
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): January 26, 2005

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):

- 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))
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Item 8.01 Other Events.

On January 26, 2005, 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 hormone-refractory prostate 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.

<u>Exhibit No.</u>	<u>Description</u>
99	Press Release dated January 26, 2005 issued by the Registrant

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: January 27, 2005

Index to Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99	Press Release dated January 26, 2005 issued by the Registrant

Marshall Edwards, Inc.**FDA grants fast track designation for phenoxodiol in oral dosage form for Prostate Cancer**

(Washington, DC □ January 26, 2005) 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 hormone-refractory prostate cancer (HRPC).

The successful application for fast track status was based on data derived in a Phase Ib/IIa study, conducted in two Australian hospitals, in which men with late stage HRPC were treated with the oral dosage form of phenoxodiol as a monotherapy.

The preliminary outcome of this study was presented to the American Association of Cancer Research (AACR) conference on Basic, Translational and Clinical Advances in Prostate Cancer in November 2004 (for the press release and study findings, see <http://tinyurl.com/5zeck>). In the study, dosages of phenoxodiol ranging from 200mg to 400mg 8-hourly had a significant effect on disease progression, as evidenced by falls in PSA levels, and suppression of those levels for a period of at least 6 months. Most of the patients remain on phenoxodiol therapy for periods up to 18 months without evidence of disease progression.

Of particular relevance to the FDA is that prostatic adenocarcinoma that is refractory to both hormonal therapy and cytotoxic chemotherapy is associated with severe morbidity and a life expectancy of less than 1 year, and as such meets the criteria for a serious and life-threatening disease.

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>

□ This decision of the FDA underpins our confidence in phenoxodiol being an effective therapy for late-stage prostate cancer. The next step is to take phenoxodiol into a pivotal study where we will test its ability to halt disease progression in men with prostate cancer who have failed the standard treatment of hormone therapy and docetaxel chemotherapy, □ said Dr. Graham Kelly, Executive Chairman of Marshall Edwards, Inc.

Mr. Christopher Naughton, CEO of Marshall Edwards, Inc., said, □ This decision represents a significant endorsement of the potential of phenoxodiol, coming just 2 months after the FDA granted fast track status for phenoxodiol for late-stage ovarian cancer. The Company now has two opportunities to pursue for the continuing development of phenoxodiol for the benefit of both prostate cancer and ovarian cancer patients. □

Phenoxodiol in intravenous form was granted fast track status by the FDA in November 2004 for its intended use in patients with recurrent ovarian cancer.

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) that 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

Phenoxodiol works selectively on tumor cells, thought to be due to its interaction with the enzyme, 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 Prostate Cancer

Prostate cancer is one of the most common types of cancer among men in Western countries. The American Cancer Society estimates there will be 232,000 new cases of prostate cancer in the United States in 2005 and that about 30,350 men will die of this disease. Prostate cancer is strongly associated with the male sex hormone, testosterone, and most early cases of prostate cancer respond for some time to hormonal therapy that blocks the ability of testosterone to stimulate the cancer. However, the majority of cases of prostate cancer eventually become independent of testosterone, at which time they are known as hormone-refractory prostate cancer (HRPC). The cancer at this stage typically is metastatic, with a patient survival time typically in the range of 1 to 2 years.

The FDA recently approved the combination of docetaxel (Taxotere®) and prednisone for the treatment of HRPC. That combination produced an overall increase in survival of 10 weeks (from an average of 16.4 months to an average of 18.9 months).

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 diphenolic 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.