NOVOSTE CORP /FL/
Form 8-K
August 20, 2002

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) August 19, 2002

NOVOSTE CORPORATION
(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

Florida	0-20727	59-2787476
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification)

3890 Steve Reynolds Blvd., Norcross, GA 30093
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code (770) 717-0904

(Former name or former address, if changed since last report)

ITEM 5. OTHER EVENTS

On August 19, 2002, the registrant issued a press release announcing that it had initiated a voluntary product recall of its Beta-Cath(TM) 3.5F delivery catheters. The recall was related to the Company's belief that handling issues specific to the distal rail design of the Beta-Cath(TM) 3.5F delivery catheters may have the potential to compromise patient safety. The Beta-Rail 3.5F delivery catheter will be returned to the Company and, pending FDA approval of a new training program, the product will be relaunched. The FDA has been informed of the Company's decision to recall the product and discussions relating to improvements of the Beta-Rail 3.5F system training program and planned product relaunch are ongoing. A copy of the press release is attached as Exhibit 99.2 and incorporated by reference herein. The Company conducted a telephone conference call at 2 P.M. on August 19, 2002 to discuss the product recall and other issues raised in the release. The following are excerpts from the teleconference call:

- The recall was the result of isolated incidents in which the Beta-Cath(TM) 3.5F catheter tip separated. These incidents occurred in less than 1/10 of one percent of patients on whom procedures utilizing 3.5F catheters were performed. There have been no deaths as a result of these incidents and at no time has there been a radiation safety issue, as the radiation source train is safely contained within its own dedicated lumen.

- In Europe, which represents only about 5% of the Company's business, the Company is planning to implement the same modified training program that it will utilize in the U.S.

- The Company believes that the recall will impact approximately 200 of its U.S. customers, most of whom currently utilize its 5F catheters as well as the 3.5F. Because of the challenges that have been involved in meeting the demand for the 3.5F catheters, the Company believes that there is not a large number of them in stock at customer hospitals. Prior to the recall, 3.5F catheter sales growth had been in line with previously announced guidance.

- The Company offered a preliminary outlook for the third and fourth quarters of 2002. Third quarter revenues are expected at between $12 million and $16 million. The previous fourth quarter revenue guidance of between $18 million and $21 million was not changed. No guidance was offered with respect to anticipated earnings or earnings per share for the remainder of 2002. The Company expects to offer sales incentives to customers during the recall period.

- Pending the FDA's response to the Company's proposed training program and planned product relaunch, the Company expressed its belief that the majority of the financial impact of the recall would occur in the third quarter.

- The company expects to use cash from operations during the remainder of the third quarter of $1 to $2 million per month based on reduced revenue and higher costs associated with the recall.

- One-time recall expenses expected to be incurred in the third quarter, irrespective of lost revenues, may be as much as $750,000, with $300,000 expected to relate to recalled inventory and $450,000 expected to be allocated to selling and general expenses.

Statements made in this press release that look forward in time or that express management's beliefs, expectations or estimates regarding future occurrences are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those projected in these forward-looking statements based upon known and unknown risks and uncertainties, including the risk that the FDA will not approve the re-release of the 3.5F catheter, in conjunction with a revised training program, on a timely basis or at all, that the Company will be unable to convert a number of its 3.5F customers to 5F catheters, that pricing competition with respect to 5F catheters will reduce the Company's expected revenues, continued market acceptance of the Beta-Cath(TM) System, continued demonstration of safety, efficacy, and device performance in post-market surveillance studies, competition and technological changes. These and other risks are detailed in documents filed by Novoste with the SEC including its Form 10-K for the year ended December 31, 2001 and its Form 10-Q for the quarter ended June 30, 2002.

ITEM 7. FINANCIAL STATEMENTS AND EXHIBITS.

(a) Financial Statements.

Not applicable.

(b) Pro Forma Financial Information.

Not applicable.

(c) Exhibits.

Exhibit Number	Description
ITEM 99.1	PRESS RELEASE DATED AUGUST 19, 2002

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.

Dated: August 20, 2002

NOVOSTE CORPORATION
(Registrant)

By: /S/ EDWIN B. CORDELL, JR.
Edwin B. Cordell, Jr.
Vice President, CFO, Finance and Treasurer

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