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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): November 4, 2004

Marshall Edwards, Inc.

(Exact name of registrant as specified in its charter)

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

140 Wicks Road, North Ryde, NSW, 2113 Australia
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (011) 61 2 8877-6196

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 (*see* General Instruction A.2. below):

- 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))

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Item 8.01 Other Events.

On November 4, 2004, Marshall Edwards, Inc. (“the Registrant”) issued a press release announcing that the U.S. Food and Drug Administration has granted the investigational anti-cancer drug, phenoxodiol, Fast Track status for its intended use in patients with recurrent ovarian cancer. A copy of the Registrant’s press release is attached hereto as Exhibit 99 and is incorporated herein by reference.

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Item 9.01 Financial Statements and Exhibits.

(c) Exhibits.

Exhibit No.	Description
99	Press Release dated November 4, 2004 issued by the Registrant

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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/ David R Seaton

David R. Seaton
Chief Financial Officer
(Duly Authorized Officer and Principal Financial Officer)

Dated: November 8, 2004

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Index to Exhibits

Exhibit No.	Description
99	Press Release dated November 4, 2004 issued by the Registrant

Exhibit 99

November 4, 2004

FDA Grants Marshall Edwards, Inc. Fast-track Designation for Phenoxodiol for Recurrent Ovarian Cancer

(Washington, DC – November 4, 2004) Marshall Edwards, Inc., (Nasdaq: MSHL/LSE AIM:MSH) today announced that the U.S. Food and Drug Administration (FDA) has granted the investigational anti-cancer drug, phenoxodiol, Fast Track status for its intended use in patients with recurrent ovarian cancer.

In approving phenoxodiol for fast track status, the letter from FDA stated:

"We are granting fast track designation for the following reasons:

1. Recurrent ovarian cancer that is resistant or refractory to platins and taxanes is a life-threatening condition

2. Phenoxodiol intravenous demonstrates potential to address an unmet medical need by restoring chemo-sensitivity in resistant/refractory ovarian cancer."

The Fast Track application submitted to the FDA contained clinical data including tumor measurements based on radiographic examination. The data are from the current Phase Ib/IIa study where patients with recurrent ovarian and primary peritoneal cancers are receiving phenoxodiol (intravenous dosage form) in combination with paclitaxel in those patients where the cancer is refractory or resistant to taxanes, or in combination with cisplatin where the cancer is refractory or resistant to platinum-based drugs.

Under the FDA Modernization Act of 1997, designation as a Fast Track product means that the drug for the designated indication is eligible for accelerated marketing approval programs. More information on the FDA Fast Track program is available at http://www.fda.gov/cber/inside/fastrk.htm

"We are developing phenoxodiol for the treatment of a wide range of cancers, but for the purpose of this Fast Track Program, we are focusing on its use as a chemo-sensitizing agent in recurrent, late-stage ovarian cancer", said Dr. Graham Kelly, Executive Chairman of Marshall Edwards, Inc.

"Ovarian cancer is one of the most devastating forms of cancer, with half of the women diagnosed with it dying within five years," Dr. Kelly said. "The FDA's decision to accept phenoxodiol into its Fast Track Program reflects the dire need to provide help for women with this deadly disease once they become resistant to standard anti-cancer drugs."

Mr. Christopher Naughton, CEO of Marshall Edwards, Inc., said, "Our goal is to continue the development of phenoxodiol as rapidly as possible for the benefit of ovarian cancer patients. We

look forward to working closely with the FDA as we continue the development of phenoxodiol for this and all other indications under development."

About phenoxodiol

Phenoxodiol is an investigational product that regulates signal transduction pathways in cancer cells resulting in the break down of the intra-cellular proteins — XIAP (X-linked Inhibitor of Apoptosis Protein) and FLIP (Fas Ligand Inhibitory Protein) — which block the ability of the cancer cell to undergo apoptosis via the death receptor mechanism.1 While these proteins play a vital role in preventing unintentional cell death in healthy cells, they are over-expressed in many forms of cancer, as well as being associated with the development of resistance to anti-cancer drugs.2

Pre-clinical studies have shown that by targeting these anti-apoptotic proteins, phenoxodiol is able to promote death of ovarian cancer cells that are highly resistant to standard anti-cancer drugs, as well as being able to restore sensitivity in these cells to standard anti-cancer drugs such as taxanes. 3

Phenoxodiol works selectively on tumor cells because of its interaction with the tumor-specific NADH oxidase, which is restricted to cancer cells. Clinical trials to date have revealed no significant drug related adverse side effects.

Phenoxodiol is an investigational drug and, as such, is not approved for marketing in the United States.

About Ovarian Cancer

Ovarian cancer is the most lethal gynecological malignancy, and the fourth leading cause of cancer related death in women in the United States. The American Cancer Society reports that an estimated 25,580 new cases of ovarian cancer will be diagnosed each year in the United States and 16,090 deaths will occur. The lifetime probability of women developing ovarian cancer is 1 in 59. The high mortality is due mainly to the inability to detect early disease, with approximately 80 percent of patients being diagnosed in advanced-staged disease. However, even in those patients diagnosed with Stage I or Stage II disease, the five-year survival rate ranges from 60 to 90 percent depending on the degree of tumor differentiation. Despite treatment advances over the past decade, there has been no advance in overall survival. The reason for this is the high rate of relapse. Of patients who respond to first-line chemotherapy, less than 10 to 15 percent of these will remain in remission, and most relapsed cases are chemo-resistant. The failure of some ovarian cancers to respond to first-line chemotherapy and the development of resistance to multi-drug therapies represent the major hurdles to effective therapy of ovarian cancer.

About the current study

The current Phase Ib/IIa study is an open label, randomized study being conducted at two sites (Yale-New Haven Hospital, New Haven, CT, USA, and Royal Women's Hospital, Melbourne, VIC, Australia) and involving women with recurrent ovarian cancer that is either resistant or refractory to taxane- and/or platinum-based drugs. The definition of 'resistant' is disease

progression within six months of commencement of drug therapy, and ‘refractory’ is disease progression while undergoing drug therapy.

Patients are being randomized to one of three treatment groups – (i) phenoxodiol + cisplatin, (ii) phenoxodiol + paclitaxel, and (iii) paclitaxel only, converting to phenoxodiol + paclitaxel after disease progression has been demonstrated. Phenoxodiol is administered by intravenous infusion on two consecutive days per week and the second drug administered intravenously immediately following the second phenoxodiol administration. Treatment is weekly on a continuous basis until either disease progression or complete response as determined by the absence of detectable disease. There are 20 subjects per treatment group. Phenoxodiol is being administered at a dosage of 3 mg/kg; the dosages of paclitaxel and cisplatin are standard but adjustable to ensure that toxicity is no greater than Grade 1,4 being the least toxic grade.

About Novogen Limited and Marshall Edwards, Inc.

Phenoxodiol has been developed by Novogen Limited, an Australian biopharmaceutical company that is specializing in the development of therapeutics based on the isoflavonoid ring structure. Novogen, based in Sydney, Australia, is developing a range of therapeutics across the fields of oncology, cardiovascular disease and inflammatory diseases.

Marshall Edwards, Inc. has licensed from Novogen Limited. the rights to bring phenoxodiol to the global market.

More information on phenoxodiol and on the Novogen group of companies can be found at www.marshalledwardsinc.com and www.novogen.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 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 protect our patents or proprietary rights and obtain necessary rights to third party patents and intellectual property 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.

# # #

1. Kamsteeg M et al., 2003. Phenoxodiol – an isoflavone analog – induces apoptosis in chemoresistant ovarian cancer cells. Oncogene 22:2611.

2. Cheng JQ et al., 2002. Drug Resist Update 5, 131.

3. Sapi E et al., 2004. Resistance of ovarian carcinoma cells to (Taxotere) docetaxel is XIAP dependent and reversible by phenoxodiol. Oncology Research (In Press)

4. National Cancer Institute Common Toxicity Criteria (CTC version 2)