gordoncapital RESEARCH

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INVITROCUE LIMITED (IVQ) Sept Quarter Update

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 (5/11/18):	$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 (A)
Revenue	83	741	593
EBITDA	-1,008	-1,703	-4,521
Net Profit	-20,474	-1,835	-4,657
Net cash flow ops	-2,929	-1,842	-3,882
Cash	1,773	602	2,319
Tot. Assets	2,288	1,337	3,695

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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November 2018

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 released its Appendix 4C for the quarter ended 30 September 2018. During the period under review, the company generated cash receipts of $101K and achieved a net operating cash flow deficit of $924K. Cash balances as at 30 September 2018 were $1.6 million.

Highlights of the Reporting Period include:

- Incorporation of a Hong Kong corporate entity
- Recruitment of the first patient sample from Malaysia as part of Invitrocue's regional expansion
- Receipt of grant from the Chinese government to conduct validation work on lung cancer models of Onco-PDO™
- Laboratory team expansion in China in advance of accelerating marketing efforts
- Inaugural global oncology summit of key opinion leaders held in Germany

ANALYSIS AND COMMENT

Invitrocue is in the early stages of commercialising its ground breaking Onco-PDO test and its cash burn reflects the increase in supporting activity as it builds momentum. In particular, legal, travel and conference expenses are rising as the company moves closer to executing joint venture agreements and increases its marketing efforts. Staff costs have also increased in recent quarters as the company has filled technical (lab) positions that are required to support the scale-up of the business.

The Liver cells testing business, which is primarily used by pharmaceutical companies for testing pre-clinical compounds for toxicity, has continued to be hampered by equipment awaiting repairs. As a consequence, revenues from this business unit have remained at low levels. We understand these repairs have been completed and that key clients are now re-engaging which will lead to a resumption of testing and a build-up in revenues in the coming months. This will alleviate some of the cash burn being incurred in building the Onco-PDO business. After achieving over $700K revenue from cell testing in FY 2017 revenue slumped in FY 2018 due to equipment failures and there is now a reasonable expectation that revenues will recover to at least the same levels over the next 12 to 18 months.

The Onco-PDO test has the potential to transform treatment protocols for cancer patients with significantly reduced costs, greater confidence in treatment strategies and success of first line treatments with much reduced patient trauma. This is important as the behaviour of cancers is typically unique to each patient and therefore results from particular treatments are not necessarily predictable. The Onco-PDO test will remove this uncertainty.

Since completing the first commercial test of Onco-PDO in April 2018, further tests have been completed from cancer patients in Hong Kong and Malaysia. Volumes remain low, however logistics and supporting management systems are being tested and refined whilst a core group of oncologists are building confidence levels in the process. As the test has not yet being incorporated in any public health insurance system, all are being undertaken by privately paying patients which inevitably results in a slower build up in activity. The German operation will be in a position to undertake the first tests on private patients before the end of the current

quarter heralding the launch of a local laboratory in Munich. The company is awaiting a licence to enable it to market in Singapore where it has its central testing laboratory and the support of local hospitals.

The next laboratory to be established is likely to be in Hong Kong where a local subsidiary has been established and where a pool of oncologists are already working with the company to recruit patients. A Hong Kong lab will service Hong Kong and Chinese patients seeking treatment in Hong Kong.

During the period under review, the company received a small grant from the Chinese government to conduct validation work on lung cancer models. We understand that this work involves running tests with a small group of patients and comparing the results with the actual results from treatment performed by the oncologist. In this work, the oncologist is not informed of the results of the Onco-PDO test, whereas in a normal operating environment, he/she would be informed of the results of the test which will be used as input into treatment strategies and decisions. This validation work will typically be required ahead of approval to use the test on public patients and to gain access to the health insurance systems. Similar validation work will be required in Germany and the UK, without which marketing would be limited to privately funded patients, greatly reducing the addressable market.

A priority marketing strategy being used by the company is to align with key influencers. In this regard, the company has strengthened its Board with the appointment of Dr Gary Pace as an NED and management has been engaging heavily with leading oncologists and researchers at leading universities and cancer hospitals in Europe, Asia and Australia and is now hosting its own conferences to educate cancer treatment professionals. On 1 October, the company brought together international experts on oncology, precision medicine, and biochemistry from leading global institutes, cancer centres and universities for its inaugural education summit for clinicians titled *Oncology: The future of cancer treatment*. During the summit, international speakers presented on cutting edge innovations and recent findings in the field of oncology and clinicians shared their experiences of using Onco-PDO as an innovative solution and leading technology to empower patients and their physicians to improve potential treatment outcomes. More of these events are expected to be undertaken over the next year or two.

The operating cash burn is running at around $900K - $1 million per quarter. Revenues should rise as both the cell testing business rebuilds and as the number of Onco-PDO tests builds momentum. However, costs will also rise in the short term as joint venture labs are established in Asia, Europe and Australia. At this early stage, we think that the company could become cash flow positive during FY 2020. Capital raising has been a regular feature of the quarterly cash flow reports and we expect that further top ups will be undertaken (typically with small placements) over the next six months to ensure adequate funding through the commercialisation phase.

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** – All efforts are now directed at building the infrastructure to support a rapid roll-out of the Onco-PDO service. Agreements to establish joint venture labs are being negotiated and technical staff are being employed.
- **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 current 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.

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 Hanry 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 Invirtocue'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. Growth stalled in FY 2018 due to equipment failures and an extended wait for repairs. However, as clients re-engage, revenue is expected to recover and grow 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. Invirotcue 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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