STERIS CORP
Form 8-K
December 20, 2010

# UNITED STATES

# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 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) December 20, 2010**

# STERIS Corporation

**(Exact name of registrant as specified in its charter)**

| **Ohio** | **1-14643** | **34-1482024** |
|---|---|---|
| **(State or other jurisdiction of incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |

**5960 Heisley Road, Mentor, Ohio** **44060-1834**
**(Address of principal executive offices)** **(Zip Code)**
**Registrant s telephone number, including area code (440) 354-2600**

**Not Applicable**

**(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))

**ITEM 8.01. Other Events.**

STERIS Corporation today announced that the Company has commenced shipment of its STERIS SYSTEM 1E Liquid Chemical Sterilant Processing System. The shipments of the SYSTEM 1E units will not have a material impact on the Company s third quarter financial results.

As previously announced, the Company has been awaiting FDA s response to its request for clearance, modification, or re-labeling of certain accessories for SYSTEM 1E, although those accessories are not required by FDA to sell the SYSTEM 1E. The Company recently received clearance from FDA of the SYSTEM 1E Chemical Indicator. The Company remains in discussion with FDA regarding its 510(k) submission for the SYSTEM 1E Biological Indicator, as well as its request to re-label SYSTEM 1 Quick Connects and modify SYSTEM 1 Trays already in the field for use in SYSTEM 1E. No assurance can be made that FDA will agree with the Company s submissions or requests.

Separately, the Company has received clearance from FDA of its modified Reliance EPS Endoscope Processing System ( EPS System ) and will resume shipments of the product in the U.S. immediately. The shipments of the EPS Systems will not have a material impact on the Company s third quarter financial results. The Company voluntarily submitted information to FDA in April 2010 regarding modifications to the EPS System. In July 2010, the FDA advised the Company that it believed a new 510(k) for those modifications should be submitted. Thereafter, the Company suspended sales of the EPS System in the U.S., and filed the 510(k) submission in August 2010. This clearance is the result of that 510(k) submission.

This Form 8-K may contain statements concerning certain trends, expectations, forecasts, estimates, or other forward-looking information affecting or relating to the Company or its industry, products or activities that are intended to qualify for the protections afforded forward-looking statements under the Private Securities Litigation Reform Act of 1995 and other laws and regulations. Forward-looking statements speak only as to the date of this report, and may be identified by the use of forward-looking terms such as may, will, expects, believes, anticipates, plans, estimates, projects, targets, forecasts, outlook, impact, potential, confidence, improve, opt and seeks, or the negative of such terms or other variations on such terms or comparable terminology. Many important factors could cause actual results to differ materially from those in the forward-looking statements including, without limitation, disruption of production or supplies, changes in market conditions, political events, pending or future claims or litigation, competitive factors, technology advances, actions of regulatory agencies, and changes in laws, government regulations, labeling or product approvals or the application or interpretation thereof. Other risk factors are described herein and in the Company s Form 10-K and other securities filings. Many of these important factors are outside STERIS s control. No assurances can be provided as to any result or the timing of any outcome regarding the requests or submissions referenced in this Form 8-K or otherwise with respect to any regulatory action, administrative proceedings, government investigations, litigation, warning letters, consent decree, rebate program, transition, cost reductions, business strategies, earnings or revenue trends or future financial results. References to products, the consent decree, or the transition or rebate program, are summaries only and do not alter or modify the specific terms of the product clearance or literature or the decree or program. Unless legally required, the Company does not undertake to update or revise any forward-looking statements even if events make clear that any projected results, express or implied, will not be realized. Other potential risks and uncertainties that could cause actual results to differ materially from those in the forward-looking statements include, without limitation, (a) the potential for increased pressure on pricing that leads to erosion of profit margins, (b) the possibility that market demand will not develop for new technologies, products or applications or the Company s rebate program, transition plan or other business initiatives will take longer, cost more or produce lower benefits than anticipated, (c) the possibility that application of or compliance with laws, court rulings, certifications, regulations, regulatory actions, including without limitation those relating to previously disclosed FDA warning letters, government investigations, the December 3, 2009 or February 22, 2010 FDA notices, the April 20, 2010 consent decree and related transition plan and rebate program, the SYSTEM 1E device, the Reliance EPS System, the outcome of the pending requests and clearances referenced herein, or other requirements or standards may delay, limit or prevent new product introductions, affect the production and marketing of existing products or services or otherwise affect Company performance, results, prospects or value, (d) the potential of international unrest or effects of fluctuations in currencies, tax assessments or rates, raw material costs, benefit or retirement plan costs, or other regulatory compliance costs, (e) the possibility of reduced demand, or reductions in the rate of growth in demand, for the Company s products and services, (f) the possibility that anticipated growth, cost savings, rebate assumptions, new product acceptance or approvals, including without limitation SYSTEM 1E and accessories thereto, or other results may not be achieved, or that transition, labor, competition, timing, execution, regulatory, governmental, or other issues or risks associated with our business, industry or initiatives including, without limitation, the consent decree, the transition from the SYSTEM 1 processing system, or those matters described in our Form 10-K for the year ended March 31, 2010 or other securities filings may adversely impact company performance, results, prospects or value, (g) the effect of the contraction in credit availability, as well as the ability of our and suppliers to adequately access the credit markets when needed, and (h) those risks described in our Annual Report on Form 10-K for the year ended March 31, 2010 and the Form 10-Q for the quarter ended September 30, 2010.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

STERIS CORPORATION

By /s/ Mark D. McGinley
Mark D. McGinley
Senior Vice President, General Counsel, and Secretary

Date: December 20, 2010