
Investor Update
2nd Quarter 2019

Dear Shareholders,

Welcome to the second quarter 2019 newsletter.

In the second quarter of this year the company has submitted the two papers regarding the MiCheck® trial to the journal "European Urology", progressed MiCheck® validation studies with two large industry players and commenced set-up of a Minomic subsidiary in Hangzhou, China.



1. Commercialisation of the MiCheck® Test

Making the MiCheck® test available for use in the US, the world's largest healthcare market, remains our first priority. As we have discussed in previous updates Minomic is undertaking several parallel strategies to ensure the commercialisation of MiCheck®. Updates on each of these are detailed below:

MiCheck® Prospective Trial

The two papers detailing the results of the Prospective Trial have now been submitted to the journal "European Urology" (impact factor 17.3). The first paper describes the MiCheck® 01 clinical trial in detail, while the second paper describes the development of the MiCheck® test.

MiCheck® Rollout Strategy – USA

US-based LDT Rollout

During the second quarter of 2019 Minomic's laboratory partner, Rockville Maryland based Cirrus Dx, have continued to advance the internal steps required to validate MiCheck® within in their own quality system targeting test availability early in the second-half of this year. In an important step toward achieving reimbursement for MiCheck®, Novitas Healthcare, a Medicare Administrative Contractor (MAC) responsible for Medicare reimbursement in large number of US states, has issued a proposed Local Coverage Determination (LCD) for a prostate cancer testing that could enable MiCheck® to achieve a competitive reimbursement for the test once it becomes available. While the rollout is taking a little longer than first anticipated we are pleased that it is now moving to a conclusion.



Early Access Program (EAP)

Minomic has now confirmed participation from five large Urology Practices to refer patient samples immediately upon the test becoming available. Minomic and Cirrus will host a meeting to be held at Cirrus' laboratory once this testing is completed where we will share data accumulated from the EAP with the clinicians.

In May Dr Walsh met with a number of these clinicians as well as Kyle Armantrout and Megan Henken from Cirrus Laboratories at the American Urology Association Annual Meeting in Chicago.

Engagement – Large Diagnostic Companies

In parallel with our LDT strategy, Minomic continues to progress licensing discussions with a number of Diagnostic companies. We are initiating validation studies with two large diagnostic companies, these studies will enable Minomic to undertake advanced testing and evaluations with the companies providing important validation of MiCheck® in their laboratories. In addition, Minomic is in Term Sheet negotiations with a third company who is also undertaking their own in-house validation of the MiCheck® technology.

MiCheck® China

Brad Walsh and David Burdis visited China again this quarter to progress Minomic's entry to the Chinese market. Whilst there we signed a memorandum indicating our intention to 'land' in the China Australia Medical Innovation Park, which is located in Binjiang district, Hangzhou. We are now in the process of setting up a wholly owned subsidiary which is called

杭州迈诺密生物技术有限公司

(Hangzhou Minomi Biotechnology Co., Ltd.).



Shown above is the BioClub team with Brad Walsh at the China Australia Medical Innovation Park (CAMIP) building. In the picture on the right, Brad Walsh is delivering the “Entrepreneur’s Opening Address” at the BioClub official opening. The picture below shows the participants in the signing ceremony for the Minomic China landing agreement.

Hong Kong Stock Exchange (HKEX) Biotech Week

In May, David Burdis and Brad Walsh attended the HKEX Biotech Week.

The event enabled Minomic to meet with a number of venture firms and potential partners providing an excellent platform to highlight Minomic’s technology and the investment opportunity.



Commercialisation Program Graduation Ceremony. We congratulate Dr Shimoni on this prestigious award.

2. Minomic Collaborations

Two IDEAL Hub Steering Committee meetings have been held in this quarter attended by Dr Walsh. Progress is on track with the Minomic project group from the IDEAL Hub. On 6 Jun 2019, the Annual Ideal Hub workshop was held at the University of Technology Sydney to review annual progress. Dr Walsh, Dr Campbell and Dr Lu attended this workshop and met with IDEAL Hub academic researchers.

Above is Professor Jin Dayong, IDEAL Hub Director at the workshop day. Below is IDEAL Hub Postdoctoral Fellow Dr Olga Simoni with the Brandwood Biomedical Regulatory Award she received at the recent Medical Device

3. Intellectual Property

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

Patent Family	Stage of Development
1. Cell Surface Prostate Cancer Antigen for Diagnosis	PCT completed, Registered SG, CN, US National Phase process continuing: AU, CA, EU, HK, JP and KR
2. Monoclonal ANTI-GPC-1 Antibodies and Uses Thereof	PCT completed, National Phase continuing: AU, CN, CA, EU, HK, JP, KR, SG and US
3. Glypican Epitopes and Uses Thereof	PCT completed, National Phase continuing: AU, CN, CA, EU, HK, JP, KR, SG and US
4. Biomarker Combinations for Prostate Disease	PCT completed, National Phase continuing: AU, CN, CA, EU, HK, JP, KR, SG and US
5. Biomarker Combinations for Determining Aggressive Prostate Cancer	Provisional patent lodged

4. Events

Australian Academy of Technology and Engineering Annual Innovation Dinner

Brad Walsh attended the Australian Academy of Technology and Engineering Annual Innovation Dinner – an exciting ‘night of nights’ celebrating STEM innovation in Australia which included the presentation of the Academy’s awards such as the prestigious Clunies Ross Awards and the Batterham Medal. The event also

hosted The Minister for Industry, Science and Technology, The Hon. Karen Andrews, who gave the opening address.



Pictured here are Minister Andrews (third from left) with a number of IMNIS program attendees including Dr Marguerite Evans-Galea, IMNIS Executive Director (centre) and Ms Shivani Sachdev (third from right - Brad Walsh's 2019 IMNIS mentee).

2019 American Association of Clinical Chemistry (AACC) meeting

The 2019 AACC meeting will take place on 4-8 August 2019 in Anaheim, California. Carl Stubbings and Brad Walsh will attend and meet with both potential MiCheck® licensees, potential partners and Key Opinion Leaders from the Clinical Chemistry industry. <https://www.aaccmeeting.org/>

5. Capital Raising

As a new round of funding is being finalised, monies received are being applied to both our US rollout of the MiCheck® test and the establishment of operations in China. In China the first activities will be completion of a comprehensive market research report and a bridging study to assess whether the MiCheck® test will require any modifications for a Chinese population. The market research report will enable us to assess the value of the Chinese opportunity and inform our market entry strategy.

In conclusion, the second quarter of 2019 has seen strong progress in the rollout of MiCheck® in both the US and China as both an LDT and in the future a licensed product.