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MARSHALL EDWARDS, INC.

2009 Annual Report

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, 2009

or

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

For the transition period from _____ to _____

Commission File Number: 000-50484

Marshall Edwards, Inc.

(Exact name of registrant as specified in its charter)

DELAWARE

*(State or other jurisdiction of
Incorporation or organization)*

51-0407811

*(I.R.S. Employer
Identification No.)*

140 Wicks Road, North Ryde, NSW, 2113 Australia

(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code:

(011) 61 2 8877- 6196

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

Title of Each Class

Name of Each Exchange on Which Registered

Common Stock, \$0.00000002 par value

NASDAQ Global Market

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

None

(Title of Class)

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (Section 229.405 of this chapter) is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company

(Do not check if a smaller reporting company)

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

The aggregate market value of the voting common equity held by non-affiliates of the registrant was approximately \$14.7 million based on the closing price of the registrant's Common Stock as reported on the NASDAQ Global Market on December 31, 2008.

As of August 24, 2009, the number of shares outstanding of the issuer's common stock, \$0.00000002 par value, was 73,463,233.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of this registrant's definitive proxy statement for its 2009 annual meeting to be filed with the U.S. Securities and Exchange Commission no later than 120 days after the end of the fiscal year ended June 30, 2009 are incorporated by reference in Part III of this Annual Report on Form 10-K.

MARSHALL EDWARDS, INC.

TABLE OF CONTENTS

	<u>Page</u>
PART I	
Item 1: Business	5
Item 1A: Risk Factors	18
Item 1B: Unresolved Staff Comments	27
Item 2: Properties	27
Item 3: Legal Proceedings	27
Item 4: Submissions of Matters to a Vote of Security Holders	27
PART II	
Item 5: Market for the Registrants Common Equity, Related Stockholder Matters and Issuer Purchases of Securities	28
Item 6: Selected Financial Data	30
Item 7: Management’s Discussion and Analysis of Financial Condition and results of Operations	30
Item 7a: Quantitative and Qualitative Disclosures about Market Risk	36
Item 8: Financial Statements and Supplementary Data	37
Item 9: Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	59
Item 9A(T): Controls and Procedures	59
Item 9B: Other Information	59
PART III	
Item 10: Directors, Executive Officers and Corporate Governance	60
Item 11: Executive Compensation	60
Item 12: Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	60
Item 13: Certain Relationships and Related Transactions, and Director Independence	60
Item 14: Principle Accountant Fees and Services	60
PART IV	
Item 15: Exhibits, Financial Statement Schedules	60

Cautionary Statement about Forward-Looking Statements

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

- our inability to obtain required additional financing or financing available to us on acceptable terms, particularly in the context of the global financial crisis;
- our inability to maintain or enter into, and our dependence upon, collaboration or contractual arrangements necessary for the clinical development of phenoxodiol and other drug candidates;
- our limited operating history;
- our failure to successfully commercialize our product candidates;
- our termination of new enrollment into the OVATURE Phase III clinical trial;
- costs and delays in the clinical development program and/or receipt of U.S. Food and Drug Administration (the “FDA”) or other required governmental approvals, or the failure to obtain such approvals, for our product candidates;
- uncertainties in clinical trial results;
- our inability to maintain or enter into, and the risks resulting from our dependence upon, collaboration or contractual arrangements necessary for the development, manufacture, commercialization, marketing, sales and distribution of any products;
- our inability to control the costs of manufacturing our products;
- continued cooperation and support of Novogen Limited, our parent company;
- competition and competitive factors;
- our inability to protect our patents or proprietary rights and obtain necessary rights to third party patents and intellectual property to operate our business;
- our inability to operate our business without infringing the patents and proprietary rights of others;
- costs stemming from our defence against third party intellectual property infringement claims;
- difficulties in enforcement of civil liabilities against our officers and directors who are residents of jurisdictions outside the U.S.;
- general economic conditions;
- the failure of any products to gain market acceptance;
- technological changes;
- government regulation generally and the receipt of the regulatory approvals;
- changes in industry practice; and
- one-time events.

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

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

PART I

Item 1. *Business*

Overview of Our Business

We are a developmental stage pharmaceutical company listed on the NASDAQ Global Market under the symbol “MSHL”. We were incorporated on December 1, 2000 as a wholly-owned subsidiary of Novogen Limited, an Australian company. Novogen Limited’s ordinary shares trade on the Australian Stock Exchange under the symbol “NRT,” and American Depositary Receipts trade in the U.S. under the symbol “NVGN” on the NASDAQ Global Market. As at the date of this Annual Report on Form 10-K Novogen owns approximately 71.3% of our outstanding common stock.

Our business purpose is the development and commercialization of drugs for the treatment of cancer. We are presently engaged in the clinical development and commercialization of a drug candidate called phenoxodiol which we have licensed from a subsidiary of Novogen Limited (Novogen Limited and/or its subsidiaries are referred to herein as “Novogen”). We have also licensed two other investigational anti-cancer compounds, triphendiol and NV-143, from Novogen.

Our immediate development priority is to use our current funds of approximately \$19 million to complete the analysis of the data obtained from the 142 patients enrolled into the OVATURE Phase III clinical trial, while pursuing negotiations for out-licensing phenoxodiol should evidence of efficacy and safety emerge from the OVATURE analysis. Our other priorities include initiating the triphendiol clinical program and in-licensing further promising anti-cancer compounds from Novogen.

We believe that the proceeds from the registered direct offering closed in July 2008 and savings generated from ceasing the OVATURE Phase III clinical trial will provide us with sufficient cash resources to fund these operations over the next twelve months.

We will, however, need additional funds in order complete the planned clinical development programs beyond the current objectives.

Recent Developments

License Agreement for NV-128

In August 2009, we entered into a third license agreement with Novogen for the oncology compound NV-128. NV-128 is an investigational cancer compound which has been shown in pre-clinical laboratory studies to promote cancer cell death by targeting the specific protein regulatory pathway (*i.e.*, AKT-mTOR pathway) in ovarian cancer cells that have become resistant to many drugs used to kill cancer cells. Structurally, NV-128 is an analog of phenoxodiol and triphendiol, but in contrast to phenoxodiol, NV-128 uses different molecular mechanisms to promote the death of cancer cells.

The License Agreement for NV-128 is an agreement under which Novogen grants to MEPL a worldwide non-transferable license under its patents and patent applications and in its know-how to conduct clinical trials and commercialize and distribute NV-128.

Phenoxodiol

OVATURE Phase III Clinical Trial

The OVATURE Phase III clinical trial is a major multi-centre international Phase III clinical trial of orally-administered phenoxodiol in combination with carboplatin in women with advanced ovarian cancer resistant or refractory to platinum-based drugs to determine its safety and effectiveness when used in combination with carboplatin. Originally, the OVATURE Phase III clinical trial was approved by the FDA under a Special Protocol Assessment (“SPA”) program indicating that the study design, clinical endpoints and statistical analysis are acceptable to the FDA. The protocol provided for an interim analysis of the data, which, if statistically significant,

could be used to support a request for accelerated marketing approval. Under the SPA, an analysis of the interim results was possible after the targeted patient recruitment was completed and 95 patients had disease progression.

In April 2009, we announced our decision to terminate enrollment into the Phase III OVATURE clinical trial and our intention to undertake an unblinded analysis of the available data from the trial. Subject to the approval of relevant ethics boards, the patients currently enrolled in the trial will be unblinded and given the option to discontinue or continue their treatment according to the study protocol. However, we have ceased recruiting new patients to the OVATURE Phase III clinical trial, and the available data from the 142 completed and current patients will be analyzed for safety and efficacy outcomes.

We decided to terminate new enrollment into the Phase III OVATURE clinical trial and assess the available patient data, in part, because we believe that the global financial downturn makes it unlikely that we will be able to raise the necessary capital through debt or equity issuances in the near future to fund the trial to completion as originally planned. Additionally, changes in the standard of care over the period that the OVATURE Phase III clinical trial has been in operation resulted in fewer women meeting the inclusion criteria of the OVATURE protocol, which slowed patient recruitment rates.

The termination of patient enrollment into the Phase III OVATURE clinical trial and unblinded analysis of the available data from the trial have been discussed with the FDA, because the analysis will not be performed as described in the approved SPA.

Prostate Cancer

MEI is conducting a Phase II prostate cancer clinical trial using phenoxodiol as first line treatment in men with early stage disease (35 patients with androgen dependent disease but rising PSA) compared to patients with late stage hormone refractory disease (25 patients with chemotherapy naïve androgen independent disease). The study is being conducted at Yale Cancer Center and the West Haven Veterans Administration Hospital Connecticut in the US. Both of these patient groups represent areas of unmet medical need in this common cancer. The trial is continuing to recruit patients.

Triphendiol

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

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

Triphendiol has been granted Orphan Drug status by the FDA for the treatment of pancreatic cancer and for the treatment of cholangiocarcinoma, or bile duct cancer, as well as for the treatment of Stage IIB through Stage IV malignant melanoma.

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

In January 2009, we announced that triphendiol had been granted an Investigational New Drug (IND) approval by the FDA to undertake clinical studies with triphendiol as a chemosensitizing agent in combination with gemcitabine in patients with unresectable locally advanced or metastatic pancreatic and bile duct cancers.

Scientific Overview

Phenoxodiol, triphendiol, NV-143 and NV-128 belong to a class of drugs that we refer to as Multiple Signal Transduction Regulators (“MSTRs”).

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

We believe that phenoxodiol, triphendiol, NV-143 and NV-128 are able to exert a multiplicity of effects, including both ‘pro-survival’ and ‘pro-death’ signaling systems, because their primary target on the tumor cell is a protein whose function in the tumor cell is so fundamental that to shut it down produces a broad range of adverse consequences.

Phenoxodiol

The potential explanation for this effect of MSTRs on the fundamental biochemistry of tumor cells was provided by a discovery by a research team at Purdue University in Indiana. This team has a long-standing research interest in a family of proteins at the cell surface that are involved in electron transport across the cell membrane enabling hydrogen ion (proton) export at a controlled rate. This function is so fundamental to normal cell function and viability, that any loss of function of this proton pump will disrupt a wide range of biochemical processes. One of the key components of this proton pump mechanism is a family of cell surface proteins known as NADH oxidases. These proteins are situated on the outside of the cell membrane of all living matter and regulate the flow of waste hydrogen across the cell membrane. The laboratory studies at Purdue University have shown that a variant form of the surface oxidase which promotes more rapid hydrogen export, is preferentially expressed on cancer cells, although similar oxidase activity has been identified on small numbers of non-cancer cells undergoing abnormally rapid cell division. Phenoxodiol is able to bind to and inhibit the activity of these oxidase variants, with the resulting inhibition of hydrogen ion removal (H⁺ efflux) from these cells. This leads to extensive disruption to signaling pathways and to eventual inhibition of cell proliferation and activation of apoptosis, the process of programmed cell death by which a cell dies naturally. Phenoxodiol appears to have little or no effect on the form of oxidase present on normal healthy cells, providing an explanation for how phenoxodiol selectively targets cancer cells. Independent research at the Malaghan Institute of Medical Research at Victoria University, Wellington, New Zealand, has confirmed that phenoxodiol inhibits plasma membrane electron transport in cancer cells, as well as in some other abnormally dividing cells, but not in normal cells.

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

These findings are relevant because of results from laboratory studies at Yale University that have revealed that the killing effect of phenoxodiol on cancer cells occurs through the loss of the ability of the tumor cell to manufacture anti-apoptotic proteins such as XIAP and c-FLIP. Collectively, these third party studies provide a rational mechanism of action of phenoxodiol starting with the inhibition of surface oxidase, leading in turn to the loss of intracellular sphingosine-1-phosphate (S-1-P), and eventually to the loss of anti-apoptotic proteins.

Recent laboratory studies conducted by Novogen and Yale University have confirmed that this chain of biochemical events following exposure of tumor cells to phenoxodiol also explains how phenoxodiol is able to reverse resistance to standard anti-cancer drugs such as platinum, gemcitabine and taxanes, on the basis that FLIPshort protein is responsible for inhibiting the sensitivity of the Fas-ligand protein (death receptor) to the toxic signaling mediated via these drugs.

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

Triphendiol, NV-143 and NV-128 are analogues of phenoxodiol, but exhibit significantly different biologies to phenoxodiol. In parallel with phenoxodiol, these drug candidates display pre-clinical anti-cancer activity across a broad range of tumor types, high selectivity for cancer cells, and the ability to chemosensitize tumor cells to the cytotoxic effects of most standard chemotoxic drugs. However, these drugs differ from phenoxodiol in inducing cell death by both caspase dependent and caspase independent mechanisms and by showing a substantially greater ability to induce apoptosis in pancreatic cancer, bile duct cancer, and melanoma cells; triphendiol also shows an ability to increase the sensitivity of cancer cells to radiotherapy (radiosensitizers).

Triphendiol

Triphendiol is a derivative of phenoxodiol and was selected for further development based on superior pre-clinical anti-cancer activity against a range of cancers, especially pancreas and bile duct cancers and melanoma. In non-clinical studies, triphendiol invoked cell cycle arrest leading to programmed cell death in cell lines representative of late stage pancreatic and bile duct carcinoma. Apoptosis induction was independent of p53 status and proceeded via the mitochondrial cell death pathway. We have also demonstrated that triphendiol is able to sensitize cell lines representative of both pancreatic cancer and cholangiocarcinoma (bile duct cancer) to the standard of care drug, gemcitabine. Proof of concept studies in animal models of pancreatic cancer and cholangiocarcinoma demonstrated that orally delivered triphendiol is effective at inhibiting tumour proliferation and limiting terminal tumour burden. In further Good Laboratory Practice compliant toxicology studies, triphendiol was shown to be non-clastogenic (i.e., not capable of causing damage to chromosomes) and non-mutagenic (i.e., not causing genetic damage), and is well tolerated in rodent and non-rodent chronic repeat dose studies when delivered orally. These data have indicated that clinical development of triphendiol as a biliary cancer therapeutic is warranted. Two Phase Ia clinical studies have been completed in Australia investigating triphendiol pharmacokinetics and safety when delivered either orally or as an intravenous infusion. No medication related adverse events were reported. Triphendiol is a synthetic molecule. A scaleable synthetic manufacturing method has been developed as has a validated analytical method for the quantitation of the active pharmaceutical ingredient (API). The FDA has granted an Investigational New Drug status to triphendiol to enable a Phase Ib efficacy and safety study to be conducted in the U.S.

NV-143

NV-143 is a derivative of triphendiol and is a highly potent, pan acting investigational anti-cancer drug. It is active against every melanoma cell line tested to date and is able to sensitize melanoma cell lines to the standard of care drug, dacarbazine, and members of the platinum drug family. Proof of concept studies in animal models of melanoma have demonstrated that orally delivered NV-143 retards tumor proliferation. The NV-143 mechanism of action in melanoma has not been fully elucidated. NV-143 is non-clastogenic in laboratory studies.

NV-128

NV-128 belongs to a class of drugs known as mTOR inhibitors. NV-128's effect on the mTOR protein reduces the potential for the cancer cell to develop resistance to chemotherapeutic drugs. NV-128, an analogue of our lead investigational anti-cancer agents triphendiol (NV-196) and phenoxodiol (NV-06), has demonstrated activity as a single agent and as a chemosensitizing agent against cancer cell lines representative of non-small cell lung carcinoma (NSCLC). Proof of concept xenograft studies in animals have confirmed that orally delivered NV-128 retards NSCLC tumor proliferation. Laboratory studies are in progress in pre-clinical in vitro experiments to examine activity against late stage colorectal, breast, and gastric cancers and hepatocellular carcinoma, both as a single agent and in combination with current standard of care drugs. Pharmacokinetic studies of NV-128 delivered orally and intraperitoneally have been conducted in rodents. These studies have demonstrated that NV-128 is bioavailable, producing therapeutically significant concentrations in blood plasma, and is completely excreted 24 hours post administration.

NV-128 appears to reduce uncontrolled cancer cell proliferation by several different mechanisms. NV-128 disrupts the internal cell signaling pathway, and also induces changes in mitochondrial membranes. The mitochondrial membrane changes have been associated with early stages of programmed cell death, or apoptosis, and are mediated via a novel mTOR pathway. In mature cancer cells as well as in cancer stem cells, the mTOR protein is involved in enhancing tumor growth and may be associated with resistance to chemotherapeutic drugs. Inhibition of the mTOR pathway appears to shut down many of the cellular survival pathways, including proteins that protect the mitochondria of cancer cells. NV-128 has been demonstrated to block both mTORC1 and mTORC2 pathways of mTOR activation. Data demonstrate that through minor modification of the parent isoflavene compounds, novel analogues can be generated, which promote cell death via alternative mechanisms to those described for phenoxodiol and triphendiol, opening up new opportunities for treatment of an even broader range of cancers.

Competition

The development of our 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 our drug candidates are being developed. Some of these potential competing drugs are further advanced in development than our drug candidates and may be commercialized sooner. Even if we are successful in developing effective drugs, our drug candidates may not compete successfully with products produced by our competitors.

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

Intellectual Property

Novogen has been granted patents and has additional patent applications pending in a number of countries which cover a family of chemically related compounds with potentially broad ranging and complementary anti-cancer effects. Novogen has granted to us an exclusive license, with respect to its patent rights and intellectual property know-how to develop, market and distribute the isoflavonoid compounds phenoxodiol, triphendiol, NV-143 and NV-128 as anti-cancer agents, except in topical form.

Phenoxodiol

We have licensed from Novogen the rights to the Novogen patents and applications as they relate to phenoxodiol as an anti-cancer agent. Excluded from these rights is phenoxodiol in a topical formulation. The patent rights we have licensed from Novogen can be largely classified into two broad groups: patent rights relating to phenoxodiol used as an anti-cancer agent, which we refer to as “therapeutic patent rights,” and patent rights relating to the manufacture of phenoxodiol for anti-cancer purposes, which we refer to as “manufacturing patent rights.” The therapeutic patent rights with respect to phenoxodiol comprise the following patent families:

- phenoxodiol in the treatment of cancer (thirteen pending patent applications, seventeen issued patents, and two allowed patent applications which are anticipated to proceed to grant in the coming months);
- the use of phenoxodiol in compositions and methods for protecting skin from ultraviolet induced immunosuppression and skin damage (three pending patent applications, eight issued patents, and two allowed patent applications which are anticipated to proceed to grant in the coming months);
- the use of phenoxodiol, in combination with chemotherapeutic agents, for increasing cancer cell sensitivity to treatment and in cancer therapy (eleven pending patent applications, four issued patents, and one allowed patent application which is anticipated to proceed to grant in the coming months);
- phosphate ester prodrugs of phenoxodiol (eight pending patent applications); and
- the use of phenoxodiol in the modulation of the immune system (provisional patent application filed) (see also triphendiol and NV-128 below).

The manufacturing patent rights, relating to the production of isoflavan derivatives, including phenoxodiol, comprises a patent family in which eleven patent applications are pending, five patents have issued and one patent application has been allowed and is anticipated to proceed to grant in the coming months.

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

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

Triphendiol and NV-143

These compounds are isoflavan derivatives of phenoxodiol. The licensed patent rights relate to the novel compounds themselves (“composition of matter” rights) and to uses of these compounds as anti-cancer agents and sensitizers of cancer cells and tumors to chemotherapy and radiotherapy, except in topical form. The licensed patent rights fall into several families of patent applications:

- composition of matter rights in respect of triphendiol and NV-143 and uses of these compounds as anti-cancer agents (thirteen pending patent applications); and
- uses of triphendiol and NV-143 as chemo-sensitizers and radiosensitizers of tumors and cancer cells (ten pending patent applications and one issued patent) (see also NV-128 below);
- the use of triphendiol for inducing programmed cell death (three pending patent applications) (see also NV-128 below); and
- the use of triphendiol in the modulation of the immune system (provisional patent application filed) (see also phenoxodiol above).

NV-128

NV-128 is a further novel isoflavan derivative of phenoxodiol. The licensed patent rights in respect of NV-128 relate to the novel compound itself (“composition of matter” rights) and to uses of the compound as an anti-cancer agent, except in topical form. The licensed patent rights fall into several patent families as follows:

- composition of matter rights in respect of NV-128 and uses of this compound as an anti-cancer agent (thirteen pending patent applications);
- the use of NV-128 as a chemo-sensitizer and radiosensitizer of tumors and cancer cells (ten pending patent applications and one issued patent) (see also triphendiol and NV-143 above);
- two patent families (one international patent application filed, and three pending patent applications, respectively) relating to the use of NV-128 for inducing programmed cell death; and
- the use of NV-128 in the modulation of the immune system (provisional patent application filed) (see also phenoxodiol above).

As patent applications in the U.S. are maintained in secrecy until published by the USPTO at 18 months from filing for all cases filed after November 29, 2000, or at issue, for cases filed prior to November 29, 2000 we cannot be certain that Novogen was the first to make the inventions covered by the Novogen patents and applications referred to above. Additionally, publication of discoveries in the scientific or patent literature often lags behind the actual discoveries. Moreover, pursuant to the terms of the Uruguay Round Agreements Act, patents filed on or after June 8, 1995 have a term of twenty years from the date of such filing, irrespective of the period of time it may take for such patent to ultimately issue. This may shorten the period of patent protection afforded to therapeutic uses of phenoxodiol, triphendiol, NV-143 or NV-128, as patent applications in the biopharmaceutical sector often take considerable time to issue. However, in some countries the patent term may be extended.

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

The pharmaceutical industry is highly competitive and patents may have been applied for by, and issued to, other parties relating to products competitive with phenoxodiol, triphendiol, NV-143 or NV-128. Use of these compounds and any other drug candidates may give rise to claims that they infringe the patents or proprietary rights of other parties, existing now and in the future. An adverse claim could subject us to significant liabilities to such other parties and/or require disputed rights to be licensed from such other parties. We cannot be sure that any license required under any such patents or proprietary rights would be made available on terms acceptable to us, if at all. If we do not obtain such licenses, we may encounter delays in product market introductions, or may find that the development, manufacture or sale of products requiring such licenses may be precluded. We have not conducted any searches or made any independent investigations of the existence of any patents or proprietary rights of other parties.

Relationship with Novogen

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

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

Phenoxodiol

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

Triphendiol and NV-143

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

NV-128

Under a third license agreement, Novogen granted us an exclusive world-wide, non-transferable license, under the Novogen patent rights, to conduct clinical trials and commercialize and distribute all forms of administering NV-128, except topical applications. The agreement covers uses of NV-128 in the field of prevention, treatment or cure of cancer in humans. NV-128 is currently in pre-clinical development stage.

License Option deed

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

Services

Pursuant to a services agreement, Novogen provides services reasonably required by us relating to the development and commercialization of phenoxodiol, triphendiol, NV-143, NV-128 or other option compounds in relation to which we have exercised our rights under the License Option Deed. We do not currently intend to directly employ any staff and are reliant upon Novogen for the provision of resources to conduct our business.

Manufacturing

Under the Manufacturing License and Supply Agreement, we have granted Novogen a sublicense to manufacture and supply phenoxodiol to us in its primary manufactured form for both the OVATURE clinical program and phenoxodiol's ultimate commercial use. Novogen has taken the strategic decision not to manufacture large scale Active Pharmaceutical Ingredients ("API") for cancer drugs, including phenoxodiol, as these can be more economically supplied by third parties with particular expertise in this area.

Research and Development

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

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

- the relevant molecular targets of action of our licensed drug candidates;
- the relative therapeutic benefits and indications of our licensed drug candidates as a monotherapy or as part of combinational therapy with other chemotoxics;

- the most appropriate cancer targets for phenoxodiol, triphendiol, NV-143 and NV-128; and
- the relative therapeutic indications of different dosage forms of our licensed drug candidates.

Research expenses were \$7.777 million for the year ended June 30, 2009, \$9.325 million for the year ended June 30, 2008 and \$5.761 million for the year ended June 30, 2007.

Research and development costs incurred since inception through June 30, 2009 amount to \$33,043,000.

Regulation

U.S. Regulatory Requirements

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

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

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

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

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

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

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

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

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

Each NDA must be accompanied by a user fee, pursuant to the requirements of the Prescription Drug User Fee Act, or PDUFA, and its amendments. According to the FDA's fee schedule, effective on October 1, 2008 for the fiscal year 2009, the user fee for an application requiring clinical data, such as an NDA, is \$1,247,200. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual product fee for prescription drugs and biologics (\$71,520), and an annual establishment fee (\$425,600) on facilities used to manufacture prescription drugs and biologics. A written request can be submitted for a waiver for the application fee for the first human drug application that is filed by a small business, but there are no waivers for product or establishment fees. We are not at the stage of development with our products where we are subject to these fees, but they are significant expenditures that may be incurred in the future and must be paid at the time of application submissions to FDA.

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

the discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market.

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

The FDA's policies may change, and additional governmental regulations may be enacted that could delay, limit, or prevent regulatory approval of our products or affect our ability to manufacture, market, or distribute our products after approval. Moreover, increased attention to the containment of healthcare costs in the U.S. and in foreign markets could result in new government regulations that could have a material adverse effect on our business. Our failure to obtain coverage, an adequate level of reimbursement, or acceptable prices for our future products could diminish any revenues we may be able to generate. Our ability to commercialize future products will depend in part on the extent to which coverage and reimbursement for the products will be available from government and health administration authorities, private health insurers, and other third-party payers. European Union member states and U.S. government and other third-party payers increasingly are attempting to contain healthcare costs by consideration of new laws and regulations limiting both coverage and the level of reimbursement for new drugs. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U.S. or abroad.

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

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

Under the Drug Price Competition and Patent Term Restoration Act of 1984 a sponsor may obtain marketing exclusivity for a period of time following FDA approval of certain drug applications, regardless of patent status, if the drug is a new chemical entity or if new clinical studies were required to support the marketing application for the drug. This marketing exclusivity prevents a third party from obtaining FDA approval for an identical or nearly identical drug under an Abbreviated New Drug Application or a "505(b)(2) New Drug Application." The statute also allows a patent owner to obtain an extension of applicable patent terms for a period equal to one-half the period of time elapsed between the filing of an IND and the filing of the corresponding NDA plus the period of time

between the filing of the NDA and FDA approval, with a five year maximum patent extension. We cannot be certain that Novogen will be able to take advantage of either the patent term extension or marketing exclusivity provisions of these laws.

The Best Pharmaceuticals for Children Act, or BPCA, signed into law on January 4, 2002, was reauthorized and amended by the FDA Amendments Act of 2007 or FDAAA. The reauthorization of BPCA provides an additional six months of patent protection to NDA applicants that conduct acceptable pediatric studies of new and currently-marketed drug products for which pediatric information would be beneficial, as identified by FDA in a Pediatric Written Request. The Pediatric Research Equity Act, or PREA, signed into law on December 3, 2003, also was reauthorized and amended by FDAAA. The reauthorization of PREA requires that most applications for drugs and biologics include a pediatric assessment (unless waived or deferred) to ensure the drugs' and biologics' safety and effectiveness in children. Such pediatric assessment must contain data, gathered using appropriate formulations for each age group for which the assessment is required, that are adequate to assess the safety and effectiveness of the drug or the biological product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the drug or the biological product is safe and effective. The pediatric assessments can only be deferred provided there is a timeline for the completion of such studies. The FDA may waive (partially or fully) the pediatric assessment requirement for several reasons, including if the applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed.

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.

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

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

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

The first phase of evaluation, known as the Application Entry Process, is usually a short period during which an application is assessed on an administrative level to ensure that it complies with the basic guidelines. The TGA may request further details from the applicant, and may agree with sponsors that additional data (which while not actually required by the application, could enhance the assessment outcome) may be submitted later at an agreed time. The TGA must decide within at least 40 working days whether it will accept the application for evaluation.

Once an application is accepted for evaluation, aspects of the data provided are allocated to evaluators within the different relevant sections, who prepare clinical evaluation reports. Following evaluation, the chemistry and quality control aspects of a product may be referred to a Pharmaceutical Sub-Committee (PSC), which is a sub-committee of the TGA prescription medicine expert advisory committee, the Australian Drug and Evaluation Committee (ADEC) to review the relevant clinical evaluation reports.

The clinical evaluation reports (along with any resolutions of the ADEC sub-committee) are then sent to the sponsoring company who then has the opportunity to comment on the views expressed within the evaluation report, provide corrections and to submit supplementary data to address any issues raised in the evaluation reports.

Once the evaluations are complete, the TGA prepares a summary document on the key issues on which advice will be sought from the either the ADEC (for new medicines) or from the Peer Review Committee (PRC) for existing or generic products. This summary is sent to the sponsoring company which is able to submit a response to the ADEC or PRC dealing with issues raised in the summary and those not previously addressed in the evaluation report. The ADEC/PRC provide independent advice on the quality, risk-benefit, effectiveness and access of the drug and conduct medical and scientific evaluations of the application. The ADEC meets every 2 months to examine the applications referred by the TGA and its resolutions are provided to the sponsoring company after 5 working days after the ADEC meeting.

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

From the time that the TGA accepts the initial application for evaluation, the TGA must complete the evaluation and make a decision on the registration of the product within at least 255 working days. If not completed within 255 working days, the TGA forfeits 25% of the evaluation fee otherwise payable by the sponsor, but any time spent waiting for a response from the sponsor is not included in the 255 working days. The TGA also has a system of priority evaluation for products that meet certain criteria, including where the product is a new chemical entity that it is not otherwise available on the market as an approved product, and is for the treatment of a serious, life-threatening illness for which other therapies are either ineffective or not available.

European Union Regulatory Requirements

Outside the U.S., our ability to market our products will also be contingent upon receiving marketing authorizations from the appropriate regulatory authorities and compliance with applicable post-approval regulatory requirements. Although the specific requirements and restrictions vary from country to country, as a general matter, foreign regulatory systems include risks similar to those associated with FDA regulation, described above. Under EU regulatory systems, marketing authorizations may be submitted either under a centralized or a national procedure. Under the centralized procedure, a single application to the European Medicines Agency (EMA) leads to an approval granted by the European Commission which permits the marketing of the product throughout the EU. The centralized procedure is mandatory for certain classes of medicinal products, but optional for others. For example, all medicinal products developed by certain biotechnological means, and those developed for cancer and other specified diseases and disorders, must be authorized via the centralized procedure. We assume that the centralized procedure will apply to our products that are developed by means of a biotechnology process. The national procedure is used for products that are not required to be authorized by the centralized procedure. Under the national procedure, an application for a marketing authorization is submitted to the competent authority of one member state of the EU. The holders of a national marketing authorization may submit further applications to the competent authorities of the remaining member states via either the decentralized or mutual recognition procedure. The decentralized procedure enables applicants to submit an identical application to the competent authorities of all member states where approval is sought at the same time as the first application, while under the mutual recognition procedure, products are authorized initially in one member state, and other member states where approval is sought are then requested to recognize the original authorization based upon an assessment report prepared by the original authorizing competent authority. Both the decentralized and mutual recognition procedures should take no longer than 90 days, but if one member state makes an objection, which under the legislation can only be based on a possible risk to human health, the application will be automatically referred to the Committee for Medicinal Products for Human Use (CHMP) of the EMA. If a referral for arbitration is made, the procedure is suspended. However, member states that have already approved the application may, at the request of the applicant, authorize the product in question without waiting for the result of the arbitration. Such authorizations will be without prejudice to the outcome of the arbitration. For all other concerned member states, the opinion of the CHMP, which is binding, could support or reject the objection or alternatively could reach a compromise position acceptable to all EU countries concerned. The arbitration procedure may take an additional year before a final decision is reached and may require the delivery of additional data.

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

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

Accordingly, there is a marked degree of change and uncertainty both in the regulation of clinical trials and in respect of marketing authorizations which face us for our products in Europe.

Government Funding

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

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

Under the START Program, Novogen must meet certain project development and commercialization obligations. Novogen has met the project development obligations and has received final payment thereon. Novogen believes that it is currently in compliance with its commercialization schedule and that it has fulfilled all of its obligations under the terms of the START Program and expects to continue to do so in the future. For additional information on the consequences to us in the event Novogen fails to comply with its obligations under the START Program, see the "Intellectual Property" and "Risk Factors" sections of this Annual Report on Form 10-K.

Employees

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

Item 1A. Risk Factors

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

Risks Related to Our Business

We have terminated new enrollment into our OVATURE Phase III clinical trial and may not be able to pursue commercialization of phenoxodiol at this time.

We have terminated new enrollment into the OVATURE Phase III clinical trial, in part, because we believe that the global financial downturn makes it unlikely that we will be able to raise the necessary capital through debt or equity issuances in the near future to fund the trial to completion as originally planned. We have ceased recruiting the necessary number of additional patients to complete the trial as originally planned. As a result of our termination

of new enrollment into the OVATURE Phase III clinical trial, we may not be able to pursue commercialization of phenoxodiol at this time.

If our un-blinded data analysis of the patient data from the OVATURE Phase III clinical trial does not demonstrate the safety and efficacy of phenoxodiol for the treatment of platinum-resistant late-stage ovarian cancer, we may be unable to out-license phenoxodiol to third parties for this purpose.

We have decided to undertake an un-blinded analysis of the available data from the 142 completed or current patients in the OVATURE Phase III clinical trial to assess the safety and efficacy of phenoxodiol for the treatment of platinum-resistant late-stage ovarian cancer. If our analysis demonstrates the safety and efficacy of phenoxodiol, we may be able to out-license phenoxodiol to third parties and receive licensing revenues. If our analysis shows that phenoxodiol is not safe and /or not effective, however, we may not be able to out-license phenoxodiol to third parties.

We will need additional funds to progress the clinical trial program for triphendiol beyond its early stages and to develop new in-licensed compounds from Novogen. The actual amount of funds we will need will be determined by a number of factors, some of which are beyond our control.

The factors which will determine the actual amount of funds that we will need to progress the clinical trial programs for triphendiol may include the following:

- the number of sites included in the trials;
- the length of time required to enroll suitable patients;
- the number of patients who participate in the trials and the rate that they are recruited;
- the number of treatment cycles patients complete while they are enrolled in the trials; and
- the efficacy and safety profile of the product.

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

The recent global financial crisis may negatively impact our liquidity and our ability to continue our planned future clinical trials program, by precluding us from raising funds through equity investments on terms favorable to us or at all.

We have traditionally raised capital through the sale of equity securities to investors. Recently the financial services industry and credit markets have experienced a period of unprecedented turmoil characterized by bankruptcy, failure and collapse or sale of various financial institutions. Although the ultimate outcome of these events cannot be predicted, they may preclude us from raising the capital necessary to finance our business operations through the sale of equity securities on terms favorable to us or at all. In order to obtain the additional funding necessary to conduct our business, we may need to rely on collaboration and /or licensing opportunities. We cannot assure you that we will be able to raise the funds necessary or find appropriate collaboration or licensing opportunities to fund our future business plan.

If the data from our current Phase II Clinical trial for phenoxodiol for prostate cancer which is currently underway at Yale University does not demonstrate safety and efficacy we may have to stop the trial

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 development initiatives for this product. This will have a significant impact on the trading price of our securities.

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

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

- triphendiol is in the early stages of clinical development and we will need to conduct significant clinical testing to prove safety and efficacy before applications for marketing can be filed with the FDA, or with the regulatory authorities of other countries;
- the un-blinded analysis of the available data from the OVATURE Phase III clinical trial does not provide adequate safety and efficacy outcomes;
- data obtained from pre-clinical and clinical tests can be interpreted in different ways, which could delay, limit or prevent regulatory approval;
- development and testing of product formulation, including identification of suitable excipients, or chemical additives intended to facilitate delivery of our drug candidates;
- it may take us many years to complete the testing of other drug candidates, and failure can occur at any stage of this process; and
- negative or inconclusive results or adverse medical events during a clinical trial could cause us to delay or terminate our development efforts.

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

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

You should consider our prospects in light of the risks and difficulties frequently encountered by early stage and developmental companies. Although we were incorporated in December 2000, we have only been in operation since May 2002. We have incurred net losses of \$62,911,000 since our inception through June 30, 2009, including net losses of \$11,180,000, \$12,410,000 and \$13,820,000 for the years ended June 30, 2009, 2008 and 2007, 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 may not be able to establish the strategic partnerships necessary to develop, market and distribute our product candidates.

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

We may not be able to secure and maintain suitable Clinical Research Organisations (CROs) or clinical research institutions to manage and conduct our clinical trials.

We rely on suitable CROs to manage larger clinical trials on our behalf and clinical research institutions, of which there are many, to conduct our clinical trials. Our reliance upon third party CROs and clinical 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 CROs and clinical research institutions over costs and the ownership of intellectual property discovered during the clinical trials. If we are unable to reach agreement with suitable CROs and clinical research institutions on acceptable terms, or if any resulting agreement is terminated and we are unable to quickly replace the applicable CRO or clinical research institution with another qualified CRO or institution on acceptable terms, the research could be delayed and we may be unable to complete development or commercialize our drug candidates, which will adversely affect our ability to generate operating revenues.

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 our drug candidates.

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 our drug candidates are being developed. Some of these potential competing drugs are further advanced in development than our drug candidates and may be commercialized sooner. Even if we are successful in developing effective drugs, our compounds may not compete successfully with products produced by our competitors.

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

We have no direct control over the costs of manufacturing our drug candidates. Increases in the costs of manufacturing our drug candidates would increase our costs of conducting clinical trials and could adversely affect our future profitability.

We do not intend to manufacture phenoxodiol, triphendiol, NV-143 or NV-128 ourselves and we will rely on third parties for our supplies of our drug candidates both for clinical trials and for commercial quantities in the future. Novogen has taken the strategic decision not to manufacture on a large scale API for cancer drugs as these can be more economically supplied by third parties with particular expertise in this area. We have identified contract facilities that are registered with the FDA, have a track record of large scale API manufacture and have already invested in capital and equipment. 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.

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

The conduct of our clinical trials and approval of our marketing application for our product candidates may be delayed or adversely affected if the third-party manufacturers whom we rely upon for the production of phenoxodiol fail to comply with FDA's regulatory requirements for current cGMP. The FDA requires drug manufacturers to establish and maintain quality control procedures for manufacturing, processing and holding drugs and investigational products, and products must be manufactured in accordance with defined specifications. The failure of

contract manufacturers to supply investigational product in compliance with the defined specifications for phenoxodiol may delay the completion of our clinical trials. As part of the pre-market approval process, the manufacturer will be inspected by the FDA to ensure compliance with cGMP. The failure of contract manufacturers to comply with applicable regulations may result in a delay or prevent approval of our marketing application.

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 \$24.3 million. Although we believe that this amount of insurance coverage is appropriate for our business at this time, it is subject to deductibles and coverage limitations, and the market for such insurance is becoming more restrictive. We may not be able to obtain or maintain adequate protection against potential liabilities. If we are unable to sufficiently insure against potential product liability claims, we will be exposed to significant liabilities, which may materially and adversely affect our business development and commercialization efforts.

Our rights to develop and exploit phenoxodiol and the anti-cancer compounds triphendiol, NV-143 and NV-128 are subject to the terms and conditions of agreements we have entered into with Novogen. Under these agreements our rights may be terminated under certain circumstances, some of which may be beyond our control.

We have licensed the intellectual property in the phenoxodiol technology and the anti-cancer compounds triphendiol, NV-143 and NV-128 from Novogen. Under the terms of the License Agreement for Phenoxodiol, all forms of administering phenoxodiol for the treatment of cancer, excluding topical applications, are licensed to us through our wholly-owned subsidiary, MEPL. Under the terms of the License Agreement for Triphendiol and NV-143, all forms of administering drugs containing the anti-cancer compounds triphendiol and NV-143, excluding topical applications, are licensed to us through MEPL. Under the terms of the License Agreement for NV-128, all forms of administering NV-128, excluding topical applications, are licensed to us through MEPL. If we fail to meet our obligations under our license agreements, the Manufacturing License and Supply Agreement or the Services Agreement with Novogen, any or all of these agreements may be terminated by Novogen and we could lose our rights to develop phenoxodiol or anti-cancer drugs containing triphendiol, NV-143 and NV-128. To date, we have no reason to believe that we will be unable to satisfy our obligations under these agreements. In addition, each of these agreements may be terminated immediately by Novogen in the event that MEPL undergoes a change of control without the consent of Novogen. Under the terms of the License Agreement for Phenoxodiol, the Manufacturing License and Supply Agreement and the Services Agreement, a “change of control” means (i) a change in control of more than half the voting rights attaching to the shares of MEPL, (ii) a change in control of more than half of the issued shares of MEPL (not counting any share which carries no right to participate beyond a specified amount in the distribution of either profit or capital) or (iii) a change in control of the composition of the board of directors of MEPL. Under the terms of the License Agreement for Triphendiol and NV-143 and the License Agreement for NV-128, a “change in control” means the acquisition by any person or group of more than half of the combined voting power of MEPL’s then outstanding securities entitled to vote generally in the election of directors of MEPL or any merger, consolidation, recapitalization, exchange or tender offer as a result of which a person or a group other than the shareholders of MEPL immediately before the transaction owns after the transaction more than half of the combined voting power of the then outstanding securities entitled to vote generally in the election of directors of MEPL. Each of these agreements may also be terminated if we cease for any reason to be able to lawfully carry out all the transactions required by each respective agreement.

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

The rights granted to us under the License Agreements, the Manufacturing License and Supply Agreement and the License Option Deed with Novogen are fundamental to our business. The License Agreement for Phenoxodiol grants us the right to make, have made, market, distribute, sell, hire or otherwise dispose of phenoxodiol products in the field of prevention, treatment or cure of cancer in humans by pharmaceuticals delivered in all forms except topical applications. The License Agreement for Triphendiol and NV-143 and the License Agreement for NV-128 grant us the

right to make, have made, market, distribute, sell, hire or otherwise dispose of anti-cancer drugs containing the compounds triphendiol and NV-143 and NV-128 in the field of prevention, treatment or cure of cancer in humans by pharmaceuticals delivered in all forms except topical applications. Our business purpose is to develop and commercialize cancer drugs including phenoxodiol and drugs containing the compounds triphendiol and NV-143 and NV-128, which we would be unable to pursue without the rights granted to us under the license agreements. The License Option Deed grants us an exclusive first right to accept and exclusive last right to match any proposed dealing by Novogen of its intellectual property rights with a third party relating to certain compounds (other than phenoxodiol) developed by Novogen and its affiliates which have applications in the field of prevention, treatment or cure of cancer in humans. The License Option Deed is important to our business because it allows us to maintain control over the sale by Novogen of complementary as well as potentially competitive intellectual property rights to third party competitors. Any loss of the rights under any of these agreements will likely cause us to cease operations.

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

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

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. Novogen has applied for patents in a number of countries with respect to the use of phenoxodiol for the treatment, prevention or cure of cancer and methods of production of phenoxodiol. We have licensed both issued patents and pending patent applications from Novogen in relation to these technologies. Novogen has recently been issued a U.S. patent for pharmaceutical compositions comprising phenoxodiol. Novogen has issued patents in the U.S., the United Kingdom, Australia, China, Hong Kong, New Zealand, Singapore, Mexico and the Czech Republic related to phenoxodiol for the treatment of a variety of cancers and has issued patents in the U.S., Australia, New Zealand, Singapore and Sweden covering the use of phenoxodiol to prevent or treat skin cancer resulting from ultraviolet damage. Issued Novogen patents in the U.S., Europe, Australia, New Zealand, Singapore, Mexico and Sweden cover the use of phenoxodiol to treat or prevent UV-induced immunosuppression. In addition, Novogen has issued patents in Australia, New Zealand, Singapore, South Africa and Turkey relating to methods of production of phenoxodiol. For each of the patent families discussed above, there remain pending patent applications in various other jurisdictions.

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

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

The pharmaceutical industry is highly competitive and patents have been applied for by, and issued to, other parties relating to products competitive with our licensed compounds. 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 contracted formulation development and manufacturing process development work for phenoxodiol. This process has identified a number of excipients, or additives to improve drug delivery, which may be used in the formulations of phenoxodiol. Excipients, among other things, perform the function of a carrier of the active drug ingredient. Some of these identified excipients or carriers may be included in third party patents in some countries. We intend to seek a license if we decide to use a patented excipient in the marketed product or we may choose one of those excipients that do not have a license requirement.

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

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

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

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

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

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

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

Our results are affected by fluctuations in currency exchange rates.

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

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

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

Risks Related to Our Relationship with Novogen

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

Novogen beneficially owns approximately 71.3% of our outstanding shares of common stock. As a result, Novogen will have the ability to effectively determine the outcome of all matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets.

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

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

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

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

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

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

We currently rely on Professor Alan Husband, Novogen Research Director, and Mr. Christopher Naughton, our President and Chief Executive Officer, to provide the strategic direction for the clinical development of our licensed compounds. If we are unable to secure the ongoing services of these key personnel, the commercialization program for these product candidates will be disrupted and will cause delays in obtaining marketing approval. Novogen has entered into employment agreements with Professor Husband and Mr. Naughton.

Novogen can compete with us.

We have no contract, arrangement or understanding with Novogen to preclude it from developing a product which may be competitive with phenoxodiol, triphendiol, NV-143 or NV-128 or to use these compounds for any uses other than anti-cancer applications. Novogen has reserved the intellectual property rights and know-how rights relating to topical applications of these compounds even in the field of cancer. There can be no assurance that Novogen or its subsidiaries will not pursue alternative technologies or product candidates as a means of developing treatments for the conditions targeted by phenoxodiol or any other product candidate which we seek to exploit.

We are dependent on Novogen for our personnel.

We have no employees. We rely on Novogen and other service companies to provide or procure the provision of staff and other financial and administrative services under our services agreement with Novogen. We believe Novogen has fully complied with the terms of our services agreement. To successfully develop our drug candidates, we will require ongoing access to the personnel who have, to date, been responsible for the development of our drug candidates. The services agreement does not specify a minimum amount of time that Novogen employees must devote to our operations. If we are unable to secure or if we lose the services of these personnel, the ability to develop our drug candidates could be materially impaired. Moreover, if our business experiences substantial and rapid growth, we may not be able to secure the services and resources we require from Novogen or from other persons to support that growth.

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

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

Risks Related to Our Common Stock

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

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

- developments concerning phenoxodiol and our other drug candidates triphendiol, NV-143 and NV-128;
- 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;
- the instability in the stock market as a result of the current global financial crisis;
- changes in the market valuations of similar companies;
- the liquidity of any market for our securities; and
- additional sales by us or Novogen of shares of our common stock.

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

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

The market price of our common stock could decline as a result of sales of substantial amounts of our common stock in the public market, or the perception that these sales could occur.

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

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

Item 1B. *Unresolved Staff Comments*

None.

Item 2. *Properties*

We do not own or lease any property.

Item 3. *Legal Proceedings*

None.

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

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

PART II

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

The following tables set forth for the period indicated the high and low sale prices of our common stock as reported by the NASDAQ Global Market.

	Nasdaq Global Market	
	High \$	Low \$
Common Stock		
Year Ended June 30, 2008		
First Quarter	3.36	2.21
Second Quarter	3.98	2.15
Third Quarter	2.91	1.49
Fourth Quarter	4.10	1.98
Year Ended June 30, 2009		
First Quarter	3.32	1.12
Second Quarter	2.08	0.30
Third Quarter	0.98	0.25
Fourth Quarter	1.34	0.38

As of August 21, 2009, there were 73,463,233 shares of our common stock outstanding and approximately 1,400 stockholders on record of our common stock. This number was derived from our shareholder records and does not include beneficial owners of our common stock whose shares are held in the name of various dealers, clearing agencies, banks, brokers and other fiduciaries.

Dividends

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

Stock Repurchases

We have not repurchased any shares of common stock during the fourth quarter of the fiscal year ended June 30, 2009.

Equity Compensation

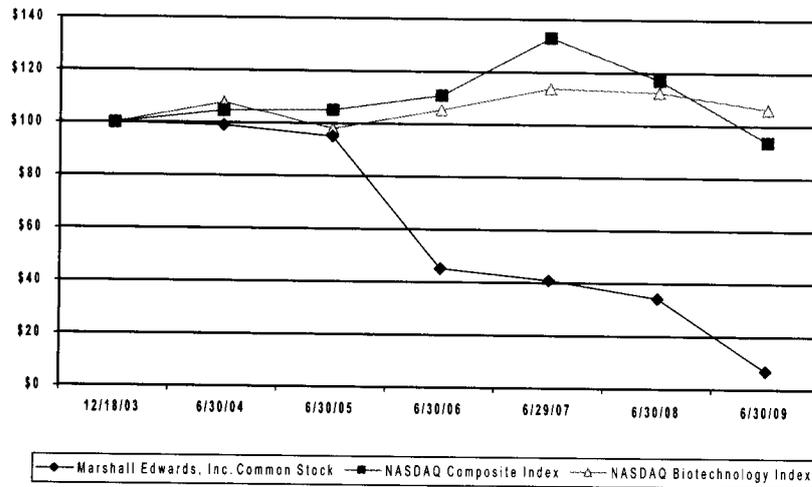
The following table sets forth, as of June 30, 2009 outstanding awards and shares remaining available for future issuance under our compensation plans under which equity securities are authorized for issuance.

Plan Category	(a) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	(b) Weighted-average Exercise Price of Outstanding Options, Warrants and Rights	(c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
Equity compensation plans approved by security holders . . .	50,000	\$0.63	6,950,000
Equity compensation plans not approved by security holders . . .	None	Not Applicable	Not Applicable
Total	50,000	\$0.63	Indeterminable

Stock Performance Graph

The graph set forth below compares the change in our cumulative total stockholder return on our common stock between December 18, 2003 (the date our common stock commenced public trading) and June 30, 2009 with the cumulative total return of the NASDAQ Composite Index and the NASDAQ Biotechnology Index during the same period. This graph assumes the investment of \$100 on December 18, 2003 in our common stock and each of the comparison groups and assumes reinvestment of dividends, if any. We have not paid any dividends on our common stock, and no dividends are included in the report of our performance.

Stock Performance Comparison



	12/18/03	6/30/04	6/30/05	6/30/06	6/29/07	6/30/08	6/30/09
Marshall Edwards, Inc. Common Stock	\$100.00	\$ 99.07	\$ 95.07	\$ 45.20	\$ 40.93	\$ 34.27	\$ 6.93
NASDAQ Composite Index	\$100.00	\$104.68	\$105.15	\$111.04	\$133.08	\$117.22	\$ 93.81
NASDAQ Biotechnology Index	\$100.00	\$107.78	\$ 98.00	\$105.44	\$113.95	\$112.62	\$106.31

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,				
	2009	2008	2007	2006	2005
	(In thousands, except per share data)				
Revenues:					
Interest and other income	\$ 228	\$ 674	\$ 645	\$ 446	\$ 308
Total revenues	228	674	645	446	308
Loss from operations	(11,179)	(12,407)	(13,819)	(7,385)	(6,421)
Income tax expense	(1)	(3)	(1)	(1)	—
Net loss arising during development stage	\$ (11,180)	\$ (12,410)	\$ (13,820)	\$ (7,386)	\$ (6,421)
Net loss per common share:					
Basic and diluted	\$ (0.15)	\$ (0.18)	\$ (0.22)	\$ (0.13)	\$ (0.11)
Weighted average common shares outstanding	73,071,844	68,302,566	63,179,366	56,938,000	56,938,000

Balance Sheet Data

	As of June 30,				
	2009	2008	2007	2006	2005
	(In thousands)				
Cash and cash equivalents	\$19,067	\$19,743	\$16,158	\$10,054	\$ 9,238
Total assets	\$19,356	\$19,978	\$16,290	\$10,395	\$19,364
Total stockholders' equity	\$15,213	\$16,535	\$13,777	\$ 9,135	\$16,521

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

The following discussion and analysis should be read in conjunction with "Item 8. Financial Statements and Supplementary Data" included below. Operating results are not necessarily indicative of results that may occur in future periods. This discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. The actual results may differ materially from those anticipated in the forward-looking statements as a result of many factors including, but not limited to, those set forth under "Cautionary Statement About Forward-Looking Statements" and "Risk Factors" in Item 1A. included above in this Annual Report on Form 10-K. All forward-looking statements included in this document are based on the information available to us on the date of this document and we assume no obligation to update any forward-looking statements contained in this Annual Report on Form 10-K.

Overview

Our main focus since commencing operations is to undertake human clinical testing of phenoxodiol. Our operations were expanded to include the additional licensed drug candidates triphendiol and NV-143 and most recently, NV-128. During fiscal year 2007, we commenced the OVATURE Phase III clinical trial. We have reached agreement under the SPA process with the FDA on the design of our OVATURE pivotal study protocol for phenoxodiol. The trial 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 April 2009, we announced our determination to terminate enrollment into the OVATURE Phase III clinical trial and our intention to undertake an un-blinded analysis of the available data from the trial. The patients currently enrolled in the trial will continue their treatment according to the study protocol. However, we will cease recruiting new patients to participate in the OVATURE Phase III clinical trial and the available data from the 142 completed and current patients will be analyzed for safety and efficacy outcomes.

The termination of patient enrollment into the OVATURE study and unblinded analysis of the available data from the trial have been discussed with FDA, because the analysis will not be performed as described in the approved SPA.

We decided to terminate new enrollment into the OVATURE Phase III clinical trial and assess the available patient data, in part, because we believe that the global financial downturn makes it unlikely that we will be able to raise the necessary capital through debt or equity issuances in the near future to fund the trial to completion as originally planned. Additionally, changes in the standard of care over the period that the OVATURE Phase III clinical trial has been in operation resulted in fewer women meeting the inclusion criteria of the OVATURE protocol, which slowed patient recruitment rates.

In August, 2009, we entered into a third license agreement with Novogen for the investigational oncology compound NV-128. In consideration of the license granted to us we paid Novogen a license fee of \$1,500,000 on August 7, 2009.

We believe that the proceeds from our registered direct offering closed in July 2008 and savings generated from ceasing the OVATURE Phase III clinical trial will provide us with sufficient cash resources to fund these operations over the next twelve months.

We will, however, need additional funds in order complete the planned clinical development programs beyond the current objectives.

As of June 30, 2009, we had accumulated losses of \$62,911,000.

We have not generated any revenues from operations since inception other than interest on cash assets.

We do not employ any staff directly but obtain services from Novogen under the 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.

Expenses to date have consisted primarily of costs associated with conducting the clinical trials of phenoxodiol including OVATURE, costs incurred under the Phenoxodiol License Agreement, as amended, the License Agreement for Triphendiol and NV-143, the Services Agreement and the Manufacturing License 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.

As at the date of the Annual Report on Form 10-K, Novogen owns approximately 71.3% of the outstanding shares of our common stock.

Liquidity and Capital Resources

At June 30, 2009, we had cash resources of \$19,067,000 compared to \$19,743,000 at June 30, 2008. The decrease was due to expenditures in the clinical trial program and other corporate expenses incurred in the period, partially offset by our registered direct offering in July 2008, as described below. Funds are invested in short term money market accounts, pending use.

On July 28, 2008 we entered into a securities subscription agreement with Novogen and OppenheimerFunds, Inc. ("Oppenheimer") pursuant to which we sold 2,908,295 and 1,700,000 shares of common stock to Novogen and Oppenheimer, respectively, with Oppenheimer acting as adviser to each of the following parties severally and not jointly: (i) Oppenheimer International Growth Fund; (ii) Mass Mutual International Equity Fund; (iii) Oppenheimer International Growth Fund/VA; (iv) AZL Oppenheimer International Growth Fund; (v) OFITC International Growth Fund; and (vi) OFI International Equity Fund, at a purchase price of \$2.17 per share, the consolidated

closing bid price of our common stock as quoted by the NASDAQ Market Intelligence Desk at 4:00 PM EST on July 28, 2008. The shares were registered under the Securities Act of 1933, as amended (the "Securities Act") under a Shelf Registration Statement on Form F-3. We received gross proceeds of \$10 million from the sale of the shares.

Following the closing of the registered direct offering described above in July 2008, Novogen retained approximately 71.3% of our common stock.

In July 2008, we issued a warrant to Mr. John O'Connor exercisable for 46,083 shares of common stock, as consideration for investor relation services rendered by him to us. The warrant has an exercise price of \$2.17 per share. The warrant may be exercised immediately and expires five years from the date of issuance, on July 30, 2013. The warrant has not been registered under the Securities Act. We issued the warrant to Mr. O'Connor in a private placement made in reliance upon the exemption from securities registration afforded by Section 4(2) of the Securities Act.

In January 2009, we issued a stock option exercisable for 50,000 shares of common stock to Associate Professor Gil Mor of Yale University in recognition of his contribution to the development of phenoxodiol under the Marshall Edwards, Inc 2008 Stock Omnibus Equity Compensation Plan (the "2008 Stock Omnibus Equity Compensation Plan"). The option has an exercise price of \$0.63 per share of common stock. The options are exercisable immediately and expire five years from date of issue.

Given the current state of the global financial markets, we do not expect to be able to raise additional capital through the issuance of equity or debt in the near term.

Source and Uses of Cash

Cash Used in Operating Activities

Cash used in operating activities for the twelve months ended June 30, 2009 was \$10,554,000 compared to \$11,498,000 for the same period in 2008.

Cash Requirements

The Company intends to allocate its current funds of approximately \$19 million to completing the OVATURE data analysis of 142 patients, pursuing negotiations for out-licensing phenoxodiol should evidence of efficacy and safety emerge from the OVATURE analysis, initiating the triphendiol clinical program and in-licensing further promising anti-cancer compounds from Novogen.

Specifically we intend to:

- Commence the clinical development of the drug candidate triphendiol in the U.S. for which an IND has been granted by the FDA, allowing clinical trials to commence in the U.S. for pancreatic and bile duct cancers. In addition, this drug was designated by the FDA as an Orphan Drug for treatment of pancreatic cancer, bile duct cancer, and late stage melanoma;
- In August 2009 we completed negotiations with Novogen to in-license the mTOR inhibitor NV-128, which has shown compelling preclinical results to date. In consideration of the license granted to us we paid Novogen a license fee of \$1,500,000.

Ongoing operations through the conduct of the pre clinical and clinical trial program will continue to consume cash resources without generating revenues. In order to obtain the additional funding necessary to conduct our business, we may need to rely on collaboration and /or licensing opportunities. We cannot assure you that we will be able to raise the funds necessary to fund our programs or find appropriate collaboration or licensing opportunities.

Payments to Novogen

Future payments to Novogen under the terms of the Phenoxodiol License Agreement, as amended and the License Agreement for Triphendiol and NV-143 and the License agreement for NV-128 are detailed in Note 6 of the financial statements "Related Party Transactions"

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

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

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,		
	2009	2008	2007
	(In thousands)		
Interest and other income	\$ 228	\$ 674	\$ 645
Total revenues	<u>228</u>	<u>674</u>	<u>645</u>

Research and development expenses

	Years Ended June 30,		
	2009	2008	2007
	(In thousands)		
Clinical trial study costs	\$(5,719)	\$(5,928)	\$(2,255)
Drug/manufacturing scale-up costs	(198)	(1,310)	(1,860)
Research and development service charge	(1,456)	(2,065)	(1,145)
Other	(404)	(22)	(501)
Total Research and Development Costs	<u>(7,777)</u>	<u>(9,325)</u>	<u>(5,761)</u>

License Fees

	Years Ended June 30,		
	2009	2008	2007
	(In thousands)		
License Fees	<u>(2,000)</u>	<u>(1,000)</u>	<u>(5,000)</u>

Selling, general and administrative expenses

	Years Ended June 30,		
	2009	2008	2007
	(In thousands)		
Legal and professional fees	\$ (479)	\$ (527)	\$ (488)
Administrative service charge	(808)	(989)	(818)
Share based payment	(90)	—	(1,642)
Other	<u>(253)</u>	<u>(1,240)</u>	<u>(755)</u>
Total selling, general and administrative expenses	<u>(1,630)</u>	<u>(2,756)</u>	<u>(3,703)</u>

Year Ended June 30, 2009 Compared to the Year Ended June 30, 2008

We recorded a consolidated loss of \$11,180,000 and \$12,410,000 for the years ended June 30, 2009 and 2008, respectively.

Revenues: We received interest on cash assets and cash equivalents of \$228,000 for the year ended June 30, 2009 versus \$674,000 for the year ended June 30, 2008. This decrease was due to lower interest rates as a result of the global financial crisis.

Research and Development: Research and development expenses reduced \$1,548,000 to \$7,777,000 for the year ended June 30, 2009 compared to \$9,325,000 for the year ended June 30, 2008. This decrease was primarily due to a reduction in the cost of drug for the OVATURE clinical trial which was mostly manufactured in prior years. The research and development service charge from Novogen decreased for the year ended June 30, 2009, due to favorable currency movements in the U.S. dollar compared to the Australian dollar as these charges are denominated in Australian dollars.

Also included in clinical trial study costs are the expenses associated with the termination of the enrollment in the OVATURE Phase III clinical trial.

License Fees: Milestone license fees of \$2,000,000 have been expensed in the twelve months ended June 30, 2009 under the terms of the License Agreement for Triphendiol and NV-143. This license fee was due on the date of enrollment of the first clinical trial subject in a Phase II clinical trial of the licensed product. As this event did not occur the payment was due and paid on June 30, 2009.

Selling, General and Administrative: Selling, general and administrative expenses decreased by \$1,126,000 to \$1,630,000 for the year ended June 30, 2009 compared to \$2,756,000 for the year ended June 30, 2008. The decrease was due primarily to our decision to conserve cash and reduce expenses associated with public relations, travelling expenses and reduced administration service fees paid to Novogen.

Foreign exchange gains/(losses) are included in selling, general and administrative expenses and occur when revaluing cash denominated in foreign currencies and upon consolidation of our wholly owned subsidiary MEPL. MEPL uses U.S. dollars as its functional currency and also engages in transactions in foreign currencies. Further, MEPL's accounts and financial statements are denominated in Australian dollars. Translation of MEPL's financial statements into U.S. dollars did not have a material impact on our financial position. At June 30, 2009, we had not established a foreign currency hedging program. Net foreign exchange gains during the twelve months ended June 30, 2009 were \$242,000 compared with net exchange losses of \$255,000 during the twelve months ended June 30, 2008.

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

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

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

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

License Fees: Milestone license fees of \$1,000,000 have been expensed in the twelve months ended June 30, 2008 under the terms of the License Agreement for Triphendiol and NV-143. The second lump sum license fee of \$5,000,000 due under the terms of the Amended and Restated License Agreement was expensed in the twelve months ended June 30, 2007. This license fee was due on the later of November 1, 2003 or such later date when the cumulative total of all funds received from debt or equity issuances and revenue received from commercialization (income other than sales) and sales of phenoxodiol products exceeded \$50,000,000. Following the private placement or PIPE which closed in July 2006, the funds received from equity issuances exceeded \$50,000,000 which triggered this license fee payment.

Selling, General and Administrative: Selling, general and administrative expenses decreased by \$947,000 to \$2,756,000 for the year ended June 30, 2008 compared to \$3,703,000 for the year ended June 30, 2007. The decrease was due primarily to the cost of the share-based payment, valued at \$1,642,000, in fiscal 2007 for a commitment fee paid to YA Global Investments, LP (YA Global Investments, formerly Cornell Capital Partners,

LP) in connection with a Standby Equity Distribution Agreement (“SEDA”) entered into by us and YA Global Investments as of July 11, 2006. These savings were partially off set by increased costs for general corporate expenses including an increase in legal compliance costs, travel expenses, public relations and service fees paid to Novogen reflecting an increase in corporate and accounting services and insurance.

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

Off-Balance Sheet Arrangements

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

Contractual Obligations

For details of our contractual obligations at June 30, 2009 see Note 4 to the financial statements “Expenditure Commitments”.

Critical Accounting Estimates

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

Clinical Trials Expenses

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

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.

Clinical trial expenses of \$5,719,000 have been included in the financial statements for the year ended June 30, 2009, of which \$3,086,000 has been accrued at June 30, 2009. These estimates are based on the number of patients in each trial and the drug administration cycle.

Following the termination of enrolment into the OVATURE Phase III clinical trial, claims for clinical trial expenses have been received totalling \$2,224,000. Approximately \$1,181,000 has been accrued and is subject to continued negotiation and represents management’s best estimate of amounts that may be payable. Depending on the outcome of these negotiations, the actual costs may be different to the amount accrued in completing the financial statements.

The remaining balance of \$1,043,000 is currently being disputed as management believe the costs are outside the scope of the contracts and do not believe that these amounts are due and owing. These amounts are disclosed as a contingent liability in Note 10 to the financial statements “Contingent Liability”.

Stock Based Compensation

On December 9, 2008, we adopted the 2008 Stock Omnibus Equity Compensation Plan and cancelled the Marshall Edwards, Inc. Share Option Plan (the “Share Option Plan”). No options were issued under the Share Option Plan. The 2008 Stock Omnibus Equity Compensation Plan provides for the issuance of a maximum of 7,000,000 shares of common stock in connection with the grant of options and/or other stock-based or stock-

denominated awards to our non-employee directors, officers, employees and advisors. To date, we have issued options exercisable for 50,000 shares of common stock under the 2008 Stock Omnibus Equity Compensation Plan.

We account for stock based payments in accordance with SFAS No. 123R “Share-Based Payments”. The costs of these equity-settled transactions are determined using a binomial model to calculate the fair value at the date on which they are granted. With respect to the fair value of the 62,091 warrants representing 248,364 warrant shares issued August 6, 2007 to Blue Trading, LLC as part of a placement fee, the warrant representing 46,083 warrant shares issued to Mr. John O’Connor on July 30, 2008, in consideration for investor relations services rendered, and stock options representing 50,000 shares of common stock issued to Associate Professor Gil Mor of Yale University on January 28, 2009, in recognition of his contribution to the development of phenoxodiol under the 2008 Stock Omnibus Equity Compensation Plan, the following assumptions were used:

	<u>August 6, 2007</u>	<u>July 30, 2008</u>	<u>January 28, 2009</u>
Dividend yield	0%	0%	0%
Expected volatility	71%	81%	111%
Historical volatility	71%	81%	111%
Risk-free interest rate	4.13%	3.36%	1.70%
Expected life of warrant	5 years	5 years	5 years
Warrant fair value	\$1.78	\$1.41	\$0.50

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

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

Interest Rate Risk

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

We have cash reserves held primarily in U.S. and Australian dollars and we place funds on deposit with financial institutions and are generally at call.

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

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

We have no interest rate exposure due to rate changes for long-term debt.

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

Foreign Currency Risk

We conduct a portion of our business in various currencies, primarily in U.S. dollars and Australian dollars, Euros and British pounds. At June 30, 2009, we had not established a foreign currency hedging program. Net foreign exchange gains during the twelve months ended June 30, 2009 were \$242,000 compared with net exchange losses of \$255,000 during the twelve months ended June 30, 2008. Foreign exchange gains and losses occur upon consolidation of MEPL, which uses U.S. dollars as its functional currency and also engages in transactions in foreign currencies. MEPL’s accounts are denominated in Australian dollars. Translation of MEPL’s financial statements into U.S. dollars did not have a material impact on our financial position.

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

Item 8. Financial Statements and Supplementary Data

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

Report of BDO Kendalls Audit and Assurance (NSW-VIC) Pty Ltd Independent Registered Public Accounting Firm	38
Consolidated Balance Sheets	39
Consolidated Statements of Operations	40
Consolidated Statements of Cash Flows	41
Consolidated Statements of Stockholders' Equity	42
Notes to Consolidated Financial Statements	43



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Report of Independent Registered Public Accounting Firm

Board of Directors
Marshall Edwards, Inc.

We have audited the accompanying consolidated balance sheet of Marshall Edwards, Inc. (a development stage company) as of June 30, 2009 and 2008, and the related statements of operations, stockholders' equity, and cash flows for each of the years in the three year period ended June 30, 2009, and for the period from December 1, 2000 (inception) through June 30, 2009. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (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 audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Marshall Edwards, Inc. at June 30, 2009 and 2008, and the consolidated results of its operations and its cash flows for each of the years in the three year period ended June 30, 2009 and the period from December 1, 2000 (inception) through June 30, 2009, in conformity with accounting principles generally accepted in the United States of America.

BDO Kendalls Audit & Assurance (NSW-VIC) Pty Ltd

Sydney, NSW, Australia
August 27, 2009

BDO Kendalls is a national association
of separate partnerships and entities
Liability limited by a scheme approved
under Professional Standards Legislation.

MARSHALL EDWARDS, INC.
(A Development Stage Company)
CONSOLIDATED BALANCE SHEETS

	<u>June 30,</u> <u>2009</u>	<u>June 30,</u> <u>2008</u>
(In thousands, except share and per share data)		
ASSETS		
Current assets		
Cash and cash equivalents	\$ 19,067	\$ 19,743
Deferred Offering Costs	—	110
Prepaid expenses and other current assets	<u>289</u>	<u>125</u>
Total current assets	<u>19,356</u>	<u>19,978</u>
Total assets	<u><u>\$ 19,356</u></u>	<u><u>\$ 19,978</u></u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 736	\$ 1,130
Accrued expenses	3,186	1,884
Amount due to related company	<u>221</u>	<u>429</u>
Total current liabilities	4,143	3,443
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:		
73,463,233 at June 30, 2009 and 68,854,938 at June 30, 2008	—	—
Additional paid-in capital	78,124	68,266
Deficit accumulated during development stage	<u>(62,911)</u>	<u>(51,731)</u>
Total stockholders' equity	<u>15,213</u>	<u>16,535</u>
Total liabilities and stockholders' equity	<u><u>\$ 19,356</u></u>	<u><u>\$ 19,978</u></u>

See accompanying notes.

MARSHALL EDWARDS, INC.
(A Development Stage Company)
CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended June 30,			Period from December 1, 2000 (Inception) through June 30, 2009
	2009	2008	2007	
	(In thousands, except share and per share data)			
Revenues:				
Interest and other income	\$ 228	\$ 674	\$ 645	\$ 2,646
Total revenues	<u>228</u>	<u>674</u>	<u>645</u>	<u>2,646</u>
Operating expenses:				
Research and development	(7,777)	(9,325)	(5,761)	(33,043)
License fees	(2,000)	(1,000)	(5,000)	(20,000)
Selling, general and administrative	(1,630)	(2,756)	(3,703)	(12,507)
Total operating expenses	<u>(11,407)</u>	<u>(13,081)</u>	<u>(14,464)</u>	<u>(65,550)</u>
Loss from operations	(11,179)	(12,407)	(13,819)	(62,904)
Income tax expense	(1)	(3)	(1)	(7)
Net loss arising during development stage . .	<u>\$ (11,180)</u>	<u>\$ (12,410)</u>	<u>\$ (13,820)</u>	<u>\$(62,911)</u>
Net loss per common share:				
Basic and diluted	<u>\$ (0.15)</u>	<u>\$ (0.18)</u>	<u>\$ (0.22)</u>	
Weighted average common shares outstanding	<u>73,071,844</u>	<u>68,302,566</u>	<u>63,179,366</u>	

See accompanying notes.

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

	<u>Years Ended June 30,</u>			<u>Period from</u>
	<u>2009</u>	<u>2008</u>	<u>2007</u>	<u>December 1, 2000</u>
	(In thousands)			<u>(Inception) through</u>
				<u>June 30, 2009</u>
Operating activities				
Net loss arising during development stage	(11,180)	(12,410)	(13,820)	(62,911)
Adjustments to reconcile net loss to net cash used in operating activities:				
Share based payments	90	—	1,642	1,732
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets	(164)	(18)	139	(289)
Accounts payable	(394)	(67)	777	736
Accrued expenses	1,302	900	346	3,186
Amounts due to related company	<u>(208)</u>	<u>97</u>	<u>130</u>	<u>221</u>
Net cash used in operating activities	(10,554)	(11,498)	(10,786)	(57,325)
Financing activities				
Net proceeds from issuance of Common Stock	9,878	15,193	16,915	76,622
Deferred Offering Costs	<u>—</u>	<u>(110)</u>	<u>(25)</u>	<u>(230)</u>
Net cash used in financing activities	9,878	15,083	16,890	76,392
Net increase/(decrease) in cash and cash equivalents . . .	(676)	3,585	6,104	19,067
Cash and cash equivalents at beginning of period	<u>19,743</u>	<u>16,158</u>	<u>10,054</u>	<u>—</u>
Cash and cash equivalents at end of period	<u>19,067</u>	<u>19,743</u>	<u>16,158</u>	<u>19,067</u>
Income taxes paid	<u>(1)</u>	<u>(3)</u>	<u>(1)</u>	<u>(7)</u>

See accompanying notes.

MARSHALL EDWARDS, INC.
(A Development Stage Company)
CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

	Common Stock (shares)	Additional paid in capital	Deficit Accumulated During Development Stage	Accumulated Other Comprehensive Income/(Loss)	Total
	(In thousands, except share data)				
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)	<u>2,523,000</u>	<u>9,022</u>			<u>9,022</u>
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	<u>31</u>
Comprehensive Loss					(3,002)
Common Stock issued June 26, 2003	<u>9,000</u>	<u>36</u>			<u>36</u>
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)	<u>(31)</u>
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)	<u>2,392,000</u>	<u>15,522</u>			<u>15,522</u>
Balance at June 30, 2004	56,938,000	34,636	(11,694)	—	22,942
Net loss arising during development stage . .			(6,421)		<u>(6,421)</u>
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)		<u>(7,386)</u>
Comprehensive Loss					(7,386)
Balance at June 30, 2006	56,938,000	34,636	(25,501)	—	9,135
Net loss arising during development stage . .			(13,820)		<u>(13,820)</u>
Comprehensive Loss					(13,820)
Common Stock issued July 11, 2006	6,329,311	16,820			16,820
Shares issued as share-based payment (refer Note 7)	123,626	443			443
Warrants issued as share-based payment (refer Note 7)		<u>1,199</u>			<u>1,199</u>
Balance at June 30, 2007	63,390,937	53,098	(39,321)	—	13,777
Net loss arising during development stage . .			(12,410)		<u>(12,410)</u>
Comprehensive Loss					(12,410)
Common Stock issued August 6, 2007	5,464,001	14,727			14,727
Warrants issued as share-based payment (refer Note 7)		<u>441</u>			<u>441</u>
Balance at June 30, 2008	68,854,938	68,266	(51,731)	—	16,535
Net loss arising during development stage . .			(11,180)		<u>(11,180)</u>
Comprehensive Loss					(11,180)
Common Stock issued July 31, 2008	4,608,295	9,768			9,768
Warrants issued as share-based payment (refer Note 7)		<u>90</u>			<u>90</u>
Balance at June 30, 2009	<u>73,463,233</u>	<u>\$78,124</u>	<u>\$(62,911)</u>	<u>\$ —</u>	<u>\$ 15,213</u>

See accompanying notes.

MARSHALL EDWARDS, INC.
(A Development Stage Company)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
June 30, 2009

1. Summary of Significant Accounting Policies

Principles of Consolidation

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

Estimates

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

Revenue Recognition

Interest

The only revenue earned by the Company to date is interest on cash balances, which is recognized on an accruals basis.

Cash and Cash Equivalents and Short Term Investments

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

Income Taxes

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

Effective July 1, 2007, the Company adopted Financial Accounting Standards Interpretation 48 (FIN 48), “Accounting for Uncertainty in Income Taxes — an interpretation of FASB No 109”. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of uncertain tax positions taken or expected to be taken in a company’s income tax return, and also provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN 48 utilizes a two step approach for evaluating uncertain tax positions accounted for in accordance with SFAS No. 109, “Accounting for Income Taxes” (SFAS 109). Step one, recognition, requires a company to determine if the weight of available evidence indicates that a tax position is more likely than not to be sustained upon audit, including resolution of related appeals or litigation processes, if any. Step two, measurement, is based on the largest amount of benefit, which is more likely than not to be realized upon ultimate settlement. The cumulative effect of adopting FIN 48 on July 1, 2007 is recognized as a change in accounting principle, recorded as an adjustment to the opening balance of accumulated deficit on the adoption date. As a result of the implementation of FIN 48, the Company did not recognise any increase or decrease in the liability for unrecognized tax benefits related to tax

MARSHALL EDWARDS, INC.
(A Development Stage Company)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

positions taken in prior periods, therefore, there was no corresponding adjustment in accumulated deficit. Additionally, FIN 48 specifies that tax positions for which the timing of the ultimate resolution is uncertain should be recognized as long term liabilities. The Company's total amount of net tax losses carried forward as of July 1, 2008 adoption date was \$64 million.

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

Fair Value of Financial Instruments

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

Foreign Currency Translation

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

Translation of MEPL's financial statements into U.S. dollars does not have a material impact on the Company's financial position.

Research and Development Expenses

Research and development expenses relate primarily to the cost of conducting human clinical and pre-clinical trials of the licensed cancer compounds. Research and development costs are charged to earnings in the period incurred.

Clinical development costs are a significant component of research and development 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 statements.

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.

Clinical trial expenses of \$5,719,000 have been included in the financial statements for the year ended June 30, 2009, of which \$3,086,000 has been accrued at June 30, 2009. These estimates are based on the number of patients in each trial and the drug administration cycle.

Following the termination of enrolment into the OVATURE Phase III clinical trial, claims for clinical trial expenses have been received totalling \$2,224,000. Approximately \$1,181,000 has been accrued and is subject to continued negotiation and represents management's best estimate of amounts that may be payable. Depending on the outcome of these negotiations, the actual costs may be different to the amount accrued in completing the financial statements.

The remaining balance of \$1,043,000 is currently being disputed as management believe the costs are outside the scope of the contracts and do not believe that these amounts are due and owing. These amounts are disclosed as a contingent liability in Note 10 to the financial statements.

MARSHALL EDWARDS, INC.
(A Development Stage Company)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

License Fees

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

Stock-Based Compensation

The Company's 2008 Stock Omnibus Equity Compensation 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. In January 2009, 50,000 options were issued to a consultant for consulting services provided to the Company.

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

We account for stock based payments in accordance with SFAS No. 123R "Share-Based Payments". The costs of these equity-settled transactions are determined using a binomial model to calculate the fair value at the date on which they are granted. With respect to the fair value of the 62,091 warrants representing 248,364 warrant shares issued August 6, 2007 to Blue Trading, LLC as part of a placement fee, the warrant representing 46,083 warrant shares issued to Mr. John O'Connor on July 30, 2008, in consideration for investor relations services rendered, and stock options representing 50,000 shares of common stock issued to Associate Professor Gil Mor of Yale University on January 28, 2009, in recognition of his contribution to the development of phenoxodiol under the 2008 Stock Omnibus Equity Compensation Plan, the following assumptions were used:

	<u>August 6, 2007</u>	<u>July 30, 2008</u>	<u>January 28, 2009</u>
Dividend yield	0%	0%	0%
Expected volatility	71%	81%	111%
Historical volatility	71%	81%	111%
Risk-free interest rate	4.13%	3.36%	1.70%
Expected life of warrant	5 years	5 years	5 years
Warrant fair value	\$1.78	\$1.41	\$0.50

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

Basic and Diluted Loss Per Share

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

Stockholders' Equity

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

MARSHALL EDWARDS, INC.
(A Development Stage Company)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Deferred Offering Costs

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

Recent Accounting Standards

In November 2008, the Securities and Exchange Commission (SEC) released a proposed roadmap regarding the potential use by U.S. issuers of financial statements prepared in accordance with International Financial Reporting Standards (IFRS). IFRS is a comprehensive series of accounting standards published by the International Accounting Standards Board. Under the proposed roadmap, the Company may be required to prepare financial statements in accordance with IFRS as early as fiscal 2015. The SEC will make a determination in 2011 regarding the mandatory adoption of IFRS. The Company is currently assessing the impact that this potential change would have on its consolidated financial statements.

In March 2008, the FASB issued SFAS No. 161, “Disclosures about Derivative Instruments and Hedging Activities — An Amendment of FASB Statement No. 133” (or SFAS 161). SFAS 161 became effective on January 1, 2009. This statement revises the requirements for the disclosure of derivative instruments and hedging activities that include the reasons a company uses derivative instruments, how derivative instruments and related hedged items are accounted for under SFAS 133 and how derivative instruments and related hedged items affect a company’s financial position, financial performance and cash flows. The implementation of SFAS 161 was not material to the Company’s consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), “Business Combinations” (or SFAS 141(R)) which is a revision of SFAS 141. SFAS 141(R) requires an acquirer in a business combination to measure all assets acquired, the liabilities assumed and any non-controlling interest in the acquiree at their fair values on the date of acquisition with limited exceptions. This statement also requires the acquirer in a business combination achieved in stages to recognize the identifiable assets and liabilities, as well as the non-controlling interest in the acquiree, at the full amounts of their fair values. SFAS 141(R) will further require that acquired in-process research and development (or IPR&D) as of the acquisition date be capitalized at fair value. Assets acquired and liabilities assumed arising from contingencies at the acquisition date are to be measured at their fair value and acquisition costs generally will be expensed as incurred. This statement is effective for years beginning after January 1, 2009. This statement will affect the Company’s accounting for any future acquisitions.

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

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

In September 2006, the FASB issued SFAS No. 157 (or SFAS 157), “Fair Value Measurements” which the Company adopted as of the beginning of fiscal 2009. This pronouncement defines fair value, establishes a

MARSHALL EDWARDS, INC.
(A Development Stage Company)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

framework for measuring fair value and expands disclosures about fair value measurements. The implementation of SFAS 157 was not material to the Company's consolidated financial statements.

In February 2008, the FASB issued FSP FAS 157-2 which delays the effective date of SFAS 157 for all non-financial assets and non-financial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). This FSP partially defers the effective date of SFAS 157 to the beginning of fiscal 2010, and interim periods within those fiscal years for items within the scope of this FSP. The Company is currently evaluating the impact of adopting FSP FAS 157-2 and does not anticipate a material effect.

In October 2008, the FASB issued FSP 157-3, "Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active." FSP 157-3 clarifies the application of SFAS 157 in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. FSP 157-3 was effective upon issuance, including prior periods for which financial statements have not been issued. The Company's adoption of FSP 157-3 did not have a material effect on the Company's consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159 (or SFAS 159), "The Fair Value Option for Financial Assets and Financial Liabilities" which permits an entity to measure certain financial assets and financial liabilities at fair value. The purpose of SFAS 159 is to improve financial reporting by allowing entities to mitigate volatility in reported earnings caused by the measurement of related assets and liabilities using different attributes, without having to apply complex hedge accounting provisions. Under SFAS 159, entities that elect the fair value option (by instrument) will report unrealized gains and losses in earnings at each subsequent reporting date. The fair value option election is irrevocable, unless a new election date occurs. SFAS 159 establishes presentation and disclosure requirements to help financial statement users understand the effect of the entity's election on its earnings, but does not eliminate disclosure requirements of other accounting standards. Assets and liabilities that are measured at fair value must be displayed on the face of the balance sheet. SFAS 159 became effective as of the beginning of fiscal 2009. The Company chose not to elect the fair value option for its financial instruments other than those already measured at fair value in accordance with SFAS 157. As a result, the adoption of this Statement did not have an impact on the Company's consolidated financial statements.

In June 2008, the FASB issued FASB Staff Position EITF 03-6-1, "Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities" (or FSP EITF 03-6-1). FSP EITF 03-6-1 addresses whether instruments granted in share-based payment transactions are participating securities prior to vesting, and therefore need to be included in the computation of earnings per share under the two-class method as described in SFAS No. 128, "Earnings per Share." Under the guidance in FSP EITF 03-6-1, unvested share-based payment awards that contain non-forfeitable rights to dividends or dividend equivalents (whether paid or unpaid) are participating securities and need to be included in the computation of earnings per share pursuant to the two-class method. FSP EITF 03-6-1 is effective as of the beginning of fiscal 2010. The Company is currently evaluating the impact of adopting FSP EITF 03-6-1.

2. Income Taxes

Loss from operations consists of the following jurisdictions:

	Year Ended June 30,		
	2009	2008	2007
	(In thousands \$)		
Domestic	(452)	(448)	(1,928)
Foreign	(10,727)	(11,959)	(11,891)
	(11,179)	(12,407)	(13,819)

MARSHALL EDWARDS, INC.

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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,					
	2009		2008		2007	
	(In thousands \$)	%	(In thousands \$)	%	(In thousands \$)	%
Tax at US statutory rates	3,801	34	4,342	35	4,837	35
Australian tax	(429)	(4)	(598)	(5)	(595)	(5)
R&D Tax concession	504	5	666	5	121	1
Change in valuation allowance	<u>(3,877)</u>	<u>(35)</u>	<u>(4,413)</u>	<u>(35)</u>	<u>(4,364)</u>	<u>(31)</u>
	<u>(1)</u>	<u>—</u>	<u>(3)</u>	<u>—</u>	<u>(1)</u>	<u>—</u>

Deferred tax liabilities and assets are comprised of the following:

	Year Ended June 30,	
	2009	2008
	(In thousands \$)	
Deferred tax liabilities		
Unrealised Foreign Exchange Gain	<u>(74)</u>	<u>(13)</u>
Total deferred tax liabilities	(74)	(13)
Deferred tax assets		
Tax carried forward losses	19,550	19,160
Share based payments	605	574
Unrealised Foreign Exchange Loss	0	89
Consultant and other accruals	<u>939</u>	<u>510</u>
Total deferred tax assets	21,094	20,333
Valuation allowance for deferred tax assets	<u>(21,020)</u>	<u>(20,320)</u>
Net deferred tax assets and liabilities	<u>—</u>	<u>—</u>

Management evaluates the recoverability of the deferred tax asset and the amount of the required valuation allowance. Due to the uncertainty surrounding the realization of the tax deductions in future tax returns, the Company has recorded a valuation allowance against its net deferred tax asset at June 30, 2009 and 2008. 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, 2009 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 \$2, 272,000 at June 30, 2009. The federal net operating losses will begin to expire in 2022.

Foreign tax losses of approximately \$62,590,000 at June 30, 2009, may be carried forward indefinitely.

MARSHALL EDWARDS, INC.
(A Development Stage Company)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

3. Loss Per Share

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

	Years Ended June 30,		
	2009	2008	2007
	(In thousands, except share data)		
Numerator			
Net loss arising during development stage	(11,180)	(12,410)	(13,820)
Numerator for diluted earnings per share	<u>\$ (11,180)</u>	<u>\$ (12,410)</u>	<u>\$ (13,820)</u>
Denominator			
Denominator for basic earnings per share -			
Weighted average number of shares used in computing net loss per share, basic and diluted	73,071,844	68,302,566	63,179,366
Effect of dilutive securities	—	—	—
Dilutive potential common shares	<u>73,071,844</u>	<u>68,302,566</u>	<u>63,179,366</u>
Basic and Diluted net loss per share	\$ (0.15)	\$ (0.18)	\$ (0.22)

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,		
	2009	2008	2007
	(Number of warrant shares)		
Warrants exercisable prior to July 11, 2010 at an exercise price of \$4.35	2,815,258	2,815,258	2,815,258
Warrants exercisable prior to August 6, 2012 at an exercise price of \$3.60	2,185,598	2,185,598	—
Warrants exercisable prior to August 6, 2012 at an exercise price of \$3.00	248,364	248,364	—
Warrants exercisable prior to July 30, 2013 at an exercise price of \$2.17	46,083	—	—
Warrants exercisable prior to January 28, 2014 at an exercise price of \$0.63	<u>50,000</u>	<u>—</u>	<u>—</u>
Common shares issuable upon exercise of outstanding warrants	<u>5,345,303</u>	<u>5,249,220</u>	<u>2,815,258</u>

During July 2008, the Company issued 4,608,295 shares of common stock in connection with a registered direct offering. For further details see Note 7 "Equity".

MARSHALL EDWARDS, INC.

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

4. Expenditure Commitments and Contingencies

At June, 30, 2009, the Company had contractual obligations for the conduct of clinical trials, pre-clinical research and development and manufacturing process development of approximately \$1,423,000. 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:

<u>Contractual Obligations</u>	<u>Total</u>	<u>Payment Due by Period</u>			
		<u>Less Than 1 Year</u>	<u>1 — 3 Years</u>	<u>3 — 5 Years</u>	<u>More Than 5 Years</u>
		(In thousands)			
Purchase Obligations	<u>\$1,423</u>	<u>\$816</u>	<u>\$344</u>	<u>\$263</u>	<u>\$—</u>
Total	<u>\$1,423</u>	<u>\$816</u>	<u>\$344</u>	<u>\$263</u>	<u>\$—</u>

No amounts have been included for future payments to Novogen which may arise in connection with the Phenoxodiol License Agreement, the License Agreement for Triphendiol and NV-143, the Services Agreement or the Manufacturing License and Supply Agreement as future payments under the terms of the agreements are subject to termination provisions. The terms of the agreements, including future payments, are detailed in Note 6 “Related Party Transactions.”

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

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

Pursuant to the terms of a Guarantee and Indemnity Agreement, the Company has guaranteed the payment and performance of the obligations of MEPL to Novogen and its subsidiaries, Novogen Laboratories Pty Limited and Novogen Research Pty Limited, under the Phenoxodiol License Agreement, the Manufacturing License and Supply Agreement and the Services Agreement. Novogen has guaranteed the performance of the obligations of Novogen Research Pty Limited under the Phenoxodiol License Agreement and the obligations of Novogen Laboratories Pty Limited under the Manufacturing License and Supply Agreement to MEPL. Each of the Company and Novogen’s obligations in the Guarantee and Indemnity Agreement are absolute, unconditional and irrevocable.

Due to the termination of enrolment into the OVATURE Phase III clinical trial, commitments have reduced from \$17.7 million at June 30, 2008 to \$1.4 million for the year ended June 30, 2009.

MARSHALL EDWARDS, INC.
(A Development Stage Company)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

5. Segment Information

The Company's focus is the clinical development and commercialization of its licensed cancer compounds. The business contains two major segments based on geographic location.

	Year Ended June 30,								
	2009			2008			2007		
	USA	Australia	Total	USA	Australia	Total	USA	Australia	Total
	(In thousands)								
Statement of Operations									
Interest Revenue	207	21	228	606	68	674	505	140	645
Loss from operations	(452)	(10,727)	(11,179)	(448)	(11,959)	(12,407)	(1,928)	(11,891)	(13,819)
Income Tax Expense	(1)	—	(1)	(3)	—	(3)	(1)	—	(1)
Net loss arising during development stage	(453)	(10,727)	(11,180)	(451)	(11,959)	(12,410)	(1,929)	(11,891)	(13,820)
Balance Sheet									
Segment assets	74,318	3,153	77,471	65,149	3,131	68,280	50,231	1,399	51,630
Elimination of investment in subsidiary	(58,115)	—	(58,115)	(48,302)	—	(48,302)	(35,340)	—	(35,340)
Consolidated Assets	<u>\$ 16,203</u>	<u>\$ 3,153</u>	<u>\$ 19,356</u>	<u>\$ 16,847</u>	<u>\$ 3,131</u>	<u>\$ 19,978</u>	<u>\$ 14,891</u>	<u>\$ 1,399</u>	<u>\$ 16,290</u>
Segment liabilities	<u>\$ 77</u>	<u>\$ 4,066</u>	<u>\$ 4,143</u>	<u>\$ 312</u>	<u>\$ 3,131</u>	<u>\$ 3,443</u>	<u>\$ 110</u>	<u>\$ 2,403</u>	<u>\$ 2,513</u>

6. Related Party Transactions

License Agreement for Phenoxodiol

In September 2003, the Company entered into a license agreement pursuant to which Novogen granted to MEPL a worldwide non-transferable license under its patents and patent applications and in its know-how to conduct clinical trials and commercialize and distribute phenoxodiol products. The license agreement covers uses of phenoxodiol in the field of prevention, treatment or cure of cancer in humans delivered in all forms except topical applications. The license is exclusive until the expiration or lapsing of the last relevant Novogen patents or patent applications in the world and thereafter is non-exclusive. MEPL may terminate the agreement by giving three months' notice to Novogen. MEPL paid \$5,000,000 to Novogen in February 2004 which was the first lump sum license fee payment due under the terms of the license agreement. Also, MEPL paid \$2,000,000 to Novogen in January 2005 and \$4,000,000 in January 2006 which was the annual milestone license fee payments due under the license agreement. The Company paid a second lump sum license fee of \$5,000,000 to Novogen in July 2006 following the raising of funds in a private placement. This license fee was due on the later of November 1, 2003 or such later date when the cumulative total of all funds received from debt or equity issuances and revenue received from commercialization (income other than sales) and sales of phenoxodiol products exceeded \$50,000,000. Following the private placement or PIPE which closed on July 11, 2006 the funds received from equity issuances exceeded \$50,000,000 which triggered this license fee payment. Future amounts payable to Novogen under terms of the license agreement are as follows:

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

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 license agreement with Novogen; or

MARSHALL EDWARDS, INC.

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

(b) the date of expiration or lapsing of the last licensed patent right which MEPL would, but for the license granted in the license agreement, infringe in any country in the geographical territory covered by the license agreement by doing in that country any of the things set out in the license agreement.

2. In addition to the amounts above, the Phenoxodiol License Agreement was amended in June 2006 and April 2007 to provide that upon the earliest receipt by MEPL of the first:

(i) approval by the U.S. Food and Drug Administration (the “FDA”) of a New Drug Application (“NDA”) for phenoxodiol;

(ii) approval or authorization of any kind to market phenoxodiol in the U.S.; or

(iii) approval or authorization of any kind by a government agency in any other country to market phenoxodiol.

MEPL will be required to pay Novogen Research Pty Limited \$8,000,000, together with interest on such amount from (and including) December 31, 2006 to (but excluding) the Approval Date. Thereafter, MEPL will be required to make license milestone fee payments of \$8,000,000 to Novogen Research Pty Limited on December 31 of the year of the Approval Date and on December 31 of each year thereafter during the exclusivity period under the Phenoxodiol License Agreement.

No license fees have been accrued in respect of phenoxodiol at June 30, 2009.

License Agreement Triphendiol and NV-143

In May 2006, the Company entered into a second license agreement with Novogen for two oncology compounds, triphendiol and NV-143 (the “License Agreement for Triphendiol and NV-143”). Triphendiol is being developed initially in oral form for the treatment of pancreatic and bile duct cancer and is currently in Phase I human testing. NV-143 is targeted for the treatment of melanoma, also in oral dose form, and is in the pre-clinical testing stage. The License Agreement for Triphendiol and NV-143 is an agreement under which Novogen grants to MEPL a worldwide non-transferable license under its patents and patent applications and in its know-how to conduct clinical trials and commercialize and distribute triphendiol and NV-143 products. The License Agreement for Triphendiol and NV-143 covers uses of triphendiol and NV-143 in the field of prevention, treatment or cure of cancer in humans delivered in all forms except topical applications. The license is exclusive until the expiration or lapsing of the last relevant Novogen patents or patent applications in the world and thereafter is non-exclusive. MEPL may terminate the agreement by giving three months notice to Novogen. The Company is required to make payments under the terms of the License Agreement for Triphendiol and NV-143 with Novogen as follows:

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

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

a) the first license product containing triphendiol to reach a milestone as set forth below; and

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

The milestone license fees are:

i) \$1,000,000 on the date an investigational new drug application (“IND”) for the licensed product goes into effect or the equivalent approval of a government agency is obtained in another country. If this

MARSHALL EDWARDS, INC.

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

event does not occur before March 31, 2008 then this amount will be due on this date. The amount of \$1,000,000 was paid to Novogen on March 31, 2008 under the terms of this agreement;

ii) \$2,000,000 on the date of enrollment of the first clinical trial subject in a Phase II clinical trial of the licensed product. If this event does not occur before June 30, 2009, then this amount will be due on this date. The amount of \$2,000,000 was paid to Novogen on June 30, 2009 under the terms of this agreement;

iii) \$3,000,000 on the date of enrollment of the first clinical trial subject in a Phase III clinical trial of the licensed product. If this event does not occur before December 31, 2011, then this amount will be due on this date; and

iv) \$8,000,000 on the date of first receipt of a NDA for the licensed product from the FDA or equivalent approval from a government agency in another country. If this event does not occur before December 31, 2013, then this amount will be due on this date.

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

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

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

Amended and Restated License Option Deed

On September 24, 2003, MEPL and Novogen entered into an Amended and Restated License Option Deed (the "License Option Deed"). The License Option Deed grants MEPL an exclusive right to accept and an exclusive right to match any proposed dealing by Novogen of its intellectual property rights with a third party relating to synthetic compounds (other than phenoxodiol) that have known or potential applications in the field of prevention, treatment or cure of cancer in humans in all forms other than topical applications.

Amended and Restated Services Agreement

On September 24, 2003, the Company, Novogen and MEPL entered into an Amended and Restated Services Agreement (the "Services Agreement"). The Company does not currently intend to directly employ any staff. Under the terms of the Services Agreement, Novogen Limited or its subsidiaries have agreed to provide services reasonably required by the Company relating to the development and commercialization of phenoxodiol and other licensed products, including triphendiol and NV-143. Novogen has agreed to provide these services at cost plus a 10% mark-up. The Company may terminate the agreement on three months written notice to Novogen.

Transactions giving rise to expenditures amounting to \$2,264,000, \$3,054,000 and \$1,963,000, were made under the Services Agreement with Novogen during the twelve months ended June 30, 2009, 2008 and 2007 respectively. Of these amounts, \$1,456,000, \$2,065,000 and \$1,145,000 related to service fees paid to Novogen for research and development services provided in the twelve months ended June 30, 2009, 2008 and 2007 respectively, reflecting the time spent by Novogen research staff on the development of phenoxodiol, triphendiol and NV-143. Additionally, \$808,000, \$989,000 and \$818,000 of the total expenditures during the twelve months ended June 30, 2009, 2008 and 2007, respectively, related to costs incurred for administration and accounting services provided by Novogen.

MARSHALL EDWARDS, INC.
(A Development Stage Company)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

At June 30, 2009 and 2008, \$221,000 and \$429,000, respectively, was due and owing to Novogen under the services agreement and is included in amounts due to related company.

Amended and Restated Manufacturing License and Supply Agreement

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

Transactions giving rise to expenditures amounting to \$nil, \$38,000 and \$153,000 were made under the Manufacturing License and Supply Agreement with Novogen during the twelve months ended June 30, 2009, 2008 and 2007, respectively.

At June 30, 2009 and June 30, 2008 no amount was due and owing to Novogen under the Manufacturing License and Supply Agreement.

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

7. Equity

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

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

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

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

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

In connection with the December 2003 offering, the Company's common stock and warrants commenced trading separately on the NASDAQ Global Market. The Company received proceeds of \$15,522,000, net of \$2,431,000 transaction costs in the December 2003 offering.

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

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

MARSHALL EDWARDS, INC.

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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

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

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

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

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

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

The Company entered into a registration rights agreement with the investors party to the securities subscription agreement and Blue Trading, LLC, and agreed to file a resale registration statement with the SEC registering the

MARSHALL EDWARDS, INC.
(A Development Stage Company)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

common stock and the common stock issuable upon exercise of the warrants sold pursuant to the securities subscription agreement for resale thereunder. The Company filed the registration statement on October 2, 2007. The resale registration statement was declared effective October 19, 2007.

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

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

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

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

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

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

In January 2009, the Company issued 50,000 stock options to Associate Professor Gil Mor of Yale University, in recognition of his contribution to the development of phenoxodiol under the Marshall Edwards, Inc. 2008 Omnibus Equity Compensation Plan. The options have an exercise price of \$0.63 and may be exercised immediately and expire five years from the date of issuance on January 28, 2014.

MARSHALL EDWARDS, INC.
(A Development Stage Company)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

8. Significant Events After Balance Date

License Agreement for NV-128

On August 4, 2009, the Company, through MEPL, entered into a license agreement with Novogen pursuant to which Novogen granted to MEPL an exclusive, worldwide, non-transferable license under its patents and patent applications and in the intellectual property rights related to its know how to conduct clinical trials, commercialize and distribute NV-128. NV-128 is an investigational cancer compound which has been shown in pre-clinical laboratory studies to promote cancer cell death by targeting the specific protein regulatory pathway (i.e., AKT-mTOR pathway) in ovarian cancer cells that have become resistant to many drugs used to kill cancer cells. The license agreement covers the use of NV-128 in the field of prevention, treatment and cure of cancer in humans delivered in all forms except topical applications. The license agreement remains in effect until (i) the expiration or lapsing of the last relevant patents or patent applications in the world or (ii) Novogen's assignment to MEPL of the last relevant patents or patent applications in the world so that MEPL may assume the filing, prosecution and maintenance of such patents or patent applications. Thereafter, the license becomes a non-exclusive, perpetual and irrevocable license covering any remaining intellectual property rights related to the know how with respect to NV-128. MEPL may terminate the license by giving three months notice to Novogen.

1. The Company paid U.S. \$1,500,000 to Novogen Research in August 2009, which was the first lump sum license fee payment under the terms of the license agreement.

2. Future amounts payable to Novogen upon the achievement of certain milestones are as follows:

i) \$1,000,000 on the date an investigational new drug application ("IND") for the licensed product goes into effect or the equivalent approval of a government agency is obtained in another country. If this event does not occur before December 31, 2011 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 licensed product. If this event does not occur before December 31, 2012, then this amount will be due on this date;

iii) \$3,000,000 on the date of enrollment of the first clinical trial subject in a Phase III clinical trial of the licensed product. If this event does not occur before December 31, 2014, then this amount will be due on this date; and

iv) \$8,000,000 on the date of first receipt of a NDA for the licensed product from the FDA or equivalent approval from a government agency in another country. If this event does not occur before December 31, 2017, then this amount will be due on this date.

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

The license agreement is able to be cancelled without penalty by MEPL by giving three months notice.

The subsequent event information has been evaluated up to August 27, 2009.

MARSHALL EDWARDS, INC.

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

9. Quarterly Financial Data (Unaudited)

<u>2009 for the Quarter Ended</u>	<u>Jun-30</u>	<u>Mar-31</u>	<u>Dec-31</u>	<u>Sep-30</u>	<u>Year</u>
	(In thousands except per share data)				
Revenue	27	29	76	96	228
Loss from operations	(5,425)	(1,904)	(1,599)	(2,251)	(11,179)
Net Loss arising during development stage	(5,425)	(1,904)	(1,599)	(2,252)	(11,180)
Basic and diluted loss per share	(0.07)	(0.03)	(0.02)	(0.03)	(0.15)
<u>2008 for the Quarter Ended</u>	<u>Jun-30</u>	<u>Mar-31</u>	<u>Dec-31</u>	<u>Sep-30</u>	<u>Year</u>
	(In thousands except per share data)				
Revenue	92	149	215	218	674
Loss from operations	(3,401)	(3,331)	(2,310)	(3,365)	(12,407)
Net Loss arising during development stage	(3,401)	(3,332)	(2,311)	(3,366)	(12,410)
Basic and diluted loss per share	(0.05)	(0.05)	(0.03)	(0.05)	(0.18)

10. Contingent Liabilities

The Company has received claims in connection with the termination of enrollment into the OVATURE Phase III clinical trial, amounting to \$1,043,000. The Company has disputed these claims as it believes that they are outside the scope of the contracts and it does not believe that these amounts are due and owing.

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

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

None.

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

(a) *Disclosure Controls and Procedures*

At the end of the period covered by this Annual Report on Form 10-K, the Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the Company's disclosure controls and procedures. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Act is accumulated and communicated to the issuer's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Based on that evaluation, the Company's Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures are effective to ensure that the information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

A control system no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within the Company are detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met and, as set forth above, our Chief Executive Officer and Chief Financial Officer have concluded, based on their evaluation as of the end of the period covered by this Annual Report on Form 10-K, that our disclosure controls and procedures were sufficiently effective to provide reasonable assurance that the objectives of our disclosure control system were met.

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

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

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

Management assessed the effectiveness of the Company's internal control over financial reporting as of June 30, 2009 based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework. Based on this assessment, management believes that the Company's internal control over financial reporting is effective as of June 30, 2009.

This Annual Report on Form 10-K does not include an attestation report of the Company's independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's independent registered public accounting firm pursuant to temporary rules of the SEC that permit the Company to provide only Management's Report in this Annual Report on Form 10-K.

(c) *Changes in Internal Controls*

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

Item 9B. *Other Information*

Not applicable

PART III

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

Code of Ethics

We have adopted a Code of Business and Ethics policy that applies to our directors and employees (including our principal executive officer and our principal financial officer), and have posted the text of our policy on our website (www.marshalledwardsinc.com). 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, 2009 (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*

The information required by this item is included in Part II Item 5 of this Annual Report on Form 10-K and 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(15)
- 4.1 Specimen Stock Certificate(3)
- 4.2 Specimen Warrant Certificate(4)
- 4.3 Specimen Warrant Certificate(22)
- 4.4 Form of Warrant Agreement(5)
- 4.5 Warrant Agreement(16)
- 4.6 Amended and Restated Warrant Agreement(19)
- 4.7 Form of Warrant(6)
- 4.8 Form of Warrant(17)
- 4.9 Form of Warrant(21)
- 4.10 Warrant dated July 30, 2008 issued to Mr John O'Connor(23)
- 10.1 Amended and Restated License Agreement between Novogen Research Pty Limited and Marshall Edwards Pty Limited(7)
- 10.2 Amended and Restated Manufacturing License and Supply Agreement between Novogen Laboratories Pty Limited and Marshall Edwards Pty Limited(12)
- 10.3 Amended and Restated License Option Deed between Novogen Research Pty Limited and Marshall Edwards Pty Limited(9)
- 10.4 Amended and Restated Services Agreement among Novogen Limited, Marshall Edwards, Inc. and Marshall Edwards Pty Limited(10)
- 10.5 Guarantee and Indemnity among Marshall Edwards, Inc., Novogen Laboratories Pty Limited, Novogen Research Pty Limited and Novogen Limited(11)
- 10.6 License Agreement between Novogen Research Pty Limited and Marshall Edwards Pty Limited(12)
- 10.7 Amendment Deed between Novogen Research Pty Limited and Marshall Edwards Pty Limited(13)
- 10.8 Registration Rights Agreement, dated July 11, 2006 by and among Marshall Edwards, Inc. and the investors as signatories thereto(14)
- 10.9 Registration Rights Agreement, dated as of August 6, 2007 by and among Marshall Edwards, Inc. and the purchases signatory thereto(18)
- 10.10 Registration Rights Agreement, dated as of September 26, 2007 by and among Marshall Edwards, Inc. and Blue Trading, LLC(20)
- 10.11 Securities Subscription Agreement dated as of July 28, 2008 by and among Marshall Edwards, Inc., Novogen Limited and OppenheimerFunds, Inc.(24)
- 10.12 Marshall Edwards, Inc. 2008 Stock Omnibus Equity Compensation Plan(25)
- 10.13 License Agreement dated August 4, 2009 by and between Novogen Research Pty Limited and Marshall Edwards Pty Limited(26)
- 21.1 Subsidiaries of Marshall Edwards, Inc.(2)
- 23.1 Consent of BDO Kendalls Audit and Assurance (NSW — VIC) Pty Ltd*
- 31.1 Certification required by Rule 13a-14(a) or Rule 15d-14(a)*
- 31.2 Certification required by Rule 13a-14(a) or Rule 15d-14(a)*
- 32.1 Certification required by Rule 13a-14(b) or Rule 15d-14(b) and section 1350 of Chapter 63 of Title 18 of the U.S. Code (18 U.S.C. 1350)*

* Filed herewith.

- (1) Incorporated by reference to Exhibit 3.1 to Registrant's Registration Statement on Form S-1 filed on September 25, 2003 (Reg. No. 333-109129).
- (2) Incorporated by reference to Exhibit 21 to Registrant's Registration Statement on Form S-1 filed on September 25, 2003 (Reg. No. 333-109129).

- (3) Incorporated by reference to Exhibit 4.1 to Registrant's Registration Statement on Form S-1 filed on October 31, 2003 (Reg. No. 333-109129).
- (4) 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).
- (5) Incorporated by reference to Exhibit 10.3 to Registrant's Current Report on Form 8-K filed on July 12, 2006.
- (6) Incorporated by reference to Exhibit 10.4 to Registrant's Current Report on Form 8-K filed on July 12, 2006.
- (7) 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).
- (8) 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).
- (9) 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).
- (10) 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).
- (11) 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).
- (12) Incorporated by reference to Exhibit 99.1 to Registrant's Current Report on Form 8-K filed on May 16, 2006.
- (13) Incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K filed on June 9, 2006
- (14) Incorporated by reference to Exhibit 10.2 to Registrant's Current Report on Form 8-K filed on July 12, 2006.
- (15) Incorporated by reference to Exhibit 3.1 to Registrant's Current Report on Form 8-K filed on July 30, 2007.
- (16) Incorporated by reference to Exhibit 10.3 to Registrant's Current Report on Form 8-K filed on August 6, 2007.
- (17) Incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K filed on August 6, 2007.
- (18) Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on August 6, 2007.
- (19) Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K/A filed on September 27, 2007.
- (20) Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K/A filed on September 27, 2007.
- (21) Incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K/A filed on September 27, 2007.
- (22) Incorporated by reference to Exhibit 4.4 to Registrant's Annual Report on Form 10-K filed on September 27, 2007.
- (23) Incorporated by reference to Exhibit 4.1 to Registrant's Current Report on Form 8-K filed on July 30, 2008.
- (24) Incorporated by reference to Exhibit 10.13 to the Registrant's Current Report on Form 8-K filed on July 30, 2008.
- (25) Incorporated by reference to Exhibit 4.1 to Registrant's Registration Statement on Form S-8 (Reg No. 333-156985) filed on January 28, 2009.
- (26) Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on August 7, 2009.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Exchange Act, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized, on August 27, 2009.

MARSHALL EDWARDS, INC.
A Delaware Corporation

By: /s/ Christopher Naughton

Christopher Naughton
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities indicated on August 27, 2009.

<u>Signatures</u>	<u>Title</u>
By: <u>/s/ Christopher Naughton</u> Christopher Naughton	President, Chief Executive Officer and Director
By: <u>/s/ David Seaton</u> David Seaton	Secretary, Chief Financial Officer
By: <u>/s/ Leah Cann</u> Leah Cann	Director
By: <u>/s/ Bryan Williams</u> Bryan Williams	Director
By: <u>/s/ Paul Nestel</u> Paul Nestel	Director
By: <u>/s/ Philip Johnston</u> Philip Johnston	Director

CORPORATE INFORMATION

Board of Directors and Executive Officers

Bryan Williams

Non-Executive Chairman
Director
Monash Institute of Medical Research

Christopher Naughton

President and Chief Executive Officer, Director

Managing Director
Novogen Limited

Chairman
Glycotex, Inc.

David Seaton

Chief Financial Officer and Secretary

Chief Financial Officer
Novogen Limited

Chief Financial Officer and Secretary, Director
Glycotex, Inc.

Outside Legal Counsel

Morgan, Lewis & Bockius LLP
New York, NY

Independent Auditors

BDO Kendalls Audit & Assurance (NSW-VIC) Pty Ltd.
Australia

Paul Nestel

Director
Senior Faculty
Baker Heart Research & Diabetes Institute

Philip Johnston

Director
Chairman
Novogen Limited
Director
Glycotex, Inc.

Leah Cann

Director
Founder
Leah Rush Cann Research and Consulting, LLC

Transfer Agent

Computershare Investor Services, LLC
Chicago, IL

Investor Relations

Investor Relations
Marshall Edwards, Inc.
140 Wicks Road
North Ryde, New South Wales 2113
Australia
www.marshalledwardsinc.com

Annual Meeting

The Annual Meeting of Stockholders will be held on Tuesday, December 8, 2009 at 1.00 p.m. (local time) at the offices of Morgan, Lewis & Bockius LLP, located at 101 Park Avenue, New York, New York 10178.