

SECURITIES AND EXCHANGE COMMISSION

FORM 8-K

Current report filing

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FILER

SANTARUS INC

CIK: **1172480** | IRS No.: **330734433** | State of Incorporation: **DE** | Fiscal Year End: **1231**
Type: **8-K** | Act: **34** | File No.: **000-50651** | Film No.: **13528944**
SIC: **2834** Pharmaceutical preparations

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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): January 14, 2013

SANTARUS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation or Organization)

0-50651
(Commission
File Number)

33-0734433
(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)

3721 Valley Centre Drive, Suite 400, San Diego, California 92130
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 8.01 Other Events.

On January 14, 2013, Santarus, Inc. (“Santarus”) announced that the U.S. Food and Drug Administration (“FDA”) has approved Uceris™ (budesonide) extended release tablets for the induction of remission in patients with active, mild to moderate ulcerative colitis. In connection with the approval, Santarus committed to a post-marketing requirement to conduct an 8-week randomized, double-blind, placebo-controlled clinical study in children 5 to 17 years of age with active, mild to moderate ulcerative colitis. Santarus expects to commence the commercial launch of Uceris in March 2013.

Forward-Looking Statements

Santarus cautions you that statements included in this report that are not a description of historical facts are forward-looking statements. The inclusion of forward-looking statements should not be regarded as a representation by Santarus that any of its plans or objectives will be achieved. Actual results may differ materially from those set forth in this release due to the risks and uncertainties inherent in Santarus’ business, including, without limitation: Santarus’ ability to successfully launch Uceris and generate revenues from Uceris, Zegerid®, Glumetza® and its other currently promoted commercial products and its authorized generic Zegerid product; Santarus’ ability to successfully advance the development of, obtain regulatory approval for and ultimately commercialize, its development-stage products, including the timing and outcome of the Uceris Phase IIIb clinical study and the Uceris post-marketing clinical study; other difficulties or delays relating to the development, testing, manufacturing and marketing of, and obtaining and maintaining regulatory approvals for, Santarus’ products; and other risks detailed in Santarus’ prior periodic filings with the Securities and Exchange Commission.

You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement and Santarus undertakes no obligation to revise or update this news release to reflect events or circumstances after the date hereof. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.

