

Research Note

# iQnovate

## Revolutionizing the Biotech Sector





### Date: 21 May 2017

Name:	iQnovate Ltd		
Country:	Australia		
Price:	AUD 0.45		
ISIN Code:	AU0000001QN5		
Reuters Code:	IQN.AX		
Market Cap (AUD m):	56.0		
EV (AUD m):	55.5		
Cash & cash eq. (AUD m):	0.5		
Shares outstanding (m):	124.3		
Volume:	322,100		
Free float:	100%		
52-week Range:	0.30-0.70		

AUD m	2014/15A	2015/16A	2016/17E
Total Revenues	0.775	2.762	4.000
Net (Loss)/Profit	(4.369)	(7.394)	(6.000)
Net loss per share (cents)	(10.80)	(6.49)	(2.80)
Cash increase/(decrease)	1.800	(0.333)	20.000
Cash and marketable sec.	2.492	2.159	22.159



### **Executive Summary**

- iQnovate Limited (NSX:IQN) is a life science organisation, providing intellectual property asset management services for Biopharma assets, medical devices and diagnostics, and also provides scientific advice to the global Biopharmaceutical industry. It is a true pioneer as one of the first biotech IP asset management companies that has a unique position to provide integrated scientific advisory services and contract drug development services to biotech companies across the globe.
- The advantages of iQnovate's outsourced approach offer a very interesting value proposition for biotech companies at a time when the sector as a whole is struggling to address challenges from efforts to reduce healthcare cost and ongoing increasing costs for drug development and clinical trials. Just as Contract Research Organizations (CROs) changed the industry's approach to clinical trials, iQnovate may improve efficiencies at every stage of drug development, by enabling outsourcing of the drug development lifec cycle, from clinical development to regulatory submission, reimbursement, commercialization, pharmacovigilance, label expansion etc. This will be truly revolutionary.
- iQnovate's business model is similar to that of a Contract Research Organization (CRO). The main difference is
  that CROs focus only on providing capacity services to the clinical trial aspect of drug development whereas
  iQnovate offers a capability based model as opposed to a capacity model and a much broader range of
  services at different stages of the life cycle, both research stage and when the drug is in the market. Valued at
  more than USD 25 billion in 2015, the global CRO market is expected to grow at a CAGR of more than 6%over
  the next 6 years. the factors contributing to this growth include increasing R&D, outsourcing and M&A activity,
  patent expirations, as well as government organizations assigning projects to the CROs.
- iQnovate is participating in a subsidiary that has acquired an innovative and novel biosensor for use as a saliva glucose monitoring device. As part of its business strategy the company is preparing an IPO of Glucose Biosensor Systems (Greater China) (GBSGC) on the Nasdaq during 2017. The objective of the listing will be to fund the commercialization and launch of the Glucose Biosensor into the Chinese market. The blood glucose monitoring market in China is estimated to be USD 4 billion annually.
- iQnovate is in the process of preparing for the migration from the NSX to the ASX. After having established its
  presence on the NSX, the business is ready to list on the ASX to give the company access to a wider market
  with a broader investor base. iQnovate's planned cross listing on the Nasdaq is expected to follow the ASX
  listing.



### **Company Profile & Strategy**

iQnovate is publicly listed with the National Stock Exchange of Australia (NSX: IQN) and cross listed on the OTC in New York USA (OTC: IQNDY). iQnovate is an essential part of the iQ Group Global, which includes iQX ltd (NSX: IQX) and iQ3Corp ltd (ASX: IQ3). Being part of this group, IQN has access to extensive financial and corporate advisory services, investment opportunities, medical and clinical affairs, scientific due diligence and pharmaceutical sales possibilities. In that way, iQnovate is a true pioneer. The board consists of people with extensive management experience in healthcare, retail pharmacy, finance and accounting.



#### Overview of iQ Group Global

Source: iQnovate Ltd

The Company's contract drug development services represent industry best practices and deliver efficiencies, productivity gains and economies of scale for clients. Most of iQnovate's drug



development services address pipeline products that have yet to be commercialized, but iQnovate can also help clients to devise and execute strategies that extend patent lives and maximize returns on mature, off-patent drugs.

iQnovate also has two subsidiaries in FarmaForce Ltd and Clinical Research Corporation Pty Ltd (CRC). FarmaForce is a Contract Sales Organization (CSO) catering to the Australian pharmaceutical industry, while CRC is a life sciences organization providing strategic medical affairs, targeted clinical affairs, and specialist scientific advisory and due diligence services to the Australian biopharmaceutical sector.

#### FarmaForce

FarmaForce (FFC) is a CSO focused on providing an outsourced integrated service offering to companies in the global healthcare industry. These clients include:

- Several of the top 10 Global pharmaceutical companies, both with patent protected prescription drugs and OTC
- Biotechnology companies
- Generic pharma companies
- Foreign pharma companies with no direct sales presence in Australia
- Medical devices and diagnostic companies

In executing its core business strategy, FarmaForce is a pioneer; entering a market estimated to be worth approximately US\$9 billion and with a projected CAGR of 13.9%. FarmaForce's current contracts include top 10 global pharmaceutical companies for whom they are providing mid to long term, strategic sales force solutions in respect of their product portfolio.



In October 2015, FarmaForce successfully went public at the ASX as the first publicly listed CSO in Australia and raised over AUD 5 million.

In the first half year of 2016/2017 the company generated revenue of AUD 1.6 million, an increase of 19% with the year before. Offsetting this revenue increase was an increase in labour costs as a result of timing of the inception of new contracts against an earlier commencement of its larger sales teams. FarmaForce's business is growing rapidly as it continues to build share of voice in the market as the most valuable contract sales organization. Current partnerships are increasing in scope and dollar values, as well as new partnerships being formed. As initially planned, FarmaForce is realising investment in digital technologies which will enable the company's current and prospective clients to model and forecast future market entry strategies and engage with the company's business development team. It is further developing technologies that will enable "digital" engagement of the target group it sells to (general practitioners and specialists) this will result in a more efficient sale cycle. This is an innovation that is expected to deliver premium value to clients, company and shareholders

#### Clinical Research Corporation (CRC)

CRC Pty Ltd is an organisation that provides contract medical affairs services to the pharmaceutical industry throughout the entire drug development life cycle, from preclinical to clinical through to registration, reimbursement and commercialisation. Its full suite of Medical Affairs Services offers CRC's clients tailor made solutions from pre-launch all the way to commercialisation and beyond.

#### Glucose Biosensor System

Apart from its subsidiaries, iQnovate owns several assets that are in development phase. One of



the most important assets is the Biosensor platform technology. IQnovate is developing this asset for its first diagnostic application which is a saliva glucose self test, aiming to take market share from the conventional finger prick test. iQnovate is a majority shareholder and with IQX Ltd a Group company, through a subsidiary entity, have acquired 100 percent of this innovative and novel biosensor from Newcastle University. iQnovate is focused on the launch of the biosensor as a saliva glucose monitoring device. As part of its business strategy the company is preparing an IPO of Glucose Biosensor Systems (Greater China) (GBSGC) on the Nasdaq during 2017. The objective of the listing will be to fund the launch of the Glucose Biosensor into the Chinese market, through a dedicated network of exclusive State distributors (approx. 30). The blood glucose monitoring market in China is estimated to be USD 4 billion annually.

#### Business Model and Strategy

iQnovate's initial business development focus is Australia's many pharmaceutical, biotech and medical device companies. Data gathered by Medicines Australia (peak Pharmaceutical industry organization) indicates more than 40 innovator and 10 generic pharmaceutical companies located in Australia, numerous smaller firms developing novel compounds and several hundred medical devices companies. Australia is also emerging as a top location for biotechnology companies seeking to penetrate the global market. The company's business model is not dissimilar to the model the contract research organizations founded in the 90's and since then has created a multibillion dollar industry within the biopharmaceutical sector. Within a pharma company the core business units creating revenue thus growth and innovation are Sales & Marketing and Research & Development. The IQN model comes to address the development part of the research and development equation. Currently, it takes about ten years to develop a product before it can be registered and approved for human use. A drug compound starts its lifecycle in the lab (preclinical phase) and then moves on to the first human clinical trials, phase I, were safety



and other pharmacologic parameters are assessed. This usually involves 20-100 patients and is conducted by the company in-house. The following Phase II and Phase III are usually outsourced to a CRO (clinical research organization). Given the cost and time to develop drugs, pharmaceutical manufacturers and biotech companies are increasingly outsourcing development activities to remove fixed costs and gain efficiencies. Unlike CROs, iQnovate's advisory and drug development services address the full spectrum of drug and/or medical device development activities. These activities include pre-screening and discovery, pre-clinical assessment, clinical development, pre-launch planning, registration, reimbursement, commercialization and the actual launch campaign.



#### Drug Discovery and Development Process

iQnovate can provide all of these services normally handled by an in-house medical affairs team and assist its clients in the following areas:

 Full contract assignment, in which iQnovate functions as an outsourced medical affairs team for the client and assumes end-to-end responsibility for drug development through commercialization. iQnovate will also assume ongoing management of the marketed drug including 'pharmacovigilance' (i.e. collection and analysis of additional safety data for an already approved drug).



- Regulatory management activities that are part of the medical affairs team function, including pharmacovigilance on any ongoing basis.
- Medical prelaunch services, which entails outreach to the medical community before a new drug is registered to ensure a successful launch and rapid market share gains.
- Management of the mature drug portfolio. In this area, iQnovate's services include 'descheduling' of a drug via a further regulatory process which allows the drug to be sold in pharmacy-only or grocery-only markets, thereby increasing the drug's lifespan and commercial value.
- Regulatory submissions for additional indications. iQnovate can help clients extend patent life of drugs by seeking regulatory approval for additional indications. This requires the generation of additional data from clinical trials, literature reviews and new stand-alone applications for registration and reimbursement

The IQN value proposition is formulating and executing the prelaunch strategy, registering the compound with the regulators, ensuring reimbursement by payors, providing the early stage prelaunch access programs to patients and physicians, formulating the medical communications and patient support programs and then handing over to the marketing authorization holder.





### A Growing Market for CROs and CSOs

The pharmaceutical industry has been restructuring its research and development units due to constant pressure from patent expiry, generic competition, and declining revenues in order to achieve cost-cutting. This has resulted in increased outsourcing leading to growth in strategic partnerships from 12 to 15 percent in 2014 to greater than 30 percent in the next two years. Contract Research Organizations (CROs) are responding to these market dynamics to enhance their service offerings either through expansion or mergers & acquisitions.





The Global CRO market in 2015 reached approximately USD 26 billion and is expected to grow at a CAGR of 7-8 percent to reach USD 36.7 billion by 2020 (see graph above). This is due to increased outsourcing with an adoption rate of greater than 50 percent seen within the pharmaceutical and biotechnology industry. More than 78 percent of the global CRO market revenue comes from the clinical CRO market. The clinical CRO market reached USD 21.2 billion in 2014 and is expected to grow at a CAGR of 6.4 percent to reach USD 25.5 billion by 2017. This



market growth is directly related to around 50 percent of Phase II through IV activities already being outsourced by pharma companies. The right graph below shows the percentage of CRO market share by trial phase.



Phase III trials specifically dominated with revenues estimated at more than USD 11 billion, as approximately 90% of the cost associated with drug development occur at this stage. Additionally, the occurrence of chronic diseases such as cancer, Alzheimer's and infectious diseases, has caused the US government to increase funding for R&D. Industry growth drivers are:

- Continued R&D productivity
- Acceleration of new therapies and technologies
- Continued establishment and growth of strategic partnerships
- Big data and analytics
- Collaborations to drive efficiencies and reduce average R&D costs for new compounds



iQnovate's business model is similar to that of a CRO. The main difference is that CROs generally focus only on the clinical trial aspect of drug development and have little or no involvement in other activities. CROs are usually hired to conduct large-scale clinical trials that drug candidates must undergo to gather data for a regulatory submission. Twenty years ago, most drug trials were conducted in-house, but today, most biopharmaceutical companies outsource clinical trials to a CRO. Growth in the CRO industry has been phenomenal, vaulting from mere start-ups in the 1990's to a USD30 billion industry today. The key driver of CRO industry growth is the time and cost savings that outsourcing clinical trials can deliver.



### Saliva Glucose Biosensor: Huge Market

iQnovate is participating in a subsidiary that has acquired an innovative and novel biosensor, the first clinical application for this biosensor is for use as a saliva glucose monitoring device. As part of its business strategy the company is preparing an IPO of Glucose Biosensor Systems (Greater China) (GBSGC) on the Nasdag during 2017. The objective of the listing will be to fund the launch of the Glucose Biosensor into the Chinese market. The blood glucose monitoring market in China is estimated to be USD 4 billion annually.

One of the main reasons for glucose testing is to monitor blood sugar level in patients with diabetes. When someone has diabetes, their body cannot maintain healthy levels of glucose in blood. The three main types of diabetes are: type I, type II and gestational diabetes. In the case of type I, the pancreas cannot produce insulin, a hormone that allows cells to use glucose and produce energy. Type II diabetes, on the other hand, is a two-part affliction: first, the pancreas does not produce enough insulin, and second, insulin can no longer play its role properly because cells in the body are unaffected by it (insulin resistance ). All types of diabetes are complex and require daily care and management.

Many people who live with diabetes do not feel any particular symptoms, unless they are experiencing hyperglycemia (glucose level is too high) or hypoglycemia (glucose level is too low). When hyperglycemia is not managed, it can cause significant damage to some organs, which then leads to further complications. It is important to monitor blood sugar levels to prevent hypoglycemia which can cause loss of consciousness.

Monitoring blood glucose levels on regular basis is an essential part of managing diabetes. The two main approaches for monitoring are Self-monitoring of blood glucose (SMBG) and Continuous Glucose Monitoring (CGM). SMBG is done periodically by the patient using a blood glucose measuring device, called a glucometer. It requires pricking a finger with a lancet and



applying a drop of blood on the test strip and inserting it into the glucometer device. Test strips are supplied by the manufacturer and are generally device-specific, although generic test strips are also available. CGM is a small wearable device that tracks a patients' glucose throughout the day and night, notifying the patient of highs and lows so the person can take action.



There is an incessant rise in the number of diabetic people worldwide. According to International Diabetic Federation, there were 387 million people living with diabetes in 2015, and this number is poised to reach 592 million by 2035. The market for blood glucose test strips was estimated at USD 13.7 billion in 2015 and is expected to reach USD 18.5 billion by 2020. The growth of the market is driven by the launch of advanced test strips based on innovative technology which provide more accurate and reliable results. In terms of volume, the disposable blood glucose test



strip market is expected to reach 27.6 billion strips by 2020. Furthermore, the increased awareness in diabetes and the need for monitoring glucose levels on regular basis are also contributing to market growth.



The test strips are based on various technologies such as electrochemical and photometric. The majority of test strips are based on electrochemical technology. The photometric technology market is expected to witness the highest growth. Roche, LifeScan, Abbott Diabetes care, and Bayer are the leading players in the blood glucose test strip market, by volume. These players possess state of the art manufacturing facilities and strong sales and distribution network which have helped them to gain a leading position in the market.



### Leveraging from fast growing Digital Healthcare

Digital healthcare is an upcoming discipline that involves the use of information and communication technologies to help address issues and challenges faced by patients. These technologies include both hardware and software solutions and services. Generally, digital healthcare is concerned about the development of interconnected health systems to improve the use of computational technologies, smart devices, computational analysis techniques and communication media to aid healthcare professionals and patients manage diseases and health risks, as well as promoting health and wellbeing.

The global digital health market was valued at USD 55.3 billion in 2014 and is expected to increase to USD 233.3 billion by 2020. During this time, the mobile-health segment of the industry (mHealth) is expected to generate the second largest revenue share, reaching USD 59.2 billion in 2020. According to recent market research reports, the global mHealth Devices and Services market was valued at approximately USD 10.5 billion in 2014 and is expected to reach USD 50-60 billion by 2020, growing at a CAGR of 30-35% between 2015 and 2020. Of this, glucose meters is projected to be the fastest growing segment in global mHealth devices market registering a CAGR of 41% during the forecast period.

mHealth is experiencing a growth trend as consumers demand more accessibility to their health professionals and as a result, transparency in health care becomes more important. North America is the largest regional segment of the global mHealth solutions market. In 2014, North America accounted for the largest share of 32.1% of the mHealth solutions market, followed by Europe, Asia-Pacific, Latin America, and the Middle East and Africa. Although Europe will continue to dominate the mHealth solutions market during the forecast period, European



countries and Asia-Pacific countries (particularly China and India) are expected to offer significant growth opportunities for market players in the forecast period. China's market is expected to generate large growth within the overall global market, reaching RMB 12.5 billion or USD 1.9 billion in 2017.

The emergence of the digital health market is expected to increase the potential of big data and analytics which will transform the consumer healthcare market. However, some hesitation still exists amongst consumers in regards to the privacy of personal information and the security of data systems.



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