



INVITROCUE LIMITED (IVQ)

New appointments

Bringing the vision of personalised oncology to reality

DIRECTORS

Dr Steven Fang, Managing Director
Prof Hanry Yu, Non-Executive Director
Ms Jamie Choo, Non-Executive Director
Ms Ng Ee Ting, Non-Executive Director
Mr Koh Chow Yee, Non-Executive Director
Dr Andreas Lindner, Non-Executive Director
Dr Gary Pace, Non-Executive Director

MARKET DATA

ASX Code: IVQ
Current Price (26/6/18): \$0.089
52-week Share Price Range: \$0.06 - \$0.12
Market Capitalisation: \$45.7 million

CAPITAL STRUCTURE

Shares on Issue (listed): 513.6 million

FINANCIAL SUMMARY

\$'000	FY 2016 (A)	FY 2017 (A)	FY 2018 (F)
Revenue	83	741	~800
EBITDA	-1,008	-1,703	~-2,500
Net Profit	-20,474	-1,835	~-2,500
Net cash flow ops	-2,929	-1,842	~-3,200
Cash	1,773	602	
Tot. Assets	2,288	1,337	

SHAREHOLDERS

Fang Boon Sing 25.6%
Faith Champ Entps Ltd 18.2%
Yu Hanry 11.0%
Inbridge Ventures Pte Ltd 8.5%

SENIOR ANALYST

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INVESTMENT PROPOSITION

Invitrocue's core proposition is its capability to build a patient's own cancer or micro-tumour in its laboratory for testing against approved first line chemo drugs and identifying alternative drug treatment. This test has the potential to markedly improve the effectiveness of cancer treatment with a marked reduction in costs with greatly reduced patient trauma.

A major milestone was achieved in April with the first commercial sales of the company's Onco-PDO cancer screening test. This heralds its commercial launch.

Invitrocue's roll-out strategy is focussed on securing access to leading cancer laboratories for the building of such cancer avatars through research alliances with major cancer research centres in selected markets. By mid-2019, labs are expected to be in operation in Asia/Pacific and Europe with each expected to quickly reach an average of about 3 to 5 tests per day.

First commercial revenues of significance for liver cell tests were achieved in FY 2017 and high rates of growth from liver cells and cancer tests are anticipated over the next few years as further services are introduced and as the client base expands. A "hockey stick" growth profile is quite possible with a "take-off" occurring once a critical mass of testing laboratories is in place for the Onco-PDO personalised oncology service.

Investor support for the value proposition is evidenced by the company's success in raising new equity, in August, at a premium to the then market price (latest raise was at a 20% premium).

EVENT

Invitrocue has announced the appointment of the appointment of Dr. Gary W. Pace as an Independent Non-Executive Director and Assoc Prof Narayanan Gopalakrishna Iyer as Chair, Medical Advisory Board (MAB).

Dr. Pace brings more than 40 years of experience in the development and commercialization of advanced life sciences and related technologies, including biotechnology, pharmaceuticals and medical devices. He is a serial entrepreneur and has held senior positions in small to large-scale life sciences ventures and companies in Australia, the USA and Europe. Dr. Pace is currently a director of ResMed (NYSE: RMD), Pacira Pharmaceuticals Inc (NASDAQ: PCRX) and Simavita Ltd (ASX: SVA) and Antisense Therapeutics Ltd (ASX: ANP) as well as several private companies.

Assoc Prof Iyer currently leads the Cancer Therapeutics Research Laboratory at the National Cancer Centre of Singapore (NCCS) and is a Head and Neck surgeon at NCCS and Singapore General Hospital. He is also a Head and Senior Consultant at Sing Health Duke NUS' Head and Neck Centre and previously completed surgical fellowships in Australia and the US.

ANALYSIS AND COMMENT

A key element in the company's development strategy has been to establish close links with and the support of key regional and global influencers and both appointments fit this criteria and will play important roles as Invitrocue accelerates the commercialisation of Onco-PDO. Both appointments reflect the company's transitioning from a science to commercial focus and Assoc Prof Iyer, In particular, provides clinical impact with oncologists and treatment facilities in driving the commercial use of the Onco-PDO test.

Dr Pace brings considerable corporate experience to the company, especially with early stage commercialisation and business development and will play a key role with Invitrocue with the commercialisation of Onco-PDO over the next two or three years. His experience with disruptive technologies, such as with Resmed will be invaluable to Invitrocue as it challenges existing protocols in the treatment and management of cancer.

Assoc Prof Iyer is an important contributor globally to oncology research and personalised patient treatment and is currently a member of Invitrocue's Medical Advisory Board (MAB) which consists of highly experienced and internationally respected oncology experts from Asia, Australia and Europe. The advisors provide guidance to the management team on the development of Onco-PDO and the strategic expansion of the personalised tumour test business unit.

Assoc Prof Iyer appointment as Chairman of the MAB will deepen the relationship between the two with Invitrocue being able to draw on both his experience, contacts and relationships in the local medical fraternity whilst his role as a practising surgeon is expected to result in a significant flow of patient referrals, from him and his colleagues, for the Onco-PDO test.

Newsflow from Invitrocue has been sparse in recent months but we understand that there has been a significant build up in activity and that the upcoming September quarter cash flow report will provide an enhanced picture of the company's recent progress in commercialising Onco-PDO, in particular.

KEY POINTS

-) **Patented technology** – Invitrocue’s bio-analytic solutions for the healthcare, pharmaceutical and cosmetics industries are underpinned by its high speed, low cost platform for replicating and testing human liver and cancer cells.
-) **Two commercial business units leveraging this technology** - Invitrocue is maximising the commercial opportunities of the technology with multiple revenue streams from independent markets.
-) **Scaling up now underway** – Group revenue jumped from \$83K in FY 2016 to \$741K in FY 2017 as revenue primarily from liver cell tests for pre-clinical drug trials gained traction. Revenue is expected to exceed \$2 million in FY 2019 as cancer cell testing builds momentum.
-) **Personalised Oncology services will quickly emerge as the core business** - Cancer treatment is an enormous market with considerable opportunities for more effective and more efficient treatment protocols. Accordingly, revenue from testing cancer cells (personalised oncology; Onco-PDO) will quickly surpass the contribution from liver cell testing.
-) **Rapid growth anticipated** – The number of tests processed at the Singapore lab will build rapidly from the currently level of about 3 per week as additional technicians are employed and as local and regional oncologists increase their use of the technology. Negotiations currently underway with cancer research institutions are expected to lead to the opening more testing laboratories which will drive quantum leaps in activity over the next two or three years.
-) **Growth to accelerate as independent laboratories are certified** - Scaling of the Onco-PDO business will occur in stages as independent laboratories are certified to perform the tests. Maybe 10 – 15 laboratories worldwide are required to service the global market.
-) **Potential to build into a large business** – Revenue growth will be driven by the pace of the certification of laboratories but it is conceivable that revenues could exceed US\$100 million in five or so years.
-) **Capital light business model** – Outsourced product manufacturing and service delivery will minimise capital requirements and corporate overheads. Gross margins are expected to settle between 45% and 50% once volume in both business segments reaches commercial levels. A modest loss is anticipated in FY 2019 before a breakthrough to profitability in FY 2020.

BUSINESS OVERVIEW

Invitrocue provides bio-analytic solutions to the healthcare, pharmaceutical and cosmetics industries. The company has leveraged its patented technology into two commercial pathways; testing chemical compounds for toxicity, which is used by pharmaceutical companies in pre-clinical drug development, and testing of cancer cells to aid oncologists in identifying treatment regimens for individual patients opening the way to personalised treatment based on the unique characteristics of each patient.

These solutions are underpinned by the company’s patented high speed, low cost platform for growing, replicating and testing human liver and cancer cells. This platform is a 3-dimensional cell-based scaffolding

technology which enables human cells to replicate quickly with a far more realistic representation of the in vivo (in body) condition compared with traditional 2-dimensional processes.

Invitrocue was founded in Singapore in 2012 by Prof Harry Yu (currently a non-executive Director) and Dr Steven Fang (currently CEO) to further develop and commercialise analytical services for pharmaceutical companies based on these patented technologies. Research and testing laboratory facilities were established in Singapore and the company subsequently listed on the ASX in early 2016.

Invitrocue's core capability and value proposition is the generation of data regarding human cell response to drug compounds. This data is critical in the development of drugs and cosmetics and is becoming increasingly important in the treatment of cancer and other diseases.

The competitive advantages of the company's technology and processes are:

-) Better representation of in vivo (in body) cell development
-) Better prediction of drug response
-) Cells can be kept alive longer (8 weeks compared with typically 2 weeks)
-) Lower cost compared with other 3D based processes
-) Eliminates the need for animal testing

Liver Cell Services is Invitrocue's most established business stream. It provides a range of services to pharmaceutical and cosmetics businesses including drug metabolism assays, liver toxicity assays, infectious disease assays testing (such as hepatitis) and liver disease modelling. The company also sells liver cells; HepaCue fresh hepatocytes and mice carrying humanised liver cells.

These products and services are primarily used in pre-clinical drug development studies and in testing cosmetics. A key business driver is the move away from animal testing. Accordingly, Invitrocue offers a practical, cost effective alternative in an increasing range of diseases.

The company's 3D scaffolding technology for growing cells has obvious application in testing cancer cells and opened the opportunity to develop a **personalised oncology** business. With continuing advances in identifying genetic aberrations in individuals, the ability to develop specifically targeted treatment options, especially for cancer patients, improves. Accordingly, some degree of personalised treatment is now part of the standard of care in the first diagnosis of cancer to the extent that genetic abnormalities can be identified. This would typically be through the identification of a biomarker (A biologic feature that can be used to measure the presence or progress of disease or the effects of treatment – medicinenet).

However, the success rate of any specific treatment is typically low, maybe as low as 35%, whilst there are relatively few biomarkers relative to the variance in the population. As a result, multiple treatment strategies, often employing combinations, are typical. Against this background, Invitrocue has developed a service (Onco PDO) whereby cancer cells can be tested for response to any number of drugs or combinations thereof. The service has a rapid turnaround (about 10 days) and is relatively inexpensive. Over 200 pilot tests have been conducted with the first commercial tests undertaken in Singapore in April 2018. A collaboration agreement has been established with a leading cancer research centre in Northern Ireland, which will be the testing centre for the UK whilst agreements with similar centres elsewhere in Asia/Pacific and Europe are expected to be concluded shortly providing a broad geographic reach.

BUSINESS DRIVERS AND GROWTH PROFILE

Commercialisation of the Liver Cells Services business commenced in 2016 with revenue now growing strongly off a low base as more clients have been secured and as these clients increase their use of these services. The Onco PDO business commenced commercial sales in early 2018 and will rapidly scale up over the next year as collaboration agreements are concluded to established testing facilities in key locations in Australia, Japan and Germany to support existing facilities in Singapore and Northern Ireland.

Pharmaceutical and cosmetics companies use the company's Liver Cell services in pre-clinical product development to test toxicity and product performance. Invitrocue's technology eliminates the need for animal testing which is increasingly problematic and subject to increasing restrictions (largely banned for cosmetics). Revenue grew rapidly off a low base in FY 2017 as these services gained market traction. More services and increased client support will drive sustained high rates of growth over the next few years.

Toxicity studies are critical in the pre-clinical early stage development of drugs (and cosmetics) and are typically undertaken on animals. Whilst now largely banned for testing of cosmetics, animals are still widely used by the pharmaceutical industry. Nonetheless, the trend is away from animal testing and legislative support, to this end, is building around the world. Accordingly, the business case for in vitro testing is strong and Invitrocue is enjoying strong growth as market acceptance of its technology gains momentum.

The development strategy is focussed on expanding the range of diseases which it can support. Currently, the company offers analysis for compound ranking and liver toxicity, malaria and leishmaniasis and is due to add non-alcoholic steatohepatitis, hepatitis B, mechanistic toxicity and drug repurposing during calendar 2018.

Revenue from Liver Cells Services grew sharply in FY 2017 from less than \$100K to over \$700K as marketing efforts were stepped up and as clients build confidence in the company's services. Revenue is expected to grow rapidly over the next few years as the range of services and capabilities expand and as the current portfolio of about 15 clients increases. We speculate that this has the potential to be a \$3 million to \$5 million business within a few years.

Invitrocue is taking a staged approach to scaling up the Onco-PDO business with the current stage of activity can best be characterised as model testing, with low key, targeted marketing, processing in its own laboratories and the establishment of relationships with potential partners in external markets. Accordingly, activity is at relatively low levels, although building rapidly. In second half of 2018, we expect the company to be processing about 10 or so tests per week which should more than double over the following twelve months.

Marketing will build in advanced markets during 2018 and 2019, and to this end the company is working with key opinion leaders and building relationships with cancer hospitals and research institutes.

Over 200 pilot tests were undertaken to validate the key elements of the model; principally being able to efficiently receive and process the tests and distribute the results. Progressively manufacturing of the test kits will be scaled up and laboratories around the world will be certified to perform the tests. Test kits are currently manually assembled but the process will be automated during 2019 as volumes build. Five test sites, in Asia, Australia and Europe, are expected to be operational by the end of calendar 2018 with maybe 10 to 15 laboratories, worldwide, being sufficient to perform anticipated medium to long term volumes.

Whilst it is difficult to assess the potential and the pace of growth for Onco-PDO, we think that more than 4,000 tests could be undertaken in FY 2021 generating gross revenue of over US\$15 million. It is conceivable that within 5 years, Invitrocue could have 10 or more laboratories processing some 3,000 tests each per annum generating around US\$100 million per annum.

The collaboration agreements that are being negotiated with research institutions will enable Invitrocue to establish processing facilities in existing laboratories. Invitrocue will meet operational costs but will otherwise avoid the potentially high capital costs that would otherwise be required. With low overheads, profit breakeven is relatively low and capital requirements are expected to be modest.

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