HEMOSENSE INC
Form 8-K
December 19, 2006

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

December 13, 2006

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 November 29, 2006, the United States Food and Drug Administration, or the FDA, issued a Warning Letter to the Company. The Company received the Warning Letter on December 1, 2006 but because the Warning Letter was not sent to the regulatory contact on file with the FDA, and the actual addressee was out of the office for several days at the time, the package was consequently misplaced unopened. The Warning Letter was opened and read on December 13, 2006. The Warning Letter will be posted to the FDA s website at www.fda.gov

The November 29, 2006 Warning Letter was issued by the FDA as 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 15 through July 13 of this year.

The Warning Letter indicates among other things that the FDA believes the Company s responses to the 483 notice were insufficient because the Company did not include analysis of root cause and because the Company s corrective and preventive actions to address the specific observations have not yet been completed. The Company is in the process of preparing a further written response to the FDA to address these concerns.

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: December 18, 2006

By: /s/ James D. Merselis
James D. Merselis
President and Chief Executive Officer