

**UNITED STATES  
SECURITIES AND EXCHANGE  
COMMISSION**

**Washington, D.C. 20549**

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**FORM 10-K**

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

**For the fiscal year ended June 30, 2008**

**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**

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**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**

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

<b>Title of Each Class</b>	<b>Name of Each Exchange on which Registered</b>
Common Stock, \$0.00000002 par value	Nasdaq Global Market

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

**None**

(Title of Class)

Indicate by a check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by a check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

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.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definition of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	<input type="radio"/>	Accelerated filer	<input type="radio"/>
Non-accelerated filer	<input checked="" type="radio"/>	Smaller reporting company	<input type="radio"/>

(Do not check if a smaller reporting company)

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 \$40.1 million based on the closing price of the registrant's Common Stock as reported on the Nasdaq Global Market on December 31, 2007.

As of September 10, 2008, the number of shares outstanding of the issuer's common stock, \$0.00000002 par value, was 73,463,233

### **Documents Incorporated by Reference**

Portions of this registrant's definitive proxy statement for its 2008 annual meeting to be filed with the U.S. Securities and Exchange Commission no later than 120 days after the end of the fiscal year ended June 30, 2008 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 Securities 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 us, are intended to identify forward-looking statements. We have based these forward-looking statements largely on current expectations and projections about future events and financial trends that we believe 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 required additional financing or financing available to us on acceptable terms;
- our inability to maintain or enter into, and our dependence upon, collaboration or contractual arrangements necessary for the clinical development of phenoxodiol and other drug candidates;
- our limited operating history;
- our failure to successfully commercialize our product candidates;
- costs and delays in the clinical development program and/or receipt of U.S. Food and Drug Administration (the “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;
- our inability to control the costs of manufacturing our products;
- continued cooperation and support of Novogen Limited, 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;
- costs stemming from our defence against third party intellectual property infringement claims;
- difficulties in enforcement of civil liabilities against our officers and directors who are residents of jurisdictions outside the U.S.;

- 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 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 listed on the Nasdaq Global Market under the symbol “MSHL”. We were incorporated on December 1, 2000 as a wholly-owned subsidiary of Novogen Limited, an Australian company. Novogen Limited’s ordinary shares trade on the Australian Stock Exchange under the symbol “NRT,” and American Depositary Receipts trade in the U.S. under the symbol “NVGN” on the Nasdaq Global Market. As at the date of this report Novogen owns approximately 71.3% of our outstanding common stock.

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 have licensed from a subsidiary of Novogen Limited (Novogen Limited and/or its subsidiaries are referred to herein as “Novogen”). We believe that phenoxodiol 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 effect on normal cells detected in pre-clinical testing, a feature which has been reflected in a good safety profile in human clinical studies. We have also licensed two other investigational anti-cancer compounds, triphendiol (formerly NV-196) and NV-143, from Novogen.

Our strategy is to undertake clinical development and testing of phenoxodiol, focusing on those therapeutic indications that will expedite drug marketing approval by regulatory bodies, leading to phenoxodiol’s commercialization and wide scale distribution. We also plan to develop triphendiol and NV-143 for therapeutic indications not currently targeted by phenoxodiol.

Pre-clinical testing has shown phenoxodiol to have broad anti-cancer activity against a range of human cancer cell lines, including prostate, ovarian and squamous cell carcinoma. Phenoxodiol commenced Phase I clinical studies in Australia in 2000, and the FDA granted phenoxodiol Fast Track status in 2004 for treatment of patients with recurrent late stage ovarian cancer that is resistant or refractory to platinum and taxanes. In 2005, the FDA granted phenoxodiol Fast Track status for treatment of patients with hormone refractory prostate cancer, which is prostate cancer that grows and is not inhibited by hormone therapy.

The immediate clinical development priority for phenoxodiol is to focus on three forms of cancer — ovarian cancer, prostate cancer and squamous cell carcinoma of the cervix and vagina.

In ovarian cancer, we are testing the ability of phenoxodiol to overcome chemotherapy drug resistance mechanisms, reversing resistance to platinum and taxanes in particular. This is an international Phase III pivotal study (known as OVATURE) in patients who have become resistant or refractory to at least two lines of platinum therapy, where phenoxodiol is being tested in combination with weekly carboplatin to delay tumor progression as measured by progression-free survival.

We are also developing phenoxodiol for use in squamous cell carcinoma of the cervix, vagina and vulva. A Phase I study is ongoing with a view to providing evidence of both a biological and clinical effect following administration of phenoxodiol as a single agent in this aggressive form of cancer.

A positive outcome in the current study could lead to two potential therapeutic indications: (i) the use of phenoxodiol as a monotherapy in early-stage disease including pre-malignant disease; and (ii) the use of phenoxodiol in combination with standard drugs such as cisplatin for the treatment of non-resectable disease.

Prostate cancer is the third tumor type of a number of tumors which we believe are likely to be responsive to phenoxodiol single agent therapy. We have completed a Phase II study in advanced hormone refractory disease in Australia and we are currently conducting a Phase II study using phenoxodiol as first line treatment in early stage disease at Yale Cancer Center and the West Haven Veterans Administration Hospital Connecticut in the U.S. Both of these studies address areas of unmet medical need in this common cancer.

In May 2006, we entered into a license agreement with Novogen which granted to us, through our wholly-owned subsidiary, Marshall Edwards Pty Limited (“MEPL”), an exclusive, worldwide non-transferable license under its patent and patent applications and in its know how to conduct clinical trials, commercialize and distribute the anti-cancer drug candidates, triphendiol and NV-143.

Triphendiol is a synthetic investigational anti-cancer compound developed by Novogen, based on an isoflavan ring structure. Similar to phenoxodiol, triphendiol is a signal transduction inhibitor. Preliminary screening studies conducted by Novogen have identified triphendiol as a candidate for product development showing a favorable in vitro toxicity profile against normal cells and broad activity against cancer cells. Two Phase I human clinical studies of triphendiol have been completed in Australia. Triphendiol is being developed initially in oral form for the treatment of pancreatic and bile duct cancers, we expect to file an IND in 2008 to enable Phase Ib/IIa studies in pancreatic cancer patients to proceed in the U.S.

NV-143 is currently in pre-clinical testing. Preliminary screening studies have identified broad anti-cancer activity against cancer cells representative of melanoma, glioma, prostate, ovarian, breast and lung cancer. NV-143 also exhibits broadly acting chemo-sensitizing activity or the ability to increase the sensitivity of cells to chemotherapeutic drugs that are used to control the growth of cancer cells. The mechanisms by which NV-143 elicits its anti-cancer/chemo-sensitizing effect remain unresolved. NV-143 may initially be developed to target the treatment of melanoma.

## **Recent Developments**

### ***Financing***

On July 28, 2008 we entered into a securities subscription agreement with OppenheimerFunds Inc and Novogen Limited pursuant to which we sold 1,700,000 and 2,908,295 shares of common stock to Oppenheimer and Novogen respectively, at a purchase price of \$2.17 per share. The aggregate proceeds from the sale of shares was \$10,000,000. The shares are registered under the Securities Act of 1933, as amended, pursuant to an effective shelf registration statement. On July 30, 2008 we filed a Prospectus Supplement to the registration Statement covering the sale of shares to Oppenheimer and Novogen.



## ***Phenoxodiol***

### OVATURE Phase III Clinical Trial

The OVATURE trial is a major multi-centre international Phase III clinical trial of orally-administered phenoxodiol in combination with carboplatin in women with advanced ovarian cancer resistant or refractory to platinum-based drugs to determine its safety and effectiveness when used in combination with carboplatin. The OVATURE trial has been approved by the FDA under a Special Protocol Assessment (“SPA”) program indicating that the study design, clinical endpoints and statistical analysis are acceptable to the FDA. The protocol provides for an interim analysis of the data, which, if statistically significant, can be used to support a request for accelerated marketing approval. An analysis of the interim results will be possible after the targeted patient recruitment is completed and 95 patients have disease progression.

The OVATURE trial is recruiting ovarian cancer patients whose cancer initially responded to chemotherapy but has since become resistant or refractory to traditional platinum treatment. Patients are being recruited at clinical sites across the U.S., U.K., Europe and Australia.

In May 2008, we announced that the FDA agreed that the accrual time for the OVATURE study may be extended to facilitate complete patient enrollment. Increasing the accrual period allowed for a reduction in the total number of patients in the study, without changing the required statistical analyses. As a result, the OVATURE study will enroll 340 patients at 60 - 80 clinical sites throughout the U.S., U.K., Europe, and Australia. Initially, this study was announced to enroll 470 patients.

In June 2008, a review by the Independent Data Monitoring Committee (IDMC) recommended that the OVATURE trial continue. The IDMC is responsible to ensure that patients recruited to the study are not exposed to unnecessary safety risks, that the study continues to meet its clinical objectives, and that it is run according to the required standards of Good Clinical Practice. Following a scheduled review of safety and efficacy data, the IDMC recommended that the study remain open and continue as planned towards its target of 340 patients.

### Prostate Cancer

In October 2007 we announced that we are currently conducting a Phase II clinical trial using phenoxodiol as first line treatment in men with early stage disease (35 patients with androgen dependent disease but rising prostate specific antigen, or PSA) compared to patients with late stage hormone refractory disease (25 patients with chemotherapy naïve androgen independent disease). The study is being conducted at Yale Cancer Center and the West Haven Veterans Administration Hospital Connecticut in the U.S. Both of these patient groups represent areas of unmet medical need in this common cancer.

## ***Triphendiol***

Triphendiol is a synthetic investigational anti-cancer compound based on an isoflavan ring structure which we are developing. Similar to phenoxodiol, triphendiol is a signal transduction inhibitor. Preliminary screening studies have identified triphendiol as a candidate for product development showing a favorable in vitro toxicity profile against normal cells and broad activity against cancer cells. In March 2008, we announced that data to be presented at the annual meeting of the American Association for Cancer Research (AACR) suggested that triphendiol may aid in the treatment of pancreatic cancer. These data indicated that in laboratory testing in vitro and in animals bearing human pancreatic and bile duct tumors, the activity of triphendiol against these cancers was demonstrated.

Triphendiol is being developed initially in oral form for the treatment of pancreatic and bile duct cancers.

Triphendiol has completed two Phase I human trials in Australia which have demonstrated a good safety profile and acceptable pharmacokinetic profile, i.e. the characteristics of a drug that determine its absorption, distribution and elimination in the body, when administered orally.

In January 2008, we announced that triphendiol has been granted Orphan Drug status by the FDA for the treatment of pancreatic cancer and for the treatment of cholangiocarcinoma, or bile duct cancer. In February 2008, we announced that triphendiol had been granted Orphan Drug status by the FDA for the treatment of Stage IIB through Stage IV malignant melanoma.

An Orphan Drug refers to a product that is intended for use in a disease or condition that affects fewer than 200,000 individuals in the U.S. A grant of Orphan Drug status provides seven years of market exclusivity for the orphan indication after approval by the FDA, as well as study design assistance and eligibility for grant funding from the FDA during its development. Triphendiol is in the early stages of clinical development and significant clinical testing will be required to prove safety and efficacy before marketing applications may be filed with the FDA.

## **Scientific Overview**

Phenoxodiol, triphendiol and NV-143 belong 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 prolonged 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 progression of the signal, prevent or reduce the ability of the tumor cell to divide or to survive. We believe that single 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 in 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 our three drug candidates increase 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 to facilitate cancer cell death.

We believe that our three drug candidates are able to exert a multiplicity of effects, including both ‘pro-survival’ and ‘pro-death’ signaling systems, because their primary target on the tumor cell is a protein whose function in the tumor cell is so fundamental to cell biochemistry that to shut it down produces a broad range of adverse 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 electron transport across the cell membrane enabling hydrogen ion (proton) export at a controlled rate. This function is so fundamental to normal cell function and viability, that any loss of function of this proton pump will disrupt a wide range of biochemical processes. One of the key components of this proton pump mechanism is a cell surface protein known as NADH oxidase. These proteins are situated on the outside of the cell membrane of all living matter and regulate the flow of waste hydrogen across the cell membrane. The laboratory studies at Purdue University have shown that a variant form of the surface oxidase which promotes more rapid hydrogen export, is preferentially expressed on cancer cells, although similar oxidase activity has been identified on small numbers of non-cancer cells undergoing extremely rapid cell division. Phenoxodiol is able to bind to and inhibit the activity of these oxidase variants, with the resulting inhibition of hydrogen ion removal (H<sup>+</sup> efflux) from these cells. This leads 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. Phenoxodiol appears to have little or no effect on the form of oxidase present on normal healthy cells, providing an explanation for how phenoxodiol selectively targets cancer cells for its cytotoxic effects. Independent research at the Malaghan Institute of Medical Research at Victoria University, Wellington, New Zealand, has confirmed that phenoxodiol inhibits the protein pump in cancer cells, as well as in some other abnormally dividing cells, but not in normal cells.

Other laboratory studies at The Hanson Institute Centre for Cancer Research at Royal Adelaide Hospital in Australia have demonstrated potent anti-tumour and anti-angiogenic (i.e., preventing formation of blood vessels) properties of phenoxodiol. These properties of phenoxodiol are associated with down regulation of a key signal transduction molecule, sphingosine kinase. Sphingosine kinase is a terminal component of the plasma membrane sphingomyelin pathway leading to the formation of sphingosine-1-phosphate a bioactive lipid and a key pro-survival secondary messenger acting via the signal transduction kinase, Akt. Two important biological outcomes of this are (i) cytostasis, (i.e. the prevention of the growth and multiplication of cells) through p53-independent induction of the cell cycle regulatory protein, p21WAF1/CIP1, and (ii) apoptosis (i.e., programmed cell death), through inhibition of phosphorylation of the anti-apoptotic factors, XIAP (inhibitor of apoptosis protein) and FLIPshort (caspase-8 inhibitory protein). These processes facilitate activation of executioner caspases via the tumour necrosis factor (TNF) family of death receptors. Researchers at Purdue University have shown this effect is a consequence of the interaction between phenoxodiol and the surface oxidase on cancer cells.

These findings are relevant because of results from laboratory studies at Yale University that have revealed that the killing effect of phenoxodiol on cancer cells occurs through the loss of the ability of the tumor cell to manufacture anti-apoptotic proteins such as XIAP and c-FLIP. Collectively, these third party studies provide a rational mechanism of action of phenoxodiol starting with the inhibition of surface oxidase, leading in turn to the loss of intracellular sphingosine-1-phosphate (S-1-P), and eventually to the loss of anti-apoptotic 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 explains how phenoxodiol is able to reverse resistance to standard anti-cancer drugs such as platinum, gemcitabine and taxanes, on the basis that FLIPshort protein is responsible for inhibiting the sensitivity of the Fas-ligand protein (death receptor) to the toxic signaling mediated via these drugs.

Phenoxodiol appears to restore sensitivity to these drugs in cells such as ovarian cancer cells that have acquired resistance to these drugs. In addition, pretreatment of tumor cells with phenoxodiol considerably increases the sensitivity of non-resistant tumor cells to the cytotoxic (i.e., toxic to cells, preventing their production or growth or causing cell death) effects of standard chemotherapy drugs. These effects are achieved without increasing the cellular toxicity of the standard chemotherapy drugs to non tumor-cells.

Triphendiol and NV-143 are analogues of phenoxodiol, but exhibit significantly different biologies to phenoxodiol. In parallel with phenoxodiol, both drug candidates display pre-clinical anti-cancer activity across a broad range of tumor types, high selectivity for cancer cells, and the ability to chemosensitize tumor cells to the cytotoxic effects of most standard chemotoxic drugs. However, both drugs differ from phenoxodiol in showing a substantially greater ability to induce apoptosis in pancreatic cancer, bile duct cancer, and melanoma cells; they also show an ability to increase the sensitivity of cancer cells to radiotherapy (radiosensitizers).

## **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.

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 oncology 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, in recruiting qualified personnel. They compete with us in recruiting eligible patients to participate in clinical studies and in attracting partners for joint ventures. They also licence 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 patent applications pending in a number of countries which cover a family of chemically related compounds with potentially broad ranging and complementary anticancer effects. Novogen has granted to us an exclusive licence, with respect to its patent rights and intellectual property know-how to develop, market and distribute phenoxodiol, triphendiol and NV-143 as anti-cancer agents, except in topical form.

### *Phenoxodiol*

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 (eighteen patent applications pending, sixteen patents issued, and one patent application allowed which is anticipated to proceed to grant in the coming months);
- compositions and methods for protecting skin from ultraviolet induced immunosuppression and skin damage, including phenoxodiol (five patent applications pending and eight patents issued); and
- therapeutic methods and compositions involving isoflav-3-ene and isoflavan structures, including phenoxodiol (eleven patent applications pending and one patent granted).

The family relating to the manufacturing patent rights relate to the production of isoflavone derivatives, including phenoxodiol (twelve patent applications pending and five patents issued).

Regarding the treatment of cancer, Novogen has been granted a U.S. Patent (No. 6,649,648) by the U.S. Patent and Trademark Office (USPTO) relating to the treatment of cancerous disease with isoflavone derivatives including phenoxodiol. U.S. Patent No. 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.

More recently, Novogen has been granted U.S. Patent No. 7,202,273 with broad claims to pharmaceutical compositions comprising phenoxodiol.

#### *Triphendiol and NV-143*

These compounds are isoflavan derivatives of phenoxodiol. The licensed patent rights relate to the novel compounds themselves ("composition of matter" rights) and to uses of these compounds as anti-cancer agents and sensitizers of cancer cells and tumors to chemotherapy and radiotherapy. The patent rights fall into two families of patent applications:

- composition of matter rights in respect of triphendiol and NV-143 and uses of these compounds as anti-cancer agents (twelve pending patent applications); and
- uses of triphendiol and NV-143 as chemo-sensitizers and radiosensitizers of tumors and cancer cells (eleven patent applications pending).

As patent applications in the U.S. 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 we cannot be certain that Novogen was the first to make the inventions covered by the Novogen patents and applications referred to above. Additionally, publication of discoveries in the scientific or patent literature often lag behind the actual discoveries. 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 uses of

phenoxodiol, triphendiol or NV-143 , as patent applications in the biopharmaceutical sector often take considerable time to issue. However, in some countries the 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 relating to our products. We cannot be sure that confidentiality will be maintained or disclosure prevented by these agreements. We also cannot be sure that our proprietary information or intellectual property will be protected by these agreements 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, triphendiol or NV-143 . Use of these compounds 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 licence 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 licences, we may encounter delays in product market introductions, or may find that the development, manufacture or sale of products requiring such licences 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 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. 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 which are discussed below.

### *Phenoxodiol*

Under the licence agreement, Novogen granted us an exclusive world-wide, non-transferable licence, 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.

### *Triphendiol and NV-143*

Under a second licence agreement, Novogen granted us an exclusive world-wide, non-transferable licence, under the Novogen patent rights, to conduct clinical trials and commercialize and distribute all forms of administering triphendiol and NV-143, except topical applications. The agreement covers uses of triphendiol and NV-143 in the field of prevention, treatment or cure of cancer in humans. Our business is also currently focused on advancing the clinical program underway for the development of triphendiol and NV-143.

### *Licence Option deed*

Under a licence 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.

### *Services*

Pursuant to a services agreement, Novogen provides services reasonably required by us relating to the development and commercialization of phenoxodiol, triphendiol, NV-143, or other option compounds in relation to which we have exercised our rights under the licence option deed. We do not currently intend to directly employ any staff and are reliant upon Novogen for the provision of resources to conduct our business.

### *Manufacturing*

Under a manufacturing licence and supply agreement, we have granted Novogen a sublicense to manufacture and supply phenoxodiol to us in its primary manufactured form for both the OVATURE clinical program and phenoxodiol's ultimate commercial use. Novogen has taken the strategic decision not to manufacture large scale Active Pharmaceutical Ingredients ("API") for cancer drugs, including phenoxodiol, as these can be more economically supplied by third parties with particular expertise in this area. We have entered into contracts with third parties to ensure that sufficient quantities of phenoxodiol can be manufactured in compliance with cGMP (Current Good Manufacturing Practices), to supply the necessary quantities of API for the OVATURE trial. We will need to arrange similar contracts in the future to secure the supply of triphendiol and NV-143.

## **Research and Development**

The objective of our research and development program is the generation of data sufficient to achieve regulatory approval of phenoxodiol, triphendiol and NV-143 in one or more dosage forms in major markets such as the U.S., and/or to allow us to enter into a commercial relationship with another party. The data are 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, triphendiol and NV-143;
- the relative therapeutic benefits and indications of phenoxodiol, triphendiol and NV-143 as a monotherapy or as part of combinational therapy with other chemotoxics;
- the most appropriate cancer targets for phenoxodiol, triphendiol and NV-143; and
- the relative therapeutic indications of different dosage forms of phenoxodiol, triphendiol and NV-143.

Research expenses were \$9.325 million for the year ended June 30, 2008, \$5.761 million for the year ended June 30, 2007 and \$3.427 million for the year ended June 30, 2006.

Research and development costs incurred since inception through June 30, 2008 amount to \$25,266,000.

## **Regulation**

### *U.S. Regulatory Requirements*

The FDA, and comparable regulatory agencies in other 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 U.S., 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 U.S. 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 Investigational New Drug Application, or IND, application, including results of pre-clinical tests and protocols for clinical tests, which must become effective before clinical trials may begin in the U.S.;
- obtaining approval of Institutional Review Boards or IRB's 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 studies 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 studies, 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 in the U.S. Additionally, an independent IRB 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 IRB 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, 2007 for the fiscal year 2008, the user fee for an application requiring clinical data, such as an NDA, is \$1,178,200. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual product fee for prescription drugs and biologics (\$65,030), and an annual establishment fee (\$392,700) 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 may 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 ensure success in later stage clinical trials. Data obtained from pre-clinical and clinical activities are 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 U.S. 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 member states 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 U.S. 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 approval 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 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 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, or BPCA, signed into law on January 4, 2002, was reauthorized and amended by the FDA Amendments Act of 2007 or FDAAA. The reauthorization of BPCA provides an additional six months of patent protection to NDA applicants that conduct acceptable pediatric studies of new and currently-marketed drug products for which pediatric information would be beneficial, as identified by FDA in a Pediatric Written Request. The Pediatric Research Equity Act, or PREA, signed into law on December 3, 2003, also was reauthorized and amended by FDAAA. The reauthorization of PREA requires that most applications for drugs and biologics include a pediatric assessment (unless waived or deferred) to ensure the drugs' and biologics' safety and effectiveness in children. Such pediatric assessment must contain data, gathered using appropriate formulations for each age group for which the assessment is required, that are adequate to assess the safety and effectiveness of the drug or the biological product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the drug or the biological product is safe and effective. The pediatric assessments can only be deferred provided there is a timeline for the completion of such studies. The FDA may waive (partially or fully) the pediatric assessment requirement for several reasons, including if the applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed.

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.

Medicines with a higher level of risk (prescription medicines, some non-prescription medicines) are evaluated for quality, safety and efficacy and are registered on the ARTG. Medicines with a lower risk (over the counter medicines including vitamins) are assessed only for quality and safety. Medicines included in the ARTG can be identified by the AUST R number (for registered medicines) or an AUST L number (listed medicines) that appears on the packaging of the medicine.

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 (based on the European Union requirements) to support the quality, safety and efficacy of the drug for its intended use and payment of a fee. Application details are available on the TGA website <http://www.tga.gov.au>.

The TGA requires a 26B certificate from Applicants who are required to submit safety and efficacy data when making their application, and who, when making their application, rely on data previously submitted to the TGA by another person in relation to an approved product. This certificate states that the applicants will not enter the market with a product that would infringe a patent on the product; or, that they have notified the patent owner of their intention enter the market before the expiry of any applicable patent. All other applicants may provide notice that such a certificate is not required.

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 may request further details from the applicant, and may agree with sponsors that additional data (which while not actually required by the application, could enhance the assessment outcome) may be submitted later at an agreed time. The TGA must decide within at least 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 within the different relevant sections, who prepare clinical evaluation reports. Following evaluation, the chemistry and quality control aspects of a product may be referred to a Pharmaceutical Sub-Committee (PSC), which is a sub-committee of the TGA prescription medicine expert advisory committee, the Australian Drug and Evaluation Committee (ADEC) to review the relevant clinical evaluation reports.

The clinical evaluation reports (along with any resolutions of the ADEC sub-committee) are then sent to the sponsoring company who then has the opportunity to comment on the views expressed within the evaluation report, provide corrections and to submit supplementary data to address any issues raised in 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 either the ADEC (for new medicines) or from the Peer Review Committee (PRC) for existing or generic products. This summary is sent to the sponsoring company which is able to submit a response to the ADEC or PRC dealing with issues raised in the summary and those not previously addressed in the evaluation report. The ADEC/PRC provide independent advice on the quality, risk-benefit, effectiveness and access of the drug and conduct medical and scientific evaluations of the application. The ADEC meets every 2 months to examine the applications referred by the TGA and its 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 or PRC 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 at least 255 working days. If not completed within 255 working days, the TGA forfeits 25% of the evaluation fee otherwise payable by the sponsor, but any time spent waiting for a response from the sponsor is not included in the 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 U.S., 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 a national procedure. Under the centralized procedure, a single application to the European Medicines 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, and those developed for cancer and other specified diseases and disorders, 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 national procedure is used for products that are not required to be authorized by the centralized procedure. Under the national procedure, an application for a marketing authorization is submitted to the competent authority of one member state of the EU. The holders of a national marketing authorization may submit further applications to the competent authorities of the remaining member states via either the decentralized or mutual recognition procedure. The decentralized procedure enables applicants to submit an identical application to the competent authorities of all member states where approval is sought at the same time as the first application, while under the mutual recognition procedure, products are authorized initially in one member state, and other member states where approval is sought are then requested to recognize the original authorization based upon an assessment report prepared by the original authorizing competent authority. Both the decentralized and mutual recognition procedures 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, the application will be automatically referred to the Committee for Medicinal Products for Human Use (CHMP) of the EMA.

If a referral for arbitration is made, the procedure is suspended. However, member states that have already approved the application may, at the request of the applicant, authorize the product in question without waiting for the result of the arbitration. Such authorizations will be without prejudice to the outcome of the arbitration. For all other concerned member states, the opinion of the CHMP, which is binding, could support or reject the objection or alternatively could reach a compromise position acceptable to all EU countries concerned. 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 U.S., 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.

The conduct of clinical trials in the European Union is governed by the European Clinical Trials Directive (2001/20/EC), which was implemented in May 2004. This Directive governs how regulatory bodies in member states control clinical trials. No clinical trial may be started without a clinical trial authorization granted by the national competent authority and favorable ethics approval.

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 licence 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 on Form 10-K.

## **Employees**

We do not have any employees. Novogen and other contract service providers, provide us with staff and other financial and administrative services under our services agreement with Novogen.

## Item 1A. Risk Factors

**In addition to the other information in this Annual Report on Form 10-K the following risk factors should be considered carefully in evaluating us and our business.**

### **Risks Related to Our Business**

***We will need additional funds to complete the OVATURE Phase III clinical trial for phenoxodiol and to progress the clinical trial program for triphendiol and NV-143. The actual amount of funds we will need will be determined by a number of factors, some of which are beyond our control.***

The factors which will determine the actual amount of funds that we will need to complete the OVATURE Phase III clinical trial for phenoxodiol and to progress the clinical trial programs for triphendiol and NV-143 may include the following:

- 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 and the rate that they are recruited;
- the number of treatment cycles patients complete while they are enrolled in the trials; and
- the efficacy and safety profile of the product.

If we are unable to obtain additional funds on favorable terms we may be required to cease or reduce our operations. Also, if we raise more funds by selling additional securities, the ownership interests of holders of our securities will be diluted.

***We may not complete our OVATURE Phase clinical III trial on schedule, or at all, or it may be conducted improperly, which will delay or preclude FDA marketing approval and increase costs.***

The completion of our OVATURE Phase III clinical trial may be delayed or terminated for many reasons, including, but not limited to, if:

- we are unable to identify and contract clinical trial sites and clinical investigators at the rate we expect or those sites are delayed from commencing patient recruitment due to regulatory hospital ethics committee approvals or those investigators do not perform to our anticipated patient recruitment schedule or comply with the clinical trial protocol;
- patients are not available to enroll at the rate we currently expect, or trial sites are unable to recruit their target patient numbers due to the strict inclusion criteria of the OVATURE protocol which may reduce the patient pool available to participate in the trial;
- subjects experience an unacceptable rate or severity of adverse side effects;
- third party clinical investigators do not conduct the trial in compliance with Good Clinical Practice and regulatory requirements, or other third parties do not perform data collection and analysis in a timely or accurate manner;



- our contracted Clinical Research Organization responsible for managing the OVATURE trial fails to provide the contracted services in a timely manner as stipulated in the contract.
- one or more Institutional Review Boards 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 costs will increase if we have material delays in our OVATURE pivotal trial, or if we are required to modify, suspend, terminate or repeat it.

***If the data from our OVATURE Phase III clinical trial do not demonstrate the safety and effectiveness of phenoxodiol to the FDA's satisfaction, we will not receive FDA approval to market phenoxodiol in the U.S.***

In 2004, the FDA granted phenoxodiol Fast Track status for patients with recurrent late stage ovarian cancer that is resistant or refractory to platinum and taxanes. More recently we completed an SPA where the FDA reviewed and agreed with the design of a Phase III study of phenoxodiol in combination with carboplatin in women with platinum-resistant ovarian cancer (ovarian cancer that does not respond to platinum based anti-cancer agents such as cisplatin). If the FDA concludes, using agreed upon clinical endpoints, that the data from our pivotal clinical trial have failed to demonstrate the safety and effectiveness of phenoxodiol to the satisfaction of the FDA, we will not receive FDA approval to market phenoxodiol in the U.S. We cannot assure you that the results of our Phase III trial will be successful.

***The third-party manufacturers that we rely upon for the production of phenoxodiol for our clinical trials and for future commercial quantities, may not be in compliance with FDA regulatory requirements.***

The conduct of our clinical trials and approval of our marketing application for phenoxodiol may be delayed or adversely affected if the third-party manufacturers that we rely upon for the production of phenoxodiol fail to comply with FDA's regulatory requirements for current Good Manufacturing Practices, or cGMP. The FDA requires drug manufacturers to establish and maintain quality control procedures for manufacturing, processing and holding drugs and investigational products, and products must be manufactured in accordance with defined specifications. The failure of contract manufacturers to supply investigational product in compliance with the defined specifications for phenoxodiol may delay the completion of our clinical trials. As part of the pre-market approval process, the manufacturer will be inspected by the FDA to ensure compliance with cGMP. The failure of contract manufacturers to comply with applicable regulations may result in a delay or prevent approval of our marketing application.

***If we do not receive marketing approval, our commercial prospects for phenoxodiol will be impaired.***

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.

If our clinical trials are unsuccessful, our prospects for commercializing phenoxodiol will be impaired and we may be required to cease or reduce our operations. This will have a significant impact on the trading price of our securities.

***Final approval by regulatory authorities of our drug candidates 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 our drug candidates for commercial use:

- triphendiol and NV-143 are 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;
- 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, or chemical additives intended to facilitate delivery of our drug candidates;
- it may take us many years to complete the testing of other drug candidates, and failure can occur at any stage of this process; and
- negative or inconclusive results or adverse medical events during a clinical trial could cause us to delay or terminate our development efforts.

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 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 \$51,731,000 since our inception through June 30, 2008, including net losses of \$12,410,000, \$13,820,000 and \$7,386,000 for the years ended June 30, 2008, 2007 and 2006, respectively. We anticipate that we will incur operating losses and negative operating cash flow for the foreseeable future. We have not yet commercialized any drug candidates and cannot be sure that we will ever be able to do so, or that we may ever become profitable. We have expanded our clinical trials significantly with the commencement of the OVATURE Phase III clinical trial, which will result in increasing losses and we may continue to incur substantial losses in the future even if we begin to generate revenues from the distribution and sale of phenoxodiol.

***We may not be able to establish the strategic partnerships necessary to develop, 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 is 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 have not yet submitted an Investigational New Drug Application, or IND, for triphendiol or NV-143 product candidates with the FDA and until an IND becomes effective, we will not be able to perform human clinical trials in the U.S.***

Although we have conducted two Phase I clinical trials of triphendiol in Australia, we have not yet submitted an IND to the FDA. NV-143 has not yet commenced clinical trials in humans. Until an IND becomes effective, we will not be able to perform human clinical trials of our triphendiol or NV-143 product candidates in the U.S. Approval to begin clinical testing in the U.S. requires submission of: (i) adequate information on the safety and manufacturing of triphendiol or NV-143 to assure the proper identification quality, purity and strength of the investigational product, (ii) summary of pharmacological and toxicological effects, pharmacokinetics (how the drug is absorbed and metabolized) and biological disposition in animals, (iii) the proposed protocol for any planned clinical study, and (iv) a brief description of the overall plan for investigating the product. Although we are preparing an IND for triphendiol for submission to the FDA, we do not know whether or when the IND will become effective.

***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.

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 oncology 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.

***We have no direct control over the costs of manufacturing phenoxodiol, triphendiol or NV-143 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, triphendiol or NV-143 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. Novogen has taken the strategic decision not to manufacture on a large scale Active Pharmaceutical Ingredients, or API, for cancer drugs, including phenoxodiol, as these can be more economically supplied by third parties with particular expertise in this area. The contract facilities that have been identified are registered with the FDA, have a track record of large scale API manufacture and have already invested in capital and equipment. We have completed the novation to MEPL of contracts that Novogen had entered into with third parties to validate the developed scalable manufacturing method to ensure that sufficient quantities of phenoxodiol can be manufactured in compliance with the FDA's current cGMP and to complete the analytical and stability work necessary for a New Drug Application, or NDA, submission for marketing approval. An NDA will be submitted if the planned Phase III study is successful, and approval of the NDA is required to market phenoxodiol. We will need to arrange similar contracts in the future to secure the supply of triphendiol and NV-143. We have no direct control over the costs of manufacturing our product candidates. If the costs of manufacturing increase or if the cost of the materials used increases, these costs will be passed on to us making the cost of conducting clinical trials more expensive. 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.

***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. 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, triphendiol or NV-143, 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 \$17.4 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.

***Our rights to develop and exploit phenoxodiol and the anti-cancer compounds triphendiol and NV-143 are subject to the terms and conditions of agreements we have entered into with Novogen. 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 and the anti-cancer compounds triphendiol and NV-143 from Novogen. Under the terms of the license agreement for phenoxodiol, all forms of administering phenoxodiol for the treatment of cancer, excluding topical applications, are licensed to us through our wholly-owned subsidiary, MEPL. Under the terms of the license agreement for triphendiol and NV-143, all forms of administering drugs containing the anti-cancer compounds triphendiol and NV-143, excluding topical applications, are licensed to us through MEPL. If we fail to meet our obligations under our license agreements, 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 or anti-cancer drugs containing triphendiol and NV-143. To date, 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 MEPL undergoes a change of control without the consent of Novogen. Under the terms of the license agreement for phenoxodiol, the manufacturing license and supply agreement and the services agreement, a “change of control” means a change in control of more than half the voting rights attaching to the shares of MEPL, a change in control of more than half of the issued shares of MEPL (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 MEPL. Under the terms of the license agreement for triphendiol and NV-143, a “change in control” means the acquisition by any person or group of more than half of the combined voting power of MEPL’s then outstanding securities entitled to vote generally in the election of directors of MEPL or any merger, consolidation, recapitalization, exchange or tender offer as a result of which a person or a group other than the shareholders of MEPL immediately before the transaction owns after the transaction more than half of the combined voting power of the then outstanding securities entitled to vote generally in the election of directors MEPL. Each of these agreements may also be terminated if we 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 agreements, the manufacturing license and supply agreement and the license option deed with Novogen are fundamental to our business. The license agreement for phenoxodiol 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. The license agreement for triphendiol and NV-143 grants us the right to make, have made, market, distribute, sell, hire or otherwise dispose of anti-cancer drugs containing the compounds triphendiol and NV-143 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 and drugs containing the compounds triphendiol and NV-143, which we would be unable to pursue without the rights granted to us under the license agreements. 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 our product candidates 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 U.S. 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 and methods of production of phenoxodiol. We have licensed both issued patents and pending patent applications from Novogen in relation to these technologies. Novogen has recently been issued a U.S. patent for pharmaceutical compositions comprising phenoxodiol. Novogen has issued patents in the U.S., the United Kingdom, Australia, China, Hong Kong, New Zealand, Singapore, Mexico and the Czech Republic related to phenoxodiol for the treatment of a variety of cancers and has issued patents in the U.S., Australia, New Zealand, Singapore and Sweden covering the use of phenoxodiol to prevent or treat skin cancer resulting from ultraviolet damage. Issued Novogen patents in the U.S., Europe, Australia, New Zealand, Singapore, Mexico and Sweden cover the use of phenoxodiol to treat or prevent UV-induced immunosuppression. In addition, Novogen has issued patents in Australia, New Zealand, Singapore, South Africa and Turkey relating to methods of production of phenoxodiol. For each of the patent families discussed above, there remain pending patent applications in various other jurisdictions.

Novogen's patent 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 U.S. 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, should any patents issue, 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 U.S. 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.

We have currently contracted formulation development and manufacturing process development work for phenoxodiol. This work is being conducted to ensure that there is a robust production process which meets the expected commercial quantities of phenoxodiol and that dose formulations are manufactured on a cost effective basis.

This process has identified a number of excipients, or additives to improve drug delivery, which may be used in the formulations of phenoxodiol. Excipients, among other things, perform the function of a carrier of the active drug ingredient. 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 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 defence 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 by 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.***

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

***Our results are affected by fluctuations in currency exchange rates.***

Much of our expenditures and potential revenue will be spent or derived outside of the U.S. As a result, fluctuations between the U.S. 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.

**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 71.3% 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 securities 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.

***Three of our directors and our secretary and chief financial officer are officers and/or directors of Novogen Limited and other Novogen subsidiaries, which may create a conflict of interest as well as prevent them from devoting their full attention to us.***

Three of our board members currently serve as board members of Novogen Limited. Simultaneous service as a Novogen Limited director or officer could create, or appear to create, a conflict of interest when such directors are presented with decisions that could have different implications for us and Novogen Limited.

Mr. Philip Johnston is the chairman of Novogen Limited, Mr. Christopher Naughton is the managing director of Novogen Limited and Professor Paul John Nestel is a director of Novogen Limited. Mr. David Seaton is the chief financial officer of Novogen Limited. The responsibilities of Messrs. Johnston, Naughton and Seaton and Professor Nestel to Novogen Limited could prevent them from devoting their full attention to us, which could be harmful to the development of our business.

***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 our commercialization program.***

We currently rely on Professor Alan Husband, Novogen Research Director, and Mr. Christopher Naughton, our President and Chief Executive Officer, 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 with Professor Husband and Mr. Naughton.

***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, triphendiol or NV-143 or to use these compounds for any uses other than anti-cancer applications. Novogen has reserved the intellectual property rights and know-how rights relating to topical applications of these compounds 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 and other service companies 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. To successfully develop our drug candidates, we will require ongoing access to the personnel who have, to date, been responsible for the development of our drug candidates. 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 our drug candidates 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.

***In the event that Novogen undergoes a change in control while remaining our controlling stockholder, we will become subject to the control and influence of Novogen's new controlling stockholder who may have views regarding the development of our business that differ from the development strategies we are currently pursuing.***

In the event that Novogen undergoes a change in control while remaining our controlling stockholder, we will become subject to the control and influence of Novogen's new controlling stockholder who will have the ability to indirectly determine the outcome of all matters submitted to our stockholders for approval through its control of Novogen. This entity may have views regarding the development of our business that differ from the development strategies we are currently pursuing. Such controlling stockholder may cause Novogen to use its influence and voting power to change the direction in which we are developing our business. Such changes may include, but are not limited to, a decreased focus on the development of any of our current drug candidates and an increased focus on the development of alternative drug candidates, which may or may not be targeted to treat cancers. Additionally, this entity may seek to renegotiate the terms of our existing license agreements, manufacturing and supply agreement and services agreement with Novogen.

### **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 and our other drug candidates triphendiol and NV-143;
- 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; 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 U.S., 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.

***Future sales of our common stock may depress the market price of our common stock and cause stockholders to experience dilution.***

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, or the perception that these sales could occur.

***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 agreements, 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 1B. Unresolved Staff Comments**

None.

**Item 2. Properties**

We do 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 Global Market.

Common Stock	Nasdaq Global Market	
	High \$	Low \$
<b>Year Ended June 30, 2007</b>		
First Quarter	3.75	2.58
Second Quarter	3.68	2.82
Third Quarter	4.90	3.08
Fourth Quarter	4.28	2.75
<b>Year Ended June 30, 2008</b>		
First Quarter	3.36	2.21
Second Quarter	3.98	2.15
Third Quarter	2.91	1.49
Fourth Quarter	4.10	1.98
<b>Warrants (with December 2006 expiry)</b>		
<b>Year Ended June 30, 2007</b>		
First Quarter	0.30	0.02
Second Quarter	0.29	0.01
Third Quarter	N/A	N/A
Fourth Quarter	N/A	N/A
<b>Year Ended June 30, 2008</b>		
First Quarter	N/A	N/A
Second Quarter	N/A	N/A
Third Quarter	N/A	N/A
Fourth Quarter	N/A	N/A

As of August 15, 2008, there were 73,463,233 shares of our common stock outstanding and approximately 1,445 stockholders on record of our common stock. This number was derived from our shareholder records and does not include beneficial owners of our common stock whose shares are held in the name of various dealers, clearing agencies, banks, brokers and other fiduciaries.

## 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.

## Stock Repurchases

We have not repurchased any shares of common stock during the fourth quarter of the fiscal year ended June 30, 2008.

## Equity Compensation

The following table sets forth, as of June 30, 2008 outstanding awards and shares remaining available for future issuance under our 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  (excluding securities reflected in column (a))
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 (the “Plan”) provides our directors, employees, employees of our affiliates and certain of our contractors and consultants with the opportunity to participate in our ownership. To date, no options have been issued under the Plan. The Compensation Committee, appointed by the Board of Directors, addresses participation, the number of options offered and any conditions of exercise. In making these determinations the Compensation 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 Compensation Committee. Options granted will be exercisable at a price determined by the Compensation 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:

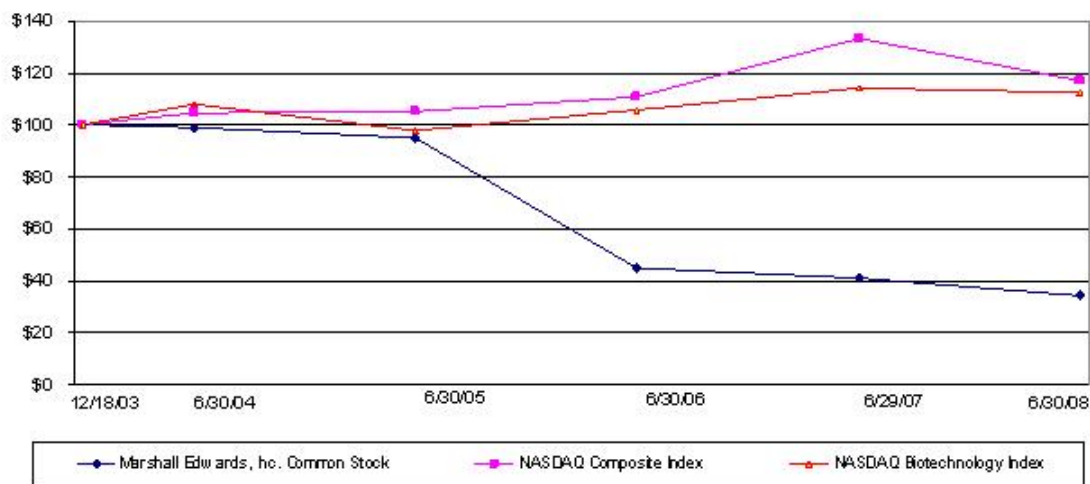
- Options will lapse if the participants cease to be engaged by us or our affiliates. The committee will have the discretion to waive this provision.
- The terms of the Plan also provide for adjustments to the rights of an option holder as a result of a reorganisation of our capital or other corporate 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 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.

### Stock Performance Graph

The graph set forth below compares the change in our cumulative total stockholder return on our common stock between December 18, 2003 (the date our common stock commenced public trading) and June 29, 2008 with the cumulative total return of the NASDAQ Composite Index and the NASDAQ Biotechnology Index during the same period. This graph assumes the investment of \$100 on December 18, 2003 in our common stock and each of the comparison groups and assumes reinvestment of dividends, if any. We have not paid any dividends on our common stock, and no dividends are included in the report of our performance.

Stock Performance Comparison



	12/18/03	6/30/04	6/30/05	6/30/06	6/29/07	6/30/08
Marshall Edwards, Inc. Common Stock	\$100.00	\$ 99.07	\$ 95.07	\$ 45.20	\$ 40.93	\$34.27
NASDAQ Composite Index	\$100.00	\$104.68	\$105.15	\$111.04	\$133.08	\$117.22
NASDAQ Biotechnology Index	\$100.00	\$107.78	\$ 98.00	\$105.44	\$113.95	\$112.62





## 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,				
	2008	2007	2006	2005	2004
	<i>(in thousands, except per share data)</i>				
Revenues:					
Interest and other income	\$ 674	\$ 645	\$ 446	\$ 308	\$ 193
Total revenues	674	645	446	308	193
Loss from operations	(12,407)	(13,819)	(7,385)	(6,421)	(8,538)
Income tax expense	(3)	(1)	(1)	-	-
Net loss arising during development stage	\$ (12,410)	\$ (13,820)	\$ (7,386)	\$ (6,421)	\$ (8,538)
Net loss per common share:					
Basic and diluted	\$ (0.18)	\$ (0.22)	\$ (0.13)	\$ (0.11)	\$ (0.16)
Weighted average common shares outstanding	68,302,566	63,179,366	56,938,000	56,938,000	54,954,578

### Balance Sheet Data

	As of June 30,				
	2008	2007	2006	2005	2004
	<i>(in thousands)</i>				
Cash and cash equivalents	\$ 19,743	\$ 16,158	\$ 10,054	\$ 9,238	\$ 24,819
Total assets	\$ 19,978	\$ 16,290	\$ 10,395	\$ 19,364	\$ 24,849
Total stockholders' equity	\$ 16,535	\$ 13,777	\$ 9,135	\$ 16,521	\$ 22,942

## 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 Statement About Forward-Looking Statements” and “Risk Factors” in Item 1A. included above in this Annual Report on Form 10-K. 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 on Form 10-K.

### Overview

During fiscal year 2008, we continued to establish clinical trial sites and to recruit patients for the OVATURE Phase III clinical trial and continued to recruit patients into the existing clinical trial programs for the treatment of prostate cancer and cervical cancer for phenoxodiol and progressed the pre clinical and clinical program for triphendiol.

We do not employ any staff directly but obtain services from Novogen under a services agreement and other third party service providers under various contract arrangements. We have incurred losses since inception and expect to incur operating losses and generate negative cash flows from operations for the foreseeable future as we expand our research and development activities.

As of June 30, 2008, we had accumulated losses of \$51,731,000.

We have 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 our drug candidates and costs incurred under the licence agreements, the services agreement and the manufacturing licence and supply agreements with Novogen, including the costs of the clinical trial drug supplies as well as costs associated with phenoxodiol production scale-up activities, drug supply from third party contractors and general corporate expenses.

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

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

We believe that the proceeds of \$10,000,000 from the registered direct offering closed in July 2008 provides us with sufficient cash resources to fund our planned operations over the next twelve months which includes progressing the Phase III OVATURE trial and the planned pre clinical development of triphendiol and NV-143.

We will however need additional funds to complete the OVATURE trial and to progress the clinical development program for triphendiol and NV-143 beyond the current objectives.

In connection with our preparation to raise additional funds, we filed a shelf registration statement with the SEC in March 2008. The shelf registration statement was declared effective by the SEC on April 3, 2008. The shelf registration statement permits us to sell, from time to time, up to \$75,000,000 of common stock, preferred stock and warrants or any combination of the foregoing. Pursuant to SEC regulations however we cannot sell securities from the shelf registration statement which represent more than one third of the market value of our public float in any 12 month period.

We expect to incur quarterly and annual operating losses for the foreseeable future due to several factors including the timing and extent of research and development efforts, particularly with expected increases in expenses relating to the OVATURE trial and the planned clinical trials of triphendiol. The extent and possible outcomes of current and future clinical trial activities makes accurate prediction of future operating results difficult or impossible.

As at the date of the report Novogen owns approximately 71.3% of the outstanding shares of our common stock.

### **Liquidity and Capital Resources**

At June 30, 2008, we had cash resources of \$19,743,000 compared to \$16,158,000 at June 30, 2007. The increase was due to the net proceeds of the capital raising in August 2007 of \$15,193,000, which were partially offset by the payment of the \$1,000,000 milestone licence fee in March 2008 and expenditures in the clinical trial program and other corporate expenses incurred during the year. In addition, in July, 2008 we raised proceeds of \$10,000,000 in a registered direct share offering.

Funds which are not required for payment of current expenditures are invested in short term money accounts, pending use.

## **Source and Uses of Cash**

### *Cash Used in Operating Activities*

Cash used in operating activities for the year ended June 30, 2008 was \$11,498,000 compared to \$10,786,000 for the same period in 2007. The increase in cash outflow of \$712,000 for the year ended June 30, 2008 was due primarily to additional cash outflow incurred in connection with the increased costs associated with the Phase III OVATURE trial and other corporate purposes.

### *Cash Requirements*

We are currently conducting the OVATURE Phase III clinical study to support marketing approval of phenoxodiol for ovarian cancer and progressing the pre clinical development of triphendiol and NV-143.

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

We do not intend to incur any significant capital expenditures in the foreseeable future.

### *Payments to Novogen*

Future payments to Novogen under the terms of the Phenoxodiol License Agreement, the License Amendment Deed for Phenoxodiol, the Further Amended and Restated License Agreement and the License Agreement for Triphendiol and NV-143 are detailed in Note 6 of the financial statements "Related Party Transactions" on page 60 of this Annual Report on Form 10-K.

We will also be required to make payments to Novogen under the Services Agreement and Manufacturing License and Supply Agreement.

## 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	Years Ended June 30,		
	2008	2007	2006
	<i>(in thousands)</i>		
Interest and other income	\$ 674	\$ 645	\$ 446
Total revenues	<u>674</u>	<u>645</u>	<u>446</u>

Research and development expenses	Years Ended June 30,		
	2008	2007	2006
	<i>(in thousands)</i>		
Clinical trial study costs	\$ (5,928)	\$ (2,255)	\$ (840)
Drug/manufacturing scale-up costs	(1,310)	(1,860)	(1,856)
Research and development service charge	(2,065)	(1,145)	(588)
Other	(22)	(501)	(143)
Total Research and Development Costs	<u>(9,325)</u>	<u>(5,761)</u>	<u>(3,427)</u>

License Fees	Years Ended June 30,		
	2008	2007	2006
	<i>(in thousands)</i>		
License Fees	<u>(1,000)</u>	<u>(5,000)</u>	<u>(3,000)</u>

Selling, general and administrative expenses	Years Ended June 30,		
	2008	2007	2006
	<i>(in thousands)</i>		
Legal and professional fees	\$ (527)	\$ (488)	\$ (394)
Administrative service charge	(989)	(818)	(707)
Share based payment	-	(1,642)	-
Other	(1,240)	(755)	(303)
Total operating expenses	<u>(2,756)</u>	<u>(3,703)</u>	<u>(1,404)</u>

### Year Ended June 30, 2008 Compared to the Year Ended June 30, 2007

We recorded a consolidated loss of \$12,410,000 and \$13,820,000 for the years ended June 30, 2008 and 2007, respectively.

**Revenues:** We received interest on cash assets and cash equivalents of \$674,000 for the year ended June 30, 2008 versus \$645,000 for the year ended June 30, 2007. This increase was due to higher cash balances combined with an increase in interest rates.

**Research and Development:** Research and development expenses increased \$3,564,000 to \$9,325,000 for the year ended June 30, 2008 compared to \$5,761,000 for the year ended June 30, 2007. This increase was primarily due to increased clinical trial costs incurred associated with the OVATURE trial reflecting the increasing number of patients on study and the commissioning of new trial sites.

**Licence Fees:** Milestone licence fees of \$1,000,000 have been expensed in the twelve months ended June 30, 2008 under the terms of the License Agreement for Triphendiol and NV-143. The second lump sum licence fee of \$5,000,000 due under the terms of the Amended and Restated License Agreement was expensed in the twelve months ended June 30, 2007. This licence fee was due on the later of 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 exceeded \$50,000,000. Following the private placement or PIPE which closed in July 2006, the funds received from equity issuances exceeded \$50,000,000 which triggered this licence fee payment.

**Selling, General and Administrative:** Selling, general and administrative expenses decreased by \$947,000 to \$2,756,000 for the year ended June 30, 2008 compared to \$3,703,000 for the year ended June 30, 2007. The decrease was due primarily to the cost of the share-based payment valued at \$1,642,000 in fiscal 2007 for a commitment fee paid to YA Global Investments, LP (YA Global Investments formerly Cornell Capital Partners, LP) in connection with a Standby Equity Distribution Agreement ("SEDA") entered into by us and YA Global Investments as of July 11, 2006. These savings were partially off set by increased costs for general corporate expenses including an increase in legal compliance costs, travel expenses, public relations and service fees paid to Novogen reflecting an increase in corporate and accounting services and insurance.

Foreign exchange gains/(losses) are included in selling, general and administrative expenses and occur when revaluing cash denominated in foreign currencies and upon consolidation of our wholly owned subsidiary MEPL. MEPL uses U.S. dollars as its functional currency and also engages in transactions in foreign currencies. Further, 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 our financial position. At June 30, 2008, we had not established a foreign currency hedging program. Net foreign exchange losses during the twelve months ended June 30, 2008 were \$255,000 compared with net exchange losses of \$98,000 during the twelve months ended June 30, 2007.

#### **Year Ended June 30, 2007 Compared to the Year Ended June 30, 2006**

We recorded a consolidated loss of \$13,820,000 and \$7,386,000 for the years ended June 30, 2007 and 2006, respectively.

**Revenues:** We received interest on cash assets and cash equivalents of \$645,000 for the year ended June 30, 2007 versus \$446,000 for the year ended June 30, 2006. This increase was due to higher cash balances combined with an increase in interest rates.

**Research and Development:** Research and development expenses increased \$2,334,000 to \$5,761,000 for the year ended June 30, 2007 compared to \$3,427,000 for the year ended June 30, 2006. This increase was primarily due to increased clinical trial costs incurred associated with the OVATURE trial and the additional costs incurred under the Services Agreement reflecting the increased time spent by Novogen research staff on the development of phenoxodiol, triphendiol and NV-143.

**Licence Fees:** Milestone licence fees of \$5,000,000 were expensed for the year ended June 30, 2007 compared to \$3,000,000 for the year ended June 30, 2006. The \$5,000,000 expensed in the year ended June 30, 2007 represents the second lump sum licence fee due under the terms of the licence agreement. This second lump sum licence fee was due on the later of November 1, 2003 or such later date when the cumulative total of all funds received from debt or equity issuances and revenues

received from commercialization (income other than sales) and sales of phenoxodiol products exceeds \$50,000,000. Following the private placement or PIPE capital raising closed on July 11, 2006, the funds received from equity issuances exceeded \$50,000,000 which triggered this licence fee payment. The \$3,000,000 expensed in the year ended June 30, 2006 represents 50 percent (\$2,000,000) of the December 31, 2005 annual milestone licence fee of \$4,000,000 (the other 50 percent was incurred and accrued in the year ended June 30, 2005) and \$1,000,000 that was payable on execution of the new licence agreement with Novogen in relation to the drug candidates triphendiol and NV-143 licenced in May 2006.

**Selling, General and Administrative:** Selling, general and administrative expenses increased by \$2,299,000 to \$3,703,000 for the year ended June 30, 2007 compared to \$1,404,000 for the year ended June 30, 2006. The increase was due primarily to the cost of the share-based payment of the SEDA commitment fee paid to YA Global Investments in the form of shares and warrants which were valued at \$1,642,000 and general corporate expenses including an increase in legal compliance costs, travel and service fees paid to Novogen reflecting an increase in corporate and accounting services and insurance.

Foreign exchange gains/(losses) are included in selling, general and administrative expenses and occur when revaluing cash denominated in foreign currencies and upon consolidation of our wholly owned subsidiary MEPL. MEPL uses U.S. dollars as its functional currency and also engages in transactions in foreign currencies. Further, 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 our financial position. At June 30, 2008, we had not established a foreign currency hedging program. Net foreign exchange losses during the twelve months ended June 30, 2007 were \$98,000 compared with net exchange losses of \$2,000 during the twelve months ended June 30, 2006.

### **Off-Balance Sheet Arrangements**

We do not currently have any off-balance sheet arrangements.

### **Contractual Obligations**

For details of our contractual obligations at June 30, 2008 see Note 4 to the financial statements "Expenditure Commitments on page 58 of this report.

### **Critical Accounting Estimates**

The preparation of the consolidated financial statements in conformity with accounting principles generally accepted in the U.S. 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 \$5,928,000 have been included in the financial statements for the year ended June 30, 2008, of which \$1,648,000 has been accrued at June 30, 2008. 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.

#### *Manufacturing Scale-up Expenses*

Estimates have been used in determining the expense liability under certain manufacturing scale-up and drug supply 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.

Drug supply/manufacturing scale-up expenses of \$1,310,000 have been included in the financial statements for the year ended June 30, 2008, of which \$72,000 has been accrued at June 30, 2008. These estimates are based on the milestones completed for each of the service contracts.

#### *Stock Based Compensation*

We account for stock based payments in accordance with SFAS No. 123R “Share-Based Payments”. The costs of these equity-settled transactions are determined using a binomial model to calculate the fair value at the date on which they are granted. With respect to the fair value of 600,000 warrants issued July 11, 2006, in connection with the commitment fee under the SEDA and the 62,091 warrants representing 248,364 warrant shares issued August 6, 2007 to Blue Trading, LLC as part of a placement fee, the following assumptions were used:

	July 11, 2006	August 6, 2007
Dividend yield	0%	0%
Expected volatility	76%	71%
Historical volatility	76%	71%
Risk-free interest rate	5.45%	4.13%
Expected life of warrant	4 years	5 years
Warrant fair value	\$1.998	\$1.777

The dividend yield reflects the assumption that the current dividend payout, which is zero, will continue with no anticipated increases. The expected life of the warrant is based on historical data and is not necessarily indicative of exercise patterns that may occur. The expected volatility reflects the assumption that the historical volatility is indicative of future trends, which may also not necessarily be the actual outcome.

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

### **Interest Rate Risk**

Our exposure to market interest rates relates primarily to the investments of cash balances.

We have cash reserves held primarily in US\$ and A\$ and we place funds on deposit with financial institutions and are generally at call.

We do not use derivative financial instruments. We place our cash deposits with high credit quality financial institutions, and, by policy, limit the amount of credit exposure to any single counter-party. We are adverse to principal loss and we ensure the safety and preservation of our invested funds by limiting default risk, market risk, and reinvestment risk.

The Company mitigates default risk by depositing funds with high credit quality financial institutions and by constantly positioning its portfolio to respond appropriately to a significant reduction in a credit rating of any financial institution.

The Company has no interest rate exposure due to rate changes for long-term debt

We do not consider the effects of interest rate movements to be a material risk to our financial condition.

### **Foreign Currency Risk**

We conduct a portion of our business in various currencies, primarily in U.S. dollars and Australian dollars, Euros and British pounds. At June 30, 2008, we had not established a foreign currency hedging program. Net foreign exchange losses during the twelve months ended June 30, 2008 were \$255,000 compared with net exchange losses of \$98,000 during the twelve months ended June 30, 2007. 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 our financial position.

We do not consider the effects of foreign currency movements to be a material risk to our financial condition.



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

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

Report of BDO Kendalls (NSW) Independent Registered Public Accounting Firm  
Consolidated Balance Sheets  
Consolidated Statements of Operations  
Consolidated Statements of Stockholders' Equity  
Consolidated Statements of Cash Flows  
Notes to Consolidated Financial Statements



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## Report of Independent Registered Public Accounting Firm

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, 2008 and 2007, and the related statements of operations, stockholders' equity, and cash flows for each of the years in the three year period ended June 30, 2008, and for the period from December 1, 2000 (inception) through June 30, 2008. 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 audits in accordance with the standards of the Public Company Accounting Oversight Board (U.S.). 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 audits 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 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 financial position of Marshall Edwards, Inc. at June 30, 2008 and 2007, and the consolidated results of its operations and its cash flows for each of the years in the three year period ended June 30, 2008 and the period from December 1, 2000 (inception) through June 30, 2008, in conformity with accounting principles generally accepted in the United States of America.

**BDO Kendalls (NSW)**  
Sydney, NSW, Australia

**September 12, 2008**



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

	<u>June 30,</u> <u>2008</u>	<u>June 30,</u> <u>2007</u>
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 19,743	\$ 16,158
Deferred Offering Costs	110	25
Prepaid expenses and other current assets	125	107
Total current assets	<u>19,978</u>	<u>16,290</u>
Total assets	<u>\$ 19,978</u>	<u>\$ 16,290</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable	\$ 1,130	\$ 1,197
Accrued expenses	1,884	984
Amount due to related company	429	332
Total current liabilities	<u>3,443</u>	<u>2,513</u>
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: 68,854,938 at June 30, 2008 and 63,390,937 at June 30, 2007	-	-
Additional paid-in capital	68,266	53,098
Deficit accumulated during development stage	<u>(51,731)</u>	<u>(39,321)</u>
Total stockholders' equity	<u>16,535</u>	<u>13,777</u>
Total liabilities and stockholders' equity	<u>\$ 19,978</u>	<u>\$ 16,290</u>

*See accompanying notes.*

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

	Years Ended June 30,			Period from
	2008	2007	2006	December 1, 2000 (Inception) through June 30, 2008
<b>Revenues:</b>				
Interest and other income	\$ 674	\$ 645	\$ 446	\$ 2,418
Total revenues	<u>674</u>	<u>645</u>	<u>446</u>	<u>2,418</u>
<b>Operating expenses:</b>				
Research and development	(9,325)	(5,761)	(3,427)	(25,266)
License fees	(1,000)	(5,000)	(3,000)	(18,000)
Selling, general and administrative	(2,756)	(3,703)	(1,404)	(10,877)
Total operating expenses	<u>(13,081)</u>	<u>(14,464)</u>	<u>(7,831)</u>	<u>(54,143)</u>
Loss from operations	(12,407)	(13,819)	(7,385)	(51,725)
Income tax expense	(3)	(1)	(1)	(6)
Net loss arising during development stage	<u>\$ (12,410)</u>	<u>\$ (13,820)</u>	<u>\$ (7,386)</u>	<u>\$ (51,731)</u>
<b>Net loss per common share:</b>				
Basic and diluted	<u>\$ (0.18)</u>	<u>\$ (0.22)</u>	<u>\$ (0.13)</u>	
Weighted average common shares outstanding	<u>68,302,566</u>	<u>63,179,366</u>	<u>56,938,000</u>	

*See accompanying notes.*

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

	Years Ended June 30,			Period from
	2008	2007	2006	December 1, 2000 (Inception) through June 30, 2008
<b>Operating activities</b>				
Net loss arising during development stage	(12,410)	(13,820)	(7,386)	(51,731)
Adjustments to reconcile net loss to net cash used in operating activities:				
Share based payments	-	1,642	-	1,642
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets	(18)	139	(120)	(125)
Accounts payable	(67)	777	166	1,130
Accrued expenses	900	346	235	1,884
Amounts due to related company	97	130	(1,984)	429
Net cash used in operating activities	<u>(11,498)</u>	<u>(10,786)</u>	<u>(9,089)</u>	<u>(46,771)</u>
<b>Financing activities</b>				
Net proceeds from issuance of Common Stock	15,193	16,915	-	66,744
Deferred Offering Costs	(110)	(25)	(95)	(230)
Withdrawal from/(investment in) short-term deposits	-	-	10,000	-
Net cash provided by/(used in) financing activities	<u>15,083</u>	<u>16,890</u>	<u>9,905</u>	<u>66,514</u>
Net increase/(decrease) in cash and cash equivalents	3,585	6,104	816	19,743
Cash and cash equivalents at beginning of period	<u>16,158</u>	<u>10,054</u>	<u>9,238</u>	<u>-</u>
Cash and cash equivalents at end of period	<u><u>19,743</u></u>	<u><u>16,158</u></u>	<u><u>10,054</u></u>	<u><u>19,743</u></u>
Income taxes paid	<u>(3)</u>	<u>(1)</u>	<u>(1)</u>	<u>(6)</u>

*See accompanying notes.*

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

	<u>Common Stock</u> <i>(shares)</i>	<u>Additional paid in capital</u>	<u>Deficit accumulated during development stage</u>	<u>Accumulated other comprehensive income/(loss)</u>	<u>Total</u>
<b>Balance June 30, 2001</b>	49,500,000	\$ -	\$ -	\$ -	\$ -
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>	52,023,000	9,022	(123)	-	8,899
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>	52,032,000	9,058	(3,156)	31	5,933
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>	56,938,000	\$ 34,636	\$ (11,694)	\$ -	\$ 22,942
Net loss arising during development stage			(6,421)		(6,421)
Comprehensive Loss					(6,421)
<b>Balance at June 30, 2005</b>	56,938,000	\$ 34,636	\$ (18,115)	\$ -	\$ 16,521
Net loss arising during development stage			(7,386)		(7,386)
Comprehensive Loss					(7,386)
<b>Balance at June 30, 2006</b>	56,938,000	34,636	(25,501)	-	\$ 9,135
Net loss arising during development stage			(13,820)		(13,820)
Comprehensive Loss					(13,820)
Common Stock issued July 11, 2006	6,329,311	16,820			16,820
Shares issued as share-based payment (refer Note 7)	123,626	443			443
Warrants issued as share-based payment (refer Note 7)		1,199			1,199
<b>Balance at June 30, 2007</b>	63,390,937	53,098	(39,321)	-	\$ 13,777
Net loss arising during development stage			(12,410)		(12,410)
Comprehensive Loss					(12,410)
Common Stock issued August 6, 2007	5,464,001	14,727			14,727
Warrants issued as share-based payment (refer Note 7)		441			441
<b>Balance at June 30, 2008</b>	68,854,938	68,266	(51,731)	-	\$ 16,535

*See accompanying notes.*

**MARSHALL EDWARDS, INC.**  
**(A Development Stage Company)**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**June 30, 2008**

**1. Summary of Significant Accounting Policies**

**Principles of Consolidation**

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, Marshall Edwards Pty Limited (“MEPL”). 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 U.S. 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 by the Company to date is interest on cash balances, which is recognized on an accruals basis.

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

Cash on hand and in banks and short-term deposits are stated at their 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 U.S., 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. There is a full valuation allowance against net operating losses.

Effective July 1, 2007, the Company adopted Financial Accounting Standards Interpretation 48 (FIN 48), “Accounting for Uncertainty in Income Taxes – an interpretation of FASB No 109”.



FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of uncertain tax positions taken or expected to be taken in a company's income tax return, and also provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN 48 utilizes a two step approach for evaluating uncertain tax positions accounted for in accordance with SFAS No. 109, "Accounting for Income Taxes" (SFAS 109). Step one, recognition, requires a company to determine if the weight of available evidence indicates that a tax position is more likely than not to be sustained upon audit, including resolution of related appeals or litigation processes, if any. Step two, measurement, is based on the largest amount of benefit, which is more likely than not to be realized upon ultimate settlement. The cumulative effect of adopting FIN 48 on July 1, 2007 is recognized as a change in accounting principle, recorded as an adjustment to the opening balance of accumulated deficit on the adoption date. As a result of the implementation of FIN 48, the Company did not recognise any increase or decrease in the liability for unrecognized tax benefits related to tax positions taken in prior periods, therefore, there was no corresponding adjustment in accumulated deficit. Additionally, FIN 48 specifies that tax positions for which the timing of the ultimate resolution is uncertain should be recognized as long term liabilities. The Company's total amount of net tax losses carried forward as of July 1, 2008 adoption date was \$64 million.

The Company's major tax jurisdictions are the U.S. and Australia and its tax years since inception remain subject to examination by the appropriate governmental agencies in those jurisdictions due to its tax loss position.

### **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 (being the functional currency of MEPL) 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 MEPL'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 and pre-clinical trials of phenoxdiol, triphendiol and NV-143. Research and development costs are charged to earnings in the period incurred.

### **Licence 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.

Other stock-based payments have been accounted for in accordance with SFAS No. 123R "Share-Based Payments". The Company therefore recognizes the cost of goods acquired or the expense for services received in a share-based payment transaction when it obtains the goods or as services are received. The Company recognizes a corresponding increase in equity or a liability depending on the classification of the share-based instrument granted.

## **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 and warrants are excluded, whereas for diluted earnings per share they are included unless the effect is anti-dilutive.

## **Stockholders' Equity**

Ordinary share capital is recognised at the fair value of the consideration received by the Company. Any transaction costs arising on the issue of shares are recognized directly in equity as a reduction in the share proceeds received.

## **Deferred Offering Costs**

Where costs associated with a capital raising have been incurred at balance date and it is probable that the capital raising will be successfully completed after balance date, such costs are deferred and offset against the proceeds subsequently received from the capital raising.

## **Recent Accounting Standards**

In March 2008, the FASB issued SFAS No. 161, "Disclosures about Derivative Instruments and Hedging Activities - An Amendment of FASB Statement No. 133" (or SFAS 161). This statement revises the requirements for the disclosure of derivative instruments and hedging activities that include the reasons a company uses derivative instruments, how derivative instruments and related hedged items are accounted under SFAS 133 and how derivative instruments and related hedged items affect a company's financial position, financial performance and cash flows. SFAS 161 will be effective in the fourth quarter of fiscal 2009. The Company is currently evaluating the impact of adopting SFAS 161 and does not anticipate a material effect.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), "Business Combinations" (or SFAS 141(R)) which is a revision of SFAS 141. SFAS 141(R) requires an acquirer in a business combination to measure all assets acquired, the liabilities assumed and any non-controlling interest in the acquiree at their fair values on the date of acquisition with limited exceptions. This Statement also requires the acquirer in a business combination achieved in stages to recognize the identifiable assets and liabilities, as well as the non-controlling interest in the acquiree, at the full amounts of their fair values.

SFAS 141(R) will further require that acquired in-process research and development as of the acquisition date is to be capitalized at fair value. Assets acquired and liabilities assumed arising from contingencies at the acquisition date are to be measured at their fair value and acquisition costs generally will be expensed as incurred. This statement is effective for business combinations for which the acquisition date is on or after April 1, 2009. The Company is currently evaluating the impact of adopting SFAS 141(R) and does not anticipate a material effect.

In December 2007, and in conjunction with SFAS 141(R), the FASB issued SFAS No. 160, "Non-controlling Interests in Consolidated Financial Statements - An Amendment of ARB No. 51" (or SFAS 160). This Statement requires companies to report a non-controlling interest in a subsidiary as equity in its consolidated financial statements and to disclose the amount of consolidated net income attributable to the parent and to the non-controlling interest in the consolidated statement of income. SFAS 160 also clarifies that a transaction resulting in a change to the parent's ownership in a subsidiary that does not result in deconsolidation will be deemed as an equity transaction, while a gain or loss will be recognized by the parent when a subsidiary is deconsolidated. This statement is effective as of the beginning of fiscal 2010. The Company is currently evaluating the impact of adopting SFAS 141(R) and does not anticipate a material effect.

In December 2007, the FASB ratified the consensus reached by the Emerging Issues Task Force (EITF) on Issue No. 07-1, "Accounting for Collaborative Arrangements" (EITF 07-1). This Issue defines a collaborative arrangement, establishes reporting requirements and clarifies the manner in which revenues, costs and sharing payments between parties and with third parties be presented in the consolidated statement of income. This Issue is effective as of the beginning of fiscal 2010. The Company is currently evaluating the impact of adopting EITF 07-1.

In June 2007, the FASB ratified the consensus reached by EITF on Issue No. 07-3, "Accounting for Non-refundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities" (EITF 07-3). Non-refundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. Such amounts should be recognized as an expense when the related goods are delivered or services are performed, or when the goods or services are no longer expected to be provided. This Issue is effective as of the beginning of fiscal 2009. EITF 07-3 is not expected to have a material effect on the Company's consolidated financial statements.

## 2. Income Taxes

Loss from operations consists of the following jurisdictions:

	Year ended June 30,		
	2008	2007	2006
	<i>(in thousands \$)</i>		
Domestic	(448)	(1,928)	(196)
Foreign	(11,959)	(11,891)	(7,189)
	<u>(12,407)</u>	<u>(13,819)</u>	<u>(7,385)</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:

	Year ended June 30,					
	2008		2007		2006	
	<i>(in thousands \$)</i>	%	<i>(in thousands \$)</i>	%	<i>(in thousands \$)</i>	%
Tax at US statutory rates	4,342	35	4,837	35	2,585	35
Australian tax	(598)	(5)	(595)	(5)	(359)	(5)
R&D Tax concession	666	5	121	1	91	1
Change in valuation allowance	(4,413)	(35)	(4,364)	(31)	(2,317)	(31)
	<u>(3)</u>	-	<u>(1 )</u>	-	<u>(1)</u>	-

Deferred tax liabilities and assets are comprised of the following:

	Year ended June 30,	
	2008	2007
	<i>(in thousands \$)</i>	
Deferred tax liabilities		
Unrealised Foreign Exchange Gain	(13)	(13)
Total deferred tax liabilities	<u>(13)</u>	<u>(13)</u>
Deferred tax assets		
Tax carried forward losses	19,160	12,993
Share based payments	574	574
Unrealised Foreign Exchange Loss	89	39
Consultant and other accruals	510	277
Total deferred tax assets	<u>20,333</u>	<u>13,883</u>
Valuation allowance for deferred tax assets	(20,320)	(13,870)
Net deferred tax assets and liabilities	<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, 2008 and 2007. 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, 2008 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 \$1,787,000 at June 30, 2008. The federal net operating losses will begin to expire in 2022.

Foreign tax losses of approximately \$61,783,000 at June 30, 2008, 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:

	Years ended June 30,		
	2008	2007	2006
	<i>(In Thousands, except share data)</i>		
<b>Numerator</b>			
Net loss arising during development stage	(12,410)	(13,820)	(7,386)
Numerator for diluted earnings per share	<u>\$ (12,410)</u>	<u>\$ (13,820)</u>	<u>\$ (7,386)</u>
<b>Denominator</b>			
Denominator for basic earnings per share -			
Weighted average number of shares used in computing net loss per share, basic and diluted.	68,302,566	63,179,366	56,938,000
Effect of dilutive securities	-	-	-
Dilutive potential common shares	<u>68,302,566</u>	<u>63,179,366</u>	<u>56,938,000</u>
Basic and Diluted net loss per share	\$ (0.18)	\$ (0.22)	\$ (0.13)

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:

	As at June 30,		
	2008	2007	2006
	<i>(Number of warrant shares)</i>		
Warrants exercisable prior to July 11, 2010 at an exercise price of \$4.35	2,815,258	2,815,258	2,392,000
Warrants exercisable prior to August 6, 2012 at an exercise price of \$3.60	2,185,598	-	-
Warrants exercisable prior to August 6, 2012 at an exercise price of \$3.00	<u>248,364</u>	<u>-</u>	<u>-</u>
Common shares issuable upon exercise of outstanding warrants	<u>5,249,220</u>	<u>2,815,258</u>	<u>2,392,000</u>

During August 2007, the Company issued 5,464,001 shares of common stock and warrants exercisable for 2,433,962 shares of common stock in connection with a PIPE capital raising. For further details see Note 7 "Equity".

### 4. Expenditure Commitments and Contingencies

At June, 30, 2008, the Company had contractual obligations for the conduct of clinical trials, pre-clinical research and development and manufacturing process development of approximately \$17,712,000. 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>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	\$ 17,712	\$ 9,496	\$ 6,074	\$ 2,142	\$ -
<b>Total</b>	<b>\$ 17,712</b>	<b>\$ 9,496</b>	<b>\$ 6,074</b>	<b>\$ 2,142</b>	<b>\$ -</b>

No amounts have been included for future payments to Novogen which may arise in connection with the Phenoxodiol License Agreement, the License Agreement for Triphendiol and NV-143, the Services Agreement or the Manufacturing License and Supply Agreement as future payments under the terms of the agreements are subject to termination provisions. The terms of the agreements, including future payments, 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 provides that it will indemnify Novogen in connection with certain actions brought against Novogen by any of the Company's stockholders or any other person.

Pursuant to the terms of a Guarantee and Indemnity Agreement, the Company has guaranteed the payment and performance of the obligations of MEPL to Novogen and its subsidiaries, Novogen Laboratories Pty Limited and Novogen Research Pty Limited, under the Phenoxodiol 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 Phenoxodiol License Agreement and the obligations of Novogen Laboratories Pty Limited under the Manufacturing License and Supply Agreement to MEPL. 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 the clinical development and commercialization of phenoxodiol, triphendiol and NV-143. The business contains two major segments based on geographic location.

	<b>2008</b>			<b>Year Ended June 30, 2007</b>			<b>2006</b>		
	<b>USA</b>	<b>Australia</b>	<b>Total</b>	<b>USA</b>	<b>Australia</b>	<b>Total</b>	<b>USA</b>	<b>Australia</b>	<b>Total</b>
<b>Statement of Operations</b>	<i>(in thousands)</i>								
Interest Revenue	606	68	674	505	140	645	348	98	446
Loss from operations	(448)	(11,959)	(12,407)	(1,928)	(11,891)	(13,819)	(196)	(7,189)	(7,385)
Income Tax Expense	(3)	-	(3)	(1)	-	(1)	(1)	-	(1)
Net loss arising during development stage	(451)	(11,959)	(12,410)	(1,929)	(11,891)	(13,820)	(197)	(7,189)	(7,386)
<b>Balance Sheet</b>									
Segment assets	65,149	3,131	68,280	50,231	1,399	51,630	33,767	2,895	36,662
Elimination of	(48,302)	-	(48,302)	(35,340)	-	(35,340)	(26,267)	-	(26,267)

investment in subsidiary									
Consolidated									
Assets	<u>\$ 16,847</u>	<u>\$ 3,131</u>	<u>\$ 19,978</u>	<u>\$ 14,891</u>	<u>\$ 1,399</u>	<u>\$ 16,290</u>	<u>\$ 7,500</u>	<u>\$ 2,895</u>	<u>\$ 10,395</u>
Segment liabilities	<u>\$ 312</u>	<u>\$ 3,131</u>	<u>\$ 3,443</u>	<u>\$ 110</u>	<u>\$ 2,403</u>	<u>\$ 2,513</u>	<u>\$ 180</u>	<u>\$ 1,080</u>	<u>\$ 1,260</u>

## **6. Related Party Transactions**

### **Licence Agreement for Phenoxodiol**

In September 2003, the Company entered into a licence agreement pursuant to which Novogen granted to MEPL a worldwide non-transferable licence under its patents and patent applications and in its know-how to conduct clinical trials and commercialize and distribute phenoxodiol products. The licence 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 licence 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 licence fee payment due under the terms of the licence agreement. Also, MEPL paid \$2,000,000 to Novogen in January 2005 and \$4,000,000 in January 2006 which was the annual milestone licence fee payments due under the licence agreement. The Company paid a second lump sum licence fee of \$5,000,000 to Novogen in July 2006 following the raising of funds in a private placement. This licence fee was due on the later of 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 exceeded \$50,000,000. Following the private placement or PIPE which closed on July 11, 2006 the funds received from equity issuances exceeded \$50,000,000 which triggered this licence fee payment. Future amounts payable to Novogen under terms of the licence agreement are as follows:

1. Until the expiration of the exclusivity period of the licence, MEPL must pay Novogen 2.5% of all net sales and 25% of commercialization income. After the exclusivity period of the licence, 1.5% of net sales must be paid to Novogen. The preconditions to such payments have not yet occurred.

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 licenced patent right which MEPL would, but for the licence granted in the licence agreement, infringe in any country in the geographical territory covered by the licence agreement by doing in that country any of the things set out in the licence agreement.

2. In addition to the amounts above, beginning in 2006, an \$8 million annual milestone licence fee is payable under the amended terms of the licence agreement at the end of each calendar year during the exclusivity period of the licence. The 2006 licence fee has been deferred under the licence amendment deed which is discussed below.

### **Licence Amendment Deed for Phenoxodiol**

In June 2006, the Company entered into an amendment deed to the licence agreement for phenoxodiol. Pursuant to the original term of the licence agreement for phenoxodiol the Company was required to pay an \$8,000,000 licence milestone fee to Novogen in December 2006. The amendment deed extends the date that the \$8,000,000 licence milestone fee is payable until the earliest receipt by MEPL of the first:



- (i) approval by the FDA of a New Drug Application (NDA) for phenoxodiol;
- (ii) approval or authorization of any kind to market phenoxodiol in the U.S.; or
- (iii) approval or authorization of any kind by a government agency in any other country to market phenoxodiol.

Upon receipt of any of the above (the "Approval Date"), the Company must pay to Novogen, \$8,000,000, together with interest on that amount from (and including) December 31, 2006, calculated at the bank bill rate. This milestone licence fee replaces the \$8,000,000 December 31, 2006 milestone fee.

### **Further Amended and Restated License Agreement**

Following agreement in March 2007, MEPL and Novogen entered into another amendment deed to the licence agreement for phenoxodiol for the purpose of further amending and restating the license agreement (the "Further Amended and Restated License Amendment").

The combined result of the Licence Amendment Deed for Phenoxodiol and the Further Amended and Restated License Agreement will be that upon the Approval Date, MEPL will be required to pay Novogen \$8,000,000, together with interest on such amount from (and including) December 31, 2006 to (but excluding) the Approval Date. Thereafter, MEPL will be required to make license milestone fee payments of \$8,000,000 to Novogen on December 31 of the year of the Approval Date and on December 31 of each year thereafter during the exclusivity period under the License Agreement.

No licence fees have been accrued at June 30, 2008.

### **Licence Agreement Triphendiol and NV-143**

In May 2006, the Company entered into a second license agreement with Novogen for two oncology compounds, triphendiol and NV-143 (the "License Agreement for Triphendiol and NV-143"). Triphendiol is being developed initially in oral form for the treatment of pancreatic and bile duct cancer and is currently in Phase I human testing. NV-143 is targeted for the treatment of melanoma, also in oral dose form, and is in the pre-clinical testing stage. The License Agreement for Triphendiol and NV-143 is an agreement under which Novogen 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 triphendiol and NV-143 products. The License Agreement for Triphendiol and NV-143 covers uses of triphendiol and NV-143 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. The Company is required to make payments under the terms of the License Agreement for Triphendiol and NV-143 with Novogen as follows:

1. A lump sum license fee of \$1,000,000 was payable to Novogen on the commencement date of the license in consideration of the license granted. This initial lump sum license fee was paid to Novogen in May 2006.
2. In further consideration of the license granted, MEPL must pay to Novogen the following milestone license fees upon the occurrence of the corresponding milestone as set forth below;

- a) the first license product containing triphendiol to reach a milestone as set forth below; and
- b) the first licensed product containing NV-143 to reach a milestone as set forth below.

The milestone license fees are:

- i) \$1,000,000 on the date an investigational new drug application (“IND”) for the licensed product goes into effect or the equivalent approval of a government agency is obtained in another country. If this event does not occur before March 31, 2008 then this amount will be due on this date. The amount of \$1,000,000 was paid to Novogen on March 31, 2008 under the terms of this agreement;
- ii) \$2,000,000 on the date of enrollment of the first clinical trial subject in a Phase II clinical trial of the licensed product. If this event does not occur before June 30, 2009, then this amount will be due on this date;
- iii) \$3,000,000 on the date of enrollment of the first clinical trial subject in a Phase III clinical trial of the licensed product. If this event does not occur before December 31, 2011, then this amount will be due on this date; and
- iv) \$8,000,000 on the date of first receipt of a NDA for the licensed product from the FDA or equivalent approval from a government agency in another country. If this event does not occur before December 31, 2013, then this amount will be due on this date.

3. MEPL must pay Novogen royalties of 5.0% of all net sales and 25% of commercialization income for the term of the license. The royalty rate is reduced by 50% if the licensed patent rights in any country or territory expire, lapse, are revoked, do not exist or are assigned to MEPL and the product is entirely manufactured and supplied in such country.

4. Minimum royalties of \$3,000,000 per year are payable following the date of first receipt of an NDA for a licensed product from the FDA (or equivalent approval from a government agency in any other country) until the expiration of the term.

The licence agreement is able to be cancelled without penalty by MEPL by giving three months notice. Therefore licence fees due under the licence agreement are recognised as an expense when the milestone event occurs.

### **Amended and Restated Licence Option Deed**

On September 24, 2003, MEPL and Novogen entered into an Amended and Restated Licence Option Deed (the “Licence Option Deed”). The licence 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.

### **Amended and Restated Services Agreement**

On September 24, 2003, the Company, Novogen and MEPL entered into an Amended and Restated Services Agreement (the “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 and other licenced products, including triphendiol and NV-143. 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 expenditures amounting to \$3,054,000, \$1,963,000 and \$1,294,000, were made under the Services Agreement with Novogen during the twelve months ended June 30, 2008, 2007 and 2006 respectively. Of these amounts, \$2,065,000, \$1,145,000 and \$588,000 related to service fees paid to Novogen for research and development services provided in the twelve months ended June 30, 2008, 2007 and 2006 respectively, reflecting the time spent by Novogen research staff on the development of phenoxodiol, triphendiol and NV-143. Additionally, \$989,000, \$818,000 and \$707,000 of the total expenditures during the twelve months ended June 30, 2008, 2007 and 2006, respectively, related to costs incurred for administration and accounting services provided by Novogen.

At June 30, 2008 and 2007, \$429,000 and \$177,000, respectively, was due and owing to Novogen under the services agreement and is included in amounts due to related company.

### **Amended and Restated Manufacturing Licence and Supply Agreement**

On September 24, 2003, MEPL and Novogen entered into an Amended and Restated Manufacturing Licence and Supply Agreement (the "Manufacturing Licence and Supply Agreement"). Under the terms of the Manufacturing Licence and Supply Agreement, MEPL has granted to Novogen an exclusive, non-transferable sub licence to manufacture and supply phenoxodiol in its primary manufactured form. Novogen has agreed to supply phenoxodiol to MEPL for the clinical trial development program and phenoxodiol's ultimate commercial use. Phenoxodiol supplied by Novogen under the terms of this agreement will be charged at cost plus a 50% markup.

Transactions giving rise to expenditures amounting to \$38,000, \$153,000 and \$527,000 were made under the manufacturing licence and supply agreement with Novogen during the twelve months ended June 30, 2008, 2007 and 2006, respectively.

At June 30, 2008 and June 30, 2007 no amount was due and owing to Novogen under the Manufacturing Licence and Supply Agreement.

Novogen has taken the strategic decision not to manufacture large scale Active Pharmaceutical Ingredients for cancer drugs, including phenoxodiol, as these can be more economically supplied by third parties with particular expertise in this area.

## **7. Equity**

MEI 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 AIM. Following the listing, Novogen 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 Global Market. The Company received proceeds of \$15,522,000, net of \$2,431,000 transaction costs in the December 2003 offering.

On December 18, 2006, 2,392,000 warrants which were issued in connection with the December 2003 public offering expired and no shares of common stock were issued relating to those warrants.

In January 2006, the Company voluntarily cancelled the trading of its common stock on the AIM.

On July 11, 2006, the Company entered into a securities subscription agreement with certain accredited investors providing for the placement of 6,329,311 shares of the Company's common stock and warrants exercisable for 2,215,258 shares of the Company's common stock at a purchase price of \$2.90 per unit. Each unit consisted of one share of common stock and 0.35 of a warrant to purchase one share of common stock. The warrants have an exercise price of \$4.35 per share, subject to certain adjustments. The exercise price and number of shares issuable upon exercise of such warrants are subject to adjustment in the event of stock dividends, stock splits and other similar events. The warrants may be exercised no less than six months from the closing date and will expire four years from the date of issuance, or July 11, 2010. The Company closed the private placement on July 11, 2006. In connection with the private placement or PIPE, the Company received proceeds of \$16.8 million net of \$1.5 million commissions and other costs.

In connection with the securities subscription agreement described above the Company entered into a registration rights agreement pursuant to which the Company is obligated to file a resale registration statement with the SEC covering the shares of common stock issued in connection with the securities subscription agreement, in addition to the shares of common stock underlying the warrants issued in connection with the securities subscription agreement. The Company filed the registration statement on August 9, 2006. The resale registration statement was declared effective September 5, 2006.

On July 11, 2006, the Company entered into a standby equity distribution agreement (the "SEDA"), with YA Global Investments, LP (YA Global Investments formerly Cornell Capital Partners, LP). Under the SEDA, the Company may have issued and sold to YA Global Investments shares of its common stock for a total purchase price of up to \$15 million, once a resale registration statement was in effect.

In connection with the SEDA, the Company paid YA Global Investments a commitment fee of 123,626 shares of its common stock and warrants to purchase 600,000 shares of its common stock which expire on July 11, 2010. The warrants have an exercise price of \$4.35 per share, subject to certain adjustments. The exercise price and number of shares issuable upon exercise of such warrants are subject to adjustment in the event of stock dividends, stock splits and other similar events. The commitment fee, comprising shares and warrants, is a share-based payment and has been accounted for in accordance with FAS123R "Share-based Payment". The fair values of shares and warrants issued have been recognized directly as equity in the balance sheet and as selling, general and administration expenses in the income statement in the year ended June 30, 2007.

The Company did not issue any shares of common stock under the terms of the SEDA and in August 2007 the Company cancelled the SEDA.

On August 1, 2007, the Company entered into a securities subscription agreement with certain accredited investors providing for the placement of 5,464,001 shares of its common stock at a purchase price of \$3.00 per share. The investors in the transaction also received a warrant to purchase an additional 4 shares of common stock for every block of 10 shares of common stock purchased. All of the warrants have an exercise price of \$3.60 per share. The warrants may be exercised beginning February 6, 2008 and will expire five years from the date of issuance, or August 6, 2012. The Company also issued 62,091 warrants to Blue Trading, LLC, which acted as the placement agent in the private placement, as part of the placement fee. The warrants issued to Blue Trading, LLC have an exercise price of \$3.00 per share and each warrant is convertible for 4 shares of common stock. These warrants may be exercised immediately and will expire five years from the date of issuance, on August 6, 2012. The fair value of warrants issued as part of the placement fee, valued at \$441,000, have been recognized directly as equity in the balance sheet and offset against issued share capital as a cost of the raising in the year ended June 30, 2008. The Company closed the private placement, or PIPE, on August 6, 2007. In connection with the PIPE, the Company received proceeds of \$15.2 million net of \$1.2 million in commissions and other costs.

The Company entered into a registration rights agreement with the investors party to the securities subscription agreement and Blue Trading, LLC, and agreed to file a resale registration statement with the SEC registering the common stock and the common stock issuable upon exercise of the warrants sold pursuant to the securities subscription agreement for resale thereunder. The Company filed the registration statement on October 2, 2007. The resale registration statement was declared effective October 19, 2007.

Under the terms of the July 11, 2006 and the August 1, 2007 PIPEs, the Company is required to maintain effective registration statements covering the resale shares of common stock issued in the PIPEs and the shares of common stock issuable upon exercise of the warrants issued in the PIPEs. In relation to the July 11, 2006 PIPE, at the date of issuance, the Company assessed the terms of the registration rights agreement, and as the penalty for not maintaining the registration of common stock is less than the difference between the value of registered shares and unregistered shares, the equity has been classified as permanent equity. The August 1, 2007 PIPE has been assessed as permanent equity under FASB Staff Position No. EITF 00-19-2, described below.

On January 1, 2007 the Company adopted FASB Staff Position No. EITF 00-19-2 (FSP 00-19-2). FSP 00-19-2 requires the contingent obligation to make future payments under the registration rights agreements be recognized separately in accordance with FASB Statement No. 5, Accounting for Contingencies and the underlying warrants be recognized without regard to the contingent obligation. The adoption of FSP 00-19-2 had no effect on the Company's financial statements as the warrants issued in connection with the PIPEs will remain classified as permanent equity and management does not currently believe that it is probable a payment will be made under either of the registration rights agreements.

The Company filed a shelf registration statement with the SEC in March 2008. The shelf registration statement was declared effective by the SEC on April 3, 2008. The shelf registration statement permits the Company to sell, from time to time, up to \$75,000,000 of common stock, preferred stock and warrants or any combination of the foregoing. Pursuant to SEC regulations, however, the Company cannot sell securities from the shelf registration statement which represent more than one third of the market value of the Company's public float during any 12-month period.

## 8. Significant Events After Balance Date

The Company entered into a Securities Subscription Agreement dated as of July 28, 2008 with Novogen and OppenheimerFunds, Inc. (“Oppenheimer”) pursuant to which the Company has sold 2,908,295 and 1,700,000 shares of common stock to Novogen and Oppenheimer, respectively, with Oppenheimer acting as adviser to each of the following parties severally and not jointly: (i) Oppenheimer International Growth Fund; (ii) Mass Mutual International Equity Fund; (iii) Oppenheimer International Growth Fund/VA; (iv) AZL Oppenheimer International Growth Fund; (v) OFITC International Growth Fund; and (vi) OFI International Equity Fund, at a purchase price of \$2.17 per share, the consolidated closing bid price of the Company’s Common Stock as quoted by the Nasdaq Market Intelligence Desk at 4:00 PM EST on July 28, 2008. The shares were registered under the Securities Act of 1933, as amended, pursuant to a shelf registration statement on Form S-3 (File No. 333-149807), which was declared effective by the SEC on April 3, 2008. The Company received gross proceeds of \$10 million from the sale of the shares.

Following the registered direct offering closed in July 2008, Novogen retained approximately 71.3% of the Company’s common stock.

In July 2008 the Company also issued 46,083 warrants to Mr John O’Connor to purchase 46,083 shares of common stock, as consideration for investor services rendered by him to the Company. The warrants have an exercise price of \$2.17 per share and may be exercised immediately and expire five years from the date of issuance, on July 30, 2013.

## 9. Quarterly Financial Data (Unaudited)

<b>2008 for the quarter ended</b>	<b>Jun-30</b>	<b>Mar-31</b>	<b>Dec-31</b>	<b>Sep-30</b>	<b>Year</b>
					(in thousands except per share data)
Revenue	92	149	215	218	674
Loss from operations	(3,401)	(3,331)	(2,310)	(3,365)	(12,407)
Net Loss arising during development stage	(3,401)	(3,332)	(2,311)	(3,366)	(12,410)
Basic and diluted loss per share	(0.05)	(0.05)	(0.03)	(0.05)	(0.18)

<b>2007 for the quarter ended</b>	<b>Jun-30</b>	<b>Mar-31</b>	<b>Dec-31</b>	<b>Sep-30</b>	<b>Year</b>
					(in thousands except per share data)
Revenue	156	171	183	135	645
Loss from operations	(2,042)	(1,722)	(2,175)	(7,880)	(13,819)
Net Loss arising during development stage	(2,042)	(1,723)	(2,175)	(7,880)	(13,820)
Basic and diluted loss per share	(0.03)	(0.03)	(0.03)	(0.13)	(0.22)

## 10. Contingent Liabilities

Under the terms of the license agreements with Novogen, milestone license fee payments are payable upon achieving certain milestones. Details of the payments due under these agreements are detailed in Note 6 “Related Party Transactions.” The license agreements are subject to termination provisions.

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

None.

### **Item 9A(T). Controls and Procedures**

#### *(a) 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 Chief Executive Officer and Chief 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 ("the Exchange Act")). Based on that evaluation, the Company's Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures are effective to ensure that the information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

A control system no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within the company are detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met and, as set forth above, our Chief Executive Officer and Chief Financial Officer have concluded, based on their evaluation as of the end of the period covered by this Annual Report, that our disclosure controls and procedures were sufficiently effective to provide reasonable assurance that the objectives of our disclosure control system were met.

#### *(b) Management's Annual Report on Internal Controls Over Financial Reporting*

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a - 15(f) under the Exchange Act. The Company's internal control was designed to provide reasonable assurance to the Company's management and Board of Directors regarding the preparation and fair presentation of published financial statements. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Management maintains a comprehensive system of controls intended to ensure that transactions are executed in accordance with management's authorization, assets are safeguarded, and financial records are reliable. Management also takes steps to ensure that information and communication flows are effective, and to monitor performance, including performance of internal control procedures.

Management assessed the effectiveness of the Company's internal control over financial reporting as of June 30, 2008 based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework. Based on this assessment, management believes that the Company's internal control over financial reporting is effective as of June 30, 2008.

This Annual Report does not include an attestation report of the Company's independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's independent registered public accounting firm pursuant to temporary rules of the SEC that permit the Company to provide only Management's Report in this Annual Report.

*(c) Changes in Internal Controls*

There were no changes in internal control over financial reporting during the most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

**Item 9b. Other Information**

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 herein by reference to our proxy statement for the fiscal year ended June 30, 2008 (the "Proxy Statement").

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

The information required by this item is incorporated herein by reference to 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 herein by reference to the Proxy Statement.

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

The information required by this item is incorporated herein by reference to the Proxy Statement.

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

The information required by this item is incorporated by reference to 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 Restated Certificate of Incorporation (1)
- 3.2 Amended and Restated Bylaws (18)
- 4.1 Specimen Stock Certificate (3)
- 4.2 Specimen Warrant Certificate (4)
- 4.3 Specimen Warrant Certificate (5)
- 4.4 Specimen Warrant Certificate (26)
- 4.5 Warrant Agreement (6)
- 4.6 Form of Warrant Agreement (7)
- 4.7 Warrant Agreement (19)
- 4.8 Amended and Restated Warrant Agreement (23)
- 4.9 Form of Warrant (8)
- 4.10 Form of Warrant (20)
- 4.11 Form of Warrant (25)
- 4.12 Warrant dated July 30, 2008 issued to Mr John O'Connor (27)
- 10.1 Amended and Restated Licence Agreement between Novogen Research Pty Limited and Marshall Edwards Pty Limited (9)
- 10.2 Amended and Restated Manufacturing Licence and Supply Agreement between Novogen Laboratories Pty Limited and Marshall Edwards Pty Limited (10)
- 10.3 Amended and Restated Licence Option Deed between Novogen Research Pty Limited and Marshall Edwards Pty Limited (11)
- 10.4 Amended and Restated Services Agreement among Novogen Limited, Marshall Edwards, Inc. and Marshall Edwards Pty Limited (12)
- 10.5 Guarantee and Indemnity among Marshall Edwards, Inc., Novogen Laboratories Pty Limited, Novogen Research Pty Limited and Novogen Limited (13)
- 10.6 Marshall Edwards, Inc. Share Option Plan (14)
- 10.7 Licence Agreement between Novogen Research Pty Limited and Marshall Edwards Pty Limited (15)
- 10.8 Amendment Deed between Novogen Research Pty Limited and Marshall Edwards Pty Limited (16)
- 10.9 Registration Rights Agreement by and among Marshall Edwards, Inc. and the investors as signatories thereto (17)

- 10.10 Securities Subscription Agreement, dated as of August 1, 2007 by and among Marshall Edwards, Inc. and the investors listed on schedule 2.1 thereto (21)
- 10.11 Registration Rights Agreement, dated as of August 6, 2007 by and among Marshall Edwards, Inc. and the purchases signatory thereto (22)
- 10.12 Registration Rights Agreement, dated as of September 26, 2007 by and among Marshall Edwards, Inc. and Blue Trading, LLC (24)
- 10.13 Securities Subscription Agreement dated as of July 28, 2008 by and among Marshall Edwards, Inc., Novogen Limited and OppenheimerFunds, Inc. (28)
- 21.1 Subsidiaries of Marshall Edwards, Inc. (2)
- 23.1 Consent of BDO Kendalls (NSW)\*
- 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)\*
- 32.1 Certification required by Rule 13a-14(b) or Rule 15d-14(b) and section 1350 of Chapter 63 of Title 18 of the U.S. Code (18 U.S.C. 1350)\*

\* Filed herewith.

- (1) Incorporated by reference to Exhibit 3.1 to Registrant's Registration Statement on Form S-1 filed on September 25, 2003 (Reg. No. 333-109129).
- (2) Incorporated by reference to Exhibit 21 to Registrant's Registration Statement on Form S-1 filed on September 25, 2003 (Reg. No. 333-109129).
- (3) Incorporated by reference to Exhibit 4.1 to Amendment No. 1 to Registrant's Registration Statement on Form S-1 filed on October 31, 2003 (Reg. No. 333-109129).
- (4) Incorporated by reference to Exhibit 4.3 Amendment No. 1 to Registrant's Registration Statement on Form S-1 filed on October 31, 2003 (Reg. No. 333-109129).
- (5) Incorporated by reference to Exhibit 4.2 to Registrant's Registration Statement on Form S-3 filed on August 9, 2006 (Reg. No. 333-136440).
- (6) Incorporated by reference to Exhibit 4.2 to Amendment No. 1 to Registrant's Registration Statement on Form S-1 filed on October 31, 2003 (Reg. No. 333-109129).
- (7) Incorporated by reference to Exhibit 10.3 to Registrant's Current Report on Form 8-K filed on July 12, 2006.
- (8) Incorporated by reference to Exhibit 10.4 to Registrant's Current Report on Form 8-K filed on July 12, 2006.
- (9) Incorporated by reference to Exhibit 10.1 to Registrant's Registration Statement on Form S-1 filed on September 25, 2003 (Reg. No. 333-109129).
- (10) Incorporated by reference to Exhibit 10.2 to Registrant's Registration Statement on Form S-1 filed on September 25, 2003 (Reg. No. 333-109129).
- (11) Incorporated by reference to Exhibit 10.3 to Registrant's Registration Statement on Form S-1 filed on September 25, 2003 (Reg. No. 333-109129).
- (12) Incorporated by reference to Exhibit 10.4 to Registrant's Registration Statement on Form S-1 filed on September 25, 2003 (Reg. No. 333-109129).
- (13) Incorporated by reference to Exhibit 10.5 to Registrant's Registration Statement on Form S-1 filed on September 25, 2003 (Reg. No. 333-109129).
- (14) Incorporated by reference to Exhibit 10.6 to Registrant's Registration Statement on Form S-1 filed on September 25, 2003 (Reg. No. 333-109129).
- (15) Incorporated by reference to Exhibit 99.1 to Registrant's Current Report on Form 8-K filed on May 16, 2006.
- (16) Incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K filed on June 9, 2006.
- (17) Incorporated by reference to Exhibit 10.2 to Registrant's Current Report on Form 8-K filed on July 12, 2006.
- (18) Incorporated by reference to Exhibit 3.1 to Registrant's Current Report on Form 8-K filed on July 30, 2007.
- (19) Incorporated by reference to Exhibit 10.3 to Registrant's Current Report on Form 8-K filed on August 6, 2007.
- (20) Incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K filed on August



- (21) Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on August 6, 2007.
- (22) Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on August 6, 2007.
- (23) Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K/A filed on September 27, 2007.
- (24) Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K/A filed on September 27, 2007.
- (25) Incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K/A filed on September 27, 2007.
- (26) Incorporated by reference to Exhibit 4.4 to Registrant's Annual Report on Form 10-K filed on September 27, 2007.
- (27) Incorporated by reference to Exhibit 4.1 to Registrant's current report on Form 8-K filed on July 30, 2008.
- (28) Incorporated by reference to Exhibit 10.13 to the Registrant's current report on Form 8-K filed on July 30, 2008.

# 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 12, 2008.

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 12, 2008.

Signatures	Title
By: <u>/s/ Christopher Naughton</u>	President, Chief Executive Officer and Director

Christopher Naughton

By: <u>/s/ David Seaton</u>	Secretary, Chief Financial Officer
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David Seaton

By: <u>/s/ Stephen Breckenridge</u>	Director
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Stephen Breckenridge

By: <u>/s/ Bryan Williams</u>	Director
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Bryan Williams

By: <u>/s/ Paul Nestel</u>	Director
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Paul Nestel

By: <u>/s/ Philip Johnston</u>	Director
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Philip Johnston

By: <u>/s/ William Rueckert</u>	Director
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William Rueckert



## Exhibit 23.1

Marshall Edwards, Inc.  
140 Wicks Road  
NORTH RYDE NSW 2113  
AUSTRALIA

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

We hereby consent to the incorporation by reference in the Registration Statement on Form S-3 (No. 333-136440), Registration Statement on Form S-3 (No 333-146453) and Registration Statement on Form S-3 (No 333 149807), of Marshall Edwards, Inc. of our report dated September 12, 2008, relating to the consolidated financial statements which appear in this Form 10-K.

### **BDO Kendalls (NSW)**

Sydney, NSW, Australia

September 12, 2008



## Exhibit 31.1 CERTIFICATION

I, Christopher Naughton, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended June 30, 2008 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) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) 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
  - (d) 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 12, 2008

/s/ CHRISTOPHER NAUGHTON

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Christopher Naughton



## Exhibit 31.2

### CERTIFICATION

I, David Ross Seaton, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended June 30, 2008 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) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) 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
  - (d) 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: September12, 2008

DAVID SEATON

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David R. Seaton



**CERTIFICATION**

Each of the undersigned hereby certifies, for the purposes of Section 1350 of Chapter 63 of Title 18 of the U.S. Code, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, in his capacity as an officer of Marshall Edwards, Inc. ("Marshall Edwards") that, to his knowledge, this Annual Report of Marshall Edwards on Form 10-K for the period ended June 30, 2008, fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended, and that the information contained in such a report fairly presents, in all material respects, the financial condition and results of operation of Marshall Edwards.

/s/ CHRISTOPHER NAUGHTON

Christopher Naughton  
Chief Executive Officer

/s/ DAVID SEATON

David R. Seaton  
Chief Financial Officer

A signed original of this written statement required by Section 906 has been provided to Marshall Edwards and will be retained by Marshall Edwards and furnished to the Securities and Exchange Commission or its staff upon request.

