



truscreen
a world without
cervical cancer

NZX/ASX Announcement

30 May 2023

TruScreen FY23 Preliminary Results

(all numbers in New Zealand Dollars)

Highlights

- Despite COVID interruptions in China and Vietnam, product revenues were in line with prior year, with 7% growth in H2 YOY
- Device sales up 88% YOY with 49 units spread across China, Vietnam, Mexico, Russia. Device installations increase by 15% YOY to 217
- Major breakthroughs in China with recommendations in joint peak organisations¹ Blue Paper and CSCCP Guideline
- Outstanding clinical results from Saudi Arabia clinical trial

Cervical cancer technology company **Truscreen Group Limited (ASX/NZX: TRU)** (the Company) has released its preliminary unaudited financial results for the year ended 31 March 2023.

Financial Results for the year ended 31 March 2023

Truscreen generated product sales in line with the prior year at \$1.7m (2022: \$1.7m).

As markets recovered post COVID TruScreen saw renewed demand for its TruScreen Cervical Cancer Screening Device from China, Vietnam, Mexico and Russia. The extended lockdown in China resulted in reduced number of tests in that market, impacting on overall SUS unit sales which declined by approximately 9%.

Other income decreased by 44% to \$0.54m (2022: \$0.97m) given a decrease in the research and development tax offset, and a 23% fall attributable to the removal of Australian government COVID assistance.

Total overhead expenses, excluding depreciation, amortisation and impairment declined to \$3.3m (2022: \$3.9m), attributable to a reduction in research and development given that the product is now more mature and robust.

The Company incurred an operating loss, before depreciation, amortisation and impairment, of \$2.3m (2022: loss \$2.5m), a 6% improvement on the prior year. Total loss for the year was \$2.4m (2022: \$7.9m), with the previous year including a non-cash provision for depreciation and impairment of the remaining carrying value of non-current assets in that year in the amount of \$5.4m.

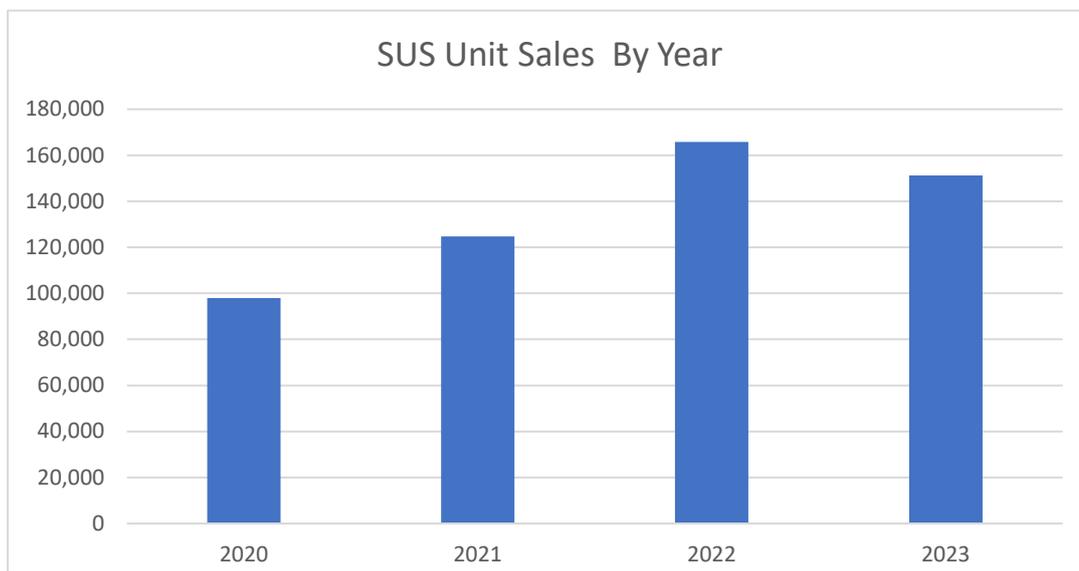
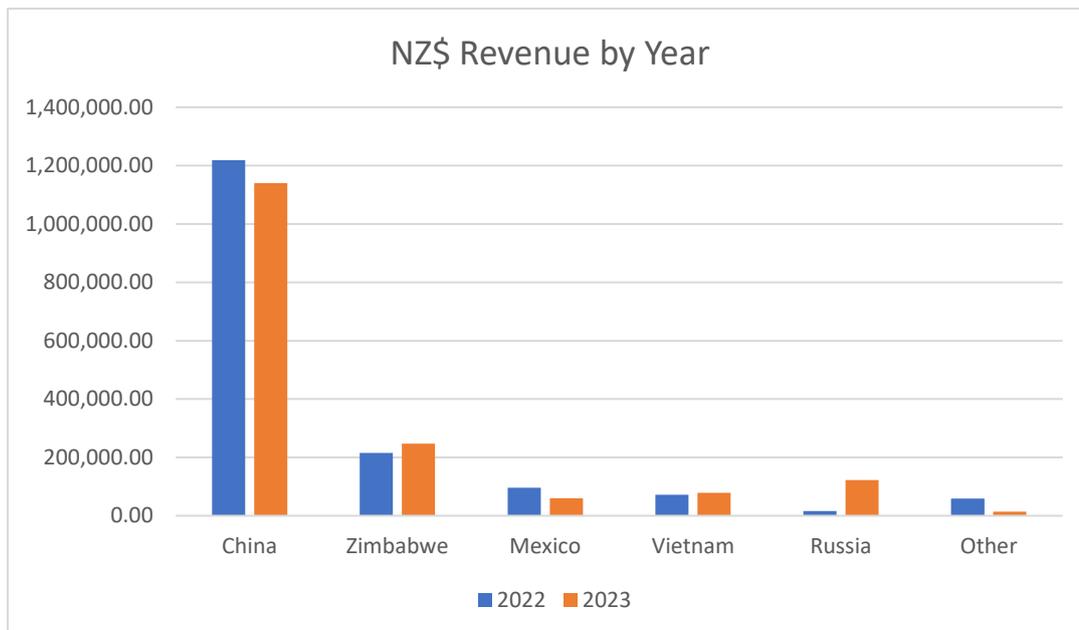
While the global certainties have reduced your Board has determined that given ongoing the level of uncertainty that exists in markets in which it distributes its product, namely Russia and Eastern Europe, that the carrying value of non-current assets, including those acquired this year, remain fully impaired.

¹ Chinese Association of Gynaecologists Oncologists (COGA), Cervical Cancer Prevention and Control Research Committee of China, Women and Children's Health Research Institute, Cancer Prevention and Control Professional Committee of China Preventive Healthcare Association, National Healthcare Industry Entity Management Association, and the Genital Health Division of China Population Culture Promotion Association.

The provision for impairment, will be reviewed as uncertainties recede at future balance dates and reversed where applicable. The provision is non-cash and has no impact on the operations of the Company.

Net operating cash outflow for the year was lower at \$2.2m (2022: \$2.5m) reflecting higher receipts from customers and lower costs.

As at 31 March 2023, Truscreen had cash and cash equivalents of \$2.2m (2022: \$2.8m).



Operational Key Performance and Update

Highlights of the 2023 financial year.

- ✓ TruScreen China business to be significantly bolstered with recognition in the China Blue Paper and endorsement from Chinese Society for Colposcopy and Cervical Pathology (CSCCP)
- ✓ China ramps up for Health Check centres
- ✓ Zimbabwe government continues roll out of the TruScreen program
- ✓ Outstanding clinical evaluation results from Saudi Arabia
- ✓ Russia expands operations into Kazakhstan
- ✓ Vietnam demonstrating a positive trajectory with further hospital approvals
- ✓ Mexico opens cervical cancer screening centre
- ✓ TruScreen hosts first Global Medical Symposium and readies for Medical Device Regulation

China Recognition in China Blue Paper and Endorsement from CSCCP

Subsequent to year end TruScreen was recognised in a China Blue Paper “Cervical Cancer Three Stage Standardized Prevent and Treatment”. Blue Papers are promulgated to act as the definitive position on leading edge developments in all industries in China and are recognised as an endorsement by the experts and leaders in the relevant field.

The publication presents a consensus on the most successful and innovative technologies and methods to eradicate cervical cancer in China, in line with the World Health Organisation (WHO) strategy. The paper was the result of four years of research and collaboration by many experts in gynaecology, including a number of leaders (1) in the field who attended the publication launch.

The Blue Paper specifically highlights TruScreen in a section titled “Artificial Intelligence Technology For Cervical Cancer Screening”, describing it’s origin, substantial clinical trials, and the benefits of using TruScreen as a standalone primary cervical cancer screening method, which has demonstrated superior sensitivity and specificity results, in comparison to screening of LBC and HPV.

Separately, the TruScreen technology has also been endorsed in CSCCP’s (Chinese Society for Colposcopy and Cervical Pathology) China Cervical Cancer Screening Management Guideline, one of the most important specialist medical clinical guidelines governing management of cervical cancer.

CSCCP’s decision to include TruScreen technology in its new Guideline emphasises the role of new technology in a booming Chinese healthcare sector. The decision is based on the body of evidence supporting TruScreen clinical use world-wide and after extensive consultations with healthcare practitioners and decision makers.



CSCCP is a member of IFCPC (The International Federation of Cervical Pathology and Colposcopy) which is dedicated to reducing the burden of cervical cancer worldwide. The guideline issued by CSCCP is a leading clinical standard for doctors and other healthcare providers as well as government bodies.

China, after the COVID lockdown years, is now seeing a strong pipeline of significant growth opportunities. This includes 7 hospital tenders won with 13 installations pending, 23 hospitals where TruScreen has been approved and waiting for tender outcomes, and 78 hospitals where Obstetric and Gynecologic Department acceptance have been received and are waiting for the next stage of hospital approval.

China distributor, Beijing Siweixiangtai Tech Co. Ltd (SWXT), placed an order for 40 TruScreen cervical cancer screening devices for installation into China's growing public Health Check Sector late in the financial year, with delivery of the devices now having been completed in April and May 2023. This followed the first installation having been achieved at The People's Liberation Army General Hospital, one of the leading health check centers in the country, in February 2023.

Zimbabwe government continues roll out of the TruScreen program

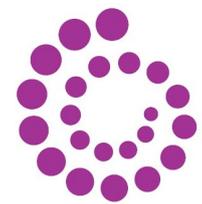
TruScreen successfully secured a tender for the supply of a further 10,800 SUS (Single Use Sensor) which were shipped in March 2023, with the program due to recommence in May 2023.

TruScreen's screening program in Masvingo Province is a collaborative effort between the Ministry of Health and Child Care, National AIDS Council, and local health partners. The program aims to provide screening services to women in remote and underserved communities, where access to healthcare is often limited. The screening program, which began in 2022, has already screened over 10,000 women in Masvingo Province.

Outstanding clinical evaluation results from Saudi Arabia

The leading private medical services provider in Saudi Arabia, Dr. Sulaiman Al-Habib Medical Group (SHMG), completed the analysis of results from its cervical screening clinical evaluation of TruScreen Ultra and Liquid Based Cytology (LBC) during the year.

A cohort of 507 women were examined with TruScreen and LBC across multiple medical centres of SHMG. The preliminary results indicated TruScreen's sensitivity at 83.3% (LBC: 66%) and specificity at 95% (LBC 98%).



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Russia expands operations into Kazakhstan

TruScreen's Russia distributor JSC IMSystems extended its presence to Kazakhstan during the year, which will now be the base of expansion by IMSystems to other Central Asian countries. Kazakhstan has a population of 18 million spread over an area of 2.7 million square kilometres (the 9th largest country in the world). Central Asian doctors and healthcare professionals are mostly trained in Russian universities and hospitals.

On the strength of our Russian distributors expansion into Kazakhstan and to accelerate screening programmes in Russia and neighbouring Central Asian countries, JSC IMSystems received 11 TruScreen cervical cancer screening devices and 6,120 SUS during the year.

Vietnam demonstrating a positive trajectory with further hospital approvals

TruScreen anticipates that Vietnam will become a market of major focus with significant potential.

A TruScreen seminar hosted by Tu Du Hospital, the most influential gynaecological hospital in South Vietnam, was held during the year receiving substantial interest, being attended by over 100 doctors.

TruScreen has achieved MOH approval for a number of the most influential hospitals in Vietnam and is expecting to receive local accreditation shortly, thereby removing the requirement for individual hospitals to seek prior MOH approval, which will shorten the sales cycle.

Mexico opens cervical cancer screening centre

TruScreen established a cervical cancer screening centre in a new clinic in Ciudad de Mexico (Mexico City) operated by leading healthcare provider Mexpharm Medical Clinical during the year.

The centre run by Mexpharm Medical Clinical, a leader in healthcare care in Mexico, showcases TruScreen's medical technology, acts as a training centre, and provides screening services to the local population. Mexico has a large addressable market with a population of more than 65 million being female, of whom around half fall within the prime cervical cancer screening age of 25-64 years.

TruScreen hosts Global Medical Symposium and readies for new global Medical Device Regulation

TruScreen completed its first global virtual medical symposium to key opinion leaders from 7 countries, on cervical cancer screening during the year.

The medical symposium was chaired by Professor Neville Hacker, one of the world leaders in gynaecology-oncology, 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.

TruScreen has expended significant effort during the year in preparing for the Medical Device Regulation (MDR). MDR is a new regulatory framework that replaced the Medical Device Directive (MDD) for medical devices being made and/or sold in the European Union. The MDR aims to strengthen the safety and efficacy of medical devices, improve patient safety, and enhance transparency and accountability in the medical device industry. The MDR introduces more stringent requirements for manufacturers, including increased clinical evidence requirements, stricter pre-market controls and post-market surveillance requirements, and new rules for economic operators, such as importers and distributors.

TruScreen has also expended significant effort in finalising its Chinese regulatory (NMPA) approval. In addition to providing approval for the latest TruScreen device updates, this variation will also include recertification to the updated NMPA standards.

Corporate

Appointment of CEO

The Company appointed Dr. Beata Edling as CEO in October 2022. Dr Edling 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 holds a MD from the Medical University, Gdansk, Poland, and has completed part 1 of her Fellowship with Royal College of Surgeons, Australia. Dr Edling completed her PhD at the University of New South Wales, Australia, has a MBA from Sydney's Australian Graduate School of Management, is multi-lingual and speaks several European languages

Capital Raising

The Company raised approximately \$1.6m, before costs in March 2023, through a placement of \$600,000 and \$1 million through 1 for 5 pro rata renounceable rights issue. In total the Company issued 53,775,755 new shares at \$0.03 each.

This announcement approved for release by the Board.



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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 tool 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, Zimbabwe, 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.

In FY22, over 170,000* TruScreen examinations were performed 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/.

**Based on Single Use Sensor sales.*



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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](#)