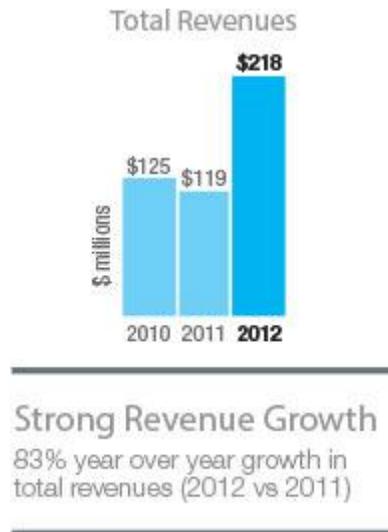


# Santarus, Inc. 2012 Annual Report

## 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.

## UCERIS AND ULCERATIVE COLITIS

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 hydrochloride extended release tablets), CYCLOSET® (bromocriptine mesylate) tablets and FENOGLIDE® (fenofibrate) 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.

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 frequently for information, including social media outlets and key medical information websites.

**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.**

## **ZEGERID RE-LAUNCH**

ZEGERID is an oral proton pump inhibitor indicated for adult patients to treat heartburn and other symptoms of gastroesophageal 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).

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.

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.

## **INVESTIGATIONAL DRUG PIPELINE**

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.

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

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 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 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.

## **Gastroenterology**

### **Uceris™ Gastroenterologists**



(Budesonide) extended release tablets – indicated for the induction of remission in patients with acute, mild-to-moderate ulcerative colitis

Please see [www.Uceris.com](http://www.Uceris.com) for full prescribing and safety information.

## **Zegerid® Gastroenterologists**



(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](http://www.Zegerid.com) for full prescribing and safety information.

## **Type 2 Diabetes**

### **Glumetza® Endocrinologists & Selected PCPs**



(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](http://www.Glumetzaxr.com) for full prescribing and safety information, including a Black Box warning.

### **Cycloset® Endocrinologists & Selected PCPs**



(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](http://www.Cycloset.com) for full prescribing and safety information.

## High Cholesterol

### Fenoglide® Endocrinologists & Selected PCPs



(Fenofibrate) tablets – a prescription medicine used to treat high cholesterol in adult patients  
*Please see [www.Fenoglide.com](http://www.Fenoglide.com) for full prescribing and safety information.*

### Development PHASE 1 2 3 Pipeline

### SPECIALTY FOCUS

## LATE STAGE

Ruconest® (recombinant human C1 esterase inhibitor)	● ● ●	Allergists/Immunologists
Rifamycin SV MMX®	● ● ●	Gastroenterologists

## EARLY STAGE

SAN-300 (Anti-VLA-1 antibody)	● ●	Rheumatologists/Gastroenterologists/Allergists/Immunologists
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## Selected Financial Data

### Consolidated Statement of Operations Data

	Years Ended December 31,				
	2012	2011	2010	2009	2008
<i>(In thousands, except per share amounts)</i>					
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
<i>(In thousands)</i>					
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](http://www.sec.gov).*

### **Safe Harbor Statement**

Any statements in this report and the information incorporated herein by reference about our expectations, beliefs, plans, objectives, assumptions or future events or performance that are not historical facts are forward-looking statements. You can identify these forward-looking statements by the use of words or phrases such as "believe," "may," "could," "will," "estimate," "continue," "anticipate," "intend," "seek," "plan," "expect," "should," or "would." Among the

factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties inherent in our business including, without limitation: our ability to 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.

Santarus®, FENOGLIDE®, UCERIS™, and ZEGERID® are trademarks of Santarus, Inc. GLUMETZA® is a trademark of Biovail Laboratories International S.r.l. licensed exclusively in the United States to Depomed, Inc. CYCLOSET® is a trademark of VeroScience LLC. MMX® is a trademark of Cosmo Technologies Limited. RUCONEST® is a trademark of Pharming Group N.V.

Full prescribing and safety information for Santarus' products are available at [www.santarus.com](http://www.santarus.com).