gross decreases related to prior year tax positions		—
Gross increases related to current year tax positions		1,728
Settlements		—
Lapse of statute of limitations		—
Unrecognized tax benefits at December 31, 2008	$	1,728

The Company is subject to taxation in the United States and various state jurisdictions. The Company's tax years for 1997 and forward are subject to examination by the United States and California tax authorities due to the carryforward of unutilized net operating losses and research and development credits.

Pursuant to Sections 382 and 383 of the Internal Revenue Code ("IRC"), annual use of the Company's net operating loss and research and development credit carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three year period. The Company determined that no ownership change had occurred through December 31, 2008 as defined in the provision of Section 382 of the IRC. Since no ownership change has yet occurred, there is no limitation with regards to the usage of net operating loss and research and development credit carryforwards as of December 31, 2008. Therefore, the Company re-established the deferred tax assets for net operating losses and research and development credits that were removed from deferred tax assets in 2007.

Although the Company had a book loss for 2008, the Company does have taxable income due to the disallowance of certain deductions until future years. The Company had a total income tax expense of approximately $534,000 for the year ended December 31, 2008 which is comprised of Federal and state tax liabilities. The Company was subject to the Federal Alternative Minimum Tax totaling approximately $302,000 for the year ended December 31, 2008. The significant components of the state tax expense were related to tax liabilities in California, Michigan and Texas. The Company generated a tax liability in the state of California due to the suspension of the net operating loss carryforwards for the 2008 and 2009 tax years. The tax liabilities for Michigan and Texas were related to modified business taxes and/or gross margin taxes.

At December 31, 2008, the Company had Federal and state income tax net operating loss carryforwards of approximately $202.0 million and $162.0 million, respectively. The Federal and California tax loss carryforwards will begin to expire in 2012, unless previously utilized. The Company has other state tax loss carryforwards that will begin to expire in 2009, unless previously utilized. In addition, the Company has Federal and California research and development credit carryforwards of approximately $2.8 million and $1.0 million, respectively. The Federal research and development credit carryforwards will begin to expire in 2018 unless previously utilized. The California research and development credits carry forward indefinitely.

Significant components of the Company's deferred tax assets as of December 31, 2008 and 2007 are listed below. A valuation allowance of $110.5 million and $18.6 million at December 31, 2008 and 2007, respectively, has been recognized to offset the net deferred tax assets as realization of such assets is uncertain. Amounts are shown as of December 31, of the respective years (in thousands):

	December 31,	
	2008	2007
Deferred tax assets:		
Net operating loss carryforwards	$ 77,052	$ —
Research and development credits	3,510	—
Capitalized research and development	162	177
Depreciation and amortization	5,285	139
Accrued rebates	9,842	7,367
Deferred revenue	4,101	6,098
Allowance for product returns	3,876	2,249
Other	6,662	2,563
Total deferred tax assets	110,490	18,593
Valuation allowance	(110,490)	(18,593)
Net deferred tax assets	$ —	$ —

12. Quarterly Financial Information (unaudited)

The following table sets forth quarterly results of operations for each quarter within the two-year period ended December 31, 2008. The information for each of these quarters is unaudited and has been prepared on the same basis as the Company's audited financial statements. In the opinion of management, all necessary adjustments, consisting only of normal recurring accruals, have been included to fairly present the unaudited quarterly results when read in conjunction with the Company's audited financial statements and related notes. The operating results of any quarter are not necessarily indicative of results for any future period.

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	(in thousands, except per share amounts)			
2008:				
Product sales, net	$ 19,415	$ 23,954	$ 28,106	$ 29,745
Total revenues	24,466	36,005	32,209	37,521
Cost of product sales	1,695	1,701	1,924	2,025
Total costs and expenses	32,646	33,062	36,338	47,328
Net income (loss)	(7,619)	3,205	(3,952)	(10,151)
Basic and diluted net income (loss) per share	(0.15)	0.06	(0.08)	(0.19)
2007:				
Product sales, net	$ 17,027	$ 18,800	$ 19,527	$ 24,049
Total revenues	18,958	20,730	26,458	28,282
Cost of product sales	1,647	1,663	1,782	2,209
Total costs and expenses	36,312	34,427	34,065	36,966
Net income (loss)	(16,436)	(12,936)	(6,902)	(7,991)
Basic and diluted net loss per share	(0.32)	(0.25)	(0.13)	(0.16)

Schedule II – Valuation and Qualifying Accounts
(in thousands)

	Balance at Beginning of Period	Additions: Provision Related to Current Period Sales	Additions: Charged Against Balance Sheet Accounts	Deductions: Actual Cash Discounts, Chargebacks, and Other Discounts Related to Current Period Sales	Deductions: Actual Cash Discounts, Chargebacks, and Other Discounts Related to Prior Period Sales	Balance at End of Period
Allowance for cash discounts, chargebacks, and other sales discounts:						
For the year ended December 31, 2008	$ (1,527)	$ (14,051)	$ -	$ 11,484	$ 846	$ (3,248)
For the year ended December 31, 2007	(687)	(7,153)	-	5,876	437	(1,527)
For the year ended December 31, 2006	(245)	(3,175)	100	2,486	147	(687)

	Balance at Beginning of Period	Additions Charged to Costs and Expenses	Deductions	Balance at End of Period
Allowance for excess and obsolete inventory:				
For the year ended December 31, 2008	$ (166)	$ (178)	$ 36 (1)	$ (308)
For the year ended December 31, 2007	(409)	(195)	438 (1)	(166)
For the year ended December 31, 2006	(207)	(397)	195 (1)	(409)

	Balance at Beginning of Period	Additions: Provision Related to Current Period Sales	Additions: Provision Related to Prior Period Sales	Deductions: Actual Returns or Credits Related to Current Period	Deductions: Actual Returns or Credits Related to Prior Period	Other	Balance at End of Period
Allowance for product returns:							
For the year ended December 31, 2008	$ (5,947)	$ (6,080)	$ -	$ 39	$ 1,737	$ -	$ (10,251)
For the year ended December 31, 2007	(1,623)	(4,495)	(1,895)	43	2,023	-	(5,947)
For the year ended December 31, 2006	(4,464)	-	-	-	-	2,841 (2)	(1,623)

(1) Deductions in allowance for excess and obsolete inventory represent physical disposition of inventory.

(2) Deductions in allowance for product returns represent actual product returns of approximately $1.9 million and a reduction in the allowance due to the determination that the Company could reasonably estimate future product returns.

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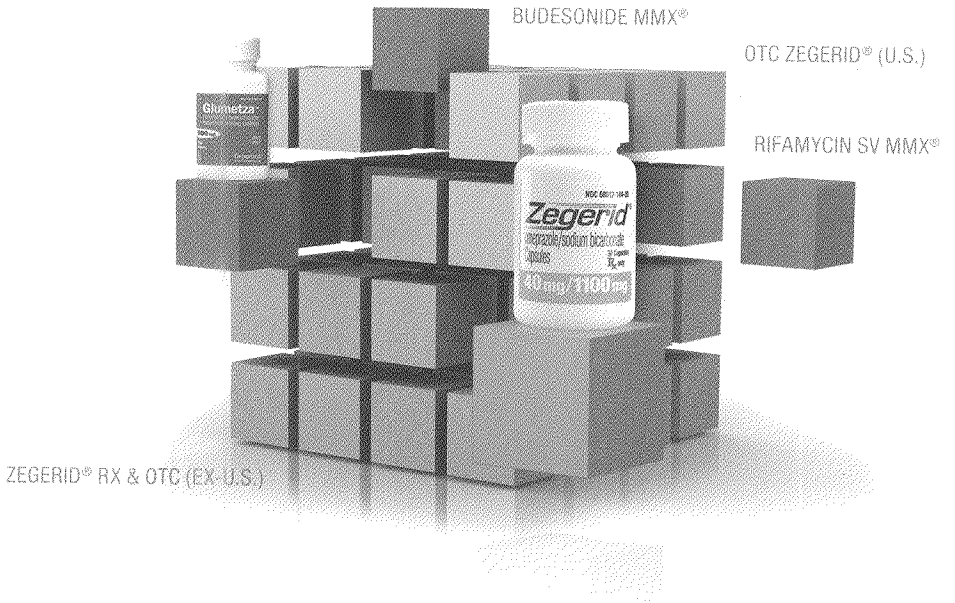
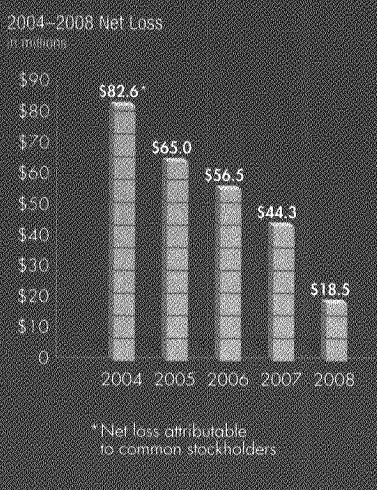
SANTARUS 08 ANNUAL REPORT

What's New?



Santarus is pleased to demonstrate its commitment to its shareholders by using this green annual report format. To see our online interactive annual report go to www.santarus.com/ar2008.

We are pleased to report a year of substantial progress in which we grew revenues and effectively managed our costs, added an important new product to our commercial portfolio and licensed two late-stage lower GI product candidates for our development pipeline. These accomplishments reflect solid execution of our strategy and move us closer to our goal of becoming a premier specialty pharmaceutical company.



DEAR STOCKHOLDERS:

We achieved record total revenues in 2008 of $130.2 million, up 38% over 2007, which included a 37% increase in product-related revenues to $111.0 million and a 45% increase in license and royalty revenue to $19.2 million. Our record product revenues were mainly driven by the growth of ZEGERID® (omeprazole/sodium bicarbonate) net sales, which grew 27% from 2007 – a substantial increase given the challenging overall dynamics in the proton pump inhibitor (PPI) market. In fact, ZEGERID was the only branded PPI last year with reported double-digit prescription growth.

We also reduced our net loss in 2008 by 58% to $18.5 million compared with 2007. Notably, our 2008 net loss included $13.9 million in fees and expenses associated with our strategic collaboration for two late-stage development products, which we announced in December 2008. We reduced our operating cash burn for 2008 to approximately $6.5 million and are pleased to report that we generated approximately $7.2 million in positive cash flow from operating activities in the fourth quarter of 2008.

In December 2008, we licensed the exclusive right to develop and commercialize budesonide MMX® and rifamycin SV MMX® for the U.S. market through a strategic collaboration with Cosmo Technologies Limited (Cosmo), a wholly owned subsidiary of Cosmo Pharmaceuticals SpA.

In July 2008, we obtained the exclusive right to promote GLUMETZA® (metformin hydrochloride extended release tablets) in the U.S. through a promotion agreement with Depomed, Inc. GLUMETZA is a once-daily, extended-release formulation of metformin that incorporates patented drug-delivery technology and is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes.

We reported solid growth of our immediate-release ZEGERID products and initial success with extended-release GLUMETZA in 2008. We intend to continue building on this momentum in 2009.

Gerald T. Proehl
President and
Chief Executive Officer

David F. Hale
Chairman of the Board

ZEGERID Capsules and Powder for Oral Suspension New and total prescriptions for ZEGERID grew each sequential quarter throughout 2008 as we continued to gain share within our called-on physicians in the PPI market. We were able to achieve this growth by maintaining a significant presence with our targeted group of gastroenterologists and high-PPI prescribing primary care physicians, while effectively reducing our promotional spending.

We believe our sales organization's consistent delivery of messages about ZEGERID's product attributes to our targeted physicians throughout the year led to our 26% increase in total prescriptions compared with the prior year. As further evidence of our success, our market research indicates that awareness of the ZEGERID brand increased with our targeted physicians in 2008 compared with 2007, reaching levels that we believe are comparable to those of the other branded PPIs with these same physicians.

Results of Phase IV pharmacodynamic clinical trials with ZEGERID conducted over the last few years have strengthened our message of rapid and continued acid control in the daytime and nighttime – a message that we believe differentiates ZEGERID from delayed-release PPIs. In our most recent study announced in early 2008, we compared immediate-release ZEGERID Capsules with two branded, delayed-release PPIs to evaluate the effect of morning PPI dosing over seven days on 24-hour gastric acid control in 51 patients with symptoms of GERD. The results, which were presented in an abstract at the May 2008 Digestive Disease Week meeting, showed that patients taking ZEGERID reached a gastric pH greater than 4 (a pH level greater than 4 is a typical measure of gastric acid control) in 20 minutes, which was

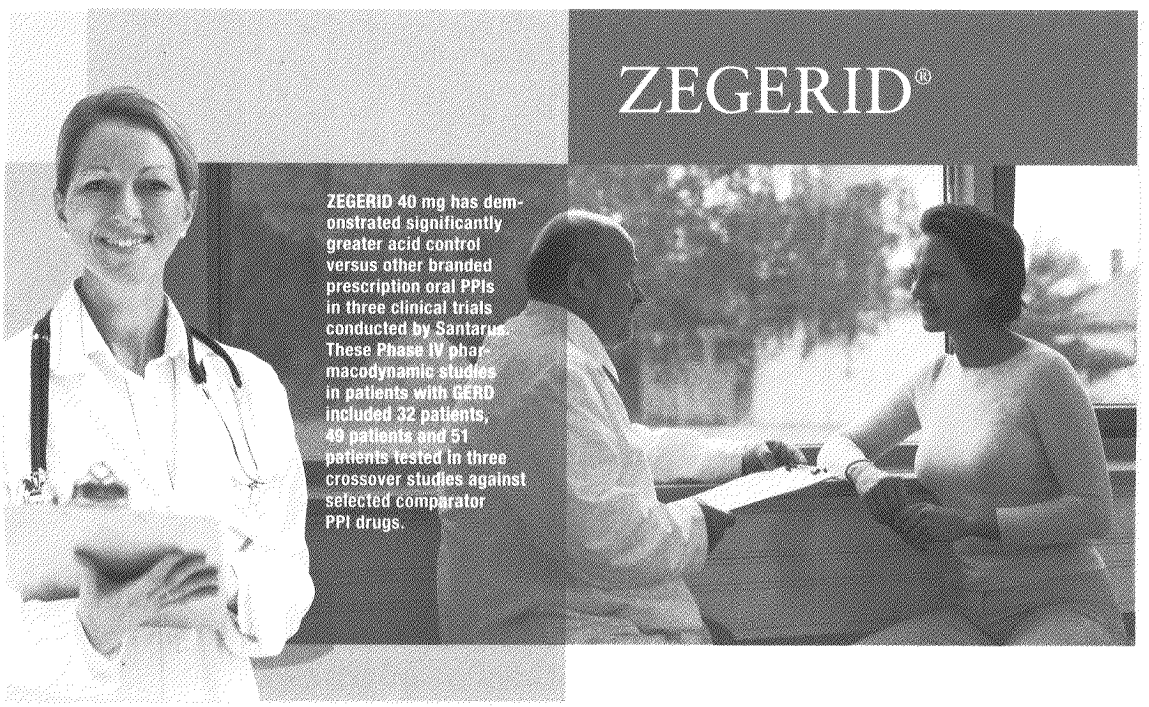
ZEGERID OFFERS IMMEDIATE-RELEASE
AND CONTINUED ACID CONTROL

significantly faster than the comparator drugs. In addition, the control of gastric acid, measured as the percent time with gastric pH greater than 4, for patients taking ZEGERID was approximately 43% longer than patients treated with the comparator drugs. This new data showing ZEGERID's acid control in the daytime adds to two other Phase IV pharmacodynamic clinical studies that demonstrated ZEGERID's ability to control acid when taken at night on an empty stomach compared with the comparator delayed-release PPIs.

We are pleased to report that ZEGERID prescriptions continued to grow in the second half of 2008 following the termination of our co-promotion agreement with Otsuka America Pharmaceutical in June 2008 – a decision we made based on our assessment that, due to lower promotion by competitors, we could maintain our share of voice while significantly reducing our expenses. In addition, we saw improvement in our average selling price for ZEGERID in 2008, with positive contribution from the pricing actions taken early in the year.

We also reported progress related to our patent infringement litigation with Par Pharmaceutical, Inc. for infringement of patents listed in the Orange Book for ZEGERID. In November 2008, we reported a successful outcome in our patent claims construction, or Markman, hearing. At the hearing, Par disputed the meaning of several terms in our patent claims. At the conclusion of the hearing, the court rejected all of Par's arguments and adopted our proposed constructions. The trial related to this patent litigation is currently scheduled to begin in July 2009.

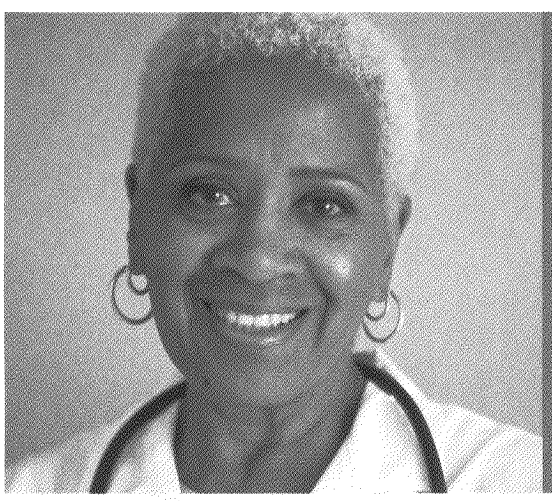
Full prescribing information for ZEGERID may be obtained by calling toll-free at (888) 778-0887 or by visiting www.Zegerid.com.



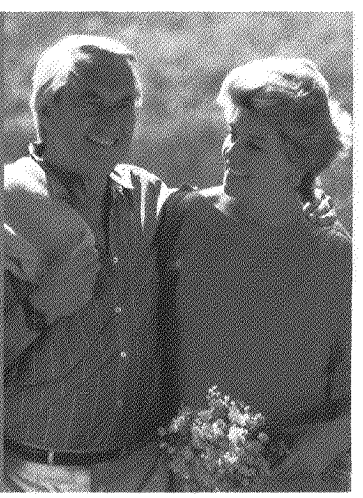
OTC License Agreement with Schering-Plough In June 2008, we received a milestone payment of $2.5 million from our agreement with Schering-Plough HealthCare Products related to progress in developing a ZEGERID branded 20 mg omeprazole product for the over-the-counter (OTC) heartburn market in the U.S., a market we estimate to be approximately $1.5 billion in size. This milestone was earned upon the U.S. Food and Drug Administration's (FDA) acceptance for filing of a New Drug Application (NDA) submitted by Schering-Plough for the OTC ZEGERID product. In January 2009, we announced that Schering-Plough received a Complete Response Letter from the FDA for its NDA. We are in regular communications with Schering-Plough, who continues to work closely with the FDA to define the nature and content of the response to the FDA. We believe that the response will be based on further analysis of existing data. If the analysis of existing data is acceptable to the FDA, Santarus does not believe there will be a need for an additional clinical study.

License and Distribution Agreement with GlaxoSmithKline In November 2007, we entered into a license agreement and a distribution agreement granting exclusive rights to GlaxoSmithKline Limited, an affiliate of GlaxoSmithKline plc (GSK) to commercialize prescription and OTC immediate-release omeprazole products in a number of international markets and to distribute and sell ZEGERID products in Puerto Rico and the U.S. Virgin Islands (USVI). Currently GSK is working to prepare the necessary regulatory filings to obtain marketing approval authorization in various countries covered by the license agreement. GSK also began distributing our ZEGERID products in Puerto Rico and the USVI in February 2008.

Immediate-release Tablet Formulation In January 2009, we submitted to the FDA an NDA for an immediate-release tablet formulation of ZEGERID, which combines omeprazole with a mix of buffers. This new tablet has the potential to provide features and benefits that we believe will be important to physicians and their patients with gastroesophageal reflux disease (GERD). Pursuant to Prescription Drug User Fee Act (PDUFA) guidelines, Santarus expects the FDA will complete its review or otherwise respond to the NDA by December 4, 2009.



Schering-Plough is developing a ZEGERID branded 20 mg omeprazole product for the OTC heartburn market in the U.S., a market estimated to be $1.5 billion in size.

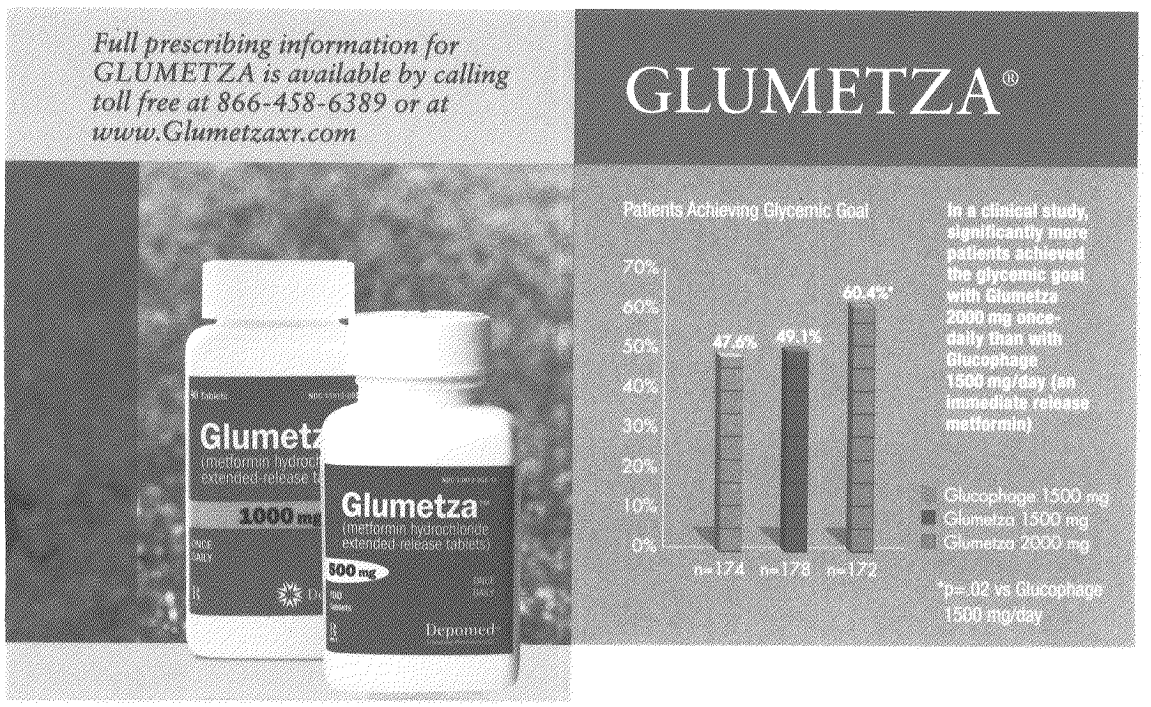


GLUMETZA Our initial promotional activities with GLUMETZA, which we began detailing in October 2008, have been successful. In fact, for the fourth quarter of 2008 we reported a $4.7 million contribution to our promotion revenue. Further, with a six percent sequential increase in new prescriptions in our first quarter of promotion, we exceeded our initial goal, which was to stabilize scripts in the first several months of promotion. Our early success followed previous sales declines for GLUMETZA during the first three quarters of the year when the product was promoted by Depomed through a much smaller sales force from January 2008 to September 2008.

We obtained rights to GLUMETZA in July 2008 under an exclusive U.S. promotion agreement with Depomed. Under our agreement, we paid a $12 million upfront fee, and may pay additional one-time sales milestones of up to $16 million in the aggregate based on the success of our GLUMETZA promotional efforts. Depomed records net sales of GLUMETZA and pays Santarus a fee ranging from 75% to 80% of the gross margin on all GLUMETZA sales in the U.S.

We believe GLUMETZA has attributes that differentiate it from other metformin products. In particular, it may allow physicians to bring patients to an optimal level of glycemic control with fewer discontinuations of therapy due to GI side effects. In a pivotal clinical trial, significantly more patients reached their glycemic goal with GLUMETZA at 2000 mg taken daily than with immediate-release metformin at 1500 mg per day. Many patients do not reach the level of glycemic control recommended by the American Diabetes Association due to their inability to tolerate the GI side effects associated with higher dosages of metformin.

Our sales organization has welcomed the promotion of GLUMETZA with enthusiasm and is finding that physicians are receptive to the product's features and benefits. GLUMETZA also has good prescribing overlap with ZEGERID in our called-on primary care physicians. We intend to build a solid and growing base of GLUMETZA business in 2009 and over the longer term.

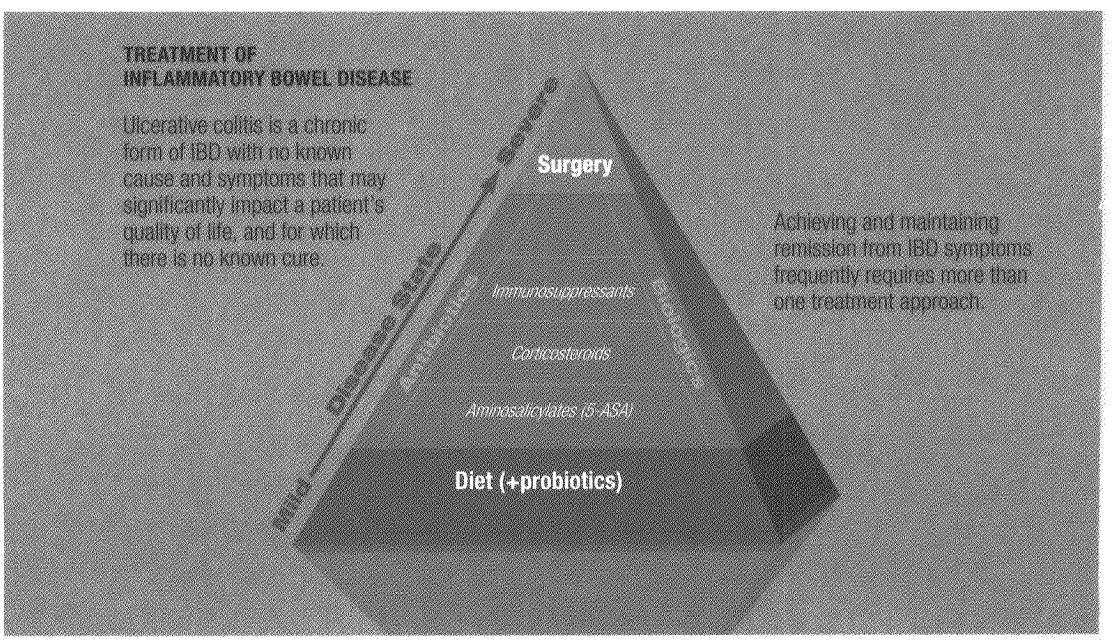


Strategic Collaboration with Cosmo Late last year we announced a strategic collaboration with Cosmo that granted Santarus exclusive rights to develop and commercialize in the U.S. two proprietary product candidates, budesonide MMX and rifamycin SV MMX, for lower GI conditions. Budesonide MMX and rifamycin SV MMX are formulated using Cosmo's patented Multi Matrix System (MMX) delivery technology, which is designed to produce a controlled-release, homogeneous local application of drug throughout the entire colon. The MMX technology is designed to retain the proven effectiveness of corticosteroid or antibiotic therapy, but potentially offers an opportunity for reduced side effects due to its targeted controlled release and limited systemic absorption. The licensing of these product candidates was an important step that supports our stated strategic objective to develop a pipeline of late-stage GI products.

For these exclusive rights, we paid an upfront fee of $2.5 million and issued to Cosmo 6 million shares of Santarus common stock. Under terms of the agreement, we may also pay Cosmo up to a total of $9 million in clinical and regulatory milestones for initial indications for the two product candidates and up to $57.5 million in commercial milestones. We will also pay tiered royalties to Cosmo ranging from 12% to 14% on net sales of licensed MMX products we sell, and Cosmo will manufacture and supply our MMX product requirements.

Importantly, we will share the cost of late-stage clinical development of the two product candidates with Cosmo, giving us the opportunity to incur significantly lower expenses in Phase III clinical testing compared with undertaking these trials on our own.

Budesonide MMX in Ulcerative Colitis Ulcerative colitis is a chronic form of inflammatory bowel disease (IBD) with no known cause and symptoms that may significantly impact a patient's quality of life, and for which there is no known cure. We see a significant unmet need for a locally acting steroid, such as budesonide MMX, for the treatment of ulcerative colitis. Mesalamine (an anti-inflammatory drug also



known as a 5-ASA) is typically used for first-line therapy for patients suffering from ulcerative colitis, but it is reported in the clinical literature that up to 30 percent of ulcerative colitis patients also require treatment with cortico-steroids. Systemically absorbed corticosteroids are currently used only for the short-term treatment of ulcerative colitis due to the significant side effects of these powerful anti-inflammatory drugs. Our goal is to develop a formulation of a corticosteroid that can be used to treat patients with ulcerative colitis for longer periods of time and with reduced side effects compared with current standard oral corticosteroid therapy.

We believe that the MMX technology may hold the key to achieving this goal. It has a solid efficacy profile, having recently been commercially introduced in the U.S. by Shire plc in a successful drug (Lialda®) that is a MMX formulation of mesalamine indicated for the treatment of ulcerative colitis.

Based on U.S. government prevalence statistics, we estimate that IBD affects approximately 1.2 million Americans, including more than 730,000 patients with ulcerative colitis. According to data from IMS Health, an independent market-research firm, the U.S. market for prescription products (excluding anti-TNF biologic drugs) for the treatment of IBD had total sales of more than $1.2 billion during 2008.

Budesonide MMX is currently being studied in two multicenter, double-blind, placebo-controlled Phase III clinical trials in North America and Europe as a first-line treatment to evaluate induction of remission in patients with mild or moderate active ulcerative colitis. We will be responsible for one-half of the total out-of-pocket costs associated with the two budesonide MMX Phase III clinical trials. The protocols for the Phase III clinical trials have been reviewed and approved by the FDA under Special Protocol Assessments.

- In each trial, patients are being dosed with budesonide MMX at either 6 mg or 9 mg once daily, compared to placebo, over an eight-week course of treatment.

SANTARUS PORTFOLIO AND PIPELINE

Drug	Partner	Indication	Ph I	Ph II	Ph III	NDA	Marketed
ZEGERID® Capsules and Powder for Oral Suspension (Rx–U.S.)		Heartburn/GERD, Erosive Esophagitis, Duodenal and Gastric Ulcers					
GLUMETZA® (Rx–U.S.)	Depomed	Type 2 Diabetes					
OTC ZEGERID® (U.S.)	Schering-Plough	Heartburn**					
ZEGERID® Tablet Formulation (Rx–U.S.)		Heartburn/GERD, Erosive Esophagitis, Duodenal and Gastric Ulcers**					
ZEGERID® Rx & OTC (Ex–U.S.)*	GSK	Heartburn/GERD, Erosive Esophagitis, Duodenal and Gastric Ulcers**					
Budesonide MMX® (U.S.)	Cosmo	Mild or Moderate Active Ulcerative Colitis**					
Rifamycin SV MMX® (U.S.)	Cosmo	Traveler's Diarrhea**					

GSK is also currently promoting ZEGERID Rx products in Puerto Rico and USVI.
***Subject to receipt of FDA and foreign regulatory approval.*

- Included in each trial is a fourth arm to compare an active reference drug, with the U.S. registration trial using Asacol® tablets and the European trial using Entocort® EC Capsules as the active comparators. Asacol is a mesalamine drug indicated for the treatment of ulcerative colitis and Entocort EC is a budesonide drug indicated for the treatment of Crohn's disease.

- The two trials are expected to enroll approximately 900 patients, or more than 100 patients per arm. In addition, up to 150 patients are expected to continue in a 12-month extended-use trial required by the FDA comparing budesonide MMX at a dosage strength of 6 mg to placebo.

- The primary endpoint of the Phase III clinical trials is the percentage of patients achieving clinical remission in each of the budesonide MMX groups versus the placebo groups after eight weeks of treatment. Clinical remission will be measured by an Ulcerative Colitis Disease Activity Index score.

Patient enrollment began in mid-2008 in Europe and in the third quarter of 2008 in the U.S. Assuming patient enrollment continues as planned, we currently expect that we will have preliminary results from the Phase III program, excluding the extension trial, during the first half of 2010. Assuming successful and timely completion of the Phase III program, including the extension trial, we plan to submit an NDA for budesonide MMX to the FDA in 2011.

Rifamycin SV MMX in Traveler's Diarrhea We and Cosmo held a pre-investigational new drug meeting with the FDA in January 2009 regarding our rifamycin SV MMX product candidate. Because rifamycin SV has not been approved for any indication in the U.S., it is considered a new molecular entity and will require additional development activities to be completed prior to an investigational new drug (IND) application submission. These studies include a multiple-dose pharmacokinetic study and a single-dose food effect study in healthy volunteers, as well as a genotoxicity study in an appropriate animal species and a reproductive toxicity study. Cosmo has agreed to conduct and fund these studies. Assuming successful completion of these activities, we expect to file an IND and initiate the Phase III U.S. registration clinical trial in traveler's diarrhea in the first half of 2010.

Left to right: William Denby, Senior Vice President, Commercial Operations; Julie DeMeules, Senior Vice President, Human Resources; Mike Step, Senior Vice President, Corporate Development; Debra Crawford, Senior Vice President and Chief Financial Officer; Gerald Proehl, President and Chief Executive Officer; Maria Bedoya-Toro, Vice President, Regulatory Affairs and Quality Assurance.

We will conduct and pay only for the Phase III U.S. registration trial while Cosmo and its European partner are responsible for the European Phase III clinical trial. Both trials are intended to support U.S. regulatory approval. We will seek to conduct the U.S. registration study at clinical sites in countries where traveler's diarrhea occurs with high frequency.

Moving Forward We are optimistic about our prospects for 2009 as we continue to build Santarus into a premier specialty pharmaceutical company. In the near term we are keenly focused on increasing revenues from ZEGERID and GLUMETZA, while managing expenses. Over the medium term we are seeking to diversify our sources of revenues through our OTC license agreement with Schering-Plough in North America and our licensing agreement with GSK in international markets. Over the longer term we will work to successfully develop our pipeline of late-stage lower GI product candidates that we believe represents significant upside potential in the years to come.

On behalf of the board of directors and management of Santarus, we thank you for your interest and continued support and invite you to watch our progress.

Sincerely,

Gerald T. Proehl
President and Chief Executive Officer

David F. Hale
Chairman of the Board

April 6, 2009

David Ballard, Senior Vice President, Clinical Research and Medical Affairs; Carey Fox, Senior Vice President, General Counsel; Warren Hall, Senior Vice President, Manufacturing and Product Development

2008 ANNUAL REPORT

What's New?

Recipients of the Santarus Leadership Award are individuals who consistently demonstrate outstanding leadership while obtaining exceptional results. These individuals exemplify the culture and core values of Santarus.

2008 LEADERSHIP AWARD RECIPIENTS

Top (left to right): Philip Yeung, Manager, Medical Affairs; Wendie Konold, Manager, Human Resources; Seth Barker, District Sales Manager; Henry Loret de Mola, Regional Account Manager; David Bavozzino, District Sales Manager; Jeff Wagner, Senior Director, Trade Sales and Development. Bottom (left to right): John Hicks, Senior Manager, Business Development; Chris Leon, Senior Manager, QA & Compliance; Jolene Elliott, Senior Manager, Finance and Administration; Rob Ackles, Senior Manager, Training and Development; Drew Romito, District Sales Manager; Carl Eisele, District Sales Manager.

IMPORTANT SAFETY INFORMATION

ZEGERID® Capsules and Powder for Oral Suspension The most frequently reported adverse events with ZEGERID are headache, diarrhea, and abdominal pain. In 178 critically ill patients treated with ZEGERID Powder for Oral Suspension, adverse events generally reflected the serious, underlying medical condition of the patients, but some adverse events occurred with more frequency in patients treated with ZEGERID Powder for Oral Suspension than in those treated with the comparator (acid-controlling) drug. For more information about these and other events, please see Table 13 of the full Prescribing Information at www.Zegerid.com. Symptomatic response to therapy does not preclude the presence of gastric malignancy. Atrophic gastritis has been noted occasionally in gastric corpus biopsies from patients treated long term with omeprazole. ZEGERID Capsules contain 304 mg of sodium per dose. ZEGERID Powder for Oral Suspension contains 460 mg of sodium per dose. This should be taken into consideration for patients on a sodium-restricted diet. Sodium bicarbonate is contraindicated in patients with metabolic alkalosis and hypocalcemia. ZEGERID is contraindicated in patients with known hypersensitivity to any component of the formulation. Since both 20 mg and 40 mg ZEGERID contain the same amount of sodium bicarbonate (1100 mg in capsules, 1680 mg in packets of powder for oral suspension), two 20 mg capsules are not equivalent to, and should not be substituted for, one 40 mg capsule, and two 20 mg packets are not equivalent to, and should not be substituted for, one 40 mg packet.

GLUMETZA® GLUMETZA is contraindicated in patients with renal disease or renal dysfunction (e.g., as suggested by serum creatinine levels greater than or equal to 1.5 mg/dL in males and greater than or equal to 1.4 mg/dL in females), known hypersensitivity to metformin HCl, and acute or chronic metabolic acidosis, including diabetic ketoacidosis with or without coma. As with all metformins, there is a boxed warning regarding lactic acidosis with GLUMETZA due to metformin accumulation during treatment. Lactic acidosis is a rare but potentially fatal occurrence. It may also occur in association with a number of pathophysiologic conditions. The risk of lactic acidosis increases with the degree of renal dysfunction and the patient's age, especially patients 80 years of age or older. In clinical trials of GLUMETZA combined with a sulfonylurea, the most common side effects included hypoglycemia, diarrhea, and nausea.

Safe Harbor Statement

Any statements in this report and the information incorporated herein by reference about our expectations, beliefs, plans, objectives, assumptions or future events or performance that are not historical facts are forward-looking statements. You can identify these forward-looking statements by the use of words or phrases such as "believe," "may," "could," "will," "estimate," "continue," "anticipate," "intend," "seek," "plan," "expect," "should," or "would." Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties inherent in our business including, without limitation: our ability to increase market demand for, and sales of, our Zegerid and Glumetza products; the scope and validity of patent protection for our products, including the outcome and duration of our patent infringement lawsuit against Par Pharmaceutical, Inc., and our ability to commercialize products without infringing the patent rights of others; whether we are successful in generating revenue under our strategic alliances, including our over-the-counter license agreement with Schering-Plough and our license and distribution agreements with GSK; our ability to successfully develop (including successful completion of the ongoing and planned phase III clinical trials) and obtain regulatory approval for our budesonide MMX and rifamycin SV MMX product candidates in a timely manner or at all; whether the FDA completes its review and approves the NDA for the new tablet formulation of our Zegerid products in a timely manner or at all; adverse side effects or inadequate therapeutic efficacy of our products or products we promote that could result in product recalls, market withdrawals or product liability claims; competition from other pharmaceutical or biotechnology companies and evolving market dynamics, including the impact of currently available generic PPI products and the introduction of additional generic or branded PPI products; our ability to further diversify our sources of revenue and product portfolio; other difficulties or delays relating to the development, testing, manufacturing and marketing of, and obtaining and maintaining regulatory approvals for, our and our strategic partners' products; fluctuations in quarterly and annual results; our ability to obtain additional financing as needed to support our operations or future product acquisitions; the impact of the recent turmoil in the financial markets; and other risks detailed in our filings with the Securities and Exchange Commission, including our annual report on Form 10-K for the fiscal year ended December 31, 2008. This report is being delivered together with our Form 10-K, which represents our complete 2008 annual report. You should read this report together with the Form 10-K, which includes additional information on our business and financial condition.

Although we believe that the expectations reflected in our forward-looking statements are reasonable, we cannot guarantee future results, events, levels of activity, performance or achievement. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.

Statement of Operations Data: (in thousands, except per share amounts)	Years Ended December 31, 2008	2007	2006	2005	2004
Revenues:					
Product sales, net	$ 101,220	$ 79,403	$ 45,980	$ 13,667	$ 634
Promotion revenue	9,837	1,803	—	—	—
License and royalty revenue	19,144	13,222	3,263	12,857	714
Total revenues	130,201	94,428	49,243	26,524	1,348
Costs and expenses:					
Cost of product sales	7,345	7,301	4,927	2,129	1,968
License fees and royalties	22,257	11,117	6,437	3,414	5,089
Research and development	11,760	6,849	7,572	11,292	24,823
Selling, general and administrative	108,012	116,503	89,828	79,391	52,354
Total costs and expenses	149,374	141,770	108,764	96,226	84,234
Loss from operations	(19,173)	(47,342)	(59,521)	(69,702)	(82,886)
Interest and other income, net	1,190	3,077	3,055	4,716	1,391
Loss before income taxes	(17,983)	(44,265)	(56,466)	(64,986)	(81,495)
Income tax expense	534	—	—	—	—
Net loss	(18,517)	(44,265)	(56,466)	(64,986)	(81,495)
Accretion to redemption value of redeemable convertible preferred stock	—	—	—	—	(1,124)
Net loss attributable to common stockholders	$ (18,517)	$ (44,265)	$(56,466)	$ (64,986)	$(82,619)
Basic and diluted net loss per share	$ (0.36)	$ (0.87)	$ (1.19)	$ (1.66)	$ (3.30)
Weighted average shares outstanding used to calculate basic and diluted net loss per share	51,835	51,061	47,355	39,188	25,017

Balance Sheet Data: (in thousands)	As of December 31, 2008	2007	2006	2005	2004
Cash, cash equivalents and short-term investments	$ 52,037	$ 64,678	$ 75,534	$ 69,367	$114,008
Working capital	3,734	25,582	59,010	59,572	94,346
Total assets	92,484	85,344	93,628	79,935	122,216
Deferred revenue, less current portion	2,436	12,722	15,444	8,571	11,429
Long-term debt, less current portion	10,000	—	—	—	38
Total stockholders' equity	9,323	15,348	46,305	54,520	85,843

The selected statement of operations data for the years ended December 31, 2005 and 2004, and the selected balance sheet data as of December 31, 2006, 2005 and 2004, are derived from our audited financial statements not included in our Form 10-K for the year ended December 31, 2008. The selected statement of operations data for the years ended December 31, 2008, 2007 and 2006 and the selected balance sheet data as of December 31, 2008 and 2007, are derived from the audited financial statements for such years and as of such dates, which are included in our Form 10-K for the year ended December 31, 2008. You should read these selected financial data together with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included in our Form 10-K for the year ended December 31, 2008, which is available upon request from Santarus or at www.sec.gov.

CORPORATE INFORMATION

Board of Directors

David F. Hale
Chairman of the Board

Gerald T. Proehl
President and Chief Executive Officer
Santarus, Inc.

Daniel D. Burgess
President and Chief Executive Officer
Mpex Pharmaceuticals, Inc.

Michael G. Carter,
M.B., Ch.B., F.R.C.P. (U.K.)
Former International Medical
and Marketing Director
Zeneca, PLC

Michael E. Herman
President, Herman Family
Trading Company
Former President, Kansas City Royals
Baseball Club and the Ewing Marion
Kauffman Foundation

Ted W. Love, M.D.
Director

Kent Snyder
President and
Chief Executive Officer
Senomyx, Inc.

Corporate Officers

Gerald T. Proehl
President and Chief Executive Officer

E. David Ballard II, M.D.
Senior Vice President, Clinical Research
and Medical Affairs

Maria Bedoya-Toro, Ph.D.
Vice President, Regulatory Affairs
and Quality Assurance

Debra P. Crawford
Senior Vice President,
Chief Financial Officer,
Treasurer and Secretary

Julie A. DeMeules
Senior Vice President,
Human Resources

William C. Denby III
Senior Vice President,
Commercial Operations

Carey J. Fox, J.D.
Senior Vice President
General Counsel

Warren E. Hall
Senior Vice President, Manufacturing
and Product Development

Michael D. Step
Senior Vice President,
Corporate Development

General Information

Corporate Headquarters
Santarus, Inc.
3721 Valley Centre Drive
Suite 400
San Diego, CA 92130

Corporate Counsel
Latham & Watkins LLP

Patent Counsel
Wilson Sonsini Goodrich & Rosati

Independent Registered
Public Accounting Firm
Ernst & Young LLP

Transfer Agent
American Stock Transfer
and Trust Company

SEC Form 10-K
A copy of our annual report
on Form 10-K is available,
without charge, upon
written request to:

Investor Relations
Santarus, Inc.
3721 Valley Centre Drive, Suite 400
San Diego, CA 92130
Phone: (858) 314-5700
Fax: (858) 314-5701
E-mail: contact@santarus.com

Annual Meeting
The annual meeting of stockholders
of Santarus, Inc. will be held at
1:00 p.m. on June 11, 2009 at
Santarus, Inc.
First Floor Meeting Room
3721 Valley Centre Drive
San Diego, CA 92130
All stockholders are cordially
invited to attend.

Market Information
Our common stock trades on
the Nasdaq Global Market
under the symbol "SNTS."

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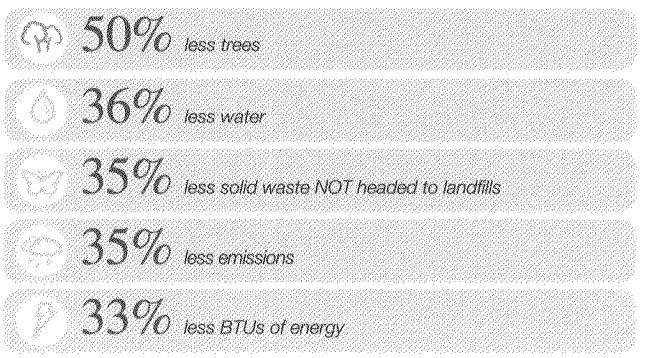
HELPING TO SUSTAIN OUR ENVIRONMENT

RENEWING OUR ENVIRONMENT FOR FUTURE GENERATIONS.

The impact of moving the Santarus 2008 annual report online and printing a smaller size of this document on green friendly paper is shown below. The paper used to print this annual report is made with 30% post consumer recycled fiber and is Green Seal™ Certified.



*Calculations are based on research done by Newsah Paper

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