

STERIS CORP
Form 8-K
January 20, 2009

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 20, 2009

STERIS Corporation

(Exact name of registrant as specified in its charter)

Ohio
(State or other jurisdiction
of incorporation)

1-14643
(Commission File Number)

34-1482024
(IRS Employer
Identification No.)

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5960 Heisley Road, Mentor, Ohio
(Address of principal executive offices)

44060-1834
(Zip Code)

Registrant's telephone number, including area code (440) 354-2600

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.

As previously disclosed, on May 16, 2008, we received a warning letter (the "warning letter") from the FDA regarding our STERIS SYSTEM 1 sterile processor and the STERIS 20 sterilant used with the processor (referred to collectively in the FDA letter and herein as the "device"). The warning letter referenced a number of changes to the device that, according to the FDA, require a new premarket notification (510(k)), and asserted that our failure to make such a 510(k) submission resulted in violations of applicable law. The warning letter also requested documentation and explanation regarding various corrective actions related to the device prior to 2003, and whether those actions should be considered corrections or removals requiring notice under applicable FDA regulations.

On July 30, 2008 (with an Addendum on October 9, 2008), we provided a detailed response contending that the assertions in the warning letter are not correct. As previously disclosed, in November 2008 we received two letters from the FDA. Subsequently, the Company and the FDA met to discuss the warning letter and the Company and the FDA have continued working together to resolve this matter.

On January 20, 2009, the Company announced that it submitted to the FDA a new liquid chemical sterilization system for 510(k) clearance. The new submission follows discussions with the FDA regarding the prior 510(k) submission issues raised in the warning letter relating to the Company's existing device. The new liquid chemical sterilization system submitted to FDA addresses the changes referenced by the FDA in the warning letter and includes additional technology updates.

The Company is communicating to Customers that STERIS will continue supporting the existing SYSTEM 1 installed base by providing accessories, sterilant, service and parts, and replacement processor units for at least a two year period. In the U.S., STERIS will continue sales of SYSTEM 1 processors only as replacements for existing units. Customers can continue using SYSTEM 1 without any change. The FDA has reviewed and accepted these actions and the FDA is not requiring modification to clinical practices or notification to doctors or patients. Once the new liquid chemical sterilization system is cleared for market use by the FDA, the Company will work with Customers to transition them to the new product.

For fiscal 2009, ending March 31, 2009, the Company anticipates that this development will not have a material impact on its consolidated financial results. Beginning in fiscal 2010, the Company anticipates that annualized revenues will be modestly impacted by approximately \$10 million until the new product is cleared and commercialized.

As previously disclosed, the existing STERIS SYSTEM 1 is the subject of an investigation by the United States Department of Justice and FDA. We continue to cooperate with the governmental agencies regarding these matters. There can be no assurance of

the ultimate outcome of the investigation, or that any matter arising out of the investigation will not result in actions by the governmental agencies or third parties, or that the governmental agencies will not initiate administrative proceedings, civil proceedings or criminal proceedings, or any combination thereof, against us. For additional information regarding these matters see *Legal Proceedings* in the Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2008 and filed with the SEC on November 10, 2008.

A copy of the press release and customer notice issued on January 20, 2009 are filed as Exhibit 99.1 and Exhibit 99.2, respectively, to this Current Report on Form 8-K and are incorporated by reference herein.

Forward-Looking Statements

This report may contain statements concerning certain trends, expectations, forecasts, estimates or other forward-looking information affecting or relating to the Company or its industry 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, potential, confidence, and seeks, or the negative of such terms or other variations of 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 government regulations or the application or interpretation thereof. Other risk factors are described in the Company's Form 10-K and other securities filings. Many of these important factors are outside of STERIS's control. No assurance can be provided as to any outcome from litigation, regulatory action, administrative proceedings, government investigations, warning letters, cost reductions, business strategies, level of share repurchases, earnings and revenue trends, expense reduction or other future financial results. 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, including, 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, including the new sterilization system referenced herein, or the Company's 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, regulations, regulatory actions, including, without limitation, the previously disclosed FDA warning letter, certifications or other requirements or standards may

delay or prevent new product introductions, affect the production and marketing of existing products, or otherwise affect the Company performance, results, 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 and growth in demand, for the Company's products and services, (f) the possibility that financial impact or other outcomes may not be as anticipated, or that transition, labor, competition, timing, execution, regulatory, governmental, or other issues or risks associated with the matters described in this report, including the impact on the currently marketed sterilizer or the ability to obtain clearance or market acceptance of the new sterilization system, may adversely impact Company performance, results, or value, (g) the effect of the credit crisis on our ability, as well as the ability of our customers 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, 2008, filed with the SEC on May 30, 2008, under Item 1A, Risk Factors.

The following disclosure is presented to update the Company's risk factors contained in its Annual Report on Form 10-K for the fiscal year ended March 31, 2008 and its Quarterly Report on Form 10-Q for the quarter ended September 30, 2008:

Most of our products, including the new liquid chemical sterilization system, must receive regulatory approvals before they can be marketed and sold in the United States and other countries.

Our operations are subject to extensive regulation in both the United States and in other countries where we do business. In Europe, our products are regulated primarily by country and community regulations of those countries within the European Economic Area and must conform to the requirements of those authorities. Government regulation applies to nearly all aspects of testing, manufacturing, safety, labeling, storing, recordkeeping, reporting, promoting, distributing, and importing or exporting of medical devices, products, and services. In general, unless an exemption applies, a sterilization, decontamination or medical device or other product, including the new liquid chemical sterilization system recently submitted to FDA for clearance, must receive regulatory approval or clearance before it can be marketed or sold. Prior to clearance by the FDA, we may not sell the new sterilization system in the United States.

Regulatory agencies may refuse to grant approval or clearance. Regulatory submissions may require the provision of additional clinical or pre-clinical data and may be time consuming and costly. Regulatory agencies may also change policies, adopt additional regulations, or revise existing regulations, each of which could prevent or delay approval or clearance of our products, including the new liquid chemical sterilization system. If we are unable to obtain this or any other required approvals or clearances, approval supplements or clearances for our products, including the new liquid chemical sterilization system or the approvals are delayed, we may not be able to market and sell these products, which could have a material adverse affect on our business, performance, value, financial condition and results of operations.

Existing and new Customers may not purchase or use the new liquid chemical sterilization system consistent with the purchase and use of the existing STERIS SYSTEM 1.

The Company has submitted a 510(k) premarket notification to the FDA for a new liquid chemical sterilization system. If the new liquid chemical sterilization system is cleared for use in the United States by the FDA, the Company may begin to market and sell the new liquid chemical sterilization system. There can be no assurance as to the extent that such new liquid chemical sterilization system will receive market acceptance or that any such demand will be consistent with the market demand of the existing STERIS SYSTEM 1. If sales or use of the new liquid chemical sterilization system are less than the existing STERIS SYSTEM 1 that could have a material adverse effect on our business, performance, financial conditions and results of operations.

Item 9.01. Financial Statements and Exhibits.

(d) *Exhibits.*

| Number | Description |
|---------------|--|
| 99.1 | Press Release dated January 20, 2009 |
| 99.2 | Customer Notice dated January 20, 2009 |

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

Date: January 20, 2009

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

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EXHIBIT INDEX

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