## **PROSPECTUS**

# Marshall Edwards, Inc.

# 2,080,000 Common Stock Units

This is our initial public offering in the United States. This prospectus covers the sale of up to an aggregate of 2,080,000 common stock units. Each common stock unit consists of:

- · one share of our common stock; and
- one warrant to purchase a share of our common stock at an exercise price equal to \$9.00.

The initial public offering price for the common stock units is \$7.50 per unit.

As part of this offering, we are offering up to an aggregate of 1,500,000 common stock units at the initial public offering price to U.S. holders of ordinary shares and American Depositary Receipts of Novogen Limited, our parent company, who beneficially owned their shares or receipts as of the close of business on October 20, 2003, and to our U.S. stockholders who beneficially owned their shares as of the close of business on October 20, 2003. See the section entitled "Plan of Distribution — Directed Share Subscription Program."

Upon completion of this offering, Novogen will own approximately 87.4% of our outstanding common stock.

Our common stock and warrants have been approved for listing on the Nasdaq National Market under the symbols "MSHL" and "MSHLW," respectively. Our common stock is listed on the Alternative Investment Market of the London Stock Exchange plc under the symbol "MSH." We will apply to list the shares of common stock being offered hereby on the Alternative Investment Market. The last reported sale price on the Alternative Investment Market on December 17, 2003 was £5.20 per share, or approximately \$9.16 per share based on the noon buying rate for sterling of £1.00 = \$1.7615 on that date.

There will be no trading market for the common stock units. The shares of common stock and warrants comprising the units will separate immediately upon completion of this offering and prior to any trading of the common stock and warrants.

# Investment in the common stock units involves a high degree of risk. See "Risk Factors" beginning on page 6.

## **Underwritten Public Offering**

Under witing Discounts

	Public Offering Price	and Commissions	Marshall Edwards, Inc.					
Per Common Stock Unit	\$ 7.50	\$ 0.525	\$ 6.975					
Total	\$4,350,000	\$304,500	\$4,045,500					
Directed Share Subscription Program								

	Public Offering Price	Selling Fee	Proceeds to Marshall Edwards, Inc.
Per Common Stock Unit	\$ 7.50	\$ 0.225	\$ 7.275
Total	\$11,250,000	\$337,500	\$10,912,500
Aggregate Offering Proceeds			\$14,958,000

We have granted Janney Montgomery Scott LLC an option to purchase up to an additional 312,000 common stock units at the public offering price, solely to cover over-allotments.

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.

# **Janney Montgomery Scott LLC**

The date of this prospectus is December 18, 2003.

# **TABLE OF CONTENTS**

**PROSPECTUS SUMMARY** 

**RISK FACTORS** 

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

**USE OF PROCEEDS** 

**DETERMINATION OF OFFERING PRICE** 

PRICE RANGE OF OUR COMMON STOCK

**DIVIDEND POLICY** 

**CAPITALIZATION** 

**DILUTION** 

SELECTED HISTORICAL CONSOLIDATED FINANCIAL DATA

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

**OPERATIONS** 

**BUSINESS** 

**MANAGEMENT** 

BENEFICIAL OWNERSHIP OF COMMON STOCK

**CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS** 

**DESCRIPTION OF OUR SECURITIES** 

SHARES ELIGIBLE FOR FUTURE SALE

**PLAN OF DISTRIBUTION** 

**LEGAL MATTERS** 

**EXPERTS** 

**AVAILABLE INFORMATION** 

ANNEX A

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS** 

# TABLE OF CONTENTS

	Page
PROSPECTUS SUMMARY	1
RISK FACTORS	6
SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS	17
USE OF PROCEEDS	18
DETERMINATION OF OFFERING PRICE	19
PRICE RANGE OF OUR COMMON STOCK	19
DIVIDEND POLICY	19
CAPITALIZATION	20
DILUTION	21
SELECTED HISTORICAL CONSOLIDATED FINANCIAL DATA	22
MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION	
AND RESULTS OF OPERATIONS	23
BUSINESS	27
MANAGEMENT	42
BENEFICIAL OWNERSHIP OF COMMON STOCK	46
CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS	47
DESCRIPTION OF OUR SECURITIES	54
SHARES ELIGIBLE FOR FUTURE SALE	58
PLAN OF DISTRIBUTION	59
LEGAL MATTERS	62
EXPERTS	62
AVAILABLE INFORMATION	62
ANNEX A — GLOSSARY OF TERMS	A-1
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS	F-1

## PROSPECTUS SUMMARY

This summary highlights key aspects of our business and our offering of common stock units 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. Unless specifically stated otherwise, the information in this prospectus assumes no exercise of the over-allotment option. 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 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 that 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 with little or no effect on normal cells based on the emerging field of signal transduction regulation, which is the regulation of the chemical signals within cells that control specific cell functions.

Our strategy is to undertake further clinical development and testing of phenoxodiol leading ultimately to its commercialization and wide scale distribution. Preclinical 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 and Phase II studie in intravenous dosage form in the United States and 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 phenoxodio 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.

We were incorporated in December 2000 as a wholly-owned subsidiary of Novogen Limited, an Australian registered company, and commenced operations in May 2002. 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. In May 2002, we sold 2,523,000 shares of our common stock and warrants to purchase an equal number of shares in a private placement that raised \$10.1 million in gross proceeds. These shares are admitted for trading on the Alternative Investment Marke of the London Stock Exchange under the symbol "MSH." Novogen currently controls approximately 91% of our outstanding common stock.

Novogen is involved in the discovery and development of new drugs based on signal transduction regulation, which it believes offers potential for effective, well-tolerated treatment of common degenerative diseases including cancer. 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 o 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 2003 there will be 220,900 new cases of prostate cancer and 28,900 people will die as a result of this cancer in the United States. The ACS has also estimated that in 2003 there will be 25,400 new cases of ovarian cancer diagnosed and 14,300 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 2003, there will be 18,200 new cases diagnosed and that there will be 5,700 deaths caused by these cancers in the United States. The ACS estimates that 2,200 deaths will occur in the United States as a result of cutaneous SCC.

#### **Risks of Our Business**

We have a limited operating history and since our inception we have incurred losses, including net losses of \$3,033,000 and \$123,000 for the years ended June 30, 2003 and 2002, respectively. Since our inception through September 30, 2003, we have sustained cumulative net losses of \$4,270,000, which includes a net loss of \$1,114,000 for the quarter ended September 30, 2003. 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**

On November 18, 2003, Novogen was granted a U.S. patent relating to the treatment of any cancerous disease with phenoxodiol, including ovarian cancer, breast cancer, prostate cancer and metastatic cancer. We have an exclusive license under this patent to commercialize phenoxodiol for the treatment of cancer.

An IND for the oral form of phenoxodiol became effective in June 2003. This action will permit the commencement of a study in collaboration with Yale University School of Medicine in patients with cancer of the cervix, vulva and vagina where phenoxodiol will be used daily in patients on a monotherapy basis for periods of up to four weeks prior to surgery or radiotherapy.

A Phase II study of the intravenous dosage form of phenoxodiol in women with ovarian cancer commenced at Yale University School of Medicine in October 2002. The clinical trial is based on laboratory studies at Yale University that showed phenoxodiol to be effective at killing ovarian cancer cells, including those resistant to all standard anti-cancer drugs. The study is fully enrolled using 40 patients with advanced, metastatic ovarian cancer that has become unresponsive to at least two standard chemotherapies.

# **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

Securities Offered 2,080,000 common stock units, each unit consisting of one share of common stock and one warrant to purchase a

share of our common stock

Offering Price \$7.50 per common stock unit

Warrant Terms Each warrant is exercisable for the purchase of one share of our common stock at an exercise price of \$9.00 per

share. The warrants are immediately exercisable and expire three years from their date of issuance. 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.

Plan of Distribution:

Directed Share Subscription Program Up to 1,500,000 common stock units will be offered by subscription to U.S. holders of our common stock who

beneficially owned their shares as of the close of business on October 20, 2003 and to U.S. holders of Novogen's ordinary shares and ADRs who beneficially owned their shares or ADRs as of the close of business on October 20, 2003. Janney Montgomery Scott LLC will act as our dealer manager in connection with our directed share subscription program. The common stock units being offered under our directed share subscription program are being offered concurrently with the common stock units to be sold in the underwritten offering. We can terminate the directed share subscription program at any time prior to the closing but are not obligated to terminate the directed share subscription program in the event the underwritten offering is terminated. As a result, if you subscribe for common stock units under the directed share subscription program, you may be obligated to purchase units even if the underwriter does not purchase any units in the underwritten offering. In addition, unless we terminate the directed share subscription program, you will be obligated to purchase units even if you are the only subscriber in the directed

share subscription program.

Underwritten Offering 580,000 common stock units will be sold on a firm commitment basis by Janney Montgomery Scott LLC, as

underwriter, along with any units not purchased in the directed share subscription program. The closing of the directed share subscription program and the underwritten offering are not conditioned upon one another and will occur concurrently. In the event the underwriter purchases the 580,000 common stock units to be sold on a firm commitment basis, it also will be obligated to purchase any and all common stock units not purchased in the directed

share subscription program.

Over-Allotment Option We have granted Janney Montgomery Scott LLC an option to purchase additional common stock units representing

up to 15% of the units sold in this offering to cover over-allotments, if any.

Common Stock Outstanding After

this Offering

56,626,000 shares (56,938,000 shares if the over-allotment option is exercised in full), not including the

2,080,000 shares (2,392,000 shares if the over-allotment option is exercised in full) of common stock underlying the

warrants offered hereby.

Use of Proceeds We intend to use approximately \$1.1 million to commence Phase II clinical trials of phenoxodiol as a monotherapy in

earlier stage cancers, and we intend to use approximately \$4.2 million to commence Phase II clinical trials of phenoxodiol in combinational therapy with other anti-cancer drugs for late stage chemo-resistant tumors. Actual amounts spent on these planned clinical trials may change subject to satisfactory results of ongoing clinical trials. We intend to use the balance for other corporate purposes, including potential payments to Novogen under the terms of the license agreement, potential licensing of other cancer compounds developed by Novogen and potential expansior

of the clinical trial program for phenoxodiol to include other forms of cancer.

Nasdaq Symbols MSHL — common stock.

MSHLW — warrants.

Listing on AIM Our common stock is listed on the Alternative Investment Market of the London Stock Exchange (the AIM) under

the symbol "MSH." We will apply to list the shares of common stock being offered hereby on the AIM. The AIM is

the London Stock Exchange's global market for small growing companies.

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 common stock units

# **Information Agent**

Innisfree M&A Incorporated acts as our information agent to respond to any questions that our U.S. stockholders and U.S. holders of ordinary shares and ADRs of Novogen may have about subscribing for common stock units in connection with the directed share subscription component of this offering. Any questions or requests for assistance concerning the method of subscribing for common stock units or for additional copies of this prospectus can be directed to the information agent at (877) 456-3510.

The Information Agent for the directed share subscription component of this offering is:



501 Madison Avenue, 20th Floor

New York, New York 10022 Banks and Brokers Call Collect: (212) 750-5833

All Others Call Toll-Free: (877) 456-3510

# **Summary Historical Consolidated Financial Data**

We are a development stage company. The following table sets forth our summary historical consolidated financial data derived from our audited consolidated financial statements for the years ended June 30, 2003 and 2002 and our unaudited consolidated financial statements as of and for the quarters ended September 30, 2003 and 2002 and for the period from December 1, 2000 (inception) through September 30, 2003, included in this prospectus. The financial statements for the years ended June 30, 2003 and 2002 have been audited by Ernst & Young LLP, independent auditors. The summary financial information should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Risk Factors" and the consolidated financial statements and the notes thereto included elsewhere in this prospectus.

			r Ended nber 30,			Year E	inded June 30,		Period from December 1, 2000 (inception) through September 30,	
		2003		2002		2003	:	2002		2003
	(in thou		ousands, except share and per share data)				(un	audited)		
		(unau	ıdited)						(un	addited)
Statement of Operations Data:										
Interest and other income	\$	21	\$	43	\$	145	\$	7	\$	173
Net loss arising during development										
stage	\$	(1,114)	\$	(511)	\$	(3,033)	\$	(123)	\$(	4,270)
Net loss per common share.	\$	(0.02)	\$	(0.01)	\$	(0.06)	\$	(0.00)		
Weighted average shares used to										
calculate loss per share	52,	,032,000	52,	023,000	52	,023,247	49,7	769,581		
Common stock outstanding at period										
end	52,	,032,000	52,	023,000	52	,032,000	52,0	23,000		
							Septer	nber 30,		
							2003	2002		
								ousands) udited)		
Balance Sheet Dat	a:						,			
Cash and cash equi	valents						\$6,375	\$8,575		
Total assets							6,567	8,591		
Stockholders' equit	y						4,838	8,387		

#### 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 units. 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.

Investors 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. In May 2002, we raised \$10.1 million in a private placement of shares of common stock and warrants. We have incurred net losses since our inception, including net losses of \$3,033,000 and \$123,000 for the years ended June 30, 2003 and 2002, respectively. For the quarter ended September 30, 2003, we incurred a net loss of \$1,114,000. 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 amended and restated license option deed with Novogen, our rights under our amended and restated 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 II clinical trials in intravenous dosage form to treat late stage ovarian cancer. An IND became effective for phenoxodiol in the United States for the oral dosage form in June 2003. The oral dosage form is also in clinical trials in Australia to treat prostate cancer and SCC. 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. While we have not encountered any material delays, difficulties or adverse events in the regulatory process to date, we cannot assure you that such delays or adverse events 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;
- 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 amended and restated 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;
- 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 of, 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 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.

Based on our current plans, we believe that the net proceeds of this offering will provide sufficient funds to:

- complete the current Phase Ib/IIa and Phase II clinical trials;
- commence Phase II clinical trials of phenoxodiol as a monotherapy in earlier stage cancers; and
- · commence Phase II clinical trials of phenoxodiol in combinational therapy with other anti-cancer drugs for late stage chemo-resistant tumors.

We will require additional funds, however, to further the evaluation of phenoxodiol beyond these 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;
- · 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.

Iressa, a signal transduction inhibitor manufactured by AstraZeneca, is a potential competing treatment that has recently been granted FDA approval for use in the treatment of advanced stage non-small cell lung cancer in patients who have already received specific chemotherapy. Other potential competition might arise from the development of drugs with a related chemical heritage to phenoxodiol. Genistein and flavopiridol TM are two chemicals with an underlying flavonoid chemical structure with known anti-cancer activity which are undergoing clinical development as anti-cancer agents. Our understanding is that genistein is in Phase II clinical studies, while we believe flavopiridol TM, under development by Aventis, is in Phase III clinical testing.

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 and AstraZeneca, 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 amended and restated 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 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 quaranteed.

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

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

Novogen's applications may not proceed to grant or may be amended to reduce the scope of protection of any patent granted. The applications and patents may also be opposed or challenged by third parties. Our commercial success will depend, in part, on the ability of Novogen and our ability to obtain and maintain effective patent protection for the technologies underlying phenoxodiol and other compounds, and to successfully defend patent rights in those technologies against third-party challenges. As patent applications in the United States are maintained in secrecy until published or issued and as publication of discoveries in the scientific or patent literature often lag behind the actual discoveries, we cannot be

certain that Novogen was the first to make the inventions covered by its pending patent applications or issued patents or that it was the first to file patent applications for such inventions. Additionally, the breadth of claims allowed in biotechnology and pharmaceutical patents or their enforceability cannot be predicted. We cannot be sure that any additional patents will issue from any of Novogen's patent applications or, should any patents issue, that we will be provided with adequate protection against potentially competitive products. Furthermore, we cannot be sure that should patents issue, they will be of commercial value to us, or that private parties, including competitors, will not successfully challenge our patents or circumvent our patent position in the United States or abroad.

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

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

We 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 our's or our other stockholders' interests.

Upon completion of this offering, Novogen will beneficially own approximately 87.4% 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 anti-cancer 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 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 would 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 this Offering

# An active trading market for shares of our common stock or our warrants may not develop following their admission to the Nasdaq National Market.

Prior to this offering, there has not been a public trading market for our common stock or our warrants in the United States. An active, liquid trading market for our common stock or our warrants may not develop or be maintained following this offering. As a result, you may not be able to sell your shares or warrants quickly or at the market price. The initial public offering price of our common stock units was determined by negotiation between us and the underwriter based on a number of factors, which may not be indicative of prices that will prevail in the U.S. trading market for the common stock and the warrants. The market price of our common stock and warrants on the Nasdaq National Market may decline below

the initial public offering price, and you may not be able to resell your shares of our common stock or warrants at or above the initial public offering price for the common stock units.

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

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

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

In addition, equity markets in general, and the market for biotechnology and life sciences companies in particular, have experienced substantial price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies traded in those markets. In addition, changes in economic conditions in the United States, Europe or globally, could impact upon our ability to grow profitably. Adverse economic changes are outside our control and may result in material adverse impacts on our business or our results of operations. These broad market and industry factors may materially affect the market price of our shares of common stock and warrants, 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.

If you are a subscriber in the directed share subscription program, you may be obligated to purchase common stock units even if you are the only subscriber or even if the underwriter does not purchase any units in the underwritten offering.

The closing of the underwritten offering and the directed share subscription program are not conditioned upon one another. Although we can terminate the directed share subscription program at any time prior to the closing if you subscribe to purchase common stock units under the directed share subscription program, you may be obligated to purchase the units even if you are the only subscriber or even if the underwriter does not purchase any units in the underwritten 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 after this offering, 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. There will be 56,626,000 shares of our common stock outstanding immediately after this offering not including the 2,080,000 shares of common stock underlying the warrants offered hereby. This does not include any shares of our common stock that may be issued upon exercise of warrants that will be outstanding after this offering.

All of the shares of our common stock sold in this offering will be freely transferable by persons other than our affiliates without restriction or further registration under the Securities Act. The remaining shares

of common stock outstanding will be "restricted securities" as defined in Rule 144 of the Securities Act. These shares may be sold in the future without registration under the Securities Act to the extent permitted by Rule 144 or other exemptions under the Securities Act. See "Shares Eligible for Future Sale."

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

If you purchase common stock units in this offering, you will in effect pay more for your shares of common stock than the amounts paid by existing stockholders for their shares. As a result, you will incur immediate and substantial dilution of \$7.00 per share (attributing no value to the warrants that are included in the common stock units), representing the difference between the initial public offering price and our pro forma as adjusted net tangible book value per share at September 30, 2003 after giving effect to this offering and the exercise in November 2003 of our then outstanding warrants. In addition, purchasers of our common stock units in this offering will have contributed approximately 56% of the aggregate price paid by all purchasers of our common stock, but will own only approximately 3.7% 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 offered hereby 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 offered hereby. 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.

# There can be no assurance that the trading price of our common stock will exceed the exercise price of the warrants being sold in this offering.

The warrants will entitle the holders to purchase one share of our common stock at an exercise price equal to \$9.00 anytime after issuance until the warrants expire on the third anniversary of their issuance. There can be no assurance that the trading price of our common stock will exceed the exercise price of the warrants. As a result, your warrants could expire and have no value.

# We will have broad discretion over the use of the net proceeds to us from this offering.

We will have broad discretion to use the net proceeds to us from this offering, and you will be relying on the judgment of our board of directors and management regarding the application of these proceeds. Although we expect to use a substantial portion of the net proceeds from this offering 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:

- · receipt of regulatory approvals;
- successful completion of clinical trials;
- · continued cooperation and support of Novogen, our parent;
- · future expenses and financing requirements; and
- · competition and competitive factors.

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.

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 expect to receive approximately \$13,608,000 in net proceeds from this offering (\$15,784,200 if the over-allotment option is exercised in full), after deducting underwriting discounts, commissions, selling fees and estimated offering expenses.

- We intend to use approximately \$1.1 million to commence Phase II clinical trials of phenoxodiol as a monotherapy in early-stage prostate cancer, SCC of the cervix, vagina and vulva, and possibly other tumors such as breast cancer where diagnosis of early stage disease is available;
- We intend to use approximately \$4.2 million to commence Phase II clinical trials of phenoxodiol in combinational therapy with standard anti-cancer drugs for late-stage, chemo-resistant ovarian cancer, and possibly other tumors such as renal cancer; and
- We intend to use the remainder for general corporate purposes, including:
  - potential payments to Novogen under the terms of the license agreement (including the first lump sum license fee of \$5 million which we intend to pay with the remaining net proceeds of this offering and with existing cash resources),
  - · 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.

#### DETERMINATION OF OFFERING PRICE

Prior to this offering, there has been no trading market for our common stock in the United States. The shares of common stock and warrants comprising the units being offered hereby will separate immediately upon completion of this offering and prior to any trading of the common stock and warrants. There will be no trading market for the common stock units. Our common stock is listed on the Alternative Investment Market of the London Stock Exchange. The initial public offering price for the common stock units was determined by negotiation between us and the underwriter based on a number of factors, including the historic trading prices of our common stock on the AIM, that may not be indicative of prices that will prevail in the trading market for our common stock in the United States. Other factors that were considered in our negotiations with the underwriter included the history and the prospects for the industry in which we compete, an assessment of our management, our prospects, the general condition of the securities markets at the time of this offering, the recent market prices of, and the demand for, publicly traded securities of generally comparable companies and certain other factors as were deemed relevant.

## PRICE RANGE OF OUR COMMON STOCK

Our common stock has traded on the AIM since May 2002 under the symbol "MSH." The following table sets forth, for the periods indicated, the high and low closing sale prices for our common stock as reported by the London Stock Exchange. The trading price for our shares of common stock on the AIM are quoted in sterling (£), the lawful currency of the United Kingdom. The following table also shows the high and low closing sales price of our common stock expressed in dollars based upon the average noon buying rate for sterling for the periods indicated.

Quarter Ended	High	Low	High	Low
June 30, 2002	£2.87	£2.35	\$4.11	\$3.36
September 30, 2002	£2.46	£2.35	\$3.81	\$3.64
December 31, 2002	£2.49	£2.46	\$3.84	\$3.79
March 31, 2003	£2.47	£2.28	\$3.96	\$3.65
June 30, 2003	£3.50	£2.35	\$5.66	\$3.80
September 30, 2003	£3.90	£3.33	\$6.28	\$5.36

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.

Quarter Ended	High	Low	Average	Period-End
June 30, 2002	\$1.5285	\$1.4310	\$1.4615	\$1.5245
September 30, 2002	\$1.5800	\$1.5192	\$1.5497	\$1.5700
December 31, 2002	\$1.6095	\$1.5418	\$1.5714	\$1.6095
March 31, 2003	\$1.6482	\$1.5624	\$1.6025	\$1.5790
June 30, 2003	\$1.6840	\$1.5500	\$1.6183	\$1.6529
September 30, 2003	\$1.6718	\$1.5728	\$1.6107	\$1.6620

On December 17, 2003, the closing sales price of our common stock as reported by the London Stock Exchange was £5.20 per share, or approximately \$9.16 per share based on the noon buying rate for sterling of £1.00 = \$1.7615 on December 17, 2003. On December 17, 2003, the shares of our common stock were held by approximately 20 holders of record.

# 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, 2003:

- on an actual basis; and
- as adjusted to reflect:
  - the issuance of 2,514,000 shares of our common stock which were issued upon the exercise of warrants in November 2003 at an exercise price of \$4.00 per share; and
  - the effect of the sale of a total of 2,080,000 common stock units in this offering, after deducting underwriting discounts, commissions, selling fees and estimated offering expenses.

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, 2003		
	Actual	As Adjusted	
	(in th	ousands)	
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, \$0.00000002 par value, 113,00,000 shares authorized, 52,032,000 shares issued and outstanding actual and 56,626,000 shares issued and outstanding as adjusted			
Additional paid-in-capital	9,058	32,722	
Deficit accumulated during development stage	(4,270)	(4,270)	
Accumulated other comprehensive income	50	50	
Total stockholders' equity	4,838	28,502	
• •			
Total debt and stockholders' equity	\$ 4,838	\$28,502	
	_		

This table excludes 2,080,000 shares of our common stock that may be issued upon exercise of the warrants that are included in the units being offered by this prospectus.

#### DILUTION

If you invest in our common stock units, your interest will be diluted to the extent of the difference between the initial public offering price per common stock unit (attributing no value to the warrants that are included in the common stock units) 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, 2003, before adjustment for this offering, but after giving effect to the issuance of 2,514,000 shares of our common stock which were issued upon exercise of warrants in November 2003 at an exercise price of \$4.00 per share, was approximately \$14,894,000, or approximately \$0.27 per share. After giving effect to the sale of 2,080,000 common stock units in this offering, and after deducting underwriting discounts, commissions, selling fees and the estimated offering expenses, our as adjusted net tangible book value at September 30, 2003 would have been \$28,502,000, or approximately \$0.50 per share. This represents an increase in net tangible book value of \$0.23 per share to our existing stockholders and an immediate dilution (i.e., the difference between the initial public offering price per unit, attributing no value to the warrants that are included in the common stock units, and the as adjusted net tangible book value per share after this offering) at September 30, 2003 of \$7.00 per share to purchasers of the common stock units offered hereby. The following table illustrates this per share dilution:

Initial public offering price per unit		\$7.50	100%
Net tangible book value per share at September 30, 2003 after giving effect			
to warrant exercises in November 2003	\$14,894		
Increase in net tangible book value per share attributable			
to the new investors	13,608		
As adjusted net tangible book value per share after this offering		0.50	
Dilution per share to new investors		\$7.00	93.33%
		_	

Assuming the over-allotment option is exercised in full, the as adjusted net tangible book value at September 30, 2003 giving effect to the exercise in November 2003 of our then outstanding warrants, would have been \$30,678,200, or \$0.54 per share, the immediate increase in net tangible book value of shares owned by existing stockholders would have been \$0.27 per share, and the immediate dilution to purchasers of the common stock units in this offering would have been \$6.96 per share.

The following table summarizes at September 30, 2003, after giving effect to the sale of 2,080,000 common stock units and the exercise in November 2003 of our then outstanding warrants, the number of shares of common stock purchased from us, the total consideration paid to us for those shares, attributing no value to the warrants that are included in the common stock units, and the consideration given by the existing stockholders and by the new investors assuming approximately 56,626,000 shares of our common stock are outstanding:

	Shares Purchas	sed	Total Considera	Average Price	
	Number	Percent	Amount	Percent	Per Share
	(in thousands)		(in thousands)		
Existing stockholders	54,546	96	\$20,184	56	\$0.37
New investors	2,080	4	15,600	44	\$7.50
Total	56,626	100	\$35,784	100	
		_			

# SELECTED HISTORICAL CONSOLIDATED FINANCIAL DATA

The following table shows selected historical financial data for the years ended June 30, 2003 and 2002, for the quarters ended September 30, 2003 and 2002 and for the period from December 1, 2000 (inception) through September 30, 2003. The information has been derived from our audited consolidated financial statements for the years ended June 30, 2003 and 2002 and our unaudited consolidated financial statements as of and for the quarters ended September 30, 2003 and 2002, included in this prospectus.

The unaudited financial statements include all adjustments, consisting of normal recurring accruals, which we consider necessary for a fair presentation of our financial position and results of operations for those periods.

The information below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Risk Factors" and the consolidated financial statements and the notes thereto included elsewhere in this prospectus.

		Quarter Ended September 30,			Year Ended June 30,				Period from December 1, 2000 (inception) through September 30,
		2003	2002			2003	2002		2003
		(unau	ıdited)	(in th	ousands, exc	cept share and	per share data)		(unaudited)
Statement of Operations Data:		(	,						(
Interest and other income	\$	21	\$	43	\$	145	\$	7	\$ 173
Net loss arising during development									
stage	\$	(1,114)	\$	(511)	\$	(3,033)	\$	(123)	\$(4,270)
Net loss per common share	\$	(0.02)	\$	(0.01)	\$	(0.06)	\$	(0.00)	
Weighted average shares used to									
calculate loss per share	52	52,032,000 52,023,000		023,000	52	52,023,247		769,581	
Common stock outstanding at period									
end	52	,032,000	52,	023,000	52	,032,000	52,	023,000	
							Septe	mber 30,	
							2003	2002	
								ousands) audited)	
Balance Sheet									
Cash and cash	equivalents						\$6,375	\$8,575	
Total assets							6,567	8,591	
Stockholders'	equity						4,838	8,387	
				22					

#### 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. Our fiscal year ends June 30. We commenced business operations in May 2002, and as a result our financial results for the fiscal year ended June 30, 2003 represent our first full year of operations. Our discussion below also includes our financial results for the quarter ended September 30, 2003.

# **Results of Operations**

We are a development stage company and our business purpose is the development and commercialization of drugs for the treatment of cancer. We are presently engaged in the clinical development of the anti-cancer drug phenoxodiol, which Novogen has licensed to us. Our main focus during fiscal 2003 and in the first quarter of fiscal 2004 was to undertake human clinical testing of phenoxodiol. We do not employ any staff directly but obtain services from Novogen under a services agreement.

We recorded a consolidated loss of \$3,033,000 and \$123,000 for the fiscal years ended June 30, 2003 and 2002, respectively. We recorded a consolidated loss of \$1,114,000 and \$511,000 for the quarters ended September 30, 2003 and 2002, respectively. We have not generated any revenues from operations since our inception. We have, however, received interest on our cash assets of \$173,000 through September 30, 2003.

Consolidated operating expenses for fiscal 2003 were \$3,178,000 versus \$129,000 for fiscal 2002. Our major operating expenses in 2003 included \$1,060,000 of costs associated with conducting the clinical trials of phenoxodiol and \$1,740,000 of costs incurred under the license agreement and the services and manufacturing agreements with Novogen including the costs of the clinical trial drug supplies. All of the \$1,060,000 of clinical trial expenses is included under research and development expenses in our financial statements for fiscal 2003. Of the \$1,740,000 of expenses, \$955,000 is included under research and development expenses, \$500,000 is included under license fees expenses and \$285,000 is included under selling, general and administrative expenses in our financial statements for fiscal 2003. Our consolidated operating expenses for the quarter ended September 30, 2003 were \$1,135,000 versus \$554,000 for the quarter ended September 30, 2002. Our major operating expenses for the quarter ended September 30, 2003 and 2002 included \$411,000 and \$77,000, respectively, of costs associated with conducting the clinical trials of phenoxodiol and \$679,000 and \$322,000, respectively, of costs incurred under the license agreement and the services and manufacturing agreements with Novogen including the costs of the clinical trial drug supplies. Our expenses increased mainly as a result of increased expenditures on our clinical trial program which increased by \$474,000 for the quarter ended September 30, 2003 to \$621,000 from \$147,000 for the quarter ended September 30, 2002 (including the cost of phenoxodiol supplied to us by Novogen) and the provision for payment of the license fee payable to Novogen under the terms of the license agreement. Of the \$1,135,000 of expenses for the quarter ended September 30, 2003, \$782,000 is included under research and development expenses versus \$334,000 for the quarter ended September 30, 2002, \$246,000 is included under license fee expenses versus none for the quarter ended September 30, 2002 and \$107,000 is included under selling, general and administrative expenses versus \$220,000 for the quarter ended September 30, 2002. The decrease in selling, general and administrative expenses for the quarter ended September 30, 2003 was primarily due to reduced currency losses and a decrease in public relations expenditures. See "Certain Relationships and Related Transactions."

# Research and Development Expenses

Research and development expenses consist mainly of our clinical trial expenditures, our payments to Novogen for research support services under the terms of the services agreement and the cost of phenoxodiol used in the clinical trials supplied by Novogen under the terms of the manufacturing license and supply agreement. Research and development expenses amounted to \$2,024,000 for the fiscal year ended June 30, 2003, \$782,000 for the quarter ended September 30, 2003 and \$334,000 for the quarter

ended September 30, 2002. Research and development costs incurred since inception through the quarter ended September 30, 2003 amount to \$2,875,000.

We expense our research and development costs as they are incurred and we expect our research and development costs to increase in the future as we progress the phenoxodiol clinical program.

We have not documented our historical research and development costs or our clinical trial costs on a project by project basis. In addition, we use the research and development resources supplied by Novogen across several projects. As a result, we cannot state precisely the costs incurred for each of our clinical projects on a project by project basis.

We expect that a large percentage of our research and development expenses in the future will be incurred in support of our 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 our research and development projects or when and to what extent we will receive cash inflows from the commercialization and sale of phenoxodiol.

# Selling, General and Administrative Expenses

Selling general and administrative expenses consist mainly of expenses associated with accounting and auditing, professional fees, public relations and administration fees paid to Novogen under the terms of the services agreement.

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.

# **Liquidity and Capital Resources**

At the end of fiscal year ended June 30, 2003, we had cash resources of \$7,244,000 and at the end of the quarter ended September 30, 2003, we had cash resources of \$6,375,000. Funds are invested in short-term money 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.

In May 2002, we raised \$10,092,000 through a private placement of 2,523,000 shares of common stock in conjunction with the listing of our common stock on the Alternative Investment Market of the London Stock Exchange. Total proceeds of \$9,022,000 were received, net of \$1,070,000 of transaction costs. The 2,523,000 shares of our common stock, which represent 4.6% of our issued common stock, were issued at \$4.00 per share. Each share had an attached warrant exercisable at any time prior to November 30, 2003 with an exercise price of \$4.00 per share. These funds were sufficient to progress the clinical development program that Novogen had commenced prior to licensing phenoxodiol to us and to commence new clinical trials. In June 2003, 9,000 warrants were exercised and in November 2003, the remaining 2,514,000 warrants were exercised.

Based on our current plans, we believe that with the net proceeds of this offering, we will have sufficient funds to complete the current Phase Ib/IIa and Phase II clinical trial program, commence Phase II clinical trials of phenoxodiol as a monotherapy in early stage cancer, and to commence Phase II clinical trials of phenoxodiol in combinational therapy with other anti-cancer drugs for late stage chemo-

resistant tumors. We believe we will have sufficient cash resources to fund our operations at least through the end of the fiscal year. Our 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, we will require additional funds 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 our license agreement with Novogen when certain milestones are met, as follows:

- A lump sum license fee of \$5,000,000 is payable to Novogen on the date when the cumulative total of all funds received from debt or equity issuances, revenue received from commercialization income, other than sales, and revenue from sales of phenoxodiol products exceeds \$25,000,000.
- A further lump sum license fee of \$5,000,000 is payable to Novogen on the later of November 1, 2003 or on the date when the cumulative total of all funds received from debt or equity issuances, revenue received from commercialization income, other than sales, and revenue from sales of phenoxodiol products exceeds \$50,000,000.

The cumulative total of funds received by us as of the date of this prospectus is \$20,184,000. This amount includes \$10,056,000 that we received since September 30, 2003 upon the exercise of 2,514,000 of our then outstanding warrants. As a result, the first lump sum license fee referred to above will become payable to Novogen upon consummation of this offering. We intend to pay the first lump sum license fee with the net proceeds of this offering and with existing cash resources.

In addition, we must pay annual license fees to Novogen under the license agreement for the calendar years ended December 31 as follows:

2003	\$1,000,000
2004	\$2,000,000
2005	\$4,000,000
Each calendar year thereafter	\$8,000,000

Any amounts payable to Novogen under the above annual payments will be reduced for amounts we pay under the first lump sum license fee referred to above. For the fiscal year ended June 30, 2003 and the fiscal quarter ended September 30, 2003, \$500,000 and \$246,000, respectively, have been included as license fee expense in the consolidated statements of operations. See "Certain Relationships and Related Transactions" for more information about our license agreement with Novogen.

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

# **Critical Accounting Estimates**

The preparation of our 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.

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

Clinical trial expenses of \$1,060,000 have been included in our financial statements for the year ended June 30, 2003, of which \$331,000 had been accrued at June 30, 2003. Clinical trial expenses of \$411,000 have been included in our financial statements for the quarter ended September 30, 2003, of which \$510,000 had been accrued at September 30, 2003. These estimates are based on the number of patients in each trial and the patient treatment cycle.

Clinical research contracts may vary depending on the clinical trial design and protocol. Generally the costs, and therefor our estimates, associated with clinical trial contracts are based on the number of patients, patient treatment 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.

## **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 our consolidated financial statements.

## **Market Risk and Risk Management Practices**

We have established controls at the board level designed to safeguard our interests and ensure integrity in the reporting to stockholders. Our practices are in place to minimize risks that arise through our activities. These include practices that:

- ensure that any capital expenditure above a certain level is approved by the board;
- · ensure that business risks are appropriately managed through an insurance and risk management program;
- ensure that safety, health, environmental standards and management's systems are monitored and reviewed to achieve high standards of compliance and performance; and
- ensure implementation of board approved operating plans and budgets and board monitoring of progress against these budgets, including the establishment and monitoring of key performance indicators.

# **Impact of Inflation**

Although inflation has slowed in recent years it is still a factor that may affect our financial performance. We do not earn sales revenue and for the foreseeable future we will not be able to increase the price of goods sold to offset inflationary effects. Costs incurred in conducting clinical trials are affected by inflation as are other inputs. There is a risk that costs will increase over time due to inflation increasing the cost to us.

#### BUSINESS

We are a developmental stage pharmaceutical company 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. We have attached as Annex A, a glossary of technical and scientific terms that we use in this prospectus.

Novogen Limited, an Australian company publicly traded on the Nasdaq National Market, owns approximately 90.7% of our outstanding common stock and, after this offering, will own approximately 87.4% of our 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 treatment and prevention of cancer market.

## **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.

Based on our clinical studies, we believe 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 recent discovery of a research team at Purdue 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+ 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. Some aspects of this function were published recently in the Nature journal, *Oncogene*.

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 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.

## **Market Opportunity**

The American Cancer Society, or ACS, has reported that, in the year 2003, approximately 1,344,100 new cancer cases are expected to be diagnosed in the United States and that since 1990, approximately 17 million new cancer cases have been diagnosed. The ACS has also reported that 556,500 people in the United States are expected to die from cancer this year.

The primary focus in the development of phenoxodiol is currently in connection with ovarian cancer, squamous cell carcinoma, or SCC of the cervix, vagina, vulva and skin, and prostate cancer. Subject to further successful clinical research and development, we believe that phenoxodiol may have potential uses in other forms of human cancers as well as in combinational therapy with other anti-cancer drugs.

The cancers for which phenoxodiol is intended to be used are relatively common. The ACS has estimated that in 2003 there will be 220,900 new cases of prostate cancer and 28,900 people will die as a result of this cancer in the United States. The ACS has also estimated that in 2003 there will be 25,400 new cases of ovarian cancer diagnosed and 14,300 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 2003, there will be 18,200 new cases diagnosed and that there will be 5,700 deaths caused by these cancers in the United States. The ACS estimates that 2,200 deaths will occur in the United States as a result of cutaneous SCC.

The treatment of prostate cancer depends on age, stage of the cancer, and other medical conditions of the patient. Current treatment options include surgery, radiation, hormonal therapy or chemotherapy (or a combination of these treatments) depending on the stage of the disease. Survival rates also depend on the stage of the disease. However, there is a low survival rate associated with advanced disease.

Treatment options for ovarian cancer include surgery, radiation therapy and chemotherapy. Treatment in advanced cases is associated with low survival rates.

SCC is a common type of cancer found in the skin and mucous membranes of the body. Cancers of the cervix, vagina and vulva are mostly of the SCC type and are recognized for their poor response to standard chemotherapy. Surgery remains the treatment of choice for these cancers and treatment in advanced cases is associated with low survival rates. Cutaneous SCC is a relatively common form of skin cancer. It is most common in sun-exposed areas and if left untreated can invade locally, requiring extensive surgery.

#### **Overall Clinical Development Strategy**

Based on the clinical and pre-clinical work conducted on phenoxodiol, we believe that based on its mode of action, phenoxodiol has the potential ultimately 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 including completing our current intravenous monotherapy ovarian cancer clinical trial currently underway at Yale University. Pending the outcome of this trial we intend to expend our intravenous program to include combinational therapy using phenoxodiol in combination with standard chemotherapy drugs in cancers which have become chemo-resistant. 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.

A secondary priority is to develop phenoxodiol for use in earlier-stage cancers. This is the basis of the planned clinical program involving oral phenoxodiol in SCC of the cervix, vagina, vulva, including our planned adjuvant trial at Yale University, and skin, and prostate cancer. 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 will provide an adequate anti-cancer effect.

# **Specific Objectives**

Our current objectives are to:

- complete the Phase Ib/IIa and Phase II clinical programs currently being undertaken for phenoxodiol as a monotherapy;
- commence a Phase II study in patients with late-stage, chemo-resistant ovarian cancer that will use phenoxodiol in combination with standard anti-cancer drugs; and
- commence Phase II studies for phenoxodiol as a monotherapy, targeting early-stage cancer of the cervix, vagina and vulva, and prostate cancer.

We anticipate that with the proceeds of this offering we will have sufficient funds for these activities. The success and timing of the clinical trials could vary significantly from current estimates. A delay in any one phase of trials is likely to delay following phases. Our long-term objectives will be to:

- commence Phase III clinical trials for phenoxodiol as both a monotherapy for early-stage cancers and for use in combinational therapy for later-stage cancers;
- seek to develop relationships with strategic partners for the development, marketing and distribution of phenoxodiol as a treatment for those cancer indications for which regulatory approval is obtained;
- · potentially expand the uses of phenoxodiol to treat other cancers; and
- pursue appropriate opportunities to develop and commercialize other anti-cancer compounds.

We will require additional funding in order to undertake our long-term objectives.

# **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.

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 bioavailable (absorbed into the body in useful form) and significantly retarded tumor development, in particular in athymic mice bearing xenografts of human prostate cancer. Such anti-cancer effects in animals were achieved without evidence of toxicity, and thus phenoxodiol was selected for development as a human anti-cancer drug.

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 preclinical 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 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 tentative evidence of efficacy across a range of different tumor types.

Phase Ia pharmacokinetic studies, which monitor the behavior of a drug within the body, conducted in cancer patients in May 2000 showed that phenoxodiol behaved similarly to steroidal hormones and was 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 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:

- that phenoxodiol has broad inhibitory activity against 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 was 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 particularly effective against ovarian cancer, melanoma and mesothelioma cell lines that were resistant to all standard chemotoxic anti-cancer drugs, pointing to the 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 and mucosal surfaces. 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.

A team of scientists at Yale University School of Medicine commenced a Phase II study in October 2002 of the intravenous dosage form of phenoxodiol in 40 patients with ovarian cancer. We expect that we will receive interim results from this study by the end of this year.

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 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 cancer 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 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.

## Phenoxodiol and Ovarian Cancer

A team of scientists at Yale University School of Medicine is currently conducting a Phase II clinical study. The study is fully enrolled, using 40 patients with advanced, metastatic ovarian cancer that has become unresponsive to at least two standard chemotherapies (the average number of different drug regimes used previously in these patients is five per patient). Phenoxodiol is being administered as a monotherapy by bolus intravenous injection on two consecutive days per week in rising dosages (one, three, 10 and 20 mg/kg/24-hr) to four groups, each of 10 women, over treatment cycles of 12 weeks. Tumor response is being assessed on the basis of tumor mass, levels of the tumor marker (CA125) in the blood, survival over 12 months, and quality of life.

This clinical trial is based on laboratory studies at Yale University School of Medicine that showed phenoxodiol to be the most effective drug at killing ovarian cancer cells, including those that are resistant to all standard anti-cancer drugs.

Following analysis of the data from the current Phase II study, currently projected to be completed by December 2003, a decision will be made concerning the next stage.

A recent pre-clinical study also extended these findings by showing that phenoxodiol proved highly effective at restoring ovarian cancer cells' sensitivity to standard anti-cancer drugs such as cisplatin. Cisplatin is a standard drug used in the treatment of ovarian cancer, but patients' tumors commonly become resistant to this drug after some months. A combination of phenoxodiol and cisplatin proved highly effective in stopping human ovarian cancer growth in animals with doses of phenoxodiol and cisplatin that alone were ineffective. This raises the prospect of obtaining an enhanced clinical response of phenoxodiol by combining it with standard chemotherapies, and the opportunity to conduct a combinational drug trial in ovarian cancer patients is currently under review.

#### Phenoxodiol and Prostate Cancer

Two Australian hospitals are currently conducting a study testing the effect of oral phenoxodiol therapy in patients with late-stage prostate cancer that has become unresponsive to hormonal therapy. Phenoxodiol is being administered orally three times per day on a daily basis over treatment cycles of 12 weeks. There will be 24 patients in this trial, with patients being allocated to seven different dose levels (from 0.72 to 9.0 mg per 24-hr). The study currently has 18 patients enrolled.

#### Phenoxodiol and Cutaneous SCC

The potential for phenoxodiol in the treatment of cutaneous SCC arose from the observation that in patients being treated for other forms of cancer who coincidentally had aggressive, malignant SCC of the skin, the SCC tumors showed objective responses within several weeks. A Phase II trial is being conducted at an Australian hospital in 30 patients with malignant SCC of the skin. Phenoxodiol is being administered orally, three times daily for a period of three months. We anticipate this study being completed by the third quarter of 2004.

### 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 products or drug candidates 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 are further advanced in development and may receive FDA or other regulatory approval and may be commercialized earlier than phenoxodiol. Some of these drugs may be directly competitive with phenoxodiol to the extent that they would obviate the need for phenoxodiol. In other cases, however, 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.

Iressa, a signal transduction inhibitor manufactured by AstraZeneca, is a potential competing treatment and has recently been granted FDA approval for use in the treatment of advanced stage non-small cell lung cancer in patients who have already received specific chemotherapy. Other potential competition might arise from the development of drugs with a related chemical heritage to phenoxodiol. Genistein and flavopiridol<sup>TM</sup> are two chemicals with a related chemical heritage of an underlying flavonoid chemical structure which are undergoing clinical development as anti-cancer agents. Our understanding is that genistein is in Phase II clinical studies, while we believe flavopiridol<sup>TM</sup>, under development by Aventis, is in Phase III clinical studies.

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>, and AstraZeneca, which has been

granted approval for Iressa, are two such companies with potentially competitive anti-cancer drugs that have greater size, resources and market presence than we do. In this respect, Aventis, AstraZeneca and others may be able to more easily develop technologies and products that would render our technologies or our drug candidates obsolete or non-competitive.

#### **Intellectual Property**

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

See "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 "product 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 product patent rights and one family belonging to the manufacturing patent rights: The three families in the product patent rights comprise phenoxodiol for the treatment of cancer (16 pending; seven issued); compositions and methods for protecting skin from ultraviolet induced immunosuppression and skin damage including phenoxodiol (10 pending; three issued); 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 (17 pending).

Novogen has recently been granted a U.S. Patent (No. 6,649,648), a product patent, by the United States Patent and Trademark Office (USPTO) relating to the treatment of any cancerous disease with phenoxodiol, including ovarian cancer, breast cancer, prostate cancer and metastatic cancer.

As patent applications in the United States are sometimes 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 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 phenoxodiol as patent applications in the biopharmaceutical sector often take considerable time to issue. 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 used to support the marketing application for the drug. Pursuant to the FDA Modernization Act of 1997, the period of exclusivity can be extended if the applicant performs certain studies in pediatric patients. 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 New Drug Application (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 provision

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 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. 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 anti-cancer 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 are discussed briefly below. Investors should also read the detailed summary of these documents set out 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 focussed on advancing the clinical program underway for the development of phenoxodiol.

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

Pursuant to the 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.

#### Commercialization

Commercialization of a drug requires approval from the regulatory body of each country in which the drug is to be marketed. Following the completion of Phase III studies, the data gathered from the clinical trial program must be collated for presentation to the appropriate regulatory authorities in each territory in a form acceptable to each authority, in order to obtain the relevant regulatory approvals to market the drug in that territory. Approval usually is granted for those specific cancer indications for which the clinical data supports efficacy.

We may choose to seek regulatory approval in our own right in any or all territories. Alternatively, we may seek to establish a strategic partnership with another pharmaceutical company to market phenoxodiol in certain territories, in which case that partner may take responsibility for application for regulatory approval.

Successful commercialization requires high quality marketing campaigns and distribution arrangements in order to gain market share as fast as possible. Global pharmaceutical companies have large and professional marketing and distribution functions that regularly introduce new drugs throughout the world. For that reason, we are likely to choose to seek a strategic partnership in any or all territories in which phenoxodiol is to be marketed. Our decision to establish a strategic partnership will depend on the success of phenoxodiol during the clinical program, the level of funding required to complete the clinical program to gain marketing approval and whether we can negotiate favorable terms with potential partners.

Decisions on both the appropriate territories in which regulatory approval will be sought and the nature of commercialization in those territories will be made by the board of directors at the appropriate time and with due regard to maximizing the commercial benefit to us.

The most significant market for phenoxodiol is the United States market. Before a drug is granted regulatory approval to be marketed and commercialized in the United States, the drug must gain approval to be tested in humans. In the United States, this requires the drug to have an effective IND. See "— Regulation-U.S. Regulatory Requirements." Phenoxodiol has achieved this status and has commenced clinical trials in the United States.

### **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;
- $\bullet$  the relative the rapeutic 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.

# 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 biologics and drugs by the FDA. The process required by the FDA before biologics or drugs may be marketed in the United States generally involves the following:

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

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

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

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

- *Phase I:* The drug is initially introduced into healthy human subjects or patients and tested for safety and dosage tolerance. Absorption, metabolism, distribution, and excretion testing is generally performed at this stage.
- *Phase II*: The drug is studied in controlled, exploratory therapeutic trials in a limited number of subjects with the disease or medical condition for which the new drug is intended to be used in

order to identify possible adverse effects and safety risks, to determine the preliminary or potential efficacy of the product for specific targeted diseases or medical conditions, and to determine dosage tolerance and the optimal effective dose.

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

We cannot be certain 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 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. NDAs are used for products that are regulated as drugs, such as synthetic chemicals. 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 for the fiscal year 2004), and an annual establishment fee (\$226,800) on facilities used to manufacture prescription drugs and biologics. 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 submission to the 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 product indications, manufacturing processes or facilities, product labeling, or other areas may require submission of an NDA Supplement to the FDA for review and approval. 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. Nonetheless, 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 payors. European Union and U.S. government and other third-party payors increasingly are attempting to contain healthcare costs by consideration of new laws and regulations limiting both coverage and the level of reimbursement for new drugs. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad.

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

#### **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.

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

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

There has recently been introduced in Europe new legislation designed to harmonise the regulation of clinical trials across the EU and that legislation is currently being implemented on a country by country basis. In addition, new proposals are under advanced consideration which, if brought into law, will effect substantial and material changes to the regulation of medicinal products in Europe. Accordingly, there is a

marked degree of change and uncertainty both in the regulation of clinical trials and in respect of marketing authorisations which face us in seeking for our products in Europe.

#### **Government Funding**

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

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

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

#### Dr. Graham Edmund Kelly, PhD, age 58, Chairman, Director

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

#### Christopher Naughton, age 50, 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 18 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 56, 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's term as one of our directors expires in 2004.

### Professor David Morritz de Kretser, age 64, 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 Kretsers 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.

#### 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 Medial 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 61, 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 2001, 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 49, 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 18 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 procedures and the adequacy of our internal control procedures. The members of the Audit Committee are Mr. Breckenridge (chairman), Mr. Johnston and Professor de Kretser, all of whom are independent as defined by applicable Nasdaq and SEC rules. 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 and Mr. Breckenridge.

### **Director and Executive Compensation**

#### Directors

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

## **Executive Officers**

Our executive officers, Dr. 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.

#### **Share Option Plan**

We have adopted a share option plan. As of the date of this prospectus, no options were outstanding under the share option plan and we have no present intention of granting any options under the share option 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.

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 17, 2003.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned Before and After this Offering	Percentage of Shares Beneficially Owned Before this Offering	Percentage of Shares Beneficially Owned After this Offering
Novogen Limited(1) 140 Wicks Road North Ryde NSW 2113 Australia	49,500,000	90.7%	87.4%
OppenheimerFunds, Inc.(2) 6803 S. Tucson Way Centennial, CO 80112-3924	3,495,300(3)	6.4%	6.2%

- (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.
- (3) This table does not include common stock units, if any, that may be purchased by OppenheimerFunds, Inc. in the directed share subscription program. See "Certain Relationships and Related Transactions."

#### 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 Amended and Restated 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.

Payee	Fee/Cost	Description
Novogen	License Fees	During the exclusivity period:  • 2.5% of the net sales of phenoxodiol products (invoice price less trade discounts and returns taken); and  • 25% of all gross income received by or on behalf of us (or our affiliates other than Novogen) from the assignment, sublicensing or other dealing with our rights under the agreement, which we refer to as commercialization income.  After the exclusivity period, 1.5% of all net sales of phenoxodiol products on the basis
Novogen	First lump sum license fee	described above.  A lump sum license fee of \$5 million is payable on the later of November 1, 2002 or the date on which the cumulative total of the funds (debt or equity) received by us or our affiliates other than Novogen and the income derived by us or our affiliates other than Novogen and from sales of phenoxodiol products or commercialization income exceeds \$25 million.
Novogen	Second lump sum license Fee	A further lump sum license fee of \$5 million is payable on the later of November 1, 2003 or the date on which the cumulative total of the funds (debt or equity) received by us or our affiliates other than Novogen and the income derived by us or our affiliates other than Novogen from sales of phenoxodiol products or commercialization income exceeds \$50 million.
Novogen	Annual License Fees	For each calendar year set out below for the duration of the exclusivity period, the annual license fees are:  • calendar year ending December 31, 2003: \$1 million;  • calendar year ending December 31, 2004: \$2 million;  • calendar year ending December 31, 2005: \$4 million; and  • each calendar year following the year ending December 31, 2005: \$8 million, less any amount payable to Novogen during that calendar year pursuant to the first lump sum license fee referred to above.
Novogen	Patent Costs	We must reimburse Novogen one half of the costs of filing, prosecution and maintenance of the licensed patent rights.
Novogen Various	Goods and Service Tax Withholding Tax	Any goods and services tax payable on any amounts paid under the agreement.  We must pay the amount of any withholding taxes payable in any country and must gross-up any royalties withheld.

Interest accrues daily on the outstanding balance of all overdue amounts payable to Novogen under the license agreement.

Since September 30, 2003, we have received \$10,056,000 upon the exercise of 2,514,000 of our outstanding warrants. As a result, the first lump sum license fee referred to above will become payable to Novogen upon consummation of this offering.

For the fiscal year ended June 30, 2003 and the quarter ended September 30, 2003, we have included \$500,000 and \$246,000, respectively, as a license fee expense in our consolidated statements of operations.

#### **Termination**

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

## The Amended and Restated 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.

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 30, 2003 and the quarter ended September 30, 2003, we have included \$165,000 and \$207,000, respectively, of expense for the cost of drugs supplied by Novogen in the consolidated statements of operations.

#### 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 resupply or payment for resupply of services.

# The Amended and Restated License Option Deed

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

# **Option Compounds**

The rights relate to all synthetic pharmaceutical compounds, known as Option Compounds, delivered or taken in all forms except topical applications (other than phenoxodiol, which is the subject of the

license agreement), developed before or during the term of the deed, by or on behalf of Novogen or its affiliates, which have known applications in the Field of prevention, treatment or cure of cancer in humans.

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

Novogen must not, and must ensure that its affiliates other than us do not, deal, solicit entertain or discuss dealings with any intellectual property rights in the Field or in relation to any Option Compounds without giving us an exclusive first right to accept and an exclusive last right to match any such dealing. If we exercise our first right to accept or last right to match, Novogen must deal with the intellectual properly 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 Amended and Restated Services Agreement

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

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

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

research provisions. We have guaranteed the obligations of our subsidiary under the services agreement. See "—Guarantee and Indemnity Agreement."

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

## Fees for Services

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

For the fiscal year ended June 30, 2003 and the quarter ended September 30, 2003, we have included \$1,075,000 and \$226,000, respectively, as an expense for services provided by Novogen in the consolidated statements of operations.

#### **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.

# **Participation in Directed Share Subscription Program**

OppenheimerFunds, Inc., an entity that beneficially owns greater than 5% of our common stock, will be entitled to participate in our directed share subscription program to the extent that it was the beneficial owner of such shares as of the close of business on October 20, 2003. Any common stock units purchased by OppenheimerFunds, Inc. under the directed share subscription program will be purchased on the same terms and conditions available to other eligible holders who participate in the program.

#### DESCRIPTION OF OUR SECURITIES

The shares of common stock and warrants offered hereby will be sold only in units. Each common stock unit consists of one share of common stock and one warrant to purchase one share of common stock. No common stock units have been issued prior to this offering. There will be no trading market for the common stock units. The shares of common stock and warrants comprising the units will separate immediately upon completion of this offering and prior to any trading of the common stock and warrants.

### **Description of our Capital Stock**

Our total authorized share capital is 113,100,000 shares consisting of 113,000,000 shares of common stock, \$0.00000002 par value per share, and 100,000 shares of preferred stock, \$0.01 par value per share. As of the date of this prospectus, 54,546,000 shares of our common stock and no shares of preferred stock are 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.

# Transfer Agent

 $Our \ transfer \ agent \ is \ Computershare \ Investor \ Services, \ LLC, \ Two \ North \ La \ Salle \ Street, \ Chicago, \ Illinois \ 60602.$ 

# **Description of our Warrants**

### Warrants included in the common stock units

Each warrant included in the common stock units represents the right to purchase one share of our common stock at an exercise price equal to \$9.00. The warrants are immediately exercisable and will expire three years after the date they are issued. 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.

Holders of the warrants may only exercise their warrants for the purchase of shares of common stock if a registration statement and current prospectus relating to these shares is then in effect and only if the shares are qualified for sale, or deemed to be exempt from qualification under applicable state securities laws. We are required to use our best efforts to maintain a current prospectus relating to these shares of common stock at all times when the market price of the common stock exceeds the exercise price of the warrants, until the expiration date of the warrants. We cannot assure you that an effective registration statement or current prospectus will be available at the time you desire to exercise your warrants.

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.

For the term of the warrants, the holders thereof are given the opportunity to profit from an increase in the per share market price of our common stock, with a resulting dilution in the interest of all other stockholders. So long as the warrants are outstanding, the terms on which we could obtain additional capital may be adversely affected. The holders of the warrants might be expected to exercise them at a time when we would, in all likelihood, be able to obtain additional capital by a new offering of securities on terms more favorable than those provided by the warrants.

# 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**

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 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

Upon completion of this offering, there will be 56,626,000 shares (56,938,000 shares if the over-allotment option is exercised in full) of our common stock outstanding not including the 2,080,000 shares of common stock underlying the warrants offered hereby (2,392,000 shares if the over-allotment option is exercised in full). Of the shares which will be outstanding after this offering:

- all 2,080,000 shares (2,392,000 shares if the over-allotment option is exercised in full) included in the common stock units and sold in this offering will be freely tradeable except for any shares purchased by our affiliates;
- 5,046,000 shares will be "restricted securities" held by non-affiliates; and
- 49,500,000 shares will be held by Novogen.

The restricted securities described above, of which 2,523,000 were issued in May 2002, and of which 2,523,000 were issued upon exercise of outstanding warrants, will be eligible for sale in the public market 90 days after the date of this prospectus, 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 (approximately 566,260 shares immediately following this offering); 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).

#### PLAN OF DISTRIBUTION

Of the common stock units offered by this prospectus, 580,000 units are being offered by means of an underwritten public offering and up to 1,500,000 units are being offered by means of a directed share subscription program to U.S. holders of ordinary shares and American Depositary Receipts of Novogen and to our U.S. stockholders who beneficially owned such shares or receipts as of the close of business on October 20, 2003. The closing of the directed share subscription program and the underwritten offering are not conditioned upon one another and will occur concurrently.

We have granted to the Janney Montgomery Scott LLC an option to purchase additional common stock units representing up to 15% of the units sold in this offering, which may be up to an aggregate of 312,000 additional common stock units, at the public offering price, less underwriting discounts and commissions listed on the cover page of this prospectus, solely to cover over-allotments, if any.

#### **Underwritten Public Offering**

Subject to the terms and conditions of an underwriting agreement entered into between us and Janney Montgomery Scott LLC, as underwriter, the underwriter has agreed to purchase, and we have agreed to sell to the underwriter, 580,000 common stock units plus any common stock units that are not subscribed for as part of the directed share subscription program (not including the over-allotment units).

The underwriting agreement provides that the obligations of the underwriter are subject to various conditions, including approval of certain legal matters by its counsel. The nature of the underwriter's obligations is that the underwriter is committed to purchase and pay for on a firm commitment basis 580,000 common stock units and any of the 1,500,000 units that are not subscribed for in the directed share subscription program. As a result, in the event the underwriter purchases the 580,000 common stock units to be sold on a firm commitment basis, the underwriter also will be obligated to purchase any and all common stock units not purchased in the directed share subscription program.

The following table shows the per common stock unit and total underwriting discounts and commissions we will pay to the underwriter. These amounts are shown assuming both no exercise and full exercise of the over-allotment option.

	Without Over-Allotment Exercise	With Over-Allotment Exercise
Per Common Stock Unit	\$ 0.525	\$ 0.525
Total	\$304,500	\$468,300

The underwriter proposes to offer the common stock units directly to the public at the initial public offering price listed on the cover page of this prospectus. After this offering, the underwriter may change the offering price to the public.

This offering of common stock units is made for delivery when, as and if accepted by the underwriter and subject to prior sale and to withdrawal, cancellation or modification of the offering without notice. The underwriter or we reserve the right to reject any order or subscription for the purchase of units in whole or in part. We have agreed to indemnify the underwriter against liabilities, including liabilities to which the underwriter may become subject under any applicable federal or state law or otherwise, and to continue to reimburse payments the underwriter may be required to make with respect to these liabilities.

In addition, the underwriting agreement also provides that, for a period of 120 days from the date of the underwriting agreement, we will not issue or make a disposition of common stock or any securities convertible into or exercisable or exchangeable for common stock without the prior written consent of the underwriter, other than in connection with the exercise of outstanding options and warrants and the grant of options.

In order to facilitate this offering, the underwriter may engage in transactions that stabilize, maintain or otherwise affect this offering. Specifically, the underwriter may over-allot or otherwise create a short position in the shares or warrants for its own account by selling more shares and warrants than we have

actually sold to it. The underwriter may elect to cover any short position by purchasing shares or warrants in the open market or by exercising the over-allotment option granted to it. In addition, the underwriter may stabilize or maintain the price of the shares or warrants by bidding for or purchasing shares or warrants in the open market. The effect of these transactions may be to stabilize or maintain the market price at a level above which might otherwise prevail in the open market. Neither we nor the underwriter makes any representation or prediction as to the direction or magnitude of any effect that such transactions may have on the price of our common stock or warrants. In addition, neither we nor the underwriter makes any representation that the underwriter will engage in such transactions or that such transactions, once commenced, will not be discontinued without notice.

### **Directed Share Subscription Program**

Of the 2,080,000 common stock units being offered pursuant to this prospectus, up to an aggregate of 1,500,000 units are being offered at the initial public offering price to U.S. holders of ordinary shares and American Despositary Receipts of Novogen, who beneficially owned their shares or receipts as of the close of business on October 20, 2003, and to our U.S. stockholders who beneficially owned their shares as of that date. Janney Montgomery Scott LLC will act as our dealer manager in connection with our directed share subscription program. The common stock units being offered under our directed share subscription program are being offered concurrently with the common stock units to be sold in the underwritten offering.

Up to an aggregate of 1,500,000 common stock units may be purchased under our directed share subscription program and subscribers are required to purchase in round lot increments of 100 common stock units. There is no maximum, however, on the number of units that any one eligible holder may subscribe for under the directed share subscription program. If there are not enough of our units available to fully satisfy all of the subscription requests, we will allocate the available units among eligible holders in our discretion with every subscriber being allocated at least 100 common stock units.

Janney Montgomery Scott LLC has agreed to purchase any units allocated to the directed share subscription program to the extent that such units are not purchased by the eligible holders under the directed share subscription program.

In the event that there are closings under the directed share subscription program and in the underwritten offering, these closings will take place concurrently and are not dependent upon one another. We can terminate the directed share subscription program at any time prior to the closing, but are not obligated to terminate the directed share subscription program in the event the underwritten offering is terminated. As a result, if you subscribe for common stock units under the directed share subscription program, you may be obligated to purchase units even if the underwriter does not purchase any units in the underwritten offering. In addition, unless we terminate the directed share subscription program, you will be obligated to purchase units even if you are the only subscriber in the directed share subscription program.

The purchase price for the units under the directed share subscription program will be the same price per unit as that offered to the public and set forth on the cover page of this prospectus. Janney Montgomery Scott LLC, as dealer manager, will receive a percentage selling fee on all units offered and sold through the directed share subscription program. The selling fee represents compensation for the dealer manager's role as it relates to due diligence, participation in the drafting of this prospectus and general coordination of the overall offering. The common stock and warrants sold under the directed share subscription program will not be subject to any lock-up agreements.

The following table shows the per common stock unit and total selling fees to be paid by us to the dealer manager assuming both no exercise and full exercise of the over-allotment option. These amounts are shown assuming that the direct share subscription program is fully subscribed.

	Without Over-Allotment Exercise	With Over-Allotment Exercise
Per Common Stock Unit	\$ 0.225	\$ 0.225
Total	\$337,500	\$337,500

We estimate that the total expenses of this offering, including both the underwritten public offering and the directed share subscription program, but excluding the underwriting discounts, commissions and selling fees, will be approximately \$1,350,000, which includes a \$150,000 non-accountable expense allowance payable to the underwriter for costs and expenses (including price stabilization) associated with this offering.

#### LEGAL MATTERS

The validity of the securities offered hereby will be passed upon for us by Morgan, Lewis & Bockius LLP. Certain legal matters will be passed upon for the underwriter by Pepper Hamilton LLP.

#### **EXPERTS**

The consolidated financial statements of Marshall Edwards, Inc. (a development stage company) at June 30, 2003 and 2002, and for the years then ended and for the period from December 1, 2000 (inception) through June 30, 2003, appearing in this prospectus and registration statement have been audited by Ernst & Young LLP, independent auditors, and the information under the caption "Summary Historical Consolidated Financial Data" 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, appearing in this prospectus and registration statement have been derived from consolidated financial statements audited by Ernst & Young LLP, as set forth in their report thereon appearing elsewhere herein.

Such consolidated financial statements and summary historical consolidated financial data are included in reliance upon such reports given on the authority of such firm as experts in accounting and auditing.

# AVAILABLE INFORMATION

We have filed with the SEC a registration statement on Form S-1 with respect to the common stock units 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.

Upon completion of this offering, we will become subject to the information and periodic reporting requirements of the Securities Exchange Act of 1934, as amended, and, in accordance therewith, will file periodic reports, proxy statements and other information with the SEC. Such periodic reports, proxy statements and other information will be available for inspection and copying 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**

"Androgens" male sex hormones, e.g. testosterone

"Anti-androgen" a process that reduces the biological impact of androgens, either by blocking the production of androgens or by

interfering with their function

"Apoptosis" the process of programmed cell death by which a cell dies naturally

**"Bioavailable"** absorbed into the body in a useable form

"Bolus injection" an intravenous injection delivered quickly (usually over several minutes)

**"Cytostatic"** the process by which a cell is prevented from dividing

"Cytotoxic" having a lethal effect on cells

"Death receptor" signaling molecule that when activated causes cell death

"in vitro" in the laboratory

"in vivo" in animals

"IND" Investigational New Drug application

**"Isoflavonoid ring structure"** a chemical term referring to a simple phenolic ring structure

"Kinases" enzymes that catalyze phosphorylation of acceptor molecules

"MSTR" Multiple Signal Transduction Regulator or Multiple Signal Transduction Regulation

"NDA" New Drug Application

"Pharmacokinetic" 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

"Phase I" generally the first trial of a drug in humans which tests for safety and dosage tolerance

"Phase II" clinical trials which test for efficacy and adverse effects of a drug

**"Phase III"** usually a multi-center study measuring efficacy in large numbers of patients

"Plasma" the liquid component of blood

**"Prostate cancer"** cancer of the prostate gland

**"Prostate smooth muscle cells"** the main type of stromal cells found in the prostate gland

"Prostate stromal cells" the principal type of non-glandular cells found in the prostate gland

"Signal transduction process" a series of chemical signals transmitted within cells that lead to the expression of a particular function by the cell

**"Sphingosine kinase"** a kinase believed to respond to important signals related to cell survival and cell growth

A-1

# INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Auditors	F-2
Consolidated Balance Sheets as of September 30, 2003 (unaudited), June 30, 2003 and 2002	F-3
Consolidated Statements of Operations for the quarters ended September 30, 2003 and 2002 (unaudited) and the years ended June 30, 2003 and 2002, and the period from	
December 1, 2000 (inception) through September 30, 2003 (unaudited)	F-4
Consolidated Statements of Stockholders' Equity	F-5
Consolidated Statements of Cash Flows for the quarters ended September 30, 2003 and 2002 (unaudited) and the years ended June 30, 2003 and 2002, and the period from	
December 1, 2000 (inception) through September 30, 2003 (unaudited)	F-6
Notes to Consolidated Financial Statements	F-7

#### REPORT OF INDEPENDENT AUDITORS

The Board of Directors

Marshall Edwards, Inc.

We have audited the accompanying consolidated balance sheets of Marshall Edwards, Inc. (a development stage company) as of June 30, 2003 and 2002, and the related consolidated statements of operations, shareholders' equity, and cash flows for the years then ended 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 auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Marshall Edwards, Inc. at June 30, 2003 and 2002, and the consolidated results of its operations and its cash flows for the years then ended and the period from December 1, 2000 (inception) through June 30, 2003, in conformity with accounting principles generally accepted in the United States.

Ernst & Young LLP

Stamford, CT

July 31, 2003

(A Development Stage Company)

# CONSOLIDATED BALANCE SHEETS

	September 30,	June	June 30,	
	2003	2003	2002	
	(unaudited)	(In the case do)		
ASSETS		(In thousands)		
Current assets:				
Cash and cash equivalents	\$ 6,375	\$ 7,244	\$9,164	
Prepaid expenses and other current assets	192	42	21	
Total current assets	6,567	7,286	9,185	
Total assets	\$ 6,567	\$ 7,286	\$9,185	
LIABILITIES AND STOCKHOLDERS' EQ	UITY			
Current liabilities:				
Accounts payable	\$ 453	\$ 433	\$ 198	
Accrued expenses	372	278	_	
Amounts due to parent company	904	642	88	
Total current liabilities	1,729	1,353	286	
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; 52,032,000 and 52,023,000 issued and outstanding shares in 2003 in 2002,				
respectively	_	_	_	
Additional paid-in capital	9,058	9,058	9,022	
Deficit accumulated during development stage	(4,270)	(3,156)	(123)	
Accumulated other comprehensive income	50 			
Total stockholders' equity	4,838	5,933	8,899	
Total liabilities and stockholders' equity	\$ 6,567	\$ 7,286	\$9,185	

(A Development Stage Company)

# CONSOLIDATED STATEMENTS OF OPERATIONS

Period from December 1, 2000 (Inception) through September 30, Quarter Ended September 30, Year Ended June 30, 2003 2003 2002 2003 2002 (unaudited) (unaudited) (In thousands, except share and per share data) Revenues: Interest and other income \$ 21 \$ 43 145 7 \$ 173 Total revenues 21 43 145 7 173 Operating expenses: Research and development (782)(334)(2,024)(69)(2,875)License fees (746) (246)(500)Selling, general and (107)(220)(654)(60)(821)administrative (554)(129)Total operating expenses (1,135)(3,178)(4,442)(122)Loss from operations (1,114)(511)(3,033)(4,269)Income tax expense (1) (1) Net loss arising during development \$(4,270) (1,114)(511)(3,033)(123)Net loss per common share: Basic and diluted (0.02)(0.01)(0.06)(0.00)Weighted average common shares outstanding 52,032,000 52,023,000 52,023,247 49,769,581

(A Development Stage Company)

# CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock	Additional Paid-in Capital	Deficit Accumulated During Development Stage	Accumulated Other Comprehensive Income	Total
	(Shares)		(7 - 4 4 - )		
Balance at June 30, 2001	49,500,000	\$ —	(In thousands)	\$ —	\$ —
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
, , , , , , , , , , , , , , , , , , ,		<u>.</u>			
Balance at June 30, 2002	52,023,000	9,022	(123)	_	8,899
Net loss arising during development stage			(3,033)		(3,033)
Foreign currency translation adjustments				31	31
Comprehensive loss					(3,002)
Common stock issued, June 26, 2003	9,000	36			36
Balance at June 30, 2003	52,032,000	9,058	(3,156)	31	5,933
Net loss arising during development stage					
(unaudited)			(1,114)		(1,114)
Foreign currency translation adjustments					
(unaudited)				19	19
Comprehensive loss (unaudited)					(1,095)
Balance at September 30, 2003 (unaudited)	52,032,000	\$9,058	\$(4,270)	\$ 50	\$ 4,838
		_	_	_	_

(A Development Stage Company)

# CONSOLIDATED STATEMENTS OF CASH FLOWS

	Quarter Ended September 30,		Year Ended June 30,		Period from December 1, 2000 (Inception) through	
	2003	2002	2003	2002	September 30, 2003	
	(unaudited)		(In thousands)		(unaudited)	
Operating activities:			(III tilo	usunus)		
Net loss arising during development stage	\$(1,114)	\$ (511)	\$(3,033)	\$ (123)	\$(4,270)	
Adjustments to reconcile net loss to cash (used in) provided by operating activities:						
Changes in operating assets and liabilities:						
Prepaid expenses and other current assets	24	5	(21)	(21)	(18)	
Accounts payable	20	(147)	381	52	453	
Accrued expenses	56	_	278	_	334	
Amounts due to parent company	262	64	554	88	904	
Net cash (used in) provided by operating activities	(752)	(589)	(1,841)	(4)	(2,597)	
Financing activities:						
Net proceeds from issuance of Common Stock	_	_	36	9,022	9,058	
Costs in connection with issuance of Common Stock	(174)	_	_	_	(174)	
Amounts payable in connection with issuance of						
Common Stock	38	_	(146)	146	38	
Net cash (used in) provided by financing activities	(136)	_	(110)	9,168	8,922	
Effect of exchange rate changes on cash and cash equivalents	19	_	31	_	50	
Net (decrease) increase in cash and cash equivalents	(869)	(589)	(1,920)	9,164	6,375	
Cash and cash equivalents at beginning of period	7,244	9,164	9,164		_	
Cash and cash equivalents at end of period	\$ 6,375	\$8,575	\$ 7,244	\$9,164	\$ 6,375	
1	,					
Income taxes paid	\$ —	\$ —	\$ —	\$ 1	\$ 1	
					_	

(A Development Stage Company)

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

June 30, 2003

(Information pertaining to the three months ended September 30, 2003 and 2002, and the information pertaining to the period from December 1, 2000 (inception) through September 30, 2003 is unaudited)

#### 1. Organization and Basis of Preparation of Financial Statements

Marshall Edwards, Inc. (the "Company" or "MEI") is a development stage company incorporated in December 2000 that commenced operations in May 2002 coinciding with its listing on the London Stock Exchange's Alternative Investment Market (AIM). In connection with its listing, 2,523,000 shares of Common Stock and 2,523,000 warrants, exercisable prior to November 30, 2003 at an exercise price of \$4.00 per share (9,000 exercised on June 26, 2003), were issued in May 2002 at \$4.00 per share. Total proceeds of \$9,022,000 were received net of \$1,070,000 of transaction costs. Following the listing, Novogen Limited, an Australian pharmaceutical company listed on both the Australian Stock Exchange and NASDAQ, retained 95.1% of the Company's Common Stock. The costs of organizing MEI were paid by Novogen and were minimal.

The Company, including its Australian subsidiary, Marshall Edwards Pty. Limited ("MEPL") (together, the "MEI Group") 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 plans 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 its subsidiary companies, other than MEI Group ("Novogen"), has granted to the MEI Group an exclusive license under its patent applications and the intellectual property rights in the relevant know-how to develop, market and distribute all forms of administering phenoxodiol for anti-cancer uses except topical applications. In addition, the MEI Group has the option of an exclusive first right and an exclusive last right to match any proposal dealing with third parties by Novogen Research Pty Ltd for the intellectual property rights and development of synthetic pharmaceutical compounds delivered or taken in all forms except topical applications (other than phenoxodiol, which is the subject of a license agreement between the Company and Novogen), developed by or on behalf of Novogen or its affiliates, which have known applications in the field of prevention, treatment or cure of cancer in humans.

The MEI Group's initial business focus is to continue the clinical program currently underway for the development and commercialization of phenoxodiol.

## 2. Accounting Policies

# Revenue Recognition

Interest

The only revenue earned to date is interest on cash and cash equivalents.

# **Principles of Consolidation**

The consolidated financial statements include the accounts of Marshall Edwards, Inc. and its subsidiary, Marshall Edwards Pty. Limited which is a whollyowned Australian company. Significant intercompany accounts and transactions have been eliminated in consolidation.

#### Estimates

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

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### Cash Equivalents

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.

#### **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 year. 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 and were not significant for all periods presented.

## 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 support services under the terms of the amended and restated services agreement and the cost of phenoxodiol used in the clinical trials supplied by Novogen under the terms of the amended and restated 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.

### **Stock-Based Compensation**

The Company's share option plan provides for the grant of options to employees of the Company and its affiliates. To date no options have been granted 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

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

options and warrants 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 is comprised of changes in foreign currency translation adjustments. 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.

#### 3. Income Taxes

Loss from operations consists of the following:

Year F	Year Ended June 30,	
2003	2002	
(In	thousands)	
\$ (186)	\$ (19)	
(2,847)	(103)	
\$(3,033)	\$(122)	
_		

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

	Year Ended June 30,			
	2003		2002	
	(In thousands)	%	(In thousands)	%
Tax at U.S. statutory rates	\$(1,062)	35	\$(43)	35
Australian tax	_	_	1	_
Valuation allowance	1,062	(35)	43	(35)
	\$ —	_	\$ 1	_
			_	

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Deferred tax liabilities and assets are comprised of the following:

	June 30	),
	2003	2002
	(In thousa	nds)
Deferred tax liabilities		
Prepayments	\$ —	\$ 4
Total deferred tax liabilities	<del></del>	4
Deferred tax assets		
Consultant and other accruals	265	6
Total deferred tax assets	265	6
Valuation allowance for deferred tax assets	(265)	(2)
Net deferred tax assets and liabilities	\$ —	\$ —
	_	

Management evaluates the recoverability of the deferred tax asset and the amount of the required valuation allowance. Due to the uncertainty surrounding the realization of the tax deductions in future tax returns, the Company has recorded a valuation allowance against its net deferred tax asset at June 30, 2003 and 2002. 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, 2003 due to the Company's inability to recognize the benefit of net operating losses. The Company had federal net operating loss carryforwards of approximately \$205,000 and \$14,000 at June 30, 2003 and 2002, respectively. The federal net operating losses will begin to expire in 2022.

Foreign income tax losses of approximately \$2,039,000 and \$103,000 at June 30, 2003 and 2002, respectively, may be carried forward indefinitely.

## 4. Loss Per Share

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

	Quarter Ende	d September 30,	Year Ended June 30,		
	2003	2002	2003	2002	
	(unai	ıdited) (In thou	sands)		
Numerator		(III tilou	sanus		
Net loss arising during development stage	\$ (1,114)	\$ (511)	\$ (3,033)	\$ (123)	
Effect of dilutive securities	_				
Numerator for diluted earnings per share	\$ (1,114)	\$ (511)	\$ (3,033)	\$ (123)	
Denominator					
Denominator for basic earnings per share — weighted average common shares outstanding	52,032,000	52,023,000	52,023,247	49,769,581	
Effect of dilutive securities	_	_	_	_	
Dilutive potential common shares	52,032,000	52,023,000	52,023,247	49,769,581	
		T 10			

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

# 5. 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.

# 6. Commitments and Contingencies

At June 30, 2003, the Company has contracted to conduct research and development expenditures amounting to approximately \$1,249,000. At September 30, 2003, the Company had contracted to conduct research and development expenditures amounting to approximately \$1,082,000. Such amounts are expected to be incurred within the next year.

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

USA

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

Australia

Eliminations

Total

# 7. Segment Information

The Company's focus is to continue the clinical program currently underway for the development and commercialization of phenoxodiol.

	USA		Australia		Eliminations		Total		
	June 30, 2003	June 30, 2002	June 30, 2003	June 30, 2002	June 30, 2003	June 30, 2002	June 30, 2003	June 30, 2002	
		(In thousands)							
Interest and other income	\$ 110	\$ 5	\$ 35	\$ 2	\$ —	\$ —	\$ 145	\$ 7	
Total revenues	\$ 110	\$ 5	\$ 35	\$ 2	\$	\$	\$ 145	\$ 7	
Loss from operations	\$ (186)	\$ (19)	\$(2,847)	\$ (103)	\$ —	\$ —	\$(3,033)	\$ (122)	
Income tax expense							\$ <u> </u>	\$ (1) ——	
Net loss arising during development stage							\$(3,033)	\$ (123)	
Segment assets	\$8,896	\$9,188	\$ 374	\$1,981	\$(1,984)	\$(1,984)	\$ 7,286	\$9,185	
Segment liabilities	\$ 43	\$ 185	\$ 1,310	\$ 101	\$ —	\$ —	\$ 1,353	\$ 286	
				_	_				
	T	IC A	A.u.o	tualia	Elimin	actions	То	tal	
	USA		Australia		Eliminations		Total		
	Sept 30, 2003	Sept 30, 2002	Sept 30, 2003	Sept 30, 2002	Sept 30, 2003	Sept 30, 2002	Sept 30, 2003	Sept 30, 2002	
	(In thousands) (Unaudited)								
Interest and other income	16	32	5	11	_	_	21	43	
Total revenues	16	32	5	11	_	_	21	43	
Loss from operations	6	29	1,108	482			1,114	511	
2000 from operations			1,100		_	_	2,22 .		
Income tax expense						_			
Net loss arising during development stage							1,114	511	
-									
Segment assets	8,930	8,996	2,921	1,579	(5,284)	(1,984)	6,567	8,591	
Segment liabilities	82	22	1,647	181			1,729	203	
Segment naturnes	02	22	1,04/	101			1,729	203	

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

# 8. Related Party Transactions

# License Agreement

The license agreement is an agreement under which Novogen grants to MEPL a worldwide non-transferable license to conduct clinical trials and commercialize and distribute all forms of phenoxodiol except topical applications. The agreement covers uses of phenoxodiol in the field of prevention, treatment or cure of cancer in humans. The license is exclusive until the expiration of the last relevant Novogen patent right in the world (expected no earlier than August 29, 2017) and thereafter is nonexclusive. The Company may terminate the agreement with three months notice. Novogen may terminate the agreement if a change of control, as defined in the license agreement, occurs without the consent of Novogen. Amounts payable to Novogen under terms of the license agreement is as follows:

- (1) A lump sum license fee of \$5,000,000 is payable to Novogen on the later of November 1, 2002 or on the 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 \$25,000,000.
- (2) A further lump sum license fee of \$5,000,000 is payable to Novogen on the later of November 1, 2003 or on the 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.

In addition to the amounts above, the Company must pay Novogen 2.5% of all net sales and 25% of commercialization income. After the exclusivity period of the license, 1.5% of net sales must be paid to Novogen.

The cumulative total of funds received by the Company is \$10,128,000.

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

2003	\$1,000,000
2004	\$2,000,000
2005	\$4,000,000
Each calendar year thereafter	\$8,000,000

Any amounts payable to Novogen under the above annual payments will be reduced for amounts paid under the first lump sum license fee referred to in (1) above. For the year ended June 30, 2003 and the quarter ended September 30, 2003, \$500,000 and \$246,000 (unaudited), respectively, has been included as license fee expense in the consolidated statements of operations.

Novogen developed phenoxodiol in part using funds from the Australian government under what is known as the START Program. In the event 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 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. 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's 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.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

# License Option Deed

The license option deed grants MEPL an exclusive right to accept and an exclusive right to match any proposed third-party dealing by Novogen of its intellectual property rights in other synthetic compounds that have known or potential anti-cancer applications in all forms other than topical applications.

#### Services Agreement

Neither the Company nor MEPL currently intends to directly employ any staff and Novogen will provide or procure services reasonably required by the MEI Group relating to the development and commercialization of phenoxodiol and for other administrative and managerial support. Novogen will provide these services at cost plus a 10% markup. Cost is based on estimates regarding the percentage of time spent by Novogen employees and consultants, a premises rental charge and a charge for asset usage and general overhead. The Company may terminate the agreement with three months notice. Novogen may terminate the agreement under certain circumstances.

# Manufacturing, License and Supply Agreement

Under the terms of the Manufacturing License and Supply Agreement, Novogen will supply phenoxodiol in its primary manufactured form for the clinical trial development program and phenoxodiol's ultimate commercial use. Novogen will supply phenoxodiol at cost plus a 50% markup. The Company or Novogen may terminate the agreement under certain circumstances.

Transactions amounting to \$1,740,000 and \$79,600 were made under the license agreement, the Services Agreement and the Manufacturing, License and Supply Agreement with Novogen during the years ended June 30, 2003 and 2002, respectively. Transactions amounting to \$679,000 (unaudited) and \$322,000 (unaudited) were made under the license agreement, the Services Agreement and the Manufacturing License and Supply Agreement with Novogen during the quarter ended September 30, 2003 and 2002, respectively.

# 2,080,000 Common Stock Units

# Marshall Edwards, Inc.

# **Janney Montgomery Scott** LLC

December 18, 2003

Through and including January 12, 2004 (the 25th day after the date of this prospectus), all dealers that buy, sell, or trade our common stock units or the shares of common stock and warrants that comprise the common stock units, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any distribution of the common stock units or the shares of common stock and warrants that comprise the common stock units.

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.