

TRUSCREEN ULTRA CLEARED FOR TAKE OFF



CE (Europe), TGA (Australia), MHRA (UK)
and WAND (New Zealand) Approved

In recent months, we have ticked off a number of goals and are now gaining good traction in our commercial progress.

We are now starting to pick up sales again after a challenging 12 months when delays in the production and approval of our new Gen II Ultra device led to an inventory gap as stocks of the Gen I TruScreen device sold out.

The doors are being opened to opportunities in the global healthcare market, with CE Mark certification for our Ultra device allowing us access to the European Union and other select markets including the Middle East, Central Asia and Latin America.

While China remains our primary focus, we are also excited about the potential in these other markets and are focused on expediting the supply of our Gen II TruScreen Ultra device as quickly as possible.

Initial shipments have already been made to Latin America and the Middle East and pleasingly, we have already received a second order from our Mexican distributor.

Our Chinese strategy remains to build our customer base, primarily large provincial hospitals, as well as encourage the selection of TruScreen technology for large screening programmes. Our Chinese distributor is doing a fantastic job driving uptake and our new highly regarded, sub-distributor in Beijing is another feather in our cap.

The registration, pricing approval, training and procurement process in China is long and involved. We have the expertise and knowledge to navigate this process and expect to see more traction with time.

Clinical validation is an extremely important part of what we do and we have been pleased by the positive results and feedback being generated

from two trials currently underway, in Australia and Mexico.

In other news, we have received confirmation from the NZX that we will not need to migrate to the NXT Market Platform during the next 12 months. We have also applied for additional Australian grant funding to support our growth.

The global cervical cancer market is estimated to be worth USD\$22 billion annually by 2020¹ and we are now firmly on track to capture a share of this multi-billion market. We are looking forward to further growth and milestone achievements as we build on the early and positive progress being made with our Gen II Ultra device.

Marty Dillion
Chief Executive Officer

GLOBAL MARKET REVIEW

- Global Cervical Cancer Screening Market estimated at USD \$15 billion annually¹
- Forecast to grow to USD \$22 billion annually by 2020¹

POTENTIAL MARKET VALUES USD\$



TRUSCREEN'S TARGET MARKETS



CE MARK GRANTED FOR GEN II TRUSCREEN ULTRA. FIRST PRODUCTION UNITS EXPORTED TO LATIN AMERICA AND MIDDLE EAST

TruScreen is strengthening its foothold in the multi-billion dollar global cervical cancer screening market, with the recent launch and CE certification of its Gen II TruScreen Ultra device.

With the latest in 21st century technology and a platform that can be continually updated to retain its position at the cutting edge of cervical cancer screening, TruScreen is well positioned to compete for a share of this huge market, which is estimated to grow to USD \$22 billion per annum by 2020.¹

ULTRA OPENS DOORS INTO GLOBAL MARKET

Mexico, Jordan and Kazakhstan have taken their first shipments of TruScreen's Gen II Ultra device, with Mexico's second order placed already.

The device shipped to Kazakhstan will be used for demonstrations and is the first step in TruScreen's Central Asian strategy.

Final import documentation is also being arranged for the Ukraine. TruScreen's local agent is a leading distributor for a range of high end medical technology, including ultrasound, tomography and radiology equipment.

TruScreen is also working with an experienced European health services executive to create a Pan European distribution solution for the Gen II Ultra device.

RECENT COMPANY HIGHLIGHTS

- TruScreen Ultra receives CE Mark certification
- Gen II Ultra ships out to Latin America, Middle East and Central Asia
- TruScreen gaining traction in China – further approvals and growing customer numbers
- More Chinese screening programs on the agenda¹
- Clinical studies back Gen II Ultra
- Ultra gains regulatory approval in Australia, New Zealand and UK

TRUSCREEN GAINING TRACTION IN CHINA

A MASSIVE OPPORTUNITY

The huge Chinese healthcare market is the primary focus for TruScreen and the company is starting to gain traction, as the benefits of its real time nature, clinical effectiveness and portability become more widely known.

Estimated by TruScreen to have a market potential of over \$800m annually, the opportunity in China's healthcare sector is huge, and the Gen II TruScreen, as the only opto – electric screening device approved by the CFDA, is uniquely positioned to capture an ever growing slice of this market.

All medical devices marketed or sold in China must have CFDA registration and approval.

New approvals have been restricted in recent times, with many healthcare and medical companies reporting long waits. TruScreen already has CFDA Approval for its Gen I device and has commenced the model upgrade process for the Gen II Ultra.

TruScreen currently has eight provincial pricing approvals in place for its Gen I device, providing access to a massive market. Pleasingly, the Gen II Ultra device does not require new pricing approval and therefore, once the CFDA model upgrade is completed, Gen II Ultra can be quickly commercialised in these eight provinces. Pricing approvals are underway in a further 15 provinces and will cover both the Gen I and Gen II Ultra devices.

STEPS TO COMMERCIALISATION IN CHINA

Entry to China

CFDA Approval

Provincial Pricing Approval

Hospital Demonstration and Familiarisation

Procurement Application

Procurement Committee Approval

Installation and Training

Commercial Use

SCREENING PROGRAM OFFERS PEACE OF MIND FOR MORE WOMEN IN CHINA

The number of public screening programs using TruScreen's technology is increasing, with the latest in Harbin City expected to screen 160,000 women.

This programme is being funded by the All China Federation of Trade

Unions (ACFTU), which is the largest trade union in the world with over 280 million members. We hope to leverage off this association and extend the use of the TruScreen technology to similar programs in other provinces throughout China.

TruScreen Gen I Device is also being evaluated for a further screening

program in Xinjiang Province, funded by the Central Government. Currently, 120 patients are undergoing a trial, and if approved, 20,000 women are expected to be screened. Xinjiang is the largest province in China, with approximately 5 million women of screening age.



NEW BEIJING SUB DISTRIBUTOR APPOINTED

Beijing is treated as a 'special' province in China and is run directly from the Central Government.

TruScreen has recently signed up a new sub-distributor in the province. This well-connected and highly regarded company already deals directly with the Beijing Municipal Council on Pap and HPV testings and is keen to 'get on the TruScreen bus'.

Dr Jerry Tan, TruScreen Ltd , conducting training of screening program medical staff at Provincial Cancer Hospital of Heilongjiang, Harbin City.

PEOPLE'S LIBERATION ARMY (PLA) GENERAL HOSPITAL JOINS THE LIST OF CHINESE MILITARY HOSPITALS USING TRUSCREEN

One of the largest military hospitals in China, the PLA General Hospital in Beijing has over 4,000 beds and 3.8 million outpatient visits every year. It is also a major teaching hospital and is used by leading political figures in China.

There are over 500 military hospitals in China, serving both military and civilian patients, and TruScreen is actively targeting 100 of these each of which has its own gynaecology department.

HOSPITAL UPTAKE ON THE RISE

- 24 new hospitals have approval to procure Gen I TruScreen
- A further 79 hospitals have commenced the official hospital procurement process to acquire the Gen I TruScreen device
- These numbers are expected to grow as TruScreen gains traction

TRUSCREEN ALGORITHM STORY

The TruScreen Algorithm is at the heart of our technology and we have been working for the past 12 months on the development of the first of our improved algorithms.

As of Calendar Year 2016 we will begin testing this algorithm on patient data then proceed to in field verification, prior to incorporation into TruScreen Ultra for release to the market.

MEXICAN MARKET STARTS JUMPING. FIRST MARKET TO ORDER ULTRA

Our Mexican distributor has had excellent results, moving rapidly from the granting of our CE mark for the Gen II Ultra in April 2016, to become the first country in the world not just to order the Gen II Ultra, but to re-order Gen II Ultra.

In addition this early success in commercial sales is underpinned by a long pipeline of potential customers in both the public and private health markets. In the public sector TruScreen has been submitted for adoption in the national guidelines of the Mexican Health Secretariat, and been submitted for tender with leading hospital groups and national

public health insurance providers. In the private sector TruScreen Gen II Ultra has been under evaluation and purchase consideration by several leading hospitals and clinics and major clinic chains. In addition, a clinical trial of TruScreen v Pap in Guadalajara found TruScreen to be **more than 3 times more effective than Pap** in identifying pre cancerous changes to the cervix.² The public and private groups currently active in considering TruScreen in Mexico include:

Pemex – The country's nationalised oil company and Mexico's largest employer.

ISSSTE – Institute for Social Security and Services – public health insurer for public employees. In conjunction

with IMSS provides health coverage for between 55 and 60 percent of Mexico's people.

IMSS – Mexican Social Security Institute - major insurer of private sector employees. In conjunction with ISSSTE provides health coverage for between 55 and 60 percent of Mexico's people.

Farmacias Similares – evaluating TruScreen in 5 clinics for roll out to the first 50 and then possibly all of its 250 private clinics.

Walmart – considering the provision of screening clinics in all of its stores in Mexico, with TruScreen to provide a real time cervical screening solution.

RECENT CLINICAL TRIAL FINDINGS POSITIVE FOR TRUSCREEN AND TRUSCREEN ULTRA

A growing number of clinical trials are underway for Gen I TruScreen and Gen II TruScreen Ultra.

Five hundred patients have taken part in the 'real world' trial at the GineMed Clinic in Guadalajara, Mexico, with results clearly showing the higher sensitivity and effectiveness of the TruScreen technology. The trial reported a TruScreen sensitivity of 76% compared to a traditional Pap Smear sensitivity of only 22%.²

"TruScreen is clearly better than Pap. It's easy to use, more comfortable and provides instant results – all making for happy, satisfied patients."

Dr Carmen Suro, Clinical Gynecologist and Colposcopist, GineMed

Another trial has recently commenced at the Royal Hospital for Women in Sydney, Australia, comparing the Gen I TruScreen device with the new Gen II Ultra. Initial feedback from the trial supervisor, Conjoint Associate Professor Michael Campion, is that Gen II Ultra is a significant improvement as far as doctor usability is concerned and continues TruScreen's advantage in patient preference.

¹ www.marketsandmarkets.com/medical-device-market-research-11.html ² Dr Ricardo Lua and Dr Carmen Sura, GineMed Clinic, Guadalajara Mexico 2015.