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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

**FORM 10-Q**

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

For the period ended September 30, 2004

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_.

Commission File Number: 000-50484

**Marshall Edwards, Inc.**

(Exact name of registrant as specified in its charter)

**DELAWARE**  
(State or other jurisdiction of  
incorporation or organization)

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

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

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

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

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

As of October 30, 2004, the number of shares outstanding of the issuer's common stock, \$0.0000002 par value, was 56,938,000.

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**MARSHALL EDWARDS, INC.**

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**PART I FINANCIAL INFORMATION**

## Item 1: Financial Statements

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

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

See accompanying notes to the consolidated financial statements.

**MARSHALL EDWARDS, INC.**  
**(A Development Stage Company)**

**CONSOLIDATED STATEMENTS OF OPERATIONS**

(In thousands, except share and per share data)

(Unaudited)

	Three Months Ended September 30,		Period from December 1, 2000 (Inception) through September 30, 2004
	2004	2003	
<b>Revenues:</b>			
Interest and other income	\$ 67	\$ 21	\$ 412
Total revenues	<u>67</u>	<u>21</u>	<u>412</u>
<b>Operating expenses:</b>			
Research and development	(439)	(782)	(4,913)
License fees	(500)	(246)	(6,500)
Selling, general and administrative	(358)	(107)	(1,922)
Total operating expenses	<u>(1,297)</u>	<u>(1,135)</u>	<u>(13,335)</u>
Loss from operations	(1,230)	(1,114)	(12,923)
Income tax expense	—	—	(1)
Net loss arising during development stage	<u>\$ (1,230)</u>	<u>\$ (1,114)</u>	<u>\$ (12,924)</u>
<b>Net loss per common share:</b>			
Basic and diluted	<u>\$ (0.02)</u>	<u>\$ (0.02)</u>	
Weighted average common shares outstanding	<u>56,938,000</u>	<u>52,032,000</u>	

*See accompanying notes to the consolidated financial statements.*

**MARSHALL EDWARDS, INC.**  
**(A Development Stage Company)**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

(In thousands)

(Unaudited)

	Three Months Ended September 30,		Period from December 1, 2000 (Inception) through September 30, 2004
	2004	2003	
<b>Operating activities</b>			
Net loss arising during development stage	\$ (1,230)	\$(1,114)	\$(12,924)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:			
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(24)	24	(54)
Accounts payable	(106)	20	86
Accrued expenses	(43)	56	394
Amounts due to parent company	366	262	1,644
Net cash used in operating activities	(1,037)	(752)	(10,854)
<b>Financing activities</b>			
Proceeds from issuance of Common Stock	—	—	38,124
Costs in connection with issuance of Common Stock	—	(174)	(3,488)
Amounts payable in connection with issuance of Common Stock	—	38	—
Net cash provided by financing activities	—	(136)	34,636
Effect of exchange rate changes on cash and cash equivalents	—	19	—
Net increase (decrease) in cash and cash equivalents	(1,037)	(869)	23,782
Cash and cash equivalents at beginning of period	24,819	7,244	—
Cash and cash equivalents at end of period	\$23,782	\$ 6,375	\$ 23,782
<b>Interest paid</b>			
Income taxes paid	\$ —	\$ 1	\$ 1

*See accompanying notes to the consolidated financial statements.*

**MARSHALL EDWARDS, INC.**  
**(A Development Stage Company)**

**CONSOLIDATED STATEMENT OF STOCKHOLDERS'  
EQUITY**

(In thousands, except share data)  
(Unaudited)

	Common Stock	Additional paid in capital	Deficit accumulated during development stage	Accumulated other comprehensive income/(loss)	Total
	(shares)				
<b>Balance at June 30, 2004</b>	<b>56,938,000</b>	<b>\$34,636</b>	<b>\$ (11,694)</b>	<b>\$ —</b>	<b>\$22,942</b>
Net loss arising during development stage			(1,230)		(1,230)
Comprehensive Loss					(1,230)
<b>Balance at September 30, 2004</b>	<b>56,938,000</b>	<b>\$34,636</b>	<b>\$ (12,924)</b>	<b>\$ —</b>	<b>\$21,712</b>

*See accompanying notes to the consolidated financial statements.*

**MARSHALL EDWARDS, INC.**  
**(A Development Stage Company)**

**NOTES TO CONSOLIDATED FINANCIAL  
STATEMENTS  
(Unaudited)  
September 30, 2004**

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

The accompanying financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. Marshall Edwards, Inc. ("MEI") believes all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three months ended September 30, 2004 are not necessarily indicative of the results that may be expected for the year ending June 30, 2005 or any other period. The balance sheet at June 30, 2004 has been derived from the audited financial statements at that date. The financial statements and notes should be read in conjunction with the audited financial statements and notes thereto for the year ended June 30, 2004 which were included in the Company's Annual Report on Form 10-K for the year ended June 30, 2004.

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

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

The Company's initial business focus is to continue the clinical program currently under way for the development and commercialization of phenoxodiol.



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

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

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

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

In connection with the December 2003 offering, the Company's common stock and warrants commenced trading separately on the Nasdaq National Market. The Company received proceeds of \$15,522,000, net of \$2,418,000 transaction costs in the December 2003 offering. Following the offering, Novogen Limited retained 86.9% of the Company's common stock.

## **2. Accounting Policies**

### **Revenue Recognition**

#### *Interest*

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

### **Principles of Consolidation**

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

### **Estimates**

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

### **Cash and cash equivalents**

Cash on hand and in banks and short-term deposits are stated at the nominal value. The Company considers all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. Most of the Company's cash is deposited in financial institutions that are FDIC insured. These deposits are in excess of the FDIC insurance limits.

**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 periods. Realized gains and losses from foreign currency transactions are reflected in the consolidated statements of operations.

Translation of Marshall Edwards Pty Limited's Financial Statements into U.S dollars does not have a material impact on the Company's financial position.

**Research and Development Expenses**

Research and development expenses relate primarily to the cost of conducting human clinical trials of phenoxodiol. Research and development costs are charged to expense as incurred.

**Stock-Based Compensation**

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

**Basic and Diluted Loss Per Share**

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

**Comprehensive Loss**

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

### 3. Loss Per Share

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

	Three Months Ended September 30,	
	2004	2003
(In Thousands, except share data)		
<b>Numerator</b>		
Net loss arising during development stage	(1,230)	(1,114)
Effect of dilutive securities	—	—
Numerator for diluted earnings per share	<u>(1,230)</u>	<u>(1,114)</u>
<b>Denominator</b>		
Denominator for basic earnings per share - weighted-average shares	56,938,000	52,032,000
Effect of dilutive securities	—	—
Dilutive potential common shares	<u>56,938,000</u>	<u>52,032,000</u>

### 4. Expenditure Commitments

At September, 30, 2004, the Company had contracted to conduct research and development expenditures of approximately \$1,947,000. Of the expenditure commitments, clinical trial amounts are based on the assumption that all patients enrolled in clinical trials will complete the maximum number of allowed treatment cycles. The amounts, assuming all treatment cycles are completed, are expected to be incurred as follows:

(In thousands)	Total	Payment due by period			
		less than 1 Year	1 - 3 Years	3 - 5 Years	More than 5 Years
Contractual Obligations					
Purchase Obligations	<u>\$1,947</u>	<u>\$1,519</u>	<u>\$428</u>	<u>\$—</u>	<u>\$—</u>
Total	<u>\$1,947</u>	<u>\$1,519</u>	<u>\$428</u>	<u>\$—</u>	<u>\$—</u>

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

## 5. Segment Information

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

	Three Months Ended September 30, 2004		Three Months Ended September 30, 2003	
	USA	Australia	USA	Australia
Loss from operations	\$ (74)	\$(1,156)	\$ (6)	\$(1,108)
Segment assets at September 30	15,374	8,462	8,930	2,921

## 6. Related Party Transactions

### License Agreement

The license agreement is an agreement under which Novogen's subsidiary, Novogen Research Pty Limited, grants to MEPL a worldwide non-transferable license under its patent and patent applications and in its know-how to conduct clinical trials and commercialize and distribute phenoxodiol products. The agreement covers uses of phenoxodiol in the field of prevention, treatment or cure of cancer in humans delivered in all forms except topical applications. The license is exclusive until the expiration or lapsing of the last relevant Novogen patents or patent applications in the world and thereafter is nonexclusive. MEPL may terminate the agreement by giving three months' notice to Novogen. MEPL paid \$5,000,000 to Novogen in February 2004 which was the first lump sum license fee payment due under the terms of the license agreement. This amount was accrued at December 31, 2003. Future amounts payable to Novogen under terms of the license agreement are as follows:

1. A second lump sum license fee of \$5,000,000 is payable to Novogen on November 1, 2003 or such later date when the cumulative total of all funds received from debt or equity issuances and revenue received from commercialization (income other than sales) and sales of phenoxodiol products exceeds \$50,000,000. The company has not yet reached these preconditions for payment.
2. In addition to the amounts above, until the expiration of the exclusivity period of the license, MEPL must pay Novogen 2.5% of all net sales and 25% of commercialization income. After the exclusivity period of the license, 1.5% of net sales must be paid to Novogen.
3. In addition to the amounts above, amounts payable for annual milestone license fees under the license agreement for the calendar years ended December 31 are as follows:

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

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

#### **License Option Deed**

The license option deed grants MEPL an exclusive right to accept and an exclusive right to match any proposed dealing by Novogen of its intellectual property rights with a third party relating to synthetic compounds (other than phenoxodiol) that have known or potential applications in the field of prevention, treatment or cure of cancer in humans in all forms other than topical applications.

#### **Services Agreement**

The Company does not currently intend to directly employ any staff. Under the terms of the services agreement, Novogen Limited or its subsidiaries have agreed to provide services reasonably required by the Company relating to the development and commercialization of phenoxodiol. Novogen has agreed to provide these services at cost plus a 10% mark-up. The Company may terminate the agreement on three months written notice to Novogen.

Transactions giving rise to expenditure amounting to \$253,000 and \$226,000 were made under the services agreement with Novogen during the three months ended September 30, 2004 and 2003 respectively.

At September 30, 2004 and 2003, \$85,000 and \$93,000, respectively, was due and owing to Novogen under the services agreement and is included in amounts due to parent company.

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

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

Transactions giving rise to expenditure amounting to \$120,000 and \$207,000 were made under the manufacturing license and supply agreement with Novogen during the three months ended September 30, 2004 and 2003 respectively.

At September 30, 2004 and 2003, \$69,000 and \$50,000, respectively, was due and owing to Novogen under the manufacturing and supply agreement and is included in amounts due to parent company.

### Special Note Regarding Forward-Looking Statements

This quarterly report includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Security Exchange Act of 1934, as amended. All statements other than statements of historical facts contained in this quarterly report, including statements regarding the future financial position, business strategy and plans and objectives of management for future operations, are forward-looking statements. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "should," "plan," "expect," and similar expressions, as they relate to the Company, are intended to identify forward-looking statements. The Company has based these forward-looking statements largely on current expectations and projections about future events and financial trends that it believes may affect financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, among other things:

- the Company's inability to obtain any additional required financing or financing available to the Company on acceptable terms;
- the Company's failure to successfully commercialize its product candidates;
- costs and delays in the development and/or receipt of FDA or other required governmental approvals, or the failure to obtain such approvals, for the Company's product candidates;
- uncertainties in clinical trial results;
- the Company's inability to maintain or enter into, and the risks resulting from our dependence upon, collaboration or contractual arrangements necessary for the development, manufacture, commercialization, marketing, sales and distribution of any products;
- competition and competitive factors;
- the company's inability to protect its patents or proprietary rights and obtain necessary rights to third party patents and intellectual property to operate its business;
- the Company's inability to operate its business without infringing the patents and proprietary rights of others;
- general economic conditions;
- the failure of any products to gain market acceptance;
- technological changes;
- government regulation generally and the receipt of the regulatory approvals;

- changes in industry practice ; and
- one time events.

These risks are not exhaustive. Other sections of this quarterly report may include additional factors which could adversely impact business and financial performance. Moreover, the Company operates in a very competitive and rapidly changing environment. You should not rely upon forward-looking statements as predictions of future events. The Company cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur. Although it believes that the expectations reflected in the forward-looking statements are reasonable, the Company cannot guarantee future results, levels of activity, performance or achievements.

The following discussion is qualified in its entirety by, and should be read in conjunction with, the more detailed information set forth in financial statements and the notes thereto appearing elsewhere in this report.

### **Overview**

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

The Company's main focus during fiscal year 2004 and in the three months to September 30, 2004 was to undertake human clinical testing of phenoxodiol. During the three months ended September 30, 2004 the Company continued to recruit patients into the existing clinical trial program. In November 2004, the Company announced that the U.S. Food and Drug Administration (FDA) has granted phenoxodiol Fast Track status for its intended use as a chemosensitizing agent in patients with recurrent late stage ovarian cancer. Under the FDA Modernization Act of 1997, designation as a Fast Track product means that phenoxodiol is eligible for certain accelerated marketing approval programs.

The Company does not employ any staff directly but obtains services from Novogen under a services agreement. The Company has incurred losses since inception and expects to incur operating losses and generate negative cash flows from operations for the foreseeable future as it expands research and development activities and moves phenoxodiol into later stages of development. As of September 30, 2004, the Company had accumulated losses of \$12,924,000.

The Company has not generated any revenues from operations since inception other than interest on cash assets.

Expenses have consisted primarily of costs associated with conducting the clinical trials of phenoxodiol and costs incurred under the license agreement, the services agreement and the manufacturing license and supply agreements with Novogen and its subsidiaries, including the costs of the clinical trial drug supplies.

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

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

### **Critical Accounting Estimates**

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

#### *Development Expenses*

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

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

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

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

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

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

The Company's 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, the Company is unable to determine the duration of or completion costs for research and development projects or when and to what extent it will receive cash inflows from the commercialization and sale of phenoxodiol.

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

#### *Clinical Trials Expenses*

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

Clinical trial expenses of \$305,000 have been accrued at September 30, 2004. These estimates are based on the number of patients in each trial and the patient treatment cycles completed or milestones achieved.

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

### **Results of Operations**

#### **Three Months Ended September 2004 and 2003**

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

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

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

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

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

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

#### **Liquidity and Capital Resources**

At September 30, 2004, the Company had cash resources of \$23,782,000 compared to \$24,819,000 at June 30, 2004. Funds are invested in short term market accounts, pending use. The implementation of the Company's business plan is dependent on the Company's ability to maintain adequate cash resources to complete the clinical development program.

The Company is also required to make payments under the terms of the License Agreement with Novogen as follows:

1. A second lump sum license fee of \$5,000,000 is payable to Novogen on November 1, 2003 or such later date when the cumulative total of all funds received from debt or equity issuances and revenue received from commercialization (income other than sales) and sales of phenoxodiol products exceeds \$50,000,000. We have not yet met these preconditions for payment.
2. In addition to the amounts above, until the expiration of the exclusivity period of the license, MEPL must pay Novogen 2.5% of all net sales and 25% of commercialization income. After the exclusivity period of the license, 1.5% of net sales must be paid to Novogen.
3. In addition to the amounts above, amounts payable for annual milestone license fees under the license agreement for the calendar years ended December 31 are as follows:

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

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

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

##### *Cash Used in Operating Activities*

Cash used in operating activities for the three months ended September 30, 2004 was \$1,037,000 compared to \$752,000 for the same period in 2003. The increase in cash outflow of \$285,000 for the three months ended September 30, 2004 was due almost exclusively to the increased operating expenses and the timing of payments in accounts payable and accrued expenses.

##### *Cash Requirements*

Based on current plans, the Company believes that it will have sufficient cash resources to fund operations at least through the end of September 2005 and to complete the current Phase I and Ib/IIa clinical trial program. Ongoing operations through the conduct of the clinical trial program will continue to consume cash resources without generating revenues.

If a Phase III clinical program, which is a multi-center study measuring efficacy in a large number of patients is undertaken, additional funds will be required to complete the program. The Company is 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 the Company will seek to raise the funds required to complete Phase III trials or enter into a collaborative arrangement with a major pharmaceutical company.

Additional cash resources may also be required if a new cancer compound is developed by Novogen and the Company secures a license under the terms of the License Option Deed.

The Company must pay amounts to Novogen under the license agreement with Novogen when certain milestones are met. For details of the amounts payable see Note 6 to the Financial Statements "Related Party Transactions", included under Item 1.

The Company does not intend to incur any significant capital expenditures in the foreseeable future.

### Item 3: Quantitative and Qualitative Disclosures about Market Risk

#### **Interest Rate Risk**

The Company places cash in “on call” deposits with high quality financial institutions.

The Company does not consider the effects of interest rate movements to be a material risk to its financial condition. The Company does not use derivative financial instruments to hedge its risks associated with the fluctuations of interest rates.

#### **Foreign Currency Risk**

The Company conducts a portion of its business in various currencies, primarily in U.S. and Australian dollars. At September 30, 2004, the Company had not established a foreign currency hedging program. Net foreign exchange losses during the three months ended September 30, 2004 were \$23,000 compared with net exchange gains of \$1,000 during the three months ended September 30, 2003. Foreign exchange gains and losses occur upon consolidation of MEPL which uses U.S. dollars as its functional currency and also engages in transactions in foreign currencies. MEPL’s accounts are denominated in Australian dollars. Translation of MEPL’s financial statements into U.S. dollars does not have a material impact on the Company’s financial position.

The Company does not consider the effects of foreign currency movements to be a material risk to its financial condition.

#### Item 4: Controls and Procedures

##### **Evaluation of Disclosure Controls and Procedures**

At the end of the period covered by this report, the Company's management, with the participation of the Company's principal executive officer and principal financial officer, evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended). Based on that evaluation, the Company's principal executive officer and principal financial officer have concluded that the Company's disclosure controls and procedures were not designed nor were functioning effectively to provide reasonable assurance that the information required to be disclosed by the Company in reports filed under the Securities Exchange Act of 1934 was recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. The identified weakness in internal control over financial reporting and in disclosure controls is described below under the heading "Change in Internal Controls".

##### **Changes in Internal Controls**

In connection with the audit of the fiscal year ended June 30, 2004, Ernst & Young, the Company's independent auditors, informed our Board of Directors that they believe that the personnel and management of Novogen who perform our accounting and financial reporting functions pursuant to the Services Agreement are not sufficiently expert in U.S. GAAP and the requirements of the SEC and the Public Company Accounting Oversight Board and that this lack of expertise represents a material weakness in the operation of our internal control over financial reporting.

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

In this regard, Ernst & Young have recommended that Novogen engage personnel with expertise or train existing personnel in the following areas:

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

We have sought assurances from Novogen that it will promptly remedy the concerns raised by Ernst & Young and Novogen has presented to us a plan for addressing these concerns. We believe that Novogen's plan is designed to ensure that the preparation of our consolidated financial statements, including the processes to review and analyze elements of our financial statement close process, is in accordance with U.S. GAAP and that relevant information about U.S. GAAP, SEC financial reporting requirements, and the requirements of the Public Company Accounting Oversight Board is available to those persons involved in the process by which our financial statements are prepared. Specifically Novogen's plan provides for additional resources and further training of the Novogen accounting team including:

- 1) the employment of additional accounting staff on the Novogen accounting team which will enable senior finance staff responsible for the preparation of U.S. GAAP financial reports to spend more time dealing with U.S. GAAP reporting issues;
- 2) increasing the level of attendance at targeted U.S. GAAP and SEC reporting courses by senior Novogen finance staff responsible for the preparation of U.S. GAAP financial reports and SEC disclosure; and
- 3) subscribing to additional information networks that provide publications and updates of SEC and U.S. GAAP releases and rule changes and of information about the requirements of the Public Company Accounting Oversight Board.

*Progress on the implementation of Novogen's plan to address the material weakness.*

During the period covered by the report, Novogen has made significant progress in implementing its plan to address the identified material weakness.

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

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

The implementation of the initiatives described above are among our highest priorities. Our Board of Directors, in coordination with our Audit Committee, will continually assess the progress and sufficiency of these initiatives and make adjustments as and when necessary. As of the date of this report, we believe that the plans outlined above, when completed, will eliminate the weakness in internal accounting control as described above. Nonetheless, a control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control system are met, and no evaluation of controls can provide absolute assurance that all control issues have been detected.

## PART II OTHER INFORMATION

### Item 2: Unregistered Sales of Equity Securities and Use of Proceeds

(b) The effective date of the registration statement (Registration No. 333-109129) filed on Form S-1 and registration statement (Registration No. 333-111291) filed on Form S-1 pursuant to Rule 462(b), both relating to the initial public offering in the United States of common stock units (each unit consisting of one share of the Company's common stock and one warrant to purchase a share of the Company's common stock at an exercise price of \$9.00 per share), was December 17, 2003. Proceeds to the Company from the offering, after deduction of underwriting discounts and commissions of approximately \$806,000 and offering costs of approximately \$1,612,000, totalled approximately \$15,522,000. As of September 30, 2004, the Company had used \$8,522,000 of the proceeds of the offering of which, \$5,000,000 was used to make the first license fee payment due to Novogen under the terms of the license agreement and \$3,522,000 was used to pay the ongoing expenses of clinical trials, amounts due to Novogen under the services agreement and the manufacturing license and supply agreement and for general corporate expenses. All remaining proceeds of the offering have been invested in short-term money market accounts.

The Company intends to use the proceeds from the offering as follows:

- Approximately \$1.1 million to commence Phase II clinical trials of phenoxodiol as a monotherapy in earlier stage cancers;
- 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; and
- 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 expansion of the clinical trial program for phenoxodiol to include other forms of cancer.

The occurrence of unforeseen events, opportunities or changed business conditions, however, could cause us to use the net proceeds of the U.S. initial public offering in a manner other than as described above.

Item 6: Exhibits and Reports on Form 8-K

a) Exhibits

**Exhibit Index**

<u>Exhibits</u>	
31.1	Certification required by Rule 13a-14(a) or Rule 15d-14(a)
31.2	Certification required by Rule 13a-14(a) or Rule 15d-14(a)
32	Certification required by Rule 13a-14(b) or Rule 15d-14(b) and section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C 1350).

(b) Reports on Form 8-K.

On September 16, 2004 the Company filed a form 8-K to notify that it had dismissed Ernst & Young and appointed BDO as its independent auditor.



**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

MARSHALL EDWARDS, INC.

/s/ DAVID SEATON

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David R. Seaton  
Chief Financial Officer  
(Duly Authorized Officer and Principal  
Financial Officer)

Date: November 10, 2004

**CERTIFICATION**

I, Christopher Naughton, certify that:

1. I have reviewed this report on Form 10-Q of Marshall Edwards, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) ) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within the entities, particularly during the period in which this report is being prepared;
  - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in the report our conclusions about the effectiveness of this disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the period covered by this report that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 10, 2004

/s/CHRISTOPHER NAUGHTON

Christopher Naughton  
Chief Executive Officer

**CERTIFICATION**

I, David Ross Seaton, certify that:

1. I have reviewed this report on Form 10-Q of Marshall Edwards, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) ) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within the entities, particularly during the period in which this report is being prepared;
  - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in the report our conclusions about the effectiveness of this disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the period covered by this report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The Company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 10, 2004

/s/ DAVID SEATON

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David R. Seaton  
Chief Financial Officer

**CERTIFICATION**

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

1. The registrant's Quarterly Report on Form 10-Q for the period ended September 30, 2004, to which this Certification is attached as Exhibit 32 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition of the registrant at the end of the period covered by the Periodic Report and results of operations of the registrant for the period covered by the Periodic Report.

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

Dated: November 10, 2004

/s/ CHRISTOPHER NAUGHTON

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Christopher Naughton  
Chief Executive Officer

/s/ DAVID SEATON

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David R. Seaton  
Chief Financial Officer