NZX/ASX Announcement

22 November 2022



Market Update

- Revenue in line with prior half year ended 30 September, in face of challenging market conditions
- Further growth potential in China on relaxation of COVID restrictions
- Developments in Vietnam, Saudi Arabia, Mexico, eastern Europe should produce results in year ahead
- Appointment of CEO, Dr Beata Edling

Cervical cancer screening technology company, TruScreen Group Limited (NZX/ASX: TRU) ('TruScreen' or 'the Company), is pleased to provide this market update which includes commentary on its unaudited financial results for the six months to 30 September 2022 (1H FY23).

Revenue was consistent for the six months YOY at \$0.74m with COVID Zero lockdowns having a negative impact in China. The Ukraine war precluded any shipments to Russia and slowed down TruScreen's ability to further develop Eastern Europe.

SUS unit sales were in line with the previous year and device sales were up on the previous year with sales of Made in China devices to China's new private health check market.

As at 30 September 2022, the Company had cash and cash equivalents of \$1.68m.

Operational Update

TruScreen has maintained its revenue base despite disruptive and challenging market conditions.

Market developments

China

TruScreen continues to support ongoing initiatives to expand its reach in China, its most established market and the world's largest addressable cervical cancer screening market (circa 404 million women of screening age).

TruScreen has recently been added to the cervical cancer screening protocol in the largest medical private check-up centre in China. The private health check-up centre within the PLA 301 General Hospital, approved the use of TruScreen in its cervical cancer screening services with installation now having commenced. The private health check-up project aims to screen 10,000 women across 10 centres in 3-6 months.

TruScreen's China distributor Beijing Siweixiangtai Technology Company Ltd (SWXT) relaunched distribution of TruScreen cervical cancer screening device to Xinjiang Uygur Autonomous Region, during the period. The Xinjiang UAR has a population of 26 million spread over an area of 1.7 million sq km. This vast area has numerous ethnic minority groups in remote locations with the Xinjiang UAR government providing special funding for cancer screening programmes.

The TruScreen cervical cancer screening device is ideally suited for Xinjiang UAR and has significant advantages in undertaking cervical cancer screening programmes in this vast area with many remote locations. The ability to provide a real time result with a robust TruScreen cervical cancer screening



device, without the need for laboratory infrastructure, will support the UAR government's programme of improving the lives of women in ethnic minorities.

Latin America

A TruScreen-based cervical cancer screening centre was opened in Ciudad de Mexico (Mexico City), operated by Mexpharm Medical Clinical, during the period.

Mexpharm Medical Clinical a leader in healthcare in Mexico, specialises in comprehensive medical care focused on the needs of patients and clinicians. It provides state-of-the-art medical technologies and doctors specialized in ophthalmology, endoscopy, gynaecology-oncology, internal medicine, anaesthesiology, and general medicine. It delivers competitively priced, quality short-stay medical care with high level of professional medical care.

The centre showcases TruScreen's medical technology, acts as a training centre, and provides screening services to local population.

Zimbabwe

The National Aids Council's (NAC) TruScreen Masvingo pilot project continues to make good progress. In FY Q2, 16 devices were installed at local clinics and hospitals, and have screened over 4,000 women, averaging ~100 screenings per month per device. Recently NAC have further strengthened their commitment to the project by allocating additional funds to increase awareness and uptake of screening via a community outreach program that will travel to the 16 sites over the next 3 months.

Vietnam

TruScreen see significant opportunity in Vietnam, despite intermittent COVID lockdown delays. TruScreen recently received approvals for clinical use of its screening device in two top hospitals in Southern Vietnam, with a further four evaluations by Ministry of Health (MoH) underway. A roll-out of TruScreen into community medical centres is scheduled in 2H FY2023.

TruScreen has recently signed a new distributor agreement with its distributor in Vietnam to include both Vietnam and Cambodia. A national conference is planned in December, building on recent success in obtaining Ministry of Health approvals for top hospitals in both Hanoi and Ho Chi Minh city.

Medical Symposium

The Company successfully completed delivery of its first global virtual medical symposium to key opinion leaders from 7 countries, on cervical cancer screening, during 1H FY2023.

The medical symposium was chaired by Professor Neville Hacker, one of the world leaders in gynaecology-oncology and a Founder of first multidisciplinary Australian Gynaecological Cancer Centre in Sydney in 1986. The speakers at the medical symposium included Associate Professor Michael Campion, Head of the Pre-Invasive Clinic at the Gynaecological Cancer Centre of the Royal Hospital for Women in Sydney, Professor Hextan Ngan from University of Hong Kong, Associate Professor Fei Chen of Peking Union Medical College Hospital in China, Dr Bernard Madzima, the CEO of the National AIDS Council in Zimbabwe and Dr Majed Alhudhud, the Director of Gynaecology Oncology Services at the Aryan Hospital Medical Group, Riyadh, Saudi Arabia.



The medical symposium, titled "Place of advanced technologies in screening for cervical cancer" had 132 registrations from Key Opinion Leaders from China, Mexico, Russia, Poland, Vietnam, Zimbabwe and Saudi Arabia. The medical symposium enabled professional discussions on TruScreen and its current clinical data and presented the success in cervical cancer screening programs in several countries.

Professor Fei Chan presented her report on the excellent results from the 3 years COGA (Chinese Obstetricians & Gynaecologists Association) trial where 15,661 women were screened across 64 hospitals.

Regulatory Compliance

TruScreen is currently investing and transitioning its documentation and regulatory processes to comply with the new Medical Device Regulation (MDR) which is mandatory in May 2024. During the half year the Company was subjected to three external audits necessary to maintain compliance with EC and ISO requirements and to determine MDR readiness. No non-conformances were identified.

Appointment of Chief Executive Officer

In recognition of the waning of the COVID 19 pandemic and the need for the Company to prepare itself for the post-pandemic economic environment, the Company moved to appoint a permanent Chief Executive Officer to provide leadership to the Company. Dr Beata Edling was appointed Chief Executive Officer in early October 2022 having previously worked with TruScreen's as the Medical Affairs and Market Access Lead.

Dr. Edling, who joined TruScreen in October 2020, is an experienced executive who previously led large and small Medical Affairs Teams and commercialised numerous medical products with global pharmaceutical companies, Sanofi-Aventis, Shire, Eli Lily and Amgen for Australia and New Zealand. Dr Edling was previously a Non-Executive Director of ASX listed Noxopharm Limited. Dr. Edling is multi-lingual and speaks several European languages. In addition to her medical degrees and training, Dr. Edling holds an MBA from Australian Graduate School of Management.

Outlook

TruScreen has managed to maintain its financial performance despite the disruptive and challenging global market conditions. We have continued to support our distributors and invest in developing our emerging new markets. We have invested heavily in transitioning our regulatory systems and processes to the new MDR framework. Our Made In China devices for China has opened up new market opportunities in China. We will continue to focus on manufacturing cost reductions to enhance gross margin. As we come out on the other side of the COVID 19 pandemic, we expect that the many initiatives of the past years will bear fruit in the years to come.

For more information, visit <u>www.truscreen.com</u> or contact:

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About TruScreen:

TruScreen Group Limited (NZX/ASX: TRU) is a New Zealand-based medical device company that has developed an Al-enabled device that can detect precancerous and cancerous cervical changes in real-time via optical and electrical measurements of cervical tissue. Unlike many cervical screening technologies that have only triage/adjunct functionality, the TruScreen device is registered as a primary screening tool.

TruScreen's cervical screening technology effectively resolves many of the ongoing issues with conventional cytology, including failed samples, poor patient follow-up, patient discomfort, and the need for supporting laboratory infrastructure.

The device is CE-marked, meaning it meets EU safety, health and environmental protection standards required for sale and use throughout Europe. It is also National Medical Products Administration approved for sale in China. In 2021, TruScreen established a manufacturing facility in China for devices marketed and sold in China.

TruScreen is currently targeting product sales to a range of low and middle-income countries, including China, Mexico, Vietnam, Russia, Zimbabwe and Saudi Arabia, where no large-scale cervical cancer screening programmes and infrastructure are currently in place. By doing so, the Company hopes to help improve the health and wellbeing of women worldwide.

To learn more, please visit: www.truscreen.com/