



truscreen
a world without
cervical cancer

NZX/ASX Announcement

30 May 2024

TruScreen FY24 Preliminary Results

(all numbers in New Zealand Dollars)

Highlights

- **SUS unit sales up 25% on prior year and device sales to distributors in line with prior year**
- **Major breakthrough in China with two peak organisations¹ including TruScreen in their cervical cancer screening guidelines - China Obstetrics and Gynecology Association (COGA) Blue Paper and endorsement from the Chinese Society for Colposcopy and Cervical Pathology (CSCCP)**
- **Commercial operations commenced in Saudi Arabia and further progress in Zimbabwe**
- **In Vietnam TruScreen achieved inclusion on the Vietnamese Ministry Of Health (MOH) approved Technical List**
- **In Mexico the national regulator, Cofepris approved TruScreen access to the public health sector**
- **Developing new market opportunities in Uzbekistan, Indonesia, and Africa**
- **Successful capital raise and appointment of new Chief Executive Officer**
- **Improved Operations metrics.**
 - **Sales up by 27%, led by SUS consumable sales increase of 25%.**
 - **Operating loss reduced by 15%**
 - **Cash outflow reduced by 9%**

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 2024.

Financial Results for the year ended 31 March 2024

Truscreen generated product sales 27% higher than the prior year at \$2.1m (2023: \$1.7m).

The sales result was underpinned by a strong result from China which grew by 45% over the prior year following the recommendations from two key peak organisations - in the COGA Blue Paper and CSCCP Guideline. Zimbabwe revenue was 34% up on the prior year with further potential when the National Aids Council screening program is extended outside of the Masvingo province.

Good progress was made in Saudi Arabia, Vietnam and Mexico with stronger sales expected in FY2025.

Gross margin improved YOY from 27.6% to 32.7%. Other income was largely in line with the prior year at \$0.5m (2023: \$0.54m) attributable to the research and development tax offset.

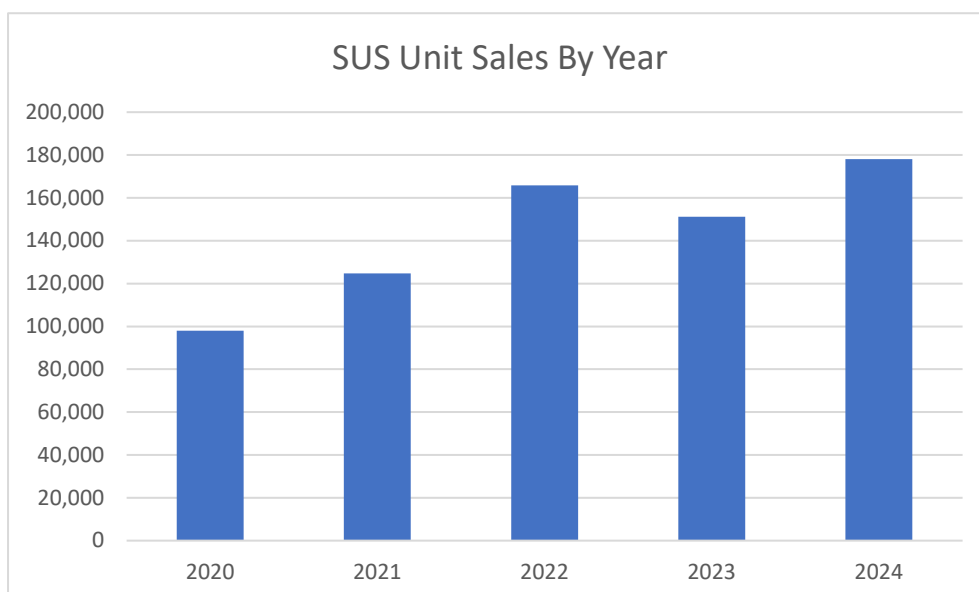
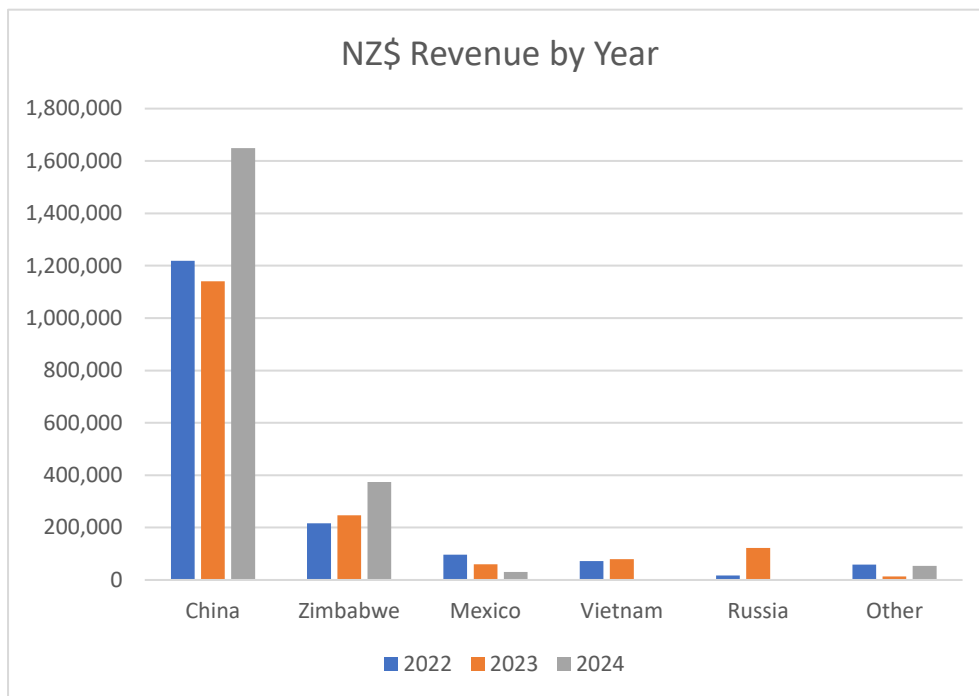
Total overhead expenses remained unchanged YOY at \$3.3m, which includes increased costs due to inflation and \$0.2m incurred in preparation for transition from the current EC regulatory code – the MDD, to the new MDR code.

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 Company incurred an operating loss for the year of \$2.1m (2023: loss \$2.4m), a 15% improvement on the prior year.

Net operating cash outflow for the year was lower at \$2.0m (2023: \$2.2m) reflecting improved revenue and margin.

As at 31 March 2024, Truscreen had cash and cash equivalents of \$2.7m (2023: \$2.2m).





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Operational Key Performance and Update

Highlights of the 2024 financial year.

- **SUS unit sales up 25% on prior year and device sales to distributors in line with prior year**
- **Major breakthroughs in China with two peak organisations² including TruScreen in their cervical cancer screening guidelines - China Obstetrics and Gynecology Association (COGA) Blue Paper and endorsement from the Chinese Society for Colposcopy and Cervical Pathology (CSCCP)**
- **Commercial operations commenced in Saudi Arabia and further progress in Zimbabwe**
- **In Vietnam TruScreen achieved inclusion on the Vietnamese Ministry Of Health (MOH) approved Technical List**
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- **Developing new market opportunities in Uzbekistan, Indonesia, and Africa**
- **Successful capital raise and appointment of new Chief Executive Officer**

China Recognition in China Blue Paper and Endorsement from CSCCP

During the year TruScreen was recognised in a COGA Blue Paper “Cervical Cancer Three Stage Standardized Prevent and Treatment”. Blue Papers 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 paper was the result of four years of research and collaboration by many experts in gynaecology, including a number of leaders³ in the field and 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 Blue Paper specifically highlights TruScreen in a section titled “Artificial Intelligence Technology For Cervical Cancer Screening”, describing its 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 in comparison to screening of LBC and HPV.

Separately, the TruScreen technology has also been endorsed in the 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.

² 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.

³ the past Chairman of The Chinese Obstetricians and Gynaecologists Association (COGA) Professor Lang Jinhe, the newly appointed COGA Chairman Professor Di Wen, Chinese Society for Colposcopy and Cervical Pathology (CSCCP) Chairwomen Professor Wei Lihui, the head of Women and Children’s Health Division of National Health Commission Xu Xiaochao, Secretary General of China Preventive Healthcare Association Zhang Lingli.



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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.

As a result of these recommendations our China business grew by 45% YOY. This growth is evidenced by 7 hospital tenders won by distributor SWXT 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.

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 2024. TruScreen is expecting that the program will expand beyond the Masvingo province in 2024/2025.

TruScreen's screening program in Masvingo Province began in 2022 and has already screened over 14,000 women in 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.

Commercial operations commence in Saudi Arabia

The Dr Sulaiman Al-Habib Medical Group installed four TruScreen devices for commercial use for the screening of cervical cancer in Saudi Arabia during the year.

Dr Sulaiman Al-Habib Medical Group (DSAMG) is the largest private hospital network in the Middle East. The adoption of TruScreen's screening technology by DSAMG private hospitals is an important reference sites for further market access in neighbouring Middle Eastern nations.

TruScreen included on the Vietnamese Ministry of Health Approved Technical List

During the year TruScreen achieved inclusion on the Vietnamese Ministry Of Health (MOH) approved Technical List. This is a significant milestone enabling TruScreen to be used nationally from top level hospitals to community health centres.

The listing, combined with recent changes to medical device procurement regulations in Vietnam reduces the need for individual hospitals to seek prior central Ministry of Health approval for purchase. These changes dramatically shorten the medical device procurement process in Vietnam. The MOH listing was based on extensive clinical evidence and positive feedback from local users at several levels of the public healthcare providers, including Key Opinion Leaders from the leading gynaecological hospital, Hanoi Obstetrics and Gynaecology Hospital.

Approval in Mexico for TruScreen to enter public health system

The national regulator of Mexico, Cofepris approved TruScreen access to the public health sector. This allows TruScreen to expand its cervical cancer screening beyond private health clinics to the wider public health sector. A 2020 census identified that only 2.3% of the population have private healthcare while 70.9% of the population accessed the public health system.

Mexico has an addressable market of 65 million women, and Cervical cancer is the second most prevalent cancer amongst women in Mexico. HPVcentre.net estimates that 9,400 women are diagnosed annually with cervical cancer with a mortality rate of 46% - 4,300 deaths.

Evaluation of TruScreen underway in Uzbekistan, Poland and North Macedonia

The Ministry of Health in Uzbekistan is evaluating TruScreen as a technology partner to deliver a component of the Uzbekistan National Screening Solution for Cervical Cancer. This program is a first for Uzbekistan and being selected would be a transformative opportunity for TruScreen, not just in Uzbekistan but also to serve as a reference site for other neighbouring Central Asian countries.

Poland continues to face significant challenges with cervical cancer. TruScreen is working with the Mother and Child Institute and has identified both private and public hospitals targeted to be the first to change from Liquid Based Cytology to TruScreen. TruScreen is shortly entering the hospital validation phase with commercial sales to follow the successful completion of this evaluation.

In North Macedonia TruScreen is currently undergoing evaluation by a local distributor who operates a Medical Clinic. When successful, TruScreen will replace Pap Smear in the clinic. This clinic will serve as a base for demonstration and training for future customers in south eastern Europe. This partnership marks a significant milestone as it would be TruScreen's first partner who is both a distributor and a key reference centre.

In addition, TruScreen, with the support of the local Austrade office, is making strides in Indonesia with partner Mursmedic. Mursmedic have commenced the product registration process for TruScreen in Indonesia. A key reference site in Jakarta has been identified and installation is to occur as soon as the product registration is completed.

TruScreen is also in the process of registration in Kenya through our logistics partner, Phillips Pharma Group. TruScreen will partner with Phillips Pharma first in Kenya, and then to expand to other countries within their footprint, including Nigeria, Uganda, Ghana and Tanzania.

Corporate

TruScreen has again expended significant effort during the year in preparing for the Medical Device Regulation (MDR), a new regulatory framework that replaced the Medical Device Directive (MDD) for medical devices being made and/or sold in the European Union, and has also expended significant effort in finalising its Chinese regulatory (NMPA) approval.

Appointment of CEO

The Company appointed Martin Dillon as CEO in March 2024. Mr Dillon, previously successfully established the TruScreen global distribution network, launched the TruScreen Ultra2 device, is well versed in the technology and is well known to distributors. Mr Dillon also managed the listing of TruScreen on the NZX in 2014.

Capital Raising

The Company raised approximately \$2.6m, before costs in March 2024, through a placement of \$1.2 million and \$1.4 million through 1 for 3 pro rata renounceable rights issue. In total the Company issued 132,565,777 new shares at \$0.02 each.

This announcement approved for release by the Board.

-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 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](#)