



NZX Announcement

4 November 2020

TruScreen Unaudited Preliminary Results for the Half-Year ended 30 September 2020

Highlights for HY2020:

- ✓ Operational SUS sales volume growth of +80% over 1H 2019;
- ✓ Expansion in China, with installed devices in new hospitals up 40% YOY;
- ✓ Expansion into Vietnam with MOH approval, and first shipment of product;
- ✓ Appointment of distributors in Eastern Europe, Aspironix s.r.o and MPG d.o.o Beograd for the Balkans;
- ✓ Appointment of replacement distributor in Mexico, Sunbird S.A. de C.V.; and
- ✓ Successful \$5.243m (before costs) capital raising completed in May/June 2020.

Cervical cancer technology company TruScreen Group Limited (NZX: TRU) (the Company, TruScreen) announces its preliminary unaudited half-yearly results for the period ended 30 September 2020. TruScreen continued to make commercial progress throughout the period.

Unaudited Preliminary Half-Yearly Financial Results for the period ended 30 September 2020 (1H 2021)

The Company reported a bottom-line loss of \$1.5m (2019: \$1.0m). The major contributor to that loss was a reduction of \$0.7m in the Australian research and development tax offset refund. The 2019 result included the impact of share-based payments of \$0.3m attributable to that half-year (1H) period.

Product revenue at \$0.6m (2019: \$0.76m) was down 22% on the prior year. Note that the 2019 period benefitted from sales to Zimbabwe of \$0.28m billed and shipped in Financial Year (FY) 2018. However, the application of NZ IFRS 15 required that this be recognised as sales on receipt of cash early in FY 2019. On a shipped and billed basis, sales were up 24%, and Single Use Sensor (SUS) revenues grew 85% on the prior period. SUS sales by volume shipped increased by 80% year on year (YOY), largely attributable to China.

Net operating cash outflow was \$1.6m (1H 2019: \$1.7m). Cash operating costs were 5% lower in the six months, at \$1.8m (1H 2019: \$1.9m). The loss for the six months included a non-cash



amortisation and depreciation charge of \$0.35m (1H 2019: \$0.30m).

At 30 September 2020, the Company had cash and cash equivalents of \$4.47m. A capital raise of \$4.97m (net of costs) was completed in April/May 2020. The capital raising was undertaken via a successful over-subscribed Share Purchase Plan and a private placement.

Operational update

TruScreen continued to make significant commercial progress in the six months to 30 September 2020, notwithstanding the challenges presented by COVID-19.

- **China screening continues to produce outstanding results**

The China Obstetrics and Gynaecology Association's (COGA) ongoing national clinical trial that originally planned to screen over 20,000 women has been reduced to 10,000 patients due to interruptions from COVID-19 lockdowns. The COGA trial is being conducted in 100 top-tier public hospitals across 10 provinces in China. The trial is comparing the TruScreen's technology to Liquid Based Cytology (LBC), and HPV DNA testing (HPV). This large-scale trial is targeting as the main outcome a nationwide consensus on the application of TruScreen's technology in China.

Preliminary trial results from Sichuan Province were presented by the lead investigator of the COGA project in Sichuan Province, at COGA's annual congress in September 2020. The Sichuan trial covered 14 hospitals and 1,243 patients in the data analysis.

The preliminary results from the Sichuan Province trial were better than, or at least on parity with, tests for HPV (Human Papillomavirus DNA Test) and LBC (Liquid-based Cytology). These results confirm trial results from Hunan Province that were announced in 2019.

TruScreen's China distributor has increased the number of in-use TruScreen cervical cancer screening devices from 49 to 69 over the course of the half-year, adding new hospitals in the Municipality of Shanghai and the Provinces of Sichuan, Hunan, Guangdong, Shandong, Jiangsu, Guangxi, Shan'xi, and Guizhou.

- **Vietnam – Approval from Vietnam Government's Ministry of Health (MOH)**

After a successful clinical trial covering 989 patients, the Company received approval from the Ministry of Health (MOH) of the Vietnam Government for the commercial rollout of the TruScreen cervical cancer screening device.



This landmark approval is granted initially for the Hanoi Obstetrics and Gynaecology Hospital (HOGH). It is anticipated that further rollouts across other public and private hospitals in Vietnam will occur this financial year.

- **Distributor development**

Prominent medical device distributor Aspironix s.r.o (Aspironix) was appointed exclusive distributor for the Czech Republic, Slovakia, and Poland. These countries have a combined cervical cancer addressable screening population of over 17.91 million women, presenting a significant market opportunity for the Company.

A further distributor, MPG d.o.o Beograd, was appointed with responsibility for Serbia, Montenegro, Bosnia, and Macedonia.

- **Corporate**

Capital Raise

With the strong support of shareholders, the Company raised \$5.243m before costs in April/May 2020, with a Share Purchase Plan raising \$3m through the issue of 74,860,021 shares at 5 cents each and a further \$2.243m through an over-subscribed placement of 30,000,000 shares at 5 cents each.

Enhanced Team Capability

The Company appointed Victoria Potarina, an executive with more than 18 years' experience at Johnson & Johnson (J & J) and other blue-chip multinational companies in FMCG, OTC, medical devices and healthcare, as CEO on 2 March 2020.

The team was further strengthened during 1H 2021 with the appointment of; *Edmond Capcelea* as Chief Technology Officer. Edmond holds a Master's Degree in Engineering Physics, and his previous roles include Divisional Director Head of Implants and Design Development at Cochlear Limited, and Senior Vice President of Research and Development at Saluda Medical. TruScreen also appointed



Dr Beata Edling MD, PhD, MBA as Medical Affairs Lead. Beata's previous roles include Executive Medical Director Amgen, Eli Lilly, Sanofi.

Jerome Villalon as Senior Software Engineer. Jerome holds a Bachelor's Degree in Information Communications Technology from UTS.

Outlook

TruScreen's goals for FY 2021 and beyond:

- Achieve >160 commercially installed devices across key markets by March 2021 (+100% on 2020)
- Target COGA consensus in China on TruScreen as a primary cervical cancer screening tool
- Increase commercial coverage in Russia, following COVID-19 recovery
- Achieve China manufacture for China TruScreen device requirements
- Through research and development and process optimisation reduce cost of production of both the TruScreen device and SUS
- Expand market presence in Eastern Europe

Commenting on the outlook, TruScreen CEO Victoria Potarina said,

"In the last 6 months Truscreen has advanced substantially in it's transformational phase. The reinforced team has identified a number of key projects which will give us greater access to the China market, improve the Company's gross margin and optimise our go to market capabilities.

Our results this half year have been impacted by COVID-19, nonetheless Truscreen has a solid growth plan which is expected to build sustainable SUS revenue streams from diverse markets over the medium term once the COVID-19 effect subsides".

- ENDS -

For more information, visit www.TruScreen.com or contact:

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About TruScreen:

TruScreen's cervical cancer screening device offers the latest technology in cervical screening, providing real-time, accurate detection of pre-cancerous and cancerous cervical cells to help improve the health and well-being of women around the world.

TruScreen's real-time cervical cancer technology utilises a digital wand which is placed on the surface of the cervix to measure electrical and optical signals from the surrounding tissues. A sophisticated proprietary algorithm framework is utilised to detect pre-cancerous change, or cervical intra-epithelial neoplasia (CIN), by optical and electrical measurement of cervical tissue.

TruScreen offers an alternative approach to cervical screening, resolving many of the ongoing issues with conventional Pap tests, including failed samples, poor patient follow-up, patient discomfort and the need for supporting laboratory infrastructure. As such, TruScreen's target market is low- and middle-income countries where no large-scale cervical cancer screening programs and infrastructure are in place, such as China, Mexico, Africa, Russia, and India. TruScreen's cervical cancer screening device is CE-marked and certified for use throughout Europe and NMPA (previously CFDA) approved for sale in China. The global market potential for TruScreen is significant.