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): September 8, 2011

Marshall Edwards, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization) 000-50484 (Commission File Number) 51-0407811 (I.R.S. Employer Identification No.)

11975 El Camino Real, Suite 101, San Diego, California 92130 (Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (858) 792-6300

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)

Dere-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Dere-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events.

On September 8, 2011, Marshall Edwards, Inc. (the "Company") issued a press release announcing the initiation of a Phase I clinical trial of the Company's drug candidate ME-143. A copy of the press release is attached as Exhibit 99.1 to this Form 8-K and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) <u>Exhibits</u>.

Exhibit No.

99.1

Description

Press release, dated September 8, 2011, relating to the initiation of a Phase I clinical trial of the Company's drug candidate ME-143.

<u>Signature</u>

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.

MARSHALL EDWARDS, INC.

By: /s/ Daniel P. Gold

Daniel P. Gold President and Chief Executive Officer

Dated: September 9, 2011

Description

Press release, dated September 8, 2011, relating to the initiation of a Phase I clinical trial of the Company's drug candidate ME-143.

Contact:

Exhibit 99.1

Pete De Spain Sr. Director, Investor Relations & Corporate Communications (858) 792-3729 <u>pete.despain@marshalledwardsinc.com</u>

MARSHALL EDWARDS ANNOUNCES INITIATION OF PHASE I CLINICAL TRIAL OF LEAD ONCOLOGY DRUG CANDIDATE ME-143

San Diego – September 8, 2011 – Marshall Edwards, Inc. (Nasdaq: MSHL), an oncology company focused on the clinical development of novel therapeutics targeting cancer metabolism, announced today the initiation of a Phase I clinical trial of the Company's lead drug candidate ME-143 in patients with refractory solid tumors. The trial is being conducted in collaboration with the Sarah Cannon Research Institute in Nashville, Tennessee, following the approval of an Investigational New Drug (IND) application by the U.S. Food and Drug Administration (FDA) last month.

This Phase I dose-escalation trial will evaluate the safety and tolerability of intravenous ME-143 in patients with refractory solid tumors. In addition, the trial is designed to characterize the pharmacokinetic profile of intravenous ME-143 and describe any preliminary clinical anti-tumor activity observed. The open-label trial is expected to enroll up to 24 patients with final data collected by the second quarter of 2012.

"We are excited to begin treating patients with ME-143, a promising drug candidate that has demonstrated anti-tumor activity in pre-clinical studies," said Robert D. Mass, MD, Chief Medical Officer of Marshall Edwards. "Together with the Sarah Cannon Research Institute, we will be obtaining important information regarding dosing, safety and potential efficacy of intravenous ME-143 over the next several months, which will inform the design of our randomized Phase II clinical trials in combination with standard-of-care chemotherapy."

Additional information regarding this trial, entitled "Phase I Open Label Multicenter Dose Escalation Study of the Safety and Pharmacokinetics of ME-143 in Patients with Refractory Solid Tumors," including enrollment criteria and site information, is available on the U.S. National Institutes of Health (NIH) clinical trials database at www.clinicaltrials.gov.

About ME-143

ME-143 is the lead oncology drug candidate from Marshall Edwards' NADH oxidase inhibitor program. It was derived from a proprietary isoflavone technology platform that has generated a number of compounds with anti-proliferative activity against tumor cells in laboratory studies. In pre-clinical studies, ME-143 has demonstrated potent activity against a number of tumor cell lines, including breast, colorectal and ovarian. In addition to broad single-agent activity, ME-143 has also shown an ability to enhance the cytotoxic effects of chemotherapy in pre-clinical studies. Marshall Edwards owns exclusive worldwide rights to ME-143. ME-143 is an investigational drug and has not been approved by the FDA for commercial distribution in the U.S. or other countries.

About Marshall Edwards

Marshall Edwards, Inc. (Nasdaq: MSHL) is a San Diego-based oncology company focused on the clinical development of novel anti-cancer therapeutics. The Company's lead programs focus on two families of small molecules that result in the inhibition of tumor cell metabolism. The first and most advanced is a NADH oxidase inhibitor program that includes lead candidate ME-143. The second is a mitochondrial inhibitor program that includes lead candidate ME-143 in September 2011 and expects to submit an IND application for ME-344 by the first quarter of 2012. For more information, please visit www.marshalledwardsinc.com.

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Under U.S. law, a new drug cannot be marketed until it has been investigated in clinical trials and approved by the FDA as being safe and effective for the intended use. Statements included in this press release that are not historical in nature are "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. You should be aware that our actual results could differ materially from those contained in the forward-looking statements, which are based on management's current expectations and are subject to a number of risks and uncertainties, including, but not limited to, our failure to successfully commercialize our product candidates; costs and delays in the development and/or FDA approval, or the failure to obtain such approval, of our product candidates; uncertainties or differences in interpretation in clinical trial results; our inability to maintain or enter into, and the risks resulting from our dependence upon, collaboration or contractual arrangements necessary for the development, manufacture, commercialization, marketing, sales and distribution of any products; competitive factors; our inability to operate our business; our inability to operate our business without infringing the patents and proprietary rights of others; general economic conditions; the failure of any products to gain market acceptance; our inability to obtain any additional required financing; technological changes; government regulation; changes in industry practice; and one-time events. We do not intend to update any of these factors or to publicly announce the results of any revisions to these forward-looking statements.