



**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**FORM 10-K**

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the period ended June 30, 2005

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from \_\_\_ to \_\_\_.

Commission File Number: 000-50484

**Marshall Edwards, Inc.**

(Exact name of registrant as specified in its charter)

**DELAWARE**  
(State or other jurisdiction of  
incorporation or organization)

**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**

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on which Registered
None	None

Securities registered pursuant to Section 12(g) of the Act:

**Common Stock, \$0.00000002 par value**  
**Warrants to Purchase Common Stock**  
(Title of Class)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (Section 229.405 of this chapter) is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. Yes  No

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes  No

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

The aggregate market value of the voting common equity held by non-affiliates of the registrant was approximately \$66.6 million based on the closing price of the registrant's Common Stock as reported on the NASDAQ National Market on December 31, 2004.

As of July 31, 2005, the number of shares outstanding of the issuer's common stock, \$0.00000002 par value, was 56,938,000.

**Documents Incorporated by Reference**

Portions of this registrant's definitive proxy statement for its 2005 annual meeting to be filed with the SEC no later than 120 days after the end of the fiscal year are incorporated by reference in Part III of this Annual Report on Form 10-K.

MARSHALL EDWARDS, INC.  
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## Cautionary Statement about Forward-Looking Statements

This Annual Report on Form 10-K includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Security Exchange Act of 1934, as amended. All statements other than statements of historical facts contained in this Annual Report, including statements regarding the future financial position, business strategy and plans and objectives of management for future operations, are forward-looking statements. The words “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “should,” “plan,” “expect,” and similar expressions, as they relate to the Company, are intended to identify forward-looking statements. The Company has based these forward-looking statements largely on current expectations and projections about future events and financial trends that it believes may affect financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, without limitation, those described in “Risk Factors” and elsewhere in this Form 10-K, including, among other things:

- our inability to obtain any additional required financing or financing available to us on acceptable terms;
- our failure to successfully commercialize our product candidates;
- costs and delays in the development and/or receipt of FDA or other required governmental approvals, or the failure to obtain such approvals, for 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;
- continued cooperation and support of Novogen, our parent company;
- competition and 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;
- technological changes;
- government regulation generally and the receipt of the regulatory approvals;
- changes in industry practice; and
- one-time events.

These risks are not exhaustive. Other sections of this Annual Report on Form 10-K may include additional factors which could adversely impact our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time and it is not possible for us to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

You should not rely upon forward looking statements as predictions of future events. We cannot assure you that the events and circumstances reflected in the forward looking statements will be achieved or occur. Although we believe that the expectations reflected in the forward looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements.

## **PART I**

### **Item 1. Business**

#### **Overview of Our Business**

We are a developmental stage pharmaceutical company, incorporated on December 1, 2000 as a wholly-owned subsidiary of Novogen Limited, an Australian Company. We commenced operation in May 2002 and our business purpose is the development and commercialization of drugs for the treatment of cancer. We are presently engaged in the clinical development and commercialization of a drug candidate called phenoxodiol, which we believe may have broad application against a wide range of cancers. Phenoxodiol appears to target a number of key components involved in cancer cell survival and proliferation based on the emerging field of signal transduction regulation, with little or no effect on normal cells detected in pre-clinical testing.

Novogen Limited, an Australian company publicly traded on the Australian Stock Exchange and the Nasdaq National Market, owns approximately 86.9% of our outstanding common stock. We were incorporated as a separate subsidiary of Novogen to focus on the development and commercialization of drugs for the treatment of cancer. In contrast, Novogen has a broader business focus which, in addition to the business conducted by us, includes a consumer health division that focuses on the development of a range of non-prescription products for the health needs of both men and women and a pharmaceutical division which focuses on the development of prescription drugs. We believe that Novogen's corporate structure, with us functioning as a corporate entity separate from Novogen's other lines of business, has provided us with:

- greater strategic focus on the development of phenoxodiol and other cancer drugs with dedicated financial resources;
- direct access to the capital markets and investors who focus on the development of cancer drugs and the ability to raise debt or equity should additional funding be required in the future; and
- the ability to offer equity interests, co-development rights and other arrangements to strategic partners who focus on the market for the treatment and prevention of cancer.

During fiscal year 2005, we made significant progress in the clinical development of phenoxodiol including:

- In May 2005, we announced preliminary results from the combination therapy trial for patients with late stage refractory ovarian cancer being conducted at Yale New Haven Hospital in the United States and the Royal Women's Hospital in Australia. These preliminary results revealed that 33% (12/36) of patients who were on combination therapy that included phenoxodiol experienced a complete or partial response.
- In January 2005, we announced that we had appointed a global research organization to manage our planned "pivotal" Phase IIb multinational ovarian cancer study. The trial will be known as the Ovature trial. We are discussing trial design with the U.S. Food and Drug Administration (FDA) to develop a trial protocol that is intended to support marketing approval of phenoxodiol, including the number of treatment arms to be included and the number of patients required to be tested in each arm of the trial.

- In November 2004, we announced that the FDA granted phenoxodiol Fast Track status for its intended use as a chemo-sensitizing agent in patients with recurrent late stage ovarian cancer. In January 2005, we announced that the FDA granted phenoxodiol Fast Track status for its intended use in patients with hormone-refractory prostate cancer. Under the FDA Modernization Act of 1997, designation as a Fast Track product means that phenoxodiol is eligible for certain programs for accelerated marketing approval.

## Scientific Overview

Phenoxodiol belongs to a class of drugs that we refer to as Multiple Signal Transduction Regulators (“MSTRs”).

Signal transduction refers to the means by which cells respond to chemical signals that come from within the cell itself, from neighboring cells, and from elsewhere in the body. These signals regulate such vital functions as the growth and survival of the cell. We believe that malfunctions in key components of the signal transduction process (whereby a series of chemical signals within a cell leads to the expression of a particular function) are fundamental to neoplastic diseases such as cancer, where cells respond abnormally to normal levels of signals, typically by over-responding to them with increased cell growth and survival.

We believe that identifying malfunctions in the signal transduction process and then designing drugs to block or correct them has become a basis for the development of the next generation of anti-cancer drugs. These drugs have become known as signal transduction inhibitors. These drugs are being designed to target a specific signaling pathway which typically is over-active in a tumor cell, and by blocking its progression, so to prevent or reduce the ability of the tumor cell to divide or to survive. We believe that signal transduction inhibitors, while displaying anti-tumor activity against a small number of different types of cancer, generally have failed to provide more than modest prolongation of survival of cancer patients. We believe this is because most human cancers involve errors of multiple signaling pathways, and inhibition of a single pathway by any one drug alone cannot reasonably be expected to provide more than a temporary halt to cancer progression.

We believe that phenoxodiol increases the potency of signal transduction inhibitors by targeting multiple signaling pathways, and in particular, those pathways vital to the survival of most, if not all, human cancer cells. In the term MSTR, “multiple” refers to the fact that more than one signaling pathway is targeted by the drug, and “regulator” refers to the fact that while the drug predominantly inhibits errant ‘pro-survival’ signaling pathways, it conversely can also activate ‘pro-death’ signaling pathways.

We believe that phenoxodiol is able to exert a multiplicity of effects, including on both ‘pro-survival’ and ‘pro-death’ signaling systems, as a result of its primary target on the tumor cell being a protein whose function in the tumor cell is so fundamental to cell biochemistry that to shut it down produces a broad range of biochemical consequences.

The potential explanation for this effect on the fundamental biochemistry of tumor cells was provided by a discovery of a research team at Purdue University in Indiana. This team has a long-standing research interest in a family of proteins at the cell surface that are involved in the transport of waste electrons, particularly hydrogen ions, across the cell membrane. This function is so fundamental to normal cell function and viability, that any loss of function of this electron pump will disrupt a wide range of biochemical processes as a consequence of elevated waste hydrogen levels. One of the key components of this electron pump mechanism is a protein known as NADH oxidase (abbreviated as NOX). This protein is situated on the outside of the cell membrane of all living matter, and regulates the flow of waste hydrogen across the cell membrane. The Purdue University studies have now shown that all forms of human cancer express a variant form of the constitutive (or normal) NOX, known as tumor-specific NADH oxidase (abbreviated as tNOX). Based on Purdue University studies, we believe

that tNOX is a primary molecular target for phenoxodiol. Phenoxodiol appears to specifically block the action of tNOX, with the resulting inhibition of H<sup>+</sup> efflux from the cell leading to extensive disruption to signaling pathways and to eventual inhibition of cell proliferation and activation of apoptosis, the process of programmed cell death by which a cell dies naturally. The Purdue studies also show that phenoxodiol has no effect on the normal form of NOX, providing an explanation for how phenoxodiol can be so selective in its action, with its cytotoxic effects being limited to cancer cells.

Purdue University studies recently have also shown that one of the important consequences of a rise in intra-cell levels of waste hydrogen ions is inhibition of an enzyme known as sphingosine kinase. This enzyme is responsible for the production of a compound within cells known as sphingosine-1-phosphate (abbreviated as S-1-P). S-1-P plays an important role in all cells in activating a wide range of 'pro survival' signal transduction mechanisms, including the production of proteins known as 'anti-apoptosis proteins' whose task it is to block the apoptosis process. S-1-P levels have been reported to be elevated in tumor cells, and in particular in tumor cells that have become resistant to standard chemotherapy drugs.

This finding is relevant because of results from laboratory studies at Yale University that have revealed that the killing effect of phenoxodiol of cancer cells occurs through the loss of the ability of the tumor cell to manufacture anti-apoptosis proteins such as XIAP and c-FLIP. Collectively, the Yale University and Purdue University results provide a rational mechanism of action of phenoxodiol starting with the inhibition of tNOX, leading in turn to the loss of S-1-P activity, leading eventually to the loss of anti-apoptosis proteins.

Recent laboratory studies conducted by Novogen and Yale University have confirmed that this chain of biochemical events following exposure of tumor cells to phenoxodiol also provides an explanation for why phenoxodiol is able to reverse resistance that builds up in tumor cells to standard anti-cancer drugs such as cisplatin, gemcitabine and taxanes.

In one aspect of this effect, phenoxodiol appears to restore sensitivity to these drugs in cells such as ovarian cancer cells that have acquired resistance to such drugs. In another aspect, pretreatment of tumor cells with phenoxodiol considerably increases the sensitivity of virgin tumor cells to the cytotoxic effects of standard chemotoxic drugs. Both of these effects are achieved without increasing the toxicity of the standard chemotoxic drugs to non tumor-cells.

### **Overall Clinical Development Strategy**

Based on the early clinical and pre-clinical work conducted on phenoxodiol, we believe that based on its mode of action, phenoxodiol has the potential to become a treatment option for a wide range of human cancers, and to be employed at various stages of cancer development ranging from early-stage cancer through to late-stage cancer.

The immediate priority, is to focus on those therapeutic indications that will expedite drug marketing approval of phenoxodiol by regulatory bodies. To this end, we will continue our work in late-stage chemo-resistant, ovarian and prostate cancers. In chemo-resistant cancers we hope to show that phenoxodiol will provide in humans what it has demonstrated in the laboratory and in animal models, which is the restoration of chemo-sensitivity to standard chemotoxic agents. In this way, phenoxodiol will be used to condition the tumor cells to the more destructive effects of drugs such as cisplatin, gemcitabine and taxanes with the combined effects of all drugs providing a potent force able to attack well established and extensive cancer disease. In January 2005, we announced that researchers from Yale University School of Medicine found that phenoxodiol considerably enhances the ability of the drug docetaxel to kill human ovarian cancer cells in the laboratory. In addition, in May 2005, we announced preliminary results from the combination therapy trial for patients with late stage refractory ovarian cancer being conducted at Yale New Haven Hospital in the United States and the Royal Women's Hospital in Australia. These preliminary results revealed that 33% (12/36) of patients who were on combination therapy that included phenoxodiol experienced a complete or partial response.

In due course, it is possible that other forms of cancer, generally regarded as unresponsive to standard drugs, will be added to this program in order to maximize the opportunity for treating chemo-resistant cancers.

Phenoxodiol is also being developed for use in earlier-stage cancers. This is the basis of the clinical program involving the use of phenoxodiol as a monotherapy in squamous cell carcinoma (SCC) of the cervix, vagina and vulva. This area also is being targeted as a matter of priority. The commercial attraction of this area is that cervical cancer is a form of cancer for which early diagnosis is commonly available, and for which a non-invasive, non-surgical drug option might be an attractive therapeutic option.

### **History of Phenoxodiol Development**

In 1995, the phenoxodiol structure was suggested as a potential metabolite of daidzein, a naturally occurring isoflavone. Isoflavones are a family of structurally-related compounds found in foods such as legumes, red clover, lentils and chickpeas. When eaten, isoflavones are converted in the body into a wide range of compounds known as isoflavone metabolites.

Commencing in 1995, Novogen scientists synthesized a number of the naturally-occurring isoflavone metabolites and screened them for anti-cancer action. The rationale for this was the purported beneficial role of dietary isoflavones in cancer prevention. Phenoxodiol was found to be the most potent anti-cancer compound among the compounds tested. It was cytostatic and cytotoxic against a wide range of human cancer cells, but without toxicity against non-tumor cells. *In vivo* (in animals) studies in laboratory animals subsequently showed that phenoxodiol administered either orally or systemically was adequately bio-available (absorbed into the body in useful form) and significantly retarded tumor development, in particular in athymic mice bearing xenografts of human prostate cancer. Such anticancer effects in animals were achieved without evidence of toxicity, and thus phenoxodiol was selected for development as a human anti-cancer drug.

Subsequent pre-clinical studies identified a range of molecular targets of phenoxodiol within human cancer cells, prompting us to classify the drug as a Multiple Signal Transduction Regulator.

The broad anti-cancer action of phenoxodiol against an extensive library of different human cancer cell lines such as prostate, breast, ovarian, lung and cervical cancer, mesothelioma, melanoma, glioma and rhabdomyosarcoma, suggested potential clinical application against a wide range of types of human cancer. Further pre-clinical studies showed that phenoxodiol has a number of indirect anti-cancer effects including a potent ability as an anti-androgen, which is a process that reduces the biological impact of male sex hormones like testosterone, and an ability to induce apoptosis of hyperplastic prostate smooth muscle cells, the main type of stromal cells found in the prostate gland, that suggested prostate cancer as a particularly suitable clinical target, leading to this form of cancer being identified early as a prime potential clinical target for the drug. However, with a view to allowing further time to identify those cancer types that are the most sensitive types of cancer to phenoxodiol, the strategy adopted was to conduct Phase I studies in patients with a wide selection of solid tumors in order to gain preliminary evidence of efficacy across a range of different tumor types.

Early animal studies had been conducted with both oral and intravenous dosage forms of phenoxodiol. For human use, both dosage forms of phenoxodiol are being trialed.

A Phase Ib safety study was commenced in Australia in November 2000 and finished in March 2002. Twenty-one patients with late-stage solid cancers of any type were given phenoxodiol by weekly bolus injections, which are intravenous injections delivered quickly, usually over several minutes, for 12 weeks. This was a dose-escalating study with different patients receiving doses ranging from 1 to 30



mg/kg/dose. An important end-point for Phase 1b safety studies is to determine the maximum tolerated dose, abbreviated as MTD, which is the highest dose of drug that can be delivered without causing life-threatening toxicity. The only safety issue reported in this study was hypersensitivity represented by rashes, headaches or fever in 3 patients which was considered likely to be associated with the material used to suspend the phenoxodiol in the intravenous dosage form. The MTD was not reached by the 30 mg/kg dose, and the study was terminated at that point, with that dosage being the highest that could practically be administered.

A second Phase 1b safety study commenced in Australia in April 2001 and concluded in 2002. Twenty-one patients with late-stage solid cancers of any type were given phenoxodiol by continuous intravenous infusion. The rationale here was to test the concept of delivering phenoxodiol on a continuous basis in order to maintain drug levels in the blood at a steady, moderate, continuous level, rather than the short, infrequent peak levels achieved with the bolus injection method. Laboratory studies had suggested that when used as a monotherapy, phenoxodiol was more effective when given to animals on a repeated and frequent basis. This again was a dose-escalating study, with different patients receiving doses from 1 to 40 mg/kg/day. As in the previous study, the MTD was not reached and no significant toxicities were encountered.

An Investigational New Drug Application (“IND”) for the intravenous dosage form of phenoxodiol became effective in the US in January 2001, allowing a third Phase 1b toxicity study to commence at The Cleveland Clinic, Ohio, in August 2001. This study concluded in 2002. Nineteen patients with late-stage solid cancers of any type were given phenoxodiol by continuous intravenous infusion in a repeat of the Australian study. The rationale here was to conduct a clinical study in the US as part of a program with the ultimate aim of seeking to conduct a study to support marketing approval in the US. This was a dose-escalating study, with inter-patient escalation from 0.5 to 64 mg/kg/day. As with the Australian study, no MTD was reached and no significant toxicities were encountered.

The main conclusions from this Phase I safety program of the intravenous dosage form were:

- that the intravenous dosage form was generally well-tolerated and without significant safety issues, but that it was associated with some intolerance (hypersensitivity);
- that continuous intravenous infusion was unlikely to deliver blood levels of drug that were thought to be potentially clinically relevant for the treatment of cancer, and that the bolus injection method was potentially better; and
- that preliminary evidence of an anti-tumor effect was obtained in some patients with solid tumors.

Concurrent with the Phase I clinical trial program outlined above, pre-clinical studies were being conducted at Yale University Medical School that focused on the use of phenoxodiol in the treatment of ovarian cancer, in particular, late-stage cancers that had become resistant to standard anti-cancer drugs. Those studies found that phenoxodiol was particularly effective in cell culture and in animals in killing highly chemo-resistant ovarian cancer cells. It also was found that phenoxodiol displayed a potent ability to restore the sensitivity of these chemo-resistant cancer cells to standard anti-cancer drugs including platinum and taxanes, the standard drugs used in the treatment of ovarian cancer.

These Yale studies led to the development of a strategy to use phenoxodiol to restore sensitivity to drugs such as cisplatin or carboplatin and paclitaxel or docetaxel in late-stage ovarian cancer that had become resistant to such drugs. It was decided to give phenoxodiol by bolus injection, and to give it on two consecutive days each week as a way of increasing the exposure of the cancer to drug. A Phase 1b safety study was conducted in the first instance using this new regimen. This was conducted at Yale-New Haven Hospital, CT, commencing 2002 and ending 2003 in patients with late-stage, platinum- and taxane-resistant ovarian cancers. It was a dose-escalating study in 40 women, with 10 women each receiving 1, 3, 10 or 20 mg/kg/day. No particular safety issues were encountered with the three lower dosages, although the 20 mg/kg dose produced two incidences of thrombocytopenia, or reduced platelet levels. This was an effect observed earlier in safety studies in dogs, and was thought to be due to the carrier compound in which the phenoxodiol was dissolved. Evidence of an anti-tumor effect (stabilization of disease) was observed in the three lower dosages, but not the highest dose.

At the conclusion of this study, a Phase IIa study was commenced in both Australia and the US in 60 women with chemo-resistant, late-stage ovarian cancer, where phenoxodiol was used in combination with cisplatin or paclitaxel to see if the chemo-resistance could be reversed. This study commenced in early 2004 and is ongoing. The investigators have reported that phenoxodiol has produced a 33% tumor response (tumor shrinkage) rate in these patients (12/36) and have concluded that this provides preliminary proof-of-concept.

The tumor responses observed in these patients led to the drug receiving Fast Track status from the FDA in 2004 for recurrent late stage ovarian cancer that is resistant or refractory to platins and taxanes.

Starting in 2002 it was decided to pursue the development of the oral dosage form of phenoxodiol. This was driven by the realization that continuous delivery of drug was preferable for an anti-cancer effect, and that the oral dosage form was a more practical way of achieving this compared to the intravenous dosage form which could only be given no more than two days per week because of the logistics of bringing patients into hospital for treatment. The oral dosage form, on the other hand, could be administered on an out-patient basis.

The first clinical study was a Phase Ib/IIa study which began in early 2002 on the use of phenoxodiol in patients with hematological tumors. This was predominantly a bio-availability and safety study, but also was intended to look for any evidence of anti-tumor activity in non-solid tumors. It was a dose-escalation study, where each patient was given a rising dose up to a maximum of 55 mg/kg/day over two 12-hourly doses. The study confirmed that the drug was readily absorbed from the gut to the extent of about 30%, and that there were no safety or intolerance issues, even at the highest dose. No evidence of anti-tumor effect was observed, leading to the conclusion that phenoxodiol is not appropriate for hematological cancers due to the presence of phenoxodiol in the blood in conjugated form (glucuronides and sulfates). While such conjugation is not thought to impede the drug's ability to attack most solid tumors, it is an impediment with blood-based cancers because of the inability of blood to deconjugate drug. Solid tissues generally possess the necessary ability to deconjugate these complexes to release the bio-active, unconjugated drug.

The next clinical study undertaken with the oral dosage form was in Australia in men with hormone-refractory prostate cancer. This study commenced in 2003 and is ongoing. Twenty-four patients are being treated with different dosages of phenoxodiol (20, 80, 200 and 400 mg) every 8-hours until they show disease progression. The investigators in this study have reported that the drug has produced a delay in disease progression in a number of men in the 200 and 400 mg dose groups, and that there have been no safety or intolerance issues.

The Prostate Specific Antigen, PSA, responses observed in some patients in this study led to the oral dosage form receiving Fast Track status from the FDA for this indication in 2004.

An IND for the oral dosage form of phenoxodiol became effective in the US in June 2003 which allowed a study in collaboration with Yale University School of Medicine to be conducted in patients with cancer of the cervix vulva and vagina. This dose-response Phase IIa study is ongoing. Phenoxodiol is being used on a neo-adjuvant, monotherapy basis in patients following a primary diagnosis of cancer. Phenoxodiol is being given at dosages of 50, 200 or 400 mg (8-hourly) for four weeks prior to surgery. The study is intended to measure the effect of treatment on tumor size and tumor biology.

A Phase IIa study commenced in Australia in early 2004 in order to assess the safety of administering high dose oral phenoxodiol therapy on a continuous basis in combination with carboplatin or cisplatin.

This study is being conducted in patients with solid cancers, and renal cancer in particular.

In early 2005, we announced that we were proposing to take phenoxodiol into a pivotal study for marketing approval with the indication to be sought of using phenoxodiol to restore sensitivity to carboplatin in platinum-refractory ovarian cancer.

### **Competition**

The development of phenoxodiol and other drug candidates is highly competitive. A number of other companies have products or drug candidates in various stages of pre-clinical or clinical development that are intended for the same therapeutic indications for which phenoxodiol is being developed. Some of these potential competing drugs are further advanced in development than phenoxodiol and may be commercialized sooner. Even if we are successful in developing effective drugs, phenoxodiol may not compete successfully with products produced by our competitors.

With respect to the use of phenoxodiol for late-stage prostate cancer, docetaxel, a drug distributed by Aventis, was approved in 2004 by the FDA for the treatment of hormone refractory prostate cancer, establishing a new bench-mark for standard chemotherapy in late-stage prostate cancer. We do not believe this is a direct competitor because our strategy is to develop phenoxodiol as a chemosensitizer for docetaxel in patients with prostate cancer who become refractory to docetaxel. A number of pharmaceutical and biotechnology companies are known to be seeking to develop drugs for the same indication.

With respect to the use of phenoxodiol as a chemo-sensitizing agent to restore sensitivity to platinum-based drugs in late-stage ovarian cancer, the experimental drug, Telcyta (Telik Inc.) is a directly competitive drug. Telcyta currently is in a Phase III registration trial suggesting that it has shown sufficient promise in a Phase II study to warrant progression to a Phase III study. The different trialing regimes being used by us with phenoxodiol and by Telik Inc with Telcyta make it difficult to compare the two drugs for efficacy in this area and, as a result, we cannot evaluate the level of competition. However, we expect that at any level of efficacy, Telcyta, should it be approved for marketing, would represent a significant competitor for phenoxodiol.

Our competitors include pharmaceutical companies and biotechnology companies, as well as universities and public and private research institutions. In addition, companies active in different but related fields represent substantial competition for us. Many of our competitors developing oncologic drugs have significantly greater capital resources, larger research and development staffs and facilities and greater experience in drug development, regulation, manufacturing and marketing than we do. These organizations also compete with Novogen, our services provider, to recruit qualified personnel, and with us to attract partners for joint ventures and to license technologies that are competitive with our technologies. As a result, our competitors may be able to more easily develop technologies and products that would render our technologies or our drug candidates obsolete or non-competitive.

### **Intellectual Property**

Novogen has been granted patents and has additional patents pending in a number of countries which cover a family of chemically related compounds with potentially broad ranging and complementary anti-cancer effects. Novogen has granted to us an exclusive license, with respect to its patent rights and intellectual property know-how to develop, market and distribute one of these compounds, phenoxodiol, as an anti-cancer agent, except in topical form. See Part III, Item 13 "Certain Relationships and Related Transactions" for more information regarding our agreements with Novogen.

We have licensed from Novogen the rights to the Novogen patents and applications as they relate to phenoxodiol as an anti-cancer agent. Excluded from these rights is phenoxodiol in a topical formulation. The patent rights we have licensed from Novogen can be largely classified into two broad

groups: patent rights relating to phenoxodiol used as an anti-cancer agent, which we refer to as “therapeutic patent rights,” and patent rights relating to the manufacture of phenoxodiol for anti-cancer purposes, which we refer to as “manufacturing patent rights.” The pending and issued Novogen patent rights can be further broken down into four families, three families belonging to the therapeutic patent rights and one family belonging to the manufacturing patent rights. The three families in the therapeutic patent rights relate to:

- phenoxodiol in the treatment of cancer (thirteen pending and nine issued);
  - compositions and methods for protecting skin from ultraviolet induced immunosuppression and skin damage, including phenoxodiol (nine pending and four issued); and
  - therapeutic methods and compositions involving isoflav-3-ene and isoflavan structure, including phenoxodiol (PCT pending).
- The family relating to the manufacturing patent rights relate to:
- o the production of isoflavone derivatives, including phenoxodiol (sixteen pending and one issued).

Novogen has been granted a U.S. Patent (No. 6,649,648) by the United States Patent and Trademark Office (USPTO) relating to the treatment of cancerous disease with isoflavone derivatives including phenoxodiol. U.S. Patent 6,649,648 also includes claims specifically directed to the treatment of ovarian cancer, breast cancer, prostate cancer, uterine cancer, bowel cancer, testicular cancer, endometrial cancer, leukemia and metastatic cancer with isoflavone derivatives including phenoxodiol.

As patent applications in the United States are maintained in secrecy until published by the USPTO at 18 months from filing, for all cases filed after November 29, 2000, or at issue, for cases filed prior to November 29, 2000, and as publication of discoveries in the scientific or patent literature often lag behind the actual discoveries, we cannot be certain that Novogen was the first to make the inventions covered by the Novogen patents and applications as they relate to phenoxodiol as an anti-cancer agent referred to above. Moreover, pursuant to the terms of the Uruguay Round Agreements Act, patents filed on or after June 8, 1995 have a term of twenty years from the date of such filing, irrespective of the period of time it may take for such patent to ultimately issue. This may shorten the period of patent protection afforded to therapeutic use of phenoxodiol as patent applications in the biopharmaceutical sector often take considerable time to issue. However, in some countries patent term may be extended.

In order to protect the confidentiality of our technology, including trade secrets and know-how and other proprietary technical and business information, we require all of our consultants, advisors and collaborators to enter into confidentiality agreements that prohibit the use or disclosure of information that is deemed confidential. The agreements also oblige our consultants, advisors and collaborators to assign to us developments, discoveries and inventions made by such persons in connection with their work with us. We cannot be sure that confidentiality will be maintained or disclosure prevented by these agreements or that our proprietary information or intellectual property will be protected thereby or that others will not independently develop substantially equivalent proprietary information or intellectual property.

The pharmaceutical industry is highly competitive and patents may have been applied for by, and issued to, other parties relating to products competitive with phenoxodiol. Use of phenoxodiol and any other drug candidates may give rise to claims that they infringe the patents or proprietary rights of other parties, existing now and in the future. An adverse claim could subject us to significant liabilities to such other parties and/or require disputed rights to be licensed from such other parties. We cannot be sure that any license required under any such patents or proprietary rights would be made available on terms acceptable to us, if at all. If we do not obtain such licenses, we may encounter delays in product market introductions, or may find that the development, manufacture or sale of products requiring such licenses may be precluded. We have not conducted any searches or made any independent investigations of the existence of any patents or proprietary rights of other parties.

## **Relationship with Novogen**

Novogen has been granted patents and has additional patent applications pending in a number of countries pertaining to phenoxodiol's family of compounds and to phenoxodiol itself and their use in anticancer therapeutics. Novogen has granted to us an exclusive license under its patent rights and the intellectual property rights in its relevant know-how to develop, market and distribute all forms of administering phenoxodiol for anti-cancer applications, except topical applications.

Novogen is active in the discovery and development of new drugs based on the emerging field of signal transduction regulation. Signal transduction regulators offer the potential for effective, well-tolerated treatment of common diseases, including cancer and heart disease. Novogen has developed a family of chemically related compounds with potentially broad ranging and complementary anti-cancer effects.

We have entered into certain key agreements with Novogen. These agreements, discussed briefly below, are more fully detailed in Part III, Item 13 "Certain Relationships and Related Transactions."

Under the license agreement, Novogen granted us an exclusive world-wide, non-transferable license, under the Novogen patent rights, to conduct clinical trials and commercialize and distribute all forms of administering phenoxodiol except topical applications. The agreement covers uses of phenoxodiol in the field of prevention, treatment or cure of cancer in humans. Our business is currently focused on advancing the clinical program underway for the development of phenoxodiol.

Under a manufacturing license and supply agreement, we have granted Novogen a sublicense to manufacture and supply phenoxodiol to us in its primary manufactured form for both the research and development program and phenoxodiol's ultimate commercial use. Novogen has a pilot phenoxodiol manufacturing plant which we believe has sufficient capacity and which can be augmented by third party manufacturing facilities to meet the projected amount of phenoxodiol required to complete the proposed clinical program.

Under a license option deed, Novogen granted us an exclusive first right to accept and an exclusive last right to match any proposed dealing by Novogen with its intellectual property rights in other synthetic compounds developed by Novogen that have known or potential anti-cancer applications in all forms other than topical applications.

Pursuant to a services agreement, Novogen provides services reasonably required by us relating to the development and commercialization of phenoxodiol. We do not currently intend to directly employ any staff and are reliant on Novogen for the provision of resources to conduct our business.

## Research and Development

The objective of our research and development program is the generation of data sufficient to achieve regulatory approval of phenoxodiol in one or more dosage forms in major markets such as the United States, and/or to allow us to enter into a commercial relationship with another party. The data is generated by our clinical trial programs.

The key aspects of this program are to provide more complete characterization of the following:

- the relevant molecular targets of action of phenoxodiol;
- the relative therapeutic indications of different dosage forms of phenoxodiol;
- the relative therapeutic benefits and indications of phenoxodiol as a monotherapy or as part of combinational therapy with other chemotoxics; and
- the most appropriate cancer targets for phenoxodiol.

Research expenses were \$2.279 million for the year ended June 30, 2005, \$2.381 million for the year ended June 30, 2004 and \$2.024 million for the year ended June 30, 2003.

## Regulation

### *U.S. Regulatory Requirements*

The U.S. Food and Drug Administration, or FDA, and comparable regulatory agencies in foreign countries, regulate and impose substantial requirements upon the research, development, pre-clinical and clinical testing, labeling, manufacture, quality control, storage, approval, advertising, promotion, marketing, distribution and export of pharmaceutical products including biologics, as well as significant reporting and record-keeping obligations. State governments may also impose obligations in these areas.

In the United States, pharmaceutical products are regulated by the FDA under the Federal Food Drug and Cosmetic Act or FDCA and other laws including in the case of biologics, the Public Health Service Act. We believe, but cannot be certain, that our products will be regulated as drugs by the FDA. The process required by the FDA before drugs may be marketed in the United States generally involves the following:

- pre-clinical laboratory evaluations, including formulation and stability testing, and animal tests performed under the FDA's Good Laboratory Practices regulations to assess potential safety and effectiveness;
- submission and approval of an IND, including results of pre-clinical tests and protocols for clinical tests, which must become effective before clinical trials may begin in the United States;
- obtaining approval of Institutional Review Boards to administer the products to human subjects in clinical trials;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the product for the product's intended use;
- development of manufacturing processes which conform to FDA current Good Manufacturing Practices, or cGMPs, as confirmed by FDA inspection;

- submission of pre-clinical and clinical test results, and chemistry, manufacture and control information on the product to the FDA in a New Drug Approval Application, or NDA; and
- FDA review and approval of an NDA, prior to any commercial sale or shipment of a product.

The testing and approval process requires substantial time, effort, and financial resources, and we cannot be certain that any approval will be granted on a timely basis, if at all.

The results of the pre-clinical tests, together with initial specified manufacturing information, the proposed clinical trial protocol, and information about the participating investigators are submitted to the FDA as part of an IND, which must become effective before we may begin human clinical trials. Additionally, an independent Institutional Review Board at each clinical trial site proposing to conduct the clinical trials must review and approve each study protocol and oversee conduct of the trial. An IND becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day period, raises concerns or questions about the conduct of the trials as outlined in the IND and imposes a clinical hold. If the FDA imposes a clinical hold, the IND sponsor must resolve the FDA's concerns before clinical trials can begin. Pre-clinical tests and studies can take several years to complete, and there is no guarantee that an IND we submit based on such tests and studies will become effective within any specific time period, if at all.

Human clinical trials are typically conducted in three sequential phases that may overlap.

- *Phase I:* The drug is initially introduced into healthy human subjects or patients and tested for safety and dosage tolerance. Absorption, metabolism, distribution, and excretion testing is generally performed at this stage.
- *Phase II:* The drug is studied in controlled, exploratory therapeutic trials in a limited number of subjects with the disease or medical condition for which the new drug is intended to be used in order to identify possible adverse effects and safety risks, to determine the preliminary or potential efficacy of the product for specific targeted diseases or medical conditions, and to determine dosage tolerance and the optimal effective dose.
- *Phase III:* When Phase II studies demonstrate that a specific dosage range of the drug is likely to be effective and the drug has an acceptable safety profile controlled, large-scale therapeutic Phase III trials are undertaken at multiple study sites to demonstrate clinical efficacy and to further test for safety in an expanded patient population.

We cannot be certain that we will successfully complete Phase I, Phase II, or Phase III testing of our products within any specific time period if at all. Furthermore the FDA, the Institutional Review Board or we may suspend or terminate clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

Results of pre-clinical studies and clinical trials, as well as detailed information about the manufacturing process, quality control methods, and product composition, among other things, are submitted to the FDA as part of an NDA seeking approval to market and commercially distribute the product on the basis of a determination that the product is safe and effective for its intended use. Before approving an NDA, the FDA will inspect the facilities at which the product is manufactured and will not approve the product unless cGMP compliance is satisfactory. If applicable regulatory criteria are not satisfied, the FDA may deny the NDA or require additional testing or information. As a condition of approval, the FDA also may require post-marketing testing or surveillance to monitor the product's safety or efficacy. Even after an NDA is approved, the FDA may impose additional obligations or restrictions (such as labeling changes), or even suspend or withdraw a product approval on the basis of data that arise after the product reaches the market, or if compliance with regulatory standards is not maintained. We cannot be certain that any NDA we submit will be approved by the

FDA on a timely basis, if at all. Also, any such approval may limit the indicated uses for which the product may be marketed. Any refusal to approve, delay in approval, suspension or withdrawal of approval, or restrictions on indicated uses could have a material adverse impact on our business prospects.

Each NDA must be accompanied by a user fee, pursuant to the requirements of the Prescription Drug User Fee Act, or PDUFA, and its amendments. According to the FDA's fee schedule, effective on October 1, 2004 for the fiscal year 2005, the user fee for an application requiring clinical data, such as an NDA, is \$672,000. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual product fee for prescription drugs and biologics (\$41,710), and an annual establishment fee (\$262,200) on facilities used to manufacture prescription drugs and biologics. A written request can be submitted for a waiver for the application fee for the first human drug application that is filed by a small business, but there are no waivers for product or establishment fees. We are not at the stage of development with our products where we are subject to these fees, but they are significant expenditures that will be incurred in the future and must be paid at the time of application submissions to FDA.

Satisfaction of FDA requirements typically takes several years. The actual time required varies substantially, based upon the type, complexity, and novelty of the pharmaceutical product, among other things. Government regulation imposes costly and time-consuming requirements and restrictions throughout the product life cycle and may delay product marketing for a considerable period of time, limit product marketing, or prevent marketing altogether. Success in pre-clinical or early stage clinical trials does not assure success in later stage clinical trials. Data obtained from pre-clinical and clinical activities is not always conclusive and may be susceptible to varying interpretations that could delay, limit, or prevent marketing approval. Even if a product receives marketing approval, the approval is limited to specific clinical indications. Further, even after marketing approval is obtained, the discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market.

After product approval, there are continuing significant regulatory requirements imposed by the FDA, including record-keeping requirements, obligations to report adverse side effects in patients using the products, and restrictions on advertising and promotional activities. Quality control and manufacturing procedures must continue to conform to cGMPs, and the FDA periodically inspects facilities to assess cGMP compliance. Additionally, post-approval changes in ingredient composition, manufacturing processes or facilities, product labeling, or other areas may require submission of an NDA Supplement to the FDA for review and approval. New indications will require additional clinical tests and submission of an NDA Supplement. Failure to comply with FDA regulatory requirements may result in an enforcement action by the FDA, including Warning Letters, product recalls, suspension or revocation of product approval, seizure of product to prevent distribution, impositions of injunctions prohibiting product manufacture or distribution, and civil and criminal penalties. Maintaining compliance is costly and time-consuming. We cannot be certain that we, or our present or future suppliers or third-party manufacturers, will be able to comply with all FDA regulatory requirements, and potential consequences of noncompliance could have a material adverse impact on our business prospects.

The FDA's policies may change, and additional governmental regulations may be enacted that could delay, limit, or prevent regulatory approval of our products or affect our ability to manufacture, market, or distribute our products after approval. Moreover, increased attention to the containment of healthcare costs in the United States and in foreign markets could result in new government regulations that could have a material adverse effect on our business. Our failure to obtain coverage, an adequate level of reimbursement, or acceptable prices for our future products could diminish any revenues we may be able to generate. Our ability to commercialize future products will depend in part on the extent to which coverage and reimbursement for the products will be available from government and health administration authorities, private health insurers, and other third-party payers. European Union and U.S. government and other third-party payers increasingly are attempting to



contain healthcare costs by consideration of new laws and regulations limiting both coverage and the level of reimbursement for new drugs. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad.

Our activities also may be subject to state laws and regulations that affect our ability to develop and sell our products. We are also subject to numerous federal, state, and local laws relating to such matters as safe working conditions, clinical, laboratory, and manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future, and the failure to comply may have a material adverse impact on our business prospects.

The FDCA includes provisions designed to facilitate and expedite the development and review of drugs and biological products intended for treatment of serious or life-threatening conditions that demonstrate the potential to address unmet medical needs for such conditions. These provisions set forth a procedure for designation of a drug as a “fast track product.” The fast track designation applies to the combination of the product and specific indication for which it is being studied. A product designated as fast track is ordinarily eligible for additional programs for expediting development and review, but products that are not in fast track drug development programs may also be able to take advantage of these programs. These programs include priority review of NDAs and accelerated approval. Drug approval under the accelerated regulations may be based on evidence of clinical effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. A postmarketing clinical study will be required to verify clinical benefit, and other restrictions to assure safe use may be imposed.

Under the Drug Price Competition and Patent Term Restoration Act of 1984 (the “Patent Act”), a sponsor may obtain marketing exclusivity for a period of time following FDA approval of certain drug applications, regardless of patent status, if the drug is a new chemical entity or if new clinical studies were required to support the marketing application for the drug. This marketing exclusivity prevents a third party from obtaining FDA approval for an identical or nearly identical drug under an Abbreviated New Drug Application (“ANDA”) or a “505(b)(2) New Drug Application.” The statute also allows a patent owner to obtain an extension of applicable patent terms for a period equal to one-half the period of time elapsed between the filing of an IND and the filing of the corresponding NDA plus the period of time between the filing of the NDA and FDA approval, with a five year maximum patent extension. We cannot be certain that Novogen will be able to take advantage of either the patent term’ extension or marketing exclusivity provisions of these laws.

The Best Pharmaceuticals for Children Act, signed into law on January 4, 2002, provides an additional six months of marketing exclusivity for new or marketed drugs, for which specific pediatric studies were conducted at the written request of the FDA. On December 3, 2003, the Pediatric Research Equity Act was signed into law, authorizing the FDA to require pediatric studies for drugs and biological products to ensure the drugs’ or products’ safety and effectiveness in children. This Act required that New Drug Applications (“NDAs”) or supplements to NDAs contain data assessing the safety and effectiveness for the claimed indication in all relevant pediatric subpopulations. Dosing and administration must be supported for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant deferrals for submission of data, or full or partial waivers. We cannot be certain that we will be able to take advantage of these statutory pediatric marketing exclusivity provisions.

#### *Australian Regulatory Requirements*

The *Therapeutic Goods Act 1989*, or 1989 Act, sets out the legal requirements for the import, export, manufacture and supply of pharmaceutical products in Australia. The 1989 Act requires that all pharmaceutical products to be imported into, supplied in, manufactured in or exported from Australia be included in the Australian Register of Therapeutic Goods, or ARTG, unless specifically exempted under the Act.

In order to ensure that a product can be included in the ARTG, a sponsoring company must make an application to the Therapeutic Goods Administration, or TGA. The application usually consists of a form accompanied by data (usually based on the European Union requirements) to support the quality, safety and efficacy of the drug and payment of a fee. Application details are available on the TGA website <http://www.tga.gov.au>.

The first phase of evaluation, known as the Application Entry Process, is usually a short period during which an application is assessed on an administrative level to ensure that it complies with the basic guidelines. The TGA must decide within 40 working days whether it will accept the application for evaluation.

Once an application is accepted for evaluation, aspects of the data provided are allocated to evaluators, who prepare evaluation reports. The evaluation reports are then sent to the sponsoring company who then has the opportunity to comment on the views expressed within the evaluation report and to submit supplementary data to address any issues raised in the evaluation reports. Following this evaluation, the chemistry and quality control aspects of a product may be referred to a sub-committee of the Australian Drug and Evaluation Committee, or ADEC, to review the evaluation reports.

Once the evaluations are complete, the TGA prepares a summary document on the key issues on which advice will be sought from the ADEC. This summary is sent to the sponsoring company which is able to submit a response to the ADEC dealing with issues raised in the summary and those not previously addressed in the evaluation report. The ADEC provides independent advice on the quality, risk-benefit, effectiveness and access of the drug and conduct medical and scientific evaluations of the application. The ADEC's resolutions are provided to the sponsoring company after 5 working days after the ADEC meeting.

The TGA takes into account the advice of the ADEC in reaching a decision to approve or reject a product. Any approval for registration on the ARTG may have conditions associated with it.

From the time that the TGA accepts the initial application for evaluation, the TGA must complete the evaluation and make a decision on the registration of the product within 255 working days. The TGA also has a system of priority evaluation for products that meet certain criteria, including where the product is a new chemical entity that it is not otherwise available on the market as an approved product, and is for the treatment of a serious, life-threatening illness for which other therapies are either ineffective or not available.

#### *European Union Regulatory Requirements*

Outside the United States, our ability to market our products will also be contingent upon receiving marketing authorizations from the appropriate regulatory authorities and compliance with applicable post-approval regulatory requirements. Although the specific requirements and restrictions vary from country to country, as a general matter, foreign regulatory systems include risks similar to those associated with FDA regulation, described above. Under EU regulatory systems, marketing authorizations may be submitted either under a centralized or decentralized procedure. Under the centralized procedure, a single application to the European Medicines Evaluation Agency (EMA) leads to an approval granted by the European Commission which permits the marketing of the product throughout the EU. The centralized procedure is mandatory for certain classes of medicinal products, but optional for others. For example, all medicinal products developed by certain biotechnological means must be authorized via the centralized procedure. We assume that the centralized procedure will apply to our products that are developed by means of a biotechnology process. The decentralized procedure provides for mutual recognition of nationally approved decisions and is used for products that are not required to be authorized by the centralized procedure. Under the decentralized procedure, the holders of a national marketing authorization may submit further applications to the competent

authorities of the remaining member states, which will then be requested to recognize the original authorization based upon an assessment report prepared by the original authorizing competent authority. The recognition process should take no longer than 90 days, but if one member state makes an objection, which under the legislation can only be based on a possible risk to human health, we have the option to withdraw the application from that country or take the application to arbitration by the Committee for Proprietary Medicinal Products (CPMP) of the EMEA. If a referral for arbitration is made, the procedure is suspended, and in the intervening time, the only EU country in which the product can be marketed will be the country where the original authorization has been granted, even if all the other designated countries are ready to recognize the product. The opinion of the CPMP, which is binding, could support or reject the objection or alternatively could reach a compromise position acceptable to all EU countries concerned. Arbitration can be avoided if the application is withdrawn in the objecting country, but once the application has been referred to arbitration, it cannot be withdrawn. The arbitration procedure may take an additional year before a final decision is reached and may require the delivery of additional data.

As with FDA approval we may not be able to secure regulatory approvals in Europe in a timely manner, if at all. Additionally, as in the United States, post-approval regulatory requirements, such as those regarding product manufacture, marketing, or distribution, would apply to any product that is approved in Europe, and failure to comply with such obligations could have a material adverse effect on our ability to successfully commercialize any product.

New European Legislation was introduced in 2001 designed to harmonize the regulation of clinical trials across the EU. This legislation has now been implemented in all EU countries. In addition, the entire EU regulatory regime has recently undergone a significant revision and new laws have been introduced that amend the current EU Medicines Directive. These amendments are due to come into effect by October 30, 2005 and are currently being implemented on a country by country basis. For example, the centralized procedure for the authorization of new medicines will be compulsory for biotechnology products and those developed for cancer and other specified diseases and disorders. Accordingly, there is a marked degree of change and uncertainty both in the regulation of clinical trials and in respect of marketing authorizations which face us for our products in Europe.

### **Government Funding**

Novogen received financial support for the phenoxodiol drug program from the Australian government under what is known as the START Program. The START Program is a merit-based program designed to encourage and assist Australian companies to undertake research and development and commercialization through a range of grants and loans. The START Program is administered by the Industry Research and Development, or IR&D Board. The IR&D Board is made up of private sector and academic members with expertise and experience in research and development and commercialization. In 1998, the Australian government agreed to provide A\$2.7 million (approximately U.S. \$1.8 million) to Novogen, enabling it to expedite phenoxodiol into clinical trials, provided that the grant money was matched by an equal expenditure by Novogen. The START grant was awarded after the government's review of the pertinent research results, the intellectual property driving the program, and the likelihood and potential for commercial success of the drug.

The terms of the grant require Novogen to obtain the consent of the Australian government to deal with the intellectual property rights which have arisen through the program conducted to date. Novogen has obtained the consent of the Australian government to the grant of the license to us and to the other arrangements between us and Novogen concerning the development and commercialization of phenoxodiol.

Under the START Program, Novogen must meet certain project development and commercialization obligations. Novogen has met the project development obligations and has received final payment thereon. Novogen believes that it is currently in compliance with its commercialization schedule and that it has fulfilled all of its obligations under the terms of the START Program and expects to continue to do so in the future. For additional information on the consequences to us in the event Novogen fails to comply with its obligations under the START Program, see the "Intellectual Property" and "Risk Factors" sections of this annual report.

### **Employees**

We do not have any employees. Novogen provides us with staff and other financial and administrative services under our services agreement with Novogen.

## Risk Factors

**In addition to the other information in this Annual Report the following risk factors should be considered carefully in evaluating us and our business.**

### Risks Related to Our Business

***We have a limited operating history, and we are likely to incur operating losses for the foreseeable future.***

You should consider our prospects in light of the risks and difficulties frequently encountered by early stage and developmental companies. Although we were incorporated in December 2000, we have only been in operation since May 2002. We have incurred net losses of \$18,115,000 since our inception, including net losses of \$6,421,000, \$8,538,000 and \$3,033,000 for the years ended June 30, 2005, 2004 and 2003, respectively. We anticipate that we will incur operating losses and negative cash flow for the foreseeable future. We have not yet commercialized any products and cannot be sure that we will ever be able to do so, or that we may ever become profitable. We expect to expand our clinical trials significantly, which will result in increasing losses, and may continue to incur substantial losses even if we begin to generate revenues from the distribution and sale of phenoxodiol.

***If we are unable to successfully develop and commercialize phenoxodiol or license other viable drug candidates, our ability to sustain future operations will be significantly diminished.***

We are currently developing only one drug, phenoxodiol. We cannot guarantee that phenoxodiol will be successful. Although we have rights to potentially develop other related compounds discovered and developed by Novogen under the terms of our license option deed with Novogen, our rights under our license agreement with Novogen are limited to the commercialization of phenoxodiol as an anti-cancer agent and these rights specifically exclude phenoxodiol in a topical application. If we are unable to successfully develop and commercialize phenoxodiol or other viable drug candidates, we may be required to cease or reduce our operations.

***If we do not receive regulatory approval for marketing phenoxodiol or such approval is withdrawn, we will not be able to commercialize phenoxodiol.***

We need regulatory approval in order to commercialize phenoxodiol. We may never receive marketing approval or if we do receive marketing approval, it will be limited to those disease states and conditions for which phenoxodiol has been proven to be safe and effective. Phenoxodiol currently is in various Phase 1b/11a clinical trials with the intention of being developed as both a monotherapy and a chemo-sensitizing agent for use with first-line chemotherapies in the areas of hormone-refractory prostate carcinoma, early stage cancer of the cervix, vagina and vulva, late stage ovarian carcinoma and renal cancer. Phenoxodiol has been granted fast track status by the FDA for use in hormone refractory prostate cancer for patients with recurrent late stage ovarian cancer. Product approval, if granted, can be withdrawn for failure to comply with regulatory requirements or upon the occurrence of adverse events following commercial introduction. In addition, our ability to market phenoxodiol in overseas countries is contingent upon receiving the required regulatory approvals in those countries. If we cannot commercialize phenoxodiol, we may be required to cease or reduce our operations. We cannot assure you that material delays, difficulties or adverse developments in the regulatory process will not be encountered in the future.

***If the data from our clinical trials does not demonstrate the safety and effectiveness of phenoxodiol to the FDA's satisfaction, we will not receive FDA approval to market phenoxodiol in the United States.***

To obtain FDA approval for marketing, our pivotal trials must generate data demonstrating that phenoxodiol is safe and effective for each indication for which approval is sought. The FDA's grant of permission to proceed with clinical trials does not constitute a binding commitment that the FDA will consider the trial design adequate to support approval, or that the data generated during pivotal trials will meet the safety and effectiveness endpoints, or otherwise produce results that will lead the FDA to grant marketing approval. If the FDA concludes that the data from our clinical trials has failed to demonstrate the safety and effectiveness of phenoxodiol for any indication, we will not receive FDA approval to market phenoxodiol for those indications in the United States.

***We may not complete our pivotal trials on schedule, or at all, or they may be conducted improperly, which may delay or preclude FDA marketing approval.***

The completion of our pivotal trials may be delayed or terminated for many reasons, including, but not limited to, if:

- the FDA does not grant permission to proceed and places the trial on clinical hold;
- subjects do not enroll in our pivotal trials at the rate we currently expect;
- subjects experience an unacceptable rate or severity of adverse side effects;
- third party clinical investigators do not perform our pivotal trial on our anticipated schedule or consistent with the clinical trial protocol, Good Clinical Practice and regulatory requirements, or other third parties do not perform data collection and analysis in a timely or accurate manner;
- inspections of our clinical trial sites by the FDA or Institutional Review Boards, (IRBs), find regulatory violations that require us to undertake corrective action, suspend or terminate one or more sites, or prohibit us from using some or all of the data in support of our marketing applications;
- one or more IRB suspends or terminates the trial at an investigational site, precludes enrollment of additional subjects, or withdraws its approval of the trial; or
- one or more of our clinical investigators withdraws from our trials or deviates from our approved protocol.

Our development costs will increase if we have material delays in our pivotal trials, or if we are required to modify, suspend, terminate or repeat a pivotal trial.

***We may not be able to secure and maintain suitable research institutions to conduct our clinical trials.***

We rely on suitable research institutions, of which there are many, to conduct our clinical trials. While we have not previously experienced problems with third parties upon whom we rely for research or clinical trials, our reliance upon research institutions, including hospitals and cancer clinics, provides us with less control over the timing and cost of clinical trials and the ability to recruit patients than if we had conducted the trials on our own. Further, there is a greater likelihood that disputes may arise with these research institutions over the ownership of intellectual property discovered during the clinical trials. If we are unable to reach agreement with suitable research institutions on acceptable terms, or if any resulting agreement is terminated and we are unable to quickly replace the applicable research institution with another qualified institution on acceptable terms, the research could be delayed and we may be unable to complete development, or commercialize phenoxodiol, which will adversely affect our ability to generate operating revenues.

***Any failure in our clinical trials could impair the commercial prospects for phenoxodiol.***

Clinical trials have a high risk of failure. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in advanced clinical trials, even after achieving promising results in earlier trials. While we have not had any material delays in our clinical testing program if we experience delays in the testing or approval process or need to perform more or larger clinical trials than originally planned our commercial prospects for phenoxodiol or any other drug candidates may be impaired and we may be required to cease or reduce our operations.

***Our ability to achieve profitability is dependent on a number of factors, many of which have uncertain outcomes.***

Our ability to achieve profitability is dependent on a number of factors including:

- completing our clinical trial program and receiving marketing approval. Clinical testing is a prerequisite to the receipt of the regulatory approval necessary to commercialize phenoxodiol. We cannot control the outcome of our testing program or whether we receive regulatory approval. We will not be able to generate sales revenues until we receive marketing approval;
- establishing strategic partnerships to market and sell phenoxodiol. Our negotiating position with potential strategic partners will be affected by the success of our clinical program. If we are unable to attract partners and negotiate favorable terms, we may have difficulty generating revenues from our commercialization of phenoxodiol;
- maintaining a low cost operation and scalable supply of phenoxodiol capable of meeting the demands of the commercial market. We have contracted with Novogen for the supply of phenoxodiol and Novogen has fully complied with the terms of our manufacturing license and supply agreement. Under the terms of the manufacturing license and supply agreement, the supply of phenoxodiol is charged to us on a cost-plus basis. We do not have direct control over the manufacturing costs of phenoxodiol. We cannot control Novogen's ability to expand its production capabilities to produce the large quantities that may be required by the commercial market. If our costs for the supply of phenoxodiol rise or if Novogen fails to supply sufficient quantities of phenoxodiol, our profitability could be adversely affected; and
- our ability to license from Novogen rights to commercialize new cancer compounds. We may license from Novogen the rights to other cancer compounds under the terms of the license option deed. If development of phenoxodiol is unsuccessful or if we choose to expand to the development of additional compounds, our success may depend on controlling the costs of developing such new compounds and negotiating a favorable license agreement with Novogen. The availability of new compounds to commercialize and the cost to develop these compounds is outside of our direct control.

***We have no direct control over the costs of manufacturing phenoxodiol and increases in these costs would increase the costs of conducting clinical trials and could adversely affect future profitability if these costs increase significantly.***

We do not intend to manufacture phenoxodiol ourselves and we will be relying on third parties for our supplies of phenoxodiol both for clinical trials and for commercial quantities in the future. We have contracted with Novogen to manufacture and supply us with our requirements of phenoxodiol. The cost of manufacturing phenoxodiol is charged to us on a cost plus markup basis. We have no direct control over the costs of manufacturing phenoxodiol. If the costs of manufacturing phenoxodiol increase or if the cost of the materials used to make phenoxodiol increases these costs will be passed on to us by Novogen making the cost of conducting clinical trials more expensive. If, in the future, a third party other than Novogen manufactures and supplies us with phenoxodiol, we will not have

direct control over those manufacturing costs. Once we are able to commercialize phenoxodiol, increases in manufacturing costs could adversely affect our future profitability if we are unable to pass all of the increased costs along to our customers.

***Final approval by regulatory authorities of phenoxodiol for commercial use may be delayed, limited or prevented, any of which would adversely affect our ability to generate operating revenues.***

Any of the following factors may serve to delay, limit or prevent the final approval by regulatory authorities of phenoxodiol for commercial use:

- phenoxodiol is in the early stages of clinical development and we will need to conduct significant clinical testing to prove safety and efficacy before applications for marketing can be filed with the FDA, or with the regulatory authorities of other countries, to approve phenoxodiol for final use;
- data obtained from pre-clinical and clinical tests can be interpreted in different ways, which could delay, limit or prevent regulatory approval;
- development and testing of product formulation, including identification of suitable excipients;
- it may take us many years to complete the testing of phenoxodiol or any other drug candidates, and failure can occur at any stage of this process;
- negative or inconclusive results or adverse medical events during a clinical trial could cause us to delay or terminate our development efforts;
- there is relatively limited scientific understanding of the means by which cells respond to chemical signals that reach them through the bloodstream, which we refer to as multiple signal transduction regulation or MSTR, the class of drug compounds to which phenoxodiol belongs; and
- the commercialization of phenoxodiol may be delayed if the FDA or another regulatory authority requires us to expand the size and/or scope of the clinical trials.

While we have not encountered any material delays or adverse events from the factors described above to date, we cannot assure you that such delays or adverse events will not be encountered in the future.

***We may not be able to establish the strategic partnerships necessary to market and distribute phenoxodiol.***

A key part of our business plan is to establish relationships with strategic partners. We must successfully contract with third parties to package, market and distribute phenoxodiol. We have not yet established any strategic partnerships. Potential partners may not wish to enter into agreements with us due to Novogen's current equity position as our majority stockholder or our contractual relationships with Novogen. Similarly, potential partners may be discouraged by our limited operating history. Additionally, our relative attractiveness to potential partners and consequently, our ability to negotiate acceptable terms in any partnership agreement will be affected by the results of our clinical program. For example, if phenoxodiol is shown to have high efficacy against a broad range of cancers we may generate greater interest from potential partners than if phenoxodiol was demonstrated to be less effective or applicable to a narrower range of cancers. There is no assurance that we will be able to negotiate commercially acceptable licensing or other agreements for the future exploitation of phenoxodiol, including the continued clinical development, manufacture or marketing of phenoxodiol. If we are unable to successfully contract for these services, or if arrangements for these services are terminated, we may have to delay our commercialization program for phenoxodiol which will adversely affect our ability to generate operating revenues.

***We face a risk of product liability claims and may not be able to obtain adequate insurance.***

Our business exposes us to the risk of product liability claims. This risk is inherent in the manufacturing, testing and marketing of human therapeutic products. We have product liability insurance coverage of up to approximately \$14 million. Although we believe that this amount of insurance coverage is appropriate for our business at this time, it is subject to deductibles and coverage limitations, and the market for such insurance is becoming more restrictive. We may not be able to obtain or maintain adequate protection against potential liabilities. If we are unable to sufficiently insure against potential product liability claims, we will be exposed to significant liabilities, which may materially and adversely affect our business development and commercialization efforts.

***We will need to raise additional funds to complete Phase III clinical trials and commercialize phenoxodiol, and the actual amount of funds we will need will be determined by a number of factors, some of which are beyond our control.***

While we believe that we have sufficient funds to complete our current clinical trial program, we will require additional funds to further the evaluation of phenoxodiol beyond the current objectives including the completion of any Phase III clinical trials for phenoxodiol, and to pursue the commercialization of phenoxodiol. The actual amount of funds that we will need will be determined by many factors, some of which are beyond our control. As a result, we may need additional funds sooner than we currently anticipate. These factors include:

- the progress of research activities, the number and scope of research programs;
- the progress of pre-clinical and clinical development activities;
- the progress of the development efforts of Novogen or any other parties with whom we enter into research and development agreements;
- our ability to establish and maintain current and new research and development and licensing arrangements;
- our ability to achieve milestones under licensing arrangements; and
- the costs involved in enforcing or defending patent claims and other intellectual property rights; and the costs and timing of regulatory approvals.

If our capital resources are insufficient to meet future capital requirements, we will have to raise additional funds. If we are unable to obtain additional funds on favourable terms we may be required to cease or reduce our operations. Also, if we raise more funds by selling additional shares of our common stock or securities convertible into or exercisable for shares of our common stock, your ownership interests may be diluted.

***Our commercial opportunity will be reduced or eliminated if competitors develop and market products that are more effective, have fewer side effects or are less expensive than phenoxodiol.***

The development of phenoxodiol and other drug candidates is highly competitive. A number of other companies have products or drug candidates in various stages of pre-clinical or clinical development that are intended for the same therapeutic indications for which phenoxodiol is being developed. Some of these potential competing drugs are further advanced in development than phenoxodiol and may be commercialized sooner. Even if we are successful in developing effective drugs, phenoxodiol may not compete successfully with products produced by our competitors.



With respect to the use of phenoxodiol for late-stage prostate cancer, docetaxel, a drug distributed by Aventis, was approved in 2004 by the FDA for the treatment of hormone refractory prostate cancer, establishing a new bench-mark for standard chemotherapy in late-stage prostate cancer. We do not believe this is a direct competitor because our strategy is to develop phenoxodiol as a chemosensitizer for docetaxel in patients with prostate cancer who become refractory to docetaxel. A number of pharmaceutical and biotechnology companies are known to be seeking to develop drugs for the same indication.

With respect to the use of phenoxodiol as a chemo-sensitizing agent to restore sensitivity to platinum-based drugs in late-stage ovarian cancer, the experimental drug, Telcyta (Telik Inc.) is a directly competitive drug. Telcyta currently is in a Phase III registration trial suggesting that it has shown sufficient promise in a Phase II study to warrant progression to a Phase III study. The different trialing regimes being used by us with phenoxodiol and by Telik Inc with Telcyta make it difficult to compare the two drugs for efficacy in this area and, as a result, we cannot evaluate the level of competition. However, we expect that at any level of efficacy, Telcyta, should it be approved for marketing, would represent a serious competitor for phenoxodiol.

Our competitors include pharmaceutical companies and biotechnology companies, as well as universities and public and private research institutions. In addition, companies active in different but related fields represent substantial competition for us. Many of our competitors developing oncologic drugs have significantly greater capital resources, larger research and development staffs and facilities and greater experience in drug development, regulation, manufacturing and marketing than us. These organizations also compete with Novogen, our services provider, to recruit qualified personnel, and with us to attract partners for joint ventures and to license technologies that are competitive with ours. As a result, our competitors may be able to more easily develop technologies and products that would render our technologies or our drug candidates obsolete or non-competitive.

***Our right to develop and exploit phenoxodiol is subject to the terms and conditions of agreements we have entered into with Novogen, and under these agreements our rights may be terminated under certain circumstances, some of which may be beyond our control.***

We have licensed the intellectual property in the phenoxodiol technology from Novogen. All forms of administering phenoxodiol for the treatment of cancer are licensed to us, excluding topical applications. If we fail to meet our obligations under our license agreement, the manufacturing license and supply agreement or the services agreement with Novogen, any or all of these agreements may be terminated by Novogen and we could lose our rights to develop phenoxodiol. As of the date of this annual report, we have no reason to believe that we will be unable to satisfy our obligations under these agreements. In addition, each of these agreements may be terminated immediately by Novogen in the event that we undergo a change of control without the consent of Novogen. A “change of control” means a change in control of more than half the voting rights attaching to the shares of our subsidiary, a change in control of more than half of the issued shares of our subsidiary (not counting any share which carries no right to participate beyond a specified amount in the distribution of either profit or capital) or a change in control of the composition of the board of directors of our subsidiary. Each of these agreements may also be terminated if we become the subject of certain bankruptcy proceedings or cease for any reason to be able to lawfully carry out all the transactions required by each respective agreement.

***Our license rights are fundamental to our business and therefore a loss of these rights will likely cause us to cease operations.***

The rights granted to us under the license agreement, the manufacturing license and supply agreement and the license option deed with Novogen are fundamental to our business.

The license agreement grants us the right to make, have made, market, distribute, sell, hire or otherwise dispose of phenoxodiol products in the field of prevention, treatment or cure of cancer in humans by pharmaceuticals delivered in all forms except topical applications. Our business purpose is to develop and commercialize cancer drugs including phenoxodiol, which we would be unable to pursue without the rights granted to us under the license agreement.

Under the manufacturing license and supply agreement, we have granted to Novogen an exclusive sub-license to manufacture and supply phenoxodiol to us in its primary manufactured form and Novogen has agreed to manufacture for us our required quantities of phenoxodiol. This agreement enables us to protect the licensed intellectual property rights used in the manufacturing process while securing the services of a manufacturing partner in Novogen, which through its equity position in us, shares a common interest in the production of phenoxodiol. The license option deed grants us an exclusive first right to accept and exclusive last right to match any proposed dealing by Novogen with its intellectual property rights with a third party relating to certain compounds (other than phenoxodiol) developed by Novogen and its affiliates which have applications in the field of prevention, treatment or cure of cancer in humans. The license option deed is important to our business because it allows us to maintain control over the sale by Novogen of complementary as well as potentially competitive intellectual property rights to third party competitors.

Any loss of the rights under any of these agreements will likely cause us to cease operations.

***The success of phenoxodiol is largely dependent on Novogen's ability to obtain and maintain patent protection and preserve trade secrets, which cannot be guaranteed.***

Patent protection and trade secret protection are important to our business and our future will depend, in part on our ability and the ability of Novogen to maintain trade secret protection, obtain patents and operate without infringing the proprietary rights of others both in the United States and abroad. Litigation or other legal proceedings may be necessary to defend against claims of infringement, to enforce our patents, or to protect our trade secrets or the trade secrets of Novogen. Such litigation could result in substantial costs and diversion of our management's attention. Novogen has not been involved in any opposition re-examination trade secret dispute, infringement litigation or any other litigation or legal proceedings pertaining to the licensed patent rights.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. Novogen has applied for patents in a number of countries with respect to the use of phenoxodiol for the treatment, prevention or cure of cancer. We have licensed both issued patents and pending patent applications from Novogen. Novogen has issued patents in the United States, Australia and Singapore covering the use of phenoxodiol to prevent, or treat skin cancer from ultraviolet damage. Novogen also has patents issued in Australia, Hong Kong, New Zealand and the United Kingdom related to phenoxodiol for the treatment of a variety of cancers and has recently received a notice of allowance in the United States that is also related to phenoxodiol for the treatment of a variety of cancers.

Novogen's applications may not proceed to grant or may be amended to reduce the scope of protection of any patent granted. The applications and patents may also be opposed or challenged by third parties. Our commercial success will depend, in part, on the ability of Novogen and our ability to obtain and maintain effective patent protection for the technologies underlying phenoxodiol and other compounds, and to successfully defend patent rights in those technologies against third-party challenges. As patent applications in the United States are maintained in secrecy until published or issued and as publication of discoveries in the scientific or patent literature often lag behind the actual discoveries, we cannot be certain that Novogen was the first to make the inventions covered by its pending patent applications or issued patents or that it was the first to file patent applications for such inventions. Additionally, the breadth of claims allowed in biotechnology and pharmaceutical patents or their enforceability cannot be predicted. We cannot be sure that any additional patents will issue from any of Novogen's patent applications or, should any patents issue, that we will be provided with

adequate protection against potentially competitive products. Furthermore, we cannot be sure that should patents issue, they will be of commercial value to us, or that private parties, including competitors, will not successfully challenge our patents or circumvent our patent position in the United States or abroad.

***Claims by other companies that we infringe their proprietary technology may result in liability for damages or stop our development and commercialization efforts.***

The pharmaceutical industry is highly competitive and patents have been applied for by, and issued to, other parties relating to products competitive with phenoxodiol. Therefore, phenoxodiol and any other drug candidates may give rise to claims that they infringe the patents or proprietary rights of other parties existing now and in the future. Furthermore, to the extent that we or Novogen or our respective consultants or research collaborators use intellectual property owned by others in work performed for us or Novogen, disputes may also arise as to the rights in such intellectual property or in resulting know-how and inventions. An adverse claim could subject us to significant liabilities to such other parties and/or require disputed rights to be licensed from such other parties.

Under the terms of the Manufacturing License and Supply Agreement, Novogen is responsible for producing the required amount of phenoxodiol for our clinical program and subsequent commercial quantities. Novogen is currently undertaking formulation development and manufacturing process development work for both the intravenous and oral dose formulations. This work is being conducted to ensure that there is a robust production process which meets the expected commercial quantities of phenoxodiol and that both the intravenous and oral dose formulations are manufactured on a cost effective basis.

During this process Novogen has identified a number of excipients that may be used in the formulations of phenoxodiol. Excipients, among other things, perform the function of a carrier of the active drug ingredient in the intravenous formulation. Some of these identified excipients or carriers may be included in third party patents in some countries. We intend to seek a license if we decide to use a patented excipient in the marketed intravenous product or we may choose one of those excipients that do not have a license requirement.

We cannot be sure that any license required under any such patents or proprietary rights would be made available on terms acceptable to us, if at all. If we do not obtain such licenses, we may encounter delays in product market introductions, or may find that the development, manufacture or sale of products requiring such licenses may be precluded. We have not conducted any searches or made any independent investigations of the existence of any patents or proprietary rights of other parties.

***We may be subject to substantial costs stemming from our defense against third-party intellectual property infringement claims.***

Third parties may assert that we or Novogen are using their proprietary information without authorization. Third parties may also have or obtain patents and may claim that technologies licensed to or used by us infringe their patents. If we are required to defend patent infringement actions brought by third parties, or if we sue to protect our own patent rights, we may be required to pay substantial litigation costs and managerial attention may be diverted from business operations even if the outcome is not adverse to us. In addition, any legal action that seeks damages or an injunction to stop us from carrying on our commercial activities relating to the affected technologies could subject us to monetary liability and require us or Novogen or any third party licensors to obtain a license to continue to use the affected technologies. We cannot predict whether we or Novogen would prevail in any of these types of actions or that any required license would be made available on commercially acceptable terms or at all.

***In the event that Novogen does not comply with its obligations under a grant from the Australian government under which phenoxodiol was, in part, developed, our rights to use the intellectual property relating to phenoxodiol and developed by Novogen may revert back to the Australian government.***

Novogen developed phenoxodiol in part using funds from the Australian government under what is known as the START Program. Under the START Program, Novogen must meet certain project development and commercialization obligations. Novogen has met the project development obligations and has received final payment thereon. Novogen believes it is currently in compliance with its commercialization schedule. Although Novogen believes that it has complied with its obligations under the START Program, if the Australian government disagrees or if Novogen undergoes a change of control without the prior consent of the Australian Government, the Australian government has a right to demand that intellectual property created during the course of the project funded by the grant be vested back in the Australian government or demand repayment of the funds paid to Novogen under the program. The Australian government may then license the intellectual property rights related to phenoxodiol to other parties and may demand other intellectual property rights from Novogen. Any such reclamation by the Australian government could preclude our use of Novogen's intellectual property in the development and commercialization of phenoxodiol and we may have to compete with other companies to whom the Australian government may license the intellectual property.

***The enforcement of civil liabilities against our officers and directors may be difficult.***

All of our officers and directors are residents of jurisdictions outside the United States. As a result it may be difficult for you to effect service of process within the United States upon our officers and directors or to enforce judgments obtained against our officers and directors or us in United States courts.

***Our revenue is affected by fluctuations in currency exchange rates.***

Much of our expenditures and potential revenue will be spent or derived outside of the United States. As a result, fluctuations between the United States dollar and the currencies of the countries in which we operate may increase our costs or reduce our potential revenue. At present, we do not engage in hedging transactions to protect against uncertainty in future exchange rates between particular foreign currencies and the U.S. dollar.

***We are authorized to issue a class of blank check preferred stock, which could adversely affect the holders of our common stock.***

Our restated certificate of incorporation allows us to issue a class of blank check preferred stock with rights potentially senior to those of our common stock without any further vote or action by the holders of our common stock. The issuance of preferred stock could decrease the amount of earnings and assets available for distribution to the holders of our common stock or could adversely affect the rights and powers including voting rights, of such holders. In certain circumstances such issuance could have the effect of decreasing the market price of our shares, or making a change in control of us more difficult.

***We are in the process of strengthening our internal control over financial reporting.***

We have determined that the personnel and management of Novogen, who perform our accounting and financial reporting functions pursuant to our services agreement with Novogen, are not sufficiently expert in U.S. GAAP and the requirements of the Securities and Exchange Commission and the Public Company Accounting Oversight Board and that this lack of expertise represents a material weakness in the operation of the our internal control over financial reporting. In addition, we have also determined that our system of financial reporting was not designed to prepare financial statements in accordance with U.S. GAAP and that our system of internal control, in particular our processes to review and analyze elements of the financial statement close process and prepare consolidated financial statements in accordance with U.S. GAAP, has not reduced to a relatively low

level the risk that errors in amounts that would be material in relation to those financial statements may occur and may not be detected within a timely period by management in the normal course of business.

We and Novogen have undertaken a re- evaluation of our internal controls and procedures and have implemented such enhancements as appropriate. While we have taken measures designed to address the above matters, we and Novogen may need to implement additional measures to further enhance our internal controls and procedures.

***We are exposed to certain potential risks from recent legislation requiring companies to evaluate their internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act of 2002.***

We are evaluating our internal controls systems in order to allow management to report on the effectiveness of our internal control over financial reporting and our registered independent public accounting firm to attest to this report, as required by Section 404 of the Sarbanes-Oxley Act. We are performing the system and process evaluation and testing, and implementing any necessary remediation required, in an effort to comply with the management reporting and public accounting firm attestation requirements and continue to incur additional expenses and devote significant management time towards completing actions required for management's evaluation. The evaluation and attestation processes required by Section 404 are new and, consequently, public companies and public accounting firms are still developing their experience in complying with these requirements. While we have developed and are implementing plans to fully implement the requirements relating to internal controls and all other aspects of Section 404 in a timely fashion, we cannot be certain as to the timing of completion of our evaluation, testing and remediation actions or the impact of the same on our operations since, like other public companies, we are undergoing the process for the first time in a regulatory environment where the standards to assess adequacy of compliance are under development. We cannot assure you that there may not be significant deficiencies or material weaknesses that would be required to be reported as a result of the process.

#### **Risks Related to Our Relationship with Novogen**

***As our majority stockholder, Novogen has the ability to determine the outcome of all matters submitted to our stockholders for approval and Novogen's interests may conflict with ours or our other stockholders' interests.***

Novogen beneficially owns approximately 86.9% of our outstanding shares of common stock. As a result, Novogen will have the ability to effectively determine the outcome of all matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets.

Novogen will have the ability to effectively control our management and affairs. Novogen's interests may not always be the same as that of our other stockholders. In addition this concentration of ownership may harm the market price of our shares by:

- delaying, deferring or preventing a change in control;
- impeding a merger, consolidation, takeover or other business combination involving us;
- discouraging a potential acquirer from making a tender, offer or otherwise attempting to obtain control of us; or
- selling us to a third party.

***A number of our directors are officers and/or directors of Novogen which may create a conflict of interest.***

Three of our six existing board members currently serve as board members of Novogen. Our President and Chief Executive Officer, Christopher Naughton, is the Managing Director of Novogen. Our Chairman and Phenoxodiol Program Director, Professor Graham Kelly, is an executive of Novogen. Our Chief Financial Officer and Secretary, David Ross Seaton, is the Chief Financial Officer of Novogen. Simultaneous service as a Novogen director or officer can create, or appear to create, a conflict of interest, when such directors or officers are presented with decisions that could have different implications for us and for Novogen.

***We depend on a number of key personnel whose services are provided by Novogen under our services agreement. If we are not able to procure these services in the future, the strategic direction of the clinical development program would be disrupted, causing a delay in phenoxodiol's commercialization.***

We currently rely on Professor Graham Kelly, our Chairman and Phenoxodiol Program Director, Professor Alan Husband, Novogen Research Director, and Mr. Christopher Naughton, our President and CEO, to provide the strategic direction for the clinical development of phenoxodiol. If we are unable to secure the ongoing services of these key personnel, the commercialization program for phenoxodiol will be disrupted and will cause delays in obtaining marketing approval. Novogen has entered into employment agreements and maintains key man life insurance policies for each of these persons.

***The ongoing criminal investigations involving Professor Kelly, our Chairman and Phenoxodiol Program Director, could have a material adverse effect on our business or cause our stock price to decline.***

Professor Kelly is one of a number of individuals who, and whose associated entities and advisors, have been the subject of investigations by certain Australian authorities relative to their alleged involvement in the evasion of Australian tax, fraud and money laundering. Professor Kelly has informed us that he does not believe that he has committed any wrongdoing and denies that he has been involved in any wrongdoing. Nevertheless, Professor Kelly may need to allocate time and resources to deal with the investigation. Additionally, if the Australian authorities were to decide to prosecute Professor Kelly upon concluding their investigation and if such prosecution were to result in a conviction, Professor Kelly may be barred from acting as an officer or director and may become unavailable to us. Any publicity related to this investigation or potential prosecution or conviction of Professor Kelly could have a material adverse effect on our business or cause our stock price to decline.

***Novogen can compete with us.***

We have no contract, arrangement or understanding with Novogen to preclude it from developing a product which may be competitive with phenoxodiol or to use phenoxodiol for any uses other than anticancer applications. Novogen has reserved the intellectual property rights and know-how rights relating to topical applications of phenoxodiol even in the field of cancer. There can be no assurance that Novogen or its subsidiaries will not pursue alternative technologies or product candidates as a means of developing treatments for the conditions targeted by phenoxodiol or any other product candidate which we seek to exploit.

***We are dependent on Novogen for our personnel.***

We have no employees. We rely on Novogen to provide or procure the provision of staff and other financial and administrative services under our services agreement with Novogen. We believe Novogen has fully complied with the terms of our services agreement. As discussed above, though, we have determined that the personnel and management of Novogen, who perform our accounting and financial reporting functions pursuant to our services agreement with Novogen, are not sufficiently expert in U.S. GAAP and the requirements of the Securities and Exchange Commission and the Public

Company Accounting Oversight Board. While we and Novogen have taken measures designed to address this matter, we cannot assure you that Novogen will be able to provide personnel and management that are sufficiently expert in these areas. To successfully develop phenoxodiol, we will require ongoing access to the personnel who have, to date, been responsible for the development of phenoxodiol. The services agreement does not specify a minimum amount of time that Novogen employees must devote to our operations. If we are unable to secure or if we lose the services of these personnel, the ability to develop phenoxodiol could be materially impaired. Moreover, if our business experiences substantial and rapid growth, we may not be able to secure the services and resources we require from Novogen or from other persons to support that growth.

***We are largely dependent on Novogen for our supply of phenoxodiol and should Novogen be unable to supply commercial quantities of phenoxodiol, it may be difficult to secure an alternative source.***

We currently intend that phenoxodiol will be supplied to us in its primary manufactured form by Novogen under the manufacturing license and supply agreement. As the manufacturing process for phenoxodiol has not been tested in the quantities needed for commercial sales, we may be unable to receive the necessary quantities in a timely manner. In addition, in order for Novogen to supply commercial quantities of phenoxodiol in due course, it will need to contract third party manufacture.

If Novogen materially and persistently fails to supply us with the quantities of phenoxodiol that we require, the manufacturing license and supply agreement permits us, and we could consider contracting with third party manufacturers for the production of phenoxodiol. Any third party manufacturer would have to satisfy cGMPs and would have to meet our quality assurance standards. In addition, it may be difficult to negotiate acceptable terms with any third party manufacturer.

### **Risks Related to Our Common Stock**

***The trading price of the shares of our common stock could be highly volatile and could decline in value and we may incur significant costs from class action litigation.***

The trading price of our common stock could be highly volatile in response to various factors, many of which are beyond our control, including:

- developments concerning phenoxodiol;
- announcements of technological innovations by us or our competitors;
- new products introduced or announced by us or our competitors;
- changes in financial estimates by securities analysts;
- actual or anticipated variations in operating results;
- expiration or termination of licenses, research contracts or other collaboration agreements;
- conditions or trends in the regulatory climate and the biotechnology, pharmaceutical and genomics industries;
- changes in the market valuations of similar companies;
- the liquidity of any market for our securities;
- trading prices of our common stock on the Alternative Investment Market of the London Stock Exchange; and
- additional sales by us or Novogen of shares of our common stock.

In addition equity markets in general and the market for biotechnology and life sciences companies in particular have experienced substantial price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies traded in those markets. In addition, changes in economic conditions in the United States, Europe or globally, could impact upon our ability to grow profitably. Adverse economic changes are outside our control and may result in material adverse impacts on our business or our results of operations. These broad market and industry factors may materially affect the market price of our shares of common stock, regardless of our development and operating performance. In the past, following periods of volatility in the market price of a company's securities, securities class-action litigation has often been instituted against that company. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources.

***You will not be able to exercise the warrants if we do not maintain the effectiveness of the registration statement and a current prospectus.***

If we do not maintain an effective registration statement and a current prospectus or comply with applicable state securities laws, you may not be able to exercise the warrants. In order for you to be able to exercise the warrants, the shares underlying the warrants must be covered by an effective registration statement and a current prospectus and be qualified for sale or exempt from qualification under the applicable securities laws of the state in which you reside. Although we cannot assure you that we will actually be able to do so, we will use our best efforts to:

- maintain an effective registration statement and a current prospectus covering the shares of our common stock underlying the warrants at all times when the market price of the common stock exceeds the exercise price of the warrants until the expiration of the warrants; and
- maintain the registration of such shares under the securities laws of the states, if any, in which we initially qualify the common stock units for sale in this offering.

***Future sales of our common stock may depress our stock price.***

The market price of our common stock could decline as a result of sales of substantial amounts of our common stock in the public market, including the shares covered by this annual report, or the perception that these sales could occur. In addition, these factors could make it more difficult for us to raise funds through future equity offerings. As of July 31, 2005, we had 56,938,000 shares of our common stock outstanding not including the 2,392,000 shares of common stock underlying the warrants.

We may also acquire other companies or technologies or finance strategic alliances by issuing equity, which may result in additional dilution to our stockholders.

***We will have broad discretion over the use of the net proceeds to us from any exercise of outstanding warrants.***

We will have broad discretion to use the net proceeds to us upon any exercise of outstanding warrants, and you will be relying on the judgment of our board of directors and management regarding the application of these proceeds. Although we expect to use a substantial portion of the net proceeds from any exercise of the warrants for general corporate purposes, including potential payments to Novogen under the terms of the license agreement, potential licensing of other cancer compounds developed by Novogen under the license option deed and potential expansion of the clinical trial program for phenoxodiol to include other forms of cancer, we have not allocated these net proceeds for specific purposes.



**Item 2. Properties**

The Company does not own or lease any property.

**Item 3. Legal Proceedings**

None.

**Item 4. Submission of Matters to a Vote of Security Holders**

No matters were submitted to a vote of security holders during the fourth quarter of the fiscal year covered by this Annual Report on Form 10-K.

## PART II

### Item 5. Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Securities

The following tables set forth for the period indicated the high and low sale prices of our common stock and warrants as reported by the Nasdaq National Market and for our common stock as reported by the AIM. The trading price for our shares of common stock on the AIM are quoted as sterling (£), the lawful currency of the United Kingdom.

Common Stock	Nasdaq National Market		AIM Market	
	High \$	Low \$	High £	Low £
<b>Year Ended June 30, 2004</b>				
First Quarter	—	—	3.93	3.25
Second Quarter	12.99	6.25	5.60	3.80
Third Quarter	13.10	7.63	6.12	5.09
Fourth Quarter	12.00	7.31	6.10	5.20
<b>Year Ended June 30, 2005</b>				
First Quarter	9.27	5.74	4.85	4.25
Second Quarter	10.49	6.71	5.10	4.60
Third Quarter	9.54	6.79	4.52	3.60
Fourth Quarter	9.32	6.72	4.05	3.60
<b>Warrants</b>				
<b>Year Ended June 30, 2004</b>				
First Quarter	—	—		
Second Quarter	8.64	2.30		
Third Quarter	7.40	3.35		
Fourth Quarter	6.95	4.65		
<b>Year Ended June 30, 2005</b>				
First Quarter	5.75	2.95		
Second Quarter	6.00	4.06		
Third Quarter	5.55	3.60		
Fourth Quarter	5.10	3.70		

The following table sets forth, for the period indicated, the high, low, average and period-end noon buying rate for sterling, expressed in dollars per sterling in New York City as certified for customs purposes by the Federal Reserve Bank of New York.

<u>Period Ended</u>	<u>High</u>	<u>Low</u>	<u>Average</u>	<u>Period-End</u>
<b>Year Ended June 30, 2004</b>				
First Quarter	\$ 1.6718	\$ 1.5728	\$ 1.6071	\$ 1.6620
Second Quarter	\$ 1.7842	\$ 1.6598	\$ 1.7079	\$ 1.7842
Third Quarter	\$ 1.9045	\$ 1.7902	\$ 1.8385	\$ 1.8400
Fourth Quarter	\$ 1.8564	\$ 1.7544	\$ 1.8071	\$ 1.8126
<b>Year Ended June 30, 2005</b>				
First Quarter	\$ 1.8734	\$ 1.7733	\$ 1.8193	\$ 1.1809
Second Quarter	\$ 1.9482	\$ 1.7790	\$ 1.8687	\$ 1.9160
Third Quarter	\$ 1.9292	\$ 1.8570	\$ 1.8911	\$ 1.8880
Fourth Quarter	\$ 1.9197	\$ 1.7930	\$ 1.8560	\$ 1.7930

As of July 29, 2005, the last reported closing price of our common stock and warrants on the Nasdaq National Market was \$7.00 and \$3.75 respectively. The price of our common stock on the AIM market was £3.97 as of July 31, 2005. There were approximately 1420 stockholders on record of our common stock

### **Dividends**

We have never declared or paid any cash dividends on our common stock and do not anticipate paying any cash dividends in the foreseeable future. We currently intend to retain future earnings, if any, to fund the expansion and growth of our business. Payments of any future cash dividends will be at the discretion of our board of directors after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs, plans for expansion and other factors that our board of directors deem relevant.

### **Use of Proceeds of Initial Public Offering**

The effective date of the registration statement (Registration No. 333-109129) filed on Form S-1 and registration statement (Registration No. 333-111291) filed on Form S-1 pursuant to Rule 462(b), both relating to the initial public offering in the United States of common stock units (each unit consisting of one share of the Company's common stock and one warrant to purchase a share of the Company's common stock at an exercise price of \$9.00 per share), was December 17, 2003. Proceeds to the Company from the offering, after deduction of underwriting discounts and commissions of approximately \$806,000 and offering costs of approximately \$1,612,000, totalled approximately \$15,522,000. As of June 30, 2005, the Company had used \$13,066,000 of the proceeds of the offering of which: \$5,000,000 was used to make the first license fee payment due to Novogen under the terms of the license agreement; \$2,000,000 was used to make the milestone license fee payment due to Novogen under the terms of the license agreement; and \$6,066,000 was used to pay the ongoing expenses of clinical trials, amounts due to Novogen under the services agreement and the manufacturing license and supply agreement and general corporate expenses. All remaining proceeds of the offering have been invested in short-term money market accounts.

The Company intends to use the balance of the proceeds invested in short-term money market accounts of approximately \$2.5 million to complete Phase II clinical trials of phenoxodiol and other research projects currently underway.

## Stock Repurchases

The Company has not repurchased any shares of common stock during the fourth quarter of the fiscal year ended June 30, 2005.

## Equity Compensation

The following table sets forth, as of June 30, 2005 outstanding awards and shares remaining available for future issuance under the Company's compensation plans under which equity securities are authorized for issuance.

Plan Category	(a) Number of securities to be issued upon exercise of outstanding options, warrants and rights	(b) Weighted-average exercise price of outstanding options, warrants and rights	(c) Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by security holders	Not Applicable	\$ Not Applicable	Not Applicable
Equity compensation plans not approved by security holders	None	\$ Not Applicable	Indeterminable
Total	None	\$ Not Applicable	Indeterminable

Our employee share option plan provides our directors, employees, employees of our affiliates and certain of our contractors and consultants with the opportunity to participate in our ownership. Our remuneration committee addresses participation, the number of options offered and any conditions of exercise. In making these determinations the committee will generally consider the participant's position and record of service to us and our affiliates and potential contribution to the growth of us and our affiliates. Any other matters tending to indicate the participant's merit may also be considered. Options will be exercisable between two years and five years after grant, unless otherwise determined by the committee appointed by the board. Options granted will be exercisable at a price determined by the committee at the time of issue (and will be subject to adjustment in accordance with the terms of the plan). Other key terms of the plan include:

- Options will lapse if the participants cease to be engaged by us or our affiliates. The committee will have the discretion to waive this provision.
- The terms of the plan also provide for adjustments to the rights of an option holder as a result of a reorganisation of our capital or other corporate event. The holder of an option is not permitted to participate in any distribution by us or in any rights or other entitlements issued by us to stockholders in respect of our shares unless the options are exercised prior to the relevant record; and
- All options vest on the occurrence of certain events such as a change of control, as defined in the share option plan.

The plan also contains standard provisions dealing with matters such as administration of the plan, amendment of the plan and termination or suspension of the plan.

## Item 6. Selected Financial Data

The following selected financial data should be read in conjunction with Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" and Item 8. "Financial Statements" included elsewhere in this Annual Report on Form 10-K.

### Statement of Operations

	Years Ended June 30,			
	2005	2004	2003	2002
<i>(in thousands, except per share data)</i>				
<b>Revenues:</b>				
Interest and other income	\$ 308	\$ 193	\$ 145	\$ 7
Total revenues	308	193	145	7
Loss from operations	(6,421)	(8,538)	(3,033)	(122)
Income tax expense	—	—	—	(1)
Net loss arising during development stage	\$ (6,421)	\$ (8,538)	\$ (3,033)	\$ (123)
<b>Net loss per common share:</b>				
Basic and diluted	\$ (0.11)	\$ (0.16)	\$ (0.06)	\$ (0.00)
Weighted average common shares outstanding	56,938,000	54,954,578	52,023,247	49,769,581

### Balance Sheet Data

	As of June 30,			
	2005	2004	2003	2002
<i>(in thousands)</i>				
Cash and cash equivalents	\$ 9,238	\$ 24,819	\$ 7,244	\$ 9,164
Total assets	\$ 19,364	\$ 24,849	\$ 7,286	\$ 9,185
Total stockholders' equity	\$ 16,521	\$ 22,942	\$ 5,933	\$ 8,899

## Item 7. Management's Discussion and Analysis of Financial Condition and results of Operations.

The following discussion and analysis should be read in conjunction with "Item 8. Financial Statements and Supplementary Data" included below. Operating results are not necessarily indicative of results that may occur in future periods. This discussion and analysis contains forward-looking statements that involve risks uncertainties and assumptions. The actual results may differ materially from those anticipated in the forward-looking statements as a result of many factors including, but not limited to, those set forth under "Cautionary Statements About Forward-Looking Statements" and "Risk Factors" in Item 1. "Business" included above in this Annual Report. All forward-looking statements included in this document are based on the information available to us on the date of this document and we assume no obligation to update any forward-looking statements contained in this Annual Report.

## Overview

We are a development stage company incorporated on December 1, 2000 as a wholly-owned subsidiary of Novogen Limited. The Company commenced operations in May 2002 and its business purpose is the development and commercialization of drugs for the treatment of cancer. The Company is presently engaged in the clinical development of the anti-cancer drug phenoxodiol. A Novogen subsidiary, Novogen Research Pty Limited, has granted to the Company's subsidiary, Marshall Edwards Pty Limited, or MEPL, a worldwide non-transferable license under its patent right and patent applications and its relevant know-how to conduct clinical trials and commercialize and distribute all forms of phenoxodiol for uses in the field of prevention, treatment, and cure of cancer in humans, except topical applications. Novogen currently owns approximately 86.9% of the outstanding shares of the Company's common stock.

The Company's main focus since commencing operations is to undertake human clinical testing of phenoxodiol. The Company does not employ any staff directly but obtains services from Novogen under a services agreement. The Company has incurred losses since inception and expects to incur operating losses and generate negative cash flows from operations for the foreseeable future as it expands research and development activities and moves phenoxodiol into later stages of development. As of June 30, 2005, the Company had accumulated losses of \$18,115,000.

During fiscal year 2005, we made significant progress in the clinical development of phenoxodiol including:

- In May 2005, we announced preliminary results from the combination therapy trial for patients with late stage refractory ovarian cancer being conducted at Yale New Haven Hospital in the United States and the Royal Women's Hospital in Australia. These preliminary results revealed that 33% (12/36) of patients who were on combination therapy that included phenoxodiol experienced a complete or partial response.
- In January 2005, we announced that we had appointed a global research organization to manage our planned "pivotal" Phase IIb multinational ovarian cancer study. The trial will be known as the Ovature trial. We are discussing trial design with the U.S. Food and Drug Administration (FDA) to develop a trial protocol that is intended to support marketing approval of phenoxodiol, including the number of treatment arms to be included and the number of patients required to be tested in each arm of the trial.
- In November 2004, we announced that the FDA granted phenoxodiol Fast Track status for its intended use as a chemo-sensitizing agent in patients with recurrent late stage ovarian cancer. In January 2005, we announced that the FDA granted phenoxodiol Fast Track status for its intended use in patients with hormone-refractory prostate cancer. Under the FDA Modernization Act of 1997, designation as a Fast Track product means that phenoxodiol is eligible for certain programs for accelerated marketing approval.

The Company has not generated any revenues from operations since inception other than interest on cash assets.

Expenses have consisted primarily of costs associated with conducting the clinical trials of phenoxodiol and costs incurred under the license agreement, the services agreement and the manufacturing license and supply agreements with Novogen and its subsidiaries, including the costs of the clinical trial drug supplies. See Part III, Item 13 "Certain Relationships on Related Transactions" for a description of these agreements.

To date, operations have been funded primarily through the sale of equity securities.

The Company expects that quarterly and annual results of operations will fluctuate for the foreseeable future due to several factors including the timing and extent of research and development efforts and the outcome and extent of clinical trial activities. The Company's limited operating history makes accurate prediction of future operating results difficult or impossible.

### **Critical Accounting Estimates**

The preparation of the consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the accompanying notes. Actual results could differ from those estimates.

#### *Clinical Trials Expenses*

Estimates have been used in determining the expense liability under certain clinical trial contracts where services have been performed but not yet invoiced. The actual costs of those services could differ in amount and timing from the estimates used in completing the financial results.

Clinical trial expenses of \$1,156,000 have been included in the financial statements for the year ended June 30, 2005, of which \$304,000 has been accrued at June 30, 2005. These estimates are based on the number of patients in each trial and the drug administration cycle.

Clinical research contracts may vary depending on the clinical trial design and protocol. Generally the costs, and therefore estimates, associated with clinical trial contracts are based on the number of patients, drug administration cycles, the type of treatment and the outcome being measured. The length of time before actual amounts can be determined will vary depending on length of the patient cycles and the timing of the invoices by the clinical trial partners.

#### *Development Expenses*

Research and development costs incurred since inception through June 30, 2005 amount to \$6,753,000.

Research and development costs are expensed as they are incurred and are expected to increase in the future as the phenoxodiol clinical program progresses.

Historical research and development costs and clinical trial costs have not been documented on a project by project basis. In addition, research and development resources are supplied by Novogen across several projects. As a result, the costs incurred for each clinical project cannot be stated precisely on a project by project basis.

The Company expects that a large percentage of research and development expenses in the future will be incurred in support of current and future clinical development programs. These expenditures are subject to a number of uncertainties in timing and cost to completion.

The duration and cost of clinical trials may vary significantly over the life of a project as a result of:

- the number of sites included in the trials;
- the length of time required to enroll suitable patients;

- the number of patients that participate in the trials;
- the indication being studied; and
- the efficacy and safety profile of the product.

The Company's strategy also includes the option of entering into collaborative arrangements with third parties to participate in the development and commercialization of phenoxodiol. In the event third parties have control over the clinical development process, the completion date would largely be under the control of that third party.

As a result of these uncertainties, the Company is unable to determine the duration of or completion costs for research and development projects or when and to what extent it will receive cash inflows from the commercialization and sale of phenoxodiol.

The Company intends to continue the clinical development of phenoxodiol and to assess the opportunity to license other cancer drugs developed by Novogen as the opportunities arise.



## Results of Operations

### Summary of Revenue and Expenses

The following table provides a summary of revenues and expenses to supplement the more detailed discussions below:

#### Revenues

	2005	Years Ended June 30, 2004 <i>(in thousands)</i>	2003
Interest and other income	\$ 308	\$ 193	\$ 145
Total revenues	308	193	145

#### Research and development expenses

	2005	Years Ended June 30, 2004 <i>(in thousands)</i>	2003
Clinical trial study costs	\$ (1,156)	\$ (774)	\$ (1,060)
Clinical trial drug costs	(612)	(761)	(164)
Research and development service charge	(385)	(811)	(790)
Other	(126)	(35)	(10)
Total Research and Development Costs	(2,279)	(2,381)	(2,024)

#### License Fees

	2005	Years Ended June 30, 2004 <i>(in thousands)</i>	2003
License Fees	(3,000)	(5,500)	(500)

#### Selling, general and administrative expenses

	2005	Years Ended June 30, 2004 <i>(in thousands)</i>	2003
Legal and professional fees	\$ (371)	\$ (250)	\$ (119)
Administrative service charge	(688)	(302)	(285)
Other	(391)	(298)	(250)
Total operating expenses	(1,450)	(850)	(654)

#### Year Ended June 30, 2005 Compared to the Year Ended June 30, 2004

The Company recorded a consolidated loss of \$6,421,000 and \$8,538,000 for the years ended June 30, 2005 and 2004, respectively.

**Revenues:** The Company received interest on cash assets and cash equivalents of \$308,000 for the year ended June 30, 2005 versus \$193,000 for the year ended June 30, 2004. This increase was due to the Company's investing activities in higher yielding interest bearing deposits and higher average cash balances following the Company's December 2003 public offering.

**Research and Development:** Research and Development expenses decreased \$102,000 to \$2,279,000 for the year ended June 30, 2005 compared to \$2,381,000 for the year ended June 30, 2004. This decrease was due primarily to a reduction in the research and development service charge from

Novogen under the terms of the services agreement reflecting lower costs incurred by Novogen and reduced time spent by Novogen personnel on the development of phenoxodiol. Clinical trial drug costs have also reduced as many patients have now completed the treatment cycles. These costs have partially been offset by an increase in clinical trial costs. This increase in clinical trial costs result from an increase patient data management and analysis costs associated with reporting and summarizing the outcomes of the clinical trials.

**License Fees:** Milestone license fees of \$2,000,000 have been accrued in the twelve months ended June 30, 2005 in connection with the annual milestone license fee of \$4,000,000 that is payable to Novogen within 30 days after December 31, 2005 under the terms of the license agreement with Novogen. Milestone license fees of \$1,000,000 were accrued during the twelve months ended June 30, 2004 in connection with the annual milestone license fee of \$2,000,000 due to Novogen within 30 days after December 31, 2004. The December 31, 2004 license fee was paid to Novogen in January 2005.

**Selling, General and Administrative:** Selling, general and administrative expenses increased by \$600,000 to \$1,450,000 for the year ended June 30, 2005 compared to \$850,000 for the year ended June 30, 2004. The increase was due primarily to the increase in costs associated with professional fees and increased costs incurred for administration and accounting services provided by Novogen under the terms of the services agreement and other fees relating to compliance with United States securities reporting requirements and FDA regulations. Included in selling, general and administrative expenses are foreign exchange gains and losses which occur when revaluing cash denominated in foreign currencies and translation gains and losses upon consolidation of MEPL. MEPL uses US dollars as its functional currency and also engages in transactions in foreign currencies. However, MEPL's accounts and financial statements are denominated in Australian dollars. Translation of MEPL's financial statements into U.S. dollars did not have a material impact on the Company's financial position. At June 30, 2004, the Company had not established a foreign currency hedging program. Net foreign exchange losses during the twelve months ended June 30, 2005 were \$24,000 compared with net exchange gains of \$58,000 during the twelve months ended June 30, 2004. MEPL's accounts are maintained in Australian dollars, however, its functional currency is US dollars. Foreign exchange gains and losses occur upon consolidation of MEPL and also as a result of translations in foreign currency.

#### **Year Ended June 30, 2004 Compared to the Year Ended June 30, 2003**

The Company recorded a consolidated loss of \$8,538,000 and \$3,033,000 for the years ended June 30, 2004 and 2003, respectively.

**Revenues:** The Company received interest on cash assets and cash equivalents of \$193,000 for the year ended June 30, 2004 versus \$145,000 for the year ended June 30, 2003. This increase was due to the Company's higher cash balances following the Company's December 2003 public offering.

**Research and Development:** Research and Development expenses increased \$357,000 to \$2,381,000 for the year ended June 30, 2004 compared to \$2,024,000 for the year ended June 30, 2003. This increase was due primarily to the increase in cost of phenoxodiol supplied for use in the clinical trial program.

**License Fees:** A license fee of \$5,000,000 was paid to Novogen in February 2004 under the terms of the license agreement following the exercise of warrants and the receipt of proceeds from the public offering completed in December 2003. Milestone license fees of \$1,000,000 were accrued at June 30, 2004 in connection with the annual milestone license fee of \$2,000,000 that was payable to Novogen on December 31, 2004 under the terms of the license agreement with Novogen.

**Selling, General and Administrative:** Selling, general and administrative increased by \$196,000 to \$850,000 for the year ended June 30, 2004 compared to \$654,000 for the year ended June 30, 2003. The increase was due primarily to the increase in costs associated with professional and other fees relating to compliance with United States reporting requirements. Other expenses including those related to compliance costs and related on-going investor relations also increased. The Company conducts a portion of its business in Australian dollars. At June 30, 2004, the Company had not established a foreign currency hedging program. Net foreign exchange gains during the twelve months ended June 30, 2004 were \$58,000 compared with net exchange gains of \$3,000 during the twelve months ended June 30, 2003. MEPL's accounts are maintained in Australian dollars, however, its functional currency is US dollars. Foreign exchange gains and losses occur upon consolidation of MEPL and also as a result of translations in foreign currency.

#### **Liquidity and Capital Resources**

At June 30, 2005, the Company had cash resources of \$19,238,000 compared to \$24,819,000 at June 30, 2004. The decrease was due to expenditures in the clinical trial program and other corporate expenses incurred during the year. Funds are invested in short term bank accounts, pending use. The implementation of the Company's business plan is dependent on the Company's ability to maintain adequate cash resources to complete the clinical development program.

#### **Source and Uses of Cash**

##### *Cash Used in Operating Activities*

Cash used in operating activities for the year ended June 30, 2005 was \$5,581,000 compared to \$7,972,000 for the same period in 2004. The decrease in cash outflow of \$2,391,000 for the year ended June 30, 2005 was due primarily to reduced losses of \$2,117,000 incurred during the year which included the milestone license fee of \$2,000,000 paid in January 2005, a reduction of \$3,000,000 from the previous years lump sum license fee, paid under the terms of the license agreement with Novogen. This reduction was partially offset by increased operating expenses for clinical trials and administrative costs.

##### *Cash Used in Financing Activities*

During the year ended June 30, 2005, \$10,000,000 was placed in a high interest yielding cash deposit account for a term of seven months. The interest earned on these funds has been accrued in the accounts.

##### *Cash Requirements*

The Company believes that it will have sufficient cash resources to fund existing operations at least through the end of June 2006 and to complete the current Phase I and Ib/IIa clinical trial program.

The Company is currently planning to conduct a pivotal clinical study to support marketing approval of phenoxodiol for ovarian cancer. The trial will use phenoxodiol in combination with carboplatin and

will assess phenoxodiol's efficacy for late stage ovarian cancer patients who are refractory to standard chemotherapies. The Company is discussing trial design with the FDA to develop a trial protocol, including the number of treatment arms needed to be completed and the number of patients required to be tested in each arm. The Company is still in the planning stage of the trial design and has not determined the cash resources needed to complete the trial.

Also, additional cash resources may be required if a new cancer compound is developed by Novogen and the Company secures a license under the terms of the Company's license option deed from Novogen. Novogen has notified the Company that its new anti-cancer compound NV-196 (previously referred to as NV-18) is now an "option compound" under the terms of the license option deed and that Novogen has commenced Phase I clinical trials. The Company has commissioned an independent report on NV-196 and will review initial clinical results before making a decision to commence license negotiations with Novogen.

Ongoing operations through the conduct of the clinical trial program will continue to consume cash resources without generating revenues.

The Company is required to make payments under the terms of the License Agreement with Novogen as follows:

1. A lump sum license fee of \$5,000,000 is payable to Novogen on November 1, 2003 or such later date when the cumulative total of all funds received from debt or equity issuances and revenue received from commercialization (income other than sales) and sales of phenoxodiol products exceeds \$50,000,000. We have not yet met these preconditions for payment.

2. In addition to the amount above, until the expiration of the exclusivity period of the license, MEPL must pay Novogen 2.5% of all net sales and 25% of commercialization income. After the exclusivity period of the license, 1.5% of net sales must be paid to Novogen. The preconditions to such payments have not yet occurred.

3. In addition to the amounts above, amounts payable for annual milestone license fees under the license agreement for the calendar years ended December 31 are as follows:

Calendar Year	
2005	\$ 4,000,000
Each calendar year thereafter during the exclusivity period	\$ 8,000,000

The "Exclusivity Period" ends on the later of:

- (a) the date of expiration or lapsing of the last Patent Right in the patents and patent applications set out in the licence agreement with Novogen; or
- (b) the date of expiration or lapsing of the last Licensed Patent Right which MEPL would, but for the licence granted in licence agreement, infringe in any country in the Territory by doing in that country any of the things set out in the licence agreement.

At June 30, 2004 an amount of \$1,000,000 was accrued and reflected in amounts due to the parent company, being 50% of the \$2,000,000 milestone payment payable to Novogen on December 31, 2004 under the terms of the license agreement with Novogen. The Company paid the \$2,000,000 due

to Novogen at the end of January 2005. Milestone license fees of \$2,000,000 have been accrued at June 30, 2005 in connection with the \$4,000,000 payment due within 30 days following December 31, 2005.

The Company will also be required to make payments to Novogen under the services agreement and manufacturing license and supply agreement.

The Company does not intend to incur any significant capital expenditures in the foreseeable future.

The Company is currently assessing its future cash requirements needed to fund new clinical trial initiatives and licensing options available to it under the license option deed.

#### *Contractual Obligations*

The following table summarizes our future payment obligations and commitments as of June 30, 2005:

(In thousands)

<b>Contractual Obligations</b>	<b>Total</b>	<b>Payment due by period</b>			
		<b>less than 1 Year</b>	<b>1 - 3 Years</b>	<b>3 - 5 Years</b>	<b>More than 5 Years</b>
Purchase Obligations	<u>\$ 2,285</u>	<u>\$ 1,821</u>	<u>\$ 464</u>	<u>\$ —</u>	<u>\$ —</u>
Total	<u>\$ 2,285</u>	<u>\$ 1,821</u>	<u>\$ 464</u>	<u>\$ —</u>	<u>\$ —</u>

No amounts have been included in the above table for future payments to Novogen which may arise in connection with the license agreement, the services agreement or the manufacturing and supply agreement.

#### *Off-Balance Sheet Arrangements*

The Company does not currently have any off-balance sheet arrangements.

## **Recent Accounting Announcements**

### **Share-Based Payments**

In December 2004, the FASB Issued Statement of Financial Accounting Standards No. 123R (Statement 123R), "Share-Based Payments", the provisions of which become effective for the Company in fiscal 2006. This Statement eliminates the alternative to use APB No. 25's intrinsic value method of accounting that was provided in Statement 123 as originally issued. Statement 123R requires companies to recognize the cost of employee services received in exchange for awards of equity instruments based on the grant-date fair value of those awards. While the fair-value-based method prescribed by Statement 123R is similar to the fair-value-based method disclosed under the provisions of Statement 123 in most respects, there are some differences. The Company's stock option plan provides for the grant of options to the Company's directors, employees, employees of the Company's affiliates and certain of the Company's contractors and consultants. To date no options have been issued under the plan.

### **Accounting Changes and Error Corrections**

In May 2005, the FASB issued Statement of Financial Accounting Standards No. 154 (SFAS 154), "Accounting Changes and Error Corrections" which provides guidance on the accounting for and reporting of accounting changes and correction of errors. This statement changes the requirements for the accounting for and reporting of a change in accounting principle and applies to all voluntary changes in accounting principle. It also applies to changes required by an accounting pronouncement in the unusual instance that the pronouncement does not include specific transition provisions. This statement is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. We do not anticipate a material effect upon the adoption of this statement.

## **Item 7a. Quantitative and Qualitative Disclosures about Market Risk**

### **Interest Rate Risk**

The Company places cash in “on call” and “short-term” deposit accounts with high quality financial institutions.

In the normal course of business operations may be exposed to fluctuations in interest rates. These fluctuations can vary the costs of financing and investing. Because we have no debt there was no material impact on earnings due to fluctuations in interest rates.

The Company does not use derivative financial instruments to hedge its risks associated with the fluctuations of interest rates.

### **Foreign Currency Risk**

The Company conducts a portion of its business in various currencies, primarily in U.S. and Australian dollars. At June 30, 2005, the Company had not established a foreign currency hedging program. Net foreign exchange losses during the twelve months ended June 30, 2005 were \$24,000 compared with net exchange gains of \$58,000 during the twelve months ended June 30, 2004. Foreign exchange gains and losses occur upon consolidation of MEPL, which uses U.S. dollars as its functional currency and also engages in transactions in foreign currencies. MEPL’s accounts are denominated in Australian dollars. Translation of MEPL’s financial statements into U.S. dollars did not have a material impact on the Company’s financial position.

The Company does not consider the effects of foreign currency movements to be a material risk to its financial condition.

**Item 8. Financial Statements and Supplementary Data**

**Marshall Edwards, Inc  
Index to Financial Statements**

Report of BDO Independent Auditors  
Consolidated Balance Sheets  
Consolidated Statements of Operations  
Consolidated Statements of Stockholders Equity  
Consolidated Statements of Cash Flows  
Notes to Consolidated Financial Statements





**Chartered Accounts  
& Advisers**

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### **Report of Independent Registered Public Accounting Firm**

The Board of Directors  
Marshall Edwards, Inc.

We have audited the accompanying consolidated balance sheet of Marshall Edwards, Inc. (a development stage company) as of June 30, 2005, and the related statements of operations, stockholders' equity, and cash flows for the year then ended, and for the period from December 1, 2000 (inception) through June 30, 2005. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit. The financial statements as of June 30, 2004 and for the period from December 1, 2000 (inception) through June 30, 2004, were audited by other auditors whose report dated August 13, 2004 expressed an unqualified opinion on those statements. The financial statements for the period from December 1, 2000 (inception) through June 30, 2004 include total revenues and net loss of \$345,000 and \$11,694,000, respectively. Our opinion on the statements of operations, stockholders' equity, and cash flows for the period from December 1, 2000 (inception) through June 30, 2005, insofar as it relates to amounts for prior periods through June 30, 2004, is based solely on the report of other auditors.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit and the report of other auditors provide a reasonable basis for our opinion.

In our opinion, based on our audit and the report of other auditors, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Marshall Edwards, Inc. at June 30, 2005, and the consolidated results of its operations and its cash flows for the year then ended and the period from December 1, 2000 (inception) through June 30, 2005, in conformity with accounting principles generally accepted in the United States of America.

### **BDO**

Sydney, NSW, Australia  
September 13, 2005



Liability limited by the Accountants  
Scheme, approved under the  
Professional Standards Act 1994 (NSW)  
*BDO is a national association of separate  
partnership and entities*

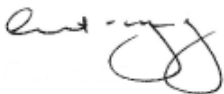
### Report of Independent Registered Public Accounting Firm

The Board of Directors  
Marshall Edwards, Inc.

We have audited the accompanying consolidated balance sheet of Marshall Edwards, Inc. (a development stage enterprise) (the "Company") as of June 30, 2004, and the related consolidated statements of operations, shareholders' equity, and cash flows for the year then ended, and for the period from December 1, 2000 (inception) through June 30, 2004. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit. The financial statements as of June 30, 2003, and for the period from December 1, 2000 (inception) through June 30, 2003, were audited by other auditors whose report dated July 31, 2003 expressed an unqualified opinion on those statements. The financial statements for the period from December 1, 2000 (inception) through June 30, 2003 include total revenues and net loss of US\$152,000 and US\$3,156,000, respectively. Our opinion on the statements of operations, shareholders' equity, and cash flows for the period from December 1, 2000 (inception) through June 30, 2004, insofar as it relates to amounts for prior periods through June 30, 2003, is based solely on the report of other auditors.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit and the report of other auditors provide a reasonable basis for our opinion.

In our opinion, based on our audit and the report of other auditors, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Marshall Edwards, Inc. at June 30, 2004, and the consolidated results of its operations and its cash flows for the year then ended and the period from December 1, 2000 (inception) through June 30, 2004, in conformity with U.S. generally accepted accounting principles.



Sydney, Australia  
13 August 2004

Liability limited by the Accountants Scheme, approved  
under the Professional Standards Act 1994 (NSW)

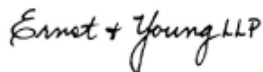
**Report of Independent Registered Public Accounting Firm**

The Board of Directors Marshall Edwards, Inc.

We have audited the accompanying consolidated statement of operations, shareholder's equity and cash flows of Marshall Edwards, Inc. (a development stage company) for the year ended June 30, 2003 and for the period from December 1, 2000 (inception) through June 30, 2003. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated results of operations and cash flows of Marshall Edwards, Inc., for the year ended June 30, 2003 and the period from December 1, 2000 (inception) through June 30, 2003, in conformity with U.S. generally accepted accounting principles.



July 31, 2003

A Member Practice of Ernst & Young Global

**MARSHALL EDWARDS, INC.**  
**(A Development Stage Company)**  
**CONSOLIDATED BALANCE SHEETS**  
(In thousands, except share and per share data)

	June 30, 2005	June 30, 2004
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 9,238	\$ 24,819
Short-term investments	10,000	—
Prepaid expenses and other current assets	126	30
Total current assets	19,364	24,849
Total assets	\$ 19,364	\$ 24,849
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable	\$ 254	\$ 192
Accrued expenses	403	437
Amount due to parent company	2,186	1,278
Total current liabilities	2,843	1,907
Stockholders' equity:		
Preferred stock, \$0.01 par value, authorized 100,000 shares, none outstanding	—	—
Common stock, \$0.00000002 par value, 113,000,000 authorized shares; shares issued and outstanding: 56,938,000 at June 30, 2005 and 56,938,000 at June 30, 2004	—	—
Additional paid-in capital	34,636	34,636
Deficit accumulated during development stage	(18,115)	(11,694)
Accumulated other comprehensive income	—	—
Total stockholders' equity	16,521	22,942
Total liabilities and stockholders' equity	\$ 19,364	\$ 24,849

*See accompanying notes.*

**MARSHALL EDWARDS, INC.**  
**(A Development Stage Company)**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
(In thousands, except share and per share data)

	2005	Years Ended June 30, 2004	2003	Period from December 1, 2000 (Inception) through June 30, 2005
<b>Revenues:</b>				
Interest and other income	\$ 308	\$ 193	\$ 145	\$ 653
<b>Total revenues</b>	<b>308</b>	<b>193</b>	<b>145</b>	<b>653</b>
<b>Operating expenses:</b>				
Research and development	(2,279)	(2,381)	(2,024)	(6,753)
License fees	(3,000)	(5,500)	(500)	(9,000)
Selling, general and administrative	(1,450)	(850)	(654)	(3,014)
<b>Total operating expenses</b>	<b>(6,729)</b>	<b>(8,731)</b>	<b>(3,178)</b>	<b>(18,767)</b>
<b>Loss from operations</b>	<b>(6,421)</b>	<b>(8,538)</b>	<b>(3,033)</b>	<b>(18,114)</b>
Income tax expense	—	—	—	(1)
<b>Net loss arising during development stage</b>	<b>\$ (6,421)</b>	<b>\$ (8,538)</b>	<b>\$ (3,033)</b>	<b>\$ (18,115)</b>
<b>Net loss per common share:</b>				
Basic and diluted	\$ (0.11)	\$ (0.16)	\$ (0.06)	
<b>Weighted average common shares outstanding</b>	<b>56,938,000</b>	<b>54,954,578</b>	<b>52,023,247</b>	

*See accompanying notes.*

**MARSHALL EDWARDS, INC.**  
**(A Development Stage Company)**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(In thousands)

	2005	Years Ended June 30, 2004	2003	Period from December 1, 2000 (Inception) through June 30, 2005
<b>Operating activities</b>				
Net loss arising during development stage	(6,421)	(8,538)	(3,033)	(18,115)
Adjustments to reconcile net loss to net cash used in operating activities:				
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets	(96)	12	(21)	(126)
Accounts payable	62	(241)	381	254
Accrued expenses	(34)	159	278	403
Amounts due to parent company	908	636	554	2,186
Net cash used in operating activities	(5,581)	(7,972)	(1,841)	(15,398)
<b>Financing activities</b>				
Net proceeds from issuance of Common Stock	—	25,578	36	34,636
Amounts payable in connection with issuance of Common Stock	—	—	(146)	—
Investment in short-term deposits	(10,000)	—	—	(10,000)
Net cash (used in) provided by financing activities	(10,000)	25,578	(110)	24,636
Effect of exchange rate changes on cash and cash equivalents	—	(31)	31	—
Net (decrease) increase in cash and cash equivalents	(15,581)	17,575	(1,920)	9,238
Cash and cash equivalents at beginning of period	24,819	7,244	9,164	—
Cash and cash equivalents at end of period	9,238	24,819	7,244	9,238
Income taxes paid	—	—	—	—

*See accompanying notes.*

**MARSHALL EDWARDS, INC.**  
**(A Development Stage Company)**  
**CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY**  
(In thousands, except share data)

	Common Stock <i>(shares)</i>	Additional paid in capital	Deficit accumulated during development stage	Accumulated other comprehensive income/(loss)	Total
<b>Balance June 30, 2001</b>	<b>49,500,000</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ —</b>
Net loss arising during development stage			(123)		(123)
Common Stock issued May 22, 2002 (including 2,523,000 warrants)	2,523,000	9,022			9,022
<b>Balance at June 30, 2002</b>	<b>52,023,000</b>	<b>9,022</b>	<b>(123)</b>	<b>—</b>	<b>8,899</b>
Net loss arising during development stage			(3,033)		(3,033)
Foreign currency translation adjustments				31	31
Comprehensive Loss					(3,002)
Common Stock issued June 26, 2003	9,000	36			36
<b>Balance at June 30, 2003</b>	<b>52,032,000</b>	<b>9,058</b>	<b>(3,156)</b>	<b>31</b>	<b>5,933</b>
Net loss arising during development stage			(8,538)		(8,538)
Foreign currency translation adjustments				(31)	(31)
Comprehensive Loss					(8,569)
Common Stock issued November 30, 2003	2,514,000	10,056			10,056
Common Stock issued December 18, 2003 (including 2,392,000 warrants)	2,392,000	15,522			15,522
<b>Balance at June 30, 2004</b>	<b>56,938,000</b>	<b>\$ 34,636</b>	<b>\$ (11,694)</b>	<b>\$ —</b>	<b>\$ 22,942</b>
Net loss arising during development stage			(6,421)		(6,421)
Comprehensive Loss					(6,421)
<b>Balance at June 30, 2005</b>	<b>56,938,000</b>	<b>34,636</b>	<b>(18,115)</b>	<b>—</b>	<b>\$ 16,521</b>

*See accompanying notes.*

**MARSHALL EDWARDS, INC.**  
**(A Development Stage Company)**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**June 30, 2005**

**1. The Company and Summary of Significant Accounting Policies**

Marshall Edwards, Inc. ("MEI") is a development stage company incorporated in December 2000 as a wholly-owned subsidiary of Novogen Limited, an Australian pharmaceutical company. MEI commenced operations in May 2002. MEI, including its wholly-owned Australian subsidiary, Marshall Edwards Pty. Limited ("MEPL") (together the "Company") is a pharmaceutical company with a primary focus on the development and commercialization of drugs for the treatment of cancer. The Company is presently engaged in the clinical development and commercialization of a drug candidate called phenoxodiol. The Company intends to develop phenoxodiol for use in a wide range of human cancers. The Company operates primarily in Australia and the United States.

Novogen Limited and certain of its subsidiary companies (collectively "Novogen"), have granted to the Company a worldwide, non transferable license under their patent and patent applications and in their know-how to conduct clinical trials and commercialize and distribute all forms of delivering phenoxodiol in the field of prevention, treatment and cure of cancer in humans except topical applications. In addition, the Company has an exclusive first right and an exclusive last right to match any proposed dealing by Novogen of its intellectual property rights with a third party relating to synthetic pharmaceutical compounds (other than phenoxodiol), that have known or potential applications in the field of prevention, treatment or cure of cancer in humans all forms other than topical applications.

The Company's business focus is to conduct the clinical program for the development and commercialization of phenoxodiol.

**Principles of Consolidation**

The consolidated financial statements include the accounts of Marshall Edwards, Inc. and its wholly-owned subsidiary, Marshall Edwards Pty. Limited. Significant intercompany accounts and transactions have been eliminated on consolidation.

**Estimates**

The preparation of the consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the accompanying notes. Actual results could differ from those estimates.

**Revenue Recognition**

*Interest*

The only revenue earned to date is interest on cash balances.



### **Cash and Cash Equivalents and Short Term Investments**

Cash on hand and in banks and short-term deposits are stated at the nominal value. The Company considers all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. Highly liquid investments with stated maturities of greater than three months are classified as short-term investments. The Company's cash, held in the US, is deposited in financial institutions that are FDIC insured. These deposits are in excess of the FDIC insurance limits. The company also holds cash with Australian financial institutions.

### **Income Taxes**

Income taxes have been provided for using the liability method in accordance with FASB Statement No. 109, "Accounting for Income Taxes." Under this method, deferred tax assets and liabilities are recognized and measured using enacted tax rates in effect for the year in which the differences are expected to be recognized. Valuation allowances are established against the recorded deferred income tax assets to the extent that management believes that it is more likely than not that a portion of the deferred income tax assets are not realizable.

### **Fair Value of Financial Instruments**

The carrying amounts of the Company's financial instruments, including cash and cash equivalents, short-term investments and accounts payable approximate fair value.

### **Foreign Currency Translation**

The financial statements of MEPL have been translated into U.S. dollars in accordance with FASB Statement No. 52, "Foreign Currency Translation." Assets and liabilities are translated into U.S. dollars using the exchange rates in effect at the balance sheet date. Income statement amounts have been translated using the average exchange rate for the periods. Realized gains and losses from foreign currency transactions are reflected in the consolidated statements of operations.

Translation of Marshall Edwards Pty Limited's Financial Statements into U.S dollars does not have a material impact on the Company's financial position.

### **Research and Development Expenses**

Research and development expenses relate primarily to the cost of conducting human clinical trials of phenoxodiol. Research and development costs are charged to expense as incurred.

### **License Fees**

Costs incurred related to the acquisition or licensing of products that have not yet received regulatory approval to be marketed, or that are not commercially viable and ready for use or have no alternative future use, are charged to earnings in the period incurred.

### **Stock-Based Compensation**

The Company's stock option plan provides for the grant of options to the Company's directors, employees, employees of the Company's affiliates and certain of the Company's contractors and consultants. To date no options have been issued under the plan.

### **Basic and Diluted Loss Per Share**

Basic and diluted earnings or loss per share is calculated in accordance with FASB Statement No. 128, "Earnings Per Share." In computing basic earnings or loss per share, the dilutive effect of stock options are excluded, whereas for diluted earnings per share they are included unless the effect is anti-dilutive. Since the Company has a loss for all periods presented, diluted and basic earnings per share are the same.

### **Comprehensive Loss**

Comprehensive loss is comprised of net loss and other comprehensive loss. Other comprehensive loss includes certain changes in Stockholders' Equity that are excluded from net loss. Comprehensive loss for all periods presented has been reflected in the Consolidated Statement of Stockholders' Equity.

### **Recent Accounting Announcements**

#### **Share-Based Payments**

In December 2004, the FASB Issued Statement of Financial Accounting Standards No. 123R (Statement 123R), "Share-Based Payments", the provisions of which become effective for the Company in fiscal 2006. This Statement eliminates the alternative to use APB No. 25's intrinsic value method of accounting that was provided in Statement 123 as originally issued. Statement 123R requires companies to recognize the cost of employee services received in exchange for awards of equity instruments based on the grant-date fair value of those awards. While the fair-value-based method prescribed by Statement 123R is similar to the fair-value-based method disclosed under the provisions of Statement 123 in most respects, there are some differences. The Company's stock option plan provides for the grant of options to the Company's directors, employees, employees of the Company's affiliates and certain of the Company's contractors and consultants. To date no options have been issued under the plan. Statement 123R is effective for the Company in Fiscal 2006.

#### **Accounting Changes and Error Corrections**

In May 2005, the FASB issued Statement of Financial Accounting Standards No. 154 (SFAS 154), "Accounting Changes and Error Corrections" which provides guidance on the accounting for and reporting of accounting changes and correction of errors. This statement changes the requirements for the accounting for and reporting of a change in accounting principle and applies to all voluntary changes in accounting principle. It also applies to changes required by an accounting pronouncement in the unusual instance that the pronouncement does not include specific transition provisions. This statement is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. We do not anticipate a material effect upon the adoption of this statement.

## 2. Income Taxes

Loss from operations consists of the following jurisdictions:

	2005	Year ended June 30, 2004 <i>(in thousands \$)</i>	2003
Domestic	(326)	(321)	(186)
Foreign	(6,095)	(8,217)	(2,847)
	<u>(6,421)</u>	<u>(8,538)</u>	<u>(3,033)</u>

The reconciliation of income tax computed at the U.S. federal statutory tax rates to income tax expense attributable to loss arising during development stage is:

	2005 <i>(in thousands \$)</i>	%	Year ended June 30, 2004 <i>(in thousands \$)</i>	%	2003 <i>(in thousands \$)</i>	%
Tax at US statutory rates	2,247	35	2,988	35	1,062	35
Australian tax	(305)	(5)	(411)	(5)	(142)	(5)
R&D Tax concession	43	1				
Under Provision	156	2				
Change in valuation allowance	(2,141)	(33)	(2,577)	(30)	(920)	(30)
	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>

Deferred tax liabilities and assets are comprised of the following:

	2005	Year ended June 30, 2004 <i>(in thousands \$)</i>	2003
<b>Deferred tax liabilities</b>			
Unrealised Foreign Exchange Gain	(4)	(25)	—
Accrued Interest Income	—	(2)	—
Prepayments	—	—	—
Total deferred tax liabilities	<u>(4)</u>	<u>(27)</u>	<u>—</u>
<b>Deferred tax assets</b>			
Tax carried forward losses	4,972	3,365	933
Unrealised Foreign Exchange Loss	8	(121)	(129)
Consultant and other accruals	700	318	154
Total deferred tax assets	<u>5,680</u>	<u>3,562</u>	<u>958</u>
Valuation allowance for deferred tax assets	<u>(5,676)</u>	<u>(3,535)</u>	<u>(958)</u>
Net deferred tax assets and liabilities	<u>—</u>	<u>—</u>	<u>—</u>

Management evaluates the recoverability of the deferred tax asset and the amount of the required valuation allowance. Due to the uncertainty surrounding the realization of the tax deductions in future tax returns, the Company has recorded a valuation allowance against its net deferred tax asset at June 30, 2005 and 2004. At such time as it is determined that it is more likely than not that the deferred tax assets will be realized, the valuation allowance will be reduced.

There was no benefit from income taxes recorded for the period from December 1, 2000 (inception) to June 30, 2005 due to the Company's inability to recognize the benefit of net operating losses. The Company had federal net operating loss carry forwards of approximately \$938,000 at June 30, 2005. The federal net operating losses will begin to expire in 2022.

Foreign tax losses of approximately \$16,462,000 at June 30, 2005, may be carried forward indefinitely.

### 3. Loss Per Share

The following table sets forth the computation of basic and diluted net loss per common share:

	2004	Years ended June 30, 2004	2003
	<i>(In Thousands, except share data)</i>		
<b>Numerator</b>			
Net loss arising during development stage	(6,421)	(8,538)	(3,033)
Effect of dilutive securities	—	—	—
Numerator for diluted earnings per share	\$ (6,421)	\$ (8,538)	\$ (3,033)
<b>Denominator</b>			
Denominator for basic earnings per share -			
Weighted average shares used in computing net loss per share, basic and diluted	56,938,000	54,954,578	52,023,247
Effect of dilutive securities	—	—	—
Dilutive potential common shares	56,938,000	54,954,578	52,023,247
Basic and Diluted net loss per share	\$ (0.11)	\$ (0.16)	\$ (0.06)

During the period presented the Company had warrants outstanding that could potentially dilute basic earnings per share in the future, but were excluded from the computation of diluted net loss per share as the effect would have been anti-dilutive. Since the Company has a loss for all periods presented, diluted and basic earnings per share are the same. The outstanding warrants consist of the following potential common shares:

	2005	As at June 30, 2004	2003
Outstanding Warrants	2,392,000	2,392,000	2,514,000

The warrants outstanding at June 30, 2005 have an exercise price of \$9.00 per share and are exercisable prior to December 18, 2006.

### 4. Expenditure Commitments and Contingencies

At June, 30, 2005, the Company had contracted to conduct research and development expenditures of approximately \$2,285,000. Of the expenditure commitments, clinical trial amounts are based on the assumption that all patients enrolled in clinical trials will complete the maximum number of allowed treatment cycles. The amounts, assuming all treatment cycles are completed, are expected to be incurred as follows:

(In thousands)	<b>Total</b>	<b>Payment due by period</b>			
		less than 1 Year	1 - 3 Years	3 - 5 Years	More than 5 Years
<b>Contractual Obligations</b>					
Purchase Obligations	\$ 2,285	\$ 1,821	\$ 464	\$ —	\$ —
<b>Total</b>	<u>\$ 2,285</u>	<u>\$ 1,821</u>	<u>\$ 464</u>	<u>\$ —</u>	<u>\$ —</u>

No amounts have been included for future payments to Novogen which may arise in connection with the license agreement, the services agreement or the manufacturing license and supply agreement as future payments under the terms of the agreements are subject to termination provisions. Payments in connection with these agreements are detailed in Note 6 “Related Party Transactions”

The company is not currently a party to any material legal proceedings.

The Company’s certificate of incorporation provided that it will indemnify Novogen in connection with certain actions brought against Novogen by any of the Company’s stockholders or any other person.

The Company has guaranteed the payment and performance of the obligations of its subsidiary, Marshall Edwards Pty Limited, to Novogen and its subsidiaries, Novogen Laboratories Pty Limited and Novogen Research Pty Limited, under the license agreement, the manufacturing license and supply agreement and the services agreement. Novogen has guaranteed the performance of the obligations of Novogen Research Pty Limited under the license agreement and the obligations of Novogen Laboratories Pty Limited under the manufacturing license and supply agreement to Marshall Edwards Pty Limited. Each of the Company and Novogen’s obligations in the guarantee and indemnity agreement are absolute, unconditional and irrevocable.

## 5. Segment Information

The Company’s focus is to continue the clinical program currently underway for the development and commercialization of phenoxodiol. The business contains two major segments based on geographic location.

	Year Ended June 30,								
	2005			2004			2003		
	USA	Australia	Total	USA	Australia	Total	USA	Australia	Total
(in thousands)									
<b>Statement of Operations</b>									
Interest Revenue	238	70	308	167	26	193	110	35	145
Loss from operations	(326)	(6,095)	(6,421)	(321)	(8,217)	(8,538)	(186)	(2,847)	(3,033)
Income Tax Expense	—	—	—	—	—	—	—	—	—
Net loss arising during development stage	(326)	(6,095)	(6,421)	(321)	(8,217)	(8,538)	(186)	(2,847)	(3,033)
<b>Balance Sheet</b>									
Segment assets	33,877	4,266	38,143	34,220	802	35,022	8,896	374	9,270
Elimination of investment in subsidiary	(18,779)	—	(18,779)	(10,173)	—	(10,173)	(1,984)	—	(1,984)
Consolidated Assets	\$ 15,098	\$ 4,266	\$ 19,364	\$ 24,047	\$ 802	\$ 24,849	\$ 6,912	\$ 374	\$ 7,286
Segment liabilities	\$ 93	\$ 2,750	\$ 2,843	\$ 110	\$ 1,797	\$ 1,907	\$ 43	\$ 1,310	\$ 1,353

## 6. Related Party Transactions

### License Agreement

The license agreement is an agreement under which Novogen's subsidiary, Novogen Research Pty Limited, grants to MEPL a worldwide non-transferable license under its patents and patent applications and in its know-how to conduct clinical trials and commercialize and distribute phenoxodiol products. The agreement covers uses of phenoxodiol in the field of prevention, treatment or cure of cancer in humans delivered in all forms except topical applications. The license is exclusive until the expiration or lapsing of the last relevant Novogen patents or patent applications in the world and thereafter is non-exclusive. MEPL may terminate the agreement by giving three months' notice to Novogen. MEPL paid \$5,000,000 to Novogen in February 2004 which was the first lump sum license fee payment due under the terms of the license agreement. Also, MEPL paid \$2,000,000 to Novogen in January 2005 which was the annual milestone license fee payment due under the license agreement. Future amounts payable to Novogen under terms of the license agreement are as follows:

1. A second lump sum license fee of \$5,000,000 is payable to Novogen on November 1, 2003 or such later date when the cumulative total of all funds received from debt or equity issuances and revenue received from commercialization (income other than sales) and sales of phenoxodiol products exceeds \$50,000,000. The Company has not yet reached these preconditions for payment.
2. In addition to the amounts above, until the expiration of the exclusivity period of the license, MEPL must pay Novogen 2.5% of all net sales and 25% of commercialization income. After the exclusivity period of the license, 1.5% of net sales must be paid to Novogen.
3. In addition to the amounts above, amounts payable for annual milestone license fees under the license agreement for the calendar years ended December 31 are as follows:

Calendar Year	
2005	\$4,000,000
Each calendar year thereafter during the exclusivity period	\$8,000,000

Milestone license fees of \$2,000,000 have been accrued in the twelve months ended June 30, 2005 in connection with the annual milestone payment of \$4,000,000 due within 30 days following the end of the calendar year, December 31, 2005. The Company has paid the December 31, 2004 annual milestone license fee of \$2,000,000 due to Novogen at the end of January 2005.

#### **License Option Deed**

The license option deed grants MEPL an exclusive right to accept and an exclusive right to match any proposed dealing by Novogen of its intellectual property rights with a third party relating to synthetic compounds (other than phenoxodiol) that have known or potential applications in the field of prevention, treatment or cure of cancer in humans in all forms other than topical applications.

#### **Services Agreement**

The Company does not currently intend to directly employ any staff. Under the terms of the services agreement, Novogen Limited or its subsidiaries have agreed to provide services reasonably required by the Company relating to the development and commercialization of phenoxodiol. Novogen has agreed to provide these services at cost plus a 10% mark-up. The Company may terminate the agreement on three months written notice to Novogen.

Transactions giving rise to expenditure amounting to \$1,073,000, \$1,113,000 and \$1,075,000 were made under the services agreement with Novogen during the twelve months ended June 30, 2005, 2004 and 2003 respectively. Of these amounts, \$385,000, \$811,000 and \$790,000 related to service fees paid to Novogen for research and development services provided in the twelve months ended June 30, 2005, 2004 and 2003 respectively, reflecting the time spent by Novogen research staff on the development of phenoxodiol. Additionally, \$688,000, \$302,000 and \$285,000 of the total expenditure during the twelve months ended June 30, 2005, 2004 and 2003 respectively related to costs incurred for administration and accounting services provided by Novogen. The increase in 2005 related to compliance with United States securities reporting requirements.

At June 30, 2005 and 2004, \$100,000 and \$229,000, respectively, was due and owing to Novogen under the services agreement and is included in amounts due to parent company.

#### **Manufacturing License and Supply Agreement**

Under the terms of the manufacturing license and supply agreement, MEPL has granted to one of Novogen's subsidiaries an exclusive, non-transferable sub license to manufacture and supply phenoxodiol in its primary manufactured form. Novogen's subsidiary has agreed to supply phenoxodiol to MEPL for the clinical trial development program and phenoxodiol's ultimate commercial use. Novogen will supply phenoxodiol at cost plus a 50% markup.

Transactions giving rise to expenditure amounting to \$612,000, \$761,000 and \$164,000 were made under the manufacturing license and supply agreement with Novogen during the twelve months ended June 30, 2005, 2004 and 2003, respectively.

At June 30, 2005 and 2004, \$79,000 and \$44,000, respectively, was due and owing to Novogen under the manufacturing license and supply agreement and is included in amounts due to parent company.

## **7. Equity**

Marshall Edwards, Inc. (the "Company") is a development stage company incorporated in December 2000 that commenced operations in May 2002 coinciding with its listing on the London Stock Exchange's Alternative Investment Market (AIM).

In May 2002, the Company sold 2,523,000 shares of its common stock and 2,523,000 warrants, raising proceeds of \$9,022,000, net of \$1,070,000 of transaction costs. The warrants were exercisable prior to November 30, 2003 at an exercise price of \$4.00 per share. The common stock was listed for trading on the London Stock Exchange's Alternative Investment Market ("AIM"). Following the listing, Novogen Limited retained 95.1% of the Company's common stock.

In June 2003, 9,000 warrants were exercised, resulting in proceeds to the Company of \$36,000. In November 2003 the remaining 2,514,000 warrants were exercised at an exercise price of \$4.00 per share with proceeds to the Company of \$10,056,000.

In December 2003, the Company sold 2,392,000 common stock units at a public offering price of \$7.50 per unit. Each common stock unit consisted of:

- one share of common stock; and
- one warrant to purchase a share of common stock, exercisable prior to December 18, 2006 at an exercise price equal to \$9.00.

In connection with the December 2003 offering, the Company's common stock and warrants commenced trading separately on the Nasdaq National Market. The Company received proceeds of \$15,522,000, net of \$2,431,000 transaction costs in the December 2003 offering. Following the offering, Novogen Limited retained 86.9% of the Company's common stock.



## 8. Quarterly Financial Data (Unaudited)

<u>2005 for the quarter ended</u>	<u>Jun-30</u>	<u>Mar-31</u>	<u>Dec-31</u>	<u>Sep-30</u>	<u>Year</u>
			(in thousands except per share data)		
Revenue	106	71	64	67	308
Net Loss	(2,076)	(1,740)	(1,375)	(1,230)	(6,421)
Net Loss arising during development stage	(2,076)	(1,740)	(1,375)	(1,230)	(6,421)
Basic and diluted loss per share	(0.04)	(0.03)	(0.02)	(0.02)	(0.11)
<u>2004 for the quarter ended</u>	<u>Jun-30</u>	<u>Mar-31</u>	<u>Dec-31</u>	<u>Sep-30</u>	<u>Year</u>
			(in thousands except per share data)		
Revenue	72	75	25	21	193
Net Loss	(1,201)	(1,541)	(4,682)	(1,114)	(8,538)
Net Loss arising during development stage	(1,201)	(1,541)	(4,682)	(1,114)	(8,538)
Basic and diluted loss per share	(0.02)	(0.03)	(0.09)	(0.02)	(0.16)

## **Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

None.

### **Item 9a.**

#### **Controls and Procedures**

##### **Evaluation of Disclosure Controls and Procedures**

At the end of the period covered by this report, the Company's management, with the participation of the Company's principal executive officer and principal financial officer, evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended). Based on that evaluation, the Company's principal executive officer and principal financial officer have concluded that the Company's disclosure controls and procedures were not designed nor were functioning effectively to provide reasonable assurance that the information required to be disclosed by the Company in reports filed under the Securities Exchange Act of 1934 was recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. The identified weakness in internal control over financial reporting and in disclosure controls is described below under the heading "Changes in Internal Controls".

##### **Changes in Internal Controls**

In 2004, the Company determined that the personnel and management of Novogen who perform our accounting and financial reporting functions pursuant to the Services Agreement are not sufficiently expert in U.S. GAAP and the requirements of the SEC and the Public Company Accounting Oversight Board and that this lack of expertise represents a material weakness in the operation of our internal control over financial reporting.

In addition, our system of financial reporting was not designed to prepare financial statements in accordance with U.S. GAAP and that our system of internal control, in particular our processes to review and analyze elements of the financial statement close process and prepare consolidated financial statements in accordance with U.S. GAAP, has not reduced to a relatively low level the risk that errors in amounts that would be material in relation to those financial statements may occur and may not be detected within a timely period by management in the normal course of business.

In this regard, we recommended that Novogen engage personnel with expertise or train existing personnel in the following areas:

- U.S. GAAP;
- financial reporting in accordance with the SEC regulations;
- requirements of the Public Company Accounting Oversight Board; and
- application of technical accounting pronouncements.

We have sought assurances from Novogen that it will promptly remedy the concerns raised and Novogen has presented to us a plan for addressing these concerns. We believe that Novogen's plan is designed to ensure that the preparation of our consolidated financial statements, including the processes to review and analyze elements of our financial statement close process, is in accordance with U.S. GAAP and that relevant information about U.S. GAAP, SEC financial reporting

requirements, and the requirements of the Public Company Accounting Oversight Board is available to those persons involved in the process by which our financial statements are prepared. Specifically Novogen's plan provides for additional resources and further training of the Novogen accounting team including:

- 1) the employment of additional accounting staff on the Novogen accounting team which will enable senior finance staff responsible for the preparation of U.S. GAAP financial reports to spend more time dealing with U.S. GAAP reporting issues;
- 2) increasing the level of attendance at targeted U.S. GAAP and SEC reporting courses by senior Novogen finance staff responsible for the preparation of U.S. GAAP financial reports and SEC disclosure; and
- 3) subscribing to additional information networks that provide publications and updates of SEC and U.S. GAAP releases and rule changes and of information about the requirements of the Public Company Accounting Oversight Board.

*Progress on the implementation of Novogen's plan to address the material weakness.*

During the period covered by the report, Novogen has made significant progress in implementing its plan to address the identified material weakness.

Novogen has already recruited an additional degree qualified accountant, enabling senior finance staff responsible for the preparation of U.S. GAAP financial reports to spend more time dealing with U.S. GAAP reporting issues. Additionally, Novogen's senior finance staff have completed training courses including the SEC Institute's SEC Reporting Conference, the SEC Institute's Workshop on Implementing SOX404 Internal Control Reporting and will continue to evaluate the merits of additional courses as they become available. Novogen has already begun to receive additional publications and updates of SEC, U.S. GAAP and Public Company Accounting Oversight Board requirements and will continue to review the adequacy of this additional information to determine whether additional resources are required.

Until we are satisfied that we have addressed our needs for sufficient expertise in preparing financial statements required in our filings under the securities law we will seek to mitigate this weakness by conferring with our outside accounting advisors with respect to the technical requirements applicable to our financial statements.

The implementation of the initiatives described above are among our highest priorities. Our Board of Directors, in coordination with our Audit Committee, will continually assess the progress and sufficiency of these initiatives and make adjustments as and when necessary. As of the date of this report, we believe that the plans outlined above, when completed, will eliminate the weakness in internal accounting control as described above. Nonetheless, a control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control system are met, and no evaluation of controls can provide absolute assurance that all control issues have been detected.

**Item 9b.**

Not applicable

## **PART III**

### **Item 10. Directors and Executive Officers of the Registrant**

#### **Code of Ethics**

We have adopted a Code of Business and Ethics policy that applies to our Directors and employees (including our principal executive officer and our principal financial officer), and have posted the text of our policy on our website ([www.marshalledwardsinc.com](http://www.marshalledwardsinc.com)). In addition, we intend to promptly disclose (i) the nature of any amendment to the policy that applies to our principal executive officer and principal financial officer and (ii) the nature of any waiver, including an implicit waiver, from a provision of the policy that is granted to one of these specified individuals, the name of such person who is granted the waiver and the date of the waiver on our website in the future.

The other information required by this item is incorporated by reference from the information under the caption "Election of Directors" and the caption "Compensation and Other Information Concerning Officers, Directors and Certain Stockholders" and the caption "16(a) Beneficial Ownership reporting Compliance" contained in our proxy statement for the fiscal year ended June 30, 2004 (the "Proxy Statement").

#### **Item 11. Executive Compensation**

The information required by this item is incorporated herein by reference from the information under the caption "Compensation and Other Information Concerning Officers, Directors and Certain stockholders" under the caption "Compensation Committee Interlocks and Insider Participation" contained in the Proxy Statement.

#### **Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters**

Certain of the information required by this item is included in Part II Item 5 of this Annual Report and certain information is incorporated by reference from the Information under the caption "Security Ownership of Certain Beneficial Owners and Management" contained in the proxy statement.

#### **Item 13. Certain Relationships and Related Transactions**

Our agreements with Novogen are each summarized below. Each of these agreements was approved by a majority of our independent directors who did not have an interest in the transaction. We believe that each of our agreements with Novogen is on terms as favorable to us as we could have obtained from unaffiliated third parties. The following description is only a summary of what we believe are the material provisions of the agreements.

##### **The License Agreement**

Novogen's subsidiary, Novogen Research Pty Limited, has granted our subsidiary, Marshall Edwards Pty Limited, a world-wide, non-transferable license under its patents and patent applications and in its licensed know-how to conduct clinical trials and commercialize and distribute phenoxodiol products. We and Novogen have each guaranteed the obligations of our respective subsidiaries under this license agreement. See "Guarantee and Indemnity Agreement." The license is exclusive until the expiration or lapsing of the last relevant Novogen patents or patent applications in the world, which we expect will be no earlier than August 29, 2017, and thereafter is non-exclusive for the remainder of the term of the agreement. The license grants us the right to make, have made, market, distribute, sell, hire or otherwise dispose of phenoxodiol products in the field (the "Field") of prevention treatment or cure of cancer in humans by pharmaceuticals delivered in all forms except topical applications.

We are obliged to continue current and undertake further clinical trials of phenoxodiol, and are responsible for paying for all materials necessary to conduct clinical trials. We must conduct all such trials diligently and professionally, must use reasonable endeavors to design and conduct clinical trials to generate outcomes which are calculated to result in regulatory approval of phenoxodiol products. We must also keep proper records of all clinical trials and allow Novogen to inspect those records.

All intellectual property rights in the medication, trial protocols, results of the clinical trials, case report forms and any other materials used in the conduct of the clinical trials are assigned by us to Novogen and we must not publish the results of clinical trials without the prior written consent of Novogen. Each party must disclose to the other party developments, improvements, enhancements or new know-how in relation to the phenoxodiol product which are made or acquired by either party.

We may not sub-license, sub-contract, or engage agents without the prior written consent of Novogen. Any proposed sub-contractors and agents must first agree in writing to comply with certain confidentiality obligations and to assign to Novogen all intellectual property rights in the Field created or acquired by them in the course of their engagement.

### ***Marketing and Commercialization***

We may market and commercialize phenoxodiol products under the license in any manner we think fit, so long as we conduct any marketing and commercialization activities on a commercially reasonable basis in compliance with applicable laws and regulations, comply with reasonable directions given by Novogen, act in a manner which we consider to be most beneficial to the interests of us and Novogen, and otherwise act in good faith to Novogen. All advertising and promotional material must be submitted to Novogen for prior approval.

### ***Fees, Charges and Costs***

The following table summarizes our responsibility for fees, charges and costs under the license agreement.

MEPL paid \$5,000,000 to Novogen in February 2004 which was the first lump sum license fee payment due under the terms of the license agreement. Also, MEPL paid \$2,000,000 to Novogen in January 2005 which was the annual milestone license fee payment due under the license agreement. Future amounts payable to Novogen under terms of the license agreement are as follows:

1. A second lump sum license fee of \$5,000,000 is payable to Novogen on November 1, 2003 or such later date when the cumulative total of all funds received from debt or equity issuances and revenue received from commercialization (income other than sales) and sales of phenoxodiol products exceeds \$50,000,000.
2. In addition to the amounts above, until the expiration of the exclusivity period of the license, MEPL must pay Novogen 2.5 % of all net sales and 25% of commercialization income. After the exclusivity period of the license, 1.5% of net sales must be paid to Novogen.

3. Amounts payable for annual milestone license fees under the license agreement for the calendar years ended December 31 are as follows:

Calendar Year	
2005	\$4,000,000
Each calendar year thereafter	\$8,000,000

For the fiscal year ended June 30, 2005 we have included \$3,000,000 as a license fee expense in our consolidated statements of operations.

#### **Termination**

We may terminate the license agreement at any time, by giving three months' notice to Novogen. We may also terminate the agreement if Novogen commits a breach of any of its material obligations under the agreement, becomes the subject of certain bankruptcy proceedings or is unable to lawfully perform its obligations. Novogen may terminate the agreement if we commit a breach of any of our material obligations under the agreement, become the subject of certain bankruptcy proceedings or are unable to lawfully perform our obligations. Novogen may also terminate the agreement immediately if a change of control, as defined in the license agreement, occurs without the consent of Novogen.

#### **The Manufacturing License and Supply Agreement**

Our subsidiary, Marshall Edwards Pty Limited has granted to Novogen's subsidiary, Novogen Laboratories Pty Limited, an exclusive, non-transferable sub-license to manufacture and supply phenoxodiol to us in its primary manufactured form. We and Novogen have each guaranteed the obligations of our respective subsidiaries under this manufacturing license and supply agreement. See "Guarantee and Indemnity Agreement." Novogen must not sublicense its rights or engage agents or subcontractors to exercise its rights or perform its obligations under the agreement without our prior written consent.

#### **Supply of Phenoxodiol**

We provide to Novogen rolling forecasts quarterly of our estimated supply requirements for phenoxodiol, and issue purchase orders for phenoxodiol to Novogen specifying the volume of phenoxodiol required. Novogen must confirm the quantity it is able to supply to fulfill the purchase order within 5 business days of receiving the purchase order. Novogen must then supply the volume of phenoxodiol it agreed to supply, and must otherwise use all reasonable endeavors to fulfill the purchase order. Novogen must manufacture and deliver phenoxodiol to us at a port nominated by us. Title to the phenoxodiol does not pass to us until we have paid the purchase price (as described below) and retention of title arrangements apply. We are not obligated to purchase any minimum amount of phenoxodiol from Novogen.

We must also provide to Novogen at least one year's advance written notice of the date on which the phenoxodiol product will be first offered for sale commercially.

If Novogen materially and persistently fails to supply the amount of phenoxodiol ordered by us by the required date, we may manufacture (or engage a third party, without Novogen's consent, to manufacture) the amount of the shortfall of phenoxodiol until Novogen demonstrates that it is able to consistently supply phenoxodiol in accordance with our requirements. In this case, Novogen must take all reasonable steps to make available to us or the third party, on commercial terms, the know-how necessary to enable that manufacture to occur.

### ***Fees and Charges***

The purchase price for phenoxodiol supplied is the total costs to Novogen plus a mark-up of 50%. The purchase price may be adjusted quarterly by Novogen by reference to the actual costs referred to above for the preceding quarter. If at any time we do not pay any amount due to Novogen, Novogen may suspend the supply of phenoxodiol to us until payment is received. Interest accrues daily on the outstanding balance of all overdue amounts payable to Novogen under the manufacturing license and supply agreement.

For the fiscal year ended June 2005, we expensed \$612,000 in fees under the manufacturing and supply agreement.

### ***Manufacturing Developments and Improvements***

Each party must disclose to the other any new developments, improvements and new know-how relating to the manufacture of phenoxodiol which are made or acquired by it during the term of the agreement. All intellectual property rights in developments, improvements and new know-how made or acquired by Novogen are to be assigned to us. We must provide to Novogen such technical information and assistance as Novogen reasonably requests in order to exercise its rights and perform its obligations.

Each party acknowledges that nothing in the agreement shall have the effect of transferring or assigning to Novogen any right, title or interest in any intellectual property rights in the phenoxodiol products licensed under the agreement.

Novogen agrees to notify us immediately on becoming aware of any infringement of the intellectual property rights in the licensed products or any claim by a third party that the activities of the parties under the agreement infringe such third party's intellectual property rights. If required, Novogen agrees to be a party to any proceedings brought by us in relation to any infringement of intellectual property rights in the licensed products and also agrees, at our cost, to provide all reasonable assistance in relation to such proceedings and to execute such documents as we reasonably require.

### ***Termination***

Either party may terminate the agreement immediately at any time if the other party becomes the subject of certain bankruptcy proceedings, becomes unable to carry out the transactions contemplated by the agreement or breaches its obligations and does not cure such breach within 21 days notice. We may also terminate the agreement immediately if the license agreement expires or is terminated. Novogen may also terminate the agreement immediately if a change of control, as defined in the manufacturing license and supply agreement, occurs without the consent of Novogen.

### ***Limitation of Liability***

The liability of Novogen for breach of conditions or warranties imposed by statute is limited to the replacement of goods, supply of equivalent goods, repair or replacement value of goods or the re-supply or payment for re-supply of services.

### ***The License Option Deed***

Novogen's subsidiary, Novogen Research Pty Limited has granted our subsidiary, Marshall Edwards Pty Limited, an exclusive first right to accept and an exclusive last right to match any proposed dealing by Novogen with its intellectual property rights with a third party relating to certain synthetic pharmaceutical compounds (other than phenoxodiol) developed by Novogen or its affiliates.

### ***Option Compounds***

The rights relate to all synthetic pharmaceutical compounds, known as Option Compounds, delivered or taken in all forms except topical applications (other than phenoxodiol, which is the subject of the license agreement), developed before or during the term of the deed, by or on behalf of Novogen or its affiliates, which have known applications in the Field of prevention, treatment or cure of cancer in humans.

### ***Dealings in Option Compounds and Exercise of Rights***

Novogen must not, and must ensure that its affiliates other than us do not, deal, solicit entertain or discuss dealings with any intellectual property rights in the Field or in relation to any Option Compounds without giving us an exclusive first right to accept and an exclusive last right to match any such dealing. If we exercise our first right to accept or last right to match, Novogen must deal with the intellectual property rights in favor of us on the terms and conditions proposed. We have 15 business days to exercise those rights and, if we fail to do so, Novogen may deal with those intellectual property rights in favor of a third party provided that the terms are no more favorable to that third party than those first offered to us or which we declined to match.

### ***Protection of Intellectual Property***

Novogen must act in good faith toward us in relation to its obligations under the deed and must ensure that all persons involved in any research or development work in the Field in relation to Option Compounds assign all intellectual property rights relating to the Option Compounds to Novogen. Novogen must also ensure that its affiliates, other than us, do the same. Novogen continues to be solely responsible for the maintenance of any patent rights in the Option Compounds, which it may maintain and enforce at its sole discretion and expense.

### ***Development Reports***

Novogen must provide to us from time to time, and in no event less frequently than every six months, development reports relating to the clinical trials and development of Option Compounds, and must notify us immediately of any regulatory approvals granted and assessments made by any government agency.

### ***Term and Termination***

The term of the deed is sixteen years from the commencement date of the agreement, unless terminated earlier. We may terminate the deed at any time on three months' notice to Novogen. Either party may terminate the deed immediately at any time if the other party becomes the subject of certain bankruptcy proceedings, becomes unable to carry out the transactions contemplated by the agreement or breaches its obligations and does not cure such breach within 21 days notice.

Novogen may also terminate the deed immediately if a change of control, as defined in the license option deed, occurs without the consent of Novogen.

### ***The Services Agreement***

Novogen has agreed to provide a range of services to us, or procure that its subsidiaries provide those services.

These services include providing general assistance and advice on research and development and commercializing phenoxodiol products and other compounds in which we may acquire intellectual property rights in the future, such as Option Compounds in relation to which we have exercised our rights under the license option deed.



Novogen's obligations also include providing, within the agreed budgets described below, our needs with respect to secretarial, marketing, finance, logistics, administrative and managerial support. Novogen also plans, conducts and supervises pre-clinical and clinical trials with phenoxodiol and with other compounds in which we have intellectual property rights. Novogen also provides scientific and technical advice on management of pre-clinical and clinical research programs undertaken by us and manages such research provisions. We have guaranteed the obligations of our subsidiary under the services agreement. See "Guarantee and Indemnity Agreement."

Novogen may not sub-contract the provision of any part of the services without our prior written consent.

### ***Fees for Services***

We pay services fees to Novogen on a monthly basis in accordance with an agreed annual budget. At the beginning of each financial year Novogen prepares a budget estimate for us with respect to the percentage of time spent by Novogen's employees and consultants in the provision of services to us in the previous financial year and any relevant considerations which are likely to influence the time spent for the following financial year. Each estimate must include the remuneration paid by Novogen to each person expected to provide the services and the percentage of time Novogen expects those persons will spend on our business, the allocated on-costs attributable to each person, a premises rental charge and a charge for asset usage and general overheads. The total estimate is to be the sum of these charges plus a mark-up of 10%. We also pay Novogen's reasonable out of pocket expenses incurred in providing the services to us. At the end of the fiscal year an adjustment is made to reflect actual costs incurred where they differ from budget.

For the fiscal year ended June 2005, we expensed \$1,073,000 in fees under the services agreement.

### ***Intellectual Property and Confidentiality***

All intellectual property rights created by Novogen in the performance of the services for or at the request of us are licensed to us. Each party also has obligations to the other party to honor the other's confidential information.

### ***Termination***

We may terminate our rights and obligations under the services agreement on three months' written notice to Novogen. Either we or Novogen may terminate the agreement immediately at any time if the other party becomes the subject of certain bankruptcy proceedings, becomes unable to carry out the transactions contemplated by the agreement, breaches its obligations and does not cure such breach within 21 days notice or if a change of control in the other party occurs. Novogen may also terminate the agreement immediately if a change of control, as defined in the services agreement, occurs without the consent of Novogen.

### ***Guarantee and Indemnity Agreement***

We have guaranteed the payment and performance of the obligations of our subsidiary, Marshall Edwards Pty Limited, to Novogen and its subsidiaries, Novogen Laboratories Pty Limited and Novogen Research Pty Limited, under the license agreement, the manufacturing license and supply agreement and the services agreement. Novogen has guaranteed the performance of the obligations of Novogen Research Pty Limited under the license agreement and the obligations of Novogen Laboratories Pty Limited under the manufacturing license and supply agreement to Marshall Edwards Pty Limited. Each of our and Novogen's obligations in the guarantee and indemnity agreement are absolute, unconditional and irrevocable.

**Indemnification**

We and Novogen have each agreed to indemnify the other if either of our respective subsidiaries default in the performance of any obligation under the license agreement, the manufacturing license and supply agreement or the services agreement. The defaulting party must indemnify the other against all losses, liabilities and expenses, including legal expenses on a full indemnity basis, incurred, directly or indirectly, as a result of that default. The party in default must pay the amount of those losses, liabilities and expenses on demand to the non-defaulting party. Furthermore, if Marshall Edwards Pty Limited defaults on its payment obligations, we must pay that money as directed by Novogen.

**Termination**

This agreement is a continuing obligation, and remains in full force until all the guaranteed obligations have been irrevocably paid and performed in full.

**Item 14. Principal Accountant Fees and Services.**

The information required by this item is incorporated by reference from the information under the caption "Principal Accountant Fees and Services" contained in the Proxy Statement.

## PART IV

### Item 15. Exhibits and Financial Statement Schedules

#### (a) 1. Financial Statements

Reference is made to the Index to Financial Statements under Item 8, Part II hereof.

#### 2. Financial Statement Schedules

The Financial Statement Schedules have been omitted either because they are not required or because the information has been included in the financial statements or the notes thereto included in this Annual Report on Form 10-K.

#### 3. Exhibits

#### Exhibit Index

##### Exhibits

3.1	Amended and Restated Certificates of Incorporation. (1)
3.2	Amended and Restated Bylaws. (1)
4.1	Specimen Stock Certificate. (1)
4.2	Warrant Agreement. (1)
4.3	Specimen Warrant Certificate. (1)
10.1	Amended and Restated License Agreement between Novogen Research Pty Limited and Marshall Edwards Pty Limited. (1)
10.2	Amended and Restated Manufacturing License and Supply Agreement between Novogen Laboratories Pty Limited and Marshall Edwards Pty Limited. (1)
10.3	Amended and Restated License Option Deed between Novogen Research Pty Limited and Marshall Edwards Pty Limited. (1)
10.4	Amended and Restated Services Agreement among Novogen Limited, Marshall Edwards, Inc. and Marshall Edwards Pty Limited. (1)
10.5	Guarantee and Indemnity among Marshall Edwards, Inc., Novogen Laboratories Pty Limited, Novogen Research Pty Limited and Novogen Limited. (1)
10.6	Marshall Edwards, Inc. Share Option Plan. (1)
21	Subsidiaries of Marshall Edwards, Inc. (1)
23.1	Consent of Ernst & Young
23.2	Consent of Ernst & Young LLP
31.1	Certification required by Rule 13a-14(a) or Rule 15d-14(a)
31.2	Certification required by Rule 13a-14(a) or Rule 15d-14(a)
32	Certification required by Rule 13a-14(b) or Rule 15d-14(b) and section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C 1350).

---

(1) Incorporated by reference to exhibits to the Registration Statement on Form S-1 filed on December 18, 2003, as amended (Reg. No. 333-109129).

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on September 13, 2005.

MARSHALL EDWARDS, INC.  
A Delaware Corporation

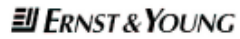
By: /s/ Christopher Naughton

Christopher Naughton  
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated on September 13, 2005.

<u>Signatures</u>	<u>Title</u>
By: <u>/s/ Christopher Naughton</u> Christopher Naughton	President, Chief Executive Officer and Director
By: <u>/s/ David Seaton</u> David Seaton	Secretary, Chief Financial Officer
By: <u>/s/ Graham Kelly</u> Graham Kelly	Director
By: <u>/s/ Stephen Breckenridge</u> Stephen Breckenridge	Director
By: <u>/s/ David de Kretser</u> David de Kretser	Director
By: <u>/s/ Paul Nestel</u> Paul Nestel	Director
By: <u>/s/ Philip Johnston</u> Philip Johnston	Director

Exhibit 23.1



**Ernst & Young Centre**  
680 George Street  
Sydney NSW 2000  
Australia

Tel 61 2 9248 5555  
Fax 61 2 9248 5959  
DX Sydney Stock  
Exchange 10172

GPO Box 2646  
Sydney NSW 2001

**Consent of Independent Registered Public Accounting Firm**

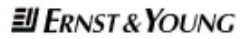
We consent to the incorporation by reference in the Registration Statement (Post-Effective Amendment No.3 to Form S-1 No. 333-109129 on Form S-3) of Marshall Edwards, Inc. and in the related Prospectus of our report dated August 13, 2004, with respect to the consolidated financial statements of Marshall Edwards, Inc., included in this Annual Report (Form 10-K) for the year ended June 30, 2005.

/s/ Ernst & Young

Sydney, Australia  
September 12, 2005

A handwritten signature in dark ink, appearing to be 'Ernst &amp; Young' written in a cursive style.

Liability limited by the Accountants Scheme, approved  
under the Professional Standards Act 1994 (NSW)



n Ernst & Young LLP  
1111 Summer Street  
Stamford, Connecticut 06905

n Phone: (203) 674-3000  
Fax: (203) 674-3001  
www.ey.com

**Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the Registration Statement (Post-Effective Amendment No.3 Form S-1 No. 333-109129) on Form S-3 of Marshall Edwards, Inc. and in the related Prospectus of our report dated July 31, 2003, with respect to the 2003 consolidated financial statements of Marshall Edwards, Inc., included in the Annual Report (Form 10-K) for the year ended June 30, 2005.

A handwritten signature in black ink that reads 'Ernst &amp; Young LLP'.

/s/ Ernst & Young LLP

Stamford, Connecticut  
September 12, 2005

A Member Practice of Ernst & Young Global

**CERTIFICATION**

I, Christopher Naughton, certify that:

1. I have reviewed this report on Form 10-K of Marshall Edwards, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) ) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within the entities, particularly during the period in which this report is being prepared;
  - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in the report our conclusions about the effectiveness of this disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrants fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: September 13, 2005

/s/ CHRISTOPHER NAUGHTON

Christopher Naughton  
Chief Executive Officer

**CERTIFICATION**

I, David Ross Seaton, certify that:

1. I have reviewed this report on Form 10-K of Marshall Edwards, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) ) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within the entities, particularly during the period in which this report is being prepared;
  - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in the report our conclusions about the effectiveness of this disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrants fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The Company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: September 13, 2005

/s/ DAVID SEATON

David R. Seaton  
Chief Financial Officer



**CERTIFICATION**

Pursuant to the requirement set forth in Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. § 1350), Christopher Naughton, the President and Chief Executive Officer of Marshall Edwards, Inc. (the “registrant”), and David R. Seaton, the Chief Financial Officer of the registrant, each hereby certifies that, to his or her knowledge:

1. The registrant’s Annual Report on Form 10-K for the period ended June 30, 2005, to which this Certification is attached as Exhibit 32 (the “Periodic Report”), fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition of the registrant at the end of the period covered by the Periodic Report and results of operations of the registrant for the period covered by the Periodic Report.

These certifications accompany the Form 10-K to which they relate, are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

Dated: September 13, 2005

/s/ CHRISTOPHER NAUGHTON  
Christopher Naughton  
Chief Executive Officer

/s/ DAVID SEATON  
David R. Seaton  
Chief Financial Officer