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By Carol S. Remond

A Dow Jones Newswires Column

MedEnclosure LLC isn't your run-of-the-mill medical-device company.

The maker of the MedClose Vascular Closure System has no real office, one full-time executive who mostly works from his house outside Florida, where the company is located, and its largest shareholder is a consulting firm that owed the federal government \$188,919 in back taxes in February.

That firm, CTM Group Inc., is a corporate proxy for Paul Shabty, a founder and former executive of CPC of America Inc. (CPCF), MedEnclosure's parent company. Two now-defunct coffee businesses associated with Shabty have in the past also used MedEnclosure's address.

CPC of America had only \$39,511 in cash on its books as of March 31. But despite this lack of revenue, the company has been very generous with its consultants and executive.

According to filings with the Securities and Exchange Commission, CTM Group received payments totaling \$7.78 million between 2002 and 2006, while Rod A. Shipman, the company's current chief executive, received \$2.65 million in compensation during the same period. Biomed Research Inc., a consulting firm helping CPC of America develop and gain federal approvals for MedClose and a heart device now abandoned by the company, received \$1.8 million between 2004 and 2006. Another \$613,093 is left on Biomed Research's contract.

CPC of America has been attempting to develop a viable medical device for almost 10 years, netting a \$30.2 million deficit since its inception.

But recently the company's search for medical progress suffered a major setback when the Food and Drug Administration made public a warning letter questioning the safety of human trials conducted by MedEnclosure in the U.S. The letter shows that the FDA and the company, unbeknown to investors, have been at odds for a year.

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In the letter, which was sent to MedEnclosure and CPC of America in April, the FDA alleges that MedEnclosure misled researchers and the independent review board (IRB) overseeing its clinical investigation about the dangers attached to MedClose. The letter was also addressed to Michael Dayton, president of Biomed Research.

MedClose is a device designed to seal arterial punctures. The device uses Tisseel, a form of sealant made by Baxter International Inc. (BAX).

Unable To Gain Access

The warning letter, which was posted on the FDA Web site in May, describes the results of FDA inspections of MedEnclosure and Biomed Research. In both cases, an FDA inspector was unable to gain access to the facilities. In the letter, the FDA says it has determined that MedEnclosure violated regulations governing the proper conduct of clinical studies involving investigative devices.

"You failed to provide investigators with the information they need to conduct the investigation properly and failed to ensure that IRB review was obtained," the FDA letter reads.

Daniel Donahue, securities lawyer for CPC of America, said it's "an almost virtual company" whose sole focus is "the development and regulatory compliance of the MedClose device." He said that the fact that both CPC of America's CEO Shipman and Biomed Research's president Dayton work out of their houses isn't unusual.

CPC of America said in an email statement that it leases its office space from the CTM Group on a month-to-month basis for about \$1,000 per month. The company said it's "aware that other tenants, including businesses operated by CTM Group, are operating, and in the past have operated, from that location." CPC of America said that "given the present level of operations conducted by

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the employees of CPC, the company considers its present leased facilities to be more than adequate for its present needs and the lease terms to be fair." The company also said "the existence of other tenants at the facility has never interfered with CPC's use of the facility and CPC is not concerned by the presence of other tenants at the facility as long as those other tenants do not interfere with CPC's use of its leased space."

According to SEC filings, CTM Group's Shabty is a founder of CPC of America and served as its president, treasurer and chairman in 1996 and early 1997. Shabty was convicted in Southern District Court of Florida of one count of mail fraud in 1994 and was sentenced to one year of probation and a fine of \$500. Shabty's conviction was disclosed in CPC of America's SEC filings until March 1999. According to a March 15 SEC filing, the CTM Group owns 3.1 million shares of CPC of America, or 29.9%, currently worth about \$5.6 million.

The CTM Group and Shabty didn't return several telephone calls seeking comment. According to a federal tax lien notice dated Feb. 26, 2007, the firm owed \$188,919 in back taxes.

Larry Pilot, MedEnclosure's FDA counsel, said that contrary to the FDA's allegations, MedClose's human trials were conducted in a manner consistent with regulations.

'Significant Risk Device'

The FDA warning letter describes how after seeking and obtaining an Investigational Device Exemption (IDE) from the FDA, MedEnclosure "initiated a study outside the IDE regulations" and misled researchers into believing that MedClose didn't present a significant risk. Under IDE regulations, research is closely monitored because the product is labeled as a significant risk device.

The April FDA letter shows that the agency sent the company a letter reminding it that MedClose is a significant risk device in November 2006, a month after FDA inspectors failed to gain entry to MedEnclosure and Biomed

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Research. The letter also shows that the FDA unsuccessfully requested information about MedClose's research on three different occasions in 2006 before sending its investigator to check out MedEnclosure and Biomed Research.

MedEnclosure's FDA counsel Pilot told Dow Jones Newswires that the FDA's allegations are erroneous and that clinical trials were conducted under review by an independent review board which functioned as "a surrogate for the FDA."

The Independent Investigational Review Board Inc., an IRB based in Plantation, Fla., that was overseeing MedEnclosure's trials, had originally labeled MedClose as a non-significant risk device" in early 2006. It reversed itself later that year and reclassified the product as a significant risk device.

Kim Lerner, IIRB's chairman, declined to say what prompted the change in MedClose's classification. Referring questions to the FDA, Lerner said that the agency "is the ultimate determinant on how devices are classified."

The FDA declined to comment, citing privacy laws.

A spokesman for Baxter, the maker of Tisseel, said the company is currently evaluating its supply agreement with Biomed Research.

In its response to the warning letter, MedEnclosure told the FDA that it needs to receive "further information from you, specifically the documentation associated with and supporting the 'results' that you reference" before replying in full to the warning letter seeking access to facilities where MedClose devices are held as well as MedClose records. MedEnclosure's response doesn't stipulate what documents it's seeking.

Company Blames FDA

MedEnclosure in its letter to the FDA blames the federal agency for causing IIRB to reverse its original finding that MedClose wasn't a significant risk device. According to MedEnclosure, human trials have been suspended in the

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U.S., but they continue in Canada.

Biomed Research president Dayton declined to comment, citing a confidentiality agreement. Biomed Research's Web site looks to have been under construction since it went live in 2003. MedEnclosure's Web site is also under construction, although information about the company appears to have been posted on it in the past.

The name of the physician who led MedClose's human trials in the U.S. isn't known. Information available online shows that three researchers from the University of South Florida performed animal research with MedClose between 2002 and 2005.

Joel Strom, a USF doctor who tested MedClose on pigs earlier, said the device didn't work and was very cumbersome to use. "It needed a lot of development," Strom said.

CPC of America's troubles with the FDA had a dramatic impact on its stock price in November 2006 with the stock plummeting from a high of \$35.90 on Nov. 7 to about \$19 a week later. Of course at the time, investors didn't know what triggered the drop since none of the information disclosed in the FDA letter was public at the time.

Would be investors should remain wary of CPC of America's stock, which currently trades around \$18.40 a share, particularly given the company's recent dismissive answer to the FDA warning letter.

(Carol S. Remond is an award-winning columnist who won a Gerald Loeb Award in 2005 for best news service content with "Exposing Small-Cap fraud," a series of articles that described how three small companies unscrupulously pumped up their stocks.)

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