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## **Investor Update** **1<sup>st</sup> Quarter 2019**

Dear Shareholders,

Welcome to the first quarter 2019 newsletter.

In the first quarter of this year the company signed a commercial agreement with a CLIA Certified lab, Cirrus Dx (detailed below), in the US and registered a new provisional patent covering the MiCheck<sup>®</sup> algorithm. The early adopter program has also moved forward with five US large urology practices signing up for the program. There have also been further face-to-face visits in China to spearhead clinical studies ahead of registration in that market.



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

Making the MiCheck<sup>®</sup> 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<sup>®</sup>. Updates on each of these are detailed below:

#### **MiCheck<sup>®</sup> Prospective Trial**

Now that all the trial activities are complete two papers have been drafted for publication that will enable Minomic to report the trial results to the broader clinical and patient communities in the US, Europe and further afield. The decision of the company and the Principal Investigator, Dr Neal Shore, has been to publish these papers "back-to-back". Hence the first paper has been held back from submission until the drafting of the second paper was completed. Both papers will now be submitted to the same journal, at the same time. The papers are now being finalised and will be submitted in Q2, 2019.

Our continuing interaction with licensees and clinicians has helped refine the MiCheck<sup>®</sup> algorithm and gave rise to a new provisional patent titled "Biomarker Combinations for Determining Aggressive Prostate Cancer" which was lodged on February 8<sup>th</sup>. This intellectual property required registering prior to signing the agreement with Cirrus Dx.

#### **MiCheck<sup>®</sup> Rollout Strategy – USA**

##### ***US-based CLIA Lab Rollout***

During the first quarter of 2019 Minomic executed a Laboratory Service and Licensing Agreement with Rockville Maryland based Cirrus Dx. Cirrus Dx is a CLIA Certified "High Complexity" laboratory, that will, once validation has been completed, be able to offer MiCheck<sup>®</sup> as a Laboratory Developed Test (LDT) in the USA. Both the Cirrus Dx and Minomic teams have been working diligently to finalise the technical transfer with the goal of making the LDT version of MiCheck<sup>®</sup> available to referring clinicians by June. This is an important step in the commercialisation of MiCheck<sup>®</sup>. Our partnership with Cirrus Dx will provide the Company with three important outcomes:



- “Real World Data” which can be used in subsequent FDA approval submissions
- Validation of MiCheck® and its clinical utility
- Royalty revenues

Cirrus Dx is building a strong franchise in the urological testing space and we are very excited to part of that development.

#### ***Early Access Program (EAP)***

To ensure there is an immediate demand for the test Minomic and Cirrus have been actively recruiting Urology Practices to refer patient samples immediately the test becomes available. To date, we have engaged with five large Urology Practices with 1-2 Providers within each practice agreeing to support MiCheck® by referring selected patients immediately. This strategy will enable robust testing of logistics, reimbursement and finalisation of reporting formats. Minomic and Cirrus will host a “soft launch” with our EAP clinicians at the American Urology Association meeting in Chicago in early May with a follow-up meeting to be held at Cirrus’ laboratory in July where we will share data accumulated from the EAP.

#### ***Engagement – Large Diagnostic Companies***

In parallel with our LDT strategy, Minomic continues to progress licensing discussions with a number of Diagnostic companies. These negotiations include joint development collaborations with a goal of completing a Term Sheet with one or more partners in the near future. Two of these companies have requested validation studies using the MiCheck® test. A third has provided a draft term sheet to the company.

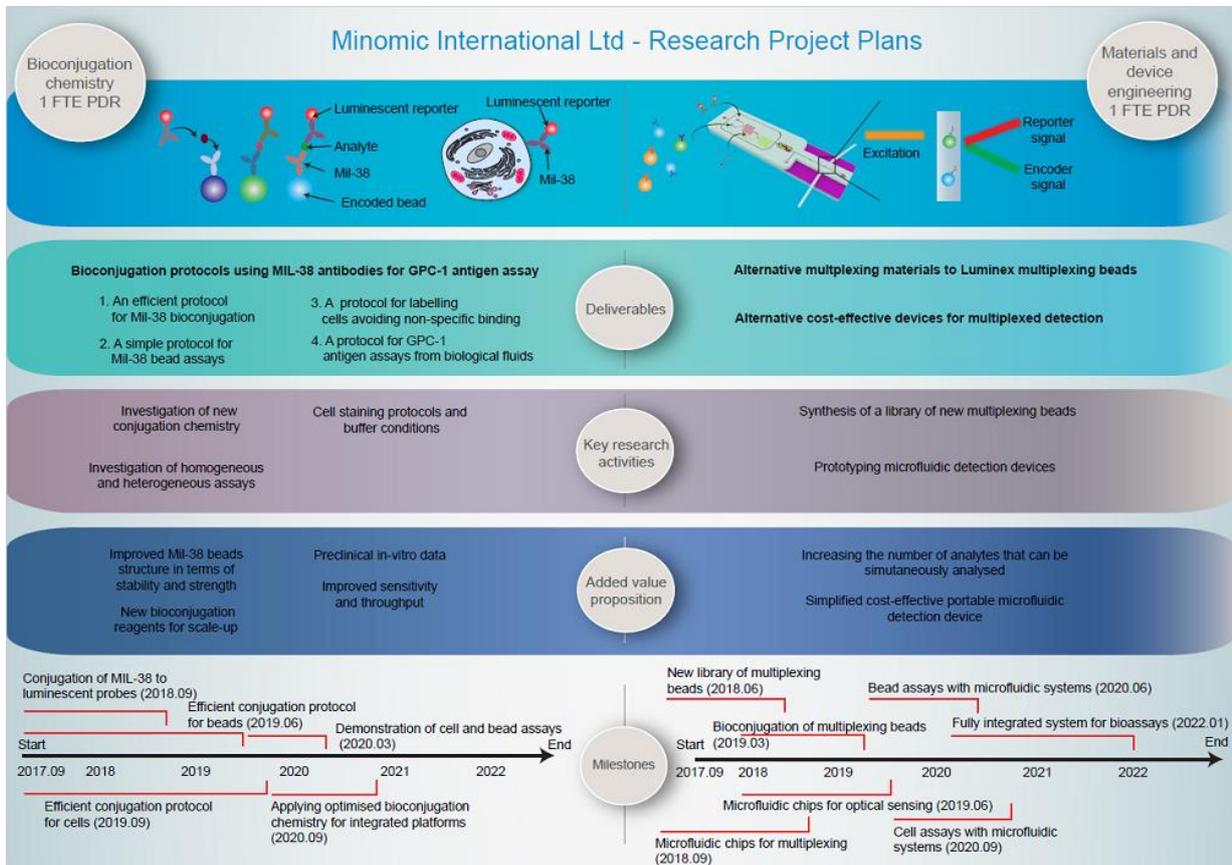
#### ***MiCheck® China***

Dr Brad Walsh has visited China three times in this quarter to further plans for a rollout of MiCheck® in China. This is likely to be in the form of a joint venture in the city of Hangzhou and requires clinical trials to be run in China in order to satisfy Chinese registration requirements. The joint venture will require funding from Chinese investors to enable a viable business to be established and discussions are ongoing with a number of parties who have the capability to invest in such a venture. As the planning crystallises we will further inform shareholders of progress.

## **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. There are plans in Q2 of 2019 to hold a meeting at the University of Technology Sydney which will be attended by a number of the Minomic researchers.

An overall outline of the projects and the timelines are given in the accompanying diagram produced by Professor Jin Dayong, Hub director and the Minomic project team.



### 3. Intellectual Property

The table below gives an update of the patent estate and the stage of development of each patent family. As noted above a new provisional patent has been submitted to cover the MiCheck® algorithm development arising from the Prospective Trial analyses and will comprise Family 5 as it progresses.

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

We provide an update of these exciting programs as follows: **The American Society of Clinical Oncology – Genitourinary Cancers Symposium** took place on 14-16 February 2019 in San Francisco, California. **Principal Investigator Neal Shore** jointly presented a poster with **Dr Douglas Campbell**, describing MiCheck®'s superior test performance in comparison to other prostate cancer diagnostic tests such as PHI.



The poster was viewed favourably by prominent urologists including an editor of the European Urology Journal.



#### 5. The retirement of Dr Stewart Washer

It is not often in the history of the company that I write to you with a sense of regret. Our Chairman, Dr Stewart Washer, due to his multiple other business commitments recently had to resign from the board of Minomic International Ltd. He has also resigned from the board of GlyTherix Ltd.

Stewart feels his increasing commitments mean there is insufficient time to devote to Minomic and GlyTherix when both are at a very busy stage in their development.

Stewart was appointed to the board of Minomic in July 2013 and has provided invaluable input and counsel to the company in its commercialisation efforts to date. We will greatly miss his contribution going forward. I would like to wish him the very best as he establishes Emerald Clinics as a leader in managing the treatment of patients with cannabinoid medicines.

The company will appoint a new chairman in due course following an assessment of the skills and profile required. As the company has now reached the commercialisation phase of its development life-cycle it will require someone with good industry experience and thus the process will likely need a few months to conclude. We will keep shareholders informed as events progress.

In conclusion, the first quarter of 2019 has begun the year with the rollout of MiCheck® and the possibility of addressing multiple markets as both an LDT and in the future a licensed product.