



## November 2018 Strategic case study examination

### Pre-seen material



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## **Novak Pharmaceuticals**

You are a senior manager in the finance function at Novak Pharmaceuticals (“Novak”). You report directly to the Board and advise on special projects and strategic matters.

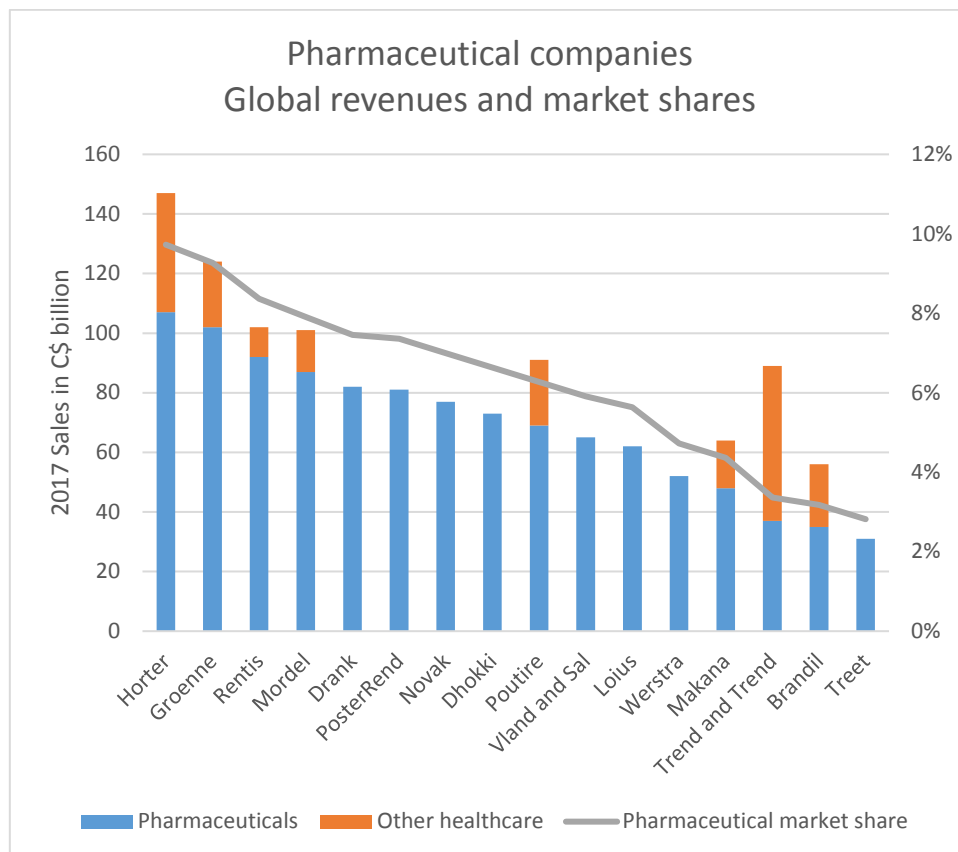
Novak is based in Cronland where the currency is the C\$. Cronland requires companies to prepare their financial statements in accordance with IFRS.

Novak is quoted on the Cronland Stock Exchange. This is an active and well-regulated exchange. Companies which are quoted on the exchange are required to adhere to the Cronland Code of Corporate Governance, which sets out detailed regulations relating to the governance arrangements for quoted companies.

## Industry background

Pharmaceutical companies develop and manufacture pharmaceutical drugs that are used as medications to prevent, cure or treat diseases. This is a major industry that employs more than five million people worldwide. Global sales of pharmaceutical products exceed USD 1,100 billion every year. The industry tends to be identified with managing the healthcare of human patients, and so excludes peripheral areas such as veterinary medicines and health-related products other than prescription medicines (medicines prescribed by qualified medical professionals from an approved and licenced list). Some pharmaceutical companies also engage in non-pharmaceutical activities, such as the manufacture of medicines that can be purchased without a prescription, while others do not.

The pharmaceutical industry has many significant companies, with no single company accounting for more than 10% of the global market. Most companies operate globally, locating both factories and research centres in a strategic manner, with a view to building relationships with local markets. Having a local presence can affect the extent to which drugs are licensed and prescribed.

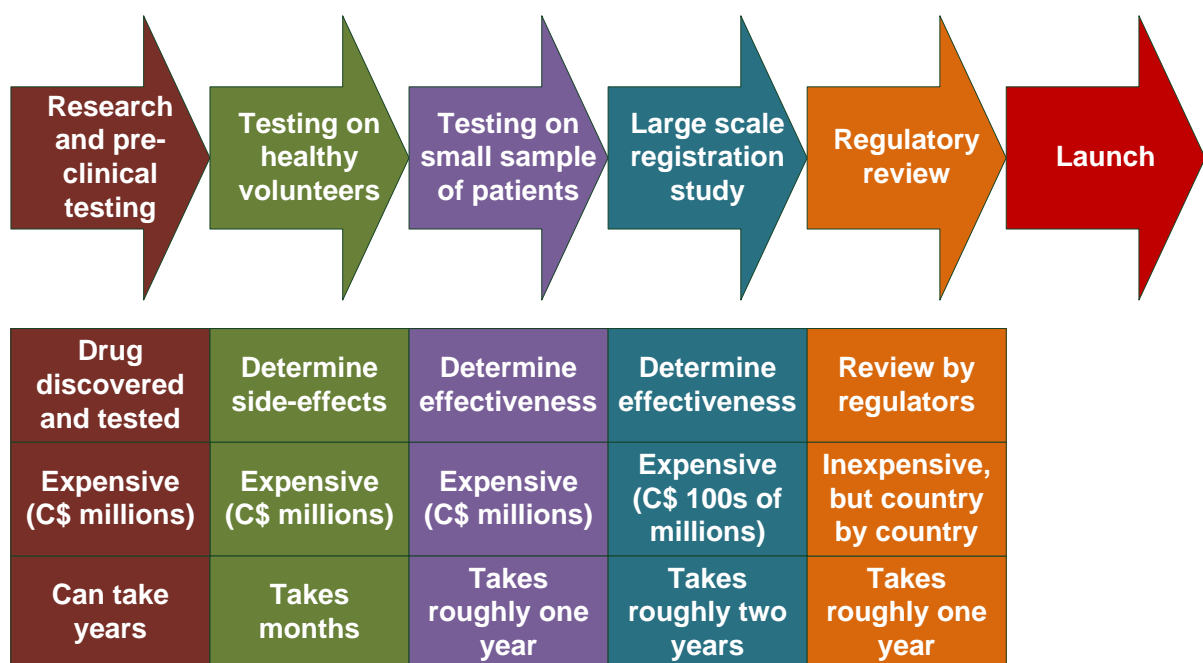


## Research and development

The prosperity of individual companies does not necessarily reflect the strength or weakness of the pharmaceutical market as a whole. Generally, trends in sales and operating profits are driven by success or failure in launching new drugs and in maintaining the market position of existing products.

Any given pharmaceutical drug is licensed for use in a specific situation. For example, an antibiotic might be licensed for use in the treatment of a particular type of infection. Drugs that are regarded as the most effective treatments available for a common disease can generate massive sales revenues and the companies that manufacture them can make most of their profits from a few key products. Such leads can be lost, though, if a competitor develops a superior product in that category.

Developing and testing a new drug is a costly and time-consuming process:



Pharmaceutical companies are constantly conducting research into the creation of new drugs. This research may be conducted by in-house corporate research facilities or through the funding of research by university departments.

The initial study is likely to be conducted in a laboratory, perhaps testing the effects of chemical compounds on samples of human tissue or on animals. The compounds themselves may be developed through knowledge of the chemical properties of different materials. Computer models can also be used to predict the interaction between, say, molecules of chemical compounds and diseased cells.

The discovery of a new drug is only the start of a long and expensive process. There are several further stages, each of which could result in the return to a previous stage for refinement of the formula or the abandonment of the project. It has been estimated that as many as 90% of all projects are abandoned during research and testing.

Before a drug can be sold commercially, it must undergo extensive testing in order to establish that the drug is an effective treatment for the condition or conditions for which it is indicated and that it is safe. Safety is a relative term because many pharmaceutical products have side effects that can make the patient feel unwell. In some cases, the side effects can

have serious and even fatal consequences. One of the functions of testing is to establish that the side effects are known and manageable. For example, drowsiness is a common side effect of many drugs. Patients can be warned that they should not drive or operate



machinery when that is a risk. Drugs that threaten severe side effects may be authorised for sale if they can treat a serious illness. Doctors may make informed decisions to prescribe drugs that could cause injury because the alternative is to leave a serious disease untreated and the consequences of doing so outweigh the risks associated with the treatment.

The first set of tests involves giving the drug to healthy volunteers, who are generally paid for their participation in the trial. This is

intended to identify any side-effects that the drug may have. Potentially harmful side effects, such as elevated blood pressure, can be monitored and treated before the test subjects come to any significant harm. Less serious side effects, such as mild nausea or headaches can be noted.

Assuming that the drug has no dangerous side effects, it can progress to clinical trials. In the first instance, these will be conducted on a small number of patients in order to test the effectiveness of the drug and to have a further check that any side effects are tolerable. Then a large-scale study is carried out as a final check on the safety and effectiveness of the drug.

Drug testing is a complicated business, partly because of the psychological placebo effect, in which patients may report a physical response to a drug because they believe that it is affecting them. Drug tests usually involve selecting a suitably large sample of test subjects and giving some a dummy version of the medication. All participants know that they may be receiving either a real dose or not and so it is easier to determine the real effect of the medication. The subjects who receive the dummy version are called the “control group” and their results are compared with those of the subjects who actually received the drug.

It can cost C\$ billions to bring a new drug to market, when taking the costs of development and testing into account.

## **Regulatory authorities**

Most countries have strict regulations about the licensing and use of pharmaceutical products. These regulations are intended to ensure that new drugs have been properly tested in accordance with national laws. Each country has its own organisation to ensure that its laws have been complied with.

Each country requires pharmaceutical companies to submit applications that fully detail the tests carried out and the results that have been obtained before a drug can be passed as safe for use. In Cronland, the Pharmaceutical Testing Authority (PTA) is the responsible body. Fortunately, most countries have very similar requirements and so it takes very little time and effort to adapt applications to make them suitable for submission to other countries.

The regulators continue to take an interest in the safety of drugs once they have been licensed for use. Pharmaceutical companies are required to publish contact details that enable doctors and pharmacists to report concerns about possible side effects or adverse reactions. If a pharmaceutical company believes that there is a cause for concern with one of its products then it must contact the regulators in each country in which the drug is licensed.

The regulators may then leave it to the pharmaceutical company to investigate or they may suspend the licence until the results of any investigation are known.

## Intellectual property

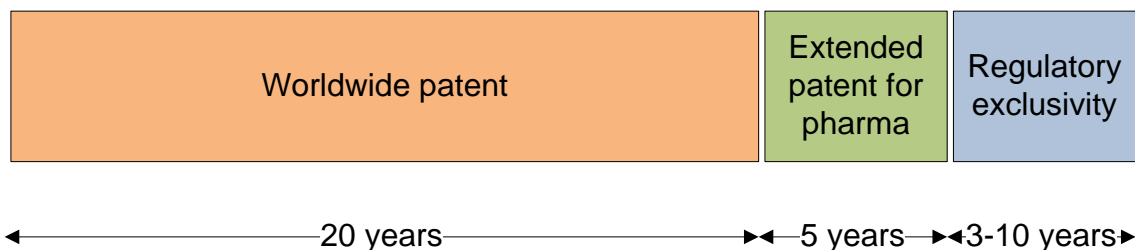
There would be little incentive for pharmaceutical companies to invest in research and development if competitors could copy and sell their products. Pharmaceutical companies are protected in two ways, through both patents and regulatory exclusivities.

Drugs can be patented in the same manner as for any other product. The most effective way to patent a drug is to identify the active ingredient, which is essentially the “new” product, and patent that. So, the patent essentially gives its owner the exclusive right to manufacture and sell a chemical compound.

Worldwide patents on pharmaceuticals have a life of 20 years. Unfortunately, patents are usually applied for and granted at an early stage of development and testing and so they may have less than ten years left to run by the time a new drug is launched. There have been cases where a drug’s patent expired prior to launch because of delays in development and testing.

Many countries, including Cronland, have legislation that permits pharmaceutical companies to extend their patents by up to five years. This protection is not available in every country.

Regulatory exclusivities are an additional source of protection and incentive to pharmaceutical companies. Essentially, they extend the protection offered by patents. The rules associated with regulatory exclusivities vary between countries. In Cronland, a new chemical compound would receive an additional five years’ exclusivity. A modification or reformulation of an existing compound would be protected for a further three years. Those periods are extended for a further six months if the drug is deemed safe for use by children. “Orphan drugs” that target rare conditions affecting fewer than 5 citizens in 10,000 could be protected for up to a further 10 years.



Thus, the intellectual property is protected worldwide by patent for at least 20 years. Many countries, including Cronland, permit patents on pharmaceuticals to be extended by up to an additional five years. Thereafter, the intellectual property may be protected by a regulatory exclusivity for a period that can be determined by the nature of the pharmaceutical.

Patent holders have the right to exclusivity in the manufacture and sale of patented products. They also have the right to permit others to manufacture their products under licence. Licence agreements are common in the pharmaceutical industry, with patent holders receiving either royalties or reciprocal rights to manufacture their counterpart’s product.

Once a product reaches the end of its protection, it is said to be “off-patent”. Effectively, that means that anybody can manufacture it and sell it commercially without the need for permission or the payment of a licence fee. This can prove problematic for any company that is relying on a few best-selling products because each will eventually go off-patent and that

could attract other manufacturers, who will compete on price and so drive down unit selling prices.

The different rules on extension of patents and regulatory exclusivity can mean that a pharmaceutical product goes off patent at different times in different countries. For example, the law in the country of Froland restricts protection to the initial 20 year period, with no right to extend. That can mean that there could be a period during which manufacturers are permitted to make and sell products in Froland, but cannot export them to countries such as Cronland because they are still protected there.

The fact that a drug is essentially a chemical compound that can be created to a formula means that off-patent drugs are often described as “generics”. For example, acetylsalicylic acid is more commonly known as “aspirin”. It is a generic drug that is manufactured worldwide by many different manufacturers. The medicinal qualities of the compound itself are not affected by the manufacture, although there may be differences in packaging or in presentation.

Trademarks are an important source of competitive advantage because they can, in theory, continue indefinitely. It is common for pharmaceutical companies to sell their products under a trademarked name that becomes familiar to patients. When the drug goes off-patent then it may be manufactured by other companies, but they will not be permitted to sell it under the trademarked name unless they purchase a licence. Patients may be reluctant to switch to a drug that has a different name to the one that they have been taking, even though it is chemically identical.

## Obtaining pharmaceutical drugs

In most countries, pharmaceutical drugs can only be prescribed by qualified medical practitioners and dispensed by registered pharmacists. Most countries have a licensing body that ensures that the appropriate testing has been undertaken and that the results indicate that the product is safe. Generally, most pharmaceutical drugs are sold worldwide, although there are drugs that have been banned in some countries despite being available elsewhere.

It is unusual for the patients who use pharmaceutical products to pay for them directly. In many countries, including Cronland, the government funds healthcare and the pharmaceutical products prescribed by hospitals and general practitioners are paid for by the government’s health service. Other countries do not have state-funded healthcare, but most individuals buy health insurance and the insurer pays for any drugs that are required.



Manufacturing and distribution costs are very small when compared to the costs incurred on research, development and testing. The selling price of the relatively few drugs that make it to market must be sufficient to cover both successful and unsuccessful drugs. This can make some drugs very expensive, especially if the diseases that they are to be prescribed to treat are rare.

Both state-funded and insurance-funded health providers take the price they pay into account when deciding whether a drug can be prescribed. This decision focusses on the cost of permitting the drug’s use and has nothing to do with its safety. Some pharmaceutical products would cost many thousands or even millions of C\$ over the patient’s lifetime,

particularly if the drug treats symptoms rather than curing the disease, so that stopping treatment could be harmful and even fatal.

The Cronland Health Service (CHS) has a Pharmaceutical Review Agency (PRA) that reviews all new drugs from the perspective of cost-effectiveness. The PRA has a limited interest in the clinical issues, although sometimes drugs are rejected because they offer very little in terms of improving the patient's quality of life. The PRA tends to focus mainly on the budgetary implications of approving a new drug. There have been many cases in which expensive drugs have been rejected even though they would literally save patients' lives. The PRA has to consider the impact that approval might have in terms of diverting other resources. There is a limit to the amount that can be spent on newly developed drugs before they start to have an impact on other commitments. There have been cases where a new drug is launched that would cost hundreds of thousands, or even millions, of C\$ for a full course of treatment for each patient. The PRA has been known to refuse approval for certain drugs because of the net social cost of spending money to treat one patient that would otherwise be used to treat many patients who rely on the CHS for less expensive treatments.

The fact that a drug has been reviewed and deemed safe by the Pharmaceutical Testing Authority (PTA) does not mean that it will be viewed as cost-effective by the PRA. Each agency has its own interest and both must be satisfied.

## **Over-the counter medicines and non-pharmaceutical products**

The major companies in the global pharmaceutical industry have different approaches to the question of diversification. Many pharmaceutical companies produce nothing but pharmaceutical products that are, essentially, drugs that can only be prescribed by a qualified person, usually a doctor, dentist or nurse. Other companies have wider interests in healthcare.

Some major pharmaceutical companies also manufacture over-the-counter (OTC) medicines. These can be purchased without a prescription and so enable users to self-medicate without having to visit their doctor. Typically, a user might treat a headache or a minor injury using a mild painkiller, such as aspirin or paracetamol.

OTC medicines can be sold from a variety of retailers including pharmacies, but also including general retailers and supermarkets. They are frequently branded versions of generic drugs. For example, some OTC painkillers have a brand name despite relying primarily on paracetamol as their active ingredient. Other products combine compounds. For example, products sold to treat the symptoms of the common cold virus may be nothing



more than paracetamol to reduce temperature and an anti-histamine to prevent sneezing.

OTC medicines generally have shorter and less risky product development cycles. They may comprise proven generic compounds that require little further testing or they may be low-risk in the sense that users will be required to take only small doses of mild drugs.

Some pharmaceutical companies also manufacture disposables that are intended for healthcare, such as

dressings and diagnostic test supplies. These can have synergies in marketing and distribution to the hospitals and health services that purchase pharmaceutical drugs and the pharmacies and retailers who retail OTC drugs.



## Novak's history

The company traces its origins back to an apothecary's shop (a forerunner to a modern-day pharmacy) that was established in the early 19<sup>th</sup> Century by Saul Novak in Cronland's capital city.

The shop was very successful because of a treatment devised by Mr Novak for relieving the symptoms of bronchitis, a serious respiratory illness. The shop had further success with an ointment that reduced the inflammation associated with sprained ankles. Mr Novak opened five further shops before setting up a laboratory that was used to manufacture popular products in bulk and to establish a space for the development of new products.



Novak was incorporated as a company in the middle of the 19<sup>th</sup> Century. The company grew steadily, becoming quoted on the Cronland Stock Exchange in 1960. Novak has developed many successful pharmaceutical products. Novak led the industry in developing treatments for serious infections. Novak's "Dromor" was launched in the 1980s. It was a radical new antibiotic and it continues to be prescribed

today, although it is now off-patent and so is no longer manufactured exclusively by Novak.

Novak has two major research centres, one in Cronland and the other in Westralia. Each centre employs 1,500 talented chemists and pharmacists, supported by skilled technicians. Both research centres have the very latest equipment. Novak also has 12 factories, three of which are in Cronland and the remainder are spread worldwide.

Novak is currently the seventh largest pharmaceutical company in the world when ranked in terms of revenue from the sale of pharmaceutical products. These rankings are volatile and are generally not a particularly good indicator of a pharmaceutical company's underlying strength. The launch of a single successful new product or the expiry of a patent can significantly alter the rankings.



## **Novak's mission statement and corporate values**

### **Mission**

Novak's mission is to provide society with innovative and effective solutions to disease and ill health.

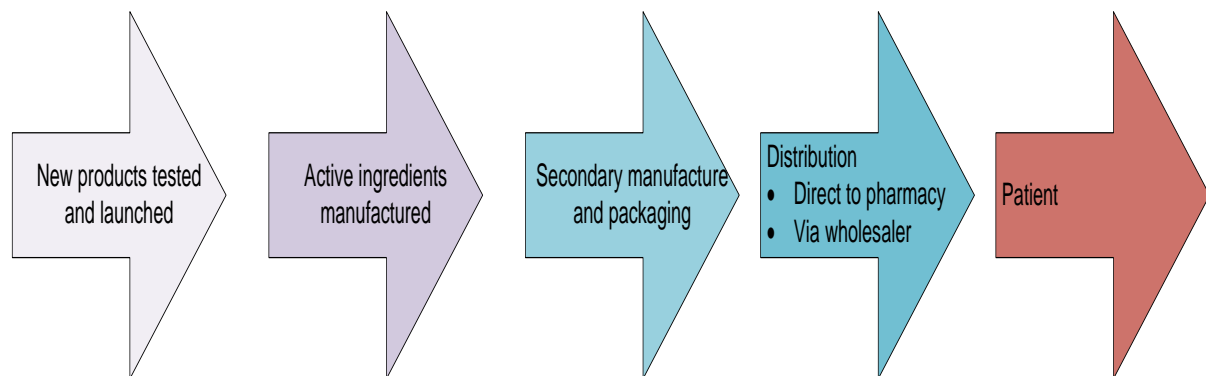
### **Corporate values**

1. Novak works to extend and enhance human lives.
2. Novak is committed to the highest standards of ethics. The safety of consumers is paramount.
3. Novak's research will be driven by the needs of consumers.
4. Novak will be commercially responsible, recognising that sustainable profits fund cutting-edge research activities in addition to rewarding shareholders for their investment.
5. Novak will offer employees a safe and secure working environment, in which all feel valued and respected.

## Novak's strategy

Novak focusses exclusively on the development and manufacture of pharmaceutical drugs. The company has traditionally had great strength in the development of new drugs. Novak is regarded as highly innovative and that attracts high-quality research staff. The medical profession is also likely to pay attention to any new products by Novak because of its past successes.

Novak's supply chain is typical of the pharmaceutical industry:



Novak does not manufacture generics, other than products that it developed itself and that are now out of patent.

Once a product has been approved for use, Novak must manufacture the active ingredients that give the drug its medicinal properties. The objective is to manufacture the chemical compound that has been identified during the development phase. The cost varies according to the materials and the complexity of the product. Quality control must be a priority in order to ensure the purity of the compound, otherwise there is a risk that the patient will receive too weak, or too strong, a dose.

Active pharmaceutical ingredients are generally taken in such small doses that they need to be combined with a buffer to make them manageable and the resulting medicine must then be packaged so that it does not deteriorate in storage. During the development phase, Novak will decide on the most appropriate form of administration. It could be orally in the form of a tablet, capsule or syrup or it could be injected through a syringe or intravenous drip.

The manufacturing process is complicated by the fact that demand for some pharmaceuticals varies because numbers of cases of the diseases for which they are indicated can vary. Sometimes that is due to seasonal factors and sometimes there are unexpected outbreaks of infectious or contagious diseases. Novak's production schedules have to be flexible.

Novak has a large global sales force, under the supervision of regional sales managers responsible for America, Australia & New Zealand, Europe, Africa & the Middle East, and Asia Pacific. Sales are made directly to larger pharmacies, such as those in large hospitals and major chains of retail pharmacists. Novak also makes sales to specialist wholesalers, who then supply smaller pharmacies.

Finally, patients are prescribed the products by their doctors, nurses or dentists. That is usually on the basis of a clinical diagnosis by the health professional and a decision that a particular drug is indicated to deal with the patient's condition.

Novak's business model is heavily driven by research and development. There are many diseases that are either untreatable or the pharmaceuticals that are available have severe

side effects. Novak has been at the forefront of developing new technologies to streamline the development and testing of drugs. These include advances in genetic engineering and also the development of new delivery technologies that target diseased cells more effectively. Such advances enable treatments to be aimed more directly at the root of the disease, either offering new treatments or allowing previously dangerous drugs to be given in smaller doses that are nevertheless effective.

Over the years, Novak has expanded both organically and through acquisition, including three last year. The targets for acquisition have generally been selected on the basis of existing products or evidence of promising new products in development. Novak has often found it more cost-effective to acquire a leading competitor in a given field than to develop a superior product.

Two of Novak's most successful drugs went off-patent at the end of 2016 and the company has suffered some recent disappointments in the testing of potential new drugs. Novak's Board is confident that the company will soon launch three major products, each of which has the potential to generate significant revenues and profits.

## Costings

The following costings show the cost of making Mintac, one of Novak's most successful antibiotics. This tablet is used extensively for treating chest infections. It is popular with doctors because it has very few side effects and that makes it safe to prescribe to elderly patients, who are particularly susceptible to indicated diseases. Mintac has eight years of patent protection still remaining.

	C\$ per kg of processed API	C\$/tablet
Active pharmaceutical ingredients (API)	42.07	0.008
Formulation cost	145.94	0.029
Excipient ingredients	28.05	0.006
Other manufacturing costs	70.03	0.014
Packaging	190.45	0.038
	<u>476.54</u>	<u>0.095</u>
Selling price		5.27

The active pharmaceutical ingredients (API) are the raw materials used to make a kilogram of the active pharmaceutical product that gives Mintac its effectiveness. Sufficient API to make a kilogram of the active product in Mintac costs C\$42.07. The formulation cost of C\$145.94 comprises the labour and overheads that are required to process the API into a kilogram of the active pharmaceutical product.

Excipient ingredients comprise the non-medicinal materials that are required to manufacture a usable pharmaceutical product. The recommended dosage of Mintac is 200mg of the active pharmaceutical product, which is too small a quantity to be handled and used by patients. Mintac is taken orally in pill form, so the excipient ingredients are used to create an inert buffer material that is mixed in very precise proportions with the active product. This makes it possible to create a much larger tablet from a 200mg dose. The buffer is designed to dissolve at a predetermined rate in the patient's stomach, releasing the active pharmaceutical product into the patient's body.

Other manufacturing costs comprise the processes associated with converting the mixture of active pharmaceutical product and excipient ingredients into pills. Packaging costs involve packing the pills safely in blister strips and inserting the strips into boxes.

Most patients are required to take four Mintac tablets a day for seven days, by which time they should be free of infection. That means that a course of treatment will sell for  $4 \times 7 \times \text{C}\$5.27 = \text{C}\$147.56$ .

The manufacturing cost to Novak of that course of treatment is  $4 \times 7 \times \text{C}\$0.095 = \text{C}\$2.66$ .

For licensed drugs there are other substantial costs such as the amortisation of legal and patent fees. We include these in "Cost of sales".



## **Novak's board of directors**

### ***Dirk Lepain, Chief Executive***

Dirk originally trained as a pharmacist and spent much of his career with a major quoted chain of retail pharmacies. He was Chief Operating Officer of that company for five years before joining Novak as Chief Executive in 2014.

### ***Dr Anton Frind, Director of Research***

Anton has a PhD in pharmacy from Barron University in Cronland. He spent 20 years conducting academic research into the action of pharmaceutical products on the central nervous system. On appointment he was one of Barron University's youngest ever professors and he co-authored papers with senior consultants at major teaching hospitals. Anton left academic life to become Novak's Director of Research in 2009.

### ***Dr Mary Tang, Director of Production***

Mary has a PhD in pharmacy from Cronland University. Before joining Novak, she worked in the research laboratory of a major pharmaceutical company where she specialised in veterinary medicines. She joined Novak in 2008 as a senior production manager and was promoted to Director of Production in 2014.

### ***Fiona Dubin, Director of Sales and Marketing***

Fiona has had a long and distinguished career in marketing. Before joining Novak, Fiona held senior marketing positions in several major quoted companies, including a spell on the board of a major car manufacturer. Fiona joined Novak as Director of Sales and Marketing in 2016.

### ***Randal Edwards, Director of Finance***

Randal has been Novak's Director of Finance since 2016. He is a professionally qualified accountant. Before joining Novak, Randal was Finance Director of a quoted healthcare manufacturer.

### ***Juliane Horst, Director of Legal Affairs***

Juliane is an experienced lawyer. After completing a law degree, she joined a major law firm as a junior associate. She spent several years in the firm's Dispute Resolution Department, where she was responsible for advising clients on civil disputes. She was promoted to partner, specialising in intellectual property disputes.

She left the firm to join Novak's Board in 2015.

***Dorothy Novak, Chair***

Dorothy's great grandfather was the nephew of Saul Novak, the company's founder. Dorothy was the full-time Chief Executive of the Novak Charity Foundation, which was founded by her grandfather after Novak was floated and the family divested itself of much of its equity. She has served as Novak's chair for three years.

***Professor Winston Alade, non-executive director***

Winston joined Novak's Board as a non-executive director in 2015. He was previously a professor of pharmacy at Cronland's Southern City University.

***Marcia Conelli, non-executive director***

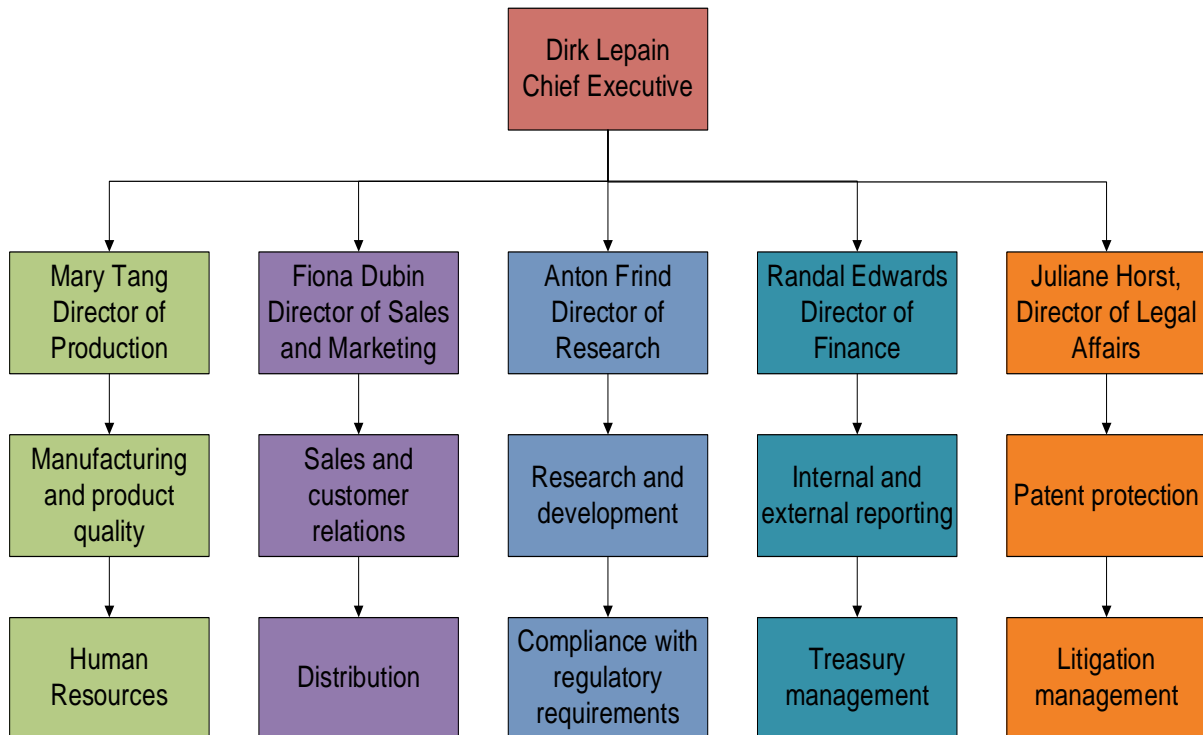
Marcia had a long and distinguished career in the banking industry. She joined Novak as a non-executive director in 2017.

***Dr Henry Wong, non-executive director***

Henry is a medical doctor. Prior to joining Novak, he held several prestigious positions, the most recent of which being that of Clinical Director of Central City General Infirmary. He joined Novak as a non-executive in 2016.



## Organisation Chart







## **Extract from Novak's Corporate Social Responsibility Report for the year ended 31 December 2017**

Novak's mission is to provide society with innovative and effective solutions to disease and ill health. In order to do so, we strive to be responsible and effective stewards of our shareholders' wealth. This enables us to generate wealth with a view to offering investors a realistic return while also retaining funds that can be used to finance the development of improved medicines that will benefit humankind.

### **Economic**

Novak is one of the world's largest pharmaceutical companies (in terms of sales revenue). It holds a dominant position in several key classes of pharmaceutical products, including antibiotics.

Novak is a global enterprise with 12 factories in 10 countries.

We are a responsible and ethical organisation. We aim to be good citizens in the many countries in which we do business. For example, we obey the spirit of all local tax regulations, as well as the letter.

### **Environmental**

Novak has reduced carbon emissions from manufacturing activities by 26% since 2008. Further reductions are being sought.

Carbon emissions associated with distribution have increased by 6% since 2008. That increase is partly a reflection of increased sales volume. The nature of our product also requires that we take care in the safe storage and transportation of products. Any deterioration or contamination could threaten patient safety. We are working on ways to reduce these emissions.

Wherever possible, Novak uses renewable and recyclable materials for packaging purposes, provided that doing so is consistent with product quality and patient safety.

### **Social**

#### *Tackling disease*

Novak patented 98 new compounds during the year ended 31 December 2017. Many of these will be developed into future pharmaceutical products.

Novak provides formal training to health workers in developing countries. This gives patients access to care and advice that would otherwise be denied to them.

Novak offers extensive support to healthcare professionals, including sponsorship of lecture programmes in hospitals, extensive web-based training programmes and subsidised subscriptions to leading medical journals for junior doctors.

Novak has a policy of making its products affordable to patients in developing countries. Treatments for serious conditions are sold at subsidised prices. During the year ended 31 December 2017, Novak donated more than twenty million doses of Kartiam, its anti-malarial drug, to health services in developing countries.

Novak is committed to the sale of safe and effective medication. All new products are tested to a standard that we think would exceed the most stringent regulations of any country.

Novak is working to develop new and effective alternatives to testing new pharmaceuticals on live subjects. Exciting new technologies are emerging from computer simulation and from DNA sequencing that enable new compounds to be tested using virtual techniques in the first instance. These new technologies are already proving effective in filtering out potentially harmful compounds at an early stage. They also offer the possibility that new drugs will be developed more quickly as well as being potentially safer and more effective than existing products.

### *Employment*

Novak employs 108,000 people worldwide. We have a policy of paying a living wage to every employee, taking notice of the cost of living in the various countries in which we operate.

Novak has a diverse workforce. Staff are recruited and promoted on the basis of merit.

Novak's bursary scheme operates in several countries, sponsoring school pupils, college and university students from disadvantaged backgrounds to continue their studies. Participants in the scheme are eligible for work placements during vacation time. More than 95% of participants are subsequently offered full-time employment with Novak on the completion of their studies.



The following information has been extracted from Novak's financial statements for the year ended 31 December 2017

**Novak**

**Consolidated statement of profit or loss  
for the year ended 31 December**

	<b>2017</b>	<b>2016</b>
	<b>C\$m</b>	<b>C\$m</b>
Revenue	77,149	81,412
Cost of sales	<u>(25,459)</u>	<u>(26,052)</u>
Gross profit	51,690	55,360
Selling and administration	(23,145)	(22,987)
Research	(13,115)	(13,426)
Royalty income	<u>2,253</u>	<u>2,412</u>
Operating profit	17,683	21,359
Finance expenses	<u>(1,624)</u>	<u>(1,766)</u>
Profit before taxation	16,059	19,593
Taxation	<u>(5,942)</u>	<u>(7,053)</u>
Profit for the year	<u><u>10,117</u></u>	<u><u>12,540</u></u>

**Novak**

**Consolidated statement of changes in equity  
for the year ended 31 December 2017**

	Shares and share premium <b>C\$m</b>	Retained earnings <b>C\$m</b>	Currency reserve <b>C\$m</b>	Total <b>C\$m</b>
As at 1 January 2017	15,000	40,651	9,478	65,129
Profit for the year		10,117		10,117
Dividends		(9,000)		(9,000)
Movement			2,017	2,017
As at 31 December 2017	<u><u>15,000</u></u>	<u><u>41,768</u></u>	<u><u>11,495</u></u>	<u><u>68,263</u></u>

**Novak****Consolidated statement of financial position  
as at 31 December**

	<b>2017</b>	<b>2016</b>
	<b>C\$m</b>	<b>C\$m</b>
<b>Non-current assets</b>		
Property, plant and equipment	23,373	23,422
Goodwill	15,236	14,260
Other intangible assets	39,870	41,872
	<u>78,479</u>	<u>79,554</u>
<b>Current assets</b>		
Inventories	13,275	12,996
Trade receivables	11,858	13,468
Cash and cash equivalents	7,456	8,389
	<u>32,589</u>	<u>34,853</u>
Total assets	<u>111,068</u>	<u>114,407</u>
<b>Equity</b>		
Shares and share premium	15,000	15,000
Currency reserve	11,495	9,478
Retained earnings	41,768	40,651
	<u>68,263</u>	<u>65,129</u>
<b>Non-current liabilities</b>		
Borrowings	32,000	37,000
<b>Current liabilities</b>		
Trade payables	4,875	5,233
Taxation	5,930	7,045
	<u>10,805</u>	<u>12,278</u>
	<u>111,068</u>	<u>114,407</u>

## Extracts from a competitor's financial statements

### PosterRend

#### Consolidated statement of profit or loss for the year ended 31 December

	<b>2017</b>	<b>2016</b>
	<b>C\$m</b>	<b>C\$m</b>
Revenue	81,289	79,684
Cost of sales	(26,012)	(24,702)
Gross profit	55,277	54,982
Selling and administration	(23,574)	(23,325)
Research	(16,014)	(15,897)
Royalty income	3,487	3,195
Operating profit	19,176	18,955
Finance expenses	(1,500)	(1,250)
Profit before taxation	17,676	17,705
Taxation	(6,010)	(6,197)
Profit for the year	<u>11,666</u>	<u>11,508</u>

### PosterRend

#### Consolidated statement of changes in equity for the year ended 31 December 2017

	Shares and share premium	Retained earnings	Currency reserve	Total
	<b>C\$m</b>	<b>C\$m</b>	<b>C\$m</b>	<b>C\$m</b>
As at 1 January 2017	25,000	49,054	9,178	83,232
Profit for the year		11,666		11,666
Dividends		(8,000)		(8,000)
Movement			3,186	3,186
As at 31 December 2017	<u>25,000</u>	<u>52,720</u>	<u>12,364</u>	<u>90,084</u>

**PosterRend**  
**Consolidated statement of financial position**  
**as at 31 December**

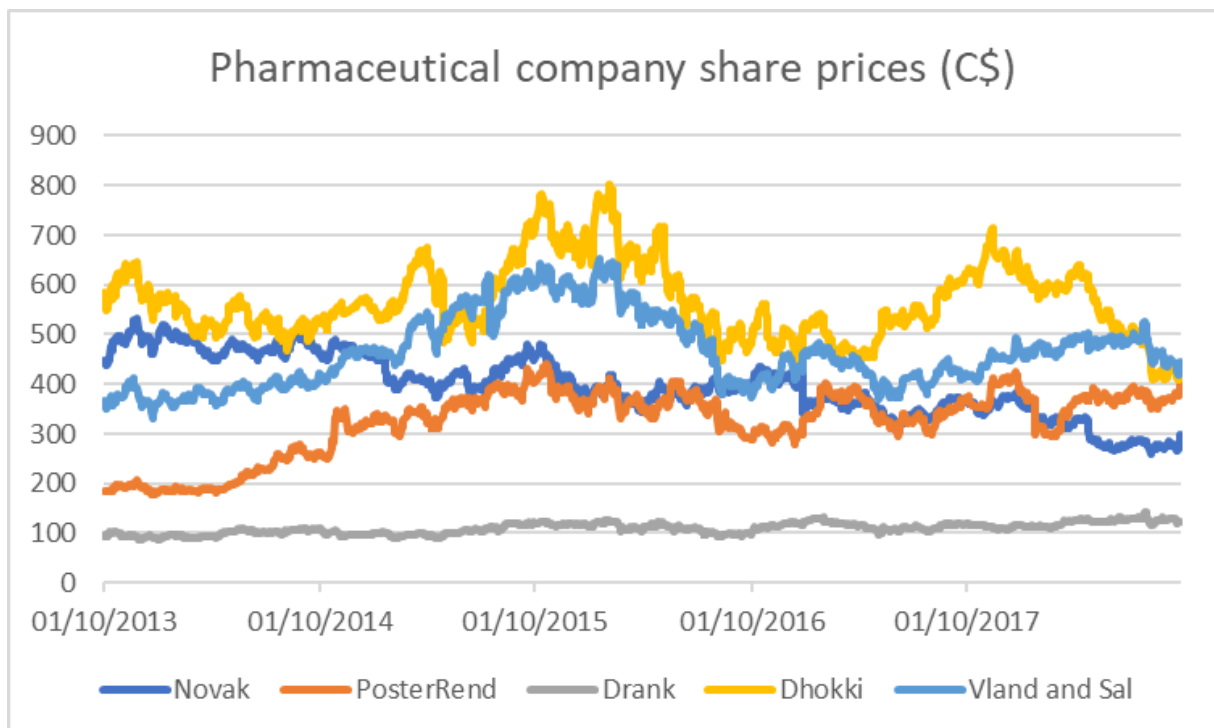
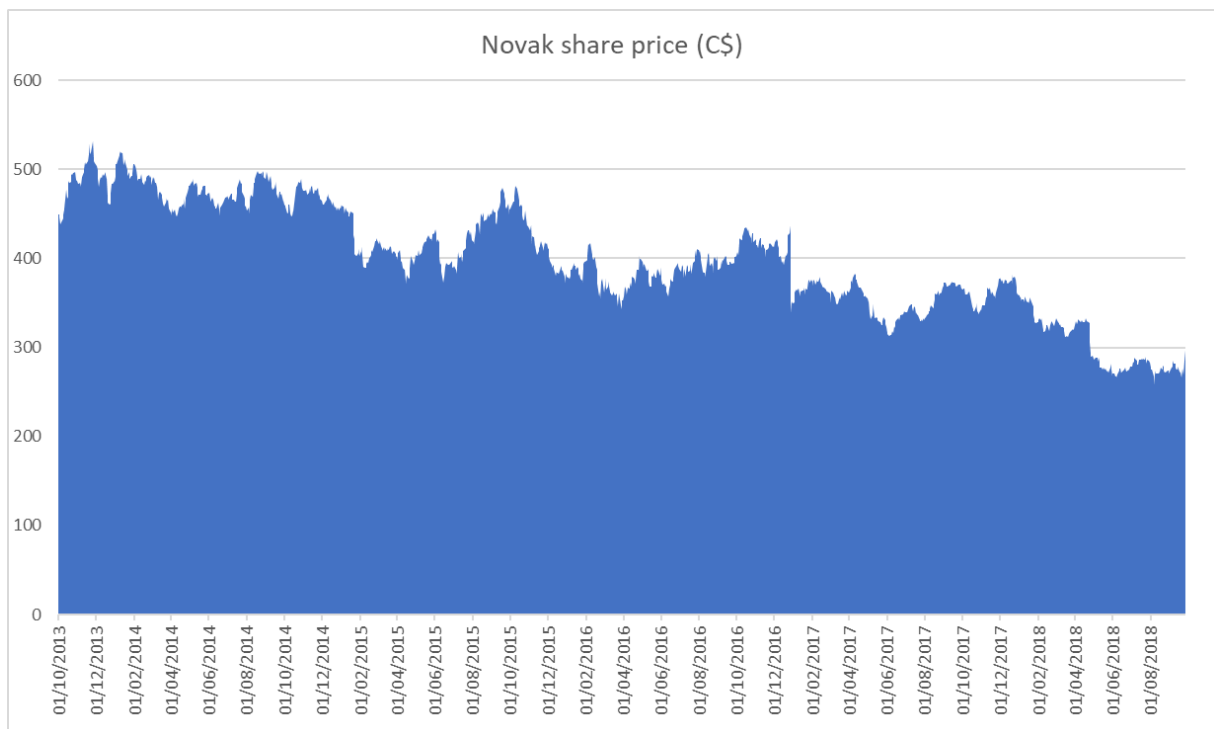
	<b>2017</b>	<b>2016</b>
	<b>C\$m</b>	<b>C\$m</b>
<b>Non-current assets</b>		
Property, plant and equipment	35,015	27,136
Goodwill	17,528	16,879
Other intangible assets	44,157	42,749
	<u>96,700</u>	<u>86,764</u>
<b>Current assets</b>		
Inventories	14,785	14,216
Trade receivables	12,749	12,036
Cash and cash equivalents	6,875	6,574
	<u>34,409</u>	<u>32,826</u>
<b>Total assets</b>	<u><u>131,109</u></u>	<u><u>119,590</u></u>
<b>Equity</b>		
Shares and share premium	25,000	25,000
Currency reserve	12,364	9,178
Retained earnings	52,720	49,054
	<u>90,084</u>	<u>83,232</u>
<b>Non-current liabilities</b>		
Borrowings	30,000	25,000
<b>Current liabilities</b>		
Trade payables	5,027	5,222
Taxation	5,998	6,136
	<u>11,025</u>	<u>11,358</u>
	<u><u>131,109</u></u>	<u><u>119,590</u></u>



### Extract from risk report in Novak’s Annual Report

Risk factors	
Doctors are often reluctant to change their prescribing habits.	Novak invests heavily in ensuring that hospital doctors and general practitioners are updated on its latest products.
The licensing of pharmaceuticals is constantly changing	Pharmaceutical products have a long development process and regulations can change before a new product can be authorised.
Staff skill shortages	Novak relies heavily on its ability to recruit and retain employees with the necessary skills to support both research and manufacturing.
Financing risk	It can be difficult to get finance for projects of C\$50 million or more due to the difficulty of proving a viable market for the drug exists.
Reputation risk	There is a risk that the public could lose faith in the products due to unforeseen events.

## Share prices





# Cronland Independent News

## Eight injured during pharmaceutical testing

Eight volunteers in a drug trial were rushed by ambulance to Central City General Infirmary last night after they suffered fits and breathing difficulties. The volunteers were understood to be employed by Horter in trials of an anti-inflammatory pharmaceutical product that the company is developing.

A hospital spokesperson commented that eight patients had been admitted. Two had been transferred to the intensive care unit, but all were expected to make a full recovery.

Pharmaceutical companies make extensive use of volunteers for drug testing. Typically, volunteers are young and unemployed. They are paid for their participation, typically C\$250 to C\$300. They are required to sign waivers that prevent them from claiming damages in the event that they are harmed during the testing.

Drug companies are working hard to reduce the extent to which they test products on laboratory animals and human subjects (“in vivo” testing). Simulation software can model the effects of drugs on the human body and tests can be carried out on cell cultures in laboratories (“in vitro” testing). Sadly, it remains necessary to conduct final tests on human beings before a drug can be authorised for use on patients.

# Cronland Local

## PRA rejects new drug

The Pharmaceutical Review Agency has confirmed that it will not permit the Cronland Health Service to prescribe Denovax, the recently developed drug that promised to help asthma sufferers to manage their conditions. A spokesperson from Werstra, the global pharmaceutical company that developed the drug, expressed disappointment at the announcement. “Clinical trials of Denovax proved that the product is safe and effective.”

The Pharmaceutical Review Agency’s report stated that Denovax was an effective remedy that would benefit patients with severe forms of asthma, but the product was simply too expensive for purchase from public funds.

# Cronland Independent News

## Orphan diseases to be discussed at Summit

Orphan diseases are defined as being rare, affecting only a small proportion of any given country's population. This can be a misleading description because large countries could have tens of thousands or even hundreds of thousands of victims. That is potentially a lot of human suffering that goes unnoticed. Worse, pharmaceutical companies have little commercial incentive to develop products that will have a limited market because of the relatively small number of potential patients requiring prescriptions.

Most countries have complex rules relating to patent protection of pharmaceuticals. These generally include additional protection for the orphan drugs that have been developed to treat orphan diseases. In practice, this simply means that the pharmaceutical company will have a longer period of patent protection, which does little to offset the fact that annual sales are restricted.

World leaders attending the forthcoming economic summit are planning to devote a session to debate possible responses to this problem. There may be ways in which pharmaceutical companies can be incentivised, or even compelled, to deal with this.