
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): August 21, 2007

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.)

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 7.01 Regulation FD Disclosure

On August 21, 2007, Marshall Edwards, Inc. (the "Company") commenced mailing a newsletter (the "Newsletter") to its stockholders updating stockholders on the status of the Company's Phase III clinical trial known as "OVATURE".

The information contained in this report, including the Newsletter attached as Exhibit 99.1 hereto and incorporated by reference herein, is being furnished pursuant to General Instruction B of Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Newsletter of Marshall Edwards, Inc.

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: August 21, 2007

Index to Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Newsletter of Marshall Edwards, Inc.

OVATURE Phase III trial Update



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 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.

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Ovarian cancer is the deadliest of the gynecologic cancers and the fifth leading cause of cancer death among U.S. women.^{1,2}



5.2%

Ovarian cancer occurs in about 1 out of 69 women.

In the United States, approximately 22,000 women are diagnosed with the disease each year. About 15,000 women in the United States die from ovarian cancer each year, and, currently, 55 percent of the women diagnosed with ovarian cancer die from it within five years. Among black women, only 40 percent survive five years or more. Ovarian cancer frequently becomes resistant to standard chemotherapy drugs, which is known as "chemoresistance". Chemoresistance makes it difficult to manage and treat ovarian cancer successfully.

Phenoxodiol is an investigational drug that is being developed for the treatment of ovarian cancer. Laboratory studies using cancer cells from patients with ovarian cancer have shown that phenoxodiol can restore sensitivity (i.e. overcome chemoresistance) of cancer cells to standard chemotherapy drugs. Accordingly, Marshall Edwards Inc. is now conducting the OVArian Tumor REsponse (OVATURE) study with hundreds of patients planned to take part to investigate the safety and efficacy of oral phenoxodiol in combination with carboplatin for the treatment of recurrent ovarian cancer.

The OVATURE study

470 patients
60 centres

OVATURE

phenoxodiol
+carboplatin

placebo
+carboplatin

The OVATURE study is a Phase III clinical trial investigating the safety and efficacy of oral phenoxodiol in combination with a weekly dose of carboplatin in women with late-stage recurrent ovarian cancer.

Patients with progressive or recurrent ovarian cancer that has become resistant or refractory to the second line platinum therapy (cisplatin or carboplatin) are eligible to participate. This is an exciting trial as it provides the opportunity to investigate the efficacy and safety of phenoxodiol as a platinum chemosensitizing agent for this indication, as well as to explore further the use of a weekly dose of carboplatin for these patients.

This Phase III study will recruit 470 patients at approximately 30 centers in the United States and an additional 30 hospitals throughout Europe and Australia. In the OVATURE trial, patients are randomly divided into two groups and receive either oral phenoxodiol in combination with carboplatin or carboplatin with an inactive control capsule (placebo). Neither patient nor doctor will know which group each patient is in.

Instead of receiving the customary carboplatin treatment of one intravenous infusion every three weeks, all patients will receive carboplatin on a weekly basis. This is based on the observation from laboratory studies that when given with phenoxodiol, carboplatin should be given as frequently as possible, and also because some studies have shown that patients whose tumors have become resistant to the three-week standard regimen of carboplatin may respond to the weekly administration of the drug.

An important aspect of the study plan is that it is designed to enable an interim analysis of results after enrollment has been completed and at least 95 patients have progressed. The preliminary analysis will compare the duration of progression free survival (PFS), the time during which the patients' tumors shrink or fail to grow larger, in response to treatment in the phenoxodiol plus carboplatin group compared to the carboplatin plus placebo group.



The regulatory issues

Government approval is required in most countries before a new drug such as phenoxodiol can be commercially distributed for use in patients. Approval for marketing is based on a rigorous assessment of the safety and efficacy of the drug for its chosen indication, in this case, advanced platinum-resistant ovarian cancer. Each country has its own regulatory body for this purpose, and in the United States, the Food and Drug Administration (FDA) is charged with this responsibility. Since the pharmaceutical markets in the US represent approximately half of the total pharmaceutical world market, the Company has decided to seek registration in the US as the first step towards commercialization of phenoxodiol. To this end, extensive discussions were held with the FDA to ensure the phenoxodiol development program would meet the regulatory requirements. A significant step was to apply for Fast Track status for phenoxodiol for the treatment of advanced chemo-resistant ovarian cancer.

The Fast Track programs of the FDA are designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. Strong scientific evidence including clinical data demonstrating the potential of the drug must be provided to the FDA before a drug can be designated for the Fast Track development program.

On the basis of data obtained previously in Phase II clinical studies of phenoxodiol, the FDA granted Fast Track designation for development of phenoxodiol for treating refractory ovarian cancer.

The Phase II trials produced encouraging results: In patients with advanced disease resistant or refractory to platinum (cisplatin or carboplatin) or taxane, stabilization or regression was observed in 71% of subjects administered phenoxodiol in combination with platinum and 74% of subjects administered phenoxodiol in combination with taxane, without any significant side effects attributable to phenoxodiol. In one of the taxane-resistant patients administered phenoxodiol in combination with taxane, a complete response was observed, with no detectable tumor after treatment. All these findings were verified by independent radiological analysis performed by an expert not associated with the Company or the Phase II study.

The credibility of the data was enhanced by the performance of a subset analysis of the platinum-resistant patients to break out the data according to time since last platinum therapy, to confirm the effect was phenoxodiol-dependent and not a reflection of spontaneous return to sensitivity, which can occur in patients who have been off the platinum therapy for more than 6 months. This analysis confirmed that among patients who were within 6 months of last treatment, and therefore still solidly resistant, 80% demonstrated tumor stabilization or shrinkage.

The award of Fast Track status ensured a more rapid review by the FDA of the Phase III OVATURE study protocol and provided an opportunity for more frequent discussions with the FDA. For example, Marshall Edwards Inc. recently met with the FDA to discuss preclinical and manufacturing information to be provided in the marketing application for phenoxodiol.

In addition, the OVATURE study protocol was reviewed by the FDA under the Special Protocol Assessment process.

These milestones not only confirmed the view that a Phase III program in platinum-resistant ovarian cancer was a justified next step in the phenoxodiol drug development program, but also provided a more certain regulatory pathway to requesting accelerated marketing approval for phenoxodiol. A request for accelerated approval for phenoxodiol will be based on the interim analysis after enrollment completion and progression of at least 95 patients demonstrating a significant improvement in PFS of phenoxodiol-treated patients.

Site approvals and logistics

Once FDA agreement had been achieved on the Phase III OVATURE study design, the next regulatory step has been to obtain ethical approval to conduct the study at each of the 60 sites. This involved submission of the protocol and patient informed consent forms for review by an Institutional Review Board (IRB) or Institutional Ethics Committee (IEC) acting for each site. For sites in Europe, an additional submission was required to obtain government approval to conduct the study, as had been obtained in the US via the FDA. Once ethics approvals were obtained, usually requiring a review period of 6-8 weeks, contract negotiations ensued to ensure both the Company and the institutions governing each site have a binding agreement for their respective responsibilities: for the institutions, to maintain accurate records and standards of care and for the Company, to make agreed payments and supply the drug.

Contract research organization

Since the OVATURE study involves an international network of hospitals and oncology clinics, it has been important to ensure that each site complies with good clinical practice (GCP) and are properly qualified to undertake the study, that the personnel fully understand the protocol and the data collection methods, and that international and regional regulatory requirements for the conduct of clinical trials are observed. To this end, the Company selected Covance as the trial manager, providing both advisory and logistic support to identify the 60 international site locations, manage contract negotiations and monitor the conduct of the study at each site. Covance is a well regarded international Contract Research Organization (CRO), and its wide reach over international jurisdictions has ensured the study integrity is maintained at all times. Regular meetings are held between the Company's clinical staff and various coordinators in the Covance organization.

To ensure strict protocol compliance and proper training of doctors and their clinical staff, Investigator Meetings have been held separately for Australian, European and US site personnel. The first meeting was held in Sydney for Australian site staff, followed by meetings in Barcelona for EU/UK sites and Miami for US sites.



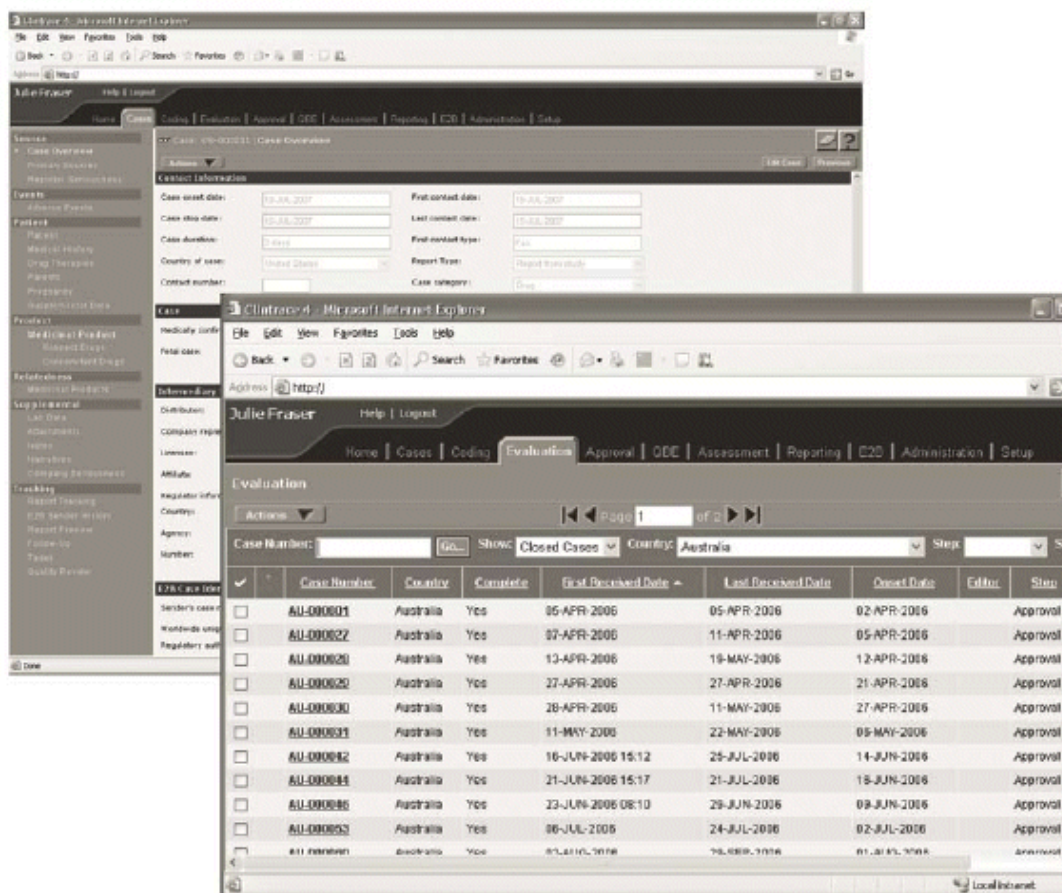
Drug supply

In parallel with the selection, qualification and contractual issues with sites, the Company faced a considerable challenge in ensuring that sufficient amounts of phenoxodiol would be available to service the needs of the study, manufactured to appropriate standards of quality control and with approved packaging and distribution arrangements in place. Scale-up of manufacturing has been addressed by prior collaboration with two contract manufacturing facilities, primarily one in Switzerland and the other in the US.

Packaging and labeling were required to ensure that the doctors, their staff and their patients, as well as all Company personnel, had no way of knowing whether patients were on active or control treatments. This "double blind" approach is essential to avoid bias in interpretation of patient progress and disease progression. Drug is labeled and distributed to trial sites by a central authority managed by Covance, where computer-generated randomization takes place to ensure a truly random distribution of patients to active and control groups irrespective of their disease state.



Caution: New Drug – Limited by US law to investigational use.



Data management

The study outcomes with respect to both safety and efficacy will only be of any use in regulatory submissions, if the data are collected in an approved manner and in a form which lends itself to appropriate statistical analysis. This involves the collection, co-ordination, validation and archiving of data for all global sites with the enforcement of data standards according to international conventions ensuring compliance with International Good Clinical Practice (Worldwide), as well as FDA (USA), EMEA (Europe) and TGA (Australia) requirements.

Data collected must include patient-related data (demographics, medical history, clinical status at entry, disease status at various time points throughout study, treatment compliance, endpoint data, adverse events, concomitant medications, etc.) and protocol-related data (schedule of examinations and tests, treatment data, etc.). In short, the data management objective is to ensure data consistency and validity so that patients' outcomes can be evaluated and compared to one another, and a meaningful study report can be written to support the phenoxodiol marketing application.

Financing the program

The cost of the OVATURE study will be in excess of US\$25 million. Although this is a modest amount by pharmaceutical industry standards, it is a large expense for Marshall Edwards Inc.

The Company had around US\$20 million in cash available at the start of the study and the ability to access a further US\$15 million from a 'stand-by equity facility' it had negotiated during 2006.

In August 2007, the 'stand-by equity facility' was cancelled and replaced by US\$16.4 million in cash received in return for equity, raised from a selected number of institutional investors.

The OVATURE study is a major commitment for the Company, and further studies with phenoxodiol and the development of other drugs are planned.

The potential benefits to the Company, its shareholders and ovarian cancer patients from a successful OVATURE trial are expected to be considerable.

Phenoxodiol marketing strategy

Subject to a positive outcome of the OVATURE study, the Company proposes to out-license the sales and marketing of phenoxodiol to a larger and established pharmaceutical company. JPMorgan of New York has been commissioned to assess the timing and advise the Company on this licensing program.

The expected financial returns to Marshall Edwards Inc. from the likely milestone payments and sales royalties are anticipated to bring benefits in the longer term to all shareholders and patients, and facilitate the development of more drugs targeted to specific cancer treatments.



Program management



Professor Alan J Husband PhD, DSc, FASM

Professor Husband is Group Director of Research for Marshall Edwards, Inc. and the Novogen group of companies, as well as an Executive Director on the Board of Novogen. In this position, he is responsible for the day to day management of the OVATURE program including both clinical and preclinical aspects of the phenoxodiol drug development program. Professor Husband has over 30 years experience in basic and applied medical research and research management. In addition to his role with the Company, he holds a fractional professorial appointment at the University of Sydney where he has achieved international recognition for contributions in immunology and pathology, publishing over 200 scientific papers as well as several books. These basic research activities coupled with extensive experience in commercialisation of new technologies in the biotechnology industry prior to joining the Company, underpin his present position with the Company, a position he has held since 1996. During this time, Professor Husband has managed the Company's drug discovery and clinical trial programs.

Professor Husband leads a talented team of scientists, and medical, clinical and regulatory professionals within the Company. The team has enabled the establishment of an active cutting edge research program to understand the chemistry and mechanisms of action of phenoxodiol and its related analogues in biological systems, the application of these to treatment of a range of human cancers in clinical studies, culminating in the design and implementation of the Phase III OVATURE Trial.

The team is supported by experts in a variety of fields, with key collaborators in cancer biology and cancer medicine in top flight institutions around the world. The Ovature program is ably assisted by a Steering Committee of experts in ovarian cancer and by high profile principal investigators at the various trial sites, such as Professors Tom Rutherford and Gil Mor at Yale University, Dr David O'Malley of the Ohio State University Medical Center and Dr John Schorge at University of Texas Southwestern Medical Center in the US, Professor Hani Gabra of the Imperial College London, in the UK, Professor Ignace Vergote, University Hospital Leuven, in Belgium, Dr Jose M. Del Campo of the Hospital Vall d'Hebron in Barcelona, Spain, Prof. Marek Spaczynski of the Polozniczy Szpital Kliniczny in Poland, and Professors Michael Quinn and Michael Friedlander respectively from Royal Womens Hospital in Melbourne and Prince of Wales Hospital in Sydney, Australia.

References

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2. U.S. Cancer Statistics Working Group. United States Cancer Statistics: 1999-2003 Incidence and Mortality Web-based Report. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute; 2007. Available at: www.cdc.gov/uscs.