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ADM TRONICS UNLIMITED INC/DE

Form 8-K

September 06, 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

Date of Report (Date of earliest event reported): September 5, 2005

ADM TRONICS UNLIMITED, INC.
(Exact name of registrant as specified in its charter)

Delaware	000-17629	22-1896032
(State or other	(Commission	(IRS Employer
jurisdiction of	File Number)	Identification
incorporation)		No.)

224-S Pegasus Avenue, Northvale, New Jersey 07647
(Address of principal executive offices) (Zip Code)

(201) 767-6040
Registrant's Telephone Number

Check the appropriate box below if the Form 8-K 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.

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A majority-owned subsidiary of ADM Tronics Unlimited, Inc. (the "Company"), Ivivi Technologies, Inc. ("Ivivi"), has been notified that the Cleveland Clinic Florida, a not-for-profit multi-specialty medical group practice (the "Clinic"), has approved Ivivi's application to conduct a study relating to the use of Ivivi's non-invasive pulsed electromagnetic field technology ("PEMF") on patients with ischemic cardiomyopathy. The study, which will be the first controlled human clinical trial using Ivivi's PEMF for a cardiac indication, will have the following three objectives:

- o to establish the safety of PEMF in treatment of patients with ischemic cardiomyopathy (a heart condition resulting from decreased blood flow to the heart);
- o to evaluate the efficacy of PEMF on myocardial perfusion (the flow of blood through the heart), ventricular function (the function performance of the ventricle of the heart), clinical symptoms of angina (severe chest pains from the heart) and exercise tolerance after one and three-month treatments in patients with ischemic cardiomyopathy; and
- o to assess the sustainability of PEMF on ischemic myocardium (the decrease in blood flow to the heart) two months after completion of the therapy.

The Company expects that the human clinical trials will commence during its fiscal quarter ending December 31, 2005 and will be completed during 2006.

The primary endpoint of the study is improvement in regional myocardial perfusion and function. The secondary endpoint of the study is improvement in patient angina and exercise tolerance. The Company believes that the effects of PEMF on increasing blood flow and angiogenesis (the regeneration of new blood vessels) in chronically injured tissues, along with its non-invasive and non-pharmacological features, could provide potential as a therapeutic alternative for revascularization (the creation of new blood vessels), especially in patients for whom standard percutaneous or surgical revascularization is not suitable treatment.

The human clinical trials are a pre-requisite to the filing of applications to the U.S. Food and Drug Administration to market PEMF for the indications set forth above; however, there can be no assurance that the results of such trials will be positive or even if the results are positive, that the Company will receive the requisite FDA clearance or approval for such indications. Further, there can be no assurance that the trials will commence or be completed within the timeframes anticipated by the Company.

Except for historical information contained herein, the matters set forth in this report are "forward looking" statements (as defined in the Private Securities Litigation Reform Act of 1995). Although the Company believes the expectations reflected in such forward-looking statements are based upon reasonable assumptions, there can be no assurance that its expectations will be realized. Forward-looking statements involve certain risks and uncertainties that could cause actual results to differ materially from the Company's expectations. Factors that could contribute to such differences include those identified in the Company's Form 10-KSB for the fiscal year ended March 31, 2005 and those described from time to time in the Company's other filings with the Securities and Exchange Commission.

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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.

ADM Tronics Unlimited, Inc.
By: /s/ Andre' DiMino
Name: Andre' DiMino
Title: President

Dated: September 6, 2005