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

# **FORM 8-K**

**CURRENT REPORT** Pursuant to Section 13 or 15(d) of the **Securities Exchange Act of 1934** 

Date of Report (Date of earliest event reported): April 3, 2007

# Marshall Edwards, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of

000-50484 (Commission File Number)

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

incorporation or organization)

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

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

Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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#### Item 1.01. Entry into a Material Definitive Agreement.

On April 3, 2007, Marshall Edwards Pty Limited ("MEPL"), a wholly owned subsidiary of Marshall Edwards, Inc. (the "Company"), and Novogen Research Pty Limited ("Novogen Research"), a wholly owned subsidiary of Novogen Limited, entered into an amendment deed (the "Amendment") to the Further Amended and Restated License Agreement, dated September 24, 2003 (the "License Agreement"), between MEPL and Novogen Research.

Pursuant to the Amendment, the U.S. \$8,000,000 milestone payment due from MEPL on December 31, 2007 will become payable to Novogen Research at such time as MEPL receives: (i) approval by the U.S. Food and Drug Administration of a new drug application for phenoxodiol; (ii) approval or authorization of any kind to market phenoxodiol in the United States; or (iii) approval of a foreign governmental body to market phenoxodiol abroad (the "Approval Date"). Upon the Approval Date, MEPL will be required to pay Novogen Research U.S. \$8,000,000, together with interest on such amount from (and including) December 31, 2006 to (but excluding) the Approval Date. Thereafter, MEPL will be required to make license milestone fee payments of U.S. \$8,000,000 to Novogen Research on December 31st of the year of the Approval Date and on December 31st of each year during the exclusivity period under the License Agreement.

Pursuant to the License Agreement, Novogen Research granted MEPL an exclusive world-wide, non-transferable license, under the Novogen patent rights, to conduct clinical trials and commercialize and distribute all forms of administering phenoxodiol except topical applications. The License Agreement covers uses of phenoxodiol in the field of prevention, treatment and cure of cancer in humans. The Amendment does not change the term of the License Agreement which remains in effect until terminated by either Novogen Research or MEPL.

The terms of the Amendment were established through arms-length negotiations between the independent members of the board of directors of Novogen Limited and the independent members of the Company's board of directors. The Amendment was approved by the Company's Audit Committee, as contemplated by the rules of the Nasdaq Stock Market for related party transactions, as well as by the Company's board of directors. The Amendment was also approved by MEPL's board of directors. A majority of the members of the Company's board of directors are independent in accordance with the Nasdaq Stock Market's listing requirements.

The foregoing description of the Amendment does not purport to be complete and is qualified in its entirety by reference to the full text of the Amendment filed as Exhibit 10.1 hereto, and is incorporated herein by reference.

#### Item 9.01. Financial Statements and Exhibits.

(c) <u>Exhibits</u> .	
Exhibit No.	Description
10.1	Amendment Deed, dated April 3, 2007, by and between Novogen Research Party Limited and Marshall Edwards Pty Limited.
99.1	Press Release issued by Marshall Edwards, Inc., dated as of April 4, 2007

Signature

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MARSHALL EDWARDS, INC.

By: /s/ David R. Seaton

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

Dated: April 5, 2007

# Index to Exhibits

Exhibit No.	Description
10.1	Amendment Deed, dated April 3, 2007, by and between Novogen Research Party Limited and Marshall Edwards Pty Limited.
99.1	Press Release issued by Marshall Edwards, Inc., dated as of April 4, 2007.

Exhibit 10.1

# BLAKE DAWSON WALDRON

LAWYERS

# **Amendment Deed**

Novogen Research Pty Limited ABN 87 060 202 931

Marshall Edwards Pty Limited ABN 36 099 665 675

 Level 36
 Kerel 36

 Grosvenor Place
 Kerel 325

 225 George Street
 Kerel 32

 Sydney NSW 2000
 Kerel 32

 Telephone: +61 2 9258 6000
 Srd April 2007

 Fax: + 61 2 9258 6999
 Ref: BLM FZD 02 1372 3369

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#### AMENDMENT DEED

#### DATE 3rd April 2007

#### PARTIES

Novogen Research Pty Limited ABN 87 060 202 931 of 140 Wicks Road, North Ryde NSW 2113 Australia (Novogen Research)

Marshall Edwards Pty Limited ABN 36 099 665 675 of 140 Wicks Road, North Ryde NSW 2113 Australia (MEPL)

#### RECITALS

A. The parties are parties to the Licence Agreement.

B. The parties wish to amend the Licence Agreement on the terms of this document.

#### **OPERATIVE PROVISIONS**

#### 1. INTERPRETATION

#### 1.1 **Definitions**

The following definitions apply in this document.

Effective Date means the date this document is executed by the last of the parties to execute it.

**Licence Agreement** means the agreement entitled "Amended and Restated Licence Agreement" between Novogen Research and MEPL dated 24 September 2003, as further amended by an Amendment Deed between the parties dated 6 June 2006.

#### 1.2 Terms defined in the Licence Agreement

Terms that are not defined in clause 1.1 and that are defined in the Licence Agreement (as amended by this document) have the same meaning in this document.

#### 1.3 Rules for interpreting this document

Headings are for convenience only, and do not affect interpretation. The following rules also apply in interpreting this document, except where the context makes it clear that a rule is not intended to apply.

(a) A reference to:

(i) legislation (including subordinate legislation) is to that legislation as amended, re-enacted or replaced, and includes any subordinate legislation issued under it;

- (ii) a document or agreement, or a provision of a document or agreement, is to that document, agreement or provision as amended, supplemented, replaced or novated;
- (iii) a party to this document or to any other document or agreement includes a permitted substitute or a permitted assign of that party;
- (iv) a person includes any type of entity or body of persons, whether or not it is incorporated or has a separate legal identity, and any executor, administrator or successor in law of the person; and
- (v) anything (including a right, obligation or concept) includes each part of it.
- (b) A singular word includes the plural, and vice versa.
- (c) A word which suggests one gender includes the other genders.
- (d) If a word is defined, another part of speech has a corresponding meaning.
- (e) If an example is given of anything (including a right, obligation or concept), such as by saying it includes something else, the example does not limit the scope of that thing.
- (f) The word **agreement** includes an undertaking or other binding arrangement or understanding, whether or not in writing.

#### 2. CONSIDERATION

Each party acknowledges that it has received valuable consideration for entering into this document.

#### 3. AMENDMENT

- (a) The Licence Agreement is amended, with effect on the Effective Date, as attached in Annexure A.
- (b) Subject to paragraph (c), paragraph (a) does not affect any right or obligation that arises before the Effective Date.
- (c) The amendments in paragraph (a) are deemed to have taken effect on and from the date the Licence Agreement was executed by the last of the parties to execute it.

## 4. REPRESENTATIONS AND WARRANTIES

#### 4.1 Representations and warranties

Each party represents and warrants that:

- (a) (status) it is a company limited by shares under the Corporations Act;
- (b) (**power**) it has full legal capacity and power:

- (i) to own its property and assets and to carry on its business; and
- (ii) to enter into this document and to carry out the transactions that it contemplates;
- (c) (corporate authority) it has taken all corporate action that is necessary or desirable to authorise its entry into this document and its carrying out the transactions that it contemplates;
- (d) (Authorisations) it holds each Authorisation that is necessary or desirable to:
  - (i) execute this document and to carry out the transactions that it contemplates; and
  - (ii) ensure that this document is legal, valid, binding and admissible in evidence,

and it is complying with any conditions to which any of these Authorisations is subject;

- (e) (document effective) this document constitutes its legal, valid and binding obligations, enforceable against it in accordance with its terms (except to the extent limited by equitable principles and laws affecting creditors' rights generally), subject to any necessary stamping or registration;
- (f) (no contravention) neither its execution of this document, nor the carrying out by it of the transactions that it contemplates, does or will:
  - (i) contravene any law to which it or any of its property is subject or any order of any Government Agency that is binding on it or any of its property;
  - (ii) contravene any Authorisation;
  - (iii) contravene any undertaking or instrument binding on it or any of its property; or
  - (iv) contravene its constitution; and
- (g) (no trust) it is not entering into this document as trustee of any trust or settlement.

#### 4.2 Reliance on representations and warranties

Each party acknowledges that the other party has executed this document and agreed to take part in the transactions that it contemplates in reliance on the representations and warranties that are made or repeated in this clause.

#### 5. GENERAL

#### 5.1 Governing law

This document is governed by the law in force in New South Wales.

#### 5.2 Liability for expenses

Each party must pay its own expenses incurred in negotiating, executing, stamping and registering this document.

#### 5.3 Giving effect to this document

Each party must do anything (including execute any document), and must ensure that its employees and agents do anything (including execute any document), that the other party may reasonably require to give full effect to this document.

#### 5.4 Amendment

This document can only be amended, supplemented, replaced or novated by another document signed by the parties.

#### 5.5 Counterparts

This document may be executed in counterparts.

EXECUTED as a deed.

#### EXECUTED by NOVOGEN **RESEARCH PTY LIMITED:**

/s/ Christopher Naughton Signature of director

Christopher Naughton

Name

#### **EXECUTED** by MARSHALL EDWARDS PTY LIMITED:

/s/ Christopher Naughton Signature of director

Christopher Naughton

Name

/s/ Ronald Lea Erratt Signature of director/secretary

Ronald Lea Erratt Name

/s/ David Ross Seaton Signature of director/secretary

David Ross Seaton Name

# BLAKE DAWSON WALDRON

LAWYERS

ANNEXURE A

# Further Amended and Restated Licence Agreement

Novogen Research Pty Limited ABN 87 060 202 931

Marshall Edwards Pty Limited ABN 36 099 665 675

Level 41 225 George Street Sydney NSW 2000 Telephone: +61 2 9258 6000 Fax: +61 2 9258 6999

24 September 2003 Ref: SJD.BLM.02-1308-9508

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#### FURTHER AMENDED AND RESTATED LICENCE AGREEMENT

DATE 24 September 2003

#### PARTIES

Novogen Research Pty Limited ABN 87 060 202 931 ("Novogen Research")

Marshall Edwards Pty Limited ABN 36 099 665 675 ("MEPL")

#### RECITALS

- A. Novogen Research is the proprietor of certain patents, the applicant for certain patent applications and the owner of certain know how relating to:
  - (a) a method of preparation of the compound known as "phenoxodiol"; and
  - (b) agents comprising phenoxodiol and compositions containing it and its use as a human therapeutic treatment.
- B. MEPL wishes to conduct clinical trials relating to the use of phenoxodiol and to exploit phenoxodiol throughout the world for certain human therapeutic uses.
- C. In May 2002 Novogen Research agreed to grant to MEPL a licence to conduct clinical trials and to exploit phenoxodiol on terms and conditions set out in a licence agreement between the parties (the "**Original Licence Agreement**").
- D. The parties have agreed to amend and restate the terms of the Original Licence Agreement as set out in this document with effect from the date of this document.

# **OPERATIVE PROVISIONS**

### 1. INTERPRETATION

#### 1.1 **Definitions**

The following definitions apply in this document.

"Affiliate" means:

- (a) in relation to a body corporate, each of:
  - (i) that body's related bodies corporate;
  - (ii) that body's directors; and
  - (iii) the persons who have a substantial holding (as that term is defined in the Corporations Act) in that body; and
- (b) in relation to a natural person, any:
  - (i) spouse;

- (ii) relative by blood or adoption of that person or that person's spouse; and
- (iii) body corporate in which that person and Affiliates of that person hold in aggregate more than 20% of the voting shares.

"Authorisation" means:

- (a) an authorisation, consent, declaration, exemption, notarisation or waiver, however it is described; and
- (b) in relation to anything that could be prohibited or restricted by law if a Government Agency acts in any way within a specified period, the expiry of that period without that action being taken,

including any renewal or amendment.

"**Bank Bill**" means a bill of exchange (as defined in the *Bills of Exchange Act 1909* (Cth)) that has been accepted by a bank authorised under a law of the Commonwealth or any state to carry on banking business.

"Bank Bill Rate" means, for a period:

- (a) the average, expressed as a yield per cent per annum (rounded up (if necessary) to 4 decimal places) of all rates quoted on each day in the period as the 180 day bank-accepted bill rate on the web site of the Reserve Bank of Australia at www.rba.gov.au (or any web site that replaces that web site); or
- (b) if no rate can be calculated under paragraph (a), the bid rate available to MEPL at about 11.00 am (Sydney time) on that day, as conclusively determined in good faith by MEPL, for Bank Bills that have the tenor described in paragraph (a).

"Business Day" means a day that is not a Saturday, Sunday or public holiday in Sydney, Australia.

"Change of Control" of MEPL means a change in:

- (a) Control of the composition of the board of directors of the corporation;
- (b) Control of more than half the voting rights attaching to shares in the corporation; or
- (c) Control of more than half the issued shares of the corporation (not counting any share which carries no right to participate beyond a specified amount in the distribution of either profit or capital),

which, for the avoidance of doubt, does not include a change in:

- (d) Control of the composition of the board of directors of Novogen Limited;
- (e) Control of more than half the voting rights attaching to shares in Novogen Limited; or

(f) Control of more than half the issued shares of Novogen Limited (not counting any share which carries no right to participate beyond a specified amount in the distribution of either profit or capital).

"Clinical Trial" means a clinical evaluation of the stability, tolerability, synergy or efficacy of a Product for use in the Field.

"Clinical Trial Materials" means all medication, Trial Protocols, results of Clinical Trials, case report forms, study aids, and any other materials used in, or arising out of, the conduct of Clinical Trials.

"Clinical Trial Subject" means a person who is enrolled in a Clinical Trial, whether or not that person meets all eligibility criteria for enrolment into the Clinical Trial set out in any Trial Protocol or otherwise.

"Commencement Date" means the date the Original Licence Agreement was executed by the last of the parties to execute it.

"**Commercialisation Income**" means all gross income received by or on behalf of MEPL or its related bodies corporate (other than Novogen Research and Novogen Laboratories) as a result of or in connection with any assignment, sublicensing, or other dealing with MEPL's rights under this document, other than income received solely in consideration of the sale, hiring or other disposal of Product.

"Commonwealth" means the Commonwealth of Australia.

"Confidential Information" means:

- (a) in relation to Novogen Research, the Clinical Trial Materials, the Licensed Know How, all Novogen Developments and MEPL Developments, all documents, records and reports relating to the Licensed Intellectual Property or Products, which are provided by MEPL under this document and all other written or oral information disclosed by Novogen Research to MEPL under this document, other than information which MEPL can establish:
  - (i) was in the public domain when it was given to MEPL;
  - (ii) becomes, after being given to MEPL, part of the public domain, except through disclosure contrary to this document; or
  - (iii) was lawfully received by MEPL from another person having the unrestricted legal right to disclose that information without requiring the maintenance of confidentiality; and
- (b) in relation to MEPL, all written or oral information disclosed by MEPL to Novogen Research under this document, other than information referred to in paragraph (a) and information which Novogen Research can establish:
  - (i) was in the public domain when it was given to it;

- (ii) becomes, after being given to it, part of the public domain, except through disclosure contrary to this document; or
- (iii) was lawfully received by it from another person having the unrestricted legal right to disclose that information without requiring the maintenance of confidentiality.

"**Control**" means a power or control that is direct or indirect or that is, or can be, exercised as a result of, by means of or by the revocation or breach of a trust, an agreement, a practice, or any combination of them, whether or not they are enforceable. It does not matter whether the power or control is express or implied, formal or informal, exercisable alone or jointly with someone else.

"Corporations Act" means the Corporations Act 2001 (Cth).

"Deed of Acknowledgment and Undertaking" means the document so entitled to be entered into between Novogen Limited and the Industry Research and Development Board for and on behalf of the Commonwealth.

"**Default Rate**" means, in relation to an amount which has not been paid to a party, a rate equal to the sum of that party's cost of funding the amount (if that party were to borrow that amount and as determined conclusively by that party) and 2% per annum.

"Disclosing Party" in relation to any information means the party who disclosed to another party that information.

"Dispute" has the meaning given to that term in clause 20.1.

"Dispute Notice" has the meaning given to that term in clause 20.2.

"Encumbrance" means a mortgage, charge, pledge, lien, hypothecation or title retention arrangement, a right of set-off or right to withhold payment of a deposit or other money, a notice under section 255 of the *Income Tax Assessment Act 1936* (Cth), section 260-5 in schedule 1 to the *Taxation Administration Act 1953* (Cth) or any similar legislation, or an easement, restrictive covenant, caveat or similar restriction over property, or an agreement to create any of them or to allow any of them to exist.

"Exclusivity Period" means the period commencing on the Commencement Date and ending the later of:

- (a) the date of expiration or lapsing of the last Patent Right in the patents and patent applications set out in schedule 1 and 2; or
- (b) the date of expiration or lapsing of the last Licensed Patent Right which MEPL would, but for the licence granted in clause 2.1, infringe in any country in the Territory by doing in that country any of the things set out in clause 2.1.

"FDA Approval" means the approval by the Food and Drug Administration of the United States of an investigational new drug (IND) application for a Product to commence phase 1 Clinical Trials in the United States.

"**Field**" means the prevention, treatment or cure of cancer in humans by pharmaceuticals delivered or administered by injection or by any other means but excluding topical applications. For the avoidance of doubt, "non-topical applications" shall be any means of administration other than to the skin.

"Fixed and Floating Charge" means the document entitled "Deed of Fixed and Floating Charge" between Novogen Research and St George Bank Limited dated 30 June 1997.

"Force Majeure Event" means any occurrence or omission as a direct or indirect result of which the party relying on it is prevented from or delayed in performing any of its obligations (other than a payment obligation) under this document and that is beyond the reasonable control of that party, including forces of nature, industrial action and action or inaction by a Government Agency.

"Government Agency" means:

- (a) a government or government department or other body;
- (b) a governmental, semi-governmental or judicial person; or
- (c) a person (whether autonomous or not) who is charged with the administration of a law.

#### "GST" means:

- (a) the same as in the GST Law; and
- (b) any other goods and services tax, or any tax applying to this transaction in a similar way; and
- (c) any additional tax, penalty tax, fine, interest or other charge under a law for such a tax.

"GST Law" means the same as "GST law" means in A New Tax System (Goods and Services Tax) Act 1999 (Cth).

"**Insolvency Event**" means, for a person, being in liquidation or provisional liquidation or under administration, having a controller (as defined in the Corporations Act) or analogous person appointed to it or any of its property, being taken under section 459F(1) of the Corporations Act to have failed to comply with a statutory demand, being unable to pay its debts or otherwise insolvent, dying, ceasing to be of full legal capacity or otherwise becoming incapable of managing its own affairs for any reason, taking any step that could result in the person becoming an insolvent under administration (as defined in section 9 of the Corporations Act), entering into a compromise or arrangement with, or assignment for the benefit of, any of its members or creditors, or any analogous event, otherwise than in the course of a reorganisation, reconstruction, amalgamation or merger.

"**Intellectual Property Rights**" means any and all existing and future intellectual and industrial property rights throughout the world, whether conferred by statute, common law or equity, including rights in relation to copyright, trade marks, designs, circuit layouts, plant varieties, business and domain names, trade secrets and Know How (including the

right to apply for registration of any such rights), Patent Rights and other results of intellectual activity in the industrial, commercial, scientific, literary or artistic fields.

"Know How" means technical and other information which is not in the public domain including inventions, discoveries, concepts, data, formulae, ideas, specifications, procedures for experiments and tests, results of experimentation and testing, results of research and development and information in laboratory records, data collected during the course of Clinical Trials, case reports, data analyses and summaries and submissions to and information from ethical committees and regulatory authorities.

"Licensed Intellectual Property" means the Licensed Patent Rights and the Intellectual Property Rights in the Licensed Know How.

"Licensed Know How" means the Manufacturing Know How, all existing Know How of Novogen Research in relation to Products and its uses in the Field and all Know How in Clinical Trial Materials, Novogen Developments and MEPL Developments.

"Licensed Patent Rights" means the Product Patent Rights, the Manufacturing Patent Rights and all Patent Rights in any Novogen Developments and MEPL Developments.

"Manufacturing Know How" means all existing Know How of Novogen Research in relation to the synthesis and manufacture of Products.

"Manufacturing Licence and Supply Agreement" means the agreement of that title between MEPL and Novogen Laboratories dated on or about the date of this document.

"Manufacturing Patent Rights" means all Patent Rights in the patents and patent applications set out in schedule 2.

"MEPL Developments" means all developments, improvements, enhancements, adaptations and new Know How, whether patentable or otherwise, in relation to the Product or the Licensed Intellectual Property, which during the Term are made or acquired by MEPL, its employees, agents or contractors.

#### "Milestone Licence Fee" means:

- (a) for the calender year ending 31 December 2003: US\$1,000,000;
- (b) for the calender year ending 31 December 2004: US\$2,000,000;
- (c) for the calender year ending 31 December 2005: US\$4,000,000; and
- (d) upon the receipt by MEPL of the first:
  - (i) approval by the FDA of a New Drug Application (NDA) for a Product (on an accelerated basis or otherwise);
  - (ii) approval or authorisation of any kind to market a Product in the United States; or
  - (iii) approval or authorisation of any kind by a Government Agency in any other country to market a Product,

(the **Approval Date**): US\$8,000,000, together with interest on that amount from (and including) 31 December 2006 to (but excluding) the Approval Date, at the Bank Bill Rate;

(e) for the calendar year of the year of the Approval Date, and for each calendar year during the Exclusivity Period thereafter: US\$8,000,000,

less any amount payable to Novogen Research during that calendar year under clause 7.1.

"**Net Sales**" in relation to any Product means the gross invoice or contract price of that Product sold, hired or otherwise disposed of by MEPL, its Affiliates (other than Novogen Laboratories) or sub-licensees (which for avoidance of doubt includes sub-licensees via one or more interposing sub-licences, but does not include mere distributors) to the first person who is not its Affiliate or sub-licensee, after deducting (to the extent not already deducted):

(a) trade and quantity discounts; and

(b) returns, rebates and allowances actually taken.

"**Novogen Developments**" means all developments of, improvements to, enhancements to, or adaptations of Products or Licensed Know How, whether patentable or otherwise, in the Field which during the Term are made or acquired by Novogen Research, Novogen Limited or Novogen Laboratories Pty Limited (ABN 42 002 489 947) or their employees, contractors or agents, which Novogen Research is free to license or disclose to MEPL, but does not include any Option Compound or any new isoflavonoid compound having a formula which does not fall within the claims of the Product Patent Rights.

"Novogen Limited" means Novogen Limited ABN 37 063 259 754.

"**Option Compound**" has the meaning given in the document entitled "Amended and Restated Licence Option Deed" between Novogen Research and MEPL dated 24 September 2003.

"**Patent Rights**" means existing and future patents (including any divisions, continuations, continuations in part, renewals, reissues, extensions, supplementary protection certificates, utility models and foreign equivalents thereof) and rights with respect to existing and future patent applications and patentable inventions, including the right to apply for registration of any such rights.

"**Product**" means any product or formulation containing the compound known as "phenoxodiol" (or NV-06) for delivery or administration by injection or by any other means but excluding topical applications, whether in primary manufactured form, final packaged form or otherwise, and whether in combination with any other compound or component, active or otherwise. For the avoidance of doubt, "non-topical applications" shall be any means of administration of the Product other than to the skin.

"Product Patent Rights" means all Patent Rights in the patents and patent applications set out in schedule 1.

"Quarter" means, in respect of any calender year in the Term, the four quarters of that year, the first of which commences on the first day of that year.

"START Grant Agreement" means the agreement entitled "R & D Start Grant Agreement No: STG/00220" between Novogen Limited and the Industry Research and Development Board for and on behalf of the Commonwealth, dated 24 December 1998.

"**Tax**" means a tax, levy, duty, charge, deduction or withholding, however it is described, that is imposed by a Government Agency, together with any related interest, penalty, fine or other charge.

"Term" means the term of this document as determined under clause 19.

"Territory" means the world.

"Trial Protocol" means a protocol for the conduct of a Clinical Trial as may be developed by MEPL from time to time.

#### 1.2 Rules for interpreting this document

Headings are for convenience only, and do not affect interpretation. The following rules also apply in interpreting this document, except where the context makes it clear that a rule is not intended to apply.

- (a) A reference to:
  - (i) legislation (including subordinate legislation) is to that legislation as amended, re-enacted or replaced, and includes any subordinate legislation issued under it;
  - (ii) a document or agreement, or a provision of a document or agreement, is to that document, agreement or provision as amended, supplemented, replaced or novated;
  - (iii) a party to this document or to any other document or agreement includes a permitted substitute or a permitted assign of that party;
  - (iv) a person includes any type of entity or body of persons, whether or not it is incorporated or has a separate legal identity, and any executor, administrator or successor in law of the person; and
  - (v) anything (including a right, obligation or concept) includes each part of it.
- (b) A singular word includes the plural, and vice versa.
- (c) A word which suggests one gender includes the other genders.
- (d) If a word is defined, another part of speech has a corresponding meaning.
- (e) If an example is given of anything (including a right, obligation or concept), such as by saying it includes something else, the example does not limit the scope of that thing.

- (f) The word "agreement" includes an undertaking or other binding arrangement or understanding, whether or not in writing.
- (g) The words "subsidiary", "holding company" and "related body corporate" have the same meanings as in the Corporations Act.
- (h) A reference to "US\$" is to the currency of the United States of America.

#### 1.3 Business Days

If the day on or by which a person must do something under this document is not a Business Day:

- (a) if the act involves a payment that is due on demand, the person must do it on or by the next Business Day; and
- (b) in any other case, the person must do it on or by the previous Business Day.

#### 1.4 Application of this document

- (a) This document varies and amends the Original Licence Agreement with effect from the date of execution of this document.
- (b) The terms and conditions of this document replace the terms and conditions of the Original Licence Agreement.

#### 2. LICENCE TO EXPLOIT THE PRODUCT

#### 2.1 Grant of licence

Novogen Research by this document grants to MEPL for the Term a non-transferable licence under the Licensed Patent Rights and the Intellectual Property Rights in the Licensed Know How to:

- (a) make, have made, sell, hire or otherwise dispose of Products in the Territory for use in the Field;
- (b) offer to make, sell, hire or otherwise dispose of Products in the Territory for use in the Field;
- (c) use and import Products into any country in the Territory for the purpose of exercising its rights under paragraphs (a) and (b);
- (d) use, reproduce, apply, develop, modify and enhance the Licensed Know How in the Field;
- (e) keep Products and the Licensed Know How for the purpose of doing any of the things in paragraphs (a) to (d); and
- (f) use any method or process claimed or disclosed in the Manufacturing Patent Rights or forming part of the Manufacturing Know How for the purpose of exercising its rights under paragraphs (a) to (e).

#### 2.2 Exclusivity

The licence granted in clause 2.1 is:

- (a) exclusive in the Field and in the Territory during the Exclusivity Period; and
- (b) non-exclusive in the Field and in the Territory from the date of expiration of the Exclusivity Period until the end of the Term.

#### 2.3 Expiration of Licensed Patent Rights

If during the Term all Licensed Patent Rights in any country in the Territory lapse or are held invalid, then subject to clause 19.1, the licence granted in clause 2.1 shall continue in full force and effect in that country on the same terms as a licence under the Intellectual Property Rights in the Licensed Know How only.

#### 2.4 Sub-licences

- (a) Subject to paragraphs (b) and (c), MEPL may not grant sub-licences under any of the rights granted to it under this document without the prior written consent of Novogen Research.
- (b) MEPL may grant a sub-licence to Novogen Laboratories on the terms and conditions of the Manufacturing Licence and Supply Agreement.
- (c) Novogen Research must grant its consent to any sub-licence proposed to be granted by MEPL in the circumstances set out in clause 3.9 of the Manufacturing Licence and Supply Agreement provided that sub-licence is in terms substantially consistent with those in the Manufacturing Licence and Supply Agreement.

#### 2.5 Sub-contractors

MEPL may not engage agents or sub-contractors to perform its obligations under this document:

- (a) without the prior written consent of Novogen Research; and
- (b) unless such agents or sub-contractors first agree in writing:
  - (i) to comply with confidentiality obligations substantially identical to those of MEPL under this document; and
  - (ii) to assign to Novogen Research all Intellectual Property Rights in the Field created or acquired by them in the course of their engagement.

#### 3. CLINICAL TRIALS

#### 3.1 Clinical Trials to date

- Novogen Research represents and warrants to MEPL that:
- (a) Novogen Limited has sponsored and funded phase 1 Clinical Trials in Australia;

- (b) Novogen Limited has obtained the FDA Approval; and
- (c) the FDA Approval has not been revoked or amended.

#### 3.2 **Obligation to conduct Clinical Trials**

MEPL shall continue current Clinical Trials and undertake further Clinical Trials on the terms and conditions of this document.

#### 3.3 Conduct of Clinical Trials

MEPL must and must ensure that its agents, contractors and sub-licensees:

- (a) fund or arrange adequate third party funding of Clinical Trials;
- (b) use all reasonable endeavours to design and conduct Clinical Trials to generate outcomes which are calculated to result in regulatory approval of a Product for use in the Field;
- (c) conduct Clinical Trials diligently, in good scientific manner, in compliance with any applicable laws, rules and regulations of any Government Agency in the Territory (including any laws governing the protection and privacy of personal information), in accordance with any Trial Protocol and any other reasonable directions given by Novogen Research from time to time, and consistently with the requirements of any applicable good laboratory practices;
- (d) ensure that all Clinical Trial Materials are handled appropriately and stored securely by MEPL, its employees, contractors and agents for the duration of the Clinical Trials;
- (e) ensure that MEPL's employees, contractors, sub-licensees and agents who are involved in carrying out Clinical Trials fully understand and adhere to any Trial Protocol; and
- (f) take all reasonable measures, in consultation with Novogen Research, to protect Clinical Trial Subjects at risk following a serious adverse drug experience.

## 3.4 Clinical Trial Materials

MEPL shall be solely responsible for providing all Clinical Trial Materials necessary for the conduct of Clinical Trials.

#### 3.5 Facilities and personnel

In order to comply with its obligations under this clause 3, MEPL must, and must ensure that its employees, agents, contractors and sub-licensees use appropriate skill, experience, equipment and facilities.

#### 3.6 Records of Clinical Trials

MEPL must maintain complete and accurate records in good scientific manner, which fully record:

- (a) all work done and results achieved in the course of Clinical Trials;
- (b) details of MEPL's employees, agents, contractors and sub-licensees engaged to conduct Clinical Trials, all Clinical Trial Subjects and all other persons involved in Clinical Trials; and
- (c) the Clinical Trial Materials.

#### 3.7 Inspection of records

Novogen Research or its nominee may, during normal business hours and upon reasonable notice to MEPL, inspect and copy the records maintained by MEPL under clause 3.6, and may take and retain such copies as Novogen Research thinks fit.

#### 3.8 Reports on Clinical Trials

- (a) Within 5 Business Days of a written request by Novogen Research from time to time during the Term, MEPL shall submit a written report to Novogen Research on the status of all Clinical Trials.
- (b) MEPL shall immediately report to Novogen Research any serious adverse drug experience which occurs during the course of Clinical Trials, and if requested by Novogen Research, MEPL shall cooperate in reporting that experience to any relevant third party or Government Agency.

#### 3.9 Publication of results of Clinical Trials

MEPL must not, and must ensure that its employees, agents, contractors and sub-licensees do not, publish, present in public or make available to any third party the results of any Clinical Trials without the prior written consent of Novogen Research.

#### 3.10 Intellectual Property Rights in Clinical Trial Materials

By this document, MEPL assigns to Novogen Research absolutely and as beneficial owner, the entire right, title and interest in all Intellectual Property Rights in all Clinical Trial Materials.

#### 4. DEVELOPMENTS

#### 4.1 MEPL Developments

MEPL shall disclose to Novogen Research all MEPL Developments as soon as is reasonably practicable after becoming aware of them, and by this document MEPL assigns to Novogen Research absolutely and as beneficial owner the entire right, title and interest in all Intellectual Property Rights in all MEPL Developments.

#### 4.2 Novogen Developments

Novogen Research shall disclose to MEPL all Novogen Developments as soon as is reasonably practicable after becoming aware of them.

#### 5. MARKETING AND COMMERCIALISATION

# 5.1 Marketing and commercialisation

Subject to clauses 5.2 to 5.9, MEPL may, at its sole cost and expense, exploit Products in the Field in the Territory in such manner as it thinks fit.

# 5.2 Commercialisation

MEPL must, and must procure that each of its agents, contractors and sub-licensees:

- (a) conduct any marketing and commercialisation activities on a commercially reasonable basis, in compliance with any applicable laws, rules and regulations of any Government Agency;
- (b) observe all reasonable directions and instructions given to it by Novogen Research about marketing and commercialisation of any Product, including directions about the preparation of or amendment of any advertising, publicity, sales literature or other document relating to the Product; and
- (c) otherwise act as it reasonably considers to be most beneficial to the interests of MEPL and Novogen Research.

# 5.3 Records and customer relations

MEPL must, and must procure that each of its agents, contractors and sub-licensees:

- (a) keep accurate and separate records and accounts of the supply of Products sufficient to enable the recall of Products by batch number, and must submit copies of those records to Novogen Research immediately upon request by Novogen Research;
- (b) note details of any customer complaints about Products and details of any return of any Product and must provide those details to Novogen Research in writing as soon as is practicable after becoming aware of them;
- (c) provide all reasonable assistance to Novogen Research if Novogen Research wishes to investigate any customer complaint or return of any Product; and
- (d) consult with Novogen Research regarding any action to be taken about any customer complaint or return of any Product.

# 5.4 Marketing and promotion

MEPL must, and must procure that its agents, contractors and sub-licensees:

- (a) act in good faith towards Novogen Research and actively promote sales of Products and develop markets for Products throughout the Territory;
- (b) not during the Term do anything which might injure or destroy the market in the Territory for Products;

- (c) subject to applicable laws and regulations in the Territory, advertise Products to keep customers and potential customers informed of them;
- (d) subject to applicable laws and regulations in the Territory, disseminate samples of Products and technical and promotional literature about Products; and
- (e) subject to applicable laws and regulations in the Territory, establish advertising or promotional programs for Products.

#### 5.5 Approval of promotional and advertising material

MEPL must, and must procure that its agents, contractors and sub-licensees:

- (a) submit to Novogen Research for prior approval by Novogen Research representative samples of any promotional piece, advertising or technical narrative in relation to Products;
- (b) use promotional pieces, advertising and technical narratives only in accordance with the prior written consent of Novogen Research and any conditions attaching to that consent; and
- (c) make no representation or warranty about Products except with the prior written consent of Novogen Research.

#### 5.6 Compliance with laws

No consent granted by Novogen Research under clause 5.5 shall relieve MEPL of its obligations under this clause 5 and MEPL remains solely responsible for the compliance of any promotional activity with applicable laws despite any consent by Novogen Research under clause 5.5.

#### 5.7 Storage and handling

MEPL must, and must procure that its agents, contractors and sub-licensees:

- (a) store Products safely and securely and in accordance with the reasonable written directions of Novogen Research from time to time; and
- (b) permit Novogen Research to inspect Products in the possession, custody or control of MEPL, its agents, contractors and sub-licensees.

#### 5.8 Compliance with laws

MEPL must, and must procure that its agents, contractors and sub-licensees, ensure that all Products comply with the requirements of all applicable laws in jurisdictions within the Territory in which MEPL exploits those Products, and MEPL must inform Novogen Research immediately in writing upon becoming aware of any failure to comply with those requirements.

#### 5.9 Packing and transport of Products

MEPL must, and must procure that its agents, contractors and sub-licensees, ensure that all Products are stored and packed in a secure and appropriate manner so that the Products are reasonably likely to reach their destination in good condition under normal conditions of transport.

#### 6. START GRANT AGREEMENT

#### 6.1 Acknowledgment

MEPL acknowledges to Novogen Research that:

- (a) Novogen Limited has obligations to the Commonwealth under the START Grant Agreement with respect to the conduct of Clinical Trials and the commercialisation of Products; and
- (b) Novogen Limited has undertaken (or proposes to undertake) to the Commonwealth under the Deed of Acknowledgment and Undertaking to procure that certain of its obligations under the START Grant Agreement are fulfilled by its subsidiaries, including MEPL.

#### 6.2 Compliance with the START Grant Agreement

MEPL must not, and must procure that its agents, contractors and sub-licensees do not:

- (a) exercise MEPL's rights or perform MEPL's obligations in a manner which is inconsistent with the obligations of Novogen Limited under the START Grant Agreement; or
- (b) otherwise do anything which may cause Novogen Limited to be in default of its obligations under the START Grant Agreement or the Deed of Acknowledgment and Undertaking.

#### 6.3 Compliance with reasonable directions

If at any time during the Term Novogen Limited is in default of its obligations to the Commonwealth under the START Grant Agreement or the Deed of Acknowledgment and Undertaking, MEPL must comply with all reasonable directions of Novogen Research to rectify that default.

#### 7. LICENCE FEES

#### 7.1 First lump sum licence fee

In consideration of the licence granted in clause 1.4, MEPL must pay to Novogen Research a first lump sum licence fee of US\$5,000,000 on the later of:

- (a) 1 November 2002; or
- (b) the date on which the cumulative total of any:

- (i) funding (whether debt or equity);
- (ii) Commercialisation Income; and
- (iii) income as a result of or in connection with the sale, hiring or other disposal of Products,

received by MEPL and its related bodies corporate (other than Novogen Research and Novogen Laboratories), exceeds US\$25,000,000.

#### 7.2 Second lump sum licence fee

In further consideration of the licence granted in clause 1.4, MEPL must pay to Novogen Research a second lump sum licence fee of US\$5,000,000 on the later of:

- (a) 1 November 2003; or
- (b) the date on which the cumulative total of any:
  - (i) funding (whether debt or equity);
  - (ii) Commercialisation Income; and
  - (iii) income as a result of or in connection with the sale, hiring or other disposal of Products,

received by MEPL and its related bodies corporate (other than Novogen Research and Novogen Laboratories), exceeds US\$50,000,000.

#### 7.3 Royalties during the Exclusivity Period

In further consideration of the licence granted in clause 1.4, MEPL must, during the Exclusivity Period, pay to Novogen Research:

- (a) 2.5% of all Net Sales of Products in the Territory, Quarterly in arrears, within 30 days of the end of each Quarter; and
- (b) 25% of all Commercialisation Income, Quarterly in arrears within 30 days of the end of each Quarter.

### 7.4 Royalties after the Exclusivity Period

In further consideration of the licence granted in clause 1.4, MEPL must, from the expiration of the Exclusivity Period until the end of the Term, pay to Novogen Research 1.5% of all Net Sales of Products in the Territory, Quarterly in arrears, within 30 days of the end of each Quarter.

#### 7.5 Milestone Licence Fees

In further consideration of the licence granted in clause 1.4, MEPL must pay to Novogen Research the Milestone Licence Fees during the Exclusivity Period. MEPL must pay:

- (a) each Milestone Licence Fee payable for a calendar year within 30 days following the end of the relevant calendar year; and
- (b) the Milestone Licence Fee payable on the Approval Date within 30 days following the Approval Date.

#### 8. PAYMENT TERMS

#### 8.1 Payments

All amounts due and payable under clause 7 must be calculated and paid in United States dollars and must be paid by bank cheque or electronic transfer to an account notified by Novogen Research in writing.

#### 8.2 Interest on overdue accounts

Interest shall accrue at the Default Rate on the outstanding balance of all overdue amounts payable under clause 7, calculated daily.

#### 9. REPORTS AND ACCOUNTING

#### 9.1 Books and records

In addition to those records which MEPL must make and keep under clauses 3.6 and 5.3, MEPL must, and must ensure that its agents, contractors and sublicensees, make, keep and maintain for the Term and a period of six years after the end of the Term, separate and complete records and books of account relating to:

- (a) all marketing, sale, distribution, exploitation and commercialisation of Products; and
- (b) any assignment, sublicensing, or other dealing with MEPL's rights under this document,

which must contain clear particulars sufficient to enable the calculation of all amounts payable under clause 7.

#### 9.2 Auditor's certificates

Within 60 days of a written request by Novogen Research at any time during the Term or within six years after the end of the Term, MEPL must produce a certificate by the auditors or accountants of MEPL as to the accuracy and completeness of the records and books of account referred to in clause 13.1.

#### 9.3 **Quarterly statements**

MEPL must, and must procure that its agents, contractors and sub-licensees, prepare statements for each Quarter showing:

(a) the progress of marketing and commercialisation of Products;

- (b) details of any Commercialisation Income received by or on behalf of MEPL and its subsidiaries in the period to which the statement relates;
- (c) details of any funding received by or on behalf of MEPL and its subsidiaries, by way of debt, equity or otherwise;
- (d) details of all income received by or on behalf of MEPL and its subsidiaries as a result of or in connection with the sale, hiring or other disposal of Product; and
- (e) the calculation of any payments due under clause 7;

and must submit those statements to Novogen Research within 30 days of the end of the Quarter to which they relate, together with payment of the amount due to Novogen Research under clause 7. All figures in the statements must be in United States dollars.

#### 9.4 Certification

Novogen Research may give notice to MEPL at any time that it disputes any statement submitted by MEPL under clause 9.3 and that it wishes to have the statement certified by an independent accountant at its own cost. In order to do so, Novogen Research and its nominee may inspect MEPL's records and books of account, and those of MEPL's contractors and sub-licensees under clause 9.7.

#### 9.5 Adjustments

- (a) A certification of a statement under clause 9.4 is final and binding on the parties.
- (b) Within 14 days of notice in writing by Novogen Research of the certification under clause 9.4, the parties must make any adjustments required as a result of the certification, including:
  - (i) any refund by Novogen Research to MEPL of the amount of any overpayment; and
  - (ii) any payment by MEPL to Novogen Research of the amount of any underpayment.
- (c) If the certification reveals the amount paid to Novogen Research was underestimated by 5% or more, then within 14 days of notice of the certification, MEPL must also reimburse Novogen Research the cost of certification.

#### 9.6 Interest on adjustments

Interest at the Default Rate (calculated daily) on the amounts payable under clause 9.5 accrues from and including the 14<sup>th</sup> day after the date of notice of the certification by Novogen Research to MEPL.

#### 9.7 Inspection

Novogen Research may, during normal business hours and upon reasonable notice, by its authorised representatives (including accountants and auditors) inspect the records and books of account referred to in clause 9.1. Such authorised representatives may take such

copies and extracts of the records and books of account as they think fit and MEPL must, and must ensure that its contractors and sublicensees give such authorised representatives such assistance as is necessary, including by providing access to facilities, hardware, software and documents, to enable the Commercialisation Income and all amounts payable by MEPL to Novogen Research under this document to be ascertained or verified.

#### 10. OTHER COSTS

#### 10.1 Maintenance of Licensed Patent Rights

Subject to clause 10.2, Novogen Research is responsible at its sole cost and expense for filing, prosecution and maintenance in the Territory of the Licensed Patent Rights.

#### 10.2 Reimbursement by MEPL

MEPL must reimburse Novogen Research one half of the costs incurred by Novogen Research during the Exclusivity Period in filing, prosecuting and maintaining the Licensed Patent Rights, within 30 days of presentation by Novogen Research of invoices for those amounts, together with copies of all invoices, receipts and other documents evidencing those costs.

#### 10.3 Registration of Products

MEPL must, at its own cost and expense:

- (a) register and maintain the registration of Products for use in the Field in accordance with any applicable laws, rules and regulations of any Government Agency; and
- (b) do everything necessary to apply for and obtain each Authorisation from a Government Agency required by any applicable law in the Territory for the importation, promotion, distribution, storage, sale and use of Products in the Field.

### 11. GOODS AND SERVICES TAX

#### 11.1 **GST Law definitions**

Words defined in the GST Law have the same meaning in this clause 11, unless the context makes it clear that a different meaning is intended.

#### 11.2 GST payable in addition to other amounts

In addition to paying all amounts payable by MEPL under this document, MEPL must:

(a) pay to Novogen Research an amount equal to any GST payable on any supply by Novogen Research under or in connection with this document without deduction or set-off of any other amount;

#### (b) make that payment:

(i) if Novogen Research must pay GST on or after receiving the consideration or any part of it — as and when MEPL must pay or provide the consideration or that part of it;

- (ii) if Novogen Research must pay GST on issuing an invoice under this document on the earlier of the due date for payment of that invoice, or 10 Business Days following the end of the month in which Novogen Research issued that invoice; and
- (iii) if Novogen Research must pay GST upon the occurrence of some other event within 5 Business Days of a written request by Novogen Research for payment for the GST, which may be in the form of a tax invoice (or an adjustment note); and
- (c) indemnify Novogen Research against, and pay Novogen Research on demand the amount of:
  - (i) all GST on the transactions contemplated by this document; and
  - (ii) any loss, liability or expense directly or indirectly incurred in connection with or arising from or caused by any failure by MEPL to pay any amount as and when required by this clause 11, for example, any additional tax, penalty tax, fine, interest or other charge under a GST Law.

#### 11.3 Tax invoice

Within 28 days of a written request from MEPL, Novogen Research must issue a tax invoice (or an adjustment note) to MEPL for any supply for which Novogen Research may recover GST from MEPL under this document, and must include in the tax invoice (or adjustment note) the particulars required by the GST Law for MEPL to obtain an input tax credit for that GST.

#### 11.4 Adjustments

Novogen Research must refund to MEPL any overpayment by MEPL for GST, but Novogen Research need not refund to MEPL any amount for GST paid to the Commissioner of Taxation unless Novogen Research has received a refund or credit of that amount.

## 11.5 GST where MEPL supplies Novogen Research

If MEPL must pay GST for anything provided or supplied by MEPL under this document, Novogen Research must pay to MEPL an amount equal to that GST in exactly the same way as MEPL must so do for any GST Novogen Research must pay, and this clause 11 applies to that GST as if MEPL was Novogen Research, and Novogen Research was MEPL.

# 12. OTHER DEDUCTIONS AND WITHHOLDINGS

If at any time an applicable law obliges MEPL to make a deduction or withholding in respect of any Tax from any payment by MEPL to Novogen Research under this document, MEPL must:

(a) notify Novogen Research of the obligation promptly after MEPL becomes aware of it;

- (b) ensure that the deduction or withholding does not exceed the minimum amount required by law;
- (c) pay to the relevant Government Agency on time the full amount of the deduction or withholding and promptly deliver to Novogen Research a copy of any receipt, certificate or other proof of payment; and
- (d) indemnify Novogen Research against the deduction or withholding, by paying to Novogen Research, at the time that the payment is due, an additional amount that ensures that, after the deduction or withholding is made, Novogen Research receives a net sum equal to the sum that it would have received if the deduction or withholding had not been made.

#### 13. INTELLECTUAL PROPERTY RIGHTS

#### 13.1 Acknowledgment

Each party acknowledges that nothing in this document effects an assignment or transfer to MEPL of any right, title or interest in the Licensed Intellectual Property, and MEPL must not represent that it has any right, title or interest in the Licensed Intellectual Property other than the rights expressly granted to it under this document.

#### 13.2 Maintenance of Licensed Intellectual Property

MEPL must do all things necessary in storing, manufacturing, packing, supplying, commercialising and otherwise dealing with the Products to maintain the Licensed Intellectual Property and must not cause or permit to be done anything which may damage or endanger the Licensed Intellectual Property.

#### 13.3 Notification

MEPL must notify Novogen Research immediately upon becoming aware of:

- (a) any actual or apparent infringement by any person of the Licensed Intellectual Property; or
- (b) any assertion or claim by any person that the activities of a party under this document infringe the Intellectual Property Rights of any person.

#### 13.4 Proceedings by MEPL

Subject to clauses 13.5 and 13.7, MEPL may in its discretion and for its own benefit enforce and defend in the Territory the Licensed Intellectual Property during the Exclusivity Period, and in the event it does so, MEPL shall have the conduct and control of any proceedings, including the right to settle them.

# 13.5 Directions by Novogen Research

During the Exclusivity Period, MEPL shall take such proceedings in respect of any actual or suspected infringement in the Territory of the Licensed Intellectual Property, and shall

defend any claim of infringement against the parties, as directed by notice in writing by Novogen Research from time to time.

#### 13.6 Joinder of Novogen Research

If it is necessary that Novogen Research be a party to any proceedings commenced by MEPL, Novogen Research shall join such proceedings as a plaintiff and shall at MEPL's cost provide all reasonable assistance, and execute any documents MEPL reasonably requests, in relation to the proceedings.

#### 13.7 Proceedings by Novogen Research

If MEPL fails to take or defend any proceedings within 28 days of receipt of a notice under clause 13.5, then without prejudice to any other right Novogen Research may have, Novogen Research may commence or defend those proceedings itself, and in the event it does so Novogen Research shall have the conduct and control of the proceedings including the right to settle them.

#### 13.8 Joinder of MEPL

If it is necessary that MEPL be a party to any proceedings taken under clause 13.7, MEPL shall join such proceedings as a plaintiff and shall provide all reasonable assistance, and execute any documents Novogen Research reasonably requests, in relation to the proceedings.

# 13.9 Damages and settlement amounts

If in any proceedings commenced by Novogen Research under clause 13.7, damages or an account of profits are awarded to any party to this document, or an amount is received by any party by way of settlement of those proceedings, all such damages, profits and settlement amounts must be paid to Novogen Research within 5 Business Days of receipt.

#### 13.10 Assignment of Intellectual Property Rights

For the avoidance of doubt, if in any proceedings commenced or defended under this clause 13, a court makes an order in favour of a party to this document other than Novogen Research in relation to the ownership of any Intellectual Property Rights forming part of the Licensed Intellectual Property, the parties agree that those Intellectual Property Rights are by this document assigned absolutely to Novogen Research.

# 14. CONFIDENTIAL INFORMATION

14.1 Confidentiality

Each party must:

- (a) keep and maintain all Confidential Information of the other party strictly confidential;
- (b) use Confidential Information of the other parties only for the purposes for which it is disclosed; and

(c) not disclose any Confidential Information of another party other than to its employees, authorised sub-contractors, legal advisers, auditors or other consultants requiring the information for the purposes of this document and then only upon those persons undertaking in writing to keep that information strictly confidential.

## 14.2 Security

For the purposes of clause 14.1, each party must establish and maintain effective security measures to safeguard the Confidential Information of the other party from unauthorised use or access and must notify the Disclosing Party immediately upon becoming aware of any suspected or actual unauthorised use or disclosure of its Confidential Information.

# 14.3 Exceptions to obligations of confidentiality

The obligations in clauses 14.1 and 14.2 do not apply to the extent that a party is required by law to disclose any Confidential Information, provided the party promptly gives notice to the Disclosing Party of that requirement and discloses only that portion of its Confidential Information which it is legally required to disclose.

# 14.4 **Public domain**

No Confidential Information shall be deemed to be in the public domain merely because it contains information which is in the public domain or is embraced by a general disclosure which is in the public domain.

# 15. REPRESENTATIONS AND WARRANTIES

## 15.1 Warranties of each party

Each party represents and warrants that:

- (a) (status) it is a company limited by shares under the Corporations Act;
- (b) (**power**) it has full legal capacity and power to:
  - (i) own its property and to carry on its business; and
  - (ii) enter into this document and to carry out the transactions that this document contemplates;
- (c) (corporate authority) it has taken all corporate action that is necessary or desirable to authorise its entry into this document and its carrying out the transactions that this document contemplates;
- (d) (Authorisations) it holds each Authorisation that is necessary or desirable to:
  - (i) enable it to properly execute this document and to carry out the transactions that this document contemplates;
  - (ii) ensure that this document is legal, valid, binding and admissible in evidence; or

(iii) enable it to properly carry on its business,

and it is complying with any conditions to which any of these Authorisations is subject;

- (e) (**documents effective**) this document constitutes its legal, valid and binding obligations, enforceable against it in accordance with its terms (except to the extent limited by equitable principles and laws affecting creditors' rights generally), subject to any necessary stamping or registration;
- (f) (no contravention) neither its execution of this document nor the carrying out by it of the transactions that this document contemplates, does or will:
  - (i) contravene any law to which it or any of its property is subject or any order of any Government Agency that is binding on it or any of its property;
  - (ii) contravene any Authorisation;
  - (iii) contravene any undertaking or instrument binding on it or any of its property;
  - (iv) contravene its constitution; or
  - (v) require it to make any payment or delivery in respect of any financial indebtedness before it would otherwise be obliged to do so.

# 15.2 Representations and warranties by Novogen Research

Novogen Research represents and warrants that:

- (a) **(ownership)** to the best of its knowledge Novogen Research is the legal and beneficial owner of the Licensed Intellectual Property and to the best of its knowledge no other person has or shall have any claim of ownership with respect to the Licensed Intellectual Property;
- (b) (no dealings) subject to the START Grant Agreement, it has not assigned or granted to any person any right, title or interest in or in relation to the Licensed Intellectual Property;
- (c) (no Encumbrance) subject to the Fixed and Floating Charge, the Licensed Intellectual Property is free from any Encumbrance;
- (d) (filing, prosecution and maintenance) Novogen Research has diligently filed, prosecuted and maintained the patents and patent applications listed in schedule 1 and as at the Commencement Date all filing, prosecution and maintenance fees have been paid;
- (e) (confidentiality) to its knowledge Novogen Research has kept the Licensed Know How confidential and to its knowledge there has been no breach of that confidentiality;

- (f) (no infringement) to its knowledge the exercise by MEPL, in any country in which a patent application in schedule 1 has been filed, of the rights granted to MEPL under this document with respect to the Licensed Intellectual Property does not infringe the Intellectual Property Rights of any person; and
- (g) (no further Patent Rights) other than the Licensed Patent Rights, Novogen Research has no Patent Rights which are necessary in order for MEPL to exercise its rights and perform its obligations under this document.

# 15.3 Validity of Licensed Patent Rights

MEPL acknowledges that Novogen Research makes and has made no representation, warranty, statement or promise to the effect that:

- (a) any letters patent will be granted in respect of the Licensed Intellectual Property in any country in the Territory; or
- (b) if any letters patent are granted in respect of the Licensed Intellectual Property in any country in the Territory, such letters patent will be valid.

#### 15.4 Reliance on representations and warranties

Each party acknowledges that the other party has executed this document and agreed to take part in the transactions that this document contemplates in reliance on the representations and warranties that are made in this document.

# 16. LIMITATION OF LIABILITY

# 16.1 Limitation of liability of Novogen Research

Subject to clause 16.2 and to the extent permitted by law, the liability of Novogen Research to MEPL under this document and any other liability of Novogen Research to MEPL, whether in contract, tort (including negligence and breach of statutory duty) or otherwise is limited to US\$200,000.

# 16.2 Liability for infringement of Intellectual Property Rights

Clause 16.1 does not apply to any liability which Novogen Research may have to MEPL with respect to any breach by Novogen Research of the representations and warranties in clauses 15.2(a), (b), (c) and (f).

#### 16.3 Exclusion of conditions and warranties

Except for the warranties expressly made in this document, all conditions, warranties, undertakings or representations express or implied arising by statute, general law or otherwise are expressly excluded to the extent permitted by law.

#### 16.4 Indirect and consequential loss

Notwithstanding any other provision of this document, and to the extent permitted by law, in no circumstances is Novogen Research liable in contract, tort (including negligence or breach of statutory duty) or otherwise, and whatever the cause, to compensate MEPL for:

- (a) any increased costs or expenses;
- (b) any economic loss, loss of profit, revenue, business, contracts or anticipated savings; or
- (c) any other special, indirect or consequential loss or damage of any nature.

# 17. INDEMNITIES AND INSURANCE

#### 17.1 Clinical Trial indemnity

MEPL must indemnify and keep indemnified Novogen Research, its directors, employees and agents against all damages, costs or expenses (including legal costs and expenses on an indemnity basis) in respect of any claims, demands, actions, proceedings or prosecution which may be brought or commenced as a result of or in relation to:

- (a) the conduct of Clinical Trials generally; or
- (b) any personal injury to or death of a Clinical Trial Subject arising out of or relating to the administration of the Products or any clinical intervention or procedure provided for or required for the purposes of the Clinical Trials to which the Clinical Trial Subjects would not have been exposed but for their participation in the Clinical Trials,

except to the extent that the claim, demand, action, proceeding or prosecution arose from an action or omission of MEPL in accordance with a direction given by Novogen Research under this document or from any negligence (including breach of statutory duty) of Novogen Research or any breach by Novogen Research of its obligations under this document.

## 17.2 Commercialisation indemnity

MEPL must indemnify and keep indemnified Novogen Research, its directors, employees and agents against all damages, costs or expenses (including legal costs and expenses on an indemnity basis) in respect of any claims, demands, actions, proceedings or prosecution which may be brought or commenced as a result of or in relation to:

- (a) the licensing or sub-licensing of the Licensed Intellectual Property;
- (b) the sale, distribution or other commercialisation or exploitation of Products; or
- (c) any packaging, marketing, advertisement or promotion of Products,

by MEPL, its employees, agents, contractors and sub-licensees, including any warranty claims, product liability claims, product recalls and claims for personal injury or property damage, except to the extent that the claim, demand, action, proceeding or prosecution arose from an action or omission of MEPL in accordance with a direction given by Novogen Research under this document, from the negligence (including breach of statutory duty) of Novogen Research or the breach by Novogen Research of its obligations under this document.

#### 17.3 MEPL's insurance policies

MEPL must take out and maintain in force in the Territory comprehensive general liability insurance including advertising and product liability insurance for personal injury and property damage and product recall insurance, in relation to all Products on terms satisfactory to Novogen Research.

### 17.4 Name of Novogen Research

If requested by Novogen Research, MEPL must ensure that that Novogen Research is included on the policies referred to in clause 17.3 as a joint insured or loss payee.

#### 17.5 Certificates of currency

At the request of Novogen Research from time to time, MEPL must provide to Novogen Research a certificate of currency evidencing its compliance with its obligations under this clause 17.

## 17.6 Default

If within 15 Business Days of a request by Novogen Research under clause 17.5, MEPL does not comply with its obligations under that clause, Novogen Research may (but is not obliged to) take out and maintain the insurance and may recover any premiums paid as a debt due by MEPL.

#### 17.7 Expiry

MEPL shall maintain each insurance policy referred to in clause 17.3 until the expiry date of the last Product sold, hired or otherwise disposed of by or on behalf of MEPL or its sub-licensees.

## 17.8 Novogen Research's insurance

Novogen Research must take out and maintain in force in the Territory comprehensive general liability insurance policies in relation to its obligations under this document on terms reasonably satisfactory to MEPL.

# 18. FORCE MAJEURE

#### 18.1 Notice and suspension of obligations

If a party to this document is affected, or likely to be affected, by a Force Majeure Event:

- (a) that party must immediately give the other prompt notice of that fact including:
  - (i) full particulars of the Force Majeure Event;
  - (ii) an estimate of its likely duration;
  - (iii) the obligations affected by it and the extent of its effect on those obligations; and

- (iv) the steps taken to rectify it; and
- (b) the obligations under this document of the party giving the notice are suspended to the extent to which they are affected by the relevant Force Majeure Event as long as the Force Majeure Event continues.

#### 18.2 Effort to overcome

A party claiming a Force Majeure Event must use its best endeavours to remove, overcome or minimise the effects of that Force Majeure Event as quickly as possible. However, this does not require a party to settle any industrial dispute in any way it does not want to.

#### 18.3 Termination

If a Force Majeure Event continues for more than 3 months, any party may terminate this document by giving at least 10 Business Days notice to the other parties.

#### 19. TERM AND TERMINATION

#### 19.1 Term

- (a) Subject to paragraph (b), the rights and obligations of the parties under this document begin on the Commencement Date and continue until this document is terminated in accordance with this clause 19.
- (b) The variations made by this document to the Original Licence Agreement are effective from the date of this document.

#### 19.2 Termination by Novogen Research

Novogen Research may terminate this document at any time:

- (a) immediately if MEPL defaults in the performance of any of its obligations under this document which in Novogen Research's reasonable opinion is capable of remedy and fails to remedy that default within 21 days of receiving written notice from Novogen Research specifying the default and requiring the default to be remedied;
- (b) on 21 days written notice if MEPL defaults in the performance of any of its material obligations under this document which in Novogen Research's reasonable opinion is not capable of remedy; and
- (c) immediately by notice in writing if:
  - (i) there is a Change of Control of MEPL without Novogen Research's written consent (which shall not be unreasonably withheld or delayed or conditioned);
  - (ii) MEPL is involved in an Insolvency Event; or

(iii) MEPL ceases for any reason to be able lawfully to carry out all the transactions which this document contemplates may be carried out by MEPL.

# 19.3 Termination by MEPL

MEPL may terminate this document at any time:

- (a) on three month's written notice to Novogen Research;
- (b) immediately if Novogen Research defaults in the performance of any of its obligations under this document which in MEPL's reasonable opinion is capable of remedy and fails to remedy that default within 21 days of receiving written notice from MEPL specifying the default and requiring the default to be remedied;
- (c) on 21 days written notice if Novogen Research defaults in the performance of any of its material obligations under this document which in MEPL's reasonable opinion is not capable of remedy; and
- (d) immediately by notice in writing if:
  - (i) Novogen Research is involved in an Insolvency Event; or
  - (ii) Novogen Research ceases for any reason to be able lawfully to carry out all the transactions which this document contemplates may be carried out by Novogen Research.

## 19.4 Consequences to MEPL of termination

Upon termination of this document MEPL must:

- (a) immediately cease using and exploiting the Products;
- (b) within 14 Business Days return to Novogen Research or destroy at Novogen Research's election, all Products, Clinical Trial Materials, all copies (including electronic copies) of any labelling and packaging materials relating to Products and any other Confidential Information of Novogen Research in MEPL's possession, custody or power; and
- (c) cooperate with Novogen Research and do everything necessary to bring about the orderly and medically and ethically permissible termination of all Clinical Trials,

provided that MEPL may complete in accordance with its obligations under this document any contracts for sale or supply of Products to which MEPL is bound prior to the date of termination.

## 19.5 Consequences to Novogen Research of termination

Upon termination of this document Novogen Research must return to MEPL or destroy at MEPL's election within 10 Business Days, all Confidential Information of MEPL in the possession, custody or power of Novogen Research.

#### 19.6 Survival and accrued rights

Upon termination under this clause 19, this document is at an end as to its future operation except for:

- (a) the enforcement of any right or claim which arises on or has arisen before termination; and
- (b) the obligations of the parties under clauses 1, 3.6, 3.7, 3.9, 5.3, 9, 13.1, 13.9, 14, 16, 17, 20, 21 and 23 (except clause 23.4) and this clause 19 which survive termination.

#### 20. DISPUTE RESOLUTION

#### 20.1 Disputes

If a dispute arises out of or in relation to this document (including any dispute as to breach or termination of the document or as to any claim in tort, in equity or pursuant to any statute) (a "**Dispute**"), a party to this document may not commence any court or arbitration proceedings relating to the Dispute unless it has complied with this clause 20 except where the party seeks urgent interlocutory relief.

# 20.2 Notice of Dispute

A party to this document claiming that a Dispute has arisen under or in relation to this document must give written notice to the other party specifying the nature of the Dispute (a "**Dispute Notice**").

#### 20.3 Negotiation

Upon receipt by a party of a Dispute Notice, Novogen Research and MEPL must procure that their respective Managing Directors meet to endeavour to resolve the Dispute expeditiously by negotiation.

# 20.4 Resolution of Dispute

If the parties have not resolved the Dispute under clause 20.3 within 14 days of receipt of a Dispute Notice, the parties must endeavour to resolve the Dispute expeditiously using informal dispute resolution techniques such as mediation, expert evaluation or determination or similar techniques agreed by the parties.

## 20.5 Mediation

If the parties do not agree within 28 days of receipt of a Dispute Notice (or such further period as the parties agree in writing) as to:

- (a) the dispute resolution technique and procedures to be adopted;
- (b) the timetable for all steps in those procedures; and
- (c) the selection and compensation of the independent person required for such technique,

the parties must mediate the Dispute in accordance with the Mediation Rules of the Law Society of New South Wales.

# 21. NOTICES

- (a) A notice, consent or other communication under this document is only effective if it is in writing, signed and either left at the addressee's address or sent to the addressee by mail or fax. If it is sent by mail, it is taken to have been received 3 working days after it is posted. If it is sent by fax, it is taken to have been received when the addressee actually receives it in full and in legible form.
- (b) The parties' addresses and fax numbers are those set out below, or as a party notifies the other:

<b>Novogen Research</b> Address: Fax number: Attention:	140 Wicks Road, North Ryde NSW 2113 AUSTRALIA Int + 612 9878 0055 Managing Director
<b>MEPL</b> Address: Fax number: Attention:	140 Wicks Road, North Ryde NSW 2113 AUSTRALIA Int + 612 9878 0055 Managing Director

# 22. AMENDMENT AND ASSIGNMENT

#### 22.1 Amendment

This document can only be amended, supplemented, replaced or novated by another document signed by the parties.

#### 22.2 Assignment

- (a) MEPL may only dispose of, declare a trust over or otherwise create an interest in its rights under this document with the prior written consent of Novogen Research.
- (b) Novogen Research may dispose of, declare a trust over or otherwise create an interest in its rights under this document without the consent of MEPL, and may disclose to any potential holder of the right or interest any information relating to this document or any party to it.

# 23. GENERAL

# 23.1 Governing law

- (a) This document is governed by the law in force in New South Wales.
- (b) Each party submits to the non-exclusive jurisdiction of the courts exercising jurisdiction in New South Wales, and any court that may hear appeals from any of those courts, for any proceedings in connection with this document, and waives any right it might have to claim that those courts are an inconvenient forum.

# 23.2 Liability for expenses

Each party must pay its own expenses incurred in negotiating, executing, stamping and registering this document.

# 23.3 Relationship of the parties

Nothing in this document creates a relationship of employment, partnership or joint venture between the parties under the laws of any applicable jurisdiction and no party may act or has the authority to act as agent of or in any way bind or commit another party to any obligation.

#### 23.4 Giving effect to this document

Each party must do anything (including execute any document), and must ensure that its employees and agents do anything (including execute any document), that the other party may reasonably require to give full effect to this document.

#### 23.5 Waiver of rights

A right may only be waived in writing, signed by the party giving the waiver, and:

- (a) no other conduct of a party (including a failure to exercise, or delay in exercising, the right) operates as a waiver of the right or otherwise prevents the exercise of the right;
- (b) a waiver of a right on one or more occasions does not operate as a waiver of that right if it arises again; and
- (c) the exercise of a right does not prevent any further exercise of that right or of any other right.

#### 23.6 Operation of this document

- (a) This document contains the entire document between the parties about its subject matter. Any previous understanding, document, representation or warranty relating to that subject matter is replaced by this document and has no further effect.
- (b) Any right that a person may have under this document is in addition to, and does not replace or limit, any other right that the person may have.
- (c) Any provision of this document which is unenforceable or partly unenforceable is, where possible, to be severed to the extent necessary to make this document enforceable, unless this would materially change the intended effect of this document.

# 23.7 Operation of indemnities

(a) Each indemnity in this document survives the expiry or termination of this document.

(b) A party may recover a payment under an indemnity in this document before it makes the payment.

# 23.8 Consents

Where this document contemplates that a party may agree or consent to something (however it is described), that party may:

- (a) agree or consent, or not agree or consent, in its absolute discretion; and
- (b) agree or consent subject to conditions,

unless this document expressly contemplates otherwise.

# 23.9 Exclusion of contrary legislation

Any legislation that adversely affects an obligation of a party, or the exercise by a party of a right or remedy, under or relating to this document is excluded to the full extent permitted by law.

# 23.10 Counterparts

This document may be executed in counterparts.

**EXECUTED** as an agreement.

# **EXECUTED** by **NOVOGEN RESEARCH PTY LIMITED**

Signature of director	Signature of director/secretary	
Name of director	Name of director/secretary	
EXECUTED by MARSHALL EDWARDS PTY LIMITED		
Signature of director	Signature of director/secretary	
Name of director	Name of director/secretary	
		33.

# **SCHEDULE 1**

# **Product Patent Rights**

Application/patent	No.	Status
Australia	731951	Granted
Australia	19723/01	Under examination
Australia	750031	Granted
Australia	PP1124	Completed provisional patent application
Australia	PO2039	Completed provisional patent application
Australia	PS1594	Completed provisional patent application
Australia	2002950294	Completed provisional patent application
Australia	2002951607	Completed provisional patent application
Australia	2002953453	Completed provisional patent application
Brazil	9713180-6	Under examination
Brazil	9814343-3	Under examination
Canada	2,265,049	Under examination
Canada	2316349	Pending
Czech Republic	PV 699-99	Under examination
Europe	97937345.3	Pending
Europe	98960911.0	Pending
Hong Kong	1019553	Granted
Hungary	P9903971	Under examination
Israel	128765	Under examination

Application/patent	No.	Status
Israel	136784	Pending
Japan	10-511105	Under examination
Mexico	992092	Pending
Mexico	006311	Pending
New Zealand	334025	Granted
New Zealand	506063	Under examination
New Zealand	505377	Accepted
Norway	19990965	Pending
Norway	20003201	Pending
People's Republic of China	97198690.8	Under examination
Portugal	98/08503	Pending
Singapore	64139	Granted
Singapore	74235	Granted
Sweden	2286-3	Under examination
Turkey	TR19990885B	Granted
Turkey	2000/2064	Pending
United Kingdom	2331015	Granted
United States of America	09/254026	Under examination
United States of America	Serial number not allocated Continuation of 09/254026	Filed 6 August 2003
United States of America	10/212847	Under examination
United States of America	10/176762	Under examination
United States of America	6455032	Granted
Zimbabwe	12/99	Accepted
International	PCT/AU03/00427	Pending
International	PCT/AU97/00563	National phase entry completed

Application/patent

International

No.

PCT/AU98/01054

Status

National phase entry completed

36.

# **SCHEDULE 2**

# **Manufacturing Patent Rights**

Application	No.	Status
Australia	26510/00	Under examination
Australia	PP8685	Completed provisional patent application
Brazil	0008222-8	Pending
Canada	2362819	Pending
China	00803816.3	Under examination
Czech Republic	PV 2001-2920	Pending
Europe	00904727.5	Under examination
Hong Kong	02103732.5	Pending
Hungary	PO105218	Pending
Israel	144008	Pending
Japan	2000-599749	Pending
Mexico	008233	Pending
New Zealand	512696	Lapsed
New Zealand	527700 (divisional)	Pending
Norway	20013945	Pending
Singapore	200103867-8	Pending
South Africa	20016502	Pending
Turkey	01/2367	Under examination
United States of America	09/889701	Under examination
International	PCT/AU00/00103	National phase entry completed

Marshall Edwards, Inc.

## CONTACT: David Sheon — 202 518-6384 (USA) Mr Christopher Naughton (CEO, Marshall Edwards, Inc) – +612 8878 6196 (Australia)

# FOR IMMEDIATE RELEASE

#### MARSHALL EDWARDS, INC. RENEGOTIATES ANNUAL LICENSE PAYMENTS FOR PHENOXODIOL

**Washington and Sydney, Australia: April 4, 2007** - Marshall Edwards, Inc. (Nasdaq: MSHL) has renegotiated with Novogen Limited (ASX: NRT — Nasdaq: NVGN) the timing of the payment of its annual \$US 8 million milestone license payments for the investigational anti-cancer drug, phenoxodiol.

Under the terms of an amendment deed to the original license agreement signed yesterday, the payment of future milestone license fees due on 31 December, 2007 and each year subsequently will now commence at the end of the calendar year in which phenoxodiol first receives approval for marketing in the USA or any other country.

The marketing approval may be a result of Accelerated Approval of a New Drug Application by the U.S. Food and Drug Administration (FDA) or otherwise.

MSHL's President and CEO, Mr Christopher Naughton, said renegotiating the timing of the milestone license fee payments would enable MSHL to focus its cash resources on completing the phenoxodiol phase III clinical trial Ovature, which was reviewed under a Special Protocol Assessment by FDA.

"The Ovature ovarian cancer clinical trial has now started and we look forward to patient recruitment continuing over the coming year; and it is appropriate that the future milestone license payments will now only be due following phenoxodiol's approval for marketing," Mr Naughton said.

MSHL is a US clinical oncology company and is 78.1 percent owned by Novogen.

Novogen Limited, based in Sydney, Australia, is developing a range of therapeutics across the fields of oncology, cardiovascular, and inflammatory diseases.

More information on phenoxodiol and on the Novogen group of companies can be found at <u>www.marshalledwardsinc.com</u> and <u>www.novogen.com</u>.

Under U.S. law, a new drug cannot be marketed until it has been investigated in clinical trials and approved by the FDA as being safe and effective for the intended use. Statements included in this press release that are not historical in nature are "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. You should be aware that our actual results could differ materially from those contained in the forward-looking statements, which are based on management's current expectations and are subject to a number of risks and uncertainties, including, but not limited to, our failure to successfully commercialize our product candidates; costs and delays in the development and/or FDA approval, or the failure to obtain

such approval, of our product candidates; uncertainties in clinical trial results; our inability to maintain or enter into, and the risks resulting from our dependence upon, collaboration or contractual arrangements necessary for the development, manufacture, commercialization, marketing, sales and distribution of any products; competitive factors; our inability to protect our patents or proprietary rights and obtain necessary rights to third arty patents and intellectual property to operate our business; our inability to operate our business without infringing the patents and proprietary rights of others; general economic conditions; the failure of any products to gain market acceptance; our inability to obtain any additional required financing; technological changes; government regulation; changes in industry practice; and one-time events. We do not intend to update any of these factors or to publicly announce the results of any revisions to these forward-looking statements.