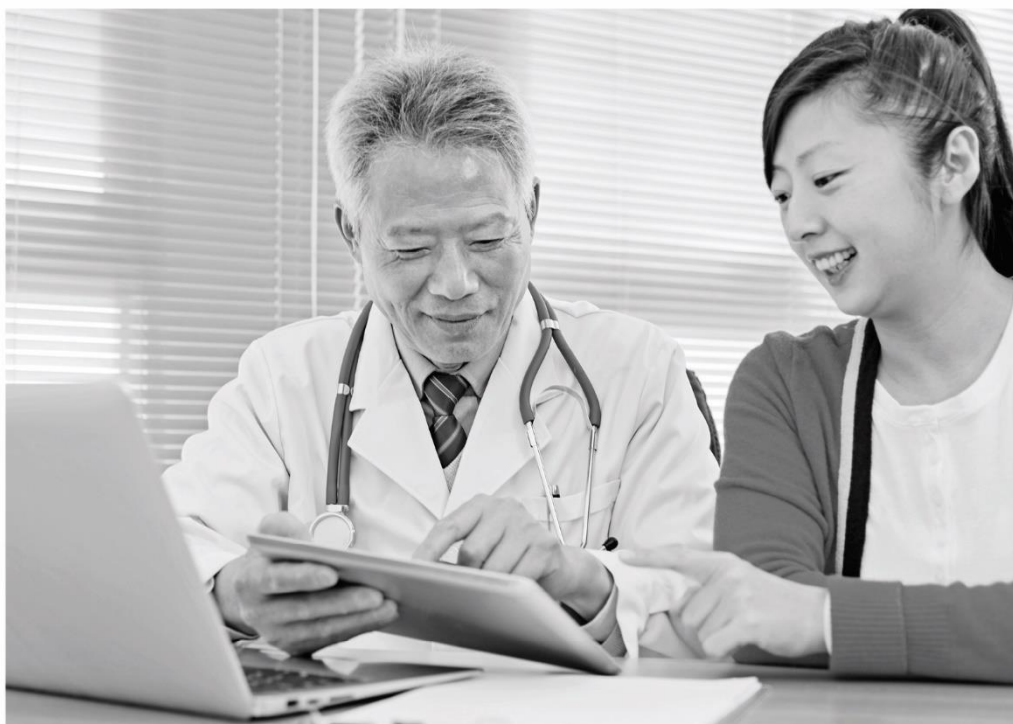




## TruScreen Annual Meeting

September 2018

Shareholders Address



**FY18 ANNUAL MEETING**  
**SHAREHOLDERS ADDRESS**  
**27 SEPTEMBER 2018**

**INTRODUCTION**

Welcome to the 2018 AGM.

**FY18 HIGHLIGHTS**

2018 was a year of significance as the company entered full commercialisation late in the financial year.

Some of the key operational highlights include:

- Strong sales growth of 2<sup>nd</sup> Gen TruScreen to China commenced during 4<sup>th</sup> quarter. (50% of the year's sales were generated in the fourth quarter)
- Completed the testing and validation in February 2018 of its second-generation device including in market clinical trials where impressive results were obtained.
- Expanded its global sales and distribution network into Africa, Latin America and India (covering a combined screening population of approx. 1 billion women)
- Obtained CFDA registration in China in December 2017

- Commenced set-up of our own specialised optical front-end manufacturing facility
- Announced a number of large international public health initiatives, mostly in China
- Continued a program of global awareness of TruScreen's capabilities
- Successfully completed a capital raising campaign earlier in the financial year.

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## FY18 FINANCIAL RESULTS

- A review of the year's financial results indicates that total revenue of \$2.178 M which was up +56% on that of the prior year.
- The company incurred a net loss of \$4.168 M for the FY18 year. This loss was slightly greater than expected due to the delay obtaining CFDA approval in China.
- The company was successful in raising additional \$4.9M of capital at 16c (a +31 % increase as of today).
- A healthy financial position at the end of the financial year with net assets of \$11.615 M, cash and cash equivalents of \$1.212 M and a normal operational cash burn of \$200k per month.
- The market capitalization of \$48.17M today which represents an increase of **+42%** over the past 12 months.
- Zero debtor financial risk (i.e. all debtors paid in full)

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## **REGULATORY and CLINICAL MATTERS**

- Chinese CFDA approval in December 2017
- Regulatory approval in other jurisdictions including Mexico, Ukraine, Jordan, UK, South Africa, India, Turkey, Vietnam, Europe, Kazakhstan and Zimbabwe.
- The Royal Hospital for Women in Sydney completed an important trial to determine the clinical capability of TruScreen.
- The company successfully completed its International Quality audit, and its ISO 13485 Quality Certification, and EC Certification in Europe were maintained.
- Trials at the National Institute of Cancer in Mexico were conducted and they have supported our application for government purchasing approval.
- Commenced clinical trial in India at the All India Institute of Medical Science (AIIMS)

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## **MARKET UPDATE**

Generation of sales during the financial year were initially slow due to delays in obtaining regulatory approval in our key market, China. However, sales escalated significantly in the fourth quarter as the company commenced supplying a backlog of sales orders to China.

A brief summary of our individual markets during the year is as follows:

### **a) China**

Facts:

- 400 million women of screening age
  - Initial distribution agreement signed 2014
  - 71% of FY18 of TruScreen sales (\$531k)
  - FY19 Budgeted sales \$2.1mil
- 
- Regulatory approval (CFDA) for the 2<sup>nd</sup> generation device obtained in December 2017. (A significant portion of the year's sales were supplied to China in the fourth quarter)
  - Appointed a new sub- distributor (Biochem) in China who will have the major focus of managing government sale channels
  - Selected as the preferred primary screening solution for a chain of high-tech female health clinics to be established in 50 municipal hospitals throughout China.

- Truscreen has reached agreement for TruScreen to be installed in 190 public hospitals in the Xinjiang province
- Reached agreement with the Women and Childrens division of the Centre for Disease Control (CDC) for a program involving 12,000 women in China
- Commenced a major product evaluation involving 10,000 patients by the Chinese Obstetrics and Gynaecological Association (COGA)

## **b) Mexico**

### Facts:

- 31 million women of screening age
  - Distribution agreement signed 2015
  - 12% of FY18 TruScreen sales (\$100k)
  - FY19 Budgeted sales \$1.2mil
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- The Ministry of health in Mexico commenced a valuation of Truscreen for inclusion in the Mexican government's catalogue of preferred medical devices for use in public hospitals. This evaluation is currently overdue and expected shortly
  - Clinical Trial results showed TruScreen + 200% more sensitive than pap in identifying high grade cervical changes (CIN2+)
  - Regulatory:
    - Endorsed by National Cancer Institute – Stage 2, 400 patients commenced in Oct 2017
    - Submitted revised application in July 2018 for inclusion in Cuadro Basico (the government hospital purchasing catalogue)
    - Evaluation commenced by the main National Health Insurer, ISSSTE(who conduct 500,000 pap tests per year)



### **c) India**

#### Facts:

- 300 million women of screening age
  - Distribution agreement signed 2017
  - Sales commencing in FY19
  - FY19 Budgeted sales \$1.6mil
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- Appointed major distributor in Mar 2017 – KLAB
  - Commenced clinical trial in India at the All India Institute of Medical Science (AIIMS)
  - Cleared all import and other regulatory requirements to sell TruScreen in India

## **b) Africa/Zimbabwe**

### Facts:

- 227 million women of screening age
  - 13.1 million women in Africa suffer from HIV
  - 17.8 million women globally suffer from HIV
  - HIV affected women are 6 times more likely to develop Cervical Cancer
  - All HIV affected women should be screened for Cervical Cancer annually
  - FY19 Budgeted sales \$610k (FY18 \$33k)
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- Zimbabwe Ministry of Health support for major aid application (up to \$30M over 4 years) to use TruScreen for a national screening program.
  - First order received for approx. \$450k by National Aids Council for cervical cancer screening of HIV affected women.
  - Zimbabwe is a Key Opinion Leader in Eastern Africa and it is anticipated that the successful implementation of this innovative programme will lead to other countries embracing TruScreen as a solution to their own cervical cancer screening needs.

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## **Subsequent Activities**

The company has made significant progress since the end of the 2018 financial year. The key matters include the following:

- Sales to 30 September 2018 expected to be \$1.578m (previous year \$NZD 226K) and for the 12 months to 31 March 2018 budget \$6.86m (previous year \$0.804m).
- Significant growth in sales to China (\$508K in the first two quarters)
- Announced initiatives in Africa and Zimbabwe where TruScreen has been selected by the Zimbabwe Ministry of Health as a preferred screening tool for HIV affected women. An initial order of \$450,000 has been received from the National AIDS Council and joint application for \$30m funding over four years has been lodged.
- Initiated a pilot study for the use of TruScreen in regional and remote locations by the Papua New Guinea government.
- Entered into a new distribution agreement in respect of the Middle East
- Successfully launched a new optical electrical front-end manufacturing facility in Sydney with increased capacity and profit margins
- Concluded clinical trials at the Royal Hospital for Women in Sydney into the performance of TruScreen2 with results to be published at the World HPV symposium in October 2018.
- Completed a capital raising of \$1.5 million.

### **2019 Goals and Objectives**

- Expand sales by + 500%
- Achieve monthly profitability by year's end
- Consider dual listing and / or migration to a larger exchange
- Consumate and expand government screening opportunities
- Achieve inclusion in Chinese, Indian and Mexican government programs
- Initiate discussions with global pharma distribution organisations
- Pursue major international health funding programs
- Continue to seek operational and manufacturing efficiencies

### **Closure**

As founder, largest shareholder and Chairman for the past four years I advised the Board several months ago that I propose to step down as Chairman effective at the close of this meeting. A new Chairman will be appointed by the board and I take this opportunity to thank all shareholders for their past support.