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COMPUTERIZED THERMAL IMAGING INC

Form 8-K

December 20, 2001

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

December 20, 2001

Date of Report
(Date of Earliest Event Reported)

COMPUTERIZED THERMAL IMAGING, INC.

(Exact name of registrant as specified in its charter)

| | | |
|---|-----------------------------|--|
| Nevada | 000-23955 | 87-0458721 |
| ----- | ----- | ----- |
| (State or Other Jurisdiction of Incorporation or Organization) | (Commission File Number) | (I.R.S. Employer Identification Number) |

TWO CENTERPOINTE DRIVE, SUITE 450
LAKE OSWEGO, OREGON 97035

(Address of principal executive offices)

(503) 594-1210

(Registrant's telephone number)

Not Applicable

(Former Name and Address of Principal Executive Offices)

Item 9. Regulation FD Disclosure.

On December 20, 2001, we posted a letter to our shareholders onto our website: www.cti-net.com. The letter discusses clinical studies the Company is conducting that are unrelated to the Company's pending FDA Pre-Market Application. The letter is attached hereto as exhibit 99.4 and incorporated by reference.

Item 7. Exhibits

The following exhibit is filed herewith:

Exhibit 99.4. Letter to shareholders dated December 20, 2001.

SIGNATURES

Pursuant to the requirements of the Securities and Exchange Act of

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1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned hereunto duly authorized.

COMPUTERIZED THERMAL IMAGING, INC.

Date: 12/20/2001

By: /s/ Bernard J. Brady

Bernard J. Brady
Chief Financial Officer,
Secretary & Treasurer

EXHIBIT 99.4

Message to CTI Shareholders;

We recently announced a Breast Cancer Imaging System clinical study at McKay-Dee Hospital in Ogden, Utah. This is the start of several smaller clinical studies we plan to conduct around the country at various hospitals and cancer centers. McKay-Dee was selected for our first study because of its excellent radiological staff, and its close proximity to our engineering and clinical research staff. These new studies are unrelated to the clinical trials conducted for the U.S. Food and Drug Administration PMA submission. These are focused studies with specialized clinical protocols that will further educate and inform the radiology community of the systems utility. We plan to generate additional peer review papers for medical journal publication during 2002 and will utilize the study outcomes to further our efforts for patient reimbursement with the insurance industry.

We have begun discussions with several hospital and research facilities around the country and are in various stages of completion with their local Internal Review Board (IRB) approval process. We believe that these specialized study groupings will enhance the system's capabilities. Study topics will include angiogenesis, neoadjuvantive imaging and chemotherapy, high-risk patient groups, non-disease effects on aging and premenopausal conditions.

In addition, we continue to work closely with the FDA on our PMA submission and are pleased with the progress that has been made to date. While we cannot comment at this time when the FDA will approve our Pre-Market Application, the FDA is performing its normal in-depth scientific, regulatory and manufacturing reviews required by its procedures. This process is exactly the same process we have already completed for modules one through four.

The study at McKay-Dee and the other studies we are planning are in addition to our efforts to receive PMA approval as an adjunct to mammography for breast cancer detection. These studies are important to CTI as they provide the foundation for accelerated acceptance within the radiology community, insurance industry and most of all, the women affected by this dreaded disease.

John Brenna
President

Except for historical information contained herein, the matters discussed in this announcement, including but not limited to references to sales performance objectives and intellectual property developments, are forward-looking statements that involve risks and uncertainties. The forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities

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Litigation Reform Act of 1995. In addition to the factors set forth above, other important factors that could cause actual results to differ materially include, but are not limited to, technical risks associated with new technology development, government regulatory approvals and access to working capital. Additional information concerning factors that could cause actual results to differ materially from those in the forward-looking statements is contained from time to time in the Company's SEC filings. Copies of these filings may be obtained by contacting the Company or the SEC. The Company undertakes no obligation to update any of the forward-looking statements contained in its press releases.