

AUGUST 2023

NEWSLETTER

TruScreen Group Limited (NZX/ASX:TRU)

CEO Update

My recent trip to Asia and Eastern Europe has confirmed that TruScreen has an outstanding product and distributors who are dedicated to the TruScreen technology. We are working tirelessly to grow our existing focus markets China, and Mexico, while expanding into new promising markets. The first quarter of the financial year started strongly with good year-on-year growth. Collaborating closely with distributors, we're maximizing efforts for national roll out in Zimbabwe, Saudi Arabia, and Vietnam. In Saudi Arabia, we are driving sales through the largest network of private clinics and hospitals. Most importantly, in China, we will commence a large-scale screening project: the Health Check project, which will screen 10,000 women in the next 3 years, in addition to ongoing growth of commercial operations in China.

We're pleased to have achieved a significant boost to our growth during the first quarter of this financial year. TruScreen's technology was endorsed in the latest edition of CSCCP's China Cervical Cancer Screening Guideline, published in the July 2023 edition of CSCCP's journal, Chinese Journal of Clinical Gynaecology and Obstetrics. This endorsement followed a media announcement during the May 2023 national congress of CSCCP in Beijing.

This achievement builds upon our earlier success at the beginning of the financial year when TruScreen was included in the prestigious Blue Book in China. In this publication, the TruScreen brand is featured in a dedicated chapter on AI technology, recognized as a named AI technology for cervical cancer screening. Our commitment to advancing healthcare through cutting-edge AI technology is now acknowledged and endorsed by leading medical authorities in the field.

As we continue to strengthen our position, we are paving the way for the evidence-based adoption of our technology in our targeted growth markets. Thank you for your ongoing support. We value your feedback and welcome your thoughts. Please visit our website at www.truscreen.com to get in touch.

Sincerely,
Beata Edling
Chief Executive Officer

In this issue:

Strengthening collaborations in Vietnam

China Visit

TruScreening program continues in Zimbabwe

Presentation at Biotech NZ, Dunedin

Regulatory Updates



Strengthening Collaborations in Vietnam

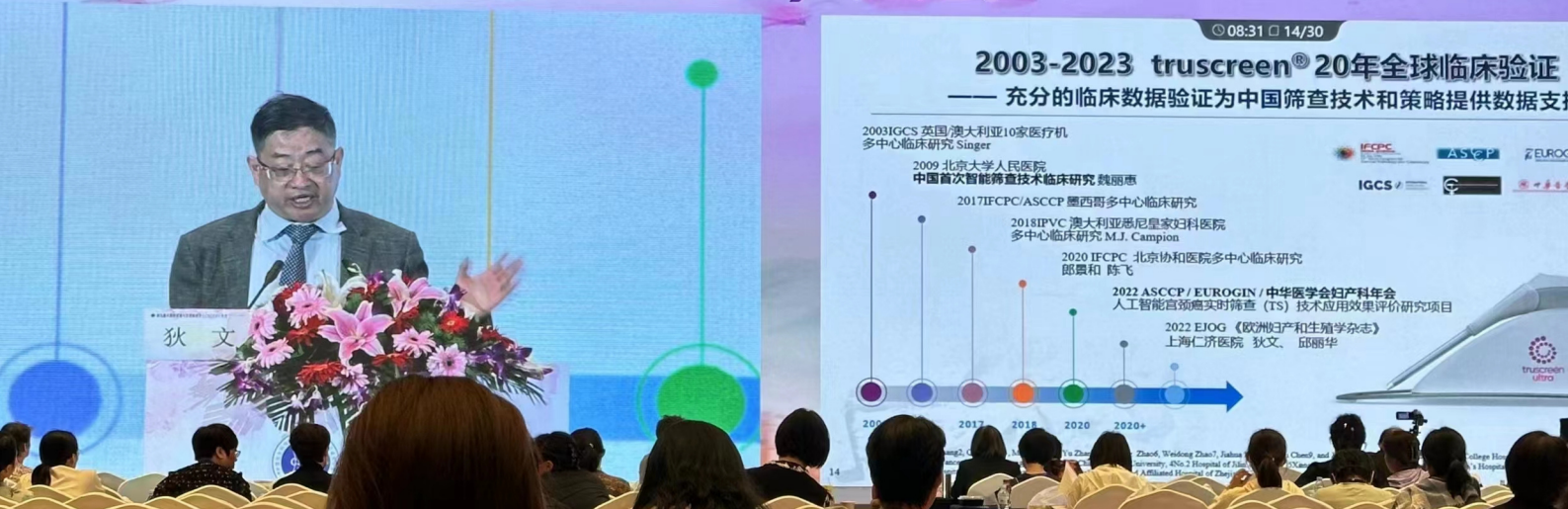
TruScreen's CEO, Dr Beata Edling, and Lead Commercial Manager for APAC, Dr. Jerry Tan, recently travelled to Vietnam to support the company's growing presence in the local market. The trip was to strengthen relationships, gain firsthand understanding of the market, and set the platform for accelerating performance and business growth in the coming year. During their visit, the TruScreen team reviewed detailed market access plans and growth opportunities with the Gorton Health Services (GHS), TruScreen's Distributor in Vietnam. GHS has achieved Ministry of Health approval in new 2 key public hospitals, with plans for implementation of TruScreen in four other major hospitals well advanced and our technology has gained strong support from key opinion leaders.



Meeting with the Board of Directors of Hung Vuong Hospital, Ho Chi Minh City

Drs Edling and Tan also visited several prominent hospitals, including Hung Vuong Gynaecology Hospital, where they met with Dr. Nghiem, Deputy Director, and other senior doctors and managers to explore potential collaborations to create a model of care based on TruScreen's technology. This meeting offered a valuable opportunity for the TruScreen delegation to interact with Vietnamese hospitals and listen to doctors' feedback regarding TruScreen's screening technology. The feedback received from the doctors of Hung Vuong Hospital was overwhelmingly positive. They acknowledged the immense potential of TruScreen's Optical-Electrical technology in Vietnam, recognising the numerous advantages it brings to both patients and healthcare professionals. The technology's ability to facilitate rapid screening and early detection of cervical cancer were well received by the hospital's medical staff, including the Director of Gynaecological Services.

TruScreen is confident on the potential in Vietnam and that we can make a significant impact on Vietnam's cervical cancer screening landscape. We have a committed and professional distributor in GHS, and strong support from key opinion leaders.



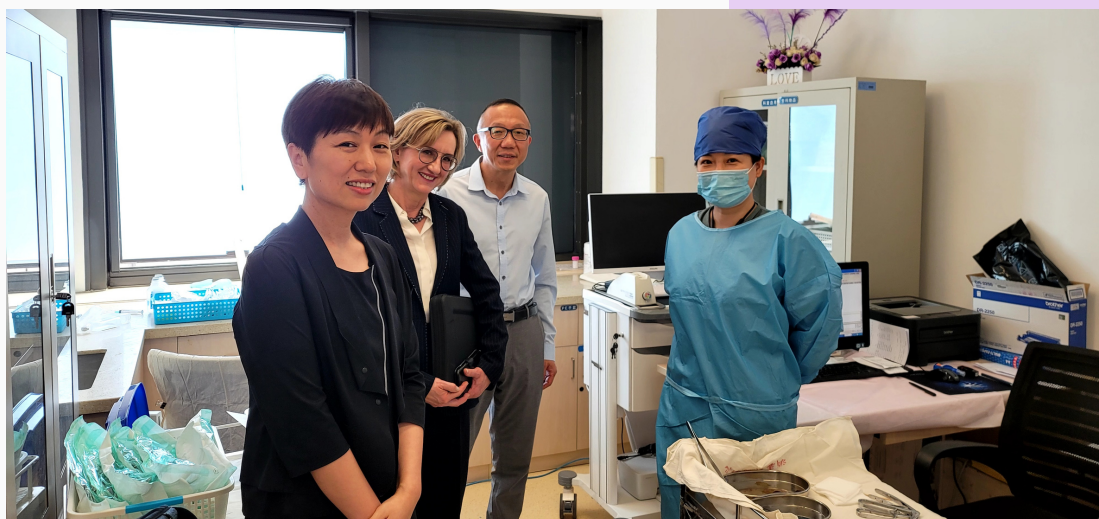
China Visit

During their recent visit to Beijing, Dr Edling and Dr Tan met with our Chinese Distributor, Siweixiangtai Tech Co. Ltd (SWXT). The primary objective of the visit was to explore collaborative strategies to enhance sales performance and foster business growth. Through this visit, both parties sought to identify ways of working together effectively to achieve mutual success and better serve the healthcare needs of the Chinese population.

Drs Edling and Tan visited a major referral hospital in Beijing, with over 1,000 beds. The Head of the Gynaecology and Obstetrics, Prof Feng, has shown strong support for the TruScreen technology and sees the AI technology as an important path forward in achieving eradication of cervical cancer in China in line with the World Health Organisation's strategy objectives. The Chinese Government actively promotes healthcare technology advancements, and TruScreen's devices for China are Made in China.

TruScreen executives also had the opportunity to meet with Professor Meng, the vice-head of CSCCP and an early adopter and supporter of TruScreen's technology. They discussed the future evolution of cervical cancer screening technologies in the coming decade.

Drs Edling and Tan left China with a better appreciation of the progress achieved by SWXT, and the very significant potential of the Chinese market for years to come.





TruScreening Program Continues in Masvingo Province, Zimbabwe

TruScreen is delighted to share that the Zimbabwe government's TruScreening program resumed in June 2023, with strong screening numbers seen over the first two months.

The program in Masvingo Province is a collaborative effort between the Ministry of Health and Child Care, National AIDS Council, and local health partners. The program provides screening services to women in remote and clinically under-served communities, where access to healthcare can be limited. The screening program, which began in 2022, has screened over 15,000 women in Masvingo Province (as at 31 July 2023).

Cervical cancer is a significant health issue in Zimbabwe. However, many women lack access to adequate screening and treatment services, which puts them at a greater risk of developing advanced-stage cancer that can lead to death. TruScreen's innovative technology addresses this gap by providing accessible screening services to women in the region.

Presentation at the BioTech New Zealand, Dunedin

TruScreen's CEO, Dr Beata Edling, presented our achievements and future plans at the well-regarded BiotechNZ event on 20th July in Dunedin, New Zealand. Alongside several reputable biotech companies, we introduced our "Mission driven growth" amidst the challenges of the pandemic. The event, sponsored by ASX, NZX and major companies, attracted numerous investors. Our presentation received an enthusiastic reception leading to further investor interest and potential collaboration opportunities



Regulatory Update

MDR readiness

As previously reported, the Medical Device Regulation (MDR) is a new global regulatory framework that replaced the Medical Device Directive (MDD) for medical devices being made and/or sold in the European Union after May 2024. The MDR strengthens the safety and efficacy of medical devices, improves patient safety, and enhances transparency and accountability in the medical device industry. The MDR introduces more stringent requirements for manufacturers, including increased clinical evidence requirements, stricter pre-market controls and post-market surveillance requirements, and new rules for economic operators, such as importers and distributors.

TruScreen's activities in support of the transition to MDR are well underway and the formal application process for MDR certification has commenced. TruScreen has secured the necessary audit by the notified body, TUV SUD Singapore, to seek MDR conformity assessment by May 2024. We are confident, we meet the criteria for compliancy. While costly and effort-consuming, achieving the MDR compliance will ensure that TruScreen technology is competitive and trusted as a leading medical device

NMPA variation application

TruScreen is in the final stages of completing its Chinese regulatory (NMPA) variation approval submission. This important milestone will grant approval for the latest TruScreen device updates and recertification to the updated NMPA standards. Submission is on track to be completed by the end of August 2023, further strengthening TruScreen's position in the Chinese market.

Mexico

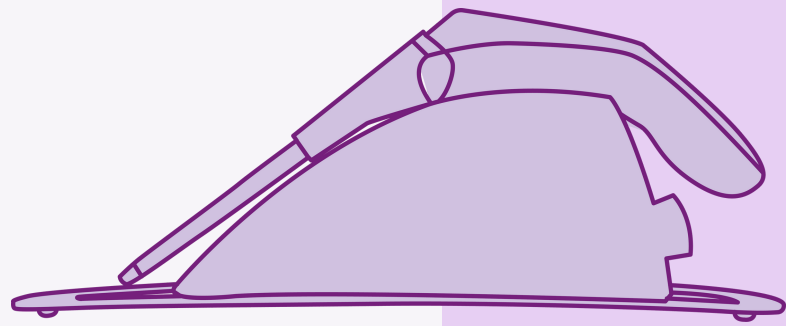
In January 2023, TruScreen took a significant step to register our technology and device with COFEPRIS. This will facilitate the regulatory evaluation process to obtain updated approval, enabling TruScreen to enter the public health sector, including government screening programs. Such programs present promising opportunity to expand TruScreen's marketing reach in Mexico. We expect the COFEPRIS decision by December 2023.

Russia-Kazakhstan certification renewal

All documents required for the certification renewal of TruScreen in Russia and Kazakhstan have been submitted to our distribution partner for submission to local regulators. We are currently waiting for a response from these regulators, which is expected within the next 6 to 12 months.

This Newsletter has been approved by The Board.

The path to a healthy



future

About TruScreen

TruScreen Group Limited (NZX/ASX: TRU) is a medical device company that has developed and manufactures an AI-enabled device for detecting abnormalities in the cervical tissue in real-time via measurements of the low level of optical and electrical stimuli.

TruScreen's cervical screening technology enables cervical screening, negating sampling and processing of biological tissues, failed samples, missed follow-up, discomfort, and the need for costly, specialised personnel and supporting laboratory infrastructure.

The TruScreen device, TruScreen Ultra®, is registered as a primary screening device for cervical cancer screening.

The device is CE Marked/EC certified, ISO 13485 compliant and is registered for clinical use with the TGA (Australia), MHRA (UK), NMPA (China), SFDA (Saudi Arabia), Roszdravnadzor (Russia), and COFEPRIS (Mexico). It has Ministry of Health approval for use in Vietnam, Israel, Ukraine, and the Philippines, among others and has distributors in 29 countries. In 2021, TruScreen established a manufacturing facility in China for devices marketed and sold in China.

TruScreen technology has been recognised in CSCCP's (Chinese Society for Colposcopy and Cervical Pathology) China Cervical Cancer Screening Management Guideline.

TruScreen has been recognised in a China Blue Paper "Cervical Cancer Three Stage Standardized Prevent and Treatment" published on 28 April 2023.

In financial year 2023 alone, over 140,000* examinations have been performed with the TruScreen device. To date, over 200 devices have been installed and used in China, Vietnam, Mexico, Zimbabwe, Russia, and Saudi Arabia. TruScreen's vision is "A world without the cervical cancer"©.

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

*Based on Single Use Sensor sales.

For more information about the cervical cancer and cervical cancer screening in New Zealand and Australia, please see these useful links:

New Zealand: [National Cervical Screening Programme | National Screening Unit \(nsu.govt.nz\)](#)

Australia: [Cervical cancer | Causes, Symptoms & Treatments | Cancer Council](#)