



truscreen
a world without
cervical cancer

29 November 2024

NZX/ASX Announcement

TruScreen Unaudited Interim Results for the Half Year Ended 30 September 2024

Highlights for TruScreen in FY25 to date:

- **First half year product sales up 5% on same period over prior year**
- **China continues to perform strongly**
- **Market entry to Indonesia underway with completion of registration**
- **Major validation screening program for Tashkent, Uzbekistan subject to completion of product registration**
- **Increasing publications of trial results by global professional journals**
- **Post 30 September 2024, announcement of MOU to launch 5-year cervical cancer screening program in Ho Chi Minh City (See NZX/ASX announcement 25 November 2024)**

Cervical cancer screening technology company, TruScreen Group Limited (NZX/ASX: TRU) ('TruScreen' or 'the Company'), is pleased to provide its unaudited interim financial results for the six months to 30 September 2024 (1H FY25), along with the following Review of Operations. TruScreen reports according to the New Zealand financial year, which runs from 1 April to 31 March.

After 3 years of COVID19 interruptions from 2020 to 2022, the Company resumed its commercialisation of its TruScreen AI-enabled, non-invasive cervical cancer screening technology. The low- and middle-income markets that the Company are in, have also resumed their public health programs with a focus on women's health. World Health Organisation (WHO) is pushing ahead with its global strategy (approved by its member nations) of eliminating cervical cancer by the end of the century and achieving milestone targets of **70% coverage of screening and 90% treatment of precancerous lesions** by the end of 2030. This is TruScreen's target market.

Sales revenue of products increased by 5% over the prior period year on year to \$1.03 million. The Company reported a reduced operating loss of \$1.13 million (1H FY24: \$1.35 million).

Ongoing strong results from China offset timing delays of orders in other markets from product registrations.

Net operating cash outflow was reduced to \$0.9 million (1H FY24: \$1.4 million).

As at 30 September 2024, the Company had cash and cash equivalents of \$1.7 million.

Half-Year Commentary

TruScreen has improved its sales over the corresponding period in FY 2024 and expects revenue growth to accelerate as market entry activities are converted to sales.

Market Development and Outlook

Global recognition by national Governments and NGOs

TruScreen is now included in screening guidelines published by WHO, UNITAID (including the Clinton Health Access Initiative and Australia's Daffodil Foundation), The Chinese Obstetricians and Gynaecologists Association (COGA), the China Society for Colposcopy and Cervical Pathology (CSCCP), Cofepris public health approval in Mexico, the Vietnam Hospital national Technical List and the Russian Cervical Cancer Screening Guideline.

As well as including TruScreen in its cervical cancer screening guideline WHO invited TruScreen to present at its November 2024 global meeting in Edinburgh to further the use of Artificial Intelligence (AI) tools for visualisation of the cervix for cervical screening and treatment.

In Vietnam the Ho Chi Minh City Public Health Association has signed a tripartite 5-year memorandum of understanding (MOU) with TruScreen to screen 260,000 women. This is the largest public screening program outside of China for which TruScreen has been selected as the exclusive screening technology.

China

Consumable sales (SUS) in China exceeded 90,000 units in the first half of FY2025, and these sales continue to underpin TruScreen's revenue. Following the submission of documents for the NMPA's registration variation, devices in China will be upgraded with new software, improving the user experience for doctors and clinicians and leading to an increase in hospitals installing TruScreen with increases in hospitals usage of consumable SUS (Single Use Sensors).

Our distributor in China, Beijing Siweixiangtai Tech Ltd. Co (SWXT) is focusing its sales activities on the existing key province of Beijing and four other key expansion markets – Jiangsu, Guangdong, Shanghai and Zhejiang.

This focus has resulted in Jiangsu province, after the initial installation of TruScreen in the Affiliated hospital of Nantong University, having eight private hospitals confirming the adoption of the TruScreen technology, with an estimated monthly SUS usage of 300-500 units per device per month (> than twice the current average SUS usage per device per month).

Vietnam

TruScreen, with its distributor Gorton Health Services (GHS) and the Ho Chi Minh City Public Health Association (HPHA) have signed an MOU to launch a public cervical cancer screening program in Ho Chi Minh City. The program targets cervical cancer screening of 260,000 women over the next five years. This program is in addition to TruScreen's planned installations in major District Hospitals, targeted by GHS following the inclusion of TruScreen in the Vietnam Ministry of Health national Technical List and the ensuing simplification of the public hospital procurement process.

Purchases of TruScreen in these hospitals were delayed as the hospitals waited for the Ministry of Health new approval guidelines following the Technical List inclusion. This has now been finalised and four major public hospitals in Vietnam have obtained procurement approval and are installing

TruScreen for their cervical cancer screening programs. Two key hospitals are expected to follow shortly.

To support our activities in Vietnam Professor Michael Campion, chair of TruScreen's Medical Advisory Committee will be conducting a training seminar in Tu Du hospital in early January 2025. Key opinion leaders and screening clinicians will be updated on the use of TruScreen for the primary screening of women for cervical cancer.

Mrs Nguyen Thi Tuyet Hanh, Director Gorton Health Services, Professor Le Truong Giang, Chair, Ho Chi Minh Public Health Association, Martin Dillon, CEO TruScreen, signing MOU for Vietnam Screening program

Mexico

Sunbird S.A de C.V, TruScreen's distributor in Mexico, is focusing on private and public health sector sales in Mexico City.

Their key target is to have TruScreen selected as the technology for health checkup clinics in Mexico City. The program has a potential for up to 20 devices to be installed with strong SUS pull through over a two-year period.

In addition, Sunbird is leveraging the government's focus on AI in medicine to highlight TruScreen's AI capabilities. Sunbird has commenced a series of cervical cancer screening webinars to increase sales to gynaecologists in the private health sector in Mexico.

Uzbekistan

The National Pharmaceutical Safety Committee of Uzbekistan has submitted documents for the registration of TruScreen. On completion of the registration, the Ministry of Health and the President's Office will begin validation of TruScreen for a major public screening program.

The validation is expected to commence in Q1 CY2025 in Tashkent and is a precursor for a larger national program, starting with fourteen primary healthcare clinics in Tashkent and rolling out to provinces in Uzbekistan.

Indonesia

Following product registration in Indonesia TruScreen has advanced discussion with a health clinic group in Java and a major medical products distributor to commence commercialisation of TruScreen in the world's largest Islamic nation. Training with key medical heads of the clinics is scheduled for December 2024, with commercial sales expected to begin in Q1 CY2025.

Zimbabwe

The Ministry of Health has requested a periodic re-validation of TruScreen for January 2025. Once completed, tenders will be called for the next round of TruScreen enabled cervical cancer screening in Harare and regional Zimbabwe.

Thailand, Malaysia and Singapore

Intega Pte Ltd- a Singapore based medical technology distributor, was appointed TruScreen's distributor for Singapore, Malaysia, and Thailand. Meetings were held with key hospitals in Singapore to scope out the steps required for TruScreen to access the public hospital system in Singapore.

This is a first step in TruScreen's expansion in the ASEAN region and completes a continuous vertical East Asian market, from Indonesia in the south, north through ASEAN (Association of South-East Asian Nations) region, then Vietnam and China in the north. ASEAN is the fastest growing economic regional bloc in Asia. Note that Vietnam is a member of ASEAN and the territory is not included with Intega.

Jordan, Palestine and Rwanda

TruScreen was featured in expos and symposia in Jordan, Palestine and Rwanda by its distributor, Sadaf Medical. Devices and SUS were ordered for installation in Rwanda and Jordan in Q1 CY2025.

Poland

In mid-December 2024 TruScreen will submit to the Institute of Mother and Child hospitals in Warsaw and Lodz a plan and protocol for the evaluation of TruScreen for use in the Polish public health system. The 3-month evaluation is planned for 200 women in public hospitals.

Recent global publications

During the first 6 months of FY 2025, recognition of TruScreen in several international publications have strengthened our global position in the cervical cancer screening world.

- In August (See NZX/ASX announcement 5 August 2024) TruScreen was shown to outperform Pap in a Saudi Arabian study involving 507 women. In the study, titled "Beyond Tradition: Investigating TruScreen's Performance Versus Pap Smear in Cervical Cancer Detection", TruScreen was shown to have a sensitivity 83.3% (Pap 66.7%) and a specificity 95% (Pap 98.2%). The authors concluded that TruScreen "represents a reliable, practical screening tool for cervical neoplasms" and that their results "provide an evidence-based approach for policymakers when selecting the optimal cervical cancer screening strategy in countries without an established national screening program."
- In November (See NZX/ASX announcement 11 November 2024) trial results were reinforced by a study titled "Evaluation of a real-time optoelectronic method for the detection of cervical intraepithelial neoplasia and cervical cancer in patients with different transformation zone types" conducted by Dr Fengyi Xiao & Professor Long Sui from The Cervical Diseases Centre, Obstetrics and Gynaecology Hospital of Fudan University, Shanghai, China. Published in the leading research journal, Germany's Springer Nature, the authors concluded that TruScreen cervical cancer screening results were comparable and even better (for patients with type 3 TZ) than conventional LBC (Liquid based Cytology).

- This study also reinforces for our key China market the COGA (Chinese Obstetricians and Gynaecologists Association) large scale clinical trial of 15,661 patients conducted across 9 China Provinces over 3 years, that determined TruScreen to be a simple, effective and rapid real-time method to screen for cervical cancer.
- In October 2024 TruScreen was selected by UNITAID, an agency of the World Health Organisation (WHO) and included in its Technology Landscape Report to its member nations. (see NZX/ASX announcement 3 October 2024).
- TruScreen was also selected as one of six global companies, from a cohort of 580 companies, that will have an impact on global women's health. The evaluation was conducted by Austrian based StartUs Insights. (See NZX/ASX announcement 29 October 2024)

Regulatory compliance

TruScreen successfully completed a compliance audit of its CE Mark with the European Medical Device Directive and with International Standard ISO13485 during the half year, with the auditor, Germany's based TUV.

Looking Ahead

TruScreen is at the turning point of its commercialisation phase. Sales have been increasing as markets and medical key opinion leaders become more aware of the advantages that TruScreen brings to cervical cancer screening. Recent developments, with the increased recognition by WHO, NGO's, government guidelines, and the invitations to develop public screening programs in Ho Chi Minh City and Uzbekistan indicate that TruScreen technology is now at a point where adoption of our unique technology will accelerate, improving our financial performance and improving global women's health.

This announcement was approved for release by the Board.

-ENDS-

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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 23 countries. In 2021, TruScreen established a manufacturing facility in China for devices marketed and sold in China, with the "Made in China" registration.

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, by COGA (*Chinese Obstetricians and Gynaecologists Association*).

In financial year 2023 alone, over 140000¹ 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/.

¹Based on Single Use Sensor sales.

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](#)