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

13002247

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, 2012

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.)**
3611 Valley Centre Drive, Suite 400 San Diego, California	**92130**
(Address of Principal Executive Offices)	**(Zip Code)**

(858) 314-5700
(Registrant's telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

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

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

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes ☐ No ☒

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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

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

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐ Smaller reporting company ☐
(Do not check if a smaller reporting company)

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

As of June 29, 2012, the last business day of the registrant's most recently completed second quarter, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $380.2 million, based on the closing price of the registrant's common stock on the Nasdaq Global Select Market on June 29, 2012 of $7.09 per share.*

The number of outstanding shares of the registrant's common stock, par value $0.0001 per share, as of February 15, 2013 was 63,907,327.

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, 2012 are incorporated by reference into Part III of this report.

* Excludes the common stock held by executive officers, directors and stockholders whose ownership exceeded 10% of the registrant's common stock outstanding at June 29, 2012. 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, 2012

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PART I

Forward-Looking Statements

Any statements in this report and the information incorporated herein by reference about our expectations, beliefs, plans, objectives, assumptions or future events or performance that are not historical facts are forward-looking statements. You can identify these forward-looking statements by the use of words or phrases such as "believe," "may," "could," "will," "estimate," "continue," "anticipate," "intend," "seek," "plan," "expect," "should," or "would." Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties inherent in our business including, without limitation: our ability to successfully launch Uceris™ and generate revenues from our other currently promoted commercial products and our authorized generic Zegerid® product; our ability to successfully advance the development of, obtain regulatory approval for and ultimately commercialize, our investigational drugs; our ability to maintain patent protection for our products, including the difficulty in predicting the timing and outcome of ongoing and any future patent litigation; our ability to achieve continued progress under our strategic alliances, and the potential for early termination of, or reduced payment under, these agreements; our dependence on our strategic partners for certain aspects of our development programs, including risks related to their financial stability; adverse side effects, inadequate therapeutic efficacy or other issues related to our products that could result in product recalls, market withdrawals or product liability claims; competition from other pharmaceutical or biotechnology companies and evolving market dynamics; other difficulties or delays relating to the development, testing, manufacturing and marketing of, and obtaining and maintaining regulatory approvals for, our products; fluctuations in quarterly and annual results; our ability to obtain additional financing as needed to support our operations or future product acquisitions; the impact of healthcare reform legislation and any instability in the financial markets; and other risks detailed below under Part I — Item 1A — Risk Factors.

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

Corporate Information

We were incorporated in California in December 1996 and reincorporated in Delaware in July 2002. Our principal executive offices are located at 3611 Valley Centre Drive, Suite 400, San Diego, California 92130 and our telephone number is (858) 314-5700. Our web site address is www.santarus.com. The information contained in, or that can be accessed through, our web site is not part of this report. Unless the context requires otherwise, in this report the terms "Santarus," "we," "us" and "our" refer to Santarus, Inc., a Delaware corporation, together with its consolidated subsidiary.

We own or have rights to various trademarks, copyrights and tradenames used in our business, including the following: Santarus®, Zegerid®, Glumetza®, Cycloset®, Fenoglide®, MMX® and MMX Multi-Matrix System® and Ruconest®. We have applied for trademark registration for various other names and logos, such as Uceris™. 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

We are a specialty biopharmaceutical company focused on acquiring, developing and commercializing proprietary products that address the needs of patients treated by physician specialists. The following table provides an overview of our product portfolio:

Santarus Product Portfolio	
Marketed and Approved Products	
Uceris™ (budesonide) extended release tablets (Rx – U.S.)	Marketed for the induction of remission of active, mild to moderate ulcerative colitis; phase IIIb clinical study for add-on therapy to 5-ASA drugs ongoing; commercially launched in February 2013
Zegerid® (omeprazole/sodium bicarbonate) capsules and powder for oral suspension (Rx – U.S.)	Marketed to treat certain upper gastrointestinal, or GI, conditions, including gastroesophageal reflux disease; capsule formulation is also distributed as authorized generic
Glumetza® (metformin hydrochloride extended release tablets) (Rx – U.S.)	Marketed as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes
Cycloset® (bromocriptine mesylate) tablets (Rx – U.S.)	Marketed as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes
Fenoglide® (fenofibrate) tablets (Rx – U.S.)	Marketed as an adjunct to diet to treat high cholesterol
Investigational Drugs	
Ruconest® (recombinant human C1 esterase inhibitor) (Rx – U.S., Canada and Mexico)	Positive top-line phase III clinical study results for treatment of acute attacks of angioedema in patients with hereditary angioedema announced in November 2012; BLA submission to FDA planned during the second quarter of 2013
Rifamycin SV MMX® (Rx – U.S.)	Positive top-line phase III clinical study results for treatment of travelers' diarrhea announced in September 2012; second phase III clinical study in same indication being conducted by Dr. Falk Pharma
SAN-300 (anti-VLA-1 mAb) (Rx – Worldwide)	Phase I clinical study completed in December 2012 in healthy volunteers; phase IIa clinical study for treatment of rheumatoid arthritis planned to begin during the fourth quarter of 2013
Strategic Alliances	
Merck Zegerid OTC® (OTC – U.S.)	Marketed for treatment of frequent heartburn
GlaxoSmithKline Immediate-release Omeprazole products (Rx and OTC – Specified Ex-U.S. countries)	Marketed in Mexico, Ecuador, Kenya, Nigeria, French W. Africa and Tanzania to treat certain upper GI conditions; regulatory submissions made in certain Latin American, African and Asian countries; preparation of additional regulatory filings ongoing

Marketed and Approved Products

Our commercial organization currently promotes the following products in the U.S. prescription pharmaceutical market:

- Uceris (budesonide) extended release tablets is available in 9 mg tablets and is a locally acting corticosteroid in an oral tablet formulation that utilizes proprietary multi-matrix system, or MMX, colonic delivery technology. Uceris is indicated for the induction of remission in patients with active, mild to moderate ulcerative colitis.

- Zegerid (omeprazole/sodium bicarbonate) capsules and powder for oral suspension is available in 20 mg and 40 mg dosage strengths and is a proprietary immediate-release formulation of the proton pump inhibitor, or PPI, omeprazole. Zegerid is indicated for short-term treatment of active duodenal ulcer, short-term treatment of active benign gastric ulcer, treatment of gastroesophageal reflux disease, or GERD, maintenance of healing of erosive esophagitis and reduction of risk of upper gastrointestinal, or GI, bleeding in critically ill patients. In addition, we receive a significant percentage of the gross margin on sales of an authorized generic version of Zegerid capsules.

- Glumetza (metformin hydrochloride extended release tablets) is available in 500 mg and 1000 mg tablets and is a once-daily, extended-release formulation of metformin that incorporates patented drug delivery technology. Glumetza is indicated as an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 diabetes.

- Cycloset (bromocriptine mesylate) tablets is available in 0.8 mg tablets and is a novel formulation of bromocriptine, a dopamine receptor agonist that acts on the central nervous system. Cycloset is indicated as an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 diabetes.

- Fenoglide (fenofibrate) tablets is available in 40 mg and 120 mg tablets and is a proprietary formulation of fenofibrate that incorporates patented drug delivery technology. Fenoglide is indicated as an adjunct to diet to reduce elevated low-density lipoprotein-cholesterol, or LDL-C, total cholesterol, triglycerides and apolipoprotein B, or Apo B, and to increase high-density lipoprotein-cholesterol, or HDL-C, in adult patients with primary hyperlipidemia or mixed dyslipidemia. Fenoglide also is indicated as an adjunct to diet for treatment of adult patients with hypertriglyceridemia.

Investigational Drugs

In addition to our commercial products, we are focused on advancing the following investigational drugs to commercialization:

- Ruconest (recombinant human C1 esterase inhibitor) is a recombinant version of the human protein C1 esterase inhibitor, which is produced using proprietary transgenic technology. In November 2012, we announced positive top-line results from the phase III clinical study to evaluate the safety and efficacy of Ruconest for the treatment of acute attacks of angioedema in patients with hereditary angioedema, or HAE. We plan to submit a biologics license application, or BLA, to the U.S. Food and Drug Administration, or FDA, during the second quarter of 2013, seeking approval to market Ruconest for this indication.

- Rifamycin SV MMX is a broad spectrum, non-systemic antibiotic in a novel oral tablet formulation, which utilizes proprietary MMX colonic delivery technology. In September 2012, we announced positive top-line results from the first phase III clinical study to evaluate the safety and efficacy of rifamycin SV MMX for the treatment of patients with travelers' diarrhea. Dr. Falk Pharma GmbH, or Dr. Falk, is currently conducting a second phase III clinical study evaluating rifamycin SV MMX for the treatment of travelers' diarrhea.

- SAN-300 (anti-VLA-1 antibody) is a novel early stage anti-VLA-1 monoclonal antibody, or mAb, investigational drug that we initially expect to develop for the treatment of rheumatoid arthritis. In

December 2012, we completed a phase I dose-escalation clinical study in healthy volunteers to determine the safety, tolerability, pharmacokinetics and pharmacodynamics of single doses of SAN-300. We plan to begin a phase IIa clinical study evaluating SAN-300 for treatment of rheumatoid arthritis during the fourth quarter of 2013.

Strategic Alliances

To leverage our PPI technology and diversify our sources of revenue, we have licensed certain exclusive rights to MSD Consumer Products, Inc., a subsidiary of Merck & Co., Inc., or Merck, to develop, manufacture and sell over-the-counter, or OTC, Zegerid products in the U.S. and Canada. We have also licensed certain exclusive rights to our PPI technology to Glaxo Group Limited, an affiliate of GlaxoSmithKline, plc, or GSK, to develop, manufacture and commercialize prescription and OTC immediate-release omeprazole products in more than 100 specified countries (including markets within Africa, Asia, the Middle-East, and Latin America).

Strategy

Our goal is to be recognized as a premier specialty biopharmaceutical company with a successful record of developing and commercializing differentiated proprietary products that address unmet patient needs while delivering revenue and earnings growth. We are focused on maintaining a balanced portfolio with marketed products and investigational drugs for indications managed by specialist physicians in endocrinology, gastroenterology, allergy/immunology, and rheumatology. In addition, we will make investments in research and development and selling, general and administrative expenses to achieve meaningful, sustainable growth in revenues and profits. Key elements of our business strategy include the following:

- ***Successfully Launching Uceris and Increasing Sales of Our Other Promoted Prescription Products.*** Our commercial resources are focused on successfully launching Uceris and increasing market demand for, and sales of, our other promoted prescription products. Our field sales organization currently promotes and sells these products to gastroenterologists, endocrinologists and other selected physicians. We believe that these products offer differentiated treatment options and represent attractive commercial opportunities.

- ***Advancing Our Investigational Drugs to Commercialization and Maximizing the Value of Our Overall Product Portfolio.*** In addition, we are focused on advancing our investigational drugs to commercialization, and on maximizing the value of our overall product portfolio by pursuing new formulations or indications for our existing products. We believe these investigational drugs have the potential to offer unique features and benefits to address unmet medical needs of patients treated by physician specialists.

- ***Expanding Our Product Portfolio.*** We are also focused on further expanding our product portfolio through co-promotion, in-licensing or acquisition of products that would be complementary to our existing products or that otherwise have attractive commercial potential.

Marketed and Approved Products

Uceris (budesonide) Extended Release Tablets

Uceris (budesonide) extended release tablets 9 mg is a locally acting corticosteroid in an oral tablet formulation that utilizes proprietary MMX colonic delivery technology. Uceris is indicated for the induction of remission in patients with active, mild to moderate ulcerative colitis. The Uceris formulation is designed to release budesonide throughout the entire length of the colon, targeting delivery to the site of action for ulcerative colitis. In addition, Uceris is designed to provide an attractive safety profile, with no clinically significant differences in glucocorticoid-related side effects between Uceris and placebo being noted after 8 weeks to 12 months of treatment during the phase III clinical program. We have rights to commercialize Uceris in the U.S. under a strategic collaboration with Cosmo Technologies Limited, or Cosmo, as further described below. We received FDA approval of Uceris in January 2013 and commercially launched this product in February 2013.

In connection with receipt of FDA approval of Uceris, we committed to a post-marketing requirement to conduct an 8-week randomized clinical study in children 5 to 17 years of age with active, mild to moderate ulcerative colitis. We currently plan to submit the protocol for this study later this year and expect to initiate the study once we have reached agreement with the FDA on the study design.

In addition, in February 2012 we began patient enrollment in a multicenter, randomized, double-blind placebo-controlled phase IIIb clinical study evaluating whether there is an incremental benefit when Uceris 9 mg is added to current oral aminosalicylate, or 5-ASA, therapy for patients with active, mild to moderate ulcerative colitis who are not adequately controlled on background 5-ASA therapy. The phase IIIb study is evaluating patients with active, mild to moderate ulcerative colitis who continue using their current 5-ASA treatment regimen and for an 8 week period will add either Uceris 9 mg or placebo administered once daily. We expect to enroll approximately 500 patients, with 250 in each treatment arm, at clinical sites in the U.S., Canada and Europe. We expect to complete patient enrollment in the phase IIIb study in mid-2013.

In February 2013, we submitted a citizen petition to the FDA requesting that the FDA (1) develop and publish an individual bioequivalence recommendation for budesonide extended release tablets and (2) refrain from approving any abbreviated new drug application, or ANDA, that identifies Uceris as the reference listed drug unless the generic product is shown to be bioequivalent based on appropriate data from a clinical efficacy endpoint study, comparative pharmacokinetic testing, in vitro dissolution testing, and pharmacoscintigraphy studies. We cannot predict when or if the FDA will respond to, or otherwise take any action with respect to, the citizen petition.

Currently, there are four issued U.S. patents that we believe provide coverage for Uceris, with expiration dates in 2020. Additional information about the intellectual property for Uceris is set forth below under the heading "Business – Intellectual Property – Uceris."

Inflammatory Bowel Disease and Ulcerative Colitis

According to the prevalence statistics provided by the Crohn's & Colitis Foundation of America, inflammatory bowel disease, or IBD, affects an estimated 1.4 million Americans. Ulcerative colitis and Crohn's disease are the two main forms of IBD. Ulcerative colitis is a chronic form of IBD characterized by inflammation of the lining of the colon. According to the Crohn's & Colitis Foundation of America, as many as 700,000 people in the U.S. suffer from ulcerative colitis. Symptoms of active ulcerative colitis include rectal bleeding, abdominal pain, increased stool frequency, loss of appetite, fever and weight loss. The cause of ulcerative colitis is unknown and no known cure exists. Treatments for ulcerative colitis are aimed at inducing and maintaining remission of inflammation and its symptoms.

Strategic Collaboration with Cosmo

In December 2008, we entered into a strategic collaboration with Cosmo, including a license agreement, stock issuance agreement and registration rights agreement, under which we were granted exclusive rights in the U.S. to develop and commercialize Uceris and rifamycin SV MMX, an investigational drug described further below under the heading, "Business – Investigational Drugs – Rifamycin SV MMX."

License Agreement

Under the license agreement, Cosmo granted us the exclusive right to develop, market and commercialize Uceris and rifamycin SV MMX in the U.S. As upfront consideration, we issued 6,000,000 shares of our common stock and made a cash payment of $2.5 million to Cosmo. In addition, following the completion of the phase III studies for Uceris, Cosmo elected to receive payment of a $3.0 million clinical milestone through the issuance of 972,132 shares of our common stock. Following FDA acceptance for filing of the new drug application, or NDA, for Uceris, Cosmo elected to receive payment of a $4.0 million regulatory milestone through the issuance of 906,412 shares of our common stock. Following the first commercial sale of Uceris which occurred in February 2013, Cosmo has the option to elect, on or before April 15, 2013, whether to receive payment of a $7.0 million commercial milestone in cash or through the issuance of 565,793 shares of our common stock. We may also be required to pay Cosmo commercial milestones of up to $22.5 million for Uceris and $28.0 million for rifamycin SV MMX. In addition, we may also be required to pay Cosmo an additional $2.0 million regulatory milestone for the initial indication for

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

We will be required to pay tiered royalties to Cosmo equal to 12% (on annual net sales of each licensed product up to $120 million) and 14% (on annual net sales of each licensed product in excess of $120 million). Such royalties are subject to reduction in certain circumstances, including in the event of market launch in the U.S. of a generic version of a licensed product. Our obligation to pay the specified royalties under the license agreement will continue for the life of the relevant patents (including certain patent applications) covering each licensed product. Following that period, the parties have agreed to negotiate in good faith a reduced royalty arrangement for the continued use of Cosmo's know-how and trademarks related to the licensed products.

We were responsible for one-half of the total out-of-pocket costs associated with the Uceris phase III clinical program and for all of the out-of-pocket costs for the rifamycin SV MMX phase III U.S. registration study. We are also responsible for all of the out-of-pocket costs for the ongoing Uceris phase IIIb clinical study. In the event that additional clinical work is required to obtain U.S. regulatory approval for rifamycin SV MMX, the parties will agree on cost sharing. Cosmo is responsible for any additional pre-clinical costs for rifamycin SV MMX and for any product development and scale-up costs for either of the licensed products.

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

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

Cosmo is responsible for manufacturing and supplying all of our drug product requirements during the term of the license agreement, and we and Cosmo have entered into a separate commercial supply agreement for Uceris.

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

Stock Issuance Agreement/Registration Rights Agreement

As described above, we have issued to Cosmo a total of 7,878,544 shares of our common stock as upfront consideration and as milestone payments. We will make additional payments to Cosmo upon the achievement of certain development and commercial milestones, which milestones may be paid in cash or through issuance of additional shares of common stock, at Cosmo's option. Our obligation to issue additional shares of common stock to Cosmo upon the achievement of one or more milestones is subject to certain limitations, including that the total number of shares of common stock issued to Cosmo shall not exceed 10,300,000 shares. Any such additional shares to be issued will be valued at the average daily closing price of the common stock as reported on the Nasdaq Global Market for the 30 consecutive trading days ending on the day immediately prior to the achievement of the applicable milestone. For the six months following the issuance of any shares of common stock upon achievement of milestones, Cosmo has agreed that it will not transfer or dispose of any such issued shares.

Under the terms of the registration rights agreement, as amended, we filed resale registration statements on Form S-3 with the Securities and Exchange Commission, or SEC, to register the resale of the shares we have issued to Cosmo. We are obligated to file additional registration statements for any additional shares issued to Cosmo under

the stock issuance agreement and to use best efforts to have any such registration statements declared effective by the SEC.

Zegerid Capsules and Zegerid Powder for Oral Suspension

Zegerid (omeprazole/sodium bicarbonate) 20 mg and 40 mg capsules and powder for oral suspension is an immediate-release formulation of the PPI omeprazole and is indicated for short-term treatment of active duodenal ulcer, short-term treatment of active benign gastric ulcer, treatment of GERD, maintenance of healing of erosive esophagitis and reduction of risk of upper GI bleeding in critically ill patients. Zegerid is designed to provide long-lasting acid control in an immediate-release formulation. We acquired rights to our immediate-release PPI technology under a license agreement with the University of Missouri, as further described below.

We determined in late June 2010 to cease promotion of the Zegerid products in connection with the launch of a generic version of Zegerid capsules that occurred after an April 2010 lower court decision that the patents covering our Zegerid products were invalid due to obviousness. At this same time, we also launched an authorized generic version of our Zegerid capsules product under a distribution and supply agreement with Prasco LLC, or Prasco, as further described below. In September 2012, the U.S. Court of Appeals for the Federal Circuit reversed in part the April 2010 decision of the lower court and found that certain of the asserted patent claims were not invalid. In December 2012, the Federal Circuit issued an order denying a combined petition for panel and en banc rehearing filed by Par Pharmaceutical, Inc., or Par, and issued its mandate, remanding the case to the lower court for further proceedings pertaining to damages. Following the Federal Circuit's decision and subsequent denials of a petition for rehearing, we resumed promotion of Zegerid in February 2013.

In connection with the approval of Zegerid powder for oral suspension, we committed to commence clinical studies to evaluate the product in pediatric populations. We have not yet commenced any of the studies and have requested a waiver of this requirement from the FDA.

Currently, there are three issued U.S. patents that we believe provide coverage for Zegerid, with expiration dates in 2016. Additional information about the intellectual property for Zegerid, including ongoing patent infringement litigation, is set forth below under the heading "Business – Intellectual Property – Zegerid and Pending Patent Litigation."

Upper Gastrointestinal Diseases and Disorders

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

- Heartburn is pain or a burning sensation in the throat or chest area resulting from the reflux of acid from the stomach into the esophagus. An individual consistently experiencing heartburn at least twice per week is generally diagnosed as having GERD. It has been demonstrated that more than 61 million American adults report GERD-related symptoms at least once a week.

- Erosive esophagitis is characterized by erosions and ulcers from the repeated exposure of the esophagus to acid and digestive enzymes. It is estimated that as many as 30% of GERD patients, or approximately 16 million patients, have erosive esophagitis in the U.S.

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

Exclusive License Agreement with the University of Missouri

In January 2001, we entered into an exclusive, worldwide license agreement with the University of Missouri for patents and pending patent applications relating to specific formulations of PPIs with antacids and other buffering agents and methods of using these formulations. Pursuant to the terms of the license agreement, we paid the University of Missouri an upfront licensing fee of $1.0 million in 2001, a one-time $1.0 million milestone fee in 2003 following the filing of our first NDA and a one-time $5.0 million milestone fee in July 2004 following the FDA's approval of Zegerid powder for oral suspension 20 mg. We are required to make additional milestone payments to the University of Missouri upon initial commercial sale in specified territories outside the U.S., which may total up to $3.5 million in the aggregate. We are also required to make milestone payments, up to a maximum of $86.3 million, based on first-time achievement of significant sales thresholds, the first of which was a one-time $2.5 million milestone payment upon initial achievement of $100.0 million in annual calendar year net product sales, which was paid to the University of Missouri in the first quarter of 2009, and the next of which is a one-time $7.5 million milestone payment upon initial achievement of $250.0 million in annual calendar year net product sales. We are also obligated to pay mid-single digit royalties to the University of Missouri on net sales of our products and any products sold by Prasco, Merck and GSK under our existing license and distribution agreements. 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.

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

Distribution and Supply Agreement with Prasco

In April 2010, as part of our contingency plan to prepare for a possible launch of a generic version of our Zegerid prescription products, we entered into a distribution and supply agreement with Prasco that granted Prasco the right to distribute and sell an authorized generic version of our Zegerid prescription products in the U.S. As described above, Prasco initiated sales of an authorized generic version of Zegerid capsules in late June 2010. Under the terms of the distribution and supply agreement, which was amended in November 2012, Prasco is obligated to use commercially reasonable efforts to distribute and sell such products in the U.S. Prasco agreed to purchase all of its authorized generic product requirements from us and pays us a specified invoice supply price for such products. Prasco is also obligated to pay us a significant percentage of the gross margin on sales of the authorized generic products.

The term of the distribution and supply agreement will continue until June 2015, five years after the date of launch of the first authorized generic product, with automatic one year renewals thereafter unless either party elects not to renew by giving notice at least six months prior to the expiration of the applicable renewal period. The distribution and supply agreement may also be terminated under certain other specified circumstances. We may terminate the distribution and supply agreement with respect to any of the covered products not yet launched at any time prior to the first commercial sale of such product or upon 30 days' prior written notice in the event that a competitive product that was previously launched is no longer available. In addition, we may terminate the distribution and supply agreement with regard to Zegerid capsules upon 30 days' prior written notice (a) at any time after May 30, 2013, in the event that we determine to cease distribution and sales of an authorized generic version of Zegerid capsules or (b) in connection with any settlement of patent litigation relating to Zegerid capsules, subject to certain obligations to mitigate certain penalties that Prasco may incur in limited situations. We may also terminate the agreement for any reason upon nine months' prior written notice.

Prasco may terminate the distribution and supply agreement with respect to a particular product if we fail to deliver a commencement notice with respect to such product within 60 days after the launch of a competitive

product, or if we fail to deliver launch quantities of the applicable product to Prasco and such failure prevents Prasco from making the first commercial sale of such product within such 60-day period. Prasco may also terminate the agreement if Prasco's net selling price of a licensed product decreases to less than a specified percentage above the invoice supply price for such product and we do not correspondingly reduce the invoice supply price.

In addition, either party may terminate the distribution and supply agreement in the event of the other party's uncured material breach or bankruptcy or insolvency, or if the licensed products are withdrawn from the U.S. market. In the event of termination, the rights granted by us to Prasco associated with the authorized generic products will cease.

Glumetza (metformin hydrochloride extended release tablets)

Glumetza (metformin hydrochloride extended release tablets) is a once-daily, extended-release formulation of metformin in 500 mg and 1000 mg dosage strengths that incorporates patented drug delivery technology and is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. Metformin is one of the most commonly prescribed oral medications for the treatment of type 2 diabetes, and it is used to improve glycemic control in patients with diabetes. The extended-release delivery system is designed to offer patients with type 2 diabetes an ability to reach their optimal dose of metformin with fewer GI side effects. We began promoting the Glumetza products in October 2008 under an exclusive promotion agreement entered into with Depomed, Inc., or Depomed. In August 2011, we entered into a new commercialization agreement with Depomed under which we assumed broader commercial, manufacturing and regulatory responsibilities for Glumetza, as further described below.

Currently, there are four issued U.S. patents that are owned or licensed by Depomed that we believe provide coverage for the Glumetza 500 mg dose product, with expiration dates in 2016, 2020 and 2021. There are three issued U.S. patents that are owned or licensed by Depomed that we believe provide coverage for the Glumetza 1000 mg dose product, with expiration dates in 2020 and 2025. In connection with settlement agreements entered into in February 2012 and January 2013, a first generic filer was granted the right to begin selling a generic version of Glumetza in February 2016 and a subsequent generic filer was granted the right to begin selling a generic version of Glumetza in August 2016. Additional information about the intellectual property for Glumetza, including ongoing patent infringement litigation, is set forth below under the heading "Business – Intellectual Property – Glumetza and Pending Patent Litigation."

Type 2 Diabetes

Type 2 diabetes is the most common form of diabetes, accounting for 90% to 95% of all diagnosed diabetes cases, according to the National Institute of Diabetes and Digestive and Kidney Diseases of the National Institutes of Health. Diabetes is a disease in which levels of glucose, a type of sugar found in the blood, are above normal. Over time, high blood glucose levels damage nerves and blood vessels, which can lead to complications such as heart disease, stroke, blindness, kidney disease and nerve problems. According to the Centers for Disease Control and Prevention, approximately 26 million people in the U.S. have diabetes.

Commercialization Agreement with Depomed

In August 2011, we entered into a commercialization agreement with Depomed granting us exclusive rights to manufacture and commercialize Glumetza prescription products in the U.S., including its territories and possessions and Puerto Rico. The commercialization agreement replaced an existing promotion agreement between the parties entered into in July 2008, pursuant to which we have promoted Glumetza in the U.S.

Under the commercialization agreement, primary responsibility for manufacturing, distribution, pharmacovigilance and regulatory affairs has been transitioned to us and we have assumed sole decision-making authority on pricing, contracting and promotion for Glumetza. In addition, we will continue to be responsible for advertising and promotional activities for Glumetza in the U.S. We began distributing and recording product sales for Glumetza under this new arrangement in September 2011.

We were required to pay to Depomed royalties on net product sales in the territory of 26.5% in 2011 and 29.5% in 2012, and we are required to pay to Depomed royalties on net product sales in the territory of 32.0% in 2013 and 2014 and 34.5% in 2015 and beyond prior to generic entry of a Glumetza product. We have the exclusive right to commercialize authorized generic versions of the Glumetza products. In the event of generic entry of a Glumetza product in the territory, the parties will equally share proceeds based on a gross margin split. We will pay no additional sales milestones to Depomed, as was required under the prior promotion agreement. In addition, starting in 2012, we reduced minimum marketing expenditures and sales force promotion obligations during the term of the commercialization agreement until such time as a generic to Glumetza enters the market.

Pursuant to the terms of the commercialization agreement, Depomed has the option to co-promote Glumetza products to physicians other than those we call on, subject to certain limitations. If Depomed exercises this right, it will be entitled to receive a royalty equal to 70% of net sales attributable to prescriptions generated by its called on physicians over a pre-established baseline.

During the term of the commercialization agreement, neither party is permitted to, directly or indirectly, develop, promote, market or sell in the territory any single agent metformin products for human use, other than the Glumetza and authorized generic products covered by the commercialization agreement. We also have exclusive rights to use the Glumetza trademark in the territory.

The commercialization agreement provides for a right of first negotiation in favor of us in the event that Depomed desires to grant rights to a third party to develop or commercialize a pharmaceutical product containing Depomed's proprietary drug delivery technology in combination with metformin and any other generic active pharmaceutical ingredient.

The commercialization agreement will continue in effect for so long as we commercialize branded Glumetza or authorized generic products, unless terminated sooner. Subject to 120 days' prior written notice to Depomed, we have the right to terminate the agreement at any time. Subject to 60 days' prior written notice to us, Depomed may terminate the agreement if we fail to meet our obligations with respect to minimum promotion and expenditure obligations and fail to cure such breach within a specified time period. 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 a force majeure event prevents the other party from carrying out its material obligations under the agreement for a period of at least six months. Finally, either party may terminate the agreement if the other party becomes insolvent, files or consents to the filing of a petition under any bankruptcy or insolvency law or has any such petition filed against it, and within a specified time period, such filing has not been dismissed.

Cycloset (bromocriptine mesylate) Tablets

Cycloset (bromocriptine mesylate) 0.8 mg tablets is a novel formulation of bromocriptine, and is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes both as mono-therapy and in combination with other oral antidiabetic agents. Bromocriptine is a dopamine receptor agonist, and Cycloset is the first FDA-approved drug for patients with type 2 diabetes to target the activity of dopamine, a chemical messenger between neurons within the central nervous system. Although unknown, Cycloset's proposed mechanism of action is based on the observation that low morning levels of dopamine in the hypothalamus may lead to glucose and lipid dysregulation. In addition, in a 3,000 patient clinical study, Cycloset was shown to improve glycemic control without increasing cardiovascular event risk. We began promoting Cycloset in November 2010 under a distribution and license agreement with S2 Therapeutics, Inc., or S2, and VeroScience, LLC, or VeroScience, as further described below.

Currently, there are three issued U.S. patents that we have licensed from S2 and VeroScience that we believe provide coverage for Cycloset, with expiration dates in 2014, 2015 and 2023. Additional information about the intellectual property for Cycloset is set forth below under the heading "Business – Intellectual Property – Cycloset."

Distribution and License Agreement with S2 and VeroScience

In September 2010, we entered into a distribution and license agreement with S2 and VeroScience granting us exclusive rights to manufacture and commercialize the Cycloset prescription product in the U.S., subject to the right of S2 to co-promote Cycloset as described below. Under the terms of the distribution and license agreement, we paid S2 and VeroScience an upfront fee totaling $5 million. We record sales of Cycloset and pay a product royalty to S2 and VeroScience of 35% of the gross margin associated with net sales of Cycloset up to $100 million of cumulative total gross margin, increasing to 40% thereafter. Gross margin is defined as net sales less cost of goods sold. In the event net sales of Cycloset exceed $100 million in a calendar year, we will pay an additional 3% of the gross margin to S2 and VeroScience on incremental net sales over $100 million.

We are responsible for overseeing the manufacturing and distribution of Cycloset, and accordingly, S2's agreements relating to the manufacture of Cycloset were assigned to us. We are also responsible for all costs associated with our sales force and for all other sales and marketing-related expenses associated with our promotion of Cycloset. S2 retains the right to co-promote Cycloset at its sole cost and expense under the same trademark in portions of the U.S. where we are not actively promoting Cycloset. VeroScience, the holder of the U.S. regulatory approval for Cycloset, is responsible for overseeing regulatory matters. A joint steering committee consisting of representatives from the three companies has been formed to share information concerning the Cycloset development, manufacturing and promotion efforts in the U.S.

We have agreed not to manufacture or commercialize, directly or indirectly, any product containing bromocriptine or bromocriptine mesylate as an active ingredient in the U.S. during the term of the distribution and license agreement and ending on the earlier of 12 months following the end of the term or the first commercial sale of a generic product, as defined in the agreement. S2 and VeroScience have both agreed not to commercialize, directly or indirectly, any product containing bromocriptine or bromocriptine mesylate as an active ingredient in the U.S. for the treatment of type 2 diabetes during the term of the agreement and ending on the earlier of the end of the term or the first commercial sale of a generic product, other than in certain specified circumstances.

The distribution and license agreement will continue in effect until we cease to market or sell Cycloset in the U.S., unless terminated sooner. We may terminate the agreement at any time subject to 120 days' prior written notice. We may also terminate the agreement immediately in specified circumstances relating to a significant recall or market withdrawal of Cycloset, in the event of certain regulatory or governmental actions that would prevent us from performing our obligations under the agreement or in the event of FDA approval of a third party ANDA for an "AB" rated equivalent of Cycloset. Either us on the one hand or S2 and VeroScience on the other hand may terminate the agreement in the following circumstances: (a) if the other party fails to perform any material term of the agreement and fails to cure such breach, subject to prior written notice within a specified time period; (b) if a force majeure event prevents the carrying out of material obligations of the other party under the agreement for a period of at least six months; or (c) upon the insolvency or occurrence of other specified bankruptcy events.

Fenoglide (fenofibrate) Tablets

Fenoglide (fenofibrate) 40 mg and 120 mg tablets is a proprietary formulation of fenofibrate and is indicated as an adjunct to diet to reduce elevated LDL-C, total cholesterol, triglycerides and Apo B, and to increase HDL-C, in adult patients with primary hyperlipidemia or mixed dyslipidemia. Fenoglide also is indicated as an adjunct to diet for treatment of adult patients with hypertriglyceridemia. We began promoting Fenoglide in February 2012, under the terms of a license agreement with Healthcare Royalty Partners, L.P., or HRP, and Shore Therapeutics, Inc., or Shore, as further described below.

Currently, there are two issued U.S. patents that we believe provide coverage for the Fenoglide products, with expiration dates in 2024. In connection with a settlement agreement entered into in December 2011, Shore granted the first generic filer the right to begin selling a generic version of Fenoglide in October 2015. Additional information about the intellectual property for Fenoglide, including ongoing patent infringement litigation, is set forth below under the heading "Business – Intellectual Property – Fenoglide and Pending Patent Litigation."

High Cholesterol

High cholesterol is one of the major controllable risk factors for coronary heart disease, heart attack and stroke. As blood cholesterol rises, so does the risk of coronary heart disease. When too much LDL-C, or "bad" cholesterol, circulates in the blood, it can slowly build up in the inner walls of the arteries that feed the heart and brain. Together with other substances, it can form plaque, a thick, hard deposit that can narrow the arteries and make them less flexible. This condition is known as atherosclerosis. If a clot forms and blocks a narrowed artery, a heart attack or stroke can result. According to the American Heart Association, cardiovascular disease is the number one cause of death in the U.S., and it is estimated that approximately 2,200 Americans die of cardiovascular disease each day. High cholesterol is one of the co-morbid conditions frequently associated with type 2 diabetes.

License Agreement with HRP and Shore

In December 2011, we entered into a license agreement with HRP and Shore, granting us exclusive rights to commercialize Fenoglide prescription products in the U.S. In partial consideration of the licenses and rights granted under the license agreement, we paid Shore an $11 million upfront fee. In addition, we are obligated to pay Shore tiered royalties on net sales of Fenoglide. The royalties are 5% on net sales of up to $10 million (commencing in 2013), a 20% royalty on net sales between $10 million and $20 million, and a 25% royalty on net sales above $20 million. We will also be obligated to pay Shore one-time, success-based milestones contingent on sales achievement: $2 million if calendar year net sales equal or exceed $20 million and $3 million if calendar year net sales equal or exceed $30 million.

Under the terms of the license agreement, we are responsible for commercial, manufacturing and regulatory activities for Fenoglide. In connection with the assumption of these responsibilities, Shore's existing agreements relating to the manufacture and supply of Fenoglide, as well as existing inventory, have been assigned to us. Shore is financially responsible for returns of Fenoglide sold or distributed prior to the effective date of the license agreement, and for Fenoglide rebates, chargeback claims and discount or savings card redemptions pursuant to agreements in effect prior to the effective date. We are responsible for all other Fenoglide returns, rebates, chargebacks and discount or savings card redemptions.

We have agreed to use commercially reasonable efforts to commercialize Fenoglide within the U.S. In addition, prior to the entry of any generic version of Fenoglide, we are required to provide certain minimum detailing efforts and sales and marketing expenditures.

During the term of the license agreement, Shore is not permitted to, directly or indirectly, develop, manufacture or commercialize any fenofibrate products for human use in the U.S., and HRP is not permitted to, directly or indirectly, develop, manufacture or commercialize Fenoglide for human use in the U.S. We also have exclusive rights to use the Fenoglide trademark in the U.S.

The license agreement will remain in effect until we cease to commercialize licensed products in the U.S., unless terminated sooner. Subject to 180 days' prior written notice to Shore, we may terminate the license agreement at any time. Under certain circumstances following the introduction of a generic version of Fenoglide, we may also terminate the agreement upon 90 days' prior written notice to Shore in the event we elect to cease sales of licensed products. Either we or Shore may terminate the agreement in the following circumstances: (a) if the other party fails to perform any material term of the agreement and fails to cure such breach, subject to prior written notice within a specified time period; or (b) upon the insolvency or occurrence of other specified bankruptcy events.

Investigational Drugs

Ruconest (recombinant human C1esterase inhibitor)

Ruconest is a recombinant version of the human protein C1 esterase inhibitor, which is produced using proprietary transgenic technology. Ruconest was granted orphan drug designation by the FDA for the treatment of acute attacks of angioedema in patients with HAE. We have rights to commercialize Ruconest in North America under a license agreement with Pharming Group NV, or Pharming, as further described below.

In November 2012, we announced that when compared with placebo, Ruconest demonstrated a significantly shorter time to beginning of relief of symptoms, the primary endpoint, in a pivotal phase III clinical study that was conducted to evaluate the safety and efficacy of Ruconest 50 IU/kg for the treatment of acute attacks of angiodema in patients with HAE. The time to beginning of symptom relief was defined as the time from the beginning of infusion of study medication (Ruconest or placebo) until the beginning of a persistent beneficial effect, based on the patients' responses to a treatment effect questionnaire for the primary attack location. The study was conducted under a protocol agreed with the FDA through the special protocol assessment, or SPA, process. In the study, a statistically significant difference in the time to beginning of symptom relief was observed between Ruconest (n=44) and placebo (n=31) in the intent-to-treat (ITT) population (n=75), which included all randomized patients (p=0.031). In addition, Ruconest was generally well tolerated in the phase III clinical study and the frequency of patients experiencing at least one treatment emergent adverse event in the Ruconest treated group was less than in the placebo group.

The positive results from the phase III study are consistent with the efficacy data previously reported from two smaller randomized, controlled clinical studies with Ruconest in patients with HAE. We plan to submit a BLA to the FDA during the second quarter of 2013, seeking approval to market Ruconest for the treatment of acute attacks of angioedema in patients with HAE.

We currently are exploring clinical and regulatory strategies with the goal of initiating a proof-of-concept study in late 2013 to evaluate Ruconest for the treatment of acute pancreatitis.

Currently, there are two issued U.S. patents that we believe provide coverage for the Ruconest investigational drug, with expiration dates in 2022 and 2024. In addition, we believe Ruconest, as a biological product, is entitled under the Patient Protection and Affordable Care Act, or PPACA, to a period of 12 years of data exclusivity. Additional information about the intellectual property for the Ruconest product is set forth below under the heading "Business – Intellectual Property – Ruconest."

Hereditary Angioedema

HAE is a genetic disorder in which the patient is deficient in or lacks a functional plasma protein C1 inhibitor, resulting in unpredictable and debilitating episodes of intense swelling of the extremities, face, trunk, genitals, abdomen and upper airway. The frequency and severity of HAE attacks vary and are most serious when they involve laryngeal edema, which can close the upper airway and cause death by asphyxiation. According to the U.S. Hereditary Angioedema Association, epidemiological estimates for HAE range from one in 10,000 to one in 50,000 individuals.

License and Supply Agreements with Pharming

In September 2010, we entered into a license agreement and a supply agreement with Pharming, under which we were granted certain non-exclusive rights to develop and manufacture, and certain exclusive rights to commercialize Ruconest in the U.S., Canada and Mexico for the treatment of HAE and other future indications, as further described below.

License Agreement

Under the license agreement, Pharming granted us the non-exclusive rights to develop and manufacture and the exclusive right to commercialize licensed products in the U.S., Canada and Mexico.

In partial consideration of the licenses granted under the license agreement, we paid Pharming a $15 million upfront fee. In addition, in November 2012 we paid Pharming a $10 million milestone following successful achievement of the primary endpoint of the phase III clinical study. We may also be required to pay Pharming additional success-based regulatory and commercial milestones totaling up to an aggregate of $25 million, including a $5 million milestone upon FDA acceptance for review of a BLA for Ruconest and a $20 million milestone upon the earlier of first commercial sale of Ruconest in the U.S. or 90 days following receipt of FDA approval. In addition, we will be required to pay the following one-time performance milestones if we achieve certain aggregate net sales levels of Ruconest: a $20 million milestone if calendar year net sales exceed $300 million and a $25

million milestone if calendar year net sales exceed $500 million. As consideration for the licenses and rights granted under the license agreement, and as compensation for the commercial supply of Ruconest by Pharming pursuant to the supply agreement described below, we will pay Pharming a tiered supply price, based on a percentage of net sales of Ruconest, subject to reduction in certain events, as follows: 30% of net sales less than or equal to $100 million, 32% of net sales greater than $100 million but less than or equal to $250 million, 34% of net sales greater than $250 million but less than or equal to $500 million, 37% of net sales greater than $500 million but less than or equal to $750 million, and 40% of net sales greater than $750 million.

Under the license agreement, Pharming was responsible for conducting the phase III clinical study for Ruconest for the treatment of acute attacks of angioedema in patients with HAE and all costs of such clinical development. We are working together with Pharming to prepare the BLA for this indication for submission to the FDA. We will be responsible for seeking regulatory approval for this indication in the U.S., Canada and Mexico.

Either party may propose the development of Ruconest for additional indications in the U.S., Canada and Mexico, to which the other party may opt-in to participate in the development.

We have agreed to use commercially reasonable efforts to promote, sell and distribute Ruconest in the U.S., Canada and Mexico, including launching Ruconest for the treatment of acute attacks of angioedema in patients with HAE in the U.S. within 120 days following receipt of U.S. regulatory approval. During the term of the license agreement, Pharming has agreed not to, and to insure that its distributors and dealers do not, sell Ruconest to any customer in the U.S., Canada and Mexico. Both parties have agreed not to manufacture, develop, promote, market or distribute any other forms of C1 inhibitors for use in the U.S., Canada and Mexico during the term.

The license agreement will continue in effect until we cease to sell Ruconest in the U.S., Canada and Mexico, unless terminated sooner. Either party may terminate the agreement in the following circumstances: (a) if the other party breaches any material term of the agreement and fails to cure such breach within a specified time period following written notice; or (b) upon the insolvency or occurrence of other specified bankruptcy events. We may also terminate the license agreement at any time subject to 12 months' prior written notice.

Following termination by Pharming or by us at will, the rights associated with Ruconest revert to Pharming and the supply agreement will terminate. Following termination by us for uncured material breach, bankruptcy or insolvency, the licenses granted to us will survive, we will have a right to reduce the supply price, and the supply agreement will remain in effect.

Supply Agreement

Under the supply agreement, Pharming will manufacture and exclusively supply to us, and we will exclusively order from Pharming, Ruconest at the supply price for commercialization activities. Pharming will manufacture and supply recombinant human C1 inhibitor products to us at cost for development activities. Pharming will be responsible for obtaining and maintaining all manufacturing approvals and related costs.

In the event of a supply failure, we have certain step-in rights to cure any payment defaults under Pharming's third party manufacturing agreements or to assume sole responsibility for manufacturing and supply. In connection with the supply agreement, we entered into a deed of usufruct with Pharming Intellectual Property B.V. and Pharming Technologies B.V., under which we were granted certain supplemental property interests in the form of a right of usufruct to manufacturing related intellectual property and access to manufacturing materials and know-how, in order to assume such manufacturing and supply responsibilities.

The supply agreement is subject to the term and termination provisions of the license agreement.

Rifamycin SV MMX

Rifamycin SV MMX is a broad spectrum, non-systemic antibiotic in a novel oral tablet formulation, which utilizes proprietary MMX colonic delivery technology and is being developed for the treatment of patients with travelers' diarrhea and potentially for other diseases that have a bacterial component in the intestine. Rifamycin SV has demonstrated a broad spectrum of *in vitro* activity targeted to the main enteropathogens that cause travelers'

diarrhea. In addition, due to the negligible systemic absorption of rifamycin SV, we believe that rifamycin SV MMX will offer an opportunity for limited side effects and will be less prone to the development of antibiotic-resistant strains of bacteria, a major concern with systemically delivered antibiotics.

In September 2012, we announced that rifamycin SV MMX demonstrated a statistically significant reduction in the time to last unformed stool, or TLUS, the primary endpoint in a phase III clinical study in patients with travelers' diarrhea. In the ITT population (n=264), the median TLUS was 46.0 hours for rifamycin SV MMX (n=199) compared with 68.0 hours for placebo (n=65), p = 0.0008. In addition, rifamycin SV MMX was generally well tolerated in this study and the frequency of treatment emergent adverse events was similar to placebo. The most frequent treatment emergent adverse events experienced by ≥ 2% of patients in either treatment group were: headache, diarrhea, infectious diarrhea, constipation, amoebic dysentery and GI infection. There were three patients who experienced serious adverse events, all of which were assessed by the investigator as not related to the study drug.

Dr. Falk Pharma GmbH, Cosmo's European development partner, is conducting a second phase III clinical study to evaluate the efficacy of rifamycin SV MMX versus ciprofloxacin with the primary endpoint of TLUS in patients with travelers' diarrhea. Based on a prespecified interim analysis, an independent data monitoring committee has recommended that approximately 250 patients be added to the study, which originally targeted enrolling approximately 780 patients. Dr. Falk is working with the Indian regulatory authorities to gain approval for this amendment to the protocol. We anticipate that the estimated timeline for completion of the study will be updated once Dr. Falk receives approval to move forward with the amended protocol. Assuming positive results in the second phase III clinical study, we and Dr. Falk plan to share the clinical data from our respective phase III studies for inclusion in each company's regulatory submissions.

Currently, there are two issued U.S. patents that we believe provide coverage for the rifamycin SV MMX investigational drug, with expiration dates in 2020 and 2025. In addition, rifamycin SV MMX, as a new chemical entity, is entitled to a period of five years of data exclusivity. Additional information about the intellectual property for the rifamycin SV MMX product is set forth below under the heading "Business – Intellectual Property – Rifamycin SV MMX."

Travelers' Diarrhea/Intestinal Infections

Intestinal infections are caused by bacteria, viruses or parasites. A common infection of the intestine is travelers' diarrhea, which is primarily caused by the ingestion of food or water contaminated by pathogenic strains of bacteria. According to the U.S. Centers for Disease Control and Prevention, each year between 20% and 50% of international travelers (an estimated 10 million people) develop diarrhea, primarily caused by bacteria.

Other diseases that may have a bacterial component in the intestine include infectious diarrhea, IBD, irritable bowel syndrome, Clostridium difficile-associated diarrhea, pouchitis, diverticular disease and hepatic encephalopathy.

In December 2008, we entered into a strategic collaboration with Cosmo, including a license agreement, stock issuance agreement and registration rights agreement, under which we were granted exclusive rights to develop and commercialize Uceris and rifamycin SV MMX in the U.S. Our strategic collaboration with Cosmo is described above under the heading "Business — Marketed and Approved Products — Uceris (budesonide) Extended Release Tablets — Strategic Collaboration with Cosmo."

SAN-300 (anti-VLA-1 antibody)

SAN-300 is a humanized anti-VLA-1 monoclonal antibody, or mAb, that we believe may offer a novel approach to the treatment of inflammatory and autoimmune diseases. We acquired rights to this program through the acquisition of closely held Covella Pharmaceuticals, Inc., or Covella, and related license and services and supply agreements with Biogen Idec MA, or Biogen. SAN-300 was initially developed by Biogen and licensed to Covella in January 2009.

SAN-300 is an inhibitor of VLA-1, also known as $\alpha_1\beta_1$ integrin, and has shown activity in multiple preclinical models of inflammatory and autoimmune diseases. This integrin, a cell adhesion molecule, plays a key role in the migration, retention and proliferation of activated T cells and monocytes at sites of chronic inflammation. We believe that SAN-300 has potential application as a drug candidate in multiple inflammatory and autoimmune diseases, including rheumatoid arthritis, IBD, psoriasis and organ transplantation.

In December 2012, we completed a phase I dose-escalation clinical study in healthy volunteers to determine the safety, tolerability, pharmacokinetics and pharmacodynamics of single doses of SAN-300 in both intraveneous, or IV, and subcutaneous formulations. The phase I study was conducted in Australia and enrolled a total of 66 healthy volunteers. We plan to begin a phase IIa clinical study evaluating SAN-300 for treatment of rheumatoid arthritis during the fourth quarter of 2013.

Currently, there are seven issued U.S. patents that we believe provide coverage for SAN-300, with expiration dates in 2020 and 2022. In addition, we believe SAN-300, as a biological product, is entitled under the PPACA to a period of 12 years of data exclusivity. Additional information about the intellectual property for SAN-300 is set forth below under the heading "Business – Intellectual Property – SAN-300."

Rheumatoid Arthritis

Rheumatoid arthritis is a systemic autoimmune disease that occurs when the immune system, which normally defends the body from invading organisms, turns its attack against the synovial membrane lining the joints, resulting in inflammation, pain, swelling, stiffness, and loss of function. According to the National Institute of Arthritis and Musculoskeletal and Skin Diseases, or NIAMS, a component of the National Institutes of Health, scientists estimate that about 1.3 million people, or about 0.6 percent of the U.S. adult population, have rheumatoid arthritis.

Acquisition of SAN-300 Development Program

Merger Agreement

In September 2010, we acquired the worldwide rights to SAN-300 through the acquisition of Covella, pursuant to the terms of a merger agreement. Prior to our acquisition of Covella, Covella was a privately held company owned by a small number of stockholders, including Mark Totoritis, our Senior Vice President, Clinical Research, among others. Dr. Totoritis received a portion of the merger consideration and also may be entitled to additional milestone and royalty payments.

Under the terms of the merger agreement, we paid a total upfront of $162,000 in cash and issued 181,342 in unregistered shares of our common stock to the Covella stockholders. We also assumed responsibility for payment of approximately $1.2 million in Covella liabilities and transaction expenses. We may be required to make clinical and regulatory milestone payments to the former Covella stockholders totaling up to an aggregate of $37.7 million (consisting of a combination of cash and our common stock) based on success in developing product candidates (with the first such milestone being payable upon successful completion of the first phase IIb clinical study). We may also be required to pay a royalty equal to a low single digit percentage rate of net sales of any commercial products resulting from the anti-VLA-1 mAb technology. Our obligation to pay the royalties continues on a country-by-country basis until the date which is the later of: (i) expiration of the last valid claim of the patents licensed by Covella pursuant to the license agreement in such country; or (ii) 10 years after the first commercial sale of the products in such country.

Both we and Covella agreed to customary representations, warranties and covenants in the merger agreement. The Covella stockholders agreed to indemnify us for certain matters, including breaches of representations and warranties and covenants included in the merger agreement, up to a maximum specified amount and subject to other limitations. We agreed to indemnify the Covella stockholders for certain matters, including breaches of representations, warranties and covenants included in the merger agreement, up to a maximum specified amount and subject to other limitations.

Amended License and Amended Services and Supply Agreement with Biogen

In connection with the merger agreement, we and Covella entered into a license agreement amendment in September 2010 with Biogen, amending an existing license agreement entered into in January 2009 between Covella and Biogen. Under the terms of the amended license, Biogen has granted us an exclusive, worldwide license to patents and certain know-how and other intellectual property owned and controlled by Biogen relating to SAN-300 and the anti-VLA-1 mAb development program. We are required to use commercially reasonable efforts to develop and commercialize at least one licensed product.

In connection with the execution of the amended license, we paid to Biogen $50,000 in cash and 55,970 in unregistered shares of our common stock. In addition, we may be obligated to make various clinical, regulatory and sales milestone payments based upon our success in developing and commercializing product candidates (with the first such milestone being payable upon successful completion of the first phase IIb clinical study). The amounts of the clinical and regulatory milestone payments vary depending on the type of product, the number of indications, and other specifically negotiated milestones. If SAN-300 is the first to achieve all applicable milestones for three indications, we will be required to pay Biogen maximum aggregate clinical and regulatory milestone payments of $97.2 million. The amount of the commercial milestone payments we will be required to pay Biogen will depend on the level of net sales of a particular product in a calendar year. The maximum aggregate commercial milestone payments to Biogen total $105.5 million for SAN-300, assuming cumulative net sales of at least $5 billion of such product, and total $60.25 million for products containing certain other compositions as described in the license, assuming cumulative net sales of at least $5 billion of such products. In addition, we will be required to pay tiered royalties ranging from low single digit to low double digit percentage rates, subject to reduction in certain limited circumstances, on net sales of products developed under the amended license. Our obligation to pay the royalties continues on a country-by-country basis until the date which is the later of: (i) expiration of the last valid claim of the patents licensed by us pursuant to the license agreement in such country; or (ii) 10 years after the first commercial sale of a licensed product in such country.

Under the amended license, Biogen has a right of first offer to supply our requirements of licensed products and a right of negotiation in the event that we decide to sublicense the right to commercialize a licensed product to a third party.

Unless the amended license is terminated earlier, it will remain in effect on a country-by-country basis until no further royalties would be due in such country. Each party is entitled to terminate the amended license upon the other party's uncured material breach or bankruptcy or insolvency, subject to certain cure and dispute resolution rights. In addition, we may terminate the amended license in our sole discretion upon 60 days' prior written notice. Following termination, the rights associated with the licensed products will revert to Biogen, subject to certain limited exceptions.

Also in connection with the merger agreement, we assumed a services and supply agreement between Covella and Biogen, which was subsequently amended in November 2011 and in December 2012. Under the services and supply agreement, Biogen agreed to supply to Covella materials manufactured by Biogen for use in the SAN-300 development program. In addition, upon Covella's (or its affiliates' or sublicensees') achievement of the first regulatory approval set forth in the amended license, Biogen is entitled to receive a one-time milestone payment equal to approximately $11.7 million, which is equivalent to the cost of the materials supplied under the services and supply agreement. In the event the amended license is terminated by either Covella or Biogen prior to Covella's (or its affiliates' or sublicensees') achievement of the first regulatory approval set forth in the amended license, Covella is required to pay Biogen a one-time termination fee of $3.0 million.

Strategic Alliances

To leverage our PPI technology and diversify our sources of revenue, we have entered into strategic alliances with other pharmaceutical companies that have capabilities in markets that we do not address.

OTC License Agreement with Merck

In October 2006, we licensed exclusive rights to Merck under our PPI technology to develop, manufacture, market and sell Zegerid brand OTC products in the lower dosage strength of 20 mg of omeprazole in the U.S. and Canada. Under the license agreement, Merck is required to use active, sustained and diligent efforts to conduct and complete in a timely manner all activities required to develop licensed products, receive marketing approval for licensed products and market, sell and generate and meet market demand for licensed products in the licensed territories. Merck commenced commercial sales of Zegerid OTC (omeprazole 20 mg/sodium bicarbonate 1100 mg capsules) in March 2010.

Under the license agreement, we received a $15.0 million upfront license fee in November 2006 and have received $27.5 million in milestone payments to date. We may receive up to an additional $37.5 million in aggregate milestone payments upon the achievement of specified sales milestones. We are also entitled to receive low double-digit royalties, subject to adjustment in certain circumstances, on net sales of any OTC products sold by Merck under the license agreement. In turn, we are obligated under our license agreement with the University of Missouri to pay royalties to the University of Missouri based on net sales of any OTC products sold by Merck.

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

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

Additional information about the intellectual property for Zegerid OTC, including ongoing patent infringement litigation, is set forth below under the heading "Business – Intellectual Property – Zegerid and Pending Patent Litigation."

License Agreement with GSK

In November 2007, we entered into a license agreement granting exclusive rights to GSK under our PPI technology to commercialize prescription and OTC immediate-release omeprazole products in a number of international markets.

Under the license agreement, we granted GSK the exclusive right to develop, manufacture and commercialize prescription and OTC immediate-release omeprazole products for sale in more than 100 countries within Africa, Asia, the Middle-East and Latin America. GSK is required to use commercially reasonable efforts to seek regulatory approval for, and to launch, market and sell licensed products in the licensed territories and is required to do so within specified time frames in certain "major countries," defined in the license agreement as Brazil, China, Mexico, South Africa, South Korea, Taiwan and Turkey. To date, GSK has elected not to pursue development in China and Taiwan and has returned the rights to those territories to us. GSK will be responsible for all costs associated with its activities related to the license agreement.

Currently, GSK has launched licensed products in Mexico, Ecuador, Kenya, Nigeria, French W. Africa and Tanzania and has made regulatory filings in other selected countries in Africa, Asia and Latin America. GSK is continuing work to prepare the regulatory filings necessary to obtain marketing approval authorization in additional countries covered by the license agreement.

Under the license agreement, we received an $11.5 million upfront fee. We will also receive tiered royalties equal to a percentage of net sales, ranging from the mid-teens to mid-twenties, of any licensed products sold by GSK under the license agreement. The royalties are subject to reduction on a country-by-country basis in the event that sales of any generic products achieve a specific level of market share, referred to as "generic competition" in such country. In turn, we will be obligated under our license agreement with the University of Missouri to pay royalties to

the University of Missouri based on net sales of any licensed products sold by GSK. GSK's obligation to pay royalties under the license agreement will continue as long as GSK is selling licensed products, unless the license agreement is terminated earlier or in the event GSK exercises its option to make a buy-out payment in 2027, the 20th anniversary of the license agreement. To support GSK's initial launch costs, we agreed to waive the initial $2.5 million of aggregate royalties payable to us.

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

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

Sales and Marketing

We have established a commercial organization that is focused on the marketing, promotion and sale of the Uceris, Zegerid, Glumetza, Cycloset and Fenoglide prescription products in the U.S. Our sales organization currently calls on gastroenterologists, endocrinologists and other selected physicians.

Our commercial organization is comprised of approximately 300 sales and marketing personnel, including in-house staff, field sales representatives (both employee and contract), sales managers and account managers. Our field sales representatives, including approximately 150 Santarus employees and 85 contract sales representatives, are positioned in major metropolitan areas across the U.S. In connection with the launch of Uceris in February 2013, we added approximately 85 new sales representatives, increasing our total number of sales representatives to approximately 235.

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

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

Manufacturing and Distribution

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

Although there are potential sources of supply other than our existing suppliers, any new supplier would be required to qualify under applicable regulatory requirements.

Uceris and Rifamycin SV MMX

For Uceris and rifamycin SV MMX, we rely on Cosmo, located in Italy, to manufacture and supply all of our drug product requirements. We have agreed to purchase such requirements exclusively from Cosmo during the term of our license agreement with Cosmo. We have entered into a supply agreement relating to Uceris and plan to enter into a supply agreement relating to rifamycin SV MMX in the future.

Under the terms of our supply agreement with Cosmo relating to the commercial supply of Uceris, we have agreed to pay Cosmo a supply price equal to 10% of net sales. Cosmo will reimburse us for costs associated with packaging, which is handled by a third party. The term of the supply agreement continues for so long as our license agreement with Cosmo remains in effect. We may terminate the agreement at any time if we decide to no longer market the product by providing six months prior written notice. We may also terminate the agreement with 30 days' prior written notice in the event any governmental agency takes any action, or raises any objection, that prevents us from importing, exporting, purchasing or selling the product or otherwise makes such activity unlawful. We may also terminate the agreement if any regulatory proceeding, or other action, by the FDA or a foreign regulatory authority imposes on the manufacturing facility an import ban or withdraws any license required by Cosmo to manufacture the product. In addition, either party may terminate the agreement in the event of the other party's uncured material breach, subject to prior written notice within a specified time period, or in the event of the other party's insolvency or bankruptcy.

Zegerid

We currently rely on Norwich Pharmaceuticals, Inc., or Norwich, located in New York, as the sole third-party manufacturer of the brand and related authorized generic Zegerid capsules product. We have entered into a supply agreement with Norwich that continues in force indefinitely unless terminated by either party with 18 months' prior 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 currently rely on Patheon for the manufacture of Zegerid powder for oral suspension. The agreement, as amended, has an initial five-year term, which expires in October 2014. Thereafter, the term of the agreement continues in force indefinitely, except that either party may terminate the agreement at any time by providing the other party with 18 months' prior written notice. In addition, we may terminate the agreement at any time if we decide to no longer market a product by providing six months' prior written notice. We may also terminate the agreement with 30 days' prior written notice in the event any governmental agency takes any action that prevents us from purchasing or selling a 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, or in the event of the other party's insolvency or bankruptcy.

Under our authorized generic agreement with Prasco, we supply our authorized generic of prescription Zegerid capsules to Prasco, and Prasco is responsible for invoicing and distribution to pharmaceutical wholesalers and other customers.

Glumetza

For Glumetza 500 mg, we assumed from Depomed a commercial manufacturing agreement with Patheon, and, accordingly, we rely on a Patheon facility located in Puerto Rico as the sole third party manufacturer of Glumetza 500 mg. The current term of the manufacturing agreement with Patheon expires in June 2014. Thereafter, the manufacturing agreement automatically renews for additional terms of two years each, unless one party gives notice to terminate 12 months prior to the expiration of the current term. Neither party to the manufacturing agreement has

given notice to terminate. In addition, we may terminate the manufacturing agreement upon 180 days' prior written notice to Patheon if, due to market conditions, selling the Glumetza product becomes commercially unfeasible and we discontinue selling the product. 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, or in the event of the other party's insolvency or bankruptcy.

For Glumetza 1000 mg, we currently rely on Depomed to oversee product manufacturing and supply. Depomed, in turn, relies on a Valeant Pharmaceuticals International, Inc. facility located in Canada as the sole third party manufacturer of Glumetza 1000 mg.

Cycloset

In connection with the license of rights to Cycloset, we assumed a manufacturing services agreement with Patheon, and, accordingly, we rely on a Patheon facility located in Ohio as the sole third-party manufacturer for Cycloset. The manufacturing services agreement with Patheon is non-exclusive and although we are not required to purchase any minimum quantity of the product under the agreement, we have agreed to purchase not less than a specified percentage of the total amount of Cycloset offered for sale by us in the U.S. For so long as Patheon manufactures the required percentage for us, Patheon has agreed not to manufacture bromocriptine mesylate products, regardless of dosage form, for any other third party without our express written consent. The agreement expires in December 2016, and thereafter automatically continues for two-year renewal terms, unless 18 months' prior written notice is provided by either party. We may terminate the agreement at any time if we decide to discontinue the product by providing Patheon advance notice within a specified period of time. We may also terminate the agreement with 30 days' prior written notice in the event any governmental agency takes any action or raises any objection that prevents us from importing, exporting, purchasing or selling the product. Either party may immediately terminate the agreement if the other party fails to perform any material term of the agreement or in the event of the other party's insolvency, bankruptcy or if the agreement is assigned by the other party for the benefit of creditors. In addition, 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 opportunity to cure.

Fenoglide

In connection with the license of rights to Fenoglide, we assumed a commercial supply agreement with Catalent Pharma Solutions, LLC, or Catalent, and accordingly, we rely on a Catalent facility located in Kentucky to manufacture Fenoglide.

Ruconest

For our Ruconest investigational drug, we rely on Pharming to oversee product manufacturing and supply. In turn, Pharming utilizes certain of its own facilities as well as third-party manufacturing facilities for supply, all of which are located in Europe.

SAN-300

For our SAN-300 investigational drug, we plan to utilize materials previously manufactured by Biogen for the production of clinical trial materials. In the future, Biogen has a right of first offer to supply our product requirements.

Distribution

We sell our brand prescription products primarily to pharmaceutical wholesalers, who in turn seek to distribute the products to retail pharmacies, mail order pharmacies, hospitals and other institutional customers. We have retained third-party service providers to perform a variety of functions related to the distribution of our approved products, including logistics management, sample accountability, storage and transportation. We have also entered into channel services agreements with some wholesalers under which we receive certain distribution management services and data reporting from the wholesalers, in exchange for a fee. Sales to our three largest wholesalers in 2012, McKesson Corporation, Cardinal Health, Inc. and AmerisourceBergen Corporation, accounted for

approximately 35%, 31% and 18%, respectively of our annual revenues. The loss of any of these wholesalers as customers could materially and adversely affect our business, results of operations, financial condition and cash flows.

Intellectual Property

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

Due to the length of time and expense associated with bringing new pharmaceutical products to market, we recognize that there are considerable benefits associated with developing, licensing or acquiring products that are protected by existing patents or for which patent protection can be obtained. 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 or information.

Uceris

We have exclusive rights to develop and commercialize Uceris in the U.S. under our strategic collaboration with Cosmo. Currently, there are four issued U.S. patents that are owned by Cosmo and licensed to us that we believe provide coverage for Uceris (U.S. Patent Nos. 7,431,943, 7,410,651; RE43,799 and 8,293,273), each of which expires in 2020.

Zegerid and Pending Patent Litigation

We have entered into an exclusive, worldwide license agreement with the University of Missouri for patents and pending patent applications relating to specific formulations of PPIs with antacids and other buffering agents and methods of using these formulations. Currently, there are three issued U.S. patents that we believe provide coverage for our Zegerid products (U.S. Patent Nos. 5,840,737; 6,780,882; and 7,399,772), each of which expires in 2016. In addition to the issued U.S. patent coverage described above, several international patents have been issued.

Zegerid Rx and Zegerid OTC Patent Litigation

Zegerid Rx Litigation

In April 2010, the U.S. District Court for the District of Delaware ruled that five patents covering Zegerid capsules and Zegerid powder for oral suspension (U.S. Patent Nos. 6,489,346; 6,645,988; 6,699,885; 6,780,882; and 7,399,772) were invalid due to obviousness. These patents were the subject of lawsuits we filed in 2007 against Par in response to ANDAs filed by Par with the FDA. The University of Missouri, licensor of the patents, is joined in the litigation as a co-plaintiff. In May 2010, we filed an appeal of the District Court's ruling to the U.S. Court of Appeals for the Federal Circuit. Following the District Court's decision, Par launched its generic version of Zegerid capsules in late June 2010.

In September 2012, the U.S. Court of Appeals for the Federal Circuit reversed in part the April 2010 decision of the District Court. The Federal Circuit found that certain claims of asserted U.S. Patent Nos. 6,780,882 and 7,399,772, which Par had been found to infringe, were not invalid due to obviousness. These patents represent two of the five patents that were found to be invalid by the District Court, and the Federal Circuit affirmed the District Court's finding of invalidity for the asserted claims from the remaining three patents. The Federal Circuit also upheld the District Court's finding that there was no inequitable conduct. Following the Federal Circuit's decision, Par announced that it had ceased distribution of its generic Zegerid capsules product in September 2012. In December 2012, the Federal Circuit issued an order denying a combined petition for panel and en banc rehearing filed by Par and issued its mandate, remanding the case to the District Court for further proceedings pertaining to damages. In February 2013, we filed an amended complaint with the District Court for infringement of U.S. Patent Nos. 6,780,882 and 7,399,772 and requested a jury trial with respect to the issue of damages in connection with Par's launch of its generic version of Zegerid capsules in June 2010. In March 2013, Par filed its amended answer, which alleges, among other things, failure to state a claim upon which relief can be granted and non-infringement based on purported invalidity of the two asserted patents. In addition, Par filed a motion for a judgment on the pleadings, alleging, among other things, that the two asserted patents are invalid because the Federal Circuit purportedly did not expressly address certain prior art references considered by the District Court. Although we do not believe that Par has a meritorious basis upon which to further challenge validity of the asserted patents in this proceeding, we cannot be certain of the timing or outcome of this or any other proceedings.

In December 2011, we filed a lawsuit in the U.S. District Court for the District of New Jersey against Zydus Pharmaceuticals USA, Inc., or Zydus, for infringement of the patents listed in the Orange Book for Zegerid capsules. The University of Missouri, licensor of the patents, is joined in the litigation as a co-plaintiff. Zydus had filed an ANDA with the FDA regarding its intent to market a generic version of Zegerid capsules prior to the expiration of the listed patents. In September 2012, we amended our complaint to be limited to U.S. Patent No. 7,399,772, which patent was found not to be invalid in the September 2012 Federal Circuit decision. In October 2012, Zydus filed its answer, which alleges, among other things, failure to state a claim upon which relief can be granted. The lawsuit was commenced within the requisite 45-day time period, resulting in an FDA stay on the approval of Zydus' proposed product for 30 months or until a decision is rendered by the District Court, which is adverse to the asserted patent. The Markman hearing for this matter has been scheduled in July 2013 and a trial has been scheduled in January 2014. Absent a court decision, the 30-month stay is expected to expire in May 2014. We are not able to predict the timing or outcome of this lawsuit.

In August 2012, we filed a lawsuit in the U.S. District Court for the District of New Jersey against Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc., collectively referred to herein as Dr. Reddy's, for infringement of the patents listed in the Orange Book for Zegerid capsules. The University of Missouri, licensor of the patents, is joined in the litigation as a co-plaintiff. Dr. Reddy's had filed an ANDA with the FDA regarding its intent to market a generic version of Zegerid capsules prior to the expiration of the listed patents. In October 2012, we amended our complaint to be limited to U.S. Patent No. 7,399,772, which patent was found not to be invalid in the September 2012 Federal Circuit decision. Also in October 2012, Dr. Reddy's filed its answer, which alleges, among other things, non-infringement, invalidity, failure to state a claim upon which relief can be granted and estoppel. The lawsuit was commenced within the requisite 45-day time period, resulting in an FDA stay on the approval of Dr. Reddy's proposed product for 30 months or until a decision is rendered by the District Court, which is adverse to the asserted patent. The Markman hearing for this matter has been scheduled in July 2013 and a trial has been scheduled in July 2014. Absent a court decision, the 30-month stay is expected to expire in January 2015. We are not able to predict the timing or outcome of this lawsuit.

Zegerid OTC Litigation

In September 2010, Merck filed a lawsuit in the U.S. District Court for the District of New Jersey against Par for infringement of the patents listed in the Orange Book for Zegerid OTC. We and the University of Missouri, licensors of the listed patents, are joined in the lawsuit as co-plaintiffs. Par had filed an ANDA with the FDA regarding its intent to market a generic version of Zegerid OTC prior to the expiration of the listed patents. In October 2012, Merck amended its complaint to be limited to U.S. Patent No. 7,399,772, which patent was found not to be invalid in the September 2012 Federal Circuit decision. Also in October 2012, Par filed its answer, which alleges, among other things, failure to state a claim upon which relief can be granted, non-infringement and invalidity. Par has received tentative approval of its proposed generic Zegerid OTC product. The lawsuit was

commenced within the requisite 45-day time period, resulting in an FDA stay on the approval of Par's proposed product for 30 months or until a decision is rendered by the District Court, which is adverse to the asserted patent. Although the 30-month stay expired in February 2013, the parties have agreed that Par will not launch its generic Zegerid OTC product unless there is a District Court judgment favorable to Par or in certain other specified circumstances. The Markman hearing for this matter has been scheduled in July 2013 and a trial has been scheduled in January 2015. We are not able to predict the timing or outcome of this lawsuit.

In September 2010, Merck filed a lawsuit in the U.S. District Court for the District of New Jersey against Perrigo Research and Development Company, or Perrigo, for infringement of the patents listed in the Orange Book for Zegerid OTC. We and the University of Missouri, licensors of the listed patents, were joined in the lawsuits as co-plaintiffs. Perrigo had filed an ANDA with the FDA regarding its intent to market a generic version of Zegerid OTC prior to the expiration of the listed patents. In January 2013, this case was settled allowing entry into the market by Perrigo upon expiration of the applicable patents (or earlier under certain circumstances), and the District Court entered an order dismissing the case with prejudice.

In December 2011, Merck filed a lawsuit in the U.S. District Court for the District of New Jersey against Zydus for infringement of the patents listed in the Orange Book for Zegerid OTC. We and the University of Missouri, licensors of the listed patents, are joined in the litigation as co-plaintiffs. Zydus had filed an ANDA with the FDA regarding its intent to market a generic version of Zegerid OTC prior to the expiration of the listed patents. In September 2012, Merck amended its complaint to be limited to U.S. Patent No. 7,399,772, which patent was found not to be invalid in the September 2012 Federal Circuit decision. In October 2012, Zydus filed its answer, which alleges, among other things, failure to state a claim upon which relief can be granted. The lawsuit was commenced within the requisite 45-day time period, resulting in an FDA stay on the approval of Zydus' proposed product for 30 months or until a decision is rendered by the District Court, which is adverse to the asserted patent. Absent a court decision, the 30-month stay is expected to expire in May 2014. The Markman hearing for this matter has been scheduled in July 2013 and a trial has been scheduled in January 2014. We are not able to predict the timing or outcome of this lawsuit.

Glumetza and Pending Patent Litigation

We have exclusive rights to manufacture and commercialize the Glumetza products in the U.S., including its territories and possessions and Puerto Rico, under our commercialization agreement with Depomed. Currently, there are four issued U.S. patents that are owned or licensed by Depomed that we believe provide coverage for the Glumetza 500 mg dose product (U.S. Patent Nos. 6,340,475; 6,635,280; 6,488,962; and 6,723,340), with expiration dates in 2016, 2020 and 2021. There are three issued U.S. patents that are owned or licensed by Depomed that we believe provide coverage for the Glumetza 1000 mg dose product (U.S. Patent Nos. 6,488,962; 7,780,987; and 8,323,692), with expiration dates in 2020 and 2025.

In November 2009, Depomed filed a lawsuit in the U.S. District Court for the Northern District of California against Lupin Limited and its wholly owned subsidiary, Lupin Pharmaceuticals, Inc., collectively referred to herein as Lupin, for infringement of certain patents listed in the Orange Book for Glumetza. The lawsuit was filed in response to an ANDA filed with the FDA by Lupin regarding Lupin's intent to market generic versions of Glumetza 500 mg and 1000 mg tablets prior to the expiration of the listed patents. In February 2012, we and Depomed entered into a settlement agreement with Lupin that grants Lupin the right to begin selling a generic version of Glumetza in February 2016, or earlier under certain circumstances. In March 2012, the U.S. District Court for the Northern District of California entered an order dismissing the litigation.

In June 2011, Depomed filed a lawsuit in the U.S. District Court for the District of New Jersey against Sun Pharma Global FZE, Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Industries Inc., collectively referred to herein as Sun, for infringement of the patents listed in the Orange Book for Glumetza. Valeant International Bermuda, or Valeant, was joined in the lawsuit as a co-plaintiff. The lawsuit was filed in response to an ANDA filed with the FDA by Sun regarding Sun's intent to market generic versions of Glumetza 500 mg and 1000 mg tablets prior to the expiration of the listed patents. In January 2013, we, Depomed and Valeant entered into a settlement agreement with Sun that grants Sun the right to begin selling a generic version of Glumetza in August 2016, or earlier under certain circumstances. In January 2013, the District Court dismissed the lawsuit without

prejudice in view of the settlement agreement. The settlement agreement is subject to review by the U.S. Department of Justice and the Federal Trade Commission.

In April 2012, Depomed filed a lawsuit in the U.S. District Court for the District of Delaware against Watson Laboratories, Inc. — Florida, Watson Pharmaceuticals, Inc. and Watson Pharma, Inc., collectively referred to herein as Watson, for infringement of the patents listed in the Orange Book for Glumetza 1000 mg at the time the lawsuit was filed (U.S. Patent Nos. 6,488,962 and 7,780,987). Valeant is joined in the lawsuit as a co-plaintiff. The lawsuit was filed in response to an ANDA filed with the FDA by Watson regarding Watson's intent to market a generic version of Glumetza 1000 mg tablets prior to the expiration of the listed patents. Depomed and Valeant commenced the lawsuit within the requisite 45-day time period, resulting in an FDA stay on the approval of Watson's proposed product for 30 months or until a decision is rendered by the District Court, which is adverse to the asserted patents. Absent a court decision, the 30-month stay is expected to expire in September 2014. Watson has filed an answer in the case that asserts, among other things, non-infringement and invalidity of the asserted patents, failure to state a claim, lack of subject matter jurisdiction, and has also filed counterclaims. In February 2013, Depomed amended its complaint to add infringement of a newly listed Orange Book patent (U.S. Patent No. 8,323,692), as well as two non-Orange Book listed patents (U.S. Patent Nos. 7,736,667 and 8,329,215). The Markman hearing for this matter has been scheduled in April 2014, and the trial has been scheduled in May 2014. We are not able to predict the timing or outcome of this lawsuit.

In February 2013, Depomed filed a lawsuit in the U.S. District Court for the District of Delaware against Watson Laboratories, Inc. — Florida, Watson Pharmaceuticals, Inc. and Watson Pharma, Inc., collectively referred to herein as Watson, for infringement of the patents listed in the Orange Book for Glumetza 500 mg at the time the lawsuit was filed (U.S. Patent Nos. 6,340,475; 6,488,962; 6,635,280 and 6,723,340). Valeant is joined in the lawsuit as a co-plaintiff. The lawsuit was filed in response to an ANDA filed with the FDA by Watson regarding Watson's intent to market a generic version of Glumetza 500 mg tablets prior to the expiration of the listed patents. Depomed and Valeant commenced the lawsuit within the requisite 45-day time period, resulting in an FDA stay on the approval of Watson's proposed product for 30 months or until a decision is rendered by the District Court, which is adverse to the asserted patents. Absent a court decision, the 30-month stay is expected to expire in July 2015.

Under the terms of our commercialization agreement with Depomed, Depomed will manage the ongoing patent infringement litigation relating to Glumetza, subject to certain consent rights in favor of us, including with regard to any proposed settlements. We are responsible for 70% of the future out-of-pocket costs, and Depomed is responsible for 30% of the future out-of-pocket costs, related to patent infringement cases.

Cycloset

We have exclusive rights to manufacture and commercialize Cycloset in the U.S. under our distribution and license agreement with S2 and VeroScience. Currently, there are three issued U.S. patents that we have licensed from S2 and VeroScience that we believe provide coverage for Cycloset (U.S. Patent Nos. 5,679,685; 5,716,957; and 7,888,310), with expiration dates in 2014, 2015 and 2023.

Fenoglide and Pending Patent Litigation

We have exclusive rights to manufacture and commercialize Fenoglide in the U.S. under the terms of a license agreement with HRP and Shore. Currently, there are two issued U.S. patents that we believe provide coverage for the Fenoglide products (U.S. Patent Nos. 7,658,944, and 8,124,125), with expiration dates in 2024.

Prior to the execution of the license agreement, Shore entered into a settlement arrangement with Impax Laboratories, Inc., or Impax, in connection with patent infringement litigation associated with Impax's ANDA for a generic version of Fenoglide and a related paragraph IV challenge. The settlement terms grant Impax a sublicense to begin selling a generic version of Fenoglide on October 1, 2015, or earlier under certain circumstances. In February 2012, the U.S. District Court for the District of Delaware entered an order dismissing the litigation, and we assumed Shore's obligations associated with the sublicense to Impax.

In January 2013, we filed a lawsuit in the U.S. District Court for the District of Delaware against Mylan Inc. and Mylan Pharmaceuticals Inc., collectively referred to herein as Mylan, for infringement of the patents listed in the

Orange Book for Fenoglide 120 mg and 40 mg (U.S. Patent Nos. 7,658,944, and 8,124,125). Veloxis Pharmaceuticals A/S, or Veloxis, is joined in the lawsuit as a co-plaintiff. The lawsuit was filed in response to an ANDA filed with the FDA by Mylan regarding Mylan's intent to market a generic version of Fenoglide 120 mg and 40 mg tablets prior to the expiration of the listed patents. We commenced the lawsuit within the requisite 45-day time period, resulting in an FDA stay on the approval of Mylan's proposed product for 30 months or until a decision is rendered by the District Court, which is adverse to the asserted patents, whichever may occur earlier. Absent a court decision, the 30-month stay is expected to expire in June 2015. Mylan has filed an answer in the case that asserts, among other things, non-infringement, invalidity, and failure to state a claim, and has also filed counterclaims. We are not able to predict the timing or outcome of this lawsuit.

Ruconest

We have exclusive rights to develop and commercialize the Ruconest investigational drug in the U.S., Canada and Mexico under our license and supply agreements with Pharming. Currently, there are two issued U.S. patents that are owned by Pharming and licensed to us that we believe provide coverage for Ruconest (U.S. Patent Nos. 7,067,713 and RE43,691), which expire in 2022 and 2024. In addition, we believe Ruconest, as a biological product, is entitled under the PPACA to a period of 12 years of regulatory exclusivity in the U.S.

Rifamycin SV MMX

We have exclusive rights to develop and commercialize the rifamycin SV MMX investigational drug in the U.S. under our strategic collaboration with Cosmo. Currently, there are two issued U.S. patents that are owned by Cosmo and licensed to us that we believe provide coverage for rifamycin SV MMX (U.S. Patent Nos. 7,431,943 and 8,263,120), which expire in 2020 and 2025. In addition, we believe rifamycin SV MMX, as a new chemical entity, is entitled to a period of five years of data exclusivity.

SAN-300

We acquired worldwide rights to develop and commercialize the SAN-300 investigational drug in connection with our acquisition of Covella. Currently, there are seven issued U.S. patents that are owned by Biogen and licensed to us that we believe provide coverage for SAN-300 (U.S. Patent Nos. 7,358,054; 7,462,353; 6,955,810; 7,723,073; 7,910,099; 8,084,031; and 8,084,028), which expire in 2020 and 2022. In addition, we believe SAN-300, as a biological product, is entitled under the PPACA to a period of 12 years of regulatory exclusivity in the U.S.

Trademarks

We own, or have licensed the rights to use, the trademarks for each of our brand pharmaceutical products, as well as for our corporate name and logo. We have applied for trademark registration for various other names and logos. Over time, we intend to maintain registrations on trademarks that remain valuable to our business.

Competition

The pharmaceutical and biotechnology industries are intensely competitive in the markets in which our commercial products compete and investigational drugs may compete, and there are many other currently marketed products that are well-established and successful, as well as development programs underway. In addition, many of our competitors are large, well-established companies in the pharmaceutical and biotechnology fields with significantly greater financial resources, sales and marketing capabilities, manufacturing capabilities, experience in obtaining regulatory approvals for product candidates, and other resources than we do. Larger pharmaceutical and biotechnology companies typically have significantly larger field sales force organizations and invest significant amounts in advertising and marketing their products. As a result, these larger companies are able to reach a greater number of physicians and consumers than we can with our smaller sales organization.

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

Uceris competes with many other products, including:

- branded 5-aminosalicylate prescription products (such as Asacol®, Lialda®, Pentasa® and Apriso®);
- generic 5-aminosalicylate prescription products (such as sulfasalzine, mesalamine, and balsalazide);
- generic prescription corticosteroids (such as prednisone and hydrocortisone);
- branded and generic prescription immunosuppressive products (such as aziothioprine and 6-mercaptopurine); and
- branded anti-TNF-α prescription products (such as Remicade® and Humira®).

Zegerid (branded and authorized generic) competes with many other products, including:

- branded PPI prescription products (such as Nexium®, Aciphex® and Dexilant®);
- generic PPI prescription products (such as delayed-release omeprazole, delayed-release lansoprazole and delayed-release pantoprazole);
- OTC PPI products (such as Prilosec OTC®, Prevacid® 24HR and store-brand versions); and
- other prescription and/or OTC acid-reducing agents (such as histamine-2 receptor antagonists and antacids).

Glumetza competes with many other products, including:

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

In addition, various companies are developing new products that may compete with the Glumetza products in the future. For example, Depomed has licensed rights to use its extended-release patents in combination with canagliflozin, a sodium-glucose transporter-2, or SGLT2, compound being developed by Janssen. Depomed has also licensed rights to use its extended-release metformin patents to Boehringer Ingelheim for use with certain fixed dose combination products that include proprietary Boehringer Ingelheim compounds.

Like Glumetza, Cycloset competes with many other products, including:

- dipeptidyl peptidase IV inhibitors, or DPP-4, products (such as Januvia® and Onglyza®);
- glucagon-like peptide 1, or GLP-1, receptor agonist products (such as Byetta®, Victoza® and Bydureon®);
- thiazolidinedione, or TZD, products (such as Avandia® and Actos®);
- sulfonylureas products (such as Amaryl® and Glynase®); and
- branded and generic metformin products.

In addition, various companies are developing new products that may compete with the Cycloset product in the future. For example, SGLT2 and new DPP-4 inhibitor products in development could compete with Cycloset in treating type 2 diabetes patients in the future. In addition, companies could develop combination products that include bromocriptine mesylate as one of the active ingredients for the treatment of type 2 diabetes.

Fenoglide competes with many other products, including:

- other branded and generic formulations of fenofibrate (such as Tricor®, Antara® and Lipofen®), gemfibrozil (such as Lopid®), and fenofibric acid (such as Trilipix®); and
- other prescription treatments for primary hyperlipidemia, mixed dyslipidemia, and hypertriglyceridemia (such as statins and niacin).

In addition, various companies are developing new products that may compete with Fenoglide in the future. For example, monoclonal antibodies targeting PCSK9 for reducing LDL-C could compete with Fenoglide in the future. In addition, companies could develop combination products with fenofibrate as one of the active ingredients for the

treatment of primary hyperlipidemia, mixed lipidemia, or hypertriglyceridemia. For example, rosuvastatin calcium and fenofibric acid are being studied in combination for the treatment of mixed dyslipidemia.

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

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

In addition, if approved, our investigational drugs will compete with many other drug and biologic products that are already entrenched in the marketplace, as well as face competition from other product candidates currently under development.

Research and Development

Our research and development expenses were $25.8 million for 2012, $18.4 million for 2011 and $17.4 million for 2010. Research and development expenses have historically consisted primarily of costs associated with clinical studies of our investigational drugs as well as clinical studies designed to further differentiate our products from those of our competitors, development of and preparation for commercial manufacturing of our products, compensation and other expenses related to research and development personnel and facilities expenses.

Our research and development efforts are currently focused on the Uceris phase IIIb program and our Ruconest, rifamycin SV MMX and SAN-300 investigational drugs. Additional information about these development programs is set forth above under the headings "Business – Marketed and Approved Products" and "Business – Investigational Drugs."

In the future, we may conduct additional clinical studies to further differentiate our marketed products and investigational drugs, as well as conduct research and development related to any future products that we may in-license or otherwise acquire. Although we are currently focused primarily on the advancement of Uceris and the Ruconest, rifamycin SV MMX and SAN-300 investigational drugs, we anticipate that we will make determinations as to which development projects to pursue and how much funding to direct to each project on an ongoing basis in response to the scientific, clinical and commercial merits of each project. We are unable to estimate with any certainty the research and development costs that we may incur in the future.

Government Regulation

Governmental authorities in the U.S. and other countries extensively regulate the research, development, 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, or FDCA, the Public Health Service Act, and other federal statutes and regulations, subjects pharmaceutical products to rigorous review. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending NDAs or biologics license applications, or BLAs, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

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

Clinical Testing and the FDA Approval Process

To obtain approval of a new product from the FDA, we must, among other requirements, submit data supporting safety and efficacy as well as detailed information on the manufacture, quality control and composition of the product and proposed labeling. The testing and collection of data and the preparation of necessary applications are expensive and time-consuming. The FDA may not act quickly or favorably in reviewing these applications, and we may encounter significant difficulties and/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 or biological product 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, or IND, which must become effective before human clinical studies may begin in the U.S.; performance of adequate and well-controlled human clinical studies to establish the safety and efficacy of the proposed drug or biological product for its intended use; submission of an NDA or BLA; and approval of an NDA or BLA by the FDA.

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements including good laboratory practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information including information about product chemistry, manufacturing and controls and a proposed clinical trial protocol. Long term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

Clinical trials involve the administration of the investigational new drug or biological product to healthy volunteers or patients under the supervision of a qualified investigator. The sponsor typically conducts human clinical studies in three sequential phases, but the phases may overlap. In phase I clinical studies, the product is tested in a small number of patients or healthy volunteers, primarily to evaluate safety, metabolism, pharmacokinetics, and pharmacological actions 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 studies. Phase III clinical studies typically involve additional clinical evaluation of safety and clinical efficacy in an expanded population at geographically-dispersed test sites.

Clinical studies must be conducted in accordance with the FDA's good clinical practices requirements as well as protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND. The FDA may order the temporary or permanent discontinuation of a clinical study at any time or impose other sanctions if it believes that the clinical study is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical study patients. An institutional review board, or IRB, generally must approve the clinical study design and patient informed consent at each clinical site and may also require the clinical study 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 studies, together with, among other things, detailed information on the manufacture, quality control and composition of the product and proposed labeling, in the form of an NDA or BLA, including payment of a user fee for most NDAs or BLAs. The FDA has 60 days from its receipt of an NDA or BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. The FDA may request additional information rather than accepting an NDA or BLA for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA or BLA. The FDA has agreed to certain performance goals, known as PDUFA goals, in the review of NDAs or BLAs. The goal for initial review of applications for non-priority drug or biological products is ten months while the goal for initial review of most applications for priority review drugs or biologicals, that is, drugs or biologicals that FDA determines represent a significant improvement over existing therapy, is six months.

The review process and the target action date under PDUFA may be extended by three months if the FDA requests or the NDA or BLA sponsor otherwise provides certain additional information or clarification regarding information already provided in the submission. The FDA may also refer applications for novel products or products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug or biological product is manufactured. FDA will not approve the product unless compliance with cGMP is satisfactory and the NDA or BLA contains data that provide substantial evidence that the drug or biological product is safe and effective in the indication studied.

Following completion of the FDA's review of the NDA or BLA and the clinical and manufacturing procedures and facilities, the FDA will issue an action letter, which will either be an "approval" authorizing commercial marketing of the drug or biological for certain indications or a "complete response letter" containing the conditions that must be met in order to secure approval of the NDA or BLA. These conditions may include deficiencies identified in connection with the FDA's evaluation of the NDA or BLA submission or the clinical and manufacturing procedures and facilities. Until any such conditions or deficiencies have been resolved, the FDA may refuse to approve the NDA or BLA.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Marketing Exclusivity Under the Hatch-Waxman Act

Under the Hatch-Waxman Act, newly-approved drugs and indications benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Act provides five-year marketing exclusivity to the first applicant to gain approval of an NDA for a new chemical entity, meaning that the FDA has not previously approved any other new drug containing the same active moiety. The Hatch-Waxman Act prohibits the submission of an ANDA or a Section 505(b)(2) NDA for another version of such drug during the five-year exclusive period; however, submission of an ANDA or Section 505(b)(2) NDA containing a paragraph IV certification is permitted after four years, which may trigger a 30-month stay of approval of the ANDA or Section 505(b)(2) NDA. Protection under Hatch-Waxman will not prevent the submission or approval of another full NDA; however, the applicant would be required to conduct its own preclinical and adequate and well-controlled clinical trials to demonstrate safety and effectiveness. The Hatch-Waxman Act also provides three years of marketing exclusivity for the approval of new and supplemental NDAs, including Section 505(b)(2) NDAs, for, among other things, new indications, dosages or strengths of an existing drug, if new clinical investigations that were conducted or sponsored by the applicant are essential to the approval of the application. Additionally, six months of marketing exclusivity is available under Section 505A of the FDCA if, in response to a written request from the FDA, a sponsor submits and the agency accepts certain requested information relating to the use of the approved drug in the pediatric population.

The Orphan Drug Act

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S. Orphan drug designation must be requested before submitting an NDA or BLA for that orphan indication. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the

regulatory review and approval process. If a product that has orphan drug designation is the first to subsequently receive FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity for seven years in the U.S. (i.e., the FDA may not approve any other applications to market the same drug for the same disease for seven years, except in limited circumstances). Orphan drug exclusivity does not prevent FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA or BLA application user fee.

Other Regulatory Requirements

Following FDA approval, marketed prescription products continue to be subject to a number of post-approval regulatory requirements. If we seek to make certain changes to an approved product, such as the addition of a new labeled indication or 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. 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.

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.

Several states now require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to individual physicians in these states. Other states prohibit providing various other marketing-related activities. Still other states require the posting of information relating to clinical studies and their outcomes. In addition, several states require pharmaceutical companies to implement compliance programs or marketing codes.

In addition, we and the third-party manufacturers on which we rely for the manufacture of our products are subject to requirements that drug and biological products 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 and biological manufacturing facilities to evaluate compliance with cGMP requirements. Regulatory authorities may withdraw product approvals

or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

Also, as part of the sales and marketing process, pharmaceutical companies frequently provide samples of approved drug and biological products to physicians. This practice is regulated by the FDA and other governmental authorities, including, in particular, requirements concerning recordkeeping and control procedures. Civil or criminal penalties may be assessed for non-compliance.

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

Patient Protection and Affordable Care Act of 2010

Our industry is highly regulated and changes in law may adversely impact our business, operations or financial results. The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or PPACA, is a sweeping measure intended to expand healthcare coverage within the U.S., primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. The law imposed a new fee on certain manufacturers and importers of branded prescription drugs, which includes drugs and biologicals. The annual fee is apportioned among the participating companies based on each company's sales of qualifying products to, and used by, certain U.S. government programs during the preceding year.

Additionally, several provisions of the new law, which have varying effective dates, may affect us and will likely increase certain of our costs. For example, an increase in the Medicaid rebate rate from 15.1% to 23.1% was effective as of January 1, 2010, and the volume of rebated drugs has been expanded to include beneficiaries in Medicaid managed care organizations, effective as of March 23, 2010.

The PPACA also created a regulatory pathway for the abbreviated approval for biological products that are demonstrated to be "biosimilar" or "interchangeable" with an FDA-approved biological product. In order to meet the standard of interchangeability, a sponsor must demonstrate that the biosimilar product can be expected to produce the same clinical result as the reference product, and for a product that is administered more than once, that the risk of switching between the reference product and biosimilar product is not greater than the risk of maintaining the patient on the reference product. Such biosimilars would reference biological products approved in the U.S. The law establishes a period of 12 years of data exclusivity for reference products, which protects the data in the original BLA by prohibiting sponsors of biosimilars from gaining FDA approval based in part on reference to data in the original BLA.

The PPACA also imposes new reporting and disclosure requirements for pharmaceutical and device manufacturers with regard to payments or other transfers of value made to physicians and teaching hospitals. In addition, pharmaceutical and device manufacturers will also be required to report and disclose investment interests held by physicians and their immediate family members during the preceding calendar year.

The reforms imposed by the new law will significantly impact the pharmaceutical industry; however, the full effects of the PPACA cannot be known until these provisions are implemented. It is also possible that the PPACA may be modified or repealed in the future. Moreover, in the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of our products or investigational drugs.

Employees

As of January 31, 2013, we had 290 employees. A total of 61 employees were engaged in clinical research, regulatory, quality assurance, product development and manufacturing, and medical affairs, 201 were engaged in

sales, marketing, commercial operations and business development, and 28 were engaged in administration and finance.

Available Information

We make available free of charge on or through our Internet web site our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission. Our Internet address is www.santarus.com. Information is also available through the SEC's website at www.sec.gov or is available at the SEC's Public Reference Room located at 100 F Street, NE, Washington DC, 20549. Information on the operation of the Public Reference Room is available by calling the SEC at 1-800-SEC-0330. The information in or accessible through the SEC and our web site are not incorporated into, and are not considered part of, this filing. Further, our references to the URLs for these websites are intended to be inactive textual references only.

Item 1A. Risk Factors

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

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

- our ability to generate revenues from our marketed products: Uceris™ (budesonide) extended release tablets, Zegerid® (omeprazole/sodium bicarbonate) capsules and powder for oral suspension, Glumetza® (metformin hydrochloride extended release tablets), Cycloset® (bromocriptine mesylate) tablets, and Fenoglide® (fenofibrate) tablets;

- our ability to continue to generate revenues from our authorized generic Zegerid (omeprazole/sodium bicarbonate) capsules prescription product;

- our ability to maintain patent coverage for our promoted commercial products, including whether favorable outcomes are obtained in pending and any future patent infringement lawsuits;

- our ability to successfully advance the development of, obtain regulatory approval for and ultimately commercialize, our investigational drugs: Ruconest® (recombinant human C1 esterase inhibitor), rifamycin SV MMX® and SAN-300; and

- our ability to further expand our product portfolio through co-promotion, in-licensing or acquisition of products that would be complementary to our existing products or that otherwise have attractive commercial potential.

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

Risks Related to Our Business and Industry

We are dependent upon our ability to generate revenues from our promoted commercial products, and we cannot be certain that we will be successful.

Our ability to generate product revenue in the near term will depend in part on the success of our promoted commercial products, which in turn will depend on several factors, including:

- our ability to successfully launch Uceris and to generate and increase market demand for, and sales of, our promoted commercial products;
- our ability to maintain patent coverage for our promoted commercial products, including whether favorable outcomes are obtained in pending and any future patent infringement lawsuits;
- the performance of third-party manufacturers and their ability to maintain commercial manufacturing operations in accordance with regulatory and quality requirements and as necessary to meet commercial demand for the products and avoid supply interruptions;
- the occurrence of adverse side effects, inadequate therapeutic efficacy or other issues relating to the products, and any resulting product liability claims or product recalls;
- the availability of adequate levels of reimbursement coverage for the products from third-party payors, particularly in light of the availability of other branded and generic competitive products; and
- our ability to effectively market our promoted commercial products in accordance with the requirements of the U.S. Food and Drug Administration, or FDA, and other governmental and regulatory authorities.

We promote Uceris under a strategic collaboration with Cosmo Technologies Limited, or Cosmo. We promote Zegerid under a license agreement with the University of Missouri. We promote Glumetza under a commercialization agreement with Depomed, Inc., or Depomed. We promote Cycloset under a distribution and license agreement with S2 Therapeutics, Inc., or S2, and VeroScience, LLC, or VeroScience. We promote Fenoglide under a license agreement with Healthcare Royalty Partners, L.P., or HRP, and Shore Therapeutics, Inc., or Shore. Our ability to successfully commercialize our marketed products is also subject to risks associated with these agreements, including the financial condition of our partners, the potential for termination of the agreements, and our reliance on our partners for certain key activities. We cannot be certain that our marketing of our promoted commercial products will result in increased demand for, and sales of, those products.

We are also dependent on our ability to generate and increase revenues from sales of our authorized generic Zegerid prescription products.

Under the terms of our distribution and supply agreement with Prasco LLC, or Prasco, Prasco distributes and sells an authorized generic of prescription Zegerid capsules in the U.S. Prasco pays us a specified invoice supply price and a percentage of the gross margin on sales of the authorized generic products.

We are dependent on Prasco and cannot be certain that Prasco will be able to maintain or increase revenues related to the authorized generic product. Even if physicians prescribe Zegerid products, third-party payors and pharmacists may encourage patients to use generic versions of other proton pump inhibitor, or PPI, products. In many cases, insurers and other healthcare payment organizations encourage the use of generic brands through their prescription benefits coverage and payment or reimbursement policies. Any inability to generate and increase sales of our authorized generic Zegerid prescription products would have a negative impact on our financial condition and results of operations.

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

We will not be permitted to market Ruconest, rifamycin SV MMX and SAN-300 or any other investigational drugs for which we may acquire rights in the U.S. until we complete all necessary development activities and obtain regulatory approval from the FDA.

To market a new drug in the U.S., we must submit to the FDA and obtain FDA approval of a new drug application, or NDA, or a biologics license application, or BLA. An NDA or BLA must be supported by extensive clinical and preclinical data, as well as extensive information regarding chemistry, manufacturing and controls, or CMC, to demonstrate the safety and effectiveness of the applicable investigational drug. The FDA's regulatory review of NDAs and BLAs is becoming increasingly focused on product safety attributes, and even if approved, investigational drugs may not be approved for all indications requested and such approval may be subject to limitations on the indicated uses for which the drug may be marketed, restricted distribution methods or other limitations.

Failure can occur at any stage of clinical testing. The clinical study process may fail to demonstrate that our products are safe for humans or effective for their intended uses. Our clinical tests must comply with FDA and other applicable U.S. and foreign regulations, including a requirement that they be conducted in accordance with good clinical practices. We may encounter delays based on our inability to timely enroll enough patients to complete our clinical studies. We may suffer significant setbacks in advanced clinical studies, even after showing promising results in earlier studies. Based on results at any stage of clinical studies, we may decide to discontinue development of an investigational drug. We or the FDA may suspend clinical studies at any time if the patients participating in the studies are exposed to unacceptable health risks or if the FDA finds deficiencies in our applications to conduct the clinical studies or in the conduct of our studies.

Regulatory approval of an NDA or a BLA is difficult, time-consuming and expensive to obtain. The number and types of preclinical studies and clinical trials that will be required for NDA or BLA approval varies depending on the investigational drug, the disease or the condition that the investigational drug is designed to target and the regulations applicable to any particular investigational drug. Despite the time and expense associated with preclinical and clinical studies, failure can occur at any stage, and we could encounter problems that cause us to repeat or perform additional preclinical studies, CMC studies or clinical studies. The FDA and similar foreign authorities could delay, limit or deny approval of an investigational drug for many reasons, including because they:

- may not deem an investigational drug to be adequately safe and effective;
- may not find the data from preclinical studies, CMC studies and clinical studies to be sufficient to support a claim of safety and efficacy;
- may interpret data from preclinical studies, CMC studies and clinical studies significantly differently than we do;
- may not approve the manufacturing processes or facilities utilized for our development activities or our proposed commercial manufacturing operations;
- may conclude that we have not sufficiently demonstrated long-term stability of the formulation for which we are seeking marketing approval;
- may change approval policies (including with respect to our investigational drugs' class of drugs) or adopt new regulations; or
- may not accept a submission due to, among other reasons, the content or formatting of the submission.

Even if we believe that data collected from our preclinical studies, CMC development program and clinical studies of our investigational drugs are promising and that our information and procedures regarding CMC are sufficient, our data may not be sufficient to support marketing approval by the FDA or any other U.S. or foreign regulatory authority, or regulatory interpretation of these data and procedures may be unfavorable. In addition, before the FDA approves one of our investigational drugs, the FDA may choose to conduct an inspection of one or more clinical or manufacturing sites. These inspections may be conducted by the FDA both at U.S. sites as well as

overseas. Any restrictions on the ability of FDA investigators to travel overseas to conduct such inspections, either because of financial or other reasons including political unrest, disease outbreaks or terrorism, could delay the inspection of overseas sites and consequently delay FDA approval of our investigational drugs.

Our product development costs will increase and our product revenues will be delayed if we experience delays or setbacks for any reason. In addition, such failures could cause us to abandon an investigational drug entirely. If we fail to take any current or future investigational drug 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.

To market any drugs outside of the U.S., we and current or future collaborators must comply with numerous and varying regulatory requirements of other countries. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods, including obtaining reimbursement approval in select markets. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

In addition to the general development and regulatory risks described above, each of our investigational drugs is subject to the following additional risks:

Ruconest (recombinant human C1 esterase inhibitor)

Ruconest is a recombinant version of the human protein C1 esterase inhibitor, which is produced using proprietary transgenic technology. We have rights to commercialize Ruconest in North America under a license agreement with Pharming Group NV, or Pharming.

In November 2012, we announced that when compared with placebo, Ruconest demonstrated a significantly shorter time to beginning of relief of symptoms, the primary endpoint, in a pivotal phase III clinical study that was conducted to evaluate the safety and efficacy of Ruconest 50 IU/kg for the treatment of acute attacks of angioedema in patients with HAE. We plan to submit a BLA to the FDA during the second quarter of 2013, seeking approval to market Ruconest for the treatment of acute attacks of angioedema in patients with HAE.

In addition, we currently are exploring clinical and regulatory strategies with the goal of initiating a proof-of-concept study in late 2013 to evaluate Ruconest for the treatment of acute pancreatitis. This program is very early stage, and we cannot be certain that we will be able to initiate the study in a timely manner or at all or otherwise pursue development for this indication.

We cannot be certain as to whether the BLA will be timely submitted or whether the FDA will accept the BLA for review following submission and ultimately approve it. Although the top-line results from the phase III study were positive, we cannot be sure that the FDA will concur with our clinical interpretation of the results or the conduct of the study. Ultimately, the FDA may provide us with a complete response letter or take other action that could delay or prevent approval. The FDA may ultimately conclude that we have not demonstrated sufficient safety or efficacy to approve a BLA filing for this investigational drug or may require additional clinical studies or other development programs before approving Ruconest. The costs of any additional clinical studies and development programs could be significant, and we and Pharming may not have sufficient resources to complete any additional development requirements in a prompt manner or at all.

We are dependent on Pharming for many activities related to the Ruconest development program, including conduct of the phase III study and manufacturing and supply, and there are significant risks concerning Pharming's ability to continue to perform these functions based on its limited financial resources. Any inability of Pharming to continue to fund its operations would have a material adverse effect on the Ruconest development program.

Moreover, Ruconest utilizes Pharming's transgenic technology platform for the production of recombinant human proteins, and to date there has been only one other prescription product approved by the FDA that utilizes transgenic technology. As a result, Ruconest is subject to risks related to the novelty of its technology platform as well as other general development risks, any of which may result in additional costs and delays prior to our ability to obtain U.S. regulatory approval for, and commercialize, Ruconest.

Rifamycin SV MMX

In September 2012, we announced positive top-line results from a phase III clinical study to evaluate the safety and efficacy of rifamycin SV MMX for the treatment of patients with travelers' diarrhea. The study results showed that rifamycin SV MMX, when compared with placebo, demonstrated a statistically significant reduction in the time to last unformed stool, or TLUS, the primary endpoint of the study. We have licensed rights to develop and commercialize rifamycin SV MMX in the U.S. from Cosmo.

Dr. Falk Pharma GmbH, or Dr. Falk, Cosmo's European development partner, is conducting a second phase III clinical study to evaluate the efficacy of rifamycin SV MMX versus ciprofloxacin with a primary endpoint of TLUS in patients with travelers' diarrhea. Based on a prespecified interim analysis, an independent data monitoring committee has recommended that approximately 250 patients be added to the study, which originally targeted enrolling approximately 780 patients. Dr. Falk is working with the Indian regulatory authorities to gain approval for this amendment to the protocol. We anticipate that the estimated timeline for completion of the study will be updated once Dr. Falk receives approval to move forward with the amended protocol. The Dr. Falk study has taken longer than originally anticipated and we cannot be certain that it will be completed in a timely manner or at all. Assuming positive results in the second phase III clinical study, we and Dr. Falk plan to share the clinical data from our respective phase III studies for inclusion in each company's regulatory submissions. We cannot be certain that Dr. Falk will be able to complete its study in a timely manner or that results from Dr. Falk's study will be positive or provide a sufficient basis for planned regulatory submissions.

SAN-300 (anti-VLA-1antibody)

We have acquired the exclusive worldwide rights to a humanized anti-VLA-1 monoclonal antibody, or mAb, development program, through the acquisition of Covella Pharmaceuticals, Inc., or Covella, and a related license agreement with Biogen Idec MA Inc., or Biogen. SAN-300, our anti-VLA-1 mAb, is an inhibitor of VLA-1, also known as $\alpha_1\beta_1$ integrin, and has shown activity in multiple preclinical models of inflammatory and autoimmune diseases. We initially expect to develop SAN-300 for the treatment of rheumatoid arthritis.

In December 2012, we completed a phase I dose-escalation clinical study in healthy volunteers to determine the safety, tolerability, pharmacokinetics and pharmacodynamics of single doses of SAN-300 in both intraveneous, or IV, and subcutaneous formulations. The phase I study was conducted in Australia and enrolled a total of 66 healthy volunteers . We plan to begin a phase IIa clinical study evaluating SAN-300 for treatment of rheumatoid arthritis during the fourth quarter of 2013.

Although SAN-300 has shown activity in pre-clinical models, it is at a very early stage of development, and has only recently completed the initial phase of human clinical testing. As a result, we cannot be certain that further clinical testing and any necessary additional pre-clinical testing will be timely or successful, and there are many significant risks for this early-stage development program.

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

As an integral component of our clinical development programs, we engage clinical investigators and CROs to enroll patients and conduct and manage our clinical studies, including CROs located both within and outside the U.S. In addition, it is anticipated that U.S. regulatory approval for many of our investigational drugs will be supported in part by clinical studies that have been or are being conducted by our strategic partners in connection with CROs or other third parties. Accordingly, our ability to successfully commercialize these products is subject to risks associated with our agreements with these partners, including the potential for early termination of the agreements and the financial condition of our partners. As a result, many key aspects of this process have been and will be out of our direct control and are impacted by general conditions both within and outside the U.S. If the CROs and other third parties that we rely on for patient enrollment and other portions of our clinical studies fail to perform the clinical studies in a timely and satisfactory manner and in compliance with applicable U.S. and foreign regulations, including the FDA's regulations relating to good clinical practices, we could face significant delays in

completing our clinical studies or we may be unable to rely in the future on the clinical data generated. If these CROs or other third parties 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 patient enrollment criteria, our clinical protocols, regulatory requirements or for other reasons, our clinical studies may be extended, delayed or terminated, we may be required to repeat one or more of our clinical studies and we may be unable to obtain or maintain regulatory approval for or successfully commercialize our products.

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

The pharmaceutical and biotechnology industries are intensely competitive in the markets in which our commercial products compete and our investigational drugs may compete, and there are many other currently marketed products that are well-established and successful, as well as development programs underway. In addition, many of our competitors are large, well-established companies in the pharmaceutical and biotechnology fields with significantly greater financial resources, sales and marketing capabilities, manufacturing capabilities, experience in obtaining regulatory approvals for product candidates, and other resources than we do. Larger pharmaceutical and biotechnology companies typically have significantly larger field sales force organizations and invest significant amounts in advertising and marketing their products. As a result, these larger companies are able to reach a greater number of physicians and consumers than we can with our smaller sales organization.

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

Our marketed prescription products currently compete with many other drug products.

Uceris competes with many other products, including:

- branded 5-aminosalicylate prescription products (such as Asacol®, Lialda®, Pentasa® and Apriso®);
- generic 5-aminosalicylate prescription products (such as sulfasalzine, mesalamine, and balsalazide);
- generic prescription corticosteroids (such as prednisone and hydrocortisone);
- branded and generic prescription immunosuppressive products (such as aziothioprine and 6-mercaptopurine); and
- branded anti-TNF-α prescription products (such as Remicade® and Humira®).

Zegerid (branded and authorized generic) competes with many other products, including:

- branded PPI prescription products (such as Nexium®, Aciphex® and Dexilant®);
- generic PPI prescription products (such as delayed-release omeprazole, delayed-release lansoprazole and delayed-release pantoprazole);
- OTC PPI products (such as Prilosec OTC®, Prevacid® 24HR and store-brand versions); and
- other prescription and/or OTC acid-reducing agents (such as histamine-2 receptor antagonists and antacids).

Glumetza competes with many other products, including:

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

In addition, various companies are developing new products that may compete with the Glumetza products in the future. For example, Depomed has licensed rights to use its extended-release patents in combination with canagliflozin, a sodium-glucose transporter-2, or SGLT2, compound being developed by Janssen. Depomed has

also licensed rights to use its extended-release metformin patents to Boehringer Ingelheim for use with certain fixed dose combination products that include proprietary Boehringer Ingelheim compounds.

Like Glumetza, Cycloset competes with many other products, including:

- dipeptidyl peptidase IV inhibitors, or DPP-4, products (such as Januvia® and Onglyza®);
- glucagon-like peptide 1, or GLP-1, receptor agonist products (such as Byetta®, Victoza® and Bydureon®);
- thiazolidinedione, or TZD, products (such as Avandia® and Actos®);
- sulfonylureas products (such as Amaryl® and Glynase®); and
- branded and generic metformin products.

In addition, various companies are developing new products that may compete with the Cycloset product in the future. For example, SGLT2 and new DPP-4 inhibitor products in development could compete with Cycloset in treating type 2 diabetes patients in the future. In addition, companies could develop combination products that include bromocriptine mesylate as one of the active ingredients for the treatment of type 2 diabetes.

Fenoglide competes with many other products, including:

- other branded and generic formulations of fenofibrate (such as Tricor®, Antara® and Lipofen®), gemfibrozil (such as Lopid®), and fenofibric acid (such as Trilipix®); and
- other prescription treatments for primary hyperlipidemia, mixed dyslipidemia, and hypertriglyceridemia (such as statins and niacin).

In addition, various companies are developing new products that may compete with Fenoglide in the future. For example, monoclonal antibodies targeting PCSK9 for reducing LDL-C could compete with Fenoglide in the future. In addition, companies could develop combination products with fenofibrate as one of the active ingredients for the treatment of primary hyperlipidemia, mixed lipidemia, or hypertriglyceridemia. For example, rosuvastatin calcium and fenofibric acid are being studied in combination for the treatment of mixed dyslipidemia.

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

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

In addition, if approved, our investigational drugs will compete with many other drug and biologic products that are already entrenched in the marketplace, as well as face competition from other product candidates currently under development.

Our ability to generate revenues also depends on the success of our strategic alliances with MSD Consumer Products, Inc., a subsidiary of Merck & Co., Inc., or Merck, and Glaxo Group Limited, an affiliate of GlaxoSmithKline, plc, or GSK.

Our ability to generate revenues in the longer term will also depend on whether our strategic alliances with Merck and GSK lead to revenue growth from existing omeprazole products and the successful commercialization of additional omeprazole products, and we cannot be certain that we will receive any additional milestone payments or sales-based royalties from these alliances. Under these agreements, we depend on the efforts of Merck and GSK, and we have limited control over their commercialization efforts. We are also subject to the risk of termination of each of these agreements.

We cannot be certain that these strategic partners will continue to devote significant resources to the sale or development of products under the agreements. Any determination by Merck or GSK to cease promotion or development of products under our strategic alliances would limit our potential to receive additional payments under these agreements, and adversely affect our ability to generate sufficient revenues to grow our business.

See also "Risks Related to Our Intellectual Property" for a description of the Zegerid related patent litigation and the potential impact on our strategic alliances.

We do not currently have any manufacturing facilities and instead rely on third-party manufacturers and our strategic partners for supply.

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

We have limited control over our third-party manufacturers and strategic partners, including with respect to regulatory compliance and quality assurance matters. Any delay or interruption of supply related to a failure to comply with regulatory or other requirements, or in connection with transfer of manufacturing activities to alternate facilities, would limit our ability to sell 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 investigational drugs, if the FDA finds significant issues with any of our manufacturers during the pre-approval inspection process, the approval of those drugs 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 materials into the U.S. is subject to regulation by the FDA, and the FDA can refuse to allow an imported item into the U.S. if it is not satisfied that the product complies with applicable laws or regulations.

For Uceris, we rely on Cosmo, located in Italy, to manufacture and supply all of our drug product requirements. We recently entered into a manufacturing and supply agreement with Cosmo relating to the commercial supply of Uceris.

For Zegerid, we currently rely on Norwich Pharmaceuticals, Inc., located in New York, as the sole third-party manufacturer of the brand and related authorized generic product. In addition, we rely on a Patheon Inc., or Patheon, facility located in Canada for the supply of Zegerid powder for oral suspension.

For Glumetza 500 mg, we assumed from Depomed a commercial manufacturing agreement with Patheon, and, accordingly, we rely on a Patheon facility located in Puerto Rico as the sole third-party manufacturer of Glumetza 500 mg. We currently rely on Depomed to oversee product manufacturing and supply of Glumetza 1000 mg. In turn, Depomed relies on a Valeant Pharmaceuticals International, Inc. facility located in Canada as the sole third-party manufacturer of Glumetza 1000 mg.

In connection with the license of rights to Cycloset, we assumed a manufacturing services agreement with Patheon, and, accordingly, we rely on a Patheon facility located in Ohio as the sole third-party manufacturer for Cycloset.

In connection with the license of rights to Fenoglide, we assumed a commercial supply agreement with Catalent Pharma Solutions, LLC, or Catalent, and accordingly, we rely on a Catalent facility located in Kentucky as the sole third-party manufacturer for Fenoglide.

For our Ruconest investigational drug, we rely on Pharming to oversee product manufacturing and supply. In turn, Pharming utilizes certain of its own facilities as well as third-party manufacturing facilities for supply, all of which are located in Europe.

For our rifamycin SV MMX investigational drug, we will rely on Cosmo, located in Italy, to manufacture and supply all of our drug product requirements. We plan to enter into a manufacturing and supply agreement with Cosmo relating to the commercial supply of rifamycin SV MMX.

For our SAN-300 investigational drug, we are utilizing materials previously manufactured by Biogen for the production of clinical trial materials. In the future, Biogen has a right of first offer to supply our product requirements. We plan to contract with a third-party manufacturer in the event Biogen elects not to supply our product requirements.

We and our strategic partners also rely in many cases on sole source suppliers for active ingredients and other product materials and components. Any significant problem that our strategic partners or the third-party manufacturers or suppliers experience could result in a delay or interruption in the supply until the problem is cured or until we or our partners locate an alternative source of supply. In addition, because these sole source manufacturers and suppliers in many cases provide services to a number of other pharmaceutical companies, they may experience capacity constraints or choose to prioritize one or more of their other customers.

Although alternative sources of supply exist, the number of third-party manufacturers with the manufacturing and regulatory expertise and facilities necessary to manufacture the finished forms of our pharmaceutical products or the key ingredients in our products is limited, and it would take a significant amount of time to arrange for alternative manufacturers. Any new supplier of products or key ingredients would be required to qualify under applicable regulatory requirements and would need to have sufficient rights under applicable intellectual property laws to the method of manufacturing such products or ingredients. The FDA may require us to conduct additional clinical studies, 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.

Any delay, interruption or cessation of production by our third-party manufacturers or strategic partners of our commercial products or investigational drugs or their respective materials and components, as a result of any of the above factors or otherwise, may limit our ability to meet demand for our commercial products resulting in lost potential revenue or, with respect to investigational drugs, delay any ongoing clinical trials, which could have a material adverse impact on our business, results of operations and financial condition.

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

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

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

Any regulatory approval is limited to those specific diseases and indications for which our products are deemed to be safe and effective by the FDA. In addition to the FDA approval required for new formulations, any new

indication for an approved product also requires FDA approval. If we are not able to obtain FDA approval for any desired future indications for our products, our ability to effectively market and sell our products may be reduced and our business may be adversely affected.

While physicians may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical studies and approved by the regulatory authorities, our ability to promote the products is limited to those indications that are specifically approved by the FDA. These "off-label" uses are common across medical specialties and may constitute an appropriate treatment for many patients in varied circumstances. Regulatory authorities in the U.S. generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off-label use. If our promotional activities fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines relating to promotion and advertising may cause the FDA to delay its approval or refuse to approve a product, the suspension or withdrawal of an approved product from the market, recalls, fines, disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could harm our business.

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

Following receipt of regulatory approval, any products that we market continue to be subject to extensive regulation. These regulations impact many aspects of our operations, including the manufacture, labeling, packaging, adverse event reporting, storage, distribution, advertising, promotion and record keeping related to the products. The FDA also frequently requires post-marketing testing and surveillance to monitor the effects of approved products or place conditions on any approvals that could restrict the commercial applications of these products. For example, in connection with the approval of Zegerid powder for oral suspension, we committed to commence clinical studies to evaluate the product in pediatric populations. We have not yet commenced any of the studies and have requested a waiver of this requirement from the FDA. Similarly, in connection with the approval of Uceris, we committed to a post-marketing requirement to conduct an 8-week randomized clinical study in children 5 to 17 years of age with active, mild to moderate ulcerative colitis. We currently plan to submit the protocol for this study later this year and expect to initiate the study once we have reached agreement with the FDA on the study design. 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.

The Patient Protection and Affordable Care Act, or PPACA, enacted in 2010, imposes new reporting and disclosure requirements for pharmaceutical and device manufacturers with regard to payments or other transfers of value made to physicians and teaching hospitals. In addition, pharmaceutical and device manufacturers will also be required to report and disclose investment interests held by physicians and their immediate family members during the preceding calendar year. Failure to submit required information may result in civil monetary penalties for payments, transfers of value or ownership or investment interests not reported in an annual submission. The reforms imposed by the PPACA will significantly impact the pharmaceutical industry; however, the full effects of the new law cannot be known until these provisions are implemented. In addition, although the PPACA was recently upheld by the U.S. Supreme Court, it is possible that the PPACA may be modified or repealed in the future.

If not preempted by this federal law, several states require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to individual physicians in the states. Other states prohibit providing various other marketing related activities. Still other states require the posting of information relating to clinical studies and their outcomes. In addition, certain states require pharmaceutical companies to implement compliance programs or marketing codes. Currently, several additional states are considering similar proposals. Compliance with these laws is difficult and time consuming, and companies that do not comply with these state laws face civil penalties. 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, results of operations and growth prospects.

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

We are subject to new legislation, regulatory proposals, managed care initiatives and other legal developments that may increase our costs and adversely affect our ability to market our products.

In March 2010, the President signed the PPACA, which makes extensive changes to the delivery of healthcare in the U.S. This act includes numerous provisions that affect pharmaceutical companies, some of which were effective immediately and others of which will be taking effect over the next several years. For example, the act seeks to expand healthcare coverage to the uninsured through private health insurance reforms and an expansion of Medicaid. The act also imposes substantial costs on pharmaceutical manufacturers, such as an increase in liability for rebates paid to Medicaid, new drug discounts that must be offered to certain enrollees in the Medicare prescription drug benefit, an annual fee imposed on all manufacturers of brand prescription drugs in the U.S., increased disclosure obligations and an expansion of an existing program requiring pharmaceutical discounts to certain types of hospitals and federally subsidized clinics. The act also contains cost-containment measures that could reduce reimbursement levels for healthcare items and services generally, including pharmaceuticals. It also will require reporting and public disclosure of payments and other transfers of value provided by pharmaceutical companies to physicians and teaching hospitals. These measures could result in decreased net revenues from our pharmaceutical products and decreased potential returns from our development efforts. Although the PPACA was recently upheld by the U.S. Supreme Court, it is possible that the PPACA may be modified or repealed in the future.

In addition, there have been a number of other legislative and regulatory proposals aimed at changing the pharmaceutical industry. These include proposals to permit reimportation of pharmaceutical products from other countries and proposals concerning safety matters. For example, in an attempt to protect against counterfeiting and diversion of drugs, a bill was introduced in a previous Congress that would establish an electronic drug pedigree and track-and-trace system capable of electronically recording and authenticating every sale of a drug unit throughout the distribution chain. This bill or a similar bill may be introduced in Congress in the future. California has already enacted legislation that requires development of an electronic pedigree to track and trace each prescription drug at

the saleable unit level through the distribution system. California's electronic pedigree requirement is scheduled to take effect beginning in January 2015. Compliance with California and any future federal or state electronic pedigree requirements will likely require an increase in our operational expenses and will likely be administratively burdensome. As a result of these and other new proposals, we may determine to change our current manner of operation, provide additional benefits or change our contract arrangements, any of which could have a material adverse effect on our business, financial condition and results of operations.

We, as well as many other pharmaceutical companies, sponsor prescription drug coupons and other cost-savings programs to help reduce the burden of co-payments and co-insurance. During 2012, lawsuits have been filed against several pharmaceutical companies alleging, among other things, that the drug-makers violated anti-trust laws and the Racketeer Influenced and Corrupt Organizations Act, or RICO, when they provided coupon programs to privately-insured consumers that subsidize all or part of the cost-sharing obligation (co-pay or co-insurance) for a branded prescription drug or drugs. We cannot be certain as to whether we will be named in any future similar lawsuit or concerning the potential outcome of the ongoing litigation.

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

Our business exposes us to potential liability risks that may arise from the clinical testing, manufacture and sale of our marketed products and investigational drugs. 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 study liability insurance with a coverage limit of $15.0 million, this coverage may prove to be inadequate. Furthermore, we cannot be certain that our current insurance coverage will continue to be available for our commercial or clinical study 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.

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

We are a small company and, as of December 31, 2012, had 251 employees. Our success depends on our continued ability to retain and motivate highly qualified management, clinical, regulatory, manufacturing, product development, business development and sales and marketing personnel. We may not be able to recruit and retain qualified personnel in the future, due to competition for personnel among pharmaceutical businesses, and the failure to do so could have a significant negative impact on our future product revenues and business results.

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

Our future growth may depend on our ability to identify and in-license or acquire additional products, and if we do not successfully do so, or otherwise fail to integrate any new products into our operations, we may have limited growth opportunities.

We are continuing to seek to acquire or in-license products, businesses or technologies that we believe are a strategic fit with our business strategy. Future in-licenses or acquisitions, however, may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;

- disruption of our business and diversion of our management's time and attention to develop acquired products or technologies;
- a reduction of our current financial resources;
- difficulty or inability to secure financing to fund development activities for such acquired or in-licensed technologies;
- incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions; and
- higher than expected acquisition and integration costs.

We may not have sufficient resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. In particular, we may compete with larger pharmaceutical companies and other competitors in our efforts to establish new collaborations and in-licensing opportunities. These competitors likely will have access to greater financial resources than us and may have greater expertise in identifying and evaluating new opportunities. In addition, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts.

If we become subject to unsolicited public proposals from activist stockholders due to our shifting strategic focus or otherwise, we may experience significant uncertainty that would likely be disruptive to our business and increase volatility in our stock price.

Even if we are successful in future in-licenses or acquisitions, other companies who have shifted focus to new products and additional development programs have been the target of unsolicited public proposals from activist stockholders. The unsolicited and often hostile nature of these public proposals can result in significant uncertainty for current and potential licensors, suppliers, patients, physicians and other constituents, and can cause these parties to change or terminate their business relationships with the targeted company. Companies targeted by these unsolicited proposals from activist stockholders may not be able to attract and retain key personnel as a result of the related uncertainty. In addition, unsolicited proposals can result in stockholder class action lawsuits. The review and consideration of an unsolicited proposal as well as any resulting lawsuits can be a significant distraction for management and employees, and may require the expenditure of significant time, costs and other resources.

If we were to receive unsolicited public proposals from activist stockholders, we may encounter all of these risks and, as a result, may be delayed in executing our core strategy. We could be required to spend substantial resources on the evaluation of the proposal as well as the review of other opportunities that never come to fruition. If we were to receive any of these unsolicited public proposals, the future trading price of our common stock is likely to be even more volatile than in the past, and could be subject to wide price fluctuations based on many factors, including uncertainty associated with the proposals.

Risks Related to Our Intellectual Property

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

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

Patents

Our commercial success will depend in part on the patent rights we have licensed or will license and on patent protection for our own inventions related to the products that we market and intend to market. Our success also depends on maintaining these patent rights against third-party challenges to their validity, scope or enforceability.

Our patent position is subject to uncertainties similar to other biotechnology and pharmaceutical companies. For example, the U.S. Patent and Trademark Office, or PTO, or the courts may deny, narrow or invalidate patent claims, particularly those that concern biotechnology and pharmaceutical inventions.

We may not be successful in securing or maintaining proprietary or patent protection for our products, and protection that we have and do secure may be challenged and possibly lost. In addition, our competitors may develop products similar to ours using methods and technologies that are beyond the scope of our intellectual property rights. Other drug companies may challenge the scope, validity and enforceability of our patent claims and may be able to develop generic versions of our products if we are unable to maintain our proprietary rights. We also may not be able to protect our intellectual property rights against third-party infringement, which may be difficult to detect.

We have licensed the primary patent rights for each of our products and investigational drugs. Although we consult with our strategic partners and licensors concerning our licensed patent rights, in most cases those partners remain primarily responsible for prosecution activities. We cannot control the amount or timing of resources that our strategic partners and licensors devote to these activities. 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 or that the issued patents will be properly maintained. In addition, we are subject to the risk that one or more of our licenses could be terminated and any loss of our license rights would negatively impact our ability to develop, manufacture and commercialize our products and investigational drugs.

In addition, any patent litigation settlement agreements we enter with regard to our products could be subject to further review by the U.S. Department of Justice and the Federal Trade Commission. Any legal or regulatory challenge to one or more of our settlement agreements by the U.S. Department of Justice and/or the Federal Trade Commission could adversely impact our business and revenues.

Uceris

We have exclusive rights to develop and commercialize Uceris in the U.S. under our strategic collaboration with Cosmo. Currently, there are four issued U.S. patents that are owned by Cosmo and licensed to us that we believe provide coverage for Uceris (U.S. Patent Nos. 7,431,943, 7,410,651; RE43,799 and 8,293,273), each of which expires in 2020.

Zegerid and Pending Patent Litigation

We have entered into an exclusive, worldwide license agreement with the University of Missouri for patents and pending patent applications relating to specific formulations of PPIs with antacids and other buffering agents and methods of using these formulations. Currently, there are three U.S. patents that we believe provide coverage for our Zegerid products (U.S. Patent Nos. 5,840,737; 6,780,882; and 7,399,772), each of which expires in 2016. In addition to the issued U.S. patent coverage described above, several international patents have been issued.

Zegerid Rx and Zegerid OTC Patent Litigation

Zegerid Rx Litigation

In April 2010, the U.S. District Court for the District of Delaware ruled that five patents covering Zegerid capsules and Zegerid powder for oral suspension (U.S. Patent Nos. 6,489,346; 6,645,988; 6,699,885; 6,780,882; and 7,399,772) were invalid due to obviousness. These patents were the subject of lawsuits we filed in 2007 against Par Pharmaceutical, Inc., or Par, in response to abbreviated new drug applications, or ANDAs, filed by Par with the FDA. The University of Missouri, licensor of the patents, is joined in the litigation as a co-plaintiff. In May 2010, we filed an appeal of the District Court's ruling to the U.S. Court of Appeals for the Federal Circuit. Following the District Court's decision, Par launched its generic version of Zegerid capsules in late June 2010.

In September 2012, the U.S. Court of Appeals for the Federal Circuit reversed in part the April 2010 decision of the District Court. The Federal Circuit found that certain claims of asserted U.S. Patent Nos. 6,780,882 and 7,399,772, which Par had been found to infringe, were not invalid due to obviousness. These patents represent two

of the five patents that were found to be invalid by the District Court, and the Federal Circuit affirmed the District Court's finding of invalidity for the asserted claims from the remaining three patents. The Federal Circuit also upheld the District Court's finding that there was no inequitable conduct. Following the Federal Circuit's decision, Par announced that it had ceased distribution of its generic Zegerid capsules product in September 2012. In December 2012, the Federal Circuit issued an order denying a combined petition for panel and en banc rehearing filed by Par and issued its mandate, remanding the case to the District Court for further proceedings pertaining to damages. In February 2013, we filed an amended complaint with the District Court for infringement of U.S. Patent Nos. 6,780,882 and 7,399,772 and requested a jury trial with respect to the issue of damages in connection with Par's launch of its generic version of Zegerid capsules in June 2010. In March 2013, Par filed its amended answer, which alleges, among other things, failure to state a claim upon which relief can be granted and non-infringement based on purported invalidity of the two asserted patents. In addition, Par filed a motion for a judgment on the pleadings, alleging, among other things, that the two asserted patents are invalid because the Federal Circuit purportedly did not expressly address certain prior art references considered by the District Court. Although we do not believe that Par has a meritorious basis upon which to further challenge validity of the asserted patents in this proceeding, we cannot be certain of the timing or outcome of this or any other proceedings.

In December 2011, we filed a lawsuit in the U.S. District Court for the District of New Jersey against Zydus Pharmaceuticals USA, Inc., or Zydus, for infringement of the patents listed in the Orange Book for Zegerid capsules. The University of Missouri, licensor of the patents, is joined in the litigation as a co-plaintiff. Zydus had filed an ANDA with the FDA regarding its intent to market a generic version of Zegerid capsules prior to the expiration of the listed patents. In September 2012, we amended our complaint to be limited to U.S. Patent No. 7,399,772, which patent was found not to be invalid in the September 2012 Federal Circuit decision. In October 2012, Zydus filed its answer, which alleges, among other things, failure to state a claim upon which relief can be granted. The lawsuit was commenced within the requisite 45 day time period, resulting in an FDA stay on the approval of Zydus' proposed product for 30 months or until a decision is rendered by the District Court, which is adverse to the asserted patent. The Markman hearing for this matter has been scheduled in July 2013 and a trial has been scheduled in January 2014. Absent a court decision, the 30-month stay is expected to expire in May 2014. We are not able to predict the timing or outcome of this lawsuit.

In August 2012, we filed a lawsuit in the U.S. District Court for the District of New Jersey against Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc., collectively referred to herein as Dr. Reddy's, for infringement of the patents listed in the Orange Book for Zegerid capsules. The University of Missouri, licensor of the patents, is joined in the litigation as a co-plaintiff. Dr. Reddy's had filed an ANDA with the FDA regarding its intent to market a generic version of Zegerid capsules prior to the expiration of the listed patents. In October 2012, we amended our complaint to be limited to U.S. Patent No. 7,399,772, which patent was found not to be invalid in the September 2012 Federal Circuit decision. Also in October 2012, Dr. Reddy's filed its answer, which alleges, among other things, non-infringement, invalidity, failure to state a claim upon which relief can be granted and estoppel. The lawsuit was commenced within the requisite 45 day time period, resulting in an FDA stay on the approval of Dr. Reddy's proposed product for 30 months or until a decision is rendered by the District Court, which is adverse to the asserted patent. The Markman hearing for this matter has been scheduled in July 2013 and a trial has been scheduled in July 2014. Absent a court decision, the 30-month stay is expected to expire in January 2015. We are not able to predict the timing or outcome of this lawsuit.

Zegerid OTC Litigation

In September 2010, Merck filed a lawsuit in the U.S. District Court for the District of New Jersey against Par for infringement of the patents listed in the Orange Book for Zegerid OTC. We and the University of Missouri, licensors of the listed patents, are joined in the lawsuit as co-plaintiffs. Par had filed an ANDA with the FDA regarding its intent to market a generic version of Zegerid OTC prior to the expiration of the listed patents. In October 2012, Merck amended its complaint to be limited to U.S. Patent No. 7,399,772, which patent was found not to be invalid in the September 2012 Federal Circuit decision. Also in October 2012, Par filed its answer, which alleges, among other things, failure to state a claim upon which relief can be granted, non-infringement and invalidity. Par has received tentative approval of its proposed generic Zegerid OTC product. The lawsuit was commenced within the requisite 45-day time period, resulting in an FDA stay on the approval of Par's proposed product for 30 months or until a decision is rendered by the District Court, which is adverse to the asserted patent. Although the 30-month stay expired in February 2013, the parties have agreed that Par will not launch its generic

Zegerid OTC product unless there is a District Court judgment favorable to Par or in certain other specified circumstances. The Markman hearing for this matter has been scheduled in July 2013 and a trial has been scheduled in January 2015. We are not able to predict the timing or outcome of this lawsuit.

In September 2010, Merck filed a lawsuit in the U.S. District Court for the District of New Jersey against Perrigo Research and Development Company, or Perrigo, for infringement of the patents listed in the Orange Book for Zegerid OTC. We and the University of Missouri, licensors of the listed patents, were joined in the lawsuits as co-plaintiffs. Perrigo had filed an ANDA with the FDA regarding its intent to market a generic version of Zegerid OTC prior to the expiration of the listed patents. In January 2013, this case was settled allowing entry by Perrigo upon expiration of the applicable patents (or earlier under certain circumstances), and the District Court entered an order dismissing the case with prejudice.

In December 2011, Merck filed a lawsuit in the U.S. District Court for the District of New Jersey against Zydus for infringement of the patents listed in the Orange Book for Zegerid OTC. We and the University of Missouri, licensors of the listed patents, are joined in the litigation as co-plaintiffs. Zydus had filed an ANDA with the FDA regarding its intent to market a generic version of Zegerid OTC prior to the expiration of the listed patents. In September 2012, Merck amended its complaint to be limited to U.S. Patent No. 7,399,772, which patent was found not to be invalid in the September 2012 Federal Circuit decision. In October 2012, Zydus filed its answer, which alleges, among other things, failure to state a claim upon which relief can be granted. The lawsuit was commenced within the requisite 45-day time period, resulting in an FDA stay on the approval of Zydus' proposed product for 30 months or until a decision is rendered by the District Court, which is adverse to the asserted patent. Absent a court decision, the 30-month stay is expected to expire in May 2014. The Markman hearing for this matter has been scheduled in July 2013 and a trial has been scheduled in January 2014. We are not able to predict the timing or outcome of this lawsuit.

Any adverse outcome in the Zegerid Rx and Zegerid OTC litigation described above would adversely impact our business, including the amount of revenues we receive from sales of Zegerid brand and authorized generic prescription products and our ability to receive, milestone payments and royalties under our agreement with Merck. For example, the royalties payable to us under our license agreement with Merck are subject to reduction in the event it is ultimately determined by the courts (with the decision being unappealable or unappealed within the time allowed for appeal) that there is no valid claim of the licensed patents covering the manufacture, use or sale of the Zegerid OTC product and third parties have received marketing approval for, and are conducting bona fide ongoing commercial sales of, generic versions of the licensed products. Any negative outcome may also negatively impact the patent protection for the products being commercialized pursuant to our ex-US license with GSK. Although a U.S. ruling is not binding in countries outside the U.S., similar challenges to those raised in the U.S. litigation may be raised in territories outside the U.S. At this time we are unable to estimate possible losses or ranges of losses for ongoing actions.

Regardless of how these litigation matters are ultimately resolved, the litigation has been and will continue to be costly, time-consuming and distracting to management, which could have a material adverse effect on our business.

Glumetza and Pending Patent Litigation

We have exclusive rights to manufacture and commercialize the Glumetza products in the U.S., including its territories and possessions and Puerto Rico, under our commercialization agreement with Depomed. Currently, there are four issued U.S. patents that are owned or licensed by Depomed that we believe provide coverage for the Glumetza 500 mg dose product (U.S. Patent Nos. 6,340,475; 6,635,280; 6,488,962; and 6,723,340), with expiration dates in 2016, 2020 and 2021. There are three issued U.S. patents that are owned or licensed by Depomed that we believe provide coverage for the Glumetza 1000 mg dose product (U.S. Patent Nos. 6,488,962; 7,780,987; and 8,323,692), with expiration dates in 2020 and 2025.

In November 2009, Depomed filed a lawsuit in the U.S. District Court for the Northern District of California against Lupin Limited and its wholly owned subsidiary, Lupin Pharmaceuticals, Inc., collectively referred to herein as Lupin, for infringement of certain patents listed in the Orange Book for Glumetza. The lawsuit was filed in response to an ANDA filed with the FDA by Lupin regarding Lupin's intent to market generic versions of Glumetza 500 mg and 1000 mg tablets prior to the expiration of the listed patents. In February 2012, we and Depomed entered

into a settlement agreement with Lupin that grants Lupin the right to begin selling a generic version of Glumetza in February 2016, or earlier under certain circumstances. In March 2012, the U.S. District Court for the Northern District of California entered an order dismissing the litigation.

In June 2011, Depomed filed a lawsuit in the U.S. District Court for the District of New Jersey against Sun Pharma Global FZE, Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Industries Inc., collectively referred to herein as Sun, for infringement of the patents listed in the Orange Book for Glumetza. Valeant International Bermuda, or Valeant, was joined in the lawsuit as a co-plaintiff. The lawsuit was filed in response to an ANDA filed with the FDA by Sun regarding Sun's intent to market generic versions of Glumetza 500 mg and 1000 mg tablets prior to the expiration of the listed patents. In January 2013, we, Depomed and Valeant entered into a settlement agreement with Sun that grants Sun the right to begin selling a generic version of Glumetza in August 2016, or earlier under certain circumstances. In January 2013, the District Court dismissed the lawsuit without prejudice in view of the settlement agreement. The settlement agreement is subject to review by the U.S. Department of Justice and the Federal Trade Commission.

In April 2012, Depomed filed a lawsuit in the U.S. District Court for the District of Delaware against Watson Laboratories, Inc. — Florida, Actavis, Inc. and Watson Pharma, Inc., collectively referred to herein as Watson, for infringement of the patents listed in the Orange Book for Glumetza 1000 mg at the time the lawsuit was filed (U.S. Patent Nos. 6,488,962 and 7,780,987). Valeant is joined in the lawsuit as a co-plaintiff. The lawsuit was filed in response to an ANDA filed with the FDA by Watson regarding Watson's intent to market a generic version of Glumetza 1000 mg tablets prior to the expiration of the listed patents. Depomed and Valeant commenced the lawsuit within the requisite 45-day time period, resulting in an FDA stay on the approval of Watson's proposed product for 30 months or until a decision is rendered by the District Court, which is adverse to the asserted patents. Absent a court decision, the 30-month stay is expected to expire in September 2014. Watson has filed an answer in the case that asserts, among other things, non-infringement and invalidity of the asserted patents, failure to state a claim, lack of subject matter jurisdiction, and has also filed counterclaims. In February 2013, Depomed amended its complaint to add infringement of a newly listed Orange Book patent (U.S. Patent No. 8,323,692), as well as two non-Orange Book listed patents (U.S. Patent Nos. 7,736,667 and 8,329,215). The Markman hearing for this matter has been scheduled in April 2014, and the trial has been scheduled in May 2014. We are not able to predict the timing or outcome of this lawsuit.

In February 2013, Depomed filed a lawsuit in the U.S. District Court for the District of Delaware against Watson Laboratories, Inc. — Florida, Actavis, Inc. and Watson Pharma, Inc., collectively referred to herein as Watson, for infringement of the patents listed in the Orange Book for Glumetza 500 mg at the time the lawsuit was filed (U.S. Patent Nos. 6,340,475; 6,488,962; 6,635,280 and 6,723,340). The lawsuit was filed in response to an ANDA filed with the FDA by Watson regarding Watson's intent to market a generic version of Glumetza 500 mg tablets prior to the expiration of the listed patents. Depomed commenced the lawsuit within the requisite 45-day time period, resulting in an FDA stay on the approval of Watson's proposed product for 30 months or until a decision is rendered by the District Court, which is adverse to the asserted patents. Absent a court decision, the 30-month stay is expected to expire in July 2015.

Under the terms of our commercialization agreement with Depomed, Depomed will manage the ongoing patent infringement litigation relating to Glumetza, subject to certain consent rights in favor of us, including with regard to any proposed settlements. We are responsible for 70% of the future out-of-pocket costs, and Depomed is responsible for 30% of the future out-of-pocket costs, related to patent infringement cases. Although Depomed has indicated that it intends to vigorously defend and enforce its patent rights, we are not able to predict the timing or outcome of ongoing or future actions. At this time we are unable to estimate possible losses or ranges of losses for ongoing actions.

Any adverse outcome in the litigation described above would adversely impact our business and revenues. Regardless of how these litigation matters are ultimately resolved, the litigation will continue to be costly, time-consuming and distracting to management, which could have a material adverse effect on our business.

Cycloset

We have exclusive rights to manufacture and commercialize Cycloset in the U.S. under our distribution and license agreement with S2 and VeroScience. Currently, there are three issued U.S. patents that we have licensed from S2 and VeroScience that we believe provide coverage for Cycloset (U.S. Patent Nos. 5,679,685; 5,716,957; and 7,888,310), with expiration dates in 2014, 2015 and 2023.

Fenoglide and Pending Patent Litigation

We have exclusive rights to manufacture and commercialize Fenoglide in the U.S. under the terms of a license agreement with HRP and Shore. Currently, there are two issued U.S. patents that we believe provide coverage for the Fenoglide products (U.S. Patent Nos. 7,658,944, and 8,124,125), with expiration dates in 2024.

Prior to the execution of the license agreement, Shore entered into a settlement arrangement with Impax Laboratories, Inc., or Impax, in connection with patent infringement litigation associated with Impax's ANDA for a generic version of Fenoglide and a related paragraph IV challenge. The settlement terms grant Impax a sublicense to begin selling a generic version of Fenoglide on October 1, 2015, or earlier under certain circumstances. In February 2012, the U.S. District Court for the District of Delaware entered an order dismissing the litigation, and we assumed Shore's obligations associated with the sublicense to Impax.

In January 2013, we filed a lawsuit in the U.S. District Court for the District of Delaware against Mylan Inc. and Mylan Pharmaceuticals Inc., collectively referred to herein as Mylan, for infringement of the patents listed in the Orange Book for Fenoglide 120 mg and 40 mg (U.S. Patent Nos. 7,658,944, and 8,124,125). Veloxis Pharmaceuticals A/S, or Veloxis, is joined in the lawsuit as a co-plaintiff. The lawsuit was filed in response to an ANDA filed with the FDA by Mylan regarding Mylan's intent to market a generic version of Fenoglide 120 mg and 40 mg tablets prior to the expiration of the listed patents. We commenced the lawsuit within the requisite 45-day time period, resulting in an FDA stay on the approval of Mylan's proposed product for 30 months or until a decision is rendered by the District Court, which is adverse to the asserted patents, whichever may occur earlier. Absent a court decision, the 30-month stay is expected to expire in June 2015. Mylan has filed an answer in the case that asserts, among other things, non-infringement, invalidity, and failure to state a claim, and has also filed counterclaims. We are not able to predict the timing or outcome of this lawsuit.

Ruconest

We have exclusive rights to develop and commercialize the Ruconest investigational drug in the U.S., Canada and Mexico under our license and supply agreements with Pharming. Currently, there are two issued U.S. patents that are owned by Pharming and licensed to us that we believe provide coverage for Ruconest (U.S. Patent Nos. 7,067,713 and RE43,691), which expire in 2022 and 2024. In addition, we believe Ruconest, as a biological product, is entitled under the PPACA to a period of 12 years of regulatory exclusivity in the U.S.

Rifamycin SV MMX

We have exclusive rights to develop and commercialize the rifamycin SV MMX investigational drug in the U.S. under our strategic collaboration with Cosmo. Currently, there are two issued U.S. patents that are owned by Cosmo and licensed to us that we believe provide coverage for rifamycin SV MMX (U.S. Patent Nos. 7,431,943 and 8,263,120), which expire in 2020 and 2025. In addition, we believe rifamycin SV MMX, as a new chemical entity, is entitled to a period of five years of data exclusivity.

SAN-300

We acquired worldwide rights to develop and commercialize the SAN-300 investigational drug in connection with our acquisition of Covella. Currently, there are seven issued U.S. patents that are owned by Biogen and licensed to us that we believe provide coverage for SAN-300 (U.S. Patent Nos. 7,358,054; 7,462,353; 6,955,810; 7,723,073; 7,910,099; 8,084,031; and 8,084,028), which expire in 2020 and 2022. In addition, we believe SAN-300, as a biological product, is entitled under the PPACA to a period of 12 years of regulatory exclusivity in the U.S.

Trademarks

We own, or have licensed the rights to use, the trademarks for each of our brand pharmaceutical products, as well as for our corporate name and logo. We have applied for trademark registration for various other names and logos. Over time, we intend to maintain registrations on trademarks that remain valuable to our business.

The trademarks and trademark applications we own and license are important to our success and competitive position. Any objections we receive from the PTO, foreign trademark authorities or third parties relating to our registered trademarks and pending applications could require us to incur significant expense in defending the objections or establishing alternative names. There is no guarantee we will be able to secure any of our pending trademark applications with the PTO or comparable foreign authorities.

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

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

The products we currently market, and those we may market in the future, may infringe patent and other rights of third parties. In addition, our competitors, many of which have substantially greater resources than us and have made significant investments in competing technologies or products, may seek to apply for and obtain patents that will prevent, limit or interfere with our ability to make, use and sell products either in the U.S. or international markets. Intellectual property litigation in the pharmaceutical industry is common, and we expect this to continue. Any third party patent infringement litigation may result in a loss of rights and would be time-consuming and costly. In addition, we may be required to negotiate licenses with one or more third parties with terms that may or may not be favorable to us.

Risks Related to Our Financial Results and Need for Financing

We may incur operating losses in the future and may not be able to sustain profitability.

The extent of any future operating losses and our ability to sustain profitability are highly uncertain. We have been engaged in developing and commercializing drugs and have generated significant operating losses since our inception in December 1996. Our commercial activities and continued product development and clinical activities will require significant expenditures. For the year ended December 31, 2012, we recognized $218.0 million in total revenues, and, as of December 31, 2012, we had an accumulated deficit of $285.7 million.

We may incur additional operating losses and capital expenditures as we support the continued marketing of our products and development of our investigational drugs, as well as any other products or investigational drugs that we acquire or in-license.

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

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, marketed products, as well as the success and costs of our development programs are uncertain and therefore our future prospects are uncertain. The level of our revenues and results of operations at any given time will be based primarily on the following factors:

- commercial success of our marketed prescription products;
- potential to receive revenue from Zegerid authorized generic products;

- results of clinical studies and other development programs;
- our ability to obtain regulatory approval for our investigational drugs and any future investigational drugs we develop or in-license;
- whether we are able to maintain patent protection for our products, including whether favorable outcomes are obtained in the pending litigation;
- interruption in the manufacturing or distribution of our products;
- progress under our strategic alliances with Merck and GSK, including the impact on these alliances from generic competition and the potential for early termination of, or reduced payments under, the related agreements;
- timing of new product offerings, acquisitions, licenses or other significant events by us, our strategic partners or our competitors; and
- legislative changes, including healthcare reform, affecting the products we may offer or those of our competitors.

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.

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

We believe that our current cash, cash equivalents and short-term investments and use of our line of credit will be sufficient to fund our current operations through at least the next twelve months; however, our projected revenue may decrease or our expenses may increase and that would lead to our cash resources being consumed earlier than we expect. Although we do not believe that we will need to raise additional funds to finance our current operations through at least the next twelve months, we may pursue raising additional funds for various reasons, including to expand our commercial presence, in connection with licensing or acquisition of new marketed products or investigational drugs, to continue development of investigational drugs in our pipeline, or for other general corporate purposes. Sources of additional funds may include funds generated through equity and/or debt financing or through strategic collaborations or licensing agreements.

Our existing universal shelf registration statement, which was declared effective in December 2011, may permit us, from time to time, to offer and sell up to approximately $75.0 million of equity or debt securities. However, there can be no assurance that we will be able to complete any such offerings of securities. Factors influencing the availability of additional financing include the progress of our commercial and development activities, investor perception of our prospects and the general condition of the financial markets, among others.

In addition, our ability to borrow additional amounts under our loan agreement with Comerica Bank, or Comerica, depends upon a number of conditions and restrictions, and we cannot be certain that we will satisfy all borrowing conditions at a time when we desire to borrow such amounts under the loan agreement. For example, we are subject to a number of affirmative and negative covenants, each of which must be satisfied at the time of any proposed borrowing. If we have not satisfied these various conditions, or an event of default otherwise has occurred, we may be unable to borrow additional amounts under the loan agreement, and may be required to repay any amounts previously borrowed.

We cannot be certain that our existing cash, cash equivalents and short-term investments and use of our line of credit will be adequate to sustain our current operations. To the extent we require additional funding, we cannot be certain that such funding will be available to us on acceptable terms, or at all. If adequate funds are not available on terms acceptable to us at that time, our ability to continue our current operations or pursue new product opportunities would be significantly limited.

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

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

- impair our ability to obtain additional financing in the future for working capital needs, capital expenditures and general corporate purposes;
- increase our vulnerability to general adverse economic and industry conditions;
- make it more difficult for us to satisfy other debt obligations we may incur in the future;
- require us to dedicate a substantial portion of our cash flows from operations to the payment of principal and interest on our indebtedness, thereby reducing the availability of our cash flows to fund working capital needs, capital expenditures and other general corporate purposes; and
- expose us to higher interest expense in the event of increases in interest rates because our indebtedness under the loan agreement with Comerica bears interest at a variable rate.

If an event of default occurs under the loan agreement, we may be unable to borrow additional amounts, and may be required to repay any amounts previously borrowed. The events of default under the loan agreement include, among other things, a material adverse effect on (i) our business operations, condition (financial or otherwise) or prospects, (ii) our ability to repay the obligations under the loan agreement or otherwise perform our obligations under the loan agreement, or (iii) our interest in, or the value, perfection or priority of Comerica's security interest in the collateral, which generally includes all of our cash and accounts receivable, but excludes intellectual property. For a description of the loan agreement, see Management's Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources.

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

Under our loan agreement with Comerica, we are subject to specified affirmative and negative covenants, including limitations on our ability: to undergo certain change of control events; to convey, sell, lease, license, transfer or otherwise dispose of assets; to create, incur, assume, guarantee or be liable with respect to certain indebtedness; to grant liens; to pay dividends and make certain other restricted payments; and to make investments. In addition, under the loan agreement we are required to maintain our cash balances with either Comerica or another financial institution covered by a control agreement for the benefit of Comerica. We are also subject to specified financial covenants with respect to a minimum liquidity ratio and, in specified limited circumstances, minimum EBITDA requirements, as defined in the loan agreement. Our subsidiary must also guarantee our obligations under the loan agreement, and we are required to pledge the stock of our subsidiary to the lender to secure our obligations under the loan agreement.

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

Our ability to use our net operating losses to offset taxes that would otherwise be due could be limited or lost entirely if we do not continue to generate taxable income in a timely manner or if we trigger an "ownership change" pursuant to Section 382 of the Internal Revenue Code which, if we continue to generate taxable income, could materially and adversely affect our business, financial condition, and results of operations.

As of December 31, 2012, we had Federal and state income tax net operating loss carryforwards, or NOLs, of approximately $118.1 million and $129.7 million, respectively. Our ability to use our NOLs to offset taxes that would otherwise be due is dependent upon our generation of future taxable income before the expiration dates of the NOLs, and we cannot predict with certainty whether we will be able to generate future taxable income. In addition, even if we generate taxable income, realization of our NOLs to offset taxes that would otherwise be due could be

restricted by annual limitations on use of NOLs triggered by an "ownership change" under Section 382 of the Internal Revenue Code and similar state provisions. An "ownership change" may occur when there is a 50% or greater change in total ownership of our company by one or more 5% shareholders within a three-year period. The loss of some or all of our NOLs could materially and adversely affect our business, financial condition and results of operations. In addition, California and certain states have suspended use of NOLs for certain taxable years, and other states may consider similar measures. As a result, we may incur higher state income tax expense in the future. Depending on our future tax position, continued suspension of our ability to use NOLs in states in which we are subject to income tax could have an adverse impact on our operating results and financial condition.

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

Our results of operations could be materially negatively affected by economic conditions generally, both in the U.S. and elsewhere around the world. Continuing concerns over U.S. spending and deficits, inflation, energy costs, geopolitical issues, the availability and cost of credit, the U.S. mortgage market and a difficult residential real estate market in the U.S. have contributed to increased volatility and diminished expectations for the economy and the markets going forward. Domestic and international equity markets have experienced and may continue to experience heightened volatility and turmoil based on domestic and international economic conditions and concern, including concerns over U.S. spending and deficits. In the event these economic conditions and concerns continue and the markets continue to remain volatile, our results of operations could be adversely affected by those factors in many ways, including making it more difficult for us to raise funds if necessary, and our stock price may decline. In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits. If economic instability continues, we cannot be assured that we will not experience losses on these deposits.

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

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

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

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

The market prices for securities of specialty biopharmaceutical companies in general have been highly volatile and may continue to be highly volatile in the future. In addition, we have not paid cash dividends since our inception and do not intend to pay cash dividends in the foreseeable future. Furthermore, our loan agreement with Comerica prohibits us from paying dividends. Therefore, investors will have to rely on appreciation in our stock price and a liquid trading market in order to achieve a gain on their investment.

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

- announcements concerning our commercial progress and activities, including sales and revenue trends for the we promote and the status of the patent litigation relating to such products;

- the sales and revenue trends for authorized generic Zegerid prescription products;

- announcements concerning our products or competitive products, including progress under development programs, results of clinical studies or status of regulatory submissions;
- announcements concerning any recalls or supply interruptions caused by manufacturing issues or otherwise;
- announcements made by our strategic partners concerning their business or the products they develop or promote;
- developments, including announcements concerning progress, delays or terminations, pursuant to our strategic alliances with Merck and GSK;
- other disputes or developments concerning proprietary rights, including patents and trade secrets, litigation matters, and our ability to patent or otherwise protect our products and technologies;
- conditions or trends in the pharmaceutical and biotechnology industries, including the impact and possible repeal of healthcare reform;
- 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 concerning borrowings under our loan agreement, takedowns under our existing universal shelf registration statement or other developments relating to the loan agreement, universal shelf registration statement or our other financing activities;
- acquisition of products or businesses by us or our competitors;
- litigation and government inquiries; or
- economic and political factors, including election results, sovereign debt uncertainty, wars, terrorism and political unrest.

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

Although we believe that our current cash, cash equivalents and short-term investments and use of our line of credit will be sufficient to fund our current operations through at least the next twelve months, we may pursue raising additional funds for various reasons, including to expand our commercial presence, in connection with licensing or acquisition of new marketed products or investigational drugs, to continue development of investigational drugs in our pipeline, or for other general corporate purposes. Sources of additional funds may include funds generated through equity and/or debt financing, or through strategic collaborations or licensing agreements. To the extent we conduct substantial future offerings of equity or debt securities, such offerings could cause our stock price to decline. For example, we may issue securities under our existing universal shelf registration statement or we may pursue alternative financing arrangements.

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

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

A concentrated number of stockholders hold significant blocks of our outstanding common stock. Sales by our current stockholders of a substantial number of shares, or the expectation that such sales may occur, could significantly reduce the market price of our common stock. In addition, certain of our executive officers have from time to time established programmed selling plans under Rule 10b5-1 of the Securities Exchange Act of 1934, as

amended, for the purpose of effecting sales of common stock, and other employees and affiliates, including our directors and executive officers, may choose to establish similar plans in the future. If any of our stockholders cause securities to be sold in the public market, the sales could reduce the trading price of our common stock. These sales also could impede our ability to raise future capital.

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

The stock market has from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of pharmaceutical and biotechnology companies. These broad market fluctuations may cause the market price of our common stock to decline. In the past, following periods of volatility in the market price of a particular company's securities, securities class action litigation has often been brought against that company. Any securities or other class action litigation asserted against us could have a material adverse effect on our business.

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

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

These provisions include:

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

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

In addition, we have 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 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

Our primary office facility consists of approximately 40,000 square feet in San Diego, California. We lease our primary office facility pursuant to a lease agreement that expires in May 2020.

Item 3. Legal Proceedings

Zegerid Rx and Zegerid OTC Patent Litigation

Zegerid Rx Litigation

In April 2010, the U.S. District Court for the District of Delaware ruled that five patents covering Zegerid capsules and Zegerid powder for oral suspension (U.S. Patent Nos. 6,489,346; 6,645,988; 6,699,885; 6,780,882; and 7,399,772) were invalid due to obviousness. These patents were the subject of lawsuits we filed in 2007 against Par Pharmaceutical, Inc., or Par, in response to abbreviated new drug applications, or ANDAs, filed by Par with the FDA. The University of Missouri, licensor of the patents, is joined in the litigation as a co-plaintiff. In May 2010, we filed an appeal of the District Court's ruling to the U.S. Court of Appeals for the Federal Circuit. Following the District Court's decision, Par launched its generic version of Zegerid capsules in late June 2010.

In September 2012, the U.S. Court of Appeals for the Federal Circuit reversed in part the April 2010 decision of the District Court. The Federal Circuit found that certain claims of asserted U.S. Patent Nos. 6,780,882 and 7,399,772, which Par had been found to infringe, were not invalid due to obviousness. These patents represent two of the five patents that were found to be invalid by the District Court, and the Federal Circuit affirmed the District Court's finding of invalidity for the asserted claims from the remaining three patents. The Federal Circuit also upheld the District Court's finding that there was no inequitable conduct. Following the Federal Circuit's decision, Par announced that it had ceased distribution of its generic Zegerid capsules product in September 2012. In December 2012, the Federal Circuit issued an order denying a combined petition for panel and en banc rehearing filed by Par and issued its mandate, remanding the case to the District Court for further proceedings pertaining to damages. In February 2013, we filed an amended complaint with the District Court for infringement of U.S. Patent Nos. 6,780,882 and 7,399,772 and requested a jury trial with respect to the issue of damages in connection with Par's launch of its generic version of Zegerid capsules in June 2010. In March 2013, Par filed its amended answer, which alleges, among other things, failure to state a claim upon which relief can be granted and non-infringement based on purported invalidity of the two asserted patents. In addition, Par filed a motion for a judgment on the pleadings, alleging, among other things, that the two asserted patents are invalid because the Federal Circuit purportedly did not expressly address certain prior art references considered by the District Court. Although we do not believe that Par has a meritorious basis upon which to further challenge validity of the asserted patents in this proceeding, we cannot be certain of the timing or outcome of this or any other proceedings.

In December 2011, we filed a lawsuit in the U.S. District Court for the District of New Jersey against Zydus Pharmaceuticals USA, Inc., or Zydus, for infringement of the patents listed in the Orange Book for Zegerid capsules. The University of Missouri, licensor of the patents, is joined in the litigation as a co-plaintiff. Zydus had filed an ANDA with the FDA regarding its intent to market a generic version of Zegerid capsules prior to the expiration of the listed patents. In September 2012, we amended our complaint to be limited to U.S. Patent No. 7,399,772, which patent was found not to be invalid in the September 2012 Federal Circuit decision. In October 2012, Zydus filed its answer, which alleges, among other things, failure to state a claim upon which relief can be granted. The lawsuit was commenced within the requisite 45-day time period, resulting in an FDA stay on the approval of Zydus' proposed product for 30 months or until a decision is rendered by the District Court, which is adverse to the asserted patent. The Markman hearing for this matter has been scheduled in July 2013 and a trial has been scheduled in January 2014. Absent a court decision, the 30-month stay is expected to expire in May 2014. We are not able to predict the timing or outcome of this lawsuit.

In August 2012, we filed a lawsuit in the U.S. District Court for the District of New Jersey against Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc., collectively referred to herein as Dr. Reddy's, for infringement of the patents listed in the Orange Book for Zegerid capsules. The University of Missouri, licensor of the patents, is joined in the litigation as a co-plaintiff. Dr. Reddy's had filed an ANDA with the FDA regarding its intent to market a generic version of Zegerid capsules prior to the expiration of the listed patents. In October 2012,

we amended our complaint to be limited to U.S. Patent No. 7,399,772, which patent was found not to be invalid in the September 2012 Federal Circuit decision. Also in October 2012, Dr. Reddy's filed its answer, which alleges, among other things, non-infringement, invalidity, failure to state a claim upon which relief can be granted and estoppel. The lawsuit was commenced within the requisite 45-day time period, resulting in an FDA stay on the approval of Dr. Reddy's proposed product for 30 months or until a decision is rendered by the District Court, which is adverse to the asserted patent. The Markman hearing for this matter has been scheduled in July 2013 and a trial has been scheduled in July 2014. Absent a court decision, the 30-month stay is expected to expire in January 2015. We are not able to predict the timing or outcome of this lawsuit.

Zegerid OTC Litigation

In September 2010, Merck filed a lawsuit in the U.S. District Court for the District of New Jersey against Par for infringement of the patents listed in the Orange Book for Zegerid OTC. We and the University of Missouri, licensors of the listed patents, are joined in the lawsuit as co-plaintiffs. Par had filed an ANDA with the FDA regarding its intent to market a generic version of Zegerid OTC prior to the expiration of the listed patents. In October 2012, Merck amended its complaint to be limited to U.S. Patent No. 7,399,772, which patent was found not to be invalid in the September 2012 Federal Circuit decision. Also in October 2012, Par filed its answer, which alleges, among other things, failure to state a claim upon which relief can be granted, non-infringement and invalidity. Par has received tentative approval of its proposed generic Zegerid OTC product. The lawsuit was commenced within the requisite 45-day time period, resulting in an FDA stay on the approval of Par's proposed product for 30 months or until a decision is rendered by the District Court, which is adverse to the asserted patent. Although the 30-month stay expired in February 2013, the parties have agreed that Par will not launch its generic Zegerid OTC product unless there is a District Court judgment favorable to Par or in certain other specified circumstances. The Markman hearing for this matter has been scheduled in July 2013 and a trial has been scheduled in January 2015. We are not able to predict the timing or outcome of this lawsuit.

In September 2010, Merck filed a lawsuit in the U.S. District Court for the District of New Jersey against Perrigo Research and Development Company, or Perrigo, for infringement of the patents listed in the Orange Book for Zegerid OTC. We and the University of Missouri, licensors of the listed patents, were joined in the lawsuits as co-plaintiffs. Perrigo had filed an ANDA with the FDA regarding its intent to market a generic version of Zegerid OTC prior to the expiration of the listed patents. In January 2013, this case was settled allowing entry into the market by Perrigo upon expiration of the applicable patents (or earlier under certain circumstances), and the District Court entered an order dismissing the case with prejudice.

In December 2011, Merck filed a lawsuit in the U.S. District Court for the District of New Jersey against Zydus for infringement of the patents listed in the Orange Book for Zegerid OTC. We and the University of Missouri, licensors of the listed patents, are joined in the litigation as co-plaintiffs. Zydus had filed an ANDA with the FDA regarding its intent to market a generic version of Zegerid OTC prior to the expiration of the listed patents. In September 2012, Merck amended its complaint to be limited to U.S. Patent No. 7,399,772, which patent was found not to be invalid in the September 2012 Federal Circuit decision. In October 2012, Zydus filed its answer, which alleges, among other things, failure to state a claim upon which relief can be granted. The lawsuit was commenced within the requisite 45-day time period, resulting in an FDA stay on the approval of Zydus' proposed product for 30 months or until a decision is rendered by the District Court, which is adverse to the asserted patent. Absent a court decision, the 30-month stay is expected to expire in May 2014. The Markman hearing for this matter has been scheduled in July 2013 and a trial has been scheduled in January 2014. We are not able to predict the timing or outcome of this lawsuit.

Any adverse outcome in the Zegerid Rx and Zegerid OTC litigation described above would adversely impact our business, including the amount of revenues we receive from sales of Zegerid brand and authorized generic prescription products and our ability to receive, milestone payments and royalties under our agreement with Merck. For example, the royalties payable to us under our license agreement with Merck are subject to reduction in the event it is ultimately determined by the courts (with the decision being unappealable or unappealed within the time allowed for appeal) that there is no valid claim of the licensed patents covering the manufacture, use or sale of the Zegerid OTC product and third parties have received marketing approval for, and are conducting bona fide ongoing commercial sales of, generic versions of the licensed products. Any negative outcome may also negatively impact the patent protection for the products being commercialized pursuant to our ex-US license with GSK. Although a

U.S. ruling is not binding in countries outside the U.S., similar challenges to those raised in the U.S. litigation may be raised in territories outside the U.S. At this time we are unable to estimate possible losses or ranges of losses for ongoing actions.

Regardless of how these litigation matters are ultimately resolved, the litigation has been and will continue to be costly, time-consuming and distracting to management, which could have a material adverse effect on our business.

Glumetza® Patent Litigation

In November 2009, Depomed filed a lawsuit in the U.S. District Court for the Northern District of California against Lupin Limited and its wholly owned subsidiary, Lupin Pharmaceuticals, Inc., collectively referred to herein as Lupin, for infringement of certain patents listed in the Orange Book for Glumetza. The lawsuit was filed in response to an ANDA filed with the FDA by Lupin regarding Lupin's intent to market generic versions of Glumetza 500 mg and 1000 mg tablets prior to the expiration of the listed patents. In February 2012, we and Depomed entered into a settlement agreement with Lupin that grants Lupin the right to begin selling a generic version of Glumetza in February 2016, or earlier under certain circumstances. In March 2012, the U.S. District Court for the Northern District of California entered an order dismissing the litigation.

In June 2011, Depomed filed a lawsuit in the U.S. District Court for the District of New Jersey against Sun Pharma Global FZE, Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Industries Inc., collectively referred to herein as Sun, for infringement of the patents listed in the Orange Book for Glumetza. Valeant International Bermuda, or Valeant, was joined in the lawsuit as a co-plaintiff. The lawsuit was filed in response to an ANDA filed with the FDA by Sun regarding Sun's intent to market generic versions of Glumetza 500 mg and 1000 mg tablets prior to the expiration of the listed patents. In January 2013, we, Depomed and Valeant entered into a settlement agreement with Sun that grants Sun the right to begin selling a generic version of Glumetza in August 2016, or earlier under certain circumstances. In January 2013, the District Court dismissed the lawsuit without prejudice in view of the settlement agreement. The settlement agreement is subject to review by the U.S. Department of Justice and the Federal Trade Commission.

In April 2012, Depomed filed a lawsuit in the U.S. District Court for the District of Delaware against Watson Laboratories, Inc. — Florida, Actavis, Inc. and Watson Pharma, Inc., collectively referred to herein as Watson, for infringement of the patents listed in the Orange Book for Glumetza 1000 mg at the time the lawsuit was filed (U.S. Patent Nos. 6,488,962 and 7,780,987). Valeant is joined in the lawsuit as a co-plaintiff. The lawsuit was filed in response to an ANDA filed with the FDA by Watson regarding Watson's intent to market a generic version of Glumetza 1000 mg tablets prior to the expiration of the listed patents. Depomed and Valeant commenced the lawsuit within the requisite 45-day time period, resulting in an FDA stay on the approval of Watson's proposed product for 30 months or until a decision is rendered by the District Court, which is adverse to the asserted patents. Absent a court decision, the 30-month stay is expected to expire in September 2014. Watson has filed an answer in the case that asserts, among other things, non-infringement and invalidity of the asserted patents, failure to state a claim, lack of subject matter jurisdiction, and has also filed counterclaims. In February 2013, Depomed amended its complaint to add infringement of a newly listed Orange Book patent (U.S. Patent No. 8,323,692), as well as two non-Orange Book listed patents (U.S. Patent Nos. 7,736,667 and 8,329,215). The Markman hearing for this matter has been scheduled in April 2014, and the trial has been scheduled in May 2014. We are not able to predict the timing or outcome of this lawsuit.

In February 2013, Depomed filed a lawsuit in the U.S. District Court for the District of Delaware against Watson Laboratories, Inc. — Florida, Actavis, Inc. and Watson Pharma, Inc., collectively referred to herein as Watson, for infringement of the patents listed in the Orange Book for Glumetza 500 mg at the time the lawsuit was filed (U.S. Patent Nos. 6,340,475; 6,488,962; 6,635,280 and 6,723,340). The lawsuit was filed in response to an ANDA filed with the FDA by Watson regarding Watson's intent to market a generic version of Glumetza 500 mg tablets prior to the expiration of the listed patents. Depomed commenced the lawsuit within the requisite 45-day time period, resulting in an FDA stay on the approval of Watson's proposed product for 30 months or until a decision is rendered by the District Court, which is adverse to the asserted patents. Absent a court decision, the 30-month stay is expected to expire in July 2015.

Under the terms of our commercialization agreement with Depomed, Depomed will manage the ongoing patent infringement litigation relating to Glumetza, subject to certain consent rights in favor of us, including with regard to any proposed settlements. We are responsible for 70% of the future out-of-pocket costs, and Depomed is responsible for 30% of the future out-of-pocket costs, related to patent infringement cases.

Any adverse outcome in the litigation described above would adversely impact our business and revenues. Regardless of how these litigation matters are ultimately resolved, the litigation will continue to be costly, time-consuming and distracting to management, which could have a material adverse effect on our business.

Fenoglide Patent Litigation

Prior to the execution of the license agreement, Shore entered into a settlement arrangement with Impax Laboratories, Inc., or Impax, in connection with patent infringement litigation associated with Impax's ANDA for a generic version of Fenoglide and a related paragraph IV challenge. The settlement terms grant Impax a sublicense to begin selling a generic version of Fenoglide on October 1, 2015, or earlier under certain circumstances. In February 2012, the U.S. District Court for the District of Delaware entered an order dismissing the litigation, and we assumed Shore's obligations associated with the sublicense to Impax.

In January 2013, we filed a lawsuit in the U.S. District Court for the District of Delaware against Mylan Inc. and Mylan Pharmaceuticals Inc., collectively referred to herein as Mylan, for infringement of the patents listed in the Orange Book for Fenoglide 120 mg and 40 mg (U.S. Patent Nos. 7,658,944, and 8,124,125). Veloxis Pharmaceuticals A/S, or Veloxis, is joined in the lawsuit as a co-plaintiff. The lawsuit was filed in response to an ANDA filed with the FDA by Mylan regarding Mylan's intent to market a generic version of Fenoglide 120 mg and 40 mg tablets prior to the expiration of the listed patents. We commenced the lawsuit within the requisite 45-day time period, resulting in an FDA stay on the approval of Mylan's proposed product for 30 months or until a decision is rendered by the District Court, which is adverse to the asserted patents, whichever may occur earlier. Absent a court decision, the 30-month stay is expected to expire in June 2015. Mylan has filed an answer in the case that asserts, among other things, non-infringement, invalidity, and failure to state a claim, and has also filed counterclaims. We are not able to predict the timing or outcome of this lawsuit.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market Information

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

	High	Low
Year Ended December 31, 2011		
First Quarter	$3.70	$2.95
Second Quarter	$3.49	$2.88
Third Quarter	$3.49	$2.40
Fourth Quarter	$3.39	$2.56
Year Ended December 31, 2012		
First Quarter	$5.95	$3.16
Second Quarter	$7.42	$5.30
Third Quarter	$9.06	$4.82
Fourth Quarter	$11.76	$8.47

As of February 15, 2013, there were approximately 72 holders of record of our common stock.

Information about our equity compensation plans is incorporated by reference in Item 12 of Part III of this annual report on Form 10-K.

Dividend Policy

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

Recent Sales of Unregistered Securities

Not applicable.

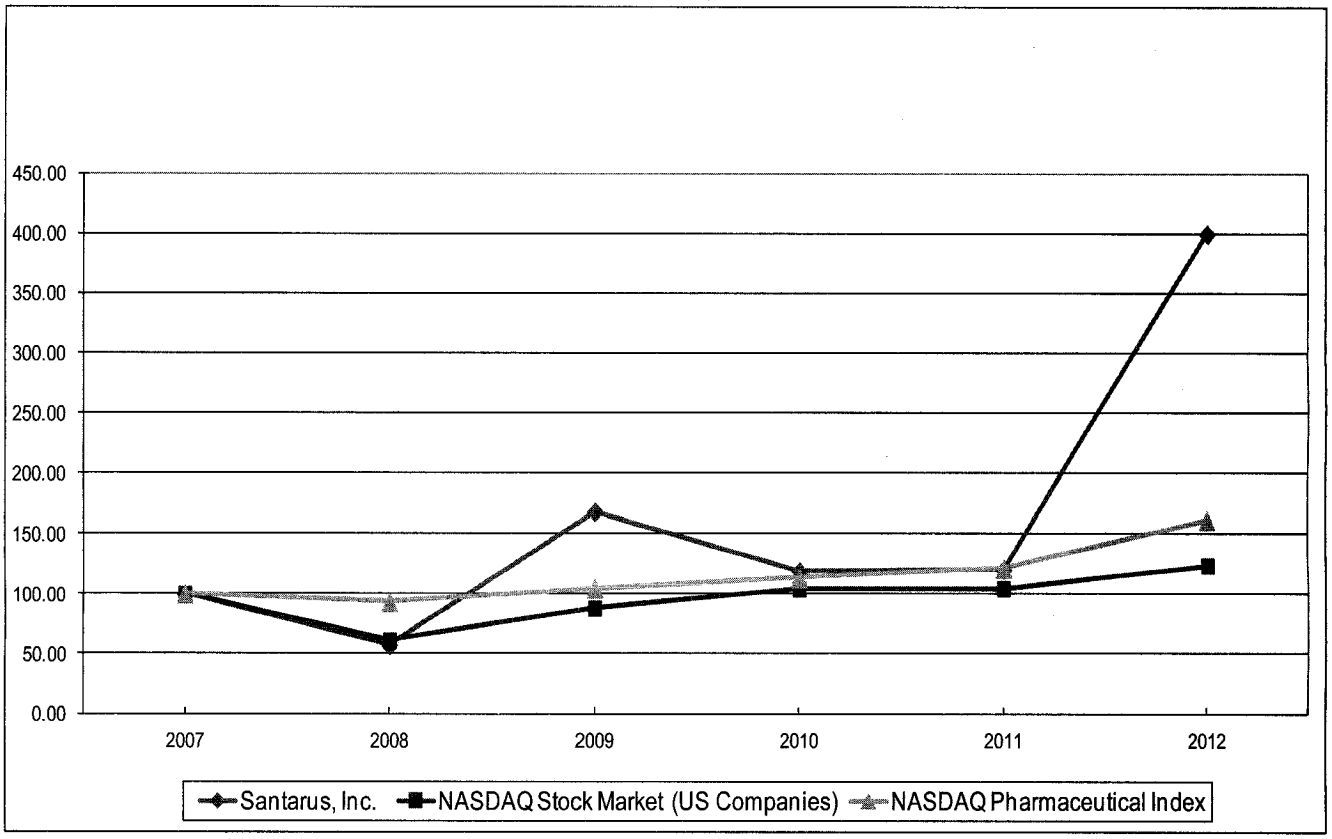
Issuer Purchases of Equity Securities

Not applicable.

Performance Graph

The following graph illustrates a comparison of the total cumulative stockholder return on our common stock for the period December 31, 2007 through December 31, 2012, to two indices: the Nasdaq Composite Index, U.S. Companies, and the Nasdaq Pharmaceuticals Index. The graph assumes an initial investment of $100 on December 31, 2007. The comparisons in the graph are required by the Securities and Exchange Commission and are not intended to forecast or be indicative of possible future performance of our common stock.

Comparison of Cumulative Total Return on Investment Since December 31, 2007



	12/31/07	12/31/08	12/31/09	12/31/10	12/30/11	12/31/12
Santarus, Inc.	$100.00	$57.10	$167.99	$118.90	$120.37	$399.31
Nasdaq Composite Index, U.S. Companies	$100.00	$61.17	$87.93	$104.13	$104.69	$123.85
Nasdaq Pharmaceuticals Index	$100.00	$93.04	$104.55	$113.33	$121.31	$161.38

Item 6. Selected Financial Data

The selected consolidated statement of operations data for the years ended December 31, 2009 and 2008, and the selected consolidated balance sheet data as of December 31, 2010, 2009 and 2008, are derived from our audited consolidated financial statements for such years and as of such dates not included in this Form 10-K. The selected consolidated statement of operations data for the years ended December 31, 2012, 2011 and 2010 and the selected consolidated balance sheet data as of December 31, 2012 and 2011, are derived from the audited consolidated financial statements for such years and as of such dates, which are included elsewhere in this Form 10-K. The selected consolidated quarterly financial data for each quarter within the two-year period ended December 31, 2012 are derived from our unaudited consolidated financial statements not included in this Form 10-K. The unaudited consolidated quarterly data have been prepared on the same basis as our audited consolidated financial statements and, in the opinion of management, all necessary adjustments, consisting only of normal recurring accruals, have been included to fairly present the unaudited consolidated quarterly results. The historical operating results of any year or quarter are not necessarily indicative of results for any future period. You should read these selected financial data together with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this Form 10-K.

	Years Ended December 31,				
	2012	2011	2010	2009	2008
	(in thousands, except per share amounts)				
Consolidated Statement of Operations Data:					
Revenues:					
Product sales, net	$ 214,538	$ 88,153	$ 90,170	$ 119,242	$ 101,220
Promotion revenue	—	27,339	31,365	23,631	9,837
Royalty revenue	3,417	3,295	3,571	—	—
Other license revenue	—	—	245	29,620	19,144
Total revenues	217,955	118,787	125,351	172,493	130,201
Costs and expenses:					
Cost of product sales	15,640	8,852	7,715	8,294	7,345
License fees and royalties	69,783	17,898	28,576	7,976	22,257
Research and development	25,808	18,383	17,431	16,244	11,760
Selling, general and administrative	86,552	68,229	82,581	105,838	108,012
Restructuring charges	—	—	7,082	—	—
Total costs and expenses	197,783	113,362	143,385	138,352	149,374
Income (loss) from operations	20,172	5,425	(18,034)	34,141	(19,173)
Other income (expense):					
Interest income	29	15	80	194	1,285
Interest expense	(337)	(459)	(461)	(460)	(95)
Total other income (expense)	(308)	(444)	(381)	(266)	1,190
Income (loss) before income taxes	19,864	4,981	(18,415)	33,875	(17,983)
Income tax expense	1,309	312	59	1,760	534
Net income (loss)	$ 18,555	$ 4,669	$ (18,474)	$ 32,115	$ (18,517)
Net income (loss) per share:					
Basic	$ 0.30	$ 0.08	$ (0.31)	$ 0.55	$ (0.36)
Diluted	$ 0.27	$ 0.07	$ (0.31)	$ 0.54	$ (0.36)
Weighted average shares outstanding used to calculate net income (loss) per share:					
Basic	62,697	60,531	58,734	57,995	51,835
Diluted	69,150	62,815	58,734	59,674	51,835

	As of December 31,				
	2012	2011	2010	2009	2008
	(in thousands)				
Consolidated Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 94,736	$ 58,608	$ 60,797	$ 93,944	$ 52,037
Working capital	75,937	38,417	34,310	47,563	3,734
Total assets	163,749	114,053	96,037	131,361	92,484
Deferred revenue, less current portion	1,639	2,163	2,635	2,678	2,436
Long-term debt	9,876	10,000	10,000	10,000	10,000
Other long-term liabilities	2,884	2,494	2,659	—	—
Total stockholders' equity	82,952	50,088	37,983	46,916	9,323

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	(in thousands, except per share amounts)			
Selected Consolidated Quarterly Financial Data (unaudited):				
2012:				
Product sales, net	$ 45,129	$ 46,308	$ 53,687	$ 69,414
Total revenues	45,880	47,192	54,670	70,213
Cost of product sales	3,484	3,703	3,276	5,177
Total costs and expenses	44,824	43,404	45,435	64,120
Net income	627	3,448	8,984	5,496
Net income per share:				
Basic	0.01	0.05	0.14	0.09
Diluted	0.01	0.05	0.13	0.08
2011:				
Product sales, net	$ 11,981	$ 14,694	$ 19,813	$ 41,665
Total revenues	22,814	26,607	26,814	42,552
Cost of product sales	1,520	1,845	2,232	3,255
Total costs and expenses	23,207	23,772	25,948	40,435
Net income (loss)	(516)	2,706	563	1,916
Net income (loss) per share:				
Basic	(0.01)	0.04	0.01	0.03
Diluted	(0.01)	0.04	0.01	0.03

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 consolidated 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 but not limited to those set forth under "Item 1A—Risk Factors" and elsewhere in this Form 10-K.

Overview

We are a specialty biopharmaceutical company focused on acquiring, developing and commercializing proprietary products that address the needs of patients treated by physician specialists.

Our commercial organization currently promotes the following products in the U.S. prescription pharmaceutical market:

- Uceris™ (budesonide) extended release tablets is available in 9 mg tablets and is a locally acting corticosteroid in an oral tablet formulation that utilizes proprietary multi-matrix system, or MMX, colonic delivery technology. Uceris is indicated for the induction of remission in patients with active, mild to moderate ulcerative colitis.

- Zegerid® (omeprazole/sodium bicarbonate) capsules and powder for oral suspension is available in 20 mg and 40 mg dosage strengths and is a proprietary immediate-release formulation of the proton pump inhibitor, or PPI, omeprazole. Zegerid is indicated for short-term treatment of active duodenal ulcer, short-term treatment of active benign gastric ulcer, treatment of gastroesophageal reflux disease, or GERD, maintenance of healing of erosive esophagitis and reduction of risk of upper gastrointestinal, or GI, bleeding in critically ill patients. In addition, we receive a significant percentage of the gross margin on sales of an authorized generic version of Zegerid capsules.

- Glumetza® (metformin hydrochloride extended release tablets) is available in 500 mg and 1000 mg tablets and is a once-daily, extended-release formulation of metformin that incorporates patented drug delivery technology. Glumetza is indicated as an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 diabetes.

- Cycloset® (bromocriptine mesylate) tablets is available in 0.8 mg tablets and is a novel formulation of bromocriptine, a dopamine receptor agonist that acts on the central nervous system. Cycloset is indicated as an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 diabetes.

- Fenoglide® (fenofibrate) tablets is available in 40 mg and 120 mg tablets and is a proprietary formulation of fenofibrate that incorporates patented drug delivery technology. Fenoglide is indicated as an adjunct to diet to reduce elevated low-density lipoprotein-cholesterol, or LDL-C, total cholesterol, triglycerides and apolipoprotein B, or Apo B, and to increase high-density lipoprotein-cholesterol, or HDL-C, in adult patients with primary hyperlipidemia or mixed dyslipidemia. Fenoglide also is indicated as an adjunct to diet for treatment of adult patients with hypertriglyceridemia.

In addition to our commercial products, we are focused on advancing the following investigational drugs to commercialization:

- Ruconest® (recombinant human C1 esterase inhibitor) is a recombinant version of the human protein C1 esterase inhibitor, which is produced using proprietary transgenic technology. In November 2012, we announced positive top-line results from the phase III clinical study to evaluate the safety and efficacy of Ruconest for the treatment of acute attacks of angioedema in patients with hereditary angioedema, or HAE. We plan to submit a biologics license application, or BLA, to the U.S. Food and Drug Administration, or FDA, during the second quarter of 2013, seeking approval to market Ruconest for this indication.

- Rifamycin SV MMX® is a broad spectrum, non-systemic antibiotic in a novel oral tablet formulation, which utilizes proprietary MMX colonic delivery technology. In September 2012, we announced positive top-line results from the first phase III clinical study to evaluate the safety and efficacy of rifamycin SV MMX for the treatment of patients with travelers' diarrhea. Dr. Falk Pharma GmbH, or Dr. Falk, is currently conducting a second phase III clinical study evaluating rifamycin SV MMX for the treatment of travelers' diarrhea.

- SAN-300 (anti-VLA-1 antibody) is a novel early stage anti-VLA-1 monoclonal antibody, or mAb, investigational drug that we initially expect to develop for the treatment of rheumatoid arthritis. In December 2012, we completed a phase I dose-escalation clinical study in healthy volunteers to determine the safety, tolerability, pharmacokinetics and pharmacodynamics of single doses of SAN-300. We plan to begin a phase IIa clinical study evaluating SAN-300 for treatment of rheumatoid arthritis during the fourth quarter of 2013.

To leverage our PPI technology and diversify our sources of revenue, we have licensed certain exclusive rights to MSD Consumer Products, Inc., a subsidiary of Merck & Co., Inc., or Merck, to develop, manufacture and sell over-the-counter, or OTC, Zegerid products in the U.S. and Canada. We have also licensed certain exclusive rights to our PPI technology to Glaxo Group Limited, an affiliate of GlaxoSmithKline, plc, or GSK, to develop, manufacture and commercialize prescription and OTC immediate-release omeprazole products in more than 100 specified countries (including markets within Africa, Asia, the Middle-East, and Latin America).

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based on our consolidated 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. We believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our financial statements.

Principles of Consolidation

Our consolidated financial statements include the accounts of Santarus and its wholly owned subsidiary, Covella Pharmaceuticals, Inc., or Covella. We do not have any interest in variable interest entities. All material intercompany transactions and balances have been eliminated in consolidation.

Inventories and Related Reserves

Inventories are stated at the lower of cost or market (net realizable value). Cost is determined by the first-in, first-out method. Inventories consist of finished goods and raw materials used in the manufacture of our commercial products. We provide reserves for potentially excess, dated or obsolete inventories based on an analysis of inventory on hand and on firm purchase commitments compared to forecasts of future sales.

Business Combinations

The authoritative guidance for business combinations establishes principles and requirements for recognizing and measuring the total consideration transferred to and the assets acquired and liabilities assumed in the acquired target in a business combination.

We accounted for the acquisition of Covella in September 2010 in accordance with the authoritative guidance for business combinations. The consideration paid to acquire Covella was required to be measured at fair value and included cash consideration, the issuance of our common stock and contingent consideration, which includes our obligation to make clinical and regulatory milestone payments based on success in developing product candidates in

addition to a royalty on net sales of any commercial products resulting from the anti-VLA-1 mAb technology. After the total consideration transferred was calculated by determining the fair value of the contingent consideration plus the upfront cash and stock consideration, we assigned the purchase price of Covella to the fair value of the assets acquired and liabilities assumed. This allocation of the purchase price resulted in recognition of intangible assets related to in-process research and development, or IPR&D, and goodwill.

We accounted for the commercialization agreement with Depomed, Inc., or Depomed, entered into in August 2011 in accordance with the authoritative guidance for business combinations. The purchase consideration was comprised of cash payments for the purchase of existing inventory, and the entire purchase price was allocated to inventory, as cost approximated fair value, and no other assets were acquired and no liabilities were assumed in the transaction. Under the commercialization agreement, we have an obligation to pay royalties to Depomed based on Glumetza net product sales. These royalties are being expensed as incurred as we determined that the royalty rates reflect reasonable market rates for the manufacturing and commercialization rights we were granted under the commercialization agreement.

We accounted for the license agreement with Healthcare Royalty Partners, L.P., or HRP, and Shore Therapeutics, Inc., or Shore, in accordance with the authoritative guidance for business combinations. The purchase consideration was comprised of an upfront cash payment, and the purchase price was allocated to prepaid royalty expense and intangible assets related to the license agreement. There were no other assets acquired or liabilities assumed under the license agreement. Under the license agreement, we have an obligation to pay royalties to Shore based on Fenoglide net product sales and certain one-time success-based milestones contingent on sales achievement. These royalties and sales milestones will be expensed as incurred as we determined that the royalty rates and sales milestone amounts reflect reasonable market rates for the manufacturing and commercialization rights granted under the license agreement.

The determination and allocation of consideration transferred in a business combination requires us to make significant estimates and assumptions, especially at the acquisition date with respect to the fair value of the contingent consideration. The key assumptions in determining the fair value are the discount rate and the probability assigned to the potential milestone or royalty being achieved. We remeasure the fair value of the contingent consideration at each reporting period, with any change in fair value being recorded in the current period's operating expenses. Changes in the fair value may result from either the passage of time or events occurring after the acquisition date, such as changes in the estimated probability or timing of achieving the milestone or royalty.

Intangible Assets and Goodwill

Our intangible assets are comprised primarily of acquired IPR&D and license agreements. Goodwill represents the excess of the cost over the fair value of net assets acquired from business combinations. We periodically assess the carrying value of our intangible assets and goodwill, which requires us to make assumptions and judgments regarding the future cash flows of these assets. The assets are considered to be impaired if we determine that the carrying value may not be recoverable based upon our assessment of the following events or changes in circumstances:

- the asset's ability to generate income from operations and positive cash flow in future periods;
- loss of legal ownership or title to the asset;
- significant changes in our strategic business objectives and utilization of the asset(s); and
- the impact of significant negative industry, regulatory or economic trends.

IPR&D will not be amortized until the related development process is complete, and goodwill is not amortized. License agreements and other intangible assets are amortized over their estimated useful lives. If the assets are considered to be impaired, the impairment we recognize is the amount by which the carrying value of the assets exceeds the fair value of the assets. Fair value is determined by a combination of third-party sources and forecasted discounted cash flows. In addition, we base the useful lives and related amortization expense on our estimate of the period that the assets will generate revenues or otherwise be used. We also periodically review the lives assigned to our intangible assets to ensure that our initial estimates do not exceed any revised estimated periods from which we expect to realize cash flows from the technologies. A change in any of the above-mentioned factors or estimates

could result in an impairment charge which could negatively impact our results of operations. We have not recognized any impairment charges on our intangible assets or goodwill through December 31, 2012.

Revenue Recognition

We recognize revenue when there is persuasive evidence that an arrangement exists, title has passed, the price is fixed or determinable, and collectability is reasonably assured.

Product Sales, Net. We sell our commercial products primarily to pharmaceutical wholesale distributors. We are obligated to accept from customers products that are returned within six months of their expiration date or up to 12 months beyond their expiration date. The shelf life of our products from the date of manufacture is as follows: Zegerid (36 months); Glumetza (24 to 48 months); Cycloset (18 months); and Fenoglide (24 to 36 months). We authorize returns for expired or damaged products in accordance with our return goods policy and procedures. We issue credit to the customer for expired or damaged returned product. We rarely exchange product from inventory for returned product. At the time of sale, we record our estimates for product returns as a reduction to revenue at full sales value with a corresponding increase in the allowance for product returns liability. Actual returns are recorded as a reduction to the allowance for product returns liability at sales value with a corresponding decrease in accounts receivable for credit issued to the customer.

We recognize product sales net of estimated allowances for product returns, estimated rebates in connection with contracts relating to managed care, Medicare, patient coupons and voucher programs, and estimated chargebacks from distributors, wholesaler fees and prompt payment and other discounts. We establish allowances for estimated product returns, rebates and chargebacks based primarily on the following qualitative and quantitative factors:

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

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

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

Our allowance for product returns was $20.6 million as of December 31, 2012 and $13.9 million as of December 31, 2011. We recognize product sales at the time title passes to our customers, and we provide for an estimate of future product returns at that time based upon historical product returns trends, analysis of product expiration dating and estimated inventory levels in the distribution channel, review of returns trends for similar products, if available, and the other factors discussed above. Due to the lengthy shelf life of our products and the terms of our returns policy, there may be a significant time lag between the date we determine the estimated allowance and when we receive the product return and issue credit to a customer. Therefore, the amount of returns processed against the allowance in a particular year generally has no direct correlation to the product sales in the same year, and we may record adjustments to our estimated allowance over several periods, which can result in a net increase or a net decrease in our operating results in those periods.

We have been tracking our Zegerid product returns history by individual production batches from the time of our first commercial product launch of Zegerid powder for oral suspension 20 mg in late 2004. We launched Cycloset in November 2010 and began distributing Fenoglide in December 2011. Under a commercialization agreement with Depomed, we began distributing and recording product sales for Glumetza in September 2011. We have provided for an estimate of product returns based upon a review of our product returns history and returns trends for similar products, taking into consideration the effect of a product's shelf life on its returns history. In 2012, based upon our analysis of product expiration dating and actual product returns history through December 31, 2012, we increased our estimate for Cycloset product returns to reflect actual experience accordingly. The increase in our estimate for Cycloset product returns reflected higher than expected actual returns, as well as an increase in the sales price of Cycloset, during the second quarter of 2012. Contributing to the higher than expected actual product returns was our receipt of regulatory approval during the second quarter of 2012 for an improved process for the manufacturing of Cycloset product. We began shipping Cycloset product manufactured under the new process in the second quarter of 2012. As a result of the availability of this new product that has the standard 18 months shelf life from the date of manufacture, we experienced higher than expected product returns of short-dated Cycloset product in accordance with our returns policy in the second quarter of 2012. In connection with the events described above, we recorded an increase in our estimated allowance for Cycloset product returns associated with product sales in prior periods of approximately $1.8 million in 2012. This change in estimate was based on our assessment of actual returns of Cycloset product during the year ended December 31, 2012. Prior to 2012, we had not experienced significant returns activity.

Our provision for product returns provided in Schedule II – Valuation and Qualifying Accounts for 2012, 2011 and 2010 was approximately $18.7 million, $4.9 million and $2.6 million, respectively, which reflected an increase in the provision for product returns as a percentage of the related gross product sales from 2011 to 2012 and 2010 to 2011. The increase in the provision for product returns as a percentage of the related gross product sales from 2011 to 2012 reflects the increased estimate for Cycloset product returns discussed above as well as an increase in the estimated returns rate for our products based on our analysis of product expiration dating and actual product returns history. The increase in the provision for product returns as a percentage of the related gross product sales from 2010 to 2011 reflects the higher estimated returns rates of certain of our Cycloset and Glumetza products due to the shorter shelf lives of these products as compared to the Zegerid products.

Our allowance for rebates, chargebacks and other discounts was $17.2 million as of December 31, 2012 and $13.8 million as of December 31, 2011. These allowances reflect an estimate of our liability for rebates due to managed care organizations under specific contracts, rebates due to various organizations under Medicare contracts and regulations, chargebacks due to various organizations purchasing our products through federal contracts and/or group purchasing agreements, and other rebates and customer discounts due in connection with wholesaler fees and prompt payment and other discounts. We estimate our liability for rebates and chargebacks at each reporting period based on a combination of the qualitative and quantitative assumptions listed above. In each reporting period, we evaluate our outstanding contracts and apply the contractual discounts to the invoiced price of wholesaler shipments recognized. Although the total invoiced price of shipments to wholesalers for the reporting period and the contractual terms are known during the reporting period, we project the ultimate disposition of the sale (e.g. future utilization rates of cash payors, managed care, Medicare or other contracted organizations). This estimate is based on historical trends adjusted for anticipated changes based on specific contractual terms of new agreements with customers, anticipated pricing strategy changes by us and/or our competitors and the other qualitative and quantitative factors described above. There may be a significant time lag between the date we determine the estimated allowance and when we make the contractual payment or issue credit to a customer. Due to this time lag, we record adjustments to our estimated allowance over several periods, which can result in a net increase or a net decrease in our operating results in those periods. For the year ended December 31, 2011, we recorded a decrease in our estimated allowance for accrued rebates associated with product sales in prior periods of $1.4 million due to decreased utilization under, as well as the termination of, certain of our managed care and other contracts associated with our Zegerid products. Our estimate for accrued rebates was impacted by reduced sales volumes resulting from Par Pharmaceutical, Inc.'s, or Par's, commencement of its commercial sale of a generic version of Zegerid capsules prescription products and our decision to cease promotion of our Zegerid prescription products at that time. Absent this discrete event, actual results were not materially different from our estimates for the years ended December 31, 2012, 2011 and 2010.

Our provision for cash discounts, chargebacks and other sales discounts provided in Schedule II – Valuation and Qualifying Accounts for 2012, 2011 and 2010 was approximately $23.8 million, $10.7 million and $10.3 million, respectively. The provision for cash discounts, chargebacks and other sales discounts as a percentage of the related gross product sales decreased from 2011 to 2012 and increased from 2010 to 2011. The decrease in cash discounts, chargebacks and other sales discounts as a percentage of the related gross product sales from 2011 to 2012 was impacted by utilization under chargeback contracts as well as the specific contractual terms. The increase in cash discounts, chargebacks and other sales discounts as a percentage of the related gross product sales from 2010 to 2011 reflected an increase in wholesaler fees. In addition, as a result of Par's launch of the generic version of Zegerid capsules in late June 2010, sales under chargeback contracts for Zegerid capsules generally decreased at a lower rate than the non-contracted portion of the Zegerid business in 2011.

In late June 2010, we began selling an authorized generic version of our prescription Zegerid capsules under a distribution and supply agreement with Prasco LLC, or Prasco. Prasco has agreed to purchase all of its authorized generic product requirements from us and pays a specified invoice supply price for such products. We recognize revenue from shipments to Prasco at the invoice supply price and the related cost of product sales when title transfers, which is generally at the time of shipment. We are also entitled to receive a significant percentage of the gross margin on sales of the authorized generic products by Prasco, which we recognize as an addition to product sales, net when Prasco reports to us the gross margin from the ultimate sale of the products. Any adjustments to the gross margin related to Prasco's estimated sales discounts and other deductions are recognized in the period Prasco reports the amounts to us.

Promotion, Royalty and Other License Revenue. We analyze each element of our promotion and licensing agreements to determine the appropriate revenue recognition. Prior to January 1, 2011, we recognized revenue on upfront payments over the period of significant involvement under the related agreements unless the fee was in exchange for products delivered or services rendered that represent the culmination of a separate earnings process and no further performance obligation existed under the contract. We follow the authoritative guidance for revenue arrangements with multiple deliverables materially modified or entered into after December 31, 2010. Under this guidance, we identify the deliverables included within the agreement and evaluate which deliverables represent separate units of accounting. Upfront license fees are generally recognized upon delivery of the license if the facts and circumstances dictate that the license has standalone value from any undelivered items, the relative selling price allocation of the license is equal to or exceeds the upfront license fees, persuasive evidence of an arrangement exists, our price to the partner is fixed or determinable and collectability is reasonably assured. Upfront license fees are deferred if facts and circumstances dictate that the license does not have standalone value. The determination of the length of the period over which to defer revenue is subject to judgment and estimation and can have an impact on the amount of revenue recognized in a given period.

Effective January 1, 2011, we adopted prospectively, the authoritative guidance that offers an alternative method of revenue recognition for milestone payments. Under the milestone method guidance, we recognize payment that is contingent upon the achievement of a substantive milestone, as defined in the guidance, in its entirety in the period in which the milestone is achieved. Other milestones that do not fall under the definition of a milestone under the milestone method are recognized under the authoritative guidance concerning revenue recognition. Sales milestones, royalties and promotion fees are based on sales and/or gross margin information, which may include estimates of sales discounts and other deductions, received from the relevant alliance agreement partner. Sales milestones, royalties and promotion fees are recognized as revenue when earned under the agreements, and any adjustments related to estimated sales discounts and other deductions are recognized in the period the alliance agreement partner reports the amounts to us.

Stock-Based Compensation

We estimate the fair value of stock options and employee stock purchase plan rights granted using the Black-Scholes valuation model. This estimate is affected by our stock price, as well as assumptions regarding a number of complex and subjective variables. These variables include the expected volatility of our stock price, the expected life of the stock option, the risk-free interest rate and expected dividends. In determining our volatility factor, we perform an analysis of the historical volatility of our common stock for a period corresponding to the expected life of the options. In addition, we consider the expected volatility of similar entities. In evaluating similar entities, we consider factors such as industry, stage of development, size and financial leverage. In determining the expected life

of the options, we use the "simplified" method. Under this method, the expected life is presumed to be the mid-point between the vesting date and the end of the contractual term. We will continue to use the "simplified" method until we have sufficient historical exercise data to estimate the expected life of the options.

The fair value of options granted is amortized on a straight-line basis over the requisite service period of the awards, which is generally the vesting period ranging from one to four years. Pre-vesting forfeitures were estimated to be approximately 0% for the years ended December 31, 2012, 2011 and 2010 as the majority of options granted contain monthly vesting terms.

The following table includes stock-based compensation recognized in our consolidated statements of operations (in thousands):

	Years Ended December 31,		
	2012	2011	2010
Cost of product sales	$ 227	$ 158	$ 140
Research and development	1,214	869	709
Selling, general and administrative	5,289	4,335	4,192
Restructuring charges	—	—	352
Total	$ 6,730	$ 5,362	$ 5,393

As of December 31, 2012, total unrecognized compensation cost related to stock options was approximately $12.2 million, and the weighted average period over which it was expected to be recognized was 2.3 years.

Income Taxes

We provide for income taxes under the liability method. This approach requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of differences between the tax basis of assets or liabilities and their carrying amounts in the financial statements. We provide a valuation allowance for deferred tax assets if it is more likely than not that these items will expire before we are able to realize their benefit.

We follow the authoritative guidance relating to accounting for uncertainty in income taxes. This guidance clarifies the recognition threshold and measurement attributes for financial statement disclosure of tax positions taken or expected to be taken on a tax return. The impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more likely than not to be sustained upon audit by the relevant taxing authority. An uncertain tax position will not be recognized if it has less than a 50% likelihood of being sustained.

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 consolidated financial statements and notes thereto included elsewhere in this Form 10-K, which contain accounting policies and other disclosures required by GAAP.

Recent Accounting Pronouncements

In June and December 2011, the Financial Accounting Standards Board, or FASB, issued authoritative guidance on the presentation of comprehensive income. Under this newly issued authoritative guidance, an entity has the option to present comprehensive income and net income either in a single continuous statement or in two separate but consecutive statements. This guidance, therefore, eliminated the option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity. We adopted the requirements of this guidance effective for our fiscal year beginning January 1, 2012. Upon adoption, the guidance did not have a material impact on our consolidated financial statements. In February 2013, the FASB amended its guidance on reporting reclassifications out of accumulated other comprehensive income. For significant items reclassified out of accumulated other comprehensive income to net income in their entirety in the same reporting period, this amendment requires reporting about the effect of the reclassifications on the respective line items in the statement where net income is presented. For items that are not reclassified to net income in their entirety in the same

reporting period, a cross reference to other disclosures currently required under GAAP is required in the notes to the financial statements. This amendment is effective for interim periods beginning after December 15, 2012. We do not anticipate this amendment will have a material impact on our consolidated financial statements.

In September 2011, the FASB issued an update to the authoritative guidance on performing goodwill impairment testing. Under the revised guidance, entities testing goodwill for impairment have the option of performing a qualitative assessment before calculating the fair value of the reporting unit (step 1 of the goodwill impairment test). If entities determine, on the basis of qualitative factors, that the fair value of the reporting unit is more likely than not less than the carrying amount, the two-step impairment test would be required; otherwise, no further testing is required. The revised guidance does not change how goodwill is calculated or assigned to reporting units, does not revise the requirement to test goodwill annually for impairment, and does not amend the requirement to test goodwill for impairment between annual tests if events and circumstances warrant. The revised authoritative guidance is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. We adopted this guidance effective for our fiscal year beginning January 1, 2012. Upon adoption, the guidance did not have a material impact on our consolidated financial statements.

Results of Operations

Comparison of Years Ended December 31, 2012, 2011 and 2010

	Years Ended December 31,		
	2012	**2011**	**2010**
Product sales, net			
Glumetza	$ 144,997	$ 36,365	$ —
Zegerid (brand and authorized generic)	48,004	43,237	89,438
Cycloset	14,434	8,516	732
Fenoglide	7,103	35	—
Total	$ 214,538	$ 88,153	$ 90,170

Product Sales, Net. Product sales, net were $214.5 million for 2012, $88.2 million for 2011 and $90.2 million for 2010. The $126.3 million increase in product sales, net consisted primarily of an increase in net sales of Glumetza which we began distributing in September 2011. Through August 2011, revenue related to our promotion of Glumetza was recorded as promotion revenue and is further described below. Also contributing to the increase in product sales, net were $7.1 million in sales of Fenoglide which we began distributing in December 2011, an increase in net sales of Cycloset primarily due to increased sales volume and an increase in sales of our Zegerid products primarily driven by sales of the authorized generic products. The $2.0 million decrease in product sales, net from 2010 to 2011 was comprised of approximately $46.2 million related to a decrease in sales of our Zegerid products, including the authorized generic products, partially offset by approximately $36.4 million in sales of Glumetza and an increase of approximately $7.8 million in sales of Cycloset which we launched in November 2010.

Promotion Revenue. Promotion revenue was $27.3 million for 2011 and $31.4 million for 2010. Promotion revenue was comprised of fees earned under our promotion agreement with Depomed for the promotion of Glumetza prescription products. Promotion revenue for 2011 was based on Glumetza sales recorded by Depomed through August 2011. The promotion agreement was replaced by a commercialization agreement with Depomed under which we began distributing and recording product sales for Glumetza in September 2011. Glumetza 500 mg was the subject of a voluntary recall and supply interruption which resulted in the unavailability of this dosage strength from June 2010 through early January 2011. Shipments of Glumetza 500 mg resumed in January 2011.

Royalty Revenue. Royalty revenue was $3.4 million for 2012, $3.3 million for 2011 and $3.6 million for 2010. Royalty revenue was comprised of royalties earned under our license agreement with Merck for Zegerid OTC and our license agreement with GSK for prescription and OTC immediate-release omeprazole products in specified countries outside the U.S.

Other License Revenue. Other license revenue was $245,000 for 2010 and was comprised of the remaining amortization of the upfront payment we received in October 2009 in connection with our license agreement with Norgine B.V., or Norgine. There was no other license revenue in 2012 and 2011.

Cost of Product Sales. Cost of product sales was $15.6 million for 2012, $8.9 million for 2011 and $7.7 million for 2010, or approximately 7%, 10% and 9% of net product sales, respectively. Cost of product sales consists primarily of raw materials, third-party manufacturing costs, freight and indirect personnel and other overhead costs associated with the sales of our commercial prescription products as well as shipments to Prasco of the authorized generic version of Zegerid capsules. Cost of product sales also includes reserves for excess, dated or obsolete commercial inventories based on an analysis of inventory on hand and on firm purchase commitments compared to forecasts of future sales. The decrease in our cost of product sales as a percentage of net product sales from 2011 to 2012 was primarily attributable to certain fixed costs being applied to increased sales volumes and increased sales prices. The increase in our cost of product sales as a percentage of net product sales from 2010 to 2011 was primarily attributable to certain fixed costs being applied to decreased sales volumes and higher manufacturing costs associated with Glumetza and Cycloset.

License Fees and Royalties. License fees and royalties were $69.8 million for 2012, $17.9 million for 2011 and $28.6 million for 2010. License fees and royalties consist of royalties due to Depomed under our commercialization agreement based upon net product sales of Glumetza, royalties earned by HRP and Shore under our license agreement based upon net product sales of Fenoglide and royalties due to the University of Missouri based upon net product sales of our Zegerid prescription products, sales of Zegerid OTC by Merck under our license agreement and products sold by GSK under our license agreement. In addition, license fees and royalties include milestone payments and upfront fees expensed or amortized under license agreements, as well as amounts payable to S2 Therapeutics, Inc., or S2, and VeroScience, LLC, or VeroScience, based on a percentage of the gross margin associated with net sales of Cycloset. License fees and royalties also include changes in the fair value of contingent consideration related to business combinations.

The $51.9 million increase in license fees and royalties from 2011 to 2012 was primarily attributable to license fees and royalties related to our commercialization agreement with Depomed entered into in August 2011 and our license agreement with HRP and Shore entered into in December 2011, as well as an increase in amounts payable to S2 and VeroScience under our license agreement. In addition, the increase was attributable to a $10.0 million milestone we paid to Pharming Group NV, or Pharming, under our license and supply agreements following successful completion of the phase III clinical study for Ruconest in November 2012 and a milestone payment to Cosmo Technologies Limited, an affiliate of Cosmo Pharmaceuticals S.p.A., or Cosmo, in 2012 based on the achievement of a regulatory milestone under our license agreement. Cosmo elected to receive payment through the issuance of 906,412 shares of our common stock. The fair value of the shares issued to Cosmo was approximately $3.7 million.

The $10.7 million decrease in license fees and royalties from 2010 to 2011 was primarily due to certain upfront fees and milestone payments expensed in 2010 as follows: a $15.0 million upfront fee we paid to Pharming in September 2010 under our license and supply agreements, a $2.7 million accrual related to the one-time $3.0 million sales milestone due to Depomed based on Glumetza net product sales in excess of $50.0 million during the 13-month period ending January 2011 and a milestone payment to Cosmo under our license agreement based on the achievement of the primary endpoints in both of the phase III studies for Uceris. Cosmo elected to receive payment through the issuance of 972,132 shares of our common stock. The fair value of the shares issued to Cosmo was approximately $2.7 million. Additionally, the decrease in license fees and royalties from 2010 to 2011 resulted from a decrease in royalties due to the University of Missouri based on decreased sales of Zegerid prescription products. These decreases were offset in part by an increase in the product royalty payable to S2 and VeroScience based on the gross margin associated with net sales of Cycloset and the royalties due to Depomed based upon net product sales of Glumetza which commenced in September 2011.

Research and Development. Research and development expenses were $25.8 million for 2012, $18.4 million for 2011 and $17.4 million for 2010. The $7.4 million increase in our research and development expenses from 2011 to 2012 was primarily attributable to an increase in costs associated with our Uceris phase IIIb clinical study and increased compensation costs associated with an increase in the number of research and development personnel and annual merit increases to existing employees. The $1.0 million increase in our research and development expenses from 2010 to 2011 was primarily attributable to an increase in costs associated with our phase I clinical study with SAN-300 and increased compensation costs associated with an increase in research and development personnel and

annual merit increases, offset in part by a decrease in costs associated with our Uceris and rifamycin SV MMX phase III clinical programs.

Our research and development efforts are currently focused on Uceris and our Ruconest, rifamycin SV MMX and SAN-300 investigational drugs.

In connection with our strategic collaboration with Cosmo entered into in December 2008, we were granted exclusive rights in the U.S. to develop and commercialize Uceris and rifamycin SV MMX. Uceris is a locally acting corticosteroid in an oral tablet formulation that utilizes proprietary MMX colonic delivery technology. Uceris (budesonide) extended release tablets 9mg is indicated for the induction of remission in patients with active, mild to moderate ulcerative colitis. In connection with receipt of FDA approval of Uceris, we committed to a post-marketing requirement to conduct an 8-week randomized clinical study in children 5 to 17 years of age with active, mild to moderate ulcerative colitis. We currently plan to submit the protocol for this study later this year and expect to initiate the study once we have reached agreement with the FDA on the study design.

In addition, in February 2012 we began patient enrollment in a multicenter, randomized, double-blind placebo-controlled phase IIIb clinical study evaluating whether there is an incremental benefit when Uceris 9 mg is added to current oral aminosalicylate, or 5-ASA, therapy for patients with active, mild to moderate ulcerative colitis who are not adequately controlled on background 5-ASA therapy. We expect to enroll approximately 500 patients, with 250 in each treatment arm, at clinical sites in the U.S., Canada and Europe. We expect to complete patient enrollment in the phase IIIb study in mid-2013.

Rifamycin SV MMX is a broad spectrum, non-systemic antibiotic in a novel oral tablet formulation, which utilizes proprietary MMX colonic delivery technology and is being developed for the treatment of patients with travelers' diarrhea and potentially for other diseases that have a bacterial component in the intestine. In September 2012, we announced that rifamycin SV MMX met the primary endpoint in a phase III clinical study in patients with travelers' diarrhea. Dr. Falk Pharma GmbH, Cosmo's European development partner, is conducting a second phase III clinical study to evaluate the efficacy of rifamycin SV MMX in patients with travelers' diarrhea. Assuming positive results in the second phase III clinical study, we and Dr. Falk plan to share the clinical data from our respective phase III studies for inclusion in each company's regulatory submissions.

We have acquired rights to Ruconest under license and supply agreements with Pharming. Ruconest is a recombinant version of the human protein C1 esterase inhibitor, which is produced using proprietary transgenic technology. In November 2012, we announced positive top-line results from the phase III clinical study to evaluate the safety and efficacy of Ruconest for the treatment of acute attacks of angioedema in patients with HAE. We plan to submit a BLA to the FDA during the second quarter of 2013, seeking approval to market Ruconest for the treatment of acute attacks of angioedema in patients with HAE.

We currently are exploring clinical and regulatory strategies with the goal of initiating a proof-of-concept study in late 2013 to evaluate Ruconest for the treatment of acute pancreatitis.

We have acquired the exclusive worldwide rights to SAN-300 through the acquisition of Covella and a related license agreement with Biogen Idec MA, or Biogen. SAN-300 is a humanized anti-VLA-1 mAb that we believe may offer a novel approach to the treatment of inflammatory and autoimmune diseases. In December 2012, we completed a phase I dose-escalation clinical study in healthy volunteers to determine the safety, tolerability, pharmacokinetics and pharmacodynamics of single doses of SAN-300 in both intraveneous, or IV, and subcutaneous formulations. The phase I study was conducted in Australia and enrolled a total of 66 healthy volunteers. We plan to begin a phase IIa clinical study evaluating SAN-300 for treatment of rheumatoid arthritis during the fourth quarter of 2013.

Research and development expenses have historically consisted primarily of costs associated with clinical studies of our investigational drugs as well as clinical studies designed to further differentiate our products from those of our competitors, development of and preparation for commercial manufacturing of our products, compensation and other expenses related to research and development personnel and facilities expenses.

A substantial portion of our external research and development costs is tracked on a direct project basis. However, because our internal research and development resources are used in several projects, the related indirect costs are not attributable to a specific investigational drug. For example, personnel and facility related costs are not tracked on a project basis. We have summarized the costs associated with our development programs in the following table (in thousands). Costs that are not attributable to a specific investigational drug, including salaries and related personnel and facilities costs, are included in the "indirect costs" category.

	Year Ended December 31,			Project to Date Through December 31, 2012[1]
	2012	2011	2010	
Direct costs:				
Uceris	$ 11,751	$ 5,421	$ 5,711	$ 34,527
Rifamycin SV MMX	1,021	1,457	2,399	5,525
Ruconest	(34)	175	403	544
SAN-300	2,543	2,508	516	5,567
Zegerid and other projects	461	376	1,644	N/A
Total direct costs	15,742	9,937	10,673	
Indirect costs	10,066	8,446	6,758	N/A
Total research and development	$ 25,808	$ 18,383	$ 17,431	

(1) Project to date amounts are included for projects on which we are primarily focused.

In the future, we may conduct additional clinical studies to further differentiate our marketed products and investigational drugs, as well as conduct research and development related to any future products that we may in-license or otherwise acquire. Although we are currently focused primarily on the Uceris phase IIIb program and the rifamycin SV MMX, Ruconest and SAN-300 investigational drugs, we anticipate that we will make determinations as to which development projects to pursue and how much funding to direct to each project on an ongoing basis in response to the scientific, clinical and commercial merits of each project. We are unable to estimate with any certainty the research and development costs that we may incur in the future. In addition, in connection with the approval of Zegerid powder for oral suspension, we committed to commence clinical studies to evaluate the product in pediatric populations. We have not yet commenced any of the studies and have requested a waiver of this requirement from the FDA.

Selling, General and Administrative. Selling, general and administrative expenses were $86.6 million for 2012, $68.2 million for 2011 and $82.6 million for 2010. The $18.4 million increase in our selling, general and administrative expenses from 2011 to 2012 was primarily attributable to the expansion of our commercial presence, including expenses associated with engaging Ventiv Commercial Services, LLC, d/b/a inVentiv Commercial Services, LLC, or inVentiv, to supplement our sales effort by adding 40 contract sales representatives, and increased compensation costs associated with an increase in our sales personnel and annual merit increases. The increase in selling, general and administrative expenses was also attributable to launch preparation activities related to Uceris and promotional activities for Fenoglide. The $14.4 million decrease in our selling, general and administrative expenses from 2010 to 2011 was primarily attributable to a decrease in compensation, benefits and related employee costs and a decrease in Zegerid promotional spending related to our decision to cease promotion of our Zegerid prescription products and implement a corporate restructuring in the third quarter of 2010. These decreases in selling, general and administrative expenses were offset in part by an increase in advertising and promotional spending associated with Cycloset and increased legal fees.

Restructuring Charges. As a result of our restructuring plan, we recorded a restructuring charge of $7.1 million in 2010, consisting of $5.0 million in one-time termination benefits including pay during the Worker Adjustment and Retraining Notification Act, or WARN, notice period in lieu of work, severance and healthcare benefits, $1.7 million in contract termination costs and $352,000 of non-cash stock-based compensation. Our decision to cease promotion of our Zegerid prescription products and implement a corporate restructuring resulted from Par's decision to launch a generic version of our Zegerid prescription products in late June 2010. The corporate restructuring

included a workforce reduction of approximately 34%, or 113 employees, in our commercial organization and certain other operations. We also significantly reduced the number of contract sales representatives that we utilized. We provided 60-day WARN notices to the affected employees to inform them that their employment would end at the conclusion of the 60-day period. We began notifying affected employees in July 2010 and substantially completed our restructuring plan in the third quarter of 2010.

Interest Income. Interest income was $29,000 for 2012, $15,000 for 2011 and $80,000 for 2010.

Interest Expense. Interest expense was $337,000 for 2012, $459,000 for 2011 and $461,000 for 2010. Interest expense was comprised primarily of interest due in connection with our revolving credit facility with Comerica Bank, or Comerica.

Income Tax Expense. Income tax expense was $1.3 million for 2012, $312,000 for 2011 and $59,000 for 2010. Our effective tax rate was 6.6% in 2012, 6.2% in 2011 and (0.5)% in 2010 impacted by utilization of net operating loss carryforwards in each year presented. At December 31, 2012, we had Federal and state income tax net operating loss carryforwards of approximately $118.1 million and $129.7 million, respectively. The Federal and California net operating loss carryforwards will begin to expire in 2024 and 2014, respectively, unless previously utilized. Utilization of our net operating loss carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period under the provision of Section 382 of the Internal Revenue Code.

Liquidity and Capital Resources

As of December 31, 2012, cash, cash equivalents and short-term investments were $94.7 million, compared to $58.6 million as of December 31, 2011, an increase of $36.1 million. This net increase resulted primarily from our net income for 2012, adjusted for non-cash charges.

Net cash provided by operating activities was $35.8 million for 2012 and $8.0 million for 2011. The primary source of cash for 2012 was our net income for the period, adjusted for non-cash charges, including $6.1 million in depreciation and amortization, $6.7 million in stock-based compensation and $3.7 million related to the issuance of common stock under a technology license agreement. The primary source of cash in 2011 was our net income for 2011, adjusted for non-cash expenses, including $5.4 million in stock-based compensation and $3.1 million in depreciation and amortization, partially offset by changes in operating assets and liabilities. Significant working capital uses of cash for 2011 included increases in accounts receivable primarily related to our commencement of distribution of Glumetza in September 2011, partially offset by increases in accounts payable and accrued liabilities and decreases in prepaid expenses and other current assets.

Net cash used in operating activities was $28.0 million for 2010. The primary use of cash for 2010 resulted from our net loss for the period, which included the $15.0 million upfront fee we paid to Pharming in connection with the license and supply agreements we entered into in September 2010, adjusted for non-cash charges, including $5.4 million in stock-based compensation, $2.9 million related to the issuance of common stock under technology license agreements, $2.3 million in depreciation and amortization, and changes in operating assets and liabilities. Significant working capital uses of cash for 2010 included decreases in accounts payable and accrued liabilities related to payment of annual corporate bonuses, accrued rebates and other expenses accrued in 2009 and increases in prepaid expenses and other current assets. These working capital uses of cash for 2010 were offset in part by decreases in inventories related to our reserves against on-hand inventories of our Zegerid products, and decreases in accounts receivable resulting from our decision to cease promotion of Zegerid and the launch of generic versions of prescription Zegerid capsules.

Net cash used in investing activities was $43.9 million for 2012, $12.5 million for 2011 and $2.3 million for 2010. These activities included purchases and sales/maturities/redemptions of short-term investments and purchases of property and equipment. For 2012, net cash used in investing activities also included approximately $2.5 million we paid to Depomed for the purchase of Glumetza inventories in connection with the commercialization agreement we entered into in August 2011. For 2011, net cash used in investing activities also included $12.3 million in cash paid for business combinations, including the $11.0 million upfront payment we made to Shore in connection with the acquisition of intangible assets and prepaid royalties related to Fenoglide and approximately $1.3 million we

paid to Depomed for the purchase of inventories related to Glumetza. For 2010, net cash used in investing activities also included the $5.0 million upfront payment we made to S2 and VeroScience in connection with the acquisition of intangible assets related to Cycloset and net cash payments of $842,000 in connection with our acquisition of Covella.

Net cash provided by financing activities was $3.7 million for 2012, $2.1 million for 2011 and $906,000 for 2010. Net cash provided by financing activities included proceeds received from the exercise of stock options and through the issuance of common stock under our employee stock purchase plan.

Contractual Obligations and Commitments

We rely on Patheon, Inc. as our manufacturer of Glumetza 500 mg, Cycloset and Zegerid powder for oral suspension, and we currently rely on Depomed to oversee the manufacturing of Glumetza 1000 mg. We rely on Norwich Pharmaceuticals, Inc. as our sole third-party manufacturer of Zegerid capsules and the related authorized generic product, and we rely on Catalent Pharma Solutions, LLC as our sole third-party manufacturer of Fenoglide. We also are required to purchase commercial quantities of certain active ingredients in our commercial products. At December 31, 2012, we had finished goods and raw materials inventory purchase commitments of approximately $5.6 million.

License Agreement and Manufacturing and Supply Agreement with Cosmo

Under our license agreement, stock issuance agreement and registration rights agreement with Cosmo entered into in December 2008, in February 2012 following FDA acceptance for filing of the NDA for Uceris, Cosmo elected to receive payment of a regulatory milestone through the issuance of 906,412 shares of our common stock. Following the first commercial sale of Uceris which occurred in February 2013, Cosmo has the option to elect, on or before April 15, 2013, whether to receive payment of a $7.0 million commercial milestone in cash or through the issuance of 565,793 shares of our common stock. We may also be required to pay Cosmo commercial milestones of up to $22.5 million for Uceris and $28.0 million for rifamycin SV MMX. In addition, we may also be required to pay Cosmo an additional $2.0 million regulatory milestone for the initial indication for rifamycin SV MMX and up to $6.0 million in clinical and regulatory milestones for a second indication for rifamycin SV MMX. The milestones may be paid in cash or through issuance of additional shares of our common stock, at Cosmo's option, subject to certain limitations. We will be required to pay tiered royalties to Cosmo equal to 12% (on annual net sales of each licensed product up to $120.0 million) and 14% (on annual net sales of each licensed product in excess of $120.0 million). Such royalties are subject to reduction in certain circumstances, including in the event of market launch in the U.S. of a generic version of a licensed product. We are also responsible for all of the out-of-pocket costs for the ongoing Uceris phase IIIb clinical study. In the event that additional clinical work is required to obtain U.S. regulatory approval for rifamycin SV MMX, the parties will agree on cost sharing. Under our manufacturing and supply agreement with Cosmo entered into in May 2012, we are obligated to purchase all of our commercial supply of Uceris from Cosmo. We are required pay Cosmo a supply price equal to 10% of net sales, and Cosmo reimburses us for costs associated with packaging, which is contracted separately by us.

License Agreement with University of Missouri

Under our exclusive worldwide license agreement with the University of Missouri entered into in January 2001 relating to specific formulations of PPIs with antacids and other buffering agents, we are required to make milestone payments to the University of Missouri upon initial commercial sale in specified territories outside the U.S., which may total up to $3.5 million in the aggregate. We are also required to make milestone payments, up to a maximum of $83.8 million remaining under the agreement, based on first-time achievement of significant sales thresholds, which includes sales by us, Prasco, Merck and GSK, the next of which is a one-time $7.5 million milestone payment upon initial achievement of $250.0 million in annual calendar year net product sales. We are also obligated to pay royalties on net sales of our Zegerid prescription products and any products sold by Prasco, Merck and GSK under our existing license and distribution agreements.

Agreements with Depomed

Under our commercialization agreement with Depomed entered into in August 2011, we are required to pay to Depomed royalties on Glumetza net product sales in the U.S. of 32.0% in 2013 and 2014; and 34.5% in 2015 and beyond prior to generic entry of a Glumetza product. We have the exclusive right to commercialize authorized generic versions of the Glumetza products. In the event of generic entry of a Glumetza product in the U.S., the parties will equally share proceeds based on a gross margin split. Under the commercialization agreement, we have certain minimum marketing expenditures and sales force promotion obligations during the term of the agreement until such time as a generic to Glumetza enters the market. Under the terms of the commercialization agreement, Depomed will continue to manage the ongoing patent infringement litigation related to Glumetza, including with regard to any proposed settlements. We are responsible for 70% of the future out-of-pocket costs, and Depomed is responsible for 30% of the future out-of-pocket costs, related to patent infringement cases.

Distribution and License Agreement with S2 and VeroScience

Under the terms of our distribution and license agreement with S2 and VeroScience entered into in September 2010, we are responsible for paying a product royalty to S2 and VeroScience of 35% of the gross margin associated with net sales of Cycloset up to $100 million of cumulative total gross margin, increasing to 40% thereafter. Gross margin is defined as net sales less cost of goods sold. In the event net sales of Cycloset exceed $100.0 million in a calendar year, we will pay an additional 3% of the gross margin to S2 and VeroScience on incremental net sales over $100 million.

License Agreement with HRP and Shore

Under the terms of our license agreement with HRP and Shore, we are responsible for paying Shore tiered royalties on net sales of Fenoglide. The royalties are 5% on net sales of up to $10.0 million (commencing in 2013), a 20% royalty on net sales between $10.0 million and $20.0 million, and a 25% royalty on net sales above $20.0 million. We will also be obligated to pay Shore one-time, success-based milestones contingent on sales achievement: $2.0 million if calendar year net sales equal or exceed $20.0 million and $3.0 million if calendar year net sales equal or exceed $30.0 million. We have agreed to use commercially reasonable efforts to commercialize Fenoglide within the U.S. In addition, prior to the entry of any generic version of Fenoglide, we are required to provide certain minimum detailing efforts and sales and marketing expenditures.

License Agreement and Supply Agreement with Pharming

Under our license agreement with Pharming entered into in September 2010, we paid Pharming a $10.0 million milestone following successful completion of the phase III clinical study in November 2012. We may also be required to pay Pharming additional success-based milestones totaling up to an aggregate of $25.0 million, including a $5.0 million milestone upon FDA acceptance for review of a BLA for Ruconest and a $20.0 million milestone upon the earlier of first commercial sale of Ruconest in the U.S. or 90 days following receipt of FDA approval. In addition, we will be required to pay certain one-time performance milestones if we achieve certain aggregate net sales levels of Ruconest. The amount of each such milestone payment varies upon the level of net sales of Ruconest: a $20.0 million milestone if calendar year net sales exceed $300.0 million and a $25.0 million milestone if calendar year net sales exceed $500.0 million. As consideration for the licenses and rights granted under the license agreement, and as compensation for the commercial supply of Ruconest by Pharming pursuant to our supply agreement, we will pay Pharming a tiered supply price, based on a percentage of net sales of Ruconest, subject to reduction in certain events, as follows: 30% of net sales less than or equal to $100.0 million, 32% of net sales greater than $100.0 million but less than or equal to $250.0 million, 34% of net sales greater than $250.0 million but less than or equal to $500.0 million, 37% of net sales greater than $500.0 million but less than or equal to $750.0 million, and 40% of net sales greater than $750.0 million.

Acquisition of Covella

We have acquired the exclusive worldwide rights to SAN-300 through the acquisition of Covella and a related license agreement with Biogen. In connection with our acquisition of Covella, under the terms of the merger agreement, we may be required to make clinical and regulatory milestone payments totaling up to an aggregate of

$37.7 million (consisting of a combination of cash and our common stock) based on success in developing product candidates (with the first such milestone being payable upon successful completion of the first Phase IIb clinical study). We may also be required to pay a royalty equal to a low single digit percentage rate of net sales of any commercial products resulting from the anti-VLA-1 mAb technology.

Amended License and Amended Services and Supply Agreement with Biogen

Under our amended license agreement with Biogen, we may be obligated to make various clinical, regulatory and sales milestone payments based upon our success in developing and commercializing development-stage products (with the first such milestone being payable upon successful completion of the first Phase IIb clinical study). The amounts of the clinical and regulatory milestone payments vary depending on the type of product, the number of indications, and other specifically negotiated milestones. If SAN-300 is the first to achieve all applicable milestones for all three indications, we will be required to pay Biogen maximum aggregate clinical and regulatory milestone payments of $97.2 million. The amount of the commercial milestone payments we will be required to pay Biogen will depend on the level of net sales of a particular product in a calendar year. The maximum aggregate commercial milestone payments to Biogen total $105.5 million for SAN-300, assuming cumulative net sales of at least $5 billion of such product, and total $60.25 million for products containing certain other compositions as described in the license, assuming cumulative net sales of at least $5 billion of such products. In addition, we will be required to pay tiered royalties ranging from low single digit to low double digit percentage rates, subject to reduction in certain limited circumstances, on net sales of products developed under the amended license.

In November 2011 and December 2012, we amended our services and supply agreement with Biogen. Under the services and supply agreement, Biogen agreed to supply to us materials manufactured by Biogen for use in the anti-VLA-1 mAb development program. The amendment provides for a revised payment structure for such material. Under the terms of our amended services and supply agreement, upon the achievement of the first regulatory approval as set forth in our amended license agreement, Biogen is entitled to receive a one-time milestone payment of approximately $11.7 million, which is equivalent to the cost of the materials supplied under the services and supply agreement. In the event the amended license agreement is terminated by us or Biogen prior to the achievement of the first regulatory approval as set forth in the amended license agreement, we will be required to pay Biogen a one-time termination fee of $3.0 million.

The following summarizes our long-term contractual obligations as of December 31, 2012, excluding potential clinical, regulatory and commercial milestones and royalty obligations under our agreements which are described above:

	Payments Due by Period				
Contractual Obligations	**Total**	**Less than One Year**	**One to Three Years**	**Four to Five Years**	**Thereafter**
			(in thousands)		
Operating leases	$ 16,686	$ 1,828	$ 7,024	$ 4,604	$ 3,230
Long-term debt	10,522	246	10,276	—	—
Other long-term contractual obligations	741	360	329	23	29
Total	$ 27,949	$ 2,434	$ 17,629	$ 4,627	$ 3,259

The amount and timing of cash requirements will depend on our ability to generate revenues from our currently promoted commercial prescription products, including our ability to maintain commercial supply. In addition, our cash requirements will depend on market acceptance of any other products that we may market in the future, the success of our strategic alliances, 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 and use of our line of credit will be sufficient to fund our current operations through at least the next twelve months; however, our projected revenue may decrease or our expenses may increase and that would lead to our cash resources being consumed earlier than we expect. Although we do not believe that we will need to raise additional funds to finance our current operations through at least the next twelve months, we may pursue raising additional funds for various reasons, including to expand our commercial presence, in connection with licensing or acquisition of new marketed products or

investigational drugs, to continue development of investigational drugs in our pipeline, or for other general corporate purposes. Sources of additional funds may include funds generated through equity and/or debt financing or through strategic collaborations or licensing agreements.

Our existing universal shelf registration statement, which was declared effective in December 2011, may permit us, from time to time, to offer and sell up to approximately $75.0 million of equity or debt securities. However, there can be no assurance that we will be able to complete any such offerings of securities. Factors influencing the availability of additional financing include the progress of our commercial and development activities, investor perception of our prospects and the general condition of the financial markets, among others.

In July 2006, we entered into our loan agreement with Comerica, which was most recently amended in February 2012, pursuant to which we may request advances in an aggregate outstanding amount not to exceed $35.0 million. In December 2008, we drew down $10.0 million under the loan agreement. The revolving loan bears interest, as selected by us, at a variable rate of interest, per annum, most recently announced by Comerica as its "prime rate" or the LIBOR rate plus 2.25%. Interest payments on advances made under the loan agreement are due and payable in arrears on a monthly basis during the term of the loan agreement. The February 2012 amendment to the loan agreement extends the maturity date of the revolving line from July 11, 2013 to February 13, 2015. Amounts borrowed under the loan agreement may be repaid and re-borrowed at any time prior to February 13, 2015, and any outstanding principal drawn during the term of the loan facility is due and payable on February 13, 2015. The loan agreement will remain in full force and effect for so long as any obligations remain outstanding or Comerica has any obligation to make credit extensions under the loan agreement.

Amounts borrowed under the loan agreement are secured by substantially all of our personal property, excluding intellectual property. Under the loan agreement, we are subject to certain affirmative and negative covenants, including limitations on our ability to: undergo certain change of control events; convey, sell, lease, license, transfer or otherwise dispose of assets; create, incur, assume, guarantee or be liable with respect to certain indebtedness; grant liens; pay dividends and make certain other restricted payments; and make investments. In addition, under the loan agreement, we are required to maintain our cash balances with either Comerica or another financial institution covered by a control agreement for the benefit of Comerica. We are also subject to specified financial covenants with respect to a minimum liquidity ratio and, in specified limited circumstances, minimum EBITDA requirements. We believe we have currently met all of our obligations under the loan agreement.

We cannot be certain that our existing cash, cash equivalents and short-term investments and use of our line of credit will be adequate to sustain our current operations. To the extent we require additional funding, we cannot be certain that such funding will be available to us on acceptable terms, or at all. To the extent that we raise additional capital by issuing equity or convertible securities, our stockholders' ownership will be diluted. Any debt financing we enter into may involve covenants that restrict our operations. If adequate funds are not available on terms acceptable to us at that time, our ability to continue our current operations or pursue new product opportunities would be significantly limited.

In addition, our results of operations could be materially affected by economic conditions generally, both in the U.S. and elsewhere around the world. Continuing concerns over U.S. spending and deficits, inflation, energy costs, geopolitical issues, the availability and cost of credit, the U.S. mortgage market and a difficult residential real estate market in the U.S. have contributed to increased volatility and diminished expectations for the economy and the markets going forward. Domestic and international equity markets have experienced and may continue to experience heightened volatility and turmoil based on domestic and international economic conditions and concern, including concerns over U.S. spending and deficits. In the event these economic conditions and concerns continue and the markets continue to remain volatile, our results of operations could be adversely affected by those factors in many ways, including making it more difficult for us to raise funds if necessary, and our stock price may decline. In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits. If economic instability continues, we cannot be assured that we will not experience losses on these deposits.

In March 2010, the President signed the Patient Protection and Affordable Care Act, or PPACA, which makes extensive changes to the delivery of healthcare in the U.S. This act includes numerous provisions that affect pharmaceutical companies, some of which were effective immediately and others of which will be taking effect over

the next several years. For example, the act seeks to expand healthcare coverage to the uninsured through private health insurance reforms and an expansion of Medicaid. The act also imposes substantial costs on pharmaceutical manufacturers, such as an increase in liability for rebates paid to Medicaid, new drug discounts that must be offered to certain enrollees in the Medicare prescription drug benefit, an annual fee imposed on all manufacturers of brand prescription drugs in the U.S., and an expansion of an existing program requiring pharmaceutical discounts to certain types of hospitals and federally subsidized clinics. The act also contains cost-containment measures that could reduce reimbursement levels for healthcare items and services generally, including pharmaceuticals. It also will require reporting and public disclosure of payments and other transfers of value provided by pharmaceutical companies to physicians and teaching hospitals. These measures could result in decreased net revenues from our pharmaceutical products and decreased potential returns from our development efforts. In addition, although the PPACA was recently upheld by the U.S. Supreme Court, it is also possible that the PPACA may be modified or repealed in the future.

As of December 31, 2012, 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.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Under the terms of our loan agreement with Comerica Bank, or Comerica, the interest rate applicable to any amounts borrowed by us under the credit facility will be, at our election, indexed to either Comerica's prime rate or the LIBOR rate. If we elect Comerica's prime rate for all or any portion of our borrowings, the interest rate will be variable, which would expose us to the risk of increased interest expense if interest rates rise. If we elect the LIBOR rate for all or any portion of our borrowings, such LIBOR rate will remain fixed only for a specified, limited period of time after the date of our election, after which we will be required to repay the borrowed amount, or elect a new interest rate indexed to either Comerica's prime rate or the LIBOR rate. The new rate may be higher than the earlier interest rate applicable under the loan agreement. As of December 31, 2012, the balance outstanding under the credit facility was $10.0 million, and we had elected the LIBOR rate plus 2.25% interest rate option, which was approximately 2.46% as of December 31, 2012. Under our current policies, we do not use interest rate derivative instruments to manage our exposure to interest rate changes. A hypothetical 10% increase or decrease in the interest rate under the loan agreement would not materially affect our interest expense at our current level of borrowing.

In addition to market risk related to our loan agreement with Comerica, we are exposed to market risk primarily in the area of changes in U.S. interest rates and conditions in the credit markets, particularly because the majority of our investments are in short-term marketable securities. We do not have any material foreign currency or other derivative financial instruments. Our short-term investment securities have consisted of corporate debt securities, government agency securities and U.S. Treasury securities which are classified as available-for-sale and therefore reported on the consolidated balance sheets at estimated market value.

Our results of operations could be materially affected by economic conditions generally, both in the U.S. and elsewhere around the world. Continuing concerns over U.S. spending and deficits, inflation, energy costs, geopolitical issues, the availability and cost of credit, the U.S. mortgage market and a difficult residential real estate market in the U.S. have contributed to increased volatility and diminished expectations for the economy and the markets going forward. Domestic and international equity markets have experienced and may continue to experience heightened volatility and turmoil based on domestic and international economic conditions and concern, including concerns over U.S. spending and deficits. In the event these economic conditions and concerns continue and the markets continue to remain volatile, our results of operations could be adversely affected by those factors in many ways, including making it more difficult for us to raise funds if necessary, and our stock price may decline. In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits. If economic instability continues, we cannot be assured that we will not experience losses on these deposits.

Item 8. Financial Statements and Supplementary Data

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

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

Not applicable.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

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

Management's Report on Internal Control Over Financial Reporting

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

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

Management is responsible for establishing and maintaining adequate internal control over our financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting. Management has used the framework set forth in the report entitled "Internal Control—Integrated Framework" published by the Committee of Sponsoring Organizations of the Treadway Commission to evaluate the effectiveness of our internal control over financial

reporting. Based on its evaluation, management has concluded that our internal control over financial reporting was effective as of December 31, 2012, the end of our most recent fiscal year. Ernst & Young LLP, our independent registered public accounting firm, has issued a report on the effectiveness of our internal control over financial reporting, which is included herein.

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

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Santarus, Inc.

We have audited Santarus, Inc.'s internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Santarus, Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, Santarus, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Santarus, Inc. as of December 31, 2012 and 2011, and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2012 of Santarus, Inc. and our report dated March 4, 2013, expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
March 4, 2013

Item 9B. Other Information

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item will be contained in our definitive proxy statement, or Proxy Statement, to be filed with the Securities and Exchange Commission in connection with the 2013 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, 2012, and is incorporated in this report by reference.

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

Item 11. Executive Compensation

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

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

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

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

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

Item 14. Principal Accountant Fees and Services

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

PART IV

Item 15. Exhibits and Financial Statement Schedules

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

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

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of December 31, 2012 and 2011

Consolidated Statements of Operations for each of the years ended December 31, 2012, 2011 and 2010

Consolidated Statements of Comprehensive Income (Loss) for each of the years ended December 31, 2012, 2011 and 2010

Consolidated Statements of Stockholders' Equity for each of the years ended December 31, 2012, 2011 and 2010

Consolidated Statements of Cash Flows for each of the years ended December 31, 2012, 2011 and 2010

Notes to Consolidated Financial Statements

2. List of financial statement schedules:

Schedule II – Valuation and Qualifying Accounts

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

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

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

Exhibit Number	Description
2.1(1)†	Agreement and Plan of Merger, dated September 10, 2010, among us, SAN Acquisition Corp., Covella Pharmaceuticals, Inc. and Lawrence C. Fritz, as the Stockholder Representative
3.1(2)	Amended and Restated Certificate of Incorporation
3.2(3)	Amended and Restated Bylaws
3.3(4)	Certificate of Designations for Series A Junior Participating Preferred Stock
4.1(4)	Form of Common Stock Certificate
4.2(5)	Amended and Restated Investors' Rights Agreement, dated April 30, 2003, among us and the parties named therein
4.3(5)	Amendment No. 1 to Amended and Restated Investors' Rights Agreement, dated May 19, 2003, among us and the parties named therein
4.4(5)†	Stock Restriction and Registration Rights Agreement, dated January 26, 2001, between us and The Curators of the University of Missouri
4.5(5)	Form of Common Stock Purchase Warrant
4.6(4)	Rights Agreement, dated 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

Exhibit Number	Description
4.7(6)	First Amendment to Rights Agreement, dated April 19, 2006, between us and American Stock Transfer & Trust Company
4.8(7)	Second Amendment to Rights Agreement, dated December 10, 2008, between us and American Stock Transfer and Trust Company
4.9(8)	Warrant to Purchase Shares of Common Stock, dated February 3, 2006, issued by us to Kingsbridge Capital Limited
4.10(8)	Registration Rights Agreement, dated February 3, 2006, between us and Kingsbridge Capital Limited
4.11(9)	Registration Rights Agreement, dated December 10, 2008, between us and Cosmo Technologies Limited
4.12(9)	Amendment No. 1 to Registration Rights Agreement, dated April 23, 2009, between us and Cosmo Technologies Limited
10.1(5)†	Stock Purchase Agreement, dated January 26, 2001, between us and The Curators of the University of Missouri
10.2(5)†	Exclusive License Agreement, dated January 26, 2001, between us and The Curators of the University of Missouri
10.3(5)†	Amendment No. 1 to Exclusive License Agreement, dated February 21, 2003, between us and The Curators of the University of Missouri
10.4(10)†	Amendment No. 2 to Exclusive License Agreement, dated August 20, 2007, between us and The Curators of the University of Missouri
10.5(5)†	Omeprazole Supply Agreement, dated September 25, 2003, among us, InterChem Trading Corporation and Union Quimico Farmaceutica, S.A.
10.6(11)†	Amendment No. 1 to Omeprazole Supply Agreement, dated November 1, 2004, among us, InterChem Trading Corporation and Union Quimico Farmaceutica, S.A.
10.7(11)†	Amendment No. 2 to Omeprazole Supply Agreement, dated July 11, 2007, among us, InterChem Trading Corporation and Union Quimico Farmaceutica, S.A.
10.8(12)†	Amendment No. 3 to Omeprazole Supply Agreement, dated December 17, 2008, among us, InterChem Trading Corporation and Union Quimico Farmaceutica, S.A.
10.9(13)†	Amendment No. 4 to Omeprazole Supply Agreement, dated October 30, 2009, among us, InterChem Trading Corporation and Union Quimico Farmaceutica, S.A.
10.10(13)†	Second Amended and Restated Manufacturing and Supply Agreement, dated October 20, 2009, between us and Patheon Inc.
10.11(14)†	Manufacturing and Supply Agreement, dated September 27, 2004, between us and OSG Norwich Pharmaceuticals, Inc.
10.12(8)	Common Stock Purchase Agreement, dated February 3, 2006, between us and Kingsbridge Capital Limited
10.13(15)	Amended and Restated Loan and Security Agreement, dated July 11, 2008, between us and Comerica Bank
10.14(16)	First Amendment to Amended and Restated Loan and Security Agreement, dated August 27, 2010, between us and Comerica Bank
10.15(17)	Second Amendment to Amended and Restated Loan and Security Agreement, dated February 13, 2012, between us and Comerica Bank
10.15(17)	Second Amended and Restated LIBOR Addendum to Amended and Restated Loan and Security Agreement, dated February 13, 2012, between us and Comerica Bank
10.16(18)†	OTC License Agreement, dated October 17, 2006, between us and Schering-Plough Healthcare Products, Inc.
10.17(19)†	Amendment No. 1 to OTC License Agreement, dated July 24, 2009, between us and Schering-Plough Healthcare Products, Inc.
10.18(20)	Amendment No. 2 to OTC License Agreement, dated August 6, 2010, between us and Schering-Plough Healthcare Products, Inc.
10.19(21)†	Amendment No. 3 to OTC License Agreement, dated April 1, 2011, between us and Schering-Plough Healthcare Products, Inc.

Exhibit Number	Description
10.20(22)	Amendment No. 4 to OTC License Agreement, dated September 23, 2011, between us and MSD Consumer Care, Inc. (formerly known as Schering-Plough Healthcare Products, Inc.)
10.21(23)†	Service Agreement, dated November 3, 2006, between us and Ventiv Commercial Services, LLC (d/b/a inVentiv Commercial Services, LLC)
10.22(11)†	Amendment No. 1 to Service Agreement, dated June 15, 2007, between us and Ventiv Commercial Services, LLC (d/b/a inVentiv Commercial Services, LLC)
10.23(24)†	Amendment No. 2 to Service Agreement, dated October 6, 2008, between us and Ventiv Commercial Services, LLC (d/b/a inVentiv Commercial Services, LLC)
10.24(25)†	Amendment No. 3 to Service Agreement, dated June 30, 2010, between us and Ventiv Commercial Services, LLC (d/b/a inVentiv Commercial Services, LLC)
10.25(26)†	Co-Promotion Agreement, dated June 28, 2007, by and between us and Victory Pharma, Inc.
10.26(10)†	Co-Promotion Agreement, dated August 24, 2007, between us and C.B. Fleet Company, Incorporated
10.27(27)†	Amendment No. 1 to Co-Promotion Agreement, dated May 6, 2008, between us and C.B. Fleet Company, Incorporated
10.28(28)†	License Agreement, dated November 30, 2007, between us and Glaxo Group Limited, an affiliate of GlaxoSmithKline plc
10.29(28)†	Distribution Agreement, dated November 30, 2007, between us and Glaxo Group Limited, an affiliate of GlaxoSmithKline plc
10.30(12)†	License Agreement, dated December 10, 2008, between us and Cosmo Technologies Limited
10.31(12)†	Stock Issuance Agreement, dated December 10, 2008, between us and Cosmo Technologies Limited
10.32(29)†	Promotion Agreement, dated July 21, 2008, between us and Depomed, Inc.
10.33(19)†	License Agreement, dated October 9, 2009, between us and Norgine B.V.
10.34(21)†	Amendment to License Agreement, dated February 11, 2011, between us and Norgine B.V.
10.35+	Amended and Restated Distribution and Supply Agreement, dated November 30, 2012, between us and Prasco, LLC
10.36(1)†	Distribution and License Agreement, dated September 3, 2010, among us, VeroScience, LLC and S2 Therapeutics, Inc.
10.37(21)†	First Amendment to Distribution and License Agreement, dated March 10, 2011, among us, VeroScience, LLC and S2 Therapeutics, Inc.
10.38(1)†	Manufacturing Services Agreement, dated May 26, 2010, between Patheon Pharmaceuticals Inc. and S2 Therapeutics, Inc.
10.39(20)	Assignment and Assumption Agreement, dated September 3, 2010, between us and S2 Therapeutics, Inc.
10.40(1)†	License Agreement, dated September 10, 2010, among us, Pharming Group N.V., on behalf of itself and each of its affiliates, including Pharming Intellectual Property B.V. and Pharming Technologies B.V.
10.41(30)	Amendment to License Agreement, dated June 18, 2012, among us, Pharming Group N.V., on behalf of itself and each of its affiliates, including Pharming Intellectual Property B.V. and Pharming Technologies B.V.
10.42(20)†	Supply Agreement, dated September 10, 2010, among us, Pharming Group N.V., on behalf of itself and each of its affiliates, including Pharming Intellectual Property B.V. and Pharming Technologies B.V.
10.43(1)†	License Agreement, dated January 22, 2009, between Covella Pharmaceuticals, Inc. and Biogen Idec MA Inc.
10.44(1)†	Amendment to License Agreement, dated September 10, 2010, among us, Covella Pharmaceuticals, Inc. and Biogen Idec MA Inc.
10.45(31)†	Amended and Restated Services and Supply Agreement, dated September 10, 2010, among us, Covella Pharmaceuticals, Inc. and Biogen Idec MA Inc.
10.46(31)	First Amendment to Amended and Restated Services and Supply Agreement, dated November 4, 2011, among us, Covella Pharmaceuticals, Inc. and Biogen Idec MA Inc.

Exhibit Number	Description
10.47+	Second Amendment to Amended and Restated Services and Supply Agreement, dated December 17, 2012, among us, Covella Pharmaceuticals, Inc. and Biogen Idec MA Inc.
10.48(22)†	Commercialization Agreement, dated August 22, 2011, between us and Depomed, Inc.
10.49(31)†	Commercial Manufacturing Agreement, dated December 19, 2006, between Patheon Puerto Rico, Inc. (f/k/a MOVA Pharmaceutical Corporation) and Depomed, Inc.
10.50(31)	Assignment and Assumption Agreement, dated November 3, 2011, between us and Depomed, Inc.
10.51(31)†	License Agreement, dated December 21, 2011, among us, Healthcare Royalty Partners, L.P. and Shore Therapeutics, Inc.
10.52(32)†	Settlement and License Agreement, dated February 22, 2012, between us, Depomed, Inc., Lupin Pharmaceuticals, Inc., and Lupin Limited
10.53(30)†	Manufacturing and Supply Agreement, dated May 18, 2012, between us and Cosmo Technologies Limited
10.54(33)	Sublease, dated December 11, 2007, between us and Avnet, Inc.
10.55(22)	First Amendment to Sublease, dated August 5, 2011, between us and Avnet, Inc.
10.56(34)	Office Lease, dated October 5, 2012, between us and Kilroy Realty, L.P.
10.57(5)#	Form of Indemnification Agreement between us and each of our directors and officers
10.58(5)#	1998 Stock Option Plan
10.59(35)#	Amendment to 1998 Stock Option Plan
10.60(36)#	Amended and Restated 2004 Equity Incentive Award Plan
10.61(35)#	Amendment No. 1 to Amended and Restated 2004 Equity Incentive Award Plan
10.62(37)#	Amendment No. 2 to Amended and Restated 2004 Equity Incentive Award Plan
10.63(38)#	Form of Stock Option Agreement under Amended and Restated 2004 Equity Incentive Award Plan
10.64(39)#	Form of Immediately Exercisable Stock Option Agreement under Amended and Restated 2004 Equity Incentive Award Plan
10.65(40)#	Amended and Restated Employee Stock Purchase Plan
10.66#	Amended and Restated Employment Agreement, dated December 19, 2012, between us and Gerald T. Proehl
10.67#	Amended and Restated Employment Agreement, dated December 19, 2012, between us and Debra P. Crawford
10.68#	Amended and Restated Employment Agreement, dated December 19, 2012, between us and Julie A. DeMeules
10.69#	Amended and Restated Employment Agreement, dated December 19, 2012, between us and William C. Denby, III
10.70#	Amended and Restated Employment Agreement, dated December 19, 2012, between us and Warren E. Hall
10.71#	Amended and Restated Employment Agreement, dated December 19, 2012, between us and Michael D. Step
10.72#	Amended and Restated Employment Agreement, dated December 19, 2012, between us and E. David Ballard, II, M.D.
10.73#	Amended and Restated Employment Agreement, dated December 19, 2012, between us and Maria Bedoya-Toro
10.74#	Amended and Restated Employment Agreement, dated December 19, 2012, between us and Carey J. Fox
10.75#	Amended and Restated Employment Agreement, dated December 19, 2012, between us and Mark Totoritis
10.76#	Amended and Restated Employment Agreement, dated December 19, 2012, between us and Wendell Wierenga
10.77(30)#	Deferred Compensation Plan
10.78(41)#	Amended and Restated 2011 Bonus Plan
10.79(42)#	2012 Bonus Plan

Exhibit Number	Description
10.80(43)#	2013 Bonus Plan
21.1	List of Subsidiaries of Santarus, Inc.
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
101.INS‡	XBRL Instance Document
101.SCH‡	XBRL Taxonomy Extension Schema Document
101.CAL‡	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF‡	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB‡	XBRL Taxonomy Extension Label Linkbase Document
101.PRE‡	XBRL Taxonomy Extension Presentation Linkbase Document

(1) Incorporated by reference to our Quarterly Report on Form 10-Q/A for the quarter ended September 30, 2010, filed with the Securities and Exchange Commission on March 8, 2011.

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

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

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

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

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

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

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

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

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

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

(12) Incorporated by reference to our Annual Report on Form 10-K for the year ended December 31, 2008, filed with the Securities and Exchange Commission on March 6, 2009.

(13)Incorporated by reference to our Annual Report on Form 10-K for the year ended December 31, 2009, filed with the Securities and Exchange Commission on March 4, 2010.

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

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

(16)Incorporated by reference to our Current Report on Form 8-K, filed with the Securities and Exchange Commission on August 30, 2010.

(17)Incorporated by reference to our Current Report on Form 8-K, filed with the Securities and Exchange Commission on February 14, 2012.

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

(19)Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended September 30, 2009, filed with the Securities and Exchange Commission on November 5, 2009.

(20)Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended September 30, 2010, filed with the Securities and Exchange Commission on November 9, 2010.

(21)Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2011, filed with the Securities and Exchange Commission on May 5, 2011.

(22)Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended September 30, 2011, filed with the Securities and Exchange Commission on November 7, 2011.

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

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

(25)Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2010, filed with the Securities and Exchange Commission on August 3, 2010.

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

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

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

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

(30)Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2012, filed with the Securities and Exchange Commission on August 7, 2012.

(31)Incorporated by reference to our Annual Report on Form 10-K for the year ended December 31, 2011, filed with the Securities and Exchange Commission on March 5, 2012.

(32)Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2012, filed with the Securities and Exchange Commission on May 8, 2012.

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

(34)Incorporated by reference to our Current Report on Form 8-K, filed with the Securities and Exchange Commission on October 10, 2012.

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

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

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

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

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

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

(41)Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2011, filed with the Securities and Exchange Commission on August 4, 2011.

(42)Incorporated by reference to our applicable Current Report on Form 8-K, filed with the Securities and Exchange Commission on February 24, 2012.

(43)Incorporated by reference to our applicable Current Report on Form 8-K, filed with the Securities and Exchange Commission on February 22, 2013.

† 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.

‡ Pursuant to Rule 406T of Regulation S-T, these interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of Section 11 or 12 of the Securities Act, are deemed not filed for purposes of Section 18 of the Exchange Act, and otherwise are not subject to liability under these sections.

(c) *Financial Statement Schedule.*

See Item 15(a)(2) above.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

SANTARUS, INC.

Dated: March 4, 2013

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 4, 2013
/s/ DEBRA P. CRAWFORD Debra P. Crawford	Senior Vice President and Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 4, 2013
/s/ DAVID F. HALE David F. Hale	Director *(Chairman of the Board of Directors)*	March 4, 2013
/s/ DANIEL D. BURGESS Daniel D. Burgess	Director	March 4, 2013
/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 4, 2013
/s/ ALESSANDRO E. DELLA CHÀ Alessandro E. Della Chà	Director	March 4, 2013
/s/ MICHAEL E. HERMAN Michael E. Herman	Director	March 4, 2013
/s/ TED W. LOVE, M.D. Ted W. Love, M.D.	Director	March 4, 2013
/s/ KENT SNYDER Kent Snyder	Director	March 4, 2013

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SANTARUS, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Santarus, Inc.

We have audited the accompanying consolidated balance sheets of Santarus, Inc. as of December 31, 2012 and 2011, and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2012. Our audits also included the financial schedule listed in the Index at Item 15(a). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Santarus, Inc. at December 31, 2012 and 2011, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2012, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

As discussed in Note 1 to the consolidated financial statements, the Company changed its method of accounting for revenue recognition as a result of the adoption of the amendments to the FASB Accounting Standards Codification resulting from Accounting Standards Update No. 2009-13, *Revenue Recognition (Topic 605): Multiple-Deliverable Revenue Arrangements*, effective January 1, 2011.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Santarus, Inc.'s internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 4, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
March 4, 2013

Santarus, Inc.

Consolidated Balance Sheets

(in thousands, except share and per share amounts)

	December 31, 2012	December 31, 2011
Assets		
Current assets:		
Cash and cash equivalents	$ 49,772	$ 54,244
Short-term investments	44,964	4,364
Accounts receivable, net	31,024	20,274
Inventories, net	9,897	5,129
Prepaid expenses and other current assets	6,678	3,714
Total current assets	142,335	87,725
Long-term restricted cash	950	1,050
Property and equipment, net	945	578
Intangible assets, net	16,254	21,787
Goodwill	2,913	2,913
Other assets	352	—
Total assets	$ 163,749	$ 114,053
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities	$ 45,824	$ 35,413
Allowance for product returns	20,574	13,895
Total current liabilities	66,398	49,308
Deferred revenue	1,639	2,163
Long-term debt	9,876	10,000
Other long-term liabilities	2,884	2,494
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at December 31, 2012 and 2011; no shares issued and outstanding at December 31, 2012 and 2011	—	—
Common stock, $0.0001 par value; 100,000,000 shares authorized at December 31, 2012 and 2011; 63,583,492 and 61,107,695 shares issued and outstanding at December 31, 2012 and 2011, respectively	6	6
Additional paid-in capital	368,594	354,288
Accumulated other comprehensive income	3	—
Accumulated deficit	(285,651)	(304,206)
Total stockholders' equity	82,952	50,088
Total liabilities and stockholders' equity	$ 163,749	$ 114,053

See accompanying notes.

Santarus, Inc.

Consolidated Statements of Operations

(in thousands, except share and per share amounts)

	Years Ended December 31,		
	2012	2011	2010
Revenues:			
Product sales, net	$ 214,538	$ 88,153	$ 90,170
Promotion revenue	—	27,339	31,365
Royalty revenue	3,417	3,295	3,571
Other license revenue	—	—	245
Total revenues	217,955	118,787	125,351
Costs and expenses:			
Cost of product sales	15,640	8,852	7,715
License fees and royalties	69,783	17,898	28,576
Research and development	25,808	18,383	17,431
Selling, general and administrative	86,552	68,229	82,581
Restructuring charges	—	—	7,082
Total costs and expenses	197,783	113,362	143,385
Income (loss) from operations	20,172	5,425	(18,034)
Other income (expense):			
Interest income	29	15	80
Interest expense	(337)	(459)	(461)
Total other income (expense)	(308)	(444)	(381)
Income (loss) before income taxes	19,864	4,981	(18,415)
Income tax expense	1,309	312	59
Net income (loss)	$ 18,555	$ 4,669	$ (18,474)
Net income (loss) per share:			
Basic	$ 0.30	$ 0.08	$ (0.31)
Diluted	$ 0.27	$ 0.07	$ (0.31)
Weighted average shares outstanding used to calculate net income (loss) per share:			
Basic	62,696,950	60,531,259	58,734,397
Diluted	69,150,415	62,814,561	58,734,397

See accompanying notes.

Santarus, Inc.

Consolidated Statements of Comprehensive Income (Loss)

(in thousands)

	Years Ended December 31,		
	2012	2011	2010
Net income (loss)	$ 18,555	$ 4,669	$ (18,474)
Unrealized gain on investments	3	—	1
Comprehensive income (loss)	$ 18,558	$ 4,669	$ (18,473)

See accompanying notes.

Santarus, Inc.

Consolidated Statements of Stockholders' Equity

(in thousands, except share amounts)

	Common stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders' equity
	Shares	Amount				
Balance at December 31, 2009	58,344,932	$ 6	$337,312	$ (1)	$ (290,401)	$ 46,916
Issuance of common stock upon exercise of stock options	237,243	—	384	—	—	384
Issuance of common stock under employee stock purchase plan	217,217	—	522	—	—	522
Issuance of common stock at $2.01 per share for business combination	181,342	—	364	—	—	364
Issuance of common stock at $2.68 per share under technology license agreement	55,970	—	150	—	—	150
Issuance of common stock at $2.805 per share under technology license agreement	972,132	—	2,727	—	—	2,727
Stock-based compensation	—	—	5,393	—	—	5,393
Net loss	—	—	—	—	(18,474)	(18,474)
Unrealized gain on investments	—	—	—	1	—	1
Comprehensive loss	—	—	—	—	—	(18,473)
Balance at December 31, 2010	60,008,836	6	346,852	—	(308,875)	37,983
Issuance of common stock upon exercise of stock options	884,324	—	1,557	—	—	1,557
Issuance of common stock under employee stock purchase plan	214,535	—	517	—	—	517
Stock-based compensation	—	—	5,362	—	—	5,362
Net income	—	—	—	—	4,669	4,669
Balance at December 31, 2011	61,107,695	6	354,288	—	(304,206)	50,088
Issuance of common stock upon exercise of stock options	1,323,514	—	3,026	—	—	3,026
Issuance of common stock under employee stock purchase plan	245,871	—	852	—	—	852
Issuance of common stock at $4.08 per share under technology license agreement	906,412	—	3,698	—	—	3,698
Stock-based compensation	—	—	6,730	—	—	6,730
Net income	—	—	—	—	18,555	18,555
Unrealized gain on investments	—	—	—	3	—	3
Comprehensive income	—	—	—	—	—	18,558
Balance at December 31, 2012	63,583,492	$ 6	$368,594	$ 3	$ (285,651)	$ 82,952

See accompanying notes.

Santarus, Inc.

Consolidated Statements of Cash Flows

(in thousands)

	Years Ended December 31,		
	2012	2011	2010
Operating activities			
Net income (loss)	$ 18,555	$ 4,669	$ (18,474)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization	6,129	3,113	2,259
Unrealized gain on trading securities, net	—	—	(2)
(Gain) loss on contingent consideration	146	(3)	157
Stock-based compensation	6,730	5,362	5,393
Issuance of common stock for technology license agreement	3,698	—	2,877
Changes in operating assets and liabilities:			
Accounts receivable, net	(10,750)	(13,118)	9,097
Inventories, net	(4,768)	1,674	2,311
Prepaid expenses and other current assets	(2,794)	2,878	(2,289)
Other assets	(352)	—	—
Accounts payable and accrued liabilities	13,004	3,421	(29,670)
Allowance for product returns	6,679	445	604
Deferred revenue	(524)	(472)	(288)
Net cash provided by (used in) operating activities	35,753	7,969	(28,025)
Investing activities			
Purchases of short-term investments	(55,030)	(14,830)	(17,809)
Sales and maturities of short-term investments	15,367	14,821	17,791
Redemption of investments	—	—	3,850
Long-term restricted cash	(950)	—	—
Purchases of property and equipment	(796)	(223)	(308)
Acquisition of intangible assets	—	—	(5,000)
Net cash paid for business combinations	(2,519)	(12,259)	(842)
Net cash used in investing activities	(43,928)	(12,491)	(2,318)
Financing activities			
Payment of commitment fee on credit facility	(175)	—	—
Exercise of stock options	3,026	1,557	384
Issuance of common stock, net	852	517	522
Net cash provided by financing activities	3,703	2,074	906
Decrease in cash and cash equivalents	(4,472)	(2,448)	(29,437)
Cash and cash equivalents at beginning of the period	54,244	56,692	86,129
Cash and cash equivalents at end of the period	$ 49,772	$ 54,244	$ 56,692
Supplemental disclosure of cash flow information:			
Interest paid	$ 337	$ 459	$ 461
Income taxes paid	$ 950	$ 66	$ 1,349

See accompanying notes.

1. Organization and Summary of Significant Accounting Policies

Organization and Business

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

Principles of Consolidation

The consolidated financial statements of the Company include the accounts of Santarus, Inc. and its wholly owned subsidiary, Covella Pharmaceuticals, Inc. ("Covella"). The Company does not have any interest in variable interest entities. All material intercompany transactions and balances have been eliminated in consolidation.

Use of Estimates in the Preparation of Financial Statements

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

Cash and Cash Equivalents

Cash and cash equivalents consist of highly liquid investments with a remaining maturity of 90 days or less when purchased.

Available-for-Sale Securities

The Company has classified its debt securities as available-for-sale and, accordingly, carries these investments at fair value, and unrealized holding gains or losses on these securities are carried as a separate component of stockholders' equity. The cost of debt securities is adjusted for amortization of premiums or accretion of discounts to maturity, and such amortization or accretion is included in interest income. Realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities are included in interest income. The cost of securities sold is based on the specific identification method.

The following is a summary of the Company's available-for-sale investment securities as of December 31, 2012 and 2011 (in thousands). All available-for-sale securities held as of December 31, 2012 and 2011 have contractual maturities within one year. There were no material gross realized gains or losses on sales of available-for-sale securities for the years ended December 31, 2012 and 2011.

	Amortized Cost	Market Value	Unrealized Gain
December 31, 2012:			
U.S. government sponsored enterprise securities	$ 44,961	$ 44,964	$ 3
December 31, 2011:			
U.S. Treasury securities	$ 1,500	$ 1,500	$ —
U.S. government sponsored enterprise securities	3,914	3,914	—
	$ 5,414	$ 5,414	$ —

The classification of available-for-sale securities in the Company's consolidated balance sheets is as follows (in thousands):

	December 31,	
	2012	2011
Short-term investments	$ 44,964	$ 4,364
Restricted cash	—	1,050
	$ 44,964	$ 5,414

Fair Value Measurements

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

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

The Company obtains the fair value of its Level 2 financial instruments from its investment managers, who obtain these fair values from professional pricing sources. The professional pricing sources determine fair value using pricing models whereby all significant observable inputs, including maturity dates, issue dates, settlement dates, reported trades, broker-dealer quotes, issue spreads, benchmark securities or other market related data, are observable or can be derived from or corroborated by observable market data for substantially the full term of the financial instrument. The Company validates the fair values of its Level 2 financial instruments provided by its investment managers by comparing these fair values to a third-party data source.

The Company's assets and liabilities measured at fair value on a recurring basis at December 31, 2012 and 2011 are as follows (in thousands):

	Fair Value Measurements at Reporting Date Using			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
December 31, 2012:				
Assets				
Money market funds	$ 48,522	$ —	$ —	$ 48,522
U.S. government sponsored enterprise securities	—	47,164	—	47,164
Deferred compensation plan assets	169	—	—	169
	$ 48,691	$ 47,164	$ —	$ 95,855
Liabilities				
Contingent consideration	$ —	$ —	$ 2,200	$ 2,200
Deferred compensation plan liabilities	169	—	—	169
	$ 169	$ —	$ 2,200	$ 2,369
December 31, 2011:				
Assets				
Money market funds	$ 40,244	$ —	$ —	$ 40,244
U.S. Treasury securities	1,500	—	—	1,500
U.S. government sponsored enterprise securities	—	17,914	—	17,914
	$ 41,744	$ 17,914	$ —	$ 59,658
Liabilities				
Contingent consideration	$ —	$ —	$ 2,054	$ 2,054
	$ —	$ —	$ 2,054	$ 2,054

The following table provides a summary of changes in fair value of the Company's Level 3 liabilities for the years ended December 31, 2012 and 2011 (in thousands):

	Years Ended December 31,	
	2012	2011
Contingent Consideration:		
Beginning balance	$ 2,054	$ 2,057
Change in fair value recorded in operating expenses	146	(3)
Ending balance	$ 2,200	$ 2,054

Level 3 liabilities include contingent milestone and royalty obligations the Company may pay related to the acquisition of Covella in September 2010. The fair value of the contingent consideration has been determined using a probability-weighted discounted cash flow model. The key assumptions in applying this approach are the discount rate and the probability assigned to the milestone or royalty being achieved. Management remeasures the fair value of the contingent consideration at each reporting period, with any change in its fair value resulting from either the passage of time or events occurring after the acquisition date, such as changes in the estimated probability or timing of achieving the milestone or royalty, being recorded in the current period's statement of operations. The Company recorded an increase in the fair value of contingent consideration of $146,000 for 2012 and a decrease in the fair value of contingent consideration of $3,000 for 2011 resulting primarily from changes in the estimated timing of achieving certain milestones and royalties and the passage of time.

Concentration of Credit Risk and Sources of Supply

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

The Company sells its products primarily to established wholesale distributors in the pharmaceutical industry. Sales to McKesson Corporation, Cardinal Health, Inc. and AmerisourceBergen Corporation represented 35%, 31% and 18% of the Company's total revenue in 2012, 27%, 23% and 18% of the Company's total revenue in 2011, and 21%, 24% and 15% of the Company's total revenue in 2010, respectively. In addition to sales to wholesale distributors, the Company's promotion revenue representing fees earned under its promotion agreement with Depomed, Inc. ("Depomed") represented 23% and 25% of the Company's total revenue in 2011 and 2010, respectively.

Credit is extended based on an evaluation of the customer's financial condition, and collateral is not required. Approximately 97% of the accounts receivable balance as of December 31, 2012 and as of December 31, 2011 represented amounts due from four customers. The Company evaluates the collectability of its accounts receivable based on a variety of factors including the length of time the receivables are past due, the financial health of the customer and historical experience. Based upon the review of these factors, the Company did not record an allowance for doubtful accounts at December 31, 2012 and 2011.

The Company relies on third-party manufacturers and its strategic partners to provide both clinical and commercial quantities of its products, and the Company does not currently have any of its own manufacturing facilities. Although there are potential sources of supply other than the Company's existing suppliers, any new supplier would be required to qualify under applicable regulatory requirements.

For the Zegerid® (omeprazole/sodium bicarbonate) capsules prescription product, the Company relies on Norwich Pharmaceuticals, Inc. located in New York as the sole third-party manufacturer of the brand and related authorized generic product. In addition, the Company relies on a Patheon, Inc. ("Patheon") facility located in Canada for the supply of Zegerid powder for oral suspension.

For Glumetza® (metformin hydrochloride extended release tablets) 500 mg, the Company assumed from Depomed a commercial manufacturing agreement with Patheon and, accordingly, the Company relies on a Patheon facility located in Puerto Rico as the sole third-party manufacturer of Glumetza 500 mg. The Company currently relies on Depomed to oversee product manufacturing and supply of Glumetza 1000 mg. In turn, Depomed relies on a Valeant Pharmaceuticals International, Inc. facility located in Canada as the sole third-party manufacturer of Glumetza 1000 mg.

In connection with the license of rights to Cycloset® (bromocriptine mesylate), the Company assumed a manufacturing services agreement with Patheon and, accordingly, the Company relies on a Patheon facility located in Ohio as the sole third-party manufacturer for Cycloset.

In connection with the license of rights to Fenoglide® (fenofibrate), the Company assumed a commercial supply and packaging agreement with Catalent Pharma Solutions, LLC ("Catalent") and, accordingly, the Company relies on a Catalent facility located in Kentucky as the sole third-party manufacturer for Fenoglide.

For the Company's Uceris™ (budesonide) prescription product and the rifamycin SV MMX® investigational drug product, the Company relies on Cosmo Technologies Limited ("Cosmo"), an affiliate of Cosmo Pharmaceuticals S.p.A., located in Italy to manufacture and supply all of the Company's drug product requirements.

For the Company's Ruconest® (recombinant human C1 esterase inhibitor) investigational drug product, the Company relies on Pharming Group NV ("Pharming") to oversee product manufacturing and supply. In turn,

Pharming utilizes certain of its own facilities as well as third-party manufacturing facilities for supply, all of which are located in Europe.

For the Company's SAN-300 (anti-VLA-1 antibody) investigational drug product, the Company utilizes materials previously manufactured by Biogen Idec MA ("Biogen") for the production of clinical trial materials. In the future, Biogen has a right of first offer to supply the Company's product requirements.

The Company and its strategic partners also rely in many cases on sole source suppliers for active ingredients and other product materials and components.

Inventories, Net

Inventories are stated at the lower of cost or market (net realizable value). Cost is determined by the first-in, first-out method. Inventories consist of finished goods and raw materials used in the manufacture of the Company's commercial 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, compared to forecasts of future sales.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation and are depreciated over the estimated useful lives of the assets (ranging from three to five years) using the straight-line method. Leasehold improvements are depreciated over the estimated useful life of the asset or the lease term, whichever is shorter.

Business Combinations

The authoritative guidance for business combinations establishes principles and requirements for recognizing and measuring the total consideration transferred to and the assets acquired and liabilities assumed in the acquired target in a business combination.

The Company accounted for the acquisition of Covella in September 2010 in accordance with the authoritative guidance for business combinations. The consideration paid to acquire Covella was required to be measured at fair value and included cash consideration, the issuance of the Company's common stock and contingent consideration, which includes the Company's obligation to make clinical and regulatory milestone payments based on success in developing product candidates in addition to a royalty on net sales of any commercial products resulting from the anti-VLA-1 monoclonal antibody ("mAb") technology. After the total consideration transferred was calculated by determining the fair value of the contingent consideration plus the upfront cash and stock consideration, the Company assigned the purchase price of Covella to the fair value of the assets acquired and liabilities assumed. This allocation of the purchase price resulted in recognition of intangible assets related to in-process research and development ("IPR&D") and goodwill.

The Company accounted for the commercialization agreement with Depomed entered into in August 2011 in accordance with the authoritative guidance for business combinations. The purchase consideration was comprised of cash payments for the purchase of existing inventory, and the entire purchase price was allocated to inventory, as cost approximated fair value, and no other assets were acquired and no liabilities were assumed in the transaction. Under the commercialization agreement, the Company has an obligation to pay royalties to Depomed based on Glumetza net product sales. These royalties are being expensed as incurred as the Company determined that the royalty rates reflect reasonable market rates for the manufacturing and commercialization rights granted under the commercialization agreement.

The Company accounted for the license agreement with Healthcare Royalty Partners, L.P. ("HRP") and Shore Therapeutics, Inc. ("Shore") in accordance with the authoritative guidance for business combinations. The purchase consideration was comprised of an upfront cash payment, and the purchase price was allocated to prepaid royalty expense and intangible assets related to the license agreement. There were no other assets acquired or liabilities assumed under the license agreement. Under the license agreement, the Company has an obligation to pay royalties to Shore based on Fenoglide net product sales and certain one-time success-based milestones contingent on sales achievement. These royalties and sales milestones will be expensed as incurred as the Company determined that the

royalty rates and sales milestone amounts reflect reasonable market rates for the manufacturing and commercialization rights granted under the license agreement.

The determination and allocation of consideration transferred in a business combination requires the Company to make significant estimates and assumptions, especially at the acquisition date with respect to the fair value of the contingent consideration. The key assumptions in determining the fair value of the contingent consideration are the discount rate and the probability assigned to the potential milestone or royalty being achieved. The Company remeasures the fair value of the contingent consideration at each reporting period, with any change in fair value being recorded in the current period's operating expenses. Changes in the fair value may result from either the passage of time or events occurring after the acquisition date, such as changes in the estimated probability or timing of achieving the milestone or royalty.

Intangible Assets and Goodwill

The Company's intangible assets are comprised primarily of acquired IPR&D and license agreements. Goodwill represents the excess of the cost over the fair value of net assets acquired from business combinations. The Company periodically assesses the carrying value of its intangible assets and goodwill, which requires the Company to make assumptions and judgments regarding the future cash flows of these assets. The assets are considered to be impaired if the Company determines that the carrying value may not be recoverable based upon the Company's assessment of the following events or changes in circumstances:

- the asset's ability to generate income from operations and positive cash flow in future periods;
- loss of legal ownership or title to the asset;
- significant changes in the Company's strategic business objectives and utilization of the asset(s); and
- the impact of significant negative industry, regulatory or economic trends.

IPR&D will not be amortized until the related development process is complete and goodwill is not amortized. License agreements and other intangible assets are amortized over their estimated useful lives. If the assets are considered to be impaired, the impairment the Company recognizes is the amount by which the carrying value of the assets exceeds the fair value of the assets. Fair value is determined by a combination of third-party sources and forecasted discounted cash flows. In addition, the Company bases the useful lives and related amortization expense on its estimate of the period that the assets will generate revenues or otherwise be used. The Company also periodically reviews the lives assigned to its intangible assets to ensure that its initial estimates do not exceed any revised estimated periods from which the Company expects to realize cash flows from the technologies. A change in any of the above-mentioned factors or estimates could result in an impairment charge which could negatively impact the Company's results of operations. The Company has not recognized any impairment charges on its intangible assets or goodwill through December 31, 2012.

Intangible assets and goodwill as of December 31, 2012 consisted of the following (in thousands):

	Weighted Average Amortization Period (years)	Gross Carrying Amount	Accumulated Amortization	Intangible Assets, Net
Intangible Assets Subject to Amortization:				
License fees	6	$ 27,500	$ (12,346)	$ 15,154
Intangible Assets and Goodwill Not Subject to Amortization:				
In-process research and development				1,100
Goodwill				2,913
				4,013
Total intangible assets, net and goodwill				$ 19,167

Intangible assets and goodwill as of December 31, 2011 consisted of the following (in thousands):

	Weighted Average Amortization Period (years)	Gross Carrying Amount	Accumulated Amortization	Intangible Assets, Net
Intangible Assets Subject to Amortization:				
License fees	6	$ 27,500	$ (6,813)	$ 20,687
Intangible Assets and Goodwill Not Subject to Amortization:				
In-process research and development				1,100
Goodwill				2,913
				4,013
Total intangible assets, net and goodwill				$ 24,700

For the years ended December 31, 2012, 2011 and 2010, total expense related to the amortization of intangible assets was approximately $5.5 million, $2.7 million and $1.9 million, respectively.

Total future amortization expense related to intangible assets subject to amortization at December 31, 2012 is as follows (in thousands):

2013	$ 5,54
2014	5,54
2015	3,92
2016	13
Total future amortization expense	$ 15,15

Revenue Recognition

The Company recognizes revenue when there is persuasive evidence that an arrangement exists, title has passed, the price is fixed or determinable, and collectability is reasonably assured.

Product Sales, Net. The Company sells its commercial products primarily to pharmaceutical wholesale distributors. The Company is obligated to accept from customers products that are returned within six months of their expiration date or up to 12 months beyond their expiration date. The shelf life of the Company's products from the date of manufacture is as follows: Zegerid (36 months); Glumetza (24 to 48 months); Cycloset (18 months); and Fenoglide (24 to 36 months). The Company authorizes returns for expired or damaged products in accordance with its return goods policy and procedures. The Company issues credit to the customer for expired or damaged returned product. The Company rarely exchanges product from inventory for returned product. At the time of sale, the Company records its estimates for product returns as a reduction to revenue at full sales value with a corresponding increase in the allowance for product returns liability. Actual returns are recorded as a reduction to the allowance for product returns liability at sales value with a corresponding decrease in accounts receivable for credit issued to the customer.

The Company recognizes product sales net of estimated allowances for product returns, estimated rebates in connection with contracts relating to managed care, Medicare, patient coupons and voucher programs, and estimated chargebacks from distributors, wholesaler fees and prompt payment and other discounts. The Company establishes allowances for estimated product returns, rebates and chargebacks based primarily on the following qualitative and quantitative factors:

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

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

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

The Company's allowance for product returns was $20.6 million as of December 31, 2012 and $13.9 million as of December 31, 2011. The Company recognizes product sales at the time title passes to its customers, and the Company provides for an estimate of future product returns at that time based upon historical product returns trends, analysis of product expiration dating and estimated inventory levels in the distribution channel, review of returns trends for similar products, if available, and the other factors discussed above. Due to the lengthy shelf life of the Company's products and the terms of the Company's returns policy, there may be a significant time lag between the date the Company determines the estimated allowance and when the Company receives the product return and issues credit to a customer. Therefore, the amount of returns processed against the allowance in a particular year generally has no direct correlation to the product sales in the same year, and the Company may record adjustments to its estimated allowance over several periods, which can result in a net increase or a net decrease in its operating results in those periods.

The Company has been tracking its Zegerid product returns history by individual production batches from the time of its first commercial product launch of Zegerid powder for oral suspension 20 mg in late 2004. The Company launched Cycloset in November 2010 and began distributing Fenoglide in December 2011. Under a commercialization agreement with Depomed, the Company began distributing and recording product sales for

Glumetza in September 2011. The Company has provided for an estimate of product returns based upon a review of the Company's product returns history and returns trends for similar products, taking into consideration the effect of a product's shelf life on its returns history.

The Company's allowance for rebates, chargebacks and other discounts was $17.2 million as of December 31, 2012 and $13.8 million as of December 31, 2011. These allowances reflect an estimate of the Company's liability for rebates due to managed care organizations under specific contracts, rebates due to various organizations under Medicare contracts and regulations, chargebacks due to various organizations purchasing the Company's products through federal contracts and/or group purchasing agreements, and other rebates and customer discounts due in connection with wholesaler fees and prompt payment and other discounts. The Company estimates its liability for rebates and chargebacks at each reporting period based on a combination of the qualitative and quantitative assumptions listed above. In each reporting period, the Company evaluates its outstanding contracts and applies the contractual discounts to the invoiced price of wholesaler shipments recognized. Although the total invoiced price of shipments to wholesalers for the reporting period and the contractual terms are known during the reporting period, the Company projects the ultimate disposition of the sale (e.g. future utilization rates of cash payors, managed care, Medicare or other contracted organizations). This estimate is based on historical trends adjusted for anticipated changes based on specific contractual terms of new agreements with customers, anticipated pricing strategy changes by the Company and/or its competitors and the other qualitative and quantitative factors described above. There may be a significant time lag between the date the Company determines the estimated allowance and when the Company makes the contractual payment or issues credit to a customer. Due to this time lag, the Company records adjustments to its estimated allowance over several periods, which can result in a net increase or a net decrease in its operating results in those periods.

In late June 2010, the Company began selling an authorized generic version of its prescription Zegerid capsules under a distribution and supply agreement with Prasco, LLC ("Prasco"). Prasco has agreed to purchase all of its authorized generic product requirements from the Company and pays a specified invoice supply price for such products. The Company recognizes revenue from shipments to Prasco at the invoice supply price and the related cost of product sales when title transfers, which is generally at the time of shipment. The Company is also entitled to receive a significant percentage of the gross margin on sales of the authorized generic products by Prasco, which the Company recognizes as an addition to product sales, net when Prasco reports to the Company the gross margin from the ultimate sale of the products. Any adjustments to the gross margin related to Prasco's estimated sales discounts and other deductions are recognized in the period Prasco reports the amounts to the Company.

Promotion, Royalty and Other License Revenue. The Company analyzes each element of its promotion and licensing agreements to determine the appropriate revenue recognition. Prior to January 1, 2011, the Company recognized revenue on upfront payments over the period of significant involvement under the related agreements unless the fee was in exchange for products delivered or services rendered that represent the culmination of a separate earnings process and no further performance obligation existed under the contract. The Company follows the authoritative guidance for revenue arrangements with multiple deliverables materially modified or entered into after December 31, 2010. Under this guidance, the Company identifies the deliverables included within the agreement and evaluates which deliverables represent separate units of accounting. Upfront license fees are generally recognized upon delivery of the license if the facts and circumstances dictate that the license has standalone value from any undelivered items, the relative selling price allocation of the license is equal to or exceeds the upfront license fees, persuasive evidence of an arrangement exists, the Company's price to the partner is fixed or determinable and collectability is reasonably assured. Upfront license fees are deferred if facts and circumstances dictate that the license does not have standalone value. The determination of the length of the period over which to defer revenue is subject to judgment and estimation and can have an impact on the amount of revenue recognized in a given period.

Effective January 1, 2011, the Company adopted prospectively, the authoritative guidance that offers an alternative method of revenue recognition for milestone payments. Under the milestone method guidance, the Company recognizes payment that is contingent upon the achievement of a substantive milestone, as defined in the guidance, in its entirety in the period in which the milestone is achieved. Other milestones that do not fall under the definition of a milestone under the milestone method are recognized under the authoritative guidance concerning revenue recognition. Sales milestones, royalties and promotion fees are based on sales and/or gross margin information, which may include estimates of sales discounts and other deductions, received from the relevant

alliance agreement partner. Sales milestones, royalties and promotion fees are recognized as revenue when earned under the agreements, and any adjustments related to estimated sales discounts and other deductions are recognized in the period the alliance agreement partner reports the amounts to the Company.

Research and Development Expenses and License Fees

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

Research and development expenditures are charged to expense as incurred. Expenses related to clinical studies 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 study protocol or scope of work to be performed, the Company modifies its estimates accordingly on a prospective basis.

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

Patent Costs

Costs related to filing and pursuing patent applications are included in selling, general and administrative expenses and expensed as incurred as recoverability of such expenditures is uncertain.

Restructuring

During 2010, the Company implemented a corporate restructuring, including a workforce reduction of approximately 34%, or 113 employees, in its commercial organization and certain other operations. The Company also significantly reduced the number of contract sales representatives it utilized. In accordance with authoritative guidance, the Company recorded a restructuring charge of approximately $7.1 million in 2010. Other than non-cash stock-based compensation of approximately $352,000, these expenses were paid in cash during 2010.

Shipping and Handling Costs

The Company generally 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 $4.0 million, $1.8 million and $3.0 million in advertising expense for the years ended December 31, 2012, 2011 and 2010, respectively.

Stock-Based Compensation

The Company estimates the fair value of stock options and employee stock purchase plan rights granted using the Black-Scholes valuation model. The Company amortizes the fair value of options granted on a straight-line basis over the requisite service period of the awards, which is generally the vesting period of one to four years. Pre-vesting forfeitures were estimated to be approximately 0% for 2012, 2011 and 2010 as the majority of options granted contain monthly vesting terms. For the years ended December 31, 2012, 2011 and 2010, the Company

recognized approximately $6.7 million, $5.4 million and $5.4 million, respectively, of total stock-based compensation.

In 2010, stock-based compensation included approximately $352,000 related to the Company's corporate restructuring implemented in the third quarter of 2010. The Company offered to accelerate the vesting of stock options by six months and extend the period for exercising vested stock options by twelve months from each affected employee's termination date.

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

	Years Ended December 31,		
	2012	2011	2010
Stock Options:			
Risk-free interest rate	0.8% – 1.4%	1.1% – 2.6%	1.8% – 3.0%
Expected volatility	71%	71% – 72%	70% – 71%
Expected life of options (years)	5.27 – 6.08	5.27 – 6.08	5.27 – 6.08
Expected dividend yield	—	—	—
Employee Stock Purchase Plan:			
Risk-free interest rate	0.1% – 0.2%	0.1%	0.1% – 0.2%
Expected volatility	71%	71%	70% – 71%
Expected life of options (years)	0.50	0.50	0.50
Expected dividend yield	—	—	—

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

Expected Volatility. In determining its volatility factor, the Company performs an analysis of the historical volatility of its common stock for a period corresponding to the expected life of the options. In addition, the Company considers the expected volatility of similar entities. In evaluating similar entities, the Company considers factors such as industry, stage of development, size and financial leverage.

Expected Life of Options. In determining the expected life of the options, the Company uses the "simplified" method. Under this method, the expected life is presumed to be the mid-point between the vesting date and the end of the contractual term. The Company will continue to use the "simplified" method until it has sufficient historical exercise data to estimate the expected life of the options.

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

The weighted average per share fair value of stock options granted in the years ended December 31, 2012, 2011 and 2010 was $3.33, $2.13 and $2.86, respectively. The weighted average per share fair value of employee stock purchase plan rights granted in the years ended December 31, 2012, 2011 and 2010 was $2.77, $1.06 and $0.95, respectively. As of December 31, 2012, total unrecognized compensation cost related to stock options and employee stock purchase plan rights was approximately $12.2 million, and the weighted average period over which it was expected to be recognized was 2.3 years.

Net Income (Loss) Per Share

Basic income (loss) per share is calculated by dividing the net income (loss) by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted income (loss) per share is computed by dividing the net income (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, contingently issuable shares, options and warrants are considered to be common stock equivalents and are only included in the calculation of diluted income (loss) per share when their effect is dilutive. Potentially dilutive securities totaling 5.3 million shares, 12.4 million shares and

17.0 million shares for 2012, 2011 and 2010, respectively, were excluded from the calculation of diluted income (loss) per share because of their anti-dilutive effect.

	Years Ended December 31,		
	2012	2011	2010
Numerator:			
Net income (loss) (in thousands)	$ 18,555	$ 4,669	$ (18,474)
Denominator:			
Weighted average common shares outstanding for basic net income (loss) per share	62,696,950	60,531,259	58,734,397
Net effect of dilutive common stock equivalents	6,453,465	2,283,302	—
Denominator for diluted net income (loss) per share	69,150,415	62,814,561	58,734,397
Net income (loss) per share			
Basic	$ 0.30	$ 0.08	$ (0.31)
Diluted	$ 0.27	$ 0.07	$ (0.31)

Segment Reporting

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

Adoption of Recent Accounting Pronouncements

In June and December 2011, the Financial Accounting Standards Board ("FASB") issued authoritative guidance on the presentation of comprehensive income. Under this newly issued authoritative guidance, an entity has the option to present comprehensive income and net income either in a single continuous statement or in two separate but consecutive statements. This guidance, therefore, eliminated the option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity. The Company adopted the requirements of this guidance effective for its fiscal year beginning January 1, 2012. Upon adoption, the guidance did not have a material impact on the Company's consolidated financial statements. In February 2013, the FASB amended its guidance on reporting reclassifications out of accumulated other comprehensive income. For significant items reclassified out of accumulated other comprehensive income to net income in their entirety in the same reporting period, this amendment requires reporting about the effect of the reclassifications on the respective line items in the statement where net income is presented. For items that are not reclassified to net income in their entirety in the same reporting period, a cross reference to other disclosures currently required under GAAP is required in the notes to the financial statements. This amendment is effective for interim periods beginning after December 15, 2012. The Company does not anticipate this amendment will have a material impact on its consolidated financial statements.

In September 2011, the FASB issued an update to the authoritative guidance on performing goodwill impairment testing. Under the revised guidance, entities testing goodwill for impairment have the option of performing a qualitative assessment before calculating the fair value of the reporting unit (step 1 of the goodwill impairment test). If entities determine, on the basis of qualitative factors, that the fair value of the reporting unit is more likely than not less than the carrying amount, the two-step impairment test would be required; otherwise, no further testing is required. The revised guidance does not change how goodwill is calculated or assigned to reporting units, does not revise the requirement to test goodwill annually for impairment, and does not amend the requirement to test goodwill for impairment between annual tests if events and circumstances warrant. The revised authoritative guidance is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. The Company adopted this guidance effective for the Company's fiscal year beginning January 1, 2012. Upon adoption, the guidance did not have a material impact on the Company's consolidated financial statements.

2. Balance Sheet Details

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

	December 31, 2012	December 31, 2011
Raw materials	$ 1,533	$ 873
Finished goods	9,968	5,450
	11,501	6,323
Allowance for excess and obsolete inventory	(1,604)	(1,194)
	$ 9,897	$ 5,129

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

	December 31, 2012	December 31, 2011
Computer equipment and software	$ 1,670	$ 1,519
Office equipment and furniture	1,634	1,238
Leasehold improvements	536	468
	3,840	3,225
Less: accumulated depreciation and amortization	(2,895)	(2,647)
	$ 945	$ 578

For the years ended December 31, 2012, 2011 and 2010, depreciation expense was approximately $426,000, $417,000 and $408,000, respectively.

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

	December 31, 2012	December 31, 2011
Accounts payable	$ 6,873	$ 4,549
Accrued compensation and benefits	9,183	7,226
Accrued rebates	11,693	10,227
Accrued license fees and royalties	7,181	4,859
Accrued research and development expenses	3,441	2,400
Accrued legal fees	1,953	2,632
Income taxes payable	950	580
Other accrued liabilities	4,550	2,940
	$ 45,824	$ 35,413

3. Significant Agreements

Strategic Collaboration with Cosmo

In December 2008, the Company entered into a strategic collaboration with Cosmo including a license agreement, stock issuance agreement and registration rights agreement, under which the Company was granted exclusive rights to develop and commercialize Uceris and rifamycin SV MMX in the U.S. As upfront consideration, the Company issued 6,000,000 shares of its common stock and made a cash payment of $2.5 million to Cosmo. In addition, following the completion of the phase III studies for Uceris in November 2010, Cosmo elected to receive payment of a clinical milestone through the issuance of 972,132 shares of the Company's common stock. Following U.S. Food and Drug Administration ("FDA") acceptance for filing of the new drug application ("NDA") for Uceris in February 2012, Cosmo elected to receive payment of a regulatory milestone through the issuance of 906,412 shares of the Company's common stock, and following the first commercial sale of Uceris which occurred in February 2013, Cosmo has the option to elect, on or before April 15, 2013, whether to receive payment of a $7.0 million commercial milestone in cash or through the issuance of 565,793 shares of the Company's common stock.

The Company may also be required to pay Cosmo commercial milestones of up to $22.5 million for Uceris and up to $28.0 million rifamycin SV MMX. In addition, the Company may also be required to pay Cosmo an additional $2.0 million regulatory milestone for the initial indication for rifamycin SV MMX and up to $6.0 million in clinical and regulatory milestones for a second indication for rifamycin SV MMX. The milestones may be paid in cash or through issuance of additional shares of the Company's common stock, at Cosmo's option, subject to certain limitations.

The Company will be required to pay tiered royalties to Cosmo equal to 12% (on annual net sales of each licensed product up to $120.0 million) and 14% (on annual net sales of each licensed product in excess of $120.0 million). Such royalties are subject to reduction in certain circumstances, including in the event of market launch in the U.S. of a generic version of a licensed product. The Company was responsible for one-half of the total out-of-pocket costs associated with the Uceris phase III clinical program and for all of the out-of-pocket costs for the rifamycin SV MMX phase III U.S. registration study. The Company is also responsible for all of the out-of-pocket costs for the ongoing Uceris phase IIIb clinical study. In the event that additional clinical work is required to obtain U.S. regulatory approval for rifamycin SV MMX, the parties will agree on cost sharing. Cosmo is responsible for any additional pre-clinical costs for rifamycin SV MMX and for any product development and scale-up costs for either of the licensed products.

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

As described above, the Company has issued to Cosmo a total of 7,878,544 shares of common stock as upfront consideration and milestone payments. The Company will make additional payments to Cosmo upon the achievement of certain development and commercial milestones, which milestones may be paid in cash or through issuance of additional shares of common stock, at Cosmo's option. The Company's obligation to issue additional shares of common stock to Cosmo upon the achievement of one or more milestones is subject to certain limitations, including that the total number of shares of common stock issued to Cosmo shall not exceed 10,300,000 shares. Any such additional shares to be issued will be valued at the average daily closing price of the common stock as reported on the Nasdaq Global Market for the 30 consecutive trading days ending on the day immediately prior to the achievement of the applicable milestone. For the six months following the issuance of any shares of common stock upon achievement of milestones, Cosmo has agreed that it will not transfer or dispose of any such issued shares.

Under the terms of the registration rights agreement, as amended, the Company filed resale registration statements on Form S-3 with the Securities and Exchange Commission ("SEC") to register the resale of the shares the Company has issued to Cosmo. The Company is obligated to file additional registration statements for any additional shares issued to Cosmo under the stock issuance agreement and to use best efforts to have any such registration statements declared effective by the SEC.

The Company recorded the upfront cash payment of $2.5 million and the fair value of the 6,000,000 shares of its common stock issued to Cosmo of approximately $7.5 million in license fees and royalties expense in 2008. The Company recorded the fair value of the 972,132 shares of its common stock issued to Cosmo for the clinical milestone achievement of approximately $2.7 million in license fees and royalties expense in 2010.

The Company recorded the fair value of the 906,412 shares of its common stock issued to Cosmo for the regulatory milestone achievement of approximately $3.7 million in license fees and royalties expense in 2012. As these shares had a six-month trading restriction pursuant to the stock issuance agreement, the Company estimated a fair value of $4.08 per share, which reflected a discount due to lack of marketability ("DLOM") of approximately 15% on the $4.80 per share closing price of its common stock on the milestone achievement date. The Company calculated the DLOM associated with the contractual restriction using the Black-Scholes valuation model for a

hypothetical put option with the following assumptions: life of the option of 0.5 years; risk-free interest rate of 0.15%; volatility of 53%; and dividend rate of 0%.

License Agreement with University of Missouri

In January 2001, the Company entered into an exclusive, worldwide license agreement with the University of Missouri for patents and pending patent applications relating to specific formulations of proton pump inhibitors with antacids and other buffering agents and methods of using these formulations. Pursuant to the terms of the license agreement, the Company issued to the University of Missouri 164,284 shares of the Company's common stock and paid an upfront licensing fee of $1.0 million, a one-time $1.0 million milestone fee following the filing of the Company's first NDA in 2003 and a one-time $5.0 million milestone fee following the FDA's approval of Zegerid powder for oral suspension 20 mg in 2004. The Company is required to make additional milestone payments to the University of Missouri upon initial commercial sale in specified territories outside the U.S., which may total up to $3.5 million in the aggregate. The Company is also required to make milestone payments, up to a maximum of $86.3 million, based on first-time achievement of significant sales thresholds, the first of which was a one-time $2.5 million milestone payment accrued in 2008 and paid in 2009 upon initial achievement of $100.0 million in annual calendar year net product sales, and the next of which is a one-time $7.5 million milestone payment upon initial achievement of $250.0 million in annual calendar year net product sales. The Company is also obligated to pay royalties on net sales of the Company's products and any products sold by Prasco, MSD Consumer Products, Inc. ("Merck"), a subsidiary of Merck & Co., Inc., and GSK under the Company's existing license and distribution agreements.

Distribution and Supply Agreement with Prasco

In April 2010, as part of the Company's contingency plan to prepare for a possible launch of a generic version of its Zegerid prescription products, the Company entered into a distribution and supply agreement with Prasco that granted Prasco the right to distribute and sell an authorized generic version of the Company's Zegerid prescription products in the U.S. In late June 2010, as a result of Par Pharmaceutical, Inc.'s ("Par's") decision to launch its generic version of Zegerid capsules, Prasco commenced shipment of an authorized generic of Zegerid capsules in 20 mg and 40 mg dosage strengths in the U.S. under the Prasco label. Under the terms of the distribution and supply agreement, which was amended in November 2012, Prasco is obligated to use commercially reasonable efforts to distribute and sell such products in the U.S. Prasco agreed to purchase all of its authorized generic product requirements from the Company and pays a specified invoice supply price for such products. Prasco is also obligated to pay the Company a significant percentage of the gross margin on sales of the authorized generic products.

Agreements with Depomed

In August 2011, the Company entered into a commercialization agreement with Depomed granting the Company exclusive rights to manufacture and commercialize Depomed's Glumetza prescription products in the U.S., including its territories and possessions and Puerto Rico. The commercialization agreement replaced an existing promotion agreement between the parties entered into in July 2008 pursuant to which the Company promoted Glumetza in the U.S. Under the terms of the promotion agreement, the Company paid Depomed a $12.0 million upfront fee. The $12.0 million upfront fee has been capitalized and included in intangible assets and is being amortized to license fee expense over the estimated useful life of the asset on a straight-line basis through early 2016. Additionally under the promotion agreement, in March 2011, the Company paid Depomed a $3.0 million sales milestone, of which $2.7 million was accrued in 2010 and the balance of which was expensed in 2011, based on having achieved Glumetza net product sales in excess of $50.0 million during the 13-month period ended January 31, 2011. Under the promotion agreement, Depomed recorded revenue from the sales of Glumetza products and was required to pay the Company a fee of 80% (through September 30, 2010) and 75% (from October 1, 2010 to August 31, 2011) of the gross margin earned from all net sales of Glumetza products in the U.S.

Under the commercialization agreement, the parties transitioned to the Company responsibility for manufacturing, distribution, pharmacovigilance and regulatory affairs. The Company continues to be responsible for advertising and promotional activities for Glumetza in the U.S., and the Company has assumed sole decision-

making authority on pricing, contracting and promotion for Glumetza. The Company began distributing and recording product sales for Glumetza in September 2011.

The Company was required to pay to Depomed royalties on Glumetza net product sales in the U.S. of 26.5% in 2011 and 29.5% in 2012, and the Company is required to pay Depomed royalties on Glumetza net product sales in the U.S. of 32.0% in 2013 and 2014 and 34.5% in 2015 and beyond prior to generic entry of a Glumetza product. The Company has the exclusive right to commercialize authorized generic versions of the Glumetza products. In the event of generic entry of a Glumetza product in the U.S., the parties will equally share proceeds based on a gross margin split. Under the commercialization agreement, the Company will pay no additional sales milestones to Depomed as was required under the prior promotion agreement. In addition, starting in 2012, the Company has reduced minimum marketing expenditures and sales force promotion obligations during the term of the agreement until such time as a generic to Glumetza enters the market.

Pursuant to the terms of the commercialization agreement, Depomed has the option to co-promote Glumetza products to physicians other than those called on by the Company, subject to certain limitations. If Depomed exercises this right, Depomed will be entitled to receive a royalty equal to 70% of net sales attributable to prescriptions generated by its called on physicians over a pre-established baseline.

Under the terms of the commercialization agreement, Depomed will manage the ongoing patent infringement litigation relating to Glumetza, subject to certain consent rights in favor of the Company, including with regard to any proposed settlements. The Company is responsible for 70% of the future out-of-pocket costs, and Depomed is responsible for 30% of the future out-of-pocket costs, related to patent infringement cases.

Depomed is financially responsible for returns of Glumetza distributed by Depomed, up to the amount of its product returns reserve account for Glumetza product returns on August 31, 2011, the date immediately before the Company began distributing Glumetza. Depomed is also financially responsible for Glumetza rebates and chargebacks up to the amount of its reserve account as of August 31, 2011 for those items. In connection with the Company's assumption of distribution and sales responsibility, the Company is responsible for all other Glumetza returns, rebates and chargebacks.

Under the authoritative guidance for business combinations, the commercialization agreement with Depomed was determined to be a business combination and was accounted for using the acquisition method of accounting. Neither separate financial statements nor pro forma results of operations have been presented because the acquisition transaction does not meet the qualitative or quantitative materiality tests under Regulation S-X. Transaction-related costs of approximately $137,000 were included in selling, general and administrative expenses for the year ended December 31, 2011.

The purchase price was approximately $3.8 million and represents the amount that the Company is required to pay Depomed in cash for the purchase of Depomed's existing inventory of Glumetza and bulk metformin hydrochloride. The entire purchase price of $3.8 million was allocated to inventory, as cost approximated fair value, and no other assets were acquired and no liabilities were assumed in the transaction. The royalties payable to Depomed based on Glumetza net product sales beginning in September 2011 are being expensed as incurred as the Company determined that the royalty rates reflect reasonable market rates for the manufacturing and commercialization rights the Company was granted under the commercialization agreement. The Company is continuing to amortize the $12.0 million upfront fee paid under the promotion agreement over the estimated useful life of the asset.

Distribution and License Agreement with S2 and VeroScience

In September 2010, the Company entered into a distribution and license agreement with S2 Therapeutics, Inc. ("S2") and VeroScience, LLC ("VeroScience") granting the Company exclusive rights to manufacture and commercialize the Cycloset prescription product in the U.S., subject to the right of S2 to promote Cycloset as described below. Under the terms of the distribution and license agreement, the Company paid to S2 and VeroScience an upfront fee totaling $5.0 million. The $5.0 million upfront fee has been capitalized and included in intangible assets and is being amortized to license fee expense over the estimated useful life of the asset on a

straight-line basis through early 2015. The Company records all sales of Cycloset and is required to pay a product royalty to S2 and VeroScience of 35% of the gross margin associated with net sales of Cycloset up to $100.0 million of cumulative total gross margin, increasing to 40% thereafter. Gross margin is defined as net sales less cost of goods sold. In the event net sales of Cycloset exceed $100.0 million in a calendar year, the Company is required to pay an additional 3% of the gross margin to S2 and VeroScience on incremental net sales over $100.0 million.

The Company launched Cycloset in November 2010 and is responsible for all costs associated with its sales force and for all other sales and marketing-related expenses associated with its promotion of Cycloset. S2 retains the right to co-promote Cycloset at its sole cost and expense under the same trademark in portions of the U.S. where the Company is not actively promoting Cycloset. VeroScience, the holder of the U.S. regulatory approval for Cycloset, is responsible for overseeing regulatory matters.

License Agreement with HRP and Shore

In December 2011, the Company entered into a license agreement with HRP and Shore granting the Company exclusive rights to commercialize Fenoglide prescription products in the U.S. Under the terms of the license agreement, the Company paid Shore an $11.0 million upfront fee. In addition, the Company is required to pay Shore tiered royalties on net sales of Fenoglide. The royalties are 5% on net sales of up to $10.0 million (commencing in 2013), a 20% royalty on net sales between $10.0 million and $20.0 million, and a 25% royalty on net sales above $20.0 million. The Company is also obligated to pay Shore one-time, success-based milestones contingent on sales achievement: $2.0 million if calendar year net sales equal or exceed $20.0 million and $3.0 million if calendar year net sales equal or exceed $30.0 million.

Under the terms of the license agreement, the Company is responsible for commercial, manufacturing and regulatory activities for Fenoglide. Shore is financially responsible for returns of Fenoglide sold or distributed prior to the effective date of the license agreement, and for Fenoglide rebates, chargeback claims and discount or savings card redemptions pursuant to agreements in effect prior to the effective date. The Company is responsible for all other Fenoglide returns, rebates, chargebacks and discount or savings card redemptions. The Company has agreed to use commercially reasonable efforts to commercialize Fenoglide within the U.S. and to provide certain minimum detailing efforts and sales and marketing expenditures.

Under the authoritative guidance for business combinations, the license agreement with HRP and Shore was determined to be a business combination and was accounted for using the acquisition method of accounting. Neither separate financial statements nor pro forma results of operations have been presented because the acquisition transaction does not meet the qualitative or quantitative materiality tests under Regulation S-X. Transaction-related costs of approximately $240,000 were included in selling, general and administrative expenses for the year ended December 31, 2011.

The purchase price was $11.0 million and represents the upfront fee that the Company paid Shore in cash under the license agreement. As the royalties payable on the first $10.0 million of Fenoglide net product sales have been waived for 2012 under the license agreement, the Company allocated $500,000 of the total purchase price to prepaid royalty expense which was expensed as incurred based upon net product sales of Fenoglide in 2012. The remaining $10.5 million of the total purchase price was allocated to intangible assets related to the license agreement and represents the acquisition date fair value of the assets. The $10.5 million in intangible assets is being amortized to license fee expense over the estimated useful life of the asset on a straight-line basis through September 2015. No other assets were acquired and no liabilities were assumed in the transaction. The royalties and sales milestones payable to Shore based on Fenoglide net product sales are being expensed as incurred or earned as the Company determined that the royalty rates and sales milestone amounts reflect reasonable market rates for the manufacturing and commercialization rights the Company was granted under the license agreement.

OTC License Agreement with Merck

In October 2006, the Company entered into a license agreement with Merck pursuant to which the Company granted Merck rights to develop, manufacture, market and sell Zegerid OTC® products in the lower dosage strength of 20 mg in the U.S. and Canada. Merck is required to use active, sustained and diligent efforts to conduct and complete in a timely manner all activities required to develop licensed products, receive marketing approval for

licensed products and market, sell and generate and meet market demand for licensed products in the licensed territories.

In November 2006, the Company received a nonrefundable $15.0 million upfront license fee from Merck. The $15.0 million upfront payment was amortized to revenue on a straight-line basis over a 37-month period through the end of 2009 which represented the period over which the Company had significant responsibilities under the agreement. In August 2007, the Company received a $5.0 million milestone payment relating to progress on clinical product development strategy. In June 2008, the Company received a $2.5 million regulatory milestone relating to FDA acceptance for filing of the NDA submitted by Merck for Zegerid OTC (omeprazole 20 mg/sodium bicarbonate 1100 mg capsules). In December 2009, the Company received a $20.0 million milestone payment following the approval of the NDA submitted by Merck for Zegerid OTC. The Company recognized the $5.0 million milestone payment, the $2.5 million milestone payment and the $20.0 million milestone payment as revenue in 2007, 2008 and 2009, respectively, due to the substantive nature of the milestones achieved and since the Company had no ongoing obligations associated with these milestones. The Company may receive up to an additional $37.5 million in milestone payments upon the achievement of specified sales milestones. The Company has determined that sales-based milestones are similar to royalties and are not considered milestones for consideration under the milestone method of revenue recognition. The Company is also entitled to receive low double-digit royalties, subject to adjustment in certain circumstances, on net sales of any over-the-counter ("OTC") products sold by Merck under the license agreement. In turn, the Company is obligated to pay royalties to the University of Missouri based on net sales of any OTC products sold by Merck.

License Agreement with Glaxo Group Limited

In November 2007, the Company entered into a license agreement with GSK, granting GSK certain exclusive rights to commercialize prescription and OTC immediate-release omeprazole products in a number of international markets. Under the license agreement, GSK is responsible for the development, manufacture and commercialization of prescription and OTC immediate-release omeprazole products for sale in more than 100 countries within Africa, Asia, the Middle-East and Latin America. GSK bears all costs for its activities under the license agreement.

Under the license agreement, in December 2007, the Company received an $11.5 million upfront fee, and the Company is entitled to receive tiered royalties equal to a percentage of net sales, ranging from the mid-teens to mid-twenties, of any licensed products sold by GSK under the license agreement. The royalties are subject to reduction on a country-by-country basis in the event that sales of any generic products achieve a specific level of market share, referred to as "generic competition" in such country. In turn, the Company is obligated to pay royalties to the University of Missouri based on net sales of any licensed products sold by GSK. GSK has an option to make a buy-out payment in 2027, the 20th anniversary of the license agreement, after which time, GSK's royalty obligations generally would end. To support GSK's initial launch costs, the Company agreed to waive the first $2.5 million of aggregate royalties payable under the license agreement. Of the total $11.5 million upfront payment, the $2.5 million in waived royalty obligations was recorded as deferred revenue and is being recognized as revenue when the royalties are earned. The remaining $9.0 million was also recorded as deferred revenue and was amortized to revenue on a straight-line basis over an 18-month period through May 2009, which represented the period the Company had significant obligations under the agreement.

License Agreement and Supply Agreement with Pharming

In September 2010, the Company entered into a license agreement and a supply agreement with Pharming under which the Company was granted certain non-exclusive rights to develop and manufacture, and certain exclusive rights to commercialize Ruconest in the U.S., Canada and Mexico for the treatment of hereditary angioedema ("HAE") and other future indications, as further described below.

License Agreement

Under the license agreement, Pharming granted the Company the non-exclusive rights to develop and manufacture and the exclusive right to commercialize licensed products in the U.S., Canada and Mexico. The Company paid Pharming a $15.0 million upfront fee in September 2010. In addition, in November 2012 the Company paid Pharming a $10.0 million milestone following successful achievement of the primary endpoint of the

phase III clinical study. The Company may also be required to pay Pharming additional success-based regulatory and commercial milestones totaling up to an aggregate of $25.0 million, including a $5.0 million milestone upon FDA acceptance for review of a BLA for Ruconest and a $20.0 million milestone upon the earlier of first commercial sale of Ruconest in the U.S. or 90 days following receipt of FDA approval. In addition, the Company will be required to pay the following one-time performance milestones if the Company achieves certain aggregate net sales levels of Ruconest: a $20.0 million milestone if calendar year net sales exceed $300.0 million and a $25.0 million milestone if calendar year net sales exceed $500.0 million. As consideration for the licenses and rights granted under the license agreement, and as compensation for the commercial supply of Ruconest by Pharming pursuant to the supply agreement described below, the Company will pay Pharming a tiered supply price, based on a percentage of net sales of Ruconest, subject to reduction in certain events, as follows: 30% of net sales less than or equal to $100.0 million, 32% of net sales greater than $100.0 million but less than or equal to $250.0 million, 34% of net sales greater than $250.0 million but less than or equal to $500.0 million, 37% of net sales greater than $500.0 million but less than or equal to $750.0 million, and 40% of net sales greater than $750.0 million. The Company recorded license fee expense of $15.0 million in 2010 and $10.0 million in 2012, representing the upfront fee paid in September 2010 and the regulatory milestone paid in November 2012, respectively.

Under the license agreement, Pharming was responsible for conducting the phase III clinical study for Ruconest for the treatment of acute attacks of angioedema in patients with HAE and all costs of such clinical development. The Company is working together with Pharming to prepare the BLA for this indication for submission to the FDA. The Company will be responsible for seeking regulatory approval for this indication in the U.S., Canada and Mexico.

Either party may propose the development of Ruconest for additional indications in the U.S., Canada and Mexico, to which the other party may opt-in.

The Company has agreed to use commercially reasonable efforts to promote, sell and distribute Ruconest in the U.S., Canada and Mexico, including launching Ruconest for the treatment of acute attacks of angioedema in patients with HAE in the U.S. within 120 days following receipt of U.S. regulatory approval. During the term of the license agreement, Pharming has agreed not to, and to insure that its distributors and dealers do not, sell Ruconest to any customer in the U.S., Canada and Mexico. Both parties have agreed not to manufacture, develop, promote, market or distribute any other forms of C1 inhibitors for use in the U.S., Canada and Mexico during the term.

Supply Agreement

Under the supply agreement, Pharming will manufacture and exclusively supply to the Company, and the Company will exclusively order from Pharming, Ruconest at the supply price for commercialization activities. Pharming will manufacture and supply recombinant human C1 esterase inhibitor products to the Company at cost for development activities. Pharming will be responsible for obtaining and maintaining all manufacturing approvals and related costs.

In the event of a supply failure, the Company has certain step-in rights to cure any payment defaults under Pharming's third party manufacturing agreements or to assume sole responsibility for manufacturing and supply. In connection with the supply agreement, the Company entered into a separate agreement with Pharming under which the Company was granted certain property interests to manufacturing related intellectual property and access to manufacturing materials and know-how, in order to assume such manufacturing and supply responsibilities under certain circumstances.

4. Acquisition of Covella

Merger Agreement

In September 2010, the Company acquired the worldwide rights to SAN-300 through the acquisition of Covella pursuant to the terms of a merger agreement. In connection with the consummation of the transactions contemplated by the merger agreement, Covella survived as a wholly owned subsidiary of the Company.

Under the terms of the merger agreement, the Company paid to the Covella stockholders upfront consideration of $862,000 in cash, including repayment of a $600,000 debt owed by Covella to one of the Covella stockholders. The Company also issued to the Covella stockholders 181,342 unregistered shares of the Company's common stock (subject to a 12-month lock-up period). The Company assumed responsibility for payment of approximately $467,000 in Covella liabilities and will make clinical and regulatory milestone payments totaling up to an aggregate of $37.7 million (consisting of a combination of cash and the Company's common stock) based on success in developing product candidates (with the first such milestone being payable upon successful completion of the first phase IIb clinical study). The Company may also be required to pay a royalty equal to a low single digit percentage rate of net sales of any commercial products resulting from the anti-VLA-1 mAb technology. See contingent consideration liability discussed below.

Both the Company and Covella agreed to customary representations, warranties and covenants in the merger agreement. The Covella stockholders agreed to indemnify the Company for certain matters, including breaches of representations and warranties and covenants included in the merger agreement, up to a maximum specified amount and subject to other limitations. The Company agreed to indemnify the Covella stockholders for certain matters, including breaches of representations, warranties and covenants included in the merger agreement, up to a maximum specified amount and subject to other limitations.

Amended License and Amended Services and Supply Agreement with Biogen

In connection with the merger agreement, the Company and Covella entered into an amendment to license agreement dated September 10, 2010 with Biogen, amending an existing license agreement dated January 22, 2009 between Covella and Biogen. Under the terms of the amended license agreement, Biogen has granted Covella an exclusive, worldwide license to patents and certain know-how and other intellectual property owned and controlled by Biogen relating to the SAN-300 and the anti-VLA-1 mAb development program. Covella is required to use commercially reasonable efforts to develop and commercialize at least one licensed product.

In connection with the execution of the amended license, the Company paid to Biogen $50,000 in cash and issued to Biogen 55,970 unregistered shares of the Company's common stock. In addition, the Company is obligated to make clinical, regulatory and sales milestone payments to Biogen based on success in developing and commercializing development-stage products (with the first such milestone being payable upon successful completion of the first phase IIb clinical study). The amounts of the clinical and regulatory milestone payments vary depending on the type of product, the number of indications, and other specifically negotiated milestones. If SAN-300 is the first to achieve all applicable milestones for three indications, the Company will be required to pay Biogen maximum aggregate clinical and regulatory milestone payments of $97.2 million. The amount of the commercial milestone payments the Company will be required to pay Biogen will depend on the level of net sales of a particular product in a calendar year. The maximum aggregate commercial milestone payments to Biogen total $105.5 million for SAN-300, assuming cumulative net sales of at least $5.0 billion of such product, and total $60.25 million for products containing certain other compositions as described in the license, assuming cumulative net sales of at least $5.0 billion of such products. In addition, the Company will be required to pay tiered royalties ranging from low single digit to low double digit percentage rates, subject to reduction in certain limited circumstances, on net sales of products developed under the amended license.

Under the amended license agreement, Biogen has a right of first offer to supply Covella's requirements of licensed products and a right of negotiation in the event that the Company decides to sublicense the right to commercialize a licensed product to a third party.

Also in connection with the merger agreement, the Company assumed a services and supply agreement between Covella and Biogen, which was subsequently amended in November 2011 and December 2012. Under the services and supply agreement, Biogen agreed to supply to Covella materials manufactured by Biogen for use in the SAN-300 development program. The amendment provides for a revised payment structure for such material. In addition, upon Covella's achievement of the first regulatory approval set forth in the amended license, Biogen is entitled to receive a one-time milestone payment equal to approximately $11.7 million, which is equivalent to the cost of the materials supplied under the services and supply agreement. In the event the amended license is terminated by either Covella or Biogen prior to Covella's achievement of the first regulatory approval set forth in the amended license, Covella is required to pay Biogen a one-time termination fee of $3.0 million.

Purchase Price

The acquisition of Covella was accounted for using the acquisition method of accounting in accordance with the authoritative guidance for business combinations and, accordingly, the Company has included the results of operations of Covella in its consolidated statement of operations from the date of acquisition. Neither separate financial statements nor pro forma results of operations have been presented because the acquisition does not meet the qualitative or quantitative materiality tests under Regulation S-X. Approximately $352,000 of costs associated with the Company's acquisition of Covella has been included in selling, general and administrative expenses for 2010.

The estimated purchase price is determined as follows (in thousands):

Cash paid on closing date	$	862
Fair value of Santarus common stock issued to sellers on closing date		364
Contingent consideration liability		1,900
	$	3,126

In addition to cash payments, the Company issued to the Covella stockholders 181,342 unregistered shares of the Company's common stock (subject to a 12-month lock-up period which expired on September 10, 2011). The total fair value of the common stock issued was approximately $364,000. The Company estimated a fair value of $2.01 per share, which reflects a discount of approximately 25% on the $2.68 closing price of its common stock on September 9, 2010. For a publicly traded stock, the fair value of a single unrestricted share of common stock is assumed to be equivalent to the quoted market price on the valuation date. However, since the 181,342 shares of common stock issued to the Covella stockholders were subject to a 12-month trading restriction, the Company calculated a discount for lack of marketability ("DLOM") applicable to the quoted market price. The Company calculated the DLOM associated with the contractual restriction using the Black-Scholes valuation model for a hypothetical put option with the following assumptions: life of the option of one year; risk-free interest rate of 0.27%; volatility of 65%; and dividend rate of 0%.

The purchase price, including the value of the consideration transferred, and the purchase price allocation for the acquisition of Covella is set forth below (in thousands):

Cash	$	20
Intangible assets		1,100
Goodwill		2,913
Liabilities assumed		(467)
Deferred tax liabilities (long-term)		(440)
	$	3,126

Intangible assets acquired consisted of IPR&D determined to be approximately $1.1 million. The fair value of the IPR&D has been determined using the multi-period excess earnings method which is a form of the discounted cash flow model. The approach was based on probability-adjusted projected net cash flows attributable to the IPR&D discounted using a weighted average cost of capital. The IPR&D is considered an indefinite-lived intangible asset until the completion or abandonment of the associated research and development efforts. The IPR&D asset is subject to impairment testing and will not be amortized until the development process is complete.

Contingent Consideration Liability

Under the terms of the merger agreement, the Company is obligated to make clinical and regulatory milestone payments based on success in developing product candidates in addition to a royalty on net sales of any commercial products resulting from the anti-VLA-1 mAb technology. The fair value of the contingent consideration at the closing date was determined to be approximately $1.9 million using a probability-weighted discounted cash flow. The key assumptions in applying this approach were the discount rate and the probability assigned to the milestone or royalty being achieved. Management remeasures the fair value of the contingent consideration at each reporting period, with any change in its fair value being recorded in the current period's statement of operations. Changes in

the fair value may result from either the passage of time or events occurring after the acquisition date, such as changes in the estimate of the probability of achieving the milestone or royalty. The Company recorded an increase in the fair value of contingent consideration of $146,000 for 2012 and a decrease in the fair value of contingent consideration of $3,000 for 2011 resulting primarily from changes in the estimated timing of achieving certain milestones and royalties and the passage of time. The Company recorded an increase in the fair value of contingent consideration of $157,000 for 2010 resulting from the passage of time from the September 2010 acquisition date through December 31, 2010. The fair value of the contingent consideration is included in long-term liabilities in the Company's consolidated balance sheets, and changes in the fair value of contingent consideration are included in operating expenses.

5. Long-Term Debt

In July 2006, the Company entered into a loan agreement with Comerica Bank ("Comerica"), which was most recently amended in February 2012, pursuant to which the Company may request advances in an aggregate outstanding amount not to exceed $35.0 million. In December 2008, the Company drew down $10.0 million under the loan agreement. Pursuant to the February 2012 amendment, the revolving loan bears interest, as selected by the Company, at either the variable rate of interest, per annum, most recently announced by Comerica as its "prime rate" or the LIBOR rate plus 2.25%. The Company has selected the LIBOR rate plus 2.25% interest rate option, which as of December 31, 2012 was approximately 2.46%. Interest payments on advances made under the amended loan agreement are due and payable in arrears on a monthly basis during the term of the amended loan agreement. The February 2012 amendment to the loan agreement extends the maturity date of the revolving line from July 11, 2013 to February 13, 2015. Amounts borrowed under the loan agreement may be repaid and re-borrowed at any time prior to February 13, 2015, and any outstanding principal drawn during the term of the loan facility is due and payable on February 13, 2015. In conjunction with the execution of the February 2012 amendment to the loan agreement, the Company paid a one-time commitment fee of $175,000. The commitment fee has been capitalized as a debt discount and is being amortized to interest expense over the remaining term of the loan agreement. The amended loan agreement will remain in full force and effect for so long as any obligations remain outstanding or Comerica has any obligation to make credit extensions under the amended loan agreement.

Amounts borrowed under the amended loan agreement are secured by substantially all of the Company's personal property, excluding intellectual property. Under the amended loan agreement, the Company is subject to certain affirmative and negative covenants, including limitations on the Company's ability to: undergo certain change of control events; convey, sell, lease, license, transfer or otherwise dispose of assets; create, incur, assume, guarantee or be liable with respect to certain indebtedness; grant liens; pay dividends and make certain other restricted payments; and make investments. In addition, under the amended loan agreement, the Company is required to maintain its cash balances with either Comerica or another financial institution covered by a control agreement for the benefit of Comerica. The Company is also subject to specified financial covenants with respect to a minimum liquidity ratio and, in specified limited circumstances, minimum EBITDA requirements as defined in the amended loan agreement. The Company believes it has currently met all of its obligations under the amended loan agreement.

6. Commitments and Contingencies

Leases

The Company leases its primary office facility and certain equipment under various operating leases. In October 2012, the Company entered into an office lease for the relocation of the Company's headquarters. The lease provides for the Company initially to lease approximately 40,144 square feet of office space and subsequently to lease an additional 7,044 square feet of office space. The term of the lease commenced on December 17, 2012 for the initial premises upon the substantial completion of specified improvements and continues for approximately 89 calendar months from the commencement date. The term is expected to commence on or about December 1, 2013 for the additional space. The term of the lease is expected to expire on or around May 31, 2020 for both spaces. The lease also provides the Company with the option to renew the lease term for two additional five year periods, subject to the conditions set forth in the lease. The lease provides for annual base rent payable in monthly installments and subject to annual increases of 3.0% during the term of the lease. The Company will not be required to pay rent for the initial premises for the first five full calendar months following the Company's occupancy of the initial premises

and will not be required to pay the rent attributable to the additional space for the first six full calendar months following the Company's occupancy of the additional space. The cumulative rent to be paid under the lease is being amortized on a straight-line basis over the term of the lease. The Company paid a security deposit of approximately $349,000 in October 2012.

In December 2007, the Company entered into a sublease agreement, which was subsequently amended in August 2011, for the Company's former office facility. The sublease expires on February 27, 2013. The Company received an allowance of approximately $559,000 to cover the cost of the Company's tenant improvements, which was provided in the form of an offset against the monthly installments of basic rent initially payable under the sublease. In conjunction with the sublease, in January 2008, the Company established a letter of credit naming the sublessor as beneficiary. The amount of the letter of credit was $200,000 as of December 31, 2012. In August 2011, the Company amended the sublease agreement to expand the leased premises. As the Company vacated the premises in December 2012, the Company expensed the remaining two months of rent and the remaining book value of the tenant improvements totaling approximately $154,000 in the aggregate.

In November 2004, the Company entered into a master lease agreement giving the Company the ability to lease vehicles under operating leases. In connection with the Company accepting delivery of vehicles and entering into lease obligations in January 2005, the Company established a letter of credit for $1.0 million naming the lessor as beneficiary. The Company entered into an agreement to reduce the letter of credit requirement to $750,000 effective in January 2011. The letter of credit is fully secured by restricted cash and has automatic annual extensions. Each lease schedule has an initial term of 12 months from the date of delivery with successive 12-month renewal terms. The Company intends to lease each vehicle, on average, approximately 36 months. The Company guarantees a certain residual value at the lease termination date. If the Company determines that it is probable that a loss will be incurred upon disposition of a vehicle resulting from the remaining book value of the lease exceeding the current fair market value of the vehicle, the Company accrues for the potential loss at the time of such determination.

At December 31, 2012, estimated annual future minimum payments under the Company's operating leases are as follows (in thousands):

2013	$ 1,828
2014	2,458
2015	2,363
2016	2,202
2017	2,268
Thereafter	5,567
Total minimum lease payments	$ 16,686

Rent expense on facilities and equipment was approximately $1.9 million, $1.6 million and $1.7 million for 2012, 2011 and 2010, respectively.

Legal Proceedings

Zegerid Rx and Zegerid OTC Patent Litigation

Zegerid Rx Litigation

In April 2010, the U.S. District Court for the District of Delaware ruled that five patents covering Zegerid capsules and Zegerid powder for oral suspension (U.S. Patent Nos. 6,489,346; 6,645,988; 6,699,885; 6,780,882; and 7,399,772) were invalid due to obviousness. These patents were the subject of lawsuits the Company filed in 2007 against Par in response to abbreviated new drug applications ("ANDAs") filed by Par with the FDA. The University of Missouri, licensor of the patents, is joined in the litigation as a co-plaintiff. In May 2010, the Company filed an appeal of the District Court's ruling to the U.S. Court of Appeals for the Federal Circuit. Following the District Court's decision, Par launched its generic version of Zegerid capsules in late June 2010.

In September 2012, the U.S. Court of Appeals for the Federal Circuit reversed in part the April 2010 decision of the District Court. The Federal Circuit found that certain claims of asserted U.S. Patent Nos. 6,780,882 and

7,399,772, which Par had been found to infringe, were not invalid due to obviousness. These patents represent two of the five patents that were found to be invalid by the District Court, and the Federal Circuit affirmed the District Court's finding of invalidity for the asserted claims from the remaining three patents. The Federal Circuit also upheld the District Court's finding that there was no inequitable conduct. Following the Federal Circuit's decision, Par announced that it had ceased distribution of its generic Zegerid capsules product in September 2012. In December 2012, the Federal Circuit issued an order denying a combined petition for panel and en banc rehearing filed by Par and issued its mandate, remanding the case to the District Court for further proceedings pertaining to damages. In February 2013, the Company filed an amended complaint with the District Court for infringement of U.S. Patent Nos. 6,780,882 and 7,399,772 and requested a jury trial with respect to the issue of damages in connection with Par's launch of its generic version of Zegerid capsules in June 2010. In March 2013, Par filed its amended answer, which alleges, among other things, failure to state a claim upon which relief can be granted and non-infringement based on purported invalidity of the two asserted patents. In addition, Par filed a motion for a judgment on the pleadings, alleging, among other things, that the two asserted patents are invalid because the Federal Circuit purportedly did not expressly address certain prior art references considered by the District Court. Although the Company does not believe that Par has a meritorious basis upon which to further challenge validity of the asserted patents in this proceeding, the Company cannot be certain of the timing or outcome of this or any other proceedings.

In December 2011, the Company filed a lawsuit in the U.S. District Court for the District of New Jersey against Zydus Pharmaceuticals USA, Inc. ("Zydus") for infringement of the patents listed in the Orange Book for Zegerid capsules. The University of Missouri, licensor of the patents, is joined in the litigation as a co-plaintiff. Zydus had filed an ANDA with the FDA regarding its intent to market a generic version of Zegerid capsules prior to the expiration of the listed patents. In September 2012, the Company amended its complaint to be limited to U.S. Patent No. 7,399,772, which patent was found not to be invalid in the September 2012 Federal Circuit decision. In October 2012, Zydus filed its answer, which alleges, among other things, failure to state a claim upon which relief can be granted. The lawsuit was commenced within the requisite 45-day time period, resulting in an FDA stay on the approval of Zydus' proposed product for 30 months or until a decision is rendered by the District Court, which is adverse to the asserted patent. The Markman hearing for this matter has been scheduled in July 2013 and a trial has been scheduled in January 2014. Absent a court decision, the 30-month stay is expected to expire in May 2014. The Company is not able to predict the timing or outcome of this lawsuit.

In August 2012, the Company filed a lawsuit in the U.S. District Court for the District of New Jersey against Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively "Dr. Reddy's") for infringement of the patents listed in the Orange Book for Zegerid capsules. The University of Missouri, licensor of the patents, is joined in the litigation as a co-plaintiff. Dr. Reddy's had filed an ANDA with the FDA regarding its intent to market a generic version of Zegerid capsules prior to the expiration of the listed patents. In October 2012, the Company amended its complaint to be limited to U.S. Patent No. 7,399,772, which patent was found not to be invalid in the September 2012 Federal Circuit decision. Also in October 2012, Dr. Reddy's filed its answer, which alleges, among other things, non-infringement, invalidity, failure to state a claim upon which relief can be granted and estoppel. The lawsuit was commenced within the requisite 45-day time period, resulting in an FDA stay on the approval of Dr. Reddy's proposed product for 30 months or until a decision is rendered by the District Court, which is adverse to the asserted patent. The Markman hearing for this matter has been scheduled in July 2013 and a trial has been scheduled in July 2014. Absent a court decision, the 30-month stay is expected to expire in January 2015. The Company is not able to predict the timing or outcome of this lawsuit.

Zegerid OTC Litigation

In September 2010, Merck filed a lawsuit in the U.S. District Court for the District of New Jersey against Par for infringement of the patents listed in the Orange Book for Zegerid OTC. The Company and the University of Missouri, licensors of the listed patents, are joined in the lawsuit as co-plaintiffs. Par had filed an ANDA with the FDA regarding its intent to market a generic version of Zegerid OTC prior to the expiration of the listed patents. In October 2012, Merck amended its complaint to be limited to U.S. Patent No. 7,399,772, which patent was found not to be invalid in the September 2012 Federal Circuit decision. Also in October 2012, Par filed its answer, which alleges, among other things, failure to state a claim upon which relief can be granted, non-infringement and invalidity. Par has received tentative approval of its proposed generic Zegerid OTC product. The lawsuit was commenced within the requisite 45-day time period, resulting in an FDA stay on the approval of Par's proposed

product for 30 months or until a decision is rendered by the District Court, which is adverse to the asserted patent. Although the 30-month stay expired in February 2013, the parties have agreed that Par will not launch its generic Zegerid OTC product unless there is a District Court judgment favorable to Par or in certain other specified circumstances. The Markman hearing for this matter has been scheduled in July 2013 and a trial has been scheduled in January 2015. The Company is not able to predict the timing or outcome of this lawsuit.

In September 2010, Merck filed a lawsuit in the U.S. District Court for the District of New Jersey against Perrigo Research and Development Company ("Perrigo") for infringement of the patents listed in the Orange Book for Zegerid OTC. The Company and the University of Missouri, licensors of the listed patents, were joined in the lawsuits as co-plaintiffs. Perrigo had filed an ANDA with the FDA regarding its intent to market a generic version of Zegerid OTC prior to the expiration of the listed patents. In January 2013, this case was settled allowing entry into the market by Perrigo upon expiration of the applicable patents (or earlier under certain circumstances), and the District Court entered an order dismissing the case with prejudice.

In December 2011, Merck filed a lawsuit in the U.S. District Court for the District of New Jersey against Zydus for infringement of the patents listed in the Orange Book for Zegerid OTC. The Company and the University of Missouri, licensors of the listed patents, are joined in the litigation as co-plaintiffs. Zydus had filed an ANDA with the FDA regarding its intent to market a generic version of Zegerid OTC prior to the expiration of the listed patents. In September 2012, Merck amended its complaint to be limited to U.S. Patent No. 7,399,772, which patent was found not to be invalid in the September 2012 Federal Circuit decision. In October 2012, Zydus filed its answer, which alleges, among other things, failure to state a claim upon which relief can be granted. The lawsuit was commenced within the requisite 45-day time period, resulting in an FDA stay on the approval of Zydus' proposed product for 30 months or until a decision is rendered by the District Court, which is adverse to the asserted patent. Absent a court decision, the 30-month stay is expected to expire in May 2014. The Markman hearing for this matter has been scheduled in July 2013 and a trial has been scheduled in January 2014. The Company is not able to predict the timing or outcome of this lawsuit.

Any adverse outcome in the Zegerid Rx and Zegerid OTC litigation described above would adversely impact the Company, including the amount of revenues the Company receives from sales of Zegerid brand and authorized generic prescription products and the Company's ability to receive, milestone payments and royalties under its agreement with Merck. For example, the royalties payable to the Company under its license agreement with Merck are subject to reduction in the event it is ultimately determined by the courts (with the decision being unappealable or unappealed within the time allowed for appeal) that there is no valid claim of the licensed patents covering the manufacture, use or sale of the Zegerid OTC product and third parties have received marketing approval for, and are conducting bona fide ongoing commercial sales of, generic versions of the licensed products. Any negative outcome may also negatively impact the patent protection for the products being commercialized pursuant to the Company's ex-US license with GSK. Although a U.S. ruling is not binding in countries outside the U.S., similar challenges to those raised in the U.S. litigation may be raised in territories outside the U.S. At this time the Company is unable to estimate possible losses or ranges of losses for ongoing actions.

Regardless of how these litigation matters are ultimately resolved, the litigation has been and will continue to be costly, time-consuming and distracting to management, which could have a material adverse effect on the Company.

Glumetza Patent Litigation

In November 2009, Depomed filed a lawsuit in the U.S. District Court for the Northern District of California against Lupin Limited and its wholly owned subsidiary, Lupin Pharmaceuticals, Inc. (collectively "Lupin") for infringement of certain patents listed in the Orange Book for Glumetza. The lawsuit was filed in response to an ANDA filed with the FDA by Lupin regarding Lupin's intent to market generic versions of Glumetza 500 mg and 1000 mg tablets prior to the expiration of the listed patents. In February 2012, the Company and Depomed entered into a settlement agreement with Lupin that grants Lupin the right to begin selling a generic version of Glumetza in February 2016, or earlier under certain circumstances. In March 2012, the U.S. District Court for the Northern District of California entered an order dismissing the litigation.

In June 2011, Depomed filed a lawsuit in the U.S. District Court for the District of New Jersey against Sun Pharma Global FZE, Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Industries Inc. (collectively "Sun")

for infringement of the patents listed in the Orange Book for Glumetza. Valeant International Bermuda ("Valeant") was joined in the lawsuit as a co-plaintiff. The lawsuit was filed in response to an ANDA filed with the FDA by Sun regarding Sun's intent to market generic versions of Glumetza 500 mg and 1000 mg tablets prior to the expiration of the listed patents. In January 2013, the Company, Depomed and Valeant entered into a settlement agreement with Sun that grants Sun the right to begin selling a generic version of Glumetza in August 2016, or earlier under certain circumstances. In January 2013, the District Court dismissed the lawsuit without prejudice in view of the settlement agreement. The settlement agreement is subject to review by the U.S. Department of Justice and the Federal Trade Commission.

In April 2012, Depomed filed a lawsuit in the U.S. District Court for the District of Delaware against Watson Laboratories, Inc. — Florida, Actavis, Inc. and Watson Pharma, Inc. (collectively "Watson") for infringement of the patents listed in the Orange Book for Glumetza 1000 mg at the time the lawsuit was filed (U.S. Patent Nos. 6,488,962 and 7,780,987). Valeant is joined in the lawsuit as a co-plaintiff. The lawsuit was filed in response to an ANDA filed with the FDA by Watson regarding Watson's intent to market a generic version of Glumetza 1000 mg tablets prior to the expiration of the listed patents. Depomed and Valeant commenced the lawsuit within the requisite 45-day time period, resulting in an FDA stay on the approval of Watson's proposed product for 30 months or until a decision is rendered by the District Court, which is adverse to the asserted patents. Absent a court decision, the 30-month stay is expected to expire in September 2014. Watson has filed an answer in the case that asserts, among other things, non-infringement and invalidity of the asserted patents, failure to state a claim, lack of subject matter jurisdiction, and has also filed counterclaims. In February 2013, Depomed amended its complaint to add infringement of a newly listed Orange Book patent (U.S. Patent No. 8,323,692), as well as two non-Orange Book listed patents (U.S. Patent Nos. 7,736,667 and 8,329,215). The Markman hearing for this matter has been scheduled in April 2014, and the trial has been scheduled in May 2014. The Company is not able to predict the timing or outcome of this lawsuit.

In February 2013, Depomed filed a lawsuit in the U.S. District Court for the District of Delaware against Watson for infringement of the patents listed in the Orange Book for Glumetza 500 mg at the time the lawsuit was filed (U.S. Patent Nos. 6,340,475; 6,488,962; 6,635,280 and 6,723,340). The lawsuit was filed in response to an ANDA filed with the FDA by Watson regarding Watson's intent to market a generic version of Glumetza 500 mg tablets prior to the expiration of the listed patents. Depomed commenced the lawsuit within the requisite 45-day time period, resulting in an FDA stay on the approval of Watson's proposed product for 30 months or until a decision is rendered by the District Court, which is adverse to the asserted patents. Absent a court decision, the 30-month stay is expected to expire in July 2015.

Under the terms of the Company's commercialization agreement with Depomed, Depomed will manage the ongoing patent infringement litigation relating to Glumetza, subject to certain consent rights in favor of the Company, including with regard to any proposed settlements. The Company is responsible for 70% of the future out-of-pocket costs, and Depomed is responsible for 30% of the future out-of-pocket costs, related to patent infringement cases.

Any adverse outcome in the litigation described above would adversely impact the Company and its revenues. Regardless of how these litigation matters are ultimately resolved, the litigation will continue to be costly, time-consuming and distracting to management, which could have a material adverse effect on the Company.

Fenoglide Patent Litigation

Prior to the execution of the license agreement, Shore entered into a settlement arrangement with Impax Laboratories, Inc. ("Impax") in connection with patent infringement litigation associated with Impax's ANDA for a generic version of Fenoglide and a related paragraph IV challenge. The settlement terms grant Impax a sublicense to begin selling a generic version of Fenoglide on October 1, 2015, or earlier under certain circumstances. In February 2012, the U.S. District Court for the District of Delaware entered an order dismissing the litigation, and the Company assumed Shore's obligations associated with the sublicense to Impax.

In January 2013, the Company filed a lawsuit in the U.S. District Court for the District of Delaware against Mylan Inc. and Mylan Pharmaceuticals Inc. (collectively "Mylan") for infringement of the patents listed in the Orange Book for Fenoglide 120 mg and 40 mg (U.S. Patent Nos. 7,658,944, and 8,124,125). Veloxis

Pharmaceuticals A/S "(Veloxis") is joined in the lawsuit as a co-plaintiff. The lawsuit was filed in response to an ANDA filed with the FDA by Mylan regarding Mylan's intent to market a generic version of Fenoglide 120 mg and 40 mg tablets prior to the expiration of the listed patents. The Company commenced the lawsuit within the requisite 45-day time period, resulting in an FDA stay on the approval of Mylan's proposed product for 30 months or until a decision is rendered by the District Court, which is adverse to the asserted patents, whichever may occur earlier. Absent a court decision, the 30-month stay is expected to expire in June 2015. Mylan has filed an answer in the case that asserts, among other things, non-infringement, invalidity, and failure to state a claim, and has also filed counterclaims. The Company is not able to predict the timing or outcome of this lawsuit.

7. Stockholders' Equity

Authorized Shares

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

Common Stock Offerings

On November 17, 2011, the Company filed a universal shelf registration statement on Form S-3 covering equity or debt securities with the SEC which was declared effective in December 2011. The universal shelf registration statement may permit the Company, from time to time, to offer and sell up to approximately $75.0 million of equity or debt securities. As of December 31, 2012, the Company has not issued securities under the universal shelf registration statement.

Stockholder Rights Plan

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

Stock Option Plans

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

In January 2004, the Company adopted the 2004 Equity Incentive Award Plan (the "2004 Plan"). The 2004 Plan was approved by the Company's stockholders in February 2004, became effective with the Company's initial public offering in April 2004 and was subsequently amended and restated in July 2004. As of December 31, 2012, the Company was authorized to issue options to purchase 22,937,561 shares of its common stock under the 2004 Plan and had 3,019,851 shares available for future issuance. In addition, the 2004 Plan contains an "evergreen provision" that allows for an annual increase in the number of shares available for issuance on the first day of the fiscal year,

equal to the lesser of 5% of the outstanding capital stock on each January 1, 2,500,000 shares, or an amount determined by the Company's board of directors. Effective January 1, 2013, the number of shares available for issuance was increased by 2,500,000 shares through the "evergreen provision." The number of shares of common stock available for issuance will be further increased by any options that are repurchased, forfeited, cancelled or expire under the 1998 Plan.

Options generally vest over periods ranging from one to four years and expire ten years from the date of grant. Certain options are immediately exercisable, and unvested common shares obtained upon early exercise of options are subject to repurchase by the Company at the original issue price. As of December 31, 2012, there were no unvested common shares outstanding subject to repurchase by the Company.

A summary of stock option activity is as follows:

Options	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2012	18,104,962	$ 4.01		
Granted	2,473,265	5.31		
Exercised	(1,323,514)	2.29		
Forfeited	(143,168)	4.53		
Expired	(21,697)	7.68		
Outstanding at December 31, 2012	19,089,848	$ 4.29	5.92	$ 127,879
Exercisable at December 31, 2012	14,447,557	$ 4.34	5.13	$ 96,178

The aggregate intrinsic value of options outstanding and options exercisable at December 31, 2012 is calculated as the difference between the exercise price of the underlying options and the market price of the Company's common stock for the shares that had exercise prices that were lower than the $10.98 closing price of the Company's common stock on December 31, 2012. The total intrinsic value of options exercised in 2012, 2011 and 2010 was approximately $6.1 million, $1.2 million and $399,000, respectively, determined as of the date of exercise. The Company received approximately $3.0 million, $1.6 million and $384,000 in cash from options exercised in 2012, 2011 and 2010, respectively.

Employee Stock Purchase Plan

In April 2004, the Company implemented the employee stock purchase plan, which was approved by the Company's stockholders in February 2004 and subsequently amended and restated in July 2004 and November 2007. Under the Amended and Restated Employee Stock Purchase Plan (the "ESPP"), employees may contribute up to 20%, subject to certain maximums, of their cash earnings through payroll deductions, to be used to purchase shares of the Company's common stock on each semi-annual purchase date. The purchase price will be equal to 85% of the market value per share on the employee's entry date into the offering period, or if lower, 85% of the fair market value on the specified purchase date. The Company initially reserved 400,000 shares of common stock for issuance under the ESPP. In addition, the ESPP contains an "evergreen provision" that allows for an annual increase in the number of shares available for issuance on the first day of the fiscal year, equal to the lesser of 1% of the outstanding capital stock on each January 1, 500,000 shares, or an amount determined by the Company's board of directors. As of December 31, 2012, the Company had issued 3,149,701 shares of common stock under the ESPP and had 1,058,253 shares available for future issuance. Effective January 1, 2013, the number of shares available for issuance was increased by 500,000 shares through the "evergreen provision."

Shares Reserved for Future Issuance

Common stock reserved for future issuance as of December 31, 2012 and 2011 are as follows:

	December 31,	
	2012	2011
Stock options issued and outstanding	19,089,848	18,104,962
Authorized for future issuance under equity compensation plans	4,078,104	3,632,375
	23,167,952	21,737,337

8. 401(k) Plan

The Company maintains a defined contribution 401(k) plan available to eligible employees. Employee contributions are voluntary and are determined on an individual basis, limited to the maximum amount allowable under federal tax regulations. Effective in January 2007 and through December 2009, the Company matched 25% of employee contributions up to 6% of eligible compensation, with cliff vesting over five years from the date of hire. Effective in January 2010, the Company increased the employer match to 50% of employee contributions up to 6% of eligible compensation, and effective in January 2013, the Company increased the employer match to 65% of employee contribution up to 6% of eligible compensation. Employer contributions were approximately $855,000 in 2012, $748,000 in 2011 and $926,000 in 2010.

9. Deferred Compensation Plan

In June 2012, the Company adopted the Santarus, Inc. Deferred Compensation Plan (the "Plan") for a select group of highly compensated employees of the Company, including its executive officers, pursuant to which participants may elect to defer receipt of compensation from the Company for purposes of retirement or otherwise. The Plan allows for deferrals by participants of up to 50% of base salary, and up to 100% of bonuses and performance-based compensation. A participant in the Plan may elect to have the participant's account credited with investment gains and losses by assuming that deferred amounts were invested in one or more hypothetical investment fund options selected by the participant. Participants are permitted to change their investment elections at any time. Plan participants are always 100% vested in the amount they defer and the earnings, gains and losses credited to their accounts. A Plan participant is entitled to receive a distribution under the Plan upon such participant's separation from service or disability or upon an unforeseeable emergency or a change in control, as well as in the event of the participant's death or at the time specified by the participant for an in-service or education distribution. The Company-owned assets are placed in a "rabbi trust" and are included in prepaid expenses and other current assets in the accompanying consolidated balance sheet. The trust assets, which consist primarily of mutual funds, had a fair value of approximately $169,000 at December 31, 2012. The corresponding liability was approximately $169,000 at December 31, 2012 and was included in other long-term liabilities in the accompanying consolidated balance sheet. Total contributions to the Plan, consisting solely of compensation deferred by participants, were approximately $167,000 for 2012.

10. Income Taxes

The Company provides for income taxes under the liability method. This approach requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of differences between the tax basis of assets or liabilities and their carrying amounts in the financial statements. The Company provides a valuation allowance for deferred tax assets if it is more likely than not that these items will expire before the Company is able to realize their benefit.

The Company follows the authoritative guidance relating to accounting for uncertainty in income taxes. This guidance clarifies the recognition threshold and measurement attributes for financial statement disclosure of tax positions taken or expected to be taken on a tax return. The impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more likely than not to be sustained upon audit by the relevant taxing authority. An uncertain tax position will not be recognized if it has less than a 50% likelihood of being sustained.

The Company's practice is to recognize interest and/or penalties related to uncertain income tax positions in income tax expense. The Company had no interest and/or penalties accrued on the Company's consolidated balance sheets at December 31, 2012 and 2011, and the Company has not recognized any interest and/or penalties in the statement of operations for the years ended December 31, 2012, 2011 and 2010 related to uncertain tax positions.

The following is a reconciliation of the Company's unrecognized tax benefits (in thousands):

	Years Ended December 31,		
	2012	2011	2010
Unrecognized tax benefits – January 1	$ 3,049	$ 2,949	$ 1,803
Gross decreases related to prior year tax positions	—	—	—
Gross increases related to current year tax positions	82	100	1,146
Settlements	—	—	—
Lapse of statute of limitations	—	—	—
Unrecognized tax benefits – December 31	$ 3,131	$ 3,049	$ 2,949

The Company is subject to taxation in the U.S. and various state jurisdictions. The Company's tax years for 1999 and forward are subject to examination by the U.S., California and other state tax authorities. The Company is currently under state income tax audits in California and New York.

Pursuant to Sections 382 and 383 of the Internal Revenue Code ("IRC"), annual use of the Company's net operating loss and research and development credit carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three year period. The Company determined that no ownership change had occurred through December 31, 2012 as defined in the provision of Section 382 of the IRC. Since no ownership change has yet occurred, there is no limitation with regards to the usage of net operating loss and research and development credit carryforwards as of December 31, 2012.

The Company had total income tax expense of approximately $1.3 million for 2012, $312,000 for 2011 and $59,000 for 2010, which was comprised of Federal and state tax liabilities. The Company was subject to the Federal Alternative Minimum Tax totaling approximately $890,000 for 2012, $161,000 for 2011 and $0 for 2010. The Company generated tax liabilities in various states in 2012 primarily due to net operating loss suspensions, insufficient net operating losses available to offset taxable income, and certain states imposing a tax based on a modified income base.

At December 31, 2012, the Company had Federal and state income tax net operating loss carryforwards of approximately $118.1 million and $129.7 million, respectively. The Federal and California net operating loss carryforwards will begin to expire in 2024 and 2014, respectively, unless previously utilized. At December 31, 2012, the Company had Federal and California research and development credit carryforwards of approximately $4.0 million and $1.8 million, respectively. The Federal research and development credit carryforwards will begin to expire in 2018 unless previously utilized. The California research and development credits carry forward indefinitely. At December 31, 2012, the Company also had Federal Alternative Minimum Tax credits of approximately $2.0 million, which will carry forward indefinitely.

Significant components of the Company's deferred tax assets as of December 31, 2012 and 2011 are listed below (in thousands). A valuation allowance of $91.4 million and $100.1 million at December 31, 2012 and 2011, respectively, has been recognized to offset the net deferred tax assets as realization of such assets is uncertain. The valuation allowance decreased by approximately $8.7 million during the year ended December 31, 2012 and $3.1 million during the year ended December 31, 2011.

	December 31,	
	2012	2011
Deferred tax assets:		
Net operating loss carryforwards	$ 46,010	$ 63,490
Research and development credits	2,910	2,877
Stock-based compensation	5,654	4,941
Depreciation and amortization	5,651	5,030
Accrued rebates	4,228	3,815
Deferred revenue	1,273	1,285
License fees and milestone payments	11,662	7,727
Allowance for product returns	7,440	5,183
Other	6,550	5,705
Total deferred tax assets	91,378	100,053
Valuation allowance	(91,378)	(100,053)
	$ —	$ —
Deferred tax liabilities:		
Indefinite life intangible	$ (440)	$ (440)
Net deferred tax assets (liabilities)	$ (440)	$ (440)

A reconciliation of the statutory income tax rate to the Company's effective tax is as follows:

	Years Ended December 31,		
	2012	2011	2010
Federal income taxes	34.0 %	34.0 %	34.0 %
State income tax, net of Federal benefit	2.2 %	3.3 %	4.2 %
Tax effect on non-deductible expenses	2.0 %	5.5 %	(2.3)%
Stock compensation expense	1.1 %	19.6 %	(5.0)%
Change in valuation allowance	(43.7)%	(63.2)%	(32.2)%
Impact of state rate change	6.7 %	9.0 %	0.1 %
Other	4.3 %	(2.0)%	0.7 %
	6.6 %	6.2 %	(0.5)%

11. Quarterly Financial Information (unaudited)

The following table sets forth quarterly results of operations for each quarter within the two-year period ended December 31, 2012. The information for each of these quarters is unaudited and has been prepared on the same basis as the Company's audited consolidated financial statements. In the opinion of management, all necessary adjustments, consisting only of normal recurring accruals, have been included to fairly present the unaudited quarterly results when read in conjunction with the Company's audited consolidated financial statements and related notes. The operating results of any quarter are not necessarily indicative of results for any future period.

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	(in thousands, except per share amounts)			
Selected Quarterly Financial Data (unaudited):				
2012:				
Product sales, net	$ 45,129	$ 46,308	$ 53,687	$ 69,414
Total revenues	45,880	47,192	54,670	70,213
Cost of product sales	3,484	3,703	3,276	5,177
Total costs and expenses	44,824	43,404	45,435	64,120
Net income	627	3,448	8,984	5,496
Net income per share:				
Basic	0.01	0.05	0.14	0.09
Diluted	0.01	0.05	0.13	0.08
2011:				
Product sales, net	$ 11,981	$ 14,694	$ 19,813	$ 41,665
Total revenues	22,814	26,607	26,814	42,552
Cost of product sales	1,520	1,845	2,232	3,255
Total costs and expenses	23,207	23,772	25,948	40,435
Net income (loss)	(516)	2,706	563	1,916
Net income (loss) per share:				
Basic	(0.01)	0.04	0.01	0.03
Diluted	(0.01)	0.04	0.01	0.03

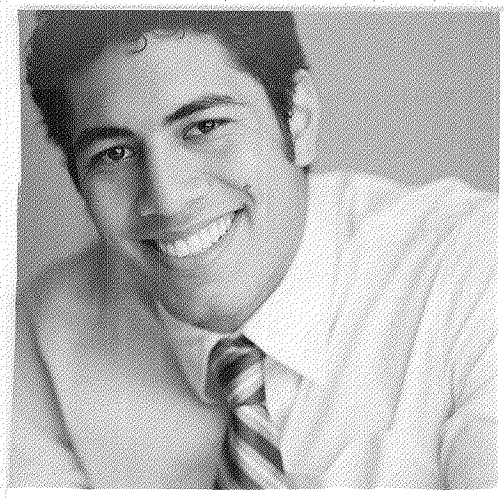
Schedule II – Valuation and Qualifying Accounts
(in thousands)

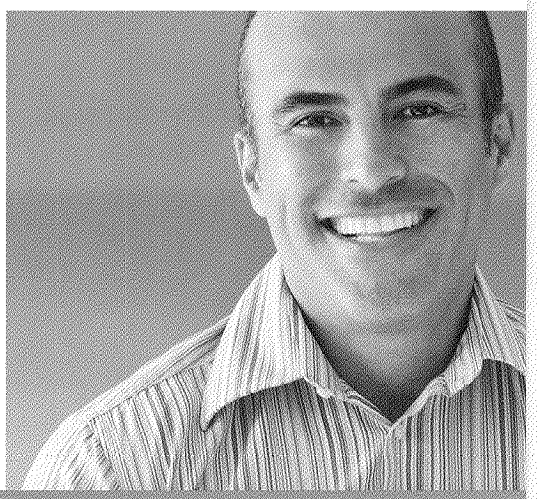
	Balance at Beginning of Period	Additions: Provision Related to Current Period Sales	Deductions: Actual Cash Discounts, Chargebacks, and Other Discounts Related to Current Period Sales	Deductions: Actual Cash Discounts, Chargebacks, and Other Discounts Related to Prior Period Sales	Balance at End of Period
Allowance for cash discounts, chargebacks, and other sales discounts:					
For the year ended December 31, 2012	$ (3,618)	$ (23,780)	$ 18,384	$ 3,508	$ (5,506)
For the year ended December 31, 2011	(1,383)	(10,658)	7,150	1,273	(3,618)
For the year ended December 31, 2010	(3,427)	(10,273)	9,008	3,309	(1,383)

	Balance at Beginning of Period	Additions: Charged to Costs and Expenses	Additions: Charged to Balance Sheet	Deductions	Balance at End of Period
Allowance for excess and obsolete inventory:					
For the year ended December 31, 2012	$ (1,194)	$ (596)	$ (26)	$ 212 (1)	$ (1,604)
For the year ended December 31, 2011	(2,190)	(577)	(12)	1,585 (1)	(1,194)
For the year ended December 31, 2010	(4)	(1,959)	(227)	-	(2,190)

	Balance at Beginning of Period	Additions: Provision Related to Current Period Sales	Additions: Provision Related to Prior Period Sales	Deductions: Actual Returns or Credits Related to Current Period	Deductions: Actual Returns or Credits Related to Prior Period	Balance at End of Period
Allowance for product returns:						
For the year ended December 31, 2012	$ (13,895)	$ (15,441)	$ (3,238)	$ 2,393	$ 9,607	$ (20,574)
For the year ended December 31, 2011	(13,450)	(4,890)	-	81	4,364	(13,895)
For the year ended December 31, 2010	(12,846)	(2,551)	-	89	1,858	(13,450)

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





Santarus 2012 annual report

A YEAR OF POSITIVE RESULTS

THE SANTARUS PRESCRIPTION FOR SUCCESS

PROPRIETARY PRODUCTS

Our goal is to be recognized as a premier specialty biopharmaceutical company with a successful record of developing and commercializing proprietary products.

SPECIALTY MARKETS

We are focused on maintaining a balanced portfolio with marketed products and investigational drugs for medical indications managed by physician specialists in endocrinology, gastroenterology, allergy/immunology and rheumatology.

PATIENT FOCUSED

We seek to provide innovative products that help physicians in the specialty markets we serve to address the unmet medical needs of their patients.

EXPANDING OUR PIPELINE

We continue to focus a significant effort on assessing additional marketed or late-stage development opportunities to license or acquire that will position Santarus for significant future growth.

2012 WAS A YEAR OF POSITIVE RESULTS. DURING 2012, SANTARUS ACHIEVED RECORD REVENUES AND SUBSTANTIALLY INCREASED NET EARNINGS. WE ADVANCED OUR DEVELOPMENT PIPELINE WITH POSITIVE RESULTS FROM LATE-STAGE CLINICAL STUDIES OF TWO OF OUR DRUGS IN DEVELOPMENT. WE ALSO WON AN IMPORTANT LEGAL DECISION IN OUR ZEGERID PATENT LITIGATION, WHICH BROUGHT THE PRODUCT BACK AS AN IMPORTANT SOURCE OF REVENUE.

LETTER TO STOCKHOLDERS:

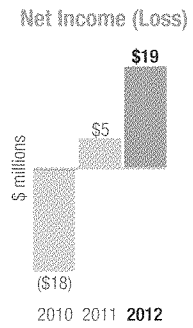
The strong performance of our marketed prescription products and the positive legal decision in September 2012 relating to ZEGERID® (omeprazole/sodium bicarbonate) capsules and powder for oral suspension resulted in record annual revenues. In addition, our net income significantly improved compared with 2011. At the same time, we took steps toward delivering sustainable growth with the advancement of our product development pipeline. In 2012 we reported positive top-line results in two Phase III programs, RUCONEST® (recombinant human C1 esterase inhibitor) and rifamycin SV MMX®, initiated a Phase IIIb study with UCERIS™ (budesonide) extended release tablets and completed a Phase I clinical study with SAN-300, our early-stage antibody.

Our financial results in 2012 were strong, with record revenues of $218 million, up 83 percent over 2011. Net income in 2012 improved to $18.6 million compared with $4.7 million in the prior year. In addition, we increased our cash, cash equivalents and short-term investments to $94.7 million as of December 31, 2012, which represents an increase of $36.1 million compared with our cash balance as of December 31, 2011.

This positive momentum has carried over into early 2013, with the FDA approval in January of UCERIS 9 mg for the induction of remission in patients with active, mild to moderate ulcerative colitis. We commercially launched UCERIS in February, just one month after approval.

With UCERIS approval, we added 85 new sales representatives to our existing core of 150 sales representatives. Our entire 235 person sales force is promoting both UCERIS and ZEGERID primarily to gastroenterologists. In addition, they are promoting GLUMETZA® (metformin

2012 net income of approximately $19 million included the expense of a $10 million milestone for successful completion of the RUCONEST® Phase III clinical study.



hydrochloride extended release tablets), CYCLOSET® (bromocriptine mesylate) tablets and FENOGLIDE® (fenofribrate) tablets to endocrinologists and high prescribing physicians who treat patients with type 2 diabetes and high cholesterol.

It is clear that our activities resulted in excellent results in 2012. We have now turned our focus to executing our commercial plans for 2013 and making the UCERIS launch a great success.

According to the Crohn's and Colitis Foundation of America, as many as 700,000 people in the U.S. suffer from ulcerative colitis.

UCERIS AND ULCERATIVE COLITIS

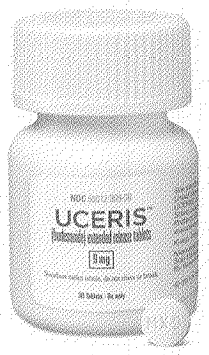
Ulcerative colitis is a form of chronic inflammatory bowel disease that produces inflammation and ulcers along the inside of the colon, which can interfere with the normal function of the colon. The disease typically starts to manifest in patients as young adults.

Ulcerative colitis is an intermittent disease with periods of exacerbated symptoms, or flares, and other periods that are relatively symptom-free. Although the symptoms of ulcerative colitis may resolve without treatment, the disease usually requires medication to go into remission.

According to the Crohn's and Colitis Foundation of America, as many as 700,000 people in the U.S. suffer from ulcerative colitis.

UCERIS is a prescription corticosteroid medicine used to induce remission of active, mild to moderate ulcerative colitis. UCERIS is taken once daily in the morning with or without food for up to 8 weeks.

Our sales representatives are promoting UCERIS to gastroenterologists who treat patients with mild to moderate ulcerative colitis. In addition, we believe that patient outreach will be crucial to the success of UCERIS. Our goal is to educate and motivate patients to seek medical attention if their disease becomes active and to ask their doctor about UCERIS. Our market research indicates that on average, patients with ulcerative colitis seek treatment for active disease about two times a year. The outreach campaign is directed to the sites where patients go most



UCERIS is an oral tablet formulated using proprietary multi-matrix system (MMX®) colonic delivery technology.

UCERIS IS A PRESCRIPTION CORTICOSTEROID MEDICINE USED TO INDUCE REMISSION OF ACTIVE, MILD TO MODERATE ULCERATIVE COLITIS. UCERIS IS TAKEN ONCE DAILY IN THE MORNING WITH OR WITHOUT FOOD FOR UP TO 8 WEEKS.

frequently for information, including social media outlets and key medical information websites.

ZEGERID RE-LAUNCH

ZEGERID is an oral proton pump inhibitor indicated for adult patients to treat heartburn and other symptoms of gastro-esophageal reflux disease (GERD).

In early September 2012 we announced the achievement of a major legal milestone with a favorable appellate court ruling in the ZEGERID patent litigation case. The appellate court overturned the Delaware District court's ruling of obviousness for certain claims from two patents covering ZEGERID capsules and powder for oral suspension. A few days later, our generic competitor announced they had ceased further shipments of their generic prescription ZEGERID capsules product.

We are very pleased with the outcome of the appellate court ruling and now have ZEGERID back as an important source of revenue.

In addition, we are pursuing our damages claim for lost profits against the generic competitor.

We re-launched ZEGERID simultaneously with the launch of UCERIS in February 2013. With our promotion, our goal in 2013 is to stem the decline of ZEGERID prescriptions which resulted from the prior generic competition.

PRODUCTS FOR TYPE 2 DIABETES AND HIGH CHOLESTEROL

GLUMETZA, CYCLOSET and FENOGLIDE performed well in 2012, with combined net sales of $166.6 million. In early 2012 we expanded our sales organization with 40 new sales representatives bringing our total to 150 individuals, and we saw the benefit of the increased call frequency from the larger sales group in the second half of the year.

GLUMETZA is our lead product for patients with type 2 diabetes. GLUMETZA is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Prescription trends for GLUMETZA were positive in 2012, with year-over-year total prescription growth of 31% (2012 compared with 2011).

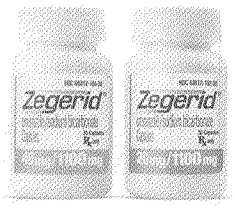
Glumetza continued to perform well in 2012 with growth of 30% in total prescriptions over the prior year.

COMMERCIAL PORTFOLIO	PRODUCT DESCRIPTION
GASTROENTEROLOGY	
UCERIS™	(Budesonide) extended release tablets – indicated for the induction of remission in patients with acute, mild-to-moderate ulcerative colitis *Please see www.Uceris.com for full prescribing and safety information.*
ZEGERID®	(Omeprazole/sodium bicarbonate) products – an oral proton pump inhibitor (PPI) used in adult patients to treat heartburn and other symptoms of gastroesophageal reflux disease (GERD) *Please see www.Zegerid.com for full prescribing and safety information.*
TYPE 2 DIABETES	
GLUMETZA®	(Metformin hydrochloride extended release tablets) – indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes *Please see www.Glumetzaxr.com for full prescribing and safety information, including a Black Box warning.*
CYCLOSET®	(Bromocriptine mesylate) tablets – indicated for use with diet and exercise to improve glycemic control in adults with type 2 diabetes *Please see www.Cycloset.com for full prescribing and safety information.*
HIGH CHOLESTEROL	
FENOGLIDE®	(Fenofibrate) tablets – a prescription medicine used to treat high cholesterol in adult patients *Please see www.Fenoglide.com for full prescribing and safety information.*

DEVELOPMENT PORTFOLIO	CLINICAL PHASE 1 2 3
LATE STAGE	
Ruconest® (recombinant human C1 esterase inhibitor)	
Rifamycin SV MMX®	
EARLY STAGE	
SAN-300 (Anti-VLA-1 antibody)	

INVESTMENT HIGHLIGHTS

UCERIS™ was approved by the U.S. Food and Drug Administration (FDA) in early 2013 for the induction of remission in patients with active, mild to moderate ulcerative colitis. Santarus commercially launched the product in February 2013 and the initial market reception has been positive.



In September 2012 we announced the achievement of a major legal milestone with a favorable appellate court ruling in the ZEGERID patent litigation. We have re-launched promotion of the product and expect ZEGERID to be an important source of revenue.

SPECIALTY FOCUS

Gastroenterologists

Gastroenterologists &
Selected Primary Care Physicians

Endocrinologists &
Selected Primary Care Physicians

Endocrinologists &
Selected Primary Care Physicians

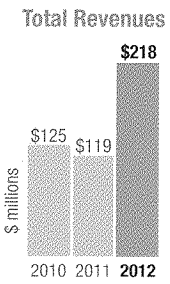
Endocrinologists
& Selected Primary Care Physicians

Allergists/Immunologists
Gastroenterologists

Rheumatologists/Gastroenterologists/Allergists/Immunologists

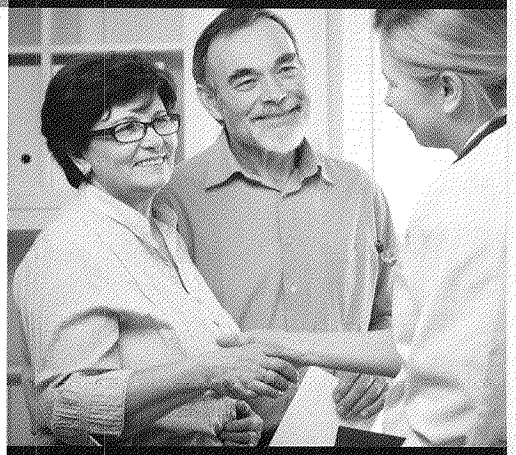
THE SANTARUS PORTFOLIO INCLUDES AN ATTRACTIVE MIX OF COMMERCIAL PRODUCTS AND DEVELOPMENT CANDIDATES THAT PROVIDE OPPORTUNITIES FOR SUSTAINABLE, LONG-TERM GROWTH.

Santarus is a profitable specialty biopharmaceutical company with a focus on proprietary products.



Strong Revenue Growth

83% year over year growth in total revenues (2012 vs 2011)



According to the Centers for Disease Control and Prevention, approximately 26 million people in the U.S. have diabetes. Type 2 diabetes is the most common form of diabetes, accounting for 90% to 95% of all diagnosed cases.

CYCLOSET has also shown growth in total prescriptions and net sales. CYCLOSET is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. The prescriber base for CYCLOSET continues to grow and anecdotal feedback from physicians who regularly prescribe the product is positive.

FENOGLIDE is a medicine to reduce high cholesterol, which is a condition that frequently occurs in patients with type 2 diabetes, so there is a good overlap with our called-on physicians.

PIPELINE AND POTENTIAL INDICATIONS

PRODUCT	POTENTIAL INDICATION	STATUS
Ruconest® (recombinant human C1 esterase inhibitor)	Acute treatment of hereditary angioedema	BLA submission planned 2Q 2013
	Prophylactic treatment of hereditary angioedema	Expect to discuss clinical study design with FDA in 2H 2013
	Acute pancreatitis	Exploring clinical and regulatory strategies to initiate proof-of-concept clinical study in late 2013
Rifamycin SV MMX®	Travelers' diarrhea	One Phase III clinical study successfully completed. Second Phase III clinical study in progress.
SAN-300 (anti-VLA-1 antibody)	Rheumatoid arthritis	Phase IIa clinical study planned to begin 4Q 2013
	Inflammatory bowel disease	Timing of commencement of Phase II study to be determined

WE BELIEVE OUR ABILITY TO BRING DEVELOPMENT PRODUCTS THROUGH CLINICAL TESTING AND REGULATORY APPROVAL, AND OUR PROVEN SUCCESS IN COMMERCIALIZING PROPRIETARY PHARMACEUTICAL PRODUCTS, MAKE SANTARUS AN ATTRACTIVE DEVELOPMENT AND COMMERCIAL PARTNER.

We are working to identify additional indications to pursue with our existing pipeline products to provide opportunity for revenue growth in the longer term.

INVESTIGATIONAL DRUG PIPELINE

In the second quarter of 2013, we expect to submit a biologics license application (BLA) for RUCONEST to the FDA, seeking approval to market RUCONEST for the treatment of acute attacks of angioedema in patients with hereditary angioedema (HAE). RUCONEST is a recombinant version of the human protein C1 inhibitor produced using proprietary transgenic technology.

In the second half of 2013, assuming the RUCONEST BLA has been accepted for review, we plan to request separate meetings with the FDA to discuss the pathways for other potential indications for RUCONEST, such as the treatment of acute pancreatitis and the prophylactic treatment of HAE.

Last September we announced positive top-line results from our Phase III clinical study with rifamycin SV MMX® in travelers' diarrhea and we are waiting for the completion of a second Phase III study being conducted by Dr. Falk Pharma in India. Rifamycin SV MMX is a broad spectrum, non-systemic antibiotic that utilizes MMX colonic delivery technology.

We have also completed a Phase I clinical study with SAN-300, our anti-VLA-1 antibody, and we are moving forward with plans to initiate a Phase IIa clinical study later this year with a subcutaneous dosage form of SAN-300 in patients with rheumatoid arthritis.

SAN-300 is a humanized monoclonal antibody that may offer a novel approach to the treatment of inflammatory and autoimmune diseases, such as rheumatoid arthritis and inflammatory bowel disease.

IN SUMMARY:
WE ACHIEVED OUR KEY BUSINESS OBJECTIVES FOR 2012.

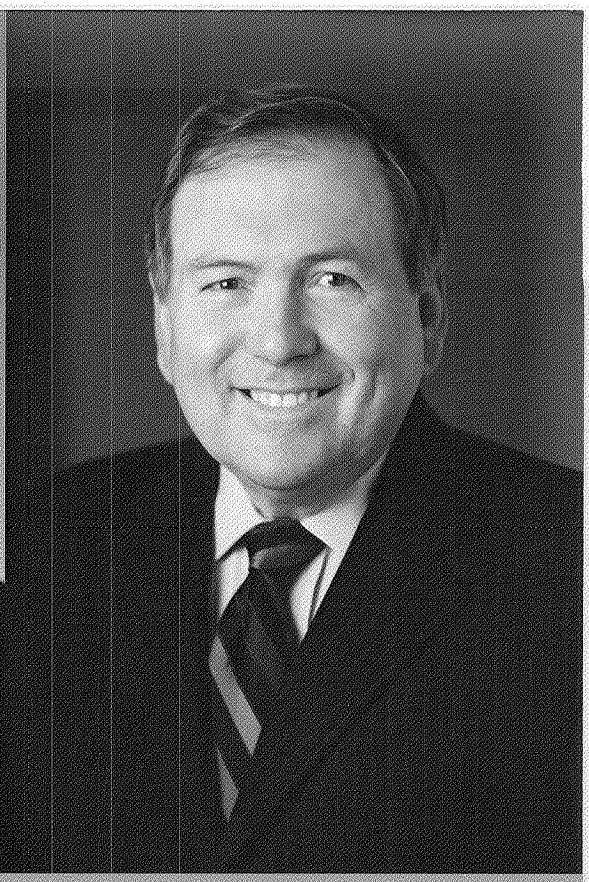
We believe execution of our strategic plan will position Santarus for significant future growth and continued positive results.

- We exceeded our 2012 financial guidance for revenue and profit objectives through strong commercial performance and careful management of our business;
- We received a favorable appellate court decision on our ZEGERID patent case and now have the product back as an important source of revenue;
- We made good progress with patient enrollment for the Phase IIIb clinical study for the use of UCERIS as an add-on therapy in ulcerative colitis, and we expect to complete enrollment in mid-2013;
- We reported positive top-line Phase III results to advance the clinical programs for RUCONEST and rifamycin SV MMX, and we plan to file the BLA for RUCONEST in the second quarter of this year; and
- We completed the SAN-300 Phase I clinical study in healthy subjects with both IV and subcutaneous dosage forms.

In addition, following numerous interactions with the FDA during the review of the UCERIS NDA throughout 2012, we received approval for the induction of remission in patients with active, mild to moderate ulcerative colitis in January 2013.

We are continuing to focus a significant effort on the assessment of additional marketed or late-stage product development opportunities to license or acquire that could further leverage our commercial operations.

As we look forward, we believe execution of our strategic plan will position Santarus for significant future growth and continued positive results.



2012 was an inflection year for Santarus. We want to thank our entire Santarus team for their dedication, hard work and perseverance, which resulted in exceptional company performance. Our success begins with our employees.

Gerald T. Proehl
President and Chief Executive Officer

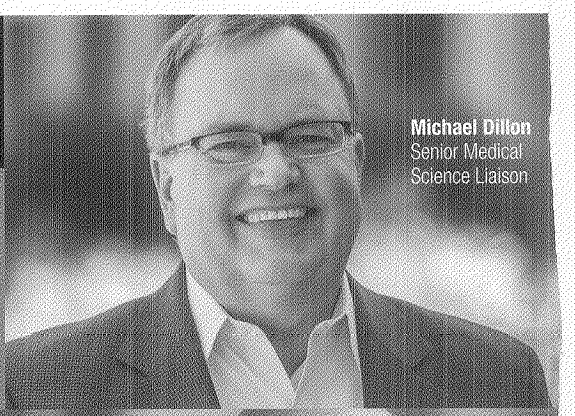
Santarus made substantial progress in growing commercial product revenues, managing expenses to produce strong profits and advancing clinical development during 2012. With the FDA approval of UCERIS, we look forward to reporting on continued positive momentum in 2013.

David F. Hale
Chairman of the Board

April 8, 2013

LEADERSHIP AWARDS

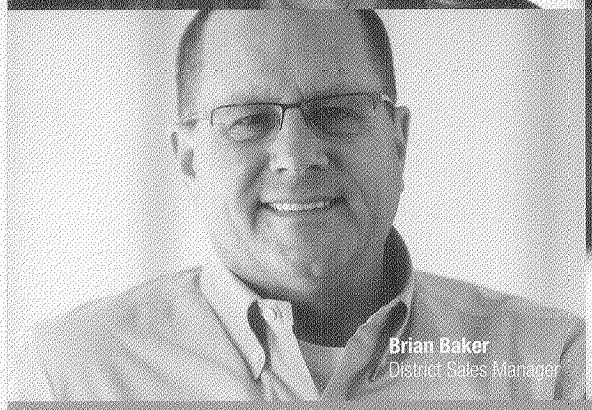
We believe our success begins with our employees. We strive to foster a work environment where ideas are encouraged and a passion for excellence is shared.



Michael Dillon
Senior Medical Science Liaison

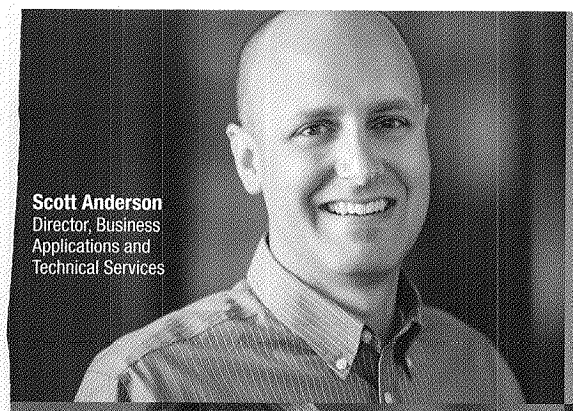
Meredith Wesley
Sr. Director, Human Resources

Brandon Main
Manager, Sales Analytics



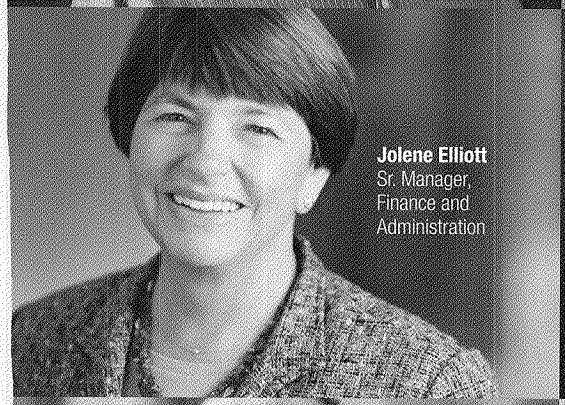
Brian Baker
District Sales Manager

Yun Hardiman
Director, Biostatistics and Data Management

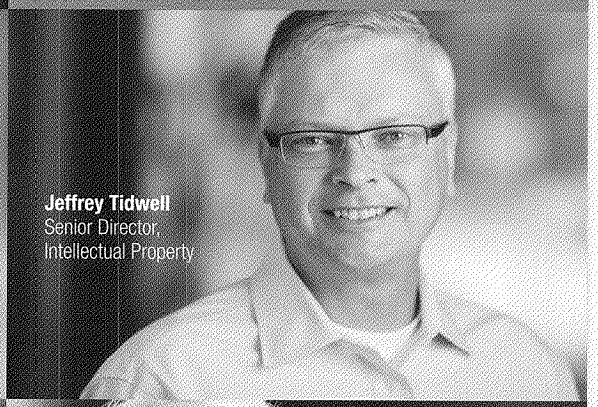


Scott Anderson
Director, Business Applications and Technical Services

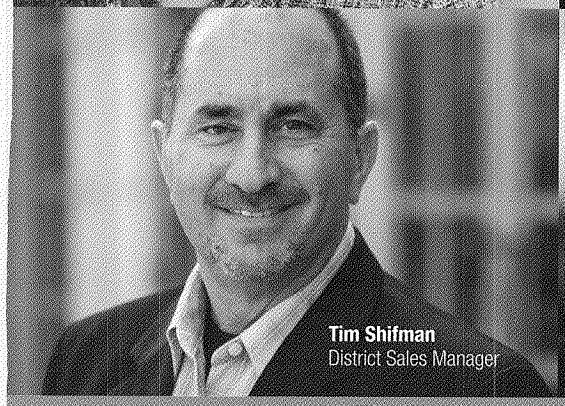
Our Core Values Are Teamwork, Ownership, Productivity, Integrity And Quality



Jolene Elliott
Sr. Manager, Finance and Administration



Jeffrey Tidwell
Senior Director, Intellectual Property



Tim Shifman
District Sales Manager

Heather Simmerman
Senior Director, QA and Compliance

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

THE REASON FOR OUR SUCCESS

SELECTED FINANCIAL DATA

Consolidated Statement of Operations Data

	Years Ended December 31,				
	2012	2011	2010	2009	2008
(in thousands, except per share amounts)					
Revenues:					
Product sales, net	$ 214,538	$ 88,153	$ 90,170	$ 119,242	$ 101,220
Promotion revenue	—	27,339	31,365	23,631	9,837
Royalty revenue	3,417	3,295	3,571	—	—
Other license revenue	—	—	245	29,620	19,144
Total revenues	217,955	118,787	125,351	172,493	130,201
Costs and expenses:					
Cost of product sales	15,640	8,852	7,715	8,294	7,345
License fees and royalties	69,783	17,898	28,576	7,976	22,257
Research and development	25,808	18,383	17,431	16,244	11,760
Selling, general and administrative	86,552	68,229	82,581	105,838	108,012
Restructuring charges	—	—	7,082	—	—
Total costs and expenses	197,783	113,362	143,385	138,352	149,374
Income (loss) from operations	20,172	5,425	(18,034)	34,141	(19,173)
Other income (expense):					
Interest income	29	15	80	194	1,285
Interest expense	(337)	(459)	(461)	(460)	(95)
Total other income (expense)	(308)	(444)	(381)	(266)	1,190
Income (loss) before income taxes	19,864	4,981	(18,415)	33,875	(17,983)
Income tax expense	1,309	312	59	1,760	534
Net income (loss)	$ 18,555	$ 4,669	$(18,474)	$ 32,115	($18,517)
Net income (loss) per share:					
Basic	$ 0.30	$ 0.08	$ (0.31)	$ 0.55	$ (0.36)
Diluted	$ 0.27	$ 0.07	$ (0.31)	$ 0.54	$ (0.36)
Weighted average shares outstanding used to calculate net income (loss) per share:					
Basic	62,697	60,531	58,734	57,995	51,835
Diluted	69,150	62,815	58,734	59,674	51,835

Consolidated Balance Sheet Data

	As of December 31,				
	2012	2011	2010	2009	2008
(in thousands)					
Cash, cash equivalents and short-term investments	$ 94,736	$ 58,608	$ 60,797	$ 93,944	$ 52,037
Working capital	75,937	38,417	34,310	47,563	3,734
Total assets	163,749	114,053	96,037	131,361	92,484
Deferred revenue, less current portion	1,639	2,163	2,635	2,678	2,436
Long-term debt	9,876	10,000	10,000	10,000	10,000
Other long-term liabilities	2,884	2,494	2,659	—	—
Total stockholders' equity	82,952	50,088	37,983	46,916	9,323

The selected consolidated statement of operations data for the years ended December 31, 2009 and 2008, and the selected consolidated balance sheet data as of December 31, 2010, 2009 and 2008, are derived from our audited consolidated financial statements for such years and as of such dates, which are not included in our Form 10-K for the year ended December 31, 2012. The selected consolidated statement of operations data for the years ended December 31, 2012, 2011 and 2010 and the selected consolidated balance sheet data as of December 31, 2012 and 2011, are derived from the audited consolidated financial statements for such years and as of such dates, which are included in our Form 10-K for the year ended December 31, 2012. The historical operating results of any year are not necessarily indicative of results for any future period. You should read these selected financial data together with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included in our Form 10-K for the year ended December 31, 2012, which is available upon request from Santarus or at www.sec.gov.

VIEW OUR ONLINE INTERACTIVE REPORT AT WWW.SANTARUS.COM/AR2012

CORPORATE INFORMATION

Board of Directors

David F. Hale
Chairman of the Board

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

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

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

Alessandro E. Della Cha
Senior Partner
Studio Legale Edoardo Ricci e Associati

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

Ted W. Love, M.D.
Director

Kent Snyder
Chief Executive Officer and
Chairman of the Board
Senomyx, Inc.

Corporate Officers

Gerald T. Proehl
President and Chief Executive Officer

Wendell Wierenga, Ph.D.
Executive Vice President,
Research and Development

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

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

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

Julie A. DeMeules
Senior Vice President,
Human Resources

William C. Denby III
Senior Vice President,
Commercial Operations

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

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

Michael D. Step
Senior Vice President,
Corporate Development

Mark C. Totoritis, M.D.
Senior Vice President, Clinical Research

General Information

Corporate Headquarters
Santarus, Inc.
3611 Valley Centre Drive
Suite 400
San Diego, CA 92130

Independent Registered
Public Accounting Firm
Ernst & Young LLP

Transfer Agent
American Stock Transfer
and Trust Company

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

Investor Relations
Santarus, Inc.
3611 Valley Centre Drive, Suite 400
San Diego, CA 92130
Phone: (858) 314-5700
Fax: (858) 314-5701
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Annual Meeting
The annual meeting of stockholders
of Santarus, Inc. will be held at
1:00 p.m. on June 11, 2013 at the
Santarus Corporate Headquarters
3611 Valley Centre Drive
Suite 400
San Diego, CA 92130
All stockholders are cordially
invited to attend.

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

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Forward-Looking Statements

Any statements in this report and the information incorporated herein by reference about our expectations, beliefs, plans, objectives, assumptions or future events or performance that are not historical facts are forward-looking statements. You can identify these forward-looking statements by the use of words or phrases such as "believe," "may," "could," "will," "estimate," "continue," "anticipate," "intend," "seek," "plan," "expect," "should," or "would." Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties inherent in our business including, without limitation: our ability to successfully launch Uceris™ and generate revenues from our other currently promoted commercial products and our authorized generic Zegerid® product; our ability to successfully advance the development of, obtain regulatory approval for and ultimately commercialize, our investigational drugs; our ability to maintain patent protection for our products, including the difficulty in predicting the timing and outcome of ongoing and any future patent litigation; our ability to achieve continued progress under our strategic alliances, and the potential for early termination of, or reduced payment under, these agreements; our dependence on our strategic partners for certain aspects of our development programs, including risks related to their financial stability; adverse side effects, inadequate therapeutic efficacy or other issues related to our products that could result in product recalls, market withdrawals or product liability claims; competition from other pharmaceutical or biotechnology companies and evolving market dynamics; other difficulties or delays relating to the development, testing, manufacturing and marketing of, and obtaining and maintaining regulatory approvals for, our products; fluctuations in quarterly and annual results; our ability to obtain additional financing as needed to support our operations or future product acquisitions; the impact of healthcare reform legislation and any instability in the financial markets; and other risks detailed in our filings with the Securities and Exchange Commission, including our annual report on Form 10-K for the fiscal year ended December 31, 2012. This report is being delivered together with our Form 10-K, which represents our complete 2012 annual report. You should read this report together with the Form 10-K, which includes additional information on our business and financial condition.

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

Full prescribing and safety information for Santarus' products are available at www.santarus.com.

Scan QR code with your mobile device to view the Santarus, Inc. website.

SANTARUS, INC.®

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