

NZX Announcement

26 June 2020

TruScreen Financial Year Ended 31 March 2020 Results

Summary

- Sales down 31% to NZ\$1.3m
- Total revenue down 18% to NZ\$2.55m
- Underlying loss (before non-cash impairment and share-based payments) down 25.7% to NZ\$2.5m
- China remains primary focus, recent entry into Vietnam
- Improvement in operating cash outflow
- Successful capital raise of NZ\$5.243m early in the new year

Cervical cancer screening technology company TruScreen Limited (NZX:TRU) (the Company) has released its audited financial results for the year ended 31 March 2020.

China continued to be Truscreen's primary market of focus with a screening population of ~ 400 million women and share of Truscreen total sales at 60% (2019:55%). Sales were adversely impacted in the final quarter with device roll out suspended due to COVID-19 restrictions.

The approval of the TruScreen cervical cancer screening device by the Ministry of Health of the Vietnam Government and the first product shipment in the new financial year is a further significant milestone for the Company. The Company continues to work with existing distributors in Low-Middle-Income-Countries (LMIC's) in furthering its acceptance in these markets with new opportunities emerging in eastern Europe.

Total income, including a research and development tax offset declined by 18% to NZ\$2.55m (2019: NZ\$3.1m). The Company continued to invest in research and development during the year in enhancing the robustness of its product for LMIC's.

With the uncertainty created by COVID-19 and the potential delay in Truscreen's device roll out programmes a review of the recoverable value of its non-current assets resulted in a non-cash impairment charge of NZ\$2.38m in the current year. This was in addition to the amortisation of intangibles in the amount of NZ\$0.52m (2019: NZ\$0.53m).

Total overhead expenses excluding impairment, amortisation and depreciation costs decreased to NZ\$2.2m for the year (2019: NZ\$2.8m), with the 2020 year also including a NZ\$0.3m non-cash charge for share based payments.

Overall the Company recorded a net loss of approximately NZ\$5.2m (2019: NZ\$3.4m). Underlying operating loss before the non-cash impairment and share-based expenses was NZ\$2.5m (2019: loss NZ\$3.4m).

Net operating cash outflow for the period was lower at NZ\$1.6m (2019: NZ\$2.7m), reflecting an improved underlying trading result and a higher research and development tax offset.



As at 31 March 2020, Truscreen had cash and cash equivalents of NZ\$1.0m (2019: NZ\$1.7 million), and was then successful in raising \$5.243m early in the new financial year with outstanding support from its shareholders.

Operational performance and update

TruScreen's large-scale evaluation programme with China's Obstetrics and Gynaecology Association (COGA) is progressing well, with eight out of the 10 participating provinces already having launched the programme, and 66 hospitals actively screening women. COGA Hunan Province interim TruScreen results of 2,065 women across 7 hospitals showed excellent results. The programme plans to screen up to 20,000 women.

Truscreen has assisted its distributors in establishing technical centres in China, Russia and Vietnam to enable technical support and technical services facilities in these major markets.

Since being granted TruScreen distributor rights in early 2019, our Russian distributor IMS has shown strong support for the TruScreen technology and is making excellent progress. IMS is promoting TruScreen as a primary screening tool, with patients requiring follow up reviews to undergo further tissue sample testings.

Following the inclusion of TruScreen in the cervical cancer Technology Landscape, TruScreen arranged a meeting in Mexico between Unitaids strategy and programme managers, and the National Institute of Cancer (INCan). INCan is a decentralised organisation operating under Mexico's Ministry of Health, providing specialised medical care to cancer patients. INCan is considered to be the governing body of cancer treatment in Mexico. Discussions centred on Mexico's strategy for cervical cancer screening and the value of TruScreen in government-funded and other public health sector screening programmes.

During the year TruScreen's distribution partner, Gorton Health Services, along with the Vietnam's Ministry of Health (MOH) commenced a TruScreen pilot study based at the Hanoi Obstetrics and Gynaecological Hospital (HOGH). The pilot programme's objective was to evaluate the TruScreen technology, prior to a national rollout of the TruScreen device as the primary screening method. Truscreen received approval from MOH early in the new financial year and then secured its first order from HOGH.

The outstanding results from TruScreen's first cervical cancer screening trial in India were announced in January 2020. The trial, conducted by the All India Institute of Medical Sciences (AIIMS) in New Delhi and the town of Ballabgarh over the period January 2018 to February 2019, screened 645 women for cervical cancer. Results of the TruScreen trial have been submitted to the Journal of the Indian Medical Association for publication.

During the year the Company was acknowledged in a joint publication that Unitaids released with the World Health Organisation and the Clinton Health Access Initiative. The report was presented at the 72nd World Health Assembly in Geneva, Switzerland in May 2019. The report is a 'technical landscape' describing the current technologies available for screening for pre-cancerous changes to the cervix. It also focuses on screening and treatment technologies and their advantages for use in low and middle-income countries.

COVID-19 has resulted in a temporary halt to the roll out of TruScreen cervical cancer screening devices in the countries within which we operate at various times. China has at the date of this report recommenced and it is expected that other countries will resume as they are able to control the spread of the virus.

The Company has used the hiatus to improve and strengthen supply chain and quality assurance processes. Given the COVID-19 related slowdown, TruScreen took steps to reduce its cost base to conserve cash and has made application for Government support where appropriate. The Company has relocated its sales and administrative premises at Surry Hills, Sydney, and has consolidated its operations in one location at West Lindfield, in northern Sydney.

Appointments

Truscreen appointed Ms Victoria Potarina as Chief Executive Officer, commencing 2 March 2020.

Ms Potarina brings more than twenty years' commercial experience, previously working at Johnson & Johnson (J&J) in both the UK and across Europe. In addition, she has held positions at multiple multinational companies in the FMCG, over-the-counter, medical devices and healthcare sectors.

While at J&J UK, Ms Potarina was Business Unit Director of the UK and Ireland Diabetes Care Division which comprised of two business units, including; LifeScan, a diagnostic systems manufacturer focusing on the diabetes market specifically blood glucose monitoring systems, and Animas, which specialises in making insulin pumps for diabetes.

Prior to this, she was LifeScan Marketing Director of Eastern Europe, a US\$200 million turnover business. During her time in this position, Ms Potarina successfully facilitated a market share turnaround in Russia and consistent year-on-year double-digit growth in Eastern Europe.

Subsequent to year end the Company appointed Mr Edmond Capcelea as Chief Technology Officer. Mr Capcelea has a Masters Degree in Engineering Physics.

Mr Capcelea's previous roles include Divisional Director Head of Implants and Design Development at Cochlear Limited where he held various positions over eighteen years, and Senior Vice President of Research and Development at Saluda Medical. Mr Capcelea has extensive experience in leading complex R&D projects from concept to commercialisation and has led the end to end product development of a wide range of Medical Devices ranging from Class I to Class III.

Resignations

Mr Robert Hunter (Director) and Mr William Hunter (Alternate Director) resigned on 1 November 2019 and Professor Ronald Jones (Director) resigned on 31 March 2020.

Mr Martin Dillon resigned as Chief Executive Officer on 31 December 2019.

Outlook

In the 2021 financial year Truscreen will continue with its strategy to become the cervical cancer screening method of choice in selected low-and-middle-income countries (LMICs) where conventional laboratory-based methods are not a good fit for purpose.

To deliver on this strategy Truscreen has developed 5 Growth strategy pillars to enable sustainable business growth and return value to our shareholders:

- Efficient roll-out in established core markets.
China is our priority market and we target to double the number of hospitals where TruScreen system will be available for patients. Russia is another large market of focus where our distributor has been implementing best in class educational programmes reaching 2,000 doctors across the country and has prepared a robust plan for further roll-out.

- Relentless focus on product quality and innovation.
Product quality remains an absolute priority. Recently implemented electronic systems of quality assurance control will provide significant efficiency in this area. We are aligned with our customers' (distributor) and our customers customer (the hundreds of doctors and nurses working with the TruScreenUltra) needs, and plan further improvements based on their feedback and requirements for a medical screening device.
- Focus on commercial efficiency.
As a growing company we need to invest to support a significant increase in product sales in 2021. While growing revenues, we will remain focused on improving gross margin through manufacturing efficiency and the benefits of increasing sales volumes.
- Expanding clinical support.
Truscreen and its distributors have invested heavily in clinical trials in a number of countries. Publication of the positive results achieved in these trials in respected medical journals is key to clinical advocacy of the TruScreen cervical cancer screening device. The publication of the study undertaken at the Royal Hospital of Women, Sydney, under our Medical Advisory Committee supervision expected in the 2021 FY will provide support for the accuracy and reliability of our system in a teaching hospital environment. To support our commercial roll-out framework TruScreen will be launching an on-line education program with certification for health care professionals, initially to be piloted in Vietnam. This approach will enable our team to manage complex commercial roll-outs with a need to educate simultaneously many doctors in different countries starting their journey with Truscreen.
- Enhance team capabilities.
TruScreen have a strong and capable team and will add talented professionals with expertise in medical devices & LMICs in line with projected business growth.

- ENDS -

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

TruScreen

Victoria Potarina

Chief Executive Officer

victoriapotarina@truscreen.com

Guy Robertson

Chief Financial Officer

guyrobertson@truscreen.com

About TruScreen:

TruScreen is a Cervical Cancer Screening Device which offers the latest technology in cervical screening, providing real-time, accurate detection of pre-cancerous and cancerous cervical cells to help improve the health and well-being of women around the world. TruScreen's real-time cervical cancer technology utilises a digital wand which is placed on the surface of the cervix to measure electrical and optical signals from the surrounding tissues. A sophisticated proprietary algorithm framework is utilised to detect pre-cancerous change, or cervical intra-epithelial neoplasia (CIN), by optical and electrical measurement of cervical tissue.



TruScreen offers an alternative approach to cervical screening, resolving many of the ongoing issues with Pap tests, including failed samples, poor patient follow-up, patient discomfort and the need for supporting laboratory infrastructures. As such, TruScreen's target market is low- and middle-income countries where no large-scale cervical cancer screening programs and infrastructure are in place, such as China, Mexico, Africa, Russia and India. TruScreen's cervical cancer screening device is CE-marked and certified for use throughout Europe and CFDA-approved for sale in China. The global market potential for TruScreen is significant.

For more information, visit our website at www.truscreen.com

Watch our video on TruScreen: <http://truscreen.com/truscreen-the-company/truscreen-ultra-video/>