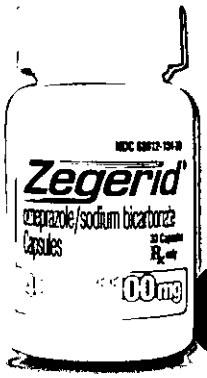
SANTARUS

2007 ANNUAL REPORT



GROWTH
ALLIANCES
DIVERSIFICATION

07 WAS A YEAR OF CREATING NEW OPPORTUNITIES

To Our Stockholders:

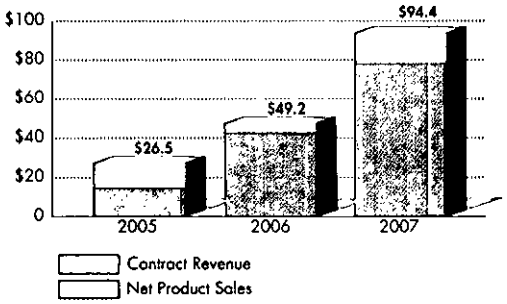
During 2007, we made significant progress in building our business by growing sales of our ZEGERID® prescription products, leveraging our immediate-release proton pump inhibitor (PPI) technology through key strategic alliances and bringing new products to our expanded commercial sales infrastructure. We are pleased to report that 2007 revenues nearly doubled compared with the prior year, as we gained market share with our ZEGERID prescription product family and increased our contract revenues. We also announced continued progress with Schering-Plough's development of ZEGERID brand over-the-counter (OTC) products and signed important license and distribution agreements with GlaxoSmithKline (GSK), including rights to develop and commercialize immediate-release omeprazole products in more than 100 countries, and we launched two co-promotion products.

Total revenues for the year were $94.4 million and included $79.4 million in net product sales, which were up 73% compared with net product sales in 2006. We also effectively controlled expenses, reducing our net loss by 22% compared with the prior year, and contributions from business development agreements allowed us to fund our operating cash needs without dilutive equity financing.

Our expanded sales organization of approximately 375 field-based personnel increased their sales call frequency on approximately 26,000 gastroenterologists and primary care physicians who are high prescribers of PPIs. We estimate that our called-on physicians accounted for approximately one-third of the $14 billion market for PPI prescriptions written in 2007.

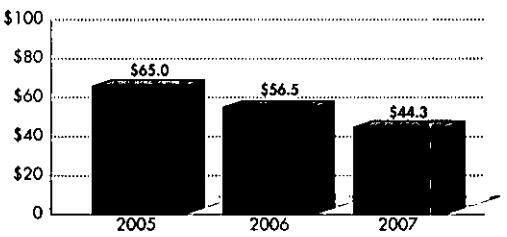
Prescriptions for our immediate-release ZEGERID products grew approximately

2005–2007 Total Revenue
in millions



We are pleased to report that 2007 revenues nearly doubled compared with the prior year, as we gained market share with our ZEGERID prescription product family and increased our contract revenues. We also effectively controlled expenses, reducing our net loss by 22% compared with the prior year, and contributions from business development agreements allowed us to fund our operating cash needs without dilutive equity financing.

2005–2007 Net Loss
in millions



David Hale, Chairman of the Board (Left)
Gerald Proehl, President and Chief Executive Officer

116% in 2007 versus 2006, an excellent performance in contrast to the 3% decline in prescriptions for the branded delayed-release PPIs as a group. Last year about 860,000 ZEGERID prescriptions were filled, nearly 460,000 more than in the prior year, comprising new patient starts and patients switched to ZEGERID from other branded PPIs. As a group, in 2007 the branded PPIs declined by 2.4 million prescriptions.

With regards to reimbursement, we believe we have achieved a level of formulary coverage with managed care organizations that is comparable to the coverage for other branded PPI products. ZEGERID products are now a preferred branded oral PPI on many health plans. A potential benefit of improved formulary coverage is that we believe patients should find it easier to obtain reimbursement for ZEGERID.

To complement our commercial initiatives, we added to our portfolio of supporting clinical data for our immediate-release ZEGERID products. In January 2008, we reported positive results from a clinical trial evaluating the effects of morning dosing of immediate-release ZEGERID Capsules versus two delayed-release branded PPIs in patients with symptoms of Gastroesophageal Reflux Disease (GERD). The results showed that ZEGERID reached a pH greater than 4 in 20 minutes, which was significantly faster than the comparator drugs, Protonix® delayed-release tablets and Prevacid® delayed-release capsules. In addition, the results showed that during a 24-hour period, ZEGERID provided significantly longer control of gastric acid (defined as the percent of time pH was greater than 4), outlasting Protonix by 43% and Prevacid by 22%. An abstract of the data has been accepted for a poster presentation at this May's annual Digestive

Donna Bonarrigo-Davies
Senior Manager, Sales & Marketing Operations

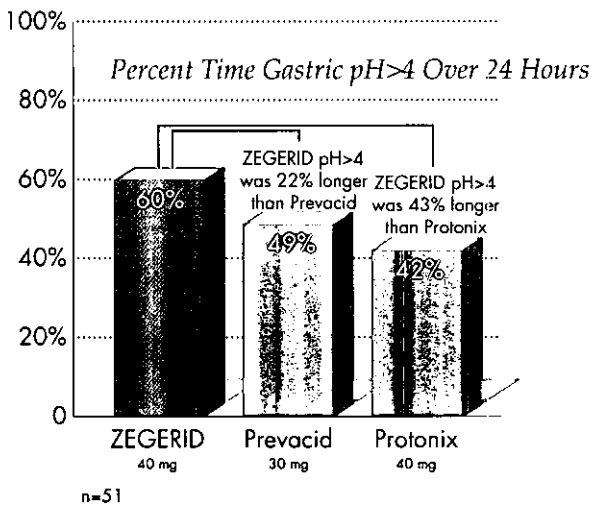
LEADERS

SANTARUS ANNUAL LEADERSHIP AWARD
On this and the following pages, we recognize individuals who consistently demonstrate outstanding leadership while obtaining exceptional results and exemplifying the culture and core values of Santarus.

David Charapp
Associate General Counsel

Santarus licensed rights to GlaxoSmithKline for immediate-release omeprazole products in over 100 countries.

New Clinical Data



n=51

ZEGERID Capsules – Control of 24-Hour Gastric Acidity After Morning Dosing (Measured on Day 7)

The correlation of pharmacodynamic data to clinical effect has not been established.
Please see Important Safety Information on page 8.

Disease Week meeting, our largest and most important annual medical conference, and a manuscript has been submitted to a peer-reviewed publication.

We formed an alliance with GSK, a leading global pharmaceutical company with well established international commercialization capabilities, to expand our immediate-release PPI technology to markets outside of North America. In November we granted an exclusive license to GSK to develop, manufacture, and commercialize prescription and OTC immediate-release omeprazole products in over 100 countries including in Africa, Asia, the Middle-East, and Central and South America. We are pleased with GSK's progress in their work to gain regulatory approval in certain countries within the covered territories, which we estimate represent approximately $2 billion in annual PPI product sales, based on market research sources. We believe these markets, which grew approximately 22% in the prior year, present an attractive commercial opportunity.

We also granted GSK rights to distribute ZEGERID brand prescription products in Puerto Rico and the U.S. Virgin Islands, where GSK's sales force is now actively promoting ZEGERID. We estimate that annual PPI sales in these territories were approximately $124 million in 2007 and grew over 20% compared to the prior 12 month period.

We received an $11.5 million upfront fee from GSK, and will collect tiered, double-digit royalties ranging from the mid-teens to the mid-twenties on net sales of any products sold under the licensing and distribution agreements.

We are also pleased to report continued progress by Schering-Plough under an agreement granting them exclusive rights

ZEGERID Marketed Products

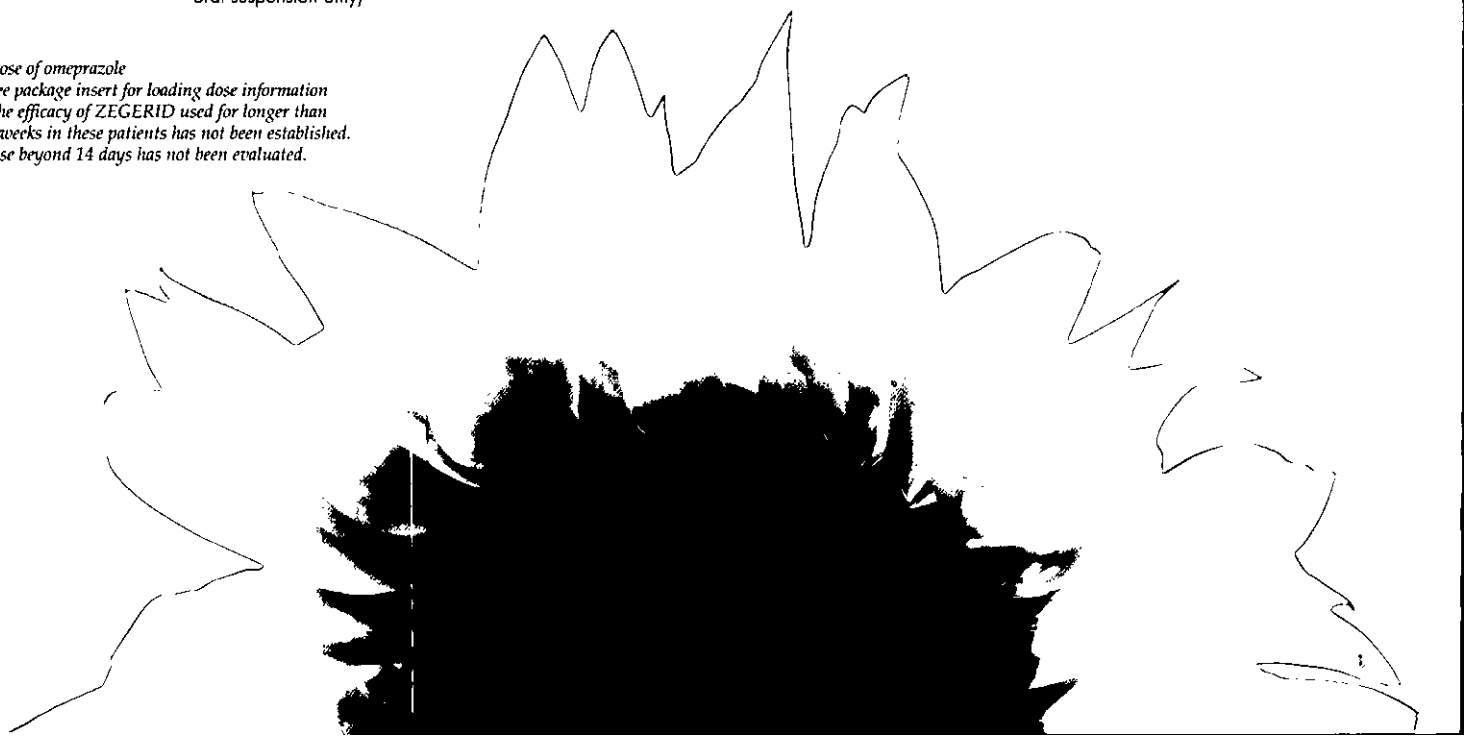
ZEGERID Capsules

ZEGERID Powder for Oral Suspension

Indications	Daily Dose[1]	Duration
Symptomatic GERD with no esophageal lesions	20 mg	Up to 4 weeks
Erosive esophagitis	20 mg	4 to 8 weeks[3]
Maintenance of healing of erosive esophagitis	20 mg	Controlled studies did not extend beyond 12 months
Treatment of active duodenal ulcer	20 mg	Most patients heal within 4 weeks; some patients may require an additional 4 weeks of therapy
Treatment of gastric ulcer	40 mg	4 to 8 weeks
Reduction of risk of upper GI bleeding in critically ill patients (40 mg powder for oral suspension only)	40 mg[2]	Up to 14 days[4]

[1] *Dose of omeprazole*
[2] *See package insert for loading dose information*
[3] *The efficacy of ZEGERID used for longer than 8 weeks in these patients has not been established.*
[4] *Use beyond 14 days has not been evaluated.*

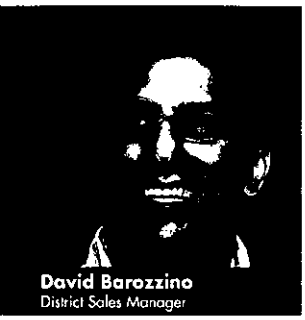
John Burick
District Sales Manager



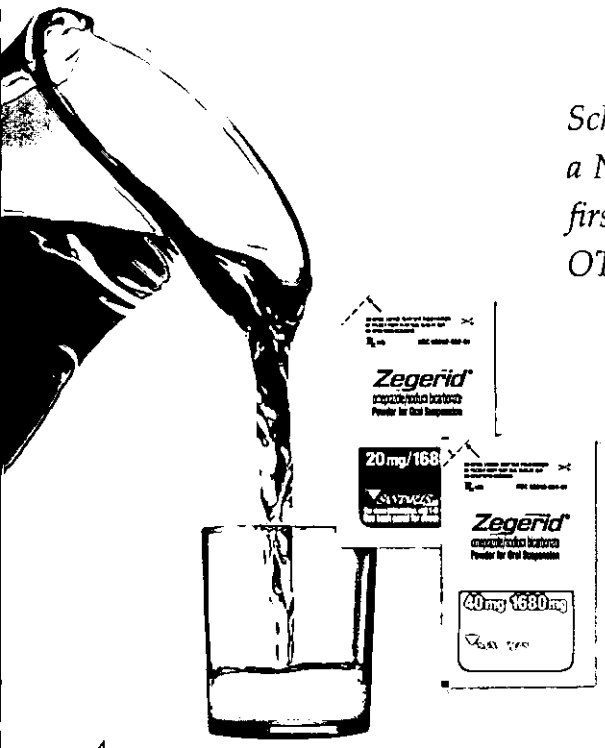
to develop, manufacture, market and sell ZEGERID brand OTC products, in the lower dosage strength of 20 mg of omeprazole, in the U.S. and Canada. Last August we received $5 million from this agreement, which represented our first milestone payment and related to progress on Schering-Plough's clinical development strategy.

We may receive up to an additional $22.5 million in milestone payments upon the achievement of specified regulatory milestones under the agreement. Schering-Plough submitted a New Drug Application (NDA) for its first licensed ZEGERID brand OTC product in March of 2008. Assuming U.S. Food and Drug Administration (FDA) approval and product launch, we could receive additional sales milestones of up to $37.5 million. In addition to the regulatory and sales milestones, we will receive low double-digit royalties on any licensed OTC product sales. We believe Schering-Plough's promotional activities for its OTC products may also positively impact brand recognition for our ZEGERID prescription products. We estimate 2007 U.S. sales for OTC heartburn products were in excess of $1.5 billion.

Last year we also took steps to leverage our commercial organization by entering into two co-promotion agreements. The first, announced last June with Victory Pharma, is for NAPRELAN® (naproxen sodium) Controlled Release Tablets. This once-daily formulation of naproxen sodium, a non-steroidal anti-inflammatory drug (or NSAID), is indicated for the treatment of a number of conditions, including arthritis and the relief of mild to moderate pain. In August, we began promoting NAPRELAN in the second sales position to our targeted primary care physicians.



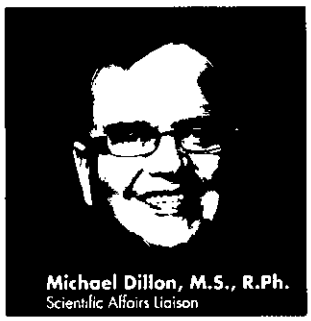
Schering-Plough submitted a New Drug Application for its first licensed ZEGERID brand OTC product in March of 2008.



We also signed an agreement last August with C.B. Fleet Company to co-promote Fleet® Phospho-soda® EZ-Prep™, a complete system for bowel cleansing used prior to a medical procedure or examination. Under this one-year agreement, we promote the Fleet product to gastroenterologists and their medical staffs, in the second sales position.

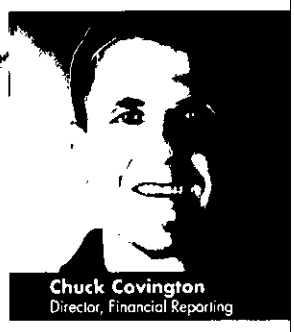
With regard to our intellectual property portfolio, we have an exclusive, worldwide license agreement with the University of Missouri for patents and pending patent applications relating to specific formulations of PPIs with antacids and other buffering agents. Currently five U.S. patents have been issued, and several U.S. patent applications are pending and are subject to this license. Last September, we were pleased that the U.S. Patent and Trademark Office formally concluded a reexamination proceeding involving one of the five issued U.S. patents that provide coverage for our ZEGERID products, and confirmed its patentability as amended during the proceeding. Our international licensed patent portfolio continues to expand and currently includes patents issued within countries in the European Patent Organization, as well as Australia, Canada, India, Mexico, New Zealand, Russia, Singapore, South Africa and South Korea, and several pending patent applications.

We remain focused on defending and enforcing the patent rights that relate to our immediate-release technology. During 2007, we filed two patent infringement lawsuits against Par Pharmaceutical, Inc., a generic drug company. The lawsuits were filed in response to Par's Abbreviated New Drug Applications (ANDAs) and associated Paragraph IV certifications, which seek approval of proposed generic versions of our ZEGERID Capsules



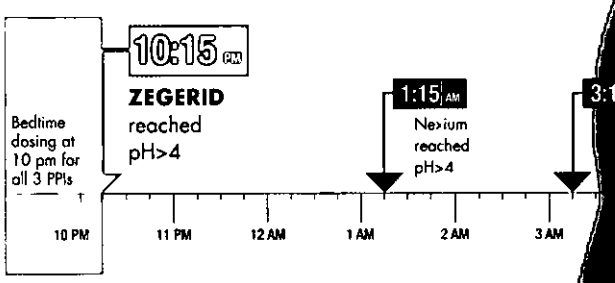
Michael Dillon, M.S., R.Ph.
Scientific Affairs Liaison

David Pearlstein
District Sales Manager



Chuck Covington
Director, Financial Reporting

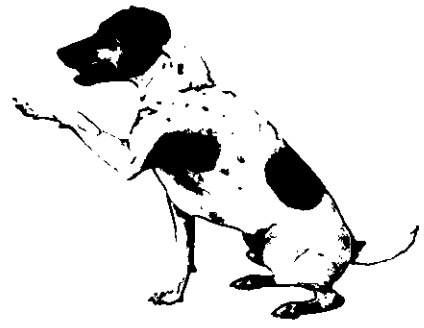
Rapid Release – ZEGERID pH>4 within 15 Minutes



n=49

Time at which the median number of subjects first reached gastric pH>4 (intracellular pH from 10 pm to 4 am) after daily bedtime dosing (10 pm) at steady state on Day 2

The correlation of pharmacodynamic data to clinical effect has not been established.
Please see Important Safety Information on page 8.

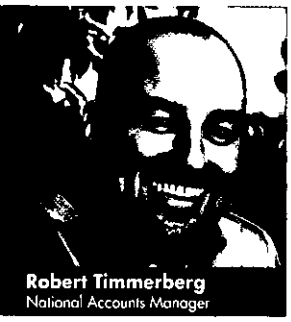


and Powder for Oral Suspension products prior to the July 2016 expiration of the patents covering those products.

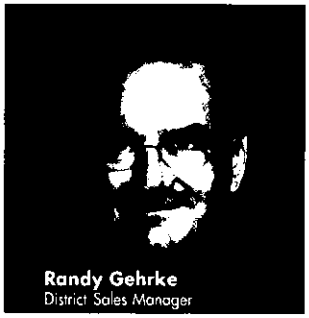
The filing of these lawsuits automatically stays the FDA's approval of the Par ANDAs until the earlier of 30 months, which would be February 2010 for the capsule and the May-June 2010 timeframe for the suspension formulation, or the date of a district court decision adverse to the asserted patents. Discovery commenced in early 2008 and a trial date has been scheduled for July 2009. We have confidence in and are prepared to vigorously defend and enforce the patents covering our ZEGERID products.

We continue to be optimistic about the prospects for Santarus. Our plan is to continue executing on our strategy to build value in our business via three key initiatives.

- First, we will continue to focus on growing sales of our ZEGERID brand prescription products. The efforts of our commercial organization are focused on increasing sales of ZEGERID through our field sales promotion, marketing programs and managed care contracting.
- Second, we will seek to further diversify our sources of revenue through strategic relationships. Our goal is to maximize the value of our proprietary PPI technology with agreements such as those with Schering-Plough and GSK, which have the potential to generate revenue and add significant value to the company. We will continue to evaluate opportunities to expand the commercialization of our PPI technology in additional markets outside of the U.S.
- Third, we will work to expand our product portfolio. We continue to evaluate products to in-license, co-promote or



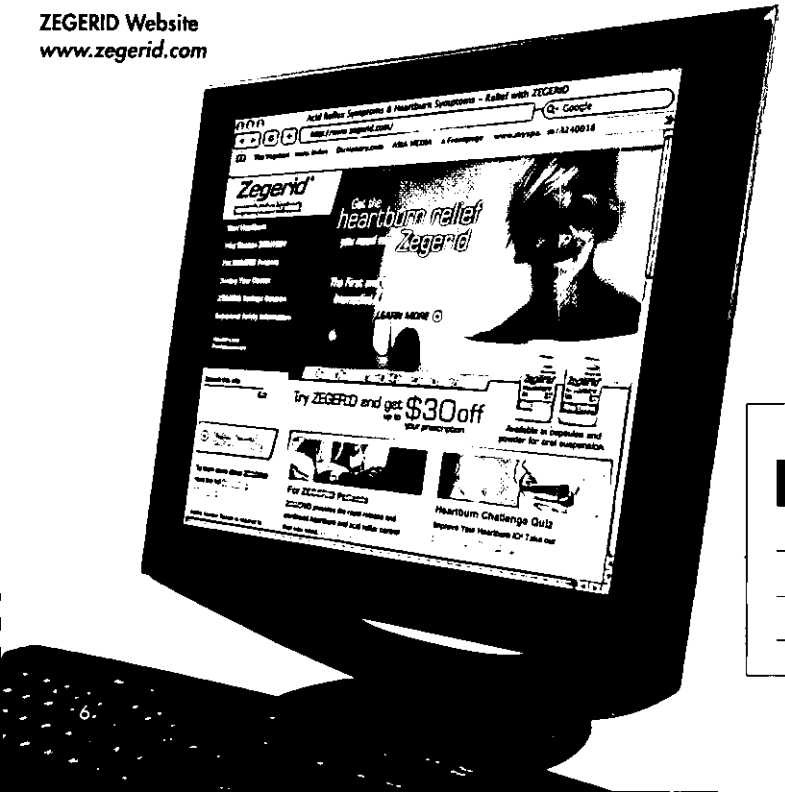
Robert Timmerberg
National Accounts Manager



Randy Gehrke
District Sales Manager

Linda Smibert
Senior Director, Business Development

ZEGERID Website
www.zegerid.com



We continue to evaluate products to in-license, co-promote or acquire. In assessing new product opportunities we look at many factors, including unmet medical need, product differentiation, market dynamics, target audience and return on investment.

Common Upper GI Diseases and Disorders Treated by PPIs

Disease	*Estimated Prevalence in the US*
GERD	54 million
Erosive Esophagitis	16 million
Gastric and Duodenal Ulcers	14 million

acquire. In assessing new product opportunities we look at many factors, including unmet medical need, product differentiation, market dynamics, target audience and return on investment. We believe that enhancing our product portfolio will contribute to the continued growth and value of our company over the longer term. Additionally, we will maintain a keen focus on managing our business with a goal of reaching breakeven by the 2008 fourth quarter. We plan to continue to control costs associated with our current operations, while seeking ways to leverage our commercial organization through additional business development activities.

We are clearly focused on those activities that we believe will support our goal of becoming a leading specialty pharmaceutical company. In 2008 we expect to continue to execute on our operational and strategic goals, and we look forward to keeping our shareholders apprised of our progress. On behalf of the board of directors and management at Santarus, we thank you for your interest and support.

Gerald T. Proehl
President and Chief Executive Officer


Gerald T. Proehl

David F. Hale
Chairman of the Board


David F. Hale

Back Row (left to right): Warren Hall, Senior Vice President, Manufacturing and Product Development; William Denby, Senior Vice President, Commercial Operations; Gerald Proehl, President and Chief Executive Officer; Mike Step, Senior Vice President, Corporate Development; David Ballard, Vice President, Clinical Research and Medical Affairs. Front Row (left to right): Debra Crawford, Senior Vice President and Chief Financial Officer; Maria Bedoya-Ioro, Vice President, Regulatory Affairs and Quality Assurance; Carey Fox, Vice President, General Counsel; Julie DeMeules, Senior Vice President, Human Resources.

Selected Financial Data

Statement of Operations Data: (in thousands, except per share amounts)	Years Ended December 31, 2007	2006	2005	2004	2003
Revenues:					
Product sales, net	$ 79,403	$ 45,980	$ 13,667	$ 634	$ —
Contract revenue	15,025	3,263	12,857	714	—
Total revenues	94,428	49,243	26,524	1,348	—
Costs and expenses:					
Cost of sales	7,301	4,927	2,129	1,968	—
License fees and royalties	11,117	6,437	3,414	5,089	1,000
Research and development	6,849	7,572	11,292	24,823	13,664
Selling, general and administrative	116,503	89,828	79,391	52,354	8,312
Total costs and expenses	141,770	108,764	96,226	84,234	22,976
Loss from operations	(47,342)	(59,521)	(69,702)	(82,886)	(22,976)
Interest and other income, net	3,077	3,055	4,716	1,391	465
Net loss	(44,265)	(56,466)	(64,986)	(81,495)	(22,511)
Accretion to redemption value of redeemable convertible preferred stock	—	—	—	(1,124)	(2,940)
Net loss attributable to common stockholders	$ (44,265)	$ (56,466)	$ (64,986)	$ (82,619)	$ (25,451)
Basic and diluted net loss per share	$ (0.87)	$ (1.19)	$ (1.66)	$ (3.30)	$ (13.71)
Weighted average shares outstanding to calculate basic and diluted net loss per share	51,061	47,355	39,188	25,017	1,857

Balance Sheet Data: (in thousands)	As of December 31, 2007	2006	2005	2004	2003
Cash, cash equivalents and short-term investments	$ 64,678	$ 75,534	$ 69,367	$114,008	$ 45,648
Working capital	25,582	59,010	59,572	94,346	42,376
Total assets	85,344	93,628	79,935	122,216	48,188
Deferred revenue, less current portion	12,722	15,444	8,571	11,429	—
Long-term debt, less current portion	—	—	—	38	224
Redeemable convertible preferred stock	—	—	—	—	57,625
Total stockholders' equity (deficit)	15,348	46,305	54,520	85,843	(13,751)

The selected statement of operations data for the years ended December 31, 2004 and 2003, and the selected balance sheet data as of December 31, 2005, 2004 and 2003, are derived from our audited financial statements not included in the Annual Report on Form 10-K for the fiscal year ended December 31, 2007. The selected statement of operations data for the years ended December 31, 2007, 2006 and 2005 and the selected balance sheet data as of December 31, 2007 and 2006, are derived from the audited financial statements for such years and as of such dates, which are included in the 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 in the Form 10-K, which accompanies this report.

Product Information Full prescribing information for Santarus products may be obtained from Santarus Medical Information by calling toll free at (888) 778-0887 or by visiting Santarus' web site at www.santarus.com or www.zegerid.com.

Important Safety Information The most frequently reported adverse events with ZEGERID are headache, diarrhea, and abdominal pain. In critically ill patients treated with ZEGERID, adverse events generally reflected the serious, underlying medical condition of the patients, and were similar for patients treated with ZEGERID and with the comparator (acid-controlling) drug. 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.

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, 2007

or

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

For the transition period from to

Commission File Number: 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.)*
10590 West Ocean Air Drive, Suite 200 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 29, 2007, 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 $224.2 million, based on the closing price of the registrant's common stock on the Nasdaq Global Market on June 29, 2007 of $5.17 per share.*

The number of outstanding shares of the registrant's common stock, par value $0.0001 per share, as of February 15, 2008 was 51,315,485.

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, 2007 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 29, 2007. 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, 2007

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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® products and any other products that we or our strategic partners market; the scope and validity of patent protection for our products, including the outcome and duration of our patent infringement lawsuits against Par Pharmaceutical, Inc., and our and our strategic partners' ability to commercialize products without infringing the patent rights of others; our dependence on a number of third parties, such as Glaxo Group Limited, an affiliate of GlaxoSmithKline, plc, under our license and distribution agreements, Schering-Plough Consumer Healthcare Products, Inc., under our over-the-counter license agreement, inVentiv Commercial Services, LLC, under our service agreement, and Otsuka America Pharmaceutical, Inc., under our co-promotion agreement; adverse side effects or inadequate therapeutic efficacy of our products or the products we co-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 proton pump inhibitor, or PPI, products and the introduction of additional generic 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 maintaining regulatory approvals for, our products; risks related to our co-promotion agreements relating to the Naprelan® and Fleet® Phospho-soda® EZ-Prep™ Bowel Cleansing System products, including our ability to generate adequate revenues to justify our level of promotional effort and expense under the agreements; our ability to obtain additional financing as needed to support our operations or future product acquisitions; 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

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., Canada and Japan and have applied for trademark registration in the EU 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 or primary care physicians. The primary focus of our current efforts is the commercialization of our proprietary, immediate-release proton pump inhibitor, or PPI, technology for the treatment of upper gastrointestinal, or GI, diseases and disorders, including gastroesophageal reflux disease, or GERD. In the U.S. prescription market, our commercial organization promotes our Zegerid® (omeprazole/sodium bicarbonate) products to targeted gastroenterologists and primary care physicians in the primary detail position, with additional promotional support provided under our contract sales organization and co-promotion arrangements. 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 prescription and OTC markets in up to 114 countries in Africa, Asia, the Middle-East, and Central and South America, as well as prescription markets in Puerto Rico and the U.S. Virgin Islands. In addition to our efforts related to our PPI technology, our commercial organization co-promotes additional primary care and gastroenterology products in the U.S. Our goal is to become a leading specialty pharmaceutical company, and we plan to continue to seek to maximize the value of our PPI technology, as well as expand our product portfolio through co-promotion, licensing or acquisition of marketed or late stage proprietary products.

Our Zegerid products are proprietary immediate-release formulations that combine omeprazole, a PPI, and one or more antacids and are currently marketed in capsule and powder for oral suspension dosage forms. 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. According to IMS Health, an independent market research firm, the U.S. market for prescription PPI products had total sales of more than $14 billion during 2007. We believe our Zegerid products offer a differentiated treatment option for physicians and their patients and represent an attractive market opportunity.

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. Although other marketed oral PPIs enjoy widespread use due to their potent acid suppression, favorable safety profiles and once-a-day dosing, they are available only in delayed-release, enteric-coated formulations. While the enteric coatings protect delayed-release PPIs from acid degradation in the stomach, they also delay absorption until the delayed-release PPIs reach the alkaline environment of the small intestine, where the enteric coatings dissolve. Our immediate-release Zegerid products are not enterically coated and are designed to provide both rapid and continued nighttime and daytime acid control.

We received approval from the FDA to market Zegerid (omeprazole/sodium bicarbonate) Capsules in February 2006 for the treatment of heartburn and other symptoms associated with GERD, treatment and maintenance of healing of erosive esophagitis and treatment of duodenal and gastric ulcers. We received approval from the FDA to market Zegerid (omeprazole/sodium bicarbonate) Powder for Oral Suspension for these same indications in 2004. In addition, Zegerid Powder for Oral Suspension 40 mg is approved for the reduction of risk of upper GI bleeding in critically ill patients, and is currently the only PPI product approved for this indication. We received FDA approval of each of our new drug applications, or NDAs, for our 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 20 mg and 40 mg in late March 2006, and launched Zegerid Powder for Oral Suspension 20 mg in October 2004 and 40 mg in February 2005.

We have established a commercial organization that targets the highest PPI-prescribing physicians in the U.S., with a focus on approximately 26,000 office-based gastroenterologists and primary care physicians. We estimate that this group of physicians collectively wrote approximately one-third of the value of PPI prescriptions written in 2007. We believe our concentration on high-volume PPI prescribers enables us to effectively promote our products with a relatively focused sales and marketing organization. Our field sales organization includes our own representatives, fully-dedicated contract sales representatives under our contract sales organization agreement with

inVentiv Commercial Services, LLC, or inVentiv, as well as additional sales representatives under our co-promotion agreement with Otsuka America Pharmaceutical Inc., or Otsuka America.

In addition to our efforts related to our Zegerid prescription products, in October 2006, 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. Under the license agreement, we have received $20.0 million in upfront and milestone fees and may receive up to an additional $22.5 million in milestone payments upon the achievement of specified regulatory milestones and up to an additional $37.5 million in milestone payments upon the achievement of specified sales milestones. We expect that Schering-Plough will submit an NDA for its first licensed OTC product in March or April of 2008. We are also entitled to receive low double-digit royalties on net sales of any licensed products sold by Schering-Plough.

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 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. GSK paid us an $11.5 million upfront fee, and we are entitled to receive tiered royalties ranging from the mid-teens to the mid-twenties on net sales of any products sold by GSK under the license and distribution agreements.

In addition, we have entered into two co-promotion arrangements to further leverage our existing commercial capabilities and generate additional revenue. While our field sales representatives continue to promote our Zegerid products in the primary detail position, they also promote Naprelan® Controlled Release Tablets, a once-daily naproxen sodium formulation for the relief of mild to moderate pain, to targeted primary care physicians and the Fleet® Phospho-soda® EZ-Prep™ Bowel Cleansing System, a system for bowel preparation prior to a medical procedure or examination, to targeted gastroenterologists. We receive a percentage of the net sales value of prescriptions generated by our targeted physicians under the Naprelan co-promotion agreement and a set fee per sales call under the Fleet co-promotion agreement.

Strategy

Our business strategy is focused on increasing sales of our Zegerid brand products in the U.S. prescription pharmaceutical market, maximizing the value of our immediate-release PPI technology in other pharmaceutical markets, and continuing to diversify our overall product portfolio and leverage our existing commercial capabilities through co-promotion, in-licensing or acquisition of additional marketed or late stage proprietary products. Our goal is to become a leading specialty pharmaceutical company that acquires, develops and commercializes proprietary products that address the needs of patients treated by gastroenterologists or primary care physicians. Key elements of our business strategy include the following:

- ***Increasing Sales of Our Zegerid Brand Prescription Products.*** Our commercial resources are primarily focused on increasing market demand for, and sales of, our Zegerid brand prescription products. Our field sales organization currently promotes Zegerid Capsules and Zegerid Powder for Oral Suspension in the primary detail position. This field sales organization includes our own representatives, as well as additional support under our contract sales organization agreement with inVentiv and our co-promotion agreement with Otsuka America. According to IMS Health, an independent market research firm, the U.S. market for prescription PPI products had total sales of more than $14 billion during 2007. We believe our Zegerid prescription products offer a differentiated treatment option for physicians and their patients and represent an attractive market opportunity.

- ***Maximizing the Value of Our Immediate-Release 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. In October 2006, we licensed exclusive rights to Schering-Plough under our PPI technology 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. In November 2007, we granted exclusive rights to GSK under our PPI technology to 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 Zegerid brand prescription products in Puerto Rico and the U.S. Virgin Islands. We believe these arrangements and potential revenue sources have the potential to add significant value to our company, and we plan to continue to evaluate additional strategies to expand the commercialization of our PPI technology both within and outside the U.S.

- ***Diversify our Product Portfolio and Further Leverage our Commercial Capabilities through Co-promotion, In-licensing or Acquisition of Additional Marketed or Late Stage Proprietary Products.*** We also intend to further diversify our product portfolio with additional marketed or late stage proprietary product opportunities. In 2007, we entered into two co-promotion arrangements to leverage our existing commercial capabilities. While our field sales representatives continue to promote our Zegerid products in the primary detail position, they also promote Naprelan Controlled Release Tablets and the Fleet Phospho-soda EZ-Prep Bowel Cleansing System to our targeted physicians. These co-promotion arrangements provide a source of potential additional revenue, while allowing our field sales representatives to maintain their primary focus on our Zegerid products. In the future, we plan to explore additional co-promotion, in-licensing and acquisition arrangements for marketed or late stage products. We plan to concentrate our efforts on proprietary products that would be complementary to our existing products and that have attractive commercial potential, as well as, in the case of development products, the potential for reduced development and regulatory risk. We believe that enhancing our product portfolio will contribute to the continued growth and value of our company over the longer term.

Zegerid Product Family

Our Zegerid brand prescription products are proprietary immediate-release formulations that combine omeprazole, a PPI, and one or more antacids. These products are currently marketed in capsule and powder for oral suspension dosage forms and are intended to treat or reduce the risk of a variety of upper GI diseases and disorders, including heartburn and other symptoms associated with GERD, erosive esophagitis, upper GI bleeding and gastric and duodenal ulcers.

Currently Marketed Zegerid Prescription Products	Omeprazole Dose	Indications	Status
Zegerid (omeprazole/sodium bicarbonate) Capsules	20 mg/40 mg	Heartburn/GERD, Erosive Esophagitis, Duodenal Ulcers, Gastric Ulcers	Launched in March 2006 (20 mg and 40 mg)
Zegerid (omeprazole/sodium bicarbonate) Powder for Oral Suspension	20 mg/40 mg	Heartburn/GERD, Erosive Esophagitis, Duodenal Ulcers, Gastric Ulcers, Reduction of Risk of Upper GI Bleeding in Critically Ill Patients	Launched in October 2004 (20 mg) and February 2005 (40 mg)

PPIs enjoy widespread use due to their potent acid suppression, favorable safety profiles and once-a-day dosing. However, all currently marketed PPIs in the U.S., other than Zegerid, are available for oral use only in delayed-release, enteric-coated formulations. While the enteric coatings protect delayed-release PPIs from acid degradation in the stomach, they also delay absorption of the active ingredients, until the delayed-release PPIs reach the alkaline environment of the small intestine, where the enteric coatings dissolve. Our immediate-release Zegerid products are not enterically coated and are designed to provide both rapid and continued nighttime and daytime acid control.

Upper Gastrointestinal Diseases and Disorders and Limitations of Current Treatments

Gastrointestinal diseases and disorders affect the digestive tract with varying degrees of severity. Upper GI diseases and disorders, such as heartburn, GERD, erosive esophagitis and upper GI bleeding, 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 and Gastroesophageal Reflux Disease (GERD). 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. A significant number of children also suffer from GERD, and studies have indicated that as many as 2% to 8% of infants and older children experience symptoms related to GERD. 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.

Physicians have many choices in treating GERD. As initial treatment, physicians will usually instruct patients to alter their dietary habits in order to reduce the frequency of heartburn symptoms. However, most patients with GERD will eventually require treatment with drugs, and some may require surgery. Antacids were introduced in the early 1900s and are still a frequent OTC treatment option. Although antacids work quickly to neutralize acid in the esophagus and stomach, they generally provide only short-term relief for approximately 30 minutes to one hour after dosing.

Introduced in the 1970s, histamine-2 receptor antagonists, or H2RAs, are compounds that reduce the production of stomach acid resulting from stimulation of histamine receptors. In 2000, antacids were combined with H2RAs for OTC treatment of heartburn. However, because the histamine receptors are only one of three potential sources of acid stimulation, H2RAs generally provide only a partial reduction of acid production. In addition, H2RAs generally work for shorter periods of time than PPIs, and may need to be dosed several times per day.

PPIs were introduced in the late 1980s and are currently the most common prescription treatment options for many upper GI diseases, including GERD. PPIs are compounds which inhibit the production of stomach acid. Following absorption into the bloodstream, PPIs travel to parietal cells located in the walls of the stomach, where they irreversibly bind to active acid-producing enzymes, known as proton pumps, and inhibit acid production. Once a PPI irreversibly binds to a proton pump, that pump will no longer produce acid. As a result, PPIs are more effective in reducing acid production as compared with H2RAs and generally need only be taken once a day. Because new proton pumps are generated continuously, dosing with PPIs generally needs to be repeated once daily if continuous acid suppression is desired.

Since PPIs are rapidly degraded in the presence of stomach acid, they require some type of protection to pass through the stomach. With the exception of Zegerid, all other currently marketed oral PPI products have enteric coatings to protect them from acid degradation. The enteric coating is designed to remain intact in the highly acidic stomach. Once the stomach empties its contents into the alkaline environment of the small intestine, the enteric coating begins to dissolve, allowing the PPI to be absorbed into the bloodstream. This results in a delay in the absorption of the PPI, until the enteric-coated PPI reaches the alkaline environment of the small intestine and is absorbed.

Erosive Esophagitis. 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. An eight-week course of therapy with PPIs will generally be effective in healing erosions associated with erosive esophagitis in the majority of patients. Surgery may be required if the esophagus becomes extremely damaged.

Gastric and Duodenal Ulcers. 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. Based on the assessment, the gastroenterologist will prescribe a course of treatment, usually a PPI, to be taken daily for up to eight weeks and an antibiotic, if appropriate.

Upper GI Bleeding. Critically ill ventilated patients are at high risk for developing erosions and upper GI bleeding when the gastric mucosa, already compromised by the stress of a critical medical condition, is exposed to stomach acid and digestive enzymes. Many physicians treat these patients prophylactically to reduce stomach acid and the risk of upper GI bleeding. Patients who develop upper GI bleeding may require blood transfusions or in some cases may require surgery, which is associated with a high mortality rate. It is estimated that as many as 4 million critically ill patients are treated annually in the U.S., with approximately 1.5 million mechanically ventilated patients at highest risk for upper GI bleeding.

Zegerid Product Differentiation

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

- *Immediate Release* — Our Zegerid products utilize one or more antacids, instead of delayed-release, enteric coatings, to protect the omeprazole from acid degradation, providing for rapid absorption of the omeprazole into the bloodstream. 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* — Our Zegerid products are designed to provide a duration of acid control similar to delayed-release PPIs and, thus, allow for once-a-day 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. This duration of acid control is comparable to the data available for the delayed-release PPIs.

- *Nocturnal Acid Control* — Zegerid Powder for Oral Suspension has demonstrated effective acid control during the night when dosed at bedtime. For example, in a 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.

- *Variety of Formulations* — Our Zegerid products are currently marketed in capsule and powder for oral suspension dosage forms. In addition to providing alternative formulations for use in the general adult population, one or more of our formulations may address the needs of specific patient populations such as pediatric, elderly and hospitalized patients. We are also continuing to develop other improved formulations of our Zegerid products, utilizing our immediate-release PPI technology.

- *Potential for Expanded Indications* — We may pursue expanded indications and uses for our products based on their specific features and benefits. For example, following completion of a pivotal Phase III clinical trial, Zegerid Powder for Oral Suspension was approved for reduction of risk of upper GI bleeding in critically ill patients. There is currently no other PPI product approved for this indication.

Currently Marketed Zegerid Prescription Products

Zegerid (omeprazole/sodium bicarbonate) Capsules

Our Zegerid Capsules product 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. In February 2006, we received approval from the FDA to market Zegerid Capsules 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 of active duodenal

ulcers, and short-term treatment (4-8 weeks) of active benign gastric ulcers. Zegerid Capsules utilize sodium bicarbonate, an antacid, instead of an enteric coating to protect the omeprazole from acid degradation. When the capsule is swallowed, the antacid neutralizes acid in the stomach, protects the omeprazole from degradation and allows for rapid absorption of the omeprazole into the bloodstream, reaching maximal plasma levels in approximately 30 minutes. We believe the capsule product provides a convenient and familiar dosage form for many patients.

To support our NDA submission for this product, we completed two pivotal PK/PD clinical trials in 2004, which evaluated both the 20 mg and 40 mg dosage strengths of Zegerid Capsules. The primary objective of the trials was to evaluate whether the immediate-release Zegerid Capsules were pharmacokinetically equivalent to delayed-release omeprazole capsules with respect to total systemic bioavailability (as measured by area under the curve, or AUC) on Day 7. The trials also assessed whether Zegerid Capsules and the delayed-release omeprazole capsules had comparable ability to suppress gastric acidity over 24 hours. The trial results demonstrated that Zegerid Capsules and the delayed-release omeprazole capsules were statistically equivalent with respect to AUC and percent decrease from baseline for integrated gastric acidity on Day 7.

As a result of its immediate-release profile, the maximum plasma concentration (Cmax) was greater and the time to maximum plasma concentration (Tmax) was shorter on Day 7 for Zegerid Capsules than for the delayed-release omeprazole capsules. While achieving more rapid absorption of omeprazole, Zegerid Capsules also maintained a comparable duration of effect on reducing the concentration of acid in the stomach as compared to delayed-release omeprazole.

In January 2008, we announced results of a clinical trial evaluating the effects of morning dosing of each of Zegerid Capsules and delayed-release PPI brands, Protonix® (pantoprazole sodium) and Prevacid (lansoprazole), on 24-hour gastric acid control in patients with symptoms of GERD. The study data indicated that the percent time with gastric pH greater than 4 for patients taking Zegerid was approximately 43% longer than patients treated with Protonix ($p<0.001$) and approximately 22% longer than patients treated with Prevacid ($p=0.005$).

We may conduct additional clinical trials designed to further differentiate our capsule product from the currently marketed delayed-release PPIs or otherwise expand its future use.

Zegerid (omeprazole/sodium bicarbonate) Powder for Oral Suspension

Our Zegerid Powder for Oral Suspension product 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. In 2004, we received approval from the FDA to market Zegerid Powder for Oral Suspension 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 of active duodenal ulcers, short-term treatment (4-8 weeks) of active benign gastric ulcers and the reduction of risk of upper GI bleeding in critically ill patients.

Similarly to Zegerid Capsules, Zegerid Powder for Oral Suspension utilizes sodium bicarbonate, an antacid, instead of an enteric coating to protect the omeprazole from acid degradation and enable rapid absorption of the omeprazole into the bloodstream. When constituted with one to two tablespoons of water to form a uniform suspension and then administered, the antacid neutralizes acid in the stomach, protects the omeprazole from degradation and allows for rapid absorption of the omeprazole into the bloodstream, reaching maximal plasma levels in approximately 30 minutes. In addition to use in the general adult population, our oral suspension dosage form is readily titratable and designed to be easily administered to critically ill patients via nasogastric tubes and may also be appropriate for patients who have difficulty swallowing solid dosage forms, such as capsules and tablets.

To support our NDA submissions for this product, we completed two pivotal PK/PD clinical trials in 2002, which evaluated both the 20 mg and 40 mg dosage strengths of Zegerid Powder for Oral Suspension and which were similar in design and outcome to the pivotal PK/PD trials conducted for Zegerid Capsules.

Also in support of our NDA submissions, in 2003 we completed a multi-center Phase III clinical trial evaluating the 40 mg dosage strength of Zegerid Powder for Oral Suspension for the reduction of risk of upper GI bleeding in

critically ill patients. Critically ill patients who require mechanical ventilation are generally at higher risk for developing significant upper GI bleeding from ulcers or erosions, and many physicians choose to prophylactically treat these patients with an acid reducing medication. Given the serious medical condition of this patient population, the blinded clinical trial compared Zegerid Powder for Oral Suspension, administered through a nasogastric tube, with intravenous, or IV, cimetidine, an H2RA, rather than a placebo. At the time of the trial, IV cimetidine was the only drug approved by the FDA for the studied indication.

A total of 359 mechanically-ventilated, critically ill patients at approximately 50 clinical sites participated in this trial. In the trial, 10 patients treated with IV cimetidine experienced clinically significant bleeding, compared to 7 patients treated with Zegerid Powder for Oral Suspension, demonstrating that our powder for oral suspension product was not inferior to IV cimetidine in reducing the risk of upper GI bleeding in critically ill patients. In addition, in the trial, Zegerid Powder for Oral Suspension achieved a median gastric pH greater than 4 within 1 to 2.5 hours after the first dose in 99% of patients treated and sustained a median daily gastric pH greater than 4 throughout the 14-day trial in 95% of the patients treated.

As additional support for the approval of Zegerid Powder for Oral Suspension 40 mg, we conducted an open-label clinical trial in 243 patients, including approximately 95 patients with gastric ulcers, to collect safety data related to this product over an eight-week treatment period, including any potential side effects or other adverse events. The data from this trial demonstrated that the safety profile of this product is similar to the safety profile described for delayed-release omeprazole, and the FDA reviewed this data in connection with its approval of our NDA.

We have also conducted two clinical trials evaluating the effects of Zegerid Powder for Oral Suspension on nighttime acid control. In 2005, we announced results from a clinical trial evaluating the effects of Zegerid Powder for Oral Suspension and Protonix delayed-release pantoprazole tablets on nocturnal gastric acidity. In this trial, after repeated once-daily dosing, Zegerid Powder for Oral Suspension produced significantly better control of nocturnal gastric acid than Protonix. The patients receiving Zegerid had a median nighttime gastric pH of 4.7, as compared to a median nighttime gastric pH of 2.0 for the patients receiving Protonix ($p<0.001$), and the nighttime percent time with gastric pH greater than 4 was greater for patients receiving Zegerid than for patients receiving Protonix (55% as compared to 27%, $p<0.001$). In addition, the percentage of patients experiencing nocturnal acid breakthrough (defined as pH less than 4 for more than 1 hour during the night) was lower for patients receiving Zegerid than for patients receiving Protonix (53% as compared to 78%, $p=0.005$).

In 2006, we announced results of a clinical trial evaluating the effects of Zegerid Powder for Oral Suspension and delayed-release PPI brands, Nexium (esomeprazole magnesium) and Prevacid (lansoprazole), on control of nocturnal gastric acidity. In this trial, significantly fewer patients experienced nocturnal acid breakthrough when treated with Zegerid at bedtime than when treated at bedtime with the comparator drugs. Only 61% of the patients experienced nocturnal acid breakthrough while treated with Zegerid, as compared to 92% of the patients treated with Nexium and 92% of the patients treated with Prevacid ($p<0.001$ for both comparisons). This means that 50% more patients experienced nocturnal acid breakthrough with either Nexium or Prevacid than with Zegerid. In addition, bedtime administration of Zegerid produced a rapid rise in gastric pH that was not observed with either delayed-release PPI. The results indicated that the median percentage of time with gastric pH greater than 4 when evaluated for the first half of the night (10:00 pm to 2:00 am) was 52% for Zegerid, 30% for Nexium and 12% for Prevacid ($p<0.001$ for both comparisons).

We may conduct additional clinical trials designed to further differentiate our powder for oral suspension product from the currently marketed delayed-release PPIs or otherwise expand its future use.

Strategic Alliances

We have entered into strategic alliances with two large pharmaceutical companies to commercialize our Zegerid products and our patented PPI technology within the OTC market in the U.S. and Canada and within both the OTC and prescription markets in a number of international territories.

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 has sales in excess of $1.5 billion annually. 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. 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.

Under the license agreement, we received a $15.0 million upfront license fee in November 2006 and a $5.0 million milestone payment in August 2007. We may receive up to an additional $22.5 million in milestone payments upon the achievement of specified regulatory milestones and up to an additional $37.5 million in milestone payments upon the achievement of specified sales milestones. We expect that Schering-Plough will submit an NDA for its first licensed OTC product in March or April of 2008. 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 on 180 days prior written notice to us anytime after submitting its first NDA for a licensed product or if Schering-Plough does not meet a specified deadline for receiving marketing approval in the U.S. for a licensed product. 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 for a number of international markets (including markets within Africa, Asia, the Middle-East, and Central and South America), 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 $2.0 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.

Under the license agreement, we received an $11.5 million upfront fee. We will also receive tiered royalties ranging from the mid-teens to mid-twenties on 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 will 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 will pay 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.

Co-Promotion Arrangements

We have entered into two co-promotion arrangements to further leverage our existing commercial capabilities. While our field sales representatives continue to promote our Zegerid products in the primary detail position, they also promote Naprelan Controlled Release Tablets and the Fleet Phospho-soda EZ-Prep Bowel Cleansing System pursuant to co-promotion agreements, as further described below.

Co-Promotion Agreement for Naprelan Controlled Release Tablets

In June 2007, we entered into a co-promotion agreement with Victory Pharma, Inc., or Victory, to co-promote Victory's Naprelan (naproxen sodium) Controlled Release Tablets to targeted primary care physicians in the U.S. The Naprelan products are a once-daily, controlled release formulation of naproxen sodium, a non-steroidal anti-inflammatory drug, or NSAID, indicated for the treatment of a number of conditions, including arthritis and the relief of mild to moderate pain.

Under the terms of the agreement, we receive a co-promotion fee calculated as a percentage of the net sales value of the prescriptions generated by our target physicians, offset by an initial credit in recognition of existing sales. We are obligated to make a minimum number of annual and quarterly second position sales calls to target physicians. Victory is responsible for creating and developing, at its cost and expense, all marketing materials for the Naprelan products, as well as for handling all manufacturing, distribution, medical affairs and regulatory support for the Naprelan products. We are responsible for all costs related to our sales force, and we purchase samples and training and promotional literature at cost from Victory or its suppliers.

During the term of the agreement, Victory is obligated to provide us with prior written notice of, and an opportunity to negotiate co-promotion rights for, any other branded pharmaceutical products that contain naproxen or naproxen sodium, which are promoted or commercialized by Victory. In addition, during the initial 18 month period of the agreement, we and Victory each agreed not to promote any naproxen or naproxen sodium prescription pharmaceutical products in the U.S., other than the Naprelan products, to the targeted primary care physicians. We also agreed, during the term of the agreement, not to promote any controlled release naproxen sodium prescription pharmaceutical products in the U.S., other than the Naprelan products.

The agreement will continue in effect until June 2014, unless terminated sooner. 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, subject to prior written notice within a specified time period. In addition, 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 stayed. Either party may also terminate the agreement under other specified circumstances relating to a significant recall or withdrawal of the Naprelan products or in the event of specified regulatory or governmental actions that would prevent a party from performing its obligations under the agreement. We may also terminate the agreement in other circumstances, such as loss of market exclusivity, subject to notice to Victory. In addition, subject to 120 days prior written notice to Victory, we may terminate the Agreement (a) at any time following the 18-month anniversary of the effective date of the agreement or (b) at any time following the effective date of the agreement if Victory is not continuing to provide marketing and promotional support for the Naprelan products at specified minimum levels.

Co-Promotion Agreement for Fleet Phospho-soda EZ-Prep Bowel Cleaning System

In August 2007, we entered into a co-promotion agreement with C.B. Fleet Company, Incorporated, or Fleet, to co-promote the Fleet Phospho-soda EZ-Prep Bowel Cleansing System to gastroenterologists in the U.S. currently called on by our field sales representatives. The Fleet product is a system for bowel preparation used prior to a medical procedure or examination, such as a colonoscopy.

Under the terms of the agreement, Fleet pays us to promote the Fleet product based on a set fee per sales call, subject to a minimum and maximum number of sales calls. We are eligible to receive co-promotion fees of up to approximately $3.0 million over the term of the agreement, subject to reduction in the event of any early termination

of the agreement. We also have the opportunity to earn bonus payments if unit sales exceed predetermined baselines. We did not pay an upfront fee and do not expect to incur any material incremental expenses associated with our promotion of the Fleet product. Fleet is responsible for providing all training materials, promotional literature and product samples throughout the term of the agreement.

Pursuant to the terms of the agreement and subject to customary limitations, each party agrees to indemnify the other party against any and all claims arising out of any material breach of the agreement or the negligence or willful misconduct of the indemnifying party. In addition, Fleet agrees to indemnify us against any and all claims arising out of any personal injury and/or property damage resulting from the handling, possession, sale or use of any Fleet products and any other liability arising out of the manufacture, marketing, labeling, distribution, sale or use of any Fleet products, including claims related to intellectual property rights and product liability claims and including claims related to our activities under the agreement, except to the extent arising out of our negligence or willful misconduct.

The agreement will continue in effect until October 2008, unless terminated sooner or extended by the parties upon mutual written agreement. Either party may terminate the agreement (a) 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; (b) 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 stayed; (c) under other specified circumstances relating to a significant recall or withdrawal of the Fleet product or in the event of specified regulatory or governmental actions that would prevent a party from performing its obligations under the agreement; and (d) at any time by providing 120 days prior written notice to the other party.

Sales and Marketing

We have established a commercial organization that is primarily focused on the promotion of our Zegerid products. The commercial organization targets the highest PPI-prescribing physicians in the U.S., with a focus on approximately 26,000 office-based gastroenterologists and primary care physicians. We estimate that this group of physicians collectively wrote approximately one-third of the value of PPI prescriptions written in 2007. We believe our concentration on high-volume PPI prescribers will enable us to effectively promote our products with a relatively focused sales and marketing organization.

Our commercial organization is comprised of approximately 375 field-based personnel, including our own field sales representatives, fully-dedicated field sales representatives under our contract sales organization agreement with inVentiv, sales managers and account managers, and we receive additional field promotional support provided under our co-promotion agreement with Otsuka America. Our own 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. Many of these representatives have prior experience with GI products, including PPIs. The efforts of our own field sales representatives are supplemented by the efforts of the inVentiv and Otsuka America representatives, who are also positioned across the U.S., in most cases jointly aligned with one of our own representatives.

This combined team of field sales representatives is primarily focused on communicating the features and benefits of our Zegerid products to our targeted physicians, which include the products' ability to offer both rapid and continued nighttime and daytime acid control. 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 upper GI market 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 to obtain formulary and reimbursement coverage for our products. Additionally, we 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.

We have entered into two co-promotion arrangements to further leverage our commercial capabilities. While our field sales representatives continue to promote our Zegerid products in the primary detail position, they also promote Naprelan Controlled Release Tablets, a once-daily naproxen sodium formulation for the relief of mild to moderate pain, to targeted primary care physicians and the Fleet Phospho-soda EZ-Prep Bowel Cleansing System, a system for bowel preparation prior to a medical procedure or examination, to targeted gastroenterologists.

Contract Sales Organization Agreement with inVentiv

To support our sales and marketing efforts, we entered into a contract sales organization agreement with inVentiv in November 2006, under which inVentiv is committed to provide up to approximately 140 contract sales representatives, as well as additional management and administrative support. We are currently utilizing approximately 120 inVentiv representatives who are located throughout the U.S. and promote our Zegerid products in the primary detail position.

In consideration for inVentiv's services under the agreement, we pay to inVentiv a fixed monthly fee, subject to adjustment based on actual staffing levels. During the term of the agreement, a portion of inVentiv's management fee will be subject to forfeiture and credited to us in the event inVentiv does not achieve specified performance targets, including targets related to the initial scale-up activities, turnover and vacancy rates and specified sales goals. 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 initial term of the agreement expires on December 1, 2008. We have the right to extend the term of the agreement for up to two additional one year terms, subject to agreement on compensation terms with inVentiv. 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. inVentiv may also terminate the agreement if we fail to make timely payments under the agreement.

Co-Promotion Agreement with Otsuka America

Also to support our sales and marketing efforts, we entered into a co-promotion agreement with Otsuka America under which Otsuka America provides approximately 170 field sales representatives to co-promote Zegerid Capsules and Zegerid Powder for Oral Suspension to our targeted physicians in the primary detail position. We originally entered into the agreement in October 2004 and amended the terms of the agreement in January 2006.

Under the terms of the agreement, we received a $15.0 million upfront payment from Otsuka America, and pay Otsuka America a royalty on total U.S. net sales of Zegerid Capsules and Zegerid Powder for Oral Suspension. Initially, the royalty rate is in the high single digits, presuming a minimum number of primary details to target physicians. We provide all marketing materials, and Otsuka America covers all costs related to its sales force.

The agreement will terminate automatically on December 31, 2009, unless terminated sooner. Either party may terminate the agreement effective at any time, by providing at least 120 days prior written notice. 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, or 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 stayed. We may also terminate the agreement under certain additional limited conditions, subject to prior written notice to Otsuka America within a specified time period.

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.

We currently rely on OSG 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 current products. Under our supply agreement with Uquifa, we must purchase all of our requirements of omeprazole from Uquifa. This agreement has an initial four-year term, which expired in September 2007, with automatic two-year renewal terms. We can terminate the agreement upon at least 12 months notice prior to the expiration of the initial term or any extension 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.

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.

We sell our approved products 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 2007, Cardinal Health, Inc., McKesson Corporation and AmerisourceBergen Corporation, accounted for approximately 32%, 32% and 14%, 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.

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. Although we do not currently own any issued patents, our Zegerid products incorporate patented technology owned by others that we have exclusively licensed. 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.

License Rights from 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. Currently, five U.S. patents have been issued and several U.S. patent applications are pending and are subject to this license. The five issued patents, U.S. Patent Nos. 5,840,737; 6,489,346; 6,645,988; 6,699,885; and 6,780,882, together 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 expire in July 2016. In addition to the U.S. patent coverage, several international patents have been issued, including in Australia, Canada, India, Mexico, New Zealand, Russia, Singapore, South Africa and South Korea, as well as in countries within the European Patent Organization, 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.

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 $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. 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 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.

In September 2007, the United States Patent and Trademark Office, or PTO, issued an Ex Parte Reexamination Certificate for U.S. Patent No. 6,699,885, or the '885 patent, which formally concluded the pending reexamination proceeding relating to the '885 patent, and confirmed the patentability of the '885 patent, as amended during the proceeding, over the references cited in the proceeding. The '885 patent is one of the five currently issued U.S. patents providing coverage for our Zegerid family of products, which patents expire in July 2016 and are licensed to us under our license agreement with the University of Missouri. For a more detailed description of this proceeding, see Part I – Item 3 – Legal Proceedings.

In December 2007, the University of Missouri filed an Application for Reissue of U.S. Patent No. 5,340,737, or the '737 patent, with the PTO. The '737 patent is one of five 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 three 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 2007, we received a notice from the European Patent Office, or EPO, that no third party oppositions were filed against EPO Patent Grant No. 1246622, relating to pharmaceutical compositions in the form of a non-enteric coated tablet and comprising proton pump inhibitors and one or more buffers. A notice of the publication of the grant of the EPO patent application was issued by the EPO in September 2006 and the period of opposition required under European patent law expired in June 2007. The European patent expires in January 2021 and is licensed to us under our license agreement with the University of Missouri.

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 on October 1, 2007. If we, in coordination with the University of Missouri, do not successfully defend the patent application against the pre-grant opposition, we may not be able to obtain patent coverage for one or more of our Zegerid products in India.

Pending Patent Infringement Litigation Filed Against 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 October 2007, we filed an amended complaint to reflect the PTO's issuance of an Ex Parte Reexamination Certificate for U.S. Patent No. 6,699,885, or the '885 patent. 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. 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. In addition, Par is seeking a declaration that U.S. Patent No. 5,840,737, or the '737 patent, another patent listed in the Orange Book for Zegerid Powder for Oral Suspension, is not infringed, invalid and/or unenforceable. We have moved to dismiss, or in the alternative, stay these claims due to the pending reissue proceeding involving this patent. Discovery is expected to begin in the near future and a trial date has been scheduled in July 2009. Both lawsuits have been consolidated for all purposes.

We 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 generic products 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 likely negatively impact our financial condition and results of operations. 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.

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., Canada and Japan and have applied for trademark registration in the EU for our brand name, Zegerid, and we have applied for trademark registration for various other names and logos. An opposition against our EU trademark application for our brand name, Zegerid, has recently concluded in our favor. Accordingly, the trademark should proceed to registration in the EU. Over time, we intend to maintain registrations on trademarks that remain valuable to our business.

Research and Development

Our research and development expenses were $6.8 million in 2007, $7.6 million in 2006 and $11.3 million in 2005. Our research and development expenses have consisted primarily of costs associated with clinical trials of our products under development as well as clinical studies designed to further differentiate our products from those of our competitors or to obtain additional labeling indications, costs of developing and manufacturing our products under development, compensation and other expenses related to research and development personnel and facilities expenses.

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. 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 PK/PD and safety studies. Although we are currently focused primarily on advancing our Zegerid family of products, 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.

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 current efforts are primarily focused on the sales and marketing of our Zegerid products, and our competitors have addressed the market for our Zegerid products through the development and marketing of many products, including:

Prescription Products:

- *PPIs: AstraZeneca plc's Prilosec® and Nexium®, TAP Pharmaceutical Products Inc.'s Prevacid®, Wyeth's and Altana's Protonix®, Johnson & Johnson's and Eisai Co., Ltd.'s Aciphex®, and generic delayed-release omeprazole and pantoprazole, among others; and*

- *Histamine-2 receptor antagonists: Merck & Co., Inc.'s Pepcid®, GlaxoSmithKline plc's Zantac® and Tagamet® and Braintree Laboratories, Inc.'s Axid®, among others.*

Over-the-Counter Products:

- *PPIs: The Procter & Gamble Company's Prilosec OTC® and store brand delayed-release omeprazole product;*

- *Histamine-2 receptor antagonists: Boehringer Ingelheim GmbH's Zantac, GlaxoSmithKline plc's Tagamet, and Johnson & Johnson's and Merck & Co., Inc.'s Pepcid AC® and Pepcid Complete®, among others; and*

- *Antacids: Johnson & Johnson's and Merck and Co., Inc.'s Mylanta® and Rolaids®, Novartis AG's Maalox® and GlaxoSmithKline plc's Gaviscon® and Tums®, among others.*

In addition, various companies are developing new products, including new PPIs, motility agents, reversible acid inhibitors, cytoprotective compounds and products that act on the lower esophageal sphincter, or LES. We may be required to compete with these or other new products that may have greater efficacy, faster onset of action or other benefits relative to our products.

Many of the currently marketed competitive products are available as generic products. For example, generic delayed-release omeprazole products in 10 mg and 20 mg dosage strengths and generic delayed-release pantoprazole products are currently available in the U.S. market, and we anticipate that additional generic delayed-release omeprazole products, including 40 mg dosage strengths, as well as other generic delayed-release PPIs, will enter the market. In addition, delayed-release omeprazole is available in a 20 mg dosage strength as a branded and store brand OTC product. We anticipate that other OTC delayed-release PPI products will also enter the market.

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 and clinical research organizations 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.

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 investigational new drug application 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 testing for 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. The 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 ordinarily has 10 months in which to complete its initial review of the NDA and respond to the applicant. The review process and the target response 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 initial review of the NDA and the clinical and manufacturing procedures and facilities, the FDA will issue an action letter, which will either include an approval authorizing commercial marketing of the drug for certain indications or contain the conditions that must be met in order to secure final approval of the NDA. If the FDA's evaluation of the NDA submission and the clinical and manufacturing procedures and facilities is not favorable, the FDA may refuse to approve the NDA.

Section 505(b)(2) New Drug Applications

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 Section 505(b)(2) applicant.

To the extent that the Section 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 Section 505(b)(2) application will not be approved until all the listed patents claiming the referenced product have expired. The Section 505(b)(2) application also will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical 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 Section 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 Section 505(b)(2) applicant. Thus, the Section 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.

We have submitted Section 505(b)(2) NDAs for each of our Zegerid products, which referenced certain preclinical and clinical studies conducted for Prilosec. Following submission of our NDAs and filing of the NDAs by the FDA, we provided notice of our Paragraph IV certifications to AstraZeneca, the holder of the Prilosec NDA, and certain related companies holding the listed patents, which included various AstraZeneca and Merck entities. In each case, AstraZeneca did not file a patent infringement lawsuit within the required 45-day period. Therefore, our NDAs were not subject to a 30-month stay of approval.

Other Regulatory Requirements

Even though the FDA has approved our Zegerid prescription products, we will 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, 2008, we had 337 employees. A total of 41 employees were engaged in clinical research, regulatory, quality assurance, product development and manufacturing, and medical affairs, 272 were in sales, marketing, commercial operations and business development, and 24 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.

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 addition to other information contained in this report as well as our other public filings with the Securities and Exchange Commission.

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 Zegerid® (omeprazole/sodium bicarbonate) Capsules and Powder for Oral Suspension prescription products, including our ability to:
    - achieve greater market acceptance of our products by our targeted primary care physicians and gastroenterologists;
    - maintain adequate levels of reimbursement coverage for our products from third-party payors; and
    - compete effectively within the gastrointestinal, or GI, and primary care fields, where many other products are well-established and successful and are marketed by competitors with significantly more experience and resources;
- whether we are able to maintain patent protection for our products, including whether we are successful in the lawsuits we filed against Par Pharmaceutical, Inc., or Par, for infringement of patents covering our Zegerid Capsules and Zegerid Powder for Oral Suspension products; and
- whether we will be able to further diversify our sources of revenue and product portfolio, including our ability to obtain additional financing to support the licensing or acquisition of new products.

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

At this time, we are largely dependent on the commercial success of our Zegerid products and proton pump inhibitor, or PPI, technology, and we cannot be certain that we will be able to achieve commercial success with these products and technology.

We have invested a significant portion of our time and financial resources in the development and commercialization of our Zegerid family of prescription products, which are currently being marketed in capsule and powder for oral suspension dosage forms. These products are proprietary immediate-release formulations of omeprazole, a PPI, and are intended to treat or reduce the risk of a variety of upper GI diseases and disorders, including gastroesophageal reflux disease, or GERD. We anticipate that in the near term our ability to generate revenues will depend on the commercial success of our currently marketed products, which in turn, will depend on several factors, including our ability to:

- successfully increase market demand for, and sales of, Zegerid Capsules and Zegerid Powder for Oral Suspension, through our own sales force, our contract sales agreement with inVentiv Commercial Services, LLC, or inVentiv, our co-promotion arrangement with Otsuka America Pharmaceutical, Inc., or Otsuka America, and any other arrangements that we may later establish;

- successfully maintain patent protection for our Zegerid family of 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;

- establish and maintain effective marketing programs and continue to build brand identity;

- obtain greater acceptance of the products by physicians, patients and third-party payors and obtain and maintain distribution at the retail level;

- establish and maintain agreements with wholesalers and distributors on commercially reasonable terms; and

- maintain commercial manufacturing capabilities as necessary to meet commercial demand for the products, as well as maintain commercial manufacturing arrangements with third-party manufacturers.

Our ability to generate revenue in the longer term will also depend on whether our strategic alliances with Glaxo Group Limited, an affiliate of GlaxoSmithKline, plc, or GSK, and Schering-Plough Healthcare Products, Inc., or Schering-Plough, will lead to the successful commercialization of additional omeprazole products using our patented PPI technology.

We expect to incur significant costs as we continue to support the commercialization of Zegerid Capsules and Zegerid Powder for Oral Suspension. We have realized modest growth in sales of our Zegerid products to date relative to our expenses to date, including expenses associated with our commercial operations, and we may be unable to achieve greater market acceptance. For the year ended December 31, 2007, we recognized $79.4 million in Zegerid net product sales. In addition, as of December 31, 2007, we had an accumulated deficit of $304.0 million.

We cannot be certain that our continued marketing of Zegerid Capsules and Zegerid Powder for Oral Suspension, including the efforts of inVentiv and Otsuka America, will result in increased demand for, and sales of, our products or that we will receive any milestone payments or sales-based royalties from our strategic alliances with GSK and Schering-Plough. The potential demand for our currently marketed prescription products may also be negatively impacted by the availability of any OTC products developed and marketed by Schering-Plough in the U.S. pursuant to our strategic alliance. If we fail to successfully commercialize our prescription products or 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 sustain and grow our business and attain profitability, and our business, financial condition and results of operations will be materially adversely affected.

In addition, even if our products continue to achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost-effective or otherwise render our products obsolete.

If we are unable to maintain adequate levels of reimbursement for our Zegerid products on reasonable pricing terms, their commercial success may be severely hindered.

Our ability to sell our products may depend in large part on the extent to which reimbursement for the costs of our products is available from private health insurers, managed care organizations, government entities and others. Third-party payors are increasingly attempting to contain their costs. We cannot predict actions third-party payors may take, or whether they will limit the coverage and level of reimbursement for our products or refuse to provide any coverage at all. Reduced or partial reimbursement coverage could make our products less attractive to patients,

suppliers and prescribing physicians and may not be adequate for us to maintain price levels sufficient to realize an appropriate return on our investment in our products or compete on price.

In many cases, insurers and other healthcare payment organizations encourage the use of less expensive alternative generic brands and OTC products through their prescription benefits coverage and reimbursement policies. The availability of generic prescription and OTC PPI products has created, and will continue to create, a competitive reimbursement environment for our prescription Zegerid branded products. Insurers and other healthcare payment organizations frequently make the generic or OTC alternatives more attractive to the patient by providing different amounts of reimbursement so that the net cost of the generic or OTC product to the patient is less than the net cost of a prescription branded product. Aggressive pricing policies by our generic or OTC product competitors and the prescription benefit policies of insurers could have a negative effect on our product revenues and profitability. Even though we are eligible to receive sales-based royalties on OTC products under our OTC license agreement with Schering-Plough, those potential revenues could be offset by the impact of lost sales of our prescription products to the extent the OTC products are preferred by customers over our current prescription products.

Many managed care organizations negotiate the price of medical services and products and develop formularies which establish pricing and reimbursement levels. Exclusion of a product from a formulary can lead to its sharply reduced usage in the managed care organization's patient population. If our products are not included within an adequate number of formularies or adequate reimbursement levels are not provided, or if those policies increasingly favor generic or OTC products, our market share and gross margins could be negatively affected, as could our overall business and financial condition.

The competition among pharmaceutical companies to have their products approved for reimbursement also results in downward pricing pressure in the industry and in the markets where our products compete. In some cases, we aggressively discount our products in order to obtain reimbursement coverage, and we may not be successful in any efforts we take to mitigate the effect of a decline in average selling prices for our products. Declines in our average selling prices also reduce our gross margins.

In addition, managed care initiatives to control costs may influence primary care physicians to refer fewer patients to gastroenterologists and other specialists. Reductions in these referrals could have a material adverse effect on the size of our potential market and increase costs to effectively promote GI products.

Our account managers contact private health insurers, managed care organizations, government entities and other third-party payors, seeking reimbursement coverage for our products similar to that for branded delayed-release PPI products. The process for obtaining coverage can be lengthy and time-consuming, in some cases taking several months before a particular payor initially reviews our product, and we may ultimately be unsuccessful in obtaining coverage. Our competitors generally have larger account management organizations, as well as existing business relationships with third-party payors relating to their PPI products, as well as other portfolio products. Moreover, the current availability of generic and OTC delayed-release omeprazole products may make obtaining reimbursement coverage for our immediate-release products more difficult because our products also utilize omeprazole as an active ingredient. If we fail to successfully secure and maintain reimbursement coverage for our products on favorable terms or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and our business will be materially adversely affected.

Our strategic partners, GSK and Schering-Plough, may not successfully commercialize products using our patented PPI technology.

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 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. 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 lead to decreased demand 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 under the agreement and has not cured the breach within 30 days notice, provided that the cure period for late payments is 15 days, and provided further that all alleged breaches are subject to dispute resolution provisions set forth in the agreement. In addition, Schering-Plough may terminate the agreement in its entirety on 180 days prior written notice to us at any time after submitting its first new drug application, or NDA, to the U.S. Food and Drug Administration, or FDA, for a licensed product or if Schering-Plough does not receive marketing approval in the U.S. for a licensed product before a specified date.

If GSK's and Schering-Plough's commercialization efforts are not successful, our ability to generate sufficient revenues to sustain and grow our business and attain profitability will be adversely affected.

The market for the GI pharmaceutical industry is 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 GI field, where currently marketed products are well-established and successful. Many of our competitors are large, well-established companies in the pharmaceutical field. Our competitors include, among others, AstraZeneca plc, TAP Pharmaceutical Products Inc., Wyeth, Altana, Eisai Co., Ltd., Johnson & Johnson, Axcan Pharma Inc., Ferring Pharmaceuticals A/S, Merck & Co., Inc., Novartis AG, Salix Pharmaceuticals, Inc., Shire Pharmaceuticals Group plc and The Procter & Gamble Company, as well as several generic manufacturers. Many of these companies already offer products that target GERD and other GI diseases and disorders that we target. Given our relatively small size and the entry of our products into a market characterized by well-established drugs, 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. It is also possible that our competitors may be able to reduce their cost of manufacturing so that they can aggressively price their products and secure a greater market share to our detriment. In addition, our competitors may be able to attract and retain qualified personnel and to secure capital resources more effectively than we can. Any of these events could adversely affect our business.

Our Zegerid products compete with many other drug products focused on upper GI diseases and disorders, which could put downward pressure on pricing and market share and limit our ability to generate revenues.

Our Zegerid products compete with many prescription and OTC products, including:

Prescription Products:

- PPIs: AstraZeneca plc's Prilosec® and Nexium®, TAP Pharmaceutical Products Inc.'s Prevacid®, Wyeth's and Altana's Protonix®, Johnson & Johnson's and Eisai Co., Ltd.'s Aciphex®, and generic delayed-release omeprazole and pantoprazole, among others; and

- Histamine-2 receptor antagonists: Merck & Co., Inc.'s Pepcid®, GlaxoSmithKline plc's Zantac® and Tagamet® and Braintree Laboratories, Inc.'s Axid®, among others.

Over-the-Counter Products:

- PPIs: The Procter & Gamble Company's Prilosec OTC® and store brand delayed-release omeprazole OTC products;

- Histamine-2 receptor antagonists: Boehringer Ingelheim GmbH's Zantac, GlaxoSmithKline plc's Tagamet, and Johnson & Johnson's and Merck & Co., Inc.'s Pepcid AC® and Pepcid Complete®, among others; and

- Antacids: Johnson & Johnson's and Merck and Co., Inc.'s Mylanta® and Rolaids®, Novartis AG's Maalox® and GlaxoSmithKline plc's Gaviscon® and Tums®, among others.

In addition, various companies are developing new products, including motility agents, reversible acid inhibitors, cytoprotective compounds, new PPIs and products that act on the lower esophageal sphincter, or LES. We may be required to compete with these or other new products that have greater efficacy or other benefits relative to our products.

Many of the currently marketed competitive products are available as generic products. For example, generic delayed-release omeprazole products in 10 mg and 20 mg dosage strengths and generic delayed-release pantoprazole products are currently available in the U.S. market, and we anticipate that additional generic delayed-release omeprazole products, including 40 mg dosage strengths, as well as other generic delayed-release PPIs, will enter the market. In addition, delayed-release omeprazole is available in a 20 mg dosage strength as a branded and store brand OTC product. We anticipate that other OTC PPI products will also enter the market. The existence of generic and OTC delayed-release PPI products could make it more difficult for branded prescription PPI products, including our Zegerid products, to gain or maintain market share and could cause prices for PPIs to drop, each of which could adversely affect our business. Moreover, the current availability of generic and OTC delayed-release omeprazole products may have an additional impact on demand and pricing for our immediate-release products because our products also utilize omeprazole as an active ingredient.

We 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 promotional efforts of inVentiv, under our contract sales organization agreement, and Otsuka America, under our co-promotion agreement, may not be successful in increasing market demand for, and sales of, our Zegerid prescription products.

To support the promotion of our Zegerid prescription products, we have entered into a contract sales organization agreement with inVentiv and a co-promotion agreement with Otsuka America. Under our agreement with inVentiv, inVentiv is committed to provide up to approximately 140 fully-dedicated contract sales representatives to promote our Zegerid products in the U.S. Our agreement with inVentiv causes us to incur significant costs, and we cannot be sure that the efforts of the contract sales force will be successful.

Under our co-promotion agreement, Otsuka America currently co-promotes Zegerid Capsules and Zegerid Powder for Oral Suspension to targeted U.S. physicians. While our agreement with Otsuka America requires its field sales representatives to promote our products in a minimum number of primary details to target physicians, we cannot be sure that Otsuka America's efforts will be successful. In addition, we and Otsuka America each have the right to terminate the agreement effective at any time by providing at least 120 days prior written notice, as well as other more limited termination rights.

Any revenues we receive from sales of our products generated by the contract sales force, Otsuka America or any other third parties will depend upon the efforts of those other parties, which in many instances will not be within our control. If we are unable to maintain our agreements with inVentiv and Otsuka America or to effectively establish alternative arrangements to market our products more broadly than we can through our internal sales force, our business could be adversely affected. In addition, despite our arrangements with inVentiv and Otsuka America to expand efforts to promote our products, we still will not be able to cover all of the PPI prescribing physicians at the same level of reach and frequency as our competitors with branded PPI products.

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

Our wholesaler customers 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 32%, 32% and 14%, respectively, of our annual revenues during 2007. 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.

If we are unable to continue to manufacture our products on a commercial basis, our commercialization efforts will be materially harmed.

The quantities of our products that our suppliers are able to manufacture in the future may fail to meet our quality specifications or may not be sufficient to meet potential commercial demand. Any problems or delays experienced in the manufacturing process for Zegerid Capsules or Zegerid Powder for Oral Suspension may impair our ability to provide commercial quantities of the products, which would limit our ability to sell the products and would adversely affect our business. While we believe we ultimately could redesign our manufacturing processes or identify alternative suppliers in response to problems we may encounter as we manufacture our products, it could take significant time to do so and may require regulatory approval, and our products may not be available from alternate manufacturers at favorable prices.

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

We have no manufacturing facilities, and we rely on third-party manufacturers to provide us with an adequate and reliable supply of our products on a timely basis. 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 as part of their business. In addition, because many 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.

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. We also 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. 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, capacity at our 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 active omeprazole and antacid pharmaceutical ingredients in our products on a commercial scale is limited, and it would take a significant amount of time to arrange for alternative manufacturers. Any new supplier of products or active pharmaceutical 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 resources have been primarily focused on commercializing our Zegerid products, and we may be unable to expand our product portfolio or integrate new products successfully.

Our resources have been primarily focused on commercializing our Zegerid family of products. Our success will depend in part on our ability to diversify our product portfolio and further leverage our commercial capabilities through co-promotion, in-licensing or acquisition of additional marketed or late stage proprietary products. We may not be able to identify appropriate licensing or acquisition opportunities to expand and diversify our pipeline of products. Even if we identify an appropriate product, competition for it may be intense. We may not be able to successfully negotiate the terms of a license or acquisition agreement on commercially acceptable terms. The

negotiation of agreements to obtain rights to additional products or to acquire companies or their products or product lines could divert our management's time and resources from other elements of our existing business. Moreover, we may be unable to finance the licensing or acquisition of a new product or an acquisition target. If we issue shares of our common stock or other securities in one or more significant acquisitions, our stockholders could suffer significant dilution of their ownership interests. We might also incur debt or experience a decrease in cash available for our operations, or incur contingent liabilities and amortization expenses relating to identifiable intangible assets, in connection with any future acquisitions.

We may not generate adequate revenues under our co-promotion agreements for Naprelan® Controlled Release Tablets and the Fleet® Phospho-soda® EZ-Prep™ Bowel Cleansing System to justify our level of promotional effort and expense under the agreements.

In June 2007, we entered into a co-promotion agreement with Victory Pharma, Inc., or Victory, pursuant to which we agreed to co-promote Naprelan Controlled Release Tablets to our targeted primary care physicians in the U.S. Under the terms of the co-promotion agreement, we will receive a co-promotion fee equal to slightly more than half of the net sales value of the prescriptions generated by our target physicians, offset by an initial credit in recognition of existing sales.

In August 2007, we entered into a co-promotion agreement with C.B. Fleet Company Incorporated, or Fleet, pursuant to which we agreed to co-promote the Fleet Phospho-soda EZ-Prep Bowel Cleansing System to our targeted gastroenterologists in the U.S. Under the terms of the co-promotion agreement, Fleet will pay us to promote the product based on a set fee per sales call, subject to a minimum and maximum number of sales calls. We will also have the opportunity to earn bonus payments if unit sales exceed predetermined baselines.

Our ability to generate adequate revenues under the co-promotion agreements 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:

- our ability to increase market demand and sales of the Naprelan and Fleet products;
- adverse side effects or inadequate therapeutic efficacy of the Naprelan or Fleet products and any resulting product liability claims or product recalls; and
- the potential for termination of the co-promotion arrangements.

Our successful co-promotion of the Naprelan products is also dependent on the strength of the intellectual property surrounding the Naprelan products and the level of competition from other products, including a generic formulation of Naprelan, which is currently commercially available in a 500 mg dosage strength and is the subject of pending patent infringement litigation initiated by Elan Corporation, plc and/or its affiliates, as the patent holder for the Naprelan products.

Our ability to successfully co-promote the Fleet product is also dependent on the FDA's continued determination that the Fleet product is safe for its intended use. A recently filed citizen's petition requests that the FDA withdraw oral sodium phosphate products for bowel cleansing from commercial marketing or reclassify them as prescription medications. Although the FDA has previously declined to act upon similar petitions filed in the past, we cannot be certain about how the FDA may act in the future.

In addition, although our sales representatives will continue to promote our Zegerid products in the primary detail position, the co-promotion of the Naprelan and Fleet products could detract from their efforts to promote our Zegerid products and have an adverse impact on Zegerid sales. If our co-promotion efforts are not successful, our ability to generate sufficient revenues to sustain and grow our business and attain profitability may be adversely affected.

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.

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 we are able to support clinical safety and efficacy.

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 will 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 regulatory approvals will be limited to those indications that are specifically submitted to the FDA for review. 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 Zegerid products and any other products that we market.

Our Zegerid products and any other products that we market will 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, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 provides a new Medicare prescription drug benefit, which became effective in January 2006, and mandates other reforms. Although we cannot predict the full effect on our business of the implementation of this new legislation, to date the new benefit, which is managed by private health insurers, pharmacy benefit managers and other managed care organizations, has resulted in additional growth in the market for generic products and it may further exacerbate industry-wide pressure to reduce the prices charged for both generic and branded PPI products. This could harm our ability to market our products and generate revenues. It is also possible that other proposals will be adopted, particularly in view of the upcoming presidential election in 2008 and the potential agenda of any new administration. As a result of the new Medicare prescription drug benefit or any other proposals, we may determine to change our current manner of operation, provide additional benefits or change our contract arrangements, any of which could harm our ability to operate our business efficiently, obtain collaborators and raise capital. We are also subject to additional price reporting obligations under the Deficit Reduction Act of 2005, which became effective on January 1, 2007. Complying with these additional reporting obligations increases our administrative burden.

In an attempt to protect against counterfeit drugs, 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 2009, but the effective

date may be extended by the California Board of Pharmacy until January 2011. Compliance with the California electronic pedigree requirement will likely require an increase in our operational expenses, and we may not be able to comply with the requirement at the time it becomes effective, particularly if the California Board of Pharmacy does not extend the effective date of the legislation beyond January 2009. In addition, we may be obligated to comply with additional pedigree requirements enacted by other states in the future.

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 of our products and the manufacture and sale of our Zegerid products and any other products we co-promote or otherwise commercialize. 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. For example, although we have not been named as a party, a significant number of product liability actions have been brought against Fleet relating to Fleet's phospho-soda products, including at least one action involving the Fleet product that we co-promote. 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.

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 satisfactory manner and in compliance with applicable U.S. and foreign regulations, or fail to perform their obligations under our agreements with them, 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. For example, the FDA has inspected and will

continue to inspect certain of our CROs' operations and trial procedures and may issue notices of any observations of failure to comply with FDA-approved good clinical practices and other regulations. If our CROs or clinical investigators are unable to respond to such notices of observations in a satisfactory manner or otherwise resolve any issues identified by the FDA or other regulatory authorities, we may be unable to use the data gathered at those sites. To the extent a single CRO conducts clinical trials for us for multiple products, the CRO's failure to comply with U.S. and foreign regulations could negatively impact each of the trials. 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.

Any products we develop in the future likely will require significant product and clinical 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 face substantial risks of failure inherent in developing pharmaceutical products. The pharmaceutical industry is subject to stringent regulation by many different agencies at the federal, state and international levels. Our products must satisfy rigorous standards of safety and efficacy before the FDA and any foreign regulatory authorities 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, 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 products 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 or rejections based on our inability to 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. 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 products 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.

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

We are a small company and, as of January 31, 2008, had 337 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, particularly for sales and marketing positions, 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 assure you 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 prior to the expiration of our patents. We also may not be able to protect our intellectual property rights against third-party infringement, which may be difficult to detect.

To date, five U.S. patents have been issued relating to technology we license from the University of Missouri and several U.S. patent applications are pending. In addition to the U.S. patent coverage, several international patents have been issued, including in Australia, Canada, India, Mexico, New Zealand, Russia, Singapore, South Africa, and South Korea, as well as in countries within the European Patent Organization, and several international patent applications are pending, all of which are subject to the University of Missouri license agreement. The patents related specifically to our Zegerid products are and will be method and/or formulation patents and will not protect the use of the active pharmaceutical ingredients outside of the formulations covered by the patents and patent applications licensed to or owned by us. The issued claims in the 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. 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. 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 September 2007, the U.S. Patent and Trademark Office, or PTO, issued an Ex Parte Reexamination Certificate for U.S. Patent No. 6,699,885, or the '885 patent, which formally concluded the pending reexamination proceeding relating to the '885 patent, and confirmed the patentability of the '885 patent, as amended during the proceeding, over the references cited in the proceeding. The '885 patent is one of the five currently issued U.S. patents providing coverage for our Zegerid family of products, which are licensed to us under our license agreement with the University of Missouri. For a more detailed description of this proceeding, see Part I – Item 3 – Legal Proceedings.

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 five 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 three 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. If we, in connection with the University of Missouri, do not successfully defend the patent application against the pre-grant opposition, we may not be able to obtain patent coverage for one or more of our Zegerid products in India.

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., Canada and Japan and have applied for trademark registration in the EU for our brand name, Zegerid®, and have applied for trademark registration for various other names and logos. An opposition against our EU trademark application for our brand name, Zegerid, has recently concluded in our favor. Accordingly, the trademark should proceed to registration in the EU. Any objections we receive from the PTO, foreign trademark authorities or third parties relating to our 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.

Par's Paragraph IV certifications under the Hatch-Waxman Act related to Zegerid Capsules and Zegerid Powder for Oral Suspension and the related patent infringement litigation 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 October 2007, we filed an amended complaint to reflect the PTO's issuance of an Ex Parte Reexamination Certificate for U.S. Patent No. 6,699,885. 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. 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. In addition, Par is seeking a declaration that U.S. Patent No. 5,840,737, or the '737 patent, another patent listed in the Orange Book for Zegerid Powder for Oral Suspension, is not infringed, invalid and/or unenforceable. We have moved to dismiss, or in the alternative, stay these claims due to the pending reissue proceeding involving this patent. Discovery is expected to begin in the near future and a trial date has been scheduled in July 2009. Both lawsuits have been consolidated for all purposes.

We 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 generic products 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 likely negatively impact our financial condition and results of operations. 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. In particular, intellectual property litigation among companies targeting the treatment of upper GI diseases and disorders is particularly common and may increase due to the large market for these products.

AstraZeneca plc, as well as other competitors and companies, including aaiPharma, TAP Pharmaceutical Products Inc. and Takeda Chemical Industries Ltd., hold various other patents relating to omeprazole and PPI products generally and could file an infringement suit claiming our current products infringe their patents. Our third-

party manufacturers may also receive claims of infringement and could be subject to injunctions and temporary or permanent exclusionary orders in the U.S. or in the countries in which they are based. While we believe that we would have meritorious defenses to such claims, the outcome of any such litigation is uncertain and defending such litigation would be expensive, time-consuming and distracting to management.

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.

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.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of their former employers or otherwise breached the terms of agreements with former employers.

Many of our employees were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. In addition, certain of our employees are parties to non-compete, non-solicitation and non-disclosure agreements with their prior employers. We may be subject to claims that these employees or we have inadvertently or otherwise breached these non-compete and non-solicitation agreements or used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we fail in defending such claims, in addition to paying money claims, we may lose valuable intellectual property rights or personnel. A loss of key personnel or their work product could hamper or prevent our ability to commercialize products, which could severely harm our business.

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 achieve profitability.

The extent of our future operating losses and the timing of profitability are highly uncertain, and we may never achieve profitability. We have been engaged in developing and commercializing drugs and have consistently generated 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, 2007, we recognized $79.4 million in net sales of our Zegerid products, and, as of December 31, 2007, we had an accumulated deficit of $304.0 million. We expect to incur additional operating losses and capital expenditures as we support the continued marketing of our Zegerid 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 collaboration or licensing agreements, or through equity, debt and/or royalty financing.

In May 2005, we filed a universal shelf registration statement on Form S-3 with the Securities and Exchange Commission, which was declared effective in June 2005. On August 22, 2005, we sold 7,350,000 shares of our common stock that were registered under the universal shelf registration statement. The universal shelf registration statement may permit us, from time to time, to offer and sell up to an additional approximately $43.8 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 activities, investor perception of our prospects and the general condition of the financial markets, among others.

In February 2006, we entered into a CEFF with Kingsbridge, which may entitle us to sell and obligate Kingsbridge to purchase, from time to time over a period of three years, shares of our common stock for cash consideration up to the lesser of $75.0 million or 8,853,165 shares, subject to certain conditions and restrictions. We filed a resale shelf registration statement on Form S-3 with the Securities and Exchange Commission to facilitate Kingsbridge's public resale of shares of our common stock which it may acquire from us from time to time in connection with our draw downs under the CEFF or upon the exercise of a warrant to purchase 365,000 shares of common stock that we issued to Kingsbridge in connection with the CEFF. The resale shelf registration statement was declared effective in February 2006. In 2006, we completed four draw downs under the CEFF and have issued a total of 5,401,787 shares in exchange for aggregate gross proceeds of $36.5 million. We did not initiate any draw downs under the CEFF during 2007. Accordingly, the remaining commitment of Kingsbridge under the CEFF for the potential purchase of our common stock is equal to the lesser of $38.5 million in cash consideration or 3,451,378 shares (which shares would be priced at a discount ranging from 6% to 10% of the average market price during any future draw down), subject to certain conditions and restrictions.

There can be no assurance that we will be able to complete any further draw downs under the CEFF. Factors influencing our ability to complete draw downs include conditions such as a minimum price for our common stock; the accuracy of representations and warranties made to Kingsbridge; our ability to maintain the effectiveness of the shelf registration statement; and the continued listing of our stock on the Nasdaq Global Market.

In July 2006, we entered into our loan agreement with Comerica, pursuant to which we may request advances in an aggregate outstanding amount not to exceed $20.0 million. As of March 3, 2008, the date of this report, we have not borrowed any amounts under the loan agreement. Our ability to borrow 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 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 amounts under the loan agreement, and may be required to repay any amounts previously borrowed.

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 because our sales prospects are uncertain.

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, our Zegerid products, as well as any other products we market are uncertain and therefore our sales 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 Zegerid Capsules and Zegerid Powder for Oral Suspension and any products which may be commercialized by GSK or Schering-Plough pursuant to our strategic alliances;
- the outcome of, or other developments related to, our patent infringement suits against Par involving Zegerid Capsules and Zegerid Powder for Oral Suspension;
- interruption in the manufacturing or distribution of our products;
- our ability to generate revenues under our co-promotion agreements with Victory and Fleet;
- our ability to obtain regulatory approval for any future products we develop;
- results of our clinical trials and safety and efficacy 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 our Zegerid products. 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.

The committed equity financing facility that we entered into with Kingsbridge may not be available to us if we elect to make a draw down, may require us to make additional "blackout" or other payments to Kingsbridge, and may result in dilution to our stockholders.

The CEFF entitles us to sell and obligates Kingsbridge to purchase, from time to time over a period of three years, shares of our 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 2006, we 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. We did not initiate any draw downs under the CEFF during 2007.

Kingsbridge will not be obligated to purchase additional shares under the CEFF unless certain conditions are met, which include a minimum price for our common stock; the accuracy of representations and warranties made to Kingsbridge; compliance with laws; the continued effectiveness of the shelf registration statement; and the continued listing of our stock on the Nasdaq Global Market. In addition, Kingsbridge is permitted to terminate the CEFF if it determines that a material and adverse event has occurred affecting our business, operations, properties or financial condition and if such condition continues for a period of 10 days from the date Kingsbridge provides us notice of such material and adverse event. Moreover, our ability to fully utilize the CEFF as a source of future financings may be limited by the remaining maximum number of 3,451,378 shares issuable under the CEFF consistent with Nasdaq Global Market listing requirements (which shares would be priced at a discount ranging from 6% to 10% of the average market price during any future draw down). If we are unable to access funds through the CEFF, or if the CEFF is terminated by Kingsbridge, we may be unable to access capital on favorable terms or at all.

We are entitled in certain circumstances, to deliver a blackout notice to Kingsbridge to suspend the use of the shelf registration statement and prohibit Kingsbridge from selling shares thereunder. If we deliver a blackout notice in the 15 trading days following the settlement of a draw down, or if the shelf registration statement is not effective in circumstances not permitted by our agreement with Kingsbridge, then we must make a payment to Kingsbridge, or issue Kingsbridge additional shares in lieu of the payment, calculated on the basis of the number of shares held by Kingsbridge (exclusive of shares that Kingsbridge may hold pursuant to exercise of the Kingsbridge warrant) and the change in the market price of our common stock during the period in which the use of the shelf registration statement is suspended. If the trading price of our common stock declines during a suspension of the shelf registration statement, the blackout or other payment could be significant.

If we sell shares to Kingsbridge under the CEFF, or issue shares in lieu of a blackout payment, it will have a dilutive effective on the holdings of our current stockholders, and may result in downward pressure on the price of our common stock. For each draw down under the CEFF, we will issue shares to Kingsbridge at a discount of up to 10% from the volume weighted average price of our common stock. If we draw down amounts under the CEFF when our share price is decreasing, we will need to issue more shares to raise the same amount than if our stock price was higher. Issuances in the face of a declining share price will have an even greater dilutive effect than if our share price were stable or increasing, and may further decrease our share price.

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 potential indebtedness under the loan agreement with Comerica may bear 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 certain affirmative and negative covenants, including limitations on our ability: 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 certain financial covenants with respect to a minimum liquidity ratio and, when the outstanding loan balances exceed $15.0 million, minimum EBITDA requirements.

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.

To service any future indebtedness and fund our working capital and capital expenditures, we will require a significant amount of cash. Our ability to generate cash depends on many factors beyond our control.

Our ability to make payments on any indebtedness will depend upon our future operating performance and on our ability to generate cash flow in the future, which is subject to general economic, financial, competitive, legislative, regulatory and other factors that are beyond our control. We cannot assure you that our business will generate sufficient cash flow from operations, or that future borrowings, including borrowings under our loan agreement with Comerica, will be available to us in an amount sufficient to enable us to pay any indebtedness or to fund our other liquidity needs.

Rises in interest rates could adversely affect our financial condition.

The interest rates applicable to any amounts we borrow under our loan agreement with Comerica will be indexed, at our election, 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. An increase in prevailing interest rates would have an immediate effect on the interest rates charged on our variable rate debt, if any. If prevailing interest rates or other factors result in higher interest rates on any debt we incur under the loan agreement, the increased interest expense could adversely affect our cash flow and our ability to service our debt. 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. We cannot be certain that we will have sufficient cash flow from our operating activities or other resources to service our future debt obligations, if any, particularly in an environment of rising interest rates.

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

Our investment securities consist of high-grade auction rate securities, corporate debt securities and government agency securities. As of December 31, 2007, our short-term investments included $4.3 million of high-grade (AAA rated) auction rate securities issued by state municipalities. Our auction rate securities are debt instruments with a long-term maturity and an interest rate that is reset in short-term intervals through auctions. The recent conditions in the global credit markets have prevented some investors from liquidating their holdings of auction rate securities 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. Although to date, we have not recorded any realized gains or losses on our investment portfolio or recognized any significant unrealized gains or losses on investments, 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. If the credit ratings of the security issuers deteriorate and any decline in market value is determined to be other-than-temporary, we would be required to adjust the carrying value of the investment through an impairment charge.

Our short operating history makes it difficult to evaluate our business and prospects.

We were incorporated in December 1996 and have only been conducting operations with respect to our Zegerid family of products since January 2001. We commercially launched our first product in October 2004. Our operations to date have involved organizing and staffing our company, acquiring, developing and securing our technology, undertaking product development and clinical trials for our products and commercially launching Zegerid Powder for Oral Suspension and Zegerid Capsules. We have relatively limited experience selling and marketing our products, and we have not yet demonstrated an ability to achieve profitability with our products. Consequently, any predictions about our future performance may not be as accurate as they could be if we had more experience successfully commercializing products.

Changes in, or interpretations of, accounting rules and regulations could result in unfavorable accounting charges or require us to change our compensation policies.

Accounting methods and policies for specialty pharmaceutical companies, including policies governing revenue recognition, expenses, accounting for stock options and in-process research and development costs are subject to further review, interpretation and guidance from relevant accounting authorities, including the Securities and Exchange Commission. Changes to, or interpretations of, accounting methods or policies in the future may require us to reclassify, restate or otherwise change or revise our financial statements, including those contained in this report.

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 may be volatile and you may not be able to sell your shares at an attractive price.

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, 2007, the trading prices for our common stock ranged from a high of $8.15 to a low of $1.90, and on February 15, 2008, the closing trading price for our common stock was $2.02. 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 suits against Par involving Zegerid Capsules and Zegerid Powder for Oral Suspension;
- the publication of prescription trend data concerning our products or competitive products;
- 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;
- 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;
- sales of large blocks of our common stock, including sales by Kingsbridge under the CEFF, our executive officers, directors or institutional investors;
- announcements concerning borrowings under the loan agreement, draw downs under the CEFF, takedowns under our existing universal shelf registration statement or other developments relating to the loan agreement, CEFF, 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 co-promotion 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 collaboration 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 additional shares of our common stock under our CEFF with Kingsbridge, 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. Similarly, sales by Kingsbridge of any shares that we may sell to it under the CEFF from time to time or upon the exercise of the warrant to purchase 365,000 shares of common stock that we issued to Kingsbridge in connection with the CEFF, 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 established programmed selling plans under Rule 10b5-1 of the Securities Exchange Act from time to time 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 a large number of 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 year, 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. These lawsuits generally are in the early stages of litigation, and 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.

We are exposed to increased costs and risks related to complying with recently enacted and proposed changes in laws and regulations, including costs and risks associated with compliance with Section 404 of the Sarbanes-Oxley Act of 2002.

Recently enacted and proposed changes in the laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and rules proposed by the Securities and Exchange Commission and by the Nasdaq Global Market, have resulted in increased costs to us. In particular, we incur additional administrative expense in connection with our compliance with Section 404 of the Sarbanes-Oxley Act, which requires management to report on, and our independent registered public accounting firm to attest to, our internal controls on an annual basis. As part of our compliance with Section 404, we also rely on the continued effectiveness and adequacy of the internal controls at our key service providers. In addition, the new rules could make it more difficult or more costly for us to obtain certain types of insurance, including directors' and officers' liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board, our board committees or as executive officers. We cannot predict or estimate the

amount of the additional costs we may incur or the timing of such costs. If we, or the third party service providers on which we rely, fail to comply with any of these laws or regulations, or if our auditors cannot timely attest to our evaluation of our internal controls, we could be subject to regulatory scrutiny and a loss of public confidence in our corporate governance or internal controls, which could have an adverse effect on our business and our stock price.

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 amended and restated certificate of incorporation and amended and restated 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 amended and restated certificate of incorporation or amended and restated 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. 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 24,000 square feet in San Diego, California. We lease our primary office facility pursuant to a lease agreement that expires in March 2008. We recently entered into a sublease for approximately 24,500 square feet in San Diego, California, which will be our new primary office facility. We plan to begin occupying this facility in March 2008, and the sublease 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 October 2007, we filed an amended complaint to reflect the U.S. Patent and Trademark Office's, or PTO's, issuance of an Ex Parte Reexamination Certificate for U.S. Patent No. 6,699,885, or the '885 patent, as further described below. 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. 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. In addition, Par is seeking a declaration that U.S. Patent No. 5,840,737, or the '737 patent, another patent listed in the Orange Book for Zegerid Powder for Oral Suspension, is not infringed, invalid and/or unenforceable. We have moved to dismiss, or in the alternative, stay these claims due to the pending reissue proceeding involving this patent. Discovery is expected to begin in the near future and a trial date has been scheduled in July 2009. Both lawsuits have been consolidated for all purposes.

We 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 generic products 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 likely negatively impact our financial condition and results of operations. 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.

In September 2007, the United States Patent and Trademark Office, or PTO, issued an Ex Parte Reexamination Certificate for the '885 patent, which formally concluded the pending reexamination proceeding relating to the '885 patent, and confirmed the patentability of the '885 patent, as amended during the proceeding, over the references cited in the proceeding. The '885 patent is one of the five currently issued U.S. patents providing coverage for our Zegerid family of products, which patents expire in July 2016 and are licensed to us under our license agreement with the University of Missouri. The reexamination process is provided for by law and generally requires the PTO to consider the scope and validity of a patent based on questions raised by a third party or the PTO. In August 2005, an unidentified third party filed a Request for Ex Parte Reexamination of the '885 patent with the PTO. The PTO granted the Request for Reexamination and issued an initial office action, to which we and the University of Missouri submitted a response. The response included our and the University of Missouri's positions relating to patentability as well as proposed amendments to certain of the claims of the '885 patent. In its September 2007 decision, the PTO confirmed the patentability of the '885 patent claims, as amended and added by us and the University of Missouri, over the references cited in the proceeding. Following the September 2007 action of the PTO, the '885 patent continues to provide patent coverage for our Zegerid products by generally covering methods for treating gastric acid related disorders by administering a composition consisting essentially of a proton pump inhibitor, or PPI (at least a portion of which is not enterically coated), and a minimum specified amount of buffering agent, where a minimum serum concentration of the PPI is achieved within specified time periods.

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 five issued patents listed in the Orange Book for Zegerid Powder for Oral Suspension. The '737 patent is not one of the three 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 on October 1, 2007. If we, in connection with the University of Missouri, do not successfully defend the patent application against the pre-grant opposition, we may not be able to obtain patent coverage for one or more of our Zegerid products in India.

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, 2006		
First Quarter	$8.50	$4.76
Second Quarter	$8.42	$5.77
Third Quarter	$8.70	$4.91
Fourth Quarter	$9.70	$7.14
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

As of February 15, 2008, there were approximately 96 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

Not applicable.

Issuer Purchases of Equity Securities

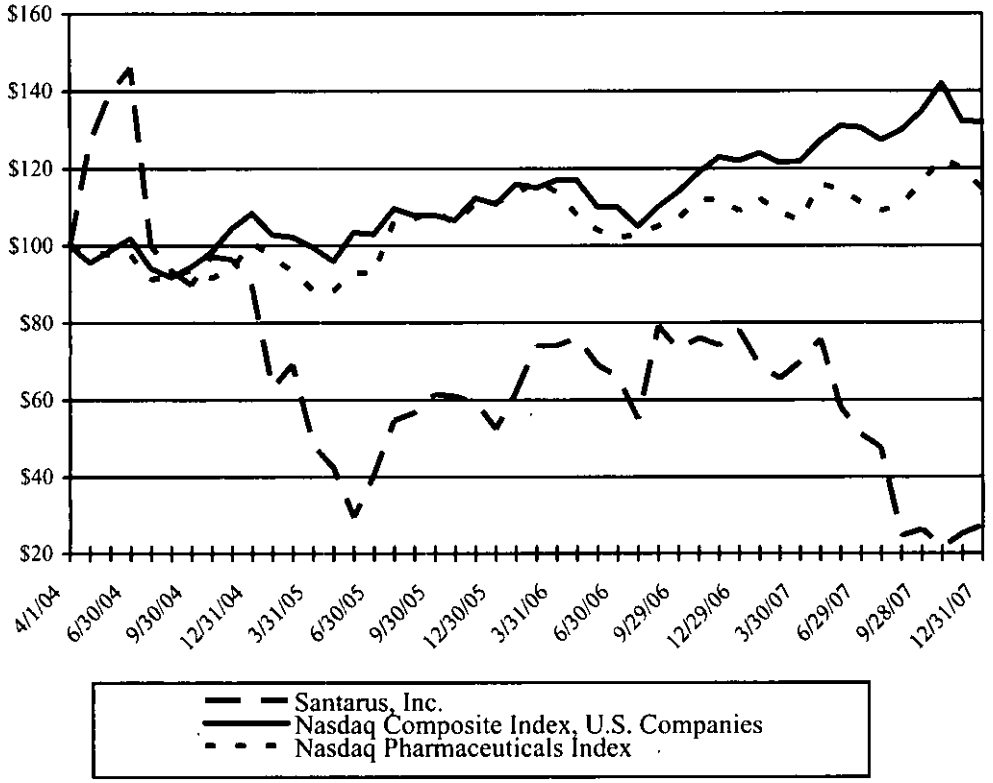
Not applicable.

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	6/30/04	12/31/04	6/30/05	12/30/05	6/30/06	12/29/06	6/29/07	12/31/07
Santarus, Inc.	$100.00	$146.00	$89.50	$40.60	$52.48	$65.84	$77.53	$51.19	$27.23
Nasdaq Composite Index, U.S. Companies ...	$100.00	$101.90	$108.50	$103.02	$110.77	$109.54	$121.70	$130.57	$131.97
Nasdaq Pharmaceuticals Index	$100.00	$97.80	$100.90	$92.79	$111.11	$102.09	$108.76	$111.11	$114.36

Item 6. Selected Financial Data

The selected statement of operations data for the years ended December 31, 2004 and 2003, and the selected balance sheet data as of December 31, 2005, 2004 and 2003, 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, 2007, 2006 and 2005 and the selected balance sheet data as of December 31, 2007 and 2006, 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,				
	2007	2006	2005	2004	2003
	(in thousands, except per share amounts)				
Statement of Operations Data:					
Revenues:					
Product sales, net	$ 79,403	$ 45,980	$ 13,667	$ 634	$ —
Contract revenue	15,025	3,263	12,857	714	—
Total revenues	94,428	49,243	26,524	1,348	—
Costs and expenses:					
Cost of sales	7,301	4,927	2,129	1,968	—
License fees and royalties	11,117	6,437	3,414	5,089	1,000
Research and development	6,849	7,572	11,292	24,823	13,664
Selling, general and administrative	116,503	89,828	79,391	52,354	8,312
Total costs and expenses	141,770	108,764	96,226	84,234	22,976
Loss from operations	(47,342)	(59,521)	(69,702)	(82,886)	(22,976)
Interest and other income, net	3,077	3,055	4,716	1,391	465
Net loss	(44,265)	(56,466)	(64,986)	(81,495)	(22,511)
Accretion to redemption value of redeemable convertible preferred stock	—	—	—	(1,124)	(2,940)
Net loss attributable to common stockholders	$ (44,265)	$ (56,466)	$ (64,986)	$ (82,619)	$ (25,451)
Basic and diluted net loss per share	$ (0.87)	$ (1.19)	$ (1.66)	$ (3.30)	$ (13.71)
Weighted average shares outstanding to calculate basic and diluted net loss per share	51,061	47,355	39,188	25,017	1,857

	As of December 31,				
	2007	2006	2005	2004	2003
			(in thousands)		
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 64,678	$ 75,534	$ 69,367	$ 114,008	$ 45,648
Working capital	25,582	59,010	59,572	94,346	42,376
Total assets	85,344	93,628	79,935	122,216	48,188
Deferred revenue, less current portion	12,722	15,444	8,571	11,429	—
Long-term debt, less current portion	—	—	—	38	224
Redeemable convertible preferred stock	—	—	—	—	57,625
Total stockholders' equity (deficit)	15,348	46,305	54,520	85,843	(13,751)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	(in thousands, except per share amounts)			
Selected Quarterly Financial Data (unaudited):				
2007:				
Product sales, net	$ 17,027	$ 18,800	$ 19,527	$ 24,049
Total revenues	18,958	20,730	26,458	28,282
Cost of sales	1,647	1,663	1,782	2,209
Total costs and expenses	36,312	34,427	34,065	36,966
Net loss	(16,436)	(12,936)	(6,902)	(7,991)
Basic and diluted net loss per share	(0.32)	(0.25)	(0.13)	(0.16)
2006:				
Product sales, net	$ 5,790	$ 8,678	$ 12,164	$ 19,348
Total revenues	6,504	9,393	12,878	20,468
Cost of sales	931	1,421	1,103	1,472
Total costs and expenses	27,141	26,777	25,973	28,873
Net loss	(19,925)	(16,673)	(12,398)	(7,470)
Basic and diluted net loss per share	(0.45)	(0.36)	(0.26)	(0.15)

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 or primary care physicians. The primary focus of our current efforts is the commercialization of our proprietary, immediate-release proton pump inhibitor, or PPI, technology for the treatment of upper gastrointestinal, or GI, diseases and disorders, including gastroesophageal reflux disease, or GERD. In the U.S. prescription market, our commercial organization promotes our Zegerid® (omeprazole/sodium bicarbonate) products to targeted gastroenterologists and primary care physicians in the primary detail position, with additional promotional support provided under our contract sales organization and co-promotion arrangements. 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 prescription and OTC markets in up to 114 countries in Africa, Asia, the Middle-East, and Central and South America, as well as prescription markets in Puerto Rico and the U.S. Virgin Islands. In addition to our efforts related to our PPI technology, our commercial organization co-promotes additional primary care and gastroenterology products in the U.S. Our goal is to become a leading specialty pharmaceutical company, and we plan to continue to seek to maximize the value of our PPI technology, as well as expand our product portfolio through co-promotion, licensing or acquisition of marketed or late stage proprietary products.

Our Zegerid products are proprietary immediate-release formulations that combine omeprazole, a PPI, and one or more antacids and are currently marketed in capsule and powder for oral suspension dosage forms. These products were developed by us 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. According to IMS Health, an independent market research firm, the U.S. market for prescription PPI products had total sales of more than $14 billion during 2007. We believe our Zegerid products offer a differentiated treatment option for physicians and their patients and represent an attractive market opportunity.

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. Although other marketed oral PPIs enjoy widespread use due to their potent acid suppression, favorable safety profiles and once-a-day dosing, they are available only in delayed-release, enteric-coated formulations. While the enteric coatings protect delayed-release PPIs from acid degradation in the stomach, they also delay absorption until the delayed-release PPIs reach the alkaline environment of the small intestine, where the enteric coatings dissolve. Our immediate-release Zegerid products are not enterically coated and are designed to provide both rapid and continued nighttime and daytime acid control.

We received approval from the FDA to market Zegerid (omeprazole/sodium bicarbonate) Capsules in February 2006 for the treatment of heartburn and other symptoms associated with GERD, treatment and maintenance of healing of erosive esophagitis and treatment of duodenal and gastric ulcers. We received approval from the FDA to market Zegerid (omeprazole/sodium bicarbonate) Powder for Oral Suspension for these same indications in 2004. In addition, Zegerid Powder for Oral Suspension 40 mg is approved for the reduction of risk of upper GI bleeding in critically ill patients, and is currently the only PPI product approved for this indication. We received FDA approval of each of our new drug applications, or NDAs, for our 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 20 mg and 40 mg in late March 2006, and launched Zegerid Powder for Oral Suspension 20 mg in October 2004 and 40 mg in February 2005.

We have established a commercial organization that is targeting the highest PPI-prescribing physicians in the U.S., with a focus on approximately 26,000 office-based gastroenterologists and primary care physicians. We estimate that this group of physicians collectively wrote approximately one-third of the value of PPI prescriptions written in 2007. We believe our concentration on high-volume PPI prescribers enables us to effectively promote our products with a relatively focused sales and marketing organization. Our field sales organization includes our own sales representatives, fully-dedicated contract sales representatives under our contract sales organization agreement with inVentiv Commercial Services, LLC, or inVentiv, as well as additional representatives under our co-promotion agreement with Otsuka America Pharmaceutical Inc., or Otsuka America.

In January 2001, we entered into an exclusive, worldwide license agreement with the University of Missouri, under which we licensed rights to its patents and patent applications relating to specific formulations of immediate-release PPIs with antacids for treating upper GI diseases and disorders. This licensed technology forms the basis of our Zegerid family of products. We paid the University of Missouri an upfront licensing fee of $1.0 million in 2001 and a one-time $1.0 million milestone fee upon the filing of our first NDA in 2003. In July 2004, we paid a one-time $5.0 million milestone fee based upon the FDA's approval of Zegerid Powder for Oral Suspension 20 mg, and 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 $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. 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.

We have a non-exclusive agreement with Otsuka America, under which Otsuka America is co-promoting Zegerid Capsules and Zegerid Powder for Oral Suspension to targeted U.S. physicians. We originally entered into the agreement in October 2004 and amended the terms of the agreement in January 2006. Under the agreement, we received a $15.0 million upfront payment from Otsuka America and pay Otsuka America a royalty on total U.S. net sales of Zegerid Capsules and Zegerid Powder for Oral Suspension. The agreement will terminate automatically on December 31, 2009, unless terminated sooner. In addition to other more limited termination rights, either party may terminate the agreement at any time by providing at least 120 days prior written notice.

In October 2006, we entered into a license agreement with Schering-Plough granting rights to develop, manufacture, market and sell Zegerid brand omeprazole products using our patented PPI technology for the OTC market in the U.S. and Canada. In November 2006, we received a $15.0 million upfront license fee. In August 2007, we received a $5.0 million milestone payment relating to progress on clinical product development strategy. We may receive up to an additional $22.5 million in milestone payments upon the achievement of specified regulatory milestones and up to an additional $37.5 million in milestone payments upon the achievement of specified sales milestones. We expect that Schering-Plough will submit an NDA for its first licensed OTC product in March or April of 2008. We 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, we 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 on 180 days prior written notice anytime after submitting its first NDA for a licensed product or if Schering-Plough does not meet a specified deadline for receiving marketing approval in the U.S. for a licensed product. 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.

In June 2007, we entered into a co-promotion agreement with Victory Pharma, Inc., or Victory, to co-promote Naprelan® (naproxen sodium) Controlled Release Tablets to targeted primary care physicians in the U.S. Naprelan Tablets are a once-daily, controlled release formulation of naproxen sodium, a non-steroidal anti-inflammatory drug, or NSAID, indicated for the treatment of a number of conditions, including arthritis and the relief of mild to moderate pain. We trained our field sales representatives and commenced promotional activities for the Naprelan products in the third quarter of 2007. Under the terms of the agreement, we receive a co-promotion fee equal to slightly more than half of the net sales value of the prescriptions generated by our target physicians, offset by an initial credit in recognition of existing sales. We are obligated to make a minimum number of annual and quarterly

second position sales calls to target physicians. Victory is responsible for creating and developing, at its cost and expense, all product marketing materials as well as for handling all manufacturing, distribution, medical affairs and regulatory support for the products. We are responsible for all costs related to our sales force, and we purchase samples and training and promotional literature at cost from Victory or its suppliers. The agreement will continue in effect until June 10, 2014 unless terminated sooner. In addition to other more limited termination rights, subject to 120 days prior written notice to Victory, we may terminate the agreement (a) at any time following the 18-month anniversary of the effective date of the agreement or (b) at any time if Victory is not continuing to provide marketing and promotional support for the products at specified minimum levels.

In August 2007, we entered into a co-promotion agreement with C.B. Fleet Company, Incorporated, or Fleet, to co-promote the Fleet® Phospho-soda® EZ-Prep™ Bowel Cleansing System to our targeted gastroenterologists in the U.S. The Fleet product is a system for bowel preparation used prior to a medical procedure or examination, such as a colonoscopy. We commenced promotional activities for the product in the fourth quarter of 2007. Under the terms of the agreement, Fleet pays us based on a set fee per sales call, subject to a minimum and maximum number of sales calls. We are eligible to receive co-promotion fees of up to approximately $3.0 million over the term of the agreement, subject to reduction in the event of any early termination of the agreement. We also have the opportunity to earn bonus payments if unit sales exceed predetermined baselines. We did not pay an upfront fee and do not expect to incur any material incremental expenses associated with our promotion of the product. Fleet is responsible for providing all training materials, promotional literature and product samples throughout the term of the agreement. The agreement will continue in effect until October 2008 unless terminated sooner or extended by the parties upon mutual written agreement. In addition to other more limited termination rights, either party may terminate the agreement at any time by providing 120 days prior written notice to the other party.

In November 2007, we 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 specified markets outside of the U.S., Europe, Australia, Japan and Canada and to distribute and sell Zegerid brand immediate-release omeprazole prescription products in Puerto Rico and the U.S. Virgin Islands, or USVI.

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 USVI in February 2008. During an initial period following the execution of the distribution agreement, we are obligated to supply Zegerid products to GSK for sale in Puerto Rico and the USVI, and GSK will pay a specified transfer price covering our fully burdened costs. GSK bears all costs for its activities under the license and distribution agreements.

Under the license agreement, in December 2007, we received an $11.5 million upfront fee, and we will also receive tiered royalties, subject to reduction in certain circumstances, on net sales of any products sold under the license and distribution agreements. In turn, we will be 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, we agreed to waive the first $2.5 million of aggregate royalties payable under the license and distribution agreements. 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 us under specified circumstances. GSK may terminate the license agreement or the distribution agreement on six months prior written notice at any time. We 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.

We have incurred significant losses since our inception. We had an accumulated deficit of $304.0 million as of December 31, 2007. These losses have resulted principally from costs incurred in connection with license fees, research and development activities, including costs of clinical trial activities associated with our Zegerid products, commercialization activities and general and administrative expenses.

We expect to incur additional operating losses and capital expenditures as we support the commercialization of Zegerid Capsules and Zegerid Powder for Oral Suspension and our commercial organization, enhance our product portfolio through development and commercialization of acquired or internally developed proprietary products and fund our administrative support activities.

In February 2006, we entered into a committed equity financing facility, or CEFF, with Kingsbridge Capital Limited, or Kingsbridge, which may entitle us to sell and obligate Kingsbridge to purchase, from time to time over a period of three years, shares of our 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, we entered into a common stock purchase agreement and registration rights agreement, and we also issued a warrant to Kingsbridge to purchase 365,000 shares of our 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. On February 3, 2006, we filed a resale shelf registration statement on Form S-3 with the Securities and Exchange Commission to facilitate Kingsbridge's public resale of shares of our common stock which it may acquire from us from time to time in connection with our draw downs under the CEFF or upon the exercise of a warrant to purchase 365,000 shares of common stock that we issued to Kingsbridge in connection with the CEFF. The resale shelf registration statement was declared effective on February 13, 2006. In 2006, we completed four draw downs under the CEFF and have issued a total of 5,401,787 shares in exchange for aggregate gross proceeds of $36.5 million. We did not initiate any draw downs under the CEFF during 2007.

In July 2006, we entered into a loan agreement with Comerica Bank, or Comerica. The credit facility under our loan agreement consists of a revolving line of credit, pursuant to which we may request advances in an aggregate outstanding amount not to exceed $20.0 million. As of March 3, 2008, the date of this report, we have not borrowed any amounts under the loan agreement.

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 commercially launched Zegerid Capsules in late March 2006 and launched Zegerid Powder for Oral Suspension 20 mg in late 2004 and the 40 mg dosage strength in early 2005.

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 $5.9 million as of December 31, 2007 and $1.6 million as of December 31, 2006. Prior to the fourth quarter of 2006, we deferred the recognition of revenue on product shipments of our Zegerid products to wholesale distributors until units were dispensed through patient prescriptions as we were unable to reasonably estimate the amount of future product returns. Units dispensed are not generally subject to return. Prior to the fourth quarter of 2006, our allowance for product returns was based on an analysis of Zegerid product shipments to our wholesale distributors in excess of the estimated number of units dispensed through patient prescriptions. In order to develop a methodology and 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. Based on the product returns history gathered over two years through the end of 2006, we determined that we had the information needed to reasonably estimate future product returns, and as a result, we reduced our allowance for product returns during the quarter ended December 31, 2006. We continue to 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. 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 provides 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.

Consistent with industry practice, we have offered promotional discounts to our customers at the time of product launch. These discounts are calculated as a fixed dollar discount off the current published list price and/or a fixed incentive fee per transaction and are treated as off-invoice allowances or customer credits. Accordingly, these discounts are recorded as a reduction of revenue in the period that the program is offered. As previously discussed, at the time of product launch and prior to the fourth quarter of 2006, we deferred the recognition of revenue on shipments of our Zegerid products to wholesale distributors until units were dispensed through patient prescriptions. As a result, we did not recognize product sales related to inventory in the distribution channel.

Our allowance for rebates, chargebacks and other discounts was $21.0 million as of December 31, 2007 and $7.8 million as of December 31, 2006. 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.

Contract Revenue. We recognize contract 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 licensing and co-promotion 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 co-promotion fees are recognized as revenue when earned under the agreements. Certain elements of our licensing and co-promotion agreements are described below:

- 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 will be recognized as revenue when the royalties are earned. The remaining $9.0 million 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 USVI under the distribution agreement.

- In August 2007, we received a nonrefundable $5.0 million milestone payment relating to progress on clinical product development strategy under our license agreement with Schering-Plough. The $5.0 million milestone payment was recognized as contract revenue in 2007 due to the substantive nature of the milestone achieved and since we have no ongoing obligations associated with the milestone.

- 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 February 2005, we received a $10.0 million milestone payment in connection with our sublicense agreement with TAP Pharmaceutical Products Inc., or TAP. We received the milestone payment after we prevailed in an alternative dispute resolution proceeding in which we alleged that TAP had achieved a development milestone. Pursuant to our license agreement with the University of Missouri, we paid 15% of the February 2005 milestone to the University of Missouri. In addition to the provisions of SAB No. 104 and EITF Issue No. 00-21, we evaluated the criteria outlined in EITF Issue No. 99-19, *Reporting Revenue Gross as a Principal Versus Net as an Agent*, in determining whether it was appropriate to record the gross amount of sublicense revenues and related costs or the net amount earned under the arrangement. Upon receipt of the milestone, we recognized the gross amount of sublicense revenue and related costs as we had no future obligations pursuant to the arrangement, we were the primary obligor in the arrangement, we had latitude in establishing the amounts received under the arrangement, and we were involved in the determination of the scope of technology sublicensed under the agreement. TAP exercised its rights to terminate the sublicense agreement effective March 7, 2006.

- In October 2004, we received a nonrefundable $15.0 million upfront payment in connection with our co-promotion agreement with Otsuka America. The $15.0 million upfront payment is being amortized to revenue on a straight-line basis over the 63-month contractual term through the end of 2009.

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 Naprelan products which we purchase from Victory under our co-promotion agreement. 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 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. 107. Under this method, the expected life is presumed to be the mid-point between the vesting date and the end of the contractual term.

For options granted prior to January 1, 2006, we amortize 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. Pre-vesting forfeitures were estimated to be approximately 0% for 2007 and 2006 as the majority of options granted contain monthly vesting terms.

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.

For 2007 and 2006, we recognized approximately $11.7 million and $9.3 million, respectively, of stock-based compensation in accordance with SFAS No. 123(R) and EITF Issue No. 96-18. For the year ended December 31, 2007, stock-based compensation of approximately $207,000, $899,000 and $10.6 million was included in cost of sales, research and development, and selling, general and administrative expenses, respectively, in the accompanying statement of operations. For the year ended December 31, 2006, stock-based compensation of approximately $124,000, $1.2 million and $8.0 million was included in cost of sales, research and development, and selling, general and administrative expenses, respectively, in the accompanying statement of operations. As of December 31, 2007, total unrecognized compensation cost related to stock options was approximately $7.5 million, and the weighted average period over which it was expected to be recognized was 2.5 years.

In October 2007, our board of directors approved certain equity compensation programs for employees below the vice president level which became effective on November 6, 2007. With the intent of positively impacting employee morale, these programs included the granting of options to purchase an aggregate total of 1,657,074 shares of our common stock as well as accelerating the vesting of out-of-the-money existing stock options with per share exercise prices of $5.00 or greater. Additionally, the decision to accelerate the vesting of these stock options was made to reduce the total stock-based compensation in our statement of operations in future financial statements relating to options granted to 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.

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, 2007, 2006 and 2005

Product Sales, Net. Product sales, net were $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 $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 late March 2006. For the year ended December 31, 2007 as compared to the year ended December 31, 2006, the amount of rebates, chargebacks and other discounts has grown primarily as a result of increased sales of our Zegerid products and increased contracting with various managed care organizations and governmental organizations relating to Medicaid and Medicare. Accordingly, reductions to revenue and corresponding increases to allowance accounts have likewise increased. 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 to reflect actual experience accordingly. This change in estimate provides for potential product returns related to sales in prior periods and resulted in an increase to our net loss of approximately $1.9 million. Product sales, net were $13.7 million for 2005 and consisted of sales of Zegerid Powder for Oral Suspension.

Contract Revenue. Contract revenue was $15.0 million for 2007, $3.2 million for 2006 and $12.8 million for 2005. Contract revenue in each period consisted of co-promotion revenue from the $15.0 million upfront fee received pursuant to our co-promotion agreement with Otsuka America entered into in October 2004, which is being amortized to revenue over the term of the agreement through December 31, 2009. In 2007 and 2006, contract revenue also included license fee revenue from the $15.0 million upfront fee received in November 2006 pursuant to

our license agreement with Schering-Plough. This upfront fee is being amortized to revenue through the end of 2009, which is the estimated period over which we have significant responsibilities under the agreement. Contract revenue in 2007 also included license fee revenue from the $11.5 million upfront fee received in 2007 pursuant to our license and distribution agreements with GSK. Of this $11.5 million upfront fee, $9.0 million is being amortized to revenue over our product supply obligation through May 2009. In addition, contract revenue in 2007 included the $5.0 million milestone payment received in August 2007 pursuant to our license agreement with Schering-Plough and co-promotion fees earned under our co-promotion agreements with Victory and Fleet. In 2005, contract revenue also included sublicense revenue which consisted of the $10.0 million milestone payment we received from TAP in February 2005 related to TAP's development activities.

Cost of Sales. Cost of sales was $7.3 million for 2007, $4.9 million for 2006 and $2.1 million for 2005, or approximately 9%, 11% and 16% of net product sales, respectively. Cost of 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 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 sales as a percentage of net product sales from 2006 to 2007 and from 2005 to 2006 was primarily 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 $11.1 million for 2007, $6.4 million for 2006 and $3.4 million for 2005. License fees and royalties consisted of royalties due to the University of Missouri and Otsuka America based upon net product sales. Additionally, in 2005, license fees and royalties included $1.5 million paid to the University of Missouri, which represented 15% of the milestone fee received pursuant to our sublicense agreement with TAP.

Research and Development. Research and development expenses were $6.8 million for 2007, $7.6 million for 2006 and $11.3 million for 2005. 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. The $3.7 million decrease in our research and development expenses from 2005 to 2006 was primarily attributable to a decrease in manufacturing development activities associated with the chewable tablet product and a decrease in compensation costs associated with research and development personnel resulting from a reduction in headcount.

Research and development expenses have 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 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. 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. Although we are currently focused primarily on advancing our Zegerid family of products, 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. Although we are currently marketing Zegerid Capsules and Zegerid Powder for Oral Suspension, and we have received FDA approval to market Zegerid Chewable Tablets, we cannot be certain when or if we will realize any profits from these products or any other development projects.

Selling, General and Administrative. Selling, general and administrative expenses were $116.5 million for 2007, $89.8 million for 2006 and $79.4 million for 2005. 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. The $10.4 million increase in our selling, general and administrative expenses from 2005 to 2006 was primarily attributable to approximately $6.3 million of additional stock-based compensation expense recognized due to our adoption of SFAS No. 123(R), increased promotional expenses including product samples and managed care marketing initiatives and costs associated with our contract sales organization agreement entered into in November 2006. These increases in our selling, general and administrative expenses were offset in part by decreased compensation costs. Although our selling, general and administrative expenses increased as a result of our contract sales organization agreement entered into in late 2006, our average sales and marketing headcount in 2006 was lower than in 2005.

Interest and Other Income, Net. Interest and other income, net was $3.1 million in 2007, $3.1 million in 2006 and $4.7 million in 2005. The $1.6 million decrease from 2005 to 2006 was primarily attributable to interest income awarded to us in connection with the $10.0 million milestone we received from TAP after we prevailed in an alternative dispute resolution proceeding in 2005, offset in part by higher interest income resulting from a higher rate of return on our cash, cash equivalents and short-term investments in 2006.

Liquidity and Capital Resources

As of December 31, 2007, cash, cash equivalents and short-term investments were $64.7 million, compared to $75.5 million as of December 31, 2006, a decrease of $10.8 million. This decrease resulted primarily from our net loss for 2007, adjusted for non-cash stock-based compensation and changes in operating assets and liabilities including an increase in accrued rebates. Included in cash, cash equivalents and short-term investments as of December 31, 2007 was the $11.5 million upfront fee we received in December 2007 under our license agreement with GSK.

Net cash used in operating activities was $12.1 million for 2007, $32.9 million for 2006 and $74.3 million for 2005. The primary use of cash was to fund our net losses for these periods, adjusted for non-cash expenses, including $11.7 million for 2007, $9.3 million for 2006 and $2.6 million for 2005 in stock-based compensation, and changes in operating assets and liabilities. 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. Significant working capital uses of cash in 2005 included decreases in accounts payable and accrued liabilities, allowance for product returns and deferred revenue.

Net cash used in investing activities was $2.0 million for 2007, and net cash provided by investing activities was $5.0 million for 2006 and $84.5 million for 2005. These activities primarily consisted of purchases and sales and maturities of short-term investments and purchases of property and equipment. Additionally, in 2005, long-term restricted cash increased in connection with establishing a letter of credit under our vehicle lease agreements.

Net cash provided by financing activities was $1.6 million for 2007, $38.9 million for 2006 and $30.7 million for 2005. These activities consisted primarily of the issuance of common stock in connection with draw downs under our CEFF with Kingsbridge in 2006 and our registered direct offering in 2005. 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 2007, 2006 and 2005.

While we support the commercialization of Zegerid Capsules and Zegerid Powder for Oral Suspension and as we continue to sponsor clinical trials and develop and manufacture our Zegerid products 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, capital

expenditures, and investment in additional office space, internal systems and infrastructure.

We currently rely on OSG 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, 2007, we had finished goods and raw materials inventory purchase commitments of approximately $3.1 million, all of which will be purchased in 2008.

The following summarizes our long-term contractual obligations as of December 31, 2007:

	Payments Due by Period				
Contractual Obligations	Total	Less than One Year	One to Three Years	Four to Five Years	Thereafter
			(in thousands)		
Operating leases	$ 5,549	$ 1,052	$ 3,460	$ 1,037	$ —
Other long-term contractual obligations	1,258	1,030	174	54	—
Total	$ 6,807	$ 2,082	$ 3,634	$ 1,091	$ —

The amount and timing of cash requirements will depend on market acceptance of Zegerid Capsules and Zegerid Powder for Oral Suspension, the Naprelan 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.

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 collaboration or licensing agreements, or through equity, debt and/or royalty financing.

In May 2005, we filed a universal shelf registration statement on Form S-3 with the Securities and Exchange Commission, which was declared effective in June 2005. In August 2005, we sold 7,350,000 shares of our common stock that were registered under the universal shelf registration statement for aggregate gross proceeds of $31.2 million. The universal shelf registration statement may permit us, from time to time, to offer and sell up to an additional approximately $43.8 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 activities, investor perception of our prospects and the general condition of the financial markets, among others.

In February 2006, we entered into the CEFF which may entitle us to sell and obligate Kingsbridge to purchase, from time to time over a period of three years, shares of our common stock for cash consideration up to the lesser of $75.0 million or 8,853,165 shares, subject to certain conditions and restrictions. We filed a resale shelf registration statement on Form S-3 with the Securities and Exchange Commission to facilitate Kingsbridge's public resale of shares of our common stock which it may acquire from us from time to time in connection with our draw downs under the CEFF or upon the exercise of a warrant to purchase 365,000 shares of common stock that we issued to Kingsbridge in connection with the CEFF. The resale shelf registration statement was declared effective in February 2006. In 2006, we completed four draw downs under the CEFF and have issued a total of 5,401,787 shares in exchange for aggregate gross proceeds of $36.5 million. We did not initiate any draw downs under the CEFF during 2007. Accordingly, the remaining commitment of Kingsbridge under the CEFF for the potential purchase of our common stock is equal to the lesser of $38.5 million in cash consideration or 3,451,378 shares (which shares would be priced at a discount ranging from 6% to 10% of the average market price during any future draw down), subject to certain conditions and restrictions. There can be no assurance that we will be able to complete any further draw downs under the CEFF. Factors influencing our ability to complete draw downs include conditions such as a minimum price for our common stock; the accuracy of representations and warranties made to Kingsbridge; the continued effectiveness of the shelf registration statement; and the continued listing of our stock on the Nasdaq Global Market.

In July 2006, we entered into our loan agreement with Comerica, pursuant to which we may request advances in an aggregate outstanding amount not to exceed $20.0 million. As of March 3, 2008, the date of this report, we have not borrowed any amounts under the loan agreement. Under the loan agreement, the revolving loan bears interest, as selected by us, at either the variable rate of interest, per annum, most recently announced by Comerica as its "prime rate" or the LIBOR rate (as computed in the LIBOR Addendum to the loan agreement) plus 2.25 percent. 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 28, 2009. 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. We expect to use the loan proceeds to support our ongoing working capital needs and for general corporate purposes. Amounts borrowed under the loan agreement are secured by all of our personal property. The collateral does not include any intellectual property, including copyrights, patents, trademarks, servicemarks and applications therefor, now owned or hereafter acquired, or any claims for damages by way of any past, present and future infringement of any such intellectual property; provided, however, that the collateral includes all accounts and general intangibles that consist of rights to payment and proceeds from the sale, licensing or disposition of all or any part, or rights in, such intellectual property. Under the loan agreement, we are subject to certain affirmative and negative covenants, including limitations on our ability: 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 certain financial covenants with respect to a minimum liquidity ratio and, when the outstanding loan balances exceed $15.0 million, minimum EBITDA requirements. We believe that 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.

As of December 31, 2007 and 2006, 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.

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 is effective for financial statements issued for fiscal years beginning after November 15, 2007. We do not expect the adoption of SFAS No. 157 to 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 gains or losses for the period in comprehensive income (loss) and in the equity section of the balance sheet. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007, and interim periods in those fiscal years. We do not expect the adoption of SFAS No. 159 to have a material impact on our financial statements.

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 in fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. We do not expect the adoption of EITF Issue No. 07-3 to have a material impact on our financial statements.

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, *Non-controlling Interests in Consolidated Financial Statements (an amendment of Accounting Research Bulletin No. 51)*. SFAS No. 160 requires that non-controlling (minority) interests be reported as a component of equity, that net income attributable to the parent and to the non-controlling 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 non-controlling 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 had a consolidated subsidiary with a non-controlling interest. As of December 31, 2007, we do not have any consolidated subsidiaries in which there is a non-controlling interest.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Under the terms of our loan agreement with 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 March 3, 2008, the date of this report, we have not borrowed any amounts under the loan agreement. Accordingly, we currently believe that changes in such interest rates would not materially affect our market risk.

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. All of our investment securities are classified as available-for-sale and therefore reported on the balance sheet at market value. Our investment securities consist of high-grade auction rate securities, corporate debt securities and government agency securities. As of December 31, 2007, our short-term investments included $4.3 million of high-grade (AAA rated) auction rate securities issued by state municipalities. Our auction rate securities are debt instruments with a long-term maturity and an interest rate that is reset in short-term intervals through auctions. The recent conditions in the global credit markets have prevented some investors from liquidating their holdings of auction rate securities 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. If the credit ratings of the security issuers deteriorate and any decline in market value is determined to be other-than-temporary, we would be required to adjust the carrying value of the investment through an impairment charge. To date, we have not recorded any realized gains or losses on our investment portfolio or recognized any significant unrealized gains or losses on investments.

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, 2007, 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, 2007, 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, 2007, 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, 2007 and 2006, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2007 of Santarus, Inc. and our report dated February 21, 2008, expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
February 21, 2008

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, 2007, 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, 2007 and 2006

Statements of Operations for the years ended December 31, 2007, 2006 and 2005

Statements of Stockholders' Equity for the years ended December 31, 2007, 2006 and 2005

Statements of Cash Flows for the years ended December 31, 2007, 2006 and 2005

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)	Warrant to Purchase Shares of Common Stock, dated February 3, 2006, issued by us to Kingsbridge Capital Limited

Exhibit Number	Description
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(7)+	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(8)+	Amendment No. 1 to Omeprazole Supply Agreement, dated November 1, 2004, among us, InterChem Trading Corporation and Union Quimico Farmaceutica, S.A.
10.7(8)+	Amendment No. 2 to Omeprazole Supply Agreement, dated July 11, 2007, among us, InterChem Trading Corporation and Union Quimico Farmaceutica, S.A.
10.8(9)†	Amended and Restated Manufacturing and Supply Agreement, dated December 19, 2006, between us and Patheon Inc.
10.9(10)†	Manufacturing and Supply Agreement, dated September 27, 2004, between us and OSG Norwich Pharmaceuticals, Inc.
10.10(10)†	Co-Promotion Agreement, dated October 4, 2004, between us and Otsuka America Pharmaceutical, Inc.
10.11(11)†	Amendment No. 1 to Co-Promotion Agreement, dated January 6, 2006, between us and Otsuka America Pharmaceutical, Inc.
10.12(6)	Common Stock Purchase Agreement, dated February 3, 2006, between us and Kingsbridge Capital Limited
10.13(12)	Loan and Security Agreement, dated July 28, 2006, between us and Comerica Bank
10.14(12)	LIBOR Addendum to Loan and Security Agreement, dated July 28, 2006, between us and Comerica Bank
10.15(13)†	OTC License Agreement, dated October 17, 2006, between us and Schering-Plough Healthcare Products, Inc.
10.16(14)†	Service Agreement, dated November 3, 2006, between us and Ventiv Commercial Services, LLC (d/b/a inVentiv Commercial Services, LLC)
10.17(8)+	Amendment No. 1 to Service Agreement, dated June 15, 2007, between us and Ventiv Commercial Services, LLC (d/b/a inVentiv Commercial Services, LLC)
10.18(15)†	Co-Promotion Agreement, dated as of June 28, 2007, by and between us and Victory Pharma, Inc.
10.19(7)+	Co-Promotion Agreement, dated August 24, 2007, between us and C.B. Fleet Company, Incorporated
10.20+	License Agreement, dated November 30, 2007, between us and Glaxo Group Limited, an affiliate of GlaxoSmithKline plc
10.21+	Distribution Agreement, dated November 30, 2007, between us and Glaxo Group Limited, an affiliate of GlaxoSmithKline plc
10.22(4)	Office Building Lease, dated August 24, 2001, between us and Torrey View Associates LP
10.23(4)	Irrevocable Stand-by Letter of Credit, dated August 24, 2001, issued by UBS Paine Webber Inc.
10.24(16)	Sublease, dated December 11, 2007, between us and Avnet, Inc.
10.25(4)#	Form of Indemnification Agreement between us and each of our directors and officers
10.26(4)#	1998 Stock Option Plan
10.27(17)#	Amendment to 1998 Stock Option Plan
10.28(18)#	Amended and Restated 2004 Equity Incentive Award Plan
10.29(17)#	Amendment No. 1 to Amended and Restated 2004 Equity Incentive Award Plan
10.30(19)#	Amendment No. 2 to Amended and Restated 2004 Equity Incentive Award Plan
10.31(20)#	Form of Stock Option Agreement under Amended and Restated 2004 Equity Incentive Award Plan

Exhibit Number	Description
10.32(21)#	Form of Immediately Exerciseable Stock Option Agreement under Amended and Restated 2004 Equity Incentive Award Plan
10.33(22)#	Amended and Restated Employee Stock Purchase Plan
10.34#	Amended and Restated Employment Agreement, dated December 5, 2007, between us and Gerald T. Proehl
10.35#	Amended and Restated Employment Agreement, dated December 5, 2007, between us and Debra P. Crawford
10.36#	Amended and Restated Employment Agreement, dated December 5, 2007, between us and Julie A. DeMeules
10.37#	Amended and Restated Employment Agreement, dated December 5, 2007, between us and William C. Denby, III
10.38#	Amended and Restated Employment Agreement, dated December 5, 2007, between us and Warren E. Hall
10.39#	Amended and Restated Employment Agreement, dated December 5, 2007, between us and Michael D. Step
10.40#	Amended and Restated Employment Agreement, dated December 5, 2007, between us and E. David Ballard, II, M.D.
10.41#	Amended and Restated Employment Agreement, dated December 5, 2007, between us and Maria Bedoya-Toro
10.42#	Amended and Restated Employment Agreement, dated December 5, 2007, between us and Carey J. Fox
10.43(23)#	2006 Bonus Plan
10.44(24)#	2007 Bonus Plan
10.45(25)#	2008 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 7, 2007.

(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 February 3, 2006.

(7) 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.

(8) 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.

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

(10) 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.

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

(12) Incorporated by reference to our Current Report on Form 8-K, filed with the Securities and Exchange Commission on August 1, 2006.

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

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

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

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

(17) 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.

(18) 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.

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

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

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

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

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

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

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

† 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 3, 2008

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 3, 2008
/s/ DEBRA P. CRAWFORD Debra P. Crawford	Senior Vice President and Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 3, 2008
/s/ DAVID F. HALE David F. Hale	Director *(Chairman of the Board of Directors)*	March 3, 2008
/s/ DANIEL D. BURGESS Daniel D. Burgess	Director	March 3, 2008
/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 3, 2008
/s/ MICHAEL E. HERMAN Michael E. Herman	Director	March 3, 2008
/s/ TED W. LOVE, M.D. Ted W. Love, M.D.	Director	March 3, 2008
/s/ KENT SNYDER Kent Snyder	Director	March 3, 2008

SANTARUS, INC.

INDEX TO FINANCIAL STATEMENTS

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, 2007 and 2006, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2007. 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, 2007 and 2006, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2007, in conformity with 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.

As discussed in Note 1 to the financial statements, effective January 1, 2006, Santarus, Inc. changed its method of accounting for share-based payments in accordance with Statement of Financial Accounting Standards No. 123 (revised 2004), "Share-Based Payment."

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, 2007, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 21, 2008, expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
February 21, 2008

Santarus, Inc.
Balance Sheets

	December 31, 2007	December 31, 2006
Assets		
Current assets:		
Cash and cash equivalents	$ 58,382,366	$ 70,883,641
Short-term investments	6,295,380	4,650,000
Accounts receivable, net	9,680,667	7,133,799
Inventories, net	6,157,383	6,979,269
Other current assets	2,339,742	1,243,333
Total current assets	82,855,538	90,890,042
Long-term restricted cash	1,400,000	1,700,000
Property and equipment, net	667,594	334,402
Other assets	421,115	703,777
Total assets	$ 85,344,247	$ 93,628,221
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities	$ 37,354,912	$ 22,534,518
Allowance for product returns	5,946,917	1,623,023
Current portion of deferred revenue	13,972,008	7,722,008
Total current liabilities	57,273,837	31,879,549
Deferred revenue, less current portion	12,722,007	15,444,015
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $.0001 par value; 10,000,000 shares authorized at December 31, 2007 and 2006; no shares issued and outstanding at December 31, 2007 and 2006	—	—
Common stock, $.0001 par value; 100,000,000 shares authorized at December 31, 2007 and 2006; 51,315,485 and 50,730,622 shares issued and outstanding at December 31, 2007 and 2006, respectively	5,132	5,073
Additional paid-in capital	319,342,022	306,033,378
Accumulated other comprehensive income	52	—
Accumulated deficit	(303,998,803)	(259,733,794)
Total stockholders' equity	15,348,403	46,304,657
Total liabilities and stockholders' equity	$ 85,344,247	$ 93,628,221

See accompanying notes.

Santarus, Inc.
Statements of Operations

	Years Ended December 31,		
	2007	2006	2005
Revenues:			
Product sales, net	$ 79,403,592	$ 45,979,504	$ 13,666,556
Contract revenue	15,024,751	3,262,548	12,857,143
Total revenues	94,428,343	49,242,052	26,523,699
Costs and expenses:			
Cost of sales	7,300,921	4,927,017	2,129,110
License fees and royalties	11,116,504	6,437,133	3,413,317
Research and development	6,849,474	7,572,072	11,291,700
Selling, general and administrative	116,503,279	89,828,051	79,391,285
Total costs and expenses	141,770,178	108,764,273	96,225,412
Loss from operations	(47,341,835)	(59,522,221)	(69,701,713)
Interest and other income, net	3,076,826	3,055,893	4,715,845
Net loss	$ (44,265,009)	$ (56,466,328)	$ (64,985,868)
Basic and diluted net loss per share	$ (0.87)	$ (1.19)	$ (1.66)
Weighted average shares outstanding to calculate basic and diluted net loss per share	51,060,650	47,355,050	39,187,537

See accompanying notes.

Santarus, Inc.
Statements of Stockholders' Equity

	Common stock		Additional paid-in capital	Deferred compensation	Accumulated other comprehensive income (loss)	Accumulated deficit	Total
	Shares	Amount					
Balance at December 31, 2004	36,328,461	$ 3,633	$ 228,881,141	$ (4,572,598)	$ (187,538)	$ (138,281,598)	$ 85,843,040
Issuance of common stock upon exercise of stock options, net of 19,485 unvested shares repurchased	81,147	8	113,535	—	—	—	113,543
Issuance of common stock under employee stock purchase plan	698,522	70	1,769,263	—	—	—	1,769,333
Issuance of common stock as stock bonus	8,957	1	38,999	—	—	—	39,000
Issuance of common stock in registered direct offering, net of issuance costs	7,350,000	735	28,967,515	—	—	—	28,968,250
Deferred compensation related to issuance of stock options to employees	—	—	115,806	(115,806)	—	—	—
Unamortized deferred compensation on cancelled stock options	—	—	(513,334)	513,334	—	—	—
Amortization of deferred compensation	—	—	—	2,475,138	—	—	2,475,138
Compensation related to non-employee stock options	—	—	114,045	—	—	—	114,045
Net loss	—	—	—	—	—	(64,985,868)	(64,985,868)
Unrealized gain on investments	—	—	—	—	183,418	—	183,418
Comprehensive loss	—	—	—	—	—	—	(64,802,450)
Balance at December 31, 2005	44,467,087	4,447	259,486,970	(1,699,932)	(4,120)	(203,267,466)	54,519,899

	Common stock		Additional paid-in capital	Deferred compensation	Accumulated other comprehensive income (loss)	Accumulated deficit	Total
	Shares	Amount					
Balance at December 31, 2005	44,467,087	4,447	259,486,970	(1,699,932)	(4,120)	(203,267,466)	54,519,899
Issuance of common stock upon exercise of stock options, net of 10,187 unvested shares repurchased	402,221	41	1,523,123	—	—	—	1,523,164
Issuance of common stock under Committed Equity Financing Facility, net of issuance costs	5,401,787	540	36,259,734	—	—	—	36,260,274
Financing cost of warrant issued in connection with Committed Equity Financing Facility	—	—	(1,282,318)	—	—	—	(1,282,318)
Issuance of warrant in connection with Committed Equity Financing Facility	—	—	1,282,318	—	—	—	1,282,318
Issuance of common stock upon exercise of warrants	14,832	1	(1)	—	—	—	—
Issuance of common stock under employee stock purchase plan	444,695	44	1,138,817	—	—	—	1,138,861
Stock-based compensation	—	—	9,324,667	—	—	—	9,324,667
Reclassification of deferred compensation due to adoption of SFAS No. 123(R)	—	—	(1,699,932)	1,699,932			—
Net loss	—	—	—	—	—	(56,466,328)	(56,466,328)
Unrealized gain on investments	—	—	—	—	4,120	—	4,120
Comprehensive loss	—	—	—	—	—	—	(56,462,208)
Balance at December 31, 2006	50,730,622	5,073	306,033,378	—	—	(259,733,794)	46,304,657
Issuance of common stock upon exercise of stock options, net of 12,001 unvested shares repurchased	84,851	9	265,735	—	—	—	265,744
Issuance of common stock under employee stock purchase plan	500,012	50	1,293,204	—	—	—	1,293,254
Stock-based compensation	—	—	11,749,705	—	—	—	11,749,705
Net loss	—	—	—	—	—	(44,265,009)	(44,265,009)
Unrealized gain on investments	—	—	—	—	52	—	52
Comprehensive loss	—	—	—	—	—	—	(44,264,957)
Balance at December 31, 2007	51,315,485	$ 5,132	$ 319,342,022	$ —	$ 52	$ (303,998,803)	$ 15,348,403

See accompanying notes.

Santarus, Inc.
Statements of Cash Flows

	Years Ended December 31,		
	2007	2006	2005
Operating activities			
Net loss	$ (44,265,009)	$ (56,466,328)	$ (64,985,868)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	587,426	591,678	624,672
Stock-based compensation	11,749,705	9,324,667	2,628,183
Changes in operating assets and liabilities:			
Accounts receivable, net	(2,546,868)	(4,470,316)	(1,862,764)
Inventories, net	821,886	(3,846,028)	(1,171,452)
Other current assets	(1,096,409)	9,590	1,228,491
Other assets	(4,255)	—	—
Accounts payable and accrued liabilities	14,820,394	13,049,240	(5,320,531)
Allowance for product returns	4,323,894	(2,840,593)	(2,593,592)
Deferred revenue	3,527,992	11,737,452	(2,857,143)
Net cash used in operating activities	(12,081,244)	(32,910,638)	(74,310,004)
Investing activities			
Purchase of short-term investments	(4,723,191)	(4,384,600)	(36,147,117)
Sales and maturities of short-term investments	3,094,658	9,189,000	121,836,000
Long-term restricted cash	300,000	250,000	(1,000,000)
Purchases of property and equipment	(650,496)	(60,627)	(65,216)
Deposits on manufacturing equipment	—	—	(114,935)
Net cash (used in) provided by investing activities	(1,979,029)	4,993,773	84,508,732
Financing activities			
Exercise of stock options	265,744	1,523,164	113,543
Issuance of common stock, net	1,293,254	37,399,135	30,737,583
Payments on equipment notes payable	—	(38,019)	(185,980)
Net cash provided by financing activities	1,558,998	38,884,280	30,665,146
(Decrease) increase in cash and cash equivalents	(12,501,275)	10,967,415	40,863,874
Cash and cash equivalents at beginning of the year	70,883,641	59,916,226	19,052,352
Cash and cash equivalents at end of the year	$ 58,382,366	$ 70,883,641	$ 59,916,226
Supplemental disclosure of cash flow information:			
Interest paid	$ 11,360	$ 14,179	$ 21,203
Supplemental schedule of noncash investing and financing activities:			
Issuance of warrant in connection with Committed Equity Financing Facility	$ —	$ 1,282,318	$ —

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 primary care 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.

The Company received approval from the U.S. Food and Drug Administration ("FDA") to market Zegerid® (omeprazole/sodium bicarbonate) Capsules in February 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 (omeprazole/sodium bicarbonate) 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 late March 2006 and launched Zegerid Powder for Oral Suspension 20 mg in late 2004 and the 40 mg dosage strength in early 2005.

Use of Estimates in the Preparation of Financial Statements

The preparation of financial statements in conformity with U.S. generally accepted accounting principles 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.

Concentration of Credit Risk and Sources of Supply

The Company invests its excess cash in highly liquid debt instruments of financial institutions, 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 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 92% of the accounts receivable balance as of December 31, 2007 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, 2007.

The Company relies on OSG Norwich Pharmaceuticals, Inc., located in New York, as the current sole third-party manufacturer of Zegerid 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 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 are product samples of the Naprelan products which the Company purchases from Victory Pharma, Inc. ("Victory") under its co-promotion agreement. 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.

Fair Value of Financial Instruments

The Company's financial instruments, including cash, cash equivalents, short-term investments and accounts payable and accrued liabilities are carried at cost which approximates fair value due to the relative short-term maturities of these instruments.

Impairment of Long-Lived Assets

In accordance with Statement of Financial Accounting Standards ("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, 2007.

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 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 commercially launched Zegerid Capsules in late March 2006 and launched Zegerid Powder for Oral Suspension 20 mg in late 2004 and the 40 mg dosage strength in early 2005.

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 $5.9 million as of December 31, 2007 and $1.6 million as of December 31, 2006. Prior to the fourth quarter of 2006, the Company deferred the recognition of revenue on product shipments of its Zegerid products to wholesale distributors until units were dispensed through patient prescriptions as the Company was unable to reasonably estimate the amount of future product returns. Units dispensed are not generally subject to return. Prior to the fourth quarter of 2006, the Company's allowance for product returns was based on an analysis of Zegerid product shipments to its wholesale distributors in excess of the estimated number of units dispensed through patient prescriptions. In order to develop a methodology and 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. Based on the product returns history gathered over two years through the end of 2006, the Company determined that it had the information needed to reasonably estimate future product returns, and as a result, the Company reduced the allowance for product returns during the quarter ended December 31, 2006. The Company continues to recognize 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. 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 provides 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.

Consistent with industry practice, the Company has offered promotional discounts to its customers at the time of product launch. These discounts are calculated as a fixed dollar discount off the current published list price and/or a fixed incentive fee per transaction and are treated as off-invoice allowances or customer credits. Accordingly, these discounts are recorded as a reduction of revenue in the period that the program is offered. As previously discussed, at the time of product launch and prior to the fourth quarter of 2006, the Company deferred the recognition of revenue on shipments of its Zegerid products to wholesale distributors until units were dispensed through patient prescriptions. As a result, the Company did not recognize product sales related to inventory in the distribution channel.

The Company's allowance for rebates, chargebacks and other discounts was $21.0 million as of December 31, 2007 and $7.8 million as of December 31, 2006. 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.

Contract Revenue. The Company recognizes contract 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 licensing and co-promotion 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 co-promotion fees are recognized as revenue when earned under the agreements.

Patent Costs

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

License Fees and Research and Development Expenses

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 Zegerid 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 and other service providers, which conduct certain research 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 has expensed amounts paid to obtain patents or acquire licenses, as the ultimate recoverability of the amounts paid was uncertain and the technology had 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.

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 $5.8 million, $5.7 million and $5.0 million in advertising expense for the years ended December 31, 2007, 2006 and 2005, respectively.

Stock-Based Compensation

Prior to January 1, 2006, as permitted by SFAS No. 123, *Accounting for Stock-Based Compensation*, the Company accounted for share-based payments to employees using the intrinsic value method of Accounting Principles Board ("APB") Opinion No. 25, *Accounting for Stock Issued to Employees*, and, as such, generally recognized no compensation cost for employee stock options when the exercise price was equal to or in excess of the fair value of the stock at the date of grant. 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, 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.

Prior to the adoption of SFAS No. 123(R), the Company presented deferred compensation as a separate component of stockholders' equity. Deferred compensation represents the difference between the exercise price and

the fair market value of the Company's common stock on the date of grant. For the year ended December 31, 2005, the Company recognized stock-based compensation expense of approximately $2.5 million resulting from the amortization of deferred compensation. In accordance with the provisions of SFAS No. 123(R), on January 1, 2006, the Company reclassified the balance in deferred compensation to additional paid-in capital on the balance sheet.

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. Pre-vesting forfeitures were estimated to be approximately 0% for the years ended December 31, 2007 and 2006 as the majority of options granted contain monthly vesting terms. 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,		
	2007	2006	2005
Stock Options:			
Risk-free interest rate	3.6% – 4.9%	4.6% – 5.0%	3.7% – 4.4%
Expected volatility	60%	60%	70%
Expected life of options (years)	5.27 – 6.08	5.27 – 6.08	4.75 – 8.00
Expected dividend yield	—	—	—
Employee Stock Purchase Plan:			
Risk-free interest rate	3.3% – 5.0%	4.8% – 5.1%	3.2% – 4.4%
Expected volatility	60%	60%	70%
Expected life of options (years)	0.50 – 2.00	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. 107. Under this method, the expected life is presumed to be the mid-point between the vesting date and the end of the contractual term.

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, 2007, 2006 and 2005 was $2.91, $4.10 and $4.34, respectively. The weighted average per share fair value of employee stock purchase plan rights granted in the years ended December 31, 2007, 2006 and 2005 was $1.70, $3.34 and $1.35, respectively. As of December 31, 2007, total unrecognized compensation cost related to stock options and employee stock purchase plan rights was approximately $7.5 million, and the weighted average period over which it is expected to be recognized is 2.5 years.

The following table illustrates the effect on net loss and net loss per share for 2005 if the Company had applied the fair value recognition provisions of SFAS No. 123 to options granted under the Company's stock plans. For purposes of this pro forma disclosure, the value of options is estimated using the Black-Scholes valuation model and amortized to expense over the options' vesting periods.

	Year Ended December 31, 2005
Net loss	
Net loss as reported	$ (64,985,868)
Add: Stock-based employee compensation included in reported net loss	2,514,138
Deduct: Stock-based employee compensation determined under fair value method	(11,220,174)
Net loss including stock-based compensation	$ (73,691,904)
Net loss per share	
Basic and diluted – as reported	$ (1.66)
Basic and diluted – including stock-based employee compensation	$ (1.88)

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:

	Years Ended December 31,		
	2007	2006	2005
Net loss	$ (44,265,009)	$ (56,466,328)	$ (64,985,868)
Unrealized gain on investments	52	4,120	183,418
Comprehensive loss	$ (44,264,957)	$ (56,462,208)	$ (64,802,450)

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,		
	2007	2006	2005
Historical:			
Numerator:			
Net loss	$ (44,265,009)	$ (56,466,328)	$ (64,985,868)
Denominator:			
Weighted average common shares	51,064,953	47,399,739	39,281,837
Weighted average unvested common shares subject to repurchase	(4,303)	(44,689)	(94,300)
Denominator for basic and diluted net loss per share	51,060,650	47,355,050	39,187,537
Basic and diluted net loss per share	$ (0.87)	$ (1.19)	$ (1.66)
Historical outstanding antidilutive securities not included in diluted net loss per share calculation:			
Common stock subject to repurchase	3,939	29,208	64,840
Options to purchase common stock	9,948,464	6,543,006	5,794,610
Stock warrants	366,284	366,284	59,405
	10,318,687	6,938,498	5,918,855

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

In September 2006, the Financial Accounting Standards Board ("FASB") issued SFAS No. 157, *Fair Value Measurements*. SFAS No. 157 establishes a framework for measuring fair value in accordance with Generally Accepted Accounting Principles ("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 is effective for financial statements issued for fiscal years beginning after November 15, 2007. The Company does not expect the adoption of SFAS No. 157 to have a material impact on its 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 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 gains or losses for the period in comprehensive income (loss) and in the equity section of the balance sheet. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007, and interim periods in those fiscal years. The Company does not expect the adoption of SFAS No. 159 to have a material impact on its financial statements.

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 in fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. The Company does not expect the adoption of EITF Issue No. 07-3 to have a material impact on its financial statements.

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, *Non-controlling Interests in Consolidated Financial Statements (an amendment of Accounting Research Bulletin No. 51)*. SFAS No. 160 requires that non-controlling (minority) interests be reported as a component of equity, that net income attributable to the parent and to the non-controlling 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 non-controlling 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 the Company had a consolidated subsidiary with a non-controlling interest. As of December 31, 2007, the Company does not have any consolidated subsidiaries in which there is a non-controlling interest.

2. Short-Term Investments

The following is a summary of short-term investment securities available-for-sale as of December 31, 2007 and 2006. 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 and 2006 consist of auction rate securities issued by state municipalities. These auction rate securities are debt instruments with a long-term maturity and an interest rate that is reset in short-term intervals (every 28 days) through auctions.

	Amortized Cost	Market Value	Unrealized Gain
December 31, 2007:			
Municipal debt obligations	$ 4,300,000	$ 4,300,000	$ —
Corporate debt securities	1,995,328	1,995,380	52
Total	$ 6,295,328	$ 6,295,380	$ 52
December 31, 2006:			
Municipal debt obligations	$ 4,650,000	$ 4,650,000	$ —

There were no gross realized gains or losses on sales of available-for-sale securities for the years ended December 31, 2007 and 2006.

3. Balance Sheet Details

Inventories, net consist of the following:

	December 31,	
	2007	2006
Raw materials	$ 1,511,220	$ 1,854,492
Finished goods	4,811,852	5,534,141
	6,323,072	7,388,633
Allowance for excess and obsolete inventory	(165,689)	(409,364)
	$ 6,157,383	$ 6,979,269

Property and equipment, net consist of the following:

	December 31,	
	2007	2006
Computer equipment and software	$ 1,295,436	$ 974,442
Office equipment and furniture	1,074,407	766,822
Leasehold improvements	345,724	345,724
	2,715,567	2,086,988
Less accumulated depreciation and amortization	(2,047,973)	(1,752,586)
	$ 667,594	$ 334,402

For the years ended December 31, 2007, 2006 and 2005, depreciation expense was approximately $314,000, $343,000 and $396,000, respectively.

Accounts payable and accrued liabilities consist of the following:

	December 31,	
	2007	2006
Accounts payable	$ 5,179,954	$ 3,386,497
Accrued compensation and benefits	5,359,756	5,587,290
Accrued rebates	19,478,658	7,130,887
Accrued royalties	3,363,914	2,708,623
Other accrued liabilities	3,972,630	3,721,221
	$ 37,354,912	$ 22,534,518

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 certain technologies and patent rights. 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 $2.5 million milestone payment upon initial achievement of $100.0 million in annual calendar year sales, which includes sales by the Company, Glaxo Group Limited, an affiliate of GlaxoSmithKline plc ("GSK") and Schering-Plough Healthcare Products, Inc. ("Schering-Plough"). 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. Under the license agreement, the Company is permitted to sublicense its rights to third parties. The Company is obligated to make payments to the University of

Missouri in connection with any sublicense, the nature of which depends on the specific sublicense structure. The license agreement 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. Management believes that it has currently met all of its obligations under the license agreement.

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, which was recognized as revenue in 2007 due to the substantive nature of the milestone achieved and since the Company has no ongoing obligations associated with the milestone. The Company may receive up to an additional $22.5 million in milestone payments upon the achievement of specified regulatory milestones 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 on 180 days prior written notice anytime after submitting its first new drug application for a licensed product or if Schering-Plough does not meet a specified deadline for receiving marketing approval in the U.S. for a licensed product. 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 specified markets outside of the U.S., Europe, Australia, Japan and Canada and to distribute and sell Zegerid brand immediate-release omeprazole prescription products in Puerto Rico and the U.S. Virgin Islands ("USVI").

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 USVI 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 USVI, 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 will also receive 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 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 USVI 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.

5. Co-Promotion Agreements

Otsuka America Pharmaceutical, Inc.

The Company has a non-exclusive agreement with Otsuka America Pharmaceutical, Inc. ("Otsuka America") under which Otsuka America is co-promoting Zegerid Capsules and Zegerid Powder for Oral Suspension to targeted U.S. physicians. The Company originally entered into the agreement in October 2004 and amended the terms of the agreement in January 2006. Under the agreement, the Company received a nonrefundable $15.0 million upfront payment from Otsuka America and pays Otsuka America a royalty on total U.S. net sales of Zegerid Capsules and Zegerid Powder for Oral Suspension. The agreement will terminate automatically on December 31, 2009, unless terminated sooner. In addition to other more limited termination rights, either party may terminate the agreement at any time by providing at least 120 days prior written notice. The $15.0 million upfront payment is being amortized to revenue on a straight-line basis over 63 months through December 31, 2009.

Victory Pharma, Inc.

In June 2007, the Company entered into a co-promotion agreement with Victory to co-promote Naprelan® (naproxen sodium) Controlled Release Tablets to targeted primary care physicians in the U.S. Naprelan Tablets are a once-daily, controlled release formulation of naproxen sodium, a non-steroidal anti-inflammatory drug ("NSAID") indicated for the treatment of a number of conditions, including arthritis and the relief of mild to moderate pain. Under the terms of the agreement, the Company receives a co-promotion fee equal to slightly more than half of the net sales value of the prescriptions generated by its target physicians, offset by an initial credit in recognition of existing sales. The Company is obligated to make a minimum number of annual and quarterly second position sales calls to target physicians. Victory is responsible for creating and developing, at its cost and expense, all product marketing materials as well as for handling all manufacturing, distribution, medical affairs and regulatory support for the products. The Company is responsible for all costs related to its sales force, and purchases samples and training and promotional literature at cost from Victory or its suppliers.

The agreement will continue in effect until June 10, 2014 unless terminated sooner. In addition to other more limited termination rights, subject to 120 days prior written notice to Victory, the Company may terminate the agreement (a) at any time following the 18-month anniversary of the effective date of the agreement or (b) at any time if Victory is not continuing to provide marketing and promotional support for the products at specified minimum levels.

C.B. Fleet Company, Incorporated

In August 2007, the Company entered into a co-promotion agreement with C.B. Fleet Company, Incorporated ("Fleet") to co-promote the Fleet® Phospho-soda® EZ-Prep™ Bowel Cleansing System to the Company's targeted gastroenterologists in the U.S. The product is a system for bowel preparation used prior to a medical procedure or

examination, such as a colonoscopy. Under the terms of the agreement, Fleet pays the Company to promote the product based on a set fee per sales call, subject to a minimum and maximum number of sales calls. The Company is eligible to receive co-promotion fees of up to approximately $3.0 million over the term of the agreement, subject to reduction in the event of any early termination of the agreement. The Company also has the opportunity to earn bonus payments if unit sales exceed predetermined baselines. Fleet will be responsible for providing all training materials, promotional literature and product samples throughout the term of the agreement.

The agreement will continue in effect until October 2008 unless terminated sooner or extended by the parties upon mutual written agreement. In addition to other more limited termination rights, either party may terminate the agreement at any time by providing 120 days prior written notice to the other party.

6. Long-Term Debt

In July 2006, the Company entered into a loan agreement with Comerica Bank ("Comerica"). As of December 31, 2007, the Company had not borrowed any amounts under the loan agreement. The credit facility under the loan agreement consists of a revolving line of credit, under which the Company may request advances in an aggregate outstanding amount not to exceed $20.0 million. Under the 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" or the LIBOR rate (as computed in the LIBOR Addendum to the loan agreement) plus 2.25 percent. 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 28, 2009. 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 the Company's personal property, excluding intellectual property. Under the loan agreement, the Company is subject to certain affirmative and negative covenants, including limitations on the Company's ability: 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, the Company is required to maintain a balance of cash at 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 certain financial covenants with respect to a minimum liquidity ratio and, when the outstanding loan balances exceed $15.0 million, minimum EBITDA requirements. Management believes that it has currently met all of its obligations under the loan agreement.

7. Commitments and Contingencies

Leases

The Company leases its primary office facility and certain equipment under various operating leases. The facility lease provides for monthly rental payments and expires in March 2008. In conjunction with the facilities lease, the Company currently has a letter of credit outstanding for $400,000 naming the landlord as beneficiary. The letter of credit is fully secured by restricted cash and has automatic extensions each year until May 2008. The letter of credit will be reduced to $100,000 at March 31, 2008.

In December 2007, the Company entered into a sublease agreement for the relocation of the Company's primary office facility. The term of the sublease is expected to commence on or around April 1, 2008 and will expire on February 27, 2013. The sublease provides for an initial annual base rent from the scheduled 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 will receive an allowance to cover the cost of the Company's tenant improvements in an amount not to exceed approximately $559,000, which will be provided in the form of an offset against the monthly installments of basic rent initially payable under 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, 2007, estimated annual future minimum payments under the Company's operating leases are as follows:

2008	$ 1,052,000
2009	1,442,000
2010	1,094,000
2011	924,000
2012	957,000
Thereafter	80,000
Total minimum lease payments	$ 5,549,000

Rent expense on facilities and equipment was approximately $2.5 million, $3.0 million and $2.7 million for the years ended December 31, 2007, 2006 and 2005, respectively.

Other Long-Term Commitments

The Company has entered into other long-term commitments for services requiring the Company to make payments of approximately $1.0 million and $66,000 in 2008 and 2009, respectively, and $54,000 in each year from 2010 to 2012.

In November 2006, the Company entered into a service agreement with inVentiv Commercial Services, LLC ("inVentiv"), a commercialization services organization, under which inVentiv provides up to approximately 140 contract sales representatives to promote the Company's Zegerid products in the U.S. The Company recognizes the revenue from Zegerid product sales generated by the promotional efforts of inVentiv and pays inVentiv a fee for providing the contract sales personnel.

The initial term of the service agreement expires on December 1, 2008. The Company has the right to extend the term of the service agreement for up to two additional one year terms, subject to agreement on compensation terms with inVentiv. The Company may terminate the service agreement at any time by providing inVentiv at least 60 days prior written notice without paying a termination fee. In addition, either party may terminate the service agreement upon an uncured material breach by the other party or upon bankruptcy or insolvency of the other party. inVentiv may also terminate the service agreement if the Company fails to make timely payment under the service 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 October 2007, the Company filed an amended complaint to reflect the U.S. Patent and Trademark Office's ("PTO's") issuance of an Ex Parte Reexamination Certificate for U.S. Patent No. 6,699,885 (the "'885 patent") as further described below. 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. 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. In addition, Par is seeking a declaration that U.S. Patent No. 5,840,737, another patent listed in the Orange Book for Zegerid Powder for Oral Suspension, is not infringed, invalid and/or unenforceable. The Company has moved to dismiss, or in the alternative, stay these claims due to the pending reissue proceeding involving this patent. Discovery is expected to begin in the near future and a trial date has been scheduled in July 2009. Both lawsuits have been consolidated for all purposes.

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 generic products 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 likely negatively impact the Company's financial condition and results of operations. An adverse outcome may also impact the patent protection for the products being commercialized pursuant to the Company's strategic alliances with 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 September 2007, the PTO issued an Ex Parte Reexamination Certificate for the '885 patent, which formally concluded the pending reexamination proceeding relating to the '885 patent, and confirmed the patentability of the '885 patent, as amended during the proceeding, over the references cited in the proceeding. The '885 patent is one of the five currently issued U.S. patents providing coverage for the Company's Zegerid family of products, which patents expire in July 2016 and are licensed to us under the Company's license agreement with the University of Missouri. The reexamination process is provided for by law and generally requires the PTO to consider the scope and validity of a patent based on questions raised by a third party or the PTO. In August 2005, an unidentified third party filed a Request for Ex Parte Reexamination of the '885 patent with the PTO. The PTO granted the Request for Reexamination and issued an initial office action, to which the Company and the University of Missouri submitted a response. The response included the Company's and the University of Missouri's positions relating to patentability as well as proposed amendments to certain of the claims of the '885 patent. In its September 2007 decision, the PTO confirmed the patentability of the '885 patent claims, as amended and added by the Company and the University of Missouri, over the references cited in the proceeding. Following the September 2007 action of the PTO, the '885 patent continues to provide patent coverage for the Company's Zegerid products by generally covering methods for treating gastric acid related disorders by administering a composition consisting essentially of a PPI (at least a portion of which is not enterically coated), and a minimum specified amount of buffering agent, where a minimum serum concentration of the PPI is achieved within specified time periods.

In December 2007, the University of Missouri filed an Application for Reissue of U.S. Patent No. 5,840,737 (the "'737 patent") with the PTO. The '737 patent is one of five issued patents listed in the Orange Book for Zegerid Powder for Oral Suspension. The '737 patent is not one of the three 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 the Company's Zegerid family of products could be impaired, which could potentially harm the Company's business and operating results.

8. 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

On May 12, 2005, the Company filed a universal shelf registration statement on Form S-3 covering equity or debt securities with the Securities and Exchange Commission, which was declared effective on June 16, 2005. On August 22, 2005, the Company completed an offering of 7,350,000 shares of common stock registered under the universal shelf registration statement at a price of $4.25 per share, raising net proceeds of approximately $29.0 million, net of placement agents' fees and offering costs.

In February 2006, the Company entered into a committed equity financing facility ("CEFF") with Kingsbridge Capital Limited ("Kingsbridge"), which may entitle the Company to sell and obligate 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.

On February 3, 2006, the Company filed a resale shelf registration statement on Form S-3 with the Securities and Exchange Commission to facilitate Kingsbridge's public resale of shares of the Company's common stock which it may acquire from the Company from time to time in connection with the Company's draw downs under the CEFF or upon the exercise of a warrant to purchase 365,000 shares of common stock that the Company issued to Kingsbridge in connection with the CEFF. The resale shelf registration statement was declared effective on February 13, 2006. In the event that an effective registration statement is not available for the resale of securities purchased by Kingsbridge in connection with a draw down, the Company may be required to pay liquidated damages. 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 Company did not initiate any draw downs under the CEFF during 2007. Accordingly, the remaining commitment of Kingsbridge under the CEFF for the potential purchase of the Company's common stock is equal to the lesser of $38.5 million in cash consideration or 3,451,378 shares (which shares would be priced at a discount ranging from 6% to 10% of the average market price during any future draw down), subject to certain conditions and restrictions. In connection with the CEFF, the Company has incurred legal fees and other financing costs of approximately $240,000.

Stockholder Rights Plan

In November 2004, the Company adopted a Stockholder Rights Plan, which was subsequently amended in April 2006 (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, 2007, 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, 2007, the Company was authorized to issue options to purchase 10,728,242 shares of its common stock under the 2004 Plan and had 2,370,241 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, 2008, 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.

In October 2007, the Company's board of directors approved certain equity compensation programs for employees below the vice president level which became effective on November 6, 2007. With the intent of positively impacting employee morale, these programs included the granting of options to purchase an aggregate total of 1,657,074 shares of the Company's common stock as well as accelerating the vesting of out-of-the-money existing stock options with per share exercise prices of $5.00 or greater. Additionally, the decision to accelerate the vesting of these stock options was made to reduce the total stock-based compensation in the Company's statement of operations in future financial statements relating to options granted to employees below the vice president level. The Company recognized $5.7 million in stock-based compensation expense associated with the stock option vesting acceleration on November 6, 2007.

Options generally vest over periods ranging from one to five years and expire ten years from the date of grant. 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, 2007, 3,939 shares issued from the early exercise of unvested options were 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
Outstanding at January 1, 2007	6,541,684	$ 6.10		
Granted	4,044,491	4.92		
Exercised	(96,852)	2.85		
Forfeited/expired	(540,859)	7.55		
Outstanding at December 31, 2007	9,948,464	$ 5.57	7.90	$ 2,378,928
Exercisable at December 31, 2007	6,949,979	$ 6.04	7.29	$ 2,070,828

The aggregate intrinsic value of options outstanding and options exercisable at December 31, 2007 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 $2.75 closing price of the Company's common stock on December 31, 2007. The total intrinsic value of options exercised in the years ended December 31, 2007, 2006 and 2005 was approximately $228,000, $1.5 million and $388,000, respectively, determined as of the date of exercise. The Company received approximately $276,000, $1.5 million and $138,000 in cash from options exercised in the years ended December 31, 2007, 2006 and 2005, 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, 2006 and 2005, stock-based compensation related to stock options issued to non-employees was approximately $46,000, $505,000 and $114,000, respectively.

For the years ended December 31, 2007 and 2006, the Company recognized approximately $11.7 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, 2007, the Company had issued 1,707,840 shares of common stock under the ESPP and had 114 shares available for future issuance. Effective January 1, 2008, 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, 2007 and 2006 are as follows:

	December 31,	
	2007	2006
Stock options issued and outstanding	9,948,464	6,543,006
Authorized for future issuance under equity compensation plans	2,370,355	3,360,676
Stock warrants outstanding	366,284	366,284
	12,685,103	10,269,966

9. 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 $376,000 in 2007.

10. 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, 2007 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 $0 accrued for interest and penalties on the Company's balance sheets at December 31, 2007 and 2006 and has recognized $0 in interest and/or penalties in the statement of operations for the year ended December 31, 2007.

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

The Company is currently undergoing a Section 382/383 analysis regarding the limitation of net operating loss and research and development credit carryforwards. Until this analysis has been completed the Company has removed the deferred tax assets for net operating losses of $82.9 million and research and development credits of $4.8 million generated through 2007 from its deferred tax asset schedule and has recorded a corresponding decrease to its valuation allowance. When this analysis is finalized, the Company plans to update its unrecognized tax benefits under FIN No. 48. The Company expects the Section 382/383 analysis to be completed within the next 12 months. Due to the existence of the valuation allowance, future changes in the Company's unrecognized tax benefits will not impact the Company's effective tax rate.

At December 31, 2007, the Company had Federal and California income tax net operating loss carryforwards of approximately $217.4 million and $111.1 million, respectively. The Federal and California tax loss carryforwards

will begin expiring in 2012, unless previously utilized. The Company also has tax loss carryforwards in various other states totaling approximately $61.0 million that will begin to expire in 2009, unless previously utilized. In addition, the Company has Federal and California research credit carryforwards of $3.5 million and $2.0 million, respectively. The Federal research and development credit carryforwards will begin to expire in 2019 unless previously utilized. The California research and development credit carryforwards will carry forward indefinitely until utilized.

Significant components of the Company's deferred tax assets as of December 31, 2007 and 2006 are listed below. A valuation allowance of $18.6 million and $94.8 million at December 31, 2007 and 2006, 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:

	December 31,	
	2007	2006
Deferred tax assets:		
Net operating loss carryforwards	$ —	$ 81,100,000
Research and development credits	—	4,637,000
Capitalized research and development	177,000	410,000
Depreciation and amortization	139,000	107,000
Accrued rebates	7,367,000	2,733,000
Deferred revenue	6,098,000	3,380,000
Other	4,812,000	2,443,000
Total deferred tax assets	18,593,000	94,810,000
Valuation allowance	(18,593,000)	(94,810,000)
Net deferred tax assets	$ —	$ —

Schedule II – Valuation and Qualifying Accounts

	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, 2007	$ (686,868)	$ (7,152,990)	$ -	$ 5,876,088	$ 436,938	$ (1,526,832)
For the year ended December 31, 2006	(244,848)	(3,175,074)	99,543	2,486,399	147,112	(686,868)
For the year ended December 31, 2005	(259,901)	(999,915)	467,774	547,194	-	(244,848)

	Balance at Beginning of Period	Additions: Charged to Costs and Expenses	Additions: Charged Against Balance Sheet Accounts	Deductions: Other	Balance at End of Period
Allowance for excess and obsolete inventory:					
For the year ended December 31, 2007	$ (409,364)	$ (194,921)	$ -	$ 438,596 (1)	$ (165,689)
For the year ended December 31, 2006	(207,145)	(396,841)	-	194,622 (1)	(409,364)
For the year ended December 31, 2005	(1,728,580)	(141,096)	(619,747)	2,282,278 (1)	(207,145)

	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	Deductions: Other	Balance at End of Period
Allowance for product returns:							
For the year ended December 31, 2007	$ (1,623,023)	$ (4,495,339)	$ (1,894,617)	$ 42,963	$ 2,023,099	$ - (2)	$ (5,946,917)
For the year ended December 31, 2006	(4,463,616)	-	-	-	-	2,840,593 (3)	(1,623,023)
For the year ended December 31, 2005	(7,057,208)	-	-	-	-	2,593,592 (4)	(4,463,616)

(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.

(3) 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.

(4) Deductions in allowance for product returns represent actual product returns of approximately $881,000 and a reduction in the allowance based upon an analysis of prescription demand in excess of product shipments to wholesale distributors.

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.
Chairman and Chief Executive Officer
Nuvelo, Inc.

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.
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.
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 12, 2008 at
the Doubletree Hotel
San Diego / Del Mar
11915 El Camino Real,
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."

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® products and any other products that we or our strategic partners market; the scope and validity of patent protection for our products, including the outcome and duration of our patent infringement lawsuits against Par Pharmaceutical, Inc., and our and our strategic partners' ability to commercialize products without infringing the patent rights of others; our dependence on a number of third parties, such as Glaxo Group Limited, an affiliate of GlaxoSmithKline, plc, under our license and distribution agreements, Schering-Plough Consumer Healthcare Products, Inc., under our over-the-counter license agreement, inVentiv Commercial Services, LLC, under our service agreement, and Otsuka America Pharmaceutical, Inc., under our co-promotion agreement; adverse side effects or inadequate therapeutic efficacy of our products or the products we co-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 proton pump inhibitor, or PPI, products and the introduction of additional generic 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 maintaining regulatory approvals for, our products; risks related to our co-promotion agreements relating to the Naprelan® and Fleet® Phospho-soda® EZ-Prep™ Bowel Cleansing System products, including our ability to generate adequate revenues to justify our level of promotional effort and expense under the agreements; our ability to obtain additional financing as needed to support our operations or future product acquisitions; 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, 2007, which accompanies this report. 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. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.

Some photographs not specifically identified in this report are solely for illustrative purposes, and are not intended to represent any particular person, situation or organization, present or past. Any resemblance to an actual person(s), situation(s) or organization(s) is purely coincidental.

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SANTARUS, INC.

3721 Valley Centre Drive, Suite 400, San Diego, California 92130
Tel: (858) 314-5700 Fax: (858) 314-5701