



Making further strides

TruScreen (ASX:TRU), a medtech company that is commercialising TRU - a cervical cancer AI enabled detection system - has made significant progress since our initiation report from early March. The company's approach to commercialise the TRU system in developing countries such as China, Mexico, Vietnam, Saudi Arabia and Zimbabwe is continuing and the innovative, disruptive technology is now commercially available in all those countries. However, as we outlined in our initiation report from early March, the company can achieve quicker market access given TRU's 'capital light' nature and lack of existing large-scale cervical cancer screening programs in LMICs (Low-Middle-Income-Countries) along with a desire by governments to change this.

Breakthroughs in key markets

China remains TRU's largest market, accounting for ~65% of its sales in FY23, as well as the one with the highest potential with up to 404m women of screening age. The positive impact of the post-Covid-19 market recovery and endorsement of the technology in the COGA Bue Book (Blue Paper) and inclusion in CSCCP's China Cervical Cancer Screening Guideline has seen TruScreen sales to soar to reported 100% growth in sales over the same quarter year on year and a 73% growth in sales of Single Use Sensor (SUS) for the same period.

TRU has made progress in other markets as well. The company has commenced the commercial operations in the largest private hospital network after the distributor BettaLife has won the tender at the Dr Sulaiman Al-Habib Medical Group. In Zimbabwe, the Ministry of Health collaboration with the National Aids Council screening program in Masvingo Province is continuing with over 14,000 women screened to date. In Poland, TruScreen was listed on the Innovation Register by the Polish Ministry of Health.

Valuation of NZ\$0.065-\$0.133 reiterated

We reiterate our valuation of TRU as outlined in our initiation report - at NZ\$0.065 per share base case and NZ\$0.133 in an optimistic case using a DCF methodology. Our valuation is based on the assumptions of market share growth in its existing and potential geographies. Key risks, as outlined on page 7, include funding risks, regulatory risks, execution risks and technology risks.

Share Price: NZ\$0.024

ASX: TRU

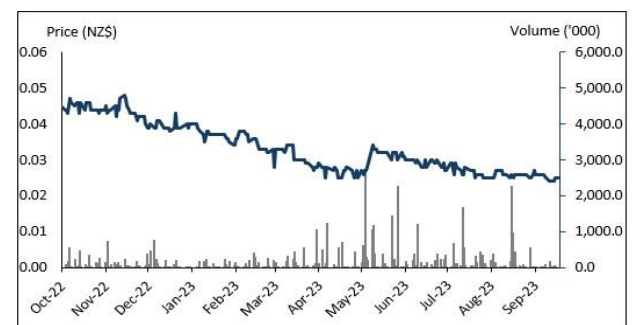
Sector: Healthcare

22 September 2023

Market Cap. (A\$ m)	11.0
# Shares outstanding (m)	459.4
# Share fully diluted (m)	464.4
Market Cap Full. Dil. (A\$m)	11.1
Free Float	88.3%
12-months high/low (A\$)	0.06/0.02
Avg. daily volume ('000)	3,359.6
Website	https://truscreen.com

Source: Company, Pitt Street Research

Share price (A\$) and avg. daily volume (k, r.h.s.)



Source: Refinitiv Eikon, Pitt Street Research

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The TruScreen opportunity

First, we briefly recap the TRU technology and the opportunity before the company. The TRU system is a cervical cancer detection system based on opto-electrical technology and comprises of a console, single use sensor (SOR) and charging station. TRU is designed to detect the presence of pre-cancerous and cancerous tissues in the cervix (Figures 1 and 2) and it does so through low level electrical and optical systems that don't require a tissue sample to be taken.

Figure 1 : TRU system – charging station, console and single use sensor Figure 2: In-box TRU device



Source: Company

TRU has been clinically demonstrated to be equal or superior to existing testing because of its higher accuracy, but also because it requires less medical infrastructure, is less invasive to patients and reduces the chance of cross-infection (Figure 3).

Figure 3: TruScreen's advantages

Feature	Benefit	Clinical Advantage
Real-time results	Immediate feedback to patient and operator	Patient can be treated if necessary at time of visit. Patient not lost to follow-up with delayed reporting
Objective result	Accurate result every time	Reproducible, consistent results to confirm accuracy
No lab facility needed	Greater access to women in remote communities. Easy to use	No qualified cytologists needed. Suitable for remote areas and developing countries. Cost savings in resources / overheads
High sensitivity	Assured level of performance. High standard of cervical screening	Improved ability to detect disease and save lives. Economic savings to global healthcare systems
Automated device and error-checking during examination	Consistent and accurate results	No chance of an unsatisfactory result
Tissue samples NOT collected	No pain or discomfort to the patient	Patient more likely to return for repeat screen

Source: World Health Organisation, Pitt Street Research, Company



TRU has wide application in Low and Middle-Income Countries (LMIC) where women typically lack access to cervical cancer screening.

Consequently, TRU has wide application in Low and Middle-Income Countries (LMICs) where women typically lack access to cervical cancer screening. The TRU system is presently certified for use throughout Europe and has approval for sale in China, Vietnam, Mexico, Russia, Saudi Arabia and Zimbabwe, with China being the company's largest market. There are over 1bn women that are of eligible screening age (25-74). China and India make up ~40% and ~30%, respectively. We also note that China accounts for over 65% of TRU's revenue.

Of the estimated 342,000 deaths from cervical cancer in 2020, about 90% of these occur in LMICs. By detecting cervical cancer earlier, it can be treated. And a system like TRU that requires minimal clinical training or infrastructure can help increase the population that undertakes screening. It follows that patients who undertake screening and are detected will be treated and there is a greater likelihood that they will survive because cases may not have otherwise been detected or detected at too late a stage to treat.

TRU's progress in CY23

CY23 has been a busy year for TRU. The company unveiled several new orders for the TRU device and disposable Single Use Sensors (SUSs) in China, Zimbabwe, Vietnam, Russia and Kazakhstan and Saudi Arabia. The positive impact of the guidelines combined with the post-Covid-19 market recovery has seen TruScreen sales to soar to reported 100% growth in sales over the same quarter year on year and a 73% growth in sales of SUSs for the same period.

Inroads in China

TRU's China's operations are growing and the growth is going to continue. To date, more than 100 devices are installed in hospitals and clinics in 22 provinces and the company grew its users by 14% year on year.

In May, TRU investors received two further pieces of good news that are expected to grow sales in China – in the form of major recognitions. First, it was recognised in a China Blue Paper by COGA (China Obstetrics and Gynaecology Association). In China, Blue Papers are promulgated to act as the definitive position on leading edge developments in all industries in China and are recognised as an endorsement by the leaders in the relevant field. The COGA Blue Paper highlighted TruScreen, describing its origin, substantial clinical trials and the benefits of using TRU as a standalone primary cervical cancer screening method.

Second, TRU was endorsed in the CSCCP's (Chinese Society for Colposcopy and Cervical Pathology) China Cervical Cancer Screening Management Guideline, one of the most important specialist medical clinical guidelines governing management of cervical cancer. This decision was based on the body of evidence supporting TruScreen clinical use world-wide and after extensive consultations with healthcare practitioners and decision makers. The importance of this milestone extends beyond China - this was the first national medical guideline in the world to recommend TRU.

All this good news comes as demand for cervical cancer screening rebounds to pre-COVID levels. China was by no means the only country to witness a decline in cervical cancer screenings, but it persisted for longer given the country's COVID Zero policy. With the policy now a thing of the past, demand is picking up and there is strong potential for TRU to capitalise. Our model



assumes that 160,000 women are screened in China in FY24. This may appear a high number but not too substantial increase from previous years. In FY22, the company screened 10,000 per month (as depicted by SUS usage). Also keep in mind that it still only 0.06% of the TRU's addressable market.

Inroads in other markets

There was good news from other markets too. TRU completed its first clinical evaluation in the Middle East. Private health services provider Dr. Sulaiman Al-Habib Medical Group (DSAMG) completed a screening of 507 women and analysis of the results showed that TRU's sensitivity was 83.3% and specificity was 95%, compared to 83.3% and 98% for the placebo Liquid Based Cytology (LBC) mechanism. This depicts that it is just as effective while providing real time results and resolving many of the issues faced with potential patient follow-up when using LBC. The clinical evaluation manuscript of the study is in submission for publication in the European Journal of Gynaecology. On the back of these positive results, Bettalife, the distributor in the Middle East has won the commercial tender at the DSAMG and commenced commercial operations.

In Vietnam, Gorton Health Services has conducted seven free screening programs in regional provinces benefiting over 1,300 women.

TruScreen has replaced liquid-based cytology as the primary screening method in the leading Hanoi OBGYN hospital. Two major hospitals have received the Ministry of Health approvals for use of the TruScreen technology. An additional 4 hospitals are seeking approvals from MoH to adopt TruScreen as the primary screening method.

The data collected from community screening programs mentioned above, has been utilised in the application to include TruScreen in the Ministry of Health's (MOH) Medical Technique List, paving the way for government health care reimbursements/subsidies. The authorities support the introduction of TruScreen in the region.

In Zimbabwe Masvingo province, the MOH and NAC continue the very successful screening program with over 14,000 women screened to date. In Mexico, TruScreen's distributor, Sunbird Medical has submitted request for access to public hospital system to Cofepris, the national regulator. If the decision is positive, TruScreen would become available to public hospitals and clinics. The Cofepris decision is expected in FY24.

Turning to Europe, TRU has been listed on the Innovation Register by the Polish Ministry of Health. This will increase awareness among specialists and clinicians in Poland. This country has an 'at risk' population of 17.1m and relatively high cervical cancer rates (3,515 cases and 1,858 deaths annually) due to the lack of a national screening or HPV vaccination program.



Our valuation of TRU

We reiterate our valuation of TRU at NZ\$0.065 per share base case and NZ\$0.133 per share bull case. Our valuation is based on assumptions of a continued roll-out of TRU using a market share-based approach. Please see our initiation report for further details on our model.

Figure 4 shows our DCF valuation summary and Figure 5 depicts the share price utilising different WACCs, everything else in our model being equal.

Figure 4: DCF valuation summary

Valuation (NZ\$'000s)	Base case	Bull case
Present value of FCF	7.43	26.20
Present value of Terminal FCF	18.42	30.66
Enterprise Value (NZ\$m)	25.85	56.87
Net debt (cash)	(4.11)	(4.11)
Equity value (NZ\$m)	29.97	60.98
Shares outstanding	459.4	459.4
Implied price (NZ\$ cents)	0.065	0.133
Adjusted Current price (A\$ cents)	0.024	0.024
Upside (%)	171%	454%

Estimates: Pitt Street Research

Figure 5: Target price sensitivity to WACC and terminal growth rate (post discount)

Sensitivity Analysis						
WACC		13.8%	14.8%	15.8%	16.8%	17.8%
Terminal Growth Rate	1.0%	0.077	0.069	0.062	0.056	0.051
	1.5%	0.080	0.071	0.064	0.057	0.052
	2.0%	0.082	0.073	0.065	0.059	0.053
	2.5%	0.085	0.075	0.067	0.060	0.054
	3.0%	0.088	0.077	0.069	0.062	0.055

Estimates: Pitt Street Research



Key risks

We see the following major risks facing TruScreen:

Funding risk. The company will continue to need capital investment as it commercialises its technology. There is the risk that the company may not be able to become self-sustaining with its current cash reserves or that it might need fresh capital and be unable to obtain it. Indeed, our model forecasts that without the NZ\$5m raising in FY24, it will have a negative cash balance at the end of the period.

Regulatory risk. There is a risk that approval timelines in certain markets could delay commercialisation plans.

Execution risk. Our investment thesis assumes TRU's execution all goes according to plan. However, it is possible that TRU's plans could be delayed due to factors outside its control or due to poor decision making by management. This may also impact the R&D progress and funding of its pipeline products.

Technology risk. Another risk is associated TRU is that other companies may commercialise superior products and that these gain market share at TRU's expense. Although TRU's technology is superior to current alternatives, there is room for other companies to enter the industry and capture market share given the inadequacy of existing solutions.



Appendix I – Analyst certification

Nick Sundich, lead analyst on this report, is an equities research analyst at Pitt Street Research.

- Nick obtained a Bachelor of Commerce/Bachelor of Arts from the University of Sydney in 2018. He has also completed the CFA Investment Foundations program.
- He joined Pitt Street Research in January 2022. Previously he worked for over three years as a financial journalist at Stockhead.
- While at university, he worked for a handful of corporate advisory firms.

Stuart Roberts, lead analyst on this report, has been an equities analyst since 2002.

- Stuart obtained a Master of Applied Finance and Investment from the Securities Institute of Australia in 2002. Previously, from the Securities Institute of Australia, he obtained a Certificate of Financial Markets (1994) and a Graduate Diploma in Finance and Investment (1999).
- Stuart joined Southern Cross Equities as an equities analyst in April 2001. From February 2002 to July 2013, his research speciality at Southern Cross Equities and its acquirer, Bell Potter Securities, was Healthcare and Biotechnology. During this time, he covered a variety of established healthcare companies, such as CSL, Cochlear and Resmed, as well as numerous emerging companies. Stuart was a Healthcare and Biotechnology analyst at Baillieu Holst from October 2013 to January 2015.
- After 15 months over 2015–2016 doing Investor Relations for two ASX-listed cancer drug developers, Stuart founded NDF Research in May 2016 to provide issuer-sponsored equity research on ASX-listed Life Sciences companies.
- In July 2016, with Marc Kennis, Stuart co-founded Pitt Street Research Pty Ltd, which provides issuer-sponsored research on ASX-listed companies across the entire market, including Life Sciences companies.
- Since 2018, Stuart has led Pitt Street Research's Resources Sector franchise, spearheading research on both mining and energy companies.

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