ICAD INC
Form 8-K
March 08, 2011

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): March 2, 2011

iCAD, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**1-9341**	**02-0377419**
(State or other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

98 Spit Brook Road, Suite 100, Nashua, NH	**03062**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: **(603) 882-5200**

Not Applicable
(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:

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 February 18, 2011, in the Orange County Superior Court (Docket No. 30-2011-00451816-CU-PL-CJC), named plaintiffs Jane Doe and John Doe filed a complaint against Xoft, Inc. ("Xoft"), iCAD, Inc. (the "Company") and Hoag Memorial Hospital Presbyterian alleging personal injury resulting from general negligence and product liability seeking unlimited damages in excess of $25,000. On March 2, 2011, the Company received an amended complaint specifying that the damages being sought aggregated an amount of at least approximately $14.5 million. It is alleged that one of the plaintiffs was a patient at a hospital who was treated with the Axxent Electronic Brachytherapy System that incorporated the Axxent Flexishield Mini. The Company believes that this patient is one of twenty seven patients treated at this hospital using the Axxent Flexishield Mini. The Axxent Flexishield Mini is the subject of a voluntary recall as discussed below.

On February 3, 2011, the Company in cooperation with the U.S. Food and Drug Administration (the "FDA") voluntarily recalled the Axxent Flexishield Mini. The voluntary recall was prompted after the Company was notified in January 2011 of the presence of microscopic particles found in certain patients' breasts during post surgery follow up imaging exams, which were later determined to be tungsten and alleged to be originating from the Axxent Flexishield Mini, an accessory device to the Company's Axxent Electronic Brachytherapy system. Based upon the Company's preliminary analysis, it believes that the particles were non-toxic. The Company is working closely with the FDA on this matter.

The Company recently acquired the Axxent Electronic Brachytherapy System and Axxent Flexishield Mini as part of its acquisition of Xoft in December 2010. Since the initial commercial sale of the Axxent Flexishield Mini in August 2009, this accessory has been sold on a very limited basis. The Company is in the process of indentifying a replacement for this accessory, and does not anticipate a material impact on its revenues resulting from this recall. It is also evaluating possible indemnification claims against Xoft as well as insurance coverage.

Because of the preliminary nature of this complaint the Company is unable to evaluate the merits of the claims, however based upon its preliminary analysis, it plans to vigorously defend the law suit.

"Safe Harbor" Statement under the Private Securities Litigation Reform Act of 1995:

Certain statements contained in this Form 8-K constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve a number of known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of the Company to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Such factors include, but are not limited to, the Company's ability to defend itself in litigation matters, the Company's ability to identify a replacement for the Axxent Flexishield Mini and other risks detailed in the Company's filings with the Securities and Exchange Commission. The words "believe", "demonstrate", "intend", "expect", "estimate", "anticipate", "likely", and similar expressions identify forward-looking statements. Readers are cautioned not to place undue reliance on those forward-looking statements, which speak only as of the date the statement was made. The Company is under no obligation to provide any updates to any information contained in this Form 8-K.

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: March 8, 2011

iCAD, INC.

By: /s/ Darlene M. Deptula-Hicks
Name: Darlene M. Deptula-Hicks
Title: Executive Vice President of Finance and
Chief Financial Officer, Treasurer