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## Quarter 2, 2017 Update

3 July 2017

Dear Shareholders,

The board and I would like to thank you for the support and confidence you have shown for Minomic as we have navigated the many development hurdles on our pathway to critically important trials for our diagnostic and therapeutic technologies. I am pleased to bring you this newsletter which covers recent notable advances in Minomic's development highlighting our progress toward clinical and commercial milestones. There has been much activity on the part of the company, our collaborators and advisors in moving forward with the development program for MiCheck<sup>®</sup> diagnostic technology and our therapeutic drug, now named Miltuximab<sup>™</sup>. These are discussed in detail below.

### 1. Commercialisation of the MiCheck<sup>®</sup> Test

Commercialisation of the MiCheck<sup>®</sup> test remains our key focus. There are several parallel activities for the commercialisation of the MiCheck<sup>®</sup> test and we report on advancement of these activities below.

#### Commencing the Prospective Trial

Thanks to the efforts of the whole Minomic team the Prospective trial design and schedule is running to plan. Final advisory meetings were held during this quarter at the American Urology Association (**AUA**) meeting in the USA. The Principal Investigator, Dr Neal Shore, and the Uro-oncology trials group, CUSP LLC, met with the Minomic team to complete the trial protocol. Following this the company has instituted a weekly cross functional team teleconference to oversee and manage the study to conclusion. This team includes CUSP LLC (trial management), Cenetron Inc. (sample logistics), BioTechne Inc. (kit manufacture) and Dr Robert Borotkanics (Biostatistics). This team also allows efficient risk management of the project. We are on track to commence sample accrual in July.

As detailed in the previous newsletter, Minomic submitted the Request Forms to the Early Detection Research Network Committee (EDRN) to access samples from their biobanks. These samples assist us with further test validation. The Early Detection Research Network Committee (EDRN) has requested data from the prospective trial to allow release of their samples and we will be following up with them when the data is available in Q4 this year.

As a result of our discussions with Professor Mark Emberton (University College London) and Professor Hashim Ahmed (Imperial College London) we now entered into a Material Transfer Agreement to use MiCheck<sup>®</sup> on their cohort of samples from the prestigious [INDEX study](#) to further validate the MiCheck<sup>®</sup> test. This represents a potentially very valuable additional data set for MiCheck<sup>®</sup>.

#### Manufacturing the MiCheck<sup>®</sup> test in a commercial kit form

An assessment of the final report from BioTechne and analysis of the sample testing results yielded impressive statistical relevance and assisted with the refining our diagnostic algorithm. We plan to enter into a formal Manufacturing agreement following the Prospective trial.

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### **Engaging with potential license partners**

We took the opportunity to meet with potential license partners at the AUA meeting in May to keep them apprised of our progress. The next step will be to provide results of the Prospective trial which will be required to progress these discussions to a license agreement.

We note there is also interest in the therapeutic program with a number of parties wishing to further explore potential partnering opportunities around the therapeutic applications of the MIL-38 antibody, which we now call Miltuximab™ (there is an international naming convention for antibodies and any chimeric monoclonal antibody must have the suffix “tuximab” after its name). There are currently several pharmaceutical companies with interest in the technology that are waiting to see the data from our present clinical trial.

### **Finalising the logistics of the US market entry strategy**

Following on from our initial January meetings at the JP Morgan conference, in May we met with potential market entry partners of the MiCheck® test. The selection of a suitable CLIA lab is proceeding and we have contacted potential partners to assess their capability and interest. We will meet with a short list candidates in late July/early August. Additionally, our US regulatory consultant, Dr Maria Chan, will be visiting us in the next few months to progress our regulatory strategy.

The health economics model for the MiCheck® test has now been developed by Professor Shelby Reed, from Duke University. The model awaits inclusion of the data from the Prospective trial to finalise the health economics analysis of the MiCheck® test. This will greatly assist when discussing the final license terms with potential partners.

## **2. Therapeutic Trial for Prostate and Other Cancers**

Following is an update on our early development of the therapeutic application of Miltuximab™.

### **First in Human Trial**

As indicated in our last update the MILGa Cancer Imaging Trial, using <sup>67</sup>Gallium labelled Miltuximab™, is a first-in-human study to evaluate the safety and tumour targeting of MILGa in patients with advanced prostate, bladder and pancreatic cancer. The primary endpoints of the study are safety and tolerability of Miltuximab™. The secondary endpoints are to qualitatively evaluate Miltuximab™ as a diagnostic tool in prostate, bladder and pancreatic tumours and to perform dosimetry analysis of tumour images to determine relative accumulation of MILGa in different organs.

We have now enrolled and infused 7 patients in this trial. These patients demonstrated good tolerance to radiolabelled Miltuximab™ with no drug related adverse events. A meeting of the independent Drug Safety Monitoring Committee has assessed in detail the first 6 patients receiving drug. Imaging case reports have been designed and agreed with an independent expert assessor, Professor Paul Roach, Royal North Shore Hospital, having now completed his detailed analysis of the first 6 patients and we look forward to receiving his report when finalised.

Drug stability continues to show good results with stability at 162 months now demonstrated. This is of key importance to marketability of the drug conjugate.



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Our project with Lake Pharma Inc., CA, US to humanise the antibody has yielded several humanised clones that show parallel binding characteristics to Miltuximab™. This is exciting news as it increases appeal of the antibody to potential commercial partners.

### 3. Minomic Collaborations

#### International Preclinical Collaborations

We provide an update of these exciting programs as follows:

*Professor John Babich, Weill Cornell University New York*

As shared in the last update a work program has been designed with Prof Babich. This program will now just use the Miltuximab labelled with the therapeutic radioisotope <sup>225</sup>Actinium, as this is of more interest to potential partners and local collaborators are already studying <sup>177</sup>Lutetium. This project is pending further preclinical work being done at Queensland University of Technology/University of Queensland that is currently in train.

*Professor Ganesh Palapattu, University of Michigan, Michigan*

Prof Palapattu and his team have now commenced work on an agreed program of prostate and bladder studies. These studies will examine the expression of the Glypican 1 target in cell lines resistant to current prostate cancer treatments and screen a wide range of prostate and bladder cancer cell lines for Glypican-1 expression to determine appropriate models for prostate and bladder xenograft studies. Additional bladder cancer xenograft studies are planned to develop models for treatment of non-muscle invasive bladder cancer.

#### National Collaborations

*Professors Thurecht and Mahler, University of Queensland, Brisbane*

Professors Thurecht and Mahler are undertaking preclinical work with the Miltuximab using two alternate cell killing mechanisms. The first mechanism conjugates Miltuximab with toxic drugs with the antibody's purpose to target the drugs to tumour cells. Minomic has now received initial data indicating Miltuximab drug conjugates (ADCs) can kill prostate cancer cells. Additional ADCs have now been shipped to Minomic for further testing. The second killing mechanism links the GPC-1 targeting portion of the antibody with an immune cell receptor and construction of this "bispecific" antibody has been completed. This material has also been shipped to Minomic for further testing. Data from these studies is expected in Q3 this year.

*Professors Nelson and Russell, The Queensland University of Technology*

Professors Nelson and Russell are continuing their mouse studies examining the role of GPC-1 in cancer growth and invasion using MIL-38 labelled with the radioisotope <sup>177</sup>Lutetium (**MILLu**). These studies will demonstrate the ability of MILLu to kill GPC-1 positive prostate cancer xenografts and provide preclinical safety information about the lutetium-labelled version of the drug. The study is showing early promise in tumour cell killing however the time required for each experiment is relatively long so at this stage we do not have further information to report.

*IDEAL ARC Hub grant – Professors Jin Dayong University of Technology, NSW and Emily Hilder, University of South Australia, SA*

The two projects that will further develop Minomic's diagnostic capabilities are close to agreement with the company and we anticipate sign-off in Quarter 3. An in principal agreement with the Hub has allowed them to assign staff for early stage planning of the work.

## 4. Intellectual Property

The paper titled “Immunofluorescence Assay for Detection of Prostate Cancer Cells in Urine Sediments: Evaluation of Glypican 1 (GPC-1) as a Biomarker of Prostate Cancer” has been submitted to the journal “The Prostate”. The paper is under review by independent reviewers. The company has now commenced the same process used for the above paper to finalise the MiCheck® Pilot Study publication for submission to the same journal as a follow up article.

The table below gives an update of the patent estate and the stage of development of each family.

Patent Family	Stage of Development
<b>1. Cell Surface Prostate Cancer Antigen for Diagnosis</b>	National Phase process is continuing in AU, CN, CA, EU, JP, KR, SG and US
<b>2. Monoclonal ANTI-GPC-1 Antibodies and Uses Thereof</b>	National Phase commenced in CN and CA
<b>3. Glypican Epitopes and Uses Thereof</b>	National Phase commences 16 July 2017
<b>4. Therapeutic antibodies and Uses Thereof</b>	National Phase commences 20 October 2017
<b>5. Biomarker Combinations for Prostate Disease</b>	National Phase commences 22 January 2018

## 5. Capital Raising and Stock Market Listing

As indicated previously we continue to work with our lawyers and tax advisers to undertake the necessary preparatory work to spin out the therapeutic assets of the company. This would be done to lock in the current value of the diagnostic MiCheck® for existing shareholders while giving these shareholders the opportunity for future value in the therapeutic asset, alongside new investors.

To this end the company is in the process of obtaining binding tax rulings in relation to the proposed separation of its diagnostic and therapeutic assets. These rulings are intended to confirm the proposed restructure has no adverse tax consequences for our shareholders.

In addition, we continue to meet with potential investors and fund raisers to keep them apprised of our progress.

## 6. Profile – Dr Neal Shore, Member, Minomic Clinical Advisory Panel, Principal Investigator for the MiCheck Prospective Study and President of LUGPA



Continuing a good tradition, we profile Doctor Neal Shore, Member of the Minomic Clinical Advisory Panel. As well as Dr Shore being our PI for the upcoming trial he has roles as director for the Carolina Urologic Research Centre and managing partner for Atlantic Urology Clinics in Myrtle Beach, South Carolina. Importantly he is the current president of the US based Large Urology Group Practice Association whose purpose is enhancing communication among large urology groups, allowing benchmarking of operations, promoting quality clinical outcomes, developing new opportunities, and improving advocacy in the legislative and regulatory arenas.

Dr. Shore serves on the boards of the Society of Urologic Oncology Board of Directors, the Society of Urologic Oncology Clinical Trials Consortium, the Large Urology Group Practice Association, NCI GU Science Steering Committee and the Urology Times. He received his medical degree from Duke University Medical School and completed his general surgery/urology training at the New York Hospital Cornell Medical Centre.

Dr Shore is an internationally recognized expert in systemic therapies for patients with advanced urologic cancers as well as an outstanding researcher for innovative therapies to treat patients suffering from prostate enlargement symptoms.

As a physician, president of LUGPA, urologic oncologist and someone who's dedicated his career for the last 20 years doing advanced cancer research in urology, and as an educator who has run many advanced prostate cancer programs for the American Urological Association, Dr Neal Shore has been remarkable in his achievements at the forefront of clinical science research. We are pleased to have him as a key member of our Clinical Advisory Panel.

In conclusion, we continue to move forward with our aim always being to bring to market a better cancer diagnostic for the benefit of all and followed by the potential prospects of new therapies for certain cancers. The year has been full of strong progress and I look forward to reporting to you the outcomes of our endeavours over the next two quarters.

Yours sincerely,



Dr Bradley Walsh  
CEO