



## STRATEGIC CASE STUDY

November 2018

DEEP DIVE



THE PHARMACEUTICAL COMPANY

## **Industry Overview**

The pharmaceutical industry is a global industry and is one of the biggest industries in the world with a market of USD 1.2 trillion. The market is dominated by few large companies which account for more than 50% of the whole market. Prominent pharmaceutical companies are renowned for their commitment towards innovation, and they spend heavily on research and development.

The modern pharmaceutical industry traces its origin to two sources: apothecaries that moved into wholesale production of drugs such as morphine, quinine, and strychnine in the middle of the 19th century and dye and chemical companies that established research labs and discovered medical applications for their products starting in the 1880s. Other firms whose names carry recognition today began with the production of organic chemicals before moving into pharmaceuticals.

The pharmaceutical industry discovers, develops, produces, and markets pharmaceutical drugs for use as medications. Pharmaceutical companies may deal in generic or brand medications and medical devices. They are subjected to a variety of laws and regulations that govern the patenting, testing, safety, efficacy and marketing of drugs.

The pharmaceutical industry has become a large and very complex enterprise. At the end of the 20th century, most of the world's largest pharmaceutical companies were located in North America, Europe, and Japan; many of the largest were multinational, having research, manufacturing, and sales taking place in multiple countries. Since pharmaceuticals can be quite profitable, many countries are trying to develop the infrastructure necessary for drug companies in their countries to become larger and to compete on a worldwide scale. The industry has also come to be characterized by outsourcing. That is, many companies contract with specialty manufacturers or research firms to carry out parts of the drug development process for them. Others try to retain most of the processes within their own company. Since the pharmaceutical industry is driven largely by profits and competition (each company striving to be the first to find cures for specific diseases), it is anticipated that the industry will continue to change and evolve over time.

However, there has been increasing controversy surrounding pharmaceutical marketing and influence. There have been accusations of influence on doctors and other health professionals through attractive and young drug sales reps, constant provision of marketing 'gifts' and biased information to health professionals, funding independent healthcare organizations and health promotion campaigns, lobbying physicians and politicians more than any other industry, sponsorship of medical schools and nurse training, influencing the curriculum of medical schools, promoting addictive pain killers (opioids) as non – addictive and hiring physicians as paid consultants on medical advisory boards.

Currently, the industry is going through a period of profound change due to factors like financial and sovereign debt crises, globalisation, demographic and epidemiological pressures, advances in communication technologies, declining of research & development productivity, shift in direction of research & development and healthcare reforms. Any company that wants to make a smooth transition will have to focus on delivering value instead of charging high prices. It will have to supplement its products with services. Most importantly, it will have to become an integral part of the healthcare continuum.

### **Microscopic view of the Pre-seen (To be read alongside the pre-seen)**

- Novak is a quoted company on the Cronland Stock Exchange and it is an active and well regulated market. Therefore, the market's reactions to Novak's decisions that are reflected in-terms of the share prices should be considered accurate and important.
- Novak already follows the Cronland Code of Corporate Governance which would be advantageous for Novak when operating globally as this would enhance the corporate image of the company and most other countries would welcome a company that adheres to a strict code of corporate governance.
- The industry has many significant companies and no single company accounts for more than 10% of the global market while Novak accounts for around 7% of the market. Therefore, the competitive rivalry in the market should be very high. Furthermore, as the industry is in a matured stage without much of a market growth, all these companies are competing for the same revenue, and therefore, a loss for one company can mean profits for another.
- In 2017, Novak has been the 7<sup>th</sup> largest company in the world in-terms of market share and the 9<sup>th</sup> largest company in-terms of revenue. Therefore, companies with smaller market shares than Novak have earned higher revenues than us. This can be due to differences in the product portfolios and also due to the fact that two of Novak's most successful drugs went off patent at the end of 2016.
- In the pharmaceutical industry, although individual companies see volatility in their revenues, the market stays fairly constant, and in fact expands with the discovery of new diseases and new medicine. Therefore, poor performance of individual companies is difficult to be justified based on the poor performance of the industry as a whole.
- For a pharmaceutical company, the 2 most important factors are the success or failure in launching new drugs and maintaining the market position of existing products. In a broader perspective, this is what all pharmaceutical companies in the world primarily focus on, when structuring the business model of the company.

- For pharmaceutical companies to earn the most revenues, they need to focus on developing successful drugs for treating common diseases. The success of such drugs depend on the effectiveness of the drug along with reduced side effects. A major issue companies face in this regard is the time that should be spent on developing a new drug. There is no guarantee about the success or failure of the drug, and there is always the chance that a competitor might come up with a superior drug.
- Most pharmaceutical companies earn a majority of their revenue from few successful products (Pareto). This is risky as the competitive advantages in the industry can be lost and the company can be adversely affected financially within a short period of time. This can cause investors to lose confidence in the company. Therefore, companies always need to ensure that the new product pipeline of the company is well managed and new products are continuously introduced to retain the market position of the company.
- Developing a new drug is a costly and time consuming process. The average cost of developing a new drug is approximately USD 2.6 billion and it takes around 7 to 10 years for a new drug to be launched. The massive time taken in developing a new drug can cause all sorts of problems because within that time period, governments might have changed leading to policy and regulatory changes and the senior management of the company (CEO, etc) might have also changed leading to a change of culture within the organisation which can affect the drugs in development. But, the only way to remain competitive in the market is to develop new drugs and products, so companies continue their R&D efforts despite the overwhelmingly low 10% success rate.
- Information Technology (IT) is becoming increasingly important in the pharmaceutical industry, especially for research and development activities. Computer simulations can predict the behaviour of certain chemical compounds in precise ways and IT is also used to make clinical trials safer by simulating the conditions in an artificial environment before drugs are tested on humans.
- Getting the approval for the drugs developed from the regulatory authorities is a tedious process and each country can have different regulations making the process even tougher. Furthermore, even if a drug gets approved, the regulatory authorities would continuously assess the performance of the drug and they can suspend the licence immediately if some anomaly is reported related to the drug. Therefore, pharmaceutical companies should assess the performance of their drugs even after they are released to the market as a continuous process.
- In a pharmaceutical company, Intellectual Property includes patents and regulatory exclusivities for the active ingredients of the newly developed drugs. When a drug is protected by a patent, the company which developed the drug can earn massive profits by selling the drug and it can also receive royalty payments from any other company who manufactures the same drug. Therefore, properly managing the

intellectual property is paramount to the success of any pharmaceutical company. However, pharmaceutical companies are often accused of exploiting patents. Patents have been designed to advance not only the interests of its creator, but also, equally, the economy and well-being of the nation. But, at present, companies have used patents to increase the prices of drugs astronomically, sometimes the price increase exceeding 500%. Therefore, pharmaceutical companies have been accused of earning unsustainable and inhumane profits by the exploitation of regulatory loopholes, especially patents.

- Trademarks are the names in which drugs are presented to patients by pharmaceutical companies. Trademarks play a very important role in solidifying a single name in the mind of patients, instead of the generic drug name. This is very helpful for pharmaceutical companies to maintain a sustainable competitive advantage, even after the drug goes “off-patent” because patients would always want a particular trademark, instead of the generic drug. (Eg: Panadol is the trademark of GlaxoSmithKline for Paracetamol)
- The business model of pharmaceutical companies is unique in its own way. More than 99% of the cost of a drug is incurred even before a drug is launched and 90% of the projects for the development of new drugs end in failure. The manufacturing and distribution cost of a drug is less than 1% of the total cost. Pharmaceutical companies need to recover the initial R&D costs incurred on drugs as well as the costs incurred for the failed projects through the few drugs that actually make it to the market. Therefore, prices of drugs made for rare diseases (orphan drugs) can be very high and this is becoming a major issue for patients suffering from “orphan diseases”.
- In Cronland, the Pharmaceutical Review Agency (PRA) is primarily focused on the cost effectiveness of drugs instead of the clinical success of drugs. Therefore, as the price of drugs is a crucial factor for new drugs to get approved from the PRA, Novak needs to focus on developing drugs that are affordable. With the level of competitive rivalry in the pharmaceutical market at present, concentrating R&D efforts on affordable drugs would be a step towards the right direction for Novak as sustainable competitive advantages are the only way to ensure the continued success of the company.
- In Cronland, the PRA looks at the net social cost of treating patients, and essentially comes to the conclusion that “saving many lives is better than saving one life”. This can be a controversial argument as there can be counter arguments stating that all lives matter and saving lives matter regardless of the number saved. Therefore, there is a high chance that this practice is not adopted in other countries in which Novak operates. Therefore, Novak might be able to get approval for expensive drugs in other countries in which it operates, and this can mean that the company can even work on highly effective, but expensive drugs knowing that there would be a global market for the drugs.

- Novak is more than 200 years old. It is highly likely that there is a very strong culture inside the company and there is a legacy that Novak carries forward. This can be a strength in terms of employee motivation, but this strong culture can stand in the way of change. The management might not want to move away from their roots, and this can cause severe problems given the extent of the business dynamism that prevails in the current marketplace. It is important that Novak becomes a change adapt organisation.
- Novak has been a pioneer in research and development in the global pharmaceutical industry. This reputation would attract quality research staff which would be a major advantage for Novak, as the success of the company entirely depends on the success of the ongoing research efforts. The experiences gained by the company by developing new drugs for the past 200 years would be really useful in making decisions in the future regarding R&D activities. Knowledge Management Systems would be an important area that Novak should focus on to make better decisions using past experiences of the company.
- The mission of Novak seems to be consistent with the company values. The corporate values further explain the mission of the company. But, a vision statement for Novak is not present. Vision is the ideal stage a company wants to achieve in the future, and it can be used as a motivator to drive the company towards that ideal future. The vision of Novak can be “To be the most admired and best-in-class healthcare partner enhancing the quality of life through prevention, cure and innovation with commitment towards society and environment”.
- Novak’s workforce is a great asset to the company. The expertise of the workforce is really important for Novak to succeed in the highly competitive market available. If Novak can have the best research staff in the industry, it has a great chance of developing new and innovative drugs that would ensure the continued success of the company.
- As the development of a new drug takes a long time, Novak needs to ensure that it maintains staff turnover at a minimum level. If the research staff that is responsible for a certain project changes all the time, it is tough to ensure the success of the project and there would be no responsibility for the subsequent failure of the project. Furthermore, as all of these research projects are confidential, high staff turnover can result in the breach of confidentiality of the project too.
- Novak does not manufacture successful off – patent drugs of other companies. The strong culture of the company focused on R&D might be the reason for this. But, this can be a lucrative market to enter because healthcare professionals would be willing to prescribe Novak’s drugs just because of the impeccable reputation held by Novak as a successful pharmaceutical company.
- Quality control is a very important area for the company as the products of the company are directly consumed by living beings and any quality issues can be catastrophic and irreversible. To ensure the quality of the drugs, Novak can



introduce Total Quality Management (TQM) to the company. This would ensure that everybody within the organisation is responsible for quality and a quality issue at one stage wouldn't be passed to the next stage without rectification. Most importantly, the root cause for quality issues would be investigated and eradicated if possible, and this would be of immense help to ensure that the same quality issues won't be repeated in the future. But, implementation of TQM has its own challenges and a careful cost benefit analysis is important before a final decision is made.

- The demand for drugs can vary suddenly due to expected and unexpected circumstances. For an example, the flu season can be reasonably predicted, so Novak can make plans on increasing the production of flu drugs (antiviral drugs) before the start of the flu season. But, there can be unexpected outbreaks of other contagious diseases and Novak needs to respond quickly to the increased demand of drugs to treat those particular conditions. Hence, flexibility in manufacturing is important for Novak, and modern manufacturing techniques and philosophies can greatly help Novak in this regard.
- Medical professionals such as doctors, nurses and dentists play a major role in the sales of Novak. When prescribing drugs, medical professionals have the choice of prescribing a generic drug, or of prescribing a specific trademarked drug. Therefore, there is a direct correlation between the amount of prescriptions issued by healthcare professionals and the sales of Novak. The company needs to ensure that healthcare professionals prescribe Novak's drug instead of our competitor's drug. For this, Novak can use its sales staff to promote the drug and they can publish articles on medical journals stating the reasons for the superiority of our drug. But, Novak needs to be careful in this regard as pharmaceutical companies are often accused of employing shady practices to promote their drugs like making monthly payments to doctors who prescribe their drugs, giving free samples of drugs, using attractive sales reps hired from modelling agencies to promote their products, presenting expensive gifts for doctors who prescribe their drug the most, etc. The Cronland Code of Corporate Governance would be helpful in this regard.
- Currently, there are two major business opportunities for Novak. Firstly, Novak can develop drugs for currently untreatable conditions like HIV, cancer, etc. Secondly, it can develop drugs with lesser side effects to treat conditions for which drugs with high side effects are already available.
- Novak has grown with the help of acquisitions. There have been 3 acquisitions last year and the attitude of the company towards acquisitions seems to be very positive. Therefore, it is highly likely that this trend of acquisitions would continue and the company needs to properly compare the costs and benefits of acquisitions before making a final decision.
- Currently, Novak is in a chaotic position as two of Novak's most successful drugs have gone off-patent at the end of 2016 and the company has had disappointing results in the research and development areas. The financials of the company reflect

this (refer financial evaluation). Novak is the 7<sup>th</sup> largest company in the world in terms of market share in 2017, which means, Novak would have been much higher on the list before 2017, as 2017 has been a disappointing year for Novak. But, this might highlight a bigger issue regarding the master plan (long term plan) of the company. If Novak knew that 2 of their most successful drugs were going off-patent by the end of 2016, there should have been a master plan to launch new drugs by the beginning of 2016, so that the overall revenue of the company would not have been adversely affected by this incident. Hence, this incident can be used as an opportunity for the company to reconsider its master plan, and ensure the existence of a promising product pipeline to ensure the sustained success of Novak.

- The cost of a single tablet of Mintac is C\$ 0.095 while the selling price is C\$ 5.27. The difference between these two amounts which amounts to C\$ 5.175 is not the profit of Novak. This amount includes the research and development expenditure of Mintac, the apportioned expenditure of the research and development expenditure of some other failed drugs and the profit of Novak. This makes the calculation of a fair selling price complicated because Novak needs to reasonably estimate the total demand of the drug throughout its lifetime and apportion the total research and development cost to a single tablet. Therefore, sales forecasting techniques might be helpful here.
- Organisation Structure
  - Dorothy Novak is a member of the founding Novak family. Although there is no mention about her ownership percentage, if she is a shareholder of the company, her independence can be questioned as the UK code of corporate governance states that non – executives should not be significant shareholders of the company although this might be allowed under The Cronland Corporate Governance code.
  - Novak has 6 executive directors and 4 Non – executive directors including the chairman. The UK Corporate Governance Code states that there should be an equal number of executive and non – executive directors on the Board. This requirement is not fulfilled in Novak although this might be allowed under The Cronland Corporate Governance code. However, the Board comprises of equal number of males and females, which shows a good gender balance on the Board.
  - A Director of Human Resources is missing, and human resources is under the Director of Production Dr Mary Tang. This is problematic due to several reasons. Firstly, the company employs over 108,000 people globally and such a big workforce would definitely appreciate if their concerns are represented at the Board level. Secondly, most of our workforce is comprised of skilled employees and they are a major asset to the company. Therefore, keeping the workforce happy is of paramount importance for the success of the company and this requires a separate individual overseeing HR. Finally,



Production is one of the most crucial areas of the company, and it is unclear as to whether Dr Mary Tang can represent two of the most important functions of the company at the Board level and fulfil the duties of both her roles in a justifiable manner.

- Information Technology (IT) is not mentioned under the main functions of the company and the senior manager responsible for IT is unclear. But, IT is becoming increasingly important in the development of new drugs and the usage of new technology is revolutionising the whole pharmaceutical industry. Therefore, IT should be considered as an important area in Novak and a senior manager should be assigned for IT to improve and manage the IT related functions of the company.
- The current structure of the company is functional. But, as Novak has a large global sales force under the supervision of 5 regional sales managers responsible for 5 main geographical regions of the world, a divisional structure based on geographic regions might be more appropriate. But, a divisional structure can lead to duplication of functions and this can increase the management costs. Hence, it is possible to establish a matrix structure by which the regional sales managers would be able to directly contact the central management staff. This would be much more efficient than the current functional structure and it would also enable the central management staff to get a better understanding about regional matters by building better relationships with the regional sales managers. That being said, matrix structure has its own unique weaknesses and those should be properly assessed before a final decision is made.
- Carbon emissions associated with distribution of the company has increased since 2008 which is not a good sign. In the modern business environment, sustainable growth is regarded as a key success factor for a company and companies are rewarded for being good corporate citizens. Therefore, Novak has to work on reducing carbon emissions associated with distribution. But, it might not be easy for Novak to give up or change the traditional methods of business because these changes might jeopardize drug safety. Therefore, Novak needs to look at more innovative ways of being environmentally friendly, without compromising the safety of its products.
- Novak carries out so many projects to be a responsible corporate citizen. It can look at Integrated Reporting (IR) and Global Reporting Initiative (GRI). Novak can report on different aspects like stakeholder inclusiveness, sustainability context, materiality and completeness. In addition, Novak can also report on finance capital, manufactured capital, intellectual capital, human capital, social and relationship capital and natural capital. This would be adding value to the company in the modern era and would make the company stand out from the competition. It would be a great marketing tool for the company too. But, Novak needs to be careful here

as it can be accused of engaging in shady business practices using CSR initiatives. For an example, when Novak sponsors lecture programmes in hospitals, this might be seen as Novak trying to influence the judgement of healthcare professionals by promoting its own agenda and products.

- Political instability in the major global markets in which Novak operates can cause severe issues to the company. This is because pharmaceutical companies have a long development process and regulations of a country can change with a regime change before a new product can be authorised causing billions of financial losses to the company. Lobbying can help to mitigate this risk to a certain extent although there can be ethical issues associated with lobbying.
- Financing new projects for the development of new drugs can be an issue because the risks of failure are so high and the results can take a very long time. Hence, finance providers would be reluctant to undertake such a risky investments. To mitigate this issue, Novak needs to maintain an excellent track record of successful projects and having better relationships with finance providers would also help. Additionally, the company can look at alternative sources of financing.
- Novak faces a considerable reputational risk due to the nature of the industry. Stringent quality control measures, careful management review and regulatory compliance would help mitigate this risk to some extent.
- Novak's share price has dropped continuously since 2013 for 4 years. Looking at the industry as a whole, the share market has been volatile, but many other competitors have not seen a continuous reduction in share prices as Novak has. In fact, the share price of PosterRend has increased over the last 4 years. Therefore, Novak doesn't seem to be performing great at the share market and the reason for this needs to be found.
- Pharmaceutical companies make extensive use of volunteers for drug testing. This practice can cause backlash from human rights activists as this can be seen as humans being used as Guinea Pigs. The ethical concerns of this practice in the modern business environment are also severe. Therefore, companies need to make use of technology for drug testing more and more instead of living beings and the regulatory authorities should also support this move.
- At present, companies are encouraged to develop drugs for "orphan diseases" by granting a longer period of patent protection for the drug. Building on from that, governments and regulatory authorities can also present companies with government funded researches (government grants) and tax incentives to encourage companies further to develop drugs for "orphan diseases".

## **Porter's Five Forces Analysis**

- Threat of new entrants – The pharmaceutical industry is a mature business, and entering this industry is not easy for a new company. The initial cost of setting up a pharmaceutical company is very high and the subsequent research and development costs can be billions of USD. Furthermore, government regulations act as a major constraint for a new entrant. If a new entrant manages to clear all these hurdles and start to prosper as a company, a giant pharmaceutical company would usually acquire the new entrant outright, eliminating the threat imposed by the new entrant. Therefore, threat of new entrants is very low in the industry.
- Supplier bargaining power – Suppliers have very little power in the pharmaceutical industry. The raw materials for manufacturing drugs are commodity products in the chemical industry, which are available from numerous sources. Most of the equipment used in manufacturing and research is available from multiple manufacturers. Suppliers usually offer multiple products to the manufacturer, which moderates pricing on rarer materials and unique equipment.
- Customer bargaining power – Pharmaceutical industry is unique among industries because the patient has an absolute lack of power regarding pricing. The prescriber of the drugs, the physician, ethically is not allowed to profit from the sale of drugs. The entity that pays for the drugs, the insurance company, only has a say in how much it will pay to the distributor of the drugs, meaning it has little power with the drug manufacturers. The insurer can refuse to pay for treatments it believes are overpriced, putting the burden on the patient and not the pharmaceutical company. The only entities with any negotiating power are the pharmacies and medical institutions that fulfil the patients' prescriptions. Even these entities have little power over newer drugs under patent or drugs with only one manufacturer. Pharmacies focus on their profit margins and have little incentive to provide patients with the lowest possible pricing.
- Competitive rivalry – With more than USD 1.3 trillion in global sales, pharmaceutical industry has a high competitive rivalry. The huge importance of intellectual property results in strong competition for high-level workers and leading researchers. Even strong non-disclosure and non-compete clauses cannot prevent the leaking of competitive information. Any potential new drug has its public information analysed for the possibility of creating a similar drug. The industry exhibits a pattern of firms merging and larger firms buying smaller firms that have promising research or lucrative intellectual property.
- Threat of substitutes – The effect of substitutes is dependent on the individual drug, although in general, threat of substitutes in the pharmaceutical industry is high. Once a drug loses its patents, generic drug manufacturers start selling copycat versions at substantially lower prices. A drug that netted USD 100 million a year in profit could become one that earns only USD 1 million a year in profit overnight.

Additionally, there is a major international problem with counterfeit drugs. The best of these counterfeits duplicates a real drug's formula and sells it at a lower price, which hurts corporate profits. The worst counterfeits are made with low-grade materials and can destroy the reputations of the legitimate products.

## **SWOT Analysis**

- **Strengths**
  - Adherence to a strong code of corporate governance.
  - Strong Trademarks – Better sales even for “off patent” drugs.
  - Legacy of the company – Motivating factor for employees and a great marketing tool.
  - A leader (trend setter) in pharmaceutical research and development – Attracts better research staff.
  - Excellent R&D resources owned by the company (Research centres, skilled research staff, latest equipment).
  - Seventh largest pharmaceutical company in the world.
  - Strong mission and corporate values.
  - Global sales force.
  - Being at the forefront of developing new technologies to streamline the development and testing of drugs.
  - Strong focus on CSR – Good for the overall image and the long term sustainability of the company.
- **Weaknesses**
  - Over reliance on a few successful drugs (Pareto).
  - Absence of a vision statement (Ideal future state) for the company.
  - Not manufacturing generic drugs of other companies.
  - Disappointing results from the testing of new drugs recently.
  - Absence of a Director of Human Resources although the company employs over 108,000 people.
  - Lack of senior management attention on IT.
  - Recent disappointing financial results of the company – Refer Financial Evaluation.
  - Steady drop in share price of the company over the last 4 years.
- **Opportunities**
  - Expansion into veterinary medicine.
  - New developments in the field of IT relating to pharmaceuticals.
  - Extended regulatory exclusivities for “Orphan drugs”.
  - Expansion into manufacturing pharmaceutical disposables (Dressings, diagnostic test supplies).
  - Global penetration through mergers and acquisitions.

- Increasing demand for quality healthcare solutions.
- Threats
  - High competitive rivalry.
  - Notably low success rate of drugs (10%).
  - Strict regulations about the licensing and use of pharmaceutical products.
  - Drugs having a limited period of patent protection due to the long development period.
  - Differences in rules and regulations regarding pharmaceuticals in different countries.
  - The Cronland Pharmaceutical Review Agency (PRA) rejecting drugs that are lifesaving, but expensive, based on the net social cost.

### **General Risks in the Industry for Novak**

- Competition from manufacturers of generic drugs is a major challenge for Novak's branded products around the world, and the loss or expiration of intellectual property rights can have a significant adverse effect on our revenues. The date at which generic competition commences may be different from the date that the patent or regulatory exclusivity expires. However, upon the loss or expiration of patent protection for one of our products, or upon the "at-risk" launch (despite pending patent infringement litigation against the generic product) by a generic manufacturer of a generic version of one of our patented products, we can lose the major portion of revenues for that product in a very short period of time, which can adversely affect our business.
- Novak cannot predict with accuracy the timing or impact of the introduction of competitive products, including new product entrants, in-line branded products, generic products, private label products and product candidates that treat diseases and conditions similar to those treated by our in-line drugs and drug candidates. The introduction of competitive products can result in erosion of the sales of our existing products and potential sales of products in development, as well as unanticipated product obsolescence.
- The discovery and development of safe, effective new products, as well as the development of additional uses for existing products, are necessary for the continued strength of Novak. Our product lines must be replenished over time in order to offset revenue losses when products lose their market exclusivity, as well as to provide for earnings growth. Our growth potential depends in large part on our ability to identify and develop new products or new indications for existing products that address unmet medical needs and receive reimbursement from payers, either through internal R&D or through collaborations, acquisitions, joint ventures or licensing or other arrangements with third parties. However, balancing current

growth, investment for future growth and the delivery of shareholder return remains a major challenge. The average costs of product development continue to rise, as do the regulatory requirements in many areas, which may affect the number of candidates funded as well as the sustainability of the R&D portfolio.

- Novak's international operations could be affected by currency fluctuations, capital and exchange controls, expropriation and other restrictive government actions, changes in intellectual property legal protections and remedies, trade regulations and procedures and actions affecting approval, production, pricing, and marketing of, reimbursement for and access to our products, as well as by political unrest, unstable governments and legal systems and inter-governmental disputes.
- Counterfeit medicine is another major risk for Novak. A counterfeit medicine is one that has been deliberately and fraudulently mislabelled as to its identity and source. A counterfeit Novak medicine, therefore, is one manufactured by someone other than Novak, but which appears to be the same as an authentic Novak medicine. Novak's global reputation makes its medicines prime targets for counterfeiting organizations. Counterfeit medicines pose a risk to patient health and safety because of the conditions under which they are manufactured—often in unregulated, unlicensed, uninspected and unsanitary sites—as well as the lack of regulation of their contents. Failure to mitigate the threat of counterfeit medicines, could adversely impact our business, by, among other things, causing the loss of patient confidence in the Novak name and in the integrity of our medicines, potentially resulting in lost sales, product recalls, and an increased threat of litigation.
- Novak is subjected to extensive, complex, costly and evolving regulation by governmental authorities in Cronland, principally by the PTA and the PRA, and foreign regulatory authorities. Failure to comply with all applicable regulatory requirements may subject us to operating restrictions and criminal prosecution, monetary penalties and other disciplinary actions, including, sanctions, warning letters, product seizures, recalls, fines, injunctions, suspension or revocation of approvals.
- Innovation is critical to the success of Novak, and drug discovery and development is time-consuming, expensive and unpredictable. The outcome of the lengthy and complex process of identifying new compounds and developing new products is inherently uncertain and involves a high degree of risk and cost. The process from early discovery or design to development to regulatory approval can take many years. Drug candidates can and do fail at any stage of the process.
- Novak's long-term success largely depends on our ability to market technologically competitive products. We rely and expect to continue to rely on a combination of intellectual property, including patent, trademark, trade dress, copyright, trade secret and domain name protection laws, as well as confidentiality and license agreements, to protect our intellectual property and proprietary rights. If we fail to obtain and maintain adequate intellectual property protection, we may not be able



to prevent third parties from launching generic versions of our branded products, using our proprietary technologies or from marketing products that are very similar or identical to ours. Our currently pending or future patent applications may not result in issued patents, or be granted on a timely basis. Similarly, any term extensions that we seek may not be granted on a timely basis, if at all. In addition, our issued patents may not contain claims sufficiently broad to protect us against third parties with similar technologies or products or provide us with any competitive advantage, including exclusivity in a particular product area. The scope of our patent claims also may vary between countries, as individual countries have distinct patent laws. We may be subject to challenges by third parties regarding our intellectual property, including, among others, claims regarding validity, enforceability, scope and effective term.

### **Future of Novak**

- IT - Novak has already made use of IT to streamline the development and testing of drugs. But, the senior management attention on IT seems to be lacking and this needs to be rectified if the company is to compete successfully in the future. Furthermore, Novak can make use of new technologies and develop our processes even further.
  - Artificial Intelligence (AI) – AI has the potential to revolutionize healthcare through mining medical records, designing treatment plans, speeding up medical imaging and drug creation. Development of pharmaceuticals through clinical trials can take more than a decade and can cost billions of USD. Speeding up this process and making it more cost-effective would have an enormous effect on today's healthcare and how soon innovations reach everyday medicine. For example, Novak can use supercomputers to search for safe, existing medicines that could be redesigned to treat a new virus. This analysis, which typically takes months or years, would only take hours due to the use of AI.
  - Augmented Reality (AR) – AR can be used to make patients better informed about the pharmaceutical products they use in a more interactive and interesting way. With the help of AR, patients can see how a certain drug works in their body in 3D, in front of their eyes, instead of just reading long descriptions on the bottle.
  - Virtual Reality (VR) - VR can be used in the field of stress release and pain reduction for patients suffering from chronic pain. This technology can be developed as an alternative to painkillers which have serious side effects. VR can also be used for marketing; product promotions in particular. VR product promotions would be much more immersive than any other technology.

- **Total Quality Management (TQM)** – TQM is the general name given to programmes which seek to ensure that goods are produced and services are supplied of the highest quality. Quality Control (QC) is crucial for Novak as a single QC issue can result in massive financial and reputational damages. As a pharmaceutical company, the ideal number of errors is none. Firstly, TQM can be immensely helpful for the company as the philosophy tries to eliminate errors (Get it right, first time). Secondly, the philosophy also highlights the importance of continuous improvement. This ensures that the company is never complacent with the current position and always strives for improvement. Thirdly, employee empowerment is a key part of this philosophy and everybody within Novak is made responsible for quality. Therefore, if a quality issue is detected within a certain part of the process, that issue would be fully addressed before it is sent to the next process. However, implementing TQM within a global company like Novak would be a herculean task and the initial implementation process would be very expensive as well. Careful further analysis is needed on TQM before a final decision is made.
- **Around the pill strategies** – To thrive in the modern business environment, it is not just enough to develop and produce drugs. Novak needs to go beyond the physical appearance of the medicine itself and offer a complete package. Such offerings are called “around the pill” digital offerings: digital health apps, devices or services that could be prescribed by a doctor or bundled with a drug. For example, this can involve a wearable monitoring device and an app, through which patients can receive positive feedback from their doctors and also receive personalized feedback generated by the app itself.
- **Value Based Pricing (VBP)** – At present, a new trend is emerging in the pharmaceutical industry based on VBP. Pharmaceutical companies are under severe pressure to demonstrate the value of their products. Value comes from achieving the highest possible health gains for patients, measured against the total cost of care. It is no longer enough to show that drugs are effective. They also need to demonstrate improved outcomes that justify the price. Novak needs to be proactive in facing this new trend. The company can start assessing the value of our products alongside the costs. This would enable Novak to be better prepared when the company needs to demonstrate the value of our products to regulators around the world.

## Financial Evaluation of Novak

Income Statement				
	2017	2016	Absolute Difference	% Difference
	C\$ m	C\$ m		
Revenue	77,149.00	81,412.00	-4,263.00	-5.24%
Cost of sales	25,459.00	26,052.00	-593.00	-2.28%
Gross Profit	51,690.00	55,360.00	-3,670.00	-6.63%
Selling and administration	23,145.00	22,987.00	158.00	0.69%
Research	13,115.00	13,426.00	-311.00	-2.32%
Royalty income	2,253.00	2,412.00	-159.00	-6.59%
Operating Profit	17,683.00	21,359.00	-3,676.00	-17.21%
Finance expenses	1,624.00	1,766.00	-142.00	-8.04%
Profit before tax	16,059.00	19,593.00	-3,534.00	-18.04%
Taxation	5,942.00	7,053.00	-1,111.00	-15.75%
Profit for the year	10,117.00	12,540.00	-2,423.00	-19.32%

- The revenue of Novak has dropped by 5.24%. The main reasons for this drop is because 2 of Novak's most successful drugs have gone off – patent at the end of 2016 and the company has faced some recent disappointments in the testing of new drugs.
- The cost of sales of the company has reduced only by 2.28% when the revenue has dropped by 5.24%. The reason might be that the cost of sales of the company includes amortisation of legal and patent fees which are fixed in nature. As the revenue has dropped by 5.24% while the cost of sales has dropped only by 2.28%, the gross profit has decreased by 6.63%.
- Selling and administration cost has increased by 0.69% although revenue has dropped by 5.24%. This might indicate poor cost management.
- Research cost has decreased by 2.32%. Reduction in research cost is not a healthy sign for Novak as the future of the company is entirely dependent on successful research.
- Royalty income has decreased by 6.59%. This is understandable as 2 of our most successful drugs have gone off –patent during the year.
- Operating profit has dropped by 17.21% which is a substantial decrease. The major reason for this is the reduction in sales revenue by 5.24% and the reduction in royalty income by 6.59%.
- Finance expenses have decreased by 8.04% while borrowings have decreased by 13.51% (Balance sheet), which means the decrease in finance cost is lesser than the decrease in borrowings. Hence, the average rate of borrowing should have increased from 2016 to 2017 (Refer ratio analysis).

- Profit before tax has dropped by 18.04% while taxation has only dropped by 15.75%. Therefore, the effective tax rate should have increased from 2016 to 2017 (Refer ratio analysis).
- Profit for the year has dropped by 19.32% and this is due to the drop of the operating profit by 17.21% and due to the increase in the effective tax rate. The reduction of the finance cost by 8.04% has helped to reduce the impact on profit for the year.

Balance Sheet				
	2017	2016	Absolute Difference	% Difference
	C\$ m	C\$ m		
<b>Non - current assets</b>				
PPE	23,373.00	23,422.00	-49.00	-0.21%
Goodwill	15,236.00	14,260.00	976.00	6.84%
Other intangible assets	39,870.00	41,872.00	-2,002.00	-4.78%
	78,479.00	79,554.00	-1,075.00	-1.35%
<b>Current assets</b>				
Inventories	13,275.00	12,996.00	279.00	2.15%
Trade receivables	11,858.00	13,468.00	-1,610.00	-11.95%
Cash and cash equivalents	7,456.00	8,389.00	-933.00	-11.12%
	32,589.00	34,853.00	-2,264.00	-6.50%
<b>Total assets</b>	111,068.00	114,407.00	-3,339.00	-2.92%
<b>Equity</b>				
Shares and share premium	15,000.00	15,000.00	0.00	0.00%
Currency reserve	11,495.00	9,478.00	2,017.00	21.28%
Retained earnings	41,768.00	40,651.00	1,117.00	2.75%
Total Equity	68,263.00	65,129.00	3,134.00	4.81%
<b>Non - current liabilities</b>				
Borrowings	32,000.00	37,000.00	-5,000.00	-13.51%
	32,000.00	37,000.00	-5,000.00	-13.51%
<b>Current liabilities</b>				
Trade payables	4,875.00	5,233.00	-358.00	-6.84%
Taxation	5,930.00	7,045.00	-1,115.00	-15.83%
	10,805.00	12,278.00	-1,473.00	-12.00%
	111,068.00	114,407.00	-3,339.00	-2.92%

- Property, plant and equipment has decreased only by 0.21%.

- Goodwill has increased by 6.84%. There have been 3 new acquisitions in 2017 and this might be the reason for this increase. Goodwill impairments might have reduced the goodwill so the actual increase in goodwill due to acquisitions might be more than 6.84%.
- Other intangible assets (OIA) have dropped by 4.78%. Other intangible assets comprise of brand recognition and intellectual property, such as patents, trademarks and copyrights. This drop in OIA is expected as 2 of our most successful drugs have gone off-patent in the last year and we have faced recent disappointment in testing of potential new drugs although Novak has patented 98 new compounds within the last year.
- Inventories have increased by 2.15% and trade receivables have reduced by 11.95%. Cash and cash equivalents have dropped by 11.12%. Total assets have gone down by 2.92% which is not a substantial reduction. All of these indicate a notable setback of the company.
- The share capital has remained unchanged. Currency reserve has increased by 21.28%. This is an accounting adjustment and is a result of the exchange rate volatility Novak faces being a global company. Retained earnings have increased by 2.75%. Borrowings have decreased by 13.51%. Trade payables have decreased by 6.84%. Taxation has decreased by 15.83% and this is mainly due to the drop in profit before tax.

Overall, from the financials, it is very clear that the company is in a disappointing financial situation. However, this might not be a one-off situation as the company's share price has steadily declined over the past 4 years although many other rival companies have performed well on the stock market. The share price has been around C\$ 520 at the end of 2013 although the share price at the end of 2017 has only been around C\$ 290 which indicates a drop of 44.23% which is alarming. Financials of 2017 might only be an indicator of a much larger issue that had been prevalent in the company for many years. Therefore, it is important for Novak to fundamentally look at the business again and re-evaluate as to what went wrong in the past few years.

## **Financial Evaluation of PosterRend (Income Statement)**

<b>Income Statement</b>				
	2017	2016	Absolute Difference	% Difference
	C\$ m	C\$ m		
Revenue	81,289.00	79,684.00	1,605.00	2.01%
Cost of sales	26,012.00	24,702.00	1,310.00	5.30%
Gross Profit	55,277.00	54,982.00	295.00	0.54%
Selling and administration	23,574.00	23,325.00	249.00	1.07%
Research	16,014.00	15,897.00	117.00	0.74%
Royalty income	3,487.00	3,195.00	292.00	9.14%
Operating Profit	19,176.00	18,955.00	221.00	1.17%
Finance expenses	1,500.00	1,250.00	250.00	20.00%
Profit before tax	17,676.00	17,705.00	-29.00	-0.16%
Taxation	6,010.00	6,197.00	-187.00	-3.02%
Profit for the year	11,666.00	11,508.00	158.00	1.37%

- The revenue of PosterRend has increased by 2.01%. They might have launched a successful drug(s) to the market last year. The cost of sales of the company has increased by 5.30% when the revenue has increased only by 2.01%. As the revenue has increased by 2.01% when the cost of sales has increased by 5.30%, the gross profit has increased only by 0.54%.
- Research cost has increased by 0.74% which is a healthy sign for PosterRend as the future of the company is entirely dependent on successful research. Royalty income has increased by 9.14%. Therefore, PosterRend might have introduced successful new drugs to the market in 2017.
- Finance expenses have increased by 20% while borrowings have also increased by 20% (Balance sheet), which means the increase in finance cost is the same as the increase in borrowings. Hence, the average rate of borrowing should have stayed constant from 2016 to 2017 (Refer ratio analysis).
- Profit before tax has dropped by 0.16% while taxation has dropped by 3.02%. Therefore, the effective tax rate should have decreased from 2016 to 2017 (Refer ratio analysis). Profit for the year has increased by 1.37% despite the increase in gross profit (0.54%) and the increase in operating profit (1.17%) being less than this. This is due to the increase in royalty income and reduction of the effective tax rate.



## Ratio Analysis

Ratio Analysis						
	Novak		% Difference	PosterRend		% Difference
	2017	2016		2017	2016	
GP Margin	67.00%	68.00%	-1.47%	68.00%	69.00%	-1.45%
OP Margin	22.92%	26.24%	-12.64%	23.59%	23.79%	-0.83%
Average Rate of Borrowing	5.08%	4.77%	6.33%	5.00%	5.00%	0.00%
Interest cover	10.89	12.09	-9.97%	12.78	15.16	-15.70%
Effective tax rate	37.00%	36.00%	2.79%	34.00%	35.00%	-2.86%
NP Margin	13.11%	15.40%	-14.86%	14.35%	14.44%	-0.63%
Dividend Cover	1.12			1.46		
Dividend Pay-out Ratio	88.96%			68.58%		
ROCE	17.64%	20.91%	-15.67%	15.97%	17.51%	-8.82%
ROEC	14.82%	19.25%	-23.03%	12.95%	13.83%	-6.34%
Gearing (Considering long term debt only)	31.92%	36.23%	-11.90%	24.98%	23.10%	8.16%
Debt Ratio (Total long term debt / Total assets)	0.29	0.32	-10.91%	0.23	0.21	9.46%
NCA Turnover (Revenue / Non - Current Assets)	0.98	1.02	-3.94%	0.84	0.92	-8.47%
Asset Turnover (Revenue / Total Assets)	0.69	0.71	-2.39%	0.62	0.67	-6.95%
Asset Turnover (Revenue / Capital Employed)	0.77	0.80	-3.47%	0.68	0.74	-8.05%
Current Ratio	3.02	2.84	6.25%	3.12	2.89	7.99%
Quick Ratio	1.79	1.78	0.41%	1.78	1.64	8.63%
Inventory Holding Period (Days)	190.32	182.08	4.53%	207.46	210.06	-1.24%
Receivables Collection Period (Days)	56.10	60.38	-7.09%	57.24	55.13	3.83%
Payables Payment Period (Days)	69.89	73.32	-4.67%	70.54	77.16	-8.58%
Working Capital Cycle (Days)	176.53	169.15	4.37%	194.17	188.03	3.27%

- The GP margin of Novak has decreased as the cost of sales has fallen by a smaller percentage than the fall in revenue. GP margin of 67% seems to be healthy. PosterRend has a slightly higher GP Margin of 68%. High GP margins seem to be common in the industry.
- The OP margin of Novak has fallen and the OP margin is 22.92% in 2017. However, the OP margin of PosterRend has stayed almost the same in 2016 and 2017. Notably, Novak has reported a higher OP margin than PosterRend in 2016 although it is the opposite in 2017.
- The average rate of borrowing of Novak has increased. This might be due to several reasons. Investments in Novak might have become riskier with our disappointing financial performance in the past year. The average rate of borrowing of PosterRend has stayed constant. Therefore, the likelihood of an industry-wide finance cost increase is remote. However, Novak has had a lower average rate of borrowing than PosterRend in 2016 although it is the opposite in 2017.
- Interest cover of Novak has fallen from 12.09 to 10.89. This is caused by the drop in the operating profit. The drop in the finance cost has reduced the impact of the

operating profit falling on the interest cover. A fall in the interest cover would not be a positive sign for lenders. This might be one the reasons why our average rate of borrowing has increased. PosterRend has a higher interest cover than us although it has fallen. The reason for this drop is the increase in finance cost.

- The effective tax rate of Novak has increased from 36% to 37% although the effective tax rate of PosterRend has fallen from 35% to 34%. PosterRend might be managing their taxes better than Novak.
- The NP margin of Novak has fallen from 15.40% to 13.11%. However, the NP margin of PosterRend has stayed almost the same in 2016 and 2017. Notably, Novak has reported a higher NP margin than PosterRend in 2016 although it is the opposite in 2017.
- The dividend cover of Novak is 1.12 and the dividend cover of PosterRend is 1.46. Dividend of 2016 is not available to calculate the dividend over of 2016. However, it can be assumed that the dividend cover of Novak must have fallen due to the disappointing results in 2017.
- Dividend pay-out ratio of Novak seems to be very high at 88.96% which means that the company has declared 89% of the profit it earned as dividends. This very high dividend payment is done while the research cost has fallen by 2.32%. Given the recent difficult situation of the company, this dividend payment seems rather reckless and irresponsible of the BOD. The Directors might have tried to please the investors by paying a large dividend. Although this will make shareholders happy in the short term, unsustainable dividend payments would be harmful for the future of the company. On the other and, PosterRend has a dividend pay-out ratio of 68.58% which seems justifiable.
- ROCE of Novak has fallen by 15.67% which is a significant fall. This is due to the fall in operating profit by 17.21%. The capital employed has also reduced which has helped to reduce the fall of ROCE due to the fall of operating profit. ROCE of PosterRend has fallen only by 8.82%. This is mainly due to the increase in capital employed. The increase in operating profit has helped to reduce the fall of ROCE due to the increase in capital employed. However, it is notable that in both the years, Novak has a higher ROCE than PosterRend. This is mainly due to the higher equity and debt values of PosterRend.
- ROEC of Novak has fallen by 23.03% which is a significant fall. This is due to the fall in net profit by 19.32%. Equity has also increased by 4.81% which has made ROEC to fall even more. ROEC of PosterRend has fallen only by 6.34%. This is mainly due to the increase in equity by 8.23%. The increase in net profit by 1.37% has helped to reduce the fall of ROEC due to the increase in equity. However, it is notable that in both the years, Novak has a higher ROEC than PosterRend. This is mainly due to the higher equity value of PosterRend.
- Gearing of Novak has fallen by 11.90% and the current gearing ratio of the company is 31.92% which seem to be fine. The drop in gearing is mainly due to the drop in

borrowings by 13.51%. Gearing of PosterRend has increased by 8.16% and the current gearing ratio of the company is 24.98% which seem to be fine. The increase in gearing is mainly due to the increase in borrowings by 20%. However, PosterRend has a lower gearing than Novak so it would be easier for them to raise debt finance for future projects.

- Debt ratio gives a good indication to the lenders about the risk they take. It indicates whether they would be able to recover their debt easily by liquidating the assets of the company in the event of a default. The debt ratio of Novak has fallen by 10.91% which is favourable. This is mainly due the reduction in borrowings by 13.51%. The debt ratio of PosterRend has increased by 9.46% which is unfavourable. This is mainly due the increase in total borrowings by 20%. However, PosterRend has a better debt ratio than Novak mainly due to its higher asset base.
- Non – current asset turnover of Novak has fallen by 3.94%. The decrease in the NCA turnover ratio is mainly because the revenue has dropped by 5.24%. Non – current asset turnover of PosterRend has fallen by 8.47%. The decrease in the NCA turnover ratio is mainly because, although the revenue has increased by 2.01%, the NCA of the company has increased by 11.45%. However, PosterRend has a lower NCA turnover ratio than Novak mainly due to its higher non-current asset base.
- Asset turnover of Novak has dropped. This drop in the asset turnover is mainly because of the revenue drop of 5.24%. Asset turnover of PosterRend has dropped. This drop in the asset turnover is mainly because of the increase in the asset base of the company. These assets might not be providing immediate results for the company given the nature of our industry, so this drop in asset turnover is acceptable. However, PosterRend has a lower Asset turnover ratio than Novak mainly due to its higher asset base.
- In Novak, current ratio and quick asset ratio both have improved. This is because when the current assets have dropped by 6.50%, the current liabilities have dropped by 12%. Drop in current assets is due to the drop in trade receivables and cash and cash equivalents despite the increase of inventories. The drop in current liabilities is due to the drop in trade payables and taxation. In PosterRend, current ratio and quick asset ratio both have improved. This is because the current assets have increased by 4.82%, and the current liabilities have dropped by 2.93%. Increase in current assets is due to the increase in trade receivables, cash and cash equivalents and inventories. The drop in current liabilities is due to the drop in trade payables and taxation.
- In Novak, Inventory holding period, receivables collection period and payables payment period have not shown any significant changes, thus resulting in no significant change in the working capital cycle. This is the same in PosterRend as well. However, PosterRend has a longer working capital cycle than Novak mainly due to its longer inventory holding period.