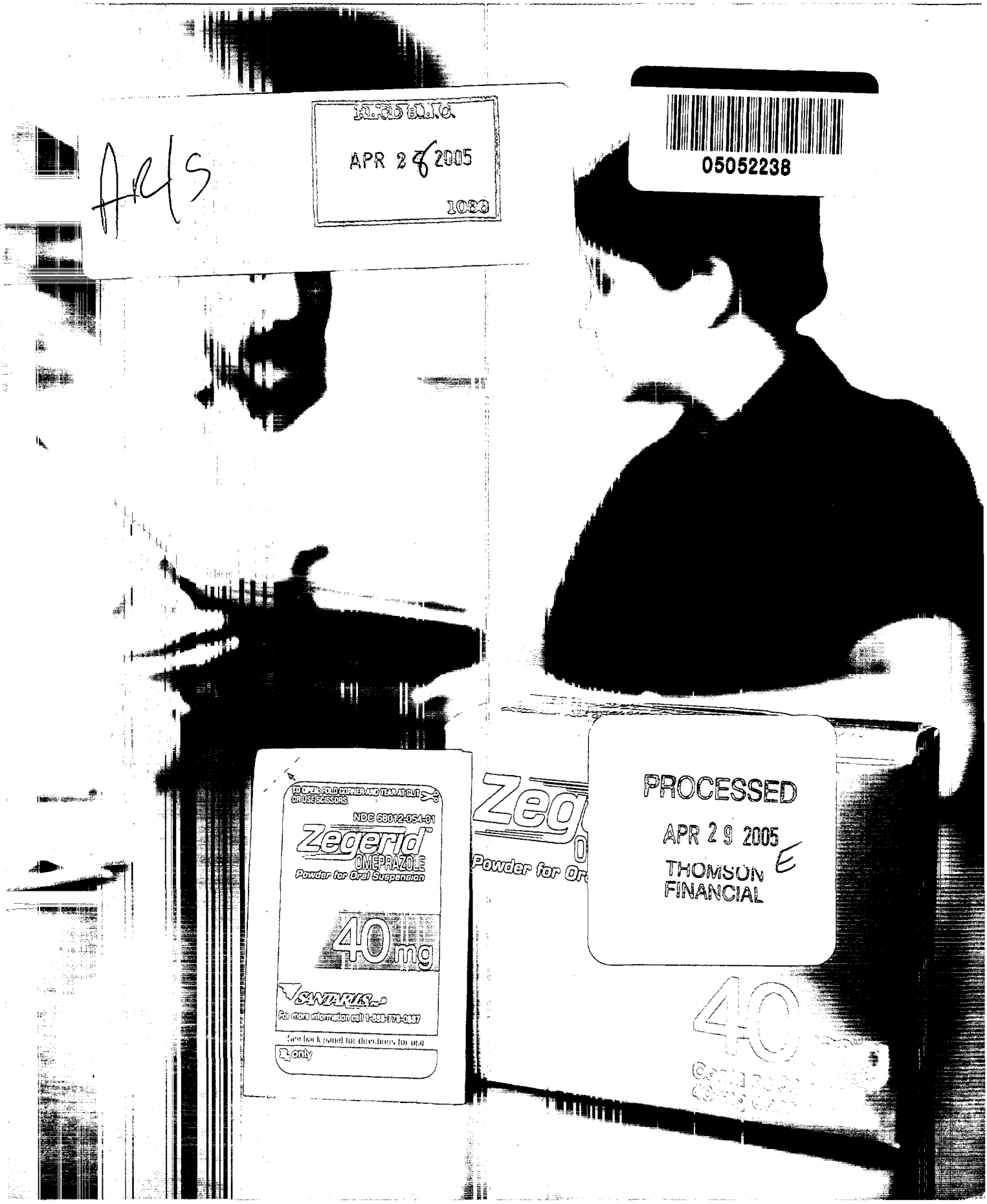
SANTARUS 2004 ANNUAL REPORT



MISSION STATEMENT

To be a highly successful specialty pharmaceutical company with expertise in the development and commercialization of proprietary products to enhance the quality of life for patients with gastrointestinal diseases and disorders.

SANTARUS IS FOCUSED ON ACQUIRING, DEVELOPING AND COMMERCIALIZING PROPRIETARY PHARMACEUTICAL PRODUCTS FOR THE PREVENTION AND TREATMENT OF GASTROINTESTINAL DISEASES AND DISORDERS. OUR FIRST PRODUCT, ZEGERID® (OMEPRAZOLE) POWDER FOR ORAL SUSPENSION 40 MG AND 20 MG, A PROPRIETARY PROTON PUMP INHIBITOR, WAS APPROVED FOR MARKETING BY THE U.S. FOOD AND DRUG ADMINISTRATION IN 2004. WE HAVE INITIATED COMMERCIAL SALES AND MARKETING OPERATIONS TO PROMOTE ZEGERID POWDER FOR ORAL SUSPENSION TO GASTROENTEROLOGISTS AND HIGH PRESCRIBING PRIMARY CARE PHYSICIANS WHO WE ESTIMATE WERE RESPONSIBLE FOR WRITING APPROXIMATELY $5.6 BILLION OF PPI PRESCRIPTIONS IN 2004.

Signed an exclusive, worldwide license agreement with the University of Missouri for intellectual property relating to immediate-release proton pump inhibitors (PPIs), and have since made rapid progress in developing ZEGERID®, a unique immediate-release formulation of omeprazole, a PPI, for treating upper gastrointestinal (GI) diseases and disorders.

2002

Completed formulation of ZEGERID (omeprazole) Powder for Oral Suspension 40 mg and 20 mg and completed pivotal pharmacokinetic/pharmacodynamic (PK/PD) clinical trials to support New Drug Applications (NDAs).

Entered into a strategic sublicense agreement with TAP Pharmaceutical Products Inc. (TAP), granting TAP North American rights to develop, manufacture and sell PPI products based on our immediate-release technology in exchange for an $8 million upfront fee and future milestone payments that may exceed $100 million, as well as royalty payments on any future sales of PPI products incorporating our technology.

2003

Completed a Phase III multicenter clinical trial evaluating ZEGERID Powder for Oral Suspension 40 mg for the reduction of risk of upper GI bleeding in critically ill patients.

Submitted an NDA for ZEGERID Powder for Oral Suspension 20 mg under an alternate FDA process for new or improved formulations of previously approved products which can expedite development timelines.

2004

Submitted an NDA for ZEGERID Powder for Oral Suspension 40 mg in February 2004.

Received two NDA approvals from the FDA for ZEGERID Powder for Oral Suspension 20 mg in June 2004 and 40 mg in December 2004; ZEGERID Powder for Oral Suspension 40 mg is the only PPI approved for reduction of risk of upper GI bleeding in critically ill patients.

Raised approximately $128 million in combined gross proceeds to support the commercial launch of ZEGERID Powder for Oral Suspension through an initial public offering in April 2004 and a follow-on public offering in July 2004.

Hired 230 sales representatives and supporting sales and marketing staff, trained the sales organization and launched ZEGERID Powder for Oral Suspension 20 mg in October 2004.

Signed co-promotion agreement with Otsuka America Pharmaceutical, Inc. (Otsuka America) in October 2004, providing a 75% increase in the number of sales representatives (from 230 reps to 400 reps) promoting ZEGERID Powder for Oral Suspension in the first position sales call; received upfront payment of $15 million.

Completed pivotal PK/PD clinical trials for ZEGERID Capsules 40 mg and 20 mg.

Completed formulation development for ZEGERID Chewable Tablets 40 mg and 20 mg and initiated pivotal PK/PD clinical trials.

"While we have accomplished a great deal in the past year, we are aware of the challenges associated with our continued commercial transition. Our management team and staff have demonstrated their ability to meet and, in many cases, exceed expectations relating to the significant milestones of the past year. We are confident that this level of dedication and commitment will continue as we move our company forward in the current year and beyond."

Just over a year ago, Santarus was a privately held company with no commercial products. Since then we have launched ZEGERID Powder for Oral Suspension 40 mg and 20 mg, the first and only immediate-release oral PPI.

Our commercial organization is creating ZEGERID brand awareness and establishing relationships with gastroenterologists and primary care physicians nationwide who are the leading prescribers of PPI products. We also have completed pivotal clinical trials with our immediate-release ZEGERID Capsules and Chewable Tablets, moving these products closer to commercialization.

To Our Stockholders:

During 2004 we made steady progress toward our goal of building Santarus into a leading specialty pharmaceutical company focused on therapies for gastrointestinal diseases and disorders. Just over a year ago, Santarus was a privately held company with no commercial products. Since then we have launched ZEGERID (omeprazole) Powder for Oral Suspension 40 mg and 20 mg, the first and only immediate-release oral PPI product.

Our commercial organization is creating ZEGERID brand awareness and establishing relationships with gastroenterologists and primary care physicians nationwide who are the leading prescribers of PPI products. We also have completed pivotal clinical trials with our immediate-release ZEGERID Capsules and Chewable Tablets, moving these products closer to commercialization.

While making commercial, clinical and regulatory headway, we funded our operations by raising $62 million in gross proceeds from an initial public offering completed in April and $66 million in gross proceeds from a follow-on public offering in July.

The ZEGERID Difference

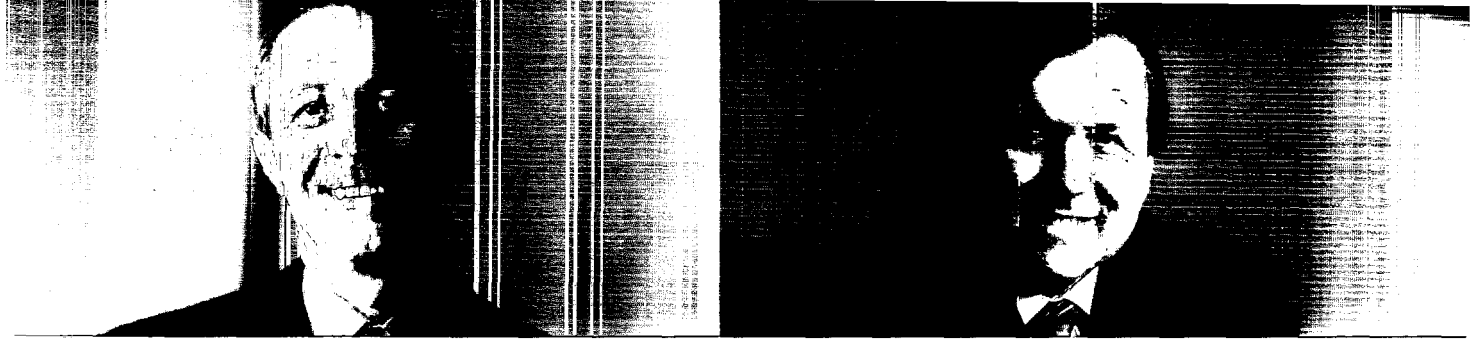
Our immediate-release ZEGERID products are designed to offer a differentiated alternative in the $12.5 billion U.S. PPI prescription market, where all currently marketed PPIs, other than ZEGERID, are available for oral use only in delayed-release, enteric coated formulations. Our ZEGERID products are based on patented technology and utilize one or more antacids to protect the PPI omeprazole from acid degradation. The antacids neutralize gastric acid and enable rapid absorption of the omeprazole into the bloodstream, which in turn allows the omeprazole to begin to inhibit acid production, while also providing a duration of acid control that allows for once-a-day dosing.

Clinical Development and Regulatory Achievements

Last year our NDAs for ZEGERID Powder for Oral Suspension 40 mg and 20 mg both were approved under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, within 10 months of submitting the NDAs to the FDA.

In mid-June, ZEGERID Powder for Oral Suspension 20 mg was approved 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 ulcers. In late December, ZEGERID Powder for Oral Suspension 40 mg was approved for the treatment of gastric ulcers and also became the first PPI approved for the reduction of risk of upper GI bleeding in critically ill patients. With this approval, we are able to provide physicians and patients with a higher dosage alternative that is comparable to the dosage strength at which a majority of delayed-release PPI prescriptions are currently written.

In addition, ZEGERID Powder for Oral Suspension 40 mg demonstrated strong gastric acid control throughout the night after once-daily dosing at bedtime in a recently completed clinical trial.



Gerald T. Proehl, President and Chief Executive Officer

David F. Hale, Chairman

The results from this trial are promising, as it has been estimated that a significant number of GERD patients experience nighttime heartburn.

Our regulatory plans for 2005 include submitting an NDA for ZEGERID Capsules 40 mg and 20 mg in the third quarter, followed by an NDA for ZEGERID Chewable Tablets 40 mg and 20 mg later in the year. We are following the same, proven 505(b)(2) regulatory pathway with these submissions. We look forward to expanding our product family with these solid dosage forms of ZEGERID and to ultimately providing physicians and patients with three differentiated ZEGERID products.

Our immediate-release ZEGERID products are designed to offer a differentiated alternative in the $12.5 billion U.S. PPI prescription market, where all currently marketed PPIs, other than ZEGERID, are available for oral use only in delayed-release, enteric coated formulations.

Sales and Marketing Activities

During the brief period between approval of ZEGERID Powder for Oral Suspension 20 mg in June and our October launch, we established a sales and marketing infrastructure and began building awareness of the ZEGERID brand with physicians. This was an impressive effort which involved hiring 230 field sales representatives who have an average of five years of pharmaceutical sales experience. Simultaneously, our marketing team developed a launch program, including a full range of promotional materials using a slogan that captures the ZEGERID difference: "Fast to the Max. Strong to the Finish."

To further support our sales efforts, we partnered with Otsuka America Pharmaceutical, Inc. for its 170 sales representatives to co-promote ZEGERID Powder for Oral Suspension 40 mg and 20 mg in the first position sales call.

With the recent launch of ZEGERID Powder for Oral Suspension 40 mg, we have initiated physician speaker programs and coupons for patients, and we are continuing with journal ads in major peer-reviewed medical journals and significant product sampling at physician offices. We also continue to make progress with managed care organizations in obtaining formulary acceptance for ZEGERID Powder for Oral Suspension. To that end, we recently signed an agreement with one of the top three pharmacy benefit managers.

While we have accomplished a great deal in the past year, we are aware of the challenges associated with our continued commercial transition. Our management team and staff have demonstrated their ability to meet and, in many cases, exceed expectations relating to the significant milestones of the past year. We are confident that this level of dedication and commitment will continue as we move our company forward in the current year and beyond.

On behalf of the board and management team at Santarus, we would like thank our stockholders for their continued support.

Sincerely,

Gerald T. Proehl
President and Chief Executive Officer

David F. Hale
Chairman

UPPER GI DISEASES AND DISORDERS OCCUR ACROSS A WIDE SPECTRUM OF PATIENTS – FROM INFANTS TO THE ELDERLY

Diseases and disorders of the upper digestive tract are highly prevalent in the U.S. In part they are a function of our lifestyle, the prevalence of obesity as well as a population that is increasingly aging. Heightened awareness of these conditions and their impact on health, in addition to access to treatment, has resulted in continued growth in the reported cases of upper GI diseases and disorders.

Most upper GI diseases and disorders are caused by or aggravated by acid in the stomach or gastric acid that refluxes up into the esophagus. Heartburn, GERD, erosive esophagitis, ulcers and upper GI bleeding fall into this category. PPIs are used to treat all of these conditions, and patients with chronic conditions may take PPIs over extended periods of time.

Gastroesophageal Reflux Disease

In the U.S., an estimated 25 million people have GERD, generally defined as frequent heartburn occurring at least twice a week. GERD encompasses a spectrum of conditions, from asymptomatic, nonerosive conditions, to symptomatic, erosive and serious states of GERD. Patients with GERD may experience episodes of nighttime heartburn even if symptoms are well controlled by medication during the daytime hours. Studies indicate that 70 – 80% of patients with GERD may suffer from heartburn during the night, interrupting sleep and causing significant discomfort. GERD sufferers are not limited to adult patients. As many as 2% to 8% of infants and older children may experience symptoms related to GERD.

Erosive Esophagitis

Erosive esophagitis is a more severe condition caused by gastric reflux. It is characterized by mucosal erosions and ulcers from the repeated exposure of the esophagus to stomach contents. Erosive esophagitis can permanently damage the esophageal lining and can lead to further complications, including cancer. It is estimated that as many as 10 million people in the U.S. suffer from this condition.

Gastric and Duodenal Ulcers

Gastric and duodenal ulcers, erosions in the lining of the stomach (gastric ulcers) or in the duodenum (duodenal ulcers), may be caused by a combination of gastric acid and inflammation due to H. pylori bacteria, or by chronic use of non-steroidal anti-inflammatory drugs (NSAIDs). Gastric and duodenal ulcers affect people of all ages, but occur most frequently in people who are between 55 and 65 years of age. We estimate that there are approximately 5 million patients with gastric or duodenal ulcers in the U.S.

Upper GI Bleeding

Critically ill patients are vulnerable to upper GI injury due to their underlying illnesses, as well as the medical interventions that alter the normal physiology and functioning of the GI tract. Critically ill ventilated patients are at high risk for developing erosions and upper GI bleeding that occur when the gastric mucosa, already compromised by stress, is continuously exposed to significant amounts of acid. These patients are frequently treated prophylactically with an acid-reducing medication to reduce the risk of bleeding. Patients who develop upper GI bleeding may require blood transfusions, or in the most serious cases, surgery. As many as 4 million critically ill patients are treated each year in the U.S., with 1.5 million mechanically ventilated patients at highest risk for upper GI bleeding.

[illegible] PATIENTS SUFFER FROM
[illegible]OSIVE ESOPHAGITIS

4

[illegible] MILLION CRITICALLY ILL PATIENTS
AT RISK OF UPPER GI BLEEDING

25

MILLION GERD PATIENTS

[illegible] MILLION CHILDREN
[illegible]XPERIENCE GERD
[illegible]YMPTOMS

[illegible] MILLION PATIENTS WITH GASTRIC
OR DUODENAL ULCER DISEASE

TREATMENT OF UPPER GI DISEASES AND DISORDERS

Currently, PPIs are generally regarded as the most effective and most frequently prescribed therapy for the treatment of many upper GI conditions.

To treat acid-related upper GI diseases and disorders, a physician may first ask patients to change their diet to reduce episodes of heartburn. However, many patients eventually require treatment with drugs or, for more serious cases, surgery. Medical therapy for GERD and other GI diseases consists of products that reduce the levels of gastric acid in the stomach. Over the years a variety of therapies have been developed to treat acid-related conditions.

- Antacids were introduced in the early 1900s and are still a frequent over-the-counter treatment option. Although antacids work quickly, they only neutralize acid for approximately 30 minutes to one hour and as a result provide only short-term relief.
- H2-receptor antagonists (H2 blockers), which were first introduced in the 1970s, reduce the production of stomach acid by reducing the stimulation of gastric histamine receptors. H2 blockers give longer symptomatic relief than antacids, but can only partially reduce stomach acid production because they impact just one of three pathways for stimulating gastric acid.
- Proton pump inhibitors (PPIs) were first introduced in 1989 and were a major advancement in the treatment of upper GI diseases and disorders. All currently marketed oral PPI products (other than ZEGERID) are delayed-release formulations that have an enteric coating to protect the drug from acid degradation as it passes through the stomach. Once a delayed-release PPI reaches the less acidic small intestine, the enteric coating dissolves and the PPI is absorbed into the bloodstream, reaching peak blood levels in up to approximately two to six hours after administration. PPIs are long acting, with once-a-day dosing for most conditions.

EVOLUTION OF TREATMENTS FOR THE UPPER GI MARKET

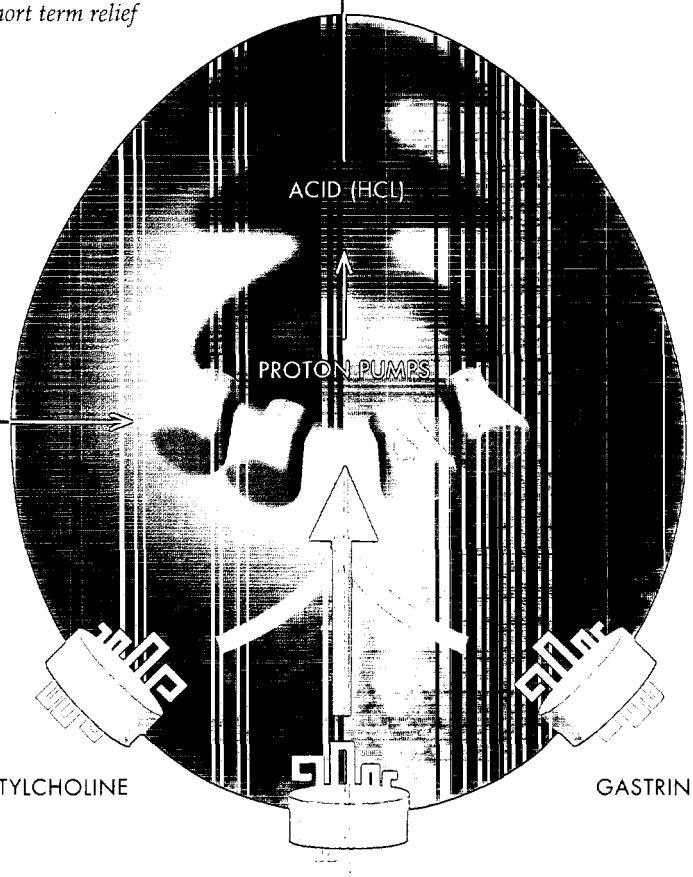
Product Features	1900-1960s Antacids	1970s H2-Receptor Antagonists	1990s Delayed-Release PPIs
Neutralizes existing acid	○		
Reduces acid production = speed of effect on gastric pH		○	
Reduces acid production = duration and effectiveness		○	○ ○

GASTRIC ACID PRODUCTION

ANTACIDS → STOMACH

Antacids neutralize acid in the stomach. They work quickly but produce only short term relief

PARIETAL CELL



PROTON PUMP INHIBITORS

PPIs irreversibly bind to acid producing proton pumps and inhibit acid production regardless of pathway

Parietal cells are specialized cells that line the wall of the stomach and produce gastric acid. PPIs block the final common pathway for gastric acid production at the cellular level. Once absorbed into the bloodstream, PPIs irreversibly bind to active acid-producing pumps in the stomach's parietal cells and inhibit acid production.

ZEGERID Powder for Oral Suspension reaches peak blood levels within 30 minutes and works rapidly to shut down the acid-producing proton pumps in parietal cells.

H2-RECEPTOR ANTAGONISTS → HISTAMINE

H2-Receptor antagonists reduce acid production through blockage of histamine pathways and block only 1 of 3 acid stimulating pathways

ZEGERID is the first and only immediate-release oral PPI approved for the U.S. market. Developed with patented technology, ZEGERID Powder for Oral Suspension 40 mg and 20 mg are formulated utilizing an antacid to protect the PPI, omeprazole, from acid degradation in the stomach. This allows the omeprazole to be rapidly absorbed into the bloodstream.

ZEGERID – THE FIRST AND ONLY IMMEDIATE-RELEASE ORAL PPI

THE ZEGERID DIFFERENCE

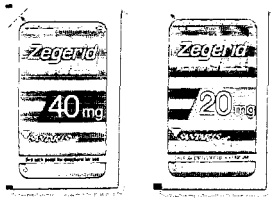
The ZEGERID products are designed to provide strong acid control and once-a-day dosing. Our team has developed three ZEGERID dosage forms at 40 mg and 20 mg: Powder for Oral Suspension, Capsules and Chewable Tablets. We received FDA approval for ZEGERID Powder for Oral Suspension 20 mg in June 2004 and 40 mg in December 2004.

ZEGERID is unique in the world of PPIs. It is the only oral PPI that offers immediate-release and sustained acid control. ZEGERID is a novel immediate-release formulation of omeprazole, a PPI previously sold only in delayed-release form. The ZEGERID products combine one or more antacids as buffering agents with omeprazole, allowing the omeprazole to be rapidly absorbed into the bloodstream. Except for ZEGERID, all oral PPIs have protective, enteric coatings to prevent acid degradation that occurs when an unprotected PPI passes through the stomach.

Our message to physicians is that ZEGERID Powder for Oral Suspension offers a new treatment option for patients who suffer from GERD and other indicated upper GI disorders:

- First and only immediate-release oral PPI
- Reaches peak plasma levels in 30 minutes
- Provides strong 24 hour acid control
- Can be taken once a day, at any time of the day on an empty stomach at least one hour before a meal

ZEGERID PRODUCT FAMILY

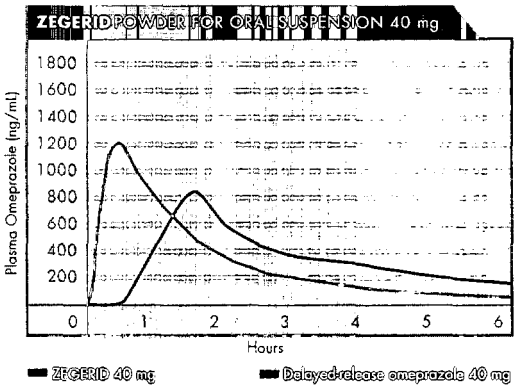
APPROVED		INDICATIONS	STATUS
ZEGERID Powder for Oral Suspension 40 mg / 20 mg		Heartburn/GERD, Erosive Esophagitis, Duodenal Ulcers, Reduction of Risk of Upper GI Bleeding in Critically Ill Patients, Gastric Ulcers	NDA for 20 mg approved June 2004; Launched October 2004 NDA for 40 mg approved December 2004; Launched February 2005

UNDER DEVELOPMENT		POTENTIAL INDICATIONS	STATUS
ZEGERID Capsules 40 mg / 20 mg		Heartburn/GERD, Erosive Esophagitis, Duodenal Ulcers, Gastric Ulcers	Pivotal PK/PD clinical trials completed Q4 2004; NDA planned Q3 2005
ZEGERID Chewable Tablets 40 mg / 20 mg		Heartburn/GERD, Erosive Esophagitis, Duodenal Ulcers, Gastric Ulcers	Pivotal PK/PD clinical trials completed Q1 2005; NDA planned second half 2005

"FAST TO THE MAX. STRONG TO THE FINISH."

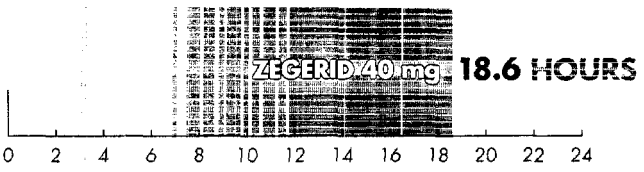
"The immediate-release formulation of ZEGERID Powder for Oral Suspension 40 mg results in a unique product that provides rapid absorption as well as sustained acid control throughout the day. Our data indicate that even though ZEGERID reaches peak plasma levels within 30 minutes, it also has a long duration of action, maintaining gastric pH over 4 for 18.6 hours."

E. David Ballard II, M.D.
Vice President, Clinical Research



The clinical data represented here show that peak plasma levels of omeprazole are achieved approximately 30 minutes after a single dose of ZEGERID Powder for Oral Suspension 40 mg. It is compared to a 40 mg dose of delayed-release omeprazole, which reaches peak plasma levels more than an hour after ZEGERID.

The clinical relevance of these data is unknown.



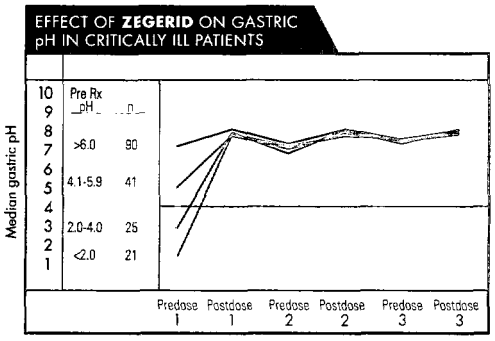
This chart represents the duration of response over a 24-hour period after healthy subjects received a daily dose of ZEGERID Powder for Oral Suspension 40 mg for 7 days. During a 24-hour period, the mean time with gastric pH above 4 was 18.6 hours. This duration of acid control is competitive with the data available for delayed-release PPIs.

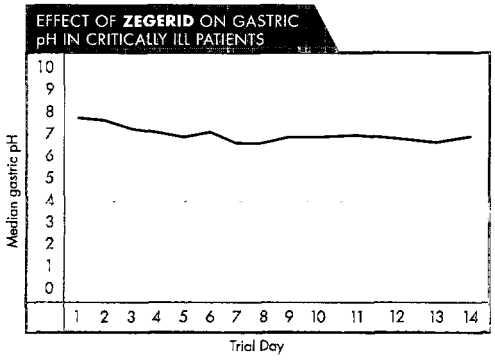
ZEGERID CLINICAL DATA
CRITICALLY ILL PATIENTS

ZEGERID Powder for Oral Suspension 40 mg is the only PPI approved to reduce the risk of upper GI bleeding in critically ill patients. Many physicians choose to prophylactically treat critically ill patients with an acid-reducing medication to reduce the risk of developing significant bleeding from ulcers or erosions.

Chart on left: *Initial effect of ZEGERID 40 mg in mechanically ventilated ICU patients*

Chart on right: *Sustained effect of ZEGERID 40 mg in mechanically ventilated ICU patients*





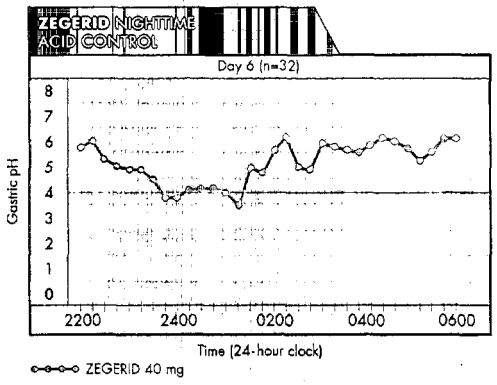
These data show the effects of ZEGERID Powder for Oral Suspension 40 mg in a multicenter, double-blind, randomized, controlled study involving critically ill patients during their first few days of therapy. ZEGERID achieved a median gastric pH > 4 within 1 to 2.5 hours after the first dose in 99% of patients treated.

In the ICU study, critically ill patients were treated for a maximum of 14 days. The graph above shows that, throughout that period, median gastric pH was maintained above 4 with a once-daily dose of ZEGERID Powder for Oral Suspension 40 mg after an initial loading dose of the drug on Day 1.

The clinical relevance of these data is unknown.

NIGHTTIME ACID CONTROL

After bedtime dosing with ZEGERID Powder for Oral Suspension 40 mg, median gastric pH was 4.7 through the nighttime period in patients with GERD, demonstrating effective control of nighttime gastric acidity in a recently completed clinical trial. The amount of time that pH is greater than 4.0 is a parameter frequently used to evaluate the clinical effects of treatment with PPIs in patients with acid-related diseases.



The data from a clinical trial with ZEGERID Powder for Oral Suspension 40 mg in controlling nighttime acidity were presented in a poster session at the American College of Gastroenterology in October 2004.

The clinical relevance of these data is unknown.

ZEGERID Powder for Oral Suspension is effective in treating a wide range of indications:

- Heartburn and other symptoms associated with gastroesophageal reflux disease (GERD)
- Erosive esophagitis – short-term treatment (four to eight weeks) of erosive esophagitis which has been diagnosed by endoscopy
- Maintenance of healing of erosive esphagitis (controlled studies do not extend beyond 12 months)
- Short-term treatment of active duodenal ulcer
- Short-term treatment (four to eight weeks) of active benign gastric ulcers
- Reduction of risk of upper GI bleeding in critically ill patients

Important Safety Information

ZEGERID Powder for Oral Suspension is contraindicated in patients with known hypersensitivity to any component of the formulation. ZEGERID is recommended for once-daily dosing, on an empty stomach at least one hour before a meal.

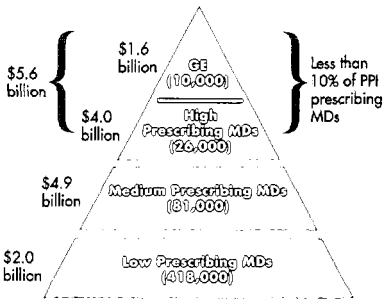
The most frequently reported adverse events with ZEGERID are headache, diarrhea, and abdominal pain. Symptomatic response to therapy does not preclude the presence of gastric malignancy. Atrophic gastritis has been noted occasionally in gastric corpus biopsies from patients treated long term with omeprazole. 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.

ZEGERID contains 460 mg sodium per dose in the form of sodium bicarbonate (1680 mg/20 mEq), which should be taken into consideration for patients on a sodium-restricted diet. Sodium bicarbonate is contraindicated in patients with metabolic alkalosis and hypocalcemia.

SALES AND MARKETING

Our regional sales directors average over 20 years of experience in selling pharmaceutical products, and our district sales managers average over 10 years of experience in pharmaceutical sales. Our sales representatives have an average of five years of pharmaceutical sales experience and approximately 40% have experience in selling PPIs.

Pictured left to right: Regional sales directors, Charles Pennewell, Douglas Peterson, Gary Fjeld and John McNamara.



We have a combined sales force of 400 sales representatives targeting 36,000 physicians including gastroenterologists (10,000) and primary care physicians (26,000) who we estimate wrote prescriptions for $5.6 billion of PPIs in 2004. By concentrating on high-volume PPI prescribers, we believe we can more effectively promote our products with a relatively small and focused sales and marketing organization.

COMMERCIAL OPERATIONS

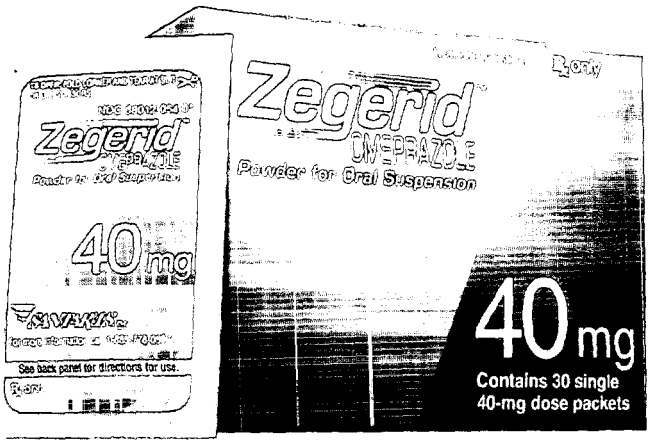
To prepare for the October 2004 launch of ZEGERID Powder for Oral Suspension 20 mg, we established our commercial organization of 230 sales representatives, developed marketing programs to begin creating ZEGERID brand awareness, initiated meetings with managed care organizations and entered into a co-promotion agreement with Otsuka America to expand our sales reach. With the February 2005 launch of ZEGERID Powder for Oral Suspension 40 mg, we are continuing to execute our commercial strategy.

Co-Promotion Agreement with Otsuka America Pharmaceutical, Inc.

To complement the efforts of our field sales organization, we entered into a five-year, non-exclusive co-promotion agreement with Otsuka America Pharmaceutical, Inc. in October 2004. Otsuka America's approximately 170 sales representatives are promoting ZEGERID in a first position sales call to our target physicians, increasing the total number of sales representatives detailing ZEGERID to target physicians from 230 sales representatives to 400 representatives.

Under the terms of the agreement with Otsuka America, we received a $15 million upfront payment, and will pay Otsuka America a royalty on net sales of ZEGERID Powder for Oral Suspension. Otsuka America also has options to extend the co-promotion agreement to include ZEGERID Capsules and Chewable Tablets, subject to U.S. marketing approval of these products. If they exercise their option, Otsuka America will pay additional milestone payments for the right to co-promote those products.

Pictured left to right: Thomas Joyce, Vice President, Marketing & National Accounts; Angela Kabbes, Executive Director, Marketing; Jon Hee, Vice President, Commercial Affairs; Blake Boland, Vice President, Sales.



Managed Care Organizations (MCOs) and Pharmacy Benefit Managers (PBMs)

In addition to our field sales organization, we have hired 18 experienced account managers who seek formulary acceptance for ZEGERID from MCOs and PBMs. These organizations are increasingly important in the selling effort for new drugs, as they determine on which tier a new drug is placed for reimbursement by insurance companies and the associated level of co-payment required.

Product Management and Support

We have hired an in-house team of experienced individuals from the pharmaceutical industry who have either marketed PPIs at other companies, or who have worked in smaller pharmaceutical companies that were successful marketing novel products in highly competitive markets. The marketing team is committed to the success of the ZEGERID brand and to the achievement of our corporate objectives.

ZEGERID Powder for Oral Suspension 40 mg and 20 mg is available in single dose packets and is taken by mixing the powder with 1 to 2 tablespoons of water and drinking. The powder goes into a uniform suspension when mixed with water.

MEDICAL AFFAIRS

Our staff of approximately 14 medical affairs employees, including scientific affairs liaisons, provides assistance and information to physicians and other medical personnel on the clinical features of ZEGERID Powder for Oral Suspension. These technically trained employees are able to respond to questions about our products from physicians, pharmacists and other medical personnel.

LOOKING TO THE FUTURE

ZEGERID has the potential to benefit a wide range of patients, from infants, to middle-aged patients, to the elderly. As we develop the ZEGERID family of products, we plan to have dosage forms to suit every patient's needs.

Our objective is to successfully establish the ZEGERID brand and family of products as the first and only immediate-release oral PPI in the U.S. market. To that end, we are focused on increasing market awareness and demand for ZEGERID Powder for Oral Suspension. In the near term, we are tailoring our marketing messages to highlight important clinical features of ZEGERID Powder for Oral Suspension 40 mg. We are also further concentrating the efforts of our sales force and taking steps to increase formulary acceptance within the competitive managed care environment.

We intend to continue to move ZEGERID Capsules and Chewable Tablets towards commercialization. To achieve this, we plan to submit an NDA for ZEGERID Capsules (40 mg and 20 mg) in the third quarter of 2005 and an NDA for ZEGERID Chewable Tablets (40 mg and 20 mg) later in 2005. Accomplishing these objectives will bring us closer to our longer-term goal of ultimately offering our ZEGERID immediate-release products in three key product formulations: Powder for Oral Suspension, Capsules and Chewable Tablets, and maximizing the potential for these immediate-release PPI products in the U.S.

From a clinical perspective, we are currently planning to undertake clinical studies of ZEGERID Powder for Oral Suspension in pediatric populations. We may also conduct other clinical trials to further differentiate our ZEGERID family of products from the currently marketed delayed-release PPIs, or otherwise expand our products' future use.

In the future, the focus of our corporate development activities may include additional co-promotion relationships for ZEGERID in the U.S. and outside of the U.S. We also intend to seek additional products that we can sell through our sales organization to gastroenterologists or primary care physicians. These products could be late-stage development products that would require our internal drug development and regulatory capabilities prior to commercialization, or marketed products that would benefit from additional coverage with gastroenterologists and primary care physicians through our experienced sales representatives.

Our senior management team brings a wealth of experience in the pharmaceutical industry. Many of our executives bring over 20 years of pharmaceutical and biotechnology experience to their positions, with significant success at developing and launching new products and growing similar companies into commercially viable organizations.

Pictured left to right: Warren Hall, Senior Vice President, Manufacturing & Product Development; Julie DeMeules, Vice President, Human Resources; Gerald Proehl, President & Chief Executive Officer; Christine Simmons, Pharm.D., Vice President, Regulatory Affairs & Quality Assurance; William Denby, Senior Vice President, Commercial Operations; Dave Stewart, Senior Vice President & Chief Financial Officer; Bonnie Hepburn, M.D., Senior Vice President, Development & Chief Medical Officer; Michael Step, Senior Vice President, Corporate Development.

We believe our success begins with our employees. We foster a work environment where ideas are encouraged and a passion for excellence is shared. We work as a team, accomplish much and have fun doing it.

SANTARUS CORPORATE VALUES

TEAMWORK – WORK TOGETHER TO ACHIEVE A COMMON GOAL IN A MUTUALLY DEPENDENT WAY. OWNERSHIP – ASSUME PERSONAL RESPONSIBILITY FOR SANTARUS' GOALS, RESOURCES, CHALLENGES AND OPPORTUNITIES. PRODUCTIVITY – ADOPT A STRONG RESULTS ORIENTATION AND EMPHASIZE THE ACHIEVEMENT OF GOALS AND OBJECTIVES. INTEGRITY – CONDUCT BUSINESS RESPONSIBLY THROUGH THE DECISIONS WE MAKE AND THE ACTIONS WE TAKE. QUALITY – CONSISTENTLY MEET OR EXCEED THE EXPECTATIONS OF BOTH INTERNAL AND EXTERNAL CUSTOMERS.

SELECTED FINANCIAL DATA

Year Ended December 31, **Statement of Operations Data:** (in thousands, except per share data)	2004	2003	2002	2001	2000
Revenues:					
Product sales, net	$ 634	$ —	$ —	$ —	$ —
Sublicense and co-promotion revenue	714	—	8,000	—	—
Total revenues	1,348	—	8,000	—	—
Costs and expenses:					
Cost of sales	1,968	—	—	—	—
License fees and royalties	5,089	1,000	1,400	1,294	107
Research and development	23,199	13,176	15,398	5,672	2,027
Selling, general and administrative	48,306	6,548	6,034	3,241	1,391
Stock-based compensation	5,672	2,252	277	87	9
Total costs and expenses	84,234	22,976	23,109	10,294	3,534
Loss from operations	(82,886)	(22,976)	(15,109)	(10,294)	(3,534)
Interest and other income (expense), net	1,391	465	414	726	(3)
Net loss	(81,495)	(22,511)	(14,695)	(9,568)	(3,537)
Accretion to redemption value of redeemable convertible preferred stock	(1,124)	(2,940)	—	—	—
Beneficial conversion of short-term notes payable to related parties	—	—	—	(135)	(95)
Net loss attributable to common stockholders	$ (82,619)	$ (25,451)	$ (14,695)	$ (9,703)	$ (3,632)
Basic and diluted net loss per share	$ (3.30)	$ (13.71)	$ (9.13)	$ (7.08)	$ (3.62)
Weighted average shares outstanding to calculate basic and diluted net loss per share	25,017	1,857	1,610	1,371	1,002

As of December 31, **Balance Sheet Data:** (in thousands)	2004	2003	2002	2001	2000
Cash, cash equivalents and short-term investments	$114,008	$ 45,648	$ 11,804	$ 22,281	$ 228
Working capital (deficit)	94,346	42,376	7,697	21,526	(1,053)
Total assets	122,216	48,188	14,207	24,332	849
Short-term notes payable to related parties	—	—	—	—	788
Deferred revenue, less current portion	11,429	—	—	—	—
Long-term debt, less current portion	38	224	479	—	50
Redeemable convertible preferred stock	—	57,625	—	—	—
Total stockholders' equity (deficit)	85,843	(13,751)	9,074	23,288	(676)

The selected statement of operations data for the years ended December 31, 2001 and 2000, and the selected balance sheet data as of December 31, 2002, 2001 and 2000, are derived from audited financial statements, which have been audited by our independent registered public accounting firm for such years and as of such dates, which are not included in the Form 10-K for the year ended December 31, 2004. The selected statement of operations data for the years ended December 31, 2004, 2003 and 2002 and the selected balance sheet data as of December 31, 2004 and 2003, 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.

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, 2004

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, CA	**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
None	None

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, par value $0.0001 per share

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of 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 an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

As of June 30, 2004, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $280.7 million, based on the closing price of the registrant's common stock on the Nasdaq National Market on June 30, 2004 of $14.75 per share.*

The number of outstanding shares of the registrant's common stock, par value $0.0001 per share, as of March 15, 2005 was 36,338,484.

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, 2004 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 common stock outstanding at June 30, 2004. 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, 2004

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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, statements about difficulties or delays in development, testing, obtaining regulatory approvals, manufacturing and marketing our products; our ability to create market demand for and generate revenues from our products; the progress and timing of our clinical trials; unexpected adverse side effects or inadequate therapeutic efficacy of our products that could delay or prevent product development or commercialization, or that could result in product recalls or product liability claims; the scope and validity of patent protection for our products and our ability to commercialize our products without infringing the patent rights of others; competition from other pharmaceutical or biotechnology companies; our ability to obtain additional financing to support our operations; and other risks detailed below under the caption "Business — 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 U.S. trademark registration and have applied for EU trademark registration for our brand name, Zegerid®, and have applied for trademark registration for various other names. 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 to enhance the quality of life for patients with gastrointestinal diseases and disorders. The primary focus of our current efforts is the development and commercialization of next generation proton pump inhibitor, or PPI, products — the most frequently prescribed drugs for the treatment of many upper gastrointestinal, or GI, diseases and disorders.

Our Zegerid products are proprietary immediate-release formulations of the PPI omeprazole in powder for oral suspension, capsule and chewable tablet formulations and are intended to treat or reduce the risk of a variety of upper GI diseases and disorders.

Immediate-Release PPI Products	Dose	Indications	Status
Approved			
Zegerid (omeprazole) Powder for Oral Suspension	20 mg	Heartburn/GERD, Erosive Esophagitis, Duodenal Ulcers	NDA approved in 2004; currently being marketed
	40 mg	Gastric Ulcers, Reduction of Risk of Upper GI Bleeding in Critically Ill Patients	NDA approved in 2004; currently being marketed
Under Development			
Zegerid (omeprazole) Capsules	20 mg/40 mg	Heartburn/GERD, Erosive Esophagitis, Duodenal Ulcers, Gastric Ulcers	Pivotal PK/PD clinical trials completed; NDA submission planned for third quarter of 2005
Zegerid (omeprazole) Chewable Tablets	20 mg/40 mg	Heartburn/GERD, Erosive Esophagitis, Duodenal Ulcers, Gastric Ulcers	Pivotal PK/PD clinical trials completed; NDA submission planned for second half of 2005

Our Zegerid products are the first immediate-release oral PPIs to be developed for the U.S. market. The formulations are based on patented technology and utilize antacids to protect the omeprazole from acid degradation in the stomach, allowing the omeprazole to be quickly absorbed into the blood stream. Although other marketed oral PPIs enjoy widespread use due to their potent acid suppression, favorable safety profile and once-a-day dosing, they are available only in delayed-release, enteric-coated formulations. While the enteric coating protects the PPI from acid degradation, it also delays absorption until the PPI reaches the less acidic small intestine. Our immediate-release Zegerid products do not have enteric coatings and are designed to be absorbed rapidly, while providing a duration of effect similar to delayed-release PPIs.

We received approval from the U.S. Food and Drug Administration, or FDA, to market Zegerid Powder for Oral Suspension 20 mg in June 2004 for the treatment of heartburn and other symptoms associated with gastroesophageal reflux disease, or GERD, treatment and maintenance of healing of erosive esophagitis and treatment of duodenal ulcers. We received FDA approval to market the 40 mg dose in December 2004 for the treatment of gastric ulcers and the reduction of risk of upper GI bleeding in critically ill patients. There is currently no other PPI product approved for the reduction of risk of upper GI bleeding indication.

Zegerid Powder for Oral Suspension is currently being marketed through a field sales force of approximately 400 representatives, which includes approximately 230 of our sales representatives in addition to approximately 170 sales representatives from our co-promotion partner, Otsuka America Pharmaceutical, Inc., or Otsuka America. Our sales representatives have an average of five years of pharmaceutical sales experience, with many also having prior PPI selling experience. The combined commercial sales organizations are targeting the highest PPI-prescribing physicians in the U.S., with a focus on approximately 10,000 gastroenterologists and 26,000 primary care physicians, who we estimate were responsible for writing approximately $5.6 billion of

PPI prescriptions in 2004. We believe this concentration of high-volume PPI prescribers will enable us to effectively promote our products with a relatively small and focused sales and marketing organization.

We are also developing immediate-release capsule and chewable tablet formulations of our Zegerid product. We believe these products will provide many of the same features as our powder for oral suspension product, with the convenience of a capsule or chewable tablet. We completed pivotal pharmacokinetic/pharmacodynamic, or PK/PD, clinical trials evaluating these products in 20 mg and 40 mg doses in late 2004 and early 2005. These trials measured blood levels of omeprazole, as well as acid control. We intend to submit new drug applications, or NDAs, for these products to the FDA during the second half of 2005, seeking approval for the treatment of GERD, erosive esophagitis and gastric and duodenal ulcers.

Our business strategy is to develop and market proprietary pharmaceutical products for the prevention and treatment of GI diseases and disorders with new formulations, enhanced drug delivery systems or expanded indications that are based on currently marketed or late stage products or compounds that have clinically demonstrated safety and efficacy. We believe this business strategy will potentially reduce development and regulatory risks and enhance market acceptance of our products. In order to continue to execute our business strategy, we plan to:

- explore additional strategic arrangements with one or more pharmaceutical companies to expand the promotion of our Zegerid family of products in the U.S.;
- out-license development, distribution and marketing rights for our Zegerid family of products to one or more pharmaceutical companies outside the U.S.; and
- enhance our product portfolio through internal development, in-licensing or co-promotion arrangements.

To date, in addition to developing our immediate-release omeprazole products, we have sublicensed our proprietary immediate-release PPI technology to TAP Pharmaceutical Products Inc., or TAP. Under the terms of the sublicense, TAP has the North American rights to develop, manufacture and sell products resulting from the use of our technology with lansoprazole and derivatives of lansoprazole. We have also entered into a co-promotion agreement with Otsuka America in October 2004, under which Otsuka America is co-promoting Zegerid Powder for Oral Suspension and has options to co-promote our capsule and chewable tablet products in the future.

Targeted 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 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 swallowing tube, or esophagus. An individual consistently experiencing heartburn at least twice per week is generally diagnosed as having GERD. According to the American Gastroenterological Association, an estimated 25 million American adults suffer from GERD. 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 a recent independent survey estimates that as many as 79% of GERD patients experience nighttime heartburn.

Physicians have many choices in treating GERD. A physician will usually first attempt to have patients alter their diet in order to reduce the frequency of heartburn symptoms. However, most patients with GERD will eventually require treatment with drugs or surgery. Antacids were introduced in the early 1900s and are still a frequent over-the-counter treatment option. Although antacids work quickly, they only neutralize acid in the esophagus and stomach for approximately 30 minutes to one hour after dosing and so provide only short-term relief.

Introduced in the 1970s, H2-receptor antagonists are compounds that reduce the production of stomach acid resulting from stimulation of histamine receptors. In 2000, antacids were combined with H2-receptor antagonists for over-the-counter treatment of heartburn. However, because the histamine receptors are only one of three potential sources of acid stimulation, H2-receptor antagonists generally provide only a partial reduction of acid production. In addition, H2-receptor antagonists generally work for a shorter period of time than PPIs.

PPIs were introduced in the late 1980s and are currently the most common prescription treatment option for upper GI diseases including GERD. PPIs are compounds which reduce the production of stomach acid. Once a PPI is absorbed into the bloodstream, it irreversibly binds to the active acid-producing pumps in parietal cells located in the stomach walls and inhibits acid production. Once a PPI irreversibly binds to a pump, that pump will no longer produce acid. As a result, PPIs are more effective in reducing acid production as compared with H2-receptor antagonists and generally need only to be taken once a day. Because new pumps and parietal cells are generated continuously, however, dosing with PPIs generally needs to be repeated once daily if continuous acid suppression is desired.

Since PPIs rapidly degrade in the presence of stomach acid, current oral PPI products, other than Zegerid, have an enteric coating to protect the drug from acid degradation. The enteric coating is designed to remain intact in the highly acidic stomach. Once the stomach empties its contents into the less acidic 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, resulting in average peak absorption time of up to two to six hours after the initial dose for enteric coated PPIs.

Erosive Esophagitis. Erosive esophagitis is characterized by erosions and ulcers from the repeated exposure of the esophagus to acid and develops in as many as 10 million patients 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 endoscopy. An eight-week course of therapy with PPIs will generally be effective in healing erosions associated with erosive esophagitis. 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. There are approximately 5 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 that occur when the gastric mucosa, already compromised by stress, is continuously exposed to significant amounts of acid. Many hospitals treat these patients prophylactically to reduce 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 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.

Our Products

Zegerid Product Differentiation

Our Zegerid approved product and products under development are proprietary immediate-release formulations of the PPI omeprazole in powder for oral suspension, capsule and chewable tablet formulations. These products 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.

PPIs enjoy widespread use due to their potent acid suppression, favorable safety profile and once-a-day dosing. However, all currently marketed PPIs, other than Zegerid, are available for oral use only in delayed-release, enteric-coated formulations. While the enteric coating protects the PPI from acid degradation, it also delays absorption until the PPI reaches the less acidic small intestine. Our immediate-release Zegerid products do not have enteric coatings and are designed to be absorbed rapidly, while providing a duration of effect similar to delayed-release PPIs.

We have developed our Zegerid family of 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 more 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, Zegerid Powder for

Oral Suspension reaches peak plasma levels in approximately 30 minutes after dosing. This compares to average peak absorption time of up to two to six hours after the initial dose for enteric-coated PPIs.

- *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, data from our pivotal PK/PD clinical trial evaluating Zegerid Powder for Oral Suspension 40 mg demonstrated that the product maintained a median gastric pH above 4.0 for 18.6 hours per day with repeated once-daily dosing. This duration of acid control is competitive with the data available for the delayed-release PPIs.

- *Variety of Formulations* – Our Zegerid products are currently available in a powder for oral suspension formulation and are being developed in capsule and chewable tablet formulations. 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.

- *Potential for Expanded Indications* – We plan to pursue expanded indications and uses for our products based on their specific features and benefits. For example, we completed a pivotal Phase III clinical trial evaluating Zegerid Powder for Oral Suspension 40 mg in critically ill patients and recently received approval to market the 40 mg dose for reduction of risk of upper GI bleeding in those patients. There is currently no other PPI product approved for this indication.

Zegerid Product Family – Approved Product

Zegerid (omeprazole) Powder for Oral Suspension

Our first product, Zegerid (omeprazole) Powder for Oral Suspension, is immediate-release omeprazole in a powder for oral suspension formulation and is available in 20 mg and 40 mg dose strengths. We received approval from the FDA to market the 20 mg dose in June 2004 for the treatment of heartburn and other symptoms associated with GERD, treatment and maintenance of healing of erosive esophagitis, and treatment of duodenal ulcers. In December 2004, we received approval from the FDA to market the 40 mg dose for the treatment of gastric ulcers and the reduction of risk of upper GI bleeding in critically ill patients. In addition, in connection with the approval of our NDAs for Zegerid Powder for Oral Suspension, we have committed to evaluate the product in pediatric populations, including in PK/PD and safety studies which we plan to initiate during the second half of 2005.

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 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, with peak plasma levels in approximately 30 minutes after dosing. In addition to use in the general adult population, our suspension formulation, which is administered in a liquid, titratable dosage form, is designed to be easily administered to critically ill patients via a nasogastric tube and may also be appropriate for patients who have difficulty swallowing a capsule or a tablet, such as pediatric or elderly patients.

To support our NDA submissions, we completed two pivotal PK/PD clinical trials in 2002 comparing the 20 mg and 40 mg doses of our powder for oral suspension product to 20 mg and 40 mg delayed-release omeprazole capsules given prior to a meal for seven days. The PK portion of these studies measured various aspects of blood levels of omeprazole. The PD portion of these studies measured acid control over a 24-hour period. Each study was conducted by a third party in at least 24 subjects. The results indicated that both the 20 mg and 40 mg doses of Zegerid Powder for Oral Suspension produced peak blood levels of omeprazole in approximately 30 minutes after dosing, as compared with peak blood levels of omeprazole in approximately one and one-half to two hours for the delayed-release omeprazole, due to the immediate-release profile of our formulations. While achieving more rapid absorption of omeprazole, the immediate-release Zegerid products also maintained a similar duration of effect on acid concentration in the stomach as compared to delayed-release omeprazole. For example, the 40 mg dose maintained a median gastric pH above 4.0 for 18.6 hours per day with repeated once-daily dosing. The amount of time that pH is greater than 4.0 is a parameter that is frequently used to evaluate the clinical effects of treatment with PPIs in patients with acid-related diseases. Studies suggest that healing rates and relief of symptoms associated with acid-related diseases can be correlated with the duration for which pH is maintained above 4.0.

In addition, in June 2003, we completed a multi-center Phase III clinical trial evaluating the 40 mg dose of Zegerid Powder for Oral Suspension for the reduction of risk of upper GI bleeding in critically ill patients. Critically ill patients who have experienced trauma are generally at higher risk for developing significant bleeding from ulcers or erosions, and many physicians choose to prophylactically treat these patients with an acid reducing medication. Given the serious condition of the patient population, the

blinded clinical trial compared Zegerid Powder for Oral Suspension, administered through a nasogastric tube, with intravenous, or IV, cimetidine, a H2-receptor antagonist, 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. The primary endpoint of the study, the occurrence of clinically significant bleeding, was the same as that used in the IV cimetidine trial which led to its approval. In the trial, 10 patients treated with IV cimetidine experienced clinically significant bleeding, compared to 7 patients treated with Zegerid Powder for Oral Suspension 40 mg, 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 40 mg achieved a median gastric pH of greater than 4.0 within 1 to 2.5 hours after the first dose in 99% of patients treated and sustained a median daily gastric pH of greater than 4.0 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. We conducted this clinical trial at the FDA's request because the maximum omeprazole blood concentration for our 40 mg product was higher than that for delayed-release omeprazole 40 mg, although similar to maximum blood concentrations resulting from approved higher doses of delayed-release omeprazole. The data from this trial demonstrated that the safety profile of our 40 mg 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.

During 2004, we also conducted a clinical trial comparing the effects of Zegerid Powder for Oral Suspension and Protonix® delayed-release pantoprazole tablets on nocturnal gastric acidity. In this trial, 36 patients with nocturnal symptoms of GERD were enrolled in an open-label crossover trial, and data from 32 patients were available for analysis. The patients were randomized to be treated with repeated evening doses of either Zegerid Powder for Oral Suspension 40 mg or Protonix delayed-release tablets 40 mg for one week. After a washout period of one week, patients were treated with the alternate drug, following the same schedule. After repeated once-daily dosing, Zegerid Powder for Oral Suspension produced statistically significantly better nocturnal gastric acid control than Protonix. The patients receiving Zegerid had a median gastric pH of 4.7, as compared to a median gastric pH of 2.0 for the patients receiving Protonix, and the percent time that gastric pH was greater than 4.0 was higher for patients receiving Zegerid than for patients receiving Protonix (55% as compared to 27%). In addition, the percentage of patients experiencing nocturnal acid breakthrough was lower for patients receiving Zegerid than for patients receiving Protonix (53% as compared to 78%).

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

Zegerid Product Family – Products Under Development

Zegerid (omeprazole) Capsules

We are also developing Zegerid (omeprazole) Capsules, which is immediate-release omeprazole in a capsule formulation, in 20 mg and 40 mg dose strengths. Similarly to Zegerid Powder for Oral Suspension, Zegerid Capsules utilize an antacid (sodium bicarbonate), 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. We expect the capsule product to provide a convenient and familiar dosage alternative for many patients.

In November 2004, we completed two pivotal PK/PD clinical trials evaluating Zegerid Capsules 20 mg and 40 mg. The trials were open-label, randomized, crossover trials, each conducted at a single site. Each trial evaluated the pharmacokinetics and pharmacodynamics of single doses and seven consecutive daily doses of Zegerid Capsules compared to delayed-release omeprazole capsules in 36 healthy subjects. 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 (AUC) on Day 7. The trials also assessed whether Zegerid Capsules and the delayed-release omeprazole capsules had similar ability to suppress gastric acidity over 24 hours. The preliminary 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 expected for an immediate-release product, 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. These results were similar to those obtained in the pivotal PK/PD trials that were conducted for Zegerid Powder for Oral Suspension 20 mg and 40 mg.

Following final analysis of the pivotal trial data and collection and analysis of sufficient stability data, we plan to submit a Section 505(b)(2) NDA to the FDA during the third quarter of 2005, seeking approval for the capsule product 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 also intend to conduct other clinical trials which may help to further differentiate our capsule product from the currently marketed delayed-release PPIs or otherwise expand its future use.

Zegerid (omeprazole) Chewable Tablets

We are also developing Zegerid (omeprazole) Chewable Tablets, which is immediate-release omeprazole in a chewable tablet formulation, in 20 mg and 40 mg dose strengths. Like our capsule product, Zegerid Chewable Tablets utilizes antacids (sodium bicarbonate and magnesium hydroxide) instead of an enteric coating to protect the omeprazole from acid degradation. When the tablet is chewed and swallowed, the antacid formulation neutralizes acid in the stomach, protects the omeprazole from degradation and allows for the rapid absorption of the omeprazole into the bloodstream. We expect the chewable tablet product to provide yet another convenient dosage form for many patients, including patients who have difficulty swallowing a capsule or a tablet, such as pediatric and elderly patients.

In February 2005, we completed two pivotal PK/PD clinical trials evaluating Zegerid Chewable Tablets 20 mg and 40 mg. The trials were open-label, randomized, crossover trials, each conducted at a single site. Each trial evaluated the pharmacokinetics and pharmacodynamics of single doses and seven consecutive daily doses of Zegerid Chewable Tablets compared to delayed-release omeprazole capsules in 36 healthy subjects. The primary objective of the trials was to evaluate whether the immediate-release Zegerid Chewable Tablets were pharmacokinetically equivalent to delayed-release omeprazole capsules with respect to total systemic bioavailability (AUC) on Day 7. The trials also assessed whether Zegerid Chewable Tablets and the delayed-release omeprazole capsules had similar ability to suppress gastric acidity over 24 hours. The preliminary trial results demonstrated that Zegerid Chewable Tablets 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 expected for an immediate-release product, the maximum plasma concentration (Cmax) was greater and the time to maximum plasma concentration (Tmax) was shorter on Day 7 for Zegerid Chewable Tablets than for the delayed-release omeprazole capsules. These results were similar to those obtained in the pivotal PK/PD trials that were conducted for Zegerid Powder for Oral Suspension 20 mg and 40 mg and Zegerid Capsules 20 mg and 40 mg.

Following final analysis of the pivotal trial data and collection and analysis of sufficient stability data, we plan to submit a Section 505(b)(2) NDA to the FDA during the second half of 2005, seeking approval for the chewable tablet product 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 also intend to conduct other clinical trials which may help to further differentiate our chewable tablet product from the currently marketed delayed-release PPIs or otherwise expand its future use.

Strategy

Our goal is to become a leading specialty pharmaceutical company that acquires, develops and commercializes proprietary products to enhance the quality of life for patients with GI diseases and disorders. Our business strategy is to develop and market proprietary pharmaceutical products with new formulations, enhanced delivery systems and expanded indications that are based on currently marketed or late stage products or compounds, which otherwise have clinically demonstrated safety and efficacy. We believe this strategy will allow us to more rapidly commercialize our products with potentially reduced development risk and cost as compared with the development of early stage new chemical entities.

Our Zegerid family of products are new immediate-release formulations of omeprazole, a well-established compound which has been approved by the FDA and marketed for over 15 years. For Zegerid Powder for Oral Suspension, we were able to move relatively quickly from product concept to NDA submission by conducting PK/PD studies comparing this product to delayed-release omeprazole, without the need to conduct preclinical or other early stage clinical testing. Moreover, we were also able to move directly into a Phase III clinical study to further differentiate this product from existing products.

In order to continue to execute our business strategy, we intend to:

- ***Explore Additional Strategic Arrangements to Expand the Promotion of Our Products in the U.S.*** We plan to explore additional strategic arrangements with one or more pharmaceutical companies to expand the promotion of our Zegerid family of products in the U.S. To date, we have sublicensed our proprietary immediate-release PPI technology to TAP, granting to TAP the North American rights to develop, manufacture and sell products resulting from the use of our technology with lansoprazole and derivatives of lansoprazole. We have also entered into a co-promotion agreement with Otsuka America in October 2004, under which Otsuka America is co-promoting Zegerid Powder for Oral Suspension and has options to co-promote our capsule and chewable tablet products in the future. We will continue to evaluate strategies to expand the promotion of our Zegerid products in the U.S. For example, in connection with the approval of Zegerid Powder for Oral Suspension 40 mg for reduction of risk of upper GI bleeding in critically ill patients, we are evaluating strategies to expand the promotion of Zegerid to the hospital market, including teaching hospitals and other influential institutions that serve this patient population, in order to create greater awareness of the Zegerid brand over time.

- ***Out-License International Development, Distribution and Marketing Rights.*** Outside of the U.S., we intend to out-license development, distribution and marketing rights for our Zegerid family of products to one or more pharmaceutical companies with established commercialization capabilities outside the U.S. We have filed several patent applications outside the U.S., and likely will more actively pursue commercialization in particular territories if and when we obtain issued patents in such territories.

- ***Enhance Our Product Portfolio through Internal Development, In-Licensing and Co-Promotion Arrangements.*** We intend to internally develop and license and acquire additional products and marketed products targeting upper and lower GI diseases and disorders. We also plan to explore co-promotion arrangements for marketed products that are relevant to our target gastroenterologists or primary care physicians. Our management team has substantial experience in product development, manufacturing, clinical development, regulatory affairs and sales and marketing through their participation at other companies in the successful development and commercialization of GI and other products. We believe this experience will allow us to successfully build our business organization and distinguish us from specialty pharmaceutical companies that focus solely on the distribution of products. We also believe that this experience and expanded focus will help us identify attractive licensing and acquisition opportunities with pharmaceutical companies, biotechnology companies and universities.

Sales and Marketing

We have established a commercial sales organization to focus on the highest PPI-prescribing physicians in the U.S. with a focus on approximately 10,000 gastroenterologists and 26,000 primary care physicians. We estimate that this group collectively wrote approximately $5.6 billion of PPI prescriptions in 2004, representing nearly one-half of the total U.S. PPI market. We believe this concentration of high-volume PPI prescribers will enable us to effectively promote our products with a relatively small and focused sales and marketing organization.

In preparation for the launch of Zegerid Powder for Oral Suspension 20 mg in October 2004, we built a field sales organization comprised of approximately 230 sales representatives. In addition to the field sales representatives, we employ approximately 25 district sales managers, 4 regional sales directors and 18 account managers. Our account managers are seeking formulary acceptance from managed care organizations similar to that for branded delayed-release PPIs. To complement our commercial sales organization, we also entered into a co-promotion agreement with Otsuka America in October 2004, under which Otsuka America's approximately 170 field sales representatives are co-promoting Zegerid Powder for Oral Suspension in the first selling position. Additionally, we use a variety of marketing programs to promote our products, including sales promotional materials, speaker programs, journal advertising, industry publications, electronic media and product sampling.

Our field sales representatives are positioned in major metropolitan areas across the U.S. and have an average of five years of pharmaceutical sales experience. Many of the representatives have prior experience with GI products, including PPIs. Each member of our sales team undergoes a rigorous training program focused on our product offerings, disease background, competitive products and our sales techniques. 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. The field sales representatives are compensated in part in accordance with an incentive bonus program based on performance.

Co-Promotion Agreement with Otsuka America Pharmaceutical, Inc.

In October 2004, we entered into a non-exclusive co-promotion agreement with Otsuka America to co-promote Zegerid Powder for Oral Suspension to U.S. physicians. Otsuka America's sales representatives began promoting Zegerid Powder for Oral Suspension 20 mg in early November 2004.

Under the terms of the co-promotion agreement, we received a $15.0 million upfront payment from Otsuka America, and will pay Otsuka America a royalty on total U.S. net sales of Zegerid Powder for Oral Suspension. Initially, the royalty rate is in the high single digits, presuming a minimum number of first position sales calls to target physicians. We provide all marketing materials, and Otsuka America covers all costs related to its sales force. In addition, we have granted Otsuka America options to extend the co-promotion arrangement under the agreement to Zegerid Capsules and Zegerid Chewable Tablets, subject to receipt of marketing approval of these products, with additional milestone payments should those options be exercised.

In order to compete effectively, we and Otsuka America may desire to further expand our sales forces beyond our current combined total of approximately 400 sales representatives. We plan to evaluate further expansion of our sales force based on the market demand for Zegerid Powder for Oral Suspension and the status of our planned regulatory submissions for Zegerid Capsules and Zegerid Chewable Tablets. Under the terms of our co-promotion agreement with Otsuka America, Otsuka America may increase the size of its sales force up to 400 sales representatives to match any expansion of our sales force in exchange for an increased royalty rate in the low double digits.

The agreement will terminate automatically on December 31, 2009, 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. We may also terminate the agreement under certain additional conditions, subject to prior written notice to Otsuka America within a specified time period.

TAP Pharmaceutical Products Agreement

In June 2002, we entered into a strategic sublicense agreement with TAP. Under the agreement, we granted TAP the North American rights to develop, manufacture and sell products resulting from the use of our immediate-release PPI technology with lansoprazole, its patented PPI marketed under the name Prevacid®, and derivatives of lansoprazole. TAP had sales of Prevacid in North America of approximately $3.8 billion in 2004, according to IMS Health. Under the agreement, TAP is required to pay a combination of fees for the licensed rights, including an upfront payment and milestone payments that may exceed $100 million. In addition, we are entitled to royalties on any future sales of products utilizing our proprietary technology that are commercialized by TAP. The sublicense is exclusive with respect to lansoprazole and non-exclusive with respect to derivatives of lansoprazole. We believe that if TAP successfully develops and commercializes one or more new products based on our licensed patent rights, TAP's commercialization efforts will, in addition to providing revenue to us, help drive market acceptance of immediate-release PPI products.

To date, we have received an $8.0 million upfront payment from TAP in July 2002 following the execution of the sublicense and a $10.0 million milestone payment in February 2005 related to TAP's development activities. We received the February 2005 milestone after we prevailed in an alternative dispute resolution proceeding that we initiated against TAP in August 2003. In the proceeding, we alleged that TAP had achieved a development milestone, and we were awarded the $10.0 milestone payment, plus interest and legal expenses. We paid 15% of the upfront sublicense fee and the February 2005 milestone to the University of Missouri and are also obligated to pay 15% of any further milestone payments, as well as share a portion of any royalty payments, we receive from TAP pursuant to our license with the University of Missouri. The milestone fees and royalty rates may be subject to adjustment during the term of the agreement based on a number of factors, including whether we commercialize or license an immediate-release formulation of any PPI other than omeprazole. In order for us to receive milestone fees in excess of $100 million under the agreement with TAP, TAP would generally need to develop and receive NDA approval for one immediate-release lansoprazole product and either TAP would need to also conduct development activities for an immediate-release lansoprazole derivative product or Takeda Chemical Industries, Ltd., or Takeda, would need to exercise its option and receive regulatory approval for lansoprazole or lansoprazole derivative products outside North America, as described more fully below. TAP is responsible for all of its product development and commercialization expenses.

Pursuant to the terms of the agreement, we also granted an option to Takeda to receive a license covering all countries outside of North America to develop, manufacture and sell products resulting from the use of our immediate-release PPI technology with lansoprazole and derivatives of lansoprazole. The rights would be exclusive with respect to lansprazole and non-exclusive with respect to derivatives of lansoprazole. In the event that Takeda exercises its option, we would be entitled to receive aggregate upfront payments of up to $5.0 million and aggregate milestone payments of up to $7.75 million, depending on whether Takeda exercises the option for all territories outside North America and whether Takeda is able to commercialize an immediate-release lansoprazole or lansoprazole derivative product through regulatory approval.

The agreement with TAP will remain in effect in the U.S. or Canada until there is no longer a valid claim under the patents covering the University of Missouri technology in the U.S. or Canada, respectively, upon which TAP's improved formulation is based, which we expect will be no earlier than 2016. In addition, we have the right to terminate the agreement if TAP does not meet diligence obligations with respect to the development of an improved PPI formulation. Either TAP or we may terminate the agreement prior to its expiration under other circumstances, including bankruptcy or uncured breach of any material provision of the agreement. TAP may also terminate the agreement without cause at any time by giving us 60 days prior written notice.

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 Patheon Inc. as our only supplier of Zegerid Powder for Oral Suspension and have entered into an agreement with Patheon which 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 obligates us to fund certain equipment purchases. This agreement has an initial five-year term beginning from July 2004 and thereafter continues in force indefinitely. Either party may terminate the agreement at any time after the initial term with 18 months written notice. We can terminate the agreement at any time if we decide to no longer market our powder for oral suspension product with six months written notice. We can also terminate this 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 subject to prior written notice within a specified time period.

In addition, in September 2004, we entered into a manufacturing and supply agreement with OSG Norwich Pharmaceuticals, Inc., or Norwich, for the supply of commercial quantities of Zegerid Capsules, which is currently under development. The agreement provides for an initial four-year term beginning upon commencement of commercial manufacturing 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. We have not yet entered into any commercial supply agreements for Zegerid Chewable Tablets.

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 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.

Although there are potential sources of supply other than Patheon, Norwich and Uquifa for our products and active pharmaceutical ingredients, 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. In addition, we have retained third parties to perform various regulatory monitoring services for us, including adverse event reporting, safety database management and other product maintenance services. We have also entered into channel services agreements with wholesalers under which we receive certain distribution management services and data reporting from the wholesalers, in exchange for a fee.

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. 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.

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, all of the products we currently market and intend to market incorporate patented technology owned by others that we have 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.

We have received U.S. and EU trademark registration for our corporate name, Santarus®. In addition, we have received U.S. trademark registration and have applied for EU trademark registration for our brand name, Zegerid®, and have applied for trademark registration for various other names. Over time, we intend to introduce new trademarks, service marks and brand names and maintain registrations on trademarks that remain valuable to our business.

License Rights from the University of Missouri

In January 2001, we entered into an exclusive, worldwide license agreement with the University of Missouri for all of its 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 and international or foreign counterpart 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.

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 the achievement of certain regulatory events related to obtaining approvals 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, and to pay royalties on net sales of our products. 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. We issued to the University of Missouri 164,284 shares of our common stock in connection with the license agreement. Under the license agreement, we are permitted to sublicense our rights to third parties. We are obligated to pay to the University of Missouri a portion of any sublicense fees, milestone payments or royalties that we receive from any sublicense, including our sublicense to TAP. Under the license agreement, we are 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 diligence obligations 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. We can terminate this agreement at any time, in whole or in part, with 60 days written notice.

Competition

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

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

Prescription Products:

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

- H2-receptor antagonists: Merck & Co., Inc.'s Pepcid®, GlaxoSmithKline plc's Zantac® and Tagamet® and Reliant Pharmaceuticals, Inc.'s Axid®, among others.

Over-the-Counter Products:

- PPIs: The Procter & Gamble Company's Prilosec OTC®;

- H2-receptor antagonists: Pfizer Inc.'s Zantac, GlaxoSmithKline's Tagamet, and Johnson & Johnson's and Merck's Pepcid® AC and Pepcid® Complete, among others; and

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

Many of our competitors are large, well-established companies in the pharmaceutical field. Given our relatively small size and the entry of our new products into a market characterized by well-established drugs, we may not be able to compete effectively. For example, our competitors may have a greater ability to undertake more extensive research and development, manufacturing, marketing and other programs. They may also have significantly greater financial and other resources than we do, and they may have significantly larger field sales force organizations and invest significant amounts in advertising and marketing their products, including through television and other direct-to-consumer methods.

In addition to competition from existing commercial products, a number of companies and research institutions have focused research and development resources on developing new products, including reversible acid inhibitors, cytoprotective compounds,

derivatives of current PPIs and motility agents and combinations thereof that may be utilized to treat GI diseases and disorders, and the pace of technological development and the number of product candidates may increase over the next few years. Future products that are developed may be based on new and different technology that may involve faster mechanisms of action than our products or exhibit other benefits relative to our products.

Our ability to compete with products that our competitors develop will depend in part on our competitors' ability to obtain patent protection for their products and product candidates and the periods of exclusivity resulting from these patents. Many of the patents covering antacids or H2-receptor antagonists have expired and are subject to generic competition. In addition, among the currently-marketed PPIs, Prilosec is the only product for which the primary patent has expired. To date, several generic companies have launched generic delayed-release omeprazole products. As more PPI patents expire, we expect our competitors to compete with us by introducing additional generic products as well as allocating additional resources to research relating to potential treatments with greater potential for patent-based exclusivity, such as prodrugs and isomers of PPIs, reversible acid inhibitors and motility agents.

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 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 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 policies adopted by FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA 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. According to the FDA, the median approval time for NDAs approved during calendar year 2003 was approximately 15 months. 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 FDA's Orange Book publication. 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 once the 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.

In 2003 and 2004, we submitted Section 505(b)(2) NDAs for our Zegerid Powder for Oral Suspension 20 mg and 40 mg products, respectively. Each of these NDAs referenced 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 include various AstraZeneca and Merck entities. In each case, AstraZeneca did not file a patent infringement lawsuit within the required 45-day period. Therefore, the NDAs for our Zegerid Powder for Oral Suspension 20 mg and 40 mg products were not subject to a 30-month stay of approval. We also intend to submit Section 505(b)(2) NDAs for Zegerid Capsules and Zegerid Chewable Tablets and anticipate providing similar Paragraph IV certifications, and AstraZeneca may file a patent infringement lawsuit against us in connection with these NDAs. Any such patent infringement litigation against us could result in a 30-month stay of approval for the particular NDA, would divert management's attention and our resources and, if successful, would be materially adverse to our business. Although AstraZeneca did not file a patent infringement lawsuit against us in connection with our NDAs for Zegerid Powder for Oral Suspension within the 45-day period, it may decide to pursue litigation at any time in the future.

Other Regulatory Requirements

Even though the FDA has approved our Zegerid Powder for Oral Suspension 20 mg and 40 mg products and to the extent the FDA approves any of our other 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 manufacturing and labeling claims, 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, as part of our post-marketing commitments to the FDA in connection with the approval of our NDAs for Zegerid Powder for Oral Suspension 20 mg and 40 mg, we have committed to evaluate the product in pediatric populations, including in PK/PD and safety studies which we plan to initiate during the second half of 2005.

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 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. The requirements governing the conduct of clinical trials and marketing authorization vary widely from country to country.

Employees

As of March 15, 2005, we had 383 employees. A total of 57 employees were engaged in clinical research, regulatory, product development and manufacturing, and medical affairs, 22 of whom hold Ph.D., M.D., Pharm.D. or equivalent degrees, 301 were in sales, marketing and business development, and 25 were in administration and finance.

Available Information

We make available free of charge on or through our Internet web site our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission, or the SEC. Our Internet address is *www.santarus.com.*

Risk Factors

The following information sets forth factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this report, the information incorporated herein by reference and those we may make from time to time.

Risks Related to Our Business and Industry

At this time, we are largely dependent on the success of our initial approved product, Zegerid Powder for Oral Suspension 20 mg and 40 mg, and we cannot be certain that we will be able to successfully commercialize this product.

We have invested a significant portion of our time and financial resources in the development and commercialization of Zegerid Powder for Oral Suspension 20 mg and 40 mg. We anticipate that in the near term our ability to generate revenues will depend on the commercial success of Zegerid Powder for Oral Suspension, which in turn, will depend on several factors, including our ability to:

- generate commercial sales of the product through our own sales force and our co-promotion arrangement with Otsuka America Pharmaceutical, Inc., or Otsuka America, or any other collaboration with pharmaceutical companies or contract sales organizations that we may later establish;
- establish effective marketing programs and build brand identity;
- obtain acceptance of the product by physicians, patients and third-party payors and obtain and maintain distribution at the retail level;
- establish and maintain our agreements with wholesalers and distributors on commercially reasonable terms; and
- demonstrate commercial manufacturing capabilities as necessary to meet commercial demand for the product, including samples, and maintain commercial manufacturing arrangements with third-party manufacturers.

We will continue to incur significant and increasing costs as we continue to support the commercial launch of Zegerid Powder for Oral Suspension, and we have encountered low initial demand for the 20 mg dosage strength. We generated a net loss of $33.3 million for the three months ended December 31, 2004, as compared to a net loss of $21.2 million for the three months ended September 30, 2004, which increase was primarily attributable to increased costs associated with our commercial activities and personnel. As of December 31, 2004, we had recognized only approximately $634,000 in net sales of Zegerid Powder for Oral Suspension and had an accumulated deficit of approximately $138.3 million, which includes our net loss of $81.5 million for 2004.

We cannot be certain that our recent launch of Zegerid Powder for Oral Suspension 40 mg and our continued marketing of the 20 mg dosage strength will result in increased demand for the product. If we fail to successfully commercialize this product 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.

Our other Zegerid products under development may not be approved by the FDA, and any failure or delay associated with our product development and clinical trials or the FDA's approval of such products would increase our product development 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 U.S. Food and Drug Administration, or FDA, and any foreign regulatory authorities will approve them for commercial use.

Only Zegerid Powder for Oral Suspension 20 mg and 40 mg has been approved for commercial sale by the FDA. We have recently completed pivotal pharmacokinetic/pharmacodynamic, or PK/PD, clinical trials evaluating the 20 mg and 40 mg doses of Zegerid Capsules and Zegerid Chewable Tablets, and we plan to submit new drug applications, or NDAs, to the FDA seeking approval for these products during the second half of 2005. In connection with its review of our NDAs, the FDA may request additional information from us, including data from additional clinical trials. In addition, the FDA ultimately may not grant marketing approval for these products.

To the extent we are not able to obtain regulatory approval for or demonstrate adequate stability for Zegerid Capsules and Zegerid Chewable Tablets, we may in the future need to develop alternative formulations of these products. Product development is generally a long, expensive and uncertain process. Successful development of formulations for our Zegerid products under development will depend on many factors, including:

- our ability to select key components, establish a stable formulation and optimize taste and other sensory characteristics;
- our ability to develop a formulation that demonstrates our intended safety and efficacy profile; and
- our ability to transfer from development stage to commercial-scale operations and the costs associated with commercial manufacturing.

If we are required to develop alternative formulations of our capsule and chewable tablet products or are significantly delayed in doing so, our ability to commercialize these products will be adversely affected.

Once we have manufactured formulations of our products that we believe will be suitable for pivotal 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.

Failure of our Zegerid products to achieve and maintain market acceptance would seriously impair our ability to reach profitability.

The commercial success of Zegerid Powder for Oral Suspension 20 mg and 40 mg and any other subsequently-approved products will depend upon acceptance of our products by the medical community, particularly gastroenterologists and primary care physicians, as well as patients and third-party payors. Market acceptance will depend upon several factors, including:

- the efficacy and safety of our products and our ability to differentiate our products from products offered by our competitors;
- effectiveness of our and any collaborators' sales and marketing efforts;
- our ability to obtain sufficient third-party insurance coverage or reimbursement;
- pricing and cost effectiveness;
- the prevalence and severity of any adverse side effects;
- availability of alternative treatments;
- relative convenience and ease of administration; and
- taste and other sensory characteristics of our products.

In addition, even if our products 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 obtain favorable reimbursement for our products, their commercial success may be severely hindered.

Our ability to sell our approved product and any subsequently-approved 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 some cases, insurers and other healthcare payment organizations try to encourage the use of less expensive generic brands and over-the-counter, or OTC, products through their prescription benefits coverage and reimbursement policies. These organizations may make the generic alternative more attractive to the patient by providing different amounts of reimbursement so that the net cost of the generic product to the patient is less than the net cost of a prescription brand product. Aggressive pricing policies by our generic product competitors and the prescription benefit policies of insurers could have a negative effect on our product revenues and profitability.

Many managed care organizations negotiate the price of medical services and products and develop formularies for that purpose. Exclusion of a product from a formulary can lead to its sharply reduced usage in the managed care organization 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 may also result in downward pricing pressure in the industry or in the markets where our products will compete. We may not be successful in any efforts we take to mitigate the effect of a decline in average selling prices for our products. Any decline in our average selling prices would 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 gastrointestinal, or GI, products.

In connection with the launches of Zegerid Powder for Oral Suspension 20 mg and 40 mg, our approximately 18 account managers have initiated contacts with 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 proton pump inhibitor, or 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 the active ingredient. If we fail to successfully secure reimbursement coverage for our products 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.

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. Competition in our industry occurs on a variety of fronts, including developing and bringing new products to market before others, developing new technologies to improve existing products, developing new products to provide the same benefits as existing products at lower cost and developing new products to provide benefits superior to those of existing products. In addition, our ability and that of our competitors to compete in our industry will depend upon our and their relative abilities to obtain and maintain intellectual property protection for products.

Many of our competitors are large, well-established companies in the pharmaceutical field. Our competitors include, among others, AstraZeneca plc, TAP Pharmaceutical Products Inc., or TAP, Wyeth, Altana, Eisai Co., Ltd., Johnson & Johnson, Axcan Pharma Inc., Ferring Pharmaceuticals A/S, Merck & Co., Inc., Novartis AG, Pfizer Inc., Salix Pharmaceuticals, Inc., Shire Pharmaceuticals Group plc and The Procter & Gamble Company. Many of these companies already offer products in the U.S. and Europe that target gastroesophageal reflux disease, or GERD, and other GI diseases and disorders that we intend to target. Given our relatively small size and the entry of our new 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 drugs;
- undertaking preclinical testing and human clinical trials;
- obtaining FDA and other regulatory approvals of drugs;
- formulating and manufacturing 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. Further, the products they develop may be based on new and different technology that may involve faster mechanisms of action than our products or exhibit other benefits relative to our products.

Many of these companies 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 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 production 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 approved product and our products under development will 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 approved product and our products under development will compete with many prescription and OTC products, including:

Prescription Products:

- PPIs: AstraZeneca's Prilosec and Nexium, TAP's Prevacid, Wyeth's and Altana's Protonix, Johnson & Johnson's and Eisai's Aciphex, and generic omeprazole, among others; and
- H2-receptor antagonists: Merck's Pepcid, GlaxoSmithKline plc's Zantac and Tagamet and Reliant Pharmaceuticals, Inc.'s Axid, among others.

OTC Products:

- PPIs: Procter & Gamble's Prilosec OTC;
- H2-receptor antagonists: Pfizer's Zantac, GlaxoSmithKline's Tagamet and Johnson & Johnson's and Merck's PepcidAC and Pepcid Complete, among others; and
- Antacids: Johnson & Johnson's and Merck's Mylanta, Novartis' Maalox, Pfizer's Rolaids and GlaxoSmithKline's Gaviscon and Tums, among others.

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

Many of the currently marketed competitive products are available in generic formulations. For example, there are several generic delayed-release omeprazole products currently available in 10 mg and 20 mg dose strengths in the U.S. market, and we anticipate that over time additional generic delayed-release omeprazole products, including 40 mg dose strengths, as well as other generic delayed-release PPIs, will enter the market. In addition, with the introduction of Prilosec OTC, delayed-release omeprazole is available in a 20 mg dose as an OTC product. 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 the active ingredient.

We have only recently established our sales and marketing capabilities and we will need to retain qualified sales and marketing personnel and collaborate successfully with our co-promotion partner, Otsuka America, to successfully commercialize Zegerid Powder for Oral Suspension and any other products that we develop, acquire or license.

We began the commercial sale of Zegerid Powder for Oral Suspension 20 mg in October 2004 and Zegerid Powder for Oral Suspension 40 mg in February 2005, and thus our company has very limited experience in selling and marketing our products. In preparation for the launch of Zegerid Powder for Oral Suspension 20 mg, we built our sales and marketing infrastructure and assembled a field sales organization comprised of approximately 230 sales representatives who target high-prescribing gastroenterologists and primary care physicians treating GI diseases and disorders in the U.S. Because our field sales force is newly established, the representatives have only recently received training and education concerning our products, and we will continue to incur significant additional expenses associated with the training and compensation of our sales representatives. To the extent we are not successful in retaining qualified sales and marketing personnel, we will not be able to effectively market our currently approved product or any future products.

In addition, we entered into a non-exclusive agreement with Otsuka America in October 2004 for Otsuka America to co-promote Zegerid Powder for Oral Suspension to U.S. physicians. Otsuka America's approximately 170 sales representatives began actively promoting Zegerid Powder for Oral Suspension to physicians in November 2004. While our agreement with Otsuka America requires its sales representatives to promote Zegerid Powder for Oral Suspension in a minimum number of first position sales calls to target physicians, we cannot be sure that Otsuka America's efforts will be successful or that our own sales force, together with any efforts made by Otsuka America to promote our product, will generate sufficient awareness or demand for our product. Even if we determine to pursue a relationship with another pharmaceutical company or contract sales organization to facilitate our sales efforts, we may not be able to enter into agreements with these entities on commercially reasonable terms, or at all. Any revenues we receive from sales of our products generated by 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 co-promotion agreement with Otsuka America or to effectively establish an alternative arrangement to market our products more broadly than we can through our internal sales force, our business could be adversely affected.

In order to compete effectively, we and Otsuka America may desire to further expand our sales forces. We plan to evaluate further expansion of our sales force based on the market demand for Zegerid Powder for Oral Suspension and the status of our planned regulatory submissions for Zegerid Capsules and Zegerid Chewable Tablets. Under the terms of our co-promotion agreement with Otsuka America, Otsuka America may increase the size of its sales force up to 400 sales representatives to match any expansion of our sales force in exchange for an increased royalty rate. However, we may not be successful in our efforts to recruit a larger sales force, and Otsuka America may choose not to expand its sales force. In order to cover all of the PPI prescribing physicians at the same level of reach and frequency as our competitors with branded PPI products, we and Otsuka America would need to significantly expand our collective sales force beyond these levels or we would need to partner with another company with a substantial primary care sales organization.

We recently commenced the commercial sale of our first approved product and could experience significant differences between actual and estimated demand for the product.

We have very limited experience selling Zegerid Powder for Oral Suspension 20 mg and 40 mg. Therefore, it has been and will continue to be difficult to estimate demand for this product with any certainty. If we overestimate demand, we may be required to write off inventories. As of December 31, 2004, we reserved approximately $1.7 million against on-hand inventories and accrued approximately $627,000 for firm purchase commitments related to excess inventories. If demand for our products increases beyond what we forecast, our third-party suppliers may not be able to increase production rapidly enough to meet the demand. Our failure to meet market demand could lead to missed opportunities to fulfill orders for our products, which would lead to lost opportunities to generate revenues and could adversely affect our relationships with physicians, patients and our wholesale customers.

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

Although we have commenced commercial manufacturing of Zegerid Powder for Oral Suspension 20 mg and 40 mg, the quantities that our supplier is able to manufacture in the future may fail to meet our quality specifications or may not be sufficient to meet potential commercial demand for the product. In addition, we will need to prepare in the future for potential commercial manufacturing of our capsule and chewable tablet products. Any problems or delays experienced in the commercial manufacturing of Zegerid Powder for Oral Suspension 20 mg and 40 mg or in preparing for commercial manufacturing of our other products may impair our ability to manufacture 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 prepare for commercial manufacturing, 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 will 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 will have limited control over the manufacturing processes of 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 manufacturers' failure to comply with regulatory requirements or otherwise 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 our products still under development, if the FDA finds significant issues with any of our manufacturers during the FDA's 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 a single third-party manufacturer located outside of the U.S., Patheon Inc., for the supply of Zegerid Powder for Oral Suspension 20 mg and 40 mg, and we are obligated under our supply agreement to purchase a significant portion of our requirements of this product from Patheon. In addition, we have entered into a commercial supply agreement with OSG Norwich Pharmaceuticals, Inc., which provides for supply of our capsule product in the event that we are able to obtain regulatory approval, and we have not yet entered into commercial supply agreements for supply of our chewable tablet product. 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 the active pharmaceutical ingredient in each of our current products. We are obligated under our supply agreement with Uquifa to purchase all of our requirements of omeprazole from this supplier. Any significant problem that our sole source suppliers experience could result in a delay or interruption in the supply to us until the supplier cures the problem or until we locate an alternative source of supply. In addition, because our sole source suppliers provide manufacturing services to a number of other pharmaceutical companies, our suppliers may experience capacity constraints or chose to prioritize one or more of their other customers over us.

Although alternative sources of supply exist, the number of third-party manufacturers with the expertise, required regulatory approvals and facilities to manufacture pharmaceutical products or active pharmaceutical ingredients on a commercial scale is very 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. In addition, we have not entered into commercial supply agreements for our chewable tablet product and may not be able to establish or maintain commercial manufacturing arrangements for that product on commercially reasonable terms.

Regulatory approval of Zegerid Powder for Oral Suspension is limited by the FDA to those indications and conditions for which we are able to support clinical safety and efficacy, and any approval we may receive for our products under development will be similarly limited.

Any regulatory approval is limited to those diseases and indications for which our products are deemed to be safe and effective by the FDA. Zegerid Powder for Oral Suspension has been approved by the FDA for the treatment of heartburn and other symptoms associated with GERD, treatment and maintenance of healing of erosive esophagitis, treatment of duodenal and gastric ulcers and reduction of risk of upper GI bleeding in critically ill patients. In addition to the FDA approval required for new formulations, any new indication to an approved product also requires FDA approval. If we are not able to obtain FDA approval for a broad range of indications for our products, our ability to effectively market and sell our products may be greatly 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 Zegerid Powder for Oral Suspension, and we will be subject to ongoing regulatory review of any of our other products that may be approved in the future.

Zegerid Powder for Oral Suspension and any of our products under development which may be approved for sale by the FDA 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, advertising, promotion and record keeping related to the products. The FDA also may 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 have committed to evaluate the product in pediatric populations, including in PK/PD and safety studies which we plan to initiate during the second half of 2005. 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.

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.

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.

Our resources are currently dedicated to our Zegerid family of products, and we may be unable to expand our product portfolio or integrate new products successfully.

Our product development, clinical research and commercialization activities are currently dedicated to developing our Zegerid family of products. Because each of these products — powder for oral suspension, capsules and chewable tablets — is derived from the same technology licensed from the University of Missouri, each product is vulnerable to substantially the same risks stemming from potential patent invalidity, misappropriation of intellectual property by third parties, reliance upon a third-party for patent

prosecution and maintenance and unexpected early termination of our license agreement. Similarly, because our current regulatory strategy for these products depends, in part, on the successful filing and acceptance of NDAs under a provision known as Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, any positions taken by the FDA concerning any Section 505(b)(2) NDAs we submit, or Section 505(b)(2) NDAs in general, could impact any subsequent NDAs we may submit. To date, we have received FDA approval of two Section 505(b)(2) NDAs, for the 20 mg and 40 mg doses of Zegerid Powder for Oral Suspension, and plan to submit additional Section 505(b)(2) NDAs for our capsule and chewable tablet products to the FDA during the second half of 2005. Our ability to successfully commercialize our products could also be jeopardized by the emergence of a single competitive product that exhibits greater efficacy, more rapid onset of action or other benefits relative to our products. Furthermore, to the extent our single approved product, Zegerid Powder for Oral Suspension, fails to gain market acceptance, it may be more difficult for us to generate sufficient credibility with physicians and patients to commercialize other products in the Zegerid product family.

Our success will depend in part on our ability to develop and commercialize future products based on different technology than the technology on which the Zegerid family of products is based. Our internal development efforts will be time-consuming and expensive and may not be successful in developing new products. We may not be able to identify appropriate licensing or acquisition opportunities to 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 other acquisition of a new product or an acquisition target. If we issue shares of our common stock 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.

Even if we can develop or acquire new products, our growth and acquisition strategy depends upon the successful integration of licensed or acquired products or companies with our existing products and business. Any failure of this integration process could delay new product development and introduction, impair our ability to market and sell our products and adversely affect our reputation.

We are dependent on our sublicense agreement with TAP Pharmaceutical Products Inc. as one source of near-term revenue.

In June 2002, we entered into a sublicense agreement with TAP, granting TAP the right to develop one or more products based on its lansoprazole PPI product and derivatives of lansoprazole. The amount of revenues from this agreement in the future is uncertain and primarily tied to TAP's success in developing a commercial product, over which we have no control. Under the terms of the agreement, TAP has the right to discontinue its development efforts and terminate the agreement without cause by giving us 60 days prior written notice.

In August 2003, we initiated an alternative dispute resolution proceeding against TAP under the terms of the sublicense agreement. In this proceeding, we asserted that TAP owed us $10.0 million in connection with the achievement of a development milestone. TAP asserted that the milestone has not yet been achieved, and a formal hearing on the matter was held in January 2005. In February 2005, we prevailed in the proceeding and were awarded the $10.0 million milestone payment, plus interest and legal expenses.

To the extent that TAP successfully develops products based on our licensed technology, those products will compete directly with our development, marketing and sales efforts. Because TAP's lansoprazole PPI product is a well-established product and TAP has greater financial and other resources than we do, TAP may be able to develop its product more rapidly and market its product more extensively than we can. As a result, we may not be able to compete successfully with TAP and our ability to gain market share and revenue for our products could be adversely affected.

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 beginning in 2006 and mandates other reforms. Although we cannot predict the full effect on our business of the implementation of this new legislation, it is possible that the new benefit, which will be managed by private health insurers, pharmacy benefit managers and other managed care organizations, will result in decreased reimbursement for

prescription drugs, which may further exacerbate industry-wide pressure to reduce the prices charged for prescription drugs. This could harm our ability to market our products and generate revenues. It is also possible that other proposals will be adopted. 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 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 Zegerid Powder for Oral Suspension and our other products under development. These risks exist even if a product is approved for commercial sale by the FDA and manufactured in facilities licensed and regulated by the FDA. Any product liability claim or series of claims brought against us could significantly harm our business by, among other things, reducing demand for our products, injuring our reputation and creating significant adverse media attention and costly litigation. Plaintiffs have received substantial damage awards in some jurisdictions against pharmaceutical companies based upon claims for injuries allegedly caused by the use of their products. Any judgment against us that is in excess of our insurance policy limits would have to be paid from our cash reserves, which would reduce our capital resources. Although we have product and clinical trials liability insurance with a coverage limit of $10.0 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 commercial services for our 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 approved product, key aspects of which will be 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. 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, 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 approved product 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 program, we engage clinical investigators and clinical research organizations, or CROs, to enroll patients and conduct and manage our clinical studies. Because we presently engage and intend to continue to engage CROs to help us conduct and manage our clinical trials, 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. 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, and we may be unable to obtain regulatory approval for or successfully commercialize our products.

Our approved product and our products under development could be rendered obsolete by technological change and medical advances which would materially affect the performance of our business.

Our approved product and our products under development may be rendered obsolete or uneconomical by the development of medical advances to treat the conditions that they address. The treatment of GI diseases and disorders is the subject of active research and development by many potential competitors, including major pharmaceutical companies, specialized biotechnology firms, universities and other research institutions. While we will seek to expand our technological capabilities to remain competitive, research and development by others may render our technology or products obsolete or noncompetitive or result in treatments or cures superior to any therapy we developed. Technological advances affecting costs of production also could adversely affect our ability to sell products.

Our regulatory strategy currently depends upon a provision of the Federal Food, Drug, and Cosmetic Act that is the subject of litigation that may have the effect of delaying or preventing the regulatory approval of our products.

Our current regulatory strategy relies upon Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, which permits the filing of an NDA where at least some of the information required for product approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Over the last few years, certain pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2) and one pharmaceutical company has sued the FDA on the matter. Although the issues in that litigation are specific to the products involved, if the FDA does not prevail, it may be required to change its interpretation of Section 505(b)(2). The FDA approved our first Section 505(b)(2) NDA for Zegerid Powder for Oral Suspension 20 mg in June 2004 and our second Section 505(b)(2) NDA for Zegerid Powder for Oral Suspension 40 mg in December 2004. However, a subsequent change in the FDA's interpretation of Section 505(b)(2), whether as a result of the FDA's pending litigation with the third party or otherwise, could prevent or delay approval of our other planned Section 505(b)(2) NDA submissions. If we are unable to rely on Section 505(b)(2) as part of the regulatory approval process for our products, we may be required to negotiate rights of reference to NDAs held by third parties or conduct preclinical or additional clinical studies before we can commercialize our products. Any obligation to conduct preclinical or additional clinical trials would result in increased costs and delay the commercialization of our products. If we were to pursue obtaining rights of reference, these NDA holders would have no obligation to grant any rights to us, and we may be unable to enter into agreements with them on a timely basis or on commercially acceptable terms.

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

We are a small company and, as of March 15, 2005, had only 383 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 may not be able to recruit and retain qualified personnel, particularly for senior clinical and sales and marketing positions, in the future due to intense 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. We are not aware of any present intention of these individuals to leave our company. 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.

We have significantly increased the size of our organization in recent months, and we may encounter difficulties managing our growth, which could adversely affect our results of operations.

We have significantly expanded the size of our organization in recent months as we established our commercial organization and launched our first product. We increased the number of our employees from 49 as of December 31, 2003 to 383 as of March 15, 2005, and we expect the number of employees to continue to grow to the extent we meet our strategic objectives. Our recent growth in number of employees and scope of activities as well as any future growth and expansion are expected to place a significant demand on our financial, managerial and operational resources.

Our success will also depend on the ability of our executive officers and senior management to continue to implement and improve our operational, management information and financial control systems and to expand, train and manage our employee base. Our inability to manage growth effectively could cause our operating costs to grow even faster than we are currently anticipating.

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 drugs and have consistently generated operating losses since our inception in December 1996. Our commercial launch activities, and continued product development and clinical activities will require significant expenditures. As of December 31, 2004, we had recognized only approximately $634,000 in net sales of our products, and we had an accumulated deficit of approximately $138.3 million, which includes our net loss of $81.5 million in 2004. We expect to continue to incur additional operating losses and capital expenditures and anticipate that our expenses will increase substantially in the foreseeable future as we continue to support the commercial launch of Zegerid Powder for Oral Suspension 40 mg, and continue our product development and clinical research programs.

We will need to raise additional funds to pursue our growth strategy or continue our operations and we may be unable to raise capital when needed.

We believe that our current cash, cash equivalents and short-term investments, including the $10.0 million milestone payment received from TAP in February 2005, will be sufficient to fund our operations for at least the next 12 months. Until we can generate significant cash from our operations, we expect to continue to fund our operations with existing cash resources that were primarily generated from the proceeds of offerings of our equity securities. In addition, we may receive revenue from our potential milestone payments from our co-promotion agreement with Otsuka America and our sublicense agreement with TAP. We may finance future cash needs through the sale of other equity securities, strategic collaboration agreements and debt financing. We likely will pursue raising additional funds during 2005, as we continue to build our business and in anticipation of the potential launch of our capsule and chewable tablet products in 2006.

We cannot be certain that our existing cash and marketable securities resources will be adequate, and failure to obtain adequate financing may adversely affect our ability to continue to operate as a going concern. We also cannot be certain that additional 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 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 achieve profitability or to respond to competitive pressures would be significantly limited, and we may be required to delay, scale back or eliminate some or all of our product and clinical development programs or delay the launch of our future products.

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, Zegerid Powder for Oral Suspension as well as any other products we may develop 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:

- success of the commercial launch of our first product and any other products that may be approved;
- our ability to maintain a productive sales force;
- demand and pricing of products we may offer;
- physician and patient acceptance of our products;

- levels of third-party reimbursement for our products;
- changes in our ability to obtain FDA approval for other products;
- interruption in the manufacturing or distribution of our products;
- results of our clinical trials;
- timing of new product offerings, acquisitions, licenses or other significant events by us or our competitors;
- regulatory approvals and legislative changes affecting the products we may offer or those of our competitors; and
- the effect of competing technological and market developments.

It will be difficult for us to forecast demand for our products with any degree of certainty, particularly during the early stages of our sales efforts for our first product. In addition, we will be increasing our operating expenses as we build our commercial capabilities and promote the product. Accordingly, we may experience significant, unanticipated quarterly losses. Because of these factors, our operating results in one or more future quarters may fail to meet the expectations of securities analysts or investors, which could cause our stock price to decline significantly.

Our 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 launched the commercial sale of 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 our first product. We only recently commercially launched our first product, and we have not yet demonstrated an ability to successfully commercialize a product. Consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully developing and commercializing products.

We are recording non-cash compensation expense that may result in an increase of our net losses for a given period.

Stock-based compensation represents an expense associated with the recognition of the difference between the deemed fair value of common stock at the time of an option grant or stock issuance and the option exercise price or price paid for the stock. Stock-based compensation is amortized over the vesting period of the option or issuance. As of December 31, 2004, deferred stock-based compensation related to option grants and stock issuances to our employees totaled $4.6 million, which will be amortized to expense on an accelerated basis as the options or stock are earned, generally over a period of four years. Also, we have granted options to consultants which, for compensation purposes, must be remeasured at each reporting date during the vesting period. This remeasurement and the corresponding effect on the related expense may result in an increase in our net losses for a given period.

Changes in, or interpretations of, accounting rules and regulations, such as expensing of stock options, 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.

For example, in accordance with new standards finalized in December 2004, the Financial Accounting Standards Board is requiring all companies to treat the fair value of stock options granted to employees as an expense effective for the first interim reporting period that begins after June 15, 2005. Currently, we are generally not required to record compensation expense in connection with stock option grants to employees, and we have relied heavily on stock options to motivate existing employees and attract new employees. When this change becomes effective, we and other companies will be required to record a compensation expense equal to the fair value of each stock option granted. The change will have a significant impact on our results of operations, although it will have no impact on our overall financial position. The specific impact of the new standards, however, cannot be

predicted at this time because it will depend on levels of stock options or other share-based payments granted in the future. When we are required to expense the fair value of stock option grants, it may reduce the attractiveness of granting stock options. If we reduce our use of stock options, it may be more difficult for us to attract and retain qualified employees.

Risks Related to Our Intellectual Property and Potential Litigation

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

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 the same uncertainty as 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 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 products until at least 2016, it is possible that generic drug makers will attempt to introduce generic immediate-release omeprazole products similar to ours prior to the expiration of our patents. Any patents related specifically to our Zegerid products will be method and/or formulation patents and will not protect the use of the active pharmaceutical ingredient outside of the formulations described in the patents and patent applications licensed to us. In addition, our competitors or other third parties, including generic drug companies, may challenge the scope, validity or enforceability of our patent claims. As a result, these patents may be narrowed in scope, invalidated or deemed unenforceable and may fail to provide us with any market exclusivity or competitive advantage even after our investment of significant amounts of money. We also may not be able to protect our intellectual property rights against third-party infringement, which may be difficult to detect. If we become involved in any dispute regarding our intellectual property rights, regardless of whether we prevail, we could be required to engage in costly, distracting and time-consuming litigation that could harm our business.

To date, five U.S. patents have been issued relating to technology we license from the University of Missouri and several U.S. and international or foreign counterpart patent applications are pending. 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 our products. 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.

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 will be 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 U.S. trademark registration and have applied for EU trademark registration for our brand name, Zegerid®, and have applied for trademark registration for various other names. 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 trademark registrations 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.

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 approved product and our products under development 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 products and other products based on that licensed technology that we may attempt to develop or commercialize in the future.

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 would also lose the right to receive potential milestone and royalty payments from TAP based on its development of products under our sublicense to TAP of the University of Missouri technology.

Our ability to market our products is subject to the intellectual property rights of third parties.

The products we currently intend to 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.

We submitted NDAs for Zegerid Powder for Oral Suspension 20 mg and 40 mg (later approved in June 2004 and December 2004) and we intend to submit NDAs for our capsule and chewable tablet products, under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act relying in part on clinical data relating to AstraZeneca's Prilosec, a delayed-release omeprazole product. In connection with these filings, we were and will be required to provide notice to AstraZeneca, as the NDA holder, and the owners of the listed patents, which include various AstraZeneca and Merck entities, of our certification that our products do not infringe the patents listed in the Orange Book for Prilosec or that those patents are invalid. Currently, there are six unexpired patents listed for Prilosec in the Orange Book. Two of the patents relate to enteric-coated formulations of omeprazole and expire in 2007. The remaining four patents relate generally to omeprazole and the process for making omeprazole and expire in 2018 and 2019, including certain marketing exclusivity.

In connection with any of our future Section 505(b)(2) NDA filings relating to omeprazole, AstraZeneca will have 45 days from the date of its receipt of notice of these certifications to file suit against us for infringement of those patents. If AstraZeneca brings suit against us within this time period based on those patents, approval of the related products would be delayed until the earliest of a court decision in our favor, a settlement of the claim involving licenses to the patents at issue or 30 months from the date of receipt of the notice of the certifications, or longer, if there is a court decision that is adverse to us. Thus, AstraZeneca will have an opportunity to file suit against us and trigger the 30-month stay with respect to any future Section 505(b)(2) NDA submissions we make, which litigation would be costly, time consuming and distracting to management. Furthermore, if there is a court decision in such an infringement matter that is adverse to us and upheld, we could become subject to an injunction for the life of the patents. In addition,

although AstraZeneca did not file suit against us within the 45-day notice period regarding our NDAs for our Zegerid Powder for Oral Suspension 20 mg and 40 mg products, it may choose to do so in the future. Although there would not be a 30-month stay in the FDA approval process for these products, any such litigation would nevertheless be costly, time-consuming and distracting to management.

Historically, AstraZeneca has aggressively asserted its patent rights related to its Prilosec product. For example, AstraZeneca has initiated patent infringement lawsuits against several drug companies that have announced plans to sell generic versions of Prilosec. The patent litigations to date have primarily focused on patents listed by AstraZeneca in the Orange Book that relate to enteric-coated formulations of omeprazole.

In addition to the patents listed in the Orange Book for Prilosec, AstraZeneca, as well as other competitors and companies, including aaiPharma, TAP 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. For example, we are aware that aaiPharma initiated a patent infringement lawsuit against a generic omeprazole maker in connection with the launch of its generic omeprazole product. 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 are unsuccessful in any challenge to our rights to 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 marketing the challenged products, or, if possible, to modify our products to avoid infringing upon those rights. If we or our third-party manufacturers 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 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.

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 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.

Our common stock had not been publicly traded prior to our initial public offering, which was completed in April 2004, and an active trading market may not develop or be sustained. We have not paid cash dividends since our inception and do not intend to pay cash dividends in the foreseeable future. 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 market prices for securities of specialty pharmaceutical companies in general have been highly volatile and may continue to be highly volatile in the future. Investors may not be able to sell their shares at or above the offering price. For example, during the year ended December 31, 2004, the closing trading prices for our common stock ranged from a high of $15.83 to a low of $8.38, and on March 15, 2005, the closing trading price for our common stock was $5.50.

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 activities, product development programs, results of our clinical trials or status

of our regulatory submissions;

- 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;
- disputes or other 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 our executive officers, directors or venture capital investors;
- 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 co-promotion partner, 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.

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

Persons who were our stockholders prior to the sale of shares in our initial public offering continue to hold a substantial number of shares of our common stock that they will be able to sell in the public market in the near future. Significant portions of these shares are held by a small number of stockholders. 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. Moreover, the holders of a substantial number of shares of common stock, including shares issuable upon exercise of outstanding warrants, 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.

We have also registered all common stock that we may issue under our employee benefits plans. As a result, these shares can be freely sold in the public market upon issuance, subject to restrictions under the securities laws. In addition, certain of our executive officers, other than our president and chief executive officer, have established programmed selling plans under Rule 10b5-1 of the Securities Exchange Act for the purpose of effecting sales of common stock, and other employees and affiliates, including our directors, president and chief executive officer and other 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.

Our stock price could decline in connection with future issuances of equity or debt securities.

Although we believe that our current cash, cash equivalents and short-term investments, including the $10.0 million milestone payment received from TAP in February 2005, will be sufficient to fund our operations for at least the next 12 months, we likely will pursue raising additional funds during 2005, as we continue to build our business and in anticipation of the potential launch of our

capsule and chewable tablet products in 2006. Accordingly, we may conduct substantial future offerings of equity or debt securities, which, in turn, could cause our stock price to decline. 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.

We may become involved in securities 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. We may become involved in this type of litigation 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.

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 Stock Market, will result in increased costs to us. In particular, we expect to incur additional administrative expense as we implement 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 as of the end of 2005. 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 are presently evaluating and monitoring developments with respect to new and proposed rules and cannot predict or estimate the amount of the additional costs we may incur or the timing of such costs. If we 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.

Our executive officers and directors and their affiliates may exercise influence over stockholder voting matters in a manner that may not be in the best interests of all of our stockholders.

Our executive officers and directors and their affiliates together control approximately 14.2% of our outstanding common stock, as of December 31, 2004. As a result, these stockholders may collectively be able to influence matters requiring approval of our stockholders, including the election of directors and approval of significant corporate transactions. The concentration of ownership may delay, prevent or deter a change in control of our company even when such a change may be in the best interests of all stockholders, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock.

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. 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 2. Properties

Our corporate headquarters facility consists of approximately 24,000 square feet in San Diego, California. We lease our corporate headquarters facility pursuant to a lease agreement that expires in March 2008. To the extent that we are able to successfully commercialize our products and continue to grow our business, we believe that we will need to lease additional office space.

Item 3. Legal Proceedings

We are not currently a party to any material legal proceedings.

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 National 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 National Market for the periods indicated.

	High	Low
Year Ended December 31, 2004		
Second Quarter	$15.88	$8.67
Third Quarter	$14.99	$8.69
Fourth Quarter	$10.80	$8.36

As of March 15, 2005, there were approximately 118 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. Any future determination related to our dividend policy will be made at the discretion of our board of directors.

Recent Sales of Unregistered Securities

During the year ended December 31, 2004, we issued and sold the following unregistered securities:

- Between January 1, 2004 and March 31, 2004, we granted options to purchase 410,700 shares of common stock to employees and directors under our stock incentive plan at exercise prices ranging from $5.25 to $10.99 per share. During such time, 219,850 shares of common stock were purchased pursuant to exercises of stock options, and no shares were repurchased and returned to the stock incentive plan option pool. The offers, sales, and issuances of the options and common stock were deemed to be exempt from registration under the Securities Act in reliance on Rule 701 in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under such rule. The recipients of such options and common stock were our employees and directors and received the securities under our stock incentive plan. Appropriate legends were affixed to the share certificates issued in such transactions. Each of these recipients had adequate access, through employment or other relationships, to information about us.

Use of Proceeds

Our initial public offering of common stock was effected through a Registration Statement on Form S-1 (File No. 333-111515) that was declared effective by the Securities and Exchange Commission on March 31, 2004. On April 6, 2004, 6,000,000 shares of common stock were sold on our behalf at an initial public offering price of $9.00 per share, for an aggregate offering price of $54.0 million, managed by SG Cowen & Co., LLC, UBS Securities LLC, Thomas Weisel Partners LLC and RBC Capital Markets Corporation. On April 16, 2004, in connection with the full exercise of the underwriters' over-allotment option, 900,000 additional shares of common stock were sold on our behalf at the initial public offering price of $9.00 per share, for an aggregate offering price of $8.1 million. Following the sale of the 6,900,000 shares, the offering terminated.

We paid to the underwriters underwriting discounts and commissions totaling approximately $4.3 million in connection with the offering. In addition, we incurred additional expenses of approximately $1.9 million in connection with the offering, which when added to the underwriting discounts and commissions paid by us, amounts to total expenses of approximately $6.2 million. Thus, the net offering proceeds to us, after deducting underwriting discounts and commissions and offering expenses, were approximately $55.9 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

As of December 31, 2004, we had used all of the net proceeds from our initial public offering to continue the development and commercial launch of Zegerid Powder for Oral Suspension 20 mg and 40 mg and the development of our other products, as well as to fund other working capital and general corporate purposes.

Item 6. Selected Financial Data

The selected statement of operations data for the years ended December 31, 2001 and 2000, and the selected balance sheet data as of December 31, 2002, 2001 and 2000, are derived from audited financial statements, which have been audited by our independent registered public accounting firm for such years and as of such dates, which are not included in this Form 10-K. The selected statement of operations data for the years ended December 31, 2004, 2003 and 2002 and the selected balance sheet data as of December 31, 2004 and 2003, 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.

	Year Ended December 31,				
	2004	2003	2002	2001	2000
	(in thousands, except per share data)				
Statement of Operations Data:					
Revenues:					
Product sales, net	$ 634	$ -	$ -	$ -	$ -
Sublicense and co-promotion revenue	714	-	8,000	-	-
Total revenues	1,348	-	8,000	-	-
Costs and expenses:					
Cost of sales	1,968	-	-	-	-
License fees and royalties	5,089	1,000	1,400	1,294	107
Research and development	23,199	13,176	15,398	5,672	2,027
Selling, general and administrative	48,306	6,548	6,034	3,241	1,391
Stock-based compensation	5,672	2,252	277	87	9
Total costs and expenses	84,234	22,976	23,109	10,294	3,534
Loss from operations	(82,886)	(22,976)	(15,109)	(10,294)	(3,534)
Interest and other income (expense), net	1,391	465	414	726	(3)
Net loss	(81,495)	(22,511)	(14,695)	(9,568)	(3,537)
Accretion to redemption value of redeemable convertible preferred stock	(1,124)	(2,940)	-	-	-
Beneficial conversion of short-term notes payable to related parties	-	-	-	(135)	(95)
Net loss attributable to common stockholders	$ (82,619)	$ (25,451)	$ (14,695)	$ (9,703)	$ (3,632)
Basic and diluted net loss per share	$ (3.30)	$ (13.71)	$ (9.13)	$ (7.08)	$ (3.62)
Weighted average shares outstanding to calculate basic and diluted net loss per share	25,017	1,857	1,610	1,371	1,002

	As of December 31,				
	2004	2003	2002	2001	2000
	(in thousands)				
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 114,008	$ 45,648	$ 11,804	$ 22,281	$ 228
Working capital (deficit)	94,346	42,376	7,697	21,526	(1,053)
Total assets	122,216	48,188	14,207	24,332	849
Short-term notes payable to related parties	-	-	-	-	788
Deferred revenue, less current portion	11,429	-	-	-	-
Long-term debt, less current portion	38	224	479	-	50
Redeemable convertible preferred stock	-	57,625	-	-	-
Total stockholders' equity (deficit)	85,843	(13,751)	9,074	23,288	(676)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	(in thousands, except per share data)			
Selected Quarterly Financial Data:				
2004:				
Product sales, net	$ —	$ —	$ —	$ 634
Total revenues	—	—	—	1,348
Cost of sales	—	—	—	1,968
Total costs and expenses	10,301	17,109	21,640	35,184
Net loss	(10,187)	(16,856)	(21,192)	(33,260)
Net loss attributable to common stockholders	(11,311)	(16,856)	(21,192)	(33,260)
Basic and diluted net loss per share	(4.94)	(0.61)	(0.62)	(0.92)
2003:				
Product sales, net	$ —	$ —	$ —	$ —
Total revenues	—	—	—	—
Cost of sales	—	—	—	—
Total costs and expenses	4,421	4,555	6,011	7,989
Net loss	(4,390)	(4,399)	(5,868)	(7,854)
Net loss attributable to common stockholders	(4,390)	(5,090)	(6,993)	(8,978)
Basic and diluted net loss per share	(0.60)	(2.81)	(3.78)	(4.47)

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 to enhance the quality of life for patients with gastrointestinal diseases and disorders. The primary focus of our current efforts is the development and commercialization of next generation proton pump inhibitor, or PPI, products — the most frequently prescribed drugs for the treatment of many upper gastrointestinal, or GI, diseases and disorders.

Our Zegerid products are proprietary immediate-release formulations of the PPI omeprazole in powder for oral suspension, capsule and chewable tablet formulations and are intended to treat or reduce the risk of a variety of upper GI diseases and disorders. We received approval from the U.S. Food and Drug Administration, or FDA, to market Zegerid Powder for Oral Suspension 20 mg in June 2004 for the treatment of heartburn and other symptoms associated with gastroesophageal reflux disease, or GERD, treatment and maintenance of healing of erosive esophagitis and treatment of duodenal ulcers. We received FDA approval to market the 40 mg dose in December 2004 for the treatment of gastric ulcers and the reduction of risk of upper GI bleeding in critically ill patients. We are also developing immediate-release capsule and chewable tablet formulations, and we intend to submit new drug applications for these products to the FDA during the second half of 2005.

Zegerid Powder for Oral Suspension is currently being marketed through a field sales force of approximately 400 representatives, which includes approximately 230 Santarus sales representatives in addition to approximately 170 sales representatives from our co-promotion partner, Otsuka America Pharmaceutical, Inc., or Otsuka America. The combined commercial sales organizations are targeting the highest PPI-prescribing physicians in the U.S., with a focus on approximately 10,000 gastroenterologists and 26,000 primary care physicians, who we estimate were responsible for writing approximately $5.6 billion of PPI prescriptions in 2004.

We were formed in December 1996 and commenced significant business activities in late 1998. From 1998 to 2000, we entered into various license agreements with universities and non-profit institutions for patented technology rights for the development of products utilizing azathioprine or cytoprotective compounds in the treatment of lower and upper GI diseases. We evaluated these compounds in preclinical and clinical trials, as appropriate, and in 2001 shifted our focus to the immediate-release PPI technology that represents our current efforts. We have terminated our development programs regarding the azathioprine compound and, in 2002, we terminated the cytoprotective compound license agreements that we had entered into in prior years.

In January 2001, we entered into an exclusive, worldwide license agreement with the University of Missouri, under which we licensed rights to all of 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 new drug application, or 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 the achievement of certain regulatory events related to obtaining approvals 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, and to pay royalties on net sales of our products.

In June 2002, under a strategic sublicense agreement, we granted TAP Pharmaceutical Products Inc., or TAP, the North American rights to develop, manufacture and sell products resulting from the use of our immediate-release PPI technology with lansoprazole and derivatives of lansoprazole. Under the agreement, TAP is required to pay a combination of fees for the licensed rights, including an upfront payment and milestone payments that may exceed $100 million. To date, we have received an upfront fee of $8.0 million in July 2002 and a $10.0 million milestone payment in February 2005 related to TAP's development activities. We received the February 2005 milestone after we prevailed in an alternative dispute resolution proceeding in which we alleged that TAP had achieved a development milestone. We paid 15% of the upfront fee and the February 2005 milestone to the University of Missouri and are also obligated to pay 15% of any further milestone payments, as well as a portion of any royalty payments, we receive from TAP to the University of Missouri. TAP is responsible for all of its product development and commercialization expenses.

In October 2004, we entered into a non-exclusive agreement with Otsuka America, for Otsuka America to co-promote Zegerid Powder for Oral Suspension to U.S. physicians. Under the terms of the agreement, we received a $15.0 million upfront payment from Otsuka America, and have agreed to pay Otsuka America a royalty on total U.S. net sales of Zegerid Powder for Oral Suspension. We also granted Otsuka America options to extend the co-promotion arrangement to Zegerid Capsules and Zegerid Chewable Tablets, subject to receipt of marketing approval of these products, with additional milestone payments should those options be exercised.

We have incurred significant losses since our inception. We had an accumulated deficit of approximately $138.3 million as of December 31, 2004. 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 current products, initial commercialization activities and general and administrative expenses.

We expect to continue to incur additional operating losses and capital expenditures and anticipate that our expenses will increase substantially in the foreseeable future as we continue to support the commercial launch of Zegerid Powder for Oral Suspension and our commercial organization, enhance our product portfolio through internal development, product and patent licensing and strategic acquisitions and grow our administrative support activities.

On April 6, 2004, we completed an initial public offering of 6,000,000 shares of common stock at a price to the public of $9.00 per share, raising net proceeds of approximately $48.3 million, net of underwriting discounts and offering expenses. On April 16, 2004, in connection with the exercise of the underwriters' over-allotment option, we completed the sale of 900,000 additional shares of common stock at the initial public offering price of $9.00 per share, raising net proceeds of approximately $7.5 million, net of underwriting discounts and estimated offering expenses.

On July 28, 2004, we completed a follow-on public offering of 6,900,000 shares of common stock at a price to the public of $9.50 per share, raising net proceeds of approximately $61.0 million, net of underwriting discounts and offering expenses. The completed offering included the full exercise of the underwriters' over-allotment option.

Revenues

Product sales consist of sales of Zegerid Powder for Oral Suspension 20 mg, which we commercially launched in the U.S. in October 2004.

Sublicense and co-promotion revenue consist of upfront fees associated with our strategic sublicense agreement with TAP entered into in June 2002 and our co-promotion agreement with Otsuka America entered into in October 2004.

Costs and Expenses

Cost of Sales. 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 Zegerid Powder for Oral Suspension 20 mg and reserves for excess, dated or obsolete commercial inventories.

License Fees and Royalties. License fees and royalties consist of upfront and milestone payments, common stock issuances, annual license maintenance fees and royalty obligations under our technology license and co-promotion agreements, and payments made to a licensor in connection with our receipt of sublicense fees. We have expensed amounts paid to obtain patents or acquire licenses, as the ultimate recoverability of the amounts paid is uncertain and the technology has no alternative future use when acquired. Future acquisitions of patents and technology licenses will be charged to expense or capitalized based upon our assessment regarding the ultimate recoverability of the amounts paid and the potential for alternative future use. Amounts capitalized would be amortized over the useful life of the technology using the straight-line method and reviewed annually or sooner, when indicators occur, for impairment.

Research and Development. Research and development expenses consist primarily of costs associated with clinical trials of our products under development, including the costs of developing and manufacturing our products under development, compensation and other expenses related to research and development personnel and facilities expenses.

Our research and development activities are primarily focused on the development of our Zegerid family of products, which are immediate-release omeprazole products in powder for oral suspension, capsule and chewable tablet formulations. We completed a pivotal pharmacokinetic/pharmacodynamic, or PK/PD, clinical trial for Zegerid Powder for Oral Suspension 20 mg in 2002, submitted our first NDA to the FDA in 2003 and received FDA approval in June 2004. We also completed a pivotal PK/PD clinical trial in 2002, as well as a pivotal Phase III clinical trial in 2003, for Zegerid Powder for Oral Suspension 40 mg, submitted our second NDA to the FDA in February 2004 and received FDA approval in December 2004. We conducted an open-label clinical trial to evaluate the safety of Zegerid Powder for Oral Suspension 40 mg as additional support for the FDA approval. During 2004, we also conducted a Phase IIIb clinical trial evaluating Zegerid Powder for Oral Suspension as compared to Protonix (delayed-release pantoprazole capsules) for control of nocturnal gastric acidity. In November 2004, we completed two pivotal PK/PD clinical trials evaluating Zegerid Capsules 20 mg and 40 mg and plan to submit our NDA to the FDA in the third quarter of 2005. In February 2005, we completed two pivotal PK/PD clinical trials evaluating Zegerid Chewable Tablets 20 mg and 40 mg and plan to submit our NDA to the FDA in the second half of 2005. From the time that we entered into our license agreement with the University of Missouri in January 2001 through December 31, 2004, our costs associated with the research and development of the Zegerid products have represented over 95% of our research and development expenses for all program areas. In addition, during the year ended December 31, 2004, costs associated with the research and development of the Zegerid products represented over 98% of our research and development expenses for all program areas, reflecting an even greater focus on these products.

In addition to continued development of Zegerid Capsules and Zegerid Chewable Tablets, we have committed to initiate PK/PD and safety studies evaluating Zegerid Powder for Oral Suspension in pediatric populations during the second half of 2005. We are unable to estimate with any certainty the costs we will incur in the continued development of our Zegerid family of products. 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 and clinical success of each product.

Product development timelines and costs may vary significantly for each of our Zegerid products and are difficult to estimate. The lengthy process of seeking regulatory approvals, and the subsequent compliance with applicable regulations, requires the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could cause our research and development expenditures to increase and, in turn, have a material adverse effect on our results of operations. Although we received FDA approval for Zegerid Powder for Oral Suspension 20 mg in June 2004 and Zegerid Powder for Oral Suspension 40 mg in December 2004, we cannot be certain when or if any net cash inflow from these products or any of our other development projects will commence.

Selling, General and Administrative. Selling, general and administrative expenses consist primarily of compensation and other expenses related to our commercial operations and corporate administrative employees, legal fees and other professional services expenses. As we only recently commercially launched our Zegerid Powder for Oral Suspension 20 mg in October 2004 and our Zegerid Powder for Oral Suspension 40 mg in February 2005, we expect our selling, general and administrative expenses to increase.

Stock-Based Compensation. Stock-based compensation represents the amortization of deferred compensation resulting from the difference between the exercise price and the deemed fair value, as estimated by us for financial reporting purposes, of our common stock on the date stock options were granted to employees and the fair value of stock awards to non-employees.

Interest and Other Income (Expense), Net

Interest and other income (expense), net consists primarily of interest income earned on our cash, cash equivalents, and short-term investments and interest expense associated with our short-term notes payable to related parties and long-term debt. The short-term notes were paid in full in February 2001.

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 annual report, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

Product sales, net. We recognize revenue from product sales in accordance with Statement of Financial Accounting Standard ("SFAS") No. 48, *Revenue Recognition When Right of Return Exists,* when there is persuasive evidence that an arrangement exists, when title has passed, the price is fixed or determinable, and we are reasonably assured of collecting the resulting receivable. We recognize product sales net of estimated allowances for product returns, managed care rebates, reimbursements relating to Medicaid, chargebacks from distributors and prompt payment and other discounts. Such estimates 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 discounts exceed the estimates we made at the time of sale, our financial position, results of operations and cash flows would be negatively impacted.

We are obligated to accept from customers the return of products that are within six months of their expiration date or 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 recently commercially launched our first product, Zegerid Powder for Oral Suspension 20 mg, in the fourth quarter of 2004, and to date, we have had no product returns. Given our limited history, we have established our allowances for potential product returns based on an analysis of product shipments to our wholesale distributors in excess of prescription demand for Zegerid Powder for Oral Suspension 20 mg in 2004. Although we believe that our estimates and assumptions are reasonable as of the date when made, actual results may differ significantly from these estimates. Our financial position, results of operations and cash flows may be materially and negatively impacted if actual returns exceed our estimated allowance for returns.

Sublicense and co-promotion revenue. We recognize sublicense and co-promotion revenue consistent with the provisions of the Securities and Exchange Commission Staff Accounting Bulletin ("SAB") No. 104, *Revenue Recognition,* which sets forth guidelines in the timing of revenue recognition based upon factors such as passage of title, installation, payments and customer acceptance. We analyze each element of our sublicense and co-promotion agreements, to determine the appropriate revenue recognition. We recognize revenue on upfront payments over the term of 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 evaluate the criteria outlined in Emerging Issues Task Force ("EITF") Issue 99-19, *Reporting Revenue Gross as a Principal Versus Net as an Agent,* in determining whether it is appropriate to record the gross amount of sublicense revenues and related costs or the net amount earned under the arrangement. We have recognized the gross amount of sublicense revenue and related costs as we have no future obligations pursuant to the arrangement, we are 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.

Clinical Trial Expenses

Research and development expenditures are charged to operations as incurred. Our expenses related to clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and clinical research organizations that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Generally, these agreements set forth the scope of work to be performed at a fixed fee or unit price. Payments under the contracts depend on factors such as the successful enrollment of patients or the completion of clinical trial milestones. Expenses related to clinical trials generally are 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 upon changes in the clinical trial protocol or scope of work to be performed, we modify our estimates accordingly on a prospective basis.

Stock-Based Compensation

In December 2002, SFAS No. 148, *Accounting for Stock-Based Compensation — Transition and Disclosure — an Amendment of FASB Statement No. 123*, was issued. SFAS No. 148 provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation from the intrinsic value-based method of accounting prescribed by APB Opinion No. 25, *Accounting for Stock Issued to Employees*, or APB 25. In addition, SFAS No. 148 amends the disclosure requirements of SFAS No. 123, *Accounting for Stock-Based Compensation*. We adopted the disclosure requirements of SFAS No. 148 effective December 31, 2002. As allowed by SFAS No. 123, we have elected to continue to apply the intrinsic value-based method of accounting prescribed in APB 25 and, accordingly, do not recognize compensation expense for stock option grants made at an exercise price equal to or in excess of the estimated fair value of the stock at the date of grant. Deferred compensation is recognized and amortized on an accelerated basis in accordance with Financial Accounting Standards Board Interpretation No. 28, *Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans*, over the vesting period of the related options.

We account for options issued to non-employees under SFAS No. 123 and EITF Issue 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 such options is periodically remeasured and income or expense is recognized during their vesting terms.

Income Taxes

We record a valuation allowance to reduce our deferred tax assets to the amount that is more likely than not to be realized. We have considered future taxable income and ongoing tax planning strategies in assessing the need for the valuation allowance. In the event we were to determine that we would be able to realize our deferred tax assets in the future in excess of their net recorded amounts, an adjustment to the deferred tax assets would increase our income in the period such determination was made. Likewise, should we determine that we would not be able to realize all or part of our net deferred tax assets in the future, an adjustment to the deferred tax assets would be charged to income in the period such determination was made. We had $54.1 million as of December 31, 2004 and $21.7 million as of December 31, 2003 in gross deferred tax assets, which were fully offset by a valuation allowance.

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 annual report, which contain accounting policies and other disclosures required by GAAP.

Results of Operations

Comparison of Years Ended December 31, 2004, 2003 and 2002

Product Sales, Net. Product sales, net were $634,000 for 2004 and consisted of sales of Zegerid Powder for Oral Suspension 20 mg, which we commercially launched in the U.S. in October 2004. In accordance with our revenue recognition policy, we recognize sales net of allowances for product returns, managed care rebates, reimbursements relating to Medicaid, chargebacks from distributors and prompt payment and other discounts. These sales allowances are generally reflected either as a direct reduction to accounts

receivable through an allowance, or as an addition to accrued expenses if the payment is due to a party other than the wholesale or retail customer. Given our limited history, we have established sales allowances for potential product returns based on an analysis of product shipments to our wholesale distributors in excess of prescription demand for Zegerid Powder for Oral Suspension 20 mg in 2004.

Sublicense and Co-Promotion Revenue. Sublicense and co-promotion revenue was $714,000 for 2004 and $8.0 million for 2002. There were no sublicense and co-promotion revenues in 2003. In 2004, sublicense and co-promotion revenue consisted of the 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. In 2002, sublicense and co-promotion revenue consisted of the upfront fee received pursuant to our strategic sublicense agreement with TAP.

Cost of Sales. Cost of sales was $2.0 million for 2004, or approximately 310% of net product sales. Cost of sales includes estimated reserves for excess, dated or obsolete inventories based on an analysis of inventory on hand and on firm purchase commitments and inventory in the distribution channel, compared to forecasts of future sales. Based upon review of initial prescription trends for Zegerid Powder for Oral Suspension 20 mg subsequent to the commercial launch in October 2004, and in light of our receipt of FDA approval to market Zegerid Powder for Oral Suspension 40 mg in December 2004, commercial inventory reserves of approximately $1.6 million were recorded in cost of sales in 2004.

License Fees and Royalties. License fees and royalties were $5.1 million for 2004, $1.0 million for 2003 and $1.4 million for 2002. In 2004, license fees and royalties consisted of the one-time $5.0 million milestone fee paid to the University of Missouri based upon the FDA's approval of Zegerid Powder for Oral Suspension 20 mg and royalties due to the University of Missouri and Otsuka America based upon net product sales. License fees and royalties in 2003 consisted of our $1.0 million milestone fee paid to the University of Missouri upon the filing of our first NDA. License fees and royalties in 2002 primarily consisted of $1.2 million paid to the University of Missouri, which represented 15% of the upfront fee received pursuant to our strategic sublicense agreement with TAP, and license maintenance fees associated with our license agreement related to the azathioprine technology. We are not currently conducting any development activities related to the azathioprine technology.

Research and Development. Research and development expenses were $23.2 million for 2004, $13.2 million for 2003 and $15.4 million for 2002. The $10.0 million increase in our research and development expenses from 2003 to 2004 was primarily attributable to increased costs associated with preparation for commercial manufacturing of Zegerid Powder for Oral Suspension, the formulation development and production of clinical trial materials for our other products under development, Zegerid Capsules and Zegerid Chewable Tablets, and the hiring of additional personnel. The increase was also attributable to the initiation and completion of pivotal PK/PD clinical trials evaluating Zegerid Capsules 20 mg and 40 mg, initiation of pivotal PK/PD clinical trials evaluating Zegerid Chewable Tablets 20 mg and 40 mg, spending associated with our Phase IIIb clinical trial evaluating Zegerid Powder for Oral Suspension as compared to Protonix (delayed-release pantoprazole capsules) for control of nocturnal gastric acidity and payment of the user fee associated with the submission of our second NDA for Zegerid Powder for Oral Suspension 40 mg in February 2004. These increases in our research and development expenses were offset in part by decreased clinical trial costs associated with our pivotal Phase III clinical trial evaluating Zegerid Powder for Oral Suspension 40 mg for the reduction of risk of upper GI bleeding in critically ill patients that was completed in June 2003 and completion of our clinical trial to evaluate the safety of Zegerid Powder for Oral Suspension 40 mg which was initiated in October 2003.

The $2.2 million decrease in our research and development expenses from 2002 to 2003 was primarily attributable to decreased clinical costs associated with the timing of initiation and completion of various clinical trials for our Zegerid products under development. In addition to the costs associated with our pivotal Phase III clinical trial, costs associated with our pivotal PK/PD clinical trials evaluating Zegerid Powder for Oral Suspension 20 mg and 40 mg were included in 2002. In 2003, we did not conduct pivotal PK/PD clinical trials, and we completed our pivotal Phase III clinical trial in June 2003. These decreases in clinical costs were offset in part by spending associated with our clinical trial to evaluate the safety of Zegerid Powder for Oral Suspension 40 mg which was initiated in October 2003, and increased manufacturing and formulation development costs associated with Zegerid Capsules and Zegerid Chewable Tablets.

Expenses related to clinical trials pursuant to contracts with research institutions and clinical research organizations represented 23% of our research and development expenses in 2004, 31% of our total research and development expenses in 2003 and 46% of our total research and development expenses in 2002. Accrued clinical trial expenses are based on estimates of the work completed under the contracts, milestones achieved and level of patient enrollment. Actual services performed, number of patients enrolled and the rate of patient enrollment may vary from our estimates, resulting in adjustments to clinical trial expenses in future periods. In the past, we

have not experienced any material deviations between accrued clinical trial expenses and actual clinical trial expenses, and management does not anticipate material deviations in the future.

Selling, General and Administrative. Selling, general and administrative expenses were $48.3 million for 2004, $6.5 million for 2003 and $6.0 million for 2002. The $41.8 million increase in our selling, general and administrative expenses from 2003 to 2004 was primarily attributable to the hiring of additional sales and marketing personnel, including our field sales organization, which grew to more than 200 sales representatives in the third quarter of 2004 and to approximately 230 sales representatives at December 31, 2004. Additionally, outside services and professional fees associated with the commercial launch of our first product, Zegerid Powder for Oral Suspension 20 mg, increased in 2004, including advertising and promotion, holding our first national sales meeting, medical education and the cost of product samples. The $514,000 increase in our selling, general and administrative expenses from 2002 to 2003 was primarily attributable to the hiring of additional personnel throughout 2002, resulting in partial year expenditures in 2002 and full year expenditures in 2003 for such personnel. This increase was offset in part by decreased consulting fees as certain of our administrative support activities were assumed by in-house personnel.

Stock-Based Compensation. We recorded non-cash compensation charges of $5.7 million in 2004, $2.3 million in 2003 and $277,000 in 2002. In connection with the grant of stock options to employees, we recorded deferred compensation of $1.4 million in 2004 and $10.5 million in 2003. We recorded this amount as a component of stockholders' equity and will amortize the amount as a charge to operations over the vesting period of the options. The compensation charges in 2004 related to research and development personnel in the amount of $1.6 million and selling, general and administrative personnel in the amount of $4.1 million. The compensation charges in 2003 related to research and development personnel in the amount of $488,000 and selling, general and administrative personnel in the amount of $1.8 million. The compensation charges in 2002 represent the fair value of stock awards to non-employees and related to selling, general and administrative personnel.

Interest and Other Income (Expense), Net. Interest and other income, net was $1.4 million in 2004, $465,000 in 2003 and $414,000 in 2002. The $926,000 increase from 2003 to 2004 was primarily attributable to an increase in interest income resulting from higher cash balances from our initial public offering of common stock in April 2004 and follow-on public offering of common stock in July 2004. The $51,000 increase in interest and other income, net from 2002 to 2003 was primarily attributable to an increase in our interest income resulting from higher cash balances from our financing activities in 2003.

Income Taxes. We have incurred net operating losses since inception and, consequently, have not recorded any federal or state income tax benefit. Our deferred tax assets primarily consist of net operating loss carryforwards and research and development tax credits. We have recorded a valuation allowance for the full amount of our deferred tax asset, as the realization of the deferred tax asset is uncertain. As of December 31, 2004, we had federal and state tax net operating loss carryforwards of approximately $109.7 million and $76.3 million, respectively. These federal and state tax loss carryforwards are available to reduce future taxable income. If not utilized, the net operating loss carryforwards will begin expiring in 2012 for federal purposes and 2007 for state purposes. Annual limitations may result in the expiration of net operating loss and credit carryforwards before they are used. Under the provisions of the Internal Revenue Code, substantial changes in our ownership may limit the amount of net operating loss carryforwards that could be utilized annually in the future to offset taxable income.

Liquidity and Capital Resources

As of December 31, 2004, cash, cash equivalents and short-term investments were $114.0 million, compared to $45.6 million as of December 31, 2003, an increase of $68.4 million. This increase resulted primarily from the proceeds from the issuance of common stock in our initial public offering in April 2004 and our follow-on public offering in July 2004, and the $15.0 million upfront payment we received from Otsuka America in October 2004 under our co-promotion agreement for Zegerid Powder for Oral Suspension, offset in part by our net loss for 2004.

Net cash used in operating activities was $47.4 million for 2004, $20.9 million for 2003 and $10.9 million for 2002. The primary use of cash was to fund our net losses for these periods, adjusted for non-cash expenses, including $446,000 for 2004, $312,000 for 2003 and $251,000 for 2002 in depreciation and amortization, $5.7 million for 2004, $2.3 million for 2003 and $277,000 for 2002 in stock-based compensation, and changes in operating assets and liabilities. Accounts payable and accrued liabilities increased in 2004 primarily due to increased spending levels associated with the commercial launch of Zegerid Powder for Oral Suspension 20 mg, increased accrued compensation and benefits associated with our increase in personnel and allowances for product returns. Additionally, we have approximately $14.3 million in deferred revenue as of December 31, 2004 related to the $15.0 million upfront payment we received from Otsuka America in October 2004, which is being amortized over the term of the agreement.

Net cash provided by (used in) investing activities was $(49.0) million for 2004, $(25.4) million for 2003 and $1.9 million for 2002. These activities primarily consisted of purchases, offset by sales and maturities of short-term investments and purchases of property and equipment. Additionally, in 2004, we made deposits of approximately $1.0 million on certain manufacturing equipment.

Net cash provided by financing activities was $117.7 million for 2004, $54.8 million for 2003 and $860,000 for 2002. These activities consisted primarily of the issuance of common stock in our initial public offering and our follow-on public offering in 2004, private sales of preferred stock in 2003, proceeds from equipment notes payable in 2002 and the exercise of stock options, which were offset in part by ongoing repayment of our notes payable. The principal balance of our equipment notes payable was $224,000 with an annual interest rate of 9.23% at December 31, 2004.

We expect our cash requirements to increase significantly in the foreseeable future to support the commercialization of Zegerid Powder for Oral Suspension 20 mg and 40 mg, while we continue to sponsor clinical trials for, seek regulatory approvals of, and develop and manufacture our current products and new product opportunities. As we support our commercial organization, expand our research and development efforts and pursue additional product opportunities, we anticipate significant cash requirements for personnel costs, advertising and promotional activities, capital expenditures and investment in additional office space, internal systems and infrastructure.

In preparation for the launch of our first product, we entered into a commercial supply agreement with Patheon in December 2003 which, among other things, obligates us to fund up to approximately $1.9 million in manufacturing equipment for Patheon. Patheon is obligated to reimburse us for this amount in the event that we purchase a specified aggregate number of units. Through December 31, 2004, we have funded approximately $1.0 million of the manufacturing equipment, and we believe we will expend an additional $210,000 in the first half of 2005. We purchase commercial quantities of Zegerid Powder for Oral Suspension 20 mg and 40 mg from Patheon as well as commercial quantities of the active ingredient from our omeprazole supplier. At December 31, 2004, we had finished goods and raw materials inventory purchase commitments of approximately $3.5 million, of which we have expensed approximately $627,000 in 2004 related to excess inventories of Zegerid Powder for Oral Suspension 20 mg.

The following summarizes our long-term contractual obligations as of December 31, 2004:

		Payments Due by Period			
Contractual Obligations	Total	Less than One Year	One to Three Years	Four to Five Years	Thereafter
			(in thousands)		
Operating leases	$ 3,155	$ 1,007	$ 2,139	$ 9	$ —
Equipment financing	224	186	38	—	—
Sponsored research agreements	263	150	113	—	—
Other long-term contractual obligations	1,454	888	566	—	—
Total	$ 5,096	$ 2,231	$ 2,856	$ 9	$ —

In November 2004, we entered into a master lease agreement giving us the ability to lease vehicles under operating leases. As of December 31, 2004, we had not entered into any vehicle lease obligations under the master agreement. In connection with accepting delivery of vehicles and entering into lease obligations in January 2005, we established a letter of credit for $1,000,000 naming the lessor as beneficiary. The letter of credit is fully secured by restricted cash and has automatic annual extensions.

The amount and timing of cash requirements will depend on market acceptance of Zegerid Powder for Oral Suspension and any other products that may receive regulatory approval, 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, including the $10.0 million milestone payment received in February 2005 from TAP under our sublicense agreement, will be sufficient to fund our operations for at least the next 12 months. Until we can generate significant cash from our operations, we expect to continue to fund our operations with existing cash resources that were primarily generated from the proceeds of offerings of our equity securities. In addition, we may receive revenue from our potential milestone payments from our co-promotion agreement with Otsuka America and our sublicense agreement with TAP. We may finance future cash needs through the sale of other equity securities, strategic collaboration agreements and debt financing. We likely will pursue raising additional funds during 2005, as we continue to build our business and in anticipation of the potential launch of our capsule and chewable tablet products in 2006.

We cannot be certain that our existing cash and marketable securities resources will be adequate, and failure to obtain adequate financing may adversely affect our ability to continue to operate as a going concern. We also cannot be certain that additional 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 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 achieve profitability or to respond to competitive pressures would be significantly limited, and we may be required to delay, scale back or eliminate some or all of our product and clinical development programs or delay the launch of our future products.

As of December 31, 2004 and 2003, 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

On December 16, 2004, the Financial Accounting Standards Board ("FASB") issued 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)"). SFAS No. 123(R) supersedes APB 25, *Accounting for Stock Issued to Employees*, and amends SFAS No. 95, *Statement of Cash Flows*. Generally, the approach in SFAS No. 123(R) is similar to the approach described in SFAS No. 123. However, SFAS No. 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative. SFAS No. 123(R) must be adopted no later than July 1, 2005. Early adoption will be permitted in periods in which financial statements have not been issued. We expect to adopt SFAS 123(R) on July 1, 2005.

As permitted by SFAS No. 123, we currently account for share-based payments to employees using APB 25's intrinsic value method and, as such, generally recognize no compensation cost for employee stock options when the exercise price is equal to or in excess of the fair value of the stock at the date of grant. Accordingly, the adoption of SFAS No. 123(R)'s fair value method will have a significant impact on our results of operations, although it will have no impact on our overall financial position. The impact of adoption of SFAS No. 123(R) cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had we adopted SFAS No. 123(R) in prior periods, the impact of that standard would have approximated the impact of SFAS No. 123 as described in the disclosure of pro forma net loss and net loss per share in Note 1 to our financial statements. SFAS No. 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption.

In November 2004, the FASB issued SFAS No. 151, *Inventory Costs, an amendment of ARB No. 43, Chapter 4*. This statement amends the guidance in ARB No. 43 Chapter 4, "Inventory Pricing," to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs and wasted material (spoilage). The provision of this statement will be effective for inventory costs during the fiscal years beginning after June 15, 2005. As a result of our manufacturing process being outsourced, we do not believe that the adoption of this statement will have a material impact on our financial condition or results of operations.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because the majority of our investments are in short-term marketable securities. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk. Some of the securities that we invest in may be subject to market risk. This means that a change in prevailing interest rates may cause the value of the investment to fluctuate. For example, if we purchase a security that was issued with a fixed interest rate and the prevailing interest rate later rises, the value of our investment will probably decline. To minimize this risk, we intend to continue to maintain our portfolio of cash equivalents and short-term investments in a variety of securities including commercial paper, money market funds and government and non-government debt securities. In general, money market funds are not subject to market risk because the interest paid on such funds fluctuates with the prevailing interest rate. As of December 31, 2004, we did not have any holdings of derivative financial or commodity instruments, or any foreign currency denominated transactions, and all of our cash and cash equivalents were in money market funds and other highly liquid investments.

Item 8. Financial Statements and Supplementary Data

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

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

Not applicable.

Item 9A. Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our 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.

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

Item 9B. Other Information

Not applicable.

PART III

Item 10. Directors and Executive Officers of the Registrant

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, 2004, and is incorporated in this report by reference.

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

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

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 Accounting 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, 2004 and 2003

Statements of Operations for the years ended December 31, 2004, 2003 and 2002

Statements of Stockholders' Equity (Deficit) for the years ended December 31, 2004, 2003 and 2002

Statements of Cash Flows for the years ended December 31, 2004, 2003 and 2002

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.

(a) *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(1)	Amended and Restated Bylaws
4.1(2)	Form of Common Stock Certificate
4.2(3)	Amended and Restated Investors' Rights Agreement, dated April 30, 2003, among us and the parties named therein
4.3(3)	Amendment No. 1 to Amended and Restated Investors' Rights Agreement, dated May 19, 2003, among us and the parties named therein
4.4(3)†	Stock Restriction and Registration Rights Agreement, dated January 26, 2001, between us and The Curators of the University of Missouri
4.5(3)	Form of Series C Preferred Stock Purchase Warrant
4.6(3)	Form of Common Stock Purchase Warrant
4.7(3)	Warrant to Purchase Shares of Common Stock, dated April 30, 2003, issued to Rockport Venture Securities, LLC
4.8(2)	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
10.1(3)†	Stock Purchase Agreement, dated January 26, 2001, between us and The Curators of the University of Missouri
10.2(3)†	Exclusive License Agreement, dated January 26, 2001, between us and The Curators of the University of Missouri
10.3(3)†	Amendment No. 1 to Exclusive License Agreement, dated February 21, 2003, between us and The Curators of the University of Missouri

Exhibit Number	Description
10.4(3)†	License Agreement, dated June 27, 2002, among us, TAP Pharmaceutical Products Inc. and Takeda Chemical Industries, Ltd.
10.5(3)†	Omeprazole Supply Agreement, dated September 25, 2003, among us, InterChem Trading Corporation and Union Quimico Farmaceutica, S.A.
10.6(3)†	Manufacturing and Supply Agreement, dated December 19, 2003, between us and Patheon Inc.
10.7(3)†	Capital Reimbursement Agreement, dated December 19, 2003, between us and Patheon Inc.
10.8(4)+	Manufacturing and Supply Agreement, dated September 27, 2004, between us and OSG Norwich Pharmaceuticals, Inc.
10.9(4)+	Co-Promotion Agreement, dated October 4, 2004, between us and Otsuka America Pharmaceutical, Inc.
10.10(3)	Office Building Lease, dated August 24, 2001, between us and Torrey View Associates LP
10.11(3)	Irrevocable Stand-by Letter of Credit, dated August 24, 2001, issued by UBS Paine Webber Inc.
10.12(3)#	Form of Indemnification Agreement between us and each of our directors and officers
10.13(3)#	1998 Stock Option Plan
10.14(5)#	Amended and Restated 2004 Equity Incentive Award Plan
10.15(6)#	Form of Stock Option Agreement under Amended and Restated 2004 Equity Incentive Award Plan
10.16(7)#	Form of Immediately Exerciseable Stock Option Agreement under Amended and Restated 2004 Equity Incentive Award Plan
10.17(5)#	Amended and Restated Employee Stock Purchase Plan
10.18(3)#	Employment Agreement, dated March 31, 2004, between us and Gerald T. Proehl
10.19(3)#	Employment Agreement, dated March 31, 2004, between us and Debra P. Crawford
10.20(3)#	Employment Agreement, dated March 31, 2004, between us and William C. Denby, III
10.21(3)#	Employment Agreement, dated March 31, 2004, between us and Warren E. Hall
10.22(3)#	Employment Agreement, dated March 31, 2004, between us and Bonnie Hepburn, M.D.
10.23(3)#	Employment Agreement, dated March 31, 2004, between us and Julie A. DeMeules
10.24(5)#	Employment Agreement, dated July 27, 2004, between us and C. Christine Simmons, Pharm.D.
10.25(6)#	Employment Agreement, dated February 7, 2005, between us and Michael D. Step
10.26(8)#	2004 Bonus Plan
10.27(8)#	2005 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 the Company's 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 the Company's Current Report on Form 8-K, filed with the Securities and Exchange Commission on November 17, 2004.

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

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

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

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

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

(8) Incorporated by reference to the Company's Current Report on Form 8-K, filed with the Securities and Exchange Commission on February 22, 2005.

† 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.

(a) *Financial Statement Schedule.*

See Item 15(a)(2) above.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities and 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 23, 2005

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 23, 2005
/s/ DEBRA P. CRAWFORD Debra P. Crawford	Senior Vice President and Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 23, 2005
/s/ DAVID F. HALE David F. Hale	Director *(Chairman of the Board of Directors)*	March 23, 2005
/s/ DANIEL D. BURGESS Daniel D. Burgess	Director	March 23, 2005
/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 23, 2005
/s/ RODNEY A. FERGUSON, J.D., PH.D. Rodney A. Ferguson, J.D., Ph.D.	Director	March 23, 2005
/s/ MICHAEL E. HERMAN Michael E. Herman	Director	March 23, 2005
/s/ TED W. LOVE, M.D. Ted W. Love, M.D.	Director	March 23, 2005
/s/ KENT SNYDER Kent Snyder	Director	March 23, 2005

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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, 2004 and 2003, and the related statements of operations, stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2004. These financial statements are the responsibility of the Company's management. Our audits also included the financial schedule listed in the Index at Item 15(a). Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purposes of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and 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, 2004 and 2003, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2004, 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.

/s/ Ernst & Young LLP

San Diego, California
March 17, 2005

Santarus, Inc.

Balance Sheets

	December 31, 2004	December 31, 2003
Assets		
Current assets:		
Cash and cash equivalents	$ 34,402,352	$ 13,063,211
Short-term investments	79,605,745	32,585,088
Accounts receivable, net	800,719	—
Inventories, net	1,961,789	—
Other current assets	2,481,414	817,216
Total current assets	119,252,019	46,465,515
Long-term restricted cash	950,000	950,000
Property and equipment, net	948,745	616,076
Other assets	1,065,006	156,563
Total assets	$ 122,215,770	$ 48,188,154
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable and accrued liabilities	$ 14,805,809	$ 3,834,257
Allowance for product returns	7,057,208	—
Current portion of deferred revenue	2,857,143	—
Current portion of long-term debt	185,980	255,274
Total current liabilities	24,906,140	4,089,531
Deferred revenue, less current portion	11,428,571	—
Long-term debt, less current portion	38,019	223,999
Series D redeemable convertible preferred stock, $.0001 par value; no shares and 43,900,000 shares authorized, issued and outstanding at December 31, 2004 and 2003, respectively	—	57,625,278
Stockholders' equity (deficit):		
Series A convertible preferred stock, $.0001 par value; no shares and 620,000 shares authorized, issued, and outstanding at December 31, 2004 and 2003, respectively	—	62
Series B convertible preferred stock, $.0001 par value; no shares and 5,276,000 shares authorized, issued and outstanding at December 31, 2004 and 2003, respectively	—	528
Series C convertible preferred stock, $.0001 par value; no shares and 13,845,648 shares authorized at December 31, 2004 and 2003, respectively; no shares and 13,701,208 shares issued and outstanding at December 31, 2004 and 2003, respectively	—	1,370
Preferred stock, $.0001 par value; 10,000,000 shares and no shares authorized at December 31, 2004 and 2003, respectively; no shares issued and outstanding at December 31, 2004 and 2003	—	—
Common stock, $.0001 par value; 100,000,000 and 104,000,000 shares authorized at December 31, 2004 and 2003, respectively; 36,328,461 and 2,398,440 shares issued and outstanding at December 31, 2004 and 2003, respectively	3,633	240
Additional paid-in capital	228,881,141	50,568,886
Deferred compensation	(4,572,598)	(8,646,845)
Accumulated other comprehensive loss	(187,538)	(13,114)
Accumulated deficit	(138,281,598)	(55,661,781)
Total stockholders' equity (deficit)	85,843,040	(13,750,654)
Total liabilities and stockholders' equity (deficit)	$ 122,215,770	$ 48,188,154

See accompanying notes.

Santarus, Inc.

Statements of Operations

	Years Ended December 31,		
	2004	2003	2002
Revenues:			
Product sales, net	$ 633,468	$ —	$ —
Sublicense and co-promotion revenue	714,286	—	8,000,000
Total revenues	1,347,754	—	8,000,000
Costs and expenses:			
Cost of sales	1,968,388	—	—
License fees and royalties	5,088,686	1,000,000	1,400,000
Research and development	23,198,637	13,175,952	15,397,706
Selling, general and administrative	48,306,599	6,548,123	6,033,741
Stock-based compensation	5,671,588	2,252,268	277,121
Total costs and expenses	84,233,898	22,976,343	23,108,568
Loss from operations	(82,886,144)	(22,976,343)	(15,108,568)
Interest and other income, net	1,390,837	465,306	413,746
Net loss	(81,495,307)	(22,511,037)	(14,694,822)
Accretion to redemption value of redeemable convertible preferred stock	(1,124,510)	(2,940,163)	—
Net loss attributable to common stockholders	$ (82,619,817)	$ (25,451,200)	$ (14,694,822)
Basic and diluted net loss per share	$ (3.30)	$ (13.71)	$ (9.13)
Weighted average shares outstanding to calculate basic and diluted net loss per share	25,016,720	1,856,879	1,610,230
The composition of stock-based compensation is as follows:			
Research and development	$ 1,623,846	$ 487,936	$ —
Selling, general and administrative	4,047,742	1,764,332	277,121
	$ 5,671,588	$ 2,252,268	$ 277,121

See accompanying notes.

Santarus, Inc.

Statements of Stockholders' Equity (Deficit)

	Convertible preferred stock		Common Stock		Additional paid-in capital	Stockholder receivables	Deferred compensation	Accumulated other comprehensive income (loss)	Accumulated deficit	Total
	Shares	Amount	Shares	Amount						
Balance at December 31, 2001	19,597,208	$ 19,597	1,656,520	$ 1,656	$ 38,760,405	$ (25,000)	$ -	$ 46,858	$ (15,515,759)	$ 23,287,757
Issuance of common stock for stockholder note upon exercise of options	-	-	108,571	109	93,891	(94,000)	-	-	-	-
Forgiveness of stockholder note	-	-	-	-	-	94,000	-	-	-	94,000
Issuance of common stock for cash upon exercise of options net of 2,065 unvested shares repurchased	-	-	216,858	217	147,940	-	-	-	-	148,157
Change in par value of preferred and common stock from $.001 to $.0001	-	(17,637)	-	(1,784)	19,421	-	-	-	-	-
Compensation related to non-employee stock options	-	-	-	-	277,121	-	-	-	-	277,121
Net loss	-	-	-	-	-	-	-	-	(14,694,822)	(14,694,822)
Unrealized loss on investments	-	-	-	-	-	-	-	(37,842)	-	(37,842)
Comprehensive loss	-	-	-	-	-	-	-	-	-	(14,732,664)
Balance at December 31, 2002	19,597,208	1,960	1,981,949	198	39,298,778	(25,000)	-	9,016	(30,210,581)	9,074,371
Issuance of common stock for cash upon exercise of options	-	-	416,491	42	370,995	-	-	-	-	371,037
Forgiveness of stockholder note	-	-	-	-	-	25,000	-	-	-	25,000
Accretion to redemption value of redeemable convertible preferred stock	-	-	-	-	-	-	-	-	(2,940,163)	(2,940,163)
Deferred compensation related to issuance of stock options to employees	-	-	-	-	10,512,825	-	(10,512,825)	-	-	-
Amortization of deferred compensation	-	-	-	-	-	-	1,865,980	-	-	1,865,980
Compensation related to non-employee stock options	-	-	-	-	386,288	-	-	-	-	386,288
Net loss	-	-	-	-	-	-	-	-	(22,511,037)	(22,511,037)
Unrealized loss on investments	-	-	-	-	-	-	-	(22,130)	-	(22,130)
Comprehensive loss	-	-	-	-	-	-	-	-	-	(22,533,167)
Balance at December 31, 2003	19,597,208	$ 1,960	2,398,440	$ 240	$ 50,568,886	$ -	$ (8,646,845)	$ (13,114)	$ (55,661,781)	$ (13,750,654)

	Convertible preferred stock		Common Stock		Additional paid-in capital	Stockholder receivables	Deferred compensation	Accumulated other comprehensive income (loss)	Accumulated deficit	Total
	Shares	Amount	Shares	Amount						
Balance at December 31, 2003	19,597,208	$ 1,960	2,398,440	$ 240	$ 50,568,886	$ -	$ (8,646,845)	$ (13,114)	$ (55,661,781)	$ (13,750,654)
Issuance of common stock for cash upon exercise of options	-	-	309,420	31	620,857	-	-	-	-	620,888
Issuance of common stock under employee stock purchase plan	-	-	64,611	6	494,268	-	-	-	-	494,274
Issuance of common stock at $4.395 per share upon exercise of warrants, net	-	-	14,376	1	(1)	-	-	-	-	-
Issuance of common stock for cash upon exercise of warrants	-	-	855	1	1,396	-	-	-	-	1,397
Accretion to redemption value of redeemable convertible preferred stock	-	-	-	-	-	-	-	-	(1,124,510)	(1,124,510)
Issuance of common stock in initial public offering, net of issuance costs of $6,247,000	-	-	6,900,000	690	55,852,310	-	-	-	-	55,853,000
Issuance of common stock in follow-on public offering, net of issuance costs of $4,553,000	-	-	6,900,000	690	60,996,310	-	-	-	-	60,997,000
Conversion of redeemable convertible preferred stock into common stock	-		12,542,697	1,254	58,748,534	-	-	-	-	58,749,788
Conversion of convertible preferred stock into common stock	(19,597,208)	(1,960)	7,198,062	720	1,240	-	-	-	-	-
Deferred compensation related to issuance of stock options to employees	-	-	-	-	1,392,895	-	(1,392,895)	-	-	-
Unamortized deferred compensation on cancelled stock options	-	-	-	-	(290,340)	-	290,340	-	-	-
Amortization of deferred compensation	-	-	-	-	-	-	5,176,802	-	-	5,176,802
Compensation related to non-employee stock options	-	-	-	-	494,786	-	-	-	-	494,786
Net loss	-	-	-	-	-	-	-	-	(81,495,307)	(81,495,307)
Unrealized loss on investments	-	-	-	-	-	-	-	(174,424)	-	(174,424)
Comprehensive loss	-	-	-	-	-	-	-	-	-	(81,669,731)
Balance at December 31, 2004	-	$ -	36,328,461	$ 3,633	$ 228,881,141	$ -	$ (4,572,598)	$ (187,538)	$ (138,281,598)	$ 85,843,040

See accompanying notes.

Santarus, Inc.
Statements of Cash Flows

	Years ended December 31,		
	2004	2003	2002
Operating activities			
Net loss	$ (81,495,307)	$ (22,511,037)	$ (14,694,822)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	446,311	312,386	251,087
Stock-based compensation	5,671,588	2,252,268	277,121
Forgiveness of stockholder note	—	25,000	94,000
Changes in operating assets and liabilities:			
Accounts receivable, net	(800,719)	—	—
Inventories, net	(1,961,789)	—	—
Other current assets	(1,664,198)	(270,569)	(257,409)
Other assets	93,274	(93,562)	15,006
Accounts payable and accrued liabilities	10,971,552	(586,371)	3,376,866
Allowance for product returns	7,057,208	—	—
Deferred revenue	14,285,714	—	—
Net cash used in operating activities	(47,396,366)	(20,871,885)	(10,938,151)
Investing activities			
Purchase of short-term investments	(96,448,301)	(45,402,660)	(10,217,160)
Sales and maturities of short-term investments	49,253,220	20,119,000	12,450,000
Purchases of property and equipment	(733,525)	(84,769)	(361,220)
Deposits on manufacturing equipment	(1,047,172)	—	—
Net cash provided by (used in) investing activities	(48,975,778)	(25,368,429)	1,871,620
Financing activities			
Exercise of stock options	620,888	371,037	148,157
Issuance of common stock, net	117,345,671	—	—
Issuance of Series D redeemable convertible preferred stock, net	—	54,685,116	—
Proceeds from equipment notes payable	—	—	809,309
Payments on equipment notes payable	(255,274)	(232,936)	(97,100)
Net cash provided by financing activities	117,711,285	54,823,217	860,366
Increase (decrease) in cash and cash equivalents	21,339,141	8,582,903	(8,206,165)
Cash and cash equivalents at beginning of the year	13,063,211	4,480,308	12,686,473
Cash and cash equivalents at end of the year	$ 34,402,352	$ 13,063,211	$ 4,480,308
Supplemental disclosure of cash flow information:			
Interest paid	$ 33,626	$ 55,964	$ 28,983
Supplemental schedule of noncash investing and financing activities:			
Issuance of stock in exchange for stockholder receivables	$ —	$ —	$ 94,000
Accretion to redemption value of redeemable convertible preferred stock	$ 1,124,510	$ 2,940,163	$ —
Conversion of redeemable convertible preferred stock to common stock upon closing of initial public offering	$ 58,749,788	$ —	$ —

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 to enhance the quality of life for patients with gastrointestinal diseases and disorders. Santarus was incorporated on December 6, 1996 as a California corporation and did not commence significant business activities until late 1998. The Company, previously named TBG Pharmaceuticals, Inc., was formed as a result of a spin-off from Prometheus Laboratories, Inc. On July 9, 2002, the Company reincorporated in the State of Delaware.

In October 2004, the Company commercially launched in the U.S. its first product, Zegerid Powder for Oral Suspension 20 mg, an immediate-release formulation of the proton pump inhibitor ("PPI") omeprazole. This product is approved by the U.S. Food and Drug Administration ("FDA") 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 ulcers. In February 2005, the Company commercially launched Zegerid Powder for Oral Suspension 40 mg, approved by the FDA for the treatment of gastric ulcers and the reduction of risk of upper gastrointestinal ("GI") bleeding in critically ill patients.

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.

Reclassification

Certain previously reported amounts have been reclassified to conform to the current period presentation.

Cash and Cash Equivalents

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

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 (deficit). 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 67% of the accounts receivable

balance as of December 31, 2004 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, and the fact that all balances were current, the Company did not record an allowance for doubtful accounts at December 31, 2004.

The Company relies on a single third-party manufacturer located outside of the U.S. for the supply of Zegerid Powder for Oral Suspension 20 mg and 40 mg, and the Company is obligated to purchase a significant portion of its requirements from this manufacturer. The Company also relies on a single third-party supplier located outside of the U.S. for the supply of omeprazole, which is the active pharmaceutical ingredient in each of the Company's current products. The Company is obligated to purchase all of its requirements of omeprazole from this supplier.

Inventories, Net

Inventories are stated at the lower of cost or market and consist of finished goods and raw materials used in the manufacture of the Company's Zegerid Powder for Oral Suspension 20 mg and 40 mg products. The Company provides reserves for potentially excess, dated or obsolete inventories based on an analysis of inventory on hand and on firm purchase commitments and inventory in the distribution channel, compared to forecasts of future sales. Based upon review of initial prescription trends for Zegerid Powder for Oral Suspension 20 mg subsequent to the commercial launch in October 2004, and in light of the Company's receipt of FDA approval to market Zegerid Powder for Oral Suspension 40 mg in December 2004, the Company reserved approximately $1.7 million against on-hand inventories and accrued approximately $627,000 for firm purchase commitments related to excess Zegerid Powder for Oral Suspension 20 mg inventories as of December 31, 2004.

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. Based on the borrowing rates currently available to the Company for debt with similar terms, management believes the fair value of the long-term debt approximates its carrying value.

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, 2004.

Revenue Recognition

Product sales, net. The Company recognizes revenue from product sales in accordance with Statement of Financial Accounting Standard ("SFAS") No. 48, *Revenue Recognition When Right of Return Exists,* when there is persuasive evidence that an arrangement exists, when title has passed, the price is fixed or determinable, and the Company is reasonably assured of collecting the resulting receivable. The Company recognizes product sales net of estimated allowances for product returns, managed care rebates, reimbursements relating to Medicaid, chargebacks from distributors and prompt payment and other discounts. Such estimates 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 discounts exceed the estimates made at the time of sale, the Company's financial position, results of operations and cash flows would be negatively impacted.

The Company is obligated to accept from customers the return of products that are within six months of their expiration date or 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 recently commercially launched its first product, Zegerid Powder for Oral Suspension 20 mg, in the fourth quarter of 2004, and to date, the Company has had no product returns. Given the Company's limited history, allowances for potential product returns have been established based on an analysis of product shipments to wholesale distributors in excess of prescription demand for Zegerid Powder for Oral Suspension 20 mg in 2004. Although management believes that the estimates and assumptions are reasonable as of the date when made, actual results may differ significantly from these estimates. The Company's financial position, results of operations and cash flows may be materially and negatively impacted if actual returns exceed estimated allowance for returns.

Sublicense and co-promotion revenue. The Company recognizes sublicense and co-promotion revenue consistent with the provisions of the Securities and Exchange Commission Staff Accounting Bulletin ("SAB") No. 104, *Revenue Recognition,* which sets forth guidelines in the timing of revenue recognition based upon factors such as passage of title, installation, payments and customer acceptance. The Company analyzes each element of sublicense and co-promotion agreements, to determine the appropriate revenue recognition. The Company recognizes revenue on upfront payments over the term of 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 evaluates the criteria outlined in Emerging Issues Task Force ("EITF") Issue 99-19, *Reporting Revenue Gross as a Principal Versus Net as an Agent*, in determining whether it is appropriate to record the gross amount of sublicense revenues and related costs or the net amount earned under the arrangement. The Company has recognized the gross amount of sublicense revenue and related costs as the Company has no future obligations pursuant to the arrangement, is the primary obligor in the arrangement, had latitude in establishing the amounts received under the arrangement and was involved in the determination of the scope of technology sublicensed under the agreement.

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 expenditures consist primarily of costs associated with clinical trials of the Company's products under development, including the costs of developing and manufacturing the Company's products under development, compensation 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 is uncertain and the technology has no alternative future use when acquired. Future acquisitions of patents and technology licenses will be charged to expense or capitalized based upon management's assessment regarding the ultimate recoverability of the amounts paid and the potential for alternative future use. Amounts capitalized would be amortized over the useful life of the technology using the straight-line method and reviewed annually for impairment. Annual license maintenance fees under cancellable agreements are capitalized and charged to expense over the corresponding twelve months. Quarterly sponsored research fees under cancellable agreements are charged to expense as paid.

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 $4.4 million in advertising expense for the year ended December 31, 2004. There were no advertising expenses recorded in the years ended December 31, 2003 or 2002.

Stock-Based Compensation

In December 2002, SFAS No. 148, *Accounting for Stock-Based Compensation — Transition and Disclosure — an amendment of FASB Statement No. 123* was issued. SFAS No. 148 provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation from the intrinsic value-based method of accounting prescribed by Accounting Principles Board ("APB") Opinion No. 25, *Accounting for Stock Issued to Employees*. In addition, SFAS No. 148 amends the disclosure requirements of SFAS No. 123, *Accounting for Stock-Based Compensation*. The Company adopted the disclosure requirements of SFAS No. 148 effective December 31, 2002. As allowed by SFAS No. 123, the Company has elected to continue to apply the intrinsic value-based method of accounting prescribed in APB Opinion No. 25 and, accordingly, does not recognize compensation expense for stock option grants made at an exercise price equal to or in excess of the fair value of the stock at the date of grant. Deferred compensation is recognized and amortized on an accelerated basis in accordance with Financial Accounting Standards Board Interpretation No. 28, *Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans*, over the vesting period of the related options.

Had compensation cost for the Company's outstanding employee stock options and Employee Stock Purchase Plan ("ESPP") purchase rights been determined based on the fair value at the grant dates for those options and rights consistent with SFAS No. 123, the Company's net loss and basic and diluted net loss per share would have been changed to the following pro forma amounts:

	Years Ended December 31,		
	2004	2003	2002
Net loss attributable to common stockholders as reported	$ (82,619,817)	$ (25,451,200)	$ (14,694,822)
Add: Stock-based employee compensation expense included in net loss	5,176,802	1,865,980	—
Deduct: Stock-based employee compensation expense determined under fair value method	(9,748,804)	(2,497,906)	(206,326)
Pro forma net loss attributable to common stockholders	$ (87,191,819)	$ (26,083,126)	$ (14,901,148)
Basic and diluted net loss per share as reported	$ (3.30)	$ (13.71)	$ (9.13)
Basic and diluted pro forma net loss per share	$ (3.49)	$ (14.05)	$ (9.25)

SFAS No. 123 pro forma information regarding net loss is required by SFAS No. 123, and has been determined as if the Company had accounted for its stock-based employee compensation under the fair value method prescribed in SFAS No. 123. The fair value of the options was estimated at the date of grant using the Black-Scholes pricing model with the following assumptions for 2004, 2003 and 2002: weighted average risk-free interest rates of 3.2%, 2.5% and 3.0%, respectively; a dividend yield of 0%; a volatility of 70%; and a weighted-average life of the option of 6.2, 6.7 and 6.5 years, respectively. The weighted average grant date fair value for accounting purposes of options granted in 2004, 2003 and 2002 was $6.78, $5.81 and $0.93, respectively. The fair value of the ESPP purchase rights was estimated at the date of grant using the Black-Scholes pricing model with the following assumptions for 2004: weighted average risk-free interest rate of 2.8%; a dividend yield of 0%; a volatility of 70%; and a weighted-average life of the rights of 1.2 years. As the Company's ESPP was implemented on April 1, 2004, no purchase rights existed in 2003 and 2002. The weighted average grant date fair value for accounting purposes of ESPP purchase rights granted in 2004 was $4.31. The effects of applying SFAS No. 123 in this pro forma disclosure are not indicative of future amounts. Stock option grants are expensed over their respective vesting periods.

The Company accounts for options issued to non-employees under SFAS No. 123 and EITF Issue 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 and income or expense is recognized during their vesting terms. For the years ended 2004, 2003 and 2002, stock-based compensation related to stock options issued to non-employees was approximately $495,000, $386,000, and $277,000, respectively. Included in non-employee stock-based compensation for the year ended December 31, 2004 was approximately $361,000 in expense associated with the accelerated vesting of certain shares of common stock that the Company's former chairman of the board of directors and his affiliates acquired in connection with earlier options grants.

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,		
	2004	2003	2002
Net loss	$ (81,495,307)	$ (22,511,037)	$ (14,694,822)
Unrealized loss on investments	(174,424)	(22,130)	(37,842)
Comprehensive loss	$ (81,669,731)	$ (22,533,167)	$ (14,732,664)

Net Loss Per Share

The Company calculated net loss per share in accordance with SFAS No. 128, *Earnings Per Share*, and SAB No. 98. 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 earnings per share when their effect is dilutive. Under the provisions of SAB No. 98, common shares issued for nominal consideration (as defined), if any, would be included in the per share calculations as if they were outstanding for all periods presented. No common shares have been issued for nominal consideration.

The net loss per share for the year ended December 31, 2004 includes the effect of the 6,900,000 shares of common stock issued in the Company's follow-on public offering of common stock in July 2004, the 6,900,000 shares of common stock issued in the Company's initial public offering of common stock in April 2004 and the 19,740,759 shares of common stock issued upon conversion of the Company's redeemable convertible preferred stock and convertible preferred stock (collectively, the "Preferred Stock") in conjunction with the initial public offering. The pro forma shares used to compute basic and diluted net loss per share represent the weighted average common shares outstanding, reduced by the weighted average unvested common shares subject to repurchase, and includes the assumed conversion of all outstanding shares of preferred stock into shares of common stock using the as-if converted method as of the beginning of each period presented or the date of issuance, if later.

	Years Ended December 31,		
	2004	2003	2002
Historical:			
Numerator:			
Net loss	$ (81,495,307)	$ (22,511,037)	$ (14,694,822)
Accretion to redemption value of redeemable convertible preferred stock	(1,124,510)	(2,940,163)	—
Net loss attributable to common stockholders	$ (82,619,817)	$ (25,451,200)	$ (14,694,822)
Denominator:			
Weighted average common shares	25,230,528	2,023,077	1,919,460
Weighted average unvested common shares subject to repurchase	(213,808)	(166,198)	(309,230)
Denominator for basic and diluted net loss per share	25,016,720	1,856,879	1,610,230
Basic and diluted net loss per share	$ (3.30)	$ (13.71)	$ (9.13)
Pro forma:			
Pro forma net loss	$ (81,495,307)	$ (22,511,037)	$ (14,694,822)
Basic and diluted pro forma net loss per share (unaudited)	$ (2.70)	$ (1.30)	$ (1.67)
Pro forma adjustments to reflect assumed weighted average effect of conversion of preferred stock (unaudited)	5,177,904	15,478,178	7,198,062
Weighted average shares outstanding to calculate basic and diluted pro forma net loss per share (unaudited)	30,194,624	17,335,057	8,808,292
Historical outstanding antidilutive securities not included in diluted net loss per share calculation:			
Redeemable convertible and convertible preferred stock	—	63,497,208	19,597,208
Common stock subject to repurchase	117,095	237,963	245,037
Options to purchase common stock	3,890,914	2,362,757	687,626
Stock warrants	59,405	167,057	145,866
	4,067,414	66,264,985	20,675,737

Segment Reporting

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

Income Taxes

In accordance with SFAS No. 109, *Accounting for Income Taxes*, a deferred tax asset or liability is determined based on the difference between the financial statement and tax basis of assets and liabilities, as measured by the enacted tax rates that will be in effect when these differences reverse. The Company provides a valuation allowance against net deferred tax assets unless, based upon the available evidence, it is more likely than not that the deferred tax assets will be realized.

New Accounting Pronouncements

On December 16, 2004, the Financial Accounting Standards Board ("FASB") issued 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)"). SFAS No. 123(R) supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and amends SFAS No. 95, *Statement of Cash Flows*. Generally, the approach in SFAS No. 123(R) is similar to the approach described in SFAS No. 123. However, SFAS No. 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative. SFAS No. 123(R) must be adopted no later than July 1, 2005. Early adoption will be permitted in periods in which financial statements have not been issued. The Company expects to adopt SFAS 123(R) on July 1, 2005.

As permitted by SFAS No. 123, the Company currently accounts for share-based payments to employees using APB Opinion No. 25's intrinsic value method and, as such, generally recognizes no compensation cost for employee stock options when the exercise price is equal to or in excess of the fair value of the stock at the date of grant. Accordingly, the adoption of Statement SFAS No. 123(R)'s fair value method will have a significant impact on the Company's results of operations, although it will have no impact on the Company's overall financial position. The impact of adoption of SFAS No. 123(R) cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had the Company adopted SFAS No. 123(R) in prior periods, the impact of that standard would have approximated the impact of SFAS No. 123 as described in the disclosure of pro forma net loss and net loss per share in Note 1 to the financial statements. SFAS No. 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption.

In November 2004, the FASB issued SFAS No. 151, *Inventory Costs, an amendment of ARB No. 43, Chapter 4*. This statement amends the guidance in ARB No. 43 Chapter 4, "Inventory Pricing," to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs and wasted material (spoilage). The provision of this statement will be effective for inventory costs during the fiscal years beginning after June 15, 2005. As a result of the manufacturing process being outsourced, the Company does not believe that the adoption of this statement will have a material impact on the Company's financial condition or results of operations.

2. Investments

The following is a summary of investments as of December 31, 2004 and 2003, which includes amounts classified as cash, cash equivalents, short-term investments and restricted cash. All investments held as of December 31, 2004 and 2003 have contractual maturities within one year.

	Amortized Cost	Market Value	Unrealized Loss
December 31, 2004:			
U.S. government and state agencies	$ 44,259,412	$ 44,164,289	$ (95,123)
Corporate debt securities	63,667,138	63,574,723	(92,415)
Money market funds	7,219,085	7,219,085	—
Total	$115,145,635	$ 114,958,097	$ (187,538)
December 31, 2003:			
U.S. government and state agencies	$ 30,128,767	$ 30,124,964	$ (3,803)
Corporate debt securities	12,669,436	12,660,125	(9,311)
Money market funds	3,813,210	3,813,210	—
Total	$ 46,611,413	$ 46,598,299	$ (13,114)

There were no gross realized gains or losses on sales of available-for-sale securities for the years ended December 31, 2004 and 2003.

3. Balance Sheet Details

Inventories, net consist of the following:

	December 31,	
	2004	2003
Raw materials	$ 2,563,767	$ —
Finished goods	1,126,602	—
	3,690,369	—
Allowance for excess and obsolete inventory	(1,728,580)	—
	$ 1,961,789	$ —

Property and equipment, net consist of the following:

	December 31,	
	2004	2003
Computer equipment and software	$ 917,767	$ 574,798
Office equipment and furniture	757,106	577,612
Leasehold improvements	345,724	178,483
	2,020,597	1,330,893
Less accumulated depreciation and amortization	(1,071,852)	(714,817)
	$ 948,745	$ 616,076

Accounts payable and accrued liabilities consist of the following:

	December 31,	
	2004	2003
Accounts payable	$ 3,045,659	$ 968,205
Accrued compensation and benefits	4,940,634	1,367,509
Accrued research and development expenses	3,583,739	1,012,660
Other accrued liabilities	3,235,777	485,883
	$ 14,805,809	$ 3,834,257

For the years ended December 31, 2004, 2003 and 2002, depreciation expense was approximately $401,000, $312,000 and $251,000, respectively.

4. Technology License Agreements

In October 2004, the Company entered into a non-exclusive agreement with Otsuka America Pharmaceutical, Inc. ("Otsuka America") for Otsuka America to co-promote Zegerid Powder for Oral Suspension to U.S. physicians. Under the terms of the agreement, the Company received a $15.0 million upfront payment from Otsuka America, and has agreed to pay Otsuka America a royalty on total U.S. net sales of the product. The Company also granted Otsuka America options to extend the co-promotion arrangement to Zegerid Capsules and Zegerid Chewable Tablets subject to receipt of marketing approval of these products, with additional milestone payments should those options be exercised. The agreement expires on December 31, 2009, subject to earlier

termination under certain circumstances. The $15.0 million upfront payment is being amortized to co-promotion revenue on a straight-line basis over the term of the co-promotion agreement, which expires on December 31, 2009.

In January 2001, the Company entered into a technology license agreement with The Curators of the University of Missouri ("Missouri"). Under the technology license agreement, 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 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 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 Missouri upon the achievement of certain regulatory events related to obtaining approvals 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, and to pay royalties on net sales of the Company's products. 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 Company recorded license fee expenses of $5.0 million and $1.0 million in 2004 and 2003, respectively, related to the milestone fees paid to Missouri. The rights under the 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.

Under the Missouri technology license agreement, the Company entered into a five-year sponsored research agreement in August 2001. The Company supports the program by granting cash, which is being paid and expensed in 20 equal quarterly installments.

In June 2002, the Company entered into a sublicense agreement which grants TAP Pharmaceutical Products Inc. ("TAP") certain rights to the technologies the Company licenses from Missouri, in exchange for an upfront fee of $8.0 million, milestone payments and royalties on any future sales, subject to conditions contained in the agreement. The Company paid 15% of the upfront fee to Missouri and is also obligated to pay 15% of any milestone payments, as well as a portion of any royalty payments received from TAP to Missouri. TAP is responsible for all of its product development and commercialization expenses. Under the terms of the agreement, TAP has the right to discontinue its development efforts and terminate the agreement without cause by giving 60 days prior written notice.

In February 2005, the Company received a $10.0 million milestone payment from TAP, after the Company prevailed in an alternative dispute resolution proceeding, which is being recognized as revenue in the first quarter of 2005. The Company initiated the alternative dispute resolution process in August 2003, asserting that TAP achieved a development milestone under the terms of the sublicense agreement. The assertion was contested by TAP, and in the proceeding, it was determined that the Company was entitled to the milestone payment plus interest and legal expenses. In March 2005, the Company paid 15% of the milestone payment received from TAP to Missouri.

5. Long-Term Debt

In August 2002, the Company entered into a financing agreement, which provided up to $1.4 million of net financing for furniture, equipment and tenant improvements through April 3, 2003. Borrowings under the loan schedule are payable over a thirty-six or forty-eight month period including principal and interest based on three- or four-year U.S. Treasury maturities (approximately 9.23% under the outstanding loan schedule). Principal payments due in 2005 and 2006 are approximately $186,000 and $38,000, respectively. The credit agreement provides the lender with security interest in all equipment financed under the line and requires payment of a security deposit should the Company's cash balances fall below certain minimum levels. As of December 31, 2004, the Company is in compliance with the required minimum cash balance provisions.

6. Commitments

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. The annual rent is subject to annual increases of 3.5%. In conjunction with the facilities lease, the Company established a letter of credit for $950,000 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 $700,000, $400,000, and $100,000 at March 31, 2006, 2007, and 2008, respectively, and the entire balance may be excused if the

Company has $40,000,000 in cash, cash equivalents and short-term investments on hand. At December 31, 2004, estimated annual future minimum payments under the Company's operating leases are as follows:

2005	$ 1,007,000
2006	1,032,000
2007	877,000
2008	230,000
2009	9,000
Total minimum lease payments	$ 3,155,000

Rent expense on facilities and equipment was approximately $1.0 million, $810,000 and $754,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

In November 2004, the Company entered into a master lease agreement giving the Company the ability to lease vehicles under operating leases. As of December 31, 2004, the Company had not entered into any vehicle lease obligations under the master agreement. 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 $1,000,000 naming the lessor as beneficiary. The letter of credit is fully secured by restricted cash and has automatic annual extensions.

Commercial Supply Agreement

In December 2003, the Company entered into a commercial supply agreement, which among other things, obligates the Company to fund up to approximately $1.9 million in manufacturing equipment for the supplier. The supplier is obligated to reimburse the Company for this amount in the event the Company purchases a specified aggregate number of units. Through December 31, 2004, the Company funded approximately $1.0 million of the manufacturing equipment.

Other Long-Term Obligations

The Company has entered into other long-term commitments for services requiring the Company to make payments of approximately $888,000 and $566,000 in 2005 and 2006, respectively.

7. Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)

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.

Reverse Stock Split

In March 2004, the Company's stockholders approved a 1-for-3.5 reverse stock split of the Company's outstanding common stock. The accompanying financial statements give retroactive effect to the 1-for-3.5 reverse stock split for all periods presented.

Initial Public Offering

On April 6, 2004, the Company completed an initial public offering of 6,000,000 shares of common stock at a price to the public of $9.00 per share raising net proceeds of approximately $48.3 million, net of underwriting discounts and offering expenses. Upon completion of the initial public offering, all outstanding shares of the Company's preferred stock automatically converted into an aggregate of 19,740,759 shares of common stock. On April 16, 2004, in connection with the full exercise of the underwriters' over-allotment option, the Company completed the sale of 900,000 additional shares of common stock at the initial public offering price of $9.00 per share raising net proceeds of approximately $7.5 million, net of underwriting discounts and offering expenses.

On July 28, 2004, the Company completed a follow-on public offering of 6,900,000 shares of common stock at a price to the public of $9.50 per share raising net proceeds of approximately $61.0 million, net of underwriting discounts and offering expenses. The completed offering included the full exercise of the underwriters' over-allotment option.

Preferred Stock

Since inception, the Company has issued shares of preferred stock, including series A convertible preferred stock, series B convertible preferred stock, series C convertible preferred stock and series D redeemable convertible preferred stock. All outstanding shares of the Company's preferred stock automatically converted into an aggregate of 19,740,759 shares of common stock upon the completion of the Company's initial public offering. A listing of preferred stock issued since the Company's inception is as follows:

- In April 2003, the Company issued 36,102,536 shares of series D redeemable convertible preferred stock ("series D preferred stock") at $1.2557 per share for net proceeds of approximately $44.9 million after deducting issuance costs of approximately $420,000. In May and June 2003, the Company issued an additional 7,797,464 shares of series D preferred stock at $1.2557 per share for net proceeds of approximately $9.8 million after deducting issuance costs of approximately $20,000.

- In February 2001, the Company issued 13,034,166 shares of series C convertible preferred stock at $2.43 per share for net proceeds received in February and March 2001 of approximately $31.6 million, after deducting issuance costs of approximately $113,000. In conjunction with the Company's private placement of series C convertible preferred stock, the Company converted approximately $1.5 million principal amount and associated accrued interest due of approximately $24,000 under subordinated convertible notes into 643,586 shares of series C convertible preferred stock.

- In December 1998, the Company converted a $232,000 short-term loan into 580,000 shares of series B convertible preferred stock at $0.40 per share. In December 1998, the Company issued 4,696,000 shares of series B convertible preferred stock at $1.00 per share for net proceeds of approximately $4.6 million after deducting issuance costs of approximately $67,000. The Company received the proceeds from the issuance of series B convertible preferred stock in January 1999.

- In December 1996, the Company issued 620,000 shares of its series A convertible preferred stock to the stockholders of Prometheus Laboratories, Inc. at $0.01 per share in conjunction with the spin-off and formation of the Company.

The series D preferred stock was redeemable at any time after April 30, 2008 upon written notice of the holders of at least two-thirds of the outstanding shares of series D preferred stock. The redemption price of the series D preferred stock was equal to the stated price of the series D preferred stock plus 8% per year (not compounded). The Company increased the carrying amount of the series D preferred stock by periodic accretions, so that the carrying amounts would equal the minimum redemption values on the earliest redemption date. Increases in the carrying amounts of the series D preferred stock were recorded as increases in the Company's accumulated deficit.

The series D preferred stock was convertible at the option of the holder into the number of shares of the Company's common stock that results from dividing the stated price of $1.2557 by the conversion price in effect at the time of conversion. The conversion price was initially set at $1.2557 subject to certain adjustments including adjustments for stock splits or specified dilutive issuances. After giving effect to the Company's 1-for-3.5 reverse stock split, the conversion price was adjusted to $4.395.

The series A, series B and series C convertible preferred stock were convertible at the option of the holder into the number of shares of the Company's common stock that resulted from dividing the stated prices of $0.10, $1.00 and $2.43, respectively, by the conversion prices in effect at the time of conversion. In connection with the Company's private placement of series D preferred stock in April 2003, the conversion prices for the series A, series B and series C convertible preferred stock were set at $0.10, $1.00 and $1.7253, respectively, subject to certain adjustments including adjustments for stock splits or specified dilutive issuances. After giving effect to the Company's 1-for-3.5 reverse stock split, the conversion prices for the series A, series B and series C convertible preferred stock were adjusted to $0.35, $3.50 and $6.0386, respectively.

Stockholder Rights Plan

In November 2004, the Company adopted a Stockholder Rights Plan (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 April 2003, in connection with the Company's series D financing, the Company issued to its placement agent warrants to purchase 20,478 shares of its common stock. The warrants were exercisable for a period of five years with an exercise price of $4.395 per share. The fair value of the warrant was not material and accordingly, none of the proceeds were allocated to the warrant. The warrants were exercised in full in 2004.

In 2000 and 2001, in connection with the issuance of short-term unsecured subordinated convertible notes, the Company issued warrants to purchase shares of preferred stock, which converted into common stock warrants with the closing of the Company's initial public offering. The warrants are exercisable for a period of five years with an exercise price equivalent to $6.0386 per share. As of December 31, 2004, warrants to purchase 59,405 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 approved by the Company's stockholders in November 1998. The 1998 Plan initially authorized the Company to issue options to purchase up to 285,714 shares of its common stock. In August 2000, February 2001, January 2002 and April 2003, the 1998 Plan was amended to authorize the Company to issue options to purchase up to 457,142, 1,071,428, 1,314,285 and 4,171,428 shares of its common stock, respectively. 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, no additional options 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 on April 1, 2004 and was subsequently amended and restated in July 2004. The Company initially reserved 3,500,000 shares of common stock for issuance under the 2004 Plan. The number of shares initially reserved for issuance was increased by 397,784 shares, which was the number of shares of common stock available for issuance under the 1998 Plan as of the completion of the Company's initial public offering, and will be further increased by any options that are repurchased, forfeited, cancelled or expire under the 1998 Plan. 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.

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. At December 31, 2004 and 2003, 117,095 and 237,963 shares issued from the early exercise of unvested options were subject to repurchase by the Company, respectively.

A summary of stock option activity is as follows:

	Shares	Weighted-Average Exercise Price
Outstanding at December 31, 2001	779,425	$0.72
Granted	246,699	1.43
Exercised	(327,494)	0.74
Cancelled	(11,004)	1.12
Outstanding at December 31, 2002	687,626	0.96
Granted	2,130,645	1.59
Exercised	(416,491)	0.89
Cancelled	(39,023)	1.81
Outstanding at December 31, 2003	2,362,757	1.52
Granted	1,962,075	9.56
Exercised	(309,423)	2.01
Cancelled	(124,495)	5.23
Outstanding at December 31, 2004	3,890,914	5.42

A summary of stock options outstanding as of December 31, 2004 is as follows:

	Options Outstanding			Options Exercisable	
Exercise Prices	Options Outstanding	Weighted-Average Remaining Life in Years	Weighted-Average Exercise Price	Number Exercisable	Weighted-Average Exercise Price
$0.70-$1.05	1,421,020	8.1	$ 0.89	1,421,020	$ 0.89
$1.225-$2.10	99,281	8.5	1.79	99,281	1.79
$3.50	501,869	9.0	3.50	501,869	3.50
$5.25	287,891	9.1	5.25	287,891	5.25
$9.00-$12.89	1,499,853	9.6	10.13	379,579	9.78
$13.80-$14.75	81,000	9.5	14.46	—	—
	3,890,914	8.9	5.42	2,689,640	3.13

As of December 31, 2004 and 2003, respectively, 2,689,640 and 2,362,757 options outstanding are exercisable, and 2,465,190 and 802,770 shares remain available for future grant under the Plan. In February 2005, the Company granted options to purchase 1,248,592 shares in connection with annual option grants to all eligible employees.

In connection with the granting of employee stock options during 2004 and 2003, the Company recorded deferred compensation of approximately $1.4 million and $10.5 million, respectively, representing the difference between the exercise price and the fair value of the Company's common stock on the date of grant. Deferred compensation is being amortized over the vesting period of the options resulting in stock-based compensation expense of approximately $5.2 million and $1.9 million for the years ended December 31, 2004 and 2003, respectively.

For the years ended December 31, 2003 and 2002, the Company granted a total of 4,998 and 4,998, respectively, in stock options to consultants. No stock options were granted to non-employees in 2004.

In 2004, the Company entered into employment agreements with each of its executive officers. The employment agreements provide additional vesting of stock options under certain circumstances, among other benefits. The agreements provide for 12 months accelerated vesting of the executive's outstanding stock options under the applicable vesting schedules in certain circumstances, including termination by death or permanent disability. In addition, the agreements provide for automatic acceleration of unvested stock options outstanding in the event the executive's employment is terminated within three months prior to a change of control, which is in addition to the change of control provisions outlined in the stock option agreements. The Company is unable to estimate the number of options that executives will ultimately retain that otherwise would have been forfeited, absent these employment agreements, and therefore, no compensation expense has been recognized to date relating to these agreements. As of December 31, 2004, the intrinsic value of 12 months accelerated vesting and 100% vesting of unvested shares is approximately $1.6 million and $3.6 million, respectively, related to stock options outstanding for executive officers.

Employee Stock Purchase Plan

On April 1, 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. 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, 2004, the Company had issued 64,611 shares of common stock under the Purchase Plan and had 335,389 shares available for future issuance.

Shares Reserved for Future Issuance

Common stock reserved for future issuance as of December 31, 2004 and 2003 are as follows:

	December 31, 2004	December 31, 2003
Conversion of redeemable convertible and convertible preferred stock	—	19,740,759
Stock options issued and outstanding	3,890,914	2,362,757
Authorized for future issuance under equity compensation plans	2,800,579	802,770
Stock warrants outstanding	59,405	80,738
	6,750,898	22,987,024

11. 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. The Company, at its discretion, may make certain contributions to the 401(k) plan. However, through December 31, 2004 no such contributions have been made.

12. Income Taxes

Significant components of the Company's net deferred tax assets as of December 31, 2004 and 2003 are shown below. A valuation allowance of $54.1 million as of December 31, 2004 has been recognized as realization of such assets is uncertain. The valuation allowance increased by $32.4 million in 2004, primarily due to operating loss carryforwards and research and development tax credits for which management does not believe the benefit is more likely than not of being realized.

	December 31, 2004	December 31, 2003
Deferred tax assets:		
Net operating loss carryforwards	$ 41,765,000	$ 16,548,000
Research and development credits	4,011,000	2,472,000
Capitalized research and development	3,145,000	1,732,000
Depreciation and amortization	1,952,000	9,000
Accrued liabilities and other	3,207,000	909,000
Total deferred tax assets	54,080,000	21,670,000
Valuation allowance	(54,080,000)	(21,670,000)
Net deferred tax assets	$ —	$ —

As of December 31, 2004, the Company has federal and state tax net operating loss carryforwards of approximately $109.7 million and $76.3 million, respectively. The federal and state tax loss carryforwards will begin expiring in 2012 and 2007, respectively, unless previously utilized. The Company also has federal and state research and development tax credit carryforwards of approximately $3.3 million and $1.1 million, respectively. The federal research and development credit will begin to expire in 2019 unless previously utilized. The California research and development credits do not expire.

Pursuant to Sections 382 and 383 of the Internal Revenue Code, annual use of the Company's net operating loss and credit carryforwards may be limited in the event a cumulative change in ownership of more than 50% has occurred within a three-year period.

Schedule II - Valuation and Qualifying Accounts

	Balance at Beginning of Period	Additions Charged Against Revenues	Additions Charged to Costs and Expenses	Additions Charged to Asset Accounts	Deductions(1)	Balance at End of Period
Allowance for cash discounts, chargebacks and other sales discounts:						
For the year ended December 31, 2004	$ -	$ (737,935)	$ -	$ -	$ 478,034	$ (259,901)
Allowance for excess and obsolete inventory:						
For the year ended December 31, 2004	-	-	(1,420,425)	(308,155)	-	(1,728,580)
Allowance for product returns:						
For the year ended December 31, 2004	-	(7,057,208)	-	-	-	(7,057,208)

(1) Deductions under allowance for cash discounts, chargebacks and other sales discounts represent actual cash discounts, chargebacks and other sales discounts taken.

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CORPORATE INFORMATION

Board of Directors

David F. Hale
Chairman of the Board
President and Chief Executive Officer
CancerVax Corporation

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

Daniel D. Burgess
Chief Operating Officer and
Chief Financial Officer
Hollis-Eden Pharmaceuticals, Inc.

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

Rodney A. Ferguson, J.D., Ph.D.
Managing Director
JPMorgan Partners

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

Ted W. Love, M.D.
President 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

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

William C. Denby, III
Senior Vice President,
Commercial Operations

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

Bonnie Hepburn, M.D.
Senior Vice President,
Drug Development and
Chief Medical Officer

Michael D. Step
Senior Vice President,
Corporate Development

Julie A. DeMeules
Vice President, Human Resources

C. Christine Simmons, Pharm.D.
Vice President, Regulatory Affairs and
Quality Assurance

General Information

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10590 West Ocean Air Drive
Suite 200
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 the Company's
annual report on Form 10-K
is available, without charge,
upon written request to:

Investor Relations
Santarus, Inc.
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 9, 2005 at the Marriott Hotel – Del Mar, 11966 El Camino Real, San Diego, CA 92130. All stockholders are cordially invited to attend.

Market Information
The Company's common stock trades on the Nasdaq National Market under the symbol "SNTS."

Safe Harbor Statement

Any statements in this report 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, statements about difficulties or delays in development, testing, obtaining regulatory approvals, manufacturing and marketing our products; our ability to create market demand for and generate revenues from our products; the progress and timing of our clinical trials; unexpected adverse side effects or inadequate therapeutic efficacy of our products that could delay or prevent product development or commercialization, or that could result in product recalls or product liability claims; the scope and validity of patent protection for our products and our ability to commercialize our products without infringing the patent rights of others; competition from other pharmaceutical or biotechnology companies; our ability to obtain additional financing to support our operations; 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, 2004, 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.

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.

Some photographs not specifically identified in this report are solely for illustrative purposes, and are not intended to represent or portray the 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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