

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

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended June 30, 2011

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.)

11975 El Camino Real, Suite 101
San Diego, CA 92130
(Address of principal executive offices) (Zip Code)
(858) 792-6300
(Registrant's telephone number, including area code)

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

<u>Title of Each Class</u>	<u>Name of Each Exchange on which Registered</u>
Common Stock, \$0.00000002 par value	The NASDAQ Stock Market LLC

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

None
(Title of Class)

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

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (Section 229.405 of this chapter) is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. Yes No

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

Large accelerated filer Accelerated filer
Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company

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

The aggregate market value of the voting common equity held by non-affiliates of the registrant was approximately \$3.3 million as of June 30, 2011, based on the closing price of the registrant's Common Stock as reported on the NASDAQ Capital Market on such date.

As of September 15, 2011, there were 10,175,089 shares of the registrant's common stock, par value \$0.00000002 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of this registrant's definitive proxy statement for its 2011 annual meeting, to be filed with the U.S. Securities and Exchange Commission no later than 120 days after the end of the fiscal year ended June 30, 2011, are incorporated by reference in Part III of this Annual Report on Form 10-K.

Table of Contents

MARSHALL EDWARDS, INC. TABLE OF CONTENTS

	<u>Page</u>
PART I	
Item 1: Business	4
Item 1A: Risk Factors	15
Item 1B: Unresolved Staff Comments	26
Item 2: Properties	26
Item 3: Legal Proceedings	26
PART II	
Item 5: Market for the Registrants Common Equity, Related Stockholder Matters and Issuer Purchases of Securities	27
Item 6: Selected Financial Data	28
Item 7: Management's Discussion and Analysis of Financial Condition and Results of Operations	28
Item 7a: Quantitative and Qualitative Disclosures about Market Risk	36
Item 8: Financial Statements and Supplementary Data	36
Item 9: Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	61
Item 9A: Controls and Procedures	61
Item 9B: Other Information	61
PART III	
Item 10: Directors, Executive Officers and Corporate Governance	62
Item 11: Executive Compensation	62
Item 12: Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	62
Item 13: Certain Relationships and Related Transactions, and Director Independence	62
Item 14: Principal Accountant Fees and Services	62
PART IV	
Item 15: Exhibits and Financial Statement Schedules	63

Forward-Looking Statements

This Annual Report on Form 10-K includes forward-looking statements, which involve a number of risks and uncertainties. These forward-looking statements can generally be identified as such because the context of the statement will include words such as “may,” “will,” “intend,” “plan,” “believe,” “anticipate,” “expect,” “estimate,” “predict,” “potential,” “continue,” “likely,” or “opportunity,” the negative of these words or other similar words. Similarly, statements that describe our future plans, strategies, intentions, expectations, objectives, goals or prospects and other statements that are not historical facts are also forward-looking statements. Discussions containing these forward-looking statements may be found, among other places, in “Business” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in this Annual Report on Form 10-K. For such statements, we claim the protection of the Private Securities Litigation Reform Act of 1995. Readers of this Annual Report on Form 10-K are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the time this Annual Report on Form 10-K was filed with the Securities and Exchange Commission, or SEC. These forward-looking statements are based largely on our expectations and projections about future events and future trends affecting our business, and are subject to risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. These risks and uncertainties include, without limitation, those discussed in “Risk Factors” and in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” of this Annual Report on Form 10-K. In addition, past financial or operating performance is not necessarily a reliable indicator of future performance, and you should not use our historical performance to anticipate results or future period trends. We can give no assurances that any of the events anticipated by the forward-looking statements will occur or, if any of them do, what impact they will have on our results of operations and financial condition. Except as required by law, we undertake no obligation to update publicly or revise our forward-looking statements to reflect events or circumstances that arise after the filing of this Annual Report on Form 10-K.

In this Annual Report on Form 10-K, “Marshall Edwards,” “we,” “us” and “our” refer to Marshall Edwards Inc. and our wholly owned subsidiary Marshall Edwards Pty Ltd. (“MEPL”) on a consolidated basis, unless the context otherwise provides.

PART I

Item 1. Business

Overview

Marshall Edwards Inc. is a development-stage oncology company incorporated in Delaware in 2000 as a wholly owned subsidiary of Novogen Limited (“Novogen”). Our common stock is listed on the Nasdaq Capital Market under the symbol “MSHL”. As of September 26, 2011, Novogen owned approximately 51.5% of the outstanding shares of our common stock, as well as all of the outstanding shares of our Series A Convertible Preferred Stock. On September 27, 2011, Novogen agreed, pursuant to the terms of a Securities Subscription Agreement between us and Novogen, to purchase an additional \$2 million of our common stock, which would increase Novogen’s ownership percentage to approximately 57.1%.

Our business purpose is the development of drugs for the treatment of cancer. We are currently focused on the clinical development of our two lead isoflavone-based drug candidates, ME-143 (formerly NV-143) and ME-344 (formerly NV-344), which we acquired in May 2011, and which we had previously licensed from Novogen Research Pty Limited, a subsidiary of Novogen. In May 2011, we completed the acquisition of certain assets and intellectual property used in connection with the discovery, development, manufacture and marketing of products based on the field of isoflavonoid technology and on compounds known as isoflavones, including those related to the drug candidates Phenoxodiol, Triphendiol, ME-143, NV-128, and ME-344, from Novogen, in accordance with the terms of the Asset Purchase Agreement, dated as of December 21, 2010, between us, Novogen and Novogen Research Pty Limited.

Clinical Product Development Programs

NADH Oxidase Inhibitors

Our most advanced program is a family of isoflavone compounds that includes Phenoxodiol, our first-generation compound that has been investigated in human clinical studies, and our next-generation compound and lead drug candidate ME-143. ME-143 in particular has demonstrated robust anti-tumor activity in pre-clinical laboratory studies and is currently under evaluation in a Phase I open label, multicenter, dose escalation study in human subjects with refractory solid tumors.

First Generation Drug Candidate: Phenoxodiol

Phenoxodiol has been administered to more than 400 patients in clinical research studies via oral or intravenous routes and appears to be well tolerated with an acceptable toxicity profile. In a Phase II clinical trial of intravenously administered Phenoxodiol in combination with platinum-based chemotherapy in women with recurrent ovarian cancer, a clinical response was observed in 19% of patients (three out of 16). These results were published in the May 2011 issue of *International Journal of Gynecological Cancer*. A Phase III clinical trial of orally administered Phenoxodiol in combination with carboplatin in women with advanced ovarian cancer resistant or refractory to platinum-based drugs was halted due to slow patient enrolment after 142 of 340 planned patients were enrolled. Data from the 142 patients indicated no statistically significant improvement in the study’s primary (progression-free survival) or secondary (overall survival) efficacy endpoints.

Pharmacokinetic studies suggest that significantly higher blood plasma levels of active drug are measured when isoflavone compounds are administered intravenously versus orally. As a result of these findings, we intend to pursue the clinical development of our next-generation compounds using an intravenous formulation.

Next Generation and Lead Drug Candidate: ME-143

ME-143 is our lead drug candidate and an active metabolite of Triphendiol, a second-generation analogue of Phenoxodiol. Pre-clinical laboratory research studies show that ME-143 demonstrates enhanced anti-tumor activity against a broad range of tumor cell lines when used alone or in combination with platinum-based chemotherapy when compared to both Phenoxodiol and Triphendiol.

[Table of Contents](#)

As a result, ME-143 was selected as the lead drug candidate for the NADH oxidase inhibitor program. We have completed investigational drug manufacturing and the required pre-clinical studies of ME-143 necessary to submit an Investigational New Drug (IND) application, which was approved by the U.S. Food and Drug Administration (FDA) in August 2011. In September 2011, we initiated a Phase I open label, multicenter, dose escalation study of ME-143 in patients with refractory solid tumors. We currently expect final safety and pharmacokinetic data from this study by the second quarter of calendar year 2012.

Mitochondrial Inhibitors

Our mitochondrial inhibitor program consists of a family of compounds that includes NV-128, our first-generation compound that has shown activity against a broad range of cancer cell lines in laboratory research studies, and our next-generation compound and lead drug candidate ME-344. ME-344 appears to be significantly more active than NV-128 in pre-clinical studies.

First Generation Drug Candidate: NV-128

NV-128 is a novel mitochondrial inhibitor which has been shown in pre-clinical laboratory studies to disrupt mitochondrial function and induce cancer cell death by two distinct mechanisms; 1) through the induction of DNA fragmentation and 2) through the process of destructive autophagy, wherein a cell consumes itself. Structurally, NV-128 is an analogue of Phenoxodiol, but, in contrast, uses different molecular mechanisms to promote the death of cancer cells.

In September 2009, we released data demonstrating that the efficacy of NV-128 in mice bearing human ovarian cancer xenografts is achieved without apparent toxicity. NV-128 is capable of inhibiting both mTORC1 and mTORC2 protein regulatory pathways which are suggested to be central to the aberrant proliferative capacity of both mature cancer cells and cancer stem cells. These data demonstrated that NV-128 may have greater safety than some other mTOR inhibitors. Additional data reported that NV-128 was judged to be without cardiac toxicity in laboratory studies.

NV-128 has shown activity in pre-clinical models against a broad range of cancers, including KRAS-mutant, Tarceva-resistant non-small cell lung cancer cell lines. Results from an ongoing laboratory research study conducted in collaboration with Dr. Gil Mor, an oncologist at the Yale School of Medicine, demonstrate that NV-128 is active against all chemotherapy-resistant ovarian tumor cells tested to date.

In April 2011, Dr. Ayesha Alvero from the Department of Obstetrics, Gynecology, and Reproductive Sciences at the Yale School of Medicine presented initial data at the American Association for Cancer Research Annual Meeting from a pre-clinical study of NV-128 demonstrating its ability to induce mitochondrial instability, ultimately leading to cell death in otherwise chemotherapy-resistant ovarian cancer stem cells. These results were later published in the August 2011 issue of *Molecular Cancer Therapeutics*.

Next Generation and Lead Drug Candidate: ME-344

ME-344 is an active metabolite of NV-128. In preliminary laboratory studies, ME-344 has demonstrated enhanced activity against a panel of human tumor cell lines as compared to NV-128. We are currently completing drug manufacturing of ME-344. We expect to conduct the necessary pre-clinical animal toxicity studies to support submission of an IND application in the first quarter of 2012. Pending FDA approval of the IND application, we plan to initiate a Phase I clinical trial of ME-344 shortly thereafter.

Scientific Overview

Marshall Edwards was formed to develop novel cancer therapeutics based on a group of compounds known as isoflavones. More than 400 new chemical structures were created based on the central design of these

naturally occurring plant isoflavones. We believe that some of these synthetic compounds, including our lead drug candidates ME-143 and ME-344, interact with specific enzyme targets, resulting in the inhibition of tumor cell metabolism, a function critical for the survival of cancer cells.

First Generation Drug Candidate: Phenoxodiol

The mechanism of action for Phenoxodiol is suggested, in part, by a discovery from a research team at Purdue University in Indiana. This team has a long-standing research interest in a family of cell surface proteins that are involved in electron transport across the cell membrane enabling hydrogen ion (proton) to export at a controlled rate. This function is so fundamental to normal cell function and viability that any loss of function of this proton pump will disrupt a wide range of biochemical processes. One of the key components of this proton pump mechanism is a family of cell surface proteins known as NADH oxidases. These proteins are situated on the outside of the cell membrane of all living matter and regulate the flow of waste hydrogen across the cell membrane. The laboratory studies at Purdue University have shown that a variant form of the surface oxidase which promotes more rapid hydrogen export, is preferentially expressed on cancer cells, although similar oxidase activity has been identified on small numbers of non-cancer cells undergoing rapid cell division. Phenoxodiol is able to bind to and inhibit the activity of these oxidase variants, with the resulting inhibition of hydrogen ion removal (H⁺ efflux) from these cells. This inhibition leads to an extensive disruption to cell signaling pathways and to eventual inhibition of cell proliferation and activation of apoptosis, the process of programmed cell death by which a cell dies naturally. Phenoxodiol appears to have little or no effect on the form of oxidase present on normal healthy cells, providing an explanation for how Phenoxodiol selectively targets cancer cells. Independent research at the Malaghan Institute of Medical Research at Victoria University, Wellington, New Zealand, has confirmed that Phenoxodiol inhibits plasma membrane electron transport in cancer cells, as well as in some other dividing cells.

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

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

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

[Table of Contents](#)

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

Our lead drug candidates ME-143 and ME-344 are analogues of Phenoxodiol, but exhibit some differences from Phenoxodiol. In parallel with Phenoxodiol, these drug candidates display pre-clinical anti-cancer activity across a broad range of tumor types, high selectivity for cancer cells, and the ability to chemosensitize tumor cells to the cytotoxic effects of most standard chemotoxic drugs. However, these drug candidates differ from Phenoxodiol in inducing cell death by both caspase dependent and caspase independent mechanisms.

Second Generation Drug Candidate: Triphendiol

Triphendiol is a derivative of Phenoxodiol and prodrug of our lead drug candidate ME-143. Preliminary laboratory screening studies identified Triphendiol as a candidate for drug development based on a favorable toxicity profile against normal cells and broad activity against cancer cells. Triphendiol was studied in two Phase I human clinical trials in Australia and demonstrated an acceptable safety and pharmacokinetic profile. In June 2011, we announced the publication of results from pre-clinical studies of Triphendiol demonstrating its anti-proliferative activity in pancreatic cancer cells as both a monotherapy and as a chemosensitizer.

Next Generation and Lead Drug Candidate: ME-143

ME-143 is an active metabolite that is produced when Triphendiol is introduced into animals and humans. ME-143 is a highly potent, pan acting investigational anti-cancer drug that demonstrates superior anti-tumor activity against a broad range of tumor cell lines compared to Phenoxodiol and Triphendiol. In addition to being more active as a single agent, ME-143 appears to be superior in its ability to synergize with platinum-based chemotherapy. In addition, in pre-clinical studies, ME-143 has been found to be active against all melanoma cell lines tested to date and is able to sensitize cell lines to the standard of care drug, dacarbazine, as well as to platinum-based chemotherapies.

First Generation Drug Candidate: NV-128

NV-128 is an analogue of Phenoxodiol but appears to interact with a distinct target protein in the tumor cell. The proposed target for NV-128 is found in the tumor cell mitochondria, the specialized area in the cell that produce energy in the form of adenosine triphosphate (“ATP”). When NV-128 interacts with its protein target, a rapid reduction in ATP occurs leading to a cascade of biochemical events within the cell leading to cell death. One outcome that is believed to be critical for cell death induction induced by NV-128 is the disruption of both the mTORC1 and mTORC2 cellular pathways. In mature cancer cells as well as in cancer stem cells, the mTOR (mammalian target of rapamycin) protein is involved in enhancing tumor growth and may be associated with resistance to chemotherapeutic drugs. Inhibition of the mTOR pathway appears to shut down many of the cellular survival pathways, including proteins that protect the mitochondria of cancer cells. NV-128’s effect on the mTOR protein may reduce the potential for the cancer cell to develop resistance to chemotherapeutic drugs. NV-128 has demonstrated broad activity against a panel of human cancer cell lines both as a single agent and as a chemosensitizing agent. Proof-of-concept xenograft studies in animals have confirmed that NV-128 retards non-small cell lung carcinoma (NSCLC) and ovarian tumor proliferation.

NV-128 disrupts internal cell signaling, and also induces changes in mitochondrial membranes. The mitochondrial membrane changes have been associated with early stages of programmed cell death, or apoptosis. Results from ongoing laboratory research studies conducted in collaboration with the Department of Obstetrics, Gynecology, and Reproductive Sciences at the Yale School of Medicine demonstrate that NV-128 is active

[Table of Contents](#)

against chemotherapy-resistant ovarian tumor stem cells. In April 2011, at the American Association for Cancer Research Annual Meeting, Dr. Alvero from the Yale School of Medicine presented pre-clinical data demonstrating the ability of NV-128 to induce mitochondrial instability, ultimately leading to cell death in chemotherapy-resistant ovarian cancer stem cells. This cell death was associated with the activation of the MEK/ERK pathway leading to mitochondrial depolarization and DNA fragmentation. The study further characterized the mechanism of action of NV-128 and demonstrated that NV-128 also promotes a state of cellular starvation, resulting in the activation of the AMP kinase pathway leading to inhibition of mTOR complexes and the induction of destructive autophagy.

Next Generation and Lead Drug Candidate: ME-344

We have identified an active metabolite of NV-128, a compound named ME-344, which has demonstrated enhanced activity against a panel of human tumor cell lines as compared to NV-128 in preliminary laboratory studies. We are currently completing drug manufacturing of ME-344. We expect to conduct the necessary pre-clinical animal toxicity studies to support submission of an IND application in the first quarter of 2012. Pending FDA approval of the IND application, we plan to initiate a Phase I clinical trial of ME-344 shortly thereafter.

Competition

The development of our drug candidates is highly competitive. A number of other companies have products or drug candidates in various stages of pre-clinical or clinical development that are intended for the same therapeutic indications for which our drug candidates are being developed. Some of these potential competing drugs are further advanced in development than our drug candidates and may be commercialized sooner. Even if we are successful in developing effective drugs, our drug candidates may not compete successfully with products produced by our competitors.

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

Relationship with Novogen

We are 51.5% owned by Novogen as of September 26, 2011. On September 27, 2011, Novogen agreed, pursuant to the terms of a Securities Subscription Agreement between us and Novogen, to purchase an additional \$2 million of our common stock, which would increase Novogen's ownership interest to 57.1%. Novogen also owns 1,000 shares of our Series A Convertible Preferred Stock which are initially convertible into 4,827,000 shares of our common stock, which would increase Novogen's ownership percentage to 69.8%. Historically, we licensed from Novogen the rights to Novogen patents and applications for our lead isoflavone-based drug candidates, as well as other compounds. Additionally, Novogen historically provided research and development services and administrative and finance services to us under service agreements. The license agreements were terminated in May 2011 in conjunction with our purchase of a portfolio of isoflavone-related assets from Novogen. The service agreements were terminated in December 2010.

Intellectual Property

We have acquired from Novogen patents and patent applications which relate to a large family of compounds with potentially broad ranging therapeutic effects. We refer to these patents and patent applications

[Table of Contents](#)

collectively as intellectual property (IP). We anticipate that this IP will be useful in our efforts to develop, market and commercialize the isoflavonoid compounds, including Triphendiol, ME-143, NV-128, ME-344, as anti-cancer agents.

With the acquisition of these patents and patent applications from Novogen, we expect to own ten issued United States patents, at least 13 United States non-provisional applications, at least two United States provisional applications, at least 40 issued foreign patents, and at least 80 foreign patent applications.

Triphendiol and ME-143

Our IP with respect to Triphendiol and ME-143 relates to the compounds and to uses of these compounds as anti-cancer agents and as immune modulators.

NV-128 and ME-344

Our IP with respect to NV-128 and ME-344 relates to the compounds and to uses of the compounds as anti-cancer agents and as immune modulators.

As most patent applications in the U.S. are maintained as confidential until published by the U.S. Patent Trade Office at 18 months from filing for all cases filed after November 29, 2000, or at issue, for cases filed prior to November 29, 2000 we cannot be certain that we or Novogen were the first to make the inventions covered by the patents and applications referred to above. Additionally, publication of discoveries in the scientific or patent literature often lags behind the actual discoveries. Moreover, pursuant to the terms of the Uruguay Round Agreements Act, patents filed on or after June 8, 1995 have a term of twenty years from the date of such filing except for provisional applications, irrespective of the period of time it may take for such patent to ultimately issue. This may shorten the period of patent protection afforded to therapeutic uses of Triphendiol, ME-143, NV-128, ME-344 or Phenoxodiol, as patent applications in the biopharmaceutical sector often take considerable time to issue. However, in some countries the patent term may be extended.

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

The pharmaceutical industry is highly competitive and patents may have been applied for by, and issued to, other parties relating to products competitive with Triphendiol, ME-143, NV-128, ME-344 or Phenoxodiol. Use of these compounds and any other drug candidates may give rise to claims that they infringe the patents or proprietary rights of other parties, existing now and in the future. An adverse claim could subject us to significant liabilities to such other parties and/or require disputed rights to be licensed from such other parties. We cannot be sure that any license required under any such patents or proprietary rights would be made available on terms acceptable to us, if at all. If we do not obtain such licenses, we may encounter delays in product market introductions, or may find that the development, manufacture or sale of products requiring such licenses may be precluded. We have not conducted any searches or made any independent investigations of the existence of any patents or proprietary rights of other parties.

Research and Development

The objective of our research and development program is the generation of data sufficient to achieve regulatory approval of our licensed drug candidates in one or more dosage forms in major markets such as the

[Table of Contents](#)

U.S. and/or to allow us to enter into a commercial relationship with another party. The data are generated by our pre-clinical studies and clinical trial programs.

The key aspects of the research and development program are to provide more complete characterization of the following:

- the relevant molecular targets of action of our drug candidates;
- the relative therapeutic benefits and indications of our drug candidates as a monotherapy or as part of combinational therapy with other chemotherapy;
- the most appropriate cancer targets for ME-143 and ME-344; and
- the relative therapeutic indications of different dosage forms of our drug candidates.

Research and development expenses were \$2,115,000 for the year ended June 30, 2011; \$4,031,000 for the year ended June 30, 2010 and \$7,777,000 for the year ended June 30, 2009. Research and development costs incurred from inception through June 30, 2011 were \$39,189,000.

Government Regulation

U.S. Regulatory Requirements

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

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

- pre-clinical laboratory evaluations, including formulation and stability testing, and animal tests performed under the FDA's Good Laboratory Practices regulations to assess pharmacological activity and toxicity potential;
- submission and approval of an Investigational New Drug Application, or IND, including results of pre-clinical tests, manufacturing information, and protocols for clinical tests, which must become effective before clinical trials may begin in the U.S.;
- obtaining approval of Institutional Review Boards, or IRBs, 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 results for pre-clinical and clinical studies, 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.

[Table of Contents](#)

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

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

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

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

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

Each NDA must be accompanied by a user fee, pursuant to the requirements of the Prescription Drug User Fee Act, or PDUFA, and its amendments. According to the FDA's fee schedule, effective on October 1, 2010 for the fiscal year 2011, the user fee for an application requiring clinical data, such as an NDA, is \$1,542,000. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual product fee for prescription drugs and biologics (\$86,520), and an annual establishment fee (\$497,200) on facilities used to manufacture prescription drugs and biologics. A written request can be submitted for a waiver for the application

[Table of Contents](#)

fee for the first human drug application that is filed by a small business, but there are no waivers for product or establishment fees. We are not at the stage of development with our products where we are subject to these fees, but they are significant expenditures that may be incurred in the future and must be paid at the time of application submissions to FDA.

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

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

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

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

The FDCA includes provisions designed to facilitate the development and expedite the review of drugs and biological products intended for treatment of serious or life-threatening conditions that demonstrate the potential

[Table of Contents](#)

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

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

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

Foreign Regulatory Requirements

Outside the U.S., our ability to market our products will also be contingent upon receiving marketing authorizations from the appropriate regulatory authorities and compliance with applicable post-approval regulatory requirements. Although the specific requirements and restrictions vary from country to country, as a general matter, foreign regulatory systems include risks similar to those associated with FDA regulation, described above.

Under European Union regulatory systems, marketing authorizations may be submitted either under a centralized or a national procedure. Under the centralized procedure, a single application to the European Medicines Agency (EMA) leads to an approval granted by the European Commission which permits the marketing of the product throughout the EU. The centralized procedure is mandatory for certain classes of medicinal products, but optional for others. For example, all medicinal products developed by certain biotechnological means, and those developed for cancer and other specified diseases and disorders, must be authorized via the centralized procedure. We assume that the centralized procedure will apply to our products

[Table of Contents](#)

that are developed by means of a biotechnology process. The national procedure is used for products that are not required to be authorized by the centralized procedure. Under the national procedure, an application for a marketing authorization is submitted to the competent authority of one member state of the EU. The holders of a national marketing authorization may submit further applications to the competent authorities of the remaining member states via either the decentralized or mutual recognition procedure. The decentralized procedure enables applicants to submit an identical application to the competent authorities of all member states where approval is sought at the same time as the first application, while under the mutual recognition procedure, products are authorized initially in one member state, and other member states where approval is sought are then requested to recognize the original authorization based upon an assessment report prepared by the original authorizing competent authority. Both the decentralized and mutual recognition procedures should take no longer than 90 days, but if one member state makes an objection, which under the legislation can only be based on a possible risk to human health, the application will be automatically referred to the Committee for Medicinal Products for Human Use (CHMP) of the EMA. If a referral for arbitration is made, the procedure is suspended. However, member states that have already approved the application may, at the request of the applicant, authorize the product in question without waiting for the result of the arbitration. Such authorizations will be without prejudice to the outcome of the arbitration. For all other concerned member states, the opinion of the CHMP, which is binding, could support or reject the objection or alternatively could reach a compromise position acceptable to all EU countries concerned. The arbitration procedure may take an additional year before a final decision is reached and may require the delivery of additional data.

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

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

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

Manufacturing

We outsource and plan to continue to outsource manufacturing responsibilities for our existing and future product candidates for development and commercial purposes.

Employees

As of June 30, 2011, we had nine employees, three of whom hold a Ph.D. or M.D. degree. Other personnel resources are used from time to time as consultants or third party service organizations on an as-needed basis. All members of our senior management team have prior experience with pharmaceutical, biotechnology or medical product companies. We believe that we have been successful in attracting skilled and experienced personnel, but there can be no assurance that we will be able to attract and retain the individuals needed. None of our employees is represented by a collective bargaining agreement, nor have we experienced work stoppages. We believe that our relations with our employees are good.

Novogen historically provided us with additional staff under service agreements which included research, development and administrative personnel. These service agreements were terminated as of December 31, 2010.

[Table of Contents](#)

Available Information

Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed with or furnished to the Securities and Exchange Commission pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge through our website at www.marshalledwardsinc.com as soon as reasonably practicable after they are electronically filed with, or furnished to, the Securities and Exchange Commission.

Item 1A. Risk Factors

Investment in our stock involves a high degree of risk. You should consider carefully the risks described below, together with other information in this Annual Report on Form 10-K and our other public filings, before making investment decisions regarding our stock. If any of the following events actually occur, our business, operating results, prospects or financial condition could be materially and adversely affected. This could cause the trading price of our common stock to decline and you may lose all or part of your investment. Moreover, the risks described below are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also affect our business, operating results, prospects or financial condition.

Risks Related to Our Business

We have limited existing financial resources and will need substantial additional funds to progress the clinical trial program for our drug candidates ME-143 or ME-344 beyond their early development stages and to develop new compounds purchased from Novogen in the Isoflavone Transaction. The actual amount of funds we will need will be determined by a number of factors, some of which are beyond our control.

We have limited cash resources and liquidity. We will need substantial additional funds to progress the clinical trial program for our drug candidates ME-143 or ME-344 and to develop any additional compounds. The factors which will determine the actual amount of funds that we will need to progress the clinical trial programs for ME-143 and ME-344 may include the following:

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

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

We cannot assure you that we will be able to obtain financing sufficient to meet our future capital and operating needs.

We expect to have to attempt to sell additional shares of common stock, and securities exercisable or convertible into shares of our common stock, in the future to satisfy our capital and operating needs. If we sell shares in the future, the prices at which we sell these future shares will vary, and these variations may be significant. Purchasers of the shares we sell pursuant to future offerings, as well as our existing stockholders, will experience significant dilution if we sell these future shares at prices significantly below the price at which previous shareholders invested.

Pursuant to the terms of a private placement of equity securities that closed in May 2011 (the "May 2011 private placement") as described in Item 7 in this Annual Report on Form 10-K, we have agreed not to offer or

[Table of Contents](#)

sell any of our or our subsidiaries' equity securities, including securities that are convertible or exchangeable for our common stock, or to file any new registration statement, other than as required by the Amended Registration Rights Agreement between us and the investors in the May 2011 private placement, until the earlier of (i) June 18, 2012 and (ii) 90 days after the registration of all of the securities we have agreed to register pursuant to the Amended Registration Rights Agreement. The foregoing restrictions on securities issuances do not apply to certain permitted issuances, specifically the issuance of up to \$4,000,000 of common stock and warrants to purchase common stock on or after September 15, 2011. On September 27, 2011, Novogen agreed, pursuant to the terms of a Securities Subscription Agreement between us and Novogen, to purchase an additional \$2 million of our common stock, which will be a permitted issuance under the terms of the May 2011 private placement.

Future sales of our common stock, including upon conversion of our outstanding Series A Convertible Preferred Stock and exercise of our outstanding Series A and Series B warrants, may depress the market price of our common stock and cause stockholders to experience dilution.

The market price of our common stock could decline as a result of sales of substantial amounts of our common stock in the public market, including upon exercise of outstanding warrants and the conversion of the Series A Convertible Preferred Stock. On May 18, 2011, pursuant to the Amended and Restated Securities Purchase Agreement dated May 16, 2011, we issued 835,217 shares of common stock together with Series A and Series B warrants initially exercisable for an aggregate amount of approximately 2,792,000 shares of common stock, which amount could increase to a maximum of approximately 4,416,000 shares of common stock to the extent the Series B warrants are exercised. As of September 26, 2011, Series B warrants for 1,294,000 shares of common stock had been exercised resulting in Series A warrants becoming exercisable for an additional 970,500 shares of common stock. Also pursuant to the Amended and Restated Securities Purchase Agreement, we agreed to issue certain additional shares of our common stock, up to a maximum amount of approximately 2,333,000 shares to the extent the Series B warrants are exercised, and to the extent the trading price of our common stock is below certain levels on specified dates. The terms of the warrants and agreement, including the anti-dilution and full-ratchet provisions, may make it difficult for us to raise additional capital consistent with prevailing market terms, if at all. The 1,000 shares of Series A Convertible Preferred Stock held by Novogen are initially convertible into an aggregate of 4,827,000 shares of our common stock. We intend to seek additional capital through one or more additional equity transactions in calendar years 2011 and 2012; however, such transactions will be subject to market conditions and there can be no assurance any such transactions will be completed.

While the May 2011 Private Placement Series A and B warrants are outstanding, it may be more difficult to raise additional equity capital.

During the term that the Series A and B warrants are outstanding, the holders of those warrants are given the opportunity to profit from a rise in the market price of our common stock. In addition, the Amended and Restated Securities Purchase Agreement dated May 16, 2011 gives the investors in the private placement the right to receive additional shares of common stock (the "Adjustment Shares", and cash, in certain circumstances if the trading price of our common stock declines. We may find it more difficult to raise additional equity capital while the warrants are outstanding or Adjustment Shares are potentially issuable under the agreement.

Negative global economic conditions may pose challenges to our business strategy, which relies on access to capital from the markets or collaborators.

Negative conditions in the global economy, including credit markets and the financial services industry, have generally made equity and debt financing more difficult to obtain, and may negatively impact our ability to complete financing transactions. The duration and severity of these conditions is uncertain, as is the extent to which they may adversely affect our business and the business of current and prospective vendors and collaborators. If negative global economic conditions persist or worsen, we may be unable to secure additional funding to sustain our operations or to find suitable collaborators to advance our internal programs, even if we achieve positive results from our research and development efforts.

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

You should consider our prospects in light of the risks and difficulties frequently encountered by early stage and developmental companies. Although we were incorporated in December 2000, we have only been in operation since May 2002. We have incurred net losses of \$77,588,000 since our inception through June 30, 2011, including net losses of \$6,781,000, \$7,896,000 and \$11,180,000 for the years ended June 30, 2011, 2010 and 2009, respectively. We anticipate that we will incur operating losses and negative operating cash flow for the foreseeable future. We have not yet commercialized any drug candidates and cannot be sure that we will ever be able to do so, or that we may ever become profitable.

Our stockholders may not realize a benefit from the Isoflavone Transaction commensurate with the ownership dilution they will experience in connection with the Isoflavone Transaction.

On May 9, 2011, we completed the acquisition of certain assets used in or generated under or in connection with the discovery, development, manufacture and marketing of intellectual property and products based on the field of isoflavonoid technology and on compounds known as isoflavones, including those related to the drug candidates Phenoxodiol, Triphendiol, ME-143 and NV-128 (the “Isoflavone-related Assets”), from Novogen in accordance with the terms of the Asset Purchase Agreement, dated as of December 21, 2010, between us, Novogen and Novogen Research Pty Limited (the “Isoflavone Asset Purchase Agreement”). The acquisition of the Isoflavone-related Assets and the other transactions contemplated by the Isoflavone Asset Purchase Agreement are referred to in this Annual Report on Form 10-K as the “Isoflavone Transaction.”

If we are unable to realize the expected strategic and financial benefits from the Isoflavone Transaction, our stockholders may experience substantial dilution of their ownership interest upon the conversion of the Series A Convertible Preferred Stock, which may be converted at any time and from time to time without the payment of any additional consideration, without receiving any commensurate benefit. As of September 26, 2011, Novogen owned approximately 51.5% of our outstanding shares of common stock. On September 27, 2011, Novogen agreed, pursuant to the terms of a Securities Subscription Agreement between us and Novogen, to purchase an additional 1,333,333 shares of our common stock for a purchase price of \$2 million, which will increase Novogen’s ownership percentage to approximately 57.1%. Additionally, upon consummation of the Isoflavone Transaction, acquired 1,000 shares of our Series A Convertible Preferred Stock which are initially convertible into an aggregate of 4,827,000 shares of our common stock, which would increase Novogen’s ownership percentage to approximately 69.8%. In addition, upon our achievement of certain development milestones relating to the Isoflavone-related Assets, the aggregate number of shares into which the Series A Convertible Preferred Stock may be converted would increase to 9,654,000, which would potentially increase Novogen’s ownership percentage to approximately 76.7%, absent the issuance of any other shares of our common stock. Although in the Isoflavone Asset Purchase Agreement Novogen made certain representations and warranties regarding its intellectual property rights in respect of the Isoflavone-related Assets, these indemnification obligations, which were limited and payable solely by the forfeiture of our securities issued as consideration in the Isoflavone Transaction expired on June 30, 2011. Accordingly, we do not expect to be adequately compensated, if at all, for the loss of any such intellectual property rights acquired in the Isoflavone Transaction.

The results of pre-clinical studies and completed clinical trials are not necessarily predictive of future results, and our current drug candidates may not have favorable results in later studies or trials.

Pre-clinical studies and Phase I and Phase II clinical trials are not primarily designed to test the efficacy of a drug candidate, but rather to test safety, to study pharmacokinetics and pharmacodynamics, and to understand the drug candidate’s side effects at various doses and schedules. Favorable results in early studies or trials may not be repeated in later studies or trials, including continuing pre-clinical studies and large-scale Phase III clinical trials, and our drug candidates in later-stage trials may fail to show desired safety and efficacy despite having progressed through earlier-stage trials. Unfavorable results from ongoing pre-clinical studies or clinical trials could result in delays, modifications or abandonment of ongoing or future clinical trials, or abandonment of a

[Table of Contents](#)

clinical program. Pre-clinical and clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals or commercialization. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be delayed, repeated or terminated, or a clinical program to be abandoned.

Our research and development program for ME-344 is in an early stage of development, and may not result in the commencement of clinical trials.

Our research and development program for ME-344 is in the discovery or pre-clinical stage of development. The process of conducting pre-clinical studies requires the commitment of a substantial amount of our resources. Our pre-clinical compounds may not result in the commencement of clinical trials. We cannot be certain that results sufficiently favorable to justify commencement of Phase I clinical trials will be obtained in these pre-clinical investigations. Even if such favorable pre-clinical results are obtained, our financial resources may not allow us to file an IND application with the FDA and commence Phase I clinical trials, or the FDA may not allow Phase I clinical trials to proceed. If we are unable to identify and develop new drug candidates, we may not be able to maintain a clinical development pipeline or generate revenues.

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

We will not generate any operating revenue until we successfully commercialize one of our drug candidates. Currently, we have drug candidates at different stages of development, and each will need to successfully complete a number of studies and obtain regulatory approval before potential commercialization.

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

- ME-143 and ME-344 are in the early stages of development, and we will need to conduct significant pre-clinical and clinical testing to demonstrate safety and efficacy of these drug candidates before applications for marketing can be filed with the FDA, or with the regulatory authorities of other countries;
- data obtained from pre-clinical and clinical studies can be interpreted in different ways, which could delay, limit or prevent regulatory approval;
- development and testing of product formulation, including identification of suitable excipients, or chemical additives intended to facilitate delivery of our drug candidates;
- it may take us many years to complete the testing of our drug candidates, and failure can occur at any stage of this process; and
- negative or inconclusive results or adverse medical events during a clinical trial could cause us to delay or terminate our development efforts.

The successful development of any of these drug candidates is uncertain and, accordingly, we may never commercialize any of these drug candidates or generate revenue.

We may not be able to establish the strategic partnerships necessary to develop, market and distribute our product candidates.

A key part of our business plan is to establish relationships with strategic partners. We must successfully contract with third parties to package, market and distribute our product candidates. We have not yet established any strategic partnerships. Potential partners may not wish to enter into agreements with us due to Novogen's current equity position as our majority stockholder.

[Table of Contents](#)

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 programs. There is no assurance that we will be able to negotiate commercially acceptable licensing or other agreements for the future exploitation of our drug product candidates including continued clinical development, manufacture or marketing. 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 which will adversely affect our ability to generate operating revenues.

We rely on third parties to conduct our clinical trials and many of our pre-clinical studies. If those parties do not successfully carry out their contractual duties or meet expected deadlines, our drug candidates may not advance in a timely manner or at all.

In the course of our discovery, pre-clinical testing and clinical trials, we rely on third parties, including laboratories, investigators, clinical contract research organizations, or CROs, and manufacturers, to perform critical services for us. For example, we rely on third parties to conduct our clinical trials and many of our pre-clinical studies. CROs are responsible for many aspects of the trials, including finding and enrolling subjects for testing and administering the trials. Although we rely on these third parties to conduct our clinical trials, we are responsible for ensuring that each of our clinical trials is conducted in accordance with its investigational plan and protocol. Moreover, the FDA and foreign regulatory authorities require us to comply with regulations and standards, commonly referred to as good clinical practices, or GCPs, for conducting, monitoring, recording, and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. Our reliance on third parties does not relieve us of these responsibilities and requirements. These third parties may not be available when we need them or, if they are available, may not comply with all regulatory and contractual requirements or may not otherwise perform their services in a timely or acceptable manner, and we may need to enter into new arrangements with alternative third parties and our clinical trials may be extended, delayed or terminated. These independent third parties may also have relationships with other commercial entities, some of which may compete with us. In addition, if such third parties fail to perform their obligations in compliance with our clinical trial protocols or GCPs, our clinical trials may not meet regulatory requirements or may need to be repeated. As a result of our dependence on third parties, we may face delays or failures outside of our direct control. These risks also apply to the development activities of collaborators, and we do not control their research and development, clinical trial or regulatory activities.

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

The development of drug candidates is highly competitive. A number of other companies have products or drug candidates in various stages of pre-clinical or clinical development that are intended for the same therapeutic indications for which our drug candidates are being developed. Some of these potential competing drugs are further advanced in development than our drug candidates and may be commercialized sooner. Even if we are successful in developing effective drugs, our compounds may not compete successfully with products produced by our competitors.

Our competitors include pharmaceutical companies and biotechnology companies, as well as universities and public and private research institutions. In addition, companies active in different but related fields represent substantial competition for us. Many of our competitors developing oncology drugs have significantly greater capital resources, larger research and development staffs and facilities and greater experience in drug development, regulation, manufacturing and marketing than we do. These organizations also compete with us and our service providers, to recruit qualified personnel, and with us to attract partners for joint ventures and to license technologies that are competitive with us. 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.

[Table of Contents](#)

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

We do not intend to manufacture our drug product candidates ourselves, and we will rely on third parties for our drug supplies both for clinical trials and for commercial quantities in the future. We have taken the strategic decision not to manufacture active pharmaceutical ingredients (“API”) for our drug candidates, as these can be more economically supplied by third parties with particular expertise in this area. We have identified contract facilities that are registered with the FDA, have a track record of large scale API manufacture, and have already invested in capital and equipment. We have no direct control over the cost of manufacturing our product candidates. If the cost of manufacturing increases, or if the cost of the materials used increases, these costs will be passed on to us, making the cost of conducting clinical trials more expensive. Increases in manufacturing costs could adversely affect our future profitability if we are unable to pass all of the increased costs along to our customers.

Even if we receive regulatory approval to commercialize our drug candidates, our ability to generate revenues from any resulting products will be subject to a variety of risks, many of which are out of our control.

Even if our drug candidates obtain regulatory approval, resulting products may not gain market acceptance among physicians, patients, healthcare payers or the medical community. We believe that the degree of market acceptance and our ability to generate revenues from such products will depend on a number of factors, including:

- timing of market introduction of our drugs and competitive drugs;
- actual and perceived efficacy and safety of our drug candidates;
- prevalence and severity of any side effects;
- potential or perceived advantages or disadvantages over alternative treatments;
- strength of sales, marketing and distribution support;
- price of our future products, both in absolute terms and relative to alternative treatments;
- the effect of current and future healthcare laws on our drug candidates; and
- availability of coverage and reimbursement from government and other third-party payers.

If any of our drugs are approved and fail to achieve market acceptance, we may not be able to generate significant revenue to achieve or sustain profitability.

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

Our business exposes it to the risk of product liability claims. This risk is inherent in the manufacturing, testing and marketing of human therapeutic products. We have product liability insurance coverage of \$5 million. The coverage is subject to deductibles and coverage limitations. We may not be able to obtain or maintain adequate protection against potential liabilities, or claims may exceed our insurance limits. If we cannot or do not sufficiently insure against potential product liability claims, we may be exposed to significant liabilities, which may materially and adversely affect our business development and commercialization efforts.

Financial reporting of our derivative liabilities is complex.

The securities we issued in the May 2011 private placement have certain features that result in mark-to-market accounting under FASB Topic ASC 815 of Derivatives and Hedging. These accounting rules require that our derivative instruments be adjusted to their fair market values at each reporting date. The fair

[Table of Contents](#)

market values are based on option pricing models and require various inputs and assumptions, including our stock price, that may change from period to period. Changes in these inputs, such as increases or decreases in our stock price, will change the value of the derivative instruments, which means that we will likely report significant non-cash gains or losses in future periods. These gains and losses can be very substantial each period and may result in significant period-over-period swings in our GAAP operating results. For example, for the year ended June 30, 2011, we recorded a non-cash net loss on the fair value of our derivative instruments of approximately \$459,000. As a result, investors are cautioned to carefully read our consolidated financial statements, the notes thereto and the Management's Discussion & Analysis of Financial Condition and Results of Operations for a more complete understanding of our operating results. Prior results may not be indicative of future results and periods reflecting significant non-cash income under these accounting rules would not correspond to significant positive cash flows that investors may normally expect.

Our financial results are affected by fluctuations in currency exchange rates.

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

Risks Related to Securities Markets and Investment in Our Stock

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

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

- failure to successfully develop drug candidates ME-143 and ME-344 (and their analogues);
- 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;
- instability in the stock market as a result of current global events;
- changes in the market valuations of similar companies;
- the liquidity of any market for our securities;
- additional sales by us or Novogen of shares of our common stock; and
- threatened or actual delisting of our common stock from a national stock exchange.

Equity markets in general, and the market for biotechnology and life sciences companies in particular, have experienced substantial price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies traded in those markets. In addition, changes in economic conditions in the U.S., Europe or globally, particularly in the context of current global events, 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

[Table of Contents](#)

market price of shares of our common stock, regardless of our development and operating performance. In the past, following periods of volatility in the market price of a company's securities, securities class-action litigation has often been instituted against that company. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources.

In addition, if the market price of our common stock remains below \$5.00 per share, under stock exchange rules, our stockholders will not be able to use such shares as collateral for borrowing in margin accounts. Further, certain institutional investors are restricted from investing in shares priced below \$5.00. This inability to use shares of our common stock as collateral and the inability of certain institutional investors to invest in our shares may depress demand and lead to sales of such shares creating downward pressure on and increased volatility in the market price of our common stock.

Because we do not intend to pay, and have not paid, any cash dividends on our shares of common stock, our stockholders will not be able to receive a return on their shares unless the value of our common stock appreciates and they sell their shares.

We have never paid or declared any cash dividends on our common stock, and we intend to retain any future earnings to finance the development and expansion of our business. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. Therefore, our stockholders will not be able to receive a return on their investment unless the value of our common stock appreciates and they sell their shares.

Our common stock may be delisted from Nasdaq.

During 2010, we received deficiency notices from Nasdaq regarding non-compliance with the minimum stockholders equity and the minimum Market Value of Publicly Held Shares in accordance with Nasdaq Listing Standards for the Nasdaq Global Market. On March 7, 2011, a Nasdaq Hearing Panel granted us until May 16, 2011 to evidence compliance with the stockholders equity and minimum Market Value of Publicly Held Shares requirement. On March 23, 2011, we received a positive response from the Nasdaq Listing Qualifications Staff indicating that our request for a transfer and continued listing on the Nasdaq Capital Market had been granted. Our common stock began trading on the Nasdaq Capital Market effective with the open of business on March 16, 2011.

Under Nasdaq rules, we are required to maintain minimum stockholders' equity of \$2.5 million. If our stockholders' equity falls below \$2.5 million, we would have 45 calendar days from the date of notification by Nasdaq to submit a plan to regain compliance. If the plan is accepted, Nasdaq can grant an extension of up to 180 calendar days from the date of the original notification for us to evidence compliance with this requirement. As a result of continuing losses from operations and the recognition of other expense for the fair value of derivative liabilities related to the securities issued in the May 2011 private placement, our stockholders' equity fell below \$2.5 million as of June 30, 2011, and therefore, may lead to de-listing of our common stock from the Nasdaq Stock Market, unless we are able to increase our stockholders' equity through an equity offering or otherwise. On September 27, 2011, Novogen agreed, pursuant to the terms of a Securities Subscription Agreement between us and Novogen, to purchase an additional \$2 million of our common stock, which upon consummation is expected to increase our shareholders' equity above \$2.5 million.

In addition, under Nasdaq rules, companies listed on the Nasdaq Capital Market are required to maintain a share price of at least \$1.00 per share and if the share price declines below \$1.00 for a period of 30 consecutive business days, then the listed company would have 180 days to regain compliance with the \$1.00 per share minimum. In the event that our share price declines below \$1.00, we may be required to take action, such as a reverse stock split, in order to comply with the Nasdaq rules that may be in effect at the time.

If we are not able to comply with the listing standards of the Nasdaq Capital Market, our common stock will be delisted from Nasdaq and an associated decrease in liquidity in the market for our common stock will occur.

[Table of Contents](#)

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

We will have broad discretion to use the net proceeds to us upon any exercise of outstanding warrants, and investors in our stock will be relying on the judgment of our board of directors and management regarding the application of these proceeds. Although we expect to use a substantial portion of the net proceeds from any exercise of the warrants for general corporate purposes and progression of our clinical trial program, we have not allocated these net proceeds for specific purposes.

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

Our restated certificate of incorporation allows us to issue 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. Although our Series A Convertible Preferred Stock, our only outstanding preferred stock, does not contain dividend or voting preferences, the issuance of a class 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.

Laws, rules and regulations relating to public companies may be costly and impact our ability to attract and retain directors and executive officers.

Laws and regulations affecting public companies, including rules adopted by the SEC and by NASDAQ, as well as the laws and regulations of foreign governments, may result in increased costs to us. These laws, rules and regulations could make it more difficult or costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on our board committees or as executive officers. We cannot estimate accurately the amount or timing of additional costs we may incur to respond to these laws, rules and regulations.

Our executive officers and directors may sell shares of their stock, and these sales could adversely affect our stock price.

Sales of our stock by our executive officers and directors, or the perception that such sales may occur, could adversely affect the market price of our stock. Our executive officers and directors may sell stock in the future, either as part, or outside, of trading plans under Securities and Exchange Commission, or SEC, Rule 10b5-1. In connection with the May 2011 private placement, each of our executive officers and directors agreed not to sell any shares of our stock until the earlier of (i) the date 90 days after the date on which all of the shares of common stock, Series A and Series B warrants and Adjustment Shares have either been registered or can be sold pursuant to Rule 144 under the Securities Act, and (ii) June 18, 2012.

Risks Relating to Our Intellectual Property

Our commercial success is dependent, in part, on obtaining and maintaining patent protection and preserving trade secrets, which cannot be guaranteed.

Patent protection and trade secret protection are important to our business and our future will depend, in part on our ability 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. Such litigation could result in substantial costs and diversion of our management's attention.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. Prior to the Isoflavone Transaction, Novogen had applied for patents in a

[Table of Contents](#)

number of countries with respect to the use of their isoflavone compounds, including Phenoxodiol, Triphendiol, ME-143, NV-128, and ME-344, for the treatment, prevention or cure of cancer and methods of production of Phenoxodiol. We acquired both issued patents and pending patent applications from Novogen in relation to these technologies, which we previously licensed from Novogen. The patent applications may not proceed to grant or may be amended to reduce the scope of protection of any patent granted. The applications and patents may also be opposed or challenged by third parties. Our commercial success will depend, in part, on our ability to obtain and maintain effective patent protection for our compounds and their use in treating, preventing, or curing cancer, 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 that we acquired or that it was the first to file patent applications for such inventions. Additionally, the breadth of claims allowed in biotechnology and pharmaceutical patents or their enforceability cannot be predicted. We cannot be sure that, should any patents issue, we will be provided with adequate protection against potentially competitive products. Furthermore, we cannot be sure that should patents issue, they will be of commercial value to us, or that private parties, including competitors, will not successfully challenge our patents or circumvent our patent position in the United States or abroad.

In addition, although in the Isoflavone Asset Purchase Agreement Novogen has made certain representations and warranties regarding its intellectual property rights in respect of the Isoflavone-related Assets, its indemnification obligations in respect of these representations and warranties are limited and expired on June 30, 2011.

Claims by other companies that we infringe on 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 the compounds that we had previously licensed and purchased in May 2011 pursuant to the Isoflavone Asset Purchase Agreement. Therefore, Phenoxodiol, Triphendiol, ME-143, ME-344, NV-128 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 our consultants or research collaborators use intellectual property owned by others in work performed for us, disputes may also arise as to the rights in such intellectual property or in resulting know-how and inventions. An adverse claim could subject us to significant liabilities to such other parties and/or require disputed rights to be licensed from such other parties.

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

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

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

Third parties may assert that we 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 any third party licensors to obtain a license to continue to use the affected technologies. We cannot predict whether we 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.

Risks Related to our Relationship with Novogen

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

As of September 26, 2011, Novogen beneficially owned approximately 51.5% of our outstanding shares of common stock. On September 27, 2011, Novogen agreed, pursuant to the terms of a Securities Subscription Agreement between us and Novogen, to purchase an additional 1,333,333 shares of our common stock, which will increase Novogen's ownership percentage to approximately 57.1%. In addition, Novogen owns 1,000 shares of our Series A Convertible Preferred Stock which are initially convertible into 4,827,000 shares of our common stock, which would increase Novogen's ownership percentage to approximately 69.8%. 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 its assets.

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

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

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

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

One of our directors is the Chairman of the Board of Novogen Limited, which may create a conflict of interest as well as prevent him from devoting his full attention to us.

One of our board members, Mr. William Rueckert, currently serves as the Chairman of the Board of Novogen, our majority shareholder. Simultaneous service as a Novogen director could create, or appear to create,

[Table of Contents](#)

a conflict of interest when such director is presented with decisions that could have different implications for us and Novogen. His responsibilities could prevent him from devoting his full attention to us, which could be harmful to the development of our business.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We have leased office space, of approximately 3,700 square feet, located at 11975 El Camino Real, Suite 101, San Diego, California 92130. The location houses the Company's executive and administrative offices. The lease commenced in July 2010 and expires in April 2013. Monthly rental rates range from \$10,109 to \$10,734 over the lease term, plus a pro rata share of certain building expenses. In addition, the Company has two options to extend the lease for one year each at the market rate in effect at the time of renewal.

We believe these facilities will adequately meet our office needs for the foreseeable future.

Item 3. Legal Proceedings

None.

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

During the fiscal years ended June 30, 2011 and 2010, our common stock was listed on the NASDAQ Global and Capital Markets under the symbol "MSHL". The following table sets forth, for the periods indicated, the high and low sale prices of our common stock for each quarterly period within the two most recent fiscal years.

	Prices	
	High \$	Low \$
Year Ended June 30, 2010		
First Quarter	17.40	4.80
Second Quarter	10.26	6.20
Third Quarter	9.00	4.60
Fourth Quarter	5.60	1.22
Year Ended June 30, 2011		
First Quarter	1.55	0.71
Second Quarter	1.40	0.73
Third Quarter	3.48	0.97
Fourth Quarter	1.99	0.92

Holders

As of September 15, 2011, there were 10,175,089 shares of our common stock outstanding and 91 holders of record of our common stock. This number was derived from our shareholder records and does not include beneficial owners of our common stock whose shares are held in the name of various dealers, clearing agencies, banks, brokers and other fiduciaries.

For a discussion of outstanding warrants and other securities convertible into shares of our common stock, please see Note 5 under Item 8 in this Annual Report on Form 10-K.

Dividends

We have never declared or paid any cash dividends on our common stock and do not anticipate paying any cash dividends in the foreseeable future. We currently intend to retain all available funds and future earnings, if any, to fund the expansion and growth of our business. Any future determination related to our dividend policy will be made at the discretion of our board of directors.

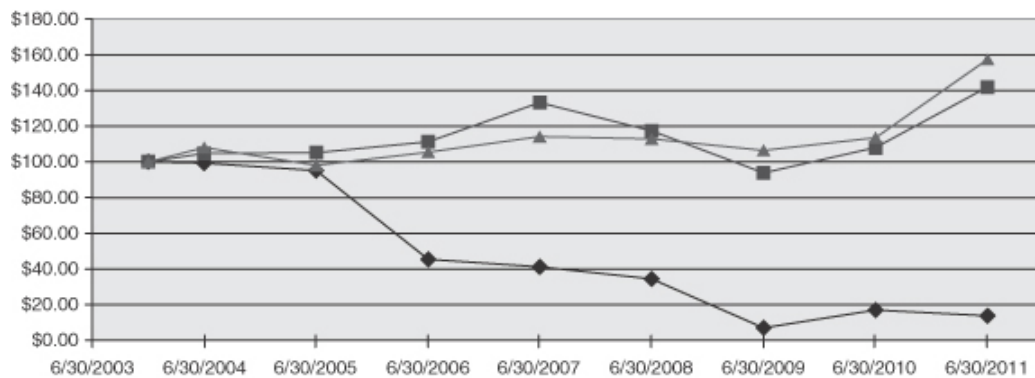
Issuer Repurchases of Equity Securities

None.

Stock Performance Graph

The graph set forth below compares the change in our cumulative total stockholder return on our common stock between December 18, 2003 (the date our common stock commenced public trading) and June 30, 2011 with the cumulative total return of the NASDAQ Composite Index and the NASDAQ Biotechnology Index during the same period. This graph assumes the investment of \$100 on December 18, 2003 in our common stock and each of the comparison groups and assumes reinvestment of dividends, if any. We have not paid any dividends on our common stock, and no dividends are included in the report of our performance.

[Table of Contents](#)



◆ Marshall Edwards, Inc. Common Stock ■ NASDAQ Composite Index ▲ NASDAQ Biotechnology Index

	12/18/03	6/30/04	6/30/05	6/30/06	6/29/07	6/30/08	6/30/09	6/30/10	6/30/11
Marshall Edwards, Inc. Common Stock	\$100.00	\$ 99.07	\$ 95.07	\$ 45.20	\$ 40.93	\$ 34.27	\$ 6.93	\$ 16.80	\$ 13.60
NASDAQ Composite Index	\$100.00	\$104.68	\$105.15	\$111.04	\$133.08	\$117.22	\$ 93.81	\$107.82	\$141.78
NASDAQ Biotechnology Index	\$100.00	\$107.78	\$ 98.00	\$105.44	\$113.95	\$112.62	\$106.40	\$113.54	\$157.38

Item 6. Selected Financial Data

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information under this item.

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

The following discussion and analysis should be read in conjunction with “Item 8. Financial Statements and Supplementary Data” included below in this Annual Report on Form 10-K. Operating results are not necessarily indicative of results that may occur in future periods.

This discussion and analysis contains forward-looking statements that involve a number of risks, uncertainties and assumptions. Actual results may differ materially from those anticipated in the forward-looking statements as a result of many factors including, but not limited to, those set forth under “Cautionary Statement About Forward-Looking Statements” and “Risk Factors” in Item 1A. included above in this Annual Report on Form 10-K. All forward-looking statements included in this Annual Report are based on the information available to us as of the time we file this Annual Report, and except as required by law, we undertake no obligation to update publicly or revise any forward-looking statements.

Overview and Recent Developments

Our business purpose is the development of drugs for the treatment of cancer. We are currently focused on the clinical development of our two lead isoflavone-based drug candidates, ME-143 and ME-344, which we acquired in the Isoflavone Transaction on May 9, 2011, and prior to the consummation of such transaction had licensed from a subsidiary of Novogen.

[Table of Contents](#)

We believe that our existing cash balances, which were approximately \$3.9 million as of June 30, 2011, together with the proceeds of approximately \$1,270,000 from July and August 2011 warrant exercises, and the proceeds from the sale of \$2 million of common stock to Novogen pursuant to the Securities Subscription Agreement dated September 27, 2011, and the expected proceeds of \$2 million from future purchases of our common stock that Novogen has committed to make, will be sufficient to fund our operations until late calendar year 2012. Changes in our research and development plans or other changes affecting our operating expenses may affect actual future use of existing cash resources. In any event, however, we will need additional financing to fund our operations in the future, including the continued development of our two lead drug candidates. To date, our operations have been funded primarily through the sale of equity securities. We have not generated any revenues from operations since inception other than interest and dividends from cash and investments. We have incurred losses since inception and expect to incur operating losses and generate negative cash flows from operations for the foreseeable future. As of June 30, 2011, we had accumulated losses of \$77.6 million since our inception in December 2000.

Expenses to date have consisted primarily of costs associated with conducting the clinical trials of Phenoxodiol, and costs incurred under various product license and services agreements with Novogen. The services agreements were terminated in December 2010. In connection with the consummation of the Isoflavone Transaction, the license agreements, and other key agreements with Novogen, were terminated.

As of September 26, 2011, Novogen owned approximately 51.5% of the outstanding shares of our common stock. Pursuant to the Securities Subscription Agreement dated September 27, 2011, Novogen has agreed to purchase an additional 1,333,333 shares of our common stock, which will increase Novogen's ownership percentage to approximately 57.1%.

The Isoflavone Transaction

In May 2011, we purchased a portfolio of Isoflavone-related Assets from Novogen and Novogen Research Pty Limited, a wholly-owned subsidiary of Novogen, in exchange for 1,000 shares of our Series A Convertible Preferred Stock and the assumption of specified potential liabilities related to these assets. Flavonoids are a family of naturally occurring plant compounds. Isoflavones are a sub-group of the flavonoid family.

Prior to the consummation of the Isoflavone Transaction, we had license agreements with Novogen for the use of some of the Isoflavone-related Assets in the development and commercialization of drugs for the treatment of cancer. These agreements, which were terminated upon consummation of the Isoflavone Transaction as described below, covered only applications of such assets for use in the treatment of cancer, excluding dermatological applications, and not all possible therapeutic indications. The Isoflavone-Related Assets also include patent families which we had not previously licensed, and which may provide additional product candidate development opportunities.

Upon the consummation of the Isoflavone Transaction, each of the following agreements, along with any other agreements relating thereto, with respect to the Isoflavone-related Assets, was terminated:

- September 2003 license agreement between our wholly-owned subsidiary Marshall Edwards Pty Limited ("MEPL") and Novogen's wholly-owned subsidiary, Novogen Research Pty Limited, pursuant to which Novogen Research Pty Limited granted MEPL 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 certain Phenoxodiol products;
- May 2006 license agreement between MEPL and Novogen Research Pty Limited pursuant to which Novogen Research Pty Limited granted MEPL 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 certain products based on two oncology compounds known as Triphendiol and NV-143; and
- August 2009 license agreement between MEPL and Novogen Research Pty Limited pursuant to which Novogen Research Pty Limited granted MEPL an exclusive, worldwide, non-transferable license under its patents and patent applications and in the intellectual property rights related to its know how to conduct clinical trials, commercialize and distribute a compound known as NV-128.

[Table of Contents](#)

Additionally, Novogen, Marshall Edwards and MEPL agreed to terminate the Services Agreement, under which Novogen had previously provided services to us relating to research and development services as well as administrative and accounting services, effective as of December 31, 2010.

Clinical Developments

In June 2011, we announced the publication of results from pre-clinical studies of Triphendiol, the prodrug of ME-143, demonstrating its anti-proliferative activity in pancreatic cancer as both a monotherapy and as a chemosensitizer.

We have completed drug manufacturing and the required pre-clinical studies of ME-143 necessary to submit an Investigational New Drug (IND) application, which was approved by the U.S. Food and Drug Administration (FDA) in August 2011. In September 2011, we initiated a Phase I open label, multi-center, dose escalation study of ME-143 in patients with refractory solid tumors. We expect final safety and pharmacokinetic data from this study during the second quarter of calendar year 2012.

In July 2011, we announced the publication of results from a pre-clinical study of NV-128, the prodrug of our lead mitochondrial inhibitor drug candidate, ME-344, showing activity in chemotherapy-resistant ovarian cancer stem cells.

We are currently completing drug manufacturing of ME-344. We expect to conduct the necessary pre-clinical animal toxicity studies to support submission of an IND application in the first quarter of 2012. Pending FDA approval of the IND application, we plan to initiate a Phase I clinical trial of ME-344 shortly thereafter. If sufficient funding is not available, we will adjust our development plans until such time as adequate funding is available.

Equity Transactions

During February and March 2011, we issued 55,201 shares of common stock resulting in net cash proceeds of \$45,000, pursuant to an At Market Issuance Sales Agreement with McNicoll, Lewis & Vlak LLC (“MLV”). Additionally, during March 2011, as part of a contemplated series of transactions with Ironridge Global Biopharma, a division of Ironridge Global IV, Ltd., a British Virgin Islands business company (“Ironridge”), we (i) issued 644,347 shares of common stock to Ironridge for a fully secured interest-bearing note receivable of \$1,001,700, (ii) issued 742 shares of Series B preferred stock to Ironridge for net cash proceeds of \$665,000, and (iii) redeemed the 742 shares of Series B preferred stock and cancelled the note receivable pursuant to a Stock Purchase Agreement with Ironridge. For discussion of these transactions, see Note 5 to the consolidated financial statements in this Annual Report on Form 10-K.

We filed a shelf registration statement on Form S-3 with the SEC on April 1, 2011, which was declared effective by the SEC in May 2011 (the “shelf registration statement”). The shelf registration statement permits us to sell, from time to time, up to \$50,000,000 of common stock, preferred stock and warrants. Pursuant to SEC regulations, however, so long as our public float remains below \$75 million, we cannot sell securities from the shelf registration statement which represent more than one third of the market value of our non-affiliated public float during any 12-month period.

May 2011 Private Placement

On May 16, 2011, we entered into an Amended and Restated Securities Purchase Agreement with certain accredited investors pursuant to which we agreed to issue certain shares of common stock and warrants, certain of which are exercisable on a cashless basis.

Pursuant to the May 2011 private placement, in May 2011 we issued to the investors: (i) 835,217 shares (the “Initial Shares”) of common stock, at a purchase price of \$1.333 per share; (ii) series A warrants (the “Series A warrants”) which initially represent the right to purchase up to 626,413 shares of common stock; and (iii) Series B warrants (the “Series B warrants”, which initially represent the right to purchase up to 2,165,534 shares of

[Table of Contents](#)

common stock. In addition, we agreed to issue certain additional shares of common stock (the "Adjustment Shares") to the extent the price of our common stock is below \$1.333 per share, but greater than or equal to \$0.75 per share, on certain dates ("Adjustment Dates") during the period ending June 26, 2012, including as a result of a subsequent offering by us of our securities at a price below the purchase price of the Initial Shares. The number of Adjustment Shares issuable will initially be limited to 649,242, subject to proportionate increases to the extent the Series B Warrants have been exercised prior to the applicable Adjustment Date, up to a maximum of 2,332,583 shares. If the trading price of our common stock is below \$0.75 per share on any Adjustment Date, we will, in addition to issuing the applicable number of Adjustment Shares, refund to the investors an amount per share of common stock received by the investors in the transaction equal to the difference between \$0.75 and the price of the common stock on such Adjustment Date. Upon the closing of the transaction, we issued warrants to the placement agent exercisable for the purchase of up to 210,053 shares of common stock which warrants are exercisable on the same terms, including as to the increase in the number of shares of common stock issuable upon exercise, as the Series A warrants. Additionally, we paid the placement agent a cash fee equal to 7% of the gross proceeds of the offering. We filed a registration statement with the SEC, which was declared effective in August 2011, covering the 835,217 shares of common stock issued in connection with the private placement.

At the closing date of the private placement, the estimated fair value of the Series A and Series B warrants, and the embedded derivatives related to the Adjustment Shares, exceeded the net proceeds from the private placement of approximately \$665,000. As a result, all of the proceeds were allocated to these derivative liabilities and no proceeds remained for allocation to additional paid-in capital.

In July and August 2011, we issued 1,294,000 shares of common stock to the investors in the May 2011 private placement pursuant to their exercise of Series B warrants. We received proceeds of approximately \$1,270,000 in conjunction with the warrant exercises. See Note 5 to the consolidated financial statements in this Annual Report on Form 10-K for more information regarding the May 2011 private placement.

Corporate Developments

Nasdaq

During 2010, we received deficiency notices from Nasdaq regarding non-compliance with the minimum stockholders equity and the minimum Market Value of Publicly Held Shares in accordance with Nasdaq Listing Standards for the Nasdaq Global Market. On March 7, 2011, a Nasdaq Hearing Panel granted us until May 16, 2011 to evidence compliance with the stockholders equity and minimum Market Value of Publicly Held Shares requirement. On March 23, 2011, we received a positive response from the Nasdaq Listing Qualifications Staff indicating that our request for a transfer and continued listing on the Nasdaq Capital Market had been granted. Our common stock began trading on the Nasdaq Capital Market effective with the open of business on March 16, 2011.

Under Nasdaq rules, we are required to maintain minimum stockholders' equity of \$2.5 million. If our stockholders' equity falls below \$2.5 million, we would have 45 calendar days from the date of notification by Nasdaq to submit a plan to regain compliance. If the plan is accepted, Nasdaq can grant an extension of up to 180 calendar days from the date of the original notification for us to evidence compliance with this requirement. As a result of continuing losses from operations and the recognition of other expense for the fair value of derivative liabilities related to the securities issued in the May 2011 Private Placement, our stockholders' equity fell below \$2.5 million as of June 30, 2011, and therefore, may lead to de-listing of our common stock from the Nasdaq Stock Market, unless we are able to increase our stockholders' equity through an equity offering or otherwise. On September 27, 2011, Novogen agreed, pursuant to the terms of a Securities Subscription Agreement between us and Novogen, to purchase an additional \$2 million of our common stock, which upon consummation is expected to increase our stockholders' equity to above \$2.5 million.

Board of Directors and Management

On June 2, 2011, we announced the appointment of Robert Mass, M.D., as Chief Medical Officer. Dr. Mass held a number of leadership positions at Genentech from 1998 to 2009, most recently as Head of Medical Affairs, BioOncology. He had previously served as a consultant for several oncology companies, including, since October 2010, Marshall Edwards.

[Table of Contents](#)

On April 13, 2011, William D. Rueckert was elected to our board of directors at our Annual Meeting of Stockholders. Philip Johnston, who served as a director since April 2001, did not stand for re-election.

On August 10, 2010, we announced the appointment of Christine A. White, M.D. to our board of directors. Dr. White replaced Professor Paul J. Nestel, who served as a director since April 2001.

Critical Accounting Policies and Management Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses and related disclosures. Actual results could differ from those estimates. We believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our consolidated financial statements:

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. Generally, the costs associated with clinical trial contracts are based on the number of patients in each trial, the service contracts associated with clinical sites, service providers and drug development contracts. The length of time before actual amounts can be determined will vary, and are therefore estimated, depending on length of the drug administration cycles and the timing of the invoices by the clinical trial partners and contractors.

Derivative Liabilities

In conjunction with the May 2011 private placement, we issued common stock on terms that included certain embedded derivative features, as well as warrants that are accounted for as derivative liabilities (see Note 5 to our consolidated financial statements included in Item 8 of this Annual Report on Form 10-K). These derivative liabilities were determined to be ineligible for equity classification due to certain price protection and anti-dilution provisions.

These derivative liabilities were initially recorded at their estimated fair value on the date of issuance of the common stock and warrants, and are subsequently adjusted to reflect the estimated fair value at each period end, with any decrease or increase in the estimated fair value being recorded as other income or expense. The fair value of these liabilities is estimated using option pricing models that are based on the individual characteristics of the common stock, the derivative liabilities on the valuation date, probabilities related to future financings, as well as assumptions for volatility, remaining expected life, and risk-free interest rate. The option pricing models of our derivative liabilities are estimates and are sensitive to changes to inputs and assumptions used in the option pricing models.

Share-based Compensation

Share-based compensation expense for employees and directors is recognized in the statement of operations based on estimated amounts, including the grant date fair value and the expected service period. For stock options, we estimate the grant date fair value using a binomial valuation model, which requires the use of multiple subjective inputs including estimated future volatility, expected forfeitures and the expected term of the awards. We estimate our expected future volatility based on our stock's historical price volatility. Our stock's future volatility may differ from our estimated volatility at the grant date. Share-based compensation recorded in our statement of operations is based on awards expected to ultimately vest and has been reduced for estimated forfeitures. Our estimated forfeiture rates may differ from actual forfeiture rates which would affect the amount of expense recognized during the period. We recognize the value of the awards on a straight-line basis over the awards' requisite service periods. The requisite service period is generally the time over which our share-based awards vest.

[Table of Contents](#)

Results of Operations

We are providing the following summary of our research and development expenses and general and administrative expenses to supplement the more detailed discussions below. The dollar values in the following tables are in thousands.

	Years Ended June 30,		
	2011	2010	2009
Research and development expenses			
Clinical and drug development costs	\$ (814)	\$(1,666)	\$(5,917)
Salaries and benefits	(232)	—	—
Related party service charges	(708)	(2,279)	(1,456)
Other	(361)	(86)	(404)
Total research and development expenses	<u>\$(2,115)</u>	<u>\$(4,031)</u>	<u>\$(7,777)</u>

	Years Ended June 30,		
	2011	2010	2009
General and administrative expenses			
Legal and professional fees	\$(1,118)	\$(727)	\$(479)
Related party service charges	(319)	(865)	(808)
Salaries and benefits	(1,948)	(193)	—
Other	(951)	(663)	(343)
Total general and administrative expenses	<u>\$(4,336)</u>	<u>\$(2,448)</u>	<u>\$(1,630)</u>

Comparisons of Years Ended June 30, 2011, 2010 and 2009

Research and Development: Research and development expenses consist primarily of clinical trial costs (including payments to contract research organizations or CROs), pre-clinical study costs, cost to manufacture our drug candidates for pre-clinical and clinical studies, related party service charges paid to Novogen and salaries and other personnel costs.

Research and development expenses decreased \$1,916,000 to \$2,115,000 for the year ended June 30, 2011 compared to \$4,031,000 for the year ended June 30, 2010. This decrease was primarily due to lower spending for contract services related to the OVATURE Phase III trial, which terminated enrollment of patients in fiscal year 2009 and completed the final analysis of clinical results in fiscal year 2010. Also, the lower costs in fiscal year 2011 resulted from the termination of the services agreement with Novogen effective December 31, 2010. Research and development expenses incurred during the year ended June 30, 2011 primarily relate to pre-clinical work associated with the development of ME-143 and ME-344. Costs incurred during the year ended June 30, 2011 also include salaries and benefit costs associated with employees hired during the year, including \$23,000 in share-based compensation expenses. In previous years, the Company utilized personnel employed by Novogen, and did not employ research and development personnel.

Research and development expenses decreased \$3,746,000 to \$4,031,000 for the year ended June 30, 2010, compared to \$7,777,000 for the year ended June 30, 2009. The decrease in research and development expenses was primarily due to lower spending following the termination of enrollment in the OVATURE Phase III clinical trial, partially offset by costs incurred to terminate the OVATURE Phase III clinical trial, and increased costs associated with the development of Triphendiol, NV-143 and NV-128.

License Fees: We paid license fees to Novogen pursuant to several license agreements that were in effect prior to their termination in conjunction with the consummation of the Isoflavone Transaction in May 2011. Milestone license fees of \$1,500,000 were expensed during the year ended June 30, 2010, under the terms of the License

[Table of Contents](#)

Agreement for NV-128. Milestone license fees of \$2,000,000 were expensed in the year ended June 30, 2009, under the terms of the License Agreement for Triphendiol and NV-143. During the year ended June 30, 2011, no license fees were due under any of the license agreements with Novogen.

General and Administrative: General and administrative expenses increased by \$1,888,000 to \$4,336,000 for the year ended June 30, 2011, compared to \$2,448,000 for the year ended June 30, 2010. The increase primarily relates to costs associated with the transfer of our operations from Australia to the United States, including hiring of U.S.-based management and staff. Historically, Novogen provided us with executive and administrative staff under service agreements, which were terminated effective December 31, 2010. Salaries and benefit costs include \$461,000 of share-based compensation expense during the year ended June 30, 2011, compared with \$64,000 during the year ended June 30, 2010. Also, during the year ended June 30, 2011, we incurred additional costs for legal and professional fees, primarily related to the acquisition of Novogen's isoflavone-based intellectual property portfolio.

General and administrative expenses increased by \$818,000 to \$2,448,000 for the year ended June 30, 2010 compared to \$1,630,000 for the year ended June 30, 2009. The increase relates to a number of factors including costs associated with the reverse share split and costs incurred in the recruitment and hiring of U.S.-based executive management. General and administrative expenses for the year ended June 30, 2009 reflected cash conservation measures, which resulted in decreased public relations expenses, travel expense, and reduced administration service fees paid to Novogen, compared with previous periods.

Foreign exchange gains and losses occur when revaluing cash denominated in foreign currencies and upon consolidation of our wholly owned subsidiary MEPL. MEPL uses U.S. dollars as its functional currency and also engages in transactions in foreign currencies. Further, MEPL's accounts and financial statements are denominated in Australian dollars. Translation of MEPL's financial statements into U.S. dollars did not have a material impact on our financial position. However, exchange rates are volatile in the current market resulting from the global events and there is a possibility that foreign exchange gains/losses may have a material impact in future periods. At June 30, 2011, we had not established a foreign currency hedging program. Net foreign exchange losses during the year ended June 30, 2011 were \$96,000 compared with net foreign exchange losses of \$141,000 during the year ended June 30, 2010 and net foreign exchange gains of \$242,000 during the year ended June 30, 2009.

Other income or expense: During the year ended June 30, 2011, we issued securities associated with the May 2011 private placement that are accounted for as derivative liabilities. The derivative liabilities were measured at their estimated fair value of \$1,174,000 as of the date of their issuance on May 18, 2011. Their estimated fair value exceeded net proceeds received in the private placement by \$508,000 which was charged to non-operating expenses for the year ended June 30, 2011. As of June 30, 2011, the derivative liabilities were revalued to \$1,125,000, resulting in a net decrease in value of \$49,000 from their date of issuance, based primarily upon a decrease in the price per share of our common stock. The decrease in value was recorded as non-operating income for the year ended June 30, 2011.

We received interest on cash assets and cash equivalents of \$34,000 for the year ended June 30, 2011 versus \$84,000 for the year ended June 30, 2010 and \$228,000 for the year ended June 30, 2009. This decrease was due to lower cash balances and lower interest rates earned by our cash deposits. We also received dividends of \$96,000 from an investment in a privately-held company during the year ended June 30, 2011. We did not receive dividends during previous years.

Off-Balance Sheet Arrangements

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

Contractual Obligations

For details of our contractual obligations at June 30, 2011, see Note 7 to the consolidated financial statements "Commitments".

Liquidity and Capital Resources

Our sources of liquidity include our cash and cash equivalents. We believe that our existing cash balances, which were approximately \$3.9 million as of June 30, 2011, together with the proceeds of approximately \$1,270,000 from July and August warrant exercises, and the proceeds from the sale of \$2 million of common stock to Novogen pursuant to the Securities Subscription Agreement dated September 27, 2011, and the expected proceeds of \$2 million from future purchases of our common stock that Novogen has committed to make, will be sufficient to fund our operations until late calendar year 2012. Our current business operations are focused on continuing the development of our two lead isoflavone based drug candidates. Specifically we intend to commence the clinical development of the drug candidate ME-143 and continue the pre-clinical development of ME-344, a next-generation analogue of NV-128, necessary to file an IND with the FDA. Changes to our research and development plans or other changes affecting our operating expenses may affect actual future use of existing cash resources. To date, we have obtained cash and funded our operations primarily through the sale of equity securities. We have accumulated losses of \$77,588,000 since inception and expect to incur operating losses and generate negative cash flows from operations for the foreseeable future. We will need additional financing to fund our operations in the future, including the continued development of our drug candidates. We intend to seek additional capital through one or more equity transactions; however, there can be no assurance that any such transaction will be completed. Pursuant to the terms of the May 2011 private placement, we have agreed not to offer or sell any of our or our subsidiaries' equity securities, including securities that are convertible or exchangeable for our common stock, or to file any new registration statement, other than as required by the Amended Registration Rights Agreement between us and the investors in the May 2011 private placement, until the earlier of (i) June 18, 2012 and (ii) 90 days after the registration of all of the securities we have agreed to register pursuant to the May 2011 private placement to the Amended Registration Rights Agreement. The foregoing restrictions on securities issuances do not apply to certain permitted issuances, specifically the issuance of up to \$4,000,000 of common stock and warrants to purchase common stock on or after September 15, 2011. If the Company is unable to obtain additional funds on favorable terms or at all, the Company may be required to cease or reduce its operations.

Sources and Uses of Our Cash

Net cash used in operations for the year ended June 30, 2011 was \$6,501,000 compared to \$10,033,000 in the year ended June 30, 2010 due to our net loss resulting from expenses incurred for research and development and general and administrative costs.

Net cash used in investing activities was \$48,000 for the year ended June 30, 2011 and \$3,000 for the year ended June 30, 2010 was for the purchase of property and equipment.

Net cash provided by financing activities was \$1,376,000 for the year ended June 30, 2011. No cash was raised through financing activities during the year ended June 30, 2010. Cash raised during the year ended June 30, 2011 reflected net proceeds of \$771,000 raised through the issuance of common stock and \$665,000 through the issuance of Series B preferred stock.

Contractual Obligations

We have contracted with various consultants and third parties to assist us in pre-clinical research and development and clinical trials work for our leading drug compounds. The contracts are terminable at any time, but obligate us to reimburse the providers for any time or costs incurred through the date of termination. Additionally, we have employment agreements with certain of our current employees that provide for severance payments and accelerated vesting for share-based awards if their employment is terminated under specified circumstances. At June 30, 2011, we had contractual obligations for the conduct of pre-clinical research and development and drug manufacturing of approximately \$607,000.

[Table of Contents](#)

In July 2010, we entered into a lease arrangement to rent approximately 3,700 square feet of office space for 33 months beginning in July 2010 for monthly rental rates ranging from \$10,109 to \$10,734 over the lease term, plus other pass-through charges. We have two options to extend the lease term for one year each at the market rate in effect at the time of renewal.

Item 7a. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

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

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

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

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

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

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

Foreign Currency Risk

We conduct our operations principally in U.S. dollars. However, we also have some exposure to Australian dollars, Euros and British pounds. At June 30, 2011, we had not established a foreign currency hedging program. Net foreign exchange losses during the year ended June 30, 2011 were \$96,000 compared with net foreign exchange losses of \$141,000 during the year ended June 30, 2010. Foreign exchange gains and losses occur as a result of transactions in foreign currencies, and upon consolidation of MEPL, which uses U.S. dollars as its functional currency. MEPL's accounts are denominated in Australian dollars. Translation of MEPL's financial statements into U.S. dollars did not have a material impact on our financial position.

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

Item 8. Financial Statements and Supplementary Data

Marshall Edwards, Inc.

Index to Financial Statements

Reports of Independent Registered Public Accounting Firms	37
Consolidated Balance Sheets	39
Consolidated Statements of Operations	40
Consolidated Statements of Cash Flows	41
Consolidated Statements of Stockholders' Equity	42
Notes to Consolidated Financial Statements	43

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Marshall Edwards, Inc.

We have audited the accompanying consolidated balance sheet of Marshall Edwards, Inc. as of June 30, 2011, and the related consolidated statements of operations, stockholders' equity, and cash flows for the year ended June 30, 2011 and for the period from inception (December 1, 2000) to June 30, 2011. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audit provides 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. as of June 30, 2011, and the consolidated results of its operations and its cash flows for the year ended June 30, 2011 and for the period from inception (December 1, 2000) to June 30, 2011, in accordance with accounting principles generally accepted in the United States of America.

/s/ BDO USA, LLP

San Diego, California
September 28, 2011



Tel: +61 2 9286 5555
Fax: +61 2 9286 5599
www.bdo.com.au

Level 19, 2 Market St
Sydney NSW 2000
GPO Box 2551 Sydney NSW 2001
Australia

Board of Directors
Marshall Edwards, Inc.

We have audited the accompanying consolidated balance sheet of Marshall Edwards, Inc. (a development stage company) as of June 30, 2010 and 2009, and the related statements of operations, stockholders' equity, and cash flows for each of the years in the three year period ended June 30, 2010, and for the period from December 1, 2000 (inception) through June 30, 2010. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Marshall Edwards, Inc. at June 30, 2010 and 2009, and the consolidated results of its operations and its cash flows for each of the years in the three year period ended June 30, 2010 and the period from December 1, 2000 (inception) through June 30, 2010, in conformity with accounting principles generally accepted in the United States of America.

/s/ **BDO Audit (NSW-VIC) Pty Ltd**

Sydney, NSW, Australia

August 26, 2010

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

	June 30,	
	2011	2010
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 3,858	\$ 9,031
Prepaid expenses and other current assets	272	102
Total current assets	4,130	9,133
Property and equipment, net	38	3
Total assets	<u>\$ 4,168</u>	<u>\$ 9,136</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 328	\$ 529
Accrued liabilities	921	925
Due to related party	—	301
Derivative liabilities	1,125	—
Total current liabilities	2,374	1,755
Commitments (Note 7)		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 100,000 shares authorized;		
Series A: 1,000 shares and 0 shares issued and outstanding at June 30, 2011 and 2010, respectively	—	—
Series B: 742 shares issued and redeemed; none outstanding at June 30, 2011 and 2010, respectively	—	—
Common stock, \$0.00000002 par value; 113,000,000 shares authorized;		
8,881,089 shares and 7,346,324 shares issued and outstanding at June 30, 2011 and 2010, respectively	—	—
Additional paid-in-capital	79,382	78,188
Deficit accumulated during the development stage	(77,588)	(70,807)
Total stockholders' equity	1,794	7,381
Total liabilities and stockholders' equity	<u>\$ 4,168</u>	<u>\$ 9,136</u>

See accompanying notes to consolidated financial statements.

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

	<u>Year Ended June 30,</u>			Period from December 1, 2000 (Inception) through June 30, 2011
	<u>2011</u>	<u>2010</u>	<u>2009</u>	
Operating expenses:				
Research and development	\$ (2,115)	\$ (4,031)	\$ (7,777)	\$ (39,189)
License fees	—	(1,500)	(2,000)	(21,500)
General and administrative	(4,336)	(2,448)	(1,630)	(19,291)
Total operating expenses	<u>(6,451)</u>	<u>(7,979)</u>	<u>(11,407)</u>	<u>(79,980)</u>
Loss from operations	(6,451)	(7,979)	(11,407)	(79,980)
Other income (expense):				
Fair value of derivative liabilities in excess of proceeds	(508)	—	—	(508)
Adjustments to fair value of derivative liabilities	49	—	—	49
Interest and dividend income	130	84	228	2,860
Income tax expense	(1)	(1)	(1)	(9)
Net loss arising during development stage	<u>\$ (6,781)</u>	<u>\$ (7,896)</u>	<u>\$ (11,180)</u>	<u>\$ (77,588)</u>
Net loss per share, basic and diluted	<u>\$ (0.89)</u>	<u>\$ (1.07)</u>	<u>\$ (1.53)</u>	
Shares used to calculate net loss per share	<u>7,643,408</u>	<u>7,346,324</u>	<u>7,307,184</u>	

See accompanying notes to consolidated financial statements.

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

	Year Ended June 30,			Period from December 1, 2000 (Inception) through June 30, 2011
	2011	2010	2009	
Cash flows from operating activities:				
Net loss arising during the development stage	\$(6,781)	\$ (7,896)	\$ (11,180)	\$ (77,588)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:				
Share-based payments	484	64	90	2,280
Fair value of derivative liabilities in excess of proceeds	508	—	—	508
Gain on adjustment to fair value of derivative liabilities	(49)	—	—	(49)
Depreciation	13	—	—	13
Changes in operating assets and liabilities:				—
Prepaid expenses and other current assets	(170)	187	(164)	(272)
Accounts payable	(201)	(207)	(394)	328
Accrued liabilities	(4)	(2,261)	1,302	921
Amounts due to related party	(301)	80	(208)	—
Net cash used in operating activities	(6,501)	(10,033)	(10,554)	(73,859)
Cash flows from investing activities:				
Purchases of property and equipment	(48)	(3)	—	(51)
Net cash used in investing activities	(48)	(3)	—	(51)
Cash flows from financing activities:				
Net proceeds from issuance of common stock	711	—	9,878	77,103
Net proceeds from issuance of preferred stock	665	—	—	665
Net cash provided by financing activities	1,376	—	9,878	77,768
Net (decrease)/increase in cash and cash equivalents	(5,173)	(10,036)	(676)	3,858
Cash and cash equivalents at beginning of the period	9,031	19,067	19,743	—
Cash and cash equivalents at end of the period	\$ 3,858	\$ 9,031	\$ 19,067	\$ 3,858
Supplemental cash flow information:				
Income taxes paid	\$ (1)	\$ (1)	\$ (1)	\$ (9)

See accompanying notes to consolidated financial statements.

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

	Series A Preferred Shares	Series B Preferred Shares	Common Shares	Note Receivable	Additional paid in capital	Deficit accumulated during development stage	Total
Balance at December 1, 2000 (inception)	—	—	—	\$ —	\$ —	\$ —	\$ —
Issuance of common stock	—	—	4,950,000	—	—	—	—
Balance June 30, 2001	—	—	4,950,000	—	—	—	—
Net loss arising during development stage	—	—	—	—	—	(123)	(123)
Issuance of common stock (including 2,523,000 warrants)	—	—	252,300	—	9,022	—	9,022
Balance at June 30, 2002	—	—	5,202,300	—	9,022	(123)	8,899
Net loss arising during development stage	—	—	—	—	—	(3,033)	(3,033)
Foreign currency translation adjustments	—	—	—	—	—	—	31
Comprehensive loss	—	—	—	—	—	—	(3,002)
Issuance of common stock	—	—	900	—	36	—	36
Balance at June 30, 2003	—	—	5,203,200	—	9,058	(3,156)	5,933
Net loss arising during development stage	—	—	—	—	—	(8,538)	(8,538)
Foreign currency translation adjustments	—	—	—	—	—	—	(31)
Comprehensive loss	—	—	—	—	—	—	(8,569)
Issuance of common stock (including 239,200 warrants)	—	—	490,600	—	25,578	—	25,578
Balance at June 30, 2004	—	—	5,693,800	—	34,636	(11,694)	22,942
Net loss arising during development stage	—	—	—	—	—	(6,421)	(6,421)
Comprehensive loss	—	—	—	—	—	—	(6,421)
Balance at June 30, 2005	—	—	5,693,800	—	34,636	(18,115)	16,521
Net loss arising during development stage	—	—	—	—	—	(7,386)	(7,386)
Comprehensive loss	—	—	—	—	—	—	(7,386)
Balance at June 30, 2006	—	—	5,693,800	—	34,636	(25,501)	9,135
Net loss arising during development stage	—	—	—	—	—	(13,820)	(13,820)
Comprehensive loss	—	—	—	—	—	—	(13,820)
Issuance of common stock	—	—	632,931	—	16,820	—	16,820
Shares issued as share-based payment	—	—	12,363	—	443	—	443
Warrants issued as share-based payment	—	—	—	—	1,199	—	1,199
Balance at June 30, 2007	—	—	6,339,094	—	53,098	(39,321)	13,777
Net loss arising during development stage	—	—	—	—	—	(12,410)	(12,410)
Comprehensive loss	—	—	—	—	—	—	(12,410)
Issuance of common stock	—	—	546,400	—	14,727	—	14,727
Share-based payments	—	—	—	—	441	—	441
Balance at June 30, 2008	—	—	6,885,494	—	68,266	(51,731)	16,535
Net loss arising during development stage	—	—	—	—	—	(11,180)	(11,180)
Comprehensive loss	—	—	—	—	—	—	(11,180)
Issuance of common stock	—	—	460,830	—	9,768	—	9,768
Share-based payments	—	—	—	—	90	—	90
Balance at June 30, 2009	—	—	7,346,324	—	78,124	(62,911)	15,213
Net loss arising during development stage	—	—	—	—	—	(7,896)	(7,896)
Comprehensive loss	—	—	—	—	—	—	(7,896)
Share-based compensation expense	—	—	—	—	64	—	64
Balance at June 30, 2010	—	—	7,346,324	—	78,188	(70,807)	7,381
Net loss arising during development stage	—	—	—	—	—	(6,781)	(6,781)
Comprehensive loss	—	—	—	—	—	—	(6,781)
Issuance of common stock	—	—	890,418	—	45	—	45
Issuance of preferred stock	1,000	742	—	—	665	—	665
Issuance of common stock for note receivable	—	—	644,347	(1,002)	1,002	—	—
Redemption of preferred stock for cancellation of note receivable	—	(742)	—	1,002	(1,002)	—	—
Share-based compensation expense	—	—	—	—	484	—	484
Balance at June 30, 2011	<u>1,000</u>	<u>—</u>	<u>8,881,089</u>	<u>\$ —</u>	<u>\$ 79,382</u>	<u>\$ (77,588)</u>	<u>\$ 1,794</u>

See accompanying notes to consolidated financial statements.

MARSHALL EDWARDS, INC.
(A Development Stage Company)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
June 30, 2011

Note 1. The Company and Summary of Significant Accounting Policies

The Company

Marshall Edwards, Inc., together with its wholly-owned subsidiary Marshall Edwards Pty Ltd (“MEPL”), collectively referred to as MEI (the “Company”) is a development stage oncology company focused on the clinical development of novel therapeutics targeting cancer metabolism. The Company was incorporated in December 2000 as a wholly-owned subsidiary of Novogen Limited (“Novogen”). Marshall Edwards’ common stock is listed on the Nasdaq Capital Market under the symbol “MSHL”. The Company commenced operations in May 2002, coinciding with the Company’s listing on the London Stock Exchange’s Alternative Investment Market (AIM). As of June 30, 2011, Novogen owned approximately 59% of the outstanding shares of the Company’s common stock.

The Company’s drug development pipeline is derived from its isoflavone technology platform that has generated a number of compounds with anti-proliferative tumor activity. These small molecules have been shown to interact with specific enzyme targets resulting in inhibition of tumor cell metabolism, a function critical for cancer cell survival. As described in Note 4, on May 9, 2011, the Company acquired its entire isoflavone-based intellectual property portfolio including assets which had previously been licensed from Novogen.

Capital Resources

Since inception, the Company’s operations have been financed primarily through the sale of equity securities. The Company has incurred losses from operations and negative cash flows since its inception due in large part to expenditures for its research and development activities, and the Company expects to continue to incur substantial losses for the foreseeable future as it continues development of its two lead drug candidates. As a result, the Company will need to obtain additional financing to fund its operations in the future. The Company intends to obtain any additional required funding through strategic relationships, public or private equity, debt financings, or other arrangements. Conditions in the financial markets and other factors could have a material adverse effect on the Company’s ability to access sufficient funding on acceptable terms, or at all. If the Company cannot raise adequate additional capital, it will be required to delay, further reduce the scope of, or eliminate one or more of its research or development programs. In addition, the Company may be required to relinquish greater, or even all, rights to product candidates at earlier stages of development or on less favorable terms than it would otherwise choose.

Management believes that the Company’s existing cash balances of approximately \$3.9 million as of June 30, 2011, together with the proceeds of \$1,270,000 from July and August 2011 warrant exercises and the proceeds from the sale of \$2 million of common stock to Novogen pursuant to the Securities Subscription Agreement dated September 27, 2011, and the expected proceeds of \$2 million from future purchases of our common stock that Novogen has committed to make, will be sufficient to fund the Company’s operations until late calendar year 2012. Changes in the Company’s research and development plans or other changes affecting its operating expenses may affect actual future use of existing cash resources. If the Company is unable to obtain additional funds on favorable terms or at all, the Company may be required to cease or reduce its operations.

Use of Estimates

The preparation of 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 disclosures made in the accompanying notes to the consolidated financial statements. The Company uses estimates for certain accruals including clinical and pre-clinical study fees and expenses, share-based compensation, and valuations of derivative liabilities, among others. Actual results could differ from those estimates.

[Table of Contents](#)

Cash and Cash Equivalents

Cash and cash equivalents consist of cash and highly liquid investments with remaining maturities of three months or less when purchased.

Fair Value of Financial Instruments

The carrying amounts of financial instruments such as cash equivalents and other current liabilities approximate the related fair values due to the short-term maturities of these instruments. The Company invests its excess cash into financial instruments which are readily convertible into cash, such as money market funds.

Concentration of Credit Risk

Financial instruments, which potentially subject the Company to concentrations of credit risk, consist primarily of cash and cash equivalents. The Company maintains accounts in federally insured financial institutions in excess of federally insured limits. The Company also maintains investments in money market funds and similar short-term investments that are not federally insured. However, management believes that the Company is not exposed to significant credit risk due to the financial positions of the depository institutions in which these deposits are held and of the money market funds in which these investments are made.

Property and Equipment

Property and equipment are stated at cost and depreciated over the estimated useful lives of the assets (generally three to seven years) using the straight-line method. Leasehold improvements are stated at cost and are amortized over the shorter of the estimated useful lives of the assets or the lease term. Capital improvements are stated at cost and amortized over the estimated useful lives of the underlying assets.

Derivative Liabilities

The Company accounts for its warrants and other derivative financial instruments as either equity or liabilities based upon the characteristics and provisions of each instrument. Warrants classified as equity are recorded as additional paid-in capital on our consolidated balance sheet and no further adjustments to their valuation are made. Some of the Company's warrants were determined to be ineligible for equity classification because of anti-dilution provisions that may result in an adjustment to their exercise price. Warrants classified as derivative liabilities and other derivative financial instruments that require separate accounting as liabilities are recorded on the Company's consolidated balance sheet at their fair value on the date of issuance and will be revalued on each subsequent balance sheet date until such instruments are exercised or expire, with any changes in the fair value between reporting periods recorded as other income or expense. Management estimates the fair value of these liabilities using option pricing models and assumptions that are based on the individual characteristics of the warrants or instruments on the valuation date, as well as assumptions for expected volatility, expected life, yield, and risk-free interest rate.

Research and Development Costs

Research and development costs are expensed as incurred and include costs paid to third-party contractors to perform research, conduct clinical trials and develop and manufacture drug materials. Clinical trial costs, including costs associated with third-party contractors, are a significant component of research and development expenses. The Company accrues research and development costs based on work performed. In determining the amount to accrue, management relies on estimates of total costs based on contract components completed, the enrollment of subjects, the completion of trials, and other events.

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 expense in the period incurred.

Share-based Compensation

The fair value of each stock option granted is estimated on the grant date under the fair value method using a binomial valuation model. The estimated fair values of the stock options, including the effect of estimated forfeitures, are expensed over the vesting period. The Company recognized share-based compensation expenses of \$484,000 and \$64,000 during the years ended June 30, 2011 and 2010, respectively.

Interest and Dividend Income

Interest on cash balances is recognized when earned. Dividend revenue is recognized when the right to receive the payment is established.

Income Taxes

The Company's income tax expense consists of current and deferred income tax expense or benefit. Current income tax expense or benefit is the amount of income taxes expected to be payable or refundable for the current year. A deferred income tax asset or liability is recognized for the future tax consequences attributable to tax credits and loss carryforwards and to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. As of June 30, 2011 and 2010, the Company has established a valuation allowance to fully reserve its net deferred tax assets. Tax rate changes are reflected in income during the period such changes are enacted. Changes in ownership may limit the amount of net operating loss carry-forwards that can be utilized in the future to offset taxable income.

The *Financial Accounting Standards Board (FASB) Topic on Income Taxes* prescribes a recognition threshold and measurement attribute criteria for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. An uncertain income tax position will not be recognized if it has less than 50% likelihood of being sustained. There were no unrecognized tax benefits as of June 30, 2011 and 2010.

Foreign Currency Translation

The functional currency of our wholly owned subsidiary in Australia, MEPL, is the U.S. dollar. Monetary assets and liabilities are translated from Australian dollars into U.S. dollars using the exchange rates in effect at the balance sheet date. Nonmonetary assets and liabilities and equity accounts are translated using historical exchange rates. Income statement amounts are 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 as a component of general and administrative expenses and, to date, have not been material.

Reclassifications

Certain prior year amounts have been reclassified to conform with the current year presentation.

[Table of Contents](#)

Net Loss Per Share

Basic and diluted net loss per share are computed using the weighted-average number of shares of common stock outstanding during the period, less any shares subject to repurchase or forfeiture. There were no shares of common stock subject to repurchase or forfeiture for the years ended June 30, 2011, 2010 and 2009. Because the Company is in a net loss position, it has excluded stock options and warrants from the calculation of diluted net loss per share because these securities are antidilutive for all years presented.

Net loss per share was determined as follows (in thousands, except per share amounts):

	Year ended June 30,		
	2011	2010	2009
Numerator			
Net loss arising during the development stage	\$ (6,781)	\$ (7,896)	\$ (11,180)
Denominator			
Weighted average common shares outstanding	7,643,408	7,346,324	7,307,184
Basic and diluted net loss per share	<u>\$ (0.89)</u>	<u>\$ (1.07)</u>	<u>\$ (1.53)</u>
Weighted average anti-dilutive securities not included in diluted loss per share			
Weighted average stock options outstanding	405,764	34,888	2,096
Weighted average warrants outstanding	585,402	529,528	256,108
Total weighted average anti-dilutive securities not included in diluted net loss per share	<u>991,166</u>	<u>564,416</u>	<u>258,204</u>

Note 2. Fair Value Disclosures

Financial assets and liabilities are measured at fair value, which is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The following is a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value:

Level 1: Quoted prices in active markets for identical instruments.

Level 2: Quoted prices for similar instruments in active markets or inputs that are observable for the asset or liability, either directly or indirectly.

Level 3: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

In conjunction with a private placement of equity securities in May 2011 (the "May 2011 private placement" as described in Note 5), the Company issued common stock on terms that included embedded derivative features, as well as warrants to purchase common stock. These instruments are accounted for as derivative liabilities (see Note 5).

The Company used Level 3 inputs for its valuation methodology for the embedded derivative liabilities and warrant derivative liabilities. The estimated fair values were determined using a Monte Carlo option valuation model based on various assumptions. The Company's derivative liabilities are adjusted to reflect estimated fair value at each period end, with any decrease or increase in the estimated fair value being recorded in other income or expense.

Table of Contents

The following table presents our valuation hierarchy for our financial assets and liabilities that are measured at fair value on a recurring basis, in thousands:

	Fair value measurements at June 30, 2011			
	Balance at June 30, 2011	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market funds	\$ 1,066	\$ 1,066	\$ —	\$ —
Liabilities:				
Warrants and other derivative instruments	\$ (1,125)	\$ —	\$ —	\$ (1,125)

	Fair value measurements at June 30, 2010			
	Balance at June 30, 2010	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market funds	\$ 5,582	\$ 5,582	\$ —	\$ —

Money market funds are included in cash and cash equivalents on the Company's consolidated balance sheets.

The following table represents the activity for our derivative liabilities, which are classified as Level 3 in our valuation hierarchy, for the year ended June 30, 2011. We did not have any derivative liabilities during the year ended June 30, 2010.

	Year ended June 30, 2011
Beginning balance	\$ —
Issuance of derivative liabilities	(1,174,000)
Gain from change in valuation of derivative liabilities	49,000
Ending balance	<u><u>\$ (1,125,000)</u></u>

Note 3. Composition of Certain Balance Sheet Items

Accrued expenses consisted of the following, in thousands:

	June 30,	
	2011	2010
Accrued pre-clinical and clinical trial expenses	\$170	\$732
Accrued compensation and benefits	270	—
Accrued legal and professional services expenses	386	169
Other	95	24
	<u><u>\$921</u></u>	<u><u>\$925</u></u>

Note 4. Related Party Transactions

Isoflavone Transaction

On December 21, 2010, the Company entered into an Asset Purchase Agreement (the "Isoflavone Asset Purchase Agreement") with Novogen and Novogen Research Pty Limited, a wholly-owned subsidiary of Novogen, pursuant to which the Company agreed to purchase certain assets used in or generated under, or in

[Table of Contents](#)

connection with, the discovery, development, manufacture and marketing of intellectual property and products based on the field of isoflavonoid technology and on compounds known as isoflavones, including those related to the drug candidates Phenoxodiol, Triphendiol, NV-143 and NV-128, "Isoflavone-related Assets", in exchange for 1,000 shares of the Company's Series A Convertible Preferred Stock. The transaction closed on May 9, 2011. Under the terms of the Isoflavone Asset Purchase Agreement, the Company also assumed certain liabilities that are related to the Isoflavone-related Assets.

The Company did not record a value for the Isoflavone-related Assets acquired, since there were no historical carrying amounts recorded by Novogen and the transaction was between entities under common control.

In conjunction with signing the Isoflavone Asset Purchase Agreement, the Company and Novogen agreed to terminate, effective upon consummation of the Isoflavone Transaction, each of the following agreements, along with any other agreements relating thereto, with respect to the Isoflavone-related Assets:

- September 2003 license agreement between the Company's wholly-owned subsidiary, MEPL, and Novogen's wholly-owned subsidiary, Novogen Research Pty Limited, pursuant to which Novogen Research Pty Limited granted MEPL 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 certain Phenoxodiol products;
- May 2006 license agreement between MEPL and Novogen Research Pty Limited pursuant to which Novogen Research Pty Limited granted MEPL 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 certain products based on two oncology compounds known as Triphendiol and NV-143;
- August 2009 license agreement between MEPL and Novogen Research Pty Limited pursuant to which Novogen Research Pty Limited granted MEPL an exclusive, worldwide, non-transferable license under its patents and patent applications and in the intellectual property rights related to its know-how to conduct clinical trials, commercialize and distribute a compound known as NV-128.

These agreements are described in greater detail below.

License Agreements

The following license agreements between the Company and Novogen were terminated, effective upon consummation of the Isoflavone Transaction:

License Agreement for Phenoxodiol, as amended

In September 2003, the Company entered into the Phenoxodiol license agreement with Novogen. The agreement, which was amended in June 2006 and April 2007, covered uses of Phenoxodiol in the field of prevention, treatment or cure of cancer in humans delivered in all forms except topical applications. Under the agreement, as amended, prior to its termination in May 2011, the license was exclusive until the expiration or lapsing of the last relevant Novogen patents or patent applications in the world and thereafter would have been non-exclusive. MEPL paid Novogen \$5,000,000 in February 2004, \$2,000,000 in January 2005, \$4,000,000 in January 2006, and \$5,000,000 in July 2006 under the terms of the agreement.

Prior to its termination, the Phenoxodiol license agreement provided for additional future payments, none of which will be due following the termination of the Phenoxodiol license agreement. Until the expiration of the exclusivity period as defined in the Phenoxodiol license agreement, MEPL would have been obligated to pay Novogen 2.5% of all net sales and 25% of commercialization income. After the exclusivity period, MEPL would have been obligated to pay Novogen 1.5% of net sales. Further, upon certain regulatory approvals, as defined in

[Table of Contents](#)

the Agreement, MEPL would have been required to pay Novogen Research Pty Limited \$8,000,000, together with interest on such amount from December 31, 2006, to the approval date. Thereafter, MEPL would have been required to make annual license milestone fee payments of \$8,000,000 to Novogen Research Pty Limited beginning the year of the regulatory approval, and each year thereafter during the exclusivity period.

License Agreement for Triphendiol and NV-143

In May 2006, the Company entered into the license agreement for Triphendiol and NV-143. The agreement covered uses of Triphendiol and NV-143 in the field of prevention, treatment or cure of cancer in humans delivered in all forms except topical applications. Under the agreement, prior to its termination in May 2011, the license was exclusive until the expiration or lapsing of the last relevant Novogen patents or patent applications in the world and thereafter would have been non-exclusive. MEPL paid Novogen \$1,000,000 in May 2006, \$1,000,000 in March 2008, and \$2,000,000 in June 2009, under the terms of the agreement.

Prior to its termination, the agreement had provided for \$3,000,000 to be paid to Novogen at the earlier of the date of enrollment of the first clinical trial subject in a Phase III clinical trial of the licensed product or December 31, 2011, and \$8,000,000 at the earlier of the date of first receipt of a NDA for the licensed product from the FDA or equivalent approval from a government agency in another country or December 31, 2013.

Additionally, MEPL would have been obligated to pay Novogen royalties of 5% of all net sales and 25% of commercialization income during the term of the license; such royalty rate would have been reduced by 50% if the licensed patent rights in any country or territory expired, lapsed, or were revoked, or did not exist or were assigned to MEPL and the product was entirely manufactured and supplied in such country. MEPL would also have owed Novogen minimum royalties of \$3,000,000 per year following the date of first receipt of an NDA for a licensed product from the FDA (or equivalent approval from a government agency in any other country) until the expiration of the term.

License Agreement for NV-128

In August 2009, the Company entered into the NV-128 license agreement. The agreement covered the use of NV-128 in the field of prevention, treatment and cure of cancer in humans delivered in all forms except topical applications. Under the agreement, the license was exclusive until the expiration or lapsing of the last relevant Novogen patents or patent applications in the world or Novogen's assignment to MEPL of the last relevant patents or patent applications in the world so that MEPL may assume the filing, prosecution and maintenance of such patents or patent applications. Thereafter, the license would have been a non-exclusive, perpetual and irrevocable license covering any remaining intellectual property rights related to the know-how with respect to NV-128. MEPL paid Novogen \$1,500,000 in August 2009 under the terms of the Agreement.

Prior to its termination, the agreement had provided for \$1,000,000 to be paid to Novogen at the earlier of the date an IND for the licensed product goes into effect or the equivalent approval of a government agency is obtained in another country or December 31, 2011, \$2,000,000 at the earlier of the date of enrolment of the first clinical trial subject in a Phase II clinical trial of the licensed product or December 31, 2012, \$3,000,000 at the earlier of the date of enrolment of the first clinical trial subject in a Phase III clinical trial of the licensed product or December 31, 2014, and \$8,000,000 at the earlier of the date of first receipt of a NDA for the licensed product from the FDA or equivalent approval from a government agency in another country or December 31, 2017.

Additionally, MEPL would have been obligated to pay Novogen royalties of 5% of all net sales and 25% of commercialization income for the term of the license, and minimum royalties of \$3,000,000 per year following the date of first receipt of an NDA for a licensed product from the FDA (or equivalent approval from a government agency in any other country) until the expiration of the term.

Amended and Restated License Option Deed

In September 2003, MEPL and Novogen entered into an Amended and Restated License Option Deed (the "License Option Deed"). The License Option Deed granted 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 Phenoxdiol) 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 agreement was terminated in May 2011.

Amended and Restated Services Agreement

In September 2003, the Company, Novogen and MEPL entered into the Services Agreement. The Company and Novogen terminated the Services Agreement effective December 31, 2010. Under the terms of the Services Agreement, Novogen or its subsidiaries agreed to provide services reasonably required by the Company relating to the development and commercialization of Phenoxdiol and other licensed products, including Triphendiol and ME-143. Novogen agreed to provide these services at cost plus a 10% mark-up.

Transactions giving rise to expenditures amounting to \$1,027,000, \$3,144,000 and \$2,264,000, were made under the Services Agreement with Novogen during the years ended June 30, 2011, 2010 and 2009, respectively. Of these amounts, \$708,000, \$2,279,000 and \$1,456,000 related to service fees paid to Novogen for research and development services provided in the years ended June 30, 2011, 2010 and 2009, respectively, reflecting the time spent by Novogen research staff on the development of Phenoxdiol, Triphendiol, NV-143 and NV-128. Additionally, \$319,000, \$865,000 and \$808,000 during the years ended June 30, 2011, 2010 and 2009, respectively, related to costs incurred for administration and accounting services provided by Novogen.

No amounts were due to Novogen under the agreement as of June 30, 2011. At June 30, 2010, \$301,000 was due to Novogen under the agreement and is included in amounts due to related party on the consolidated balance sheet.

Amended and Restated Manufacturing License and Supply Agreement

In September 2003, MEPL and Novogen entered into an Amended and Restated Manufacturing License and Supply Agreement. The agreement was terminated in conjunction with the consummation of the Isoflavone Transaction. Under the terms of the agreement, MEPL had granted to Novogen an exclusive, non-transferable sub license to manufacture and supply Phenoxdiol in its primary manufactured form. Novogen had agreed to supply Phenoxdiol to MEPL for the clinical trial development program and Phenoxdiol's ultimate commercial use at cost plus a 50% markup. No amounts were paid to Novogen under the agreement prior to its termination in May 2011.

Note 5. Stockholders' Equity

Reverse Stock Split

On March 31, 2010, the Company effected a reverse stock split of its outstanding common stock on a 1-for-10 split adjusted basis in order to comply with a bid price listing requirement for continued inclusion on the Nasdaq Global Market under Nasdaq Rule 5450(a)(1). For the purpose of this report we have adjusted all share data presented retrospectively to incorporate the 1-for-10 reverse stock split.

Equity Transactions

In May 2002, the Company sold 252,300 shares of its common stock and 252,300 warrants in an initial public offering, raising net proceeds of \$9,022,000. The warrants were exercisable prior to November 30, 2003, at an exercise price of \$40.00 per share. The Company's common stock was listed for trading on the Alternative

[Table of Contents](#)

Investment Market, a sub-market of the London Stock Exchange (AIM). Following the listing, Novogen retained 95.1% of the Company's common stock.

In June 2003, 900 warrants were exercised, resulting in proceeds to the Company of \$36,000. In November 2003, the remaining 251,400 warrants were exercised at an exercise price of \$40.00 per share with proceeds to the Company of \$10,056,000.

In December 2003, the Company sold 239,200 common stock units at a public offering price of \$75.00 per unit. Each unit consisted of one share of common stock and one warrant to purchase one share of common stock, exercisable prior to December 18, 2006, at an exercise price of \$90.00. In connection with the December 2003 offering, which raised net proceeds of \$15,522,000, the Company's common stock and warrants commenced trading separately on the NASDAQ Global Market. The 239,200 warrants subsequently expired without being exercised.

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

In July 2006, the Company consummated a private placement with certain accredited investors, which raised net proceeds of \$16.8 million. In conjunction with the private placement, the Company issued 632,931 shares of the Company's common stock and warrants exercisable for 221,525 shares of the Company's common stock at a purchase price of \$29.00 per unit. Each unit consisted of one share of common stock and 0.35 of a warrant to purchase one share of common stock. The warrants, which subsequently expired without being exercised, had an exercise price of \$43.50 per share, subject to certain adjustments. The Company filed a registration statement with the SEC, which was declared effective in September 2006, covering the shares of common stock issued in connection with the private placement and the shares of common stock underlying the warrants issued in the private placement.

In July 2006, in connection with a standby equity distribution agreement which the Company subsequently cancelled without issuing any shares, the Company paid a commitment fee of 12,363 shares of its common stock, and warrants, to purchase 60,000 shares of its common stock. The warrants, which subsequently expired without being exercised, had an exercise price of \$43.50 per share, subject to certain adjustments. The commitment fee was accounted for in accordance with FASB ASC 718 (FAS123R) "Share-based Payment". The fair values of the shares and warrants issued were recorded as equity in the balance sheet and as general and administration expenses in the income statement in the year ended June 30, 2007.

In August 2007, the Company consummated a private placement with certain accredited investors, which raised net proceeds of \$15.2 million. In conjunction with the private placement, the Company issued 546,400 shares of common stock at a purchase price of \$30.00 per share. The investors also received a warrant to purchase an additional four shares of common stock for every block of 10 shares of common stock purchased. The warrants have an exercise price of \$36.00 per share, and will expire in August 2012. The Company also issued 6,209 warrants to the placement agent, as part of the placement fee. Each warrant can be exercised for four shares of common stock. The warrants issued to the placement agent have an exercise price of \$30.00 per share and will expire in August 2012. The fair value of warrants issued to the placement agent, valued at \$441,000, has been recognized as equity in the balance sheet and offset against the proceeds raised in the offering. The Company filed a registration statement with the SEC, which was declared effective in October 2007, covering the shares of common stock issued in connection with the private placement and the shares of common stock underlying the warrants issued in the private placement.

In July 2008, the Company entered into a Securities Subscription Agreement with Novogen and certain accredited investors, which raised net proceeds of \$9.8 million. In conjunction with the private placement, the Company issued 290,829 and 170,000 shares of common stock to Novogen and the accredited investors, respectively, at a purchase price of \$21.70 per share. The shares were registered for resale under the Securities Act of 1933, as amended, pursuant to a shelf registration statement on Form S-3. In July 2008, in conjunction

[Table of Contents](#)

with the private placement, the Company issued 4,608 warrants to purchase common stock to a consultant for investment services performed for the Company. The warrants were exercisable immediately upon issuance, have an exercise price of \$21.70 per share, and expire in July 2013.

In February 2011, the Company entered into an At Market Issuance Sales Agreement under which the Company may, from time to time, issue and sell shares of its common stock pursuant to a prospectus supplement related to a shelf registration statement covering sales of common stock with an aggregate offering price of up to \$1,815,000, which the Company filed with the SEC on the same date. During February and March 2011, the Company issued 55,201 shares of common stock under the sales agreement for \$131,000, resulting in net proceeds of \$45,000 after deducting offering-related expenses.

In March 2011, the Company entered into a Stock Purchase Agreement with an accredited investor. During March 2011, as part of a contemplated series of transactions, the Company issued to the accredited investor (i) 644,347 shares of common stock for \$1,001,700, and (ii) 742 shares of the Company's newly designated Series B preferred stock, at a purchase price of \$1,000 per share. The investor paid for the common shares by issuing and delivering to the Company secured, full-recourse promissory notes totaling \$1,001,700, bearing interest at a rate of 2% per annum. Additionally, the investor paid \$742,000 in cash for 742 Series B Preferred Shares. In March 2011, the Company redeemed and cancelled all of the outstanding Series B Preferred Shares that had been issued to the investor, and cancelled the promissory notes as payment for redemption of the Series B Preferred Shares. During the year ended June 30, 2011, the Company's net proceeds from the transactions with the investor were \$665,000, after deducting offering-related expenses.

In April 2011, the Company filed a shelf registration statement on Form S-3 with the SEC (the "shelf registration statement"). The shelf registration statement was declared effective by the SEC in May 2011. The shelf registration statement permits the Company to sell, from time to time, up to \$50,000,000 of common stock, preferred stock and warrants. Pursuant to SEC regulations, so long as the Company's public float remains below \$75 million, the Company cannot sell securities from the shelf registration statement which represent more than one third of the market value of the Company's non-affiliated public float during any 12-month period.

May 2011 Private Placement

On May 2, 2011, the Company entered into a Securities Purchase Agreement ("Original Purchase Agreement") with certain accredited investors pursuant to which the Company agreed to issue and sell to the investors certain shares of the Company's common stock, and warrants to purchase additional shares of common stock. On May 16, 2011, the Company entered into an Amended and Restated Securities Purchase Agreement (the "Amended Purchase Agreement") with the investors, which amended and restated in its entirety the Original Purchase Agreement. The transaction was consummated on May 18, 2011 (the "Closing Date").

Pursuant to the Amended Purchase Agreement, in May 2011 the Company issued to the investors: (i) 835,217 shares (the "Initial Shares") of common stock, at a purchase price of \$1.333 per share; (ii) series A warrants (the "Series A warrants") which initially represent the right to purchase up to 626,413 shares of common stock; and (iii) series B warrants (the "Series B warrants") which initially represents the right to purchase up to 2,165,534 shares of common stock. In addition, the Company agreed to issue certain additional shares of common stock (the "Adjustment Shares") to the extent the price of the common stock is below \$1.333 per share, but greater than or equal to \$0.75 per share, on certain dates ("Adjustment Dates") during the period ending June 26, 2012, including as a result of a subsequent offering by the Company of its securities at a price below the purchase price of the Initial Shares. The number of Adjustment Shares issuable will initially be limited to 649,242, subject to proportionate increases to the extent the Series B warrants have been exercised prior to the applicable Adjustment Date, up to a maximum of 2,332,583 shares. If the trading price of the Company's common stock is below \$0.75 per share on any Adjustment Date, the Company will, in addition to issuing the applicable number of Adjustment Shares, refund to the investors an amount per share of common stock received by the investors in the transaction equal to the difference between \$0.75 and the price of the common stock on

[Table of Contents](#)

such Adjustment Date. Upon the closing of the May 2011 private placement, the Company issued warrants to the placement agent, for the purchase of up to 210,053 shares of common stock, which warrants are exercisable on the same terms, including as to the increase in the number of shares of common stock issuable upon exercise, as the Series A warrants. Additionally, the Company paid the placement agent a cash fee equal to 7% of the gross proceeds of the offering. The Company filed a registration statement with the SEC, which was declared effective in August 2011, covering the resale of the 835,217 shares of common stock issued in connection with the transaction.

Allocation of Proceeds

At the closing date of the May 2011 private placement, the estimated fair value of the Series A and Series B warrants, and the embedded derivatives related to the Adjustment Shares, exceeded the net proceeds from the private placement of \$666,000 (see the valuations of these derivative liabilities under “*Derivative Liabilities*” below). As a result, all of the proceeds were allocated to the derivative liabilities and no proceeds remained for allocation to additional paid-in capital.

Terms of Warrants

The Series A warrants will be exercisable any time on or after the six month anniversary of the closing of the May 2011 private placement at an initial exercise price of \$1.57 per share, subject to adjustment as provided in the Series A warrants. The number of shares of common stock issuable upon exercise of the Series A warrants will be increased by an amount equal to 75% of the number of shares of common stock issued upon each exercise of the Series B warrants. The Series A warrants will expire on the fifth anniversary of the date on which the Series A warrants first become exercisable.

The Series B warrants are exercisable by the holders at any time on or after the first date on which certain conditions relating to Stockholder Approval, which was received in June 2011, and the ability of the holders to resell the securities issued pursuant to the Amended Purchase Agreement are satisfied or waived. The initial exercise price per share of the Series B warrants is equal to the lower of (i) \$1.333, and (ii) 85% of the arithmetic average of the lowest eight weighted average prices of the common stock during the 20 consecutive trading day period (a) in the case of a voluntary exercise by the holders, ending on the trading day immediately preceding the date of delivery of a notice of exercise, and (b) in the case of a required exercise, immediately following the fifth trading day following the date of delivery of a notice of such required exercise. Under certain conditions, the Company may require the holders to exercise their Series B warrants. The Series B warrants will expire on the first anniversary of the closing of the May 2011 private placement.

In July and August 2011, the investors exercised an aggregate of 1,294,000 Series B warrants for 1,294,000 shares of common stock. The Company received proceeds of \$1,270,000 in conjunction with the exercise of the Series B warrants. Additionally, pursuant to the terms of the Amended Purchase Agreement, an additional 970,500 Series A warrants became exercisable as a result of the Series B warrant exercises (see Note 11).

Restrictions on Additional Offerings

Pursuant to the Amended Purchase Agreement, the Company has also agreed generally not to make any further offers or sales of any of its equity securities until the earlier of (i) 90 days after the date on which all of the securities required to be registered in connection with the Amended Purchase Agreement have been so registered and (ii) the date that is thirteen months after the date of the closing of the offering. However, certain offers and sales are excluded from the foregoing restriction, including the offer and sale of a specified amount of additional common stock and warrants to purchase common stock during the period beginning on the later of (a) 120 days after the closing of the offering, and (b) the earlier of the date on which the common shares have been registered pursuant to an effective registration statement or can be sold pursuant to Rule 144 without any restrictions or limitations.

[Table of Contents](#)

Derivative Liabilities

The Company accounted for the Series A and B warrants and the adjustment shares feature associated with the common stock pursuant to the Amended Purchase Agreement in accordance with accounting guidance for derivatives. The accounting guidance provides a two-step model to be applied in determining whether a financial instrument or an embedded feature in a financial instrument is indexed to an entity's own stock that would qualify such financial instruments or embedded features for a scope exception. This scope exception specifies that a contract that would otherwise meet the definition of a derivative financial instrument would not be considered as such if the contract is both (i) indexed to the entity's own stock and (ii) classified in the stockholders' equity section of the balance sheet. The Company determined that its Series A and Series B warrants are ineligible for equity classification as a result of the anti-dilution provisions in the Series A and Series B warrants that may result in an adjustment to the warrant exercise price. Additionally, the Company determined that the adjustment shares feature related to the common stock, as specified in the Amended Purchase Agreement, resulted in an embedded derivative.

The estimated fair values of the derivative liabilities as of the closing date of the May 2011 private placement and at June 30, 2011 are summarized as follows (in thousands):

	Fair Value Measurements at	
	May 18, 2011	June 30, 2011
Series A and B warrants	\$ 649	\$ 511
Embedded derivatives	525	614
	<u>\$ 1,174</u>	<u>\$ 1,125</u>

On the closing date, the derivative liabilities were recorded at an estimated fair value of \$1,174,000. Given that the fair value of the derivative liabilities exceeded the total proceeds of the private placement of \$666,000, no net amounts were allocated to the common stock. The \$508,000 amount by which the recorded liabilities exceeded the proceeds was charged to other expense at the closing date. The Company has revalued the derivative liability as of June 30, 2011, and will continue to do so on each subsequent balance sheet date until the securities to which the derivative liabilities relate are exercised or expire, with any changes in the fair value between reporting periods recorded as other income or expense. On June 30, 2011, the total value of the derivative liabilities was \$1,125,000 the decrease in the estimated fair value of the derivative liabilities for the year ended June 30, 2011 resulting in other income of \$49,000. Such decrease in the estimated fair value was primarily due to the decrease in the Company's common stock price and updates to the assumptions used in the option pricing models.

The derivative liabilities were valued at the closing date of the May 2011 private placement and at June 30, 2011 using a Monte Carlo valuation model with the following assumptions:

	May 18, 2011	June 30, 2011
Closing price per share of common stock	\$ 1.35	\$ 1.02
Expected volatility	121.5% - 122.1%	112.9% - 121.2%
Risk-free interest rate	.19% - 1.87%	.19% - 1.76%
Dividend yield	—	—
Expected lives of underlying securities	12-66 months	12-66 months

In addition, as of the valuation dates, management assessed the probabilities of Series A and Series B warrants being exercised due to trading restrictions on the unregistered shares of common stock issued or issuable from the exercise of the Series A and Series B warrants and included related assumptions in the option pricing models. Management also applied a discount for lack of marketability to the valuation of the derivative liabilities based on such trading restrictions. The option pricing model used to value the Series A and Series B warrants is particularly sensitive to such probabilities, as well as to the closing price per share of the Company's common stock.

Description of Capital Stock

The Company's 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.

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 the Company's affairs, holders of the common stock will be entitled to share rateably in all the Company's assets that are remaining after payment of the Company's 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 the Company has issued or that the Company may issue in the future. The holders of common stock have no pre-emptive rights and are not subject to future calls or assessments by the Company.

Preferred Stock

The Company's Board of Directors has the authority to issue up to 100,000 shares of preferred stock with par value of \$.01 per share 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 shares or that could have the effect of delaying, deferring or preventing a change of control.

Series A Convertible Preferred Stock

In connection with the closing of the Isoflavone Transaction, the Company designated and issued 1,000 shares of Series A Convertible Preferred Stock.

Each share of the Series A Convertible Preferred Stock issued to Novogen in conjunction with the Isoflavone Transaction is convertible into 4,827 shares of Common Stock. In the event a Phase II clinical trial involving any of the isoflavone technology acquired by the Company pursuant to the Asset Purchase Agreement has achieved a statistically significant result ($p=0.05$ or less) or a first patient is enrolled in a Phase III clinical trial involving the such technology, whichever is earlier, each share of the Series A Convertible Preferred Stock not already converted may be converted into 9,654 shares of Common Stock.

The Company has an option to purchase, in a single transaction, all of the unconverted Series A Convertible Preferred Stock for an aggregate exercise price of \$12,000,000 in cash for all of the Series A Convertible Preferred Stock and, where a portion of the Series A Convertible Preferred Stock has been converted, the exercise price shall be pro-rated. Upon the earlier of (i) the fifth anniversary of the closing of the Asset Purchase and (ii) a "change in control", as defined in the Isoflavone Asset Purchase Agreement, of Novogen, all unconverted Series A Convertible Preferred Stock will automatically convert into Common Stock in accordance with the applicable conversion ratio.

Holders of the Series A Convertible Preferred Stock are not entitled to receive any dividend or other similar distributions, except in the event that the Company's board of directors or any duly authorized committee thereof declares and authorizes a special dividend or distribution on any shares of Series A Convertible Preferred Stock. Additionally, holders of the Series A Convertible Preferred Stock are not entitled to vote any shares of the Series A Convertible Preferred Stock. The holders of the Series A Convertible Preferred Stock do not have any rights of pre-emption, except as the Company may otherwise agree in writing.

[Table of Contents](#)

Series B Preferred Stock

The Series B Preferred Shares, all of which were redeemed and cancelled on March 31, 2011 in accordance with the terms described below, entitled holders to receive dividends in the amount of 10% per annum, payable in additional shares of Series B Preferred Shares. Holders of Series B Preferred Shares did not have voting rights, nor were the Series B Preferred Shares convertible into, or exchangeable for, any of our other property or securities. Any time after the initial issuance of Series B Preferred Shares (the "Series B Initial Issuance Date"), the Company had the right, at its option, to redeem all or a portion of the Series B Preferred Shares at a price per share equal to (a) 135% of the amount equal to \$1,000 plus any accrued but unpaid dividends thereon (the "Series B Liquidation Value") if redeemed prior to the first anniversary of the Series B Initial Issuance Date, (b) 126% of the Series B Liquidation Value if redeemed on or after the first anniversary but prior to the second anniversary of the Series B Initial Issuance Date, (c) 117% of the Series B Liquidation Value if redeemed on or after the second anniversary but prior to the third anniversary of the Series B Initial Issuance Date, (d) 108% of the Series B Liquidation Value if redeemed on or after the third anniversary but prior to the fourth anniversary of the Series B Initial Issuance Date, and (e) upon or after the fourth anniversary of the Series B Initial Issuance Date, \$1,000 plus any accrued but unpaid dividends. Upon the Company's liquidation, dissolution or winding up, holders of Series B Preferred Shares were entitled to be paid out of the Company's assets, on a parity with holders of the Company's common stock, an amount equal to \$1,000 per share plus any accrued but unpaid dividends thereon.

Warrants

As of June 30, 2011, there were outstanding warrants to purchase 248,003 shares of the Company's common stock at exercise prices ranging from \$21.70 to \$36.00 per share, which expire at various dates in calendar years 2012 and 2013. Additionally, as of June 30, 2011 there were outstanding Series A warrants to purchase up to 2,250,564 shares of common stock, of which 626,413 were initially exercisable at an initial exercise price of \$1.57 per share, which expire in November 2016, and Series B warrants to purchase 2,165,534 shares of common stock at an initial exercise price of \$1.333 per share, which expire in May 2012. The Series A and Series B warrants' exercise prices are subject to adjustment as described above under '*Terms of Warrants*'.

Transfer of Common Stock to Nasdaq Capital Market

In March 2011, the Company received a response from the Nasdaq Listing Qualifications Panel indicating that the Company's request for a transfer and continued listing on the Nasdaq Capital Market had been granted. The Company's common stock began trading on the Nasdaq Capital Market on March 16, 2011.

Note 6. Share-based Compensation

In December 2008, the Company adopted the Marshall Edwards Inc. 2008 Stock Omnibus Equity Compensation Plan (the "2008 Plan"), under which 700,000 shares of common stock are authorized for issuance. The 2008 Plan provides for the grant of options and/or other stock-based or stock-denominated awards to Marshall Edwards' non-employee directors, officers, employees and advisors. As of June 30, 2011, there were a total of 375,815 options outstanding and 324,185 shares remained available for future grant under the 2008 Plan. During the year ended June 30, 2010, the Company granted options to purchase a total of 220,390 shares of common stock to the Company's Chief Executive Officer. These grants were made outside of the 2008 Plan.

[Table of Contents](#)

A summary of the Company's stock option activity and related data follows:

	Outstanding Options	
	Number of Shares	Weighted-Average Exercise Price
Balance at June 30, 2009	5,000	\$ 6.30
Granted	293,853	2.97
Forfeited/Expired	—	—
Balance at June 30, 2010	298,853	3.03
Granted	297,352	1.12
Forfeited/Expired	—	—
Balance at June 30, 2011	596,205	\$ 2.08

As of June 30, 2011, 87,648 options were vested and exercisable, with a weighted-average exercise price of \$3.21 and a remaining contractual term of 3.8 years. No stock option exercises occurred during the years ended June 30, 2011 or 2010. As of June 30, 2011, the total intrinsic value, which is the difference between the exercise price of the underlying options and the closing price of the Company's common stock of \$1.02 on that date was approximately \$20,000.

Unrecognized compensation expense related to non-vested stock options totalled \$503,000 as of June 30, 2011. Such compensation expense is expected to be recognized over a weighted-average period of 3.2 years.

The Company uses a binomial valuation model to estimate the grant date fair value of stock options. To calculate these fair values, the following assumptions were used:

	Year ended June 30,		
	2011	2010	2009
Risk-free interest rate	1.17% - 1.60%	1.95% - 2.61%	1.70%
Expected life	5 years	5 years	5 years
Expected volatility	136% - 144%	132% - 136%	111%
Dividend yield	0%	0%	0%
Weighted-average fair value	\$0.98	\$2.59	\$0.50

Exercise prices and weighted-average remaining contractual lives for the options outstanding as of June 30, 2011 were:

Options Outstanding	Exercise Price	Weighted Avg. Remaining Contractual Life (Years)	Weighted Avg. Exercise Price	Options Exercisable	Weighted Avg. Exercise Price of Options Exercisable
82,232	\$ 0.77	4.2	\$ 0.77	—	\$ —
37,500	\$ 1.15	4.3	\$ 1.15	—	\$ —
177,620	\$ 1.28	4.9	\$ 1.28	—	\$ —
73,463	\$ 1.52	4.0	\$ 1.52	18,366	\$ 1.52
110,195	\$ 1.86	3.8	\$ 1.86	32,141	\$ 1.86
110,195	\$ 5.05	3.8	\$ 5.05	32,141	\$ 5.05
5,000	\$ 6.30	2.6	\$ 6.30	5,000	\$ 6.30
596,205				87,648	\$ 3.21

Note 7. Commitments

The Company has contracted with various consultants and third parties to assist it in pre-clinical research and development and clinical trials work for its leading drug compounds. The contracts are terminable at any time, but obligate the Company to reimburse the providers for any time or costs incurred through the date of

[Table of Contents](#)

termination. Additionally, the Company has employment agreements with certain of its current employees that provide for severance payments and accelerated vesting for share-based awards if their employment is terminated under specified circumstances. At June 30, 2011, the Company had contractual obligations for the conduct of clinical trials, pre-clinical research and development and manufacturing process development of approximately \$607,000.

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

Leases

In July 2010, the Company entered into a lease arrangement to rent approximately 3,700 square feet of office space for 33 months beginning in July 2010 for monthly rental rates ranging from \$10,109 to \$10,734 over the lease term, plus other pass-through charges. The Company has two options to extend the lease term for one year each at the market rate in effect at the time of renewal. The Company recognizes rent expense on a straight-line basis over the term of the lease. Rent expense for the year ended June 30, 2011 was \$109,000. Lease payments due for the years ending June 30, 2012 and June 30, 2013 are \$125,000 and \$107,000, respectively.

Note 8. Segment Information

The Company has one operating segment, the discovery and development of pharmaceutical compounds. The Company's business contains two geographic segments. The following segment information is net of intercompany transactions.

	Year Ended June 30,								
	2011			2010			2009		
	USA	Australia	Total	USA	Australia	Total	USA	Australia	Total
	<i>(in thousands)</i>								
Statement of Operations:									
Loss from operations	\$ (5,016)	\$ (1,435)	\$ (6,451)	\$ (1,101)	\$ (6,878)	\$ (7,979)	\$ (659)	\$ (10,748)	\$ (11,407)
Other income (expense)	(329)	(1)	(330)	78	5	83	206	21	227
Net loss arising during development stage	<u>\$ (5,345)</u>	<u>\$ (1,436)</u>	<u>\$ (6,781)</u>	<u>\$ (1,023)</u>	<u>\$ (6,873)</u>	<u>\$ (7,896)</u>	<u>\$ (453)</u>	<u>\$ (10,727)</u>	<u>\$ (11,180)</u>
Balance Sheet:									
Segment assets	\$ 4,112	\$ 56	\$ 4,168	\$ 8,320	\$ 816	\$ 9,136	\$ 16,203	\$ 3,153	\$ 19,356
Segment liabilities	\$ (1,294)	\$ (1,080)	\$ (2,374)	\$ (368)	\$ (1,387)	\$ (1,755)	\$ (77)	\$ (4,066)	\$ (4,143)

Note 9. Income Taxes

Pre-tax loss consists of the following jurisdictions (in thousands):

	Year ended June 30,		
	2011	2010	2009
Domestic	\$ (6,346)	\$ (66,352)	\$ (452)
Foreign	(1,452)	(6,873)	(10,727)
	(7,798)	(73,225)	(11,179)
Elimination on consolidation	1,018	65,330	—
Pre-tax loss	<u>\$ (6,780)</u>	<u>\$ (7,895)</u>	<u>\$ (11,179)</u>

[Table of Contents](#)

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

	Year ended June 30,					
	2011		2010		2009	
	\$	%	\$	%	\$	%
Tax benefit at U.S. statutory rates	\$ 2,305	34%	\$ 2,684	34%	\$ 3,801	34%
State tax	368	5%	—	0%	—	0%
Australian tax	(58)	-1%	(275)	-3%	(429)	-4%
R&D tax concession	108	2%	428	5%	504	5%
Change in valuation allowance	(2,724)	-40%	(2,838)	-36%	(3,877)	-35%
	<u>\$ (1)</u>	<u>—</u>	<u>\$ (1)</u>	<u>—</u>	<u>\$ (1)</u>	<u>—</u>

Deferred tax liabilities and assets are comprised of the following (in thousands):

	Year ended June 30,	
	2011	2010
Deferred tax liabilities:		
Unrealized foreign exchange gain	\$ (13)	\$ (46)
Prepaid expenses	(28)	—
Total deferred tax liabilities	<u>(41)</u>	<u>(46)</u>
Deferred tax assets:		
Tax carried forward losses	32,529	24,230
Share-based payments	908	627
Unrealized foreign exchange loss	193	89
Consultant and other accruals	26	218
Fixed and intangible assets	3,311	—
Derivative	183	—
Compensation accruals	104	—
Investment in subsidiary	26,422	—
Total deferred tax assets	<u>63,676</u>	<u>25,164</u>
Valuation allowance for deferred tax assets	<u>(63,635)</u>	<u>(25,118)</u>
Net deferred tax assets and liabilities	<u>\$ —</u>	<u>\$ —</u>

Management evaluates the recoverability of the deferred tax asset and the amount of the required valuation allowance. Due to the uncertainty surrounding the realization of the tax deductions in future tax returns, the Company has recorded a valuation allowance against its net deferred tax assets at June 30, 2011 and 2010. 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 would be reduced.

There was no benefit from income taxes recorded for the period from December 1, 2000 (inception) to June 30, 2011 due to the Company's inability to recognize the benefit of net operating losses. The Company had federal and state net operating loss carry forwards of approximately \$6,904,000 and \$4,630,000 at June 30, 2011. The federal and state net operating losses will begin to expire in 2022 and 2031, respectively. Foreign tax losses of approximately \$99,707,000 at June 30, 2011, may be carried forward indefinitely.

The Company's ability to utilize its net operating loss carry-forwards may be substantially limited due to ownership changes that have occurred or that could occur in the future under Section 382 of the Internal Revenue Code and similar state and foreign laws. The Company has not completed a study to determine whether one or more ownership changes have occurred.

[Table of Contents](#)

The Company did not previously record a deferred tax asset for any basis difference in its subsidiary because the Company intended to permanently reinvest any subsidiary earnings. However, in the year ended June 30, 2011, the Company determined that it may wind up its subsidiary. As such, the Company recorded a deferred tax asset for this difference. If the Company winds up its subsidiary, its foreign tax losses would not be available for future use.

None of the Company's prior income tax returns has been selected for examination by a major taxing jurisdiction; however, the statutes of limitations for various filings remain open. The oldest filings subject to potential examination for federal, state, and foreign purposes are 2008, 2010, and 2007, respectively. The Company has not reduced any tax benefit on its financial statements due to uncertain tax positions at June 30, 2011 and it is not aware of any circumstance that would significantly change this result through the end of 2012. To the extent the Company incurs income-tax related penalties or interest, the Company recognizes them as additional income tax expense.

Note 10. Selected Quarterly Financial Information (Unaudited)

The following table presents the Company's unaudited quarterly results of operations for the years ended June 30, 2011 and 2010 (in thousands, except per share data).

	Quarter Ended				Year Ended June 30, 2011
	June 30, 2011	March 31, 2011	December 31, 2010	September 30, 2010	
Net loss arising during development stage	\$ (1,642)	\$ (1,312)	\$ (2,068)	\$ (1,759)	\$ (6,781)
Basic and diluted loss per share	\$ (0.19)	\$ (0.18)	\$ (0.28)	\$ (0.24)	\$ (0.89)

	Quarter Ended				Year Ended June 30, 2010
	June 30, 2010	March 31, 2010	December 31, 2009	September 30, 2009	
Net loss arising during development stage	\$ (1,841)	\$ (2,213)	\$ (1,433)	\$ (2,408)	\$ (7,895)
Basic and diluted loss per share	\$ (0.24)	\$ (0.30)	\$ (0.20)	\$ (0.33)	\$ (1.07)

Note 11. Subsequent Events

As discussed in Note 5, in July and August 2011, the Company issued 1,294,000 common shares and received proceeds of \$1,270,000 as a result of the exercise of Series B warrants which had been issued as part of the May 2011 private placement. In accordance with the terms of the Series A warrants, the exercise of the Series B warrants increased the aggregate amount of shares for which the Series A warrants are exercisable from 626,413 to 1,596,913.

On September 27, 2011, the Company entered into a Securities Subscription Agreement with Novogen, pursuant to which Novogen agreed to purchase 1,333,333 shares of common stock for \$1.50 per share, which was the consolidated closing bid price of the Company's common stock as quoted by the Nasdaq Stock Market's Market Intelligence Desk on September 27, 2011.

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

None.

Item 9A. Controls and Procedures

(a) Disclosure Controls and Procedures

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

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

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

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

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

Management assessed the effectiveness of the Company's internal control over financial reporting as of June 30, 2011, based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework. Based on this assessment, management believes that the Company's internal control over financial reporting is effective as of June 30, 2011.

During the year, the Company's accounting function was moved from Australia to the United States. Controls were revised to adapt to the new functions in the United States. There were no changes in internal control over financial reporting during the most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Item 9B. Other Information

Not applicable.

PART III

Item 10. Directors and Executive Officers of the Registrant

Code of Ethics

We have adopted a Code of Business and Ethics policy that applies to our directors and employees (including our principal executive officer and our principal financial officer), and have posted the text of our policy on our website (www.marshalledwardsinc.com). In addition, we intend to promptly disclose (i) the nature of any amendment to the policy that applies to our principal executive officer and principal financial officer and (ii) the nature of any waiver, including an implicit waiver, from a provision of the policy that is granted to one of these specified individuals, the name of such person who is granted the waiver and the date of the waiver on our website in the future.

The other information required by this item is incorporated herein by reference to our proxy statement for the fiscal year ended June 30, 2011 (the "Proxy Statement").

Item 11. Executive Compensation

The information required by this item is incorporated herein by reference to the Proxy Statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this item is incorporated herein by reference to the Proxy Statement.

Item 13. Certain Relationships and Related Transactions

The information required by this item is incorporated herein by reference to the Proxy Statement.

Item 14. Principal Accountant Fees and Services.

The information required by this item is incorporated herein by reference to the Proxy Statement.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) 1. Financial Statements

Reference is made to the Financial Statements under Item 8 in Part II hereof.

2. Financial Statement Schedules

The Financial Statement Schedules have been omitted either because they are not required or because the information has been included in the financial statements or the notes thereto included in this Annual Report on Form 10-K.

3. Exhibits

Exhibit Index

3.1	Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to Registrant's Registration Statement on Form S-1 filed on September 25, 2003 (Reg. No. 333-109129)).
3.2	Certificate of Amendment to the Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1.1 to Registrant's Current Report on Form 8-K filed on March 31, 2010 (File No. 000-50484)).
3.3	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to Registrant's Current Report on Form 8-K filed on July 30, 2007 (File No. 000-50484)).
3.4	Certificate of Designation of Series A Convertible Preferred Stock of Marshall Edwards, Inc. (incorporated by reference to Exhibit 3.1 to Registrant's Current Report on Form 8-K filed on May 11, 2011 (File No. 000-50484)).
3.5	Certificate of Designation of Series B Preferred Stock of Marshall Edwards, Inc. (incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K filed on March 18, 2011 (File No. 000-50484)).
4.1	Specimen Stock Certificate (incorporated by reference to Exhibit 4.1 to Amendment No. 1 to Registrant's Registration Statement on Form S-1 filed on October 31, 2003 (Reg. No. 333-109129)).
4.2	Specimen Warrant Certificate (incorporated by reference to Exhibit 4.2 to Registrant's Registration Statement on Form S-3 filed on August 9, 2006 (Reg. No. 333-136440)).
4.3	Specimen Warrant Certificate (incorporated by reference to Exhibit 4.4 to Registrant's Annual Report on Form 10-K filed on September 27, 2007 (File No. 000-50484)).
4.4	Form of Warrant Agreement (incorporated by reference to Exhibit 10.3 to Registrant's Current Report on Form 8-K filed on July 12, 2006 (File No. 000-50484)).
4.5	Warrant Agreement (incorporated by reference to Exhibit 10.3 to Registrant's Current Report on Form 8-K filed on August 6, 2007 (File No. 000-50484)).
4.6	Amended and Restated Warrant Agreement (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K/A filed on September 27, 2007 (File No. 000-50484)).
4.7	Form of Warrant (incorporated by reference to Exhibit 10.4 to Registrant's Current Report on Form 8-K filed on July 12, 2006 (File No. 000-50484)).
4.8	Form of Warrant (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K filed on August 6, 2007 (File No. 000-50484)).
4.9	Form of Warrant (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K/A filed on September 27, 2007 (File No. 000-50484)).

Table of Contents

- 4.10 Warrant dated July 30, 2008 issued to Mr John O'Connor (incorporated by reference to Exhibit 4.1 to Registrant's Current Report on Form 8-K filed on July 30, 2008 (File No. 000-50484)).
- 4.11 Form of Series A and Series B Warrants (incorporated by reference to Exhibits 10.5 and 10.6 to Registrant's Current Report on Form 8-K filed on May 16, 2011 (File No. 000-50484)).
- 10.1 Employment letter dated April 23, 2010, between Marshall Edwards, Inc. and Daniel Gold (incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K filed on April 26, 2010 (File No. 000-50484)).
- 10.2 Employment letter dated June 18, 2010, between Marshall Edwards, Inc. and Thomas Zech (incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K filed on June 23, 2010 (File No. 000-50484)).
- 10.3 Employment letter dated June 1, 2011, between Marshall Edwards, Inc. and Robert D. Mass (incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K filed on June 2, 2011 (File No. 000-50484)).
- 10.4 Amended and Restated License Agreement between Novogen Research Pty Limited and Marshall Edwards Pty Limited (incorporated by reference to Exhibit 10.1 to Registrant's Registration Statement on Form S-1 filed on September 25, 2003 (Reg. No. 333-109129)).
- 10.5 Amended and Restated Manufacturing License and Supply Agreement between Novogen Laboratories Pty Limited and Marshall Edwards Pty Limited (incorporated by reference to Exhibit 10.2 to Registrant's Registration Statement on Form S-1 filed on September 25, 2003 (Reg. No. 333-109129)).
- 10.6 Amended and Restated License Option Deed between Novogen Research Pty Limited and Marshall Edwards Pty Limited (incorporated by reference to Exhibit 10.3 to Registrant's Registration Statement on Form S-1 filed on September 25, 2003 (Reg. No. 333-109129)).
- 10.7 Amended and Restated Services Agreement among Novogen Limited, Marshall Edwards, Inc. and Marshall Edwards Pty Limited (incorporated by reference to Exhibit 10.4 to Registrant's Registration Statement on Form S-1 filed on September 25, 2003 (Reg. No. 333-109129)).
- 10.8 Guarantee and Indemnity among Marshall Edwards, Inc., Novogen Laboratories Pty Limited, Novogen Research Pty Limited and Novogen Limited (incorporated by reference to Exhibit 10.5 to Registrant's Registration Statement on Form S-1 filed on September 25, 2003 (Reg. No. 333-109129)).
- 10.9 License Agreement between Novogen Research Pty Limited and Marshall Edwards Pty Limited (incorporated by reference to Exhibit 99.1 to Registrant's Current Report on Form 8-K filed on May 16, 2006 (File No. 000-50484)).
- 10.10 Amendment Deed between Novogen Research Pty Limited and Marshall Edwards Pty Limited (incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K filed on June 9, 2006 (File No. 000-50484)).
- 10.11 Registration Rights Agreement, dated July 11, 2006 by and among Marshall Edwards, Inc. and the investors signatory thereto (incorporated by reference to Exhibit 10.2 to Registrant's Current Report on Form 8-K filed on July 12, 2006 (File No. 000-50484)).
- 10.12 Registration Rights Agreement, dated as of August 6, 2007 by and among Marshall Edwards, Inc. and the purchasers signatory thereto (incorporated by reference to Exhibit 10.2 to Registrant's Current Report on Form 8-K filed on August 6, 2007 (File No. 000-50484)).
- 10.13 Registration Rights Agreement, dated as of September 26, 2007 by and among Marshall Edwards, Inc. and Blue Trading, LLC (incorporated by reference to Exhibit 10.2 to Registrant's Current Report on Form 8-K/A filed on September 27, 2007 (File No. 000-50484)).

Table of Contents

- 10.14 Amended & Restated Registration Rights Agreement, dated as of May 16, 2011, between Marshall Edwards, Inc. and certain investors signatory thereto (incorporated by reference to Exhibit 10.2 to Registrant's Current Report on Form 8-K filed on May 16, 2011 (File No. 000-50484)).
- 10.15 Securities Subscription Agreement dated as of July 28, 2008 by and among Marshall Edwards, Inc., Novogen Limited and Oppenheimer Funds, Inc. (incorporated by reference to Exhibit 10.13 to Registrant's Current Report on Form 8-K filed on July 30, 2008 (File No. 000-50484)).
- 10.16 Marshall Edwards, Inc. 2008 Stock Omnibus Equity Compensation Plan (incorporated by reference to Exhibit 4.1 to Registrant's Registration Statement on Form S-8 filed on January 28, 2009 (Reg No. 333-156985)).
- 10.17 License Agreement dated August 4, 2009 by and between Novogen Research Pty Limited and Marshall Edwards Pty Limited (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on August 7, 2009 (File No. 000-50484)).
- 10.18 Asset Purchase Agreement, dated as of December 21, 2010, between Marshall Edwards, Inc. and Novogen Limited and Novogen Pty Limited (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on December 22, 2010 (File No. 000-50484)).
- 10.19 At Market Issuance Sales Agreement, dated February 7, 2011, between Marshall Edwards, Inc. and McNicoll, Lewis & Vlax LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on February 7, 2011 (File No. 000-50484)).
- 10.20 Stock Purchase Agreement, dated March 17, 2011, between Marshall Edwards, Inc. and Ironridge Global IV, Ltd., including the form of Certificate of Designations of Preferences, Rights and Limitations of Series B Preferred Stock attached as Exhibit 4 thereto (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on March 18, 2011 (File No. 000-50484)).
- 10.21 Amended and Restated Securities Purchase Agreement, dated as of May 16, 2011, between Marshall Edwards, Inc. and the investors signatory thereto (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on May 16, 2011 (File No. 000-50484)).
- 10.22 Amended and Restated Voting Agreement between Marshall Edwards, Inc. and Novogen Limited (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on May 16, 2011 (File No. 000-50484)).
- 10.23 Form of Indemnification Agreement (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on August 29, 2011 (File No. 000-50484)).
- 21.1 Subsidiaries of Marshall Edwards, Inc. (incorporated by reference to Exhibit 21 to Registrant's Registration Statement on Form S-1 filed on September 25, 2003 (Reg. No. 333-109129)).
- 23.1 Consent of BDO USA LLP*
- 23.2 Consent of BDO Audit (NSW - VIC) Pty Ltd*
- 31.1 Certification required by Rule 13a-14(a) or Rule 15d-14(a)*
- 31.2 Certification required by Rule 13a-14(a) or Rule 15d-14(a)*
- 32.1 Certification required by Rule 13a-14(b) or Rule 15d-14(b) and section 1350 of Chapter 63 of Title 18 of the U.S. Code (18 U.S.C. 1350)*

(*)Filed herewith.

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Marshall Edwards, Inc.
San Diego, California

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (File Nos. 333-174789, 333-173266, 333-146453 and 333-136440) and the Registration Statements on Form S-8 (File Nos. 333-174790, 333-169719, and 333-156985) of Marshall Edwards, Inc. (the "Company") of our report dated September 21, 2011, relating to the consolidated financial statements, which appears in the Annual Report on Form 10-K.

/s/ BDO USA, LLP
San Diego, California
September 28, 2011

Consent of Independent Registered Public Accounting Firm

Marshall Edwards, Inc.
11975 El Camino Real, Suite 101
SAN DIEGO, CA 92130
UNITED STATES OF AMERICA

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (File Nos. 333-174789, 333-173266, 333-146453, 333-149807 and 333-136440) and Form S-8 (File Nos. 333-174790, 333-169719, and 333-156985) of Marshall Edwards, Inc. of our report dated August 26, 2010, relating to the consolidated financial statements, which appears in this Form 10-K.

/s/ BDO Audit (NSW-VIC) Pty Limited

Sydney, NSW, Australia

September 28, 2011

CERTIFICATION

I, Daniel Gold, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended June 30, 2011 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) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) 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
 - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: September 28, 2011

/s/ Daniel Gold

Daniel Gold
Chief Executive Officer

CERTIFICATION

I, Thomas Zech, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended June 30, 2011 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) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) 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
 - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The Company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: September 28, 2011

/s/ Thomas Zech

Thomas Zech
Chief Financial Officer

CERTIFICATION

Each of the undersigned hereby certifies, for the purposes of Section 1350 of Chapter 63 of Title 18 of the U.S. Code, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, in his capacity as an officer of Marshall Edwards, Inc. ("Marshall Edwards") that, to his knowledge, this Annual Report on Form 10-K of Marshall Edwards for the year ended June 30, 2011, fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended, and that the information contained in such report fairly presents, in all material respects, the financial condition and results of operations of Marshall Edwards.

Date: September 28, 2011

/s/ Daniel Gold

Daniel Gold
Chief Executive Officer

/s/ Thomas Zech

Thomas Zech
Chief Financial Officer

A signed original of this written statement required by Section 906 has been provided to Marshall Edwards and will be retained by Marshall Edwards and furnished to the Securities and Exchange Commission or its staff upon request.