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**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**POST-EFFECTIVE AMENDMENT NO. 2**

to

**FORM S-1**  
**REGISTRATION STATEMENT**  
**UNDER**  
**THE SECURITIES ACT OF 1933**

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**Marshall Edwards, Inc.**

(Exact Name of Registrant as Specified in its Charter)

**Delaware**  
(State or Other Jurisdiction  
of Incorporation or Organization)

**2834**  
(Primary Standard Industrial  
Classification Code Number)

**51-0407811**  
(I.R.S. Employer  
Identification No.)

**Marshall Edwards, Inc.**  
**140 Wicks Road**  
**North Ryde NSW 2113**  
**Australia**  
**(011) 61 2 8877 6196**  
(Address, including zip code, and telephone number,  
including area code, of Registrant's principal executive office)

**The Corporation Trust Company**  
**The Corporation Trust Center**  
**1209 Orange Street**  
**Wilmington, Delaware 19801**  
**(302) 658-7581**  
(Name, address, including zip code, and telephone number,  
including area code, of agent for service)

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*with copies to:*

**David R. Seaton**  
**Company Secretary**  
**Marshall Edwards, Inc.**  
**140 Wicks Road**  
**North Ryde NSW 2113 Australia**  
**(011) 61 2 8877 6196**

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**101 Park Avenue**  
**New York, New York 10178**  
**(212) 309-6000**

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**Approximate date of commencement of proposed sale to the public:** As soon as practicable after this Registration Statement is declared effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box:

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box.

\_\_\_\_\_  
**Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until Registrant files a further amendment that specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the SEC, acting pursuant to Section 8(a), may determine.**

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## PROSPECTUS

# Marshall Edwards, Inc.

## 2,392,000 Shares of Common Stock Issuable Upon Exercise of Warrants

In December 2003, we completed our initial public offering in the United States of 2,392,000 common stock units. Each common stock unit consisted of one share of common stock and one warrant to purchase a share of common stock. This prospectus relates to 2,392,000 shares of common stock that may be issued upon the exercise of the outstanding warrants. The purpose of this prospectus is to fulfill our obligation to maintain a current registration of these shares of common stock. The exercise price of the warrants is \$9.00 per share. The warrants are exercisable at any time and expire at 5:00 PM Eastern Time on December 18, 2006 and may not be exercised after that date. We will receive the exercise price of the warrants when the warrants are exercised.

Our common stock and warrants are quoted on the Nasdaq National Market under the symbols “MSHL” and “MSHLW,” respectively. Our common stock also trades in the London Stock Exchange’s Alternative Investment Market (“AIM”) under the symbol “MSH.” The last reported sale price of our common stock on the Nasdaq National Market on December 8, 2004 was \$9.45 per share. The last reported sale price of our warrants on the Nasdaq National Market on December 8, 2004 was \$4.91 per share. The last reported sale price of our common stock on the Alternative Investment Market on December 8, 2004 was £4.80 per share, or approximately \$9.25 per share based on the noon buying rate for sterling of £1.00 = \$1.9283 on that date.

**Investment in our common stock involves a high degree of risk. See “Risk Factors” beginning on page 6.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.**

The date of this prospectus is December 10, 2004

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## PROSPECTUS SUMMARY

*This summary highlights key aspects of our business and our offering of shares of common stock that are described more fully elsewhere in this prospectus. This summary does not contain all of the information that you should consider before making an investment decision. You should read the entire prospectus carefully, including the Risk Factors section beginning on page 6 and our consolidated financial statements and related notes beginning on page F-1, before making an investment decision.*

*References to “we,” “us,” or “our” refer to Marshall Edwards, Inc. and its consolidated subsidiary, Marshall Edwards Pty Limited. References to “Novogen” refer to Novogen Limited and its consolidated subsidiaries, other than Marshall Edwards, Inc. and its subsidiary. We have attached as Annex A a glossary of technical and scientific terms that we use in this prospectus.*

### Our Company

We are a developmental stage pharmaceutical company, incorporated on December 1, 2000 as a wholly-owned subsidiary of Novogen Limited, an Australian Company. Novogen’s ordinary shares trade on the Australian Stock Exchange under the symbol “NRT,” and American Depositary Receipts (ADRs) trade in the United States under the symbol “NVGN” on the Nasdaq National Market. Novogen Limited currently owns approximately 86.9% of our outstanding common stock.

We commenced operation in May 2002 and our business purpose is the development and commercialization of drugs for the treatment of cancer. We are presently engaged in the clinical development and commercialization of a drug candidate called phenoxodiol, which we believe may have broad application against a wide range of cancers. Phenoxodiol appears to target a number of key components involved in cancer cell survival and proliferation based on the emerging field of signal transduction regulation, with little or no effect on normal cells.

Our strategy is to undertake further clinical development and testing of phenoxodiol leading ultimately to its commercialization and wide scale distribution. Pre-clinical testing has shown phenoxodiol to have broad anti-cancer action against an extensive library of human cancer cell lines, including prostate, ovarian and squamous cell carcinoma, or SCC. Phenoxodiol commenced Phase I clinical studies in Australia in 2000 and is currently undergoing Phase Ib/IIa studies in intravenous dosage form in the United States and Australia, a phase 1b/11a study with the oral dosage form in Australia, a phase 1b study with the oral dosage form in the U.S. and a phase 1 study where phenoxodiol is being used in combination with other standard chemotherapy drugs in Australia. A Phase I clinical trial is generally the first trial of a drug in humans which tests for safety and dosage tolerance and a Phase II clinical trial tests for efficacy and adverse effects of a drug. An investigational new drug application (IND) became effective for phenoxodiol in the intravenous dosage form in January 2001 and for phenoxodiol in the oral dosage form in June 2003. An IND must be submitted to the U.S. Food and Drug Administration (the FDA) and become effective before human clinical trials on a new drug can commence in the United States.

A subsidiary of Novogen has granted to us, through our Australian subsidiary, Marshall Edwards Pty Limited, an exclusive non-transferable license under its patent rights and intellectual property rights in its relevant know-how to develop, market and distribute all forms of administering phenoxodiol for anti-cancer uses, except topical applications. Novogen scientists first synthesized phenoxodiol in 1997 as part of a program of drug discovery based on the structure of naturally occurring isoflavones. Isoflavones are a family of structurally related molecules found in foods such as legumes, red clover, lentils and chickpeas. Although phenoxodiol was originally identified in 1995 as a potential intermediate in the metabolism of daidzein, itself a naturally occurring isoflavone, phenoxodiol does not appear to have been isolated or identified in mammals to date.

### Market Opportunity

The primary focus in the development of phenoxodiol is currently in connection with ovarian cancer, SCC of the cervix, vagina, vulva and skin, and prostate cancer, although we believe that, subject to further successful clinical research and development, phenoxodiol may have potential uses in other forms of human cancers. The cancers for which phenoxodiol is intended to be used are relatively common. The American Cancer Society (the ACS) has estimated that in 2004 there will be 230,110 new cases of prostate cancer and 29,900 people will die as a result of

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this cancer in the United States. The ACS has also estimated that in 2004 there will be 25,580 new cases of ovarian cancer diagnosed and 16,090 people will die as a result of this cancer in the United States. For SCC of the cervix, vagina and vulva, the ACS estimates that in the year 2004, there will be 16,650 new cases diagnosed and that there will be 5,540 deaths caused by these cancers in the United States.

### **Risks of Our Business**

We have a limited operating history and since our inception we have incurred losses, including net losses of \$8,538,000, \$3,033,000 and \$123,000 for the years ended June 30, 2004, 2003 and 2002 respectively. We incurred a net loss of \$1,230,000 for the quarter ended September 30, 2004. We anticipate that we will incur operating losses and negative cash flow for the foreseeable future. Since our inception through September 30, 2004, we have sustained cumulative net losses of \$12,924,000. We anticipate that we will incur operating losses and negative cash flow for the foreseeable future. To date we have not commercialized any products and are not certain that we will be able to do so. We are currently developing only one drug, phenoxodiol, and if we are unable to successfully develop and commercialize phenoxodiol or license other viable drug candidates, our ability to sustain future operations will be diminished. We have not received regulatory approval to commercialize phenoxodiol, and therefore we have not generated revenues from the distribution and sale of any products. Clinical trials have a high risk of failure and any failure could impair the commercial prospects for phenoxodiol. Furthermore, because we depend on Novogen for our intellectual property rights, our personnel and our supply of phenoxodiol, any failure by Novogen to protect the intellectual property rights related to phenoxodiol, to meet our staffing needs or to supply sufficient quantities of phenoxodiol, may hinder our operations and prospects for growth.

### **Recent Developments**

In November 2004 the Company announced that the U.S. Food and Drug Administration (FDA) has granted phenoxodiol Fast Track status for its intended use as a chemo-sensitizing agent in patients with recurrent late stage ovarian cancer. Under the FDA Modernization Act of 1997, designation as a Fast Track product means that phenoxodiol is eligible for certain accelerated marketing approval programs.

In February 2004 Yale New Haven Hospital researchers released preliminary results of a dose-finding study in women with recurrent ovarian cancer that has become unresponsive to standard chemotherapy, who received intravenous phenoxodiol. The data reflected outcomes of the first 20 of 40 measurable subjects and showed that 13 patients were able to finish a three month treatment cycle, and 5 patients were considered to have had disease stabilization. All patients ultimately showed disease progression. This trial is now complete and we are awaiting final analysis of the trial data.

Also in February 2004 a clinical trial in cervical cancer was commenced at Yale New Haven Hospital. The study is the first to be conducted in the U.S. using the oral dosage form of phenoxodiol and will be used in patients who have a primary diagnosis of cancer for a period of four weeks. Following treatment with phenoxodiol, patients will be scheduled for either surgical resection or radiotherapy. The study will evaluate the safety and ability of phenoxodiol to act as an effective anti-cancer drug when it is given as a monotherapy in early stage cancer.

A renal cancer study of phenoxodiol in combination therapy at St George Hospital was commenced in Sydney, Australia in March 2004. The study involves patients with late stage cancers that no longer respond to standard chemotherapies. In this study, phenoxodiol is administered orally.

In April 2004 we commenced a new multi-center trial to evaluate phenoxodiol as a chemo-sensitizing agent in patients with chemo-resistant ovarian cancer. The first site involves up to 40 patients at Yale New Haven Hospital. The two main objectives of the study are to investigate the degree to which phenoxodiol reverses chemo-resistance, and to compare the relative efficacies of paclitaxel and cisplatin, each in combination with phenoxodiol. A second trial site for the multi-center ovarian cancer study was established at the Royal Women's Hospital in Melbourne Australia in June 2004.

We also announced in 2004 preliminary data from the late-stage prostate cancer trial being conducted at multiple sites in Australia. The data showed that phenoxodiol is biologically active by reducing or stabilizing Prostrate Specific Antigen (PSA) levels in 8 of 12 patients receiving the study drug.

**Our Address and Telephone Number**

Our principal executive office is located at 140 Wicks Road, North Ryde NSW 2113, Australia, and our telephone number is 011-61-2-8877-6196. Our Internet web site address is <http://www.marshalledwardsinc.com>. The information contained on our web site shall not be deemed to constitute a part of this prospectus.

## This Offering

Common Stock Offered	Up to 2,392,000 shares of common stock issuable upon exercise of the outstanding warrants. Each warrant is exercisable at any time for the purchase of one share of our common stock at an exercise price of \$9.00 per share. The warrants expire on December 18, 2006. The expiration date may not be extended without an amendment to the warrant agreement by us and the warrant agent. We do not have the right to call or otherwise redeem the warrants.
Common stock outstanding prior to offering	56,938,000 shares (1)
Common Stock Outstanding after this Offering	59,330,000 shares (2)
Use of Proceeds	We will receive approximately \$21,528,000 if all the warrants are exercised for cash. We will use the proceeds from the exercise of the warrants for working capital and general corporate purposes including potential payments to Novogen under the terms of the license agreement, potential licensing of other cancer compounds developed by Novogen under the license option deed and potential expansion of the clinical trial program for phenoxodiol to include other forms of cancer.
Nasdaq Symbols	MSHL — common stock.  MSHLW — warrants.
AIM Listing	Our common stock also trades on the London Stock Exchanges Alternative Investment Market (“AIM”) under the symbol “MSH.”
Risk Factors	Investment in our securities involves a high degree of risk and could result in a loss of your entire investment. See “Risk Factors” beginning on page 6 to read about factors you should consider before buying our shares of common stock.

(1) Does not include the 2,392,000 shares issuable upon the exercise of the outstanding warrants.

(2) Assumes the exercise of all warrants and the issuance of 2,392,000 shares of our common stock in connection therewith.



**Summary Historical Consolidated Financial Data**

We are a development stage company. The following financial data are derived from our audited consolidated financial statements for the years ended June 30, 2004, 2003 and 2002 and our unaudited consolidated financial statements as of and for the three months ended September 30, 2004 and 2003 and for the period from December 1, 2000 (inception) through September 30, 2004, included in this prospectus. The financial statements for the year ended June 30, 2004 has been audited by Ernst & Young, independent registered public accounting firm. The financial statements for the two years ended June 30, 2003 have been audited by Ernst & Young LLP. The data should be read in conjunction with the consolidated financial statements, related notes, and other financial information included herein.

	Three Months Ended September 30,		Years Ended June 30,			Period from December 1, 2000 (inception) through September 30,	
	2004	2003	2004	2003	2002	2004	
	(unaudited)		(in thousands, except per share data)			(unaudited)	
<b>Statement of Operations:</b>							
Interest and other income	\$ 67	\$ 21	\$ 193	\$ 145	\$ 7	\$ 412	
Total revenues	67	21	193	145	7	412	
Loss from operations	(1,230)	\$ (1,114)	(8,538)	(3,033)	(122)	(12,923)	
Income tax expense	—	—	—	—	(1)	(1)	
Net loss arising during development stage	\$ (1,230)	\$ (1,114)	\$ (8,538)	\$ (3,033)	\$ (123)	\$ (12,924)	
<b>Net loss per common share</b>							
Basic and diluted	\$ (0.02)	\$ (0.02)	\$ (0.16)	\$ (0.06)	\$ (0.00)		
<b>Weighted average common shares outstanding</b>							
	56,938,000	52,032,000	54,954,578	52,023,247	49,769,581		
<b>Common stock outstanding at period end</b>							
	56,938,000	52,032,000	56,938,000	52,032,000	52,023,000		
						<b>As of September 30,</b>	
						2004                      2003	
						(in thousands) (unaudited)	
<b>Balance Sheet Data:</b>							
Cash and cash equivalents						\$23,782	\$ 6,375
Total assets						\$23,836	\$ 6,567
Total stockholders' equity						\$21,712	\$ 4,838

## RISK FACTORS

*Investors should carefully consider the following risks, as well as the other information contained in this prospectus before investing in our common stock. If any of the following risks actually materializes, our business could be harmed, the price of our shares of common stock could decline and investors might lose all or part of their investment.*

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

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

You should consider our prospects in light of the risks and difficulties frequently encountered by early stage and developmental companies. Although we were incorporated in December 2000, we have only been in operation since May 2002. We have incurred net losses since our inception, including net losses of \$8,538,000, \$3,033,000 and \$123,000 for the years ended June 30, 2004, 2003 and 2002 respectively. For the quarter ended September 30, 2004, we incurred a net loss of \$1,230,000. We anticipate that we will incur operating losses and negative cash flow for the foreseeable future. We have not yet commercialized any products and cannot be sure that we will ever be able to do so, or that we may ever become profitable. We expect to expand our clinical trials significantly, which will result in increasing losses, and may continue to incur substantial losses even if we begin to generate revenues from the distribution and sale of phenoxodiol.

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

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

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

We need regulatory approval in order to commercialize phenoxodiol. We may never receive regulatory approval or if we do receive regulatory approval, it will be limited to those disease states and conditions for which phenoxodiol has proven to be safe and effective. Phenoxodiol is currently in Phase 1b/11a clinical trials in intravenous dosage form to treat late stage chemo-refractory ovarian cancer. An IND became effective for phenoxodiol in the United States for the oral dosage form in June 2003 and phenoxodiol in this form is being studied as an adjunctive therapy for cervical cancer in the US. The oral dosage form is also being studied in clinical trials in Australia for prostate cancer. Product approval, if granted, can be withdrawn for failure to comply with regulatory requirements or upon the occurrence of adverse events following commercial introduction. In addition, our ability to market phenoxodiol in overseas countries is contingent upon receiving the required regulatory approvals in those countries. If we cannot commercialize phenoxodiol, we may be required to cease or reduce our operations. We cannot assure you that material delays, difficulties or adverse events in the regulatory process will not be encountered in the future.

***Our ability to achieve profitability is dependent on a number of factors, many of which are beyond our control.***

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

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

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

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

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

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

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

- phenoxodiol is in the early stages of clinical development and we will need to conduct significant clinical testing to prove safety and efficacy before applications for marketing can be filed with the FDA, or with the regulatory authorities of other countries, to approve phenoxodiol for final use;
- data obtained from pre-clinical and clinical tests can be interpreted in different ways, which could delay, limit or prevent regulatory approval;
- it may take us many years to complete the testing of phenoxodiol or any other drug candidates, and failure can occur at any stage of this process;
- negative or inconclusive results or adverse medical events during a clinical trial could cause us to delay or terminate our development efforts;

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- there is relatively limited scientific understanding of the means by which cells respond to chemical signals that reach them through the bloodstream, which we refer to as multiple signal transduction regulation or MSTR, the class of drug compounds to which phenoxodiol belongs; and
- the commercialization of phenoxodiol may be delayed if the FDA or another regulatory authority requires us to expand the size and/or scope of the clinical trials.

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

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

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

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

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

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

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

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

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

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

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

While we believe that we have sufficient funds to complete our current clinical trial program, we will require additional funds to further the evaluation of phenoxodiol beyond the current objectives including the completion of any Phase III clinical trials for phenoxodiol, and to pursue the commercialization of phenoxodiol.

The actual amount of funds that we will need will be determined by many factors, some of which are beyond our control. As a result, we may need additional funds sooner than we currently anticipate. These factors include:

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

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

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

The development of phenoxodiol and other drug candidates is highly competitive. A number of other companies have products or drug candidates in various stages of pre-clinical or clinical development to treat prostate cancer, ovarian cancer, SCC and other cancers that are the current focus of phenoxodiol.

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

Two signal transduction drugs have been approved by the FDA in recent years as cancer therapies and are potentially competing products to phenoxodiol. Iressa, distributed by AstraZeneca, has been granted approval for use in the treatment of advanced stage non-small cell lung cancer in patients who have already received specific chemotherapy. Erbitux, distributed by Bristol Myers Squibb, was recently granted approval for use in the treatment of patients with late-stage colo-rectal cancer. In the area of more traditional cytotoxic anti-cancer drugs, Taxotere, a drug distributed by Aventis, was approved recently by the FDA for the treatment of hormone refractory prostate cancer, establishing a new bench-mark for standard chemotherapy in late stage prostate cancer. We are also aware of the experimental drug, Telcyta, being developed by Telik Inc. as a chemo-sensitizing drug for various cancers, including refractory and resistant ovarian cancer which is an indication also under development for phenoxodiol.

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

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

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

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

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

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

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

Under the manufacturing license and supply agreement, we have granted to Novogen an exclusive sub-license to manufacture and supply phenoxodiol to us in its primary manufactured form and Novogen has agreed to manufacture for us our required quantities of phenoxodiol. This agreement enables us to protect the licensed

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intellectual property rights used in the manufacturing process while securing the services of a manufacturing partner in Novogen, which through its equity position in us, shares a common interest in the production of phenoxodiol.

The license option deed grants us an exclusive first right to accept and exclusive last right to match any proposed dealing by Novogen with its intellectual property rights with a third party relating to certain compounds (other than phenoxodiol) developed by Novogen and its affiliates which have applications in the field of prevention, treatment or cure of cancer in humans. The license option deed is important to our business because it allows us to maintain control over the sale by Novogen of complementary as well as potentially competitive intellectual property rights to third party competitors.

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

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

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

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

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

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

The pharmaceutical industry is highly competitive and patents have been applied for by, and issued to, other parties relating to products competitive with phenoxodiol. Therefore, phenoxodiol and any other drug candidates may give rise to claims that they infringe the patents or proprietary rights of other parties existing now and in the future. Furthermore, to the extent that we or Novogen or our respective consultants or research collaborators use intellectual property owned by others in work performed for us or Novogen, disputes may also arise as to the rights in such

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

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

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

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

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

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

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

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

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



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

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

**Risks Related to Our Relationship with Novogen**

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

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

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

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

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

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

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

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

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

We have no employees. We rely on Novogen to provide or procure the provision of staff and other financial and administrative services under our services agreement with Novogen. Novogen has fully complied with the terms of

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our services agreement. To successfully develop phenoxodiol, we will require ongoing access to the personnel who have, to date, been responsible for the development of phenoxodiol. The services agreement does not specify a minimum amount of time that Novogen employees must devote to our operations. If we are unable to secure or if we lose the services of these personnel, the ability to develop phenoxodiol could be materially impaired. Moreover, if our business experiences substantial and rapid growth, we may not be able to secure the services and resources we require from Novogen or from other persons to support that growth.

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

We currently intend that phenoxodiol will be supplied to us in its primary manufactured form by Novogen under the manufacturing license and supply agreement. As the manufacturing process for phenoxodiol has not been tested in the quantities needed for commercial sales, we may be unable to receive the necessary quantities in a timely manner. In addition, in order for Novogen to supply commercial quantities of phenoxodiol in due course, it will need to build a new manufacturing plant. To build a new manufacturing plant, Novogen will need to scale up its current pilot plant. If the plant proves difficult to scale up or requires significant redesign, our ability to commercialize phenoxodiol could be delayed. Any larger manufacturing plant built by Novogen will also have to comply with the FDA's current Good Manufacturing Practices, or cGMPs. Also, significant additional capital will be required to build the plant. Such capital may not be available to Novogen.

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

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

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

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

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

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- additional sales by us or Novogen of shares of our common stock.

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

***You will experience immediate and substantial dilution as a result of this offering and may experience additional dilution in the future.***

If you exercise the warrants, you will in effect pay more for your shares of our common stock than the amounts paid by existing stockholders for their shares. As a result, you will incur immediate and substantial dilution of \$8.27 per share, representing the difference between the exercise price and our pro forma as adjusted net tangible book value per share at September 30, 2004 after giving effect to the exercise of our outstanding warrants. In addition, purchasers of our shares of common stock in this offering will have contributed approximately 36% of the aggregate price paid by all purchasers of our common stock, but will own only approximately 4% of the shares outstanding after this offering. We may also acquire other companies or technologies or finance strategic alliances by issuing equity, which may result in additional dilution to our stockholders.

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

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

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

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

The market price of our common stock could decline as a result of sales of substantial amounts of our common stock in the public market, including the shares covered by this prospectus, or the perception that these sales could occur. In addition, these factors could make it more difficult for us to raise funds through future equity offerings. As of December 8, 2004, we had 56,938,000 shares of our common stock outstanding not including the 2,392,000 shares of common stock underlying the warrants.

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

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

We will have broad discretion to use the net proceeds to us upon any exercise of the warrants, and you will be

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

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus includes forward-looking statements. All statements other than statements of historical facts contained in this prospectus, including statements regarding our 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 our 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 described in “Risk Factors” and elsewhere in this prospectus, including, among other things:

- our inability to obtain any additional required financing or financing available to us on acceptable terms;
- our failure to successfully commercialize our product candidates;
- costs and delays in the development and/or receipt of FDA or other required governmental approvals, or the failure to obtain such approvals, for our product candidates;
- uncertainties in clinical trial results;
- our inability to maintain or enter into, and the risks resulting from our dependence upon, collaboration or contractual arrangements necessary for the development, manufacture, commercialization, marketing, sales and distribution of any products;
- competition and competitive factors;
- our inability to protect our patents or proprietary rights and obtain necessary rights to third party patents and intellectual property to operate our business;
- our inability to operate our business without infringing the patents and proprietary rights of others;
- general economic conditions;
- the failure of any products to gain market acceptance;
- our inability to obtain any additional required financing;
- 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 prospectus may include additional factors which could adversely impact our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time and it is not possible for us to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

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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.

### **USE OF PROCEEDS**

We will receive approximately \$21,528,000 if all 2,392,000 warrants are exercised for cash. We will use the proceeds from the exercise of the warrants for working capital and general corporate purposes including potential payments to Novogen under the terms of the license agreement, potential licensing of other cancer compounds developed by Novogen under the license option deed and potential expansion of the clinical trial program for phenoxodiol to include other forms of cancer.

See “Certain Relationships and Related Transactions — The Amended and Restated License Agreement — Fees, Charges and Costs” for a description of our potential payments to Novogen under the license agreement.

**PRICE RANGE OF OUR COMMON STOCK**

Our common stock and warrants have traded on the Nasdaq National Market under the symbol “MSHL” and “MSHLW,” respectively, since our initial public offering and listing on December 18, 2003. Our common stock also trades in the London Stock Exchanges Alternative Investment Market (“AIM”) under the symbol “MSH.”

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

	Nasdaq National Market		AIM Market	
	High \$	Low \$	High £	Low £
<b>Common Stock</b>				
<b>Fiscal Year Ended June 30, 2003</b>				
First Quarter	—	—	2.46	2.35
Second Quarter	—	—	2.49	2.46
Third Quarter	—	—	2.47	2.28
Fourth Quarter	—	—	3.50	2.35
<b>Fiscal Year Ended June 30, 2004</b>				
First Quarter	—	—	3.93	3.25
Second Quarter	12.99	6.25	5.60	3.80
Third Quarter	13.10	7.63	6.12	5.09
Fourth Quarter	12.00	7.31	6.10	5.20
<b>Fiscal Year Ended June 30, 2005</b>				
First Quarter	9.27	5.74	5.20	4.22
Second Quarter (through December 8)	10.49	6.71	5.15	4.50
<b>Warrants</b>				
<b>Fiscal Year Ended June 30, 2004</b>				
First Quarter	—	—	—	—
Second Quarter	8.64	2.30	—	—
Third Quarter	7.40	3.35	—	—
Fourth Quarter	6.95	4.65	—	—
<b>Fiscal Year Ended June 30, 2005</b>				
First Quarter	5.75	2.50	—	—
Second Quarter (through December 8)	6.91	3.55	—	—

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

<u>Period Ended</u>	<u>High</u>	<u>Low</u>	<u>Average</u>	<u>Period-End</u>
<b>Fiscal Year Ended June 30, 2003</b>				
First Quarter	\$1.5800	\$1.5192	\$1.5497	\$1.5700
Second Quarter	1.6095	1.5418	1.5714	1.6095
Third Quarter	1.6482	1.5624	1.6025	1.5790
Fourth Quarter	1.6840	1.5500	1.6183	1.6529
<b>Fiscal Year Ended June 30, 2004</b>				
First Quarter	\$1.6718	\$1.5728	\$1.6107	\$1.6620
Second Quarter	1.7842	1.6598	1.7079	1.7842
Third Quarter	1.9045	1.7902	1.8385	1.8400
Fourth Quarter	1.8564	1.7544	1.8063	1.8126
<b>Fiscal Year Ended June 30, 2005</b>				
First Quarter	\$1.8734	\$1.7733	\$1.8193	\$1.8090
Second Quarter (through December 8)	1.9459	1.7790	1.8472	1.9283

As of December 8, 2004, the last reported closing price of our common stock on the Nasdaq National Market was \$9.45 and there were approximately 64 stockholders of record of our common stock.

### **DIVIDEND POLICY**

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain future earnings, if any, to finance the operation and expansion of our business. Therefore, we do not anticipate paying any cash dividends on our capital stock in the foreseeable future. In addition, if we were to borrow against any credit facility that we may enter into, we may be prohibited from paying cash dividends.



**CAPITALIZATION**

The following table sets forth our capitalization as of September 30, 2004:

- on an actual basis; and

as adjusted to reflect the receipt of approximately \$21,528,000 if all the warrants are exercised for cash

This table should be read in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the consolidated financial statements and the notes thereto included elsewhere in this prospectus.

	As of September 30, 2004	
	Actual	As Adjusted
	(in thousands)	
Short-term debt		
Current portion of long-term debt	—	—
Long-term debt		
Bank borrowings	—	—
Stockholders’ equity: preferred stock, \$0.01 par value, 100,000 shares authorized; no shares issued and outstanding	—	—
Common stock, \$0.0000002 par value, 113,000,000 shares authorized, 56,938,000 shares issued and outstanding actual and 59,330,000 shares issued and outstanding as adjusted		
Additional paid-in-capital	34,636	56,164
Deficit accumulated during development stage	(12,924)	(12,924)
Accumulated other comprehensive income	—	—
Total stockholders’ equity	21,712	43,240
Total debt and stockholders’ equity	<u>\$ 21,712</u>	<u>\$ 43,240</u>

**DILUTION**

If you invest in our common stock, your interest will be diluted to the extent of the difference between the exercise price per warrant and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering. Pro forma net tangible book value per share represents the amount of our total tangible assets less total liabilities, divided by the pro forma number of shares of our common stock outstanding. Investors participating in this offering will incur immediate, substantial dilution.

Our net tangible book value at September 30, 2004, before adjustment for this offering, was approximately \$21,712,000 or approximately \$0.38 per share. After giving effect to the sale of 2,392,000 shares of common stock in this offering, our as adjusted net tangible book value at September 30, 2004 would have been \$43,240,000 or approximately \$0.73 per share. This represents an increase in net tangible book value of \$0.35 per share to our existing stockholders and an immediate dilution (i.e., the difference between the exercise price per warrant and the as adjusted net tangible book value per share after this offering) at September 30, 2004 of \$8.27 per share to purchasers of the shares of common stock offered hereby. The following table illustrates this per share dilution:

Exercise price per share of common stock		<u>\$9.00</u>	100%
Net tangible book value per share at September 30, 2004	<u>\$0.38</u>		
Increase in net tangible book value per share attributable to the new investors	<u>\$0.35</u>		
As adjusted net tangible book value per share after this offering		0.73	
Dilution per share to new investors		<u>\$8.27</u>	91.88%

The following table summarizes at September 30, 2004, after giving effect to the sale of 2,392,000 shares of common stock, the number of shares of common stock purchased from us, the total consideration paid to us for those shares and the consideration given by the existing stockholders and by the new investors assuming approximately 56,938,000 shares of our common stock are outstanding:

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
	(in thousands)		(in thousands)		
Existing stockholders	<u>56,938</u>	96	<u>\$38,124</u>	64	\$ .67
New investors	<u>2,392</u>	4	<u>21,528</u>	36	\$9.00
Total	<u>59,330</u>	100	<u>\$59,652</u>	100	

**Selected Historical Consolidated Financial Data**

We are a development stage company. The following financial data are derived from our audited consolidated financial statements for the years ended June 30, 2004, 2003 and 2002 and our unaudited consolidated financial statements as of and for the three months ended September 30, 2004 and 2003 and for the period from December 1, 2000 (inception) through September 30, 2004, included in this prospectus. The financial statements for the year ended June 30, 2004 has been audited by Ernst & Young, independent registered public accounting firm. The financial statements for the two years ended June 30, 2003 have been audited by Ernst & Young LLP. The data should be read in conjunction with the consolidated financial statements, related notes, and other financial information included herein.

	Three Months Ended September 30,		Years Ended June 30,			Period from December 1, 2000 (inception) through September 30,	
	2004	2003	2004	2003	2002	2004	
	(unaudited)		(in thousands, except per share data)			(unaudited)	
<b>Statement of Operations:</b>							
Interest and other income	\$ 67	\$ 21	\$ 193	\$ 145	\$ 7	\$ 412	
Total revenues	67	21	193	145	\$ 7	\$ 412	
Loss from operations	(1,230)	(1,114)	(8,538)	(3,033)	(122)	(12,923)	
Income tax expense	—	—	—	—	(1)	(1)	
Net loss arising during development stage	\$ (1,230)	\$ (1,114)	\$ (8,538)	\$ (3,033)	\$ (123)	\$ (12,924)	
<b>Net loss per common share</b>							
Basic and diluted	\$ (0.02)	\$ (0.02)	\$ (0.16)	\$ (0.06)	\$ (0.00)		
<b>Weighted average common shares outstanding</b>							
	56,938,000	52,032,000	54,954,578	52,023,247	49,769,581		
<b>Common stock outstanding at period end</b>							
	56,938,000	52,032,000	56,938,000	52,032,000	52,023,000		
						<b>As of September 30,</b>	
						2004                      2003	
						(in thousands) (unaudited)	
<b>Balance Sheet Data:</b>							
Cash and cash equivalents						\$23,782	\$ 6,375
Total assets						\$23,836	\$ 6,567
Total stockholders' equity						\$21,712	\$ 4,838

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with our consolidated financial statements and the notes thereto appearing elsewhere in this prospectus. 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 "Risk Factors" included above in this prospectus. 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 prospectus.

### Overview

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

Our main focus since commencing operations is to undertake human clinical testing of phenoxodiol. We do not employ any staff directly but obtain services from Novogen under a services agreement. We have incurred losses since inception and expect to incur operating losses and generate negative cash flows from operations for the foreseeable future as we expand research and development activities and move phenoxodiol into later stages of development. As of September 30, 2004, we have accumulated losses of \$12,924,000.

During 2004, we made significant progress in the clinical development of phenoxodiol including:

- The release by Yale New Haven Hospital researchers of preliminary results of a dose-finding study in women with recurrent ovarian cancer that has become unresponsive to standard chemotherapy, who received intravenous phenoxodiol. The data reflected outcomes of the first 20 of 40 measurable subjects and showed that 13 patients were able to finish a three month treatment cycle, and 5 patients were considered to have had disease stabilization. All patients ultimately showed disease progression. This trial is now complete and we are awaiting final analysis of the trial data;
- Commencing a clinical trial in cervical cancer at Yale New Haven Hospital. The study is the first to be conducted in the U.S. using the oral dosage form of phenoxodiol and will be used in patients who have a primary diagnosis of cancer for a period of four weeks. Following treatment with phenoxodiol, patients will be scheduled for either surgical resection or radiotherapy. The study will evaluate the safety and ability of phenoxodiol to act as an effective anti-cancer drug when it is given as a monotherapy in early stage cancer;
- Commencing a renal cancer study of phenoxodiol in combination therapy at St George Hospital in Sydney, Australia. The study will involve patients with late stage cancers that are no longer responding to standard chemotherapies. In this study, phenoxodiol will be administered orally;
- Commencing a new multi-center trial to evaluate phenoxodiol as a chemo-sensitizing agent in patients with chemo-resistant ovarian cancer. The first site involves up to 40 patients at Yale New Haven Hospital. The two main objectives of the study are to investigate the degree to which phenoxodiol reverses chemo-resistance, and to compare the relative efficacies of paclitaxel and cisplatin, each in combination with phenoxodiol;

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- Establishing a second trial site for the multi-center ovarian cancer study at the Royal Women's Hospital in Melbourne Australia; and
- Announcing preliminary data from the late-stage prostate cancer trial being conducted at multiple sites in Australia. The data showed that phenoxodiol is biologically active by reducing or stabilizing Prostrate Specific Antigen ("PSA") levels in 8 of 12 patients receiving the study drug.
- In November 2004, the Company announced that the U.S. Food and Drug Administration (FDA) has granted phenoxodiol Fast Track status for its intended use as a chemo-sensitizing agent in patients with recurrent late stage ovarian cancer. Under the FDA Modernization Act of 1997, designation as a Fast Track product means that phenoxodiol is eligible for certain accelerated marketing approval programs.

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

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

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

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

### **Critical Accounting Estimates**

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

#### *Clinical Trials Expenses*

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

Clinical trial expenses of \$774,000 have been included in the financial statements for the year ended June 30, 2004, of which \$333,000 has been accrued at June 30, 2004. Clinical trial expenses of \$305,000 have been accrued at September 30, 2004. These estimates are based on the number of patients in each trial and the drug administration cycle.

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

#### *Development Expenses*

Research and development costs incurred since inception through September 30, 2004 amount to \$4,913,000.

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

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

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

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

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

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

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

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

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**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	Three Months Ended September 30,		Years Ended June 30,		
	2004	2003	2004	2003	2002
	(in thousands) (unaudited)		(in thousands)		
Interest and other income	\$67	\$21	\$193	\$145	\$7
Total revenues	\$67	\$21	193	145	7
	Three Months Ended September 30,		Years Ended June 30,		
	2004	2003	2004	2003	2002
	(in thousands) (unaudited)		(in thousands)		
Research and development expenses					
Clinical trial study costs	\$(224)	\$(411)	\$ (774)	\$(1,060)	\$(11)
Clinical trial drug costs	(120)	(207)	(761)	(164)	(12)
Research and development service charge	(90)	(162)	(811)	(790)	(45)
Other	(5)	(2)	(35)	(10)	(1)
Total Research and Development Costs	(439)	(782)	(2,381)	(2,024)	(69)
	Three Months Ended September 30,		Years Ended June 30,		
	2004	2003	2004	2003	2002
	(in thousands) (unaudited)		(in thousands)		
License Fees					
License Fees	\$(500)	\$(246)	\$(5,500)	(500)	–
	Three Months Ended September 30,		Years Ended June 30,		
	2004	2003	2004	2003	2002
	(in thousands) (unaudited)		(in thousands)		
Selling, general and administrative expenses					
Legal and professional fees	\$ (95)	\$ (3)	\$(250)	\$(119)	\$(14)
Administrative service charge	(162)	(67)	(302)	(285)	(23)
Foreign exchange gains/(losses)	(23)	1	58	3	–
Other	(78)	(38)	(356)	(253)	(23)
Total operating expenses	(358)	(107)	(850)	(654)	(60)

**Three Months Ended September 2004 and 2003**

The Company recorded a consolidated loss of \$1,230,000 and \$1,114,000 for the three months ended September 2004 and 2003, respectively.

**Revenues:** The Company received interest on cash assets and cash equivalents of \$67,000 for the three months ended September 30, 2004 versus \$21,000 for the three months ended September 30, 2003. The increase was due to the Company's higher cash balances following the Company's December 2003 public offering.

**Research and Development:** Research and Development expenses decreased \$343,000 to \$439,000 for the three months ended September 30, 2004 compared to \$782,000 for the three months ended September 30, 2003. The decrease was due primarily to a reduction in the amount of phenoxodiol needed for the current clinical trial program and a reduction in hospital costs due to the completion of the patient treatment cycles in the current trial program. We expect Research and Development expenses to increase in the future in accordance with the clinical trial program.

**License Fees:** Milestone license fees of \$500,000 have been accrued in the three months ended September 30, 2004 in connection with the annual milestone license fee of \$2,000,000 that is payable to Novogen on December 31, 2004 under the terms of the license agreement with Novogen.

**Selling, General and Administrative:** Selling, administrative and general expenses increased by \$251,000 to \$358,000 for the three months ended September 30, 2004 compared to \$107,000 for the three months ended September 30, 2003. The increase was due primarily to the increase in costs associated with professional and other fees relating to compliance with United States securities reporting requirements and FDA regulations.

**Foreign Exchange Gains (Losses):** Foreign exchange gains/(losses) occur when revaluing cash denominated in foreign currencies and upon consolidation of MEI's wholly owned Australian subsidiary Marshall Edwards Pty Ltd ("MEPL"), which has 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 does not have a material impact on the Company's financial position. Net foreign exchange losses during the three months ended September 30, 2004 were \$23,000 compared with net exchange gains of \$1,000 during the three months ended September 30, 2003.

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

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

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





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

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

**Selling, General and Administrative:** Selling, administrative and general expenses increased by \$254,000 to \$850,000 for the year ended June 30, 2004 compared to \$654,000 for the year ended June 30, 2003. The increase was due primarily to the increase in costs associated with professional and other fees relating to compliance with United States reporting requirements. Other expenses including those related to the public offering completed in December 2003 and related on-going investor relations also increased.

**Foreign Exchange Gains/(Losses):** We conduct a portion of our business in Australian dollars. At June 30, 2004, we have not established a foreign currency hedging program. Net foreign exchange gains during the twelve months ended June 30, 2004 were \$58,000 compared with net exchange gains of \$3,000 during the twelve months ended June 30, 2003. The accounts of our wholly-owned Australian subsidiary, Marshall Edwards Pty. Limited ("MEPL") are maintained in Australian dollars, however, its functional currency is U.S. dollars. Foreign exchange gains and losses occur upon consolidation of MEPL and also as a result of translations in foreign currency.

### **Year Ended June 30, 2003 Compared to the Year Ended June 30, 2002**

We recorded a consolidated loss of \$3,033,000 and \$123,000 for the years ended June 30, 2003 and 2002 respectively.

We commenced operations in May 2002 following its listing on the Alternative Investment Market in the UK. Consequently, the financial results for the year ended June 30, 2003 represent the first full year of our operations. The financial results reported for the year ended June 20, 2002 are the results of only one month of operations.

**Revenues:** We received interest of \$145,000 on cash assets and cash equivalents for the year ended June 30, 2003 versus \$7,000 for the year ended June 30, 2002. We had no cash balance prior to our completion of a share offering in May 2002. As a result, we only had the benefit of interest income for one month in the year ended June 30, 2002 versus a full year of interest income in the year ended June 30, 2003.

**Research and Development:** Research and Development expenses increased \$1,955,000 to \$2,024,000 for the year ended June 30, 2003 compared to \$69,000 of the year ended June 30, 2002. We took responsibility for research and development costs of May 2002. The increase in research and development costs for the year ended June 30, 2003 over 2002 was due to the fact that the year ended June 30, 2003 was the first full year of clinical trial expenses and the associated cost of phenoxodiol supplied for use in the clinical trial program.

**License Fees:** A license fee of \$5,000,000 was paid to Novogen in February 2004 under the terms of the license agreement following the exercise of warrants and the receipt of proceeds from the public offering completed in December 2003 of which, \$500,000 had been expensed in the fiscal year ended June 30, 2003.

**Selling, General and Administrative:** Selling, administrative and general expenses increased \$594,000 to \$654,000 for the year ended June 30, 2003 compared to \$60,000 for the year ended June 30, 2002. The increase was due primarily to the fact that the year ended June 30, 2003 was the first full year of operations.

### **Liquidity and Capital Resources**

At June 30, 2004, we had cash resources of \$24,819,000 and at the end of the three months ended September 30, 2004, we had cash resources of \$23,782,000.

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Funds are invested in short term market accounts, pending use. The implementation of our business plan is dependent on our ability to maintain adequate cash resources to complete the clinical development program.

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

#### *Cash Used in Operating Activities*

Cash used in operating activities for the year ended June 30, 2004 was \$7,972,000 compared to \$1,841,000 for the same period in 2003. The increase in cash outflow of \$6,131,000 for the year ended June 30, 2004 included the payment of \$5,000,000 to Novogen under the terms of the license agreement. The remaining cash outflow of \$1,131,000 resulted from increased payments of operating expenses including clinical trial costs and drug supplies and payments to Novogen for services provided pursuant to the services agreement. Cash used in operating activities for the three months ended September 30, 2004 was \$1,037,000 compared to \$752,000 for the same period in 2003. The increase in cash outflow of \$285,000 for the three months ended September 30, 2004 was due almost exclusively to the increased operating expenses and the timing of payments in accounts payable and accrued expenses.

#### *Cash Provided from Financing Activities*

Cash provided from financing activities for the year ended June 30, 2004 was \$25,578,000.

In November 2003, 2,514,000 warrants were exercised at an exercise price of \$4.00. These warrants were issued as part of the sale of common stock in May 2002. Proceeds from the exercise of the warrants were \$10,056,000.

In December 2003, we completed an initial public offering in the United States of 2,392,000 common stock units at an initial 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 at an exercise price equal to \$9.00. The warrants are immediately exercisable from the date of issue and expire 3 years from their date of issue.

The net proceeds to us from the offering totaled approximately \$15,522,000.

No cash was provided from financing activities in the three months ended September 30, 2004.

#### *Cash Requirements*

Based on current plans, we believe that it will have sufficient cash resources to fund operations at least through the end of September 2005 and to complete the current Phase Ib/IIa and Phase II clinical trial program, complete the Phase II clinical trials of phenoxodiol as a monotherapy in early stage cancer which commenced at Yale New Haven Hospital, and to complete the Phase II clinical trials of phenoxodiol in combinational therapy with other anti-cancer drugs for late stage chemo-resistant tumors which also commenced at Yale New Haven Hospital. Ongoing operations through the conduct of the clinical trial program will continue to consume cash resources without generating revenues.

If the Phase III clinical program, which is a multi-center study measuring efficacy in a large number of patients is undertaken, additional funds will be required to complete the program. We are not able to reasonably estimate at this time either the amount required or when that amount will need to be raised. This will to a large extent be influenced by the number of patients enrolled in the trial, which can only be determined accurately upon completion of Phase II trials. If the Phase II trials are successful we will seek to raise the funds required to complete Phase III trials or enter into a collaborative arrangement with a major pharmaceutical company.

We must pay amounts to Novogen under the license agreement with Novogen when certain milestones are met. For details of the amounts payable see "Certain Relationships and Related Transactions," included in this prospectus.

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

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### *Contractual Obligations*

The following table summarizes our future payment obligations and commitments as of June 30, 2004:

(In thousands)	Payment due by period				
	Total	less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
<b>Contractual Obligations</b>					
Purchase Obligations	\$3,796	\$3,167	\$629	\$-	\$-
Total	\$3,796	\$3,167	\$629	\$-	\$-

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

### *Off-Balance Sheet Arrangements*

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

### **Recent Accounting Announcements**

Accounting pronouncements issued by the FASB or other authoritative accounting standards groups with future effective dates are either not applicable or not significant to the consolidated financial statements.

### **Quantitative and Qualitative Disclosures about Market Risk**

#### **Interest Rate Risk**

We place cash in "on call" deposits with high quality financial institutions.

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

#### **Foreign Currency Risk**

We conduct a portion of our business in various currencies, primarily in U.S. and Australian dollars. At September 30, 2004, we had not established a foreign currency hedging program. Net foreign exchange gains during the twelve months ended June 30, 2004 were \$58,000 compared with net exchange gains of \$3,000 during the twelve months ended June 30, 2003. Net foreign exchange losses during the three months ended September 30, 2004 were \$23,000 compared with net exchange gains of \$1,000 during the three months ended September 30, 2003. 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.

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

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

Ernst & Young (Australia) served as our independent accountants to audit our most recent fiscal year end. Ernst & Young were dismissed as our independent auditors and principal outside accountants effective September 12, 2004 and were replaced by BDO. The Audit Committee approved the appointment of BDO effective from September 12, 2004. The appointment of BDO occurred following a bid process which we regularly undertake to ensure we receive cost effective audit services.

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Ernst & Young's reports on our financial statements for the fiscal years ended June 30, 2003 and 2004 did not contain an adverse opinion or disclaimer of opinion and were not qualified or modified as to uncertainty, audit scope, or accounting principles.

During our two most recent fiscal years, there were no disagreements, as that term is described in Item 304(a)(1)(iv) of Regulation S-K of the Securities and Exchange Commission, between us and Ernst & Young on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of Ernst & Young, would have caused Ernst & Young to make reference to the subject matter of the disagreement in connection with its report.

During our two most recent fiscal years, there were no "reportable events," as that term is described in Item 304(a)(1)(v) of Regulation S-K, except for a material weakness in our internal control for the year ended June 30, 2004 which was identified by Ernst & Young and disclosed in Item 9a in our Annual Report on Form 10-K for the year ended June 30, 2004. Specifically, Ernst & Young noted that the personnel and management of Novogen Limited who perform our accounting and financial reporting functions pursuant to a services agreement, are not sufficiently expert in U.S. GAAP and the requirements of the Securities and Exchange Commission and the Public Company Accounting Oversight Board and that this lack of expertise represents a material weakness in the operation of our internal control over financial reporting. Ernst & Young further noted that our system of financial reporting was not designed to prepare financial statements in accordance with U.S. GAAP and that our system of internal control, in particular our processes to review and analyze elements of the financial statement close process and prepare consolidated financial statements in accordance with U.S. GAAP, has not reduced to a relatively low level the risk that errors in amounts that would be material in relation to those financial statements may occur and may not be detected within a timely period by management in the normal course of business.

We have sought assurances from Novogen that it will promptly remedy the concerns raised by Ernst & Young and Novogen has presented us a plan for addressing these concerns. Novogen's plan is designed to ensure that the preparation of our consolidated financial statements, including the processes to review and analyze elements of the financial statements is in accordance with U.S. GAAP and that relevant information about U.S. GAAP, SEC financial reporting requirements, and the requirements of the Public Company Accounting Oversight Board is available to those persons involved in the process by which the financial statements are prepared. Specifically Novogen's plan provides for additional resources and further training of the Novogen accounting team including: (1) the employment of additional accounting staff on the Novogen accounting team which will enable senior finance staff responsible for the preparation of U.S. GAAP financial reports to spend more time dealing with U.S. GAAP reporting issues; (2) increasing the level of attendance at targeted U.S. GAAP and SEC reporting courses by senior Novogen finance staff responsible for the preparation of U.S. GAAP financial reports and SEC disclosure; and (3) subscribing to additional information networks that provide publications and updates of SEC and U.S. GAAP releases and rule changes and of information about the requirements of the Public Company Accounting Oversight Board.

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

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

We have authorized and requested Ernst & Young to respond fully to the inquiries of BDO regarding the matters above.

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During our two most recent fiscal years ended June 30, 2003 and 2004, and through the appointment of BDO on September 12, 2004, we did not consult BDO on (i) either the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on our financial statements, and neither a written report nor oral advice was provided to us that BDO concluded was an important factor considered by us in reaching a decision as to the accounting, auditing or financial reporting issue; or (ii) the subject of any disagreement or reportable event.

## BUSINESS

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

Novogen Limited, an Australian company publicly traded on the Nasdaq National Market, owns approximately 86.9% of our outstanding common stock. We were incorporated as a separate subsidiary of Novogen to focus on the development and commercialization of drugs for the treatment of cancer and were not incorporated primarily as a finance vehicle. In contrast, Novogen has a broader business focus which, in addition to the business conducted by us includes a consumer health division that focuses on the development of a range of non prescription products for the health needs of both men and women and a pharmaceutical division which focuses on the development of prescription drugs. We were established by Novogen to advance Novogen's research on one specific degenerative disease, cancer. We believe that Novogen's corporate structure, with us functioning as a corporate entity separate from Novogen's other lines of business, has provided us with:

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

During 2004, we made significant progress in the clinical development of phenoxodiol including:

- The release by Yale researchers of preliminary results of a dose-finding study in women with recurrent ovarian cancer that has become unresponsive to standard chemotherapy, who received intravenous phenoxodiol. The data reflected outcomes of the first 20 of 40 measurable subjects and showed that 13 patients were able to finish a three month treatment cycle, and 5 patients were considered to have had disease stabilization. All patients ultimately showed disease progression. This trial is now complete and we are awaiting final analysis of the trial data;
- Commencing a clinical trial in cervical cancer at Yale New Haven Hospital. The study is the first to be conducted in the U.S. using the oral dosage form of phenoxodiol and will be used in patients who have a primary diagnosis of cancer for a period of four weeks. Following treatment with phenoxodiol, patients will be scheduled for either surgical resection or radiotherapy. The study will evaluate the safety and ability of phenoxodiol to act as an effective anti-cancer drug when it is given as a monotherapy in early stage cancer;
- Commencing a renal cancer study of phenoxodiol in combination therapy at St George Hospital in Sydney, Australia. The study will involve patients with late stage cancers that are no longer responding to standard chemotherapies. In this study, phenoxodiol will be administered orally;

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- Commencing a new multi-center trial to evaluate phenoxodiol as a chemo-sensitizing agent in patients with chemo-resistant ovarian cancer. The first site involves up to 40 patients at Yale New Haven Hospital. The two main objectives of the study are to investigate the degree to which phenoxodiol reverses chemo-resistance, and to compare the relative efficacies of paclitaxel and cisplatin, each in combination with phenoxodiol;
- Establishing a second trial site for the multi-center ovarian cancer study at the Royal Women's Hospital in Melbourne Australia; and
- Announcing preliminary data from the late-stage prostate cancer trial being conducted at multiple sites in Australia. The data showed that phenoxodiol is biologically active by reducing or stabilizing Prostate Specific Antigen ("PSA") levels in 8 of 12 patients receiving the study drug.
- In November 2004, the Company announced that the U.S. Food and Drug Administration (FDA) has granted phenoxodiol Fast Track status for its intended use as a chemo-sensitizing agent in patients with recurrent late stage ovarian cancer. Under the FDA Modernization Act of 1997, designation as a Fast Track product means that phenoxodiol is eligible for certain accelerated marketing approval programs.

## **Scientific Overview**

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

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

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

We believe that phenoxodiol increases the potency of signal transduction inhibitors by targeting multiple signaling pathways, and in particular, those pathways vital to the survival of most, if not all, human cancer cells. In the term MSTR, "multiple" refers to the fact that more than one signaling pathway is targeted by the drug, and "regulator" refers to the fact that while the drug predominantly inhibits errant signaling pathways, other signaling pathways (e.g., anti-survival pathways) can be activated.

We believe that phenoxodiol targets a number of key components involved in cancer cell survival and proliferation of signal transduction processes. For example, phenoxodiol appears to target enzymes called kinases that catalyze phosphorylation of acceptor molecules. These kinases appear to be involved in signaling related to cell survival and cell growth (e.g., sphingosine kinase, a kinase believed to be important to both cell survival and cell growth). Inhibition of these targets results in increased cancer cell death and cancer cell cytostasis (the inhibition of cell growth or division).

This disrupting effect of phenoxodiol is restricted to tumor cells, with non-tumor cells remaining unaffected. A potential explanation for this selective anti-tumor effect was provided by a discovery of a research team at Purdue

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University. The research team discovered that phenoxodiol targets a particular member of the ECTO-NOX family of proteins. This family of proteins regulates fundamental biological processes at the cell surface that are vital to the survival and growth of all living matter. One of these proteins, known as constitutive NADH oxidase (“CNOX”) is a fundamental source of hydrogen ions for all living cells. The Purdue University studies have now shown that all forms of human cancer express a variant form of CNOX, known as tNOX. The presence of tNOX disrupts the normal pattern of behavior of the cell, contributing to the unregulated cell growth and survival that characterizes tumor cells. This makes tNOX the first pan-cancer expressed protein, identifying it as a potentially important new target for anti-cancer drug development. Phenoxodiol appears to specifically block the action of tNOX, with the resulting inhibition of H<sup>+</sup> influx into the cell, leading to extensive disruption to signaling pathways and to eventual apoptosis, which is the process of programmed cell death by which a cell dies naturally. Phenoxodiol has no effect on CNOX, providing an explanation of how phenoxodiol can be so selective in its action, with its cytotoxic effects being limited to cancer cells.

Laboratory studies at Yale University also have revealed that the killing effect of phenoxodiol of cancer cells occurs through the caspase enzyme pathway, and that key triggers of this proteolytic pathway are the up-regulation of production in the cancer cell of pro-apoptotic factors such as Bax and the increased degradation of anti-apoptotic factors such as c-FLIP and XIAP. The latter effect facilitates death of cancer cells via either the Fas or TRAIL death receptor mechanisms, each of which is a signaling molecule that when activated causes cell death.

Recent laboratory studies conducted by Novogen and Yale University have revealed that phenoxodiol interacts well with a number of standard anti-cancer drugs such as cisplatin, gemcitabine and taxanes. In one aspect of this effect, phenoxodiol appears to restore sensitivity to these drugs in cells such as ovarian cancer cells that have acquired resistance to such drugs. In another aspect, pretreatment of tumor cells with phenoxodiol considerably increases the sensitivity of virgin tumor cells to the cytotoxic effects of standard chemotoxic drugs. Both of these effects are achieved without increasing the toxicity of the standard chemotoxic drugs to non tumor cells.

### **Overall Clinical Development Strategy**

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

The immediate priority, is to focus on those therapeutic indications that will expedite drug marketing approval of phenoxodiol by regulatory bodies. To this end, we will continue our work in late-stage chemo-resistant cancers. In chemo-resistant cancers we hope to show that phenoxodiol will provide in humans what it has demonstrated in the laboratory and in animal models that is the restoration of chemo-sensitivity to standard chemotoxic agents. In this way, phenoxodiol will be used to condition the tumor cells to the more destructive effects of drugs such as cisplatin, gemcitabine and taxanes with the combined effects of all drugs providing a potent force able to attack well established and extensive cancer disease. In the next stage of our clinical development program for phenoxodiol in the area of chemo-resistant cancers, it is possible that other forms of cancer (such as renal carcinoma, head and neck cancer), generally regarded as unresponsive to standard drugs, will be added to this program in due course in order to maximize the opportunity for treating chemo-resistant cancers.

Phenoxodiol is also being developed for use in earlier-stage cancers. This is the basis of the clinical program involving oral phenoxodiol in which Squamous Cell Carcinoma (“SCC”) of the cervix, vagina and vulva, and prostate cancer. These are also being targeted as a matter of priority. These are all forms of cancer for which early diagnosis is commonly available, and for which a non-invasive, non-surgical drug option might be an attractive therapeutic option. In this strategy, phenoxodiol is being studied in the first instance as an oral monotherapy in the expectation that phenoxodiol alone may provide an adequate anti-cancer effect.

### **History of Phenoxodiol Development**

In 1995, phenoxodiol was identified as a potential intermediate in the metabolism of daidzein, a naturally occurring isoflavone. Isoflavones are a family of structurally related molecules found in foods such as legumes, red clover, lentils and chickpeas. To date, phenoxodiol has not appeared to have been isolated or identified in mammals.



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Novogen scientists first synthesized phenoxodiol in 1997 as part of a program of drug discovery based on the structure of naturally occurring isoflavones. When screened for anti-cancer action against human cancer cells *in vitro* (in the laboratory), phenoxodiol was found to be cytostatic and cytotoxic against a wide range of human cancer cells, but without toxicity against non tumor cells. *In vivo* (in animals) studies in laboratory animals subsequently showed that phenoxodiol administered either orally or systemically was adequately bio-available (absorbed into the body in useful form) and significantly retarded tumor development, in particular in athymic mice bearing xenografts of human prostate cancer. Such anticancer effects in animals were achieved without evidence of toxicity, and thus phenoxodiol was selected for development as a human anti-cancer drug.

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

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

Phase Ia pharmacokinetic studies, which measure the way a drug is handled by the body, conducted in cancer patients in May 2000, showed that phenoxodiol, like steroidal hormones, is prone to conjugation (glucuronide and sulfates) within the body. These conjugated forms are the means by which a water-insoluble drug such as phenoxodiol is transported within the body. Conversion of these drugs to the active form requires deconjugation by relevant enzymes within end tissues to yield the bioactive (unconjugated) drug form. Bioequivalence studies showed that phenoxodiol is considerably more prone to conjugation when administered orally (greater than 99%) compared to intravenously (approximately 85%). Therefore, in the absence of definitive data on the rates of expression of deconjugating enzymes by different tumor types, it was decided to commence clinical studies with an intravenous dosage form of phenoxodiol because of the certainty of obtaining levels of unconjugated phenoxodiol in the plasma the liquid component of blood that were known in the laboratory to be highly cytotoxic to cancer cells.

A Phase Ib toxicity study was commenced in Australia in November 2000 and finished in March 2002. Twenty-one patients with late-stage solid cancers (any type) were given phenoxodiol by weekly bolus injections, which are intravenous injections delivered quickly (usually over several minutes), for 12 weeks. This was a dose-escalating study with inter-patient escalation from 1 to 30 mg/kg/dose. No dose-limiting toxicity was reached and no significant toxicities other than some hypersensitivities to the drug vehicle (cyclodextrin) were encountered.

A second Phase Ib toxicity study commenced in Australia in April 2001 and concluded in 2002. Twenty-one patients with late-stage solid cancers (any type) were given phenoxodiol by continuous intravenous infusion. This was a dose-escalating study, with inter-patient escalation from 1 to 40 mg/kg / day. No dose-limiting toxicity was reached and no significant toxicities were encountered.

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

Concurrent with the Phase I clinical trial program outlined above, pre clinical studies continued with a view to better understanding the molecular targets of phenoxodiol and the most appropriate tumor types for therapy. In terms of molecular targets, a number of important actions were identified:

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- that phenoxodiol has broad inhibitory activity against a range of kinase enzymes, resulting in disruption to a wide range of signaling pathways involved in cell survival and growth;
- that phenoxodiol-induced apoptosis occurred via the caspase cascade;
- that phenoxodiol induced apoptosis is initiated as a result of activation of death receptor (Fas, TRAIL) mechanisms and down-regulation of death receptor blockers (c-FLIP, XIAP); and
- that a key molecular target is the receptor protein, tNOX, whose inhibition leads to extensive disruption of pro-survival mechanisms.

A further key pre-clinical finding was that phenoxodiol was effective against various types of cancer cells including ovarian, mesothelioma and lung cancer cells that were resistant to all standard chemotoxic anti-cancer drugs, pointing to the potential usefulness of phenoxodiol, at least in patients with these cancers who had failed all other forms of chemotherapy.

The selection of specific tumor types in which to test phenoxodiol in Phase II clinical trials was based on a number of factors. First, the known relevance of certain actions of phenoxodiol (e.g., the targeting of death receptor activity) to the survival of certain cancer cell types; second, pre-clinical experience with the use of phenoxodiol in animals bearing human tumor xenografts; and third, observations of clinical responses in patients treated with phenoxodiol. The particular tumor types selected are ovarian cancer, prostate cancer, and SCC of skin, mucosal surfaces and renal cancer. Breast and pancreatic cancer also have been identified as potential clinical targets, and may be studied in due course. A feature of this entire group of cancers that underlies their selection from a strategic point of view is their aggressiveness and generally low sensitivity to standard chemotoxic drugs.

Novogen decided to pursue the clinical applications in prostate cancer and SCC using the oral dosage form of the drug. This followed the trial use of the oral dosage form in a number of patients who had completed the Phase I trials of the intravenous dosage form of phenoxodiol. The oral dosage form was found capable of prolonging survival in patients with advanced disease despite the presence of phenoxodiol in the blood in an almost completely conjugated form. It appears that certain types of tumors may have the capacity to deconjugate phenoxodiol conjugates to the active drug form. Clinical trials on the oral dosage form of phenoxodiol began in Australia in January 2002. This dosage form currently is being evaluated in Australian hospitals in Phase II clinical trials for the treatment of prostate cancer and in a U.S. hospital for the treatment of SCC.

An IND for the oral dosage form of phenoxodiol became effective in June 2003 which cleared the way to commence a study in collaboration with Yale University School of Medicine in patients with SCC of the cervix vulva and vagina. Phenoxodiol will be used on a monotherapy basis in patients following a primary diagnosis of cancer. Phenoxodiol will be administered daily for periods of up to 4 weeks prior to surgery or radiotherapy.

A Phase Ib/IIa study began in early 2002 on the use of phenoxodiol in patients with hematological tumors, in an attempt to test the usefulness of phenoxodiol in non-solid tumors. However, the apparent greater sensitivity of certain solid tumors to phenoxodiol and the need to focus resources on those clinical opportunities mean that an application in hematological tumors is unlikely to be taken further.

## **Competition**

The clinical development and commercialization of new anti-cancer drugs is highly competitive. As a developmental stage pharmaceutical company, we compete with pharmaceutical and biotechnology companies, academic and scientific institutions, governmental agencies and public and private research organizations.

Many pharmaceutical and biotechnology companies have drug candidates or non-drug therapies including vaccines and radiotherapies in various stages of pre clinical or clinical development to treat prostate cancer, ovarian cancer, SCC and other cancers. Some of these potentially competitive drugs and therapies are further advanced in development and may receive FDA or other regulatory approval and may be commercialized earlier than phenoxodiol. Some of these drugs and therapies may be directly competitive with phenoxodiol to the extent that they would obviate the need for phenoxodiol. In other cases, however, phenoxodiol could offer competitive

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advantages to these drugs and therapies. In other cases, these drugs or therapies may not be competitive to the extent that they are not mutually exclusive and could be used in conjunction with phenoxodiol.

Many pharmaceutical and biotechnology companies are developing drugs specifically in the area of signal transduction inhibition. Several such drugs have received marketing approval over the past five years. While much of the activity in this field is based on rational drug design, meaning that the nature of action of such drugs is overwhelmingly focused on individual signaling targets, it would be reasonable to expect that attention will be drawn increasingly to the development of drugs like phenoxodiol that have activity against multiple targets.

Two signal transduction drugs have been approved by the FDA in recent years as cancer therapies and are potentially competing products to phenoxodiol. Iressa distributed by AstraZeneca, has been granted approval for use in the treatment of advanced stage non-small cell lung cancer in patients who have already received specific chemotherapy. Erbitux, distributed by Bristol-Myers Squibb, was recently granted approval for use in the treatment of patients with late-stage colo-rectal cancer. In the area of more traditional cytotoxic anti-cancer drugs, Taxotere, a drug distributed by Aventis, was approved recently by the FDA for the treatment of hormone refractory prostate cancer, establishing a new bench-mark for standard chemotherapy in late stage prostate cancer. We are also aware of the experimental drug, Telcyta, being developed by Telik Inc. as a chemo-sensitizing drug for various cancers, including refractory and resistant ovarian cancer, which is an indication also under development for phenoxodiol.

Our competitors may develop and commercialize products that are safer, less costly and more efficacious in the treatment of cancers. In addition, we and Novogen, our services provider, face and will continue to face competition from companies, institutions, agencies and organizations, including those in fields unrelated to drug development, to recruit qualified personnel, attract partners for joint ventures and license competitive technologies.

Many of our competitors 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 at present. Aventis, which is developing Flavopiridol<sup>TM</sup>, AstraZeneca, which has been granted approval for Iressa, and Bristol-Myers Squibb are three such companies with potentially competitive anti-cancer drugs that have greater size, resources and market presence than we do.

### **Intellectual Property**

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

We have licensed from Novogen the rights to the Novogen patents and applications as they relate to phenoxodiol as an anti-cancer agent. Excluded from these rights is phenoxodiol in a topical formulation. The patent rights we have licensed from Novogen can be largely classified into two broad groups: patent rights relating to phenoxodiol used as an anti-cancer agent, which we refer to as “therapeutic patent rights,” and patent rights relating to the manufacture of phenoxodiol for anti-cancer purposes, which we refer to as “manufacturing patent rights.” The pending and issued Novogen patent rights can be further broken down into four families, three families belonging to the therapeutic patent rights and one family belonging to the manufacturing patent rights. The three families in the therapeutic patent rights comprise phenoxodiol in the treatment of cancer (15 pending and seven issued) compositions and methods for protecting skin from ultraviolet induced immunosuppression and skin damage, including phenoxodiol (nine pending and four issued), and therapeutic methods and compositions involving isoflav-3-ene and isoflavan structure, including phenoxodiol (PCT pending). The family relating to the manufacturing patent rights relate to the production of isoflavone derivatives, including phenoxodiol (16 pending and one issued).

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

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prostate cancer, uterine cancer, bowel cancer, testicular cancer, endometrial cancer, leukemia and metastatic cancer with isoflavone derivatives including phenoxodiol.

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

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

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

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

### **Relationship with Novogen**

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

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

We have entered into certain key agreements with Novogen. These agreements, discussed briefly below, are more

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fully detailed in “Certain Relationships and Related Transactions.”

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

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

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

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

### **Research and Development**

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

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

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

Research expenses were \$2.381 million for the year ended June 30, 2004, \$2.024 million for the year ended June 30, 2003 and \$0.069 million for the year ended June 30, 2002. Research expenses were \$439,000 for the three months ended September 30, 2004 and \$782,000 for the three months ended September 30, 2003.

### **Regulation**

#### *U.S. Regulatory Requirements*

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

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

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

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

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

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

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

We cannot be certain in that we will successfully complete Phase I, Phase II, or Phase III testing of our products within any specific time period if at all. Furthermore the FDA, the Institutional Review Board or we may suspend or

terminate clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

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

Each NDA must be accompanied by a user fee, pursuant to the requirements of the Prescription Drug User Fee Act, or PDUFA, and its amendments. According to the FDA's fee schedule, effective on October 1, 2003 for the fiscal year 2004, the user fee for an application requiring clinical data, such as an NDA, is \$573,500. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual product fee for prescription drugs and biologics (\$36,080), and an annual establishment fee (\$226,800) on facilities used to manufacture prescription drugs and biologics. A written request can be submitted for a waiver for the application fee for the first human drug application that is filed by a small business, but there are no waivers for product or establishment fees. We are not at the stage of development with our products where we are subject to these fees, but they are significant expenditures that will be incurred in the future and must be paid at the time of application submissions to FDA.

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

After product approval, there are continuing significant regulatory requirements imposed by the FDA, including record-keeping requirements, obligations to report adverse experiences, 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 submission of an NDA Supplement. Failure to comply with FDA regulatory requirements may result in an enforcement action by the FDA, including Warning Letters, product recalls, suspension or revocation of product approval, seizure of product to prevent distribution, impositions of injunctions prohibiting product manufacture or distribution, and civil and criminal penalties. Maintaining compliance is costly and time-consuming. We cannot be certain that we, or our present or future suppliers or third-party manufacturers, will be able to comply with all FDA regulatory requirements, and potential consequences of noncompliance could have a material adverse impact on our business prospects.

The FDA's policies may change, and additional governmental regulations may be enacted that could delay, limit, or prevent regulatory approval of our products or affect our ability to manufacture, market, or distribute our products after approval. Moreover, increased attention to the containment of healthcare costs in the United States and in

foreign markets could result in new government regulations that could have a material adverse effect on our business. Our failure to obtain coverage, an adequate level of reimbursement, or acceptable prices for our future products could diminish any revenues we may be able to generate. Our ability to commercialize future products will depend in part on the extent to which coverage and reimbursement for the products will be available from government and health administration authorities, private health insurers, and other third-party payers. European Union and U.S. government and other third-party payers increasingly are attempting to contain healthcare costs by consideration of new laws and regulations limiting both coverage and the level of reimbursement for new drugs. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad.

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

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

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

#### *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, or exported from Australia be included in the Australian Register of Therapeutic Goods, or ARTG, unless specifically exempted under the Act.

In order to ensure that a product can be included in the ARTG, a sponsoring company must make an application to the Therapeutic Goods Administration, or TGA. The application usually consists of a form accompanied by data (based on the European Union requirements) to support the quality, safety and efficacy of the drug. In the case of drugs for important medical conditions the TGA will accept either European or American dossier format in an attempt to expedite the registration process.

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



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

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

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

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

### *European Union Regulatory Requirements*

Outside the United States, our ability to market our products will also be contingent upon receiving marketing authorizations from the appropriate regulatory authorities and compliance with applicable post-approval regulatory requirements. Although the specific requirements and restrictions vary from country to country, as a general matter, foreign regulatory systems include risks similar to those associated with FDA regulation, described above. Under EU regulatory systems, marketing authorizations may be submitted either under a centralized or decentralized procedure. Under the centralized procedure, a single application to the European Medicines Evaluation Agency (EMA) leads to an approval granted by the European Commission which permits the marketing of the product throughout the EU. The centralized procedure is mandatory for certain classes of medicinal products, but optional for others. For example, all medicinal products developed by certain biotechnological means must be authorized via the centralized procedure. We assume that the centralized procedure will apply to our products that are developed by means of a biotechnology process. The decentralized procedure provides for mutual recognition of nationally approved decisions and is used for products that are not required to be authorized by the centralized procedure. Under the decentralized procedure, the holders of a national marketing authorization may submit further applications to the competent authorities of the remaining member states, which will then be requested to recognize the original authorization based upon an assessment report prepared by the original authorizing competent authority. The recognition process should take no longer than 90 days, but if one member state makes an objection, which under the legislation can only be based on a possible risk to human health, we have the option to withdraw the application from that country or take the application to arbitration by the Committee for Proprietary Medicinal Products (CPMP) of the EMA. If a referral for arbitration is made, the procedure is suspended, and in the intervening time, the only EU country in which the product can be marketed will be the country where the original authorization has been granted, even if all the other designated countries are ready to recognize the product. The opinion of the CPMP, which is binding, could support or reject the objection or alternatively could reach a compromise position acceptable to all EU countries concerned. Arbitration can be avoided if the application is withdrawn in the objecting country, but once the application has been referred to arbitration, it cannot be withdrawn. The arbitration procedure may take an additional year before a final decision is reached and may require the delivery of additional data.

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

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There has recently been introduced in Europe new legislation designed to harmonize the regulation of clinical trials across the EU and that legislation is currently being implemented on a country by country basis. In addition, the entire EU regulatory regime has recently undergone significant revision and the new law is to take effect by the end of 2005. 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 the "Risk Factors" section of this prospectus.

### **Employees**

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

### **Facilities**

We do not own or lease any facility. Novogen provides us with space for our corporate headquarters.

### **Legal Proceedings**

We are not currently a party to any material legal proceedings.

## MANAGEMENT

### Directors and Executive Officers

The following sets forth information for each of our directors and executive officers.

***Professor Graham Edmund Kelly, PhD, age 59, Chairman, Director***

Professor Kelly was appointed as our Chairman in April 2001. Professor Kelly founded Novogen in 1992 and has spent nearly 30 years in medical research involving drug development, immunology, surgery and cancer. Professor Kelly was a senior research fellow in experimental surgery in the Faculty of Medicine at the University of Sydney from 1972 to 1994 and was appointed an Adjoint Professor of the University in May 2004. He developed the  $\beta$ -1, 3-glucan and isoflavone intellectual property now owned by the Novogen Group. Professor Kelly was Executive Chairman of Novogen between 1997 and 2000 and continues to act as project leader for phenoxodiol. Professor Kelly's term as one of our directors expires in 2005.

***Christopher Naughton, age 51 President and CEO, Director***

Mr. Naughton has been our President and CEO since our inception in December 2000. He also has been the Managing Director of Novogen since March 1997. Mr. Naughton has degrees in Economics from the Australian National University and in Law from the University of New South Wales. He has completed the Program for Management Development at the Harvard Business School and is admitted to practice as an attorney in New South Wales. After working in merchant banking, he has spent the last 19 years in the pharmaceutical industry including appointments as a Director of Wellcome Australia Limited and in world wide business development with the Wellcome Foundation Limited in the UK. Mr. Naughton's term as one of our directors expires in 2005.

***Philip Andrew Johnston, age 57, Director***

Mr. Johnston has been one of our directors since April 2001. Mr. Johnston has had more than 25 years of experience in the pharmaceutical industry. He has been a Non-Executive Director of Novogen since January 1997, and Chairman of Novogen since January 2001. Mr. Johnston spent nine years as an Executive Director of Wellcome Australia Limited from June 1988 to September 1997. He was previously Director of two subsidiary companies of GlaxoWellcome. His responsibilities have encompassed production, distribution, quality assurance and consumer product development and he has been directly involved in the establishment of strategic alliances and joint ventures. Mr. Johnston has completed a number of executive development programs including programs at the University of NSW and the London Business School. Mr. Johnston is also a Director of Lipa Pharmaceutical Limited. Mr. Johnston's term as one of our directors expires in 2004.

***Professor David Morritz de Kretser, age 65, Director***

Professor de Kretser has been one of our Directors since April 2001. Professor de Kretser has been active in medicine and research for over 30 years, taking on roles including Professor of the Department of Anatomy, Monash University, where he has served as a professor since 1978. Professor de Kretser has been employed by Monash University continuously since 1978. Professor de Kretser has served as the Executive Chair of the Monash Institutes of Health and Associate Dean For Biotechnology Development at Monash University since July 2001 and the Director of the Australian Centre for Excellence in Male Reproductive Health since July 2001. He was the Founding Director of the Monash Institute of Reproduction and Development and remains as the Director of the Centre for Molecular Reproduction and Endocrinology within the institute. He has served on numerous international and national committees dealing with research and has experience on a number of professional editorial boards. He has published over 400 research papers and has been invited to speak at numerous national and international conferences and symposiums on topics such as fertility, andrology and endocrinology. Professor de Kretser's research has led to a number of patents in Australia and overseas. He is an Officer of the Order of Australia, a Fellow of the Australian Academy of Science and a Fellow of the Australian Academy of Technological Sciences and Engineering. Professor de Kretser was re-elected as a director at our annual meeting on December 9, 2003 and his term as one of our directors expires in 2006.

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### ***Professor Paul John Nestel, age 74, Director***

Professor Nestel has been one of our directors since April 2001. Professor Nestel has been a non-executive Director of Novogen since September 2001. Since January 1995, he has been Senior Principal Research Fellow and Head of the Cardiovascular Nutrition laboratory at the Baker Medical Research Institute, Victoria. Professor Nestel has also been Consultant Physician at the Alfred Hospital, Melbourne since January 1995. He is president of the International Life Sciences Institute (Australasia) and a member of the board of directors of ILSI South East Asia. He was formerly Clinical Professor in Medicine, The Flinders University of South Australia. Professor Nestel is an Officer of the Order of Australia. Professor Nestel's term as one of our directors expires in 2004.

### ***Stephen Breckenridge, age 62, Director***

Mr. Breckenridge has been one of our directors since August 2003. Mr. Breckenridge has had over 25 years experience in public practice as a Chartered Accountant in Australia and since 2004 has been the Head of Transfer Pricing for Australia and Asia at Baker McKenzie (a global law Firm). Mr. Breckenridge has been Managing Director of Breckenridge Consulting Pty Ltd which provides independent tax and management advice to multi-nationals and SME's. Until 2001, Mr. Breckenridge was a tax partner for 24 years with KPMG in Sydney where he provided corporate tax advice to a wide cross section of business in Australia and overseas with particular emphasis in more latter years on international transfer pricing. Mr. Breckenridge has also been involved in the pharmaceutical and chemical industries over a long period including serving on several industry association committees and leading industry focus groups within KPMG. Mr. Breckenridge holds a Master of Tax degree from the University of Sydney and is a Fellow of the Institute of Chartered Accountants and the Taxation Institute of Australia. Mr. Breckenridge was appointed to our board of directors on August 1, 2003 and was elected as a director at our annual meeting on December 9, 2003. His term as one of our directors expires in 2006.

### ***David Ross Seaton, age 50, Chief Financial Officer***

Mr. Seaton has been our Chief Financial Officer and Company Secretary since December 2000 and has been the Chief Financial Officer of Novogen since September 1999. He holds a degree in Business Studies as well as a Master of Commerce degree from the University of New South Wales. He has completed management development programs at Northwestern University in Chicago as well as at Duke University and at the London Business School. He has 19 years experience in the pharmaceutical industry. Prior to joining Novogen in 1999 was the Finance Director of GlaxoWellcome Australia Limited from 1995 to 1999.

## **Corporate Governance**

### ***Board of Directors***

Our board of directors has responsibility for our overall corporate governance and meets regularly throughout the year.

Four of our six existing board members are also currently directors of Novogen. We are a "controlled corporation" within the meaning given to that term by Nasdaq because Novogen owns more than 50% of our voting power. As a controlled corporation, we are exempt from the requirement that our board be composed of a majority of independent directors.

The board has established an Audit Committee to oversee our financial matters and a Remuneration Committee to review the performance of executive directors and their remuneration.

### ***Audit Committee***

The Audit Committee is responsible for overseeing our financial and accounting activities, including external audits and accounting functions. The Audit Committee meets at least twice each year. The Audit Committee's responsibilities include the annual appointment of our outside auditors and the review of the scope of audit and non-audit assignments and related fees, the accounting principles we use in financial reporting, internal auditing

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procedures and the adequacy of our internal control procedures. The members of the Audit Committee are Mr. Breckenridge (chairman), Mr. Johnston, Professor de Kretser and Professor Nestel, all of whom are independent as defined by applicable Nasdaq and SEC rules. The board of directors has determined that Stephen Breckenridge is an audit committee financial expert as defined by SEC rules.

### *Remuneration Committee*

The Remuneration Committee reviews the performance of executive directors and sets their remuneration. The Remuneration Committee also has the power to make recommendations to the full board concerning the allocation of share options to directors and employees. The remuneration and terms of appointment of non-executive directors will be set by our board of directors. The members of the Remuneration Committee are Mr. Johnston, Professor de Kretser, Mr. Breckenridge and Professor Nestel.

### **Director and Executive Compensation**

#### *Directors*

Our directors, other than Professor Kelly and Mr. Naughton, receive directors fees of \$A30,000 (approximately US\$21,500) per annum from us. Professor Kelly and Mr. Naughton do not receive any remuneration for performing their duties as our directors.

#### *Executive Officers*

Our executive officers, Professor Kelly, Mr. Naughton and Mr. Seaton, are also executive officers of Novogen and do not receive any remuneration directly from us in performing their duties as our executive officers. At the present time, their services are provided to us pursuant to the services agreement with Novogen.

### **Equity Compensation Plan Information**

The following table sets forth, as of September 30, 2004 outstanding awards and shares remaining available for future issuance under our compensation plans under which equity securities are authorized for issuance.

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

As of the date of this prospectus, no options were outstanding under the equity compensation plan (also referred to as our share option plan) and we have no present intention of granting any options under the plan. We expect that the board would authorize our remuneration committee to oversee the plan, but no such action has been taken. The following is a summary of the plan.

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The plan provides our directors, employees, employees of our affiliates and certain of our contractors and consultants with the opportunity to participate in our ownership.

The committee will address participation, the number of options offered and any conditions of exercise. In making these determinations the committee will generally consider the participant's position and record of service to us and our affiliates and potential contribution to the growth of us and our affiliates. Any other matters tending to indicate the participant's merit may also be considered.

Options will be exercisable between two years and five years after grant, unless otherwise determined by the committee appointed by the board. Options granted will be exercisable at a price determined by the committee at the time of issue (and will be subject to adjustment in accordance with the terms of the plan).

Other key terms of the plan include:

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

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

**BENEFICIAL OWNERSHIP OF COMMON STOCK**

None of our directors or executive officers own any shares of our capital stock. The following table sets forth information with respect to the beneficial ownership of our common stock by owners of more than 5% of our common stock as of December 8, 2004.

<b>Name and Address of Beneficial Owner</b>	<b>Number of Shares Beneficially Owned Before and After this Offering</b>	<b>Percentage of Shares Beneficially Owned Before this Offering</b>	<b>Percentage of Shares Beneficially Owned if all warrants are exercised</b>
Novogen Limited(1) 140 Wicks Road North Ryde NSW 2113 Australia	49,500,000	86.9%	83.4%
OppenheimerFunds, Inc.(2) 6803 S Tucson Way Centennial, CO 80112-3924	3,495,300	6.1%	5.9%

(1) Novogen Limited has sole voting and investment power with respect to the shares of common stock shown.

(2) Based on information provided to us by OppenheimerFunds, Inc., OppenheimerFunds, Inc. holds all shares attributed to it solely in its capacity as investment adviser to its clients and is the beneficial owner of the shares shown in the table by virtue of it having voting and/or dispositive power with respect to the shares of common stock shown in the table.

## CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Our agreements with Novogen are each summarized below. Each of these agreements was approved by a majority of our independent directors who did not have an interest in the transaction. We believe that each of our agreements with Novogen is on terms as favorable to us as we could have obtained from unaffiliated third parties. The following description is only a summary of what we believe are the material provisions of the agreements. Copies of the agreements have been filed with the Securities and Exchange Commission as exhibits to the registration statement of which this prospectus forms a part.

### **The License Agreement**

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

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

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

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

### **Marketing and Commercialization**

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

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

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

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



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1. A second lump sum license fee of \$5,000,000 is payable to Novogen on November 1, 2003 or such later date when the cumulative total of all funds received from debt or equity issuances and revenue received from commercialization (income other than sales) and sales of phenoxodiol products exceeds \$50,000,000.
2. In addition to the amounts above, until the expiration of the exclusivity period of the license, MEPL must pay Novogen 2.5 % of all net sales and 25% of commercialization income. After the exclusivity period of the license, 1.5% of net sales must be paid to Novogen.
3. In addition to the amounts above, amounts payable for annual milestone license fees under the license agreement for the calendar years ended December 31 are as follows:

Calendar Year	
2004	\$2,000,000
2005	\$4,000,000
Each calendar year thereafter during the exclusivity period	\$8,000,000

At June 30, 2004 an amount of \$1,000,000 was accrued and reflected in amounts due to the parent company, being 50% of the \$2,000,000 milestone payment payable to Novogen on December 31, 2004 under the terms of the license agreement with Novogen. Milestone license fees of \$500,000 have been accrued in the three months ended September 30, 2004 in connection with the payment due December 31, 2004.

### **Termination**

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

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

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

### **Supply of Phenoxodiol**

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

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

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

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

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

For the fiscal year ended June 2004, we expensed \$761,000 in fees under the manufacturing and supply agreement. Transactions giving rise to expenditure amounting to \$120,000 were made under the manufacturing license and supply agreement with Novogen during the three months ended September 30, 2004. At September 30, 2004, \$69,000 was due and owing to Novogen under the manufacturing license and supply agreement and is included in amounts due to parent company.

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

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

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

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

### ***Termination***

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

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

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

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

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

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phenoxodiol) developed by Novogen or its affiliates.

### ***Option Compounds***

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

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

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

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

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

### ***Development Reports***

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

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

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

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

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

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

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

Novogen's obligations also include providing, within the agreed budgets described below, our needs with respect to secretarial, marketing, finance, logistics, administrative and managerial support. Novogen also plans, conducts and

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supervises pre-clinical and clinical trials with phenoxodiol and with other compounds in which we have intellectual property rights. Novogen also provides scientific and technical advice on management of pre-clinical and clinical research programs undertaken by us and manages such research provisions. We have guaranteed the obligations of our subsidiary under the services agreement. See “—Guarantee and Indemnity Agreement.”

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

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

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

For the fiscal year ended June 2004, we expensed \$1,113,000 in fees under the services agreement. Transactions giving rise to expenditure amounting to \$253,000 were made under the services agreement with Novogen during the three months ended September 30, 2004. At September 30, 2004, \$85,000 was due and owing to Novogen under the services agreement and is included in amounts due to parent company.

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

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

### ***Termination***

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

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

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

### ***Indemnification***

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

***Termination***

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

## DESCRIPTION OF OUR SECURITIES

### ***General***

Our total authorized share capital is 113,100,000 shares consisting of 113,000,000 shares of common stock, \$0.0000002 par value per share, and 100,000 shares of preferred stock, \$0.01 par value per share. As of December 8, 2004, 56,938,000 shares of our common stock and no shares of preferred stock were issued and outstanding.

### ***Common Stock***

The holders of common stock are entitled to one vote per share. In the event of a liquidation, dissolution or winding up of our affairs, holders of the common stock will be entitled to share ratably in all our assets that are remaining after payment of our liabilities and the liquidation preference of any outstanding shares of preferred stock. All outstanding shares of common stock are fully paid and non-assessable. The rights, preferences and privileges of holders of common stock are subject to any series of preferred stock that we have issued or that we may issue in the future. The holders of common stock have no preemptive rights and are not subject to future calls or assessments by us.

### ***Preferred Stock***

The board has the authority to issue up to 100,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions in respect of that preferred stock, including dividend rights, dividend rates, conversion rights, voting rights, terms of redemption (including sinking fund provisions), redemption prices and liquidation preferences, and the number of shares constituting such series and the designation of any such series, without future vote or action by the stockholders. Therefore, the board without the approval of the stockholders could authorize the issue of preferred stock with voting, conversion and other rights that could affect the voting power, dividend and other rights of the holders of common stock or that could have the effect of delaying, deferring or preventing a change of control. As of the date of this prospectus, we have no plans to issue any preferred stock.

### ***Warrants***

We currently have 2,392,000 warrants outstanding. Each warrant represents the right to purchase one share of our common stock at an exercise price equal of \$9.00. The warrants are exercisable at any and will expire at 5:00 PM Eastern Time on December 18, 2006. The expiration date may not be extended without an amendment to the warrant agreement by us and the warrant agent. The number of shares of our common stock to be received upon the exercise of each warrant may be adjusted from time to time upon the occurrence of certain events, including but not limited to the payment of a dividend or other distribution in respect common stock, subdivisions, reclassifications or combinations of our common stock. The securities receivable upon exercise of each warrant may be adjusted in the event of any reorganization, consolidation, merger, liquidation or similar event. We do not have any right to call or otherwise redeem the warrants.

We have authorized and reserved for issuance all shares of common stock issuable upon exercise of each warrant.

Upon exercise of the warrants included in the units, we will, as soon as reasonably practicable, apply to the Alternative Investment Market of the London Stock Exchange for the admission of the shares of common stock underlying the warrants. Under the rules of the Alternative Investment Market, we must submit an application form in respect of such shares at least three business days before the expected date of admission of the shares of common stock underlying the warrants.

### ***Transfer Agent, Warrant Agent and Registrar***

Our transfer agent, warrant agent and registrar is Computershare Investor Services, LLC, Two North La Salle Street, Chicago, Illinois 60602.

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### **Summary of our Amended and Restated By-Laws and Restated Certificate of Incorporation and certain Provisions of the Delaware General Corporation Law (DGCL)**

The following summary of the terms and provisions of the our certificate of incorporation, by-laws, certain aspects of the DGCL does not purport to be complete. Reference should be made to our certificate of incorporation and our by-laws and to applicable law for the complete description.

#### ***Meetings of Stockholders and Voting***

Our by-laws provide for an annual meeting of stockholders, the date of which is fixed by the board. Meetings of stockholders may be held at such place as may be designated by the board. Stockholders are entitled to inspect our books and records to the extent allowable by Delaware law. Our by-laws provide that a quorum for the transaction of business at any meeting of stockholders is stockholders holding at least one-third of the shares entitled to vote at such meeting. Decisions at stockholder meetings will normally be made by a majority of votes cast except in the case of any resolution that, as a matter of law, requires a special majority. Each stockholder entitled to vote at a meeting of stockholders or to express consent or dissent to each corporate action in writing without a meeting may authorize another person or persons to act for him or her by proxy.

#### ***Appointment and Removal of Directors***

Our certificate of incorporation and by-laws provide that the number of directors will be set by resolution of the board, but shall be between two and nine. We currently have six directors.

Under our certificate of incorporation and by-laws, directors are to be appointed at the annual general meeting for a term of three years unless the director is removed, retires or the office is vacated earlier. Our board is divided into three classes with respect to the term of office, with the terms of office of one class expiring each successive year. This classified board provision could discourage a third party from making a tender offer for our shares or attempting to obtain control of our company. It could also delay stockholders who do not agree with the policies of the board of directors from removing a majority of the board of directors for two years.

A director may resign at any time. The resignation is effective on our receipt of notice. Any or all directors may be removed with or without cause by a resolution of stockholders entitled to vote to elect directors. Vacancies may be filled by resolution of a majority of directors then in office or by a sole remaining director, and any director so appointed shall serve for the remainder of the full term of the class of directors in which the vacancy occurred.

#### ***Blank Check Preferred Stock***

Our certificate of incorporation provides our board of directors with the authority, without any further vote or action by our stockholders, to issue shares of preferred stock with terms and preferences determined by our board. Our board of directors may issue shares of preferred stock on terms calculated to discourage, delay or prevent a change of control of our company or the removal of our management.

#### ***Amendments of the By-Laws***

Our by-laws provide that the power to amend the by-laws will vest in the directors, subject to the reserved power of the stockholders to amend or repeal any by-laws adopted by the board.

#### ***Amendments of the Certificate of Incorporation***

Our certificate of incorporation can be amended, after the approval and recommendation of the amendment by the board of directors, by a majority vote of our stockholders, except for certain matters submitted to the board for which the certificate of incorporation requires a vote of not less than eighty percent (80%) of the outstanding shares eligible to be cast and certain other matters for which Delaware law requires a supermajority vote.

#### ***Indemnification of Directors and Officers***

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Our certificate of incorporation provides that we will indemnify our directors and officers to the fullest extent permitted by the DGCL. Section 145 of the DGCL provides that the extent to which a corporation may indemnify its directors and officers depends on the nature of the action giving rise to the indemnification right. In actions not on behalf of the corporation, directors and officers may be indemnified for acts taken in good faith and in a manner reasonably believed to be in or not opposed to the best interests of the corporation. In actions on behalf of the corporation, directors and officers may be indemnified for acts taken in good faith and in a manner reasonably believed to be in or not opposed to the best interests of the corporation, except for acts as to which the director or officer is adjudged liable to the corporation, unless the relevant court determines that indemnification is appropriate despite such liability. Section 145 also permits a corporation to (i) reimburse present or former directors or officers for their defense expenses to the extent they are successful on the merits or otherwise and (ii) advance defense expenses upon receipt of an undertaking to repay the corporation if it is determined that payment of such expenses is unwarranted.

To supplement the general indemnification right contained in our certificate of incorporation, the by-laws provide for the specific indemnification rights permitted by Section 145 (as described above). The by-laws also permit us to purchase directors and officers insurance, but no director or officer has a right to require this.

In addition to the indemnification rights described above, our certificate of incorporation eliminates any monetary liability of directors to us or our stockholders for breaches of fiduciary duty except for (i) breaches of the duty of loyalty, (ii) acts or omissions in bad faith, (iii) improper dividends or share redemptions and (iv) transactions from which the director derives an improper personal benefit.

### ***Indemnification of Novogen***

Our certificate of incorporation provides that we will indemnify Novogen to the fullest extent permitted by the DGCL in connection with certain actions brought against Novogen by us, any of our stockholders or any other person.

### ***Transactions and Corporate Opportunities***

Under our certificate of incorporation, we are subject to certain provisions which serve to define and delineate the respective rights and duties of us, Novogen and some of our directors and officers in situations where:

- Novogen invests or engages in business activities that are the same as, or similar to, our business activities,
- directors, officers and/or employees of Novogen serve as our directors and/or officers, and
- Novogen has interest in a potential transaction or matter in which we have a similar interest in exploiting as a matter of corporate opportunity.

Pursuant to our certificate of incorporation, Novogen has no duty to refrain from investing or engaging in activities or lines of business similar to ours and neither Novogen nor any of its officers, directors, stockholders, affiliates, subsidiaries or employees will be liable to us or our stockholders for breach of any fiduciary duty by reason of any of these activities. In addition, if Novogen acquires knowledge of a potential transaction or matter which may be a corporate opportunity for both our company and Novogen, then neither Novogen nor any of its officers, directors, stockholders, affiliates, subsidiaries or employees will have a duty to communicate or offer this corporate opportunity to us and will not be liable to us or our stockholders for breach of any fiduciary duty as a stockholder by reason of the fact that Novogen or any other such person pursues or acquires the corporate opportunity for itself, directs the corporate opportunity to another person or does not communicate information regarding the corporate opportunity to us.

We do not release from potential liability our own officers and directors in instances where a corporate opportunity is offered to the officer and/or director in his or her capacity as an officer and that person:

- serves as a director, officer or employee of Novogen while holding the position of a director but not officer



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of our company; or

- serves as an officer or employee of Novogen and serves as one of our officers.

Further, any of our officers who is also a Novogen director but not a Novogen officer or employee may be potentially liable for exploiting our corporate opportunities whether or not such opportunities were offered to that officer in his or her official capacity.

By becoming one of our stockholders, you will be deemed to have notice of and consented to these provisions of our certificate of incorporation. Until Novogen ceases to beneficially own common stock representing at least 20% of the voting power of our outstanding capital stock, these provisions may not be amended or repealed.

## SHARES ELIGIBLE FOR FUTURE SALE

As of December 8, 2004, 56,938,000 shares of our common stock are outstanding not including the 2,392,000 shares of common stock underlying the warrants. Of the shares which will be outstanding as of December 8, 2004, 49,500,000 shares are held by Novogen.

The restricted securities described are subject to volume limitations, manner of sale provisions and other requirements of Rule 144, from time to time.

In general, under Rule 144 as currently in effect, a person (or persons whose shares are aggregated) who owns shares that were acquired from the issuer or an affiliate of the issuer at least one year prior to the proposed sale, including an affiliate, is entitled to sell, within any three-month period, a number of shares that does not exceed the greater of:

- one percent of the then outstanding shares of our common stock; or
- the average weekly trading volume during the four calendar weeks preceding filing of notice of such sale.

A person (or persons whose shares are aggregated) who is not deemed to have been an affiliate of the issuer at any time during the 90 days preceding a sale and who owns shares that were acquired from the issuer or an affiliate of the issuer at least two years prior to the proposed sale is entitled to sell such shares pursuant to Rule 144(k) without regard to the volume limitations, manner of sale provisions or other limitations of Rule 144.

Shares held by Novogen may be sold in the public market, subject to the volume, manner of sale and other limitations of Rule 144, but may not be sold in reliance upon Rule 144(k).

In May 2004, 2,523,000 shares of our common stock became eligible for sale under Rule 144(k).

In June 2004, 9,000 shares of our common stock became eligible for sale under Rule 144.

In November 2004, 2,514,000 shares of our common stock became eligible for sale under Rule 144.

Sales of significant amounts of our common stock by stockholders in the future, under Rule 144 or otherwise, may have an adverse effect on the price of our common stock.

**PLAN OF DISTRIBUTION**

We are offering shares of common stock issuable upon the exercise of our public warrants. The public warrants may be exercised by surrendering the certificate representing such warrants, with instructions for registration and delivery of the underlying common stock completed and the form of election to purchase on the reverse side of such certificate completed and executed, together with payment of the exercise price and any applicable taxes, to the warrant agent. If less than all of the warrants evidenced by a warrant certificate are exercised, a new certificate will be issued for the remaining number of warrants.

## LEGAL MATTERS

The validity of the shares of common stock offered hereby was passed upon for us by Morgan, Lewis & Bockius LLP.

## EXPERTS

The consolidated financial statements of Marshall Edwards, Inc. (a development stage company) at June 30, 2004 and for the year then ended and for the period from December 1, 2000 (inception) through June 30, 2004, appearing in this Prospectus and Registration Statement have been audited by Ernst & Young, independent registered public accounting firm, and at June 30, 2003 and 2002, and for each of the two years in the period ended June 30, 2003 and for the period from December 1, 2000 (inception) through June 30, 2003, by Ernst & Young LLP, independent registered public accounting firm, as set forth in their respective reports thereon appearing elsewhere herein, and are included in reliance upon such reports given on the authority of such firms as experts in accounting and auditing.

## AVAILABLE INFORMATION

We have filed with the SEC a registration statement on Form S-1, including amendments thereto, with respect to the shares of common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules which are part of the registration statement. We do not intend to use any forms of prospectus other than printed prospectuses. For further information with respect to us and our common stock and the attached rights, reference is made to the registration statement and the exhibits and schedules thereto. You may read and copy any document we or Novogen periodically file at the SEC's public reference room in Washington, D.C. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. These SEC filings are also available to the public from the SEC's website at <http://www.sec.gov>.

We are subject to the information and periodic reporting requirements of the Securities Exchange Act of 1934, as amended, and, in accordance therewith, file periodic reports, proxy statements and other information with the SEC. Such periodic reports, proxy statements and other information are available for inspection at the SEC's public reference rooms and the website of the SEC referred to above.

We are required by the Alternative Investment Market of the London Stock Exchange to prepare half-yearly reports and annual audited accounts. You may request a copy of these reports, which we will provide to you at no cost, by writing or calling us at our mailing address and telephone number: 140 Wicks Road, North Ryde NSW 2113, Australia, telephone: (011) 61 2 8877 6196.

**GLOSSARY OF TERMS**

<b>“Androgens”</b>	male sex hormones, e.g. testosterone
<b>“Anti-androgen”</b>	a process that reduces the biological impact of androgens, either by blocking the production of androgens or by interfering with their function
<b>“Apoptosis”</b>	the process of programmed cell death by which a cell dies naturally
<b>“Bioavailable”</b>	absorbed into the body in a useable form
<b>“Bolus injection”</b>	an intravenous injection delivered quickly (usually over several minutes)
<b>“Cytostatic”</b>	the process by which a cell is prevented from dividing
<b>“Cytotoxic”</b>	having a lethal effect on cells
<b>“Death receptor”</b>	signaling molecule that when activated causes cell death
<b>“in vitro”</b>	in the laboratory
<b>“in vivo”</b>	in animals
<b>“IND”</b>	Investigational New Drug application
<b>“Isoflavonoid ring structure”</b>	a chemical term referring to a simple phenolic ring structure
<b>“Kinases”</b>	enzymes that catalyze phosphorylation of acceptor molecules
<b>“MSTR”</b>	Multiple Signal Transduction Regulator or Multiple Signal Transduction Regulation
<b>“NDA”</b>	New Drug Application
<b>“Pharmacokinetic”</b>	the behavior of a drug within the body, in particular the length of time it remains within the blood and the rate at which it is eliminated from the body
<b>“Phase I”</b>	generally the first trial of a drug in humans which tests for safety and dosage tolerance
<b>“Phase II”</b>	clinical trials which test for efficacy and adverse effects of a drug
<b>“Phase III”</b>	usually a multi-center study measuring efficacy in large numbers of patients
<b>“Plasma”</b>	the liquid component of blood
<b>“Prostate cancer”</b>	cancer of the prostate gland
<b>“Prostate smooth muscle cells”</b>	the main type of stromal cells found in the prostate gland
<b>“Prostate stromal cells”</b>	the principal type of non-glandular cells found in the prostate gland
<b>“Signal transduction process”</b>	a series of chemical signals transmitted within cells that lead to the expression of a particular function by the cell
<b>“Sphingosine kinase”</b>	a kinase believed to respond to important signals related to cell survival and cell growth

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**Report of Independent Registered Public Accounting Firm**

The Board of Directors  
Marshall Edwards, Inc.

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

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

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

Sydney, Australia  
13 August 2004

Ernst & Young



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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors Marshall Edwards, Inc.

We have audited the accompanying consolidated balance sheet of Marshall Edwards, Inc. (a development stage company) as of June 30, 2003, and the related consolidated statements of operations, shareholders' equity, and cash flows and for each of the two years in the period ended June 30, 2003 and for the period from December 1, 2000 (inception) through June 30, 2003. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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 consolidated financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

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

*Ernst & Young LLP*

July 31, 2003

A Member Practice of Ernst & Young Global



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

	September 30, 2004	June 30, 2004	June 30, 2003
	(unaudited)		
<b>ASSETS</b>			
Current assets			
Cash and cash equivalents	\$ 23,782	\$ 24,819	\$ 7,244
Prepaid expenses and other current assets	\$ 54	30	42
Total current assets	<u>23,836</u>	<u>24,849</u>	<u>7,286</u>
Total assets	<u>\$ 23,836</u>	<u>\$ 24,849</u>	<u>\$ 7,286</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>			
Current liabilities			
Accounts payable	\$ 86	\$ 192	\$ 433
Accrued expenses	394	437	278
Amount due to parent company	<u>1,644</u>	<u>1,278</u>	<u>642</u>
Total current liabilities	2,124	1,907	1,353
Stockholders' equity:			
Preferred stock, \$0.01 par value, authorized 100,000 shares, none outstanding	—	—	—
Common stock, \$0.00000002 par value, 113,000,000 authorized shares; shares issued and outstanding: 56,938,000 at September 30, 2004 and June 30, 2004 and 52,032,000 at June 30, 2003	—	—	—
Additional paid-in capital	34,636	34,636	9,058
Deficit accumulated during development stage	(12,924)	(11,694)	(3,156)
Accumulated other comprehensive income	—	—	31
Total stockholders' equity	<u>21,712</u>	<u>22,942</u>	<u>5,933</u>
Total liabilities and stockholders' equity	<u>\$ 23,836</u>	<u>\$ 24,849</u>	<u>\$ 7,286</u>

*See accompanying notes.*

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

	Three Months Ended September 30			Years Ended June 30,			Period from December 1, 2000 (Inception) through September 30, 2004
	2004	2003	2004	2003	2002		
	(unaudited)						(unaudited)
Revenues:							
Interest and other income	\$ 67	\$ 21	\$ 193	\$ 145	\$ 7	\$ 412	
Total revenues	<u>67</u>	<u>21</u>	<u>193</u>	<u>145</u>	<u>7</u>	<u>412</u>	
Operating expenses:							
Research and development	(439)	(782)	(2,381)	(2,024)	(69)	(4,913)	
License fees	(500)	(246)	(5,500)	(500)	—	(6,500)	
Selling, general and administrative	(358)	(107)	(850)	(654)	(60)	(1,922)	
Total operating expenses	<u>(1,297)</u>	<u>(1,135)</u>	<u>(8,731)</u>	<u>(3,178)</u>	<u>(129)</u>	<u>(13,335)</u>	
Loss from operations	<u>(1,230)</u>	<u>(1,114)</u>	<u>(8,538)</u>	<u>(3,033)</u>	<u>(122)</u>	<u>(12,923)</u>	
Income tax expense	—	—	—	—	(1)	(1)	
Net loss arising during development stage	<u>\$ (1,230)</u>	<u>\$ (1,114)</u>	<u>\$ (8,538)</u>	<u>\$ (3,033)</u>	<u>\$ (123)</u>	<u>\$ (12,924)</u>	
Net loss per common share:							
Basic and diluted	<u>\$ (0.02)</u>	<u>\$ (0.02)</u>	<u>\$ (0.16)</u>	<u>\$ (0.06)</u>	<u>\$ (0.00)</u>		
Weighted average common shares outstanding	<u>56,938,000</u>	<u>52,032,000</u>	<u>54,954,578</u>	<u>52,023,247</u>	<u>49,769,581</u>		

See accompanying notes.

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

	Three Months Ended September 30,		Years Ended June 30,			Period from December 1, 2000 (Inception) through September 30, 2004
	2004	2003	2004	2003	2002	
	(unaudited)					(unaudited)
<b>Operating activities</b>						
Net loss arising during development stage	\$ (1,230)	\$ (1,114)	(8,538)	(3,033)	(123)	(12,924)
Adjustments to reconcile net loss to net cash used in operating activities:						
Changes in operating assets and liabilities:						
Prepaid expenses and other current assets	(24)	24	12	(21)	(21)	(54)
Accounts payable	(106)	20	(241)	381	52	86
Accrued expenses	(43)	56	159	278	—	394
Amounts due to parent company	366	262	636	554	88	1,644
Net cash used in operating activities	(1,037)	(752)	(7,972)	(1,841)	(4)	(10,854)
<b>Financing activities</b>						
Net proceeds from issuance of Common Stock	—	(174)	25,578	36	9,022	34,636
Amounts payable in connection with issuance of Common Stock	—	38	—	(146)	146	—
Net cash provided by financing activities	—	(136)	25,578	(110)	9,168	34,636
Effect of exchange rate changes on cash and cash equivalents	—	19	(31)	31	—	—
Net increase (decrease) in cash and cash equivalents	(1,037)	(869)	17,575	(1,920)	9,164	23,782
Cash and cash equivalents at beginning of period	24,819	7,244	7,244	9,164	—	—
Cash and cash equivalents at end of period	\$23,782	\$ 6,375	24,819	7,244	9,164	23,782
Income taxes paid	\$ —	\$ 1	—	—	1	1

See accompanying notes.

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

	Common Stock	Additional paid in capital	Deficit accumulated during development stage	Accumulated other comprehensive income/(loss)	Total
	(shares)				
<b>Balance June 30, 2001</b>	<b>49,500,000</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ —</b>
Net loss arising during development stage			(123)		(123)
Common Stock issued May 22, 2002 (including 2,523,000 warrants)	2,523,000	9,022			9,022
<b>Balance at June 30, 2002</b>	<b>52,023,000</b>	<b>9,022</b>	<b>(123)</b>	<b>—</b>	<b>8,899</b>
Net loss arising during development stage			(3,033)		(3,033)
Foreign currency translation adjustments				31	31
Comprehensive Loss					(3,002)
Common Stock issued June 26, 2003	9,000	36			36
<b>Balance at June 30, 2003</b>	<b>52,032,000</b>	<b>9,058</b>	<b>(3,156)</b>	<b>31</b>	<b>5,933</b>
Net loss arising during development stage			(8,538)		(8,538)
Foreign currency translation adjustments				(31)	(31)
Comprehensive Loss					(8,569)
Common Stock issued November 30, 2003	2,514,000	10,056			10,056
Common Stock issued December 18, 2003 (including 2,392,000 warrants)	2,392,000	15,522			15,522
<b>Balance at June 30, 2004</b>	<b>56,938,000</b>	<b>\$34,636</b>	<b>\$ (11,694)</b>	<b>\$ —</b>	<b>\$22,942</b>
Net loss arising during development stage (unaudited)			(1,230)		(1,230)
Comprehensive Loss (unaudited)					(1,230)
<b>Balance at September 30, 2004 (unaudited)</b>	<b>56,938,000</b>	<b>\$34,636</b>	<b>\$ (12,924)</b>	<b>\$ —</b>	<b>\$21,712</b>

See accompanying notes.

**MARSHALL EDWARDS, INC.**  
**(A Development Stage Company)**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**June 30, 2004**

**(Information pertaining to the three months ended September 30, 2004 and 2003, and the information pertaining to the period from December 1, 2000 (inception) through September 30, 2004 is unaudited)**

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

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

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

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

**Principles of Consolidation**

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

**Use of Estimates**

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

**Revenue Recognition**

*Interest*

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

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### **Cash and cash equivalents**

Cash on hand and in banks and short-term deposits are stated at the nominal value. The Company considers all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents.

### **Income Taxes**

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

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

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

### **Concentration of Credit Risk**

Financial instruments, which potentially subject the Company to concentrations of credit risk, consist primarily of cash and cash equivalents. The company limits its exposure to credit risk by placing its cash with high credit quality financial institutions. Substantially all of the Company's cash is deposited in financial institutions that are FDIC insured. These deposits are in excess of the FDIC insurance limits.

### **Foreign Currency Translation**

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

### **Research and Development Expenses**

Research and development expenses relate primarily to the cost of conducting human clinical trials of phenoxodiol. Research and development costs are charged to expense as incurred. Research and development expenses consist mainly of clinical trial expenditures, payments to Novogen for research and development services under the terms of the services agreement and the cost of phenoxodiol used in clinical trials supplied by Novogen under the terms of the manufacturing license and supply agreement.

### **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.

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### Stock-Based Compensation

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

### Basic and Diluted Loss Per Share

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

### Comprehensive Loss

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

### Recent Accounting Announcements

Accounting pronouncements issued by the financial accounting standards board or other authoritative accounting standards groups with future effective dates are either not applicable or not significant to the consolidated financial statements.

## 2. Income Taxes

Loss from operations consists of the following jurisdictions:

	2004	Year ended June 30, 2003	2002
		(in thousands \$)	
Domestic	(321)	(186)	(19)
Foreign	(8,217)	(2,847)	(103)
	(8,538)	(3,033)	(122)

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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:

	2004		Year ended June 30, 2003		2002	
	(in thousands \$)	%	(in thousands \$)	%	(in thousands \$)	%
Tax at US statutory rates	2,988	35	1,062	35	43	35
Australian tax	(411)	(5)	(142)	(5)	(5)	(5)
Change in valuation allowance	2,577	30	920	30	38	30
	—	—	—	—	—	—

Deferred tax liabilities and assets are comprised of the following:

	2004	Year ended June 30, 2003	2002
	(in thousands \$)		
Deferred tax liabilities			
Unrealised Foreign Exchange Gain	(25)	—	—
Accrued Interest Income	(2)	—	—
Prepayments	—	—	4
Total deferred tax liabilities	(27)	—	4
Deferred tax assets			
Tax carried forward losses	3,365	933	42
Unrealised Foreign Exchange Loss	(121)	(129)	(4)
Consultant and other accruals	318	154	4
Total deferred tax assets	3,562	958	42
Valuation allowance for deferred tax assets	(3,535)	(958)	(38)

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, 2004 and 2003. 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, 2004 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 \$439,000 at June 30, 2004. The federal net operating losses will begin to expire in 2022.

Foreign tax losses of approximately \$10,702,000 at June 30, 2004, may be carried forward indefinitely.



[Table of Contents](#)**3. Loss Per Share**

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

	Three Months Ended September 30		2004	Years ended June 30,	
	2004	2003		2003	2002
	(Unaudited)		(In Thousands, except share data)		
<b>Numerator</b>					
Net loss arising during development stage	\$ (1,230)	\$ (1,114)	\$ (8,538)	\$ (3,033)	\$ (123)
Effect of dilutive securities	—	—	—	—	—
Numerator for diluted earnings per share	(1,230)	(1,114)	(8,538)	(3,033)	(123)
<b>Denominator</b>					
Denominator for basic earnings per share -					
Weighted average shares used in computing net loss per share, basic and diluted.	56,938,000	52,032,000	54,954,578	52,023,247	49,769,581
Effect of dilutive securities	—	—	—	—	—
Dilutive potential common shares	56,938,000	52,032,000	54,954,578	52,023,247	49,769,581
Basic and Diluted net loss per share			\$ (0.16)	\$ (0.06)	\$ (0.00)

During all periods 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. The outstanding warrants consist of the following potential common shares:

	As at September 30,		2004	As at June 30,	
	2004	2003		2003	2002
	(Unaudited)				
Outstanding Warrants	2,392,000	2,514,000	2,392,000	2,514,000	2,523,000

The warrants outstanding at September 30, 2004 have an exercise price of \$9.00 per share and are exercisable prior to December 18, 2006.

**4. Financial Instruments**

The fair value of financial assets and liabilities approximates their carrying value in the Consolidated Balance Sheets because they are short term and at market rates of interest.

## 5. Expenditure Commitments and Contingencies

At June, 30, 2004, the Company contracted with third parties to conduct research and development expenditures of approximately \$3,796,000. At September 30, 2004, the Company had contracted to conduct research and development expenditures of approximately \$1,947,000. 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 at June 30, 2004, assuming all treatment cycles are completed, are expected to be incurred as follows:

(In thousands)	Total	Payment due by period			
		less than 1 Year	1 - 3 Years	3-5 Years	More than 5 Years
Contractual Obligations					
Purchase Obligations	\$3,796	\$3,167	\$629	\$—	\$—
Total	\$3,796	\$3,167	\$629	\$—	\$—

No amounts have been included for future payments to Novogen which may arise in connection with the license agreement, the services agreement or the manufacturing license and supply agreement. Payments in connection with these agreements are detailed in Note 7 "Related Party Transactions".

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

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

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

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**6. Segment Information**

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

	Year Ended June 30,								
	2004			2003			2002		
	USA	Australia	Total	USA	Australia	Total	USA	Australia	Total
	(in thousands)								
<b>Statement of Operations</b>									
Interest Revenue	167	26	193	110	35	145	5	2	7
Loss from operations	(321)	(8,217)	(8,538)	(186)	(2,847)	(3,033)	(19)	(103)	(122)
Income Tax Expense	—	—	—	—	—	—	—	(1)	(1)
Net loss arising during development stage	(321)	(8,217)	(8,538)	(186)	(2,847)	(3,033)	(19)	(104)	(123)
<b>Balance Sheet</b>									
Segment assets	34,220	802	35,022	8,896	374	9,270	9,188	1,981	11,169
Elimination of investment in subsidiary	(10,173)	—	(10,173)	(1,984)	—	(1,984)	(1,984)	—	(1,984)
Consolidated Assets	\$ 24,047	\$ 802	\$ 24,849	\$ 6,912	\$ 374	\$ 7,286	\$ 7,204	\$ 1,981	\$ 9,185
Segment liabilities	\$ 110	\$ 1,797	\$ 1,907	\$ 43	\$ 1,310	\$ 1,353	\$ 185	\$ 101	\$ 286

	Quarter Ended September 30,								
	2004			2003			2002		
	USA	Australia	Total	USA	Australia	Total	USA	Australia	Total
	(in thousands)								
<b>Statement of Operations</b>									
Interest Revenue	55	12	67	16	5	21	32	11	43
(Loss) from operations	(74)	(1,156)	(1,230)	(6)	(1,108)	(1,114)	(29)	(482)	(511)
Income Tax Expense	—	—	—	—	—	—	—	—	—
Net (loss) arising during development stage	(74)	(1,156)	(1,230)	(6)	(1,108)	(1,114)	(29)	(482)	(511)
<b>Balance Sheet</b>									
Segment assets	34,153	8,462	42,615	8,930	2,921	11,851	8,996	1,579	10,575
Elimination of investment in subsidiary	(18,779)	—	(18,779)	(5,284)	—	(5,284)	(1,984)	—	(1,984)
Consolidated Assets	\$ 15,374	\$ 8,462	\$ 23,836	\$ 3,646	\$ 2,921	\$ 6,567	\$ 7,012	\$ 1,579	\$ 8,591
Segment liabilities	\$ 118	\$ 2,006	\$ 2,124	\$ 82	\$ 1,647	\$ 1,729	\$ 22	\$ 181	\$ 203

**7. Related Party Transactions**

**License Agreement**

The license agreement is an agreement under which Novogen's subsidiary, Novogen Research Pty Limited, grants to MEPL a worldwide non-transferable license under its patent and patent applications and in its know-how to conduct clinical trials and commercialize and distribute phenoxodiol products. The agreement covers uses of phenoxodiol in the field of prevention, treatment or cure of cancer in humans delivered in all forms except topical applications. The license is exclusive until the expiration or lapsing of the last relevant Novogen patents or patent applications in the world and thereafter is nonexclusive. MEPL may terminate the agreement by giving three months' notice to Novogen. Novogen may also terminate the agreement immediately if a change of control, as defined in the license agreement, occurs without the consent of 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. Future amounts payable to Novogen under terms of the license agreement are as follows:

1. A second lump sum license fee of \$5,000,000 is payable to Novogen on November 1, 2003 or such later date when the cumulative total of all funds received from debt or equity issuances and revenue received from commercialization (income other than sales) and sales of phenoxodiol products exceeds \$50,000,000.
2. In addition to the amounts above, until the expiration of the exclusivity period of the license, MEPL must pay Novogen 2.5 % of all net sales and 25% of commercialization income. After the exclusivity period of the license, 1.5% of net sales must be paid to Novogen.
3. In addition to the amounts above, amounts payable for annual milestone license fees under the license agreement for the calendar years ended December 31 are as follows:

Calendar Year	
2004	\$2,000,000
2005	\$4,000,000
Each calendar year thereafter during the exclusivity period	\$8,000,000

At June 30, 2004 an amount of \$1,000,000 was accrued and reflected in amounts due to parent company, being 50% of the milestone payment due December 31, 2004. (June 2003: \$500,000 was accrued). During the years ended June 30, 2004, 2003 and 2002, \$5,500,000, \$500,000 and Nil were charged to profit and loss. Milestone license fees of \$500,000 (unaudited) have been accrued in the three months ended September 30, 2004 in connection with the payment due on December 31, 2004.

Novogen developed phenoxodiol in part using funds from the Australian government under what is known as the START Program. In the event that Novogen fails to comply with its obligations under the agreement which governs this grant, or if Novogen undergoes a change of control, the Australian government has the right to demand that the intellectual property created during the course of the project funded by the grant be vested back in the Australian government. 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 the Company's use of Novogen intellectual property in the development and commercialization of phenoxodiol and the Company may have to compete with other companies to whom the Australian government may license the intellectual property.

### ***Termination***

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

### **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.

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

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

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

### **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 administration and management support services. 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.

### ***Termination***

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

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

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

Transactions amounting to \$1,874,000, \$1,239,000 and \$79,000 were made under the services agreement and the manufacturing license and supply agreement with Novogen during the years ended June 30, 2004, June 30, 2003 and June 30, 2002 respectively. Transactions giving rise to expenditure amounting to \$373,000 (unaudited) and \$433,000 (unaudited) were made under the services agreement and the manufacturing license and supply agreement with Novogen during the three months ended September 30, 2004 and 2003, respectively. These amounts are recorded in research and development expenses and in selling general and

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administration. At June 30, 2004, \$278,000 owed to Novogen under these agreements is included in amounts due to parent company. At June 30, 2003, \$142,000 was included in amounts due to parent company. At September 30, 2004 and 2003, \$154,000 (unaudited) and \$143,000 (unaudited), respectively, was due and owing to Novogen under these agreements and is included in amounts due to parent company.

### **Termination**

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

### **Guarantee and Indemnity Agreement**

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

### **Indemnification**

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

### **Termination**

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

## **8. Equity**

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

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

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

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

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

In connection with the December 2003 offering, the Company's common stock and warrants commenced trading separately on the Nasdaq National Market. The Company received proceeds of \$15,509,000, net of \$2,431,000 transaction costs in the December 2003 offering. Following the offering, Novogen Limited retained 86.9% of the Company's common stock.





# **Marshall Edwards, Inc.**

## **2,392,000 Shares of Common Stock Issuable Upon Exercise of Warrants**

### **PROSPECTUS**

December 10, 2004

No document in connection with this offering, including this prospectus, may be issued or passed on in the United Kingdom to, or is directed at, any person, other than: (i) to persons whose ordinary activities involve them in acquiring, holding, managing or disposing of investments (as principal or agent) for the purposes of their businesses and otherwise in circumstances which will not result in an offer to the public in the United Kingdom within the meaning of the Public Offers of Securities Regulations 1995 (as amended) and in circumstances where Section 21(1) of the Financial Services and Markets Act 2000 does not apply by virtue of such person being an investment professional as that term is defined in Article 19 of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2001; or (ii) to persons to whom the document may otherwise lawfully be issued. Nothing in this prospectus should be construed as investment advice to any person. If you are a recipient of this prospectus outside of the scope of the above criteria then you may not act upon the content of this prospectus.

We are not making this offering described in this prospectus in Australia or in any state or other jurisdiction in which it is unlawful to do so nor are we selling or accepting any offers to purchase any of our common stock units from persons who are residents of such jurisdictions.

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**PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 13. Other Expenses of Issuance and Distribution.**

An estimate of expenses\*, follows:

Securities and Exchange Commission registration fee	\$ 2,660.81
NASD filing fee	3,789.00
Nasdaq National Market listing fee	105,000.00
Printing and engraving expenses	252,000.00
Transfer agent and registrar fees and expenses	7,500.00
Information agent expenses	10,000.00
Legal fees and expenses	783,000.00
Accountants' fees and expenses	100,000.00
Blue Sky fees and expenses (including legal fees)	25,000.00
Miscellaneous expenses	41,050.19
Total	\$ 1,330,000

\* All expenses, except the SEC registration fee, are estimated.

**Item 14. Indemnification of Directors and Officers.**

Our Certificate of Incorporation provides that we will indemnify our directors and officers to the full extent permitted by the DGCL. Section 145 of the DGCL provides that the extent to which a corporation may indemnify its directors and officers depends on the nature of the action giving rise to the indemnification right. In actions not on behalf of the corporation, directors and officers may be indemnified for acts taken in good faith and in a manner reasonably believed to be in or not opposed to the best interests of the corporation. In actions on behalf of the corporation, directors and officers may be indemnified for acts taken in good faith and in a manner reasonably believed to be in or not opposed to the best interests of the corporation, except for acts as to which the director or officer is adjudged liable to the corporation, unless the relevant court determines that indemnification is appropriate despite such liability. Section 145 also permits a corporation to (i) reimburse present or former directors or officers for their defense expenses to the extent they are successful on the merits or otherwise and (ii) advance defense expenses upon receipt of an undertaking to repay the corporation if it is determined that payment of such expenses is unwarranted.

To supplement the general indemnification right contained in our Certificate of Incorporation, the By-Laws provide for the specific indemnification rights permitted by Section 145 (as described above). The By-Laws also permit us to purchase Directors & Officers insurance, but no director or officer has a right to require this.

In addition to the indemnification rights described above, our Certificate of Incorporation eliminates any monetary liability of directors to us or our shareholders for breaches of fiduciary duty except for (i) breaches of the duty of loyalty, (ii) acts or omissions in bad faith, (iii) improper dividends or share redemptions and (iv) transactions from which the director derives an improper personal benefit.

**Item 15. Recent Sales of Unregistered Securities.**

On May 22, 2002, we sold 2,523,000 shares of our common stock for an aggregate of \$10.1 million. These shares of common stock were listed on the London Stock Exchange's Alternative Investment Market. These shares of common stock each had an attaching warrant entitling the holder to purchase one additional share of our common stock. These warrants were exercisable prior to November 30, 2003 and had an exercise price of \$4.00 per share.

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These securities were offered and sold by us to Oppenheimer International Growth Funds, Mass Mutual International Equity Fund, MEI Phase II LP, Liberty Square Offshore Partners, Leominster Company Ltd, ELL & Co, Foster Stockbroking Nominees Pty Ltd, Liberty Square Partners LP, Mr. John P. O'Connor, Winterflood Securities Ltd and KBC Peel Hunt Ltd. No general solicitation was made by either us or any person acting on our behalf; the securities sold are subject to transfer restrictions; and certificates for the shares contain appropriate legends stating that such securities have not been registered under the Securities Act and may not be offered or sold absent registration or pursuant to an exemption therefrom. No underwriters were involved in the foregoing sales of securities. All of these transactions were exempt from registration pursuant to Section 4(2) of the Securities Act of 1933 or Regulation S promulgated thereunder with respect to the securities offered and sold outside the United States to investors who were neither citizens nor residents of the United States.

In June 2003, we issued 9,000 shares of our common stock upon the exercise of 9,000 of the warrants that were issued in May 2002. The shares issued upon exercise of the warrants were issued to KBC Peel Hunt Ltd, a non-U.S. person, in a private placement transaction outside the United States. In November 2003, we issued 2,514,000 shares of our common stock upon the exercise of 2,514,000 of the warrants that were issued in May 2002. 875,000 of the shares issued upon exercise of the warrants were issued to Oppenheimer International Growth Funds, 875,000 of the shares issued upon exercise of the warrants were issued to Mass Mutual International Equity Fund, 175,000 of the shares issued upon exercise of the warrants were issued to MEI Phase II LP, 100,000 of the shares issued upon exercise of the warrants were issued to Fosters Stockbroking Nominees Pty Ltd 20,000 of the shares issued upon exercise of the warrants were issued to Mr. John P. O'Connor, 110,000 of the shares issued upon exercise of the warrants were issued to Leominster Company Ltd., 168,500 of the shares issued upon exercise of the warrants were issued to Liberty Square Offshore Partners, 81,500 of the shares issued upon exercise of the warrants were issued to Liberty Square Partners LP, 100,000 of the shares issued upon exercise of the warrants were issued to ELL & Co. and 9,000 of the shares issued upon exercise of the warrants were issued to Winterflood Securities Ltd. No general solicitation was made by either us or any person acting on our behalf; the shares issued upon exercise of the warrants are subject to transfer restrictions; and certificates for the shares contain appropriate legends stating that such securities have not been registered under the Securities Act and may not be offered or sold absent registration or pursuant to an exemption therefrom. No underwriters were involved in the foregoing sales of securities. These transactions were exempt from registration pursuant to Section 4(2) of the Securities Act of 1933 or Regulation S promulgated thereunder with respect to the securities offered and sold outside the United States to investors who were neither citizens nor residents of the United States.

### **Item 16. Exhibits and Financial Statement Schedules.**

(a) Exhibits.

<b>Exhibit Number</b>	<b>Exhibit</b>
1(1)	Form of Underwriting Agreement
3.1(1)	Certificate of Incorporation
3.2(1)	Bylaws
4.1(1)	Specimen Common Stock certificate
4.2(1)	Form of Warrant issued to Non-US Persons May 2002
4.3(1)	Form of Warrant Issued to US Persons May 2002
4.4(1)	Warrant Agreement
5(1)	Opinion of Morgan, Lewis & Bockius LLP
10.1(1)	Amended and Restated License Agreement between Novogen Research Pty Limited and Marshall Edwards Pty Limited
10.2(1)	Amended and Restated Manufacturing License and Supply Agreement between Novogen Laboratories Pty Limited and Marshall Edwards Pty Limited
10.3(1)	Amended and Restated License Option Deed between Novogen Research Pty Limited and Marshall Edwards Pty Limited
10.4(1)	Amended and Restated Services Agreement among Novogen Limited, Marshall Edwards, Inc. and Marshall Edwards Pty Limited
10.5(1)	Guarantee and Indemnity among Marshall Edwards, Inc., Novogen Laboratories Pty Limited,

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<u>Exhibit Number</u>	<u>Exhibit</u>
10.6(1)	Novogen Research Pty Limited and Novogen Limited
21(1)	Marshall Edwards Inc. Share Option Plan
23.1(1)	Subsidiaries of Marshall Edwards, Inc.
23.2(2)	Consent of Morgan, Lewis & Bockius LLP (contained in Exhibit 5)
23.3(2)	Consent of Ernst & Young
24(1)	Consent of Ernst & Young LLP
	Power of Attorney (included on signature page)

(1) Previously filed.

(2) File herewith.

(b) Financial Statement Schedules. All financial statement schedules have been omitted because either they are not required, are not applicable, or the information is otherwise set forth in the financial statements and notes thereto.

### **Item 17. Undertakings.**

(1) The undersigned registrant hereby undertakes:

(i) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(a) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(b) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement;

(c) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

(ii) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(iii) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(iv) To provide to the underwriters at the closing specified in the Underwriting Agreement share and warrant certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

(v) That for purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance on Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it is first declared effective.

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(vi) That for the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(2) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the provisions described under Item 14 above, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Sydney, Australia on December 10, 2004.

MARSHALL EDWARDS, INC.  
(Registrant)

By: /s/ Christopher Naughton  
Christopher Naughton  
*President and Chief Executive Officer*

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed below by the following persons, in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Christopher Naughton</u>	President and Chief Executive Officer,	December 10, 2004
Christopher Naughton	Director (Principal Executive Officer)	
<u>/s/ David R Seaton</u>	Chief Financial Officer and Secretary (Principal Financial Officer and Principal Accounting Officer)	December 10, 2004
David R. Seaton	Chairman	December 10, 2004
*		
<u>Dr. Graham E. Kelly</u>	Director	December 10, 2004
*		
<u>Philip A. Johnston</u>	Director	December 10, 2004
*		
<u>David Morritz de Kretser</u>	Director	December 10, 2004
*		
<u>Paul J. Nestel</u>	Director	December 10, 2004
*		
<u>Stephen Breckenridge</u>		
*By: <u>/s/ David R Seaton</u>		
David R. Seaton		
<i>Attorney-in-fact</i>		

INDEX TO EXHIBITS

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23.3(2)	Consent of Ernst & Young LLP
24(1)	Power of Attorney (included on signature page)

(1) Previously filed.

(2) File herewith.

Consent of Independent Registered Public Accounting Firm

We consent to the reference to our firm under the captions “Summary Historical Consolidated Financial Data”, “Selected Historical Consolidated Financial Data”, “Changes in and Disagreements with Accountants on Accounting and Financial Disclosures” and “Experts” and to the use of our report dated 13 August 2004, in Post-Effective Amendment No. 2 to the Registration Statement (Form S-1 No. 333-109129) and related Prospectus of Marshall Edwards, Inc. for the registration of 2,392,000 shares of its common stock.

/s/ Ernst & Young

Sydney  
Australia  
8 December 2004



Consent of Independent Registered Public Accounting Firm

We consent to the reference to our firm under the captions “Summary Historical Consolidated Financial Data”, “Selected Historical Consolidated Financial Data” and “Experts” and to the use of our report dated July 31, 2003, in Post-Effective Amendment No. 2 to the Registration Statement (Form S-1 No. 333-109129) and related Prospectus of Marshall Edwards, Inc. for the registration of 2,392,000 shares of its common stock.

/s/ Ernst & Young LLP

Stamford, Connecticut  
December 8, 2004

Marshall Edwards, Inc.  
140 Wicks Road  
North Ryde NSW 2113  
Australia

December 10, 2004

Securities and Exchange Commission  
Division of Corporation Finance  
450 Fifth Street, N.W., Mail Stop 3-9  
Washington, D.C. 20540-0404  
Attn: Albert Lee

**Re: Marshall Edwards, Inc.  
Post-Effective Amendment to Form S-1, filed December 10, 2004  
Registration No. 333-109129**

Dear Mr. Lee:

We are responding to the comments of the Staff of the Securities and Exchange Commission (the "Commission") in your November 24, 2004 letter to the Company with respect to the Company's Post-Effective Amendment No. 1 to Form S-1, which was filed with the Commission by the Company on November 12, 2004.

In response to your letter, set forth below are your comments in bold followed by the Company's responses to your comments.

**1. Comment: Please update the financial statements and the related discussion and disclosure through September 30, 2004 to the post-effective amendment to Form S-1. As to all other disclosure, provide updated information as of the date you file your amendment.**

Response: The Company advises the Staff that it has, today, filed with the Commission a Post-Effective Amendment No. 2 to Form S-1 (Registration No. 333-109129) in which the Company has (i) updated the financial statements and related discussion and disclosure through September 30, 2004 and (ii) as to all other disclosure, provided updated information as of the date of filing.

Please feel free to contact Steven A. Navarro (212-309-6147) or Owen S. Littman (212-309-6142) of Morgan, Lewis & Bockius LLP, the Company's outside counsel, with any questions regarding the foregoing.

Very truly yours,

MARSHALL EDWARDS, INC.

By: /s/ David R Seaton

Name: David R. Seaton

Title: Chief Financial Officer and Secretary

cc: Morgan, Lewis & Bockius LLP  
Steven A. Navarro Owen S. Littman

Ernst & Young  
Gary Daniels

BDO Australia  
Kevin Reid