HEMOSENSE INC
Form 8-K
October 13, 2005

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

October 5, 2005

Date of Report (date of earliest event reported)

HEMOSENSE, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**001-32541**	**77-0452938**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification Number)**

651 River Oaks Parkway

San Jose, California 95134

(Address of principal executive offices)

(408) 719-1393

(Registrant s telephone number, including area code)

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):

¨ 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

On October 5, 2005, the Company received a Warning Letter from the United States Food and Drug Administration, or the FDA. A copy of the Warning Letter is attached hereto as Exhibit 99.1.

The Warning Letter was a follow-up to the FDA Form 483 notice of inspectional observations relating to the FDA inspection of the Company s San Jose, California site from May 16 through June 1 of this year. The inspectional observations related to the Company s (i) failure to timely file Medical Device Reports, or MDRs, for complaints the FDA inspector reviewed claiming that the Company s INRatio device took inaccurate readings; and (ii) failure to properly define and document the procedures the Company employs to identify the statistical techniques for calibration of the Company s test strips. The Company s response to these observations dated June 14, 2005 included a description of and basis for the Company s revised MDR reporting procedure, as well as an explanation of the statistical techniques it utilizes in its test strip calibration procedure. The Company s revised reporting procedure has led the Company to file an increased number of MDRs.

The Warning Letter indicates that the FDA believes that the Company s response did not provide sufficient detail and documentation for the FDA to evaluate whether the Company s corrective actions would be adequate to prevent recurrence of the observations. The Company has submitted a further written response to the FDA, which the Company believes addresses this concern.

This Current Report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include statements relating to the Company s beliefs as to the adequacy of its original response to the FDA, and the adequacy of its further written response to the FDA. These forward-looking statements involve risks and uncertainties which may cause actual results to differ materially from those predicted in any such forward-looking statements.

Item 9.01. Financial Statements and Exhibits.

(c) Exhibits.

Exhibit No.	Description
99.1	Warning Letter from the United States Food and Drug Administration to HemoSense Corporation dated October 4, 2005

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, thereunto duly authorized.

HEMOSENSE, INC.

Date: October 12, 2005

By: /s/ James D. Merselis

James D. Merselis
President and Chief Executive Officer