

NZX/ASX Announcement

24/03/2025

TruScreen to Present at Singapore Healthcare Day Forum

- **Marty Dillon, CEO of TruScreen is presenting the company's innovative AI enabled cervical cancer screening technology at the Singapore Healthcare Day Forum**
- **The Presentation focuses on the global recognition of the TruScreen technology and of its successes to date for Low- and Middle-Income Countries**

TruScreen Group Limited ("TruScreen" or "the Company") advises that its CEO, Marty Dillon is an invited presenter at the Healthcare Day Forum held in Singapore on Monday March 24, 2025.

Mr Dillon's presentation is attached for the information of stakeholders.

TruScreen CEO, Marty Dillon commented:

This invitation follows on from a watershed 2024 year where TruScreen received recognition for our cervical cancer screening technology from leading global organisations such as the World Health Organization, UNITAID, Chinese Obstetricians and Gynaecologists Association (COGA) and the Chinese Society of Colposcopy and Clinical Pathology (CSCCP). TruScreen is proud to be one of only six Australian medtech companies invited to showcase our innovative technology at this forum. TruScreen will continue to work with its global distributors to assist with achieving the WHO strategic objective of eliminating cervical cancer by the end of the century.

Cervical cancer is the 4th highest cancer causing deaths amongst women and accounts for in excess of 350,000 global deaths per annum in the past years.

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 (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](#)



SINGAPORE 2025



24 March 2025



NATIONAL MEDICAL PRODUCTS ADMINISTRATION
国家药品监督管理局





Who is TruScreen

The TruScreen Technology

Why TruScreen

TruScreen Sales and Growth Strategy



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Who is TruScreen

Enabled by AI, **TruScreen** provides an accurate, real time cervical cancer screening solution



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Who is TruScreen

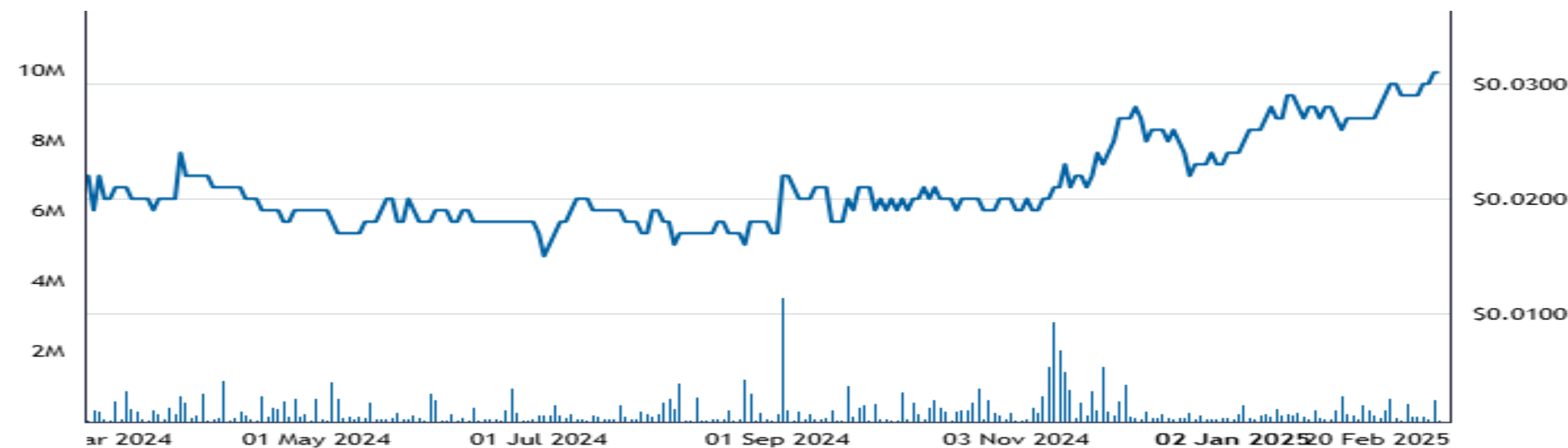
TruScreen Group Ltd is listed on both the Australian (ASX) and New Zealand (NZX) stock exchanges, with a common ticker code of TRU.

TruScreen Group Ltd is a revenue generating Life Science company with FY24 **annual sales exceeding NZD \$2m.**

Market Capitalisation at 27 February 2025:
NZD \$19.34m
Shares on Issue:
552,591,116

TruScreen Group Ltd owns TruScreen Pty Ltd, the Australian operating company that manufactures and markets the TruScreen cervical cancer screening system

TruScreen Price History (NZX)



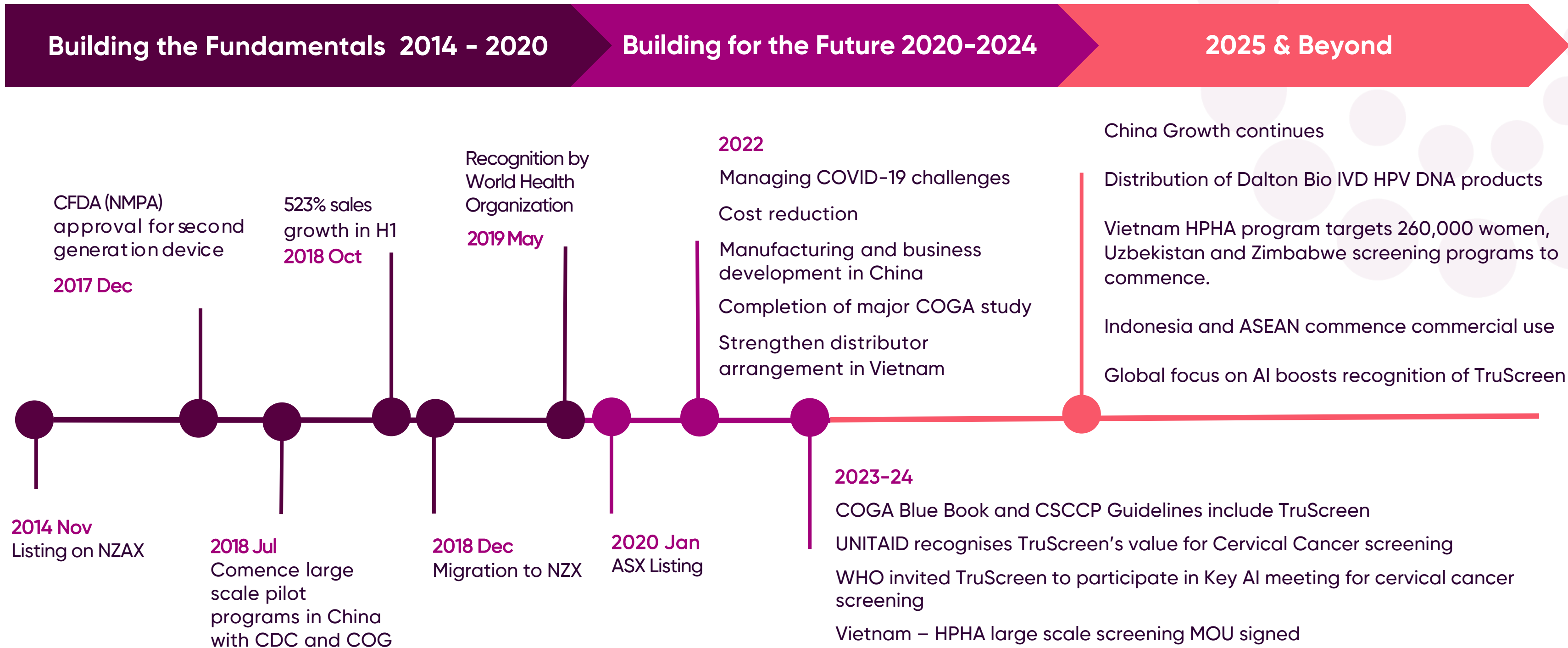
Corporate Snapshot

Shares on issue	552 million
Options	13 million
Share price	NZ\$0.035
Market capitalisation	NZ\$19.34 million
52 week high	3.7 cents
52 week low	1.5 cents

Major Shareholders

Major Shareholders	Shares	%
New Zealand Depository Nominee	64,098,833	11.6
Consolidated Nominees	39,602,400	7.17
Masfen Securities Limited	29,050,369	5.26
Bhagwanji Bhula Rama	27,791,666	5.03
New Zealand Central Securities	27,539,566	4.98
Ryan Peter Parkin	20,020,000	3.62
David and Adrienne Stewart	12,630,000	2.29

The TruScreen Journey





The TruScreen Technology



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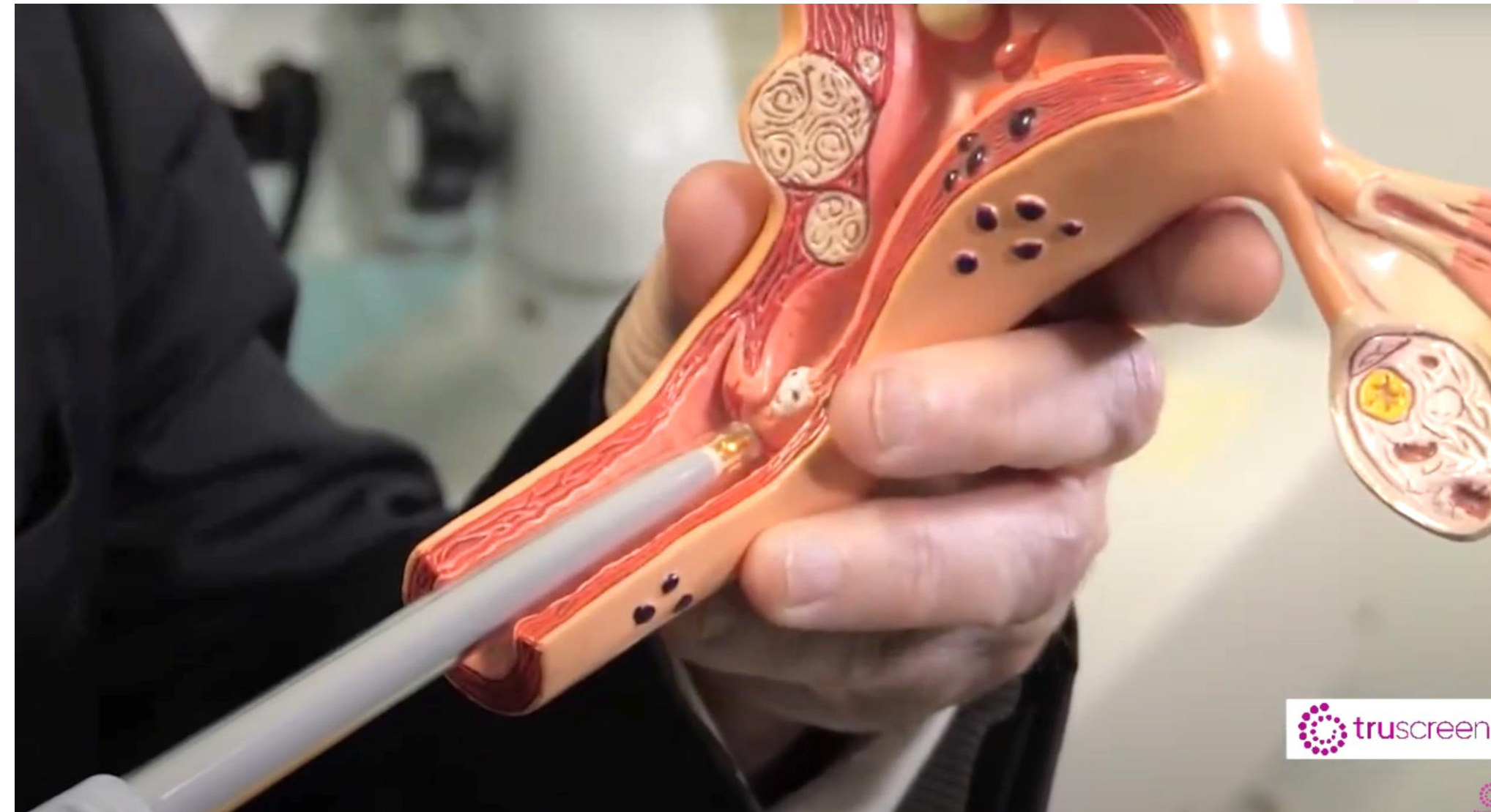
- Enabled by AI, TruScreen provides an accurate, real time cervical cancer screening solution
- Each TruScreen examination takes one to two minutes to produce results, compared to conventional Pap tests which can take days, weeks, or even months in some countries, for a result to be returned.



How it works

1

a pen-like wand covered by a **Single Use Sensor (SUS)** is used to gently touch multiple spots on the cervix. The SUS contains a precision lens and electrodes which interfaces with the cervix. It sends and picks up low level **electrical and optical signals** (14 readings per second) from the cervical tissue.



How it works

2

The TruScreen **Handheld Device (HHD)** then applies an integrated AI-enabled algorithm to analyse these signals and compares them to an integrated database of patients drawn from a wide range of geographic and ethnic backgrounds with differing histological diagnoses.

This identifies the presence of abnormal (cancerous and pre-cancerous) cells in the cervix and provides physicians with real-time results.



- ✓ Clinicians/physicians are able to **immediately plan appropriate patient care**
- ✓ Device has an expected life span of 5–7 years
- ✓ **Disposable SUS is used once per test per patient** – ensures there is no chance of cross-infection between patients
- ✓ The entire patient data collection and analysis is self-checked and controlled. **No tissue sample needs to be taken.** These measures ensure that the results are reliable and consistent, and that the examination is painless and safe
- ✓ **TruScreen has been used on over 1 million women and there has never been a single adverse event reported**





Why Truscreen



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Extensive body of clinical evidence

Over 40,000 women in clinical trials to date***

Year	Country	Investigator	N
2002	China	Dr Huang Yi	683
2002	China	Dr Wang Ziyao	301
2003	UK/Aus	Prof A. Singer	651
2008	Poland	Dr. Pruski	234
2009	China	Prof Ding Ma	302
2010	China	Dr. He Xiu-Kui	392
2010	China	Prof Fengnian Rong	532
2010	Korea	Dr. Hyeong Soo Lim	292
2011	Poland	Dr. Pruski	293
2011	China	Dr. Li Xia	500
2015	Turkey	Dr. Özgü E	285
2016	China	Dr. LI Pei,	368
2017	Mexico	Dr. Ricardo Lua	521
2018	China	Dr. Huixia Yang	2730
2018-2021	China	54 Hospitals	14,982

Year	Country	Investigator	N
2019	China	Dr. Baojin Wang	315
2019	China	Dr. Wei Zhang	1030
2019	China	Dr. Yanhong Jia	320
2020	China	Dr Kang Yanan	192
2021	China	Prof Chen Fei	974
2021	China	Dr Wei Yingting	458
2022	China	Dr Chen Zhenbo	476
2022	China	Dr Zhu Bo	283
2022	China	Dr Zhao Yuqian	1319
2022	Australia	Dr Jessica Vet	506
2023	China	Dr Luo Lianmei	318
2023	China	Dr Liu Hang	997
2024	China	Dr Yang Yueming	489
2024	China	Dr Fengyi Xiao & Long Sui	1908
2024	Saudi Arabia	Dr S Maqsood and DrM Alhudhud	507

***Total number of subjects across published and unpublished clinical studies in English, data from TruScreen device generation I and II



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COGA Trial (n= 15,661, 2018-2021) ⁴

- TruScreen specificity surpassed Liquid Based Cytology (LBC) and hrHPV
- TruScreen was determined to be a simple, effective and rapid real-time cervical cancer screening method
- TruScreen was determined to be an appropriate primary cervical cancer screening tool in regions with high morbidity and mortality to cervical cancer
- Also highlighted the superiority of TruScreen against alternative screening methods as well as the potential benefits of a TruScreen-HPV co-testing. The size of the COGA study, which was TruScreen's largest clinical evaluation to date, lends extra significance to its results and broad conclusions.

TruScreen's **sensitivity**

was well above that for LBC (87.5% v's 66.5%), with a high degree of statistical significance ($p < 0.001$).

The **sensitivity** of TruScreen-hrHPV co-testing (carrying out with multiple types of screening tests at the same time, as opposed to a single type) was higher than that of LBC-hrHPV co-testing, **98.4% vs 95.9%** (statistically significant at $p = 0.006$).

TruScreen's **specificity**

(88.4%) was higher than both LBC (86.3%) and hrHPV testing (78.3%) (also at $p < 0.001$).

Why TruScreen?

	Truscreen	Liquid Based Cytology (LBC)	HPV DNA
Real time results	✓		
Low infrastructure costs	✓		
Strong clinical results	✓	✓	✓
Objective results	✓		
Low training threshold	✓		
Portable	✓		
No cell or tissue samples taken	✓		



TruScreen Sales & Growth Strategy



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TruScreen Financials

FY 24 v FY 23

KEY FINANCIALS NZD (m)	FY 22 Actual	FY 23 Actual	FY 24 Actual
Sales	1.7	1.66	2.1
Total Revenue	2.7	2.2	2.6
COGS	1.3	1.3	1.4
R&D	1.5	0.9	0.9
EBITDA	-2.7	-2.4	-2.0
Write off of Non-Current Assets	-4.6	-0.05	-
Amortisation & Depreciation	-0.6	-	-
LOSS FOR YEAR	-7.9	-2.4	-2.0
Net Assets	3.4	2.5	3.2
Cash	2.8	2.2	2.7

- Sales increased 27% YOY
- SUS Sales increased 25% YOY
- Revenue increased 18% YOY
- EBITDA improved 15% YOY
- Net Assets increased 28% YOY
- Cash increased 23% YOY
- China SUS/Device Pull Through increased 40% YOY

TruScreen Financials

	1 st Half FY24	1 st Half FY25	% Change
Sales	\$0.98	\$1.03	5%
EBITDA	-\$1.35	-\$1.13	16%
Operating Cash Outflow	-\$1.4	- \$0.9	36%
SUS Units	91,620	96,480	5%
Devices	42	9	-79%
China SUS pull though per month per device	97	137	41%

Recurring Revenue Model

- TruScreen manufactures two devices –
 - one made in China for use in China, where locally manufactured products have preferential market access
 - one made in Australia for other markets
- For each patient screened with the TruScreen device a new disposable Single Use Sensor (SUS) must be used. **This creates a recurring revenue model with a consumable sale for each patient screened with TruScreen.**

TruScreen Sales Strategy

- Whilst many other medical technology companies seek to commercialize their devices in developed countries, **TruScreen focuses on Low and Middle Income Countries (LMICs) such as China, Mexico, Vietnam and Zimbabwe.**
- Unlike the developed western markets, these countries and other LMICs have no or minimal large-scale cervical cancer screening programs and infrastructure. This creates **a gap in the market** for TruScreen that is not available in the developed markets and allows quicker market access from a relative lack of existing competition.
- Unlike competing products such as cytology and HPV DNA screening **TruScreen is 'capital light'**, not requiring lab infrastructure to be established prior to commencing screening.

TruScreen Regulatory Approvals

Recognized by

World Health Organisation (WHO)

Unitaid

Clinton Health Access Initiative

Daffodil Foundation – Australia

China Obstetrics and Gynaecology Association

China Society for Colposcopy and Cervical Pathology

Russia Cervical Cancer Screening Guideline

Vietnam Hospital Technical List

International Approvals:

- CE Mark, European Union
- NMPA, China
- TGA, Australia
- MHRA, UK
- SFDA, Saudi Arabia
- Roszdravnadzor, Russia
- COFEPRIS, Mexico
- WAND New Zealand
- Zimbabwe Ministry of Health
- IEAKI Indonesia
- Vietnam Ministry of Health

International Quality Accreditation:

ISO 13485

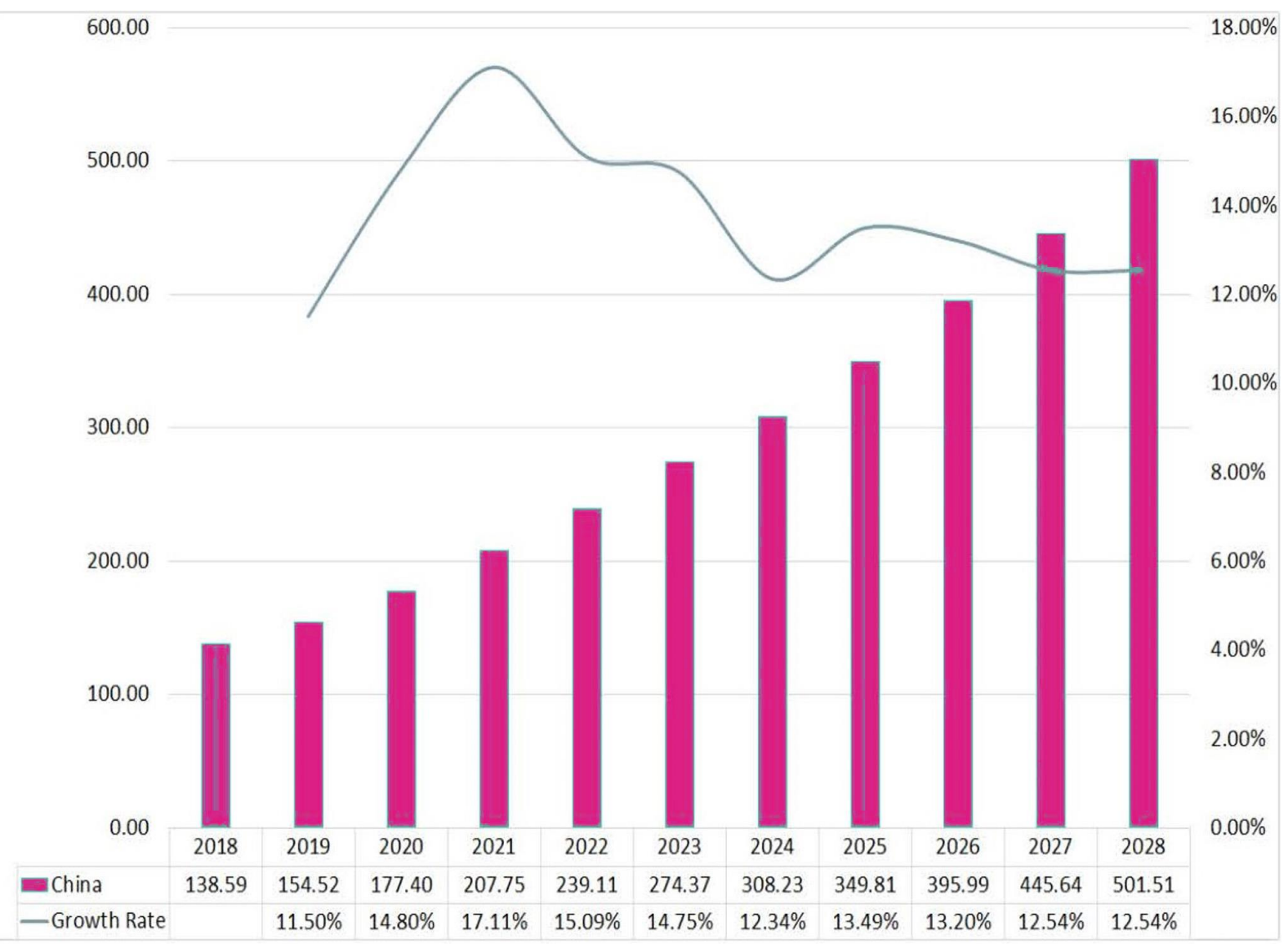
ISO 60601-1-2

CE Mark

Market Expansion

FY 24 TruScreen sales grow 27% YOY, exceeding China and APAC CAGR forecasts for HPV screening (10%).

HPV Test Market Revenue (Million USD) and Growth Rate (2018–2028)



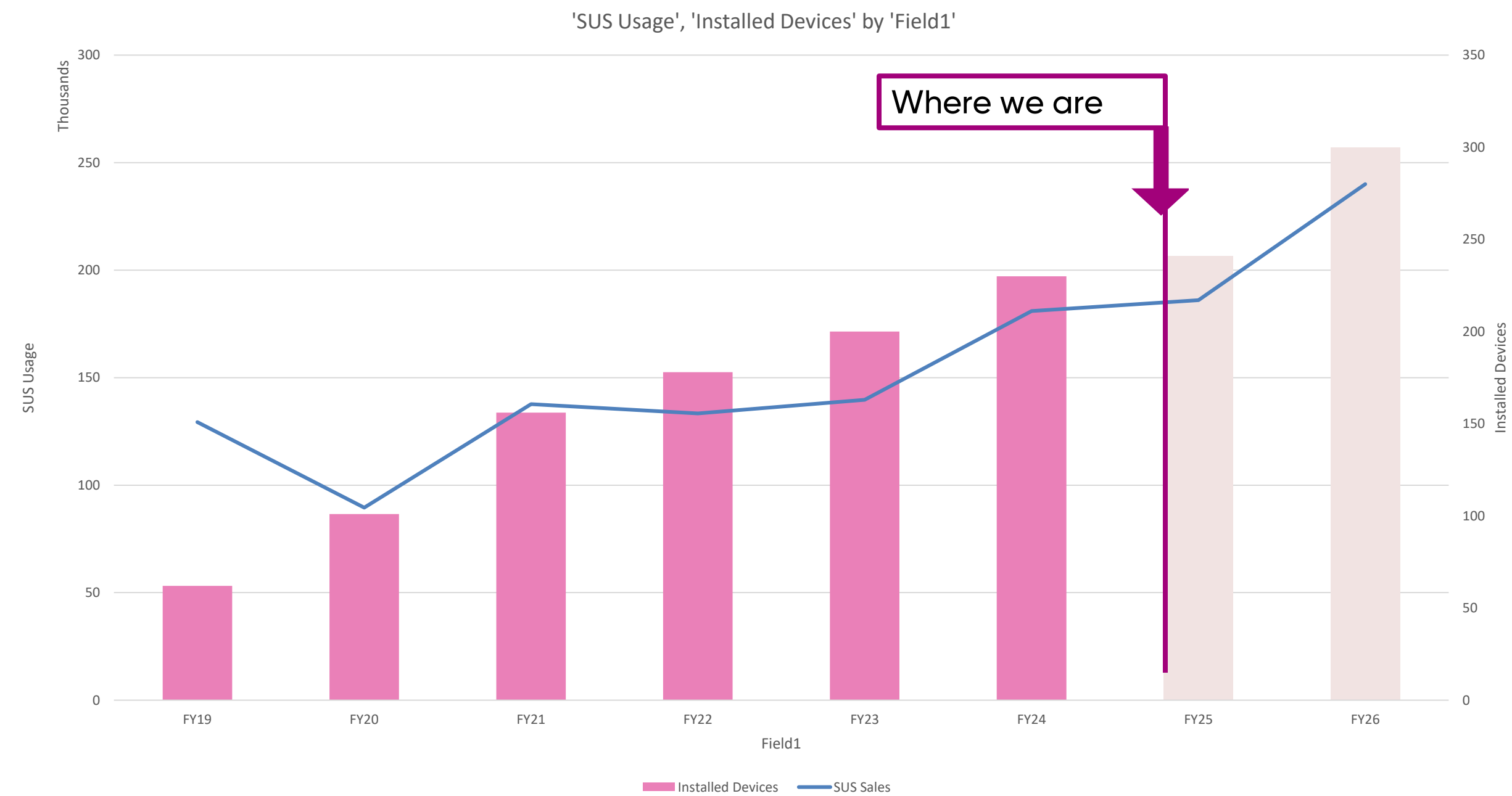
Source: Maia Research Analysis, 2023

Business Market Insights June 2023:

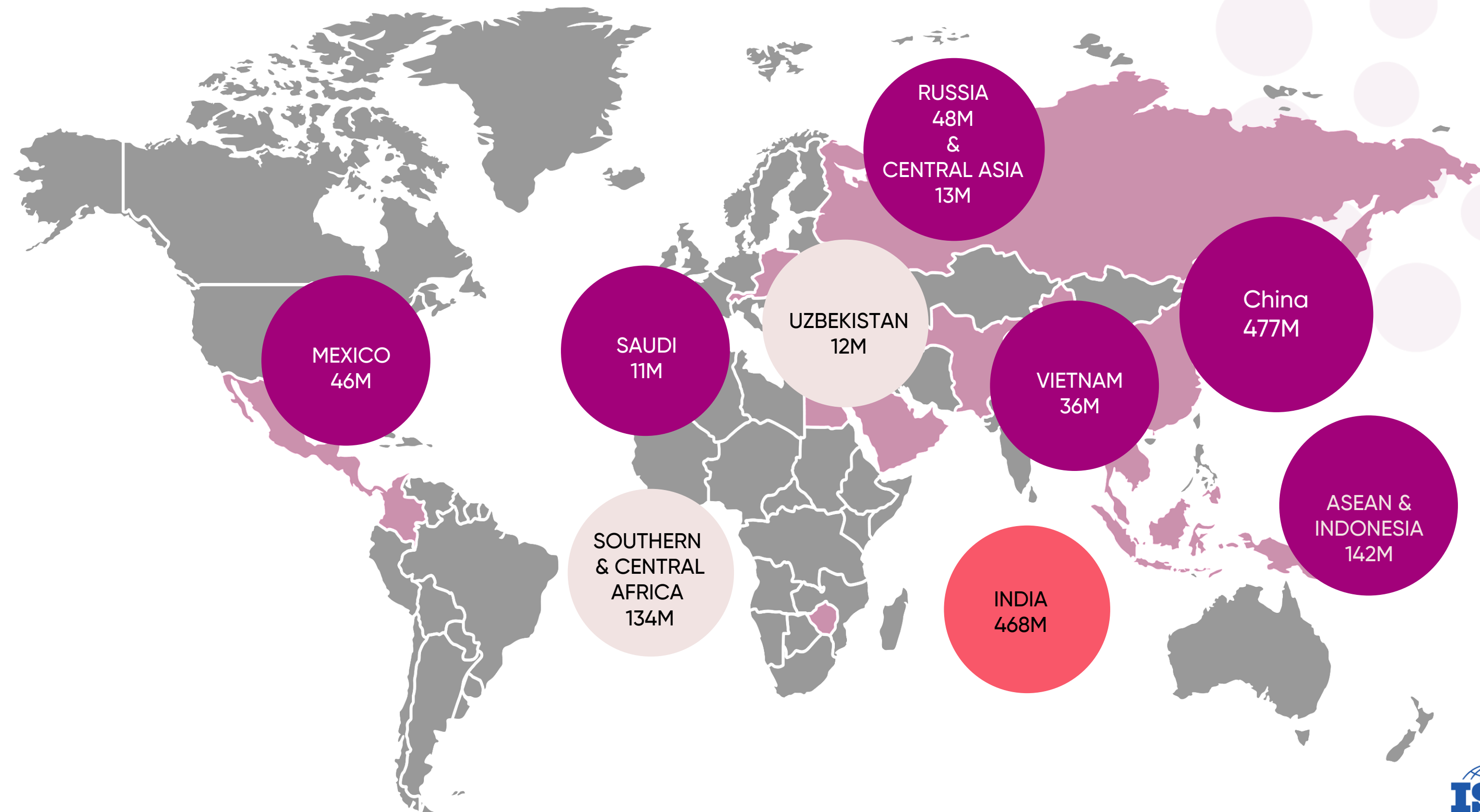
- The Asia Pacific CIN & HR-HPV treatment market is expected to grow from US\$ 2,738.94 million in 2023 to US\$ 3,949.99 million by 2028.
- It is estimated to grow at a CAGR of 7.6% from 2023 to 2028.



Device installations and SUS Sales



TruScreen's presence and global markets



Growth Strategies



Market expansion to continue with China the key focus



Focus on key growth provinces (Shandong, Jiangsu,, Hunan, Zhejiang, Guangdong, Guangxi) – Total population 496m



Strengthen China Distribution Capability via Strategic Partnership with DaltonBio



Strengthen vertical Asian market from Indonesia through China



Target Govt and NGO funded programs in Zimbabwe, Vietnam, Mexico and Uzbekistan



Build on International NGO Recognition (WHO, UNITAID, CHAI, COGA , CSCCP) to build acceptance and remove barriers to sale



Focus on countries with limited or nil cervical screening capability



Developing strategic partnerships for complementary woman's health services



Capitalise on global focus on AI enabled cervical cancer technologies – e.g. WHO



Expand product portfolio to include Dalton Bio HPV related IVD products DNA tests, including HPV DNA tests and self sampling



Reduce SUS and Device COGS and increase margins

TruScreen & Dalton Bioscience

MOU signed February 2025 between TruScreen Group Ltd and Hangzhou Dalton Bioscience

1. TruScreen to distribute globally (excluding USA and Canada) via selected distributors DaltonBio HPV related IVD products including DNA tests and Self Sampling.
2. DaltonBio to explore opportunities to assist TruScreen's AI enabled real time cervical screening device within its distribution network, notably its 200 SUB distributors in China and regulatory and distribution partners in South America

Contact us for more Information

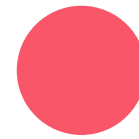


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