6 November 2023

NZX/ASX Announcement

TruScreen Unaudited Interim Results for the Half Year Ended 30 September 2023

Highlights for Half Year ended 30 September 2023

- **Product sales up 33% on same period prior year**
- **Strong performance from major market China**
- **Opening of new market in Saudi Arabia and good progress in Zimbabwe and other markets indicate a strong H2 FY 2024.**

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 2023 (1H FY24), along with the following operational update. TruScreen reports according to the New Zealand financial year, which runs from 1 April to 31 March.

Revenue from sale of goods increased by 33% over the same period prior year to $0.98 million. The China business is growing strongly and will be well supported by Zimbabwe, Saudi Arabia, Vietnam and Mexico in H2 2024. The Company reported an operating loss of $1.35 million (1H FY22: $1.22 million). The increase in operating loss was attributed to lower margin on device sales into China, to accelerate SUS pull through, and compliance costs associated with new regulatory reporting requirements in China and Europe.

SUS unit sales were up 28% over the previous year and device sales were 100% 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 $1.4 million (1H FY23: $1.2 million). The reduced cash flow is attributable to a lower Australian research and development tax offset receipt in the current half year.

As at 30 September 2023, the Company had cash and cash equivalents of $0.8 million.

Half-Year Commentary

TruScreen has maintained its revenue base despite disruptive and challenging market conditions.

Market developments

China

China's operations, through its distributor Beijing Siweixiangtai Tech Co. Ltd (SWXT), is experiencing rapid growth building on the recent recognition of the technology in a China Blue Paper "Cervical Cancer Three Stage Standardized Prevent and Treatment" published on 28 April 2023. In China, Blue Papers are promulgated to act as the definitive position on leading edge developments in all industries and are recognised as an endorsement by the leaders in the relevant field.

In addition, the CSCCP (Chinese Society of Colposcopy and Cervical Pathology) China Cervical Cancer Screening Management Guideline was the first national medical guideline in the world to recommend TruScreen as a new method for cervical cancer screening.

TruScreen has more than 100 devices installed in hospitals and clinics in 22 provinces in China. In addition, a growing pipeline includes, 14 hospital tenders won and awaiting installation, 26 hospitals which have approved TruScreen and are awaiting tender and 74 Hospitals where TruScreen has obtained OBGYN department acceptance, awaiting hospital approval.

Zimbabwe

TruScreen have just been awarded a further order of SUS (Single Use Sensor) with gross sales value NZ$300,000 to be delivered in Q3 FY 2024. The Ministry of Health's collaboration with the National Aids Council screening program in Masvingo Province has already screened over 14,000 women, and is a precursor to a national roll out.

Middle East

The largest private health services provider in the middle east, Dr. Sulaiman Al-Habib Medical Group (DSAMG) in Saudi Arabia, completed its first clinical evaluation in the Middle East, of 507 women, during the period. The analysis of the results showed that TruScreen's sensitivity was 83.3% and specificity was 95%, compared to 83.3% and 98% for the placebo Liquid Based Cytology (LBC). This demonstrates TruScreen's efficacy while providing real time results and resolving many of the issues faced with potential patient follow-up when using LBC. The clinical evaluation manuscript has been submitted for publication in the European Journal of Gynaecology.

The commencement of commercial operations at the DSAMG is an important reference for neighbouring markets in the middle east.

Vietnam

The Ministry of Health has approved 2 key hospitals with a further 4 hospitals well advance in the approval process. A recent visit by TruScreen CEO to Vietnam confirmed Vietnam as a key market for the Company which is expected to contribute to further growth in H2 FY 2024.

Other markets

During the period, TruScreen was listed on the Innovation Register, by the Polish Ministry of Health. This accreditation increases awareness among healthcare clinicians. There is an 'at risk' population of 17.1 million and high cervical cancer rates (3,515 cases and 1,858 deaths annually) from lack of national screening for cervical cancer.

Our Mexican distributor, Sunbird Medical has applied for access to the public hospital system to Cofepris, the national regulator. A decision is expected in FY2024, and if successful we expect TruScreen to be available to public hospitals and clinics.

Regulatory Compliance

The investment and transition of our regulatory processes to comply with the new Medical Device Regulation (MDR) is well advanced, for compliance by May 2024. Our China NMPA variation application was also advanced during the half year. The variation seeks approval for the latest Device software updates and recertification to the updated NMPA standards, and will further strengthen TruScreen's position in the Chinese market.

Outlook

The results for the half year provide optimism for our commercial successes in China and other markets, while investing $332,000 (2022: $410,000) in non-recurring costs, in complying with the new MDR global processes and seeking approval from China's NMPA for our device software updates. These costs will cease by end FY2024. At the August 2023 Annual General we indicated to shareholders that further growth funding is required to maintain the commercialisation momentum that we have generated over the past year.

Ends

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

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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 140000* examinations have been performed with 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.*

truscreen
a world without cervical cancer

Glossary:

Pap smear (the Papanicolaou smear) test involves gathering a sample of cells from the cervix, with a special brush. The sample is placed on a glass slide or in a bottle containing a solution to preserve the cells. Then it is sent to a laboratory for a pathologist to examine under a microscope. https://www.cancer.net/navigating-cancer-care/diagnosing-cancer/tests-and-procedures/pap-test

LBC (the liquid-based cytology) test, transfers a thin layer of cells, collected with a brush from the cervix, onto a slide after removing blood or mucus from the sample. The sample is preserved so other tests can be done at the same time, such as the human papillomavirus (HPV) test https://www.cancer.net/cancer-types/cervical-cancer/diagnosis

HPV (human papilloma virus) test is done on a sample of cells removed from the cervix, the same sample used for the Pap test or LBC. This sample is tested for the strains of HPV most commonly linked to cervical cancer. HPV testing may be done by itself or combined with a Pap test and/or LBC. This test may also be done on a sample of cells which a person can collect on their own. https://www.cancer.net/cancer-types/cervical-cancer/screening-and-prevention

Sensitivity* and *specificity mathematically describe the accuracy of a test which reports the presence or absence of a condition. If individuals who have the condition are considered "positive" and those who don't are considered "negative", then sensitivity is a measure of how well a test can identify true positives and specificity is a measure of how well a test can identify true negatives:

- **Sensitivity** (true positive rate) is the probability of a positive test result, conditioned on the individual truly being positive.
- **Specificity** (true negative rate) is the probability of a negative test result, conditioned on the individual truly being negative (Sensitivity and specificity – Wikipedia).

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

New Zealand: National Cervical Screening Programme | National Screening Unit (nsu.govt.nz)

Australia: Cervical cancer | Causes, Symptoms & Treatments | Cancer Council