NZX/ASX Announcement

16 June 2025

Key Markets Update

- **On track - Uzbekistan regulatory approval for TruScreen enables commencement of validation as prelude to a planned major screening program**
- **On track - Zimbabwe validation to commence on 7 July and completed by 21 July, a precursor to recommencement of major public screening program**
- **On track - Ho Chi Minh City screening program to commence 28 July, with staff training completed and devices shipment underway**
- **On track - First commercial sales in India with purchase order from Renovate Biologicals**
- **Dovepress publishes Beijing study confirming TruScreen's superiority to other screening methods**

TruScreen Group Limited (NZX/ASX: TRU), ("TruScreen" or "the Company"), a global leader in AI-enabled cervical cancer screening, is pleased to provide an update of its key and target markets.

Uzbekistan regulatory approval received

TruScreen has received regulatory approval by the National Pharmaceutical Safety Committee in Uzbekistan. Product registration will enable commencement of a short validation program in Tashkent. This validation is a precursor to the planned public screening program starting with 14 women and children's healthcare clinics in Tashkent. The adoption of TruScreen's unique AI enabled technology is a transformative step for Uzbekistan, with the aim of extending from Tashkent to a national program.

Uzbekistan has over 11 million women of screening age* and is also a regional healthcare reference site for neighbouring Central Asian nations.

Zimbabwe validation to be completed 21 July

Since 2022, TruScreen has screened 14,000 women in the Masvingo Province, Zimbabwe, through a public screening program managed by the Zimbabwe National AIDS Council (NAC) and the Ministry of Health and Childcare. To recommence and expand the program to the capital Harare and other provinces, a re-validation program is being undertaken by the Ministry of Health. The validation, will commence on 7 July and completed by 21 July 2025.

With limited pathology services and no nationwide recall system for follow-up treatments, traditional screening methods such as pap tests are not suitable for Zimbabwe's population. TruScreen, which enables a 'see and treat' screening service, is ideally suited to fill the gap in Zimbabwe's women healthcare system.

Ho Chi Minh City screening program commencing 28 July

In April 2025, a 5-year program to screen 260,000 women for cervical cancer using TruScreen in Ho Chi Minh City, Vietnam, was launched to assist the Government of Vietnam to achieve its goal of screening 60% of women aged 30 to 54 for cervical cancer (currently only 25% screened).

Initial training of screening staff is completed, and six TruScreen devices have been shipped to Vietnam for the start of the program which commence on 28 July 2025.

First TruScreen order from India landed

TruScreen advises that its distributor Renovate Biologicals Pvt Ltd (RBL) has placed it's first order for 10 devices and 1,080 Single Use Sensors.

India has the world's second largest screening population of over 460 million women*. Cervical cancer is the second most common cancer among women in India, but screening rates are only 2%. India's National Academy of Medical Sciences (NAMS) has recently recommended a target to achieve a 70% screening rate for cervical cancer by 2030.

TruScreen's Superiority Confirmed in Beijing Study

The results of a study conducted at Beijing Obstetrics and Gynecology Hospital, China, in July 2018 which analysed the diagnostic efficacy of different testing methods, alone and in combination, for cervical precancerous lesions has now been formally peer reviewed and published by Dovepress.

The study, entitled "*Assessment of the Real-Time Photoelectric Detection Device (TruScreen) in Screening for Cervical Precancerous Lesions in Middle-Aged Women: An Observational Study*"[1], confirms TruScreen's superiority as a standalone cervical cancer screening method, and highlights it's power to boost efficacy of results when used in combination with other testing methods such as ThinPrep cytologic tests (TCT) and HPV tests – "*effectively avoiding missed diagnoses, which is particularly important in the diagnosis and treatment of precancerous lesions*."

TruScreen demonstrated:

- the **highest sensitivity** (86.4%) and **highest specificity** (74.4%) for detecting CIN II or higher lesions, superior to those of liquid based cytology (TCT/LBC or the pap smear) alone (sensitivity, 81.8%; specificity, 38.2%) and HPV testing alone (sensitivity, 81.8%; specificity, 28.2%).
- the **highest Negative Predictive Value (NPV**) of 95.1 so it can be concluded that TruScreen has the best ability to exclude non at risk patients. Negative Predictive Value is the *probability that a patient does not have the disease*.
- the **highest Youden index** (0.608), indicating that this screening method had the best effect and the greatest authenticity. Youden index is a measurement of diagnostic test effectiveness.

Highlighting that TruScreen has low sampling technology requirements for clinicians, does not require laboratory doctors or pathologists equipped with PCR equipment to verify and requires minimal training for operators, the authors to concluded that TruScreen is particularly suitable "*in settings with limited medical resources or under special circumstances when access to healthcare is restricted.*"

TruScreen CEO, Marty Dillon commented: *"These milestone achievements are part of the fulfilment of TruScreen's plans announced with its preliminary results in May 2025 and reinforce TruScreen's strategy is on track to grow distribution capability in emerging markets, including three of the four most populous countries in the world – China, India and Indonesia."*

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 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 Dec 2023 TruScreen technology was added to the Vietnam Ministry of Health approved National Technical List, for use in Vietnam's public and private healthcare sectors and in 2024 was added to the Russian guidelines for the screening of cervical cancer.

In financial year 2024 alone, over 200,000* examinations were performed with the 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.*

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/TCT (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