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NZX/ASX Announcement

3 March 2025

TruScreen – Key Markets Update and Revenue Guidance

Highlights

- **Memorandum of Understanding signed with Hangzhou Dalton Bioscience to expand its HPV product offerings**
- **Launch of Ho Chi Minh City Public Health Association confirmed for 12 April 2025**
- **Indonesian distributor appointed and commercial sales expected to commence in April 2025**
- **Uzbekistan product registration due March 2025 which will enable the evaluation of TruScreen for a national screening program**
- **Revenue guidance for the financial year ended 31 March 2025**

TruScreen Group Limited (NZX/ASX:TRU) is pleased to provide an update of its key markets and target markets.

Memorandum of Understanding between TruScreen Group Ltd and Hangzhou Dalton Bioscience (DaltonBio)

TruScreen signed a non-binding MOU with DaltonBio, a leading China based manufacturer of high-performance HPV DNA tests and laboratory equipment for cervical cancer screening, for a strategic alliance to expand global commercial opportunities for a suite of DaltonBio's HPV related IVD (In Vitro Diagnostic) products to be marketed under the TruScreen brand.

Following due diligence TruScreen would be appointed a global distributor of DaltonBio HPV related IVD products (excluding U.S.A. and Canada). DaltonBio to explore opportunities to assist TruScreen's AI enabled real time cervical screening device within its distribution network, notably in its selected distributors in China and South America.

Global Markets

China

Number of Women of Screening Age: 476,599,793*

China is TruScreen's key market accounting for over 75% of global sales.

- **Key markets for Growth:** TruScreen's China distributor Beijing Siweixiangtai Tech Ltd. Co (SWXT) is targeting 6 key provinces for growth in 2025 - Guangxi, Jiangsu, Hunan, Zhejiang, Shanghai and Guangdong. These provinces have combined



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population of 496 million, and an addressable screening market of approximately 124 million women.

- **SUS Pull Through:** Consumable Single Use Sensor (SUS) pull through per month per device has peaked at 137 SUS per month per device, an increase of 50 % over 12 months.
- **Software Upgrade:** China's NMPA registration variations have been approved and software upgrade on Chinese devices has commenced. The upgrade will improve user experience for clinicians and extend the device's in-use service interval.
- **Private Sector Expansion:** SWXT targeting of the growing China private health sector with private clinic and Health Check Centre, saw approvals received in Jiangsu and Shenzhen.
- **Public Health Insurance:** In addition to having 11 provinces with approved pricing for TruScreen, Beijing has renewed public health insurance reimbursement for eligible patients. Shanghai has approved the final round of evaluation for public health insurance reimbursement. The administrative processes are yet to be formalised.

Vietnam

Number of Women of Screening Age: 35,887,201*

- **Ho Chi Minh City Screening Program to Launch on April 12:** As announced in November 2024, TruScreen signed a Memorandum of Understanding with the Ho Chi Minh City Public Health Association and Gorton Health Services (GHS, our Vietnam distributor) to **conduct a 5-year program to screen 260,000 women.** This will be launched on April 12, 2025.
- **Public Hospital Adoption:** Following a January presentation by Professor Michael Campion at Tu Duc Hospital in Ho Chi Minh City, 6 major Ho Chi Minh City hospitals have agreed to adopt and install TruScreen.

Mexico

Number of Women of Screening Age: 45,983,174*

- **Public Sector Focus:** Distributor Sunbird continues to engage with the newly elected government officials to introduce TruScreen to the public health sector.
- **Leveraging the government's focus on AI in medicine.** Leveraging this focus, Sunbird is in advanced discussions with IMSS, (the nation's largest public health insurer covering 38% of the population) for TruScreen inclusion in their planned cervical cancer screening program.



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- **Mobile checkup units in Mexico City:** This program has been delayed following a restructure of the national health administration system. Discussions are ongoing with Mexico City health officials.

Uzbekistan

Number of Women of Screening Age: 11,617,411*

- **National Screening Program:** TruScreen was advised that product registration by the National Pharmaceutical Safety Committee will be formalised in March. The approval is a prerequisite for a pilot screening program in Tashkent. TruScreen is dealing directly with senior Ministry of Health officials. The proposed cervical cancer screening program will see 14 primary healthcare clinics in Tashkent adopting the TruScreen technology. The next stage is to extend cervical screening programs to Uzbekistan nationally.

Indonesia

Number of Women of Screening Age: 95,961,293*

- **Distributor Appointed:** TruScreen appointed a new Indonesian medical products distributor PT Mawar Mitra Medika. Commercial sales are expected to commence in April 2025 in the world's largest Islamic nation, with a population spread over 14,000 islands. TruScreen offers an ideal solution to providing screening to a geographically dispersed and diverse population.
- **AI presentation by CEO to MOH officials and KOL's.** In December 2024, TruScreen presented to an AI Health webinar organised by Austrade and the Indonesian Ministry of Health. TruScreen was one of only two companies invited to present at this webinar, a recognition of our growing reputation as a leader in AI innovative health technology with a particular relevance to Low- and Middle-Income Countries (LMIC's).

Zimbabwe

Number of Women of Screening Age: 5,152,773

- **Ministry of Health Re-Validation:** Following changes of personnel in the Zimbabwe Ministry of Health the formal re-validation program for TruScreen was delayed to April 2025. Once the re-validation has commenced the tenders for national screening in metropolitan and regional Zimbabwe will resume.

Jordan, Palestine and Rwanda

Number of Women of Screening Age: approx. 8,849,008

- Our distributor in Jordan, Palestine and Rwanda, Sadaf Medical, recently featured TruScreen in seminars and trade shows in these countries. First commercial sales have commenced to Jordan and Rwanda.



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Revenue guidance for the financial year 31 March 2025

The planned screening programs for Zimbabwe and Vietnam have slipped from Q4 FY2025 to Q1/Q2 of FY2026. Delayed product registration for Indonesia and Uzbekistan delayed commercial activities in those markets. The timing of these revenues from the delayed commercial activities will be reported in Q1/Q2FY2026.

The Company expects revenue for the financial year 31 March 2025 to be circa \$1.7m. (2024 \$2.1m) The increasing SUS sales in the sales mix and rigorous costs management should see the Company reporting a small lower/improved loss to FY2024 loss of \$2m.

Looking Ahead

TruScreen CEO Martin Dillon commented *“The collaboration with Dalton Biosciences is a highly significant opportunity for TruScreen to augment our sales offering to all our current markets and to increase our distribution strength in China and South America. This will enable TruScreen to offer both primary screening and triage solutions to cervical cancer screening programs globally.*

Whilst programs in Uzbekistan and Zimbabwe have been delayed, their commencement in early FY2026, along with the HPHA program in Vietnam for 260,000 women over 5 years, sees TruScreen well placed for growth in FY2026.”

*All population figures are for women aged 15-64 years as detailed in the World Fact Book : <https://www.cia.gov/the-world-factbook/>

This announcement has been approved 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.



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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](#)