

# EXECUTIVE UPDATE

**2018 is looking to be a year of positive traction for TruScreen as we capitalise on the progress being made across commercial programs, product development and manufacturing.**

The latest major achievement for our company has been the receipt of Chinese Food and Drug Administration (CFDA) approval for our TruScreen2 device. This allows us to market and sell our second generation device in China and we are moving quickly to capitalise on this with TruScreen2 sales to China now commenced. (For more details on our China plans, please see page 2).

**Recent highlights include:**

- CFDA Approval for TruScreen2.
- Development of a Chinese Language version of TruScreen2's operating system and browser interface to increase usability and adoption in China.
- TruScreen director Professor Ron Jones led a delegation to India to establish a collaboration between the All India Institute of Medical Science (AIIMS) and TruScreen to conduct a program whose aim is to evaluate TruScreen2 for recommendation to the central and state governments for use in government screening programs. Professor Jones observed that India is a huge potential market for TruScreen.

- Confirmation of a meeting in Mexico with that country's Cuadro Basico committee to consider TruScreen's inclusion in their government purchasing catalogue. This is a key step in opening the door to participation in government programs and tenders.
- Recommendation by key medical advisers to have TruScreen included in the clinical guidelines for the Russian Society of Obstetricians and Gynecologists.
- Initial results from the clinical performance valuation of TruScreen2 at the Royal Hospital for Women in Sydney indicate that TruScreen2 is a significant improvement on TruScreen1.
- TruScreen has been approved by the PNG Ministry for Health for use in a pilot study of cervical cancer screening in two regional centres, Lae and Kundiawa.
- TruScreen2 has been featured at major women's health conferences in China, Latin America, Asia and Europe.
- TruScreen has been approved for a private health insurance rebate in Jordan, a first for our company globally. Whilst Jordan is only a small market, we will use this as a precedent for similar applications in larger markets.

Interest in the TruScreen2 device is strong and, while some approvals have taken longer than initially anticipated, we expect to see sales grow as early adopters transition to

commercial users across broader private and public sectors.

To meet this increased demand TruScreen is working with key suppliers to establish our own device manufacture factory and to significantly increase our current manufacturing capacity. We are also researching the establishment of offshore assembly of the TruScreen device in key markets where this is necessary for government adoption.

TruScreen has continued to improve the quality of both the TruScreen2 device and the disposable Single Use Sensor, including improved tooling, manufacturing techniques and components

As indicated at the annual meeting, we are currently reviewing the skills and capabilities the company needs as we move into this phase of our journey. In line with this, the TruScreen board has been refreshed with the replacement of two long serving directors by new directors, Professor Ron Jones and Chris Lawrence.

TruScreen is well positioned to continue progressing in its commercial journey. Our commercial performance in the first two quarters of FY18 is roughly in line with that of FY17; however, with the receipt of CFDA and increased traction in other markets, we are now witnessing a growth in sales. We will continue to invest in our company, with revenue expected to grow significantly faster than expenses in the remainder of FY18.

## THE ROAD TO COMMERCIALISATION

**TruScreen's Current Phase of Growth**

**2018: Current stage of commercial journey**

**Research and Development**

- Development of first and second generation devices and algorithm
- Clinical validation

**Distribution Partnership**

- Identify and partner with reputable distributors which have existing in-country networks and contacts

**Awareness and Acceptance**

- Build awareness and acceptance of TruScreen
- Rollout of commercial programme
- Adoption by Key Opinion Leaders
- Clinical trials and in-market validation
- Presentation at major conferences and congresses

**Adoption and Initial Sales**

- Initial sale of TruScreen devices
- Low initial usage of Single Use Sensors per device
- Expand user base with increased device sales and installations, and training of users
- Building usage as Doctor and Patient acceptance grows

**Mature Sales**

- Continued expansion of user base via device sales and installation
- Ongoing, repeat sale of Single Use Sensors as usage per device increases



# CFDA APPROVAL FOR TRUSCREEN2 WILL EXPAND REACH INTO CHINA

**China Food and Drug Administration (CFDA) approval is required for companies to market and sell their products in China and is, by global standards, an extremely rigorous validation process which certifies the engineering, quality and efficacy of our product for use in our major market.**

TruScreen2 provides a significant improvement in performance, speed and capability and we expect to see a step-up in sales in China for both our devices and for Single Use Sensors now that CFDA approval has been obtained. Existing customers will be upgraded to the new technology over time and initial orders for TruScreen2 are already confirmed.

With 400 million women of screening age, China remains the primary market opportunity for TruScreen. TruScreen is now being used in several of China's most

prestigious hospitals, including the Army's PLA General Hospital which now conducts over 1000 TruScreen tests per month.

TruScreen has also recently announced a major new sub-distributor agreement with BioChem Group in China. BioChem has entered into agreement with the Women's and Children's Healthcare Division of the Centre for Disease Control (CDC) in China to evaluate TruScreen. The goal is to have the CDC recommend TruScreen for use in major central government screening programs and for TruScreen to be included in the list of basic medical equipment for the over 30,000 community healthcare centres throughout rural China.

This is an important commercial milestone for TruScreen in China and, with a number of customers already in place, we are well positioned to strengthen our existing presence and increase usage of our technology.



# REFRESH FOR TRUSCREEN BOARD

**TruScreen's board has been refreshed with the inclusion of two new members – Professor Ron Jones and Mr Christopher Lawrence.**

Professor Jones is a world renowned expert on cervical disease, and Chris Lawrence is a significant investor in life science and technology businesses, including TruScreen.

TruScreen's Chairman Robert Hunter had previously highlighted to investors the need to refresh the board, and the resignation of two long term directors has enabled TruScreen to appoint two new directors.

Both Ron and Chris are enthusiastic about TruScreen's future and about working with their fellow directors to deliver the company's goals for 2018 and beyond.

# HEALTH INSURANCE REIMBURSEMENT IN JORDAN SETS PRECEDENT FOR OTHER MARKETS

Jordanian women are the first in the world to be able to receive a health insurance reimbursement for TruScreen following the decision of a major private health insurer to include TruScreen in its list of approved procedures for cervical cancer screening.

This achievement will allow TruScreen to be more affordable for patients and compete on a level health insurance footing with subsidised pathology based competitors such as the 60-year old cytology option (the Pap smear).

# RECOMMENDATION FOR INCLUSION IN RUSSIAN CLINICAL GUIDELINES

TruScreen's testing methodology has been recommended by key medical advisers to be included in the clinical guidelines of the Russian Society of Obstetricians and Gynecologists. This endorsement is expected to be a key to opening up major sales, not just in Russia, but in many of the surrounding countries that once formed the Soviet Union.

# TRUSCREEN GOES MOBILE IN MEXICO

TruScreen has again been selected for use in Mexico's famous Health Train – El Tren de la Salud. Organised by the Fundacion Grupo Mexico as a charity initiative, the privately sponsored Health Train operates in 22 Mexican states, bringing advanced medical screening technologies to people in remote Mexican communities.

More than 5,000 women have already been successfully screened and, following the success of the first tour, TruScreen will continue to be used to screen women in remote Mexican communities.

# TRUSCREEN CLOSES IN ON KEY GOVERNMENT ACCEPTANCE IN MEXICO

The Mexican Government have confirmed that TruScreen's Mexican representatives will meet with the Cuadro Basico Technical Committee (Junta Tecnica) in February to present TruScreen's case for allocation of a government purchasing number and inclusion in the catalogue of preferred medical products for public health institutions and programs. If the presentation is successful, the allocation of the purchasing number is expected to be confirmed within the next quarter.

# WORLD RENOWNED MEDICAL SPECIALIST LEADS DELEGATION TO INDIA

**In November, TruScreen Director, Professor Ron Jones led a TruScreen delegation to India, where his NZ government relations were critical to gaining the collaboration of the All India Institute of Medical Science (AIIMS), in a project to validate the use of TruScreen in urban and rural settings.**

AIIMS was established by a grant from the NZ Govt in 1952, and is the peak body in India for medical research and training.

Prof Jones has been involved with the TruScreen technology since the very beginning and was the Principal Investigator for a 1998 study at National Women's Hospital in Auckland, one of the key clinics used to gather early data for what was then the Cervical PolarProbe (and has now evolved into TruScreen). The data generated in that study was used to "inform" or "train" the tissue differentiating algorithm that was first placed into the TruScreen device.

His international profile and his extensive experience and expertise will, as it has in India, be a significant advantage for our company as we look to expand and build on our global footprint.

## RESEARCH COLLABORATION WITH ALL INDIA INSTITUTE OF MEDICAL SCIENCE (AIIMS)

**Collaboration with All India Institute Of Medical Science (AIIMS) to conduct screening research in India renews unique NZ-India ties.**

Following a visit to India by a TruScreen delegation led by Professor Ron Jones, the All India Institute of Medical Science (AIIMS) has agreed to collaborate with TruScreen to validate our unique real-time opto electric technology for the screening of Indian women.

The AIIMS TruScreen project will be conducted in both urban and rural settings. Screening will be conducted in the AIIMS hospital in Delhi, and CHRSP Ballabgarh, a satellite of AIIMS that services 28 villages in Haryana State.

### AIIMS

The All India Institute of Medical Science is an autonomous institution regulated by its own Act of Parliament. AIIMS was established following a £1 million gift from the New Zealand Government in 1952 and is the peak body in India for medical education and research and a key body advising the Government of India on health policy.

Dedicated to improving standards of education for undergraduate and post – graduate medical teaching across all its branches in India, AIIMS conducts education and research across 42 healthcare disciplines, and publishes over 600 research papers each year.

### CERVICAL CANCER IN INDIA

India carries one third of the global burden of deaths from cervical cancer and cervical cancer is the leading cause of cancer mortality in the country. (1) Lead Investigator for the AIIMS – TruScreen project, Professor J B Sharma, stressed the need for improved cervical cancer screening. "It is estimated that every 8 minutes one woman in India dies of cervical cancer. Since survival rates improve if the condition is diagnosed and treated early, screening for cervical cancer is important" said Professor Sharma.

There are over 300 million women of screening age in India. Professor Ron Jones, after viewing firsthand India's lack of screening infrastructure, commented that "I reiterate, India is a huge potential market for TruScreen".



*Professor Ron Jones and Professor JB Sharma alongside the plaque commemorating the foundation of AIIMS and the link to the New Zealand Government*

## PAPUA NEW GUINEA (PNG) GOVERNMENT APPROVES TRUSCREEN PILOT STUDIES FOR CERVICAL CANCER SCREENING

**The Health Department in PNG has approved two pilot clinical studies with 1,000 patients each in two sites. Located in the highlands at Kundiawa, and on the coast at Lae, these clinical studies will evaluate the effectiveness, applicability, safety and cost of TruScreen in comparison to Pap smears, with a view to having TruScreen adopted for screening in other remote areas.**

PNG has one of the highest rates of cervical cancer worldwide and this is increasing yearly. Unfortunately, the country has limited resources and no permanent or successful cervical cancer screening programmes. Laboratory facilities are limited and this restricts access to pap smears, with all cytology being sent to just one laboratory in the country. Thus results can take months to be returned to the doctor and patient. With its lack of traditional screening infrastructure, PNG faces the problem of how to screen

its large rural population. TruScreen is the world's best solution for this problem and, subject to government and other funding, would bring great benefits to the country.

This project is the first time that TruScreen has had a National Ministry of Health endorsement for study and, if successful, we expect this model to be reproducible not just in PNG but in all countries that have remote regions with limited access to health services.



# TRUSCREEN2 FEATURED INTERNATIONALLY



**TruScreen2 and the benefits of Real Time Opto-Electric cervical cancer screening have been featured in many major international, national and regional conferences including:**

## CHINA

Annual Conference of China Medical Equipment Association. *Suzhou, 20 to 23 July*

National Annual Colposcopy and HRA Technology Training Course and Workshop. *Shanghai, 28 – 30 July 2017*

COGA Hunan. Hunan Conference of China Obstetrician and Gynecologist Association. *Changsha, August 6 - 7*

COGA 2017. Annual Conference of China Obstetrician and Gynecologist Association. *August 18 – 20 Chengdu*

## EUROPE

EUROGIN 2017. European Research Organisation on Genital Infection and Neoplasia. *Amsterdam, October 8-11*

## ASIA

AOGIN 2017. Asia-Oceania Research Organisation in Genital Infection and Neoplasia. *Tokyo, October 18 -19*

## LATIN AMERICA

FLASOG 2017. Federation of Latin American Societies of Obstetrics and Gynaecology. *Cancun Mexico, September 5 - 9*

## MEXICO

COMEGO 2017. Mexican College Gynaecology and Obstetrics. *Mexico City, June 26 29*

# TRUSCREEN MOVES TO INCREASE ITS MANUFACTURING CAPABILITY

**With the increase in sales following CFDA approval and increased traction in other markets TruScreen has taken steps to both secure and increase the supply of its TruScreen2 devices.**

We have recently reached agreement with our key suppliers to assist TruScreen to establish

our own factory, and to significantly increase TruScreen's current TruScreen2 device manufacturing capacity.

In addition, TruScreen and its manufacturing partners are also working together to develop plans to have TruScreen2 assembled in key offshore markets where this is a requirement for adoption in government programs.

# TRUSCREEN'S CONTINUOUS IMPROVEMENT PROGRAM

**As part of TruScreen's continuous improvement program, TruScreen has made several improvements to its TruScreen2 technology.**

## Release of new operating firmware

TruScreen recently tested and released updated operating firmware. This included improvements in power management, wi fi connectivity and changes necessitated by the release of Microsoft's new Windows 10 operating system which many of our customers now use.

## Release of Chinese Language Version

In preparation for the CFDA approval to market TruScreen2 in China, a Chinese language version of both the TruScreen2 device graphics and computer browser screens was developed and recently released. All TruScreen2 devices sold in China now have this new home language version.

## Manufacturing Processes

TruScreen has also introduced several improvements to the processes of manufacturing and testing the TruScreen2 device, especially the calibration of the electro-optical interface.

# TRUSCREEN RECEIVES TICK OF APPROVAL FOR QUALITY

In November 2017 TruScreen was audited by international quality auditor, TUV SUD, and had both its EC certification (CE MARK) for the TruScreen2 device, and international ISO 13485 accreditation as a designer and manufacturer of medical devices affirmed.

Other quality and regulatory highlights include the granting of CFDA approval to market the TruScreen2 device in China, and conformity with changes to both the electrical safety standard, ISO 60601-1 and the new European Medical Device Directive.

# 妇产科诊疗指南制定与 宫颈病变诊疗规范化专家



# TRUSCREEN2 DELIVERS PROMISING INITIAL RESULTS IN CLINICAL EVALUATION

## TruScreen Performance

Interim results RHW (2017): Excellent. >90% Negative Predictive Value

## Truscreen in the real world - Sensitivity to CIN2+ Guadalajara 2016

TruScreen 78%

HPV DNA 56%

PAP 36%

**TruScreen's Medical Advisory Committee are currently conducting a clinical performance evaluation at the Royal Hospital for Women in Sydney and at two regional clinics in Australia. The initial results have been promising and reconfirm the ability of TruScreen2 to be a unique and valuable screening test for the prevention of cervical cancer.**

The evaluation indicates that TruScreen2 is a significant improvement upon TruScreen1, with an improved Negative Predictive Value, the key measure in Primary Screening. Whilst the evaluation has not been completed, preliminary results show TruScreen having a Negative Predictive Value greater than 90% for women in a screening environment.

These results reinforce the results of a 2016 study in Mexico (Lua et al) which showed TruScreen to be significantly more sensitive to high grade pre-cancerous changes than both Pap and HPV testing in this setting.

This higher sensitivity, combined with TruScreen's real time, objective capability, reinforce the advantage of TruScreen over the Pap smear in developing countries and indicate that TruScreen will be a substantially more accurate screening method in our target markets.

### Explanation of terms:

The usefulness of diagnostic tests, that is their ability to detect a person with disease or exclude a person without disease, is usually

described using terms such as sensitivity, specificity and predictive values.

- **Validity:** The extent to which a test measures what it is supposed to measure, in other words, the accuracy of the test
- **Sensitivity:** The ability of the test to accurately identify disease when it is present
- **Specificity:** The ability of the test to accurately classify an individual as 'disease-free' when disease is not present
- **Negative Predictive Value:** The percentage of patients with a negative test who do not have the disease. A 90% NPV is an excellent result.

CIN2 are moderately abnormal cells which are found on the surface of the cervix. CIN 2 is usually caused by certain types of human papillomavirus (HPV) and is found when a cervical screen is done. CIN 2 is not cancer, but may become cancer and spread to nearby normal tissue if not treated. TruScreen2's main focus is to accurately detect disease and this is supported by the high Negative Predictive Value interim result of >90% in the study.



# TRUSCREEN REMAINS WORLD'S BEST OPTION FOR DEVELOPING COUNTRIES

## TRUSCREEN VERSUS HPV DNA TESTING

**HPV stands for Human Papillomavirus, a common virus that affects both males and females, passed from person to person through sexual contact. HPV can stay in the body, causing changes to cells that can lead to HPV-related cancers and disease in males and females. Different types of HPV can affect different parts of the body, and some types are more harmful than others.**

However, just having an HPV infection does not mean that a patient will go on to develop cervical cancer. According to the Australian Government Department of Health, four out of five people will have an HPV infection at some point in their lives.

A 2016 clinical trial from Mexico revealed that, at any point in time, 12% of women of screening age had a current HPV infection of a type known to be associated with cervical cancer.

While several companies have developed tests for identifying the presence in cervical samples of various strains of HPV, TruScreen does not view HPV DNA testing a direct competitor for several reasons:

Single visit screening and treatment programs are genuinely needed in many countries which lack laboratory infrastructure or adequate patient recall procedures.

### TruScreen is better than HPV Testing in our target markets:

- Real Time - no loss of patients to follow up
- Enables 'single visit' cervical cancer screening
- No need to build expensive laboratory infrastructure
- No need to train a cohort of expert lab technicians
- No need to create a sample transport, handling and storage system
- No need for a results reporting system
- Tests for actual pre cancerous changes, not the relatively common HPV infection
- No overloading of scarce colposcopy and histology resources due to the latent incidence of HPV in the female population.

TruScreen is a real time test providing an immediate screening result and requires no laboratory infrastructure; whereas HPV DNA tests need to be sent away for analysis and the patient called back for reporting of results.

TruScreen is an objective test where the accuracy is inherent in the device and not subject to human error. The more steps in the diagnostic process, the more chances there are that the accuracy may be compromised unless strict protocols are followed.

TruScreen is a one step diagnosis process. HPV DNA does not look at cell changes, but rather the mere presence of a precursor HPV infection. A positive HPV DNA test must be followed by a Pap Smear or colposcopy to determine whether or not the patient actually has any disease, which adds to the cost.

The vast majority of HPV infections will spontaneously resolve without ever progressing to CIN 1, CIN 2, CIN 3 or cervical cancer. TruScreen2 accurately identifies CIN2 cells.

The HPV vaccine is not the cure-all for cervical cancer screening. The introduction of the HPV vaccine does not eliminate the need for screening as it does not protect against all HPV types nor does it have an established lifetime inoculative effect. Plus in many countries the vaccine is too expensive and has non broad community application. Thus, in both developed and developing countries, the role of and need for primary screening and triage for cervical cancer has not diminished.

