



TruScreen Stakeholder Newsletter



ASX welcomes TruScreen Group Ltd as the first ASX debut for 2021. Bottom Right Corner: Non-Executive Director Mr. Chris Horn, and Non-Executive Chairman Mr. Tony Ho.

Executive Update

Welcome to TruScreen's May 2021 Newsletter. It has been a challenging first quarter stepping into the Interim CEO role and getting a greater understanding of the day-to-day operations of the business.

CY2021 Q1 Key Activities:

- Dual Listed on the ASX with a NZ\$2 million capital raise
- Appointment of Juliet Hull as Interim CEO
- Appointment of Dr. Dexter Cheung to The Board
- FY 31 March 2021 SUS sales volume **+120%** YOY
- China market showing strong recovery
- Commenced clinical evaluation in Saudi Arabia
- Product registration submitted in 4 new markets in Central and Eastern Europe

The Covid-19 pandemic continues to pose challenges for the global market more than a year after its discovery, with access to clinics and hospitals reduced in many countries. We are pleased to see vaccine rollout well underway in our key markets as they continue on their recovery journey.

Despite the challenges faced over the last 12 months, our distribution network has remained committed to the TruScreen technology and have been taking advantage of this time to train healthcare practitioners and Key Opinion Leaders (KOL), host educational seminars, and have continued their work with local government departments and private sector customers to prepare for the recommencement of clinical and commercial activities in their territories.

We have also seen an increase in publication of data from independent clinical studies, highlighting the efficacy of the TruScreen device. We are pleased to continue to see such positive results and to know that women around the world are benefitting from our technology.

COVID has also highlighted the unique capabilities of the TruScreen device. A recently published paper from China provided invaluable insights into the benefits of TruScreen as a primary screening tool in a hospital affected by pandemic. Utilising a screening tool that relieves the pressure on hospital and laboratory facilities, in a time where they are stretched, can mean that women are still able to receive reliable cervical cancer screening.




In March 2021 we welcomed Dr. Dexter Cheung to The Board as a Non-Executive Director. Dr. Cheung is a medical device engineer with extensive experience in product research and development.

TruScreen also farewelled Mr. Chris Lawrence who announced his retirement from the board after 4 years.

Despite the global challenges, TruScreen continues to see positive progress in our key markets and activities. Our Medical Advisory Committee (MAC) has continued to work in close partnership with our key markets, assisting with seminars, ongoing education programs, and KOL engagement. As the reach and interest in the TruScreen Device continues to expand around the world, we are also putting together an International Experts Group and a Central European Advisory Board.

Following our ASX dual listing in January 2021, we are seeing strong support from both Australia and New Zealand shareholder and are excited about the future and the opportunities that lie ahead for us.

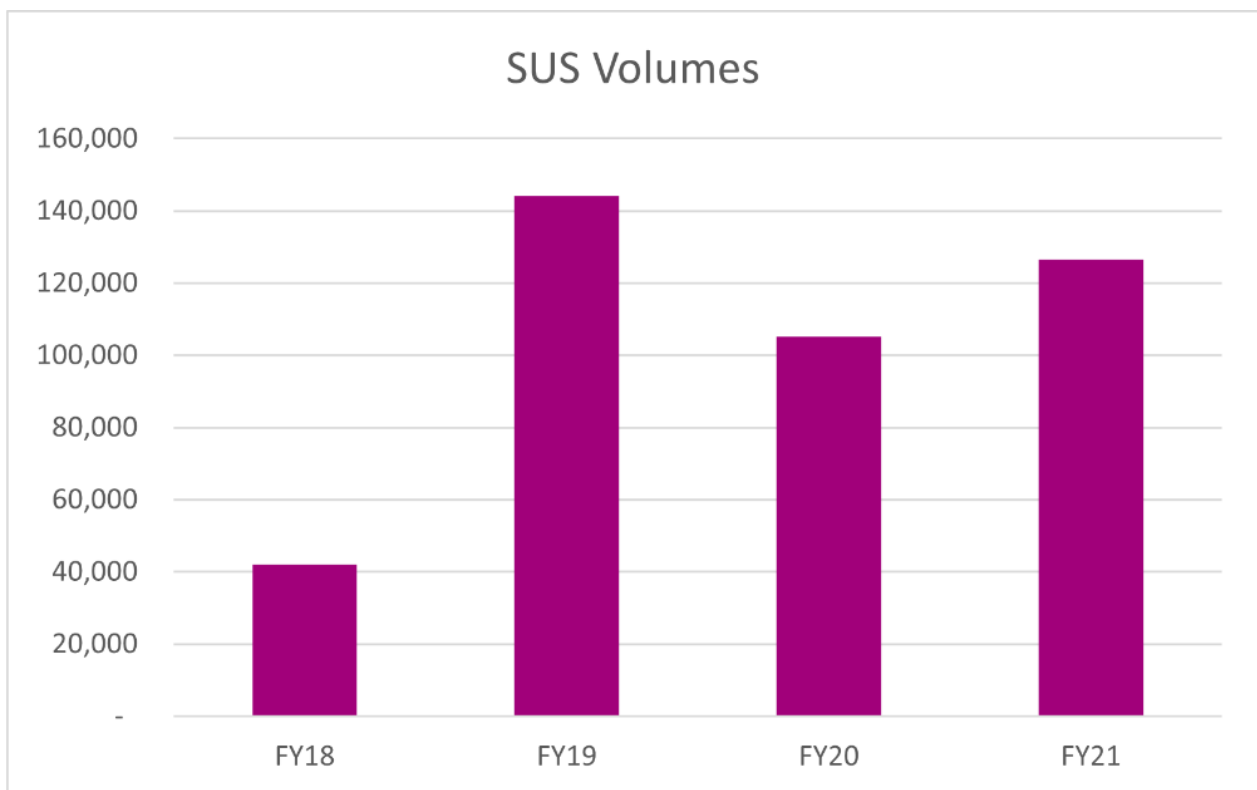
Once again, a big thank you to all our shareholders for their continued support as we navigate the changing dynamics of the world.



Juliet Hull, Interim CEO



FY2021 SUS Volume Sales +120%



April marked the start of our new financial year (FY). Our unaudited results for FY2021 show that the volume of Single Use Sensor (SUS) sales increased 120% year-on-year (YOY).

Every TruScreen examination requires a SUS. The YOY growth of SUS volumes is a good indicator that, despite the significant impacts of the global pandemic, we saw a strong increase in the usage of our cervical cancer screening devices in our markets, notably in China. This trend is expected to continue as our markets recover and TruScreen's commercial and clinical projects resume globally.

China Market Update

China remains TruScreen's key market, and in the first quarter of the 2021 calendar year we saw further progress. The installation rate of new TruScreen devices into hospitals over the last 6 months has shown strong recovery, following the impacts of the covid-19 pandemic. Clinical trials and evaluations have resumed and commercial usage of the TruScreen devices increasing. We are pleased to have a dedicated distributor who has remained focused and committed to the TruScreen technology and has delivered outstanding results during the quarter.

China had a record month of SUS usage in March 2021, with well over 8,000 commercial TruScreen examinations completed. This was the highest monthly SUS usage in our history. We now have over 80 installed devices for commercial use in China. **+165% YOY.**

The TruScreen cervical cancer screening technology is continuing to gather attention and interest throughout China. Over 100 hospitals, have completed clinical evaluations/trials, and are progressing to approval/procurement stages.

Chinese Obstetricians & Gynecologists Association's ([COGA](#)) TruScreen project is ongoing, with a total of 74 of the 77 participating hospitals having completed the data collection as of April

2021. While the pandemic has delayed the completion of this trial, completion is now expected by mid-2021. The results will be reviewed at the COGA Annual Meeting in August 2021. Results from the pilot study of the project were published in the March edition of the Journal of China Practical Gynaecology and Obstetrics, a prestigious national medical journal.

Our distributor has also been working closely with The Chinese Society of Colposcopy and Cervical Pathology (CSCCP), to secure the inclusion of the TruScreen technology in their screening guidelines, or a consensus recommendation on the use of the technology. The CSCCP is a national professional organization and a member of International Federation of Cervical Pathology and Colposcopy (IFCPC), that promotes cervical cancer screening and prevention in China.

TruScreen's Global Distributors' Conference



An inaugural virtual Distributors' Conference was successful held on 16 December 2020 with participants representing over 14 of our markets. The initiative opened a new channel for information sharing at a time where international travel is not possible. The conference included presentations from both TruScreen and our distributors, and a lively Q & A session.

We were delighted and grateful for the presentations from Francisco Camargo, of Sunbird S.A de C.V, Mexico, and Ms Su Siming, of Beijing Siweixiangtai Tech Co Ltd, China, who shared experiences in their TruScreen commercialisation pathways. Further Global Distributors' Conferences will be held in 2021.

Saudi Arabia Evaluation Study

In late January 2021 Dr. Sulaiman Al Habib Medical Group ([SHMG](#)), Saudi Arabia's largest private healthcare provider, commenced its clinical evaluation of the TruScreen device. Three of the six SHMG hospitals are participating, with over 200 of 600 TruScreen examinations completed by the end of March 2021.

The study aims to have the TruScreen device receive a recommendation for its use for cervical cancer screening in all SHMG hospitals. As reference hospitals, we anticipate once the approval is received it will increase market access throughout the region.

Extending our reach in Europe



TruScreen appointed two new distributors, in mid-2020, covering 7 countries in Central & Eastern Europe (CEE). We are pleased that four markets already have product registrations lodged with local governing bodies. We expect these countries will commence commercial activities within the 2021 calendar year.

To support the early development stage of our CEE markets, TruScreen has partnered with our local distributors and regional Key Opinion Leaders (KOL) to form our new Central European (CE) Advisory Board. This board will steer the local market access plans, including reimbursement and cervical screening projects.

An inaugural CE Advisory Board meeting with 4 KOLs, from Poland, Serbia, and Czech Republic, was held virtually in late March 2021. This meeting was an opportunity for the KOLs to discuss the value of TruScreen as a primary cervical cancer screening tool and assess individual CE market needs and opportunities for the technology. TruScreen's MAC Chairman, A/Prof Michael Campion, attended the meeting and presented his insights from the clinical research conducted at the Royal Hospital for Women in Sydney, Australia. The Advisory Board attendees were engaged in the discussions and saw the potential advantages of the TruScreen technology in a busy clinic environment. The collaboration on clinical evaluations for the TruScreen device in Central Europe is ongoing.

Furthering our commitment to Medical Affairs



Dr Beata Edling joined TruScreen in October 2020 as Medical Affairs and Market Access Lead. Dr. Edling has a MD from Gdansk, Poland, a PhD in Surgery, and an MBA from the University of New South Wales, and has an extensive background in biotechnology, healthcare management, and strategy.

Dr. Edling will guide TruScreen in scientific and clinical projects, data generation, and communication to support our commercial activities, including reimbursement within our markets. She is working closely with our KOLs and distribution network in facilitating and executing screening evaluations and programmes.

As a medical device company with a novel technology, TruScreen is focused on and committed to Medical Affairs and Market Access on a global level. Dr. Edling has led the establishment of TruScreen's International Experts Group (IEG) with internationally renowned gynaecology-oncology experts.

The IEG will collaborate with TruScreen on data generation, communication at global conferences, research planning and interpretation from the regional perspective, and collaboration with the international research and screening organisations. We welcome the opportunity for collaboration toward the implementation of the [World Health Organisation's global strategy to eliminate cervical cancer](#).

TruScreen KOL to present at World Congress for Cervical Pathology and Colposcopy

IFCPC 2021 Eliminating cervical cancer – call for action.

TruScreen MAC Chairman A/Prof. Michael Campion and Prof. Chen Fei, Academy of Medical Sciences and Peking Union Medical College in China, will each be presenting abstracts on the TruScreen technology at the 17th International Federation of Cervical Pathology and Colposcopy ([IFCPC](#)) world congress in July 2021.

A/Prof. Campion's abstract "*Performance evaluation of opto-electronic screening device in comparison to liquid-based cytology and HPV DNA testing for detection of cervical neoplasia*" and Prof. Chen Fei's abstract "*The Performance of Real-time Optoelectronic Device (TruScreen) for Early Diagnosis of Cervical Cancer and Precancerous Lesions: A Multi-center Evaluation*" will both be presented under the Innovations in Cervical Cancer Screening section of the programme.

The congress was originally scheduled for 2020 but due to the pandemic was postponed and will now go ahead as the largest conference ever organised on cervical cancer in Asia on July 1st-5th 2021. The conference's theme "Eliminating Cervical Cancer – Call for action" is in response to WHO call for Elimination of Cervical Cancer.



LEARN MORE

Millions of women worldwide are unable to access cervical cancer screening.



About TruScreen:

TruScreen cervical cancer screening device offers the latest technology in cervical screening, providing real-time, accurate detection of precancerous and cancerous cervical cells to help improve the health and well-being of women around the world.

TruScreen's real-time cervical cancer technology utilises a digital wand which is placed on the surface of the cervix to measure electrical and optical signals from the surrounding tissues. A sophisticated proprietary algorithm framework is utilised to detect pre-cancerous change, or cervical intraepithelial neoplasia (CIN), by optical and electrical measurement of cervical tissue.

TruScreen offers an alternative approach to cervical screening, resolving many of the ongoing issues with conventional Pap tests, including failed samples, poor patient follow-up, patient discomfort and the need for supporting laboratory infrastructure. As such, TruScreen's target market is low and middle-income countries where no large-scale cervical cancer screening programs and infrastructure are in place, such as China, Mexico, Africa, Russia, and India. TruScreen's cervical cancer screening device is CE-marked and certified for use throughout Europe and NMPA (formerly CFDA) approved for sale in China. The global market potential for TruScreen is significant.

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