



truscreen  
a world without  
cervical cancer

NZX/ASX Announcement

29 November 2022

## TruScreen unaudited interim results for the half-year ended 30 September 2022

### Highlights for Half Year ended 30 September 2022

- Revenue in line with prior year, 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 its unaudited financial results for the six months to 30 September 2022 (1H FY23), along with the following operational update. TruScreen reports according to the New Zealand financial year, which runs from 1 April to 31 March.

The Company reported an operating loss of \$1.22m (1H FY22: \$1.26m, which included non-cash amortisation of \$0.3m). 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.

Net operating cash outflow was \$1.2m (1H FY22: \$1.7m). The difference between the years being the Australian research and development tax refund received during the current half year, but just after the previous half year in the amount of \$0.6m. Operating cash outflows were \$1.2m (1H FY22: \$1.7m). The current period includes termination costs of personnel as the Company realigned its operations to suit prevailing global market conditions.

The Company made a provision for all non-current assets in the prior year. The loss for the previous six months 1H FY22 included a non-cash amortisation and depreciation charge of \$0.30m.

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

### Half-Year Commentary

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.

#### *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 Champion, 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 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 Lilly 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 [www.truscreen.com](http://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 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<sup>®</sup> 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".

To learn more, please visit: [www.truscreen.com/](http://www.truscreen.com/).

*\*Based on Single Disposable Sheath sales.*