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	**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

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

EXHIBIT INDEX

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

Exhibit 99.1

STERIS CORPORATION
NEWS ANNOUNCEMENT
FOR IMMEDIATE RELEASE

STERIS CORPORATION SUBMITS
NEW STERILIZATION SYSTEM TO FDA AND
ANNOUNCES DEVELOPMENTS ON SYSTEM 1 WARNING LETTER

- ***New Liquid Chemical Sterilization System Submitted for 510(k) Clearance***
- ***Third Quarter Earnings Announcement Scheduled for January 27, 2009***

Mentor, Ohio (January 20, 2009) - STERIS Corporation (NYSE: STE) today announced it has submitted to the U.S. Food and Drug Administration (FDA) a new liquid chemical sterilization system for 510(k) clearance. The new submission follows discussions with the FDA regarding issues raised in a May 2008 warning letter relating to the Company's SYSTEM 1 Sterile Processing System. The new liquid chemical sterilization system submitted to the 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 is not requiring modification of 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.

"Our highest priorities are patient safety, legal and regulatory compliance, and Customer satisfaction," said Walter Rosebrough, president and chief executive officer of STERIS Corporation. "We are pleased that our discussions with the FDA have resulted in the submission of a new liquid chemical sterilization system and a path forward in resolving the warning letter related to SYSTEM 1. We look forward to working with the Agency to obtain clearance of our new system, and resolving any remaining regulatory issues."

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.

Third Quarter Conference Call

The Company will issue fiscal 2009 third quarter earnings before the market opens on January 27, 2009, followed by a conference call at 10:00 a.m. Eastern time. The conference call can be heard live over the Internet at www.steris-ir.com or via phone by dialing 1-888-392-9976 in the United States and Canada, and 1-517-645-6486 internationally, then referencing the password “STERIS.”

About SYSTEM 1

SYSTEM 1 is a low temperature liquid sterilizer which allows healthcare providers to sterilize heat sensitive medical instruments, primarily flexible endoscopes. Revenues for SYSTEM 1, including the capital equipment, related consumables and accessories, are approximately 10% of total Company revenues.

About STERIS

The mission of STERIS Corporation is to provide a healthier today and safer tomorrow through knowledgeable people and innovative infection prevention, decontamination and health science technologies, products and services. The Company’s more than 5,000 dedicated employees around the world work together to supply a broad array of solutions by offering a combination of equipment, consumables and services to healthcare, pharmaceutical, industrial and government Customers. The Company is listed on the New York Stock Exchange under the symbol STE. For more information, visit www.steris.com.

Contacts:

News Media: Stephen Norton at 440-392-7482
Investors: Julie Winter at 440-392-7245

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This news release, and the conference call referenced here, 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 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 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 STERIS's control. No assurances 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 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, including the new sterilization system referenced here, 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 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 of 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 release or the conference call referenced here, 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," and the Quarterly Report on Form 10-Q for the quarter ended September 30, 2008 and filed with the SEC on November 10, 2008, under "Legal Proceedings."

Exhibit 99.2

IMPORTANT NOTICE

Dear Valued SYSTEM 1 Customer:

On May 15, 2008, the United States Food and Drug Administration ("FDA") sent a warning letter to STERIS stating its view, among other things, that STERIS made changes or modifications to the STERIS System 1 requiring STERIS to submit to FDA a new premarket notification ("510(k)") and obtain marketing clearance for the changed device. Accordingly, FDA stated that the currently marketed device does not have a cleared premarket notification. The regulations require a new 510(k) when changes are made to a legally marketed device that "could significantly affect the safety or effectiveness of the device" (21 CFR 807.81(a)(3)(i)).

The changes or modifications identified in the warning letter occurred between 1988 and 2002, and are as follows:

- The centrifugal circulation pump's impeller was changed from a mechanically coupled to a magnetically driven impeller;
- The high pressure pump used to circulate sterilant to and through device lumens was changed: the original pump had a flow rate of 800 mls/min and the modified pump's flow rate was 3500 mls/min: also a pressure switch was added to monitor high pressure pump leakage;
- System 1 software was changed to limit the operation of the high pressure pump to avoid high pressure pump alarms related to low facility water pressure;
- The connector design was changed from separate components to groupings of tethered components intended for use with specified endoscopes, and new connectors were developed to facilitate the adaptation of the flow unit to the instrument intended for processing;
- The chamber size of the System 1 was made larger than the test chamber referenced in the original System 1 510(k), and the STERIS 20 sterilant formula was changed to maintain the FDA-cleared sterilant concentration to accommodate the larger chamber volume; and
- Additional inert ingredients were added to STERIS 20 sterilant, *i.e.*, water, sodium hydroxide, sodium polyacrylate, EDTA and NTA.

On July 31, 2008, STERIS provided a written response to FDA disagreeing with the agency's assessment that a new 510(k) was required under the agency's regulations. Subsequently, STERIS and FDA met to discuss the warning letter. Although the parties continue to disagree about the statements in the warning letter, STERIS agreed to submit a new premarket notification for an updated STERIS System 1, which includes the changes referenced above and other technology updates. STERIS submitted this new 510(k) to FDA on January 5, 2009.

In conjunction with the submission of the 510(k) for the updated STERIS System 1, STERIS is discontinuing sales in the U.S. of the System 1 Processor that is the subject of the warning letter, except for sales related to product replacement. STERIS will continue to support existing System 1 Processors for at least two years from the date of this notice. This support will consist of selling accessories and STERIS 20 sterilant, providing service and parts, and selling replacement units on a one-for-one basis. STERIS will work with customers on a timetable to transition to the purchase of a replacement for its System 1 product.

As always, Customers should report any serious adverse event that you suspect is associated with the use of the STERIS System 1 to STERIS 1-800-548-4873 and FDA (see http://www.fda.gov/medwatch/report/hcp.htm).

If you have any questions, please contact STERIS Customer Service at 1-800-548-4873 or www.steris.com.

Sincerely,

Rosemary Niewolak
Product Manager, SYSTEM 1

January 20, 2009