

## Information for Australian Investors

### Important notice

This document contains additional information for Australian investors (**Additional Information for Australian Investors**) and accompanies the attached New Zealand product disclosure statement (**New Zealand PDS**)<sup>1</sup> for the invitation to apply for fully paid ordinary shares (**Offer Shares**) in TruScreen Group Limited (**TruScreen** or **Company**), in its public offering to investors in Australia and New Zealand<sup>2</sup> (**Offer**) in conjunction with its proposed listing on the Australian Securities Exchange (**ASX**) as an ASX Foreign Exempt Listing.

The New Zealand PDS was lodged on 10 November 2020 and should be read together with the information uploaded in relation to the Company and the Offer onto the electronic disclose register administered by the Registrar of Financial Service Providers and the New Zealand Companies Office (**Offer Register**) which is available at <https://www.companiesoffice.govt.nz/disclose>, offer number OFR12990.

You should read all of the New Zealand PDS, the entries uploaded by the Company on the Offer Register and this Additional Information for Australian Investors before deciding whether or not to purchase Offer Shares.

#### 1. Offer to Australian investors

The Offer is open generally to investors in New Zealand and Australia. The Offer in Australia (**Australian Offer**) consists of an invitation to investors that are Australian residents to apply for Offer Shares (**Australian investors**).

For further details, refer to Section 5 (Terms of the offer) of the New Zealand PDS.

#### 2. New Zealand PDS

The Australian Offer is being made in Australia under the New Zealand PDS by relying on the trans-Tasman mutual recognition scheme in Chapter 8 of the *Corporations Act 2001* (Cth) (**Corporations Act**) and the *Corporations Regulations 2001* (Cth) (**Corporations Regulations**).

This Additional Information for Australian Investors contains disclosure relevant to Australian investors to comply with requirements for a 'recognised offer' under Chapter 8 of the Corporations Act and the Corporations Regulations and the requirements of the ASX Listing Rules.

The New Zealand PDS has been prepared to comply with New Zealand regulatory requirements, which differ in some respects from Australian regulatory requirements for an offer of shares. The New Zealand PDS and this Additional Information for Australian Investors are not, and do not purport to be, a prospectus or document containing disclosure to investors for the purposes of, and do not contain all information that would be required for a prospectus, disclosure document or product disclosure statement, under Part 6D.2 or Part 7.9 of the Corporations Act.

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<sup>1</sup> The New Zealand PDS contains the application form for the Offer.

<sup>2</sup> The Offer is for an invitation to apply for up to 21,428,571 Offer Shares in TruScreen (representing 6.1% of the total Shares on issue immediately following the Offer). The Offer price is NZ\$0.07 or AUD \$0.65 per Offer Share. The Board of TruScreen has the discretion to accept oversubscriptions up to NZ\$500,000 or a further 7,142,857 shares. The maximum number of Offer Shares is 28,571,428 shares.

If you are in Australia, you may obtain a copy of the New Zealand PDS online at <https://www.companiesoffice.govt.nz/disclose>, offer number OFR12990 or by contacting the Share Registrar (email [applications@linkmarketservices.com](mailto:applications@linkmarketservices.com) or phone +64 9375 5998. A copy of the Company's constitution is also available, free of charge, on request made to the Company Secretary at [guyrobertson@truscreen.com](mailto:guyrobertson@truscreen.com).

### **3. Important information for Australian investors**

The following warning statements are required to be included in this document by Chapter 8 of the Corporations Act and the Corporations Regulations.

The Offer to Australian investors is a recognised offer made under Australian and New Zealand law. In Australia, this is Chapter 8 of the Corporations Act and the Corporations Regulations. In New Zealand, this is subpart 6 of Part 9 of the Financial Markets Conduct Act 2013 of New Zealand and the Financial Markets Conduct Regulations 2014 of New Zealand.

The Offer and the content of the New Zealand PDS are governed by New Zealand, rather than Australian, law. In the main, the Financial Markets Conduct Act 2013 of New Zealand and the Financial Markets Conduct Regulations 2014 of New Zealand set out how the Offer must be made.

There are differences in how securities and financial products are regulated under New Zealand, as opposed to Australian, law. For example, the disclosure of fees for managed investment schemes is different under New Zealand law.

The rights, remedies and compensation arrangements available to Australian investors in New Zealand securities and financial products may differ from the rights, remedies and compensation arrangements for Australian securities and financial products.

Both the Australian and New Zealand securities regulators have enforcement responsibilities in relation to this Offer. If you need to make a complaint about the Offer, please contact the Australian Securities and Investments Commission (**ASIC**). The Australian and New Zealand regulators will work together to settle your complaint.

The taxation treatment of New Zealand securities and financial products is not the same as that for Australian securities and products.

If you are uncertain about whether this investment is appropriate for you, you should seek the advice of an appropriately qualified financial adviser.

The Offer involves currency exchange risk. The currency for the security or financial product is in dollars that are not Australian dollars. The value of the security or financial product will go up and down according to changes in the exchange rate between those dollars and Australian dollars. These changes may be significant.

If you receive any payments in relation to the security or financial product that are not in Australian dollars, you may incur significant fees in having the funds credited to a bank account in Australia in Australian dollars.

If the security or financial product is able to be traded on a financial market and you wish to trade the security or financial product through that market, you will have to make arrangements for a participant in that market to sell the security or financial product on your behalf. If the financial market is a foreign market that is not licensed in Australia (such as a securities market operated by NZX Limited (**NZX**)) the way in which the market operates, the regulation of participants in that market and the information available to you about the security or financial product and trading may differ from Australian licensed markets.

#### **4. Australian Securities and Investments Commission**

Copies of the New Zealand PDS (accompanied by this Additional Information for Australian Investors) were lodged with ASIC on 10 November 2020. ASIC accepts no responsibility for the contents of the New Zealand PDS or this Additional Information for Australian Investors or the merits of the investment to which the New Zealand PDS and this Additional Information for Australian Investors relate.

#### **5. Stock exchange listings**

The Company is listed, and its Shares are quoted, on the NZX Main Board. The Company's NZX ticker code is 'TRU'.

Application has been made to NZX for permission to quote the Offer Shares on the NZX Main Board and all the requirements of NZX relating thereto that can be complied with on or before the date of this Additional Information for Australian Investors have been duly complied with. However, NZX accepts no responsibility for any statement in this Additional Information for Australian Investors. The NZX Main Board is a licensed market operated by NZX Limited, which is a licensed exchange, regulated under the Financial Markets Conduct Act 2013.

Application has also been made to ASX for permission to list the Company as a Foreign Exempt Listing and to quote the Offer Shares on ASX. The Company's ASX code will, if quoted, be 'TRU'. If the Company is admitted to ASX's official list as a Foreign Exempt Listing, it will still need to comply with the NZX Main Board Listing Rules (other than as waived by NZX), but will not need to comply with the vast majority of the ASX Listing Rule obligations. Rather, the Company will need to comply only with the rules specified in ASX Listing Rule 1.15 which are relatively procedural in nature. The Company will not be subject to substantive ASX Listing Rule requirements such as the rules on continuous disclosure, periodic reporting, shareholder approval of share issuances, escrow, transactions with persons of influence and significant transactions.

ASX takes no responsibility for the contents of the New Zealand PDS or the Additional Information for Australian Investors or for the merits of the investment to which the New Zealand PDS and the Additional Information for Australian Investors relate. Admission to the official list of ASX and quotation of the Offer Shares on ASX are not guaranteed and are not to be taken as an indication of the merits, or as an endorsement by ASX, of the Company or the Offer Shares.

#### **6. Continuous disclosure**

As noted above, the Company will not be required to comply with the continuous disclosure provisions of the ASX Listing Rules if it is admitted to the official list of ASX as a Foreign Exempt Listing. Accordingly, the Company will only need to comply with the continuous disclosure rules of the NZX Main Board Listing Rules (including as modified by any waivers, rulings or exemptions applicable to the Company or the Offer Shares). Broadly, the NZX Main Board Listing Rules require that the Company immediately release to the NZX any material information (being information that a reasonable person would expect, if it were generally available to the market, to have a material effect on the price of the Company's securities and is information that relates to the Company or its securities) it is aware of. There are exceptions to the requirement to disclose for certain information. However, for the exceptions to apply the information must be confidential and confidentiality must be maintained. There are a number of other requirements that also must be met for the exceptions to apply.

All information provided to NZX and ASX in accordance with the NZX Main Board Listing Rules and the ASX Listing Rules will be available on the NZX and ASX websites and on the Company's website.

For more information in relation to the Company's continuous disclosure guidelines, refer to the Company's market disclosure policy which is available on TruScreen's website: <http://truscreen.com/investor-centre/corporate-governance/>.

## **7. Risks**

You should refer to the information set out in Section 8 (Risks to TruScreen's business and plans) of the New Zealand PDS and the risks included on the Offer Register.

There are risks that are common to all investments in shares generally, there are risks that are specific to an investment in Offer Shares and there are risks that are specific to the Company and its operations. The risks described below do not purport to be a comprehensive statement of the risks associated with investing in Offer Shares. You should refer to the information set out in Section 8 of the New Zealand PDS for a more extensive list of risks applicable to all investors who choose to invest in Offer Shares.

### **(a) *Liquidity and realisation risk***

There can be no assurance that an active trading market in Offer Shares will develop or that the price of Offer Shares will increase. The risk may be exacerbated for you if you wish to trade your Offer Shares on ASX. As the Company's primary listing is on the NZX Main Board and its Shares are initially expected to be predominantly traded on the NZX, the volume of Shares traded on ASX might be particularly low.

### **(b) *Foreign exchange risk***

If the Company pays dividends, it may do so in New Zealand dollars. Accordingly, you may be exposed to foreign exchange risk for the conversion of dividends to Australian dollars and may incur significant fees in having the funds credited to a bank account in Australia in Australian dollars.

## **8. Selling restrictions**

Neither the New Zealand PDS nor this Additional Information for Australian Investors constitutes an offer for the issue of Offer Shares or an invitation in any place in which, or to any person to whom, it would be unlawful to make such an offer or invitation. Refer to the information under Section 5 (Terms of the offer) of the New Zealand PDS for more information on selling restrictions.

Each successful Applicant under the Australian Offer may be required to make certain representations, warranties and covenants as set out in the Application Form for the Australian Offer accompanying the New Zealand PDS.

## **9. This is not investment advice. You should seek your own financial advice**

The information provided in the New Zealand PDS and this Additional Information for Australian Investors is not financial product advice and has been prepared without taking into account the investment objectives, financial circumstances or particular needs of any individual investor.

Investors should read the whole of the New Zealand PDS and this Additional Information for Australian Investors and consider all of the risk factors that could affect the performance of the Company and other information concerning the Offer Shares in light of their own particular investment objectives, financial circumstances and particular needs (including financial and taxation issues) before deciding whether to invest in the Company.

## **10. Trading in Offer Shares on ASX**

Offer Shares allocated under the Offer are expected to be issued on 30 December 2020. Notifications to successful Applicants of their allotments under the Offer are expected to be issued by 30 December 2020.

Following allotment of the Offer Shares, Shareholders on the Australian share register will be sent an initial statement of holding that provides details of:

- the holder's Holder Identification Number (HIN) (for Clearing House Electronic Subregister System (**CHES**) holders) or Shareholder Reference Number (**SRN**) for issuer-sponsored holders; and
- the number of Offer Shares that have been allocated.

Shareholders will subsequently receive updated statements showing any changes to their shareholding in the Company.

Quotation of the Offer Shares on the NZX Main Board and ASX is expected to occur on or about 6 January 2021. Trading of Offer Shares on the ASX on a normal ('T+2') basis is expected to commence on 6 January 2021.

The Offer is conditional upon the ASX approving the admission of the Company to the official list of the ASX as an ASX Foreign Exempt Listing and for the quotation of the Offer Shares on the ASX on or before the Closing Date (as that date may be varied from time to time, and as defined in the New Zealand PDS). In the event this condition is not satisfied, then the Offer will not proceed, and all application moneys received by the Company will be refunded to investors in full and without deduction within 5 business days.

Applicants under the Australian Offer trade their Offer Shares at their own risk until they know whether, and how many, Offer Shares have been allocated to them. None of ASX, the Company, the Share Registrar (as defined below), any other person named in the New Zealand PDS, nor any of their respective directors, officers, employees or advisers accepts any liability or responsibility should any person attempt to sell or otherwise deal with Offer Shares before statements confirming allotments of Offer Shares are received by the successful Applicants under the Australian Offer.

## **11. Selling Offer Shares on ASX and CHES**

The Company will apply to participate in CHES in accordance with the ASX Settlement Operating Rules. CHES is an automated transfer and settlement system for transactions in securities quoted on ASX under which transfers are effected in an electronic (i.e. paperless) form.

Shareholdings will be registered in one of two subregisters, an electronic CHES subregister or an issuer sponsored subregister. The Offer Shares of a shareholder who is a participant in CHES or a person sponsored by a participant in CHES will be registered on the CHES subregister. All other Offer Shares will be registered on the issuer-sponsored subregister.

## **12. Differences between Australian IFRS and NZ IFRS**

The financial information provided in respect of the Company in the New Zealand PDS has been prepared applying New Zealand International Financial Reporting Standards (**NZ IFRS**).

All ongoing financial information prepared by the Company and provided directly to shareholders or to NZX or ASX will be prepared in accordance with the requirements of NZ IFRS applicable at that time, except as indicated in that ongoing financial information from time to time.

There may be some presentation, disclosure and classification differences between financial information prepared in accordance with NZ IFRS and financial information prepared in accordance with Australian generally accepted accounting principles (**Australian IFRS**). For example, financial information prepared in accordance with Australian IFRS might contain details of director remuneration that would not be required under NZ IFRS. None of these differences in presentation, disclosure or classification would be expected to change the material financial results reported under NZ IFRS.

Where financial information has not been prepared in accordance with NZ IFRS (see above) there may be material differences between the financial information presented and financial information prepared in accordance with Australian GAAP.

### **13. Applicable law**

#### ***TruScreen as a New Zealand company***

TruScreen is a company incorporated in New Zealand and is principally governed by New Zealand law, rather than Australian law. In Australia, TruScreen is registered with ASIC as a foreign company. Its general corporate activities (apart from any offering of securities in Australia) are not regulated by the Corporations Act or by ASIC but instead are regulated in New Zealand by the *Companies Act 1993* (**Companies Act**), the Financial Markets Authority and the New Zealand Registrar of Companies.

Set out below is a table summarising key features of the laws that apply to the Company as a New Zealand company (under New Zealand law, including as modified by exemptions or waivers) compared with the laws that apply to Australian publicly-listed companies generally. It is important to note that this summary does not purport to be a complete review of all matters of New Zealand law applicable to the Company or all matters of Australian law applicable to Australian publicly-listed companies or to highlight all provisions that may differ from the equivalent provisions in Australia.

**Table: Comparison of laws governing TruScreen as a New Zealand publicly-listed company with laws governing Australian publicly-listed companies generally**

Unless otherwise stated, the Corporations Act provisions do not apply to the Company as a foreign company and the ASX Listing Rule requirements do not apply to the Company given that it is proposing to be admitted to the official list of ASX as a Foreign Exempt Listing.

	<b>New Zealand</b>	<b>Australia</b>
<b>Transactions that require shareholder approval</b>	<p>Under the Companies Act, the principal transactions or actions requiring shareholder approval include:</p> <ul style="list-style-type: none"> <li>• adopting or altering the constitution of the company;</li> <li>• appointing or removing a director or auditor;</li> <li>• major transactions (being transactions involving the acquisition or disposal of assets, the acquisition of rights or interests or the incurring of obligations or liabilities, the value of which is more than half the value of the company's total assets);</li> <li>• amalgamations (other than between the Company and its wholly owned subsidiaries);</li> <li>• putting the company into liquidation; and</li> <li>• changes to the rights attached to shares.</li> </ul> <p>In addition to the Companies Act requirements listed above, shareholder approval is required under the NZX Main Board Listing Rules for:</p> <ul style="list-style-type: none"> <li>• director remuneration;</li> <li>• certain material transactions and certain transactions with related parties;</li> <li>• certain issues, buybacks and redemptions of shares; and</li> <li>• in certain circumstances, the provision of financial assistance for the purpose of, or in connection with, the acquisition of shares.</li> </ul>	<p>Under the Corporations Act, the principal transactions or actions requiring shareholder approval are generally comparable to those under the Companies Act. Shareholder approval is also required for certain transactions affecting share capital (e.g. share buybacks and share capital reductions).</p> <p>Although there is no shareholder approval requirement for major transactions, certain related party transactions require shareholder approval.</p> <p>Shareholder approval is also required under the ASX Listing Rules for:</p> <ul style="list-style-type: none"> <li>• increases in the total amount of non-executive directors' fees;</li> <li>• directors' termination benefits in certain circumstances;</li> <li>• certain transactions with related parties;</li> <li>• certain issues of shares; and</li> <li>• significant changes to the nature or scale of a company's activities or proposals to dispose of a company's main undertaking.</li> </ul>
<b>Shareholders' right to request or requisition a general meeting</b>	<p>A special meeting of shareholders must be called by the board on the written request of shareholders holding shares carrying together not less than 5% of the voting rights entitled to be exercised on the issue.</p>	<p>The Corporations Act contains a comparable right.</p> <p>Shareholders with at least 5% of the votes that may be cast at the general meeting may also call and arrange to hold a general meeting at their own expense.</p>
<b>Shareholders'</b>	<p>A shareholder may exercise the right to vote</p>	<p>The position is comparable under the</p>

	New Zealand	Australia
<b>right to appoint proxies to attend and vote at meetings on their behalf</b>	<p>at a meeting either by being present in person or by proxy. A proxy is entitled to attend and be heard, and to vote, at a meeting of shareholders as if the proxy were the shareholder.</p> <p>A proxy must be appointed by notice in writing signed by or, in the case of an electronic notice, sent by the shareholder to the company. The notice of appointment must state whether the appointment is for a particular meeting or a specified term.</p>	<p>Corporations Act.</p> <p>To be effective, the proxy appointment (and any authority under which the appointment is made) must be given to the company at least 48 hours before the meeting.</p>
<b>Changes in the rights attaching to shares</b>	<p>A company must not take action that affects the rights attached to shares unless that action has been approved by a special resolution of each affected interest group. (An 'interest group', in relation to an action or proposal affecting the rights attached to shares, means a group of shareholders whose affected rights are identical and whose rights are affected by the action or proposal in the same way and who comprise the holders of one or more classes of shares in the company).</p>	<p>The Corporations Act allows a company to set out in its constitution the procedure for varying or cancelling rights attached to shares in a class of shares.</p> <p>If a company does not have a constitution, or has a constitution that does not set out a procedure, broadly, the rights attaching to shares may only be varied or cancelled by a special resolution of the company and:</p> <ul style="list-style-type: none"> <li>• a special resolution passed at a meeting of the class of members holding shares in the affected class; or</li> <li>• written consent of members with at least 75% of the votes in the affected class.</li> </ul>
<b>Shareholder protections against oppressive conduct</b>	<p>A shareholder or former shareholder of a company (or any other entitled person) who considers that the affairs of a company have been (or are being, or are likely to be) conducted in a manner that is (or any act or acts of the company have been, or are, or are likely to be) oppressive, unfairly discriminatory, or unfairly prejudicial to him or her in any capacity may apply to the court for relief.</p> <p>The court may, if it thinks it is just and equitable to do so, make such orders as it thinks fit.</p>	<p>Under the Corporations Act, shareholders have statutory remedies for:</p> <ul style="list-style-type: none"> <li>• conduct that is contrary to the interests of the members as a whole; or</li> <li>• oppressive to, unfairly prejudicial to, or unfairly discriminatory against, a member or members in that capacity or any other capacity.</li> </ul> <p>The court can make any order as it considers appropriate.</p>
<b>Shareholders' rights to bring or intervene in legal proceedings on behalf of the company</b>	<p>A court may, on the application of a shareholder or director of a company, grant leave to that shareholder or director to bring proceedings in the name and on behalf of the company or any related company, or intervene in proceedings to which the company or any related company is a party, for the purpose of continuing, defending or discontinuing the proceedings on behalf of the company or related company. Leave may only be granted if the court is satisfied that either the company or related company</p>	<p>The Corporations Act permits certain persons to apply to the court for leave to bring, or to intervene in, proceedings to which the company is a party for the purpose of taking responsibility on behalf of the company for those proceedings, or for a particular step in those proceedings. Those who may apply are members, former members, or persons entitled to be members of the company or a related body corporate, or officers and former officers of the company.</p> <p>The court must grant the application if it is</p>



	New Zealand	Australia
	<p>does not intend to bring, diligently continue or defend, or discontinue the proceedings, or it is in the interests of the company or related company that the conduct of the proceedings should not be left to the directors or to the determination of the shareholders as a whole.</p> <p>No proceedings brought by a shareholder or a director or in which a shareholder or a director intervenes with leave of the court (as described above) may be settled or compromised or discontinued without the approval of the court.</p>	<p>satisfied that:</p> <ul style="list-style-type: none"> <li>• it is probable that the company will not itself bring the proceedings, or properly take responsibility for them, or for the steps in them;</li> <li>• the applicant is acting in good faith;</li> <li>• it is in the best interests of the company that the applicant be granted leave;</li> <li>• if the applicant is applying for leave to bring proceedings, there is a serious question to be tried; and</li> <li>• either at least 14 days before making the application, the applicant gave written notice to the company of the intention to apply for leave and of the reasons for applying, or the court considers it appropriate to grant leave even though such notice has not been given.</li> </ul> <p>Proceedings brought or intervened in with leave must not be discontinued, compromised or settled without the leave of the court.</p>
<b>'2 strikes' rule in relation to remuneration reports</b>	<p>There is no equivalent of a '2 strikes' rule in relation to remuneration reports in New Zealand. New Zealand companies are not required to publish remuneration reports so shareholders necessarily cannot vote on them.</p> <p>There is, however, an obligation to state in the company's annual report, in respect of each director or former director of the company, the total of the remuneration and the value of other benefits received by that director or former director from the company during the relevant accounting period and, in respect of employees or former employees of the company (not being directors of the company) who received remuneration and any other benefits in their capacity as employees during the relevant accounting period, the value of which was or exceeded NZ\$100,000 per annum, the number of such employees, stated in brackets of NZ\$10,000.</p>	<p>The Corporations Act requires that a company's annual report include a report by the directors on the company's remuneration framework (called a remuneration report).</p> <p>For a listed company, a resolution that the remuneration report be adopted must be put to a shareholder vote at each annual general meeting of the company's shareholders (<b>AGM</b>). The result of the vote is advisory only. However, if at 2 consecutive AGMs, at least 25% of the votes cast on the resolution were against the remuneration report (i.e. 2 strikes), an ordinary (50%) resolution must be put to shareholders at the second AGM proposing that a further meeting (spill meeting) be held within 90 days at which all of the directors who were directors when the second remuneration report was approved cease to hold office (except for the managing director who may continue to hold office indefinitely in accordance with the ASX Listing Rules).</p>
<b>Related party transactions and interests</b>	<p>The Company must comply with NZX Main Board Listing Rule requirements in respect of related party transactions, except to the extent this obligation is modified by waivers or rulings granted by NZX Regulation in respect of the Company.</p> <p>In particular, shareholder approval is</p>	<p>Under the Corporations Act, public companies, or an entity that the public company controls, must obtain shareholder approval before giving a financial benefit to a 'related party' of the public company unless an exemption applies. The exemptions include where:</p>

	New Zealand	Australia
	<p>required for material transactions between a listed company and a 'related party'. The definition of related party catches a number of persons, for example, a director of a listed company, or the holder of a relevant interest in 10% or more of a class of securities of a listed company. A related party who is a party to, or a beneficiary of, a material transaction (and its associated persons) is prohibited from voting in favour of a resolution to approve that transaction.</p> <p>The Financial Markets Conduct Act 2013 requires a director or senior manager of a listed issuer who has a 'relevant interest' in a quoted financial product of the listed issuer to give notice of this fact to NZX and to disclose any such relevant interest in the interests register of the listed issuer. Directors and senior managers are also required to disclose all trades in the issuer's securities, to the market.</p> <p>The Companies Act requires directors who are 'interested' in transactions or potential transactions with the company to make appropriate disclosure to the company. Under a company's constitution and the NZX Main Board Listing Rules, interested directors will generally not be permitted to vote on such transactions.</p> <p>Director remuneration requires approval of shareholders under the NZX Main Board Listing Rules. Certain share issues, redemptions and buybacks, and certain 'financial assistance' in connection with the purchase of shares, will also require shareholder approval if a director (or an associated person of a director) is party to that transaction.</p> <p>Each New Zealand company is required to keep an interests register, containing particulars of certain director disclosures. The Company's annual report must state particulars of entries in the interests register made during the accounting period.</p>	<ul style="list-style-type: none"> <li>the arrangement is on, or less favourable than, arm's length terms;</li> <li>the benefit is reasonable remuneration paid, or reasonable expenses reimbursed, to an officer or employee of the company or its related entities;</li> <li>the benefit is a reasonable indemnity, exemption or insurance premium given to an officer or employee of the company;</li> <li>the benefit is a reasonable payment for legal costs incurred by an officer in defending an action incurred as an officer of the public company;</li> <li>the aggregate of benefits given to a related party is less than \$5,000;</li> <li>the benefit is given to a 'closely held subsidiary'; or</li> <li>the benefit is given to the related party in their capacity as a shareholder of the company and does not discriminate unfairly against other shareholders.</li> </ul> <p>In addition, a company will be required to comply with ASX Listing Rule requirements in respect of related party transactions. Unless an exception applies, shareholder approval is required for:</p> <ul style="list-style-type: none"> <li>the acquisition of a substantial asset from, or disposal of a substantial asset to, among other persons, a related party or a person who, together with their associates, holds, or has held in the 6 months before the relevant transaction, a relevant interest in at least 10% of the total votes attached to the voting securities;</li> <li>issuing or agreeing to issue securities to related parties;</li> <li>increasing the total of non-executive directors' fees;</li> <li>directors' termination benefits in certain circumstances; and</li> <li>directors and their associates acquiring securities under an employee incentive scheme.</li> </ul> <p>The definition of 'related party' includes, among others, entities that control the public company, directors of the public company and of any entity that controls the public company, and any entity that is controlled by any of the</p>

	New Zealand	Australia
		<p>foregoing entities or persons.</p> <p>Under the ASX Listing Rules, a company is also required to disclose the 'notifiable interests' of its directors at prescribed times and any changes to those notifiable interests. Notifiable interests include a relevant interest in the shares of the company.</p>
<b>Disclosure of substantial holdings</b>	<p>The Financial Markets Conduct Act 2013 requires every person who is a 'substantial product holder' in a listed issuer to give notice to that listed issuer and NZX that they are a substantial product holder.</p> <p>'Substantial product holder' means, in relation to a listed issuer, a person who has a relevant interest in 5% or more of a class of quoted voting products of that listed issuer.</p> <p>The substantial product holder has ongoing disclosure requirements to notify the listed issuer and NZX of certain changes in the number of voting securities in which the substantial product holder has a relevant interest, if there is any change in the nature of any relevant interest in the relevant holding or where that person ceases to be a substantial product holder.</p>	<p>The Corporations Act requires every person who is a substantial holder to notify the listed company and ASX and give prescribed information in relation to their holding if:</p> <ul style="list-style-type: none"> <li>the person begins to have, or ceases to have, a substantial holding in the company;</li> <li>there is a movement of at least 1 percentage point in their holding; or</li> <li>the person makes a takeover bid for securities of the company.</li> </ul> <p>A person has a substantial holding if the total votes attached to voting shares in the company in which they or their associates have relevant interests is 5% or more of the total number of votes attached to voting shares in the company, or the person has made a takeover bid for voting shares in the company and the bid period has started and not yet ended.</p> <p>These provisions do not apply to the TruScreen as an entity established outside Australia. However, the Company will be required to release to ASX any substantial product holder notices that are released to NZX.</p>
<b>How takeovers are regulated</b>	<p>The New Zealand position under the Takeovers Code and the Financial Markets Conduct Act 2013 is comparable to the Australian position in relation to the regulation of takeovers.</p> <p>Substantial product holder notice requirements apply to relevant interests in 5% or more of a company's quoted voting securities (as discussed above under the heading 'Disclosure of substantial product holdings').</p> <p>A 20% threshold applies (under which a person (and their "associates") are prevented from increasing the percentage of voting rights held or controlled by them (and their associates) in excess of that threshold or from becoming the holder or controller of</p>	<p>The Corporations Act prohibits a person from acquiring a relevant interest in issued voting shares in a listed company if any person's voting power in the company will increase from 20% or below to more than 20%, or from a starting point that is above 20% and below 90%.</p> <p>Exceptions to the prohibition may apply to permit certain transactions (e.g. acquisitions with shareholder approval, 3% 'creep' over 6 months and rights issues that satisfy prescribed conditions).</p> <p>Substantial holder notice requirements apply (as discussed above under the heading 'Disclosure of substantial holdings').</p> <p>Compulsory acquisitions are permitted by</p>

	<b>New Zealand</b>	<b>Australia</b>
	<p>an increased percentage of voting rights if they already hold or control more than 20% of the voting rights), subject to certain 'compliance options' (including full and partial offers, 5% creep over 12 months in the 50% to 90% range and acquisitions with shareholder approval).</p> <p>Compulsory acquisitions are permitted (or can be required) by persons who hold or control 90% or more of voting rights in a company.</p>	<p>persons who hold 90% or more of voting securities in a company.</p> <p>The New Zealand takeovers regime, not the Australian takeovers regime, will apply to TruScreen as it is a New Zealand incorporated company.</p>
<b>Filing of documents</b>	<p>The Company must prepare and file the following documents with the Companies Office every year:</p> <ul style="list-style-type: none"> <li>• annual financial statements as an FMC Reporting Entity under the Financial Reporting Act 2013 and the Financial Markets Conduct Act 2013 (including the statement of financial position, statement of financial performance, statement of cash flows, statement of movements in equity, statement of accounting policies, notes to the accounts and an audit report); and</li> <li>• an annual return required under the Companies Act.</li> </ul> <p>The Companies Office must also be notified of certain changes (e.g. the appointment or resignation of directors or changes to the Company's Constitution).</p>	<p>As a foreign registered company, the Company has limited filing obligations. It is required to file annual accounts with ASIC (including the balance sheet, cash flow statement and profit and loss statement for the last financial year, as well as any other documents required to be prepared under New Zealand law). ASIC must also be notified of certain changes (e.g. a change of registered office address in Australia, change in local agent, change of company name and the appointment of directors). In relation to some filings, no separate filing is required with ASIC if the relevant information has been filed with the New Zealand Companies Office.</p> <p>Filing obligations applicable to Australian registered companies will not apply to TruScreen as a foreign company.</p>
<b>Requirement for information to be sent to shareholders</b>	<p>The Company must send the following information to its shareholders:</p> <ul style="list-style-type: none"> <li>• annual and half-yearly reports (or a statement as to how to obtain them);</li> <li>• notices of meetings of shareholders (including, where applicable, such information as necessary to enable shareholders to appraise the implications of the proposed resolutions);</li> <li>• a disclosure document where the board of the Company proposes to acquire or redeem shares in the company or offer financial assistance, if applicable;</li> <li>• where requested by a shareholder, a statement that sets out the information about the shareholder's shareholding and the rights attached to that shareholder's shares; and</li> <li>• information requested by a shareholder</li> </ul>	<p>The Corporations Act and the ASX Listing Rules require a public company to send certain information to its shareholders, including:</p> <ul style="list-style-type: none"> <li>• financial statements (annual);</li> <li>• directors' report (annual);</li> <li>• auditors report (annual);</li> <li>• notices of meetings of shareholders (which includes the information prescribed by the Corporations Act or the ASX Listing Rules (as applicable); and</li> <li>• offer documentation for certain types of capital raising undertaken by the company.</li> </ul>

	<b>New Zealand</b>	<b>Australia</b>
	or an explanation as to why the company has refused to provide the information.	

Where it is noted that New Zealand law contains comparable provisions to those existing under Australian law, and vice versa, it is emphasised that the summary table only attempts to provide general guidance, and that the detailed provisions may contain differences and may also be subject to differing interpretation by Australian and New Zealand courts.

#### **14. Australian Taxation**

You should seek your own Australian taxation advice on the implications of an investment in the Offer Shares.

#### **15. Privacy**

If you apply for Offer Shares, you will be asked to provide personal information to the Company, Link Market Services Limited (**Share Registrar**) and their respective agents who will collect and hold the personal information provided by you in connection with your Application at their respective addresses shown in Section 12 (Contact information) of the New Zealand PDS.

Personal information provided by you will be used for:

- the purposes of considering, processing and corresponding with you about your Application and in connection with your holding of Offer Shares; and
- sending you information concerning the Company, your Offer Shares and other matters the Company considers may be of interest to you by virtue of your holding of Offer Shares.

Australian law requires some of the information to be collected in connection with your Application. To do these things, the Company or the Share Registrar may disclose your personal information to their related companies, respective agents, contractors or third party service providers to whom they outsource services such as mailing and registry functions. However, all of these parties will be bound by their respective privacy policies. The Company or the Share Registrar may also disclose your personal information to ASX, NZX or other regulatory authorities.

Failure to provide the required personal information may mean that your Application is not able to be processed efficiently, if at all.

If you become a Shareholder, your information may be used or disclosed from time to time to facilitate dividend payments and corporate communications and for compliance by the Company with legal and regulatory requirements. Under the Australian *Privacy Act 1988* (Cth), you may request access to your personal information held by (or on behalf of) the Company and the Share Registrar. You can request access to your personal information by telephoning or writing to the Company or the Share Registrar using the details shown in Section 12 (Contact information) of the New Zealand PDS.

#### **16. Definitions**

Unless otherwise defined, capitalised terms in this Additional Information for Australian Investors have the same meaning as in the 'Glossary of Terms' Section of the New Zealand PDS.

## **17. Enquiries**

If you have any questions about the Australian Offer you should contact your financial or other professional adviser without delay. If you do not understand any part of the New Zealand PDS or this Additional Information for Australian Investors, or are in any doubt as to whether to invest in Offer Shares or not, it is recommended that you seek professional guidance from your solicitor, accountant or other independent and qualified professional adviser.

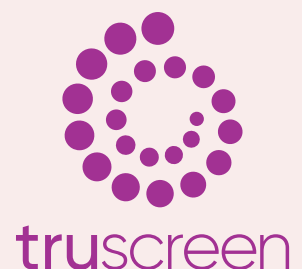
# TRUSCREEN GROUP LIMITED

(formerly TruScreen Limited)

## Product Disclosure Statement for an offer of ordinary shares in TruScreen Group Limited.

10 November 2020

This document gives you important information about this investment to help you decide whether you want to invest. There is other useful information about this offer at [www.companiesoffice.govt.nz/disclose](http://www.companiesoffice.govt.nz/disclose). TruScreen Group Limited has prepared this document in accordance with the Financial Markets Conduct Act 2013. You can also seek advice from a financial adviser to help you to make an investment decision.



# 1. Key Information Summary

## What is this?

This is an offer of ordinary shares. Ordinary shares in TruScreen Group Limited ("TruScreen") will give you a stake in the ownership of TruScreen. You may receive a return if dividends are paid, or TruScreen increases in value and you are able to sell your ordinary shares at a higher price than you paid for them.

If TruScreen runs into financial difficulties and is wound up, you will be paid only after all creditors have been paid. You may lose some or all of your investment.

## About TruScreen Group Limited

TruScreen Group Limited ("**TruScreen**" and "**the Company**") was incorporated on 9 August 2013. TruScreen manufactures and owns all rights to the TruScreen Cervical Cancer Screening System. The system comprises a medical device and Artificial Intelligence- supported (AI) process designed to detect the presence in real time of pre-cancerous and cancerous tissue on the cervix.

TruScreen is a patented cervical cancer detection system with distribution agreements in 23 countries. The Company's current key focus is China which accounts for over 50% of sales. Its products have been sold to Vietnam, Russia, Zimbabwe, Mexico, India, Zimbabwe and Saudi Arabia.

TruScreen is further described in Section 2: *TruScreen and what it does* and Section 7: *TruScreen's financial information*.

## Purpose of this Offer

The purpose of the Offer is to raise not less than NZ\$1 million and not more than NZ\$2 million of new capital through the issue of up to a maximum of 28,571,428 million new ordinary fully paid shares in TruScreen. The Offer will not proceed if applications for a minimum of NZ\$1 million (14,285,714 million new shares) are not received.

The money raised under the Offer will be applied towards the following initiatives:

- Pay for the costs associated with the offer;
- Pay for the costs associated with the dual listing of TruScreen's Shares on the ASX;
- Reduce the cost of the product via R&D initiatives;
- Investment in business expansion and team capabilities;
- Increasing working capital.



## Key terms of the offer

Description of the equity securities	Ordinary fully paid shares
Price	NZD 7 cents per Share, or AUD 6.5 cents per Share
Intended date Offer opens ("Opening Date")	26 November 2020
Intended date Offer closes ("Closing Date")	18 December 2020
Number or amount of the equity securities being offered	<p>A minimum of 14,285,714 new Shares are being offered, representing 4.1% of the total number of ordinary shares on issue immediately after the issue.</p> <p>A maximum of 21,428,571 new Shares are being offered, representing 6.1% of the total number of ordinary shares on issue immediately after the issue.</p> <p>The Board of TruScreen has the discretion to accept oversubscriptions of up to a maximum of 7,142,857 new Shares (\$500,000). If the Board resolves to accept oversubscriptions to the maximum level, the maximum number of Shares that can be offered under the Offer is 28,571,428 Shares, representing 8.2% of the total number of ordinary shares on issue.</p> <p>Any oversubscriptions received shall be apportioned as between the two geographic pools referred to below, in the same proportions as each of the two geographic pools represent as a percentage of the total Offer.</p>
Structure of the Offer	<p>The Offer has been divided in to two geographic pools. A pool of 14,285,714 new Shares (NZ\$1 million) for subscription by Australian Residents ("Australian Pool"). A pool of 7,142,857 new Shares (NZ\$500,000) for subscription by New Zealand Residents ("NZ Pool").</p> <p>In the event that one of the geographic pools is undersubscribed, then the balance of that pool may be allocated to the other pool for subscription.</p>
Scaling	TruScreen may scale applications at its sole discretion.
Liabilities, fees and charges	Except for the payment of the price for the new Shares, a subscriber for new Shares has no liability to make further payments or to pay fees or charges relating to the new Shares.
Conditional Offer	This Offer is conditional upon the ASX approving the admission of the Company to the official list of the ASX as an ASX Foreign Exempt Listing and for quotation of the Shares on the ASX on or before that Closing Date (as that date may be varied from time to time). In the event that this condition is not satisfied, then this Offer will not proceed, and all application moneys received by the Company will be refunded to investors in full and without deduction within 5 business days.

The above dates are subject to change at the discretion of the Board of TruScreen, subject to compliance with NZX Listing Rules.

### How you can get your money out

TruScreen intends to quote these Shares on the NZX Main Board and the ASX. This means you may be able to sell them on the NZX Main Board or the ASX if there are interested buyers. You may get less than you invested. The price will depend on the demand for the Shares.

An application will be made to ASX after this PDS has been lodged on the Offer Register for TruScreen to be admitted to the official list of ASX as an ASX Foreign Exempt Listing and for quotation of the Shares on the ASX. If TruScreen is admitted to the official list of ASX, then those Australian investors will have their Shares quoted on the ASX.

If you wish to sell your Shares on the NZX Main Board or the ASX (as the case may be), you will need to open a share trading account with a NZX Market Participant, or an Australian share brokerage firm, or a share trading platform, through whom your share sale may be facilitated.

### Key drivers of returns

TruScreen considers that the current and future aspects of its business that have, or may have, the most impact on the financial performance of the business, and the key strategies and plans for those aspects of the business, can be summarised as follows:

Aspects of TruScreen's business that may impact on financial performance	Key strategies and plans
<p><b>The Company's ability to generate sales revenues from the sale of its products</b></p> <p>The financial performance of the business will be driven by the Company's ability to generate sales revenues from the sale of its products.</p>	<p>TruScreen is seeking to develop its sales and distribution channels to facilitate the increase in sales of its products in its targeted jurisdictions.</p>
<p><b>Preservation of working capital</b></p> <p>The Company must preserve its working capital carefully to ensure it can trade as a going concern until it is cashflow positive.</p>	<p>TruScreen is constantly monitoring adherence to its cashflow model to ensure the Company has adequate financial resources to undertake its commercial operations.</p>
<p><b>Rollout of the TruScreen technology solution in China, Russia, and Vietnam</b></p> <p>The ability of TruScreen to develop its sales channels for its products (i.e with a view to increasing sales and revenues) in China, Vietnam, Russia, Eastern Europe, India, Latin America and Africa taken individually or collectively will have a material impact upon the financial performance of TruScreen.</p>	<p>TruScreen has adopted three key steps in its strategy to develop its sales channels in these markets, as follows:</p> <ul style="list-style-type: none"> <li>• Appointment of a distributor(s) and the gaining of regulatory approvals for the sale of TruScreen's products.</li> <li>• Gaining key opinion leader (KOL) support.</li> <li>• Commenced commercial activity in those jurisdictions.</li> </ul> <p>Further information about the above strategies is provided on page 19.</p>
<p><b>The establishment of a manufacturing facility in China</b></p> <p>The establishment of a manufacturing facility in China will achieve a lower manufacturing cost, and by registering TruScreen as a domestic product will remove the bias against foreign products for use in public health programs in China.</p>	<p>The Company is negotiating with a Chinese company which is ISO13485 accredited to manufacture the Truscreen device in Shenzhen, China.</p>

Further information regarding the aspects of TruScreen's business that may impact on the financial performance of the Company can be found in pages 17 and 18 of this PDS.

## Key risks affecting this investment

Investments in shares are risky. You should consider if the degree of uncertainty about TruScreen's future performance and returns is suitable for you. The price of these Shares should reflect the potential returns and the particular risks of these Shares. TruScreen considers that the most significant risk factors that could affect the value of the Shares are:

- **Early stage nature of the TruScreen's Commercialisation**  
While the TruScreen technology is well advanced, the roll out of its commercial business model is still at an early stage. TruScreen's commercialisation is not currently the subject of any fixed term contractual arrangements and there are no guaranteed recurring regular income streams for the TruScreen business.

TruScreen currently operates at a loss. TruScreen's operating losses may continue as TruScreen continues to expend resources to commercialise its current products, obtain regulatory clearances or approvals in new jurisdictions, and expand its marketing, sales, manufacturing and finance capabilities.

- **Cash flow**  
TruScreen may require substantial additional capital to commercialise its current products and to develop new products, including completing new product testing and clinical trials, obtaining all required regulatory approvals and clearances, scaling up manufacturing, and marketing its products into particular jurisdictions. Ultimately, like all businesses, if the Company is unable to fund its commercial operations, the future viability of the Company would be in doubt.
- **Intellectual Property**  
TruScreen's future success heavily depends on its ability to maintain the proprietary nature of its technology. If any of TruScreen's rights or ability to manufacture its products was to be limited, TruScreen's ability to continue to manufacture and market its products could be adversely affected.
- **Manufacturing Risk**  
TruScreen relies on a number of third party suppliers to manufacture certain parts of the device and the disposable Single Use Sensor<sup>1</sup> (SUS) production. As such, TruScreen cannot guarantee control over the manufacturing of all components of its products in a timely fashion. Difficulties TruScreen may encounter in manufacturing scale-up, or a failure to maintain its manufacturing facilities in accordance with good manufacturing practice regulations, international quality standards or other regulatory requirements, could result in a delay or termination of production, which could have a material adverse effect on TruScreen's financial performance.

- **Competition**  
TruScreen competes with numerous other developers and suppliers of cervical cancer screening product offerings and services. TruScreen is susceptible to being overtaken by other more established and larger organisations. It is possible that one or more pharmaceutical or other health care companies will develop therapeutic drugs, treatments or other products that will substantially reduce the prevalence of cancers or otherwise compete with, or render TruScreen's products obsolete.
- **Unsuccessful Marketing**  
Despite the best endeavours of TruScreen and its distributors, it is possible that TruScreen's initiatives to market its products could fail, which would have an adverse impact on the financial position and performance of TruScreen.

## Further Risks

This summary does not cover all the risks of investing in TruScreen Shares. You should also read Section 8 of the PDS (Risks to TruScreen's business and plans) and the other places in the PDS that describe risk factors (for example, risks arising for investors from the nature of the Shares).

## Where you can find TruScreen's financial information

The financial position and performance of TruScreen are essential to an assessment of this Offer. You should also read section 7 of the PDS – TruScreen's Financial Information. A full set of the financial statements for TruScreen can also be found on the Disclose Register at [www.business.govt.nz/disclose](http://www.business.govt.nz/disclose), offer number OFR12990.

<sup>1</sup> The Single Use Sensor (SUS) is a disposable sheath that is the only point of contact between the TruScreen device and any bodily fluids or tissue from the patient. A new SUS has to be used for each patient test.

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# Letter from the Chairman of TruScreen's Board of Directors

Dear Investor,

On behalf of the Directors of TruScreen Group Limited, it is my pleasure to introduce this Product Disclosure Statement (PDS) to you.

TruScreen aims to improve the wellbeing of women with the latest AI-based technology in cervical cancer screening by providing real-time, accurate detection of pre-cancerous and cancer cells.

In FY2020, we remained focused on the commercialisation of our proprietary electro-optical technology, which is distributed in over 23 countries. China remains our primary focus. Since commencing an evaluation with Chinese Obstetricians and Gynaecologists Association (COGA), we have increased the Company's presence in China. Demand in China has grown throughout FY2020, with further device installations and stronger Single Use Sensor (SUS) pull through.

We have also expanded our global distribution outside of China. In particular, we have grown our presence in Vietnam and the African and Russian markets, established our African HIV initiative, and expanded into the Middle East, gaining product registration in Saudi Arabia and Israel.

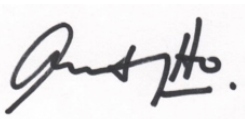
The Company continues to focus on building its presence in China and strengthening its international distribution in low and middle income countries (LMIC's) through strong relationships and partnerships with hospitals, governments and non-government organisations<sup>2</sup> (NGO's). TruScreen recently received recognition from UNITAID, the World Health Organisation and the Clinton Health Access Initiative for its ability to provide point-of-care cervical cancer screening services in these countries.

This capital raising in conjunction with the dual listing of the Company's shares on the Australian Securities Exchange (ASX) will provide the Company with the resources it needs to capitalise on the base the Company has established.

This Offer is conditional upon the ASX approving the admission of the Company to the official list of the ASX as an ASX Foreign Exempt Listing and for quotation of the Shares on the ASX on or before that Closing Date (as that date may be varied from time to time). In the event that this condition is not satisfied, then this Offer will not proceed, and all application moneys received by the Company will be refunded to investors in full and without deduction within 5 business days.

We believe that a dual listing on the New Zealand and Australian Securities Exchanges will add value to all our shareholders, and I recommend this Offer to you.

Yours sincerely



**Tony Ho**  
Chairman

<sup>2</sup> NGOs are usually non-profit and sometimes international organisations independent of governments and international governmental organisations (though often funded by governments) that are active in humanitarian, educational, health care, public policy, social, human rights, environmental, and other areas to effect changes according to their objectives

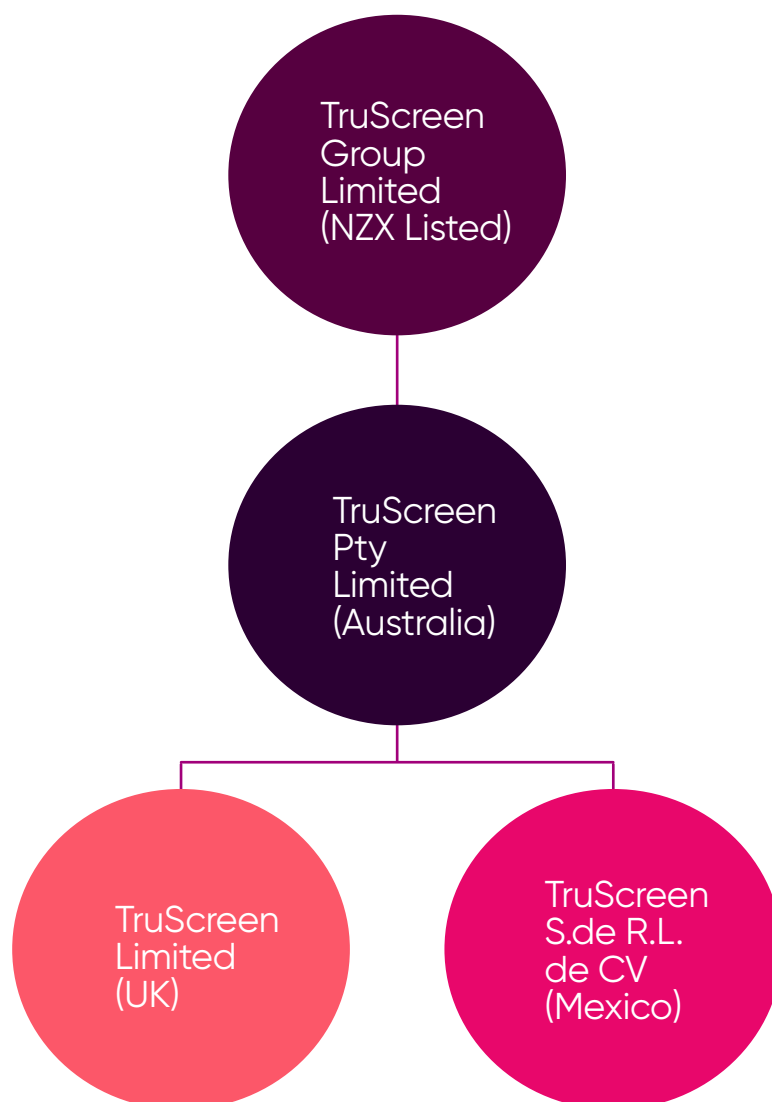
## 2. TruScreen and what it does

### Overview

TruScreen manufactures and owns all rights to the TruScreen Cervical Cancer Screening System. The system comprises a medical device and process designed to detect the presence in real time of pre-cancerous and cancerous tissue on the cervix.

TruScreen is a unique cervical cancer detection system with distribution agreements in 23 countries. The Company's current key focus is China which accounts for over 50% of sales. Its devices have been sold to Vietnam, Mexico, Zimbabwe, Russia, India and Saudi Arabia.

The diagrams below illustrate the group and the organisational structure of TruScreen.



TruScreen Group Limited (New Zealand) was incorporated on 9 August 2013. TruScreen Pty Limited (Australia) was incorporated on 26 August 2013. TruScreen Limited (UK) was incorporated on 11 July 2013. TruScreen S de R.L de C.V (Mexico) was incorporated on 17 August 2017. Truscreen Group Limited is listed on the NZX Main Board, and it is proposed that it will also be dual listed on the ASX following the completion of this Offer.

## Description of the TruScreen group of companies

- **TruScreen Group Limited (New Zealand):** This company is the parent company of the TruScreen group and its Shares are currently quoted on the NZX Main Board. TruScreen Group Limited does not undertake any commercial trading operations in its own right. It does however own 100% of the shares on issue in TruScreen Pty Limited (Australia) which in turn owns 100% of the shares in TruScreen Limited (UK) and TruScreen S de R.L de C.V (Mexico).
- **TruScreen Pty Limited (Australia):** This company is an Australian incorporated company and carries out the commercial activities referred to below.
- **TruScreen Limited (UK):** This company is incorporated in the United Kingdom and holds the CE Mark.
- **TruScreen S de R.L de C.V:** This company is incorporated in Mexico and is currently not operating.

## NATURE OF TRUSCREEN'S OPERATIONS AND MAIN ACTIVITIES

### What is TruScreen's business model?

TruScreen Pty Ltd manufactures the TruScreen cervical cancer screening system. The system consists of a Hand Held Device and Cradle and a disposable Single Use Sensor (SUS). A new SUS is used for every patient test. TruScreen sells those devices and SUS's to distributors in the countries in which TruScreen is approved for sale. Those distributors then sell the TruScreen device to Government and Private hospitals and clinics, individual doctors and government and non-government health programs.

TruScreen has a strategy to focus on the promotion and sale of TruScreen cervical cancer screening system to those large developing countries (eg China and Russia) and those low and middle income countries (LMIC's) which lack a national cervical cancer screening infrastructure.

Key attributes of the model comprise:

- Supporting existing and appointing additional distributors to sell TruScreen to the large developing countries and LMIC's;
- Maintaining international medical device manufacturing certification – ISO13485<sup>3</sup>– and the right to use the CE Mark<sup>4</sup> as prima facie proof of the efficacy of the TruScreen cervical cancer screening system;
- Conducting up to date clinical performance evaluations to validate the efficacy of the TruScreen cervical cancer screening system;

- Securing and maintaining all regulatory licenses to support the deployment of TruScreen's products in the various international jurisdictions it targets;
- Developing trusted relationships with international Governments, regulators and other key industry participants;
- Promoting TruScreen to key Non-Government Organisations who have an interest in the health of women in the developing world and who fund screening programs in LMIC's.

## What has TruScreen done to date?

### The Company's history

TruScreen's development was driven by two leading medical academics from Sydney University.

Professor Malcolm Coppleson, an international leader in colposcopy and cervical cancer, sought to establish objective technology that could improve on the conventional Pap smear test<sup>5</sup>, which has limitations in population-based screening due to its subjective nature and its need of laboratory facilities and qualified personnel to read results. His partner Dr. Bevan Reid believed that it should be possible to distinguish between normal and abnormal tissue by measuring changes in physical properties, such as electrical potential.

After extensive and intensive research and development (R&D), the TruScreen 'Opto Electrical' Technology for the detection of precancerous and cancerous cells was developed. The TruScreen Cervical Cancer Screening System is built on this technology and comprises a unique medical device, AI-based (Artificial Intelligence) algorithm technology (see outline of "TruScreen Sophisticated Algorithm Framework below) and processes designed to detect the presence, at the time of screening, of precancerous and cancerous tissue on the cervix.

Following the restructuring of the business, TruScreen Pty Ltd, a subsidiary company of TruScreen Group Limited (NZ), was formed in August 2013 to hold all TruScreen assets, including IP, and to act as the operations heart of the TruScreen business.

In 2016, the TruScreen Ultra2 second-generation device was launched. This encapsulated world-class medical technology and contained many new and unique features including a significantly increased processing capacity and faster processing which improved performance and user experience.

The TruScreen technology is at the forefront of the development of objective opto-electric tissue differentiation and it's key intellectual property is a protected trade secret.

<sup>3</sup> ISO13485 is an International Organization for Standardization (ISO) standard which represents the requirements for a comprehensive quality management system for the design and manufacture of medical devices.

<sup>4</sup> CE mark is a **certification marking** that indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area (EEA). The **CE marking** is also found on products sold outside the EEA that are manufactured in, or designed to be sold in, the EEA

<sup>5</sup> A Pap smear test is performed by opening the vaginal canal with a speculum and collecting cells at the outer opening of the cervix at the transformation zone (where the outer squamous cervical cells meet the inner glandular endocervical cells). The collected cells are examined under a microscope to look for abnormalities which could indicate the incidence of cervical cancer



## Product Overview

TruScreen utilises technology to detect precancerous change, or cervical intraepithelial neoplasia (CIN), by optical and electrical measurements of cervical tissue.

A pen-like wand touches various spots on the cervix to send and receive back electrical and optical signals from the cervical tissue. A single use sensor (SUS) with precision lens and electrodes is used to interface with the cervix and protect against cross-infection.

The TruScreen device collects the data, processes it with a proprietary AI-based algorithm and provides an immediate result, enabling the physician to immediately plan appropriate patient care.

Unlike cytology<sup>6</sup>, TruScreen does not only examine surface epithelial cells. LED light at specific frequencies is transmitted through cervical tissue identifying changes in the basal and stromal layers. This includes increases in blood circulation and variations in blood vessels that occur with precancerous change.

The TruScreen system also assesses the electrical properties and response of the cervical 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 will vary according to the capacitance of the tissue – a measurement of the ability of the tissue to either hold or dissipate a charge. Different tissue types and the properties of the tissue have different capacitance.

The device runs an AI-based algorithm (see reference to TruScreen Sophisticated Algorithm Framework below) trialled on a database of 2,000 patients from wide geographic and ethnic backgrounds with differing histological diagnoses. A sophisticated proprietary algorithm framework has been developed to distinguish between normal and abnormal (cancerous and precancerous) tissue.

## Features and Benefits

TruScreen cervical cancer screening system offers an alternative approach to traditional cervical cancer screening, resolving many of the ongoing issues with Pap smear tests including failed samples, poor patient follow up, patient discomfort and the need for supporting laboratory infrastructure.

As well as being accurate, the TruScreen cervical cancer screening system provides an instant report, thus preventing the risk of losing contact with the patient because of the delay associated with transportation of samples to laboratories for analysis and reporting.

TruScreen cervical cancer screening system is portable and is an objective, self-checking AI-supported digital system that can be used with minimal training of medical or paramedical staff, and without the infrastructure and resource costs associated with cytology-based screening.

TruScreen is also more acceptable to women than a Pap smear test because no cervical tissue needs to be taken during the test, meaning no scraping of the cervix, minimal discomfort, and real time results are provided.

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	High degree of accuracy. <sup>7</sup>	Reproducible, consistent results to confirm accuracy. Eliminates human error in interpreting results.
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 early detection of disease and save lives.
Automated device and error-checking during examination	Consistent and accurate results.	Minimises the chance of an unsatisfactory result.
Tissue samples NOT collected	Minimises pain or discomfort to the patient.	Patient more likely to return for repeat screen.

<sup>6</sup> Cytology is the examination of cells from the body under a microscope

<sup>7</sup> Qi Weihong, Zhang Wei et al. Clinical Observation of Cervical Cancer Screening System TruScreen in 1030 Cases. Electronic Journal Of Practical Gynecologic Endocrinology. Nov. A. 2019 Vol.6, No.31. Results: TS: 91.0%, 81.25%; LBC: 69.6%, 73.75%. Subjects: 1030 Published 2019

## Product Development History

Pioneering research and development on the TruScreen cervical cancer screening system for real-time cervical tissue differentiation has involved close collaboration with leading clinicians and hospitals across the world.

TruScreen's development was driven by two leading medical academics from Sydney University, that began in 1986, who sought to establish objective technology that could improve on the conventional Pap smear test. They believed that it should be possible to distinguish between normal and abnormal tissue by measuring changes in physical properties, such as electrical potential.

After an extensive and intensive R&D phase, between 1986 and 1999, TruScreen cervical cancer screening system was developed using the 'Opto Electrical' Technology for the detection of pre and cancerous cells on the cervix. TruScreen technology contains a sophisticated algorithm framework that has been developed in collaboration with the Australian Government's applied research division, CSIRO. The algorithm was researched and developed from data sets collected from the Auckland Hospital, Royal Hospital for Women (Sydney) and The Whittington hospital London between 1998 to 2000.

The first generation Truscreen was commercialised and launched to the market in 2014.

The R&D phase to develop the new device commenced with a series of independent design houses in Feb 2014 and a pilot production version was available for the granting of the CE mark in April 2016.

In 2016, the TruScreen Ultra2 second-generation device was launched. This built on TruScreen's world class medical technology with a number of improvements including significantly increased processing capacity, faster processing and significantly improved performance. In addition, the handpiece is now wireless and the enhanced device offers wi-fi connectivity, extended battery life and an LCD touchscreen.

TruScreen holds the following patents which affords the Company certain proprietary protections in respect of its intellectual property rights that it has developed:

Name of Patent Held	Nature of the Patent
Apparatus for tissue type recognition using multiple measurement techniques	Held in the name of TruScreen Pty Ltd for the USA.
Apparatus for Tissue Type Recognition Using Multiple Measurement	Held in the name of TruScreen Pty Ltd for China.

Both of the above patents concern the first generation device T1 or second generation T2 (Ultra) as they are equivalent in their outputs both electrically and optically.

The 'multiple measurement' refers to the data sets both optical and electrical that are obtained when each spot on the cervical tissue is probed - 15 to 30 spots can be taken depending on the size of the cervix. The Algorithm from the data derived can recognise the tissue type and determine whether the tissue is precancerous or cancerous.

Additional research and development is also planned to improve the manufacturing processes to reduce the cost of manufacture of the products to improve gross margins. This would be integrated with the planned relocation of manufacturing of the products to China. See page 16 for further information. Research and development is undertaken both by external third party contractors engaged by the Company and also in-house. For the year ended 31 March 2020 the Company spent \$1,584,292 on research and development. Of this amount:

- \$462,240 was attributed to TruScreen personnel costs deployed on research and development activities;
- \$300,317 was paid to external third party contractors; and
- \$820,916 was attributed towards materials, prototypes, equipment and overhead.

The Company is planning to undertake a greater percentage of research and development in-house as it strives to reduce the cost of production of both the TruScreen device and Single Use Sensor.

In recent use this device has been shown to have a high degree of accuracy.<sup>8</sup> Clinical and in-field evaluations have shown TruScreen Ultra2 device to be a unique and valuable screening test for cervical cancer.

### TruScreen sophisticated algorithm framework

More than 23 man-years were spent on algorithm development and testing to arrive at the current version of the TruScreen Ultra classifier algorithm. During development, numerous algorithms methodologies were trailed. The current TruScreen Ultra algorithm was selected following trials of 5 competing algorithms.

The TruScreen Ultra algorithm uses a trained multi-dimensional probabilistic tissue features classification engine to provide a binary classification result (Normal or Abnormal) with a high degree of Sensitivity and Specificity (see page 16). The data sets used to train the algorithm consist of patient specific clinical data combining clinical diagnosis information from colposcopy, cytology, and histology (where available) and were collected over many years of clinical studies. The training data set consists of more than 7,500 multi-probing data sets, from patients of varying ethnicities with differing histological diagnoses.

<sup>8</sup> Qi Weihong, Zhang Wei et al. Clinical Observation of Cervical Cancer Screening System TruScreen in 1030 Cases. Electronic Journal Of Practical Gynecologic Endocrinology. Nov. A. 2019 Vol.6, No.31. Results: TS: 91.0%, 81.25%; LBC: 69.6%, 73.75%. Subjects: 1030 Published 2019

## Markets

TruScreen's cervical cancer screening device is Certified for use throughout Europe (the CE Mark) and **NMPA**<sup>9</sup> approved for sale in China. It is currently available in multiple markets around the world.

After in-depth market study and evaluation, TruScreen has determined that the optimal commercialisation strategy is to first target those large developing markets and Low and Middle-Income Countries (LMIC's) where no large-scale cervical cancer screening programs and infrastructure are in place. In parallel to this commercialisation, the Company is obtaining the academic endorsement of Key Opinion Leaders to assist in both current and future global marketing efforts.

There are two main market segments for each country:

- population based screening; and
- general clinical use in hospitals and clinics.

The screening programs are mainly funded through Government public health procurement programs equating to large screening populations but in many countries, there are also significant NGO and Corporate funded screening programs. (TruScreen cervical cancer screening system was recently featured in a Cervical Cancer Technology Landscape released by Unitaaid, the World Health Organisation and the Clinton Health Access Initiative – See page 14).

The government screening programs are the key to success for TruScreen in developing markets. TruScreen appoints distributors based on their ability to demonstrate a solid relationship with Key Opinion Leaders and having strong Government contacts.

The World Health Organisation's (WHO) draft strategy to eliminate cervical cancer worldwide, once approved by member countries, would provide a significant market opportunity for its real-time screening technology for cervical cancer.

The "Draft Global Strategy Towards the Elimination of Cervical Cancer as a Public Health Problem"<sup>10</sup>, provides a favourable macro environment for the Company's screening technology. The strategy calls for a comprehensive global approach to put the 184 WHO member countries on the same path to eliminate cervical cancer by the end of the century and proposes screening targets for the period 2020-2030.

WHO notes that to achieve this target, innovative and optimal service delivery models need to be adopted, particularly in low- and middle-income countries (LMICs) where cervical cancer incidence and mortality rates are high.<sup>10</sup> TruScreen is currently the only electro-optical real-time cervical screening method available in LMICs.

Concurrent to TruScreen's efforts to maximise the sales of its products in its primary target markets the Company is also engaged in the process of selecting the second phase of target markets and identifying suitable distributors to work with in those markets. This process has been initiated in India, Central and Latin America, Eastern Europe, the Middle East and Africa.

The global market potential for TruScreen is significant. At saturation, hundreds of millions of women could benefit from this accurate, real time and relatively affordable cervical cancer screening system.

However, the single most important potential benefit from the global commercialisation of TruScreen is the saving of human life – and especially the lives that will be saved in the developing world. Approximately 300,000 women die from cervical cancer each year. Of which, over 85% are from the developing world.<sup>11</sup>

The Board considers that it is important to note that, in respect of the market in which TruScreen operates:

- The medical devices/cervical cancer screen market is, like most medical sectors, a particularly competitive market. There are a number of existing market participants that provide cervical cancer screening solutions, and there is always the prospect of new technologies being developed by trade competitors that will directly compete with the TruScreen solution and could ultimately potentially supersede the TruScreen technology in the market place, or have a material adverse impact upon the ability of TruScreen to generate meaningful revenues. Further detail about this particular risk factor is provided in section 8 on page 32; and
- TruScreen is heavily reliant on being able to successfully market its solution and products to the market participants and consumers within the cervical cancer screening market. In the event that TruScreen is unable to effectively market its solution and products to the participants within this market, then this development would have a direct and adverse impact upon the ability of TruScreen to generate revenues from this market sector. Further detail about this risk factor is provided in section 8 on page 32.

<sup>9</sup> National Medical Products Administration (Previously known as **CFDA** (China Food and Drug Administration))

<sup>10</sup> <https://www.who.int/publications/m/item/draft-global-strategy-towards-eliminating-cervical-cancer-as-a-public-health-problem>

<sup>11</sup> WHO, 2019, Human papillomavirus (HPV) and cervical cancer, viewed 28 August 2020, [https://www.who.int/en/news-room/fact-sheets/detail/human-papillomavirus-\(hpv\)-and-cervical-cancer](https://www.who.int/en/news-room/fact-sheets/detail/human-papillomavirus-(hpv)-and-cervical-cancer)

## Summary of Capital Raising Initiatives and Commercial Milestones

During the course of the period commencing on 6 September 2018 and ending on the date of this PDS, TruScreen has undertaken four external capital raisings, the details of which are as follows:

- In April/May 2020 TruScreen issued 104,860,021 new shares at 5 cents per share raising \$5,243,001. The raising comprised a Share Purchase Plan ("SPP") raising \$2 million, and the placement of an oversubscription of \$1,128,001 to shareholders pursuant to the SPP, and a further placement of \$2,115,000 to both retail and wholesale investors.
- On 12 July 2019 and 3 September 2019, TruScreen issued 9,677,363 and 1,000,000 new shares respectively, at 10.6 cents per share (with one free option issued for every share subscribed for, which option is exercisable at 13 cents per option on or before 12 July 2021. This placement raised a total of NZ\$1,131,800;
- On 9 October 2018, TruScreen issued 7,411,964 new shares at 21c per share under a Share Purchase Plan (SPP). The SPP raised NZD \$1,556,500;
- On 6 September 2018, TruScreen issued 7,142,856 Shares at 21c per share. This placement raised NZD \$1,500,000.

All of the shares issued pursuant to the above placements were issued to shareholders and/or "wholesale investors" as that term is defined in the Financial Markets Conduct Act 2013.

These funds have been used to fund further research and development of the product \$2,915,361 in the two years to 31 March 2020 (TruScreen Annual Report March 2020), developing markets for TruScreen sales \$720,902 in the two years to 31 March 2020 (TruScreen Annual Report 31 March 2020), and for general working capital.

TruScreen's forward plans are to raise up to NZ\$2.0 million associated with the dual listing of its shares on the ASX. These funds will be earmarked to strengthen team capabilities to deal with an expanding business, further research and development to reduce the costs of manufacturing the Company's product, for costs of the dual listing and for general working capital.

## Key Strengths of TruScreen

- **Only device of its type – CE Mark and NMPA (China) approved for standalone screening of cervical cancer:**  
TruScreen cervical cancer screening system uses both optical and electrical tissue differentiation to identify precancerous and cancerous changes to the cervix. TruScreen has been approved for use in Europe (certificate number G1 15 11 86519 0007 ) and China (certificate number 国械注进20152181279 ). TruScreen is the only opto-electric cervical cancer screening device currently commercialised to hold these approvals.
- **The TruScreen device and system has been clinically validated**  
TruScreen has been extensively tested in numerous studies around the world, with results showing its performance is equal to, or better than, high quality cytology tests within the same study.<sup>12 13 14 15</sup>
- **The TruScreen solution does not require supporting laboratory infrastructure**  
The TruScreen cervical cancer screening system is a real time device that provides a result at the point of examination. No biological samples are taken for analysis and thus, unlike the Pap smear test or HPV DNA analysis there is no need for a laboratory to examine a tissue sample to produce a result.
- **Recognised by WHO as an option for screening in Low and Middle Income countries**  
In May 2019, TruScreen announced that it had been acknowledged in a joint publication released by Unitaids, the World Health Organisation and the Clinton Health Access Initiative. The report, titled Cervical Cancer – Screening and Treatment of Pre-Cancerous Lesions – Technology Landscape was presented at the 72nd World Health Assembly in Geneva, Switzerland, on 20 May, 2019.

A copy of the report can be found using the link below:

[http://TruScreen.com/wp-content/uploads/2019/06/Cervical\\_Cancer\\_Technology-landscape-2019.pdf](http://TruScreen.com/wp-content/uploads/2019/06/Cervical_Cancer_Technology-landscape-2019.pdf)

Whilst TruScreen does have two principal key strengths, these positive factors need to be carefully considered and read in the context of the risk factors also associated with the TruScreen business.

The key risks relating to the TruScreen operations are disclosed in greater detail in sections 1 on page 6 and in section 8.

TruScreen device and system have been extensively validated with multiple studies. Below is the summary of the key studies run in a number of different countries.

12 Comparing Study of cervical cancer screening System and liquid-based cytology test in the screening of cervical lesions – Lu Siji and associates, East Hospital, Tongji University, Shanghai– Published Obstet Gynecol, Feb, 2009, Vol.18, No.2 (China). <https://truscreen.com/wp-content/uploads/2014/08/TruScreen-Comparing-Study-of-cervical-cancer-screening-System-and-liquid-based-cytology-test-in-the-screening-of-cervical-lesions.pdf>

13 Optoelectric Scanner TruScreen in Diagnostics of Cervical Squamous Intraepithelial Lesions – Sukhikh G.T. & Associates, Federal State Scientific Centre of obstetrics, gynaecology and perinatology after academician V.I. Kulakov, Moscow, Russia., <https://truscreen.com/wp-content/uploads/2014/08/TruScreen-electric-Scanner-TruScreen-in-Diagnostics-of-Cervical-Squamous-Intraepithelial-Lesions.pdf>

14 Korean Journal of Obstetrics and Gynecology Vol. 53 No. 10 October 2010, The efficacy of a real-time optoelectronic device as a diagnostic tool of over cervical intraepithelial neoplasia 1 lesion Hyeon Soo Lim, [https://www.researchgate.net/publication/266908378\\_The\\_efficacy\\_of\\_a\\_real-time\\_optoelectronic\\_device\\_as\\_a\\_diagnostic\\_tool\\_of\\_over\\_cervical\\_intraepithelial\\_neoplasia\\_1\\_lesion](https://www.researchgate.net/publication/266908378_The_efficacy_of_a_real-time_optoelectronic_device_as_a_diagnostic_tool_of_over_cervical_intraepithelial_neoplasia_1_lesion)

15 OPTO-ELECTRONICS REVIEW 19(4), 478–485 DOI: 10.2478/s11772-011-0040-4, Optoelectronic method for detection of cervical intraepithelial neoplasia and cervical cancer D. PRUSKI1,2, M. PRZYBYLSKI1, W. KĘDZIA1,2, H. KĘDZIA3, J. JAGIELSKA-PRUSKA2, and M. SPACZYŃSK, <https://truscreen.com/wp-content/uploads/2014/08/TruScreen-Optoelectronic-method-for-detection-of-cervical-intraepithelial-neoplasia-and-cervical-cancer.pdf>

Year	Country	Investigator	No. of patients	Results (sensitivities, specificity)
1. 2019	Henan/China <sup>16</sup>	Dr. Baojin Wang	315	TS: 82.76%, 76.67%; LBC: 65.52%, 30.00%; HPV: 75.86%, 43.33%
2. 2019	Beijing/China <sup>17</sup>	Dr. Wei Zhang	1030	TS: 91.0%, 81.25%; LBC: 69.6%, 73.75%
3. 2019	Herbei/China <sup>18</sup>	Dr. Yanhong Jia	320	TS: 78.8%, 79.5%; LBC: 59.6%, 82.5%
4. 2018	Beijing/China <sup>19</sup>	Dr. Huixia Yang	2730	TS: 76%, 69%
5. 2017	Mexico <sup>20</sup>	Dr. Ricardo Lua	521	TS: 78% (CIN2+) Cytology: 36% (CIN2+) HPV DNA: 56% (CIN2+)
6. 2016	Chongqing/China <sup>21</sup>	Dr. Li Pei, Dr. Jin-sheng Wang	368	TS: 93.2%, 100%, Positivity rate 76%  LBC: 75.0%, 64.7% Positivity rate: 55.7%
7. 2015	Turkey <sup>22</sup>	Dr. Özgü E	285	TS: 86%, 35%, NPV: 89% PPV: 28%
8. 2011	Poland <sup>23</sup>	Dr. Pruski	293	TS: 90%(CIN2+) Spec: 90% PPV: 63% NVP: 90%
9. 2011	Guangdong/China <sup>24</sup>	Dr. Li Xia	500	TS: 95%, 63% Pap: 80%, 76%
10. 2010	Guangdong/China <sup>25</sup>	Dr. He Xiu-Kui	392	TS: 74%, 78% Pap: 42%, 93% TCT: 32%, 94% HPV DNA: 47%, 84%
11. 2010	Shandong/China <sup>26</sup>	Prof Fengnian Rong	532	TS: 75%, 85% TCT: 43%, 98%
12. 2010	Korea <sup>27</sup>	Dr. Hyeong Soo Lim	292	TS: 82.8%, 81.4% LBC: 75.9%, 83.3%
13. 2009	Hubei/China <sup>28</sup>	Prof Ding Ma	302	TS: 87%, 75% Thin Prep: 75%, 92%
15. 2008	Poland <sup>29</sup>	Dr. Pruski	234	TS: 85%, 82%
15. 2003	UK/Aus <sup>30</sup>	Prof A. Singer	651	TS: 70%, 81%; Pap: 69%, 95%



For the purposes of the above table, the following terms have the following meanings:

- **Sensitivity** measures correctly a positive result for patients who have the condition that is being tested for (also known as the “true positive” rate). A test that’s highly sensitive will indicate patients who have the disease.
- **Specificity** measures correctly a negative result for people who don’t have the condition that is being tested for (also known as the “true negative” rate). A high-specificity test will correctly rule out patients who do not have the disease.
- **TS** means TruScreen
- **LBC** means Liquid-based cytology. LBC is a method of preparing samples for examination in cytopathology. The sample is collected, normally by a small brush, in the same way as for a conventional smear test, but rather than the smear being transferred directly to a microscope slide, the sample is deposited into a small bottle of preservative liquid. At the laboratory, the liquid is treated to remove other elements such as mucus before a layer of cells is placed on a slide. The technique improves specimen adequacy. It’s been widely used in developed countries (and China) but not in developing countries like Vietnam and India.
- **HPV** means HPV DNA Test. The HPV DNA Test includes a range of techniques used to test for the presence of high and low risk HPV types in the cervical tissue. These techniques may include PCR and Hybrid Capture. For cervical cancer screening, it is the high risk strains of HPV which may cause cervical cancer that is to be detected. Since FDA approved Roche’s HPV DNA testing to be used in primary screening in 2014, it became the mainstream primary screening method in all major screening guidelines (e.g. WHO, EU, Australia etc).
- **PPV** means Positive predictive value. PPV is the probability that subjects with a positive screening test truly have the disease. Negative predictive value is the probability that subjects with a negative screening test truly don’t have the disease.

16 WANG Baojin, MA Qian, ZHAO Xinxin, et al. Application Value of TCT, HPV and TruScreen in Screening Cervical Disease. Journal of Practical Obstetrics and Gynecology 2019 Nov. Vol. 35, No. 11

17 Qi Weihong, Zhang Wei et al. Clinical Observation of Cervical Cancer Screening System TruScreen in 1030 Cases. Electronic Journal Of Practical Gynecologic Endocrinology. Nov. A. 2019 Vol.6, No.31

18 Yanhong Jia. The Clinical Effectiveness of Cervical Cancer Screening System TruScreen in Cervical Cancer Screening. Electronic Journal Of Practical Gynecologic Endocrinology. Nov. A. 2019 Vol.6, No.31

19 Huixia Yang, Xinmiao Zhang, et al. The diagnostic accuracy of a real-time optoelectronic device in cervical cancer screening A PRISMA-compliant systematic review and meta-analysis. Medicine (2018) 97:29

20 Ricardo Lua, et al. Comparison of an Optoelectronic Scan of the Cervix, Cervical Cytology and HPV Genotyping for CIN Screening. Journal of Lower Genital Tract Disease. Vol 21, Number 2, Supplement 1, April 2017.

21 Li Pei, Jinsheng Wang et al. Application Effect of TruScreen System in Cervical Cancer Screening.

22 Özgü E, Yıldız Y, Özgü BS, Öz M, Danişman N, Güngör T. Efficacy of a real time optoelectronic device (TruScreen™) in detecting cervical intraepithelial pathologies: a prospective observational study. J Turk Ger Gynecol Assoc. 2015;16(1):41-44. Published 2015 Mar 1. doi:10.5152/jtgga.2015.15199

23 Pruski, D., Przybylski, M., Kędzia, W. et al. Optoelectronic method for detection of cervical intraepithelial neoplasia and cervical cancer. Opto-Electron. Rev. 19, 478 (2011).

24 LIXia, YE Qing et al. Clinical research on fluorescence microscopy technology combined with cervix pap smear in cervical cancer screening. IMHGN, November 2011, Vol. 17 No. 24

25 HE Xiu-kui, LUOXi-ping et al. An optoelectronic cervical cancer screening system for screening cervical cancer: comparison with cervical cytology. China Reproductive Health 2013,24(1):9-11

26 CUI Ying-ying, ZHANG Bei ,RONG Feng-nian. The application value of cervical cancer screening system and thinprep cytological test in the screening of cervical lesion during the women’s health screenings.

27 Hyeong Soo Lim, M.D., et al, Korean Journal of Obstetrics and Gynecology Vol. 53 No. 10 October 2010, The efficacy of a real-time optoelectronic device as a diagnostic tool of over cervical intraepithelial neoplasia 1 lesion

28 Zheng Hongbing, Ma Ding et al. Comparing Study of Truscreen® and Liquid Based Cytology Test in the Screening of Cervical Lesions.

29 D. Pruski, et al, The assessment of a real-time optoelectronic method for the detection of cervical intraepithelial neoplasia (‘CIN’), Volume107, Issue S2, Abstracts of XIX FIGO World Congress of Gynecology and Obstetrics, October 2009,

30 Singer A, Coppleson M, Canfell K, et al. A real time optoelectronic device as an adjunct to the Pap smear for cervical screening: a multicenter evaluation. Int J Gynecol Cancer 2003;13:804-11

## BUSINESS INDUSTRY AND SECTOR

TruScreen is focused on the export of the TruScreen cervical cancer screening system to large developing countries and low and middle income countries (LMIC's) which lack national cervical cancer screening infrastructures.

TruScreen is used in these countries for women of Screening age – typically 25 to 65 years. While guidelines vary from country to country, according to WHO, these women should be screened every 2 to 3 years<sup>31</sup>.

TruScreen is a device for the primary screening of cervical cancer. That means that it is suitable for use for every woman of screening age. If a patient has an abnormal TruScreen result, (or pap smear or HPV DNA test) she is then typically referred for a second opinion. Subject to different countries requirements, this is usually performed using a colposcope<sup>32</sup> to provide a magnified view of the cervix. If the patient has a normal 'TruScreen' result she is typically sent home and advised to return for her next TruScreen test in 2 or 3 years' time.

However, as a real time device TruScreen system can be used to facilitate 'See and Treat' screening in regions where there is no access to reliable colposcopy and pathology services. In this model if a patient has an abnormal TruScreen result then she may be immediately treated by use of cryotherapy<sup>33</sup> or thermal coagulation<sup>34</sup>. This mitigates the risk of a patient not returning for, or being unable to be located for, colposcopy.

The table on the right shows the number of women of screening age in our key target markets. TruScreen is targeting to reach 5% of the addressable screening population in our key markets with a potential revenue value of up to NZ\$166 million.<sup>35</sup>

Screening Population by Country	
	Millions
China	402 <sup>36</sup>
Russia	42 <sup>38</sup>
Africa	260 <sup>39</sup>
India	318 <sup>40</sup>
Middle East	75 <sup>41 42 43 44</sup>
Latin America (including Mexico)	181 <sup>45</sup>
Vietnam	24 <sup>46</sup>
Total	1,302

## CURRENT AND FUTURE KEY ASPECTS OF BUSINESS

The current and future aspects of TruScreen's business that have, or may have, the most impact on the financial performance of the business are:

- **The ability to generate sales revenues:** Ultimately the financial performance of the business will be driven by the Company's ability to generate sales revenues from the sale of its products or licence technology that it has developed through its research programmes to date. The Company is planning further research and development programs to further reduce the cost of manufacture of its products. This will be an ongoing process, and the Company will continue to assess ways in which its products can be manufactured more cost effectively.

31 World Health Organisation, 2013, Guidelines for screening and treatment of precancerous lesions for cervical cancer prevention, visited 28 August 2020, [https://www.who.int/reproductivehealth/publications/cancers/screening\\_and\\_treatment\\_of\\_precancerous\\_lesions/en/](https://www.who.int/reproductivehealth/publications/cancers/screening_and_treatment_of_precancerous_lesions/en/)

32 A colposcope is a medical device used to examine an illuminated, magnified view of the cervix as well as the vagina and vulva

33 Cryotherapy, sometimes known as cold therapy, is the local or general use of low temperatures in medical therapy. Cryotherapy can be used to treat a variety of tissue lesions

34 Thermal coagulation is a form of heat ablation used to treat CIN

35 This determination has been made by the Directors on the basis of an estimated penetration of each market (between 1% and 8% with an average of 4%) divided by 3 (each patient scanned every 3 years) multiplied by selling price if one SUS.

36 Central Intelligence Agency, The World Fact Book, CHINA, People and Society, Female ages 25–64 Years, visited 28 August 2020, <https://www.cia.gov/library/publications/the-world-factbook/geos/ch.html>

38 Central Intelligence Agency, The World Fact Book, RUSSIA, People and Society, Female ages 25–64 Years, visited 28 August 2020, <https://www.cia.gov/library/publications/the-world-factbook/geos/rs.html>

39 United Nations, Department of Economic and Social Affairs, Population Dynamics, Population by age and Sex (thousands) Africa, Female, 25–69 years, 2020, visited 28 August 2020, <https://population.un.org/wpp/DataQuery/>

40 Central Intelligence Agency, The World Fact Book, INDIA, People and Society, Female ages 25–64 Years, visited 28 August 2020, <https://www.cia.gov/library/publications/the-world-factbook/geos/in.html>

41 Central Intelligence Agency, The World Fact Book, EGYPT, People and Society, Female ages 25–64 Years, visited 28 August 2020, <https://www.cia.gov/library/publications/the-world-factbook/geos/eg.html>

42 Central Intelligence Agency, The World Fact Book, IRAN, People and Society, Female ages 25–64 Years, visited 28 August 2020, <https://www.cia.gov/library/publications/the-world-factbook/geos/ir.html>

43 Central Intelligence Agency, The World Fact Book, TURKEY, People and Society, Female ages 25–64 Years, visited 28 August 2020, <https://www.cia.gov/library/publications/the-world-factbook/geos/tu.html>

44 Central Intelligence Agency, The World Fact Book, SAUDI ARABIA, People and Society, Female ages 25–64 Years, visited 28 August 2020, <https://www.cia.gov/library/publications/the-world-factbook/geos/sa.html>

45 United Nations, Department of Economic and Social Affairs, Population Dynamics, Population by age and Sex (thousands) Latin America, Female, 25–69 years, 2020, visited 28 August 2020, <https://population.un.org/wpp/DataQuery/>

46 Central Intelligence Agency, The World Fact Book, VIETNAM, People and Society, Female ages 25–64 Years, visited 28 August 2020, <https://www.cia.gov/library/publications/the-world-factbook/geos/vn.html>

In the event that the Company is unable to implement its business strategy and ultimately generate sales revenues through the sale of its products, then such an occurrence would have a material adverse impact on the financial performance of TruScreen.

- **Preservation of working capital until positive cashflow achieved:** During the period from the date of this document to the period in which it is able to generate positive cashflow, the Company must preserve its working capital carefully to ensure it can continue to pay its debts as they fall due in the ordinary course of business, and to ensure that the value of its assets exceed the value of its liabilities.

In the event that the Company ran out of financial resources to be able to continue to fund its commercial endeavours then such an occurrence would have a material adverse impact on the financial performance of TruScreen.

- **Development of increased sales channels for the distribution of the TruScreen technology solution in China, Vietnam, Russia, Eastern Europe, India, Latin America and Africa:** The ability of TruScreen to effectively develop its sales channels (i.e with a view to increasing sales and revenues) in China, Vietnam, Russia, Eastern Europe, India, Latin America and Africa taken individually or collectively will have a material impact upon the financial performance of TruScreen.
- **Establishment of manufacturing in China:** The establishment of a manufacturing facility in China will achieve a lower manufacturing cost, and by registering TruScreen as a domestic product will remove the bias against foreign products for use in public health programs in China. The Company is negotiating with a Chinese company which is ISO13485 accredited to manufacture the TruScreen device in Shenzhen, China. The Company is also negotiating with its current Sydney based contract manufacturer to project manage and facilitate the transition of the manufacturing to the proposed contract manufacturer in China. The changeover of manufacturing of the device is planned for the June 2021 quarter.

## KEY STRATEGIES AND PLANS FOR KEY ASPECTS OF THE BUSINESS

TruScreen has developed the following key strategies and plans for the above aspects of the business:

### Revenue Generation

TruScreen has developed and is implementing an extensive business plan and strategy that if optimally executed will ultimately lead to the Company generating increased revenues from the sale of the products it develops and manufactures, and ultimately to generate profits from those commercial operations.

The key strategies being implemented by the Company to achieve these objectives are as follows:

- **Efficient roll-out in established core markets.** China is the priority market and TruScreen is targeting to double the number of hospitals where TruScreen system will be available for patients within the next year. 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. TruScreen are aligned with our customers' (distributor) and our customers customer (the hundreds of doctors and nurses working with the TruScreen Ultra2 device) needs, and plan further improvements based on their feedback and requirements for a medical screening device.
- **Focus on commercial efficiency.** As a growing company TruScreen needs to invest to support a significant increase in product sales in 2021. While growing revenues, we will remain focus on improving gross margin through manufacturing efficiency, R&D programs aimed at reducing costs of manufacture 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 is expected in the 2021 FY will provide support for the accuracy and reliability of our system in a leading 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 business requirements and projected business growth.

### Management of working capital resources

TruScreen has a detailed cashflow model to chart required capital and operational expenditure and is constantly monitoring adherence to that cashflow model to ensure the Company has adequate financial resources to undertake its commercial operations.

The Company's scalable model also means capital for expansion and development can be committed as the economics justify it.



Money raised from this Offer will also ensure TruScreen is well capitalised to implement its business plan and strategies referred to above.

### **Development of increased sales channels for the distribution of the TruScreen solution in China, Vietnam, Russia, Eastern Europe, India, Latin America, and Africa**

TruScreen has adopted three key steps in its strategy to develop its sales channels in these markets, as follows:

1. Appointment of a distributor(s) and the gaining of regulatory approvals for the sale of TruScreen's products.

TruScreen has distribution agreements in 23 countries, including the world's two largest screening populations, China and India.

2. Gaining key opinion leader (KOL) support.

TruScreen has engaged with key opinion leaders and conducted evaluation programs in the largest of its markets, including programs with the China Obstetricians and Gynaecologists Association. This program is due to conclude in 2020.

3. Commenced commercial activity.

The majority of TruScreen's sales are expected to come from China, with Russia, Mexico, Zimbabwe and Vietnam making up the majority of the balance of TruScreen's sales. Eastern Europe and India are expected to form the next group of countries to start generating meaningful revenues for the Company.

The Board would consider these initiatives to be effective if TruScreen achieved the following, in respect of each market:

- year on year growth by country in the number of installed (and operational) devices by country and a broader acceptance by the number of hospitals.
- achievement of positive trial results;
- implementing good customer/distributor training initiatives and service support;
- assisting distributors to reach and converting new customers.

A summary of TruScreen's current status and plans for growth in our key markets is as follows:

### **China**

China is TruScreen's largest, most established market and is the Company's primary commercial focus. It has over 400 million women of screening age and accounts for over 20% of all cervical cancer diagnoses worldwide<sup>47</sup>, presenting a significant market opportunity for TruScreen. TruScreen has been present in China since 2014, with the region accounting for over 65% of the Company's sales in FY2020.

The Company's long-term goal is to have TruScreen added to various national cervical screening guidelines and procurement lists. Clinical validation and Key Opinion Leader (KOL) support is the key to achieving this goal and has been our overriding focus since market entry.

In 2018 TruScreen commenced a large-scale evaluation with the Chinese Obstetricians and Gynaecologists Association (COGA), to screen up to 20,000 women across 10 provinces. The size of the trial has since been reduced to 10,000 patients due to the interruption from COVID-19 lockdowns during the first quarter of calendar year 2020. The trial, the largest TruScreen has done, aims to have TruScreen introduced into 100 top-tier teaching hospitals throughout China, forming part of the organisation's cervical cancer screening guidelines. COGA represents over 100,000 obstetricians and gynaecologists throughout China, focusing on the management, education, regulation and certification of these specialists. Since starting the evaluation TruScreen has gained KOL support from various levels of the organisation at both a provincial and national level. The trial is due for completion in late 2020, with results expected to be published in 2021.

The 3,000 patient clinical evaluation with the Women's and Children's Division of China's Centre for Disease Control (CDC) commenced in late 2018 however has been suspended by CDC until further notice. The evaluation has been suspended due to the Company's sub-distributor responsible for the oversight of this evaluation suffered financial difficulties. If the suspended clinical evaluation is terminated, sale of TruScreen cervical cancer screening device will reduce the access, but not exclude sales to those hospitals managed by the CDC. The termination of this clinical evaluation would not have a material adverse impact on the financial or operational position of the Company.

In addition to our focus on clinical studies, TruScreen has been building its commercial user base in both public and private hospitals. The TruScreen technology is currently in commercial use in 18 provinces throughout China, with further government procurement projects underway. TruScreen targets to double its presence in Chinese hospitals and reach 100 hospitals threshold in next 12 months. TruScreen is working closely with its distribution network to increase each hospital's monthly SUS usage for each installed device. This commercial base is consistently growing, as market acceptance of the technology increases, and forms a strong foundational support for TruScreen clinical initiatives within the country.

<sup>47</sup> Weim, et al, 2018, 'Rising Mortality Rate of Cervical Cancer in Younger Women in Urban China', J Gen Intern Med, vol. 34, no. 2, p.281-284, viewed 28 August 2020, <https://link.springer.com/content/pdf/10.1007%2Fs11606-018-4732-z.pdf>

## Russia

The Russian Federation is TruScreen's key market. Cervical Cancer is the fourth most common cancer for women in Russia. With a screening population of 42 million women and no organised cervical cancer screening<sup>48</sup>, TruScreen is well positioned in this market as a primary screening solution. TruScreen has been present in Russia since 2015, and after bringing on a new distribution partner in early 2019 the sales in the region grew, accounting for 20% of FY2019 sales.

The Company's focus in Russia over the last 2 years has been market education and acceptance, and KOL endorsement. In early 2020 TruScreen's regional distributor launched a nationwide TruScreen education campaign in partnership with Russia's top KOL on cervical cancer, the President of the Russian Association of Gynaecological Diseases and Neoplasia. This educational seminar engaged over 2,800 doctors and specialists, across 18 cities. The outcome of the campaign has seen a high acceptance of the technology within the group, with significant support for formal adoption as a primary screening tool. TruScreen targeted to commence large pilot projects in key regions like Chechenskaya Republic in Q2'2020 but was delayed by COVID-19 outbreak.

TruScreen is currently in preparations for a clinical evaluation with Federal State Budgetary Institution "National medical and surgical center named after N. I. Pirogov" (NMSC) of the Ministry of Health of the Russian Federation (105203 Moscow, Nizhnyaya Pervomayskaya str., 70). This study will be run by Prof. Kira Evgeny Fedorovich, Head of the Department of women's diseases and reproductive health at NMSC, Academician of the Russian Academy of Sciences, Member of the Presidium of the Russian society of obstetricians and gynaecologists (ROAG).

## Vietnam

Vietnam forms the basis of TruScreen's South-East Asian strategy, successful market establishment in the region will be used to establish market entry in other SE Asian countries. Vietnam has 24 million women of screening age<sup>49</sup>, and currently has no centralised national cervical screening program. TruScreen has been in Vietnam since 2016, with early efforts focussed on KOL and Ministry of Health (MOH) education programs.

In late 2019 TruScreen commenced a pilot study at the largest gynaecological hospital in Vietnam, Ha Noi Obstetrics and Gynaecology Hospital (HOGH), in partnership with MOH's appraisal committee. The pilot study screened almost 1,000 women, comparing the TruScreen device to the conventional Pap test. In early 2020 the MOH appraisal committee reviewed the results of the trial and endorsed and approved the TruScreen device for use in Vietnam. After the successful pilot study HOGH signed a contract committing to large scale monthly TruScreen cervical cancer screening within the hospital.

Following MOH approval, TruScreen's local distributor has begun a marketing and education campaign in the South of Vietnam. The education campaign is focussed on 10 top-level teaching hospitals, enhancing the doctor's overall understanding of cervical cancer, and introducing the TruScreen cervical cancer screening system as the primary screening tool.

## Expanding TruScreen's presence outside of the key markets

TruScreen's ability to provide accurate real-time results without access to pathology infrastructure means it is the ideal screening solution for LMICs. TruScreen continues to grow its presence in other regions, including Africa, Mexico, India, the Middle East, and Central Eastern Europe.

19 out of 20 countries with the highest cervical cancer burden are in Africa.<sup>50</sup> There are 260 million women of screening age in Africa, with 13.3 million women suffering from HIV.<sup>51</sup> Our African strategy is focused on sub-Saharan Africa, where HIV has a high prevalence. Women who suffer from HIV are 5 times more likely to be diagnosed with Cervical Cancer. In 2018 TruScreen partnered with Zimbabwe's National Aids Council for a cervical cancer screening project aiming to reach approximately 15,000 women throughout Zimbabwe.

Mexico is TruScreen's entry point into Latin America, and accounted for 11% of sales in FY2020. Mexico has a screening population of 31 million, with cervical cancer being the third most common cancer in the region.<sup>52</sup> TruScreen has been present in Mexico since 2015, having recently signed a new distribution agreement in 2020. TruScreen has been utilised in novel ways to reach the rural communities of Mexico. In 2017 & 2018, TruScreen was selected for use in Mexico's famous Health Train, El Tren de la Salud. The health train operates in 22 Mexican states, bringing advanced medical screening technologies to women living in remote communities.

India is home to a screening population of over 300 million women.<sup>53</sup> Cervical cancer is the second leading cause of cancer death in women in the country.<sup>54</sup> TruScreen has been present in the region since 2017. In 2018 & 2019 the national All India Institute of Medical Sciences (AIIMS) conducted a TruScreen trial, screening 645 women over 13 months. The trial outcomes showed TruScreen to be more accurate at detecting cervical cancer than the conventional Pap-test. The results are expected to be published in 2021 with commercial sales to start once covid-19 restrictions are lifted.

In 2020 the Company rationalised its distribution portfolio in Central and Eastern Europe (CEE), appointing a prominent medical device distributor to cover Czech Republic, Slovakia and Poland. The Company also appointed a Europe based commercial representative to drive our strategy for the

48 Central Intelligence Agency, The World Fact Book, RUSSIA, People and Society, Female ages 25–64 Years, visited 28 August 2020, <https://www.cia.gov/library/publications/the-world-factbook/geos/rs.html>

49 Central Intelligence Agency, The World Fact Book, VIETNAM, People and Society, Female ages 25–64 Years, visited 28 August 2020, <https://www.cia.gov/library/publications/the-world-factbook/geos/vn.html>

50 United Nations, Department of Economic and Social Affairs, Population Dynamics, Population by age and Sex (thousands) Africa, Female, 25–69 years, 2020, visited 28 August 2020, <https://population.un.org/wpp/DataQuery/>

51 World Health Organisation, Number of women living with HIV increases in each region of the world, 2004, visited 28 August 2020, <https://www.who.int/3by5/news34/en/>

52 ICO/IARC Information Centre on HPV and Cancer, Mexico, Human Papillomavirus and Related Cancers, Fact Sheet 2018, 2019, viewed 28 August 2020, [https://hpvcentre.net/statistics/reports/MEX\\_FS.pdf](https://hpvcentre.net/statistics/reports/MEX_FS.pdf)

53 Central Intelligence Agency, The World Fact Book, INDIA, People and Society, Female ages 25–64 Years, visited 28 August 2020, <https://www.cia.gov/library/publications/the-world-factbook/geos/in.html>

54 The George Institute for Global Health India, Cervical Cancer in India: Challenge and Opportunities, 2018, viewed 28 August 2020, <https://www.georgeinstitute.org/cervical-cancer-in-india-challenges-and-opportunities>

region. Although in the early stages of development, TruScreen views the CEE region as an important market opportunity for TruScreen.

### Establishment of manufacturing in China

TruScreen is well advanced in its planning to have its device assembled in China for the Chinese market, and to have its device registered as a domestic product manufactured in China.<sup>55</sup> This will lower manufacturing costs due to lower labour and component costs. The registration of TruScreen as a domestic product in China will also remove the bias against foreign products in the Company's most important market.

To date, TruScreen has taken the following steps towards its planning to manufacture the device in China include:

Appointment of an experienced engineer consultant for six months to lead the project;

The Company is working with the current Sydney based manufacturer in preparing a scope of work for the transition of manufacture;

The proposed Chinese manufacturer is ISO13485 accredited ;

In view of COVID-19, the Company is establishing procedures to ensure transition to China notwithstanding limitations on travel.

For more information please refer to Section 7 (TruScreen's Financial Information). A full set of the financial statements for TruScreen can also be found on the Disclose Register at [www.business.govt.nz/disclose](http://www.business.govt.nz/disclose), offer number OFR12990.

## DIRECTORS AND SENIOR MANAGERS

The Directors of TruScreen are Anthony Ho, Christopher Horn, Chris Lawrence, and Juliet Hull.

The senior managers of TruScreen are Victoria Potarina, Edmond Capacelea, Guy Robertson, Dr Jerry Tan, Paul Curran, Dr Zhenglin Wang.

### Board of Directors

Biographies for each of the directors are provided below:

**Anthony (Tony) Ho**  
**Independent Non-Executive Chairman**  
B.Com UNSW, CA, FCIS, FAICD, FGIA

Tony has a Bachelor of Commerce degree from The University of New South Wales, Sydney, and is a Member of The Institute of Chartered Accountants in Australia and New Zealand, a Fellow of the Australian Institute of Company Directors, a Fellow of the Institute of Chartered Secretaries and Administrators, and the Governance Institute of Australia. He has also completed post graduate studies in Marketing at the University of Technology, Sydney. He was a past Fellow of the Australian Marketing Institute.

Tony holds numerous non-executive directorships with a number of ASX and NZX listed companies. He is currently the non-executive chairman of Bioxyne Limited (ASX:BXN), Greenland Minerals Limited (ASX:GGG), and Cannasouth Limited (NZX:CBD).

Tony was executive director of Arthur Yates & Co Limited, retiring from that position in April 2002. He was previously a director of Yates New Zealand Limited. Prior to joining commerce, Tony was a partner of Cox Johnston & Co, Chartered Accountants, which has since merged with Ernst & Young.

**Christopher Horn**  
**Non-Executive (Independent) Director**  
B.Com UNSW, FCA

Chris Horn has been involved with TruScreen for a number of years. He is an experienced business executive and has acted in a number of management roles including 20 years as a senior partner of KPMG and its predecessor firms. He is a director of a number of private companies across a broad range of business activities including corporate advisory, financial services, and funds management.

Chris is a Commerce graduate from the University of New South Wales, Sydney, Australia and a Fellow of the Institute of Chartered Accountants in Australia and New Zealand.

Chris is also the Chair of TruScreen's Audit, Finance and Risk Committee.

**Chris Lawrence**  
**Non-Executive (non-independent) Director**

Chris Lawrence is a successful New Zealand businessman and a significant investor in life science and biotechnology businesses including TruScreen. He has spent a substantial part of his career in small business where he has had proven success in leading marketplace disruption, and translating new business models into sustainable profitable businesses. In the latter part of his career, he has dedicated a large share of his time to governance and advisory roles.

Most recently Chris' focus has been on high growth companies, with a particular focus in the biotech industry.

**Juliet Hull**  
**Non-Executive (Independent) Director**  
B. Nurse ATI, MBA MGSM

Juliet Hull has an MBA from the Macquarie Graduate School of Management, Sydney Australia, and a Bachelor of Nursing from the Auckland Technical Institute.

Juliet Hull 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.

Juliet Hull has more than twenty years' experience working in Asia and Pacific markets in Healthcare, in sales, Marketing and leadership.

<sup>55</sup> Please also refer to the paragraph titled "Establishment of Manufacturing in China" on page 18.

## Senior Managers

Biographies for each of the senior managers are provided below:

**Victoria Potarina**  
**Chief Executive Officer,**  
M. App Ling (Hons), GAICD

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

Victoria Potarina has a Master in Applied Linguistics and is a Graduate member of the Australian Institute of Company Directors. Victoria is an MBA candidate with Macquarie Graduate School of Management.

Ms Potarina brought 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. Victoria was the Statutory Director of Johnson & Johnson UK & Ireland.

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.

**Edmond Capcelea**  
**Chief Technology Officer,**  
M.Sc Eng Physics

Edmond Capcelea has a Masters degree in Engineering Physics.

Mr Capcelea is a senior medical device executive with more than 25 years of experience in medical device design and development. His expertise includes leading multidisciplinary Class II and implantable medical device product development and technology teams, both locally and overseas.

Mr Capcelea's previous roles include Divisional Director Head of Implants Design & Development and Divisional Director Head of External R&D at ASX listed Cochlear Limited, and Senior Vice President of R&D at Saluda Medical. He 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 II to Class III.

**Guy Robertson**  
**Company Secretary/Chief Financial Officer,**  
B. Com (Hons) CA

Guy Robertson has a Bachelor of Commerce degree and is a member of the Institute of Chartered Accountants in Australia and New Zealand.

Guy has over 30 years of management and leadership experience. He has extensive experience as a finance executive in Australia and Asia across a broad range of industries, in both private and listed companies.

Mr Robertson is currently a director of ASX listed Hastings Technology Metals Limited and Metal Bank Limited.

**Dr. Jerry Tan**  
**General Manager**  
**General Manager Commercial,**  
MBBS, M.Com, CPA

Dr. Jerry Tan holds a degree in Medicine and Surgery and is a qualified Gynaecologist from China. He also holds a Master degree in commerce from Macquarie University and is a Certified Practising Accountant in Australia. He is fluent in English and Mandarin.

Dr. Tan has extensive knowledge of the TruScreen product and has been involved in establishing the market in China, including, identification of distributors, product registration, market evaluation, and the conduct of clinical trials.

Dr. Tan heads up TruScreen's operations in China, Vietnam, Mexico, and India.

**Paul Curran**  
**General Manager – Regulatory/Compliance Affairs,**  
B.Sc Eng

Mr. Paul Curran has a Bachelor of Science, specialising in all areas of Medical Device Licensing, including Quality Assurance for New Product Development, Technical File development and Audit and Risk Assessment.

He is experienced in Healthcare Compliance and the control of manufacturing, including subcontractors, for the delivery of a quality assured product on time.

Mr. Curran has been involved with the TruScreen product for many years and is responsible for registrations and quality assurance.

**Dr. Zhenglin Wang**  
**Manager – Electro-Optical Production,**  
PhD (Laser), B. Sc (Opto) M. Optics

Dr Wang has a Bachelor of Science in Optoelectronic, Master degree in Optics and a PhD in Laser Physics. He previously managed the manufacture and development of a range of optical technologies including ophthalmic lasers and wavelength selective switch systems for communication technologies.



Dr. Wang led the establishment of, and now manages, the TruScreen Electro-Optical fabrication facility based in the Industry Collaboration Hub at the Commonwealth Scientific and Industrial Research Organisation (CSIRO), in Lindfield.

### **Medical Advisory Committee**

The TruScreen Medical Advisory Committee's role is to advise the directors and executives of TruScreen on clinical, scientific and medical matters. This includes the review of clinical trials, monitoring developments in the screening, diagnosis and treatment of cervical cancer, advising on screening and referral paradigms and patient management protocols.

In addition, the Medical Advisory Committee advises on additional applications of the existing TruScreen technology and any other technologies that may be of interest to TruScreen.

The members of the TruScreen Medical Advisory Committee are:

**Colonel (Dr.) Assoc Prof Michael J. Campion**  
RAAMC, CStJ, KM, KCHS, KLJ

The TruScreen Medical Advisory Committee is led by Colonel (Dr.) Assoc Prof Michael J. Campion. Dr Campion is a Senior Staff Specialist and Head of the Pre-Invasive Clinic at the Gynaecological Cancer Centre of the Royal Hospital for Women in Sydney and is a Conjoint Associate Professor, School of Women's and Children's Health, at the University of New South Wales. He has over 30 years' experience as an eminent medical practitioner and over 20 years of experience as an expert colposcopist.

In addition, Assoc Prof. Campion is the Director, Health Services Army Reserve – Eastern Region for the Royal Australian Army Medical Corps and is both a Board member and National Hospitalier, St John Ambulance, Australia. Assoc Prof. Campion has written numerous peer reviewed papers and chapters on cervical cancer, including papers on the TruScreen cervical cancer screening technology.

### **Professor Neville Hacker AM Clinical Advisory – Professor of Gynaecology**

Professor Hacker is Conjoint Professor of Gynaecological Oncology at the University of New South Wales and recently retired from clinical practice after 32 years as the director of the Gynaecological Cancer Centre, Royal Hospital for Women in Sydney, where he continues to serve as an Emeritus consultant.

He is a past President of the Society of Pelvic Surgeons, a past President of the International Gynaecological Cancer Society, former Chairman of the Oncology Committee of the RANZCOG, and a former Chairman of Examiners for Gynaecologic Oncology, RANZCOG.



**Table of substantial shareholders and of relevant interests held by directors and senior managers, etc**

<b>Substantial product holders prior to the Offer</b>			
<b>Product Holders with relevant interests in 5% or more of a class of relevant securities</b>	<b>Legal ownership or other nature of the interest</b>	<b>Number of relevant securities held</b>	<b>% of relevant securities held</b>
Robert Hunter (registered holder: Consolidated Nominees Pty Limited)	Controller of registered holder	39,602,400	11.92
Browns Island Holdings Limited	Legal and beneficial	22,400,000	6.74
Waitara Trustees Limited	Legal and beneficial	18,622,222	5.6
<b>Total</b>		<b>80,624,622</b>	<b>24.26%</b>

<b>Substantial product holders after the Offer</b>			
<b>Product Holders with relevant interests in 5% or more of a class of relevant securities</b>	<b>Legal ownership or other nature of the interest</b>	<b>Number of relevant securities held</b>	<b>% of relevant securities held<sup>56</sup></b>
Robert Hunter (Registered holder: Consolidated Nominees Pty Limited)	Controller of registered holder	39,602,400	10.97%
Browns Island Holdings Limited	Legal and beneficial	22,400,000	6.21%
Waitara Trustees Limited	Legal and beneficial	18,622,222	5.16%
<b>Total</b>		<b>80,624,622</b>	<b>22.34%</b>

<sup>56</sup> The percentages in this column of the table have been calculated on the assumption that the maximum number of 28,571,428 new ordinary Shares are issued pursuant to the Offer.

**Relevant interests of each director, proposed director, senior manager and proposed senior manager of the issuer prior to and after the offer**

Interest Holder	Legal ownership or other nature of the interest	Prior to the Offer		Immediately after the issue <sup>57</sup>	
		Number of relevant securities held	% of relevant securities held	Number of relevant securities likely to be held	% of relevant securities likely to be held
Anthony Ho	Legal and beneficial	3,500,000	1.05	3,500,000	0.97%
Christopher Lawrence	Beneficial (registered holder is Brown Island Holdings Limited)	22,400,000	6.74	22,400,000	6.21%
Christopher Horn	Legal and beneficial	2,050,000	0.62	2,050,000	0.57%
Guy Robertson	Legal and beneficial	102,170	0.03	102,170	0.03%
Timin (Jerry) Tan	Legal and beneficial	100,000	0.07	100,000	0.03%
Paul Curran	Legal and beneficial	88,530	0.026	88,530	0.02%
Total		28,240,700	8.536	28,240,700	7.82%

The following Directors and senior managers also hold options to acquire shares in the Company:

Name of recipient	Number of options	Exercise price	Vesting	Exercise Date
Anthony Ho (Director)	2,000,000	15 cents	Vested	Exercisable on or before 27 August 2022
	1,000,000	13 cents	Vested	Exercisable on or before 12 July 2021
Guy Robertson (Chief Financial Officer)	500,000	15 cents	Vested	Exercisable on or before 27 August 2022
Christopher Horn (Director)	1,000,000	15 cents	Vested	Exercisable on or before 27 August 2022
Christopher Lawrence (Director)	1,000,000	15 cents	Vested	Exercisable on or before 27 August 2022
Zhenglin Wang (Manager, Manufacturing)	500,000	15 cents	Vested	Exercisable on or before 27 August 2022

<sup>57</sup> The calculations in this column assume that the maximum number, 28,571,428, of new shares are issued pursuant to the Offer.

## Options to acquire shares in the Company

There are a total of 19,677,363 options to acquire ordinary shares in TruScreen on issue in the Company. There are two classes of options, the details of which are as follows:

Class of Option	Number of options on issue	Exercise price	Vesting	Exercise Date
TruScreen executive options	9,000,000	15 cents	Vested	Exercisable on or before 27 August 2022
Placement Options	10,677,363	13 cents	Vested	Exercisable on or before 12 July 2021

## Interests of directors and senior managers

### Director remuneration and benefits

The table below sets out:

- the total of the remuneration and the value of other benefits received by each director of TruScreen in respect of the Company or any other member of TruScreen during the most recent period; and
- the nature of any services provided by each director to which that remuneration or those benefits relate (other than services provided in that person's capacity as a director).

Director	Total remuneration and value of other benefits received	Nature of services provided	Expected differences in remuneration or benefits for FY 2021
Anthony Ho	\$110,000	Non-executive Chairman	During the financial year ended 31 March 2020, the annual directors fee payable to the director was \$80,000 per annum. During this year the Chairman was paid an additional fee of \$30,000 for acting as an executive chairman, pre appointment of a new CEO.
Christopher Lawrence	\$40,000	Non-executive Director	During the financial year ended 31 March 2020, the annual directors fee payable to the director was \$40,000 per annum.
Christopher Horn	\$50,000	Non-executive Director	During the financial year ended 31 March 2020, the annual directors fee payable to the director was \$40,000 per annum. Mr Horn received an additional \$10,000 per annum for chairing the Audit, Finance and Risk Committee of Directors.
Juliet Hull	Nil	Non-executive Director	During the financial year ending 31 March 2021, the annual directors fee proposed to be paid to the director will be \$40,000 per annum.



In addition to the above payments, the Company also issued the following options to each director as part of the TruScreen Employee Share Option Plan:

- Anthony Ho: 2,000,000 options, the details of which are provided in the Table on page 25.
- Christopher Horn: 1,000,000 options, the details of which are provided in the Table on page 25.
- Christopher Lawrence: 1,000,000 options, the details of which are provided in the Table on page 25.

#### Employee remuneration over \$100,000 per annum

As at the date of this PDS, the following employee not being a director of the Company, will receive remuneration and other benefits in their capacity as an employee, that in value exceeds NZ\$100,000 per annum.

Remuneration bracket	Number of employees
NZ\$200,000 - \$220,000	1
NZ\$300,000 - \$310,000	1

## 3. Purpose of the offer

#### Purpose of the offer

The purpose of this offer is to raise a minimum of NZ\$1,000,000 of new capital, and a maximum of NZ\$2,000,000 of new capital for TruScreen, which capital will enable the Company to implement its strategic business plan.

In the event that a minimum of NZ\$1,000,000 is not raised pursuant to this offer, the Offer will not proceed, and no new shares will be issued pursuant to this Offer.

The money raised under the Offer will be applied as follows<sup>1</sup>:

Investment in team capabilities for business expansion	\$200,000
Establish device manufacturing in China for Chinese operations	\$300,000
Reduce the cost of the product via R&D initiatives	\$300,000
Market development through market access/medical affairs capability	\$200,000
Costs associated with the offer and dual listing	\$300,000
General working capital	\$200,000
<b>Total</b>	<b>\$1,500,000</b>

<sup>1</sup> In the event the raise is less or more than \$1.5 million then one or more categories could be indexed lower or higher accordingly.

Particulars of how each intended use of funds relates to the strategies and plans of TruScreen's business is provided in Section 2. The funds will be applied towards the aforementioned purposes irrespective of whether the minimum of NZ\$1 million, or the maximum amount of NZ\$2.0 million is raised under this Offer.

#### No underwrite

The offer is not underwritten.

## 4. Key dates and offer process

The intended key dates for the offer are:

Opening Date	<b>26 November 2020</b>
Closing Date	<b>18 December 2020</b>
Settlement and allotment of Shares	<b>30 December 2020</b>
Earliest expected mailing of holding statements	<b>30 December 2020</b>
Anticipated date of quotation of the new Shares on NZX Main Board and the quotation of all Shares on ASX	<b>6 January 2021</b>

This timetable is indicative only and the dates may change. TruScreen reserves the right to vary any of the above dates as required from time to time.

An investor who wishes to subscribe for new shares in TruScreen must return their application form, together with payment of the application monies to the Registrar on or before 5pm on the date on which the Offer closes. If a valid application and payment is not received by this date, an investor's application will not be accepted by TruScreen.

#### Conditional Offer

This Offer is conditional upon the ASX approving the admission of the Company to the official list of the ASX as an ASX Foreign Exempt Listing and for quotation of the Shares on the ASX on or before that Closing Date (as that date may be varied from time to time). In the event that this condition is not satisfied, then this Offer will not proceed, and all application moneys received by the Company will be refunded to investors in full and without deduction within 5 business days.

## 5. Terms of the Offer

Description of the equity securities	New ordinary fully paid shares in TruScreen
Price	NZ 7 cents per share, or AU 6.5 cents per Share
Number or amount of the equity securities being offered	<p>A minimum of <b>14,285,714</b> new Shares are being offered, representing <b>4.1%</b> of the total number of ordinary shares on issue immediately after the issue (assuming only <b>14,285,714</b> new shares are issued).</p> <p>A maximum of <b>21,428,571</b> new Shares are being offered, representing <b>6.1%</b> of the total number of ordinary shares on issue immediately after the issue (assuming all <b>21,428,571</b> new shares are issued).</p> <p>The Board of TruScreen has the discretion to accept oversubscriptions of a up to a maximum of 7,142,857 new Shares representing a maximum of \$500,000. In the event that the Offer is fully subscribed and the Board resolves to accept oversubscriptions to the maximum level, the maximum number of Shares that can be offered under the Offer is 28,571,428 new Shares, representing 8.2% of the total number of ordinary shares on issue immediately after the issue (assuming all 28,571,428 new shares are issued).</p> <p>Any oversubscriptions received shall be apportioned as between the two geographic pools referred to below, in the same proportions as each the two geographic pools represent as a percentage of the total Offer.</p>
Offer Opening ("Opening Date")	<b>26 November 2020</b>
Offer Closing Date ("Closing Date")	<b>18 December 2020</b> TruScreen has the right at its discretion to close the Offer prior to the Offer Closing Date.
Structure of the Offer	<p>The Offer has been divided in to two geographic pools. A pool of 14,285,714 new Shares (NZ\$1 million) has been set aside for subscription by Australian Residents ("Australian Pool"). A pool of 7,142,857 new Shares (NZ\$500,000) has been set aside for subscription by New Zealand Residents ("NZ Pool").</p> <p>In the event that one of the geographic pools is undersubscribed, then the balance of that pool may be allocated to the other pool for subscription.</p>
Scaling	TruScreen may scale applications at its sole discretion.
Refunds	<p>If TruScreen does not accept your application (whether because of late receipt or otherwise) or accepts it in part, all or the relevant balance of your application money received will be repaid to you as soon as practicable and, in any event, no later than 5 Business Days after the Issue Date.</p> <p>No interest will be paid on refunds.</p>
Minimum application amounts	<b>10,000</b> shares and multiples of 1,000 shares thereafter
How to apply	<p>Application instructions are set out in section 11 of this PDS (<i>How to apply</i>).</p> <p>TruScreen reserves the right to refuse all or any part of any application for Shares under the Offer without giving a reason.</p>
Liabilities, fees and charges	With the exception of the payment of the Issue Price, a holder of ordinary shares has no liability to make further payments, or to pay any fees or charges relating to those ordinary shares.
Conditional Offer	This Offer is conditional upon the ASX approving the admission of the Company to the official list of the ASX as an ASX Foreign Exempt Listing and for quotation of the Shares on the ASX on or before that Closing Date (as that date may be varied from time to time). In the event that this condition is not satisfied, then this Offer will not proceed, and all application moneys received by the Company will be refunded to investors in full and without deduction.

The constitution of TruScreen, which prescribes the terms of the Shares, may be obtained from the Companies Office website ([www.companies-register.companiesoffice.govt.nz](http://www.companies-register.companiesoffice.govt.nz)), or from the Offer Register.

### ASX listing

An application will be made to the ASX after this PDS has been lodged on the Offer Register for TruScreen to be admitted to the official list of the ASX as an ASX Foreign Exempt Listing and for quotation of the Shares on the ASX.

If TruScreen is admitted to the official list of the ASX as a Foreign Exempt Listing, it will need to comply with the NZX Listing Rules (other than as waived by NZX) but will not need to comply with the vast majority of the ASX Listing Rule obligations. Rather, TruScreen will need to comply only with the rules specified in ASX Listing Rule 1.15 which are relatively procedural in nature. TruScreen will not be subject to substantive ASX Listing Rule requirements such as the rules on continuous disclosure, periodic reporting, shareholder approval of share issuances, escrow, transactions with persons of influence and significant transactions.

Under ASX Listing Rule 1.15, TruScreen must immediately provide to ASX all the information that it provides to the NZX that is, or is to be, made public. Such information will appear on TruScreen's announcements platform on the ASX website at [www.asx.com.au](http://www.asx.com.au).

ASX takes no responsibility for the contents of this PDS or for the merits of the investment to which this PDS relates. The fact that the ASX may admit TruScreen to the official list of the ASX and quote the Shares on the ASX is not to be taken as an indication of the merits, or as an endorsement by the ASX, of TruScreen or the Shares. The ASX is not a licensed market under the FMCA.

For the avoidance of any doubt, TruScreen is currently, and will still be, bound by the NZX Listing Rules regardless of the outcome of this Offer and the Foreign Exempt Issuer Listing application made to ASX.

### Selling restrictions

The Offer is only being made to New Zealand residents and Australian residents. The Offer is being made in Australia in reliance on the trans-Tasman mutual recognition scheme under Chapter 8 of the Corporations Act 2001 (Cth) and the Corporations Regulations 2001 (Cth).

## 6. Key features of TruScreen Shares

### The Shares

All Shares issued under the Offer will be fully paid ordinary shares in TruScreen Group Limited which rank equally with each other and all other ordinary shares in the Company on issue. The key features of the Shares do not differ from those that apply to other ordinary shares in a company generally.

Each Share gives the holder the right to:

- attend and vote at a meeting of TruScreen, including the right to cast one vote per Share on a poll (subject to any voting prohibitions under the Listing Rules);
- an equal share with other Shares in any dividends authorised by the Board;
- an equal share with other Shares in the distribution of surplus assets in any liquidation of TruScreen;
- be sent certain information to shareholders by TruScreen; and
- other rights as a shareholder conferred by the Companies Act 1993 and TruScreen's Constitution.

### Dividends and Dividend Policy

Dividend payments in respect of the Shares are not guaranteed, are at the discretion of the Directors, and will be declared only after TruScreen has been found to meet the appropriate solvency requirements.

The Company's Board currently has no intention to declare dividends, and has no expectation that the Company will pay a dividend until such time as it is trading profitably.

### No guarantee of Shares

No person or entity guarantees or undertakes any liability in respect of the Shares of TruScreen or the future value or performance of them.

### Consequences of Insolvency

No holder of TruScreen Shares will be liable to pay any further amounts to the Company or any other person in respect of those Shares if TruScreen becomes insolvent.

In a liquidation of the Company, the claims of TruScreen shareholders will rank equally with each other, and after the claims of:

- persons to whom preferential payments must be made;
- secured creditors; and
- unsecured creditors.

### Alteration of Shares

The rights attaching to the Shares are governed by TruScreen's constitution, the Companies Act 1993 and the terms under which they have been issued. The constitution may only be altered by special resolution of shareholders subject to the rights of interest groups under the Companies Act 1993, or in certain circumstances by Court Order. A special resolution of shareholders must be approved by 75% of shareholders who are entitled to vote and are voting on that resolution. In certain circumstances, a shareholder whose rights are affected by a special resolution may require TruScreen to purchase their Shares.

## 7. TruScreen's financial information



These tables provide key financial information about the TruScreen group. Full financial statements are available on the Offer Register at [www.business.govt/disclose](http://www.business.govt/disclose). If you do not understand this financial information, you can seek advice from a financial adviser or an accountant.

### Selected financial information

Financial information	Financial year ended 31 March 2018	Financial year ended 31 March 2019	Financial year ended 31 March 2020
Revenues	804,062	1,862,949	1,288,242
EBITDA	(3,632,815)	(2,786,946)	(2,146,832)
Net profit after tax	(4,168,792)	(3,380,454)	(5,196,721) <sup>1</sup>
Dividends on all equity securities of the issuer	Nil	Nil	Nil
Total assets	12,166,849	12,545,765	7,241,067
Cash and cash equivalents	1,212,454	1,737,775	1,024,153
Total liabilities	550,967	1,224,956	832,843
Total debt	Nil	Nil	Nil
Net cash flows from operating activities	(3,729,191)	(2,678,321)	(1,634,499)

<sup>1</sup> The result for the year ended 31 March 2020 includes a one off non cash impairment of intangibles in the amount of \$2,380,000 and a non cash expense of \$306,000 in respect of share based payments.

### No prospective financial information provided

This Product Disclosure Statement does not contain any prospective financial information.

In the opinion of the directors of TruScreen, after due enquiry by them, the inclusion of prospective financial information into this Product Disclosure Statement would be inappropriate as such information would be likely to deceive or mislead existing TruScreen shareholders, new investors in this Offer, and the general investing public. The reasons for this opinion are:

- TruScreen is an early stage business.
- TruScreen does not generate significant revenue as at the date of this Product Disclosure Statement, and has no significant contractual arrangements in place which provide for the generation of revenues in the future;
- TruScreen has not been trading for a sufficiently long period of time to establish a regular and established financial performance history that can be extrapolated out as being likely to be indicative of future financial performance.

## 8. Risks to TruScreen's business and plans

### Risk Overview

Investments in shares are risky. You should consider if the degree of uncertainty about TruScreen's future performance and returns is suitable for you. The price of these Shares should reflect the potential returns and the particular risks of these Shares. TruScreen considers that the most significant risk factors that could affect the value of the Shares are:

### Early stage nature of the TruScreen's Commercialisation

While the TruScreen technology is well advanced, the roll out of its commercial business model is still at an early stage. TruScreen's commercialisation is not currently the subject of any fixed term contractual arrangements and there are no guaranteed recurring regular income streams for the business. Because limited historical information is available on TruScreen's revenue trends and operations for TruScreen's cancer detection programs it is difficult to evaluate TruScreen's commercial prospects. The Company's prospects must be considered in light of the substantial risks, expenses, uncertainties and difficulties encountered by entrants into the medical device industry. These risks would include significant cost of market access entry, risk of changes in local market regulations, risks of new products emerging, risks of COVID-19 impacting health budgets, and difficulties in gaining acceptance over established alternative cervical cancer screening methods.

TruScreen currently operates at a loss. TruScreen's operating losses may continue as TruScreen continues to expend resources to commercialise its current products, obtain regulatory clearances or approvals in new jurisdictions, and expand its marketing, sales, manufacturing and finance capabilities. The further development and commercialisation of TruScreen's products will require substantial development, regulatory, sales and marketing, manufacturing and other expenditures. TruScreen has only generated limited revenues to date from product sales.

### Cash flow

There is a risk that TruScreen may not have the funding to implement its business plan if there are significant cost over runs incurred by the Company in the execution of its business plan.

TruScreen may require substantial additional capital to commercialise its current products and to develop new products, including completing new product testing and clinical trials, obtaining all required regulatory approvals and clearances, scaling up manufacturing, and marketing its products into particular jurisdictions. TruScreen has currently financed its operations through the generation of limited revenues from the sale of its products, the proceeds received from Australian Research and Development tax offsets, and the issue of new shares to raise fresh capital. Any failure to

achieve adequate funding in a timely fashion would delay TruScreen's development programs and could lead to abandonment of one or more of TruScreen's development initiatives. Ultimately, like all businesses, if the Company is unable to fund its commercial operations, the future viability of the Company would be in doubt.

### Intellectual Property

TruScreen's future success heavily depends on its ability to establish and maintain the proprietary nature of its technology. If any of TruScreen's rights or ability to manufacture its products was to be limited, TruScreen's ability to continue to manufacture and market its products could be adversely affected. For Intellectual Property protection, TruScreen relies on trade secrets and proprietary know-how, which it seeks to protect, in part, through confidentiality and proprietary information agreements. The other parties to these agreements may breach these provisions, and TruScreen may not have adequate remedies for any breach. Additionally, the Company's trade secrets could otherwise become known to or could be independently developed by competitors. If the Company was unable to protect its intellectual property rights in its product, and a trade competitor was able to construct a product similar to the Company's product, then the Company's product offering would lose its advantage in the market as competitors would also be able to compete with the Company using a product the same or similar to the Company's offering. This could have a material adverse impact upon the ability of the company to sale product. The Board considers this eventuality to be unlikely to occur.

### Manufacturing Risk

While TruScreen has established an in house manufacturing capability for its key component ( the Electro Optical Assembly) to enable it to make products in the volumes that would be necessary for it to achieve significant commercial sales it relies on its suppliers for other parts of the device and the disposable Single Use Sensor production. TruScreen may not be able to maintain and expand a reliable, efficient, full scale manufacturing facility at commercially reasonable costs in a timely fashion. Difficulties TruScreen may encounter in manufacturing scale-up, or a failure to maintain its manufacturing facilities in accordance with good manufacturing practice regulations, international quality standards or other regulatory requirements, could result in a delay or termination of production.

Since TruScreen relies on sole source suppliers for several of its product components, any failure of those suppliers to perform would harm its operations as the Company would be unable to manufacture its products to satisfy sales demand from its customers. This would in turn impact on the sales revenues to be generated by the Company.

Several of the components used in TruScreen's products are available from only one supplier, and substitutes for these components may not be obtained easily or would require substantial modifications to its products. Any significant problem experienced by one of TruScreen's sole source suppliers may result in a delay or interruption in the supply of components to TruScreen until that supplier corrects the problem or an alternative source of the component is located and qualified.



Any delay or interruption would likely lead to a delay or interruption in TruScreen's manufacturing operations. For TruScreen's products that require premarket approval, the inclusion of substitute components could require TruScreen to qualify any new supplier with the appropriate government regulatory authorities. Alternatively for products that qualify for regulatory approval, the substitute components must meet TruScreen's product specifications.

## Competition

TruScreen competes with numerous other developers and suppliers of cervical cancer screening product offerings and services. Competition from other service providers is significant and changes in the composition and extent of competitors has the potential to present opportunities, and/or impact on TruScreen's market share and profitability.

TruScreen is susceptible to being overtaken by other more established and larger organisations if they aggressively expand and integrate new competing technologies.

Furthermore, TruScreen's competitors may succeed in developing, before TruScreen fully commercialises its products, devices and technologies that permit more efficient, less expensive, non-invasive or less invasive cancer detection. It is also possible that one or more pharmaceutical or other health care companies will develop therapeutic drugs, treatments or other products that will substantially reduce the prevalence of cancers or otherwise render TruScreen's products obsolete.

## Unsuccessful Marketing

TruScreen may not be able to generate sufficient sales revenues to sustain its growth and strategic plans.

TruScreen sets annual growth targets which are reviewed regularly in the light of prevailing market conditions. Despite the best endeavours of TruScreen and its distributors, it is possible, however, that TruScreen's initiatives to market its products could fail or not produce the projected levels, which may have an adverse impact on the financial position and performance of TruScreen.

TruScreen's products are based on new methods of cervical cancer screening. If TruScreen's products do not achieve significant market acceptance and results, its sales will be limited and its financial condition may suffer. Physicians and individuals may not recommend or use TruScreen's products unless they determine that these products are an attractive alternative to current tests that have a long history of safe and effective use.

To date, TruScreen's products (when compared to its major competitors, the Pap Smear and HPV DNA analysis) have been used by only a limited number of people, and the lack of recent independent studies limits the ability of doctors or consumers to compare TruScreen's products to conventional products. If TruScreen is unable to compete effectively in the highly competitive medical device industry, TruScreen's future growth and operating results will suffer.

The medical device industry in general and the markets in which TruScreen expects to target are intensely competitive. Many of TruScreen's competitors have substantially greater financial, research, technical, manufacturing, marketing and distribution resources than TruScreen does and have greater name recognition and lengthier operating histories in the health care industry. TruScreen may not be able to effectively compete against these and other competitors.

A number of competitors are currently marketing traditional laboratory-based tests for cervical cancer screening and diagnosis. These tests are widely accepted in the health care industry and have a long history of accurate and effective use. Further, if TruScreen's products are not available at competitive prices, health care administrators who are subject to increasing pressures to reduce costs may not elect to purchase them. Also, a number of companies have announced that they are developing, or have introduced, products that permit non-invasive and less invasive cancer detection. Accordingly, competition in this area is expected to increase.

Ultimately, should the Company not be able to successfully market its products to the consumers of its products, this eventuality would have a material adverse impact upon the ability of the Company to generate sales revenues and impact negatively on the future viability of the Company as a going concern. The Board is optimistic, having regard to current experiences to date with distributors and potential consumers of the Company's product that there is a genuine market for the Company's products.

## Reliance on Distributors

TruScreen's commercial model relies on its distributors to act as the agent for registration and to create the sales of the product in their respective territories. Should the distributors fail to meet those agreed targets or to achieve product registration then TruScreen's cash flows will be negatively impacted. In addition, TruScreen's distributors act as its Customer Service representatives in their markets and poor customer service performance in a distributor's market will result in a loss of reputation for TruScreen in that market, and a subsequent loss of sales.

# 9. Tax

Tax can have significant consequences for investments. If you have queries relating to the tax consequences of the investment in TruScreen Shares, you should obtain professional advice on those consequences.

## 10. Where you can find more information

Further information relating to TruScreen or the Shares (for example, the Company's constitution and financial statements) is available on the Offer Register. A copy of the information on the offer register is available on request to the Registrar (email [applications@linkmarketservices.com](mailto:applications@linkmarketservices.com) or phone +64 9 375 5998. The Offer Register can be accessed at [www.business.govt.nz/disclose](http://www.business.govt.nz/disclose), offer number OFR12990.

Further information relating to TruScreen is also available on the public register at the Companies Office of the Ministry of Business, Innovation and Employment. His information can be accessed on the Companies Office website at [www.business.govt.nz/companies](http://www.business.govt.nz/companies)

TruScreen is required to make half-yearly and annual announcements to NZX and (once listed on ASX) to ASX and such other announcements as required by the NZX Listing Rules and the ASX Listing Rules from time to time. You will be able to obtain this information free of charge by searching under TruScreen's stock code "TRU" on NZX's website at [www.nzx.com](http://www.nzx.com) and ASX's website at [www.asx.com.au](http://www.asx.com.au).

The following information relating to TruScreen or its ordinary shares is available on request, free of charge:

- the most recent financial statements of TruScreen and all documents that are required to be incorporated in or attached to, or to accompany, those financial statements;
- TruScreen's constitution.

This information can be obtained by writing to TruScreen at the address specified in section 12 (*Contact information*).

## 11. How to apply

If you wish to participate in the Offer, you have to do so online at [www.truscreenshareoffer.co.nz](http://www.truscreenshareoffer.co.nz)

### NZ Residents

If you are a New Zealand Resident, you may apply for Shares in the NZ Pool comprised within the Offer.

If you are a New Zealand resident and wish to apply for Shares in the Offer, you must complete the online NZ Residents Application Form, and pay online on [www.truscreenshareoffer.co.nz](http://www.truscreenshareoffer.co.nz) before 5pm on the **Closing Date**.

### Australian Residents

If you are an Australian Resident, you may apply for Shares in the Australian Pool comprised within the Offer.

If you are an Australian resident and wish to apply for Shares in the Offer, you must complete online Australian Resident Application Form, and pay online on [www.truscreenshareoffer.co.nz](http://www.truscreenshareoffer.co.nz) before 5pm on the **Closing Date**.

### General

All applications made are made subject to the terms and conditions that accompany, and are comprised within the respective online Application Form.



## 12. Contact information

<b>TruScreen Group Limited</b>	<b>Registered Office</b> c/- HLB Mann Judd Limited Level 6, Equitable House 57 Symonds Street Grafton Auckland, 1010 New Zealand  Telephone: +64 9 303 2243 Email: hlb@hlb.co.nz
<b>Securities Registrar</b>	Link Market Services Limited Level 11 Deloitte Centre 80 Queen Street Auckland 1010 New Zealand  Telephone number: 09 375 5998
<b>Legal Advisors</b>	Sean Joyce – Corporate Counsel P O Box 105 745 Auckland 1143 New Zealand  Addisons Level 12 60 Carrington Street Sydney NSW 2000 Australia
<b>Auditors</b>	RSM Hayes Audit Level 11 Broadway Newmarket Auckland 1023 New Zealand

# Glossary of Terms

**AI** means artificial intelligence

**Application Form – Australian Residents** means the online Application Form to be completed by Australian residents

**Application Form – New Zealand Residents** means the online Application Form to be completed by New Zealand residents

**Australian Pool** means the pool of 14,285,714 Shares to be made available for subscription by Australian Residents.

**Australian Resident** mean an investor who is ordinarily resident in Australia, and who has an Australian address

**ASX** means the ASX Limited, or the financial market operated by ASX Limited (Australian Securities Exchange), as the context requires

**ASX Listing Rules** means the listing rules of ASX, as in force from time to time

**Board** means the board of directors of TruScreen Group Limited

**Business Day** means a day upon which the NZX Main Board is open for trading

**CE Mark** means a certification marking that indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area (EEA). The CE marking is also found on products sold outside the EEA that are manufactured in, or designed to be sold in, the EEA

**Closing Date** means 18 December 2020

**Colposcope** means a medical device used to examine an illuminated, magnified view of the cervix as well as the vagina and vulva

**Company** means TruScreen Group Limited

**Cytology** means the examination of cells from the body under a microscope

**Cryotherapy**, sometimes known as cold therapy, means the local or general use of low temperatures in medical therapy. Cryotherapy can be used to treat a variety of tissue lesions

**Electro Optical Assembly** means the assembly of electrical engineering, electronic engineering, materials science, and material physics involving components, devices (e.g. Lasers, LEDs, waveguides etc.) and systems which operate by the propagation and interaction of light with various tailored materials

**FY** means financial year

**HPV** means HPV DNA Test

**ISO13485** means an International Organization for Standardization (ISO) standard which represents the requirements for a comprehensive quality management system for the design and manufacture of medical devices

**LBC** means Liquid-based cytology

**Material Information** means information which is material to an assessment of the position and prospects of TruScreen

**Negative predictive value** means the probability that subjects with a negative screening test don't have the disease

**New Zealand Resident** mean an investor who is ordinarily resident in New Zealand, and who has a New Zealand address

**NMPA** National Medical Products Administration (Previously known as **CFDA** (China Food and Drug Administration)

**Non-government organisations (NGO's)** means organisations that are usually non-profit and sometimes international organisations independent of governments and international governmental organisations (though often funded by governments) that are active in humanitarian, educational, health care, public policy, social, human rights, environmental, and other areas to effect changes according to their objectives

**NZ Pool** means the pool of 7,142,857 Shares to be made available for subscription by New Zealand Residents.

**NZ\$** means figures are in New Zealand dollars

**NZX** means NZX Limited

**NZX Main Board** means the main equity trading platform operated by NZX Limited

**Offer** means the offer of Shares made by TruScreen under this PDS to residents of New Zealand and Australia

**Opening Date** means 26 November 2020

**Pap smear test** means the opening of the vaginal canal with a speculum and collecting cells at the outer opening of the cervix at the transformation zone (where the outer squamous cervical cells meet the inner glandular endocervical cells). The collected cells are examined under a microscope to look for abnormalities which could indicate the incidence of cervical cancer

**PDS** means this Product Disclosure Statement

**Registrar** means Link Market Services Limited

**Shares** means the ordinary fully paid shares in the capital of TruScreen

**Single Use Sensor (SUS)** means a disposable sheath that is the only point of contact between the TruScreen device and any bodily fluids or tissue from the patient. A new SUS has to be used for each patient test

**SUS** means Single Use Sensor

**TruScreen and TS** means TruScreen Group Limited

**Thermal coagulation** is a form of heat ablation used to treat CIN