



NZX/ASX Announcement

truscreen
a world without
cervical cancer

29 November 2021

TruScreen unaudited interim results for the half-year ended 30 September 2021

Highlights for Half Year ended 30 September 2021

- **Strong revenue and Single Use Sensor sales growth of 25% and 35% year on year respectively**
- **Launch of TruScreen Made in China device for the Chinese market**
- **Firmware upgrade and cervical cancer screening device enhancements**
- **Continuous expansion and first sales in Eastern Europe**
- **Ongoing excellent trial results confirm efficacy of TruScreen cervical cancer screening device**

TruScreen Group Limited (NZX/ASX: TRU) ('TruScreen' or 'the Company') is pleased to announce its unaudited half year financial results for the period ended 30 September 2021. TruScreen reports according to the New Zealand financial year, which runs from 1 April to 31 March.

Strong revenue growth of 25%

The Company reported an operating loss of \$1.26m (1H FY21: \$1.51m), a 20% reduction over the prior year. Despite the negative impacts of COVID-19 in some of our markets, notably Russia and Vietnam, product revenue increased by 25% year on year (YOY).

Pleasingly, Single Use Sensor (SUS) unit sales were 35% higher YOY, although getting new cervical cancer screening devices installed in hospitals was hampered by ongoing COVID-19 restrictions.

Net operating cash outflow was \$1.7m (1H FY21: \$1.6m). An Australian research and development tax offset was received just after quarter-end in the amount of \$0.6m. Cash operating costs were 22% higher in 1H FY22, at \$2.5m (1H FY21: \$2.1m), reflecting the Company's increased investment in research and development which resulted in re-engineered firmware that enhanced cybersecurity and facilitated self-calibration which will reduce future operating costs. The Australian tax offset for the related research will be received in the next financial year.

The loss for the six months included a non-cash amortisation and depreciation charge of \$0.30m (1H FY21: \$0.35m).

As at 30 September 2021, the Company had cash and cash equivalents of \$3.67m, which was supplemented by a research and development tax offset receipt of \$0.6m from the Australian Tax Office on 1 October 2021.

Operational Update

TruScreen continued to make good market and technical progress in 1H 22 and, going forward, is well placed to build upon this success as the COVID-19 pandemic wanes throughout our markets.



Market development - China

TruScreen has continued to successfully expand in China, its most established market and the world's largest addressable cervical cancer screening market.

With the launch of the TruScreen Made in China device, developed specifically for the Chinese market, the Company's China distributor Beijing Siweixiangtai (SWXT) has expanded its addressable distribution market. It is now marketing this TruScreen device to the growing Health Check sector. SWXT anticipates the first major placement of TruScreen devices in the private Health Check sector to commence before the end of the 2021 calendar year.

This development provides TruScreen with revenue upside, as China's Health Check sector is rapidly growing, aided by support from provincial governments, private organisations, and non-government organisations (NGOs). Major public hospitals will have separate Health Check clinics offering a wide range of women's health medical checks, including cervical cancer screening.

In July 2021, TruScreen's largest clinical evaluation, with the Chinese Obstetrics and Gynaecology Association (COGA), came to a close after screening over 15,000 women in 64 hospitals and 9 provinces around the country. The final results are expected to be presented to the COGA panel for review and consensus in the coming months.

Market development – Rest of world

TruScreen has continued to broaden its market access throughout Central and Eastern Europe, with the Company's current focus on Serbia and Poland. The market access strategies in these two countries are now being actively supported by key opinion leader engagement, clinical trials, and local clinical evaluation initiatives.

TruScreen is currently in the final planning stages for a clinical trial in Poland, led by a well-known medical opinion leader in that country. The pilot phase of this trial will screen women in five centres across Poland to evaluate the clinical performance of the TruScreen cervical cancer screening device. TruScreen anticipates the results of the trial will facilitate accelerated market access throughout Poland as well as neighbouring countries.

TruScreen has recently concluded training in Serbia targeting new key opinion leaders and clinicians. The training has enabled the commencement of planned local clinical evaluations and facilitated the commencement of early market activities with the first sales to the region completed in September.

The World Health Organisation (WHO) has highlighted that low-and-middle income countries will require innovative technologies, like TruScreen's portable and real time device, if they are to make progress in achieving the goal of eliminating cervical cancer. Leveraging our success in Zimbabwe and in partnership with its National Aids Council, we are in discussion with potential distributors in markets where TruScreen is not currently represented, and where TruScreen, as a primary cervical cancer screening device, can make a positive difference to women's health.

Upgraded firmware

After twelve months of development work, TruScreen has completed verification and validation of a key firmware update that is now being progressively released to TruScreen devices already in the market. The firmware update enhances the device's cyber security framework and allows TruScreen devices to more effectively interface with compatible hospitals' systems. By incorporating a state-of-the-art optical calibration feature, the firmware has reduced the need for the device to return to service centres for scheduled re-calibration. This reduced service-related downtime means clients have their devices online for longer time periods, boosting operational efficiencies.

The new firmware update also includes enhancements to the user interface and battery management features. These were developed in collaboration with the Company's distributors and in response to market feedback, a demonstration of the collaborative nature of the relationship TruScreen has with these crucially important groups.

Clinical trials continue to show promising results

A new study, published in the *European Journal of Obstetrics and Gynaecology and Reproductive Biology*¹, concludes that TruScreen's cervical cancer screening technology meets or exceeds the effectiveness of alternative cervical cancer screening methods. The study evaluated the efficacy of TruScreen in screening for cervical abnormalities, in a real-world primary cervical cancer screening setting in China.

The TruScreen screening device was found to be very effective at detecting cervical intraepithelial neoplasia grade 2 or worse (CIN2+ or CIN3+).

The Chinese Obstetrics and Gynaecology Association (COGA) national clinical trial which has screened ~15,000 women in 64 top-tier public hospitals across 9 provinces in China, has concluded. The COGA evaluation compares the TruScreen technology to Liquid Based Cytology (LBC) and human papillomavirus (HPV) DNA testing, targeting a nationwide consensus on TruScreen technology applications in China as the main outcome of this large-scale trial.

The final report from this trial is still awaited, however preliminary results from two major provincial trials (See NZX announcements 2 September 2019 and 19 October 2020) showed TruScreen to be better or on parity than tests for HPV and LBC.

¹ Yingting Wei, Wenjing Wang, Mengxing Cheng, Zubei Hong, Liying Gu, Jiaxin Niu, Wen Di, Lihua Qiu, Clinical evaluation of a real-time optoelectronic device in cervical cancer screening, Yingting We et al., *European Journal of Obstetrics & Gynecology and Reproductive Biology*, 2021, ISSN 0301-2115, <https://doi.org/10.1016/j.ejogrb.2021.09.027>. (<https://www.sciencedirect.com/science/article/pii/S0301211521004826>)

Corporate

TruScreen's operations are based in Sydney Australia, which for much of the six months to 30 September 2021 was under COVID-19 lockdown restrictions. Throughout the lockdown the company functioned while following the health orders with limited impact on operations. The lockdown was lifted in early October and TruScreen's offices and manufacturing sites have since reopened.

Outlook

TruScreen's Strategic Plan for FY22 and beyond will see the Company focus on three key areas: continuous product improvement, rapid expansion in China, and growth into other key markets.

Juliet Hull, TruScreen's CEO said "Our half year results reflect the significant efforts of the team, despite COVID-19's ongoing impacts. The strong revenue growth, attributed largely to SUS sales, is pleasing to see at this point in the year.

It is great to see the efforts of the last year start to materialise, with key projects in China and Europe moving ahead with pace. In addition to the strong revenue growth year on year, we have seen a 20% growth in commercial users around the world since the start of FY22. As our markets continue to recover from COVID-19 we expect to see commercial and clinical activities start to ramp up significantly."

-ENDS-

For more information, visit www.truscreen.com 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 AI-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.

TruScreen is currently targeting product sales to a range of low and middle-income countries, including China, Mexico, Vietnam, Russia, and Saudi Arabia, where no large-scale cervical cancer screening programs 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/