



Dear Shareholders,

It is a privilege to be appointed the new CEO for TruScreen Group Limited. I'm not only inspired by TruScreen's vision, but I believe that we have an obligation to bring our world-class technology to save lives around the world. I stepped into this role after consulting for TruScreen for two years prior, as the Medical Affairs and Market Access Lead. This gave me the opportunity to understand our business, its challenges, its strengths and most importantly, the people. I want to thank Juliet Hull for looking after TruScreen during the term of her interim CEO appointment. I had the benefit of learning from Juliet, while working with her and transitioning into the CEO role. Juliet has done an outstanding job leading the team through the turbulence of the Covid pandemic.

Despite the challenges posed by the pandemic, the TruScreen team held strong and has persistently progressed through the strategic plan. Over the last year, we have laid many new foundational inroads in our new and focus markets, while strengthening our foothold in established markets. Read on for the update on just some of these projects in China, Zimbabwe and Vietnam.

It takes a lot of hard work to make something complex appear simple. This is demonstrated by TruScreen recently having passed 3 quality audits, assessing our Medical Device Reporting (MDR) readiness and regulatory compliance. I'm proud to say that we have passed all three with no non-conformance.

I will bring to our TruScreen Team strong and purpose driven international collaboration, clarity and focus. I believe that the world is ready for TruScreen technology, and the time is now to make the most of the WHO strategy and to include TruScreen in the conversation on making cervical cancer the first ever cancer that becomes a rare disease. Our financial performance will be a natural consequence of our hard work and dedication.

Thank you for reading this newsletter. I look forward to meeting with all stakeholders in the time ahead. I want to hear from you. I encourage you to reach out and share your thoughts.

China Market Update

TruScreen has continued to see progress in its core Chinese market, despite ongoing COVID-19 restrictions. TruScreen's Made in China devices have begun to be installed in public hospitals, with additional tenders ongoing.

TruScreen has been added to the cervical cancer screening routine in the largest medical check-up centre in China. The health checkup centre within the People's Liberation Army General Hospital, approved adding TruScreen to its cervical cancer screening services with installation expected to follow. TruScreen's local distributor, with a government backed association, have been working towards a health checkup project which will aim to screen 10,000 women across 10 centres in 3-6 months. This project is expected to commence following installations.

Recently, 8 hospitals in Beijing obtained pricing approval and another 3 are now in the evaluation process. This process paves the way for fast-tracked adoption in these hospitals, which include top-level teaching hospitals that would be expected to generate high Single Use Sensor (SUS) pull through. Elsewhere in the region, another 4 major hospitals have awarded TruScreen tenders in the last 3 months, with 6 more expected to follow.

Despite the ongoing COVID-19 restrictions, TruScreen's distribution partner has managed to maintain good momentum throughout the country. With marketing activities shifting to online seminar to ensure that projects can continue to move ahead.

Zimbabwe NAC Project Update

The National Aids Council's (NAC) TruScreen Masvingo pilot project is on track to wrap up in Q1 CY2023. This is the second and final phase of the government pilot program for the Masvingo province, one of the most populous regions of Zimbabwe. Since July 16 devices installed at local level clinics and hospitals have screened over 4,000 women. This project has been seeing strong SUS usage, averaging ~100 screenings per month per device.

In October NAC further strengthened their commitment to the project by providing additional resources to increase awareness and uptake of screening via a community outreach program that will travel to the 16 sites over the next 3 months.

Dr. Bernard Madzima, CEO of the Zimbabwe National AIDS Council, recently said of the TruScreen technology, *"The advantage is that the women don't have to incur transport costs if they go to the clinic to be screened (with TruScreen). The referral pathway is that when the woman has been screened, they then, if the result is abnormal, they are then sent to the next level of care which would be the provincial hospital for colposcopy. **We intend to disseminate the TruScreen method throughout the country, so***

for us TruScreen really is a good way of ensuring that services are available to women at the lowest level.”

Vietnam Hospital approval

TruScreen has continued to see traction in Vietnam over recent months as the country continues its COVID-19 recovery.

As recently announced, TruScreen obtained Ministry of Health (MoH) approval for daily clinical use in two top hospitals in South Vietnam. This approval is expected to accelerate other public hospitals' MoH approval, with four hospitals currently in the MoH evaluation process pending approval. Off the back of these approvals, a TruScreen seminar will run in HCMC in December aiming to accelerate the rollout of TruScreen following the new approvals. The seminar is expected to be attended by potential users, local key opinion leaders, and hospital directors. TruScreen is also cooperating to make a member of our Medical Advisory Committee available for the seminars.

In the private sector, a two-day event in collaboration with private clinics offered free TruScreen exams for local women. This initiative is expected to be mirrored in other regions with the goal to familiarise new clinics with the technology to facilitate adoption.

Local distributor GHS has started working to enter community medical centres. As they work to introduce TruScreen into the community medical centres, free TruScreen screenings have been offered to women and initial training of users has commenced. District 8 medical center in Ho Chi Minh City is expected to conduct a pilot program involving 300 women as the first phase of the community medical centre.

TUV Audits

During the month of August, TruScreen successfully completed two regulatory annual surveillance audits with no non-conformance. The successful completion of all these audits allows TruScreen to maintain our current EC and ISO certifications.

One audit focused on the TruScreen Manufacturing site in Sydney and the second one on the legal representative site. Both audits reviewed and inspected the effectiveness and compliance of our Quality Management System to the requirements of ISO13485:2016 and the European Council Directives 93/42/EEC (MDD) – annex II (w/o 4) including the additional requirements of MDR Article 120 (3); there were no non-conformance found in either one of these audits.

Subsequently, at the beginning of October, we also had to complete a mandatory un-announced regulatory audit that focused on the same compliance areas as the August audits. The un-announced regulatory audit was also successfully completed, with no non-conformance identified.

Poland marketing activities



TruScreen's Poland based distributor, Aspironix, continues marketing efforts with participation in 2 local conferences in October. The booth was held at the 2nd Autumn Congress of the Academy of Gynecology and Obstetrics and Rodzinna 2022, a conference targeting for general practitioners and family doctors. Participation in such conferences helps to facilitate awareness and acceptance of novel technologies within the healthcare professional network.

Upcoming Dates

Half Year Results by 30th November 2022

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About us

TruScreen Group Limited (NZX/ASX: TRU) is a New Zealand-based 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, and it does not incur issues with sampling and processing of biological tissues, including 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 tool for cervical cancer screening.

The device is 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, Zimbabwe, Israel, Ukraine, and the Philippines, among others and has active distribution agreements in 23 countries. 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.

To date, over 170000* examinations had been performed with TruScreen device and 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".

**Based on Single Disposable Sheath sales.*

To learn more please visit our website

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