## 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 6, 2012

# 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 Information.

On March 6, 2012, Marshall Edwards, Inc. (the "Company") issued a press release announcing its submission of an Investigational New Drug ("IND") application to the U.S. Food and Drug Administration to initiate clinical testing for oncology drug candidate ME-344, the Company's lead mitochondrial inhibitor. 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) Exhibits

 Exhibit
 Description

 99.1
 Press release, dated March 6, 2012, relating to the submission of an IND application for drug candidate ME-344.

#### Signature

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 Chief Executive Officer

Dated: March 7, 2012

#### Exhibit Index

Description

Exhibit <u>No.</u> 99.1 Press re

Press release, dated March 6, 2012, relating to the submission of an IND application for drug candidate ME-344.

# MARSHALL EDWARDS INC

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

#### MARSHALL EDWARDS SUBMITS INVESTIGATIONAL NEW DRUG APPLICATION FOR ONCOLOGY DRUG CANDIDATE ME-344

San Diego – March 6, 2012 – Marshall Edwards, Inc. (Nasdaq: MSHL), an oncology company focused on the clinical development of novel therapeutics targeting cancer metabolism, announced today that it has submitted an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) to initiate clinical testing for oncology drug candidate ME-344, the Company's lead mitochondrial inhibitor.

"I am extremely proud of our clinical operations and pre-clinical research teams in reaching this important milestone, less than seven months since our IND for ME-143 was approved by the FDA to begin clinical testing," said Daniel P. Gold, Ph.D., President and Chief Executive Officer of Marshall Edwards. "We are prepared to initiate a Phase I clinical trial of intravenous ME-344 in patients with solid refractory tumors immediately following approval by the FDA."

Marshall Edwards also announced that it has commenced dosing of the fourth cohort in its Phase I clinical trial of intravenous ME-143 in patients with solid refractory tumors. The Company expects to collect final safety and pharmacokinetic data from this trial by June.

"We continue to execute on the clinical development plan we set forth for our two most promising drug candidates," said Robert Mass, M.D., Chief Medical Officer of Marshall Edwards. "Now, as we await approval of our IND for ME-344 and near the completion of enrollment in our Phase I clinical trial of ME-143, we are diligently preparing for our Phase II trials."

Marshall Edwards owns exclusive worldwide rights to all of its drug candidates, including ME-143 and ME-344.

#### About ME-344

ME-344 is Marshall Edwards' lead mitochondrial inhibitor and an active metabolite of NV-128, a first-generation compound. Treatment of tumor cells with the Company's mitochondrial inhibitor compounds induces a rapid loss of cellular energy and leads to the inhibition of both mammalian target of rapamycin (mTOR1 and mTOR2) pathways. In April 2011, Ayesha Alvero, M.D., Department of Obstetrics, Gynecology and Reproductive Sciences at Yale University School of Medicine, presented data at the American Association for Cancer Research Annual Meeting from a pre-clinical study of NV-128 demonstrating its ability to induce mitochondrial instability, ultimately leading to cell death in otherwise chemotherapy-resistant ovarian cancer

stem cells. These results were later published in the August 2011 issue of *Molecular Cancer Therapeutics*. In additional pre-clinical studies, ME-344 has demonstrated far superior anti-tumor activity against a broad range of human cancer cell lines compared to NV-128.

#### **About Marshall Edwards**

Marshall Edwards, Inc. (Nasdaq: MSHL) is a San Diego-based oncology company focused on the clinical development of novel therapeutics targeting cancer metabolism. The Company's lead drug candidates, ME-143 and ME-344, have been shown to interact with specific enzyme targets resulting in inhibition of tumor cell metabolism, a function critical for cancer cell survival. Marshall Edwards initiated a Phase I clinical trial of intravenous ME-143 in patients with solid refractory tumors in September 2011 and expects to collect final safety and pharmacokinetic data from the trial by June 2012. The Company submitted an Investigational New Drug application for ME-344 in March 2012 and plans to initiate a Phase I clinical trial of intravenous ME-344 in patients with solid refractory tumors following approval by the FDA. For more information, please visit www.marshalledwardsinc.com.

#### ###

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.