PITT STREET RESEARCH

# TruScreen Group Ltd

## Truly promising growth ahead

**Share Price: NZ$0.08**

**NZX: TRU**

**Sector: Healthcare Equipment & Services**

**20 November 2020**

TruScreen Group Ltd (NZX: TRU) provides an opto-electrical technology-based real-time, low cost and portable system for the detection of cancer or pre-cancerous cells in cervical tissues. TRU's disruptive technology is non-invasive for women and provides objective and fast screening, thus providing an efficient alternative to the conventional Pap smear test that requires collection of tissue samples from the cervix. We believe TRU is well-positioned to benefit from the rapid commercial roll-out of its devices in the low-and middle-income countries (LMICs), with a primary focus on China.

### Investment case

Once a device is sold, the single-use-sensors (SUS) ensure recurring revenue prospects for TRU. Further, the company has a co-investment model with its distributors, and this is expected to provide consistent opportunities to expand its operating margins. We believe that as TRU scales up its operations in other major markets, its low-risk strategy will support its bottom-line growth prospects.

### Valuation range of NZ$0.13 – NZ$0.22 per share

We value TRU at NZ$0.13 per share base case and NZ$0.22 in an optimistic case using the DCF methodology, broadly based on the assumptions of market share growth in its existing and potential geographies. Key risks that we see include (1) slower-than-expected growth in China; (2) delay in entering new markets; and (3) lower adoption within new markets.

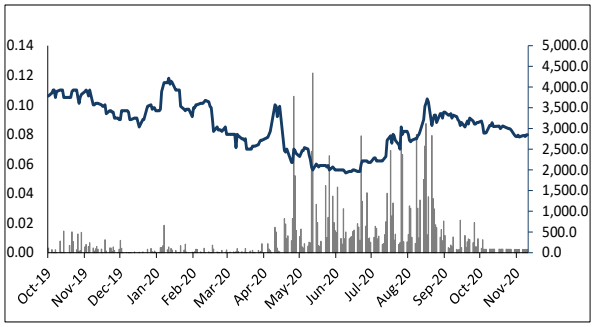
| Year to March (NZ$) | 2019A | 2020A | 2021F | 2022F | 2023F |
|---|---|---|---|---|---|
| Sales (m) | 1.9 | 1.3 | 2.0 | 3.6 | 5.1 |
| EBITDA (m) | (2.5) | (2.3) | (2.2) | (1.9) | (1.1) |
| Net Profit (m) | (3.4) | (5.2) | (2.6) | (2.3) | (1.4) |
| EPS (cents) | (1.6) | (2.3) | (0.7) | (0.6) | (0.4) |
| | | | | | |
| EBITDA Margin (%) | NM | NM | NM | NM | NM |
| RoA (%) | NM | NM | NM | NM | NM |
| | | | | | |
| EV/Sales | 22.6x | 17.6x | 10.3x | 6.5x | 4.9x |
| EV/EBITDA | NM | NM | NM | NM | NM |
| P/E | NM | NM | NM | NM | NM |

*Source: Company, Pitt Street Research*

| | |
|---|---|
| Market Cap. (NZ$ m) | 26.6 |
| # shares outstanding (m) | 332.4 |
| # shares fully diluted (m) | 352.1 |
| Market Cap Ful. Dil. (NZ$ m) | 28.2 |
| Free Float | 88.3% |
| 52-week high/low (NZ$) | 0.14 / 0.05 |
| Avg. 12M daily volume ('1000) | 380.7 |
| Website | www.truscreen.com |

*Source: Company, Pitt Street Research*

**Share price (NZ$) and avg. daily volume (k, r.h.s.)**




*Source: Refinitiv Eikon, Pitt Street Research*

| Valuation metrics | |
|---|---|
| DCF fair valuation range (NZ$) | 0.13 – 0.22 |
| WACC | 8.1% |
| Assumed terminal growth rate | 2.0% |

*Source: Pitt Street Research*

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# TruScreen Group Ltd

| Profit & Loss (NZ$m) | 2019A | 2020A | 2021F | 2022F | 2023F | 2024F | 2025F |
|---|---|---|---|---|---|---|---|
| **Total Revenue** | **1.9** | **1.3** | **2.0** | **3.6** | **5.1** | **7.6** | **9.8** |
| Operating expenses | (4.3) | (3.6) | (4.2) | (5.6) | (6.1) | (6.9) | (7.9) |
| **EBITDA** | **(2.5)** | **(2.3)** | **(2.2)** | **(1.9)** | **(1.1)** | **0.7** | **2.0** |
| Depn & Amort | (0.6) | (0.6) | (0.4) | (0.4) | (0.4) | (0.4) | (0.4) |
| **EBIT** | **(3.0)** | **(2.9)** | **(2.6)** | **(2.3)** | **(1.4)** | **0.4** | **1.5** |
| Net Interest | (0.0) | (0.1) | (0.0) | 0.0 | 0.0 | 0.0 | 0.0 |
| **Profit before tax** | **(3.1)** | **(2.9)** | **(2.6)** | **(2.3)** | **(1.4)** | **0.4** | **1.5** |
| Tax expense | - | - | - | - | - | - | - |
| One-off items | - | (2.4) | - | - | - | - | - |
| **NPAT** | **(3.1)** | **(5.3)** | **(2.6)** | **(2.3)** | **(1.4)** | **0.4** | **1.5** |

| Cash Flow (NZ$m) | 2019A | 2020A | 2021F | 2022F | 2023F | 2024F | 2025F |
|---|---|---|---|---|---|---|---|
| Profit after tax | (3.4) | (5.2) | (2.6) | (2.3) | (1.4) | 0.4 | 1.5 |
| Depreciation | 0.6 | 0.6 | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 |
| Change in trade and other receivables | (0.2) | 0.1 | (0.2) | (0.4) | (0.2) | (0.4) | (0.3) |
| Change in trade payables | 0.0 | (0.1) | 0.1 | 0.2 | 0.1 | 0.2 | 0.1 |
| Other operating activities | 0.3 | 3.0 | (0.1) | (0.3) | (0.2) | (0.4) | (0.3) |
| **Operating cashflow** | **(2.7)** | **(1.6)** | **(2.5)** | **(2.5)** | **(1.3)** | **0.1** | **1.5** |
| Capex | (0.4) | - | (0.1) | (0.2) | (0.3) | (0.4) | (0.5) |
| Other investing activities | - | - | - | - | - | - | - |
| **Investing cashflow** | **(0.4)** | **-** | **(0.1)** | **(0.2)** | **(0.3)** | **(0.4)** | **(0.5)** |
| Dividends | - | - | - | - | - | - | - |
| Equity raised (repurchased) | 3.0 | 1.1 | 7.8 | - | - | - | - |
| Debt drawdown (repaid) | 0.6 | (0.2) | (0.4) | - | - | - | - |
| Other financing activities | - | - | - | - | - | - | - |
| **Financing cashflow** | **3.6** | **0.9** | **7.4** | **-** | **-** | **-** | **-** |
| **Net change in cash** | **0.5** | **(0.8)** | **4.8** | **(2.6)** | **(1.6)** | **(0.3)** | **1.1** |
| Cash at End Period | 1.7 | 1.0 | 5.8 | 3.1 | 1.5 | 1.3 | 2.3 |

| Balance Sheet (NZ$m) | 2019A | 2020A | 2021F | 2022F | 2023F | 2024F | 2025F |
|---|---|---|---|---|---|---|---|
| Cash | 1.7 | 1.0 | 5.8 | 3.1 | 1.5 | 1.3 | 2.3 |
| Total Assets | 12.5 | 8.1 | 12.8 | 10.7 | 9.4 | 9.9 | 11.6 |
| Total Debt | 0.6 | 0.4 | - | - | - | - | - |
| Shareholders' Funds | 11.3 | 7.2 | 12.4 | 10.1 | 8.7 | 9.0 | 10.6 |

| Ratios | 2019A | 2020A | 2021F | 2022F | 2023F | 2024F | 2025F |
|---|---|---|---|---|---|---|---|
| Net Debt/Equity (%) | -9.8% | -8.5% | -46.6% | -30.9% | -17.5% | -13.8% | -21.7% |
| Return on Equity (%) | nm | nm | nm | nm | nm | 4.0% | 14.6% |

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## Introducing TruScreen, ASX: TRU

*TRU device is an opto-electrical, real-time and single-use cervical cancer screening system*

TruScreen Group Ltd (NZX: TRU), established in 2013, is engaged in providing a real-time portable cervical cancer screening system. It is based on an opto-electrical technology, and comprises a unique medical device, algorithm technology and processes designed to detect the presence of pre-cancerous and cancerous tissues in the cervix.

TRU system consists of a hand piece console, charging station and a single-use-sensor (SUS) (Figure 1). TRU's medical device is a digital wand that uses low level electrical and optical signals to detect cancerous and pre-cancerous tissues. The console collects the data and provides instant results, enabling clinicians/physicians to immediately plan appropriate patient care. This has wide application in low- and middle-income countries (LMICs) where women lack access to low-cost cervical cancer screening systems. These devices have been tested on over 40,000 women in 25 studies across 20 countries.

TRU offers a superior alternative to the conventional Pap test, which requires tissue samples from the cervix, patient follow-up and large-scale laboratory infrastructure to process and analyse the tissue samples. This real-time, single-visit and mobile screening technology does not require any high-cost lab infrastructure and can be conducted by a nurse. TRU system is presently certified for use throughout Europe and has approval for sale in China. It has been labelled as the new disruptor in cervical cancer screening globally and offers significant growth opportunity, especially in low-cost economies.

*SUS revenue is likely to be a sustainable and recurring revenue source for TRU*

The company generates revenue by selling consoles and SUS consumables, along with spare parts, to appointed distributors across various countries. Currently, TRU's largest market is China, which constitutes ~60% of total sales. TRU pursues a lean structure and co-investment model with its distributors – in-country sales and marketing activities are managed by distributors, while TRU provides technical support. End users include public and private hospitals and women's health clinics. Given the nature of TRU's business, the key focus is to roll out the screening system rapidly to generate recurring revenue from consumable use. SUS sales revenue is expected to achieve higher growth rate than device revenue. While the device has an expected life of 5–7 years, the SUS is used once per test per patient.

**Figure 1 : TRU system – charging station, console and single use sensor**


**Figure 2: In-box TRU device**

*Source: Company*

## Ten reasons to look at TRU

1. **TRU technology, with a unique position in the cervical cancer screening space, is a better alternative to conventional Pap test** that requires tissue samples from the cervix, patient follow-up and large-scale laboratory infrastructure to process and analyse the tissue samples. Besides being a non-invasive technology, which is more acceptable to women, TRU is an objective, self-checking digital portable system that provides real-time results in a single visit and can be operated with minimal training to the clinician.
2. **The system has been extensively tested,** and results of clinical trials reiterate that the system, with its Artificial Intelligence (AI) algorithm is equivalent or better than the widely used Pap smear test, in terms of cervical cancer detection. The results are free of subjective human judgment required for cellular diagnosis on conventional Pap smears.
3. It enjoys a **competitive edge in the cervical cancer screening space** through its opto-electrical technology for the detection of cancerous cells.
4. **TRU's largest market, China (~60% of total sales) continues to gain further traction** and remains an important commercial opportunity for TRU owing to its largest screening population of over 400 million women. During FY21, TRU aims to double the number of hospitals where the device will be available for patients. It has commenced a large clinical trial project with China's Obstetrics and Gynaecology Association (COGA), with over 6,000 women already screened. The preliminary trial results from COGA's Hunan and Sichuan Provinces have been promising, and COGA targets to complete the 10,000-patient project by end-2020.
5. **TRU portable system requires limited infrastructure and operator training,** making it well-suited for LMICs such as the Middle East, India, Vietnam and Eastern Europe. With a screening population of over 1 billion and ~85% of total cervical cancer deaths of approx. 350,000, LMICs will provide the next set of growth and expansion opportunities to the company.
6. **TRU pursues a co-investment model with local distributors.** It outsources its in-country sales and marketing activities to its distributors. Besides, its distributors invest heavily – along with the company – in clinical trials in numerous countries. Thus, a low-risk and highly scalable growth strategy is deployed by the company in its quest to grow in LMICs.
7. TRU's business model is based on generating revenue through (a) sale of devices and (b) sale of SUS consumables – along with spare parts. **Notably, the SUS revenue is expected to become a sustainable recurring annuity revenue stream** with a higher growth rate than the device revenue as SUS is used once per test per patient.
8. **We believe that the diverse and substantial experience of the current management and board members** will aid the company significantly in its commercialisation journey across multiple countries.
9. **TRU is gearing towards an important milestone of dual listing on ASX,** which will not only broaden its investor base but also add to its market reputation. This can be helpful while targeting new growth markets.
10. **We believe TRU should be valued higher than its current market value.** Our intrinsic value for TRU comes out to be NZ$0.15 in the base case and NZ$0.20 in the optimistic case. We believe re-rating will be driven by efficient commercial roll-out in China and other markets in Asia.

## Disruptive technology in cervical screening – an outcome of ~20 years of rigorous R&D

*PLT took ~20 years of R&D to evolve and refine the TRU technology*

TRU began the development of its system in 1986 when leading professors from Sydney University conceived the idea of a real-time opto-electronic cancer detection system. Polartechnics Ltd (PLT) was an ASX-listed biotech company that acquired TRU technology concept from the University of Sydney in 1987. It took about 20 years of R&D to evolve and refine this technology. After a period of development, the product was first known as Polar Probe, and later TruScreen in 2005.

In 1988, Sydney University and the CSIRO, Australian Government's applied research division, signed a pact to jointly research the concept and develop the algorithm framework. It was in 1989 when the intellectual technology and methodology of utilising both light and electrical impulses to identify different types of cervical tissue was conceptualised and formulated. Four years later, the initial screening devices were functional, and the first clinical trials were initiated in major hospitals in Sydney, London, Manila, Beijing and Singapore under the supervision of the world's leading gynaecologists. Thereafter, the company received the Therapeutic Goods Administration (TGA) approval in 1994 as the registration of core patents began and, in 1995, PLT commenced the global clinical trials. The designs for commercial production of consoles and SUS were finalised in 1999. Notably, PLT was granted the EC Certificate in 2001 (CE Mark). While an OEM manufacturing plant was established in China during 2005, Chinese CFDA registration was completed successfully in 2007, and the company undertook the re-registration of the device for CFDA (now NMPA) purposes. The transition to commercialisation of this technology undertaken by PLT happened over 2007–2009.

*Post the liquidation of PLT, ULFS acquired its assets for A$10,000 in December 2011*

Unfortunately, PLT went into liquidation in 2010 as funding dried up during the global financial crisis. After PLT went bust, Robert Hunter's firm, Ure Lynam Financial Services Pty Limited (ULFS), bought its assets for A$10,000 in December 2011. Notably, Robert Hunter was the former chairman of PLT. Thereafter, ULFS reactivated the ISO13485 certification and CE Mark. In 2013, as part of corporate restructuring, ULFS transferred all of the TRU business assets and operations to a newly incorporated company called TruScreen Pty Limited, a company owned by the same parties that owned ULFS. In late 2013, Truscreen Limited was established after it acquired 100% of the underlying shares of Truscreen Pty Limited, subsequently owning all of the intellectual property, inventory and commercial assets.

In 2016, TRU's Ultra 2, second-generation device was launched with a number of improvements, including increased processing capacity and improved performance through better design and components. Besides a wireless handpiece, the device offered wi-fi connectivity, extended battery life and an LCD touchscreen. The updated AI algorithm was released in 2017 and has been proven to be highly accurate, with a negative predictive value (Specificity) of ~93%[1].

[1] https://truscreen.com/truscreen-the-product/development-history/

## How the technology works

*It uses opto-electric impulses, painlessly transmitted to the cervix via a probe*

TRU system – which primarily consists of three components: the testing hand held device and console unit and the consumable SUS – utilises technology to detect pre-cancerous change, or cervical intraepithelial neoplasia (CIN), by optical and electrical measurements of cervical tissues.

A pen-like wand touches various spots on the cervix to send and receivelow level electrical and optical signals from the cervical tissue. A disposable SUS with precision lens and electrodes is used to interface with the cervix and protect against cross-infection. Unlike conventional Pap cytology, the TRU device does not examine only surface epithelial cells – light at specific frequencies is transmitted through cervical tissue for identifying changes in the basal and stromal layers (Figure 3). This includes increases in blood circulation and variations in blood vessels that occur with pre-cancerous changes. The system also assesses the electrical properties and response of the tissue. The electrical measurements are stimulated by the delivery of a very small impulse (about one volt) in millisecond pulse sequences that repeat 14 times per second. The decay response curve (Figure 4) will vary according to the capacitance of the tissue – a measurement of the ability of the tissue to either hold or dissipate a charge. Decay curves are then compared to distinguish between normal or abnormal tissues.

The TRU system comes with an embedded microcomputer that compares the tissue under observation with an integrated database of known physical tissue characteristics. In order to determine if it is a normal or abnormal (cancerous and pre-cancerous) tissue, a proprietary AI algorithm framework is utilised. In this way, TRU provides on-the-spot results, leading to appropriate patient care.

**Figure 3: TRU consoles emits optical frequencies that refracts through cervical layers and relays back tissue decay readings**

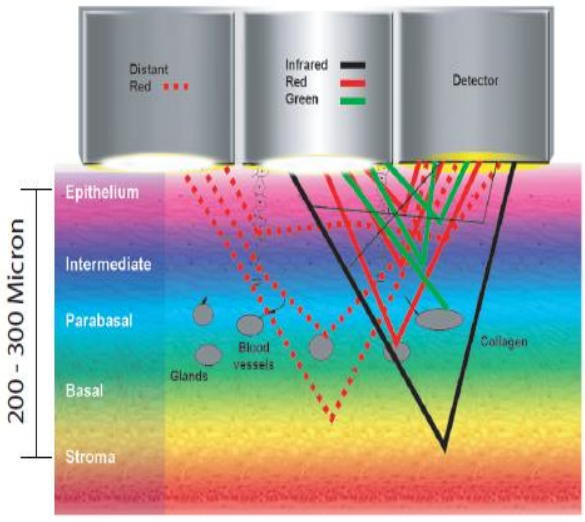
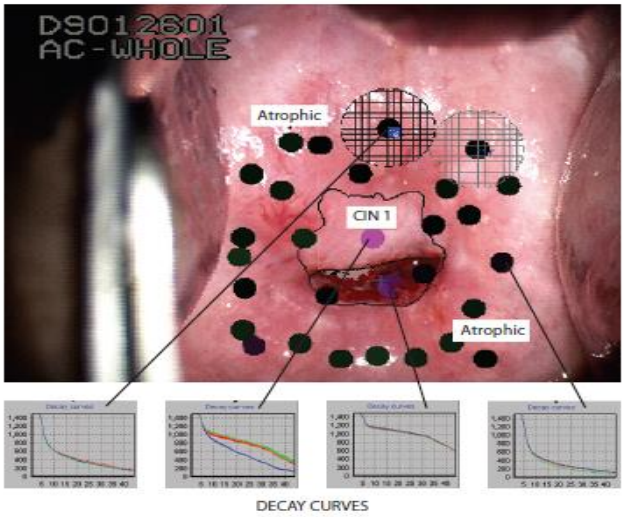



**Figure 4: Electrical decay curves and tissue capacitance**




*Source: Company*

## TruScreen device has multiple advantages over Pap test

*TRU offers a cost-effective system that does not need any established lab infrastructure*

TRU, with a unique position in the cervical screening space, has several benefits over the conventional Pap smear test (Figure 5). The closest competing technologies are cytology-based tests, i.e., conventional Pap smear and liquid-based cytology. In contrast to the Pap test, tissue samples are not collected – which minimises patient discomfort and provides results instantly at the procedure location. Besides, TRU's device is an objective, self-checking digital system that can be utilised with minimal training of the operator and without the need for laboratory infrastructure associated with cytology-based screening. Notably, several clinical trials have been completed worldwide, with the studies reiterating that the overall sensitivity of this device is equivalent or better to that of a Pap smear test.

**Figure 5: Advantage of TRU over traditional PAP smear technology**

| TRUSCREEN | PAP |
|---|---|
| **Patients** | **Patients** |
| Real-time results | Repeat visit |
| Painless | Scraping of cervix |
| Non-invasive | |
| **Clinics** | **Clinics** |
| Objective readings | Widely varying accuracy |
| Minimal training | Human error |
| Cost effective | Labour intensive |
| Single visit | Long wait times (days/weeks/months) |
| Portable | |
| **Technology** | **Technology** |
| No requirement for lab | Vaccines don't cover all HPV types |
| User-friendly | |
| Accurate readings | |

*Source: Company*

## Commercialisation strategy to focus on LMICs

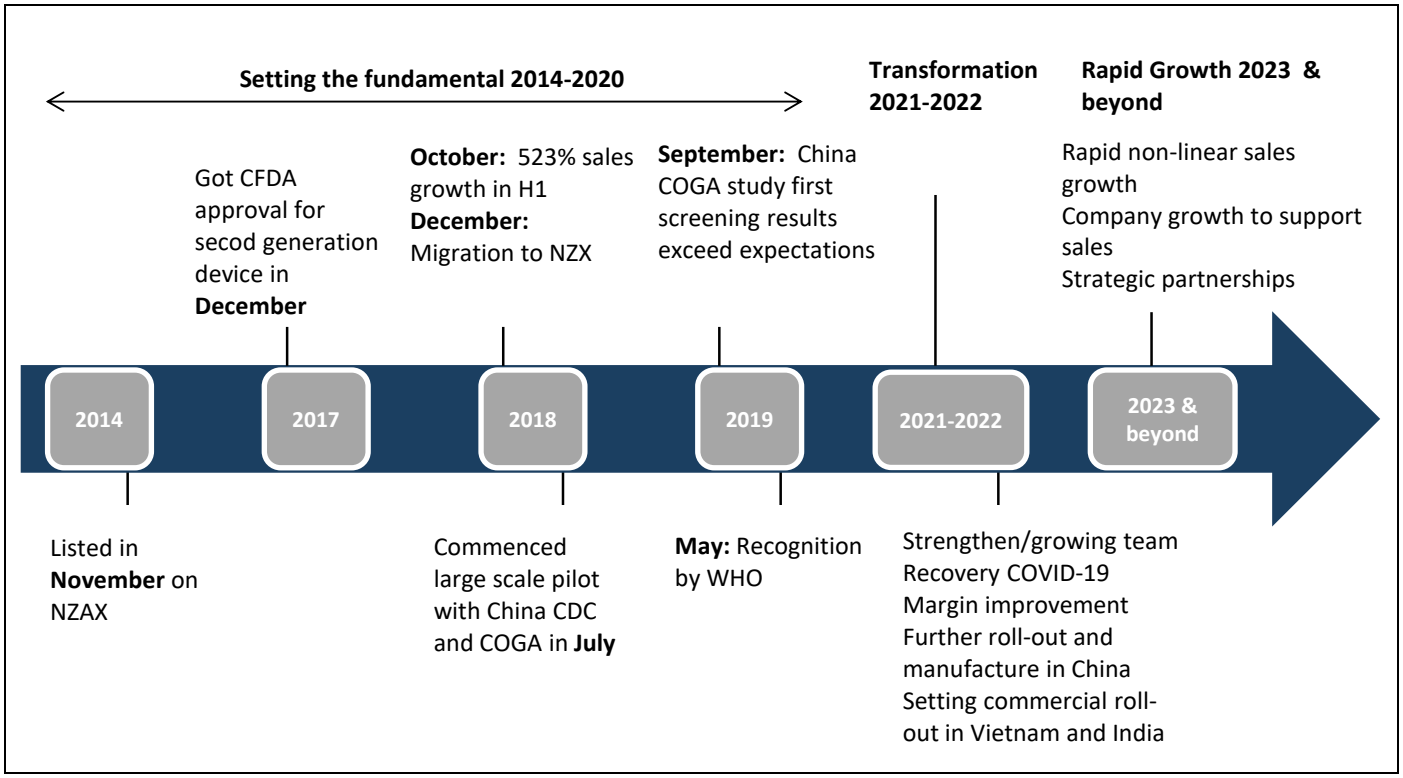
*The optimal commercialisation strategy is to first expand into LMICs*

TRU's technology has an early-mover advantage in the cervical cancer screening space and remains well positioned for commercialisation. The optimal commercialisation strategy is to first expand into LMICs, where no large-scale cervical cancer screening programmes and infrastructure exist (Figure 6). Simultaneously, the company will obtain the academic endorsement of key opinion leaders (KOLs) to assist in the overall global marketing efforts. **The Unitaid/WHO report (released in May 2019 at the World Health Organisation Assembly in Geneva) acknowledged the device's efficacy in screening and treatment technologies, along with the benefits of use in LMICs.**

The marketing strategy is to target both the public and private healthcare sectors for clinical use and the market for population-based screening programmes. The impetus for such programmes are also driven by member nations of the World Health Organisation adopting the WHO's agreed objectives for the elimination of cervical cancer by the end of the century. While these mass screening programmes are primarily funded through government procurement programmes, several countries have significant non-government organisations (NGOs) and corporate-funded screening

programmes. Notably, mass government screening programmes are the key to success for TRU in developing markets. The commercial model solely relies on the appointed distributors who initiate marketing, as well as obtain support from KOLs, government officials and doctors. The distributors have also invested in clinical trials in several countries.

**Figure 6: The commercialisation journey since inception**




*Source: Company*

On one hand, the company aims to maximise device sales in primary target markets, representing those in which TRU has already established commercial activity, such as China and Russia. Notably, China remains an important commercial opportunity for TRU, with the largest screening population in the world. TRU has commenced a large clinical trial project with COGA – with over 6,000 women screened. The preliminary trial results from COGA's Hunan and Sichuan Provinces have performed better or on parity than Pap and LBC, and COGA targets to complete the 10,000-patient project by end-2020.

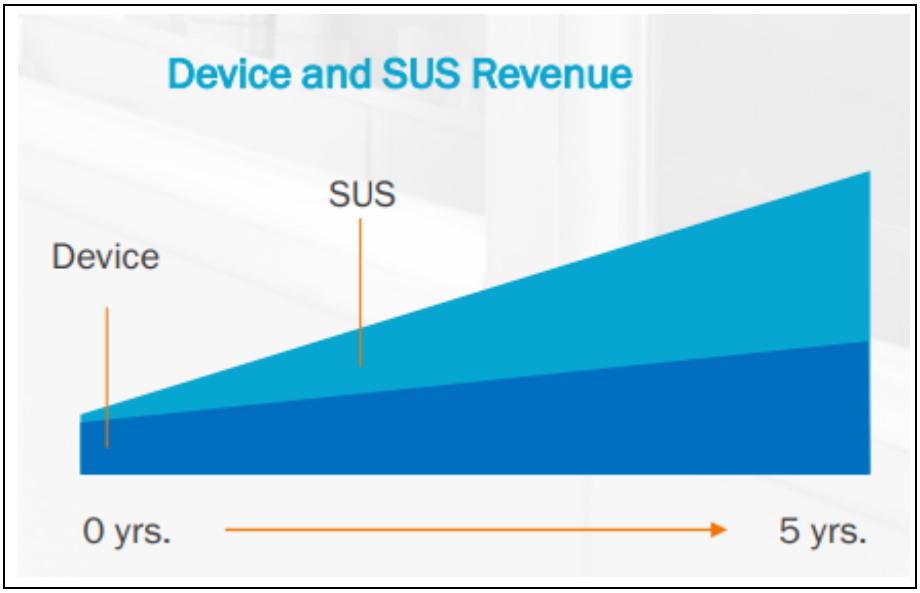
Likewise, in Russia, another large focus market in the early commercialisation stage, the company has zeroed in on healthcare personnel educational programmes to enhance commercial clinics' coverage.

***TRU's particular focus is to drive adoption in Vietnam and prepare roll-out in India***

On the other hand, it is also engaged in the process of building sales in the second phase of target markets, such as, Vietnam, Eastern Europe and Latin America. TRU's particular focus is to roll out the devices in Vietnam, following approval of the Truscreen technology by Vietnams's Ministry of Health, and prepare roll-out in Russia based on successful health care education programs finalised recently by the Russian dedicated distributor IMS. In order to strengthen its market presence in Central and Eastern Europe, TRU has appointed Aspironix, a specialised medical device distributor, to cover three

countries – the Czech Republic, Slovakia and Poland. Given the screening population of about 17.9 million women, TRU – along with Aspironix – would develop a market access plan and have already begun preliminary KOLs engagement for the region. With presence in Eastern Europe, the company expects to commence first commercial sales in H1 2021.

**Figure 7: SUS will provide a recurring and stable revenue for TRU**




*Source: Company*

TRU is expected to develop new markets for its product, with a focus on partnering with global non-government organisations. Besides, the company has zeroed in on the ongoing improvement of device in line with feedback from markets. It also focusses on the implementation of a new quality assurance system, along with the roll-out of new branding across all communication channels. Further, it plans to hire high-profile executives with expertise in medical devices/LMIC markets.

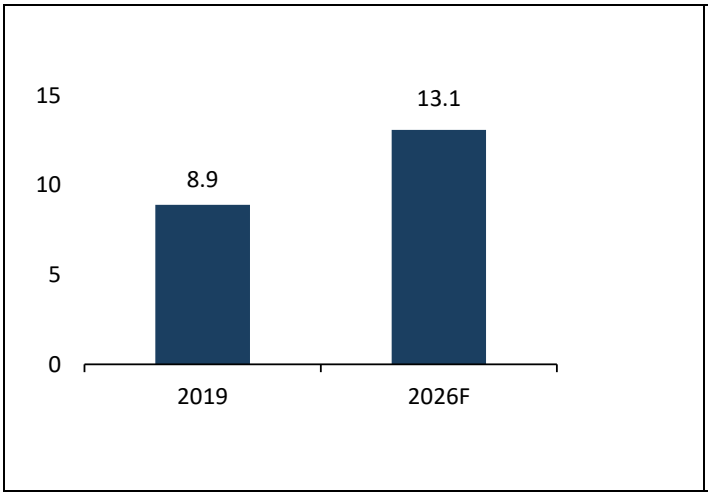
## Significant untapped market potential

In 2019, Zion Market Research valued the global cervical cancer diagnostics market (Figure 8) at ~US$8.9bn, and it is expected to post a 5.7% CAGR to reach ~US$13.1bn by 2026. The Asia Pacific region is likely to witness the highest growth compared with other regions during this period.

***The majority of cervical cancer cases originate in developing regions***

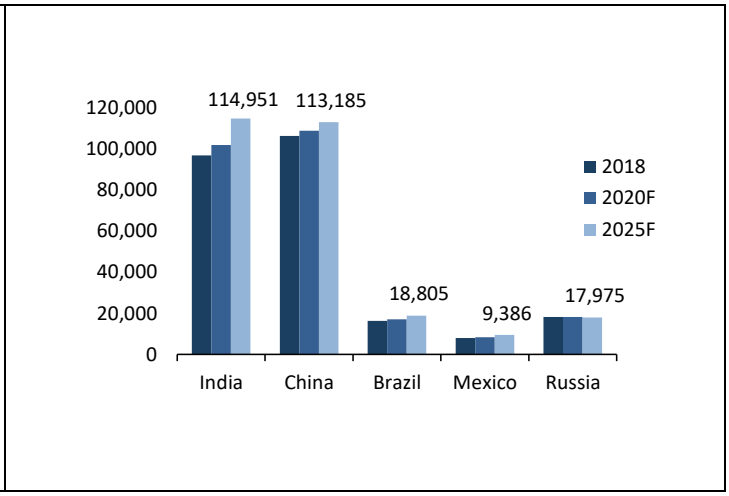
According to the World Health Organization (WHO), cervical cancer is the fourth-most frequent cancer in women globally, and the second-most common cancer in women in developing regions. The global cervical cancer patient population is expected to rise from ~570,000 in 2018 to ~640,000 in 2025 (~2% CAGR) primarily driven by lack of timely screening/diagnosis and lifestyle changes (for instance, growing use of contraceptive pills). The mortality rate of this cancer type is ~55%, with over 300,000 deaths in 2018.

**Figure 8: Global cervical cancer diagnostics market (US$bn)**




*Source: Zion Market Research*

**Figure 9: Cervical cancer patients (key geographies)**

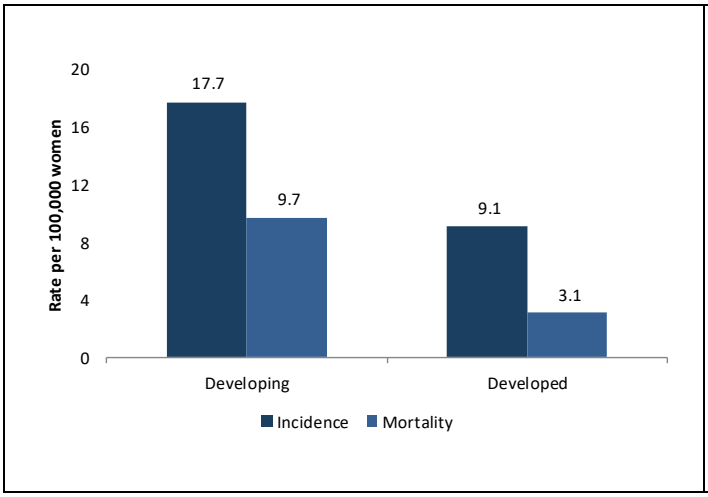



*Source: GLOBOCAN 2018, WHO, IARC*

***China and India are the largest addressable markets in terms of screening population***

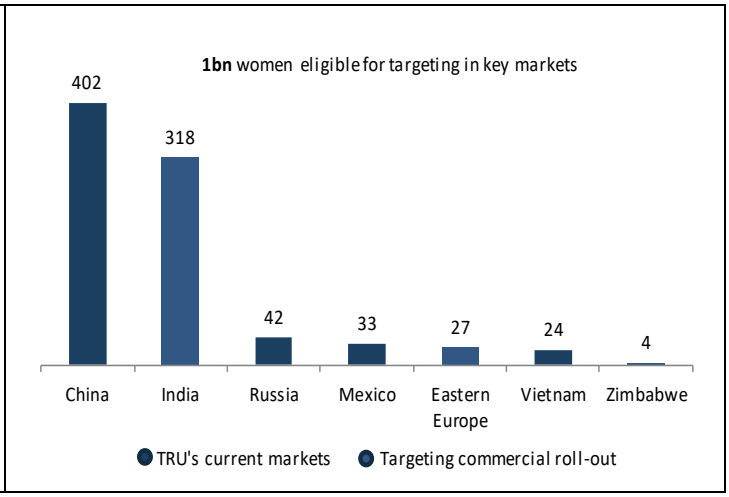
Of the total recorded and mortality cases, ~85% are from low- and middle-income countries. The ideal screening age for women for cervical cancer is 35–44 years and it is estimated that over 1 billion of women in developing regions fall in this category. China and India make up ~40% and ~30%, respectively, of this addressable population. In terms of patient population for cervical cancer (Figure 9), India is expected to surpass China by 2025. Other countries where cases are expected to witness a growing trend include Brazil, Mexico and Argentina. Timely screening allows pre-cancerous lesions to be identified at nascent stages and early treatment is likely to prevent up to 80% of the cases in these countries, which is a significant opportunity for companies such as TRU. The company's equipment does not require any sophisticated laboratory facilities and can be easily accessed by women living in remote areas, which will be a major driving factor of the equipment's usage in developing regions.

**Figure 10: Mortality rate in developing countries is relatively high**




*Source: Market Research Future*

**Figure 11: TRU screening data**




*Source: Company*

TRU's current strategy to focus on China (~60% of total sales in 2020) and future strategy for commercial roll-outs in India, Russia, Middle East and Latin America is in line with the overall direction of market growth for cervical cancer diagnostics.

**Figure 12: TRU screening data**

| Market | Screening population (million) | NGO/KOL engagement | Pilot programme | Distribution/ sales commenced | Number of devices installed |
|---|---|---|---|---|---|
| China | 401 | Yes | Yes | Yes | 68 |
| Mexico | 31 | Yes | Yes | Yes | 15 |
| Russia | 44 | Yes | Yes | Yes | 25 |
| India | 300 | Yes | Yes | No | 0 |
| Zimbabwe | 30 | Yes | Yes | No | 0 |
| Vietnam | 26 | Yes | Yes | No | 6 |

*Source: Company*

## Regulatory scenario in TRU's future markets

TRU is targeting to enter the lucrative markets of India, the Middle East and certain Latin American countries in the next 3–5 years. Globally, screening/diagnostic devices are regulated under the laws relating to medical devices. Most countries adhere to a consistent classification system for medical devices based on risk – for instance, low risk, low-to-moderate risk, moderate-to-high risk and high risk. However, the process for regulatory approvals varies with each country, with developed countries having more stringent but well-defined policies compared with developing countries.

We have provided an overview below of the regulatory framework for medical devices in TRU's future markets which provide an indication of the ease of entry in these countries.

***Regulations in India require presence of local manufacturing or distribution partners***

– **India:** Diagnostic/Screening devices are governed by the Central Drugs Standard Control Organization (CDSCO), an arm of Ministry of Health and Family Welfare, which is largely responsible for pharmaceutical regulations. The regulatory landscape for medical devices is still at a nascent stage as there were no formal guidelines for the manufacture, sale, and export and import of medical devices in India before 2017. Post the introduction of a new medical devices bill (MDR 2017), companies manufacturing or selling devices in India need to have a subsidiary or strategic business partner in the country for regulatory filings and approvals. Further, the Indian government introduced an amendment to the bill in 2020, wherein manufacturers, importers and distributors of any medical device sold in India will have to compulsorily obtain a license. The companies also need to be certified as compliant with ISO-13485 (Medical Devices – Quality Management Systems) before applying for licence registration. The registering entities have to submit all the documents including clinical investigation data, and labelling and instructions for use, for registration and approval while being accountable for conducting clinical investigation post market access.

  Overall, the registration process is relatively simple, particularly for low and moderate risk devices, but it can be time consuming due to lack of

standardised processes and procedural delays by the government for investment approvals. The average timeline for processing of registration applications can range from 45–60 to even 120—180 days. Local partners or distributors, such as the ones that TRU currently has in India, will be helpful in dealing with the regulatory hurdles.

The licenses granted by India under the current regulations are perpetual, meaning that they will continue to be valid unless they are cancelled. But the licensee is required to pay a prescribed retention fee every five years.

Due to the disruption brought by COVID, the company expects the potential roll-out of devices into the Indian market will be delayed.

- **Saudi Arabia:** All medical devices are regulated by the Saudi Food & Drug Authority (SFDA). SFDA introduced the Medical Device Interim Regulations (MDIR) in December 2017, for enhancing its regulatory policies for governing medical devices. The authority follows a risk-based classification system wherein cancer screening devices are classified as moderate risk. As per the regulations, any foreign entity seeking registration and market authorisation in Saudi Arabia is required to appoint an authorised representative (AR), who can be a legal person, an entity or a distributor, to conduct all the legal procedures. The AR has to submit the MA application, along with clinical data (in case of high-risk devices), device labelling, usage guide, promotional materials (both in English and Arabic) and approval/certification in reference markets (in English). This will be then reviewed by SFDA with the help of the Conformity Assessment Body which performs a rigorous technical review of the submitted application. In most of the cases, applications go through multiple rounds of scrutiny, before any recommendations are provided to SFDA for final approval. Post MA, the manufacturer is required to conduct market surveillance and is responsible for the clinical evaluation data.

***Regulatory filings in Saudi Arabia include multiple levels of scrutiny, sometimes involving more than one authority***

***Existing certification in Australia, Canada, Japan, the US or Europe can simplify the process in Saudi Arabia***

While the regulatory process is quite complex in Saudi Arabia, an authorisation or certification in Australia, Canada, Japan, US or Europe can simplify the process in Saudi Arabia. Proof of an existing authorisation in these countries significantly reduces the amount of documentation that has to be submitted. If the company has such proof, it only needs to comply with limited Saudi Arabia-specific requirements, for instance, regarding labelling and instructions for use.

- **United Arab Emirates (UAE):** Being the second largest medical devices market in the Middle East, the UAE government in December 2019, proposed a new federal law with the aim to consolidate and modernise its legal framework. The new law was introduced by the Drug Control Department (DCD) (regulating entity) under the Ministry of Health and is applicable to medicines (both human and veterinary), medical devices and health-related consumer goods. For a global manufacturer to register, import, store and sell medical devices in the UAE, it must establish a subsidiary with an Emirati investor with a 51% share or partner with a distributor, who will act on behalf of the company. The new law allows the marketing authorisation holder (MAH) to appoint one importer and multiple distributors for commercialisation of the products within the UAE; however, it currently does not have a provision for protecting the patents of registered advanced medical devices. The duration of the regulatory process is generally 6–9 months, with license validity of five years for all classes of medical devices, post which the companies have to file for renewal. However, some of the devices with low risk or emergency usage may be eligible for an intermediate importation approval in only

two months. In both the cases, the company has to submit complete application, quality certification, safety information, technical details and any supporting clinical data (if required) for acquiring market authorisation from the DCD.

The new law not only consolidates the pharmaceutical regulatory approval processes but also eliminates the need for multiple authorities to review the applications. That being said, the impact of the new regulations is yet to be fully ascertained as the changes have taken place only from the onset of this year.

We believe that TRU's approach to enter new markets through local partnerships, collaborations or distributors (for instance, Khandelwal Laboratories in India; BettaLife in Saudi Arabia) is a prudent strategy as it minimises the risk of regulatory hurdles as well as the required initial investment.

## Seasoned and diverse management team

The current management and board members of TRU possess substantial and diverse experience which will help the company traverse through its various development stages (Figure 13).

**Figure 13: TRU's management and board members**

| Name and Designation | Profile |
|---|---|
| Victoria Potarina<br>**Chief Executive Officer** | • Has over 20 years of experience in multiple companies in consumer goods and healthcare sectors.<br>• Was previously the Business Unit Director, Europe, at Johnson & Johnson. Before that, she was LifeScan's Marketing Director, Eastern Europe, a US$200m revenue firm.<br>• She completed several post-graduate studies from top universities including London Business School and the Kellogg School of Management, Northwestern University. |
| Edmond Capcelea<br>**Chief Technology Officer** | • Has over 20 years of experience in medical device design and development. He previously held executive roles at Cochlear Ltd and Saluda Medical.<br>• Holds a Master's in Engineering Physics.<br>• Currently leads TRU's technical department and R&D. |
| Guy Robertson<br>**Chief Financial Officer, Company Secretary** | • Is a chartered accountant with 30 years of experience.<br>• Has held several management and leadership positions across a range of industries in Australia and Asia. |
| Anthony (Tony) Ho<br>**Non-executive Chairman** | • Was Chief Financial Officer/Finance Director of a number of listed companies including M.S. McLeod Holdings Ltd, Galore Group Ltd and Edward H O'Brien group of companies.<br>• He serves as chairman of various ASX-listed companies including two life sciences companies, Bioxyne Ltd and Cannasouth Ltd.<br>• Is a member of the Institute of Chartered Accountants in Australia and New Zealand and is a fellow of the Australian Institute of Company Directors, Institute of Chartered Secretaries and Administrators, and Governance Institute of Australia. |

| | |
|---|---|
| Christopher Horn<br>**Non-executive Director** | • Has over 20 years of experience in management roles ranging from corporate advisory and financial services to fund management.<br>• Was previously a partner of KPMG Chartered Accountants.<br>• Is a fellow of the Institute of Chartered Accountants in Australia and New Zealand. |
| John (Chris) Lawrence<br>**Non-executive Director** | • A successful businessman and investor in the life sciences sector, particularly biotechnology businesses.<br>• Has worked in market place distribution roles and transformed new business models into sustainable and profitable ventures. |
| Julliet Hull<br>**Non-executive Director** | • Has more than 20 years' experience working in Asia and Pacific markets in Healthcare, in sales, Marketing and leadership.<br>• Is the NZ General Manager/Country Director for Johnson & Johnson Medical in New Zealand and has held various roles in Johnson & Johnson in Australia and New Zealand since 2012.<br>• Holds an MBA from Macquarie University and Bachelor of Nursing from Auckland University of Technology. |

*Source: Company*

## Valuing TRU

We value TRU based on a DCF approach at NZ$0.13 per share base case and NZ$0.22 per share bull case. Our key assumptions are as follows:

- **Forecast horizon**. Our DCF is built on a 10-year explicit cashflows forecast horizon followed by a terminal value growth rate of 2%.
- **Discount rate**. We assign a discount rate of 8.1% to TRU which we believe is appropriate for the business. In deriving our cost of equity, we calculate a revenue-weighted equity risk premium of approximately 7.0% based on expected revenues to be earned in TRU's operating regions at maturity stage. Embedded within our equity risk premium is a layer of country risk premiums associated with the various markets in which TRU is selling its products.
- **Top-down approach**. We apply a market share-based approach to derive TRU's expected revenues in each of its existing and potential geographical markets. Based on TRU's FY20 realised revenues and estimated sizes of its addressable markets, we back-solve for the company's current market shares in each of its operating regions. Looking forward, we assume these regional market shares will steadily expand as TRU continues to work on building its brand awareness and utility of its SUS and device. Figure 15 shows our expected revenue mix by geography for FY21.
- **Target roll-out markets**. Our modelling assumes TRU will enter the Middle East market and realise its first commercial sales in FY21. Post FY21, we assume the company will roll-out its cervical cancer screening device and technologies to other low-and-middle income nations such as India and some Latin American countries where incidences of cervical cancer are high.
- **Funding**. Post TRU's raise of NZ$5.2M in FY21, our modelling assumes a further equity raise of NZ$3M at NZ$0.09 per share, after which we expect TRU will have sufficient liquidity to sustainably fund its operations going forward. Overall, we expect TRU to achieve bottom line profitability by FY24 (Figure 16).
- **Tax rate**. We assume a corporate tax rate of 30%. As TRU has significant amount of tax losses to carry forward, our base case modelling expects TRU to begin paying its first cash tax in FY29.
- Figure 14 shows our DCF valuation summary.

**Figure 14: DCF valuation summary**

| Base Case Valuation | |
|---|---|
| Present value of FCF | 3.3 |
| Present value of Terminal FCF | 34.3 |
| **Enterprise Value (NZ$M)** | **37.6** |
| | |
| Net debt (cash) | (5.8) |
| Minority interest | - |
| **Equity value (NZ$M)** | **43.4** |
| Share outstanding (M) | 332.4 |
| **Implied price (NZ$)** | **0.13** |
| Current price (NZ$) | 0.08 |
| *Upside (%)* | *63.1%* |

| Bull Case Valuation | |
|---|---|
| Present value of FCF | 15.1 |
| Present value of Terminal FCF | 51.9 |
| **Enterprise Value (NZ$M)** | **67.0** |
| | |
| Net debt (cash) | (5.8) |
| Minority interest | - |
| **Equity value (NZ$M)** | **72.8** |
| Share outstanding (M) | 332.4 |
| **Implied price (NZ$)** | **0.22** |
| Current price (NZ$) | 0.08 |
| *Upside (%)* | *173.6%* |

*Source: Pitt Street Research*

**Figure 15: TRU FY21 revenue split by geography (NZ$m)**

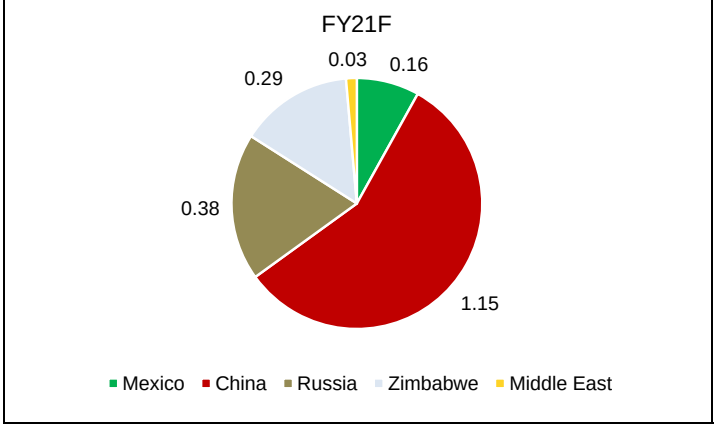
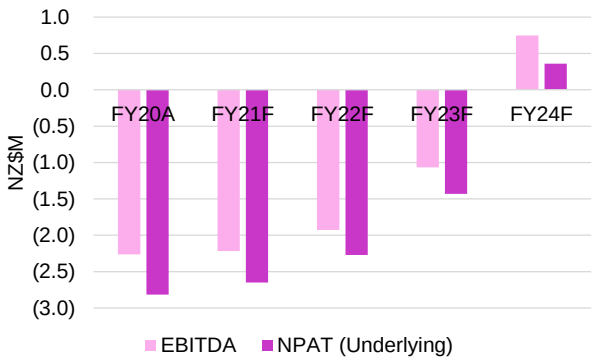



**Figure 16: EBITDA and NPAT, actual and forecasts**




*Source: Company, Pitt Street Research*

## Re-rating TRU

We believe that the current share price of TRU does not reflect its true long-term potential. We foresee TRU being re-rated by the market as it achieves its key near- and medium-term growth milestones.

In the near term, TRU's growth is expected to be driven by China with a number of company initiatives underway. It has commenced a large clinical trial project with COGA and positive results from this trial will bolster the ongoing commercial roll-out in China. TRU has also secured a pilot screening programme with Vietnam's most prestigious government hospital and this can be a springboard for its entry into this market. Further, initiation of a major SUS cost reduction project can enhance gross profit levels and bode well for the TRU stock.

In the medium term, a successful roll-out in India can act as the catalyst for TRU's re-rating. Similarly, positive traction from other target markets such as Brazil and the Middle East will help support the strong top-line growth of this stock.

## Appendix I – Glossary

**Cervical cancer –** Cancer that forms in tissues of the cervix (the organ connecting the uterus and vagina). This is usually a slow-growing cancer that may exhibit symptoms but can be detected through regular tests. Cervical cancer is almost always caused by the human papillomavirus (HPV) infection.

**Cervical Intraepithelial Neoplasia (CIN) –** It refers to a precancerous condition involving the covering layer (epithelium) of the cervix. It can be diagnosed using a microscope. The condition is graded as CIN 1, 2 or 3, according to the thickness of the abnormal epithelium (one-third, two-thirds or the entire thickness).

**Epithelium –** It refers to the covering on internal and external surfaces of the body, including the lining of vessels and other small cavities.

**HPV (Human Papillomavirus)** – Virus spread through skin and sexual contact that is a contributing factor to cervical cancer.

**Liquid-based cytology (LBC)** – A method of screening for precancerous or cancerous changes of the cervix performed by scraping cells from the cervix and rinsing the sampling device into a vial containing a liquid preservative.

**Negative predictive value (of a test) –** The likelihood of not having the disease when the test is negative.

**Pap smear –** A method developed by Dr. George Papanicolaou for screening precancerous or cancerous changes of the cervix performed by scraping cells from the cervix and fixing them on a glass slide. It is also known as conventional cytology.

**Sensitivity –** It refers to the proportion of people who have a condition and are identified correctly by a test (true positives).

**Specificity –** The proportion of people who do not have a condition and are correctly identified by a test (true negatives).

**Spectroscopy –** The study of the effect of light when exposed to cellular tissue including measuring how the tissue reacts by chemical composition and physical properties.

## Appendix II – Capital structure

| Class | In million | % of fully diluted | Note |
|---|---|---|---|
| Ordinary shares | 332.4 | 94.4% | |
| Unlisted options | 19.7 | 5.6% | Average exercise price 14 cents; expiry between July 2021 and August 2022 |
| **Fully diluted shares** | **352.1** | | |

*Source: Company*

## Appendix III – Major shareholders

The company has the following three major shareholders[2]:

- Robert Hunter (10.97%).
- Christopher Lawrence, a Non-executive Director at TRU (6.21%), who holds the stake through Browns Island Holdings Ltd.
- Lorraine Isabel Cole, a Director at Waitara Trustees Ltd (5.16%).

## Appendix IV – TRU's non-patent literature

**Ma et. al (2020),** *Comparison of the detection rate of cervical lesion with TruScreen, LBC test and HPV test: A Real-world study based on population screening of cervical cancer in rural areas of China.* PLoS One, Volume 15, Issue 7, Pages e0233986.

- The paper pertains to a comparative study of the detection rates of cervical lesions with TruScreen, LBC test and HPV test. The study was conducted in China, and a total of 9,972 patients were screened using TruScreen, the HPV test and the LBC test under the National Cervical Cancer Screening Program in Rural Areas (NCCSPRA). The detection rates of the three tests were compared. Based on the comparison, it was found that the HPV test should be the preferred method for cervical cancer screening in rural areas of China, if appropriate laboratories and personnel are available. However, factors such as minimal training requirements, simple operation, real-time results, and no need for invasive sample collection and specialised laboratories or cytologists, make TRU ideal for cervical cancer screening in low-resource regions.

**Salazar et. al (2018),** *Cervicouterine cancer screening – TruScreen vs. conventional cytology: Pilot study.* Journal of Cytology, Volume 35, Issue 3, Pages 143–148.

- The paper pertains to a study conducted (in Mexico and Latin America) to determine the sensitivity and specificity of TruScreen device and compare it with conventional cytology in cervicouterine cancer screenings. During the study, the patients were evaluated with the TruScreen device, conventional cytology, colposcopy and, if necessary, cervical biopsy. The results were analysed using statistics. Sensitivity, specificity, positive predictive value and negative predictive value of TruScreen and other methods were compared, using conventional cytology as the standard. It was seen that TruScreen demonstrated low sensitivity and high specificity when compared with conventional cytology, which had a high negative predictive value. It was concluded that more studies with a higher number of patients (with characteristics similar to those found in the region where the study was conducted) were required to ascertain the true value of TruScreen.

**Yang et. al (2018),** *The diagnostic accuracy of a real-time optoelectronic device in cervical cancer screening: A PRISMA-compliant systematic review and meta-analysis.* Medicine (Baltimore), Volume 97, Issue 29, Pages e11439.

[2] Interests shown are post offer as per https://truscreen.com/wp-content/uploads/2020/11/TruScreen-PDS-November-2020.pdf

– The paper describes a study pertaining to the diagnostic accuracy of the TruScreen device for uterine cervical cancer screening. A pool of databases was searched using medical subject headings (MeSH) and keywords. Title/abstract screening, full text check, data extraction and methodological quality assessment (with the QUADAS-2 tool) were performed by two reviewers independently. The pooled sensitivity, specificity, positive likelihood ratio (PLR), negative likelihood ratio (NLR), diagnostic odds ratio (DOR), the summary receiver operator characteristic curve and the area under the curve (AUC) were analysed using the Meta-DiSc software. Statistical heterogeneity was evaluated by Cochran's Q test, and meta-regression was conducted based on patient type; the possibility of publication bias was evaluated using the Deeks funnel plot in Stata software. Based on these software-based analyses, the diagnostic accuracy of TruScreen device was found to be moderately good. The study findings are based only on Chinese patients and cannot be generalised to other populations.

**Zlatkov et. al (2015),** *Clinical Performance Of Different Methods For Cervical Screening.* Akush Ginekol, Volume 54, Issue 6, Pages 3–9.

– The paper pertains to a study conducted in Bulgaria to compare the clinical performance of cytology and other alternative methods, including TruScreen, for cervical screening. 317 patients were divided into four groups – the first group was screened using cytology, second using visual inspection with acetic acid (VIA), third using visual inspection with Lugol's iodine (VILI) and fourth using spectrophotometric analysis with the TruScreen device. The analysis of results concluded that cytology remains the most appropriate method for cervical cancer screening. In the absence of appropriate laboratory infrastructure or trained cytopathologists, spectrophotometric analysis with TruScreen can be used for primary cervical screening. Its main advantages lie in its user friendliness and capability to produce real-time results.

**Ozgu et. al (2015),** *Efficacy of a real time optoelectronic device (TruScreen) in detecting cervical intraepithelial pathologies: a prospective observational study.* Department of Gynecologic Oncology, Zekai Tahir Burak Women Health Education and Research Hospital, Ankara, Turkey, Volume 16, Issue 1, Pages 41–4.

– The paper details a study conducted in Turkey to assess the effect of the TruScreen technology in improving the sensitivity of cervical screening programmes, either alone or in combination with pap smear or HPV DNA screening. 285 patients with abnormal pap screening results were again reviewed using TruScreen and the HPV test. Consistency and differences between the tests were compared with cervical biopsy results. Based on the comparison, it was concluded that TruScreen could be used as a primary method for cervical cancer screening, especially in the absence of trained professionals and well-equipped laboratories. These advantages make it more relevant in countries with a low socioeconomic status. However, it was also concluded that the combination of TruScreen and HPV screening did not demonstrate a significant rise in the effectiveness of screening.

**Du et. al (2015),** *Diagnostic value of TruScreen in cervical lesions screening.* Zhonghua Yi Xue Za Zhi, Volume 95, Issue 29, Pages 2379–2381.

– The paper describes a study conducted to investigate the diagnostic value of TruScreen as a novel option for screening of cervical lesions. A total of 218 patients were screened using TruScreen and the high-risk human papillomavirus (Hr-HPV) test, and the diagnostic efficacy of the tests was compared with histopathology as the standard for diagnosis. Based on the results obtained, it was noticed that Hr-HPV test shows higher sensitivity while TruScreen shows higher specificity for cervical lesions screening. It was concluded that more studies, with larger sample sizes, will be required to accurately ascertain which method is a better triage tool.

## Appendix V – TRU's intellectual property

**US 6,723,049,** *Apparatus for tissue type recognition using multiple measurement techniques,* priority date 15 June 2001, invented by Victor Nickolaevich Skladnev, Christopher Kingsley Blunsden and Rita Stella.

– The patent discloses a system and a device for recognising tissue types. The device is used to apply electrical signals to the tissue via electrodes. Included circuitry and the signal processor are used to measure the impedance magnitude and phase at various pre-decided frequencies. The phase information observed at these frequencies is compared with phase information obtained from known tissue types. Based on the comparison, the tissue is categorised into one of the known types. The device is typically used for detection of cancerous or pre-cancerous tissues, especially those seen in cervical cancer.
– Applications for the patent were filed in Australia, the US and Europe, and were granted in the US and Australia.
– The US patent received a patent term extension of 111 days and is due to expire on October 03, 2022.

## Appendix VI – Comparable companies

| Company | Location | Code | Market Cap (US$m) | Website |
|---|---|---|---|---|
| Immunovia AB | Lund, Sweden | OM: IMMNOV | 668 | www.immunovia.com |
| Telix Pharmaceuticals | Melbourne, Australia | ASX: TLX | 302 | telixpharma.com |
| VolitionRx Ltd | Austin, TX | AMEX: VNRX | 149 | www.volition.com |
| Epigenomics AG | Berlin, Germany | XTRA: ECX | 129 | www.epigenomics.com |
| ANGLE Plc | Guildford, UK | AIM: AGL | 119 | www.angleplc.com |
| PAVmed Inc | New York, NY | NasdaqCM: PAVM | 88 | www.pavmed.com |
| OncoCyte Corp | Irvine, CA | AMEX: OCX | 96 | www.oncocyte.com |
| MDxHealth SA | Herstal, Belgium | ENXTBR: MDXH | 82 | www.mdxhealth.com |
| Celcuity Inc | Minneapolis, MN | NasdaqCM: CELC | 62 | www.celcuity.com |
| Imagion Biosystems | San Diego, CA | ASX: IBX | 54 | imagionbiosystems.com |
| Rhythm Biosciences | Parkville, Australia | ASX: RHY | 36 | www.rhythmbio.com |
| Check-Cap Ltd | Isfiya, Israel | NasdaqCM: CHEK | 16 | www.check-cap.com |
| SciBase Holding AB | Stockholm, Sweden | OM: SCIB | 16 | www.scibase.com |
| Izotropic Corp | Surrey, Canada | CNSX: IZO | 14 | www.izocorp.com |
| Guided Therapeutics Inc | Norcross, GA | OTCPK: GTHP | 5 | www.guidedinc.com |
| Imagin Medical Inc | Vancouver, Canada | CNSX: IME | 4 | www.imaginmedical.com |
| TruScreen Group Ltd | Auckland, New Zealand | NZSE: TRU | 19 | www.truscreen.com |

*Source: Pitt Street Research, S&P Capital IQ; Market data as of 30 September 2020*

**Immunovia AB.** A molecular diagnostics company that develops and commercialises diagnostic tools for cancer and autoimmune diseases in Sweden and internationally. The company offers IMMray PanCan-d, a blood-based test for the detection of pancreatic cancer. The company's IMMray technology is an antibody microarray platform that can detect cancer from a blood test by surveying the various immunoregulatory proteins that would be associated with it.

**Telix Pharmaceuticals.** An oncology company that develops molecularly targeted radiation products for unmet needs in cancer care. It has assembled a portfolio of molecularly targeted radiation (MTR) therapeutic and imaging products for three different cancers. The company has a strategic collaboration with RefleXion Medical for the treatment of high-risk cancers.

**VolitionRx Ltd.** An epigenetics company that engages in the development of blood tests to help diagnose a range of cancers and other diseases worldwide. The technology allows the DNA signature of cancer to be detected in circulating nucleosomes. The company develops blood-based Nu.Q immunoassays to detect specific biomarkers.

**Epigenomics AG.** This is a cancer molecular diagnostics company that develops and commercialises blood-based diagnostic tests across multiple

cancer indications with high medical needs in Europe, North America, Asia and internationally. In addition, the company engages in the identification of biomarker opportunities for various cancers, such as bladder cancer.

**ANGLE Plc.** It develops and commercialises Parsortix cell separation system, which captures and harvests circulating tumour cells in the cancer patient's blood; and Ziplex multiplex analysis system that is used with the ovarian cancer clinical application.

**PAVmed Inc.** The company's lead product pipeline includes CarpX (a percutaneous device to treat carpal tunnel syndrome), EsoCheck (non-invasive cell collection device) and DNA biomarkers to detect oesophageal cancer precursors.

**OncoCyte Corp.** The firm engages in the development and commercialisation of non-invasive blood-based diagnostic tests for the early detection of cancer. This company's technology uses gene expression patterns associated with embryonic stem cell development to search for cancer genes in cancer tissues obtained from the blood or urine.

**MDxHealth SA.** The company develops and commercialises epigenetic and other molecular tests for cancer assessment and personalised treatment of patients.

**Celcuity Inc.** A cellular analysis company which discovers cancer sub-types and commercialises diagnostic tests to enhance the clinical outcomes of cancer patients treated with targeted therapies in the US. This company's CELx platform uses cultured cells from patient tumours and analyses them for the activity of various aberrant signalling pathways indicative of cancer.

**Imagion Biosystems.** The firm provides medical imaging technologies to detect and eliminate cancer. It has activities in nanotechnology; biotechnology; cancer diagnostics; and superparamagnetic relaxometry. The company engages in the research and development of its MagSense system to detect HER2 breast cancers.

**Rhythm Biosciences.** This company's proposed ColoSTAT blood test has the potential to efficiently detect colorectal cancer at all stages, including the early ones. ColoSTAT is the first proposed product-in-development for Rhythm Biosciences.

**Check-Cap Ltd.** A clinical stage medical diagnostics company that is developing a capsule-based system which utilises low-dose X-rays for screening of the colon to detect polyps, masses and colorectal cancers in Israel. Its patented technology is the first and only patient-friendly, preparation-free test designed to detect polyps before they may transform into cancer.

**SciBase Holding AB.** A medical technology company that develops and sells instruments for detection of skin cancer and other skin conditions, in Europe and internationally. The company offers Nevisense, a point-of-care detection device for non-visual detection of malignant melanoma.

**IzoTropic Corp.** This research and development company commercialises diagnostic products for breast cancer. It has developed a next-generation 3-D breast CT imaging technology for early diagnosis of breast cancer.

**Guided Therapeutics Inc.** It currently focuses on the commercialisation of LuViva, a non-invasive cervical cancer detection device that identifies cervical cancers and pre-cancers painlessly, non-invasively and at point of care.

**Imagin Medical Inc.** This surgical imaging company focuses on advancing new methods of visualising cancer during minimally invasive procedures. Its i/Blue Imaging System with its proprietary optics and light sensors enhances the

efficiency and accuracy of detecting cancer for removal, helping to reduce recurrence rates. The company's focus is on bladder cancer.

## Appendix VII – Analyst Qualifications

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.

Cheng Ge is an equities research analyst at Pitt Street Research.

- Cheng obtained a B.Com in Finance and LL.B from University of New South Wales, in 2013, and has passed all three levels of the CFA Program.
- Prior to joining Pitt Street Research, he has worked for several financial services firms in Sydney, where his focus was on financial advice.
- He joined Pitt Street Research in January 2020.

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