

# EXECUTIVE UPDATE

**The highlight for TruScreen in the last 12 months, has been the launch of our TruScreen2 device. We have introduced this to several markets and a number of new distribution agreements have been signed in recent months.**

TruScreen<sup>2</sup> came into being in 2016, after we made the decision to discontinue the sale and supply of the original TruScreen<sup>1</sup> device and instead focus on developing and launching our second generation device.

The feedback we are receiving is very positive. Following testing at the Royal Hospital for Women in Sydney, Associate Professor Michael Campion commented: "The new TruScreen<sup>2</sup> has leapt further forward, proving itself to be more accurate than the original device, and reinforcing TruScreen's pre-eminent position in real time cervical cancer screening."

A fundamental part of our commercial strategy is positioning TruScreen<sup>2</sup> as the preferred option for large screening programmes on a global scale. Our technology is currently under evaluation for use in Government screening programmes in Mexico and the Philippines and we have recently commenced the process to have TruScreen evaluated for inclusion in the Government of India's proposed screening programme. This is in addition to the existing TruScreen<sup>1</sup> screening programmes in China. You can read more about our progress in China and the opportunity in India in this Update.

Convincing governments and large private healthcare organisations to adopt an innovative medical technology is neither simple nor instant and regulatory approval processes can take time. However, we have already recorded initial sales of TruScreen<sup>2</sup> in Latin America, Eastern Europe and Central Asia – all countries where our technology can provide a real improvement in cervical cancer screening.

To support our growth strategy, we recently completed a \$4.09 million placement to selected investors and have announced a Share Purchase Plan for our existing shareholders at the same share price as this placement. The new capital raised will be used to strengthen our balance sheet, fund sales and marketing initiatives, expand manufacturing capabilities and continue to improve the performance of our technology. In particular, funds will be used to:

- Prepare for anticipated commercial opportunities in China and India;
- Expand commercial growth in European and Latin American markets;
- Fund clinical and familiarisation trials as required for product improvement and acceptance in Government programmes;
- Expansion of manufacturing facilities and supply capabilities;
- Build-up of inventory;
- Continued product refinement.

We are looking forward to building on our momentum from 2016.

## TRUSCREEN OBJECTIVES FOR NEXT TWELVE MONTHS:

- Finalise the clinical validation of the new TruScreen Algorithm<sup>2</sup> and release that to the market.
- Obtain regulatory approval for TruScreen<sup>2</sup> in selected countries
- Submit TruScreen<sup>2</sup> for adoption in selected international government screening programmes.
- Further establish our global distribution networks.
- Enhance sales of TruScreen<sup>2</sup>.





## TRUSCREEN EXPANDS ITS GLOBAL REACH

The launch of TruScreen2 has further strengthened TruScreen's proposition and allowed us to step up the expansion of TruScreen's global distribution network. A number of new distribution agreements have been signed in multiple new markets in recent months, with distribution partnerships established in Europe (covering 10 European countries), Central Asia and the Middle East. In total, these agreements cover territories with a screening population of 61 million women and are regions with a historical lack of quality cervical screening programmes or with local screening practices that vary considerably in quality.

"TruScreen2 is one of the most exciting opportunities I have been involved with. In Eastern Europe in particular, there is an immediate need for an expert, real time cervical cancer solution, free of dependence upon large scale laboratory infrastructure – as this infrastructure is not often readily available to the vast majority of women in these countries, and when it is available, the results are often not up to the standard experienced by women in New Zealand, Australia or the United Kingdom."

*Troels Jordansen, European Business Development Manager*

# NEW PARTNERSHIP PROVIDES ACCESS TO SIGNIFICANT OPPORTUNITY IN INDIA

**India is the world's largest populated market, with approximately 1.3 billion people, of which approximately 300 million women are of screening age. It accounts for nearly one third of global deaths from cervical cancer and lack of access to cervical screening is a major factor in this abnormally high mortality rate.**

In November 2016, the Government of India announced efforts to address this mortality rate and mandated a national screening programme for cervical cancer for females aged over 30 years. It has set aside substantive budget allowances for cervical cancer screening, commencing in 2017.

In India, and in particular rural India, there is a shortage of trained health professionals, cytologists and colposcopists. The Ministry of Health and Family Welfare has stated in its operational guidelines for screening

that a "single visit" approach (where screening and treatment is effected in the one visit) is the preferred approach for cervical cancer screening.

In contrast to other highly subjective methods, TruScreen provides an ideal solution which is objective and real time.

To gain access to this market, we have entered into commercial agreements with Khandelwal Laboratories Pvt Limited. Together, we have commenced the evaluation process for TruScreen's inclusion in the Government screening programme.

Khandelwal Laboratories is a reputable and well-established pharmaceutical and device supply company based in Mumbai, with a strong emphasis on sales and the supply of oncology products to the private and public sectors. The agreements with Khandelwal Laboratories cover the distribution of TruScreen into the public and private sectors and also the likely establishment of in-country manufacturing facilities to satisfy supply to the Indian Government.

# TRUSCREEN IN CHINA

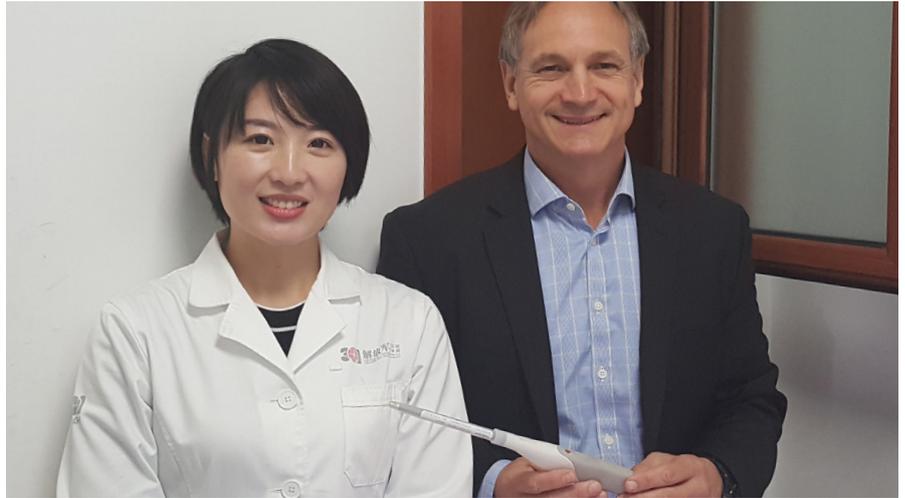
**China continues to be a significant opportunity for TruScreen and our most advanced. Our focus is on encouraging the selection of TruScreen technology for large screening programmes, as well as increasing adoption in large provincial hospitals.**

In total, 86 hospitals in China are in the process of procuring TruScreen devices and another 42 hospitals have TruScreen installed either for trial or are acting as reference centres. Twenty hospitals are now commercially using TruScreen's technology.

TruScreen has been involved in three large screening programmes, being conducted by the All-China Federation of Trade Unions, the China Doctors Association and the Shengli Oilfields programs, with over 40,000 women screened so far. Continuation of all three of these programmes has been confirmed for 2017 and the speed of women being screened is expected to increase once TruScreen<sup>2</sup> is introduced.



In December 2016, the launch of TruScreen<sup>2</sup> into China was commenced, with a presentation at the China Obstetrics and Gynaecology Association (COGA) National Congress in Beijing. COGA Deputy Chairs, Professor Zhang Zhenyu and Professor Song Lei, conducted a symposium introducing the new TruScreen<sup>2</sup> device to assembled key opinion leaders and other gynaecologists, and Professor Lui Jun presented on the China Doctors Association program and their support for the use of TruScreen<sup>2</sup> as soon as CFDA model upgrade approval is granted.



TruScreen Nurse and TruScreen CEO Martin Dillon at the Chinese People's Liberation Army General Hospital



## PROFILE: Chinese People's Liberation Army General Hospital, Beijing, China

The Chinese People's Liberation Army General Hospital (PLAGH) is one of the largest and most prestigious hospitals in China. It is well known nationally, not only because of its role of supplying healthcare services to the country's leaders, but also because of its state of the art facilities and highly qualified doctors and nurses. It was one of the first major hospitals in China to adopt the TruScreen device in its gynaecologic department for cervical cancer screening.

The existing screening process relies on the laboratory processing each patient's tests, putting a heavy burden on the hospital's resources. Moreover, as most of the patients are from other parts of the country, the delay in obtaining the laboratory results makes it hard to keep in contact with patients, potentially resulting in serious consequences due to the delayed diagnosis of early abnormalities on the cervix.

In May 2016, TruScreen was installed in a separate examination room within the hospital's outpatient department, with a dedicated nurse now conducting approximately 20 examinations a day.

Feedback on the easy use of the device and instant reporting has been very positive. Doctors have commented that TruScreen makes the management of patients more efficient, removing the need for a second patient visit to the doctor to review the cytology or HPV testing results, and also saves time allowing them to see more patients.

As more doctors realise the benefits TruScreen can offer, its usage in the hospital is expected to further increase. TruScreen's Chinese distributor is now working on the installation of a second device in the hospital to meet the high demand.

# TRUSCREEN THE 'IDEAL SOLUTION' FOR GOVERNMENT FUNDED SCREENING PROGRAMMES

**"It is evident from all our discussions that there is a great need and desire for an objective screening technology such as TruScreen, which can operate in developing countries outside the traditional laboratory infrastructure."  
Martin Dillon, CEO TruScreen**

TruScreen is currently under evaluation by several Governments for use in their public screening programmes, including in Mexico, China and the Philippines. While these evaluations can take many months and involve multiple 'in field' trials, if successful, each would add significant value to our company.

## MEXICO

(approx. 31 million women of screening age)

TruScreen<sup>2</sup> has commenced the official evaluation process for acceptance as an accepted technology for the primary screening of women for cervical cancer by the Ministry of Health in a number of states.

TruScreen<sup>2</sup> has also been undergoing evaluation for inclusion by the Federal Health Secretariat in the National Standard for the Primary Screening of Cervical Cancer. The initial pilot evaluation at the National Cancer Institute (INCAN) in Mexico City is underway, with excellent results, and TruScreen<sup>2</sup> is now undergoing a 300 patient evaluation at the same centre of excellence.

Results from the 'Real World' Clinical Trial performed in Guadalajara, Mexico in 2016, were also positive for TruScreen, with sensitivity almost twice that of the Pap tests, when performed in a real world scenario.

## PHILIPPINES

(approx. 22 million women of screening age)

TruScreen<sup>2</sup> has been selected for inclusion in a screening programme in the province of Pampanga, which commenced in December 2016. This is a pilot project designed to validate TruScreen as the first choice for government funded screening programmes in the Philippines. The aim is that, if successful, TruScreen will be gradually adopted as the preferred device for provincial Government screening programmes in the Philippines.

# NEW AND IMPROVED ALGORITHM ON THE WAY

The TruScreen technology works in two steps – firstly, the TruScreen device collects electrical and optical signals from the cervical tissue. The patient's results are then compared to an extensive database of data from thousands of patients from a wide geographic and ethnic background, with TruScreen's sophisticated algorithm framework distinguishing between normal and abnormal tissue and providing immediate results.

The Algorithm Improvement Programme has been a major focus for TruScreen in the past year.

The company has a target of 80% sensitivity\* and 90% specificity, and continues to work towards this goal.

External clinical evaluation has been planned for 2017 prior to the release of an improved algorithm to the market.

Dr Graham Pulford is the Senior Algorithm Director at TruScreen and has been instrumental in the continual development and refinement of the TruScreen algorithm: "The improvement of the TruScreen cervical tissue classification algorithm is the most exciting project of my career in statistical signal processing algorithm development."



\*Sensitivity is the ability of a test to correctly detect the presence of a particular disease (i.e. the rate of true positives), whilst specificity is the ability of a test to correctly detect the absence of a particular disease (the rate of true negatives).

# PROFESSOR RONALD JONES CNZM RELEASES BEST SELLING BOOK

**Professor Ronald William Jones CNZM, is a Member of TruScreen's Medical Advisory Committee.**

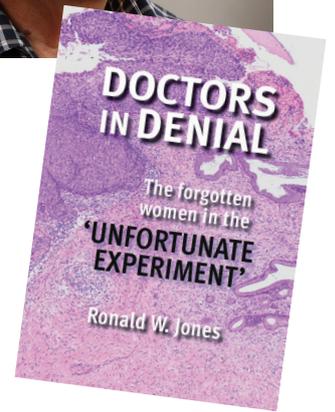
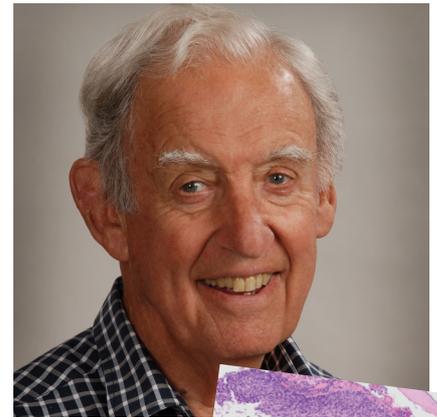
As Principal Investigator for a 1998 study at National Women's Hospital in Auckland, one of the key clinics used to gather early data for what was then the Cervical PolarProbe (and has now evolved into TruScreen), Professor Jones has been involved with the TruScreen technology since the very beginning.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

Professor Jones has recently released his bestselling book "Doctors in Denial: The forgotten women in the 'unfortunate experiment'", about a dark history in cervical cancer study during the 1960s-1980s in the National Women's Hospital in Auckland, New Zealand.

The 'unfortunate experiment' was exposed in 1984 when Professor Jones and his senior colleagues published a scientific paper that exposed the truth and the disastrous outcome of Professor Herbert Green's experiment. In a public enquiry in 1987, Judge Silvia Cartwright observed that an unethical experiment had been carried out in large numbers of women for over 20 years.

Since that time, there have been attempts to cast Green's work in a more generous light. This rewriting of history has spurred Professor Jones to set the record straight by telling his personal story: a story of the unnecessary suffering of countless women, a story of professional arrogance and misplaced loyalties, and a story of doctors in denial of the truth.

*'Doctors in Denial: The forgotten women in the 'Unfortunate Experiment' by Professor Jones is published by Otago University Press ([www.otago.ac.nz/press](http://www.otago.ac.nz/press)).*



TruScreen featured at the National Obstetrics and Gynaecology Conference in Merida, Yucatan, Mexico



TruScreen2 featured at the China National Gynecology Conference - From left: Professor Liu, TruScreen GM Commercial Jerry Tan, TruScreen CEO Martin Dillon, Professor Song, Professor Feng and Professor Chen



TruScreen hosted delegation from Kazakhstan - TruScreen GM Commercial and Clinical Dr Jerry Tan (centre) with delegates from potential Kazakhstani distributor

TruScreen and Khandelwal Laboratories become partners in India - Tom Calder, Trade Commissioner for the Australian Trade Commission in India, Sanjeev Khandelwal, Managing Director of Khandelwal Laboratories Pvt Ltd and TruScreen CEO Martin Dillon

