Santarus' CEO Discusses FDA Approval Of UCERIS (Budesonide) For The Induction Of Remission In Patients With Active, Mild To Moderate Ulcerative Colitis (Transcript)

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Santarus, Inc. (NASDAQ:SNTS)

Santarus Receives FDA Approval of UCERIS (Budesonide) for the Induction of Remission in Patients with Active, Mild to Moderate Ulcerative Colitis

January 15, 2013 09:00 am ET

Executives

Martha Hough - VP Finance & Investor Relations

Gerry Proehl - Director, President and Chief Executive Officer

Debbie Crawford - Senior Vice President, Chief Financial Officer, Treasurer and Secretary

Bill Denby - Senior Vice President, Commercial Operations

Wendell Wierenga - Executive Vice President, Research and Development

Analysts

Scott Henry - Roth Capital

David Amsellem - Piper Jaffray

Daniel Chang - Stifel

Brian Lian - SunTrust

Operator

Good morning. My name is Melissa, and I will be your conference operator today. At this time, I would like to welcome everyone to the Santarus Business Update Conference Call. All lines have been placed on mute to prevent any background noise. After the speakers' remarks, there will be a question-and-answer session. (Operator Instructions).

Martha Hough

Thank you, Melissa. Good morning, and welcome to today's call. This is Martha Hough, Vice President of Finance and Investor Relations.

Joining me on the call today are Gerry Proehl, President and Chief Executive Officer; Debra Crawford, Senior Vice President and Chief Financial Officer; Bill Denby, Senior Vice President of Commercial Operations. Dr. Wendell Wierenga, Executive Vice President of Research and Development will also be available during the question-and-answer session.

Yesterday after market closed, Santarus issued a press release announcing FDA approval of UCERIS, extended release tablets. This press release is available on our website at www.santarus.com. We will also make a replay of today's call available for the next two weeks on the Investor Relations section of our website.

Please keep in mind that risks and uncertainties involved in the company's business may affect the matters referred to in forward-looking statements made by management during today's call. As a result, the company's performance may differ from those expressed in or indicated by such forward-looking statements, which are qualified in their entirety by the cautionary statements contained in the press release and the company's Securities and Exchange Commission filings.

The content of this conference call contains time-sensitive information that is accurate only as of the date of this live broadcast on January 15, 2013. Santarus undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date of this conference call.

In this call, when talking about our company's financial outlook, we will also discuss adjusted EBITDA, a non-GAAP financial measure. You can find the reconciliation of adjusted EBITDA to GAAP net income in our press release issued yesterday.

I'll now turn the call over to Gerry Proehl.

Gerry Proehl

Thank you, Martha, and welcome to this morning's call. Yesterday FDA approval of UCERIS extended release tablets of the induction of remission of active, mild to moderate ulcerative colitis is exciting news and gives us strong momentum at the start of the New Year. We are very pleased to be preparing to launch UCERIS, an important new treatment

for the active stage of mild to moderate ulcerative colitis to patients and gastroenterologists. We believe 2013 is shaping up to be another very successful year for Santarus.

UCERIS contains budesonide a locally acting steroid in an oral utilizing MMX colonic delivery technology, designed to release budesonide throughout the calling. In clinical testing UCERIS achieved statistical significant results for the induction of remission of ulcerative colitis over eight weeks compared to placebo.

In two pivotal studies and our 12-month extended use study, the frequency of treatment related adverse events for UCERIS was similar to placebo. We believe UCERIS is uniquely positioned to fill a gap in the treatment paradigm to patient suffering acute mild to moderate ulcerative colitis.

Our commercial group has been focused on preparing for the launch of UCERIS. Bill Denby will review our progress in expanding our sales organization and describe some of our upcoming promotional initiatives later in the call. We expect to complete the manufacturing activities related to labeling and final packaging over the next eight weeks and our planning for the commercial launch of UCERIS in March.

We believe, our strategic plan to prepare Santarus for significant future growth continues to show positive results. To that end, we expect to meet or exceed our full year guidance for 2012, and we are introducing what we believe is a strong 2013 financial outlook, which include substantial growth in revenues and profits over our current guidance for 2012.

I'll now turn the call over to Debbie Crawford to provide the details of our 2012 and 2013 financial guidance. Deb?

Debbie Crawford

Thank you, Gerry, and thank you to everyone for joining our call. As Gerry said, for 2012, we expect to meet or exceed the guidance that we provided on our third quarter financial results call on November 7th.

As a reminder, our guidance includes total revenues of approximately $210 million. Net income of approximately $12 million to $14 million, which includes a total of $14 million in expense for success-based regulatory and clinical milestones and adjusted EBITDA of approximately $29 million to $32 million.

Today, we are pleased to introduce our financial outlook for full year 2013, which includes significant top line growth coupled with bottom line expansion. Our estimates are total revenues of approximately $320 million to $325 million, net income of approximately $50 million to $54 million and adjusted EBITDA of approximately $73 million to $79 million.

Additional details on selected estimated expenses for 2013 are as follows. License fees will include a $5 million expense for a success-based milestone assuming FDA acceptance for review of the RUCONEST Biologics License Application. R&D expenses of approximately $34 million to $38 million, and SG&A expenses of approximately $131 million to $134 million, which include an incremental estimated $38 million to $40 million to fund the sales force expansion of 85 sales reps and promotional and other costs related to the UCERIS launch and ZEGERID re-launch.

Bill Denby will now give a brief overview of launch activities for UCERIS and the re-launch of ZEGERID.

Bill Denby

Thanks, Deb. We have nearly completed our recruiting efforts for our planned sales force expansion to facilitate the UCERIS launch and expect to have a total of 85 newly hired sales representatives on board for the launch meeting in mid-February. The addition of the new reps will bring our total sales force to approximately 235 representatives.

Our promotional planned sales training modules, advertising, patient outreach, and internet-based advertising and other demand creation tactics and awareness programs are ready to roll out. Marketing research suggest that physician see UCERIS as a powerful new therapy for their patients filling a key unmet need in active mild to moderate ulcerative colitis, our promotional focus on the two core strengths of UCERIS that were demonstrated in our pivotal clinical studies, the efficacy of a steroid combined with a favorable tolerability and safety profile.

Health professionals will see the UCERIS branding and messages during representative visits and other promotional speaker programs as well as through non-personal promotional via advertising in the top-five GI journals and regular direct communications. This will be complimented by a comprehensive digital marketing plan, including internet advertising and a full product website be up and running soon.

We also recognized that informed patients will be crucial to the success of UCERIS. Therefore, we have developed a complementary patient campaign to educate and

doctors about UCERIS. This campaign aims to reach patients where they go most frequently for information including social media outlets and key medical information websites.

In the coming days and weeks, we will also implement a communication program to notify our distribution partners, physicians, payors, pharmacists and patients of product approval and availability in March. We plan to have all 235 sales representatives promote both, the UCERIS and ZEGERID, primarily to gastroenterologists. They will also promote GLUMETZA, CYCLOSET and FENOGLIDE to high prescribing physicians who treat patients with type 2 diabetes.

We believe that having a single sales force promote all of our products is the most efficient way to deploy our resources. It allows us to reduce the size of our larger territories and near more of our existing territories to allow for higher frequency of calls while minimizing disruption and maintaining flexibility for future promotional exchanges. We believe the higher call frequency is essentially for success in launching a new pharmaceutical product as well as supporting growth for our in-line products.

The training of our existing sales organization is already underway and will conclude with comprehensive product training at the launch meeting in mid-February. In addition, the meeting will allow us to train our entire organization on ZEGERID and train the 85 new representatives on our other in-line products. Our commercial team is extremely pleased to be working toward the goal of successfully launching UCERIS, and continuing the growth of our in-line products to achieve our financial goals for 2013.

Now, I'll turn the call back over to Gerry to wrap it up.

Gerry Proehl

Thanks, Bill. We've achieved a number of important milestones in last 12 months that we believe have created significant value for our stockholders. We substantially grow prescriptions and net sales for GLUMETZA and CYCLOSET and added FENOGLIDE to our portfolio of promoted products.

We received a favorable outcome on ZEGERID patent litigation during the second half of 2012, which we expect will positively impact our revenues and cash flow to the patent life ending in mid-2016.

On the product development side of the business, we initiated the Phase IIIb clinical study to evaluate the use of UCERIS as add-on therapy with 5-ASA drugs. We reported positive

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