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

FORM 10-K

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

For the fiscal year ended June 30, 2006

OR

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

For the transition period from _____ to _____.

Commission File Number: 000-50484

Marshall Edwards, Inc.

(Exact name of registrant as specified in its charter)

DELAWARE	**51-0407811**
(State or other jurisdiction of Incorporation or organization)	(I.R.S. Employer Identification No.)

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

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

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

Title of Each Class	**Name of Each Exchange on which Registered**
Common Stock, $0.00000002 par value	Nasdaq Global Market
Warrants to Purchase Common Stock	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 o 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 o 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 o

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. o

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

Large accelerated filer o Accelerated filer o Non-accelerated filer ☑

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

The aggregate market value of the voting common equity held by non-affiliates of the registrant was approximately $46.5 million based on the closing price of the registrant's Common Stock as reported on the Nasdaq Global Market on December 30, 2005.

As of August 31, 2006, the number of shares outstanding of the issuer's common stock, $0.00000002 par value, was 63,390,937.

Documents Incorporated by Reference

Portions of this registrant's definitive proxy statement for its 2006 annual meeting to be filed with the SEC no later than 120 days after the end of the fiscal year are incorporated by reference in Part III of this Annual Report on Form 10-K.

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

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

- our limited operating history;
- our inability to obtain any additional required financing or financing available to us on acceptable terms;
- our failure to successfully commercialize our product candidates;
- costs and delays in the development and/or receipt of FDA or other required governmental approvals, or the failure to obtain such approvals, for our product candidates;
- uncertainties in clinical trial results;
- our inability to maintain or enter into, and the risks resulting from our dependence upon, collaboration or contractual arrangements necessary for the development, manufacture, commercialization, marketing, sales and distribution of any products;
- our inability to control the costs of manufacturing our products;
- continued cooperation and support of Novogen, our parent company;
- competition and competitive factors;
- our inability to protect our patents or proprietary rights and obtain necessary rights to third party patents and intellectual property to operate our business;
- our inability to operate our business without infringing the patents and proprietary rights of others;
- 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 United States.
- general economic conditions;

- the failure of any products to gain market acceptance;
- technological changes;
- government regulation generally and the receipt of the regulatory approvals;
- changes in industry practice; and
- one-time events;

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

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

PART I

Item 1. Business

Overview of Our Business

We are a developmental stage pharmaceutical company 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’s ordinary shares trade on the Australian Stock Exchange under the symbol “NRT,” and American Depositary Receipts (“ADRs”) trade in the United States under the symbol “NVGN” on the Nasdaq Global Market. As at the date of this report Novogen owns approximately 78.1% of our outstanding common stock.

We commenced operation in May 2002 and our business purpose is the development and commercialization of drugs for the treatment of cancer. We are presently engaged in the clinical development and commercialization of a drug candidate called phenoxodiol which we have licensed from a subsidiary of 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 or no effect on normal cells detected in pre-clinical testing. We have also licensed two other anti-cancer compounds, NV-196 and NV-143, from a subsidiary of Novogen.

Our strategy is to undertake further 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 NV-196 and NV-143 for therapeutic indications not currently targeted by phenoxodiol.

Pre-clinical testing has shown phenoxodiol to have broad anti-cancer action against an extensive library of human cancer cell lines, including prostate, ovarian and squamous cell carcinoma. Phenoxodiol commenced Phase I clinical studies in Australia in 2000 and currently is undergoing a Phase Ib/IIa clinical trial (intravenous dosage form) in the United States and Australia in patients with refractory ovarian cancer, a Phase Ib study (oral dosage form) in Australia in patients with hormone-refractory prostate cancer (prostate cancer that grows and is not inhibited by hormone therapy), a Phase Ib study (oral dosage form) in the United States in patients with cervical cancer and a Phase I study (oral dose form) in Australia in patients with renal carcinoma. In 2004, the FDA granted phenoxodiol Fast Track status for patients with recurrent late stage ovarian cancer that is resistant or refractory to platins and taxanes. In 2005, the FDA granted phenoxodiol Fast Track status for its intended use in patients with hormone-refractory prostate cancer.

Recent Developments

In May 2006, we completed a Special Protocol Assessment (SPA) and reached agreement with the FDA on a pivotal Phase III study of phenoxodiol in combination with carboplatin for women with platinum-resistant ovarian cancer (ovarian cancer that does not respond to platinum based anti-cancer agents such as cisplatin and carboplatin). The SPA process allows for FDA evaluation of a clinical trial protocol that will form the basis of an efficacy claim for a marketing application, and provides a binding agreement that the study design, including patient numbers, clinical endpoints and analyses are acceptable to the FDA. As a fast track product, phenoxodiol will be eligible to apply for accelerated approval and priority review by the FDA of the marketing application for this indication.

In May 2006, we and Novogen entered into a licence agreement pursuant to which Novogen granted to us, through Marshall Edwards Pty Limited, 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, NV-196 and NV-143.

NV-196 is being developed initially in oral form for 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. We plan to engage in the clinical development and commercialization of these two additional drug candidates which will compliment the current drug candidate, phenoxodiol, in the area of cancer.

On July 11, 2006, we entered into a securities subscription agreement with certain accredited investors providing for the placement of 6,329,311 shares of our common stock and warrants exercisable for 2,215,258 shares of our 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 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. We closed the private placement on July 11, 2006.

On July 11, 2006, we entered into a standby equity distribution agreement, which we refer to as the SEDA, with Cornell Capital Partners, LP (Cornell). Under the SEDA, we may issue and sell to Cornell shares of our common stock for a total purchase price of up to $15 million, once a resale registration statement is in effect. We have sole discretion whether and when to sell shares of our common stock to Cornell. Cornell will be irrevocably bound to purchase shares of our common stock from us after we send a notice that we intend to sell shares of our common stock to Cornell. Each advance under the SEDA is limited to a maximum of $1.5 million.

In connection with the SEDA, we paid Cornell a commitment fee of 123,626 shares of our common stock and warrants to purchase 600,000 shares of our common stock that expire on July 11, 2010. The warrants have an exercise price of $4.35 per share, subject to certain adjustments.

The purchase price for shares of our common stock under the SEDA will be equal to 97% of the lowest volume weighted average price (as quoted by Bloomberg L.P.), or VWAP, of shares of our common stock (subject to a “minimum acceptable price” as described below) during the five consecutive trading days after we send notice to Cornell of our intention to sell them shares of our common stock, which we refer to as the pricing period.

The minimum acceptable price at which we may sell our shares of common stock, unless we waive (in our sole discretion) the minimum acceptable price, is no less than 97% of the VWAP for our shares of common stock on the trading day immediately preceding the date we send notice to Cornell of our intent to sell shares of our common stock. For any day in the pricing period when the VWAP is less than the minimum acceptable price, (i) that day’s VWAP will be excluded from the pricing mechanism during the pricing period: (ii) we will automatically reduce the amount of funds covered by the advance notice by 20%; and (iii) the number of shares of our common stock to be sold to Cornell (stated in the advance notice) will be reduced proportionately.

Before we can sell any shares of our common stock to Cornell by the SEDA, a resale registration statement will have to be filed with and declared effective by the SEC to cover Cornell’s resale of

shares of our common stock it buys under the SEDA. We do not expect to access the SEDA prior to 2007.

The number of shares of our common stock that we can issue to Cornell is limited by Nasdaq's Market Place Rule 4350(i)(1)(D) — the "20% rule". All of the shares of our common stock that could be issued in connection with the SEDA, the other securities issued as a commitment fee in connection with the SEDA and the shares of our common stock issued in connection with the private placement described above, cannot exceed 20% of the shares outstanding. We have determined that currently we could issue and sell all of the shares of our common stock subject to the SEDA. If circumstances change, however, we may need to obtain shareholder approval to waive the "20%" rule.

While the SEDA provides us access to significant equity financing, using the SEDA at low market prices could result in a dilution of net tangible assets per share for our current shareholders, and also may have a depressing effect on our stock price. See "Risks Related to the Cornell Transaction."

Recent Clinical Developments

During fiscal year 2006, we made significant progress in the clinical development of phenoxodiol including:

- In March 2006, we announced that Yale researchers presented data from the study conducted at Yale – New Haven Hospital, Connecticut, United States as well as the Royal Women's Hospital, Melbourne, Australia, at the Annual Meeting on Women's Cancer. The Yale researchers reported that 74 percent of patients with late-stage, platinum-resistant tumors who received the phenoxodiol and cisplatin combination showed evidence of a change in tumor growth by way of either tumor shrinkage or no increase in tumor size.
- In November 2005, we announced plans for a Phase Ib/IIa clinical study of the investigational anti-cancer drug phenoxodiol, in combination with docetaxel for women with recurrent ovarian cancer. The investigator-initiated clinical study will take place at the Yale University School of Medicine and is supported jointly by Sanofi-Aventis and Marshall Edwards.
- In November 2005, we announced results from a study showing that phenoxodiol delayed tumor progression in men suffering from late-stage hormone refractory prostate cancer. This study is being conducted at the Sir Charles Gairdner Hospital in Perth, Australia and was presented at the International Conference on Molecular Targets and Cancer Therapeutics in Philadelphia.
- In November 2005, we announced that Yale University's School of Medicine reported a further update, at the International Conference on Molecular Targets and Cancer Therapeutics in Philadelphia, on results from a clinical study conducted with women with early-stage cancer of the cervix and vagina. The data presented by Yale researchers indicated continuing confidence that the investigational drug phenoxodiol produces anti-cancer responses in women with cervical cancer.
- In October 2005, we announced updated results from two clinical studies, conducted at Yale University's School of Medicine, involving women with late-stage ovarian cancer and women with early-stage cancer of the cervix and vagina. Interim data presented by Dr. Mor at the 11th World Congress of the International Menopause Society, Meeting in Buenos Aires, Argentina, indicated that after combining phenoxodiol with either paclitaxel or cisplatin, overall survival was substantially extended beyond what was expected.

New Director

Following the appointment of Professor David de Kretser as the Governor of the Australian state of Victoria, the Board appointed Professor Bryan Williams to succeed Professor de Kretser as one of our directors.

Professor Williams is currently the Director of the Monash Institute of Medical Research in Melbourne Australia. Prior to this appointment he was Chairman of the Department of Cancer Biology, Lerner Research Institute, The Cleveland Clinic Foundation, Cleveland, Ohio.

Share Trading on the AIM Market of the London Stock Exchange

On January 17, 2006, we voluntarily cancelled the trading of our common stock on the Alternative Investment Market of the London Stock Exchange.

Scientific Overview

Phenoxodiol, NV-196 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 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 of multiple signaling pathways, and inhibition of a single pathway by any one drug alone cannot reasonably be expected to provide more than a temporary halt to cancer progression.

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

The potential explanation for this effect on the fundamental biochemistry of tumor cells was provided by a discovery of a research team at Purdue University in Indiana. This team has a long-standing research interest in a family of proteins at the cell surface that are involved in the transport of waste electrons, particularly hydrogen ions (H+), across the cell membrane. This function is so fundamental to normal cell function and viability, that any loss of function of this electron pump will disrupt a wide range of biochemical processes as a consequence of elevated waste hydrogen levels. One of the key components of this electron pump mechanism is a protein known as NADH oxidase (abbreviated as NOX). NOX is situated on the outside of the cell membrane of all living matter, and regulates the flow of waste hydrogen across the cell membrane. The Purdue University studies have now shown that all forms of human cancer express a variant form of the constitutive (or normal) NOX, known as tumor-specific NADH oxidase (abbreviated as tNOX). Based on Purdue University studies, we believe that tNOX is a primary molecular target for phenoxodiol. Phenoxodiol appears to specifically block the action of tNOX, with the resulting inhibition of H+ efflux from the cell leading to extensive disruption to signaling pathways and to eventual inhibition of cell proliferation and activation of apoptosis, the process of programmed cell death by which a cell dies naturally. The Purdue studies also show that phenoxodiol has no effect on the normal form of NOX, providing an explanation for how phenoxodiol selectively targets cancer cells for its cytotoxic effects.

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

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

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

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 effects of standard chemotherapy drugs. These effects are achieved without increasing the toxicity of the standard chemotherapy drugs to non tumor-cells.

Overall Clinical Development Strategy for Phenoxodiol

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

The immediate priority is to focus on those therapeutic indications that will expedite drug marketing approval of phenoxodiol by regulatory bodies. To this end, we will continue to focus on three forms of cancer – ovarian cancer, prostate adenocarcinoma, and squamous cell carcinoma of the cervix and vagina.

In ovarian cancer, we have initiated two studies, both of which are testing the ability of phenoxodiol to overcome multi-drug resistance mechanisms, reversing resistance to platinums and taxanes in particular. The first is a Phase III pivotal study (known as OVATURE) in patients who have become resistant or refractory to at least 2 lines of platinum therapy, where phenoxodiol will be tested in combination with weekly carboplatin to delay tumor progression as measured by progression-free survival. The second study, a Phase II study, is being conducted in collaboration with Sanofi-Aventis and Yale Medical School, and is testing a combination of phenoxodiol plus docetaxel versus docetaxel alone in patients who have failed to respond to platinum and taxane therapy.

Phenoxodiol also is being developed for use in squamous cell carcinoma (SCC) of the cervix, vagina and vulva. A Phase II study is ongoing with a view to providing evidence of both a biological and clinical effect 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 that we believe is likely to be responsive to phenoxodiol therapy. We are assessing the feasibility of conducting a Phase II study that will address areas of unmet medical need in this common cancer.

History of Phenoxodiol Development

Phenoxodiol is an analogue of genistein, a naturally-occurring plant isoflavone that was known from the 1980s to have anti-cancer activity in pre-clinical studies and in humans. Although a wide variety of plant chemicals display cytotoxicity against tumor cells, two notable features of genistein were (a) that it was highly selective (having no known effects on non-tumor cells), and (b) that its anti-cancer activity appeared to be heterogeneous (across a range of biochemical and biological functions).

In 1995, Novogen scientists commenced a synthetic analogue program that sought to increase the anti-cancer potency, but without affecting the high selectivity of the compounds. Phenoxodiol was found to be the most potent anti-cancer compound among the compounds synthesized and tested. It was cytostatic and cytotoxic against a wide range of human cancer cells, but without toxicity against non-tumor cells. *In vivo* (in animals) studies in laboratory animals subsequently showed that phenoxodiol administered either orally or systemically was adequately bio-available (absorbed into the body in useful form) and significantly retarded tumor development, in particular in athymic mice bearing xenografts of human prostate cancer. Such anti-cancer effects in animals were achieved without evidence of toxicity, and thus phenoxodiol was selected for development as a human anti-cancer drug.

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

Early animal studies had been conducted with both oral and intravenous dosage forms of phenoxodiol, but for human use, the intravenous dosage form was selected as the preferred dosage form in the first instance because of its ability to deliver high concentrations of drug within the blood.

A Phase Ib safety study was commenced in Australia in November 2000 and finished in March 2002. An important end-point for Phase Ib safety studies is to determine the maximum tolerated dose, abbreviated as MTD, which is the highest dose of drug that can be delivered without causing life-threatening toxicity. The only safety issue reported in this study was hypersensitivity represented by rashes, headaches or fever in three patients which was considered likely to be associated with the material used to suspend the phenoxodiol in the intravenous dosage form. The MTD was not reached by the 30 mg/kg dose, which is the highest that could practically be administered.

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

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

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

- that the intravenous dosage form generally was well-tolerated and without significant safety issues, although it was associated with some intolerance (hypersensitivity) that were likely to be associated with the carrier compound rather than the phenoxodiol; and
- that preliminary evidence of an anti-tumor effect was obtained in some patients with solid tumors.

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

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

At the conclusion of this study, a Phase IIa study was commenced in both Australia and the US in 40 women with chemo-resistant, late-stage ovarian cancer, where phenoxodiol was used in combination with either cisplatin or paclitaxel to see if the chemo-resistance could be reversed. This study commenced in early 2004 and was completed in late 2005. Phenoxodiol produced an overall 33% tumor response (tumor shrinkage) rate in these patients with highly chemo-resistant tumors.

The tumor responses observed in these patients supported the receipt of Fast Track status from the FDA in 2004 for phenoxodiol in combination with carboplatin for recurrent late stage ovarian cancer that is resistant or refractory to platins and taxanes.

The first oral dose clinical study was a Phase Ib/IIa study which began in early 2002 on the use of phenoxodiol in patients with hematological tumors. This was predominantly a bio-availability and safety study, but also was intended to look for any evidence of anti-tumor activity in non-solid tumors. It was a dose-escalation study, where each patient was given a rising dose up to a maximum of 55 mg/kg/day over two 12-hourly doses. The study confirmed that the drug was readily absorbed from the gut to the extent of about 30%, and that there were no safety or intolerance issues, even at the highest dose.

The next clinical study undertaken with the oral dosage form was in Australia in men with hormone-refractory prostate cancer. This study commenced in 2003 and completed in early 2005, although a number of men remain on study treatment. Twenty-four patients with metastatic disease were treated with different dosages of phenoxodiol (20, 80, 200 and 400 mg) every 8-hours until they showed disease progression. The two efficacy end-points that were measured in this study were the prostate specific antigen (PSA) doubling time (an indicator of the rate of tumor growth) and the time patients were considered by the clinicians to be deriving a clinical benefit and remained on therapy (time to disease progression). For the four different dosage strata (20, 40, 200, 400 mg), the PSA doubling times were 14, 22, 66 and 39 weeks, respectively, and the time to disease progression was 13, 17, 55 and 42 weeks, respectively. The 400 mg dose data only refers to those patients in this dosage group who had disease progression, and does not include three patients who remain on therapy for periods up

to approximately 90 weeks. No safety or intolerance issues were reported in patients in this study.

The PSA responses observed in some patients in this study led to the oral dosage form of phenoxodiol receiving Fast Track status from the FDA in 2005 for hormone-refractory prostate cancer.

An IND for the oral dosage form of phenoxodiol became effective in the US in June 2003 which allowed a study in collaboration with Yale University School of Medicine to be conducted in patients with cancer of the cervix, vulva and vagina. This dose-response Phase IIa study is ongoing. Phenoxodiol is being used on a neo-adjuvant, monotherapy basis in patients following a primary diagnosis of cancer. Phenoxodiol is being given at dosages of 50, 200 or 400 mg (8-hourly) for up to four weeks prior to surgery. The study is intended to measure the effect of treatment on tumor size and tumor biology. In early 2006, the investigators reported that the mean change in tumor diameter over the 3-4 week period of phenoxodiol therapy was +10.0% and -7.3% respectively for the 50 and 200 mg dose groups; there were five out of six patients who showed stable disease in the 50 mg group as defined by RECIST criteria, and eight out of eight patients in the 200 mg dose group who showed stable disease. The 400 mg dose stratum currently is being recruited.

A Phase IIa study commenced in Australia in early 2004 in order to determine the dose-limiting toxicity (DLT) of oral phenoxodiol therapy on a continuous basis in combination with carboplatin or cisplatin. This study is being conducted in 30 patients with solid cancers. The study is fully recruited and will terminate when the last patient is off therapy. The phenoxodiol dose was progressively increased up to 800 mg 8-hourly.

In May 2006, we announced that the FDA had granted Special Protocol Assessment status for a Phase III trial known as OVATURE. In this study, phenoxodiol is being assessed for its ability to restore sensitivity in ovarian tumors to carboplatin once those tumors have become resistant or refractory to platinum therapy. Patients will be enrolled who have received at least two lines of platinum therapy, and who have shown disease progression within six months of receiving a standard 3-weekly treatment regimen with either cisplatin or carboplatin. This is a double-blinded, placebo-controlled study involving 470 patients from 60 sites in the US, Australia, UK, Russia, Poland, Czech Republic, Belgium, Netherlands and Germany. Patients will receive a dose-dense platinum treatment regimen of weekly carboplatin and will be randomised to receive either phenoxodiol or a placebo in combination with the carboplatin. The primary efficacy end-point is progression-free survival, with disease progression being based on radiological evidence of tumor growth as defined by RECIST criteria. We will be eligible to file with the FDA for marketing approval under the Accelerated Approval program once the interim analysis is completed providing that the difference in progression-free survival outcomes between the two treatment groups has reached the required level of statistical significance. Otherwise, submission to the FDA for a New Drug Approval will occur at the completion of the study, which is when the last patient shows disease progression, or death, or survival for 18 months, whichever comes first.

NV-196 and NV-143

In May 2006, we entered into a second licence agreement with Novogen for two experimental anti-cancer drug candidates, NV-196 and NV-143.

NV-196, is a synthetic anti-cancer compound developed by Novogen, based on an isoflavan ring structure. Similar to phenoxodiol, NV-196 is a signal transduction inhibitor. Preliminary screening studies conducted by Novogen have identified NV-196 as a candidate for product development showing a favorable in vitro toxicity profile against normal cells and broad activity against cancer

cells. NV-196 is currently in Phase I human testing and is being developed initially in oral form for the treatment of pancreatic and bile duct cancers.

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. Ongoing research is being undertaken to establish the mechanisms by which NV-143 elicits its anti-cancer/chemo-sensitizing effect. NV-143 is initially being developed to target the treatment of melanoma.

Both of these new drug candidates 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 chemo-sensitize 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).

We are now engaged in a program that seeks to bring both drug candidates to market as agents that will provide chemo-sensitization and/or radio-sensitization across a number of tumor types, but particularly pancreatic cancer, bile duct cancer, and malignant melanoma.

NV-196 underwent a small Phase Ia study in 2005 in three patients. The aim of that study was to confirm the bioavailability of the oral dosage form. That study showed that an oral dosing regimen had the potential to deliver therapeutically-relevant plasma levels of the drug, and that short-term therapy with NV-196 was well tolerated.

NV-143 is still undergoing pre-clinical evaluation for determination of the most appropriate therapeutic indication, and is not expected to enter clinical trials until 2007.

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.

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

The experimental drug, Telcyta, manufactured by Telik Inc., is a directly competitive drug to our use of phenoxodiol as a chemo-sensitizing agent to restore sensitivity to platinum-based drugs in late-stage ovarian cancer. Telcyta currently is in a Phase III registration trial suggesting that it has shown

sufficient promise in a Phase II study to warrant progression to a Phase III study. The different study protocols being used by us with phenoxodiol and by Telik Inc with Telcyta make it difficult to compare the two drugs for efficacy in this area and, as a result, we cannot evaluate the level of competition. However, we expect that at any level of efficacy, Telcyta, should it be approved for marketing, would represent a serious competitor for phenoxodiol.

Our competitors include pharmaceutical companies and biotechnology companies, as well as universities and public and private research institutions. In addition, companies active in different but related fields represent substantial competition for us. Many of our competitors developing 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, to recruit qualified personnel, and with us to attract partners for joint ventures and to 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 patents pending in a number of countries which cover a family of chemically related compounds with potentially broad ranging and complementary anti-cancer effects. Novogen has granted to us an exclusive licence, with respect to its patent rights and intellectual property know-how to develop, market and distribute one of these compounds, phenoxodiol, as an anti-cancer agent, except in topical form. Novogen has subsequently also granted to us an exclusive licence in respect of two novel derivatives of phenoxodiol, NV-143 and NV-196.

Phenoxodiol

We have licenced 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 licenced 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 pending and ten issued);
- compositions and methods for protecting skin from ultraviolet induced immunosuppression and skin damage, including phenoxodiol (six pending and seven issued); and
- therapeutic methods and compositions involving isoflav-3-ene and isoflavan structure, including phenoxodiol (thirteen pending).

The family relating to the manufacturing patent rights relate to:

- the production of isoflavone derivatives, including phenoxodiol (fourteen pending and four issued).

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

specifically directed to the treatment of ovarian cancer, breast cancer, prostate cancer, uterine cancer, bowel cancer, testicular cancer, endometrial cancer, leukaemia and metastatic cancer with isoflavone derivatives including phenoxodiol.

NV-143 and NV-196

We have also licenced from Novogen the rights to patent applications as they relate to two novel anti-cancer compounds, NV-143 and NV-196. These compounds are isoflavan derivatives of phenoxodiol. The licenced 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 NV-143 and NV-196 and uses of these compounds as anti-cancer agents (four national applications and one PCT pending); and
- uses of NV-143 and NV-196 as chemo-sensitizers and radiosensitizers of tumors and cancer cells (eleven pending).

As patent applications in the United States are maintained in secrecy until published by the USPTO at 18 months from filing, for all cases filed after November 29, 2000, or at issue, for cases filed prior to November 29, 2000, and as publication of discoveries in the scientific or patent literature often lag behind the actual discoveries, we cannot be certain that Novogen was the first to make the inventions covered by the Novogen patents and applications referred to above. Moreover, pursuant to the terms of the Uruguay Round Agreements Act, patents filed on or after June 8, 1995 have a term of twenty years from the date of such filing, irrespective of the period of time it may take for such patent to ultimately issue. This may shorten the period of patent protection afforded to therapeutic uses of phenoxodiol or to NV-143 or NV-196, 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. We cannot be sure that confidentiality will be maintained or disclosure prevented by these agreements or that our proprietary information or intellectual property will be protected thereby or that others will not independently develop substantially equivalent proprietary information or intellectual property.

The pharmaceutical industry is highly competitive and patents may have been applied for by, and issued to, other parties relating to products competitive with phenoxodiol, NV-143 or NV-196. 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 licenced 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 has been granted patents and has additional patent applications pending in a number of countries pertaining to phenoxodiol's family of compounds and to phenoxodiol itself and their use in anti-cancer therapeutics. Novogen has granted to us an exclusive licence under its patent rights and the intellectual property rights in its relevant know-how to develop, market and distribute all forms of administering phenoxodiol for anti-cancer applications, except topical applications.

In May 2006, under the terms of the licence option deed with Novogen, we licenced two oncology compounds, NV-196 and NV-143, which qualified as option compounds. NV-196 is being developed initially in oral form for 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 pre-clinical testing stage. Under the terms of the licence agreement for NV-196 and NV-143, Novogen has granted to us an exclusive licence under its patent rights and the intellectual property rights in its relevant know-how to develop, market and distribute all forms of administering NV-196 and NV-143 for anti-cancer applications, except topical applications.

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

We have entered into certain key agreements with Novogen which are discussed below.

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.

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 NV-196 and NV-143, except topical applications. The agreement covers uses of NV-196 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 NV-196 and NV-143.

Under a manufacturing licence and supply agreement, we have granted Novogen a sublicence 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 commercial 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. The contract facilities that have been identified are FDA licenced, 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 develop a scalable manufacturing method to ensure that sufficient quantities of phenoxodiol can be manufactured in compliance with cGMP (Current Good Manufacturing Practices) and to complete the analytical and stability work necessary for an NDA submission. An NDA will be submitted if the 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 NV-196 and NV-143.Novogen has a pilot manufacturing plant which we believe has sufficient capacity to also provide clinical trial quantities of NV-196 and NV-143.

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.

Pursuant to a services agreement, Novogen provides services reasonably required by us relating to the development and commercialization of phenoxodiol, NV-196, NV-143, or other option compound 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 on Novogen for the provision of resources to conduct our business.

Research and Development

The objective of our research and development program is the generation of data sufficient to achieve regulatory approval of phenoxodiol, NV-196 and NV-143 in one or more dosage forms in major markets such as the United States, and/or to allow us to enter into a commercial relationship with another party. The data 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, NV-196 and NV-143;
- the relative therapeutic indications of different dosage forms of phenoxodiol, NV-196 and NV-143;
- the relative therapeutic benefits and indications of phenoxodiol, NV-196 and NV-143 as a monotherapy or as part of combinational therapy with other chemotoxics; and
- the most appropriate cancer targets for phenoxodiol, NV-196 and NV-143.

Research expenses were $3.427 million for the year ended June 30, 2006, $2.279 million for the year ended June 30, 2005 and $2.381 million for the year ended June 30, 2004.

Regulation

U.S. Regulatory Requirements

The U.S. Food and Drug Administration, or 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 United States, pharmaceutical products are regulated by the FDA under the Federal Food Drug and Cosmetic Act or FDCA and other laws including in the case of biologics, the Public Health

Service Act. We believe, but cannot be certain, that our products will be regulated as drugs by the FDA. The process required by the FDA before drugs may be marketed in the United States generally involves the following:

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

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

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

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

• *Phase I:* The drug is initially introduced into healthy human subjects or patients and tested for safety and dosage tolerance. Absorption, metabolism, distribution, and excretion testing is generally performed at this stage.

• *Phase II:* The drug is studied in controlled, exploratory therapeutic trials in a limited number of subjects with the disease or medical condition for which the new drug is intended to be used in order to identify possible adverse effects and safety risks, to determine the preliminary or potential efficacy

of the product for specific targeted diseases or medical conditions, and to determine dosage tolerance and the optimal effective dose.

• *Phase III:* When Phase II studies demonstrate that a specific dosage range of the drug is likely to be effective and the drug has an acceptable safety profile, controlled, large-scale therapeutic Phase III trials are undertaken at multiple study sites to demonstrate clinical efficacy and to further test for safety in an expanded patient population.

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

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

Each NDA must be accompanied by a user fee, pursuant to the requirements of the Prescription Drug User Fee Act, or PDUFA, and its amendments. According to the FDA's fee schedule, effective on October 1, 2006 for the fiscal year 2007, the user fee for an application requiring clinical data, such as an NDA, is $896,200. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual product fee for prescription drugs and biologics ($49,750), and an annual establishment fee ($313,100) on facilities used to manufacture prescription drugs and biologics. A written request can be submitted for a waiver for the application fee for the first human drug application that is filed by a small business, but there are no waivers for product or establishment fees. We are not at the stage of development with our products where we are subject to these fees, but they are significant expenditures that will be incurred in the future and must be paid at the time of application submissions to FDA.

Satisfaction of FDA requirements typically takes several years. The actual time required varies substantially, based upon the type, complexity, and novelty of the pharmaceutical product, among other things. Government regulation imposes costly and time-consuming requirements and restrictions throughout the product life cycle and may delay product marketing for a considerable period of time, limit product marketing, or prevent marketing altogether. Success in pre-clinical or early stage clinical trials does not 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 United States and in foreign markets could result in new government regulations that could have a material adverse effect on our business. Our failure to obtain coverage, an adequate level of reimbursement, or acceptable prices for our future products could diminish any revenues we may be able to generate. Our ability to commercialize future products will depend in part on the extent to which coverage and reimbursement for the products will be available from government and health administration authorities, private health insurers, and other third-party payers. European Union and U.S. government and other third-party payers increasingly are attempting to contain healthcare costs by consideration of new laws and regulations limiting both coverage and the level of reimbursement for new drugs. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad.

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

The FDCA includes provisions designed to facilitate and expedite the development and review of drugs and biological products intended for treatment of serious or life-threatening conditions that demonstrate the potential to address unmet medical needs for such conditions. These provisions set forth a procedure for designation of a drug as a "fast track product." The fast track designation applies to the combination of the product and specific indication for which it is being studied. A product designated as fast track is ordinarily eligible for additional programs for expediting development and review, but products that are not in fast track drug development programs may also be able to take advantage of these programs. These programs include priority review of NDAs and accelerated

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

The Best Pharmaceuticals for Children Act, signed into law on January 4, 2002, provides an additional six months of marketing exclusivity for new or marketed drugs, for which specific pediatric studies were conducted at the written request of the FDA. On December 3, 2003, the Pediatric Research Equity Act was signed into law, authorizing the FDA to require pediatric studies for drugs and biological products to ensure the drugs' or products' safety and effectiveness in children. This Act required that NDAs or supplements to NDAs contain data assessing the safety and effectiveness for the claimed indication in all relevant pediatric subpopulations. Dosing and administration must be supported for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant deferrals for submission of data, or full or partial waivers.

Australian Regulatory Requirements

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

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

The first phase of evaluation, known as the Application Entry Process, is usually a short period during which an application is assessed on an administrative level to ensure that it complies with the basic guidelines. The TGA must decide within 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 evaluation reports. Following evaluation, the chemistry and quality control aspects of a product may be referred to a sub-committee of the Australian Drug and Evaluation Committee, or ADEC, to review the relevant evaluation reports. The 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 the ADEC. This summary is sent to the sponsoring company which is able to submit a response to the ADEC dealing with issues raised in the summary and those not previously addressed in the evaluation report. The ADEC provides independent advice on the quality, risk-benefit, effectiveness and access of the drug and conduct medical and scientific evaluations of the application. The ADEC's resolutions are provided to the sponsoring company after 5 working days after the ADEC meeting.

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

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

European Union Regulatory Requirements

Outside the United States, our ability to market our products will also be contingent upon receiving marketing authorizations from the appropriate regulatory authorities and compliance with applicable post-approval regulatory requirements. Although the specific requirements and restrictions vary from country to country, as a general matter, foreign regulatory systems include risks similar to those associated with FDA regulation, described above. Under EU regulatory systems, marketing authorizations may be submitted either under a centralized or a national procedure. Under the centralized procedure, a single application to the European Medicines Agency (EMEA) 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 EMEA. 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 United States, post-approval regulatory requirements, such as those regarding product manufacture, marketing, or distribution, would apply to any product that is approved in Europe, and failure to comply with such obligations could have a material adverse effect on our ability to successfully commercialize any product.

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.

Employees

We do not have any employees. Novogen provides 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 the following risk factors should be considered carefully in evaluating us and our business.

Risks Related to Our Business

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

You should consider our prospects in light of the risks and difficulties frequently encountered by early stage and developmental companies. Although we were incorporated in December 2000, we have only been in operation since May 2002. We have incurred net losses of $25,501,000 since our inception, including net losses of $7,386,000, $6,421,000, and $8,538,000 for the years ended June 30, 2006, 2005 and 2004, 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 expect to expand our clinical trials significantly, which will result in increasing losses, and may continue to incur substantial losses even if we begin to generate revenues from the distribution and sale of phenoxodiol.

If we are unable to successfully develop and commercialize phenoxodiol or our newly licensed anti-cancer compounds NV-196 and NV-143, or license other viable drug candidates, our ability to sustain future operations will be significantly diminished.

Under our license option deed with Novogen, we acquired a license from Novogen to develop anti-cancer drugs containing the drug candidates NV-196 and NV-143. We cannot guarantee that phenoxodiol will be successful or that we will develop successful anti-cancer drugs containing NV-196 and NV-143. Our rights under our license agreement for phenoxodiol and our license agreement for NV-196 and NV-143 with Novogen are limited to the commercialization of phenoxodiol, NV-196 and NV-143 as anti-cancer agents and these rights specifically exclude the use of phenoxodiol, NV-196 and NV-143 in topical applications. If we are unable to successfully develop and commercialize phenoxodiol or other viable anti-cancer drug candidates containing NV-196 or NV-143, we may be required to cease or reduce our operations.

If the data from our clinical trials 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 United States.

In 2004, the FDA granted phenoxodiol Fast Track status for patients with recurrent late stage ovarian cancer that is resistant or refractory to platins and taxanes. In 2005, the FDA granted phenoxodiol Fast Track status for its intended use in patients with hormone-refractory prostate cancer (prostate cancer that grows and is no longer inhibited by hormone therapy). More recently we completed a Special Protocol Assessment (SPA) and reached agreement with the FDA on a pivotal 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). The SPA process allows for FDA evaluation of a clinical trial protocol that will form the basis of an efficacy claim for a marketing application. As a fast track product, phenoxodiol will be eligible for accelerated approval and priority review by the FDA of the marketing application for this indication. If the FDA concludes that the data from our pivotal clinical trial have failed to demonstrate the safety and

effectiveness of phenoxodiol, we will not receive FDA approval to market phenoxodiol for those indications in the United States. We cannot assure you that the results of our Phase III pivotal trial will be successful.

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.

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.

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

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

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

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

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

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

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

We will need to raise additional funds to complete clinical trials and commercialize NV-196 and NV-143, and the actual amount of funds we will need will be determined by a number of factors, some of which are beyond our control.

While we believe that we have sufficient funds to complete our current clinical trial program, we will require additional funds to further the evaluation of NV-196 and NV-143 beyond the current objectives. The actual amount of funds that we will need will be determined by many factors, some of which are beyond our control. As a result, we may need additional funds sooner than we currently anticipate. These factors include:

- the progress of research activities, the number and scope of research programs;
- the progress of pre-clinical and clinical development activities;
- the progress of the development efforts of Novogen or any other parties with whom we enter into research and development agreements;
- our ability to establish and maintain current and new research and development and licensing arrangements;
- our ability to achieve milestones under licensing arrangements; and

- the costs involved in enforcing or defending patent claims and other intellectual property rights; and the costs and timing of regulatory approvals.

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

We have not yet submitted an investigational new drug application (IND) for NV-196 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 United States.

Although we have conducted the first Phase I clinical trial of NV-196 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 NV-196 or NV-143 product candidates in the United States. Approval to begin clinical testing in the United States requires submission of: (1) adequate information on the safety and manufacturing of NV-196 or NV-143 to assure the proper quality, purity and strength of the investigational product, (2) summary of pharmacological and toxicological effects, pharmacokinetics (how the drug is absorbed and metabolised) and biological disposition in animals, (3) the proposed protocol for any planned clinical study, and (4) a brief description of the overall plan for investigating the product. Although we intend to prepare an IND to be submitted to the FDA, we do not know whether or when the IND will become effective.

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

We rely on suitable research institutions, of which there are many, to conduct our clinical trials. While we have not previously experienced problems with third parties upon whom we rely for research or clinical trials, our reliance upon research institutions, including hospitals and cancer clinics, provides us with less control over the timing and cost of clinical trials and the ability to recruit patients than if we had conducted the trials on our own. Further, there is a greater likelihood that disputes may arise with these research institutions over the ownership of intellectual property discovered during the clinical trials. If we are unable to reach agreement with suitable research institutions on acceptable terms, or if any resulting agreement is terminated and we are unable to quickly replace the applicable research institution with another qualified institution on acceptable terms, the research could be delayed and we may be unable to complete development, or commercialize phenoxodiol, NV-196 or NV-143, which will adversely affect our ability to generate operating revenues.

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

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

- completing our clinical trial program and receiving marketing approval. Clinical testing is a prerequisite to the receipt of the regulatory approval necessary to commercialize our product candidates. We cannot control the outcome of our testing program or whether we receive regulatory approval. We will not be able to generate sales revenues until we receive marketing approval;

- establishing strategic partnerships to market and sell our product candidates. Our negotiating position with potential strategic partners will be affected by the success of our clinical program. If we are unable to attract partners and negotiate favorable terms, we may have difficulty generating revenues from our commercialization of our product candidates;
- identifying manufacturing partners with a low cost operation and scalable supply capable of meeting the demands of the commercial market for our product candidates. We have contracted with third parties for the supply of phenoxodiol for our pivotal study and to develop a scalable manufacturing process. We will need to rely on Novogen or third party manufacturers to supply NV-196 and NV-143. We do not have direct control over the manufacturing costs of phenoxodiol, NV-196 and NV-143. If our costs for the supply of phenoxodiol, NV-196 or NV-143 rise or if our contractors fail to supply sufficient quantities of phenoxodiol, NV-196 and NV-143, our profitability could be adversely affected; and
- our ability to license from Novogen rights to commercialize new cancer compounds. We may license from Novogen the rights to other cancer compounds under the terms of the license option deed. If development of phenoxodiol is unsuccessful or if we choose to expand to the development of additional compounds, our success may depend on controlling the costs of developing such new compounds and negotiating a favorable license agreement with Novogen. The availability of new compounds to commercialize and the cost to develop these compounds is outside of our direct control.

We have no direct control over the costs of manufacturing phenoxodiol, NV-196 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 or NV-196 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, which currently provides phenoxodiol for use in clinical trials, has taken the strategic decision not to manufacture on a large scale Active Pharmaceutical Ingredients (API's) 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 FDA licensed, have a track record of large scale API's 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 develop a scalable manufacturing method to ensure that sufficient quantities of phenoxodiol can be manufactured in compliance with cGMP (Current Good Manufacturing Practices) and to complete the analytical and stability work necessary for an NDA submission. 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 NV-196 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.

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:

- NV-196 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 may not be able to establish the strategic partnerships necessary to market and distribute phenoxodiol.

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

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

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

insure against potential product liability claims, we will be exposed to significant liabilities, which may materially and adversely affect our business development and commercialization efforts.

Our rights to develop and exploit phenoxodiol and the anti-cancer compounds NV-196 and NV-143 are subject to the terms and conditions of agreements we have entered into with Novogen, and under these agreements our rights may be terminated under certain circumstances, some of which may be beyond our control.

We have licensed the intellectual property in the phenoxodiol technology and the anti-cancer compounds NV-196 and NV-143 from Novogen. Under the terms of the license agreement for phenoxodiol, all forms of administering phenoxodiol for the treatment of cancer are licensed to us, excluding topical applications. Under the terms of the license agreement for NV-196 and NV-143, all forms of administering drugs containing the anti-cancer compounds NV-196 and NV-143 are licensed to us, excluding topical applications. 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 NV-196 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 we undergo a change of control without the consent of Novogen. A “change of control” means a change in control of more than half the voting rights attaching to the shares of our subsidiary, a change in control of more than half of the issued shares of our subsidiary (not counting any share which carries no right to participate beyond a specified amount in the distribution of either profit or capital) or a change in control of the composition of the board of directors of our subsidiary. Each of these agreements may also be terminated if we become the subject of certain bankruptcy proceedings or cease for any reason to be able to lawfully carry out all the transactions required by each respective agreement.

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

The rights granted to us under the license 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 NV-196 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 NV-196 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 NV-196 and NV-143, which we would be unable to pursue without the rights granted to us under the license agreements. Under the manufacturing license and supply agreement, we have granted to Novogen an exclusive sub-license to manufacture and supply phenoxodiol to us in its primary manufactured form and Novogen has agreed to manufacture for us our required quantities of phenoxodiol. This agreement enables us to protect the licensed intellectual property rights used in the manufacturing process while securing the services of a manufacturing partner in Novogen, which through its equity position in us, shares a common interest in the production of phenoxodiol. The license option deed grants us an exclusive first right to accept and exclusive last right to match any proposed dealing by Novogen with its intellectual property rights with a third party relating to certain compounds (other than phenoxodiol) developed by Novogen and its affiliates which have applications in the field of prevention, treatment or cure of cancer in humans.

The license option deed is important to our business because it allows us to maintain control over the sale by Novogen of complimentary 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 United States and abroad. Litigation or other legal proceedings may be necessary to defend against claims of infringement, to enforce our patents, or to protect our trade secrets or the trade secrets of Novogen. Such litigation could result in substantial costs and diversion of our management's attention. Novogen has not been involved in any opposition re-examination trade secret dispute, infringement litigation or any other litigation or legal proceedings pertaining to the licensed patent rights.

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

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

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

The pharmaceutical industry is highly competitive and patents have been applied for by, and issued to, other parties relating to products competitive with phenoxodiol. Therefore, phenoxodiol and any other drug candidates may give rise to claims that they infringe the patents or proprietary rights of other

parties existing now and in the future. Furthermore, to the extent that we or Novogen or our respective consultants or research collaborators use intellectual property owned by others in work performed for us or Novogen, disputes may also arise as to the rights in such intellectual property or in resulting know-how and inventions. An adverse claim could subject us to significant liabilities to such other parties and/or require disputed rights to be licensed from such other parties.

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

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

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

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

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

Novogen developed phenoxodiol in part using funds from the Australian Government under what is known as the START Program. Under the START Program, Novogen must meet certain project development and commercialization obligations. Novogen has met the project development obligations and has received final payment thereon. Novogen believes it is currently in compliance with its commercialization schedule. Although Novogen believes that it has complied with its obligations under the START Program, if the Australian Government disagrees or if Novogen

undergoes a change of control without the prior consent of the Australian Government, the Australian Government has a right to demand that intellectual property created during the course of the project funded by the grant be vested back in the Australian Government or demand repayment of the funds paid to Novogen under the program. The Australian Government may then license the intellectual property rights related to phenoxodiol to other parties and may demand other intellectual property rights from Novogen. Any such reclamation by the Australian Government could preclude our use of Novogen's intellectual property in the development and commercialization of phenoxodiol and we may have to compete with other companies to whom the Australian Government may license the intellectual property.

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

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

Our revenue is affected by fluctuations in currency exchange rates.

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

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

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

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 78.1% of our outstanding shares of common stock. As a result, Novogen will have the ability to effectively determine the outcome of all matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets.

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

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

Three of our directors and our secretary and chief financial officer are officers and/or directors of Novogen 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. Simultaneous service as a Novogen 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.

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

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

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

Professor Kelly could have a material adverse effect on our business or cause our stock price to decline.

Novogen can compete with us.

We have no contract, arrangement or understanding with Novogen to preclude it from developing a product which may be competitive with phenoxodiol, NV-196 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 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.

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 NV-196 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, including in connection with our SEDA.

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

Future sales of our common stock may depress our stock price 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 including the shares in connection with our SEDA, or the perception that these sales could occur. Stockholders could also experience dilution in their investment if we sell shares to Cornell under the SEDA at a price which is less than our net tangible book value per share. In August 2006, we filed a resale registration statement on Form S-3 in relation to 6,452,937 shares of common stock in addition to 2,815,258 shares of common stock underlying warrants we issued in connection with a private placement to accredited investors which we closed on July 11, 2006. Once this registration statement has been declared effective by the SEC, the selling stockholders named therein will be able to sell their shares of common stock covered by the registration statement freely in the public market place. A depressed stock price could make it more difficult for us to raise funds through future equity offerings. As of August 1, 2006, we had 63,390,937 shares of our common stock outstanding not including the 5,207,258 shares of common stock underlying warrants.

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.

Risks Related to the Private Placement

If we fail to obtain and maintain registration of the common stock issued or issuable pursuant to the exercise of warrants we issued in connection with the securities subscription agreement we

entered into with certain investors effective July 11, 2006, we may be obligated to pay the investors of those securities liquidated damages.

In connection with the securities subscription agreement we entered into with certain accredited investors as of July 11, 2006, we entered into a registration rights agreement pursuant to which we are 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. We filed the registration statement on August 9, 2006.

In the event that (i) the registration statement is not declared effective by the SEC within the time prescribed by the registration rights agreement or (ii) the registration statement ceases to be effective or usable at any time while shares of common stock covered by it remain unsold or may only be sold subject to certain volume limitations, or investors are not permitted to utilize the prospectus in connection with the registration statement to resell shares of common stock covered by the registration statement, we will be obligated to pay investors who purchased shares of common stock in the private placement liquidated damages equal to 1% of the aggregate purchase price paid by each investor pursuant to the securities subscription agreement for any shares of common stock, shares of common stock issuable upon exercise of warrants or warrants then held by each investor per month (pro rated for any period less than a month) until the registration statement is effective or the investors are permitted to utilize the prospectus in connection with the registration statement to resell shares of common stock covered by the registration statement.

Liquidated damages paid to each investor in the private placement may not exceed more than 10% of the purchase price paid by such investor for shares of common stock, shares of common stock issuable upon exercise of warrants or warrants purchased under the securities subscription agreement. If we become obligated to pay liquidated damages, we would deplete our limited working capital and potentially need to raise additional funds.

Risks Related to the Cornell Transaction

If we sell shares of our stock to Cornell under the SEDA, Cornell will pay less than the market price and this incentive to sell our shares could cause our stock price to decline.

Because Cornell will purchase shares of our stock through the SEDA at a discount to market price, Cornell will have an incentive to immediately sell the shares it purchases, to realize a gain on the difference between the purchase price and the then-prevailing market price of our common stock. These sales may result in a decrease in our stock price. Cornell is deemed to beneficially own the shares corresponding to a particular advance on the date that we deliver an advance notice to Cornell, which is prior to the date the shares are delivered to Cornell. Cornell may sell such shares any time after we deliver an advance notice, and its sales during the pricing period could cause our price to decline. Even with the SEDA's price floor (the minimum acceptable price of 97% of VWAP on the day before we send an advance notice), Cornell's sales could adversely impact share price by as much as three percent or more if we waive the minimum acceptable price provision. In addition, stockholders may experience dilution if we sell shares to Cornell under the SEDA at a price which is less than our net tangible book value per share.

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 and for our common stock as reported by the Alternative Investment Market of the London Stock Exchange (AIM). The trading price for our shares of common stock on the AIM are quoted as sterling (£), the lawful currency of the United Kingdom. On January 17, 2006, we voluntarily cancelled the trading of our common stock on the AIM.

Common Stock

	Nasdaq Global Market		AIM Market	
	High $	Low $	High £	Low £
Year Ended June 30, 2005				
First Quarter	9.27	5.74	4.85	4.25
Second Quarter	10.49	6.71	5.10	4.60
Third Quarter	9.54	6.79	4.52	3.60
Fourth Quarter	9.32	6.72	4.05	3.60
Year Ended June 30, 2006				
First Quarter	7.98	5.68	4.08	3.40
Second Quarter	8.25	5.53	4.28	3.25
Third Quarter	7.29	4.36	3.80	3.20
Fourth Quarter	6.02	2.51	N/A	N/A
Warrants (with December 2006 expiry)				
Year Ended June 30, 2005				
First Quarter	5.75	2.95		
Second Quarter	6.00	4.06		
Third Quarter	5.55	3.60		
Fourth Quarter	5.10	3.70		
Year Ended June 30, 2006				
First Quarter	4.01	2.55		
Second Quarter	3.25	0.68		
Third Quarter	1.99	0.50		
Fourth Quarter	0.74	0.20		

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

Period Ended	High	Low	Average	Period-End
Year Ended June 30, 2005				
First Quarter	$1.8734	$1.7733	$1.8193	$1.1809
Second Quarter	$1.9482	$1.7790	$1.8687	$1.9160
Third Quarter	$1.9292	$1.8570	$1.8911	$1.8880
Fourth Quarter	$1.9197	$1.7930	$1.8560	$1.7930
Year Ended June 30, 2006				
First Quarter	$1.8420	$1.7303	$1.7854	$1.7696
Second Quarter	$1.7855	$1.7138	$1.7486	$1.7188
Third Quarter	$1.7885	$1.7256	$1.7532	$1.7393
Fourth Quarter	$1.8911	$1.7389	$1.8286	$1.8491

As of August 1, 2006, the last reported closing price of our common stock and warrants on the Nasdaq Global Market was $3.15 and $0.20 respectively. There were approximately 1564 stockholders on record of our common stock

Dividends

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

Use of Proceeds of Initial Public Offering

The effective date of the registration statement (Registration No. 333-109129) filed on Form S-1 and registration statement (Registration No. 333-111291) filed on Form S-1 pursuant to Rule 462(b), both relating to the initial public offering in the United States of common stock units (each unit consisting of one share of our common stock and one warrant to purchase a share of our common stock at an exercise price of $9.00 per share), was December 17, 2003. Proceeds to us from the offering, after deduction of underwriting discounts and commissions of approximately $806,000 and offering costs of approximately $1,612,000, totalled approximately $15,522,000. As of June 30, 2006, we had used all of the proceeds of the offering of which: $5,000,000 was used to make the first licence fee payment due to Novogen under the terms of the licence agreement; $2,000,000 was used to make the milestone licence fee payment due to Novogen under the terms of the licence agreement; and $7,569,000 was used to pay the ongoing expenses of clinical trials, amounts due to Novogen under the services agreement and the manufacturing licence and supply agreement and general corporate expenses. The balance of proceeds of $953,000 was used to partly pay the December 31, 2005 annual licence fee of $4,000,000 paid to Novogen at the end of January 2006.

Stock Repurchases

We have not repurchased any shares of common stock during the fourth quarter of the fiscal year ended June 30, 2006.

Equity Compensation

The following table sets forth, as of June 30, 2006 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
Equity compensation plans approved by security holders	Not Applicable	Not Applicable	Not Applicable
Equity compensation plans not approved by security holders	None	Not Applicable	Indeterminable
Total	None	Not Applicable	Indeterminable

Our employee share option plan provides our directors, employees, employees of our affiliates and certain of our contractors and consultants with the opportunity to participate in our ownership. To date, no options have been issued under the plan. Our remuneration committee addresses participation, the number of options offered and any conditions of exercise. In making these determinations the committee will generally consider the participant's position and record of service to us and our affiliates and potential contribution to the growth of us and our affiliates. Any other matters tending to indicate the participant's merit may also be considered. Options will be exercisable between two years and five years after grant, unless otherwise determined by the committee appointed by the board. Options granted will be exercisable at a price determined by the committee at the time of issue (and will be subject to adjustment in accordance with the terms of the plan). Other key terms of the plan include:

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

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

Item 6. Selected Financial Data

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

Statement of Operations

	Years Ended June 30,				
	2006	2005	2004	2003	2002
	(in thousands, except per share data)				
Revenues:					
Interest and other income	$ 446	$ 308	$ 193	$ 145	$ 7
Total revenues	446	308	193	145	7
Loss from operations	(7,385)	(6,421)	(8,538)	(3,033)	(122)
Income tax expense	(1)	—	—	—	(1)
Net loss arising during development stage	$ (7,386)	$ (6,421)	$ (8,538)	$ (3,033)	$ (123)
Net loss per common share:					
Basic and diluted	$ (0.13)	$ (0.11)	$ (0.16)	$ (0.06)	$ (0.00)
Weighted average common shares outstanding	56,938,000	56,938,000	54,954,578	52,023,247	49,769,581

Balance Sheet Data

	As of June 30,				
	2006	2005	2004	2003	2002
			(in thousands)		
Cash and cash equivalents	$10,054	$ 9,238	$24,819	$7,244	$9,164
Total assets	$10,395	$19,364	$24,849	$7,286	$9,185
Total stockholders’ equity	$ 9,135	$16,521	$22,942	$5,933	$8,899

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

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

Overview

We are a development stage company incorporated on December 1, 2000 as a wholly-owned subsidiary of Novogen. We commenced operations in May 2002 and our business purpose is the development and commercialization of drugs for the treatment of cancer. We are presently engaged in the clinical development of the anti-cancer drug phenoxodiol. Novogen’s subsidiary has granted to our subsidiary, Marshall Edwards Pty Ltd (MEPL), a worldwide non-transferable licence under its patent

right and patent applications and its relevant know-how to conduct clinical trials and commercialize and distribute all forms of phenoxodiol for uses in the field of prevention, treatment, and cure of cancer in humans, except topical applications.

Our main focus since commencing operations is to undertake human clinical testing of phenoxodiol. Operations have now expanded to include the recently licenced drug candidates NV-196 and NV-143. During fiscal year 2006, we continued to recruit patients into the existing clinical trial programs. We have reached agreement under the Special Protocol Assessment (SPA) process with the United States Food and Drug Administration (FDA) on the design of a pivotal study protocol for the investigational anti-cancer drug, phenoxodiol. The trial, known as the OVATURE study, is designed to test the ability of phenoxodiol to restore sensitivity of late-stage ovarian cancers to carboplatin, a standard form of therapy for ovarian therapy.

In May 2006, we licenced a further two oncology compounds NV-196 and NV-143 from Novogen. NV-196 is being developed initially in oral form for 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 pre-clinical testing stage. We plan to engage in the clinical development and commercialization of these two additional drug candidates which will compliment the current drug candidate, phenoxodiol, in the area of cancer.

On July 11, 2006, we entered into a securities purchase agreement with certain accredited investors providing for the placement of 6,329,311 shares of our common stock and warrants exercisable for 2,215,258 shares of our common stock at a purchase price of $2.90 per unit. The warrants have an exercise price of $4.35 per share, subject to certain adjustments. 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. We closed the private placement on July 11, 2006.

On July 11, 2006, we entered into a standby equity distribution agreement, which we refer to as the SEDA, with Cornell Capital Partners, LP. Under the SEDA, we may issue and sell to Cornell shares of our common stock for a total purchase price of up to $15 million, once a resale registration statement is in effect. We have sole discretion whether and when to sell shares of our common stock to Cornell. Cornell will be irrevocably bound to purchase shares of our common stock from us after we send a notice that we intend to sell shares of our common stock to Cornell. Each advance under the SEDA is limited to a maximum of $1.5 million. The term of the SEDA is 24 months following the date on which the SEC declares a resale registration statement relating to the SEDA shares effective.

As at the date of the report Novogen owns approximately 78.1% of the outstanding shares of our common stock.

We believe that we will have sufficient cash resources to fund the planned operations over at least the next twelve months including the OVATURE trial, the planned preclinical development of NV-196 and NV-143 and the planned human Phase I clinical program for NV-196.

We do not employ any staff directly but obtain services from Novogen under a services agreement. 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 research and development activities and move our drug candidates into later stages of development. As of June 30, 2006, we had accumulated losses of $25,501,000.

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 and its subsidiaries, including the costs of the clinical trial drug supplies.

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

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

Critical Accounting Estimates

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

Development Expenses

Research and development costs incurred since inception through June 30, 2006 amount to $10,180,000.

Research and development costs include clinical trial expenses,and are expensed as they are incurred. These costs are expected to increase in the future as the phenoxodiol clinical program progresses and as we expand our research and development to incorporate NV-196 and NV-143. The planned phenoxodiol Phase III OVATURE trial will require large patient numbers resulting in significantly increased costs.

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

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

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

- the number of sites included in the trials;
- the length of time required to enroll suitable patients;
- the number of patients that participate in the trials;
- the indication being studied; and
- the efficacy and safety profile of the product.

Our strategy also includes the option of entering into collaborative arrangements with third parties to participate in the development and commercialization of our drug candidates. In the event third parties

have control over the clinical development process, the completion dates would largely be under the control of that third party.

As a result of these uncertainties, we are unable to determine the duration of or completion costs for research and development projects or when and to what extent we will receive cash inflows from the commercialization and sale of the drug candidates.

We intend to continue the clinical development of phenoxodiol as well as NV-196 and NV-143, which were recently licenced from Novogen. We will also continue to assess the opportunity to licence other cancer drugs developed by Novogen as the opportunities arise.

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 $840,000 have been included in the financial statements for the year ended June 30, 2006, of which $205,000 has been accrued at June 30, 2006. 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 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.

We have completed the novation to MEPL of contracts that Novogen had entered into with third parties which focuses on the manufacturing process development of phenoxodiol. This work is being undertaken to develop a scalable manufacturing process which will facilitate larger scale production quantities while concurrently developing analytical methods and the documentation required for the future New Drug Application (NDA). An NDA is needed in order to market phenoxodiol and will be required if the OVATURE study is successful. The work being undertaken will also provide the drug quantities needed for the OVATURE clinical trial.

Manufacturing scale-up expenses of $1,329,000 have been included in the financial statements for the year ended June 30, 2006, of which $265,000 has been accrued at June 30, 2006. These estimates are based on the milestones completed for each of the service contracts.

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,		
	2006	2005	2004
		(in thousands)	
Interest and other income	$446	$308	$193
Total revenues	446	308	193

Research and development expenses

	Years Ended June 30,		
	2006	2005	2004
		(in thousands)	
Clinical trial study costs	$ (840)	$(1,156)	$ (774)
Clinical trial drug costs	(527)	(612)	(761)
Manufacturing scale-up costs	(1,329)	—	—
Research and development service charge	(588)	(385)	(811)
Other	(143)	(126)	(35)
Total Research and Development Costs	(3,427)	(2,279)	(2,381)

License Fees

	Years Ended June 30,		
	2006	2005	2004
		(in thousands)	
License Fees	(3,000)	(3,000)	(5,500)

Selling, general and administrative expenses

	Years Ended June 30,		
	2006	2005	2004
		(in thousands)	
Legal and professional fees	$ (394)	$ (371)	$(250)
Administrative service charge	(707)	(688)	(302)
Other	(303)	(391)	(298)
Total operating expenses	(1,404)	(1,450)	(850)

Year Ended June 30, 2006 Compared to the Year Ended June 30, 2005

We recorded a consolidated loss of $7,386,000 and $6,421,000 for the years ended June 30, 2006 and 2005, respectively.

Revenues: We received interest on cash assets and cash equivalents of $446,000 for the year ended June 30, 2006 versus $308,000 for the year ended June 30, 2005. This increase was due to an increase in interest rates combined with us investing some of our cash in short term investment deposits in the first half of the year which yield a greater rate of return than cash accounts.

Research and Development: Research and development expenses increased $1,148,000 to $3,427,000 for the year ended June 30, 2006 compared to $2,279,000 for the year ended June 30, 2005. This increase was primarily due to third party contract costs associated with the production

scale-up activities of the manufacturing process of phenoxodiol and the initial development of the NDA documentation together with the additional costs incurred under the services agreement reflecting the increase time spent by Novogen research staff on the development of phenoxodiol. These increases were partially offset by a reduction in the clinical trial study costs incurred as a number of studies are nearing completion. Clinical trial drug costs have also reduced as many patients have now completed the treatment cycles. We expect research and development clinical trial costs to increase significantly in the future due to the planned Phase III OVATURE study.

Licence Fees: Milestone licence fees of $3,000,000 were expensed for both the years ended June 30, 2006 and June 30, 2005. 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 NV-196 and NV-143 licenced in May 2006. The $3,000,000 milestone licence fees expensed in the year ended June 30, 2005 represents 50 percent ($2,000,000) of the December 31, 2005 annual milestone licence fee of $4,000,000 plus 50 percent ($1,000,000) of the December 31, 2004 annual milestone licence fee of $2,000,000.

Selling, General and Administrative: Selling, general and administrative expenses decreased by $46,000 to $1,404,000 for the year ended June 30, 2006 compared to $1,450,000 for the year ended June 30, 2005. The decrease was due primarily to a reduction in foreign exchange losses and legal fees which were partially offset by an increase in travel costs. Foreign exchange gains/(losses) are included in selling, general and administrative expenses which occur when revaluing cash denominated in foreign currencies and upon consolidation of our wholly owned subsidiary MEPL. MEPL uses US 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, 2006, we had not established a foreign currency hedging program. Net foreign exchange losses during the twelve months ended June 30, 2006 were $2,000 compared with net exchange losses of $24,000 during the twelve months ended June 30, 2005.

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

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

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

Research and Development: Research and development expenses decreased $102,000 to $2,279,000 for the year ended June 30, 2005 compared to $2,381,000 for the year ended June 30, 2004. This decrease was due primarily to a reduction in the research and development service charge from Novogen under the terms of the services agreement reflecting lower costs incurred by Novogen and reduced time spent by Novogen personnel on the development of phenoxodiol. Clinical trial drug costs have also reduced as many patients have now completed the treatment cycles. These costs have partially been offset by an increase in clinical trial costs. This increase in clinical trial costs results from an increase in patient data management and analysis costs associated with reporting and summarizing the outcomes of the clinical trials.

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

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

Liquidity and Capital Resources

At June 30, 2006, we had cash resources of $10,054,000 compared to $19,238,000 at June 30, 2005. The decrease was due to expenditures in the clinical trial program and other corporate expenses incurred during the year. Funds are invested in short term bank accounts, pending use.

On July 11, 2006, we entered into a securities subscription agreement with certain accredited investors providing for the placement of 6,329,311 shares of our common stock and warrants exercisable for 2,215,258 shares of our 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 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. We closed the private placement on July 11, 2006.

On July 11, 2006, we entered into a standby equity distribution agreement, which we refer to as the SEDA, with Cornell Capital Partners, LP. Under the SEDA, we may issue and sell to Cornell shares of our common stock for a total purchase price of up to $15 million, once a resale registration statement is in effect. We have sole discretion whether and when to sell shares of our common stock to Cornell. Cornell will be irrevocably bound to purchase shares of our common stock from us after we send a notice that we intend to sell shares of our common stock to Cornell. Each advance under the SEDA is limited to a maximum of $1.5 million.

In connection with the SEDA, we paid Cornell a commitment fee of 123,626 shares of our common stock and warrants to purchase 600,000 shares of our common stock that expire on July 11, 2010. The

warrants have an exercise price of $4.35 per share, subject to certain adjustments.

The purchase price for shares of our common stock under the SEDA will be equal to 97% of the lowest volume weighted average price (as quoted by Bloomberg L.P.), or VWAP, of shares of our common stock (subject to a "minimum acceptable price" as described below) during the five consecutive trading days after we send notice to Cornell of our intention to sell them shares of our common stock, which we refer to as the pricing period.

The minimum acceptable price at which we may sell our shares of common stock, unless we waive (in our sole discretion) the minimum acceptable price, is no less than 97% of the VWAP for our shares of common stock on the trading day immediately preceding the date we send notice to Cornell of our intent to sell shares of our common stock. For any day in the pricing period when the VWAP is less than the minimum acceptable price, (i) that day's VWAP will be excluded from the pricing mechanism during the pricing period: (ii) we will automatically reduce the amount of funds covered by the advance notice by 20%; and (iii) the number of shares of our common stock to be sold to Cornell (stated in the advance notice) will be reduced proportionately.

Before we can sell any shares of our common stock to Cornell by the SEDA, a resale registration statement will have to be filed with and declared effective by the SEC to cover Cornell's resale of shares of our common stock it buys under the SEDA. We do not expect to access the SEDA prior to 2007.

The number of shares of our common stock that we can issue to Cornell is limited by Nasdaq's Market Place Rule 4350(i)(1)(D) — the "20% rule". All of the shares of our common stock that could be issued in connection with the SEDA, the other securities issued as a commitment fee in connection with the SEDA and the shares of our common stock issued in connection with the private placement described above, cannot exceed 20% of the shares outstanding. We have determined that currently we could issue and sell all of the shares of our common stock subject to the SEDA. If circumstances change, however, we may need to obtain shareholder approval to waive the "20%" rule.

While the SEDA provides us access to significant equity financing, using the SEDA at low market prices could result in a dilution of net tangible assets per share to current shareholders, and also may have a depressing effect on our stock price. See "Risks Related to the Cornell Transaction."

Source and Uses of Cash

Cash Used in Operating Activities

Cash used in operating activities for the year ended June 30, 2006 was $9,089,000 compared to $5,581,000 for the same period in 2005. The increase in cash outflow of $3,508,000 for the year ended June 30, 2006 was due primarily to the licence fee paid to Novogen increasing from $2,000,000 in January 2005 to $4,000,000 in January 2006. In addition, a further $1,000,000 licence fee was paid to Novogen in May 2006 in connection with the new licence agreement covering the drug candidates NV-196 and NV-143. Additional cash was also used to fund the manufacturing production scale-up program.

Cash Used in Financing Activities

During the year ended June 30, 2006, $10,000,000 was returned from the high interest yielding cash deposit account following the expiration of the term. These funds were retained in the cash accounts pending use.

Cash Requirements

We are currently planning to conduct a pivotal clinical study to support marketing approval of phenoxodiol for ovarian cancer. In May 2006, we received a Special Protocol Assessment (SPA) and reached agreement with the FDA on the design of a pivotal Phase III study for the investigational anti-cancer drug, phenoxodiol. The trial, known as the OVATURE study, is designed to establish the safety and effectiveness of phenoxodiol in combination with carboplatin for late-stage ovarian cancers.

In May 2006, we licenced the two anti-cancer compounds NV-196 an NV-143 from Novogen. Additional cash resources will be required to undertake the clinical trial program for these drug candidates.

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

We believe that the proceeds of the private placement closed in July 2006, as well as our access to the SEDA, provide us with sufficient cash resources to fund our planned operations over the next twelve months which include the OVATURE trial, the planned preclinical development of NV-196 and NV-143 and the planned human Phase I clinical program for NV-196. We do not expect to access the SEDA prior to 2007.

We will however need to raise additional funds in the future in order to further the clinical development program for NV-196 and NV-143 beyond the current objectives.

Licence Agreement for Phenoxodiol

In September 2003, we entered into a licence agreement pursuant to which Novogen's subsidiary, Novogen Research Pty Limited, 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 were the annual milestone licence fee payments due under the licence agreement. We 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 exceeds $50,000,000. Following the PIPE share issue 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 for each calendar year ending December 31 during the exclusivity period of the licence. The December 31, 2006 licence fee has been deferred under the licence amendment deed which is discussed below.

Licence Amendment Deed for Phenoxodiol

In June 2006, we entered into an amendment deed to the licence agreement for phenoxodiol. Pursuant to the original term of the licence agreement for phenoxodiol we were required to pay an $8,000,000 licence milestone fee to Novogen Research Pty Limited 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 United States; 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, we 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.

At June 30, 2005 an amount of $2,000,000 was accrued and reflected in amounts due to Novogen, representing 50% of the $4,000,000 milestone payment payable to Novogen on December 31, 2005 under the terms of the licence agreement with Novogen. We paid the $4,000,000 due to Novogen at the end of January 2006. The licence amendment deed provides that the next milestone licence fee is not due until one of the approvals set out above is obtained. Therefore no licence fees have been accrued at June 30, 2006.

Licence Agreement NV-196 and NV-143

In May 2006, we entered into a second licence agreement with Novogen for two oncology compounds, NV-196 and NV-143. NV-196 is being developed initially in oral form for 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 licence agreement is an agreement under which Novogen's subsidiary, Novogen Research Pty Limited, grants 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 NV-196 and NV-143 products. The licence agreement covers uses of NV-196 and NV-143 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 $1,000,000 to Novogen in May 2006 which was the first lump sum licence fee payment due under the terms of the licence agreement. We are required to make payments under the terms of this second licence agreement with Novogen as follows:

1. A lump sum licence fee of $1,000,000 is payable to Novogen on the commencement date of the licence in consideration of the licence granted. This initial lump sum licence fee was paid to Novogen in May 2006.

2. MEPL must pay to Novogen the following milestone licence fees upon the occurrence of the corresponding milestone as set forth below:

a) the first licenced product containing NV-196 to reach a milestone as set forth below; and

b) the first licenced product containing NV-143 to reach a milestone as set forth below.

The milestone licence fees are:

i) $1,000,000 on the date an IND for the licenced 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;

ii) $2,000,000 on the date of enrollment of the first clinical trial subject in a Phase II clinical trial of the licenced 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 licenced 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 licenced 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 licence. The royalty rate is reduced by 50% if the licenced patent rights in any country or territory expire, lapse, are revoked, does not exist or is 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 licenced product from the FDA (or equivalent approval from a government agency in any other country) until the expiration of the term.

We will also be required to make payments to Novogen under the services agreement and manufacturing licence and supply agreement.

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

We are currently assessing the future cash requirements needed to fund new clinical trial initiatives

and licensing options available under the license option deed.

Contractual Obligations

At June 30, 2006, we had contractual obligations for the conduct of clinical trials, pre-clinical research and development and manufacturing process development of approximately $1,811,000. Of all 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 following table summarizes our future payment obligations and commitments as of June 30, 2006 assuming all treatment cycles are completed:

(In thousands)

		Payment due by period			
Contractual Obligations	**Total**	less than 1 Year	1 – 3 Years	3 – 5 Years	More than 5 Years
Purchase Obligations	$1,811	$1,760	$51	$—	$—
Total	$1,811	$1,760	$51	$—	$—

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

Off-Balance Sheet Arrangements

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

Item 7a. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

We place cash in “on call” and “short-term” deposit accounts with high quality financial institutions.

We do not consider the effects of interest rate movements to be a material risk to our financial condition. We do not use derivative financial instruments to hedge risks associated with the fluctuations of interest rates.

Foreign Currency Risk

We conduct a portion of our business in various currencies, primarily in U.S. and Australian dollars. At June 30, 2006, we had not established a foreign currency hedging program. Net foreign exchange losses during the twelve months ended June 30, 2006 were $2,000 compared with net exchange losses of $24,000 during the twelve months ended June 30, 2005. 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

Chartered Accountants
& Advisers

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Report of Independent Registered Public Accounting Firm

The Board of Directors
Marshall Edwards, Inc.

We have audited the accompanying consolidated balance sheet of Marshall Edwards, Inc. (a development stage company) as of June 30, 2006, and the related statements of operations, stockholders' equity, and cash flows for the year then ended, and for the period from December 1, 2000 (inception) through June 30, 2006. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit. The financial statements as of June 30, 2004 and for the period from December 1, 2000 (inception) through June 30, 2004, were audited by other auditors whose report dated August 13, 2004 expressed an unqualified opinion on those statements. The financial statements for the period from December 1, 2000 (inception) through June 30, 2004 include total revenues and net loss of $345,000 and $11,694,000, respectively. Our opinion on the statements of operations, stockholders' equity, and cash flows for the period from December 1, 2000 (inception) through June 30, 2006, insofar as it relates to amounts for prior periods through June 30, 2004, is based solely on the report of other auditors.

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

In our opinion, based on our audit and the report of other auditors, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Marshall Edwards, Inc. at June 30, 2006, and the consolidated results of its operations and its cash flows for the year then ended and the period from December 1, 2000 (inception) through June 30, 2006**,** in conformity with accounting principles generally accepted in the United States of America.

BDO
Sydney, NSW, Australia
September 1, 2006

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Report of Independent Registered Public Accounting Firm

The Board of Directors
Marshall Edwards, Inc.

We have audited the accompanying consolidated statements of operations, stockholders' equity, and cash flows of Marshall Edwards, Inc. (a development stage enterprise) (the "Company") for the year ended 30 June, 2004 and for the period from December 1, 2000 (inception) through June 30, 2004. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit. The financial statements as of June 30, 2003, and for the period from December 1, 2000 (inception) through June 30, 2003, were audited by other auditors whose report dated July 31, 2003 expressed an unqualified opinion on those statements. The financial statements for the period from December 1, 2000 (inception) through June 30, 2003 include total revenues and net loss of US$l52,000 and US$3,156,000, respectively. Our opinion on the statements of operations, stockholders' equity, and cash flows for the period from December 1, 2000 (inception) through June 30, 2004, insofar as it relates to amounts for prior periods through June 30, 2003, is based solely on the report of other auditors.

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

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

/s/ Ernst & Young

Sydney, Australia
13 August 2004

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Report of Independent Registered Public Accounting Firm

The Board of Directors Marshall Edwards, Inc.

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

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

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

/s/ Ernst & Young LLP
July 31, 2003

A Member Practice of Ernst & Young Global

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

	June 30, 2006	June 30, 2005
ASSETS		
Current assets		
Cash and cash equivalents	**$ 10,054**	$ 9,238
Short-term investments	**—**	10,000
Deferred Offering Costs	**95**	—
Prepaid expenses and other current assets	**246**	126
Total current assets	**10,395**	19,364
Total assets	**$ 10,395**	$ 19,364
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	**$ 420**	$ 254
Accrued expenses	**638**	403
Amount due to related company	**202**	2,186
Total current liabilities	**1,260**	2,843
Stockholders' equity:		
Preferred stock, $0.01 par value, authorized 100,000 shares, none outstanding	**—**	—
Common stock, $0.00000002 par value, 113,000,000 authorized shares; shares issued and outstanding: 56,938,000 at June 30, 2006 and 56,938,000 at June 30, 2005	**—**	—
Additional paid-in capital	**34,636**	34,636
Deficit accumulated during development stage	**(25,501)**	(18,115)
Total stockholders' equity	**9,135**	16,521
Total liabilities and stockholders' equity	**$ 10,395**	$ 19,364

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 December 1, 2000 (Inception) through June 30,
	2006	2005	2004	**2006**
Revenues:				
Interest and other income	**$ 446**	$ 308	$ 193	$ 1,099
Total revenues	**446**	308	193	1,099
Operating expenses:				
Research and development	**(3,427)**	(2,279)	(2,381)	(10,180)
License fees	**(3,000)**	(3,000)	(5,500)	(12,000)
Selling, general and administrative	**(1,404)**	(1,450)	(850)	(4,418)
Total operating expenses	**(7,831)**	(6,729)	(8,731)	(26,598)
Loss from operations	**(7,385)**	(6,421)	(8,538)	(25,499)
Income tax expense	**(1)**	—	—	(2)
Net loss arising during development stage	**$ (7,386)**	$ (6,421)	$ (8,538)	$(25,501)
Net loss per common share:				
Basic and diluted	**$ (0.13)**	$ (0.11)	$ (0.16)	
Weighted average common shares outstanding	**56,938,000**	56,938,000	54,954,578	

See accompanying notes.

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

	Years Ended June 30,			Period from December 1, 2000 (Inception) through June 30,
	2006	**2005**	**2004**	**2006**
Operating activities				
Net loss arising during development stage	**(7,386)**	(6,421)	(8,538)	(25,501)
Adjustments to reconcile net loss to net cash used in operating activities:				
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets	**(120)**	(96)	12	(246)
Accounts payable	**166**	62	(241)	420
Accrued expenses	**235**	(34)	159	638
Amounts due to related company	**(1,984)**	908	636	202
Net cash used in operating activities	**(9,089)**	(5,581)	(7,972)	(24,487)
Financing activities				
Net proceeds from issuance of Common Stock	**—**	—	25,578	34,636
Amounts payable in connection with issuance of Common Stock	**—**	—	—	—
Deferred Offering Costs	**(95)**	—	—	(95)
Withdrawal from/(investment) in short-term deposits	**10,000**	(10,000)	—	—
Net cash provided by/(used in) financing activities	**9,905**	(10,000)	25,578	34,541
Effect of exchange rate changes on cash and cash equivalents	**—**	—	(31)	—
Net increase/(decrease) in cash and cash equivalents	**816**	(15,581)	17,575	10,054
Cash and cash equivalents at beginning of period	**9,238**	24,819	7,244	—
Cash and cash equivalents at end of period	**10,054**	9,238	24,819	10,054
Income taxes paid	**(1)**	**—**	**—**	(2)

See accompanying notes.

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

	Common Stock	Additional paid in capital	Deficit accumulated during development stage	Accumulated other comprehensive income/(loss)	Total
	(shares)				
Balance June 30, 2001	**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
Balance at June 30, 2002	**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
Balance at June 30, 2003	**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**
Balance at June 30, 2004	**56,938,000**	**$34,636**	**$(11,694)**	**$ —**	**$22,942**
Net loss arising during development stage			**(6,421)**		**(6,421)**
Comprehensive Loss					**(6,421)**
Balance at June 30, 2005	**56,938,000**	**$34,636**	**$(18,115)**	**$ —**	**$16,521**
Net loss arising during development stage			**(7,386)**		**(7,386)**
Comprehensive Loss					**(7,386)**
Balance at June 30, 2006	**56,938,000**	**34,636**	**(25,501)**	**—**	**$ 9,135**

See accompanying notes.

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

1. The Company and Summary of Significant Accounting Policies

Marshall Edwards, Inc. ("MEI") is a development stage company incorporated in December 2000 as a wholly-owned subsidiary of Novogen. The Company commenced operations in May 2002 and its business purpose is the development and commercialization of drugs for the treatment of cancer. The Company is presently engaged in the clinical development of the anti-cancer drug phenoxodiol. Novogen's subsidiary has granted to the Company's subsidiary, Marshall Edwards Pty Ltd (MEPL), a worldwide non-transferable licence under its patent right and patent applications and its relevant know-how to conduct clinical trials and commercialize and distribute all forms of phenoxodiol for uses in the field of prevention, treatment, and cure of cancer in humans, except topical applications. As at the date of this report Novogen owns approximately 78.1% of the outstanding shares of the Company's common stock.

The Company's main focus since commencing operations has been to undertake human clinical testing of phenoxodiol. The Company's operations have now expanded to include the recently licenced drug candidates NV-196 and NV-143. During fiscal year 2006, the Company continued to recruit patients into the existing clinical trial programs. The Company has now reached agreement under the Special Protocol Assessment (SPA) process with the United States Food and Drug Administration (FDA) on the design of a pivotal study protocol for the investigational anti-cancer drug, phenoxodiol. The trial, known as the OVATURE study, is designed to test the ability of phenoxodiol to restore sensitivity of late-stage ovarian cancers to carboplatin, a standard form of therapy for ovarian cancer.

In May 2006, the Company licenced two oncology compounds, NV-196 and NV-143, from Novogen. NV-196 is being developed initially in oral form for 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 pre-clinical testing stage. The Company plans to engage in the clinical development and commercialization of these two additional drug candidates which will complement the current drug candidate, phenoxodiol, in the area of cancer.

Principles of Consolidation

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

Estimates

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

Revenue Recognition

Interest

The only revenue earned by the company to date is interest on cash balances, which is recognised 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 United States, is deposited in financial institutions that are FDIC insured. These deposits are in excess of the FDIC insurance limits. The Company also holds cash with Australian financial institutions.

Income Taxes

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

Fair Value of Financial Instruments

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

Foreign Currency Translation

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

Translation of 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 trials of phenoxodiol and has recently been expanded to include NV-196 and NV-143. Research and development costs are charged to expense as 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.

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 is excluded, whereas for diluted earnings per share it is included unless the effect is anti-dilutive. Since the Company has a loss for all periods presented, there is no dilutive effect of stock options.

Comprehensive Loss

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

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.

2. Income Taxes

Loss from operations consists of the following jurisdictions:

	Year ended June 30,		
	2006	**2005**	**2004**
		(in thousands $)	
Domestic	**(196)**	(326)	(321)
Foreign	**(7,189)**	(6,095)	(8,217)
	(7,385)	(6,421)	(8,538)

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,					
	2006 *(in thousands $)*	%	**2005** *(in thousands $)*	%	**2004** *(in thousands $)*	%
Tax at US statutory rates	**2,585**	**35**	**2,247**	**35**	2,988	35
Australian tax	**(359)**	**(5)**	**(305)**	**(5)**	(411)	(5)
R&D Tax concession	**91**	**1**	**43**	**1**	**—**	**—**
Under Provision	**(161)**	**(2)**	**156**	**2**	**—**	**—**
Change in valuation allowance	**(2,156)**	**(29)**	**(2,141)**	**(33)**	**(2,577)**	(30)
	—	—	—	—	—	—

Deferred tax liabilities and assets are comprised of the following:

	Year ended June 30,	
	2006	**2005**
	(in thousands $)	
Deferred tax liabilities		
Unrealised Foreign Exchange Gain	**(2)**	(4)
Total deferred tax liabilities	**(2)**	(4)
Deferred tax assets		
Tax carried forward losses	**7,686**	4,972
Unrealised Foreign Exchange Loss	**2**	8
Consultant and other accruals	**146**	700
Total deferred tax assets	**7,834**	5,680
Valuation allowance for deferred tax assets	**(7,832)**	(5,676)
Net deferred tax assets and liabilities	**—**	**—**

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, 2006 and 2005. 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, 2006 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 $1,036,000 at June 30, 2006. The federal net operating losses will begin to expire in 2022.

Foreign tax losses of approximately $24,413,000 at June 30, 2006, 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,		
	2006	**2005**	**2004**
	(In Thousands, except share data)		
Numerator			
Net loss arising during development stage	(7,386)	(6,421)	(8,538)
Effect of dilutive securities	—	—	—
Numerator for diluted earnings per share	$ (7,386)	$ (6,421)	$ (8,538)
Denominator			
Denominator for basic earnings per share -			
Weighted average number of shares used in computing net loss per share, basic and diluted.	56,938,000	56,938,000	54,954,578
Effect of dilutive securities	—	—	—
Dilutive potential common shares	56,938,000	56,938,000	54,954,578
Basic and Diluted net loss per share	$ (0.13)	$ (0.11)	$ (0.16)

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,		
	2006	**2005**	**2004**
Outstanding Warrants	2,392,000	2,392,000	2,392,000

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

During July 2006 the Company issued 6,452,937 shares of common stock and 2,815,258 warrants in connection with a PIPE capital raising and for securing a Standby Equity Distribution Agreement. For further details see Note 8 "Significant Events After Balance Date".

4. Expenditure Commitments and Contingencies

At June, 30, 2006, the Company had contractual obligations for the conduct of clinical trials, pre- clinical research and development and manufacturing process development of approximately $1,811,000. 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)

		Payment due by period			
Contractual Obligations	**Total**	less than 1 Year	1 – 3 Years	3 – 5 Years	More than 5 Years
Purchase Obligations	$1,811	$1,760	$51	$—	$—
Total	$1,811	$1,760	$51	$—	$—

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

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

The Company’s certificate of incorporation 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.

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

The Company has issued a letter of support to the Directors of Marshall Edwards Pty Limited guaranteeing financial support, for a period of twelve months ending October 7, 2006, should it be unable to meet any of its financial commitments.

5. Segment Information

The Company’s focus is to continue the clinical program currently underway for the development and commercialization of phenoxodiol, NV-196 and NV-143. The business contains two major segments based on geographic location.

	Year Ended June 30,								
	2006			2005			2004		
	USA	Australia	Total	USA	Australia	Total	USA	Australia	Total
					(in thousands)				
Statement of Operations									
Interest Revenue	348	98	446	238	70	308	167	26	193
Loss from operations	(196)	(7,189)	(7,385)	(326)	(6,095)	(6,421)	(321)	(8,217)	(8,538)
Income Tax Expense	(1)	—	(1)	—	—	—	—	—	—
Net loss arising during development stage	(197)	(7,189)	(7,386)	(326)	(6,095)	(6,421)	(321)	(8,217)	(8,538)
Balance Sheet									
Segment assets	33,767	2,895	36,662	33,877	4,266	38,143	34,220	802	35,022
Elimination of investment in subsidiary	(26,267)	—	(26,267)	(18,779)	—	(18,779)	(10,173)	—	(10,173)
Consolidated Assets	$ 7,500	$ 2,895	$ 10,395	$ 15,098	$ 4,266	$ 19,364	$ 24,047	$ 802	$ 24,849
Segment liabilities	$ 180	$ 1,080	$ 1,260	$ 93	$ 2,750	$ 2,843	$ 110	$ 1,797	$ 1,907

6. Related Party Transactions

Licence Agreement for Phenoxodiol

In September 2003, the Company entered into a licence agreement pursuant to which Novogen's subsidiary, Novogen Research Pty Limited, 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 PIPE share issue 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 for each calendar year ending December 31 during the exclusivity period of the licence. The December 31, 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 Research Pty Limited 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 United States; 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 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.

At June 30, 2005 an amount of $2,000,000 was accrued and reflected in amounts due to Novogen representing 50% of the $4,000,000 milestone payment payable to Novogen on December 31, 2005 under the terms of the licence agreement with Novogen. The Company paid the $4,000,000 due to Novogen at the end of January 2006. The licence amendment deed provides that the next milestone licence fee is not due until one of the approvals set out above is obtained. Therefore no licence fees have been accrued at June 30, 2006.

Licence Agreement NV-196 and NV-143

In May 2006, the Company entered into a second licence agreement with Novogen for two oncology compounds, NV-196 and NV-143. NV-196 is being developed initially in oral form for 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 licence agreement is an agreement under which Novogen’s subsidiary, Novogen Research Pty Limited, grants 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 NV-196 and NV-143 products. The licence agreement covers uses of NV-196 and NV-143 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 $1,000,000 to Novogen in May 2006 which was the first lump sum licence fee payment due under the terms of the licence agreement. The Company is required to make payments

under the terms of this second licence agreement with Novogen as follows:

1. A lump sum licence fee of $1,000,000 is payable to Novogen on the commencement date of the licence in consideration of the licence granted. This initial lump sum licence fee was paid to Novogen in May 2006.

2. In further consideration of the licence granted, MEPL must pay to Novogen the following milestone licence fees upon the occurrence of the corresponding milestone as set forth below;

a) the first licence product containing NV-196 to reach a milestone as set forth below; and

b) the first licenced product containing NV-143 to reach a milestone as set forth below.

The milestone licence fees are:

i) $1,000,000 on the date an IND for the licenced 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;

ii) $2,000,000 on the date of enrollment of the first clinical trial subject in a Phase II clinical trial of the licenced 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 licenced 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 licenced 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 licence. The royalty rate is reduced by 50% if the licenced 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 licenced product from the FDA (or equivalent approval from a government agency in any other country) until the expiration of the term.

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.

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 NV-196 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 $1,294,000, $1,073,000 and $1,113,000 were made under the services agreement with Novogen during the twelve months ended June 30, 2006, 2005 and 2004 respectively. Of these amounts, $588,000, $385,000 and $811,000 related to service fees paid to Novogen for research and development services provided in the twelve months ended June 30, 2006, 2005 and 2004 respectively, reflecting the time spent by Novogen research staff on the development of phenoxodiol. Additionally, $707,000, $688,000 and $302,000 of the total expenditures during the twelve months ended June 30, 2006, 2005 and 2004, respectively, related to costs incurred for administration and accounting services provided by Novogen.

At June 30, 2006 and 2005, $118,000 and $100,000, respectively, was due and owing to Novogen under the services agreement and is included in amounts due to related company.

Manufacturing Licence and Supply Agreement

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

Transactions giving rise to expenditures amounting to $527,000, $612,000 and $761,000 were made under the manufacturing licence and supply agreement with Novogen during the twelve months ended June 30, 2006, 2005 and 2004, respectively.

At June 30, 2006 and 2005, $74,000 and $79,000, respectively, was due and owing to Novogen under the manufacturing licence and supply agreement and is included in amounts due to related company.

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 Limited retained 95.1% of the Company's common stock.

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

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

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

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

8. Significant Events After Balance Date

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 our common stock and warrants exercisable for 2,215,258 shares of our 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 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 PIPE the company received proceeds of $17.2 million net of certain commissions and other costs.

On July 11, 2006, the Company entered into a standby equity distribution agreement (SEDA), with Cornell Capital Partners, LP. Under the SEDA, the Company may issue and sell to Cornell shares of its common stock for a total purchase price of up to $15 million, once a resale registration statement is in effect. The Company has sole discretion whether and when to sell shares of its common stock to Cornell. Cornell will be irrevocably bound to purchase shares of common stock from the Company after the Company sends a notice that it intends to sell shares of its common stock to Cornell. Each advance under the SEDA is limited to a maximum of $1.5 million.

In connection with the SEDA, the Company paid Cornell a commitment fee of 123,626 shares of its common stock and warrants to purchase 600,000 shares of its common stock that expire on July 11, 2010. The warrants have an exercise price of $4.35 per share, subject to certain adjustments.

Before the Company can sell any shares of its common stock to Cornell under the SEDA, a resale registration statement will have to be filed with and declared effective by the SEC to cover Cornell's resale of shares of our common stock it buys under the SEDA.

The Company has not issued any shares under the terms of the standby equity distribution agreement. Following the private placement, Novogen Limited retained 78.1% of the Company's common stock.

In connection with the securities subscription agreement the Company entered into with certain accredited investors as of July 11, 2006, 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.

At the date of this report the registration statement had not been declared effective. In the event that (i) the registration statement is not declared effective by the SEC within the time prescribed by the registration rights agreement or (ii) the registration statement ceases to be effective or usable at any time while shares of common stock covered by it remain unsold or may only be sold subject to certain volume limitations, or investors are not permitted to utilize the prospectus in connection with the registration statement to resell shares of common stock covered by the registration statement, the Company will be obligated to pay investors who purchased shares of common stock in the private placement liquidated damages equal to 1% of the aggregate purchase price paid by each investor

pursuant to the securities subscription agreement for any shares of common stock, shares of common stock issuable upon exercise of warrants or warrants then held by each investor per month (pro rated for any period less than a month) until the registration statement is effective or the investors are permitted to utilize the prospectus in connection with the registration statement to resell shares of common stock covered by the registration statement.

Liquidated damages paid to each investor in the private placement may not exceed more than 10% of the purchase price paid by such investor for shares of common stock, shares of common stock issuable upon exercise of warrants or warrants purchased under the securities subscription agreement. The maximum amount of liquidated damages payable would be approximately $1.8 million. If the Company becomes obligated to pay liquidated damages, the Company would deplete its limited working capital and potentially need to raise additional funds.

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 exceeds $50,000,000. Following the PIPE share issue on July 11, 2006 the funds received from equity issuances exceeded $50,000,000 which triggered this licence fee payment.

9. Quarterly Financial Data (Unaudited)

2006 for the quarter ended	Jun-30	Mar-31	Dec-31	Sep-30	Year
		(in thousands except per share data)			
Revenue	93	101	130	122	446
Net Loss	(552)	(3,252)	(1,778)	(1,803)	(7,385)
Net Loss arising during development stage	(553)	(3,252)	(1,778)	(1,803)	(7,386)
Basic and diluted loss per share	(0.01)	(0.06)	(0.03)	(0.03)	(0.13)

2005 for the quarter ended	Jun-30	Mar-31	Dec-31	Sep-30	Year
		(in thousands except per share data)			
Revenue	106	71	64	67	308
Net Loss	(2,076)	(1,740)	(1,375)	(1,230)	(6,421)
Net Loss arising during development stage	(2,076)	(1,740)	(1,375)	(1,230)	(6,421)
Basic and diluted loss per share	(0.04)	(0.03)	(0.02)	(0.02)	(0.11)

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

None.

Item 9a.

Controls and Procedures

Evaluation of Disclosure Controls and Procedures

At the end of the period covered by this report, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended). Based on this evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

The removal of the identified weakness in internal control over financial reporting and in disclosure controls, which was identified and reported in prior filings, is described below under the heading “Changes in Internal Controls”.

Changes in Internal Controls

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

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

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

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

Prior to the period covered by this report, Novogen had made significant progress in implementing its plan to address the identified material weakness. However, as of the end of such prior reporting periods we were not satisfied that Novogen had fully addressed the issues underlying the material weakness. During the period covered by this report, Novogen finalized its procedures in addressing the material weakness and we now believe that Novogen has adopted processes that are designed to ensure that the preparation of our consolidated financial statements, including the processes to review and analyze elements of our financial statement close process, is in accordance with U.S. GAAP and that relevant information about U.S. GAAP, SEC financial reporting requirements and the requirements of the Public Company Accounting Oversight Board is available to those persons involved in the process by which the financial statements are prepared. As a result, we have re-assessed the effectiveness of Novogen's disclosure controls and procedures as they relate to us and having allowed a period of time to determine the effectiveness of additional controls and procedures, we now believe that the weakness in internal accounting control as described above has been eliminated.

The changes that have been made to Novogen's internal control procedures have occurred gradually over time. Therefore, during the quarter ended June 30, 2006, there has been no change in internal control over reporting that has materially affected or is reasonably likely to materially affect our 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). 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, 2006 (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 (2)
4.1	Specimen Stock Certificate (3)
4.2	Specimen Warrant Certificate (4)
4.3	Specimen Warrant Certificate (5)
4.4	Warrant Agreement (6)
4.5	Form of Warrant Agreement (7)
4.6	Form of Warrant (8)
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	Securities Subscription Agreement by and among Marshall Edwards, Inc. and the investors listed on Schedule 2.1 thereto (17)
10.10	Registration Rights Agreement by and among Marshall Edwards, Inc. and the investors as signatories thereto (18)
10.11	Standby Equity Distribution Agreement between Marshall Edwards, Inc. and Cornell Capital Partners, L.P. (19)
10.12	Registration Rights Agreement between Marshall Edwards, Inc. and Cornell Capital Partners, L.P. (20)

2.1	Subsidiaries of Marshall Edwards, Inc. (21)
23.1	Consent of Ernst & Young*
23.2	Consent of Ernst & Young LLP*
23.3	Consent of BDO*
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 United States Code (18 U.S.C. 1350)

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* 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 3.2 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 10.1 to Registrant's Current Report on Form 8-K/A filed on July 12, 2006.

(18) Incorporated by reference to Exhibit 10.2 to Registrant's Current Report on Form 8-K filed on July 12, 2006.

(19) Incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K filed on July 12, 2006.

(20) Incorporated by reference to Exhibit 10.2 to Registrant's Current Report on Form 8-K filed on July 12, 2006.

(21) Incorporated by reference to Exhibit 21 to Registrant's Registration Statement on Form S-1 filed on September 25, 2003 (Reg. No. 333-109129).

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on September 1, 2006.

MARSHALL EDWARDS, INC.
A Delaware Corporation

By: /s/ Christopher Naughton
Christopher Naughton
Chief Executive Offer

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 1, 2006.

Signatures	Title
By: /s/ Christopher Naughton Christopher Naughton	President, Chief Executive Officer and Director
By: /s/ David Seaton David Seaton	Secretary, Chief Financial Officer
By: /s/ Graham Kelly Graham Kelly	Director
By: /s/ Stephen Breckenridge Stephen Breckenridge	Director
By: /s/ Bryan Williams Bryan Williams	Director
By: /s/ Paul Nestel Paul Nestel	Director
By: /s/ Philip Johnston Philip Johnston	Director

Exhibit 23.1

ERNST & YOUNG

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

GPO Box 2646
Sydney NSW 2001

§ Tel 61 2 9248 5555
Fax 61 2 9248 5959
Dx Sydeny Stock
Exchange 10172

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement (Post-Effective Amendment No.3 to Form S-1 No. 333-109129 on Form S-3 and Form S-3 for the registration of 9,268,195 shares of common stock) of Marshall Edwards, Inc. and in the related Prospectuses of our report dated 13 August, 2004, with respect to the consolidated financial statements of Marshall Edwards, Inc., included in the Annual Report (Form 10-K) for the year ended June 30, 2006.

/s/ Ernst & Young

Sydney, Australia
August 30, 2006

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

Exhibit 23.2

ERNST & YOUNG

Ernst & Young LLP
1111 Summer Street
Stamford, Connecticut 06905

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

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement (Post-Effective Amendment No.3 to Form S-1 No. 333-109129 on Form S-3 and Form S-3 for the registration of 9,268,195 shares of common stock) of Marshall Edwards, Inc. and in the related Prospectuses of our report dated July 31, 2003, with respect to the consolidated financial statements of Marshall Edwards, Inc., included in the Annual Report (Form 10-K) for the year ended June 30, 2006.

/s/ Ernst & Young LLP

Stamford, Connecticut
August 30, 2006

Exhibit 23.3

Chartered Accountants
& Advisers

Level 19, 2 Market Street Sydney NSW 2000
GPO Box 2551 Sydney NSW 2001
Tel. +61 2 9286 5555 Fax +61 2 9286 5599
Email: bdosyd@bdosyd.com.au
www.bdo.com.au

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the (i) Registration Statement (Post-Effective Amendment No.3 to Form S-1 No. 333-109129 on Form S-3) of Marshall Edwards, Inc. and in the related Prospectus and (ii) the Registration Statement of Form S-3 (No. 333-136440) of Marshall Edwards, Inc. and in the related Prospectus of our report dated September 1, 2006, relating to the consolidated financial statements for the years ended June 30, 2005 and June 30, 2006 appearing in the Annual Report on Form 10-K for the year ended June 30, 2006.

We also consent to the reference to us under the caption “Experts” in the Prospectus of Registration Statement No. 333-136440.

/s/ BDO

BDO
Sydney, NSW, Australia
September 1, 2006

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

Exhibit 31.1

CERTIFICATION

I, Christopher Naughton, certify that:

1. I have reviewed this report on Form 10-K for the year ended June 30, 2006 of Marshall Edwards, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within the entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in the report our conclusions about the effectiveness of this disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrants fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: September 1, 2006

/s/ Christopher Naughton
Christopher Naughton
Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, David Ross Seaton, certify that:

1. I have reviewed this report on Form 10-K for the year ended June 30, 2006 of Marshall Edwards, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have;

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within the entities, particularly during the period in which this report is being prepared:

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in the report our conclusions about the effectiveness of this disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrants fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The Company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: September 1, 2006

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

Exhibit 32.1

CERTIFICATION

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

1. The registrant's Annual Report on Form 10-K for the period ended June 30, 2006, to which this Certification is attached as Exhibit 32 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition of the registrant at the end of the period covered by the Periodic Report and results of operations of the registrant for the period covered by the Periodic Report.

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

Dated: September 1, 2006

/s/ Christopher Naughton
Christopher Naughton
Chief Executive Officer

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