CHIRON CORP
Form 8-K
August 27, 2004

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): **August 26, 2004**

Chiron Corporation

(Exact name of registrant as specified in its charter)

Delaware	**0-12798**	**94-2754624**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

4560 Horton Street, Emeryville, CA	**94608**
(Address of principal executive offices)	(Zip Code)

Registrant s telephone number, including area code **(510) 655-8730**

N/A

(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 (see General Instruction A.2. below):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events.

On August 26, 2004, Chiron Corporation announced via press release a delay in the shipment of its Fluvirin® influenza virus vaccine. Excerpts from the press release are set forth below:

NEWS RELEASE

For Immediate Release

Contacts:
Chiron Corporate Communications & Investor Relations
Media: (510) 923-6500
Investors: (510) 923-2300

CHIRON DELAYS FLUVIRIN® INFLUENZA VIRUS VACCINE SHIPMENTS

Vaccine doses expected to be available in October pending additional tests

EMERYVILLE, Calif., August 26, 2004 Chiron Corporation (NASDAQ: CHIR) today announced that, in conducting final internal release procedures for its Fluvirin® influenza virus vaccine, the company s quality systems have identified a small number of lots that do not meet product sterility specifications. While ongoing internal investigations into the root cause of the variance indicate no widespread issues with the manufacturing process, Chiron has delayed releasing any Fluvirin doses until it has completed additional release tests. Chiron currently expects that the additional tests will delay product release until early October. Because of the delay in shipment, Chiron does not expect to record any sales of Fluvirin in the third quarter of 2004....

Chiron is committed to protecting people. These extra checks will ensure that the quality, safety and effectiveness of our product meet our rigorous standards, said John Lambert, president of Chiron Vaccines. In our role as a key supplier of an important public health product, we are working with the FDA, the U.S. Department of Health and Human Services, and the CDC to meet the projected demand for the upcoming influenza season. We currently expect Fluvirin doses to be available in early October, in time to meet public health needs for this influenza season, and we expect to provide even more Fluvirin doses this season than last season.

In July, Chiron announced that it was on track to deliver an estimated total of 50 million doses of Fluvirin to the U.S. market this season, an increase from earlier projections, and that it had delivered its first 1 million doses to U.S. distributors. Assuming satisfactory results from ongoing release testing, Chiron now expects to deliver between 46 million and 48 million Fluvirin doses to the U.S. market beginning in October. The vaccine doses held at distributors

are subject to the same internal release criteria as those held at Chiron s FDA-licensed Liverpool manufacturing facility, with release anticipated in October. The planned late-season delivery of 2 million Fluvirin doses for a national stockpile held by the U.S. Centers for Disease Control and Prevention (CDC), not included in the totals above, remains on schedule....

This news release contains forward-looking statements, including statements regarding the amount of doses of Fluvirin that Chiron expects to deliver to the U.S. market and the timing of the delivery of those doses both in aggregate and with respect to the doses for the CDC s national stockpile, sales growth over prior periods, product development initiatives, and new product marketing. These forward-looking statements involve risks and uncertainties and are subject to change. No assurances can be given that additional tests on Fluvirin will yield satisfactory results or that Chiron will be able to release Fluvirin this season. Many factors could cause actual results and developments to differ materially from those expressed or implied by these forward-looking statements, including, among others, additional adverse developments resulting from the completion of Chiron s additional tests and investigation or discussions with or actions taken or required by the FDA, U.S. Department of Health and Human Services, or CDC. In addition, a full discussion of the company s operations and financial condition, including factors that may affect its business and future prospects, is contained in documents the company has filed with the SEC, including the form 10-Q for the quarter ended June 30, 2004, and the form 10-K for the year ended December 31, 2003, and will be contained in all subsequent periodic filings made with the SEC. These documents identify other important factors that could cause the company s actual performance to differ from the expectation expressed or implied by these forward-looking statements, including the outcome of clinical trials, regulatory review and approvals, manufacturing and testing capabilities, pricing pressures, intellectual property protections and defenses, litigation, stock-price volatility, and marketing effectiveness. In particular, there can be no assurance that Chiron will timely conclude testing or release of Fluvirin, maintain anticipated levels of profitability, increase sales of existing products, successfully develop and receive approval to market new products, or achieve market acceptance for such new products. In addition, the company may engage in business opportunities, the successful completion of which are subject to certain risks, including shareholder and regulatory approvals and the integration of operations.

Consistent with SEC Regulation FD, we do not undertake an obligation to update the forward-looking information we are giving today.

NOTE: Fluvirin is a trademark of Chiron Corporation.

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SIGNATURE

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.

CHIRON CORPORATION
(Registrant)

Date: August 27, 2004

By: /s/ Ursula B. Bartels
Ursula B. Bartels
Vice President and
General Counsel