

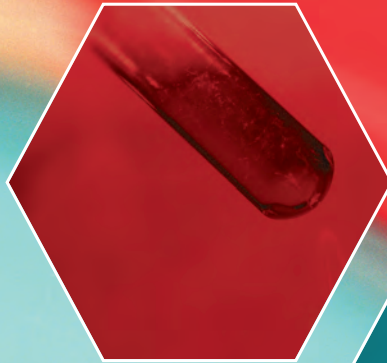
Executive Summary - Annual Report

2013

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Chairman's Letter

2013

## CHAIRMAN'S LETTER

Dear Shareholders,

2013 has been quite a year for both your Company and your Executive.

When the current Board assumed control of the Novogen Group on 5 December 2012, Novogen was a shell. All of its drug technology intellectual property had been sold to subsidiary, MEI Pharma; all other assets sold off and the funds redirected into MEI Pharma; and Novogen demerged from MEI Pharma through an *in-specie* distribution of shares.

This left Novogen with about \$900,000 in cash and its dual listing on the ASX and NASDAQ exchanges, but no other tangible or intangible assets.

But rather than see this as a problem, your Executive saw this as a welcome opportunity. We had a clean slate to work with, with no overhang from previous management or deeds or business strategies to be concerned about.

Novogen was reborn through the acquisition of Triaxial Pharmaceuticals, a private company formed by myself and Andrew Heaton and David Brown, the three ex-Novogen scientists most responsible for the original Novogen drug technology platform. The goal of this private company was to realize the potential of the original Novogen drug technology through building more complex, super forms of the drugs that would deliver a far more potent anti-cancer effect. In achieving this, we particularly wanted this new family of drugs to be highly active against the two main populations of cells within a tumor: the more common differentiated cancer cells and their less common progenitor cells, the cancer stem cells that typically are impervious to chemotherapy and that are responsible for tumor recurrence. With more powerful drugs and clear activity against the cells responsible for tumor growth and recurrence, the reborn Novogen is confident that it now has the drug technology platform to deliver a major advance in the field of chemotherapy.

The first task your Executive had in coming back into the Company was to cut fixed costs and to set about raising sufficient funds to underwrite an ambitious drug development program. Drug development doesn't come cheaply, and the more successful the drug, the more money you need. Fortunately your Executive has been down this path before, so we have a pretty good idea what's coming down the line and what we need to do to prepare for the task ahead. We have been successful in raising sufficient funds to support the program to date, but the reality is that this is something that I will need to spend more and more time on as we proceed. What I will promise shareholders, though, is that we will only look to raise enough money to get us to the next horizon and in so doing, limit shareholder dilution as much as we can.

The following Report is meant to contain itself to the financial year, July 2012 – June 2013. But that was a fractured year, broken up into five months under the control of the old Board overseeing a company in wind-down mode, followed by seven months of effort by the new Board in winding the Company back up again. And with that winding-back-up process has come a rush of opportunity and expansion of knowledge that has seen the Company start to take a new shape and form in the current reporting period that I believe is far more meaningful to shareholders than the previous obligatory, but fractured, reporting period. Novogen is in effect a new company, with new executives, a new Board, a new technology platform, new drugs, and a new business strategy.

So I encourage you to read my following CEO report with that thought in mind.

In the following Annual Report, we also have tried to strike a balance between the full extent of information required under our statutory obligations, and the key aspects of this information that many of our shareholders tell us that they just want to focus on. So, for your convenience, we have addressed this by producing both short-form and long-form versions of the Report, and to posting both on our website ([www.novogen.com](http://www.novogen.com)).

Finally, I'd like to point out that all Executives and Directors of Novogen are shareholders in your company, some of us substantial shareholders. We are in this together. We have made good progress in the very short time at the helm, but we think the best is yet to come.

We firmly believe that Novogen will change the Future of Cancer Therapy.

A handwritten signature in dark ink, appearing to read 'GK', with a stylized flourish at the end.

Graham Kelly  
Chairman



Chief Executive Officer's Report

2013

## CHIEF EXECUTIVE OFFICER'S REPORT

I will use this Report to try and outline what I see as the Company's key strengths, the strategic directions that it is taking, and what you might expect the Company to look like over the coming year.

I can't report with any authority on the year's activities up until 6 December 2012 because I wasn't involved, beyond commenting on the facts as they stand. Company assets had been liquidated and the bulk of the proceeds transferred to Novogen spin-off, MEI Pharma; all isoflavonoid drug technology intellectual property also transferred to MEI Pharma; and the only remaining asset, a 60% stake in MEI Pharma, then liquidated through an *in specie* distribution of the Company's shares in MEI Pharma to Novogen shareholders. Novogen was being prepared as a back-door listing for another company. As the founder of this Company that held such promise, you wouldn't be surprised that I was both saddened and appalled by this situation.

Novogen turned the corner and became a new company on 6 December 2012 with the acquisition of Triaxial Pharmaceuticals Pty Ltd, a company that myself and two other ex-Novogen refugees had formed. We had done so in the firm belief that the promise of the original Novogen drug technology remained unfulfilled,.

We never started Triaxial believing that we would have the opportunity to bring it back into Novogen, but fate intervened, and here we are.

Having been given a second chance, I am determined to do everything in my power to realize the Novogen potential and to repay the faith of so many long-standing and long-suffering shareholders.

But Novogen Mark 2 is far more than just a resuscitated company. It commands an entirely new drug technology platform that your executive firmly believes has the potential to change the future of chemotherapy. Novogen Mark 2 is a company reborn with an entirely new and brighter future.

## Our business

The Company's core business remains drug development, but with a focus on anti-cancer drugs.

In common with dozens, if not hundreds, of biotech companies internationally, we have an horizon which is to develop and to bring to market a drug or drugs that will find their way into the oncologist's armamentarium and hopefully make a difference to the outlook of the cancer patient.

But that is just our first horizon. Where we start to separate from the vast bulk of other biotech companies is that we have a second horizon, and that is to develop a family of drugs that will serve to allow cancer therapy to be individualized so that a patient is offered a treatment best suited to an individual cancer and one that offers a very real prospect of eradicating the source of tumor recurrence (the cancer stem cells) and thereby deliver long-term remission.

It's an extraordinarily ambitious goal, but one which we truly believe is attainable.

It's a goal built around the Company's core drug technology, super-benzopyran drugs, which we believe will take us a long way towards our goal, further than any other company has the capacity to go. But we are sufficiently ambitious to want to go the full way, and to do that, we have identified certain drug technologies and drug delivery technologies that complement our super-benzopyran drugs and that we believe may take us that one step closer to achieving almost universal long-term remission. Novogen currently is negotiating to acquire or to access those new technologies. I regret that I am not in a position to provide details of those negotiations, but I am confident that at least some of these opportunities will be disclosed before the end of this year.

## **Cancer stem cells**

If I had to define Novogen, it would be that we are positioning ourselves to become the principal supplier of drugs that provide long-term remission through the successful control of the cancer stem cell.

In broad terms, all tissues have a hierarchy of cells with two main forms of cells..... a very small number of pluripotent stem cells that are responsible for producing the various types of cells that go to make up the particular tissue, and then the final tissue cells themselves.

This cellular hierarchy generally is retained in cancer, with one big difference. The one-way production line of stem cell-to-daughter cell in normal tissue can become a reversible two-way direction in cancer tissue, with the daughter cancer cells being able to revert back to a stem cell-like state under certain conditions. These cancer stem cells are key to the cancer's ability to grow, to spread, and to survive attempts by the body and by oncologists to destroy it.

Cancer stem cells are highly resistant to radiotherapy and chemotherapy and generally manage to survive such attacks where their more prevalent daughter cells succumb. Having survived the attack, the cancer stem cells then repopulate the tumor with another generation of cancer daughter cells, but this time the daughter cells have inherited their parent cells' resistance to radiotherapy and chemotherapy. In this way, the cancer stem cells display a remarkable ability to adapt to a hostile environment either by mutating genes or activating repressed genes, all with the sole aim of ensuring the survival of the tumor. Hence the almost impossible task of second-guessing a cancer cell's survival skills.



All of the current anti-cancer drugs on the market today are directed at the daughter cancer cells and none of them show any meaningful impact on cancer stem cells. Despite this, the great majority of effort going into anti-cancer drug development today continues to be directed at these daughter cells. The targets within the cancer cell that have led to the development of some hundreds of anti-cancer drugs over the past 50 years, do not appear to apply to cancer stem cells, and until relevant targets within cancer stem cells are identified, this area of drug development will continue to struggle.

Several biotechnology companies are working in this field with a small number of signaling proteins and cell surface receptors purportedly characteristic of cancer stem cells the subject of drug development. Time will tell whether these targets are any more effective than signaling proteins and receptors have been as targets for all the hundreds of drugs used against daughter cancer cells, where the adaptability of the cancer cell has proved to be insurmountable.

The cancer stem cell is the focus of our efforts. That doesn't mean that our drugs have a lesser effect against the daughter cells of cancer stem cells ..... quite the contrary. It is just that we seem to have hit on a fault-line that cancer stem cells are susceptible to having shut down, and that is where we will be focusing our efforts.

## **Personalized chemotherapy**

Once you have the means to kill cancer stem cells, then you are one step closer to the heart of the cancer process and to the ultimate goal of customizing chemotherapy to an individual tumor.

Personalized chemotherapy is based on the fact that no two tumors are the same; that even the same histological subset of tumors varies substantially between individuals in the types of mutations present and in the sensitivity of the cancer cells to anti-cancer drugs. Even within the one tumor, there is a hierarchy of cells with an inherent range of chemosensitivities, with the cancer stem cells considerably less sensitive to chemotherapy than their daughter cells. Effective therapy needs to be able to wipe out all the different forms of cells within a tumor, and to do that across a broad range of individual genotypes and mutations.

Our objective is to be able to identify the sensitivities of both the cancer stem cells and their daughter cells to a range of chemotherapies on an individual basis in order to better inform the oncologist and the patient.

We start this objective with two key advantages that are critical to being able to provide personalized chemotherapy. The first is that the super-benzopyran drugs are showing strong activity against cancer stem cells. Without being able to kill the cancer stem cells, chemotherapy has little chance of preventing tumor recurrence. The second is that when we subtly modify the structure of our pharmacophore, we change the target, an outcome that we believe is pointing to important genomic differences between individual cancers.

## The Novogen enabling technologies

We have set the goals...now to look at how we are setting about achieving them.

### (a) Super-benzopyran drug technology platform

As I have said, the Company's business is built around its super-benzopyran drug technology. For that reason, I believe that it is worth taking the effort to understand it. I am indebted to my colleague, Dr. Andrew Heaton, for help with the following explanation.

*Like all cancer drug design, our goal is to build molecules that selectively target cancer cells while leaving normal cells unaffected, and to target as many different types of cancer cells as possible.*

*The original Novogen design strategy gave rise to compounds such as NV-128 and NV-344. These compounds were built using a very restricted set of building blocks. In effect, it was like trying to paint a masterpiece with only three colors or write a piano concerto with only three notes. Nevertheless, this limited approach still gave rise to a series of simple molecules that were relatively non-toxic to normal cells and were moderately potent against a wide range of cancer cells. Their target appeared to be biochemical mechanisms concerned with how hydrogen atoms (protons) were transported or used within the cancer cell. And the target was highly restricted to cancer cells, pointing to a mutation that was part of the cancer process and common to most forms of cancer.*

*That simple family of benzopyrans that Novogen made over the decade 1998-2008 provided a glimpse of that part of the benzopyran scaffold that was critical in attacking the cancer cell. That critical structure is known as the 'pharmacophore', or that part of the molecule that is critical to its function and which cannot be tampered with.*

*The parts of the molecule outside of this central pharmacophore, however, were fair game and able to be exploited to create more powerful drugs or drugs with different targets. However, we faced a significant restriction, which was the limited range of chemicals that our design and manufacturing capacities meant we could use in constructing compounds. In fact the original Novogen molecules like NV-*

*128 and NV-344 contain only three elements from the periodic table: carbon, hydrogen and oxygen.*

*Triaxial was born out of the realization that to improve on the anti-cancer potency of drugs such as NV-128 and NV-344, it would be necessary to come up with an entirely new way of constructing benzopyrans that allowed the inclusion of more than just carbon, hydrogen and oxygen. There was nothing wrong with the central pharmacophore .... we just needed to find a way of making it more active by improving its access to cancer cells and to increasing its killing effect once there. We often use the analogy of a scorpion because the shape of the benzopyran molecule is scorpion-like, with two forward points and a tail.*

*The two claws are the pharmacophore, which is what locks into the target; the tail of the molecule is what determines the molecule's anti-cancer potency. Triaxial's goal was to give the claws greater ability to grip the prey, at the same time as increasing the sting in the tail.*

*Increasing the sting in the tail meant being able to employ atoms beyond carbon, hydrogen and oxygen. We wanted to be able to include an array of other elements (including nitrogen, sulfur, fluorine, bromine, chlorine etc) into the molecules. This finally was achieved in a design and manufacturing process that is a key part of our growing intellectual property portfolio. In so doing, we created a family of compounds known as super-benzopyrans, as distinct from the simple benzopyrans such as NV-128 and NV-344. This breakthrough in the number of building blocks available has provided us with the ability to design an almost infinite number of molecules against a wide range of cancer cell targets.*

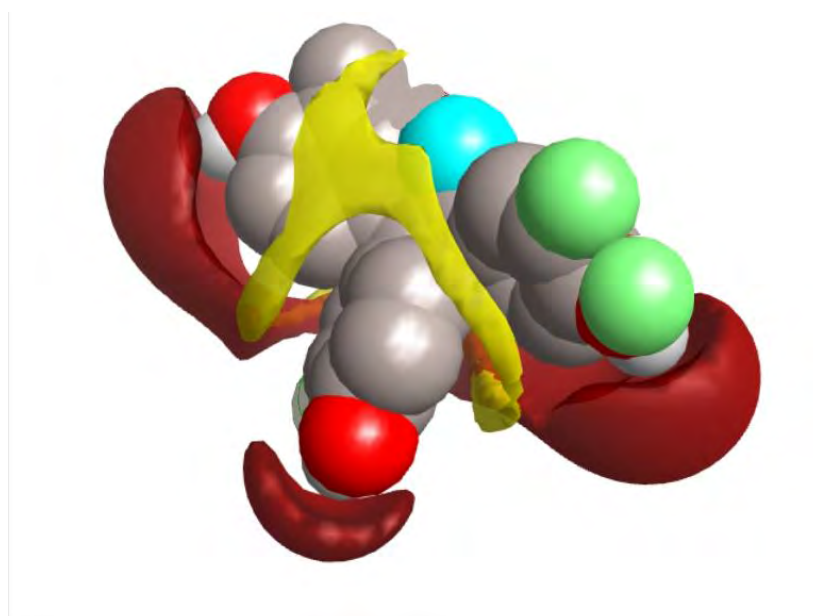
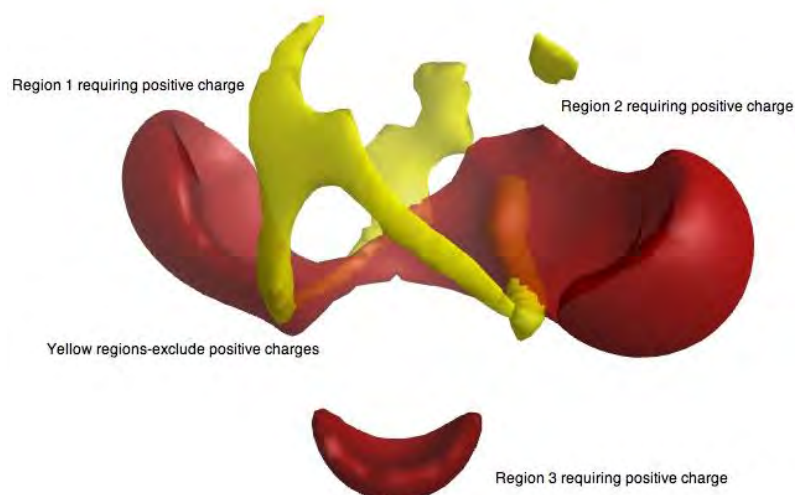
*But beyond this goal, a number of unexpected additional benefits also flowed. The first is that the number of manufacturing steps was halved, shaving significant costs off large-scale manufacture, as well as making it substantially easier to manufacture different super-benzopyrans for screening. The second is that the insertion of new atoms in the molecule's tail resulted in a change in the molecule's electrical 'signature', meaning that it donates and receives electrons far more readily than drugs such as NV-128 and NV-344. One effect of that is to make the drugs bind more strongly to their target, accounting in part for their considerably greater anti-cancer potency.*

*Our design ability has increased exponentially. Our palette has gone from 3 basic colors, to a full spectrum of colors, each of differing shades.*

*We may not as yet have fully identified our molecular target within the cancer cell, but we still are able to employ rational drug design principles. By looking at the structure of those molecules that have potent anti-cancer activity, we have been able to determine the electrical requirements of the target, along with its overall shape. The diagram shows three regions of positive charge (red), with the extent of the red indicating the required magnitude of positive charge, while regions that should not contain any positive charge are shown in yellow.*

*Using a computer, we then are able to design a drug that meets those electrical and structural requirements, as the second diagram shows. This was the design approach behind the discovery of our first lead compound, CS-6, and the basis of the Company's extensive analog program that is reaching out to find the world's first family of functionally related anti-cancer drugs.*





My non-chemist summary of this is that:

- we have taken the benzopyran drug technology, not just to the next level, but to a hitherto unimagined level
- we have uncovered a new family of drugs that we can make our own on the basis of their novelty
- we have developed a way of making benzopyran anti-cancer drugs substantially more active than before
- we now have a way of modeling the drug to better suit the cancer target
- we can now design and make super-benzopyran compounds at will in a highly efficient way
- when the time comes to bring these drugs to market, their manufacturing cost will be more than halved compared to earlier Novogen drugs.

I also want to make a point that surprises me doesn't seem to get the market recognition that I believe it deserves. And that is the logical basis of what we are doing.

The great majority of drugs that we rely on today to treat cancer were discovered either by accident or by trawling through Nature. There was no logic to it; literally millions of specimens from Nature were screened for anti-cancer activity, and when one was found, researchers then set about looking at how it worked.

These drugs continue to be the mainstay of chemotherapy to this day because they are good at what they do, poisoning functions or disrupting fundamental structures within the cancer cell. But they have two key downsides. The first is that they generally can't discriminate between cancer cells and healthy cells. The second is that cancer cells are very good at learning how to avoid the effects of such drugs, so that for the cancers that humans most commonly suffer, tumor recurrence is the all-too-common outcome.

Over time, we have come to understand how these drugs work, but even with this knowledge, modern science by and large has been unable to engineer more powerful or safer versions.

The inability to improve on these crudely effective drugs drove drug researchers into so-called *rational drug design*. The idea here is to identify a particular protein in a cancer cell that is considered important to its function or survival, and then design a drug that specifically inhibits that protein. That approach has given us a whole new family of anti-cancer drugs (eg. Herceptin, Avastin, Zytigar), all of which have contributed to better clinical outcomes for cancer patients, but which on the whole have failed to deliver anything more than marginal survival benefits to most patients.

The limited benefit of the *rationally designed* drugs comes simply because the targets chosen are not sufficiently critically important to the survival of a cancer cell. Cancer cells are remarkably adaptive and quickly learn how to circumvent the inconvenience of having a minor side-road shut down. Until the main highways in the cancer cell are identified, this approach will always be of limited value.

We use the term ***logical drug design*** to describe what we do.

We have a drug pharmacophore that is

- killing tumor cells that are resistant to standard anti-cancer drugs
- killing both cancer stem cells and their daughter cells
- killing tumor cells irrespective of their phenotype (where they arise).

AND it appears to be so effective because it is targeting an element of the cancer cell that is so fundamental to its survival, that its inhibition causes it to die by a process of chemical asphyxiation. Our target is the cancer cell's source of energy or the way it uses energy, something that the cell cannot by-pass.

AND the target appears to be restricted to cancer cells, because we see so little toxicity with this pharmacophore.

AND when we make subtle changes to the exterior of the pharmacophore, we see the target shifting, suggesting that the underlying target comes in multiple forms.

In summary, we appear to have discovered a master key that is opening multiple locks. By the process of *reverse engineering*, we now are seeking to identify those different locks and their appropriate keys, with a view to creating a family of super-benzopyran drugs capable of eradicating all cells within an individual tumor and across the spectrum of different tumor types.

That's why we call it **Logical Drug Design**.

### **(b) Other technologies**

Unfortunately I cannot go into detail at this point, other than to say it involves both another entirely new drug technology platform and a smart drug delivery system designed to deliver drugs directly to the tumor.

The strategy is simple. Faced with treatment of a significant mass of a highly aggressive, recurrent tumor resistant to all known chemotherapies and radiotherapy, nothing short of a full-frontal assault is going to be required to ensure effective killing of both the subversive cancer stem cells and their far more populous and rapidly dividing daughter cells.

We see that full-frontal assault combining a super-benzopyran drug selected for its propensity to attack cancer stem cells of a particular genotype, along with a non-selective drug capable of delivering an additional knock-out blow to the daughter cells, and to have both drugs delivered in a highly focused and concentrated way to the tumor.

### **(c) Trilexium (CS-6)**

The first lead candidate to emerge from our super-benzopyran drug development program is CS-6, now known as Trilexium.

Trilexium currently is undergoing a pre-clinical program with a view to bringing it into the clinic next year for two clinical indications: temozolomide-resistant glioblastoma multiforme and late-stage recurrent ovarian cancer.

There is not much more to be said about this drug candidate at this time other than we have committed significant resources to bringing it through into the clinic as quickly as possible. The one change to its program is the recent introduction of the 'smart' drug delivery system into the drug development program that has led to us looking at this as a potentially better alternative delivery system to the standard one we currently have employed.

### **(d) Drug discovery program**

Trilexium is just the first of many. An analog program is current and intended to deliver a family of related drugs, all with complementary anti-cancer activity that will be the backbone of our goal in delivering personalized chemotherapy. Trilexium will be just one member of that family of drugs, although as the first member of that family, we are looking to develop it as a stand-alone drug.



Appreciating the significance of this strategy requires an explanation. Something that biotech companies tend not to disclose is the limit of effectiveness of a particular experimental drug. By this, I don't mean whether it is more or less active against breast cancer cells versus prostate cancer cells: rather how effective it is on an individual tumor basis, irrespective of the type of cancer. It's not so much that they keep this secret so much as they simply don't know before they get into the clinic. And it is only there that you find that while it might be an efficient killer of cancer cells in the test-tube, in the clinic it is only working in 10% or 25% or 50% of cases. In fact, rarely is it ever known why it doesn't work in most individuals.

With our super-benzopyran drugs, we started without any preconceived ideas of how universal their effect might be. We had a pretty good idea in general terms how they were working, but we had yet to nail down the molecular target precisely, and without knowing that, it was impossible to predict just how universally effective any of those drugs might be.

Like almost every other company, we started by screening our drugs against the regular, commercially-available cancer cell lines: the same ones that the US National Cancer Institute uses in its drug-screening system. And drugs like Trilexium came up as killing everything.

But then we decided to go a step that most drug development companies haven't gone in the past, and that was to use primary cell cultures from fresh tumor biopsies. This is far more tedious and a lot more expensive than buying commercially-available cancer cell lines that have been around for years, but ultimately far more reliable in indicating likely clinical benefit.

Taking that extra step proved critical. Suddenly the universality of the cancer-killing effect was no longer present. A drug such as Trilexium might be killing cancer stem cells where no other drug has worked, but it didn't work in every case. But by tweaking the structure of Trilexium, a non-killing effect could be turned into a killing-effect, and vice versa.

From this came the realization that our technology wasn't producing the usual kind of anti-cancer drug whose action depended on the type of cancer cells (eg. breast versus prostate), but rather on the individual genotype of the cancer cell. It was at that point that the dream of personalized chemotherapy started to become a practical reality.

We believe that our super-benzopyran drugs target fundamental fault-lines that must occur within a cancer cell in order for it to behave as a cancer cell, and that the nature of those fault lines varies subtly between individuals. We appear with our ability to modify these drugs to be identifying those subtle differences.

## The immediate future

Now I'll try and paint a picture of how I see the Company's R&D program unfolding over the next 2-3 years.

- Bringing Trilexium into and through the clinic as a stand-alone chemotherapy for glioblastoma and ovarian cancer remains a priority. We already know it is unlikely to work in every case, but we expect it to have the potential to work in most cases, and with further studies, we hope to be able to identify responders and non-responders beforehand. *This is a program that Novogen believes it can take through with its own resources.*
- Trilexium is nothing more than an interim step on the way to identifying a family of super-benzopyran drugs capable of working against cancer stem cells across a broad range of genotypes. *This is a large program that Novogen will need to partner in order to provide the resources and expertise to attain that goal. The nature of that partnership is the subject of current negotiations.*
- A second drug technology (details yet to be announced) will be undertaken by Novogen using its own resources.

We currently are conducting all of our programs on a virtual basis, with no intention at this stage of bringing the necessary expertise in-house beyond the minimum number of managers required to coordinate the effort of contractors.

This is prudent financial management, giving us the ability to switch the funding tap on and off as we see fit without being restricted by an in-house structure, and being able to call quickly on the expertise of others without having to develop it in-house. However, our longer-term corporate goal of developing the means of delivering personalized chemotherapy is going to require a somewhat different corporate approach. The corporate structure and the means of funding this program are matters that are under consideration as I write and that I expect to be unveiled in the near future.

It's a busy time and an exciting future.

I want to finish with an old-fashioned notion that seems remarkably obvious to me, and yet doesn't seem to me to be articulated all that much by the Executive and Boards of public companies. And that is that you, shareholders, own the Company, and we, the executive and directors, are your employees. We are here only as long as we enjoy your trust and respect. That simple notion is what motivates me to maintain an open and frank dialogue with shareholders, and to keep you as informed as possible through announcements and through our website. Regular interaction with our shareholders inspires us, so please feel free at any time to contact me.

Yours faithfully



Graham Kelly  
Chief Executive Officer



Directors' Report

2013



## DIRECTORS' REPORT (SHORT VERSION)

The directors present their report, together with the financial statements, on the consolidated entity (referred to hereafter as the 'consolidated entity') consisting of Novogen Limited (referred to hereafter as the 'company' or 'parent entity') and the entities it controlled for the year ended 30 June 2013.

### Directors

The Company directors as at the date of this report are as follows:

Professor Graham Kelly	Chairman (appointed 7 December 2012)
Mr Robert Birch	Deputy Chairman (appointed 7 December 2012)
Dr Andrew Heaton	Executive Director (appointed 7 December 2012)
Mr John O'Connor	Non-Executive Director (appointed 25 May 2012)
Mr Steven Coffey	Non-Executive Director (appointed 8 November 2012)

Former directors who served during the twelve months ended 30 June 2013:

Mr William Rueckert	Former Chairman (resigned 7 December 2012)
Mr Peter White	Former Director (resigned 7 December 2012)
Mr Ross Youngman	Former Director (resigned 8 November 2012)
Mr Josiah Austin	Former Director (resigned 19 April 2013)

Names, qualifications, experience and special responsibilities:



*Name:*

**Professor Graham E Kelly**

*Title:*

Executive Chairman, Chief Executive Officer

*Qualifications:*

B.SC (Hons), B.V.Sc (Hons), D. Phil

*Experience and expertise:*

Graham is the founder, Chief Executive Officer ('CEO') and Chairman Novogen Limited. He is also the founding Chairman of NASDAQ-listed MEI Pharma, Inc. (formally Marshall Edwards Inc.). Both companies were built on the concept of benzopyran drug technology that emanated from his 25 years in medical cancer research and for which he held all relevant patents. Graham has overseen the design and implementation of thirty- three Phase I and II clinical trials, and a multi-national Phase III trial in conjunction with the US FDA. Graham has been awarded an Adjunct

Professorship by the University of Sydney.

*Other current directorships:* None

*Former directorships*

*(last 3 years):* Chairman of Triaxial Pharmaceuticals Pty Ltd

*Special responsibilities:* None

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*Name:*

**Robert Birch**

*Title:*

Non-Executive Director and Deputy Chairman

*Experience and expertise:*

Robert served for 23 years in the Royal Australian Navy in a career that included postings to the UK, Papua New Guinea and to the USA as a liaison officer with the US Navy. After leaving the navy he established a successful business that he has managed for over 20 years and which has given him valuable experience in financial controls and administration. Robert is a long-term Novogen shareholder and a founding investor in Triaxial Pharmaceuticals. He has taken a keen interest in both companies and in particular has consistently championed the rights of Novogen shareholders. Robert brings to the Board a valuable combination of skills embracing attention to detail and a strong sense of shareholder rights.

*Other current directorships:* None

*Former directorships*

*(last 3 years):* None

*Special responsibilities:* Chairman of the Remuneration Committee

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**Andrew Heaton**

*Title:*

Executive Director

*Qualifications:*

B.Sc. (Hons) Ph.D

*Experience and expertise:* Andrew has extensive drug discovery background. He studied the complex interactions of signaling molecules associated with the mass spawning phenomena on the Great Barrier Reef. Following completion of his Ph.D studies Andrew completed post-doctoral research discovering molecules with unique biological activity from marine environment. The theme of discovery of biologically active natural products was continued in his tenured academic position investigating a variety of traditional bush medicines. Andrew first joined Novogen in 1998 as General Manager of the drug discovery program; progressing four compounds to clinical trials. Andrew was responsible for the design and execution of the Novogen drug discovery platform that gave rise to the lead compounds: ME-128, ME 196, ME-143 and ME-344, for which he is the principal inventor on a series of global patents. Andrew has extensive global experience in translating drug discovery strategies into New Chemical Entities ('NCE's') in global clinical trials.

*Other current directorships:* None

*Former directorships*

*(last 3 years):* Director of Triaxial Pharmaceuticals Pty Ltd

*Special responsibilities:* President and CEO of Novogen North America Inc

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*Name:* **Steven Coffey**

*Title:* Non-Executive Director

*Qualifications:* B. Comm., CA

*Experience and expertise:* Steven is a chartered accountant, having spent his career in public practice since graduating from University of New South Wales in 1983. He has been a partner in the chartered accounting firm Watkins Coffey Martin since 1993. He is a registered company auditor and audits a number of large private companies as well as a number of not for profit entities. He has previously served on the board of an Australian listed public company. He is currently a board member of private family foundation.

*Other current directorships:* None

*Former directorships*



*(last 3 years):* None

*Special responsibilities:* Chairman of the Audit Committee and member of the Remuneration Committee

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*Name:* **John P O'Connor**

*Title:* Non-Executive Director

*Experience and expertise:* John has spent his working life in the financial industry. In this time he has worked both in funds management and as a stockbroker. He has worked in the UK, USA and in Australia. He has held management roles and been a partner in securities businesses. He served on the Board of Lonsec Securities, a Zurich Insurance owned business, for several years. He has been a consultant to several biotech businesses, including Novogen Limited and MEI Pharma, Inc. assisting with fundraising. He is currently on the Board of the Fragile X Association of Australia, a not-for-profit organisation.

*Other current directorships:* None

*Former directorships* NuSep Holdings Limited (appointed 10 October 2011, resigned 19 February 2012)

*(last 3 years):*

*Special responsibilities:* Member of the Audit Committee

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### **Company Secretary**

Andrew Bursill (B. Agr. Ec., Accountancy) was appointed Company Secretary on 12 December 2012 replacing director Steven Coffey who was appointed on 8 November 2012 who replaced Ronald L Erratt. Andrew has been providing outsourced CFO and Company Secretarial services to listed and unlisted public companies since 1998.

## Directors' interests in the shares and options of the Company

	Ordinary shares fully paid	No. outstanding	Options Exercise price (\$)	Expiry date
<i>Current Directors</i>				
G Kelly	3,915,204	-	-	-
R Birch	1,622,122	-	-	-
A Heaton	7,600,400	-	-	-
S Coffey	89,236	-	-	-
J O'Connor	278,551	45,644	0.5256	6 May 2014

## Principal Activities

Since its inception in 1994, the principal business of Novogen has been pharmaceutical drug development. By the beginning of the current reporting period (1 July 2012), Novogen had ceased this or any other business. The previous Novogen Board had divested the Company of all intellectual property in this area and of any resources and personnel relevant to R&D. The pharmaceutical drug development business was restored on 5 December 2012 with the acquisition of private biotechnology company, Triaxial Pharmaceuticals Pty Ltd.

## Dividends

Dividends paid during the financial year were as follows:

2013	2012
\$	\$
<u>24,774,709</u>	<u>Nil</u>

On 27 November 2012, a dividend was paid via an in-specie distribution of shares in MEI Pharma, Inc. representing 23.87 cents per ordinary share.

There were no dividends paid, recommended or declared during the previous financial year.

## Review of Operations

The loss for the consolidated entity after providing for income tax and non-controlling interest amounted to \$1,030,852 (30 June 2012 profit of: \$1,309,071).

For a detailed review of the operations of Novogen Limited since December 2012, when the company was restructured, please refer to the 'Chief Executive Officer report' at the start of the Annual Report.

The directors make no comment on the operations of MEI Pharma, Inc. which no longer is part of the consolidated entity.

## Operating and Financial Review

### Cash resources

At 30 June 2013, the Group had total funds of \$2,738,435 compared to \$8,347,908 as at 30 June 2012.

### Revenue

The Group earned revenues from continuing operations of \$1,111,936 compared to \$1,446,692 in the previous financial year.

### Funds raised

The Company undertook two capital-raising during this reporting year. The first was a private placement of ordinary shares to sophisticated investors in Australia managed by Patersons Securities. \$2,380,150 was raised by the issue of ordinary shares at a price of 16.6 cents, being a 20% discount to the closing price of 20.5 cents on 10 April 2013.

The second raising was a Share Purchase Plan offered to Australian and New Zealand Novogen shareholders that raised \$789,685 through the issue of 4,645,207 ordinary shares.

## RESEARCH AND DEVELOPMENT REPORT

### *Super-benzopyrans*

The technology platform underpinning the Company's R&D efforts is an ability to construct compounds based on a benzopyran molecular scaffold using a wide range atoms and chemical moieties. The Company refers to the resulting structures as super-benzopyrans in order to distinguish them from other anti-cancer drugs based on the basic benzopyran scaffold and which are limited to carbon hydrogen and oxygen components.

The Company is in the early stages of exploiting this technology, but in the 6 months that the Company has been engaged in this task, it has observed that super-benzopyran compounds display considerably different anti-cancer effects and more drug-like features compared to the simple benzopyrans that Novogen developed in the years 1998-2008. One of those differences is a considerable increase in anti-cancer potency. Some toxicity in animals also is being observed, something not previously encountered with the simple benzopyrans, although the side-effects are moderate and neither dose-limiting nor life-threatening. Studies are underway to better understand the nature of this toxicity, but it is believed to be a function of the super-benzopyran's greater anti-cancer potency.

The Company currently is engaged in a program with the goal of delivering a number of super-benzopyran compounds with increasingly greater and more varied anti-cancer effects. The Company has engaged the services of a Swiss chemical company, Carbogen Amcis, to assist in the design and manufacture of these new compounds that then will be screened in the laboratory for their ability to kill human cancer cells. For screening, the Company is using primary cell cultures and cancer stem cell cultures rather than the more widely-used, commercially available differentiated cancer cell lines. This is a more expensive and more time-consuming approach than normally employed, but the Company believes that it will yield data far more relevant to the clinic and ultimately save the Company considerable time and money. The Company has entered into contracts with a number of different biotechnology companies and research institutions globally to provide these screening services. The current contract calls for the delivery of 80 super-benzopyran analogs by October, which the Company expects will take several months to screen for anti-cancer cell activity.

One of the key outcomes of the analog program to date has been the observation that minor structural changes to the underlying super-benzopyran structure yields changes in the types of cancer cells responding to the different compounds. The Company believes that this represents a minor change in the protein target, rather than a shift in the general nature of the target such as its phenotype. The precise molecular target of the Company's lead candidate, Trilexium (CS-6), is under investigation at this time, but on the basis of early evidence is thought to be ability of the cancer cell's mitochondria to provide energy. The Company's working hypothesis is that the target is a protein involved in the bioenergetics of the cancer cell and that derives from a mutated gene or genes within mitochondrial and nuclear DNA.

### **Trilexium**

This is the Company's lead drug candidate. The primary clinical targets for Trilexium are ovarian cancer and glioblastoma multiforme (GBM), the main form of primary brain cancer.

The ovarian cancer indication came out of data generated from collaboration with Yale University Medical School. That data showed that Trilexium is highly cytotoxic to both ovarian cancer stem cells and to their daughter cells. The GBM clinical indication is predicated largely on two observations: (a) that Trilexium displays potent cytotoxicity against GBM cells in vitro, including primary cultures of GBM, and (b) that it has been deliberately designed to meet the known major chemical criteria for crossing the blood-brain barrier.



An important aspect of the current pre-clinical studies is the objective of identifying the preferred sub-sets of patients to target with Trilexium. In the case of patients with GBM, debulking surgery and radiotherapy followed by the drug, temozolomide (TMZ), remain the standard of care for this cancer. GBM typically is a very aggressive cancer with a median survival of about 5 months following failure of TMZ therapy. In the face of such rapid disease progression, the optimal patient parameters and preferred method of drug administration will need to be identified beforehand. Early laboratory data is indicating that Trilexium is more effective against GBM cells inherently resistant to TMZ (approximately 80% of GBM tumors) and does not re-sensitise to GBM, all of which point to using the drug as a monotherapy preferentially in those patients who fail to respond to TMZ in the first place.

In the case of ovarian cancer, Trilexium does not reverse resistance to standard of care cytotoxic drugs, so again, seems certain to be used as a monotherapy in late-stage, chemo-refractory disease.

### ***Drug expansion program***

The Company has settled on a preferred pharmacophore, this being the core part of the structure of the super-benzopyran family of molecules that is fundamental to their integrity as active anti-cancer drugs. This pharmacophore is represented in the Trilexium structure.

Using this pharmacophore as the starting point, the current drug expansion program is seeking to identify new lead drug candidates that the Company intends to use as the basis of its goal of developing a panel of super-benzopyran drugs capable of anti-cancer activity across a wide spectrum of genotypes and phenotypes (in particular cancer stem cells and their differentiated daughter cells). The design and manufacture of the first 80 analogs, and their in vitro screening for anti-cancer activity, are current.

## **Significant Changes in the State of Affairs**

### ***Kai Medical Holdings Limited***

On 27 July 2012, the previous Board of Novogen announced that it had entered into a merger agreement with Kai Medical, a US-based company whose business is focused on sleep apnoea therapy devices. That agreement was terminated shortly after when advice was received that the merger would have created problems with ASX listing rules.

### ***MEI Pharma***

Novogen was a majority (approximately 60%) shareholder in MEI Pharma, Inc (MEIP). MEIP held the consolidated entity's intellectual property in the field isoflavonoid drugs.

On 17 November 2012, Novogen shareholders approved the in-specie distribution of MEIP, that distribution eventually occurring on 27 November 2012.

### ***Glycotex***

Glycotex Inc. previously held the consolidated entity's glucan technology intellectual property for the treatment of trophic ulcers. That intellectual property was sold on 27 July 2012 for total cash proceeds of \$0.15M to a private US-based company.

On 27 November 2012, Novogen sold the remaining shell company to another private US-based company.

### ***Triaxial Pharmaceuticals***

On 5 December 2012 the company acquired the biotechnology company Triaxial Pharmaceuticals Pty Ltd ('Triaxial'). Triaxial developed a novel technology platform allowing the design and construction of novel family of compounds that Triaxial refers to as super-benzopyrans.

### ***Other***

On 5 February 2013 the company announced the filing of a provisional patent application covering the manufacture and use of super-benzopyrans.

On 18 February 2013 the company announced results of an important study concerning its lead experimental drug CS-6 (Trilexium). Initial studies showed highly effective results regarding ovarian cancer stem cells.

There were no other significant changes in the state of affairs of the consolidated entity during the financial year.

## **Matters subsequent to the end of the Financial Year**

On 4 July 2013, the Company announced that it had entered into a funding arrangement with a sophisticated US-based institutional investor providing it with up to A\$5 million of working capital over 3 years. Under the Agreement, the investor will invest up to a maximum of \$5 million in Novogen by purchasing up to 5 interest-free convertible securities with a minimum period of 120 days between tranches; the price of each security being a minimum of AU\$165,000 and a maximum of AU\$1 million by mutual consent. The Investor also will receive options that will expire at the end of three years and have an option exercise price of 130% of the average daily VWAPs per share for the 20 consecutive trading days immediately prior to 2 July 2013. Usual adjustments for reconstructions will apply.

The conversion price for the convertible securities will be, at the Investor's discretion, either 90% of the average of 3 daily VWAPs per share, as selected by the Investor, during the 20 consecutive trading days immediately prior to the relevant Conversion Notice Day, or a limited number at 130% of the average of the daily VWAPs per share for the 20 consecutive trading days immediately prior to execution of the Agreement.

The first investment of AU\$1.0 million was called on immediately by way of a converted security with a face value of AU\$1.1 million. No other matter or circumstance has arisen since 30 June 2013 that has significantly affected, or may significantly affect the consolidated entity's operations, the results of those operations, or the consolidated entity's state of affairs in future financial years.

### **Likely developments and expected results of operations**

The Company currently is engaged in discussions on two matters that, if successful, will have a significant impact on the Company's structure and R&D activities.

The first matter concerns the acquisition of a novel drug technology that the Company believes complements the super-benzopyran drug technology and will assist the Company in its aim of delivering effective chemotherapy across a broad spectrum of both cancer phenotypes and genotypes.

The second matter concerns a collaborative structure that will allow the Company to work towards its goal of individualizing chemotherapy.

Both matters are expected to be concluded by the end of this year.

### **Number of employees**

The Group employed 6 people as at 30 June 2013.

This report is made in accordance with a resolution of directors, pursuant to section 298(2)(a) of the Corporations Act 2001.

On behalf of the directors



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Graham Kelly, Chairman, September 2013 Sydney