

NZX/ASX Announcement

20 October 2021

TruScreen device - milestones achieved on growth strategy

Key Highlights

- **TruScreen device - implementing a device firmware upgrade**
- **The upgrade provides further encrypted cybersecurity and automated features, reducing device downtime**
- **TruScreen's distributor in China is now marketing the Company's Made in China device to that country's Health Check sector**
- **TruScreen is successfully evolving its Central and Eastern Europe marketing strategy, and is in the final planning stages for a clinical trial in Poland**
- **TruScreen has completed its annual ISO13485 accreditation surveillance audit**
- **Recent share overhang dissipates, with the sell down by a major shareholder now complete**

TruScreen Group Limited (NZX/ASX:TRU) ('TRU' or 'the Company') is pleased to announce the achievement of key milestones relating to the ongoing development of the Company's women's health care technology and its overseas growth strategy.

TruScreen device receives cyber security-related firmware upgrade

After twelve months of development work, TruScreen has completed verification and validation of a Firmware update that is now progressively being released to TruScreen devices already in the market. The Firmware update enhances the device's cyber security framework. As well as enhancing data security the Firmware update also allows TruScreen devices to more effectively interface with compatible hospitals' systems. It incorporates a state-of-the-art optical calibration feature to reduce the need for the device to return to service centres for re-calibration. This reduced service-related downtime means clients have their devices online for longer time periods, boosting operational efficiencies.

The new Firmware update also includes enhancements to the user interface and battery management features. These were developed in collaboration with the Company's distributors and market feedback, a demonstration of the collaborative nature of the relationship TruScreen has with these crucially important groups.

TruScreen expands addressable market in China

TruScreen has continued to successfully expand in China, its most established market and the world's largest addressable cervical cancer market.

With the launch of the TruScreen Made in China device specifically for the Chinese market, the Company's China distributor Beijing Siweixiangtai (SWXT) has expanded its addressable distribution market. It is now marketing this TruScreen device to the growing Health Check sector. SWXT anticipates the first major project in the private Health Check sector will commence by Q4 CY2021.

This development provides TruScreen with revenue upside, as China's Health Check sector is rapidly growing, aided by support from provincial governments, private organisations, and non-government organisations. Major public hospitals have a separate Health Check department offering a wide range of medical checks, including cervical cancer screening. The Health Check departments in these hospitals provide cervical screenings to twice the number of women as the specialist gynaecological departments within the same hospital, increasing the throughput of usage of the TruScreen cervical cancer screening device.

TruScreen's marketing push into Central and Eastern Europe gains momentum

TruScreen has, at the same time, continued to work on broadening its market access throughout Central and Eastern Europe, with the Company's current focus on Serbia and Poland. The market access strategies in these two countries are now being actively supported by key opinion leader engagement, clinical trials and local clinical evaluation initiatives.

TruScreen is currently in the final planning stages for a clinical trial in Poland, led by a well-known opinion leader in that country. The pilot phase of this trial will screen women in five centres across Poland. The trial's objective is to evaluate the clinical performance of the TruScreen device. TruScreen anticipates the results of the trial will facilitate market access throughout Poland as well as neighbouring countries.

In late October TruScreen training will conclude in Serbia targeting new key opinion leaders and clinicians. The training will enable the commencement of planned local clinical evaluations and facilitate the commencement of early market activities.

Annual ISO13485 accreditation surveillance audit completed

TruScreen has successfully completed a two-day ISO13485 accreditation surveillance audit by its Notified Body TUV SUD at its Sydney facility. The focus of the audit was to review and approve inhouse manufacturing and service of the TruScreen Ultra device in its state-of-the-art facility.

The accreditation audit was approved with minimal non-conformance and a new Quality Management Certificate will be issued for the Company's inhouse manufacturing.

In addition, a remote Technical Documentation review was conducted by TUV SUD renewing the continued use of the CE Mark on the TruScreen cervical cancer screening device.

Recent share overhang dissipates; interim results to be issued late November

The Company confirms that the sell down by a major shareholder, which totalled approximately 20,000,000 shares, is now complete.

The Company currently expects to issue its interim report/half year results on or around 30 November 2021.

TruScreen CEO Juliet Hull said: *"The Firmware enhancements to the TruScreen device reflects well on the commitment of the TruScreen team to better our offering. They also demonstrate our willingness to listen to the needs and desires of our distributors and client base. The result of these endeavours is the delivery of multiple tangible benefits to the TruScreen device via this Firmware upgrade. Device owners will now get an improved cyber security framework, a clear plus to data security. Their devices will additionally also more effectively interface with compatible hospitals' systems together with an efficiency benefit, as their devices will now require less downtime.*

We are equally pleased to see good progress being made in our efforts to grow the Company's global footprint. Our strategic decision to produce a TruScreen Made in China device specifically designed for the China market is gaining traction in China's rapidly growing Health Check sector. At the same time, our well-considered plans to build a presence in Central and Eastern Europe are now happening. We are extremely confident clinicians in this part of Europe will see the many advantages the TruScreen device has over other cervical cancer screening technologies"

-ENDS-



This announcement has been approved for release by the Board.

For more information, visit www.truscreen.com or contact:

Juliet Hull
Chief Executive Officer
juliethull@truscreen.com

Guy Robertson
Chief Financial Officer
guyrobertson@truscreen.com

Investor Relations

Julia Maguire
The Capital Network
+ 61 2 8999 3699
julia@thecapitalnetwork.com.au

About TruScreen:

TruScreen Group Limited (NZX/ASX: TRU) is a New Zealand-based medical device company that has developed a device that can accurately detect precancerous and cancerous cervical cells in real-time via optical and electrical measurements of cervical tissue.

TruScreen's cervical screening technology effectively resolves many of the ongoing issues with conventional Pap tests, including failed samples, poor patient follow-up, patient discomfort and the need for supporting laboratory infrastructure.

The device is CE-marked, meaning it meets EU safety, health and environmental protection standards required for sale and use throughout Europe. It is also National Medical Products Administration approved for sale in China.

TruScreen is currently targeting product sales to a range of low and middle-income countries, including China, Mexico, Africa, Russia and India, where no large-scale cervical cancer screening programs and infrastructure are currently in place. By doing so, the company hopes to help improve the health and wellbeing of women worldwide