



Prospectus 2008

Cellscreen Direct Limited ACN 133 796 488

Prospectus for the offer of 15,000,000 ordinary shares at an offer price of \$0.50 each for a minimum subscription of \$7,500,000 with a right to take over subscriptions to a maximum subscription of \$10,000,000 being 20,000,000 ordinary shares at an offer price of \$0.50.



Sponsoring Broker: Martin Place Securities Pty Limited AFSL 247 404

The Shares offered by this Prospectus are of a speculative nature. This is an important document that should be read in its entirety. If you do not understand it, you should consult your professional advisors.

This is a replacement prospectus dated 1 December 2008. It replaces a prospectus dated 27th November 2008, relating to shares of Cellscreen Direct Limited.

Corporate Directory

Board Of Directors

Ms Alison Coutts (Chairperson);
Dr Adrian Cachia;
Mr Russell Tate;
The Hon Dr Michael Wooldridge;
Mr Warwick Doughty;
Dr Peter Hughes (Managing Director);

Registered and Principal Office

Unit 40, 112 McEvoy Street
Alexandria, NSW, 2015;

European Office

Etage 2
21 Boulevard Haussman
75009 Paris
France

USA Office

c/o Daniel A. MacKenzie
Managing Director
International Specialized Imports LLC
20608 Autumn Breeze Court
Town Heights
Cornelius, North Carolina 28031

Auditors and Independent Accountants

Weston Woodley & Robertson
Level 18, 201 Elizabeth Street
Sydney NSW 2000

Solicitors to the Company

Holman Webb Lawyers
Level 17, Angel Place, 123 Pitt Street
Sydney, NSW 2000

Sponsoring Broker

Martin Place Securities
Level 3, 14 Martin Place
Sydney NSW 2000

Share Register

Computershare Investor Services Pty Ltd
Level 3
60 Carrington Street
Sydney NSW 2000

This replacement Prospectus for Cellscreen Direct Limited is dated 1 December 2008. It was lodged with the Australian Securities and Investments Commission (ASIC) on 1 December 2008. Neither ASIC nor ASX Limited (ASX) takes any responsibility for the contents of the replacement Prospectus.



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“The current global HPV diagnostic market is estimated to be worth US\$4.0 billion. The Tam Pap self sampling test kit is expected to sit inside the HPV diagnostic market.”



Key Dates and Offer Statistics

Prospectus Lodgement Date:	1st December 2008
Offer Opens:	4th December 2008
Offer Closing Date:	23rd December 2008
Expected Allotment of Shares:	2nd January 2009
Expected Dispatch of Holding Statements:	5th January 2009
Shares Expected to Commence Trading on the ASX:	6th January 2009

Note: This timetable is indicative only and Applicants are encouraged to submit their Applications as early as possible. The Company has the right to close the Offer early or extend the Offer to accept late Applications, or vary any other date or time, in each case without prior notice.

Key Offer Statistics

Offer Price:	\$0.50 per Share
Number of Shares Offered to be issued at \$0.50:	15,000,000 to 20,000,000
Minimum Subscription Amount:	\$7,500,000
Total Number of Shares On Issue following Offer:	56,745,147 to 62,627,500
Market Capitalization at the Offer Price:	\$28,372,573 to \$31,313,750



Chairperson's Letter

Dear Investors,

On behalf of our Directors, it is my pleasure to invite you to become a Shareholder in Cellscreen Direct Ltd ("Cellscreen") which was established as the holding company of Tam Pap Pty Ltd. Tam Pap Pty Ltd was established in 2006 to further develop, distribute, internationally market and licence a novel and unique molecular diagnostic test and sample process to detect the presence of Human Papillomavirus (HPV) within women. HPV is a virus that is the primary cause of cervical cancer and the Company's initial product; the Tam Pap Test kit; has been specifically developed to encourage women to take greater levels of control over their own health status.

Cellscreen's technologies and systems include:

- A DNA, polymerase chain reaction (PCR) diagnostic test process the subject of a patent application that can genotype all strains of HPV, generally accepted in Australia, Europe and the US as "high oncogenic risk types", to be acquired from Symbion on completion of the Offer in exchange for Shares in the Company;
- An ability to arrange for and conduct test analysis in multiple localities in real time;
- A business development and marketing framework that should enable the Company to quickly penetrate selected geographic regions subject to the receipt of applicable regulatory approvals; and
- The development of a "new channel to market" to facilitate the future distribution of other home-based medical diagnostic products.

Cellscreen intends to develop a sophisticated web-based technology platform to secure and transfer patient results and to transact with selected licensees of the technology in multiple destinations.

The Tam Pap home based test process provides a readymade platform for the development of other molecular diagnostic tests already under development which are likely to be progressively launched into the market over a 12 to 24 month timeframe.

The Tam Pap Process is unlike any other HPV test currently available because:

- It allows a woman to self sample within the privacy and security of her own home; and
- The process is relatively "non-invasive" in comparison to other detection tests for HPV and does not require the initial intervention of a medical practitioner.

The test analysis utilises a standard laboratory process with routine laboratory equipment and can be readily replicated

in other localities.

The Company has already "beta-tested" the efficacy of its test product within the confines of the Australian market place and is in the process of completing a clinical trial in the USA and is pleased to report that analytical results to date show the test results to be concordant with results obtained from FDA and CEM-approved gold standard assays for HPV detection and genotyping.

The Board believe that initial revenues will be derived through sales of the test kit utilising selected marketing parties in various jurisdictions. The Company has established a corporate presence within Europe and is in the process of establishing a corporate presence in the United States. The processes for obtaining FDA approval in the USA and a CE Mark in Europe have commenced with the aim of allowing for the sale and distribution of the product in those markets.

What makes Cellscreen different from other medical diagnostic companies is its ability to make its products available using a direct response marketing model. This new channel should provide a means of cost effectively marketing and distributing multiple company-sponsored products and services in the future.

This Prospectus seeks to raise a minimum \$7,500,000 at \$0.50 per Share. The proceeds of the Offer will provide Cellscreen with sufficient working capital to continue to support product development; obtain regulatory approvals; hire key staff and securing licensee distribution, marketing and public awareness.

Cellscreen provides the potential for significant returns to shareholders subject to the ability of the Company and its licensees to secure the necessary regulatory approvals, market and distribute the test kit into selected geographic target markets using a novel consumer marketing methodology for this type of product.

This Prospectus contains detailed information regarding Cellscreen's initial product, current operations, management team and future growth plans. I encourage you to read this document carefully prior to contemplating an investment decision.

On behalf of the Directors of Cellscreen Direct Limited, I look forward to welcoming you as a shareholder of the Company.

Yours sincerely



Alison Coutts
Non-Executive Chairperson



2. Important Information

This Prospectus for Cellscreen Direct Limited ("Cellscreen") or ("the Company") is dated 1st December 2008. It was lodged on 1st December 2008 with the Australian Securities and Investments Commission ("ASIC").

Neither ASIC nor ASX Limited ("ASX") takes any responsibility for the contents of this Prospectus.

No Shares will be allotted or issued on the basis of this Prospectus later than 13 months after the date of this Prospectus.

Application for Quotation

Application will be made within 7 days after the date of this Prospectus for permission for the Shares offered by this Prospectus to be listed for Quotation on the securities market operated by ASX.

Electronic Prospectus

This Prospectus will be issued in paper form and as an electronic Prospectus which may be accessed on the Internet at www.cellscreendirect.com. The Offer of Shares pursuant to the electronic Prospectus is only available to persons receiving an electronic version of this Prospectus in Australia. The Corporations Act 2001 (Cth) prohibits any person passing onto another person the Application Form unless it is attached to, or accompanied by, the complete and unaltered version of the Prospectus.

During the Offer Period, any person may obtain a hardcopy of this Prospectus by contacting Martin Place Securities Pty Limited on (02) 9222 9111.

Foreign Jurisdictions

This Prospectus does not constitute an offer in any place in which, or to persons

to whom, it would not be lawful to make an offer. Distribution of this Prospectus in jurisdictions outside Australia may be restricted by law, and persons who come into possession of this Prospectus should seek advice and observe any such restrictions. Any failure to comply with such restrictions may constitute a violation of applicable securities laws.

No Authority

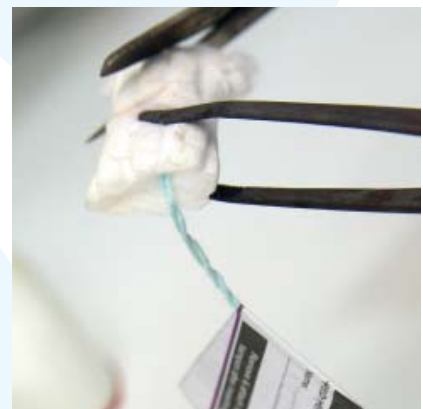
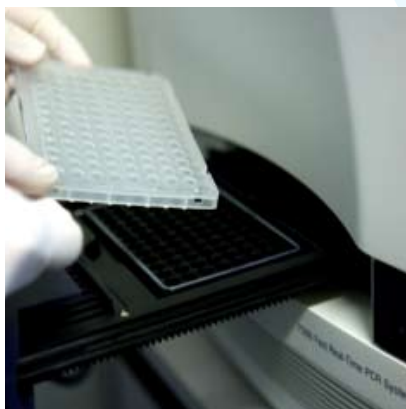
No person is authorised to give any information or to make any representation regarding the Offer. Any information or representation in relation to the Offer which is not contained in this Prospectus may not be relied upon as having been authorised by Cellscreen or its Directors.

Exposure Period

In accordance with Chapter 6D of the Corporations Act this Prospectus is subject to an exposure period of 7 days from the date of lodgement with ASIC. This period may be extended by ASIC for a further period of up to 7 days. The purpose of this exposure period is to enable this Prospectus to be examined by market participants prior to the raising of funds. If this Prospectus is found to be deficient, Applications received during the exposure period will be dealt with in accordance with Section 724 of the Corporations Act. Applications received prior to the expiration of the exposure period will not be processed until after the exposure period. No preference will



2. Important Information continued



be conferred on Applications received in the exposure period and all Applications received in the exposure period will be treated as if they were simultaneously received on the Opening Date.

Speculative

The Shares offered by this Prospectus are of a speculative nature.

Forward Looking Statements

Various statements in this Prospectus constitute statements relating to intentions, future acts and events. Such statements are generally classified as forward looking statements involving known and unknown risks, uncertainties and other important factors that could cause those future acts, events and circumstances to differ from the way or manner in which they are expressly or implicitly portrayed herein.

Applicants should seek advice

Applicants should read this document in

its entirety and, if in any doubt, consult with their professional advisers before deciding whether to apply for Shares. The Shares offered under this Prospectus carry no guarantee in respect of return of capital, return on investment, payment of dividends or the future value of the Shares.

Privacy

When you apply to invest in the Company, you will provide the Company and the Share Registrar with certain personal information to: (i) facilitate the assessment of the Application; (ii) enable the Company to assess the needs of applicants and provide appropriate facilities and services for Applicants; and (iii) carry out appropriate administration. The Company and the Share Registrar may be required to disclose this information to: (i) third parties who carry out functions on behalf of the Company; and (ii) other third parties to whom disclosure is required by law. Applicants

may request access to their personal information held by (or on behalf of) the Company by telephoning or writing to the Company Secretary.

Photographs and Diagrams

Items and undertakings depicted in photographs and diagrams in this Prospectus are not assets of the Company, unless otherwise stated. Diagrams appearing in this Prospectus are illustrative only and may not be drawn to scale.

Definitions

Throughout this Prospectus abbreviations and defined terms are used. Abbreviations and legal terms are contained in the Glossary of Terms in Section 12 of this Prospectus (defined terms are generally identified by the uppercase first letter).



3. Offer Details



3.1 Description of the Offer

This Prospectus invites subscriptions for a minimum 15,000,000 Shares and a maximum 20,000,000 Shares at an issue price of AU\$0.50 per Share to raise between \$7,500,000 and \$10,000,000. All Shares issued pursuant to this Prospectus will be issued as fully paid ordinary shares and will rank equally in all respects with the Shares already on issue. The rights attaching to the Shares are summarised in Section 11.

The Minimum Subscription for the Offer is \$7,500,000. If \$7,500,000 has not been raised within 3 months after the date of this Prospectus, all Application Monies will be refunded to Applicants.

The Company reserves the right to accept subscriptions over and above \$7,500,000 with a maximum capital raising of \$10,000,000 (20,000,000 Shares).

3.2 Opening and Closing Dates

Subscription lists will open on the Opening Date and will remain open until 5.00pm EDST on the Closing Date subject to the right of the Company to either close the Offer at an earlier time and date or to extend the closing time and date without prior notice. Applicants are encouraged to submit their Applications as early as possible.

3.3 Indicative Timetable

Quotation of Shares on ASX expected to commence 6th January 2009. The below dates are indicative only.

Opening Date	4th December 2008
Closing Date	23rd December 2008
Expected Allotment of Shares	2nd January 2009
Despatch of Statements of Shareholding	5th January 2009
Quotation of Shares on ASX expected to commence	6th January 2009

3.4 Purpose of the Offer

The purpose of this Offer is to allow the Company to continue to pursue the development of the Tam Pap Test, obtain regulatory approvals, hire key staff and secure licensees, distribution, marketing and public awareness for and of the Tam Pap Test.

Cellscreen is focussed on securing and developing its technologies and the initiation of distribution methodologies to make available its home-based molecular diagnostic test kits.

Cellscreen's initial test can simultaneously detect and genotype high risk strains of HPV using a simple tampon as a collection device. HPV is now known to be the principal cause of cell changes that could lead to cervical cancer and as such the Tam Pap Test is positioned to be an extremely valuable tool in detecting the presence of this virus. A pap smear test does not necessarily detect the presence of HPV nor does it always identify cell changes that could lead to cervical cancer.¹

The in-vitro market exceeds US\$34 billion within which there is a rapidly growing molecular diagnostics market which exceeds US\$2.5 billion. The current global HPV diagnostic market is estimated to be worth US\$4.0 billion. The Tam Pap self sampling test kit is expected to sit inside

¹Innovation Dynamics Expert Report, November 2008;

the HPV diagnostic market.

A number of attractive niche markets are appearing for the Company. Taking the USA as a prime example, the Company notes there is only one full FDA approved HPV test in this region. Given that the current HPV test available in the USA requires a pap smear type process, Cellscreen's Tam Pap Test, which simply uses a tampon, has an opportunity to not only gain market share but also grow the current market in the USA once regulatory approval is received.

Cellscreen intends to launch its flagship Tam Pap Test into various selected geographic localities to complement the current regimes of routine cervical specimen testing.

The Company has selected an offering size that it believes should be adequate to enable it to execute its business plan and position it to capture and consolidate future growth opportunities. In addition to the above purposes, it intends to use the net proceeds from this offering for general corporate purposes, including working capital and capital expenditures associated with:

- Head and Regional Office consolidation;
- Continued development and expansion of the Company's logistical fulfilment network and website exchange;
- Continued securement of international licences;
- Global commercialisation of the Tam Pap Test;
- Seeking and securing relevant regulatory approvals in various jurisdictions;
- Further corporate establishment and product approval and distribution in the USA and the

European Union;

- Continued research and development into the improvement and wider use of the Tam Pap Test; and
- Conduct of worldwide marketing initiatives.

Funds are anticipated to be applied as follows:

Table 1: Anticipated Use of Funds to 31 December 2010 - assuming Minimum Subscription of \$7,500,000 and Maximum Subscription of \$10,000,000

	Min \$	Max \$
Expenses of the Issue	772,000	949,000
Repayment of Loans to Investors	430,000	430,000
Repayment of Loans to Promoters	308,000	308,000
Web based technology platform	300,000	300,000
Marketing	775,000	775,000
Salaries and Board fees	2,055,000	2,055,000
Regulatory Approvals	200,000	200,000
Office Administration	515,000	515,000
Consultants	120,000	120,000
Travel and Accommodation	200,000	200,000
Working Capital	1,825,000	4,148,000
TOTAL	7,500,000	10,000,000

Following completion of the Offer, the Directors believe the Company will have sufficient working capital to carry out its stated objectives.

3.5 Applications for Shares

Applications must be for a minimum of 4,000 Shares (\$2,000) and thereafter in multiples of 200 Shares and can only be made by completing the Application Form attached to this Prospectus. The Company reserves the right to reject any Application or to allocate any investor fewer Shares than the number applied for.

3.6 How to Apply

Applications under the Offer may be made and will only be accepted in one of the following forms:

- On an Application Form accompanying this Prospectus;
- On a paper copy of the relevant electronic Application Form which accompanies the electronic version of the Prospectus, both of which can be found at and can be downloaded from www.cellscreeendirect.com.



Paper Application Forms, whether accompanying a paper copy of the Prospectus or which have been downloaded from www.cellscreeendirect.com must be accompanied by a personal cheque or a bank draft payable in Australian dollars, drawn on an Australian branch of an Australian registered bank for an amount equal to the number of Shares for which you wish to apply multiplied by the Application Price of \$0.50 per Share. Cheques or bank drafts should be made payable to "Cellscreen Direct Ltd Float Account" and crossed "Not Negotiable".

Applicants should ensure that cleared funds are available at the time the Application is lodged, as dishonoured cheques will result in the Application being rejected.

Applicants should return their completed Application Forms to Computershare at the following address:

**Computershare Investor Services
Pty Limited
GPO Box 2115
Melbourne VIC 3001**

by no later than 5.00pm EDST on 23rd December 2008 unless the timing is varied.

Detailed instructions on how to complete paper Application Forms are set out on the reverse of those forms. You are not required to sign the Application Form. Cellscreen reserves the right to

reject any Application (including where an Application has not been correctly completed) or allocate any person fewer Shares than that person applied for, or vary the dates and times of the Offer without prior notice and independently of other parts of the Offer. Where Applications are rejected or fewer Shares are allotted than applied for, surplus Application Monies will be refunded. No interest will be paid on any Application Monies refunded.

3.7 Pro forma Capital Structure

The proposed capital structure of Cellscreen is set out below and reflects the issued and paid up capital structure of the Company on the basis that the Offer is subscribed at \$7,500,000 and \$10,000,000.

3.8 Allotment and Allocation of Shares

Subject to the ASX granting approval for the Company to be admitted to the Official List, the allotment of Shares to Applicants will occur as soon as possible after the Offer is closed, following which statements of shareholdings will be dispatched. It is the responsibility of Applicants to determine their allocation prior to trading in Shares. Applicants who sell their Shares before they receive their holding statements will do so at their own risk. Pending the issue of the Shares or return of the Application Monies, the Application Monies will be held in trust for

the Applicants.

The Company has the right to allocate the Shares under the Offer. The Company may reject any Application or allocate any investor fewer Shares than applied for under the Offer. If an Application is not accepted, or is accepted in part only, the relevant part of the Application Monies will be refunded. Interest will not be paid on Application Monies refunded.

3.9 Stock Exchange Listing

Within 7 days after the date of this Prospectus application will be made to the ASX for the Company to be admitted to the Official List and for the Shares offered by this Prospectus to be granted Quotation. If approval for Quotation is not granted within 3 months after the date of this Prospectus, the Company will not allot or issue any Shares pursuant to the Offer and will repay all Application Monies without any interest as soon as practicable. The fact that the ASX may admit Cellscreen to its Official List is not to be taken in any way as an indication of the merits of the Company or the Shares offered pursuant to this Prospectus.


3.10 CHESS

Cellscreen will apply to participate in the Clearing House Electronic Sub-register System, operated by ASTC, a wholly owned subsidiary of ASX, in accordance with the Listing Rules and ASTC Settlement Rules. Under this system, the Company will not issue certificates

Table 2: Pro forma Capital Structure

	Minimum Subscription	Maximum Subscription
	Shares	Shares
PRE-IPO	33,233,375	33,233,375
OFFER	15,000,000	20,000,000
SYMBION	8,511,772	9,394,125
TOTAL	56,745,147	62,627,500





to investors. Instead, Shareholders will receive a statement of their holdings in the Company.

If an investor is broker sponsored, ASTC will send them a CHESS statement. The CHESS statement will set out the number of Shares allotted to the investor under the Prospectus, give details of the Shareholder's holder identification number (HIN) and give the participant identification number of the sponsor.

Alternatively, if an investor is registered on the issuer sponsored sub register, the statement will be dispatched by the Share Registrar and will contain the number of Shares allotted under the Prospectus and the Shareholder's security holder reference number (SRN).

A CHESS statement or issuer sponsored statement will routinely be sent to Shareholders at the end of any calendar month during which the balance of their holding changes. A Shareholder may request a statement at any other time, however a charge may apply for additional statements.

3.11 Overseas Investors

This Prospectus does not constitute an offer or invitation in any place in which, or to any person to whom, it would not be lawful to make such an offer or invitation. The distribution of this Prospectus in jurisdictions outside Australia may be restricted by law and persons who come into possession of this Prospectus should seek advice on and observe any such restrictions. Any failure to comply with such restrictions may constitute a violation of applicable securities laws. Lodgement of a duly completed Application Form will be taken by the Company to constitute a representation that there has been no breach of such laws. No action has been taken to register or qualify the Shares, or the Offer, or

otherwise to permit a public offering of the Shares, in any jurisdiction outside Australia.

The Offer pursuant to an Electronic Prospectus is only available to persons receiving an electronic version of this Prospectus within Australia.

3.12 Privacy Act

The Company collects information about each Applicant from the Application Form for the purposes of processing the Application and, if the Application is successful, to administer the Applicant's Shareholding in the Company.

By submitting an Application Form, each Applicant agrees that the Company may use the information in the Application Form for the purposes set out in this privacy disclosure statement and may disclose it for those purposes to the Share Registrar, the Company's related bodies corporate, agents, contractors and third party service providers (including mailing house), ASX, ASIC and other regulatory authorities.

If an Applicant becomes a Shareholder of the Company, the Corporations Act requires the Company to include information about the Shareholder (name, address and details of the Shares held) in its public register. This information must remain in the register even if that person ceases to be a Shareholder of the Company. Information contained in the Company's registers is also used to facilitate distribution payments and corporate communications (including the Company's financial results, annual reports and other information that the Company may wish to communicate to its Shareholders) and compliance by the Company with legal and regulatory requirements.

If you do not provide the information required on the Application Form, the Company may not be able to accept or

process your Application.

3.13 Taxation

The Australian taxation consequences of any investment in Shares will depend upon the investor's particular circumstances. It is an obligation of investors to make their own enquiries concerning the taxation consequences of an investment in the Company. If you are in doubt as to the course of action you should take, you should consult your professional advisers.

3.14 Restricted Securities

As a condition of admitting the Company to the Official List, the ASX is expected to classify certain securities held prior to the date of this Prospectus as escrowed securities. Prior to Quotation it will be necessary for these shareholders to enter into restriction agreements with the Company. The effect of the restriction agreements will be that the restricted securities cannot be dealt with for a period as determined by the ASX. Details of any determination by ASX will be released to the market prior to commencement of trading in the Shares.

3.15 Dividend Policy

The Company does not yet have a dividend policy.

The Company has no immediate intention to declare or distribute dividends. Payment of future dividends will depend upon the future profitability and financial position of the Company.

3.16 Pro forma Accounts

An Independent Report on the Pro-Forma Financial Accounts for the Company prepared by Weston Woodley & Robertson is set out in Section 8 of this Prospectus. As the Company is in the start-up phase of the commercialisation of the Tam Pap Test the Company has not made any forecasts as to its profitability or otherwise.



4. The Product

4.1 Introduction

Cellscreen Direct Ltd was formed as a holding company of Tam Pap Pty Ltd which will hold all of the intellectual property on which the Tam Pap Test is based. Cellscreen has a charter to develop, commercially market and distribute the Tam Pap Test kit to women on a global basis. Cellscreen intends to fulfil its sales and distribution objectives by securing selected international license partners to assist with marketing and promotion, test kit fulfilment, logistics and data transfer. The Company also intends to establish a corporate presence within the USA, having already established an office in Europe, and initiate novel and direct to consumer marketing campaigns in selected areas, opening up new channels to further distribute a pipeline of future Company sponsored products and services.

HPV (human papillomavirus) is the most common sexually acquired disease and the cause of 99.7% of cervical cancer worldwide. Cervical cancer causes in excess of 280,000 deaths per annum with over 470,000 new cases identified annually. Progression to invasive cervical cancer may be prevented by early detection and treatment of HPV infection and any associated pre-cancerous cell transformation. HPV testing is an effective pre-screening method involving DNA analysis. As more health professionals recognise the power and effectiveness of HPV testing, it is likely to become more prevalent and increasingly important in future years.²

The Company's initial product is the Tam Pap Test. The name Tam Pap is derived from the words **Tampon** and

Papillomavirus.

The Company's primary intellectual property resides within a patent pending test process to detect the high risk strains of the human papillomavirus that can lead to a cell transformation and potentially induce the onset of cervical cancer. The Company will acquire the HPV Intellectual Property relating to the test from Symbion upon listing on the ASX.

Presently cervical cancer screening is undertaken primarily through the use of pap smears which are conducted most usually by a physician. Women may find pap smears to be painful, invasive or unpleasant. The pap smear test, which was developed in the 1920's, requires the collection of sample cells from the cervix using a small brush or spatula. Some research has shown that pap smears have relatively low efficacy (less than 70% detection) and compliance. Some women are misdiagnosed. Sensitivity is lower for early stage cell changes, in part, due to the inability to distinguish between pre-cancerous cells and other cells and lesions. The pap smear test produces false negative results in approximately 15-25% of cases.³

Cellscreen's Tam Pap Test process is a world first. The process utilises a highly accurate detection test, enabling women to self-sample for HPV in their own home. It is private, safe, painless and minimally-invasive.

The Tam Pap process works as follows:

- A woman collects her own DNA sample using an ordinary tampon (any tampon brand);
- After insertion and removal the tampon is put into a secure collection pack and then the pack

is sealed. In Australia it is then sent to a Symbion Laboratory (a National Association of Testing Authorities (NATA) approved laboratory), whereas overseas it will be sent either to a Symbion Laboratory or other licensed laboratory. The laboratory uses a process to read the DNA that identifies whether the woman has an HPV infection, and if so, if she is carrying a high risk strain;

- Via her doctor or appointed nurse or clinical practitioner, the woman will receive results in the mail or by telephone, depending on local regulations.

4.2 Cellscreen Technologies

4.2.1 Tam Pap Test


Molecular diagnostics encompasses tests to identify the presence or risk of disease by identifying disease causing organisms by detection of DNA or RNA. This technique is particularly useful to identify pathogens (ie: such as bacteria and viruses) that are difficult to detect using traditional laboratory based methodologies. A DNA technique is particularly effective in revealing the presence of viruses such as high risk types of HPV. There are 15 different high risk genotypes of HPV that have been directly linked to causing cervical cancer in women. In cases when a patient's own immune system does not clear a HPV infection and it persists, there is a significant risk that the patient will develop some form of anogenital cancer.⁴

Cellscreen's "Tam Pap" home-based test kit uses a simple tampon as a collection device for the aggregation of DNA samples which are then tested for the

²Cancer News. (2005) Study shows HPV test is better predictor of cervical cancer in older women: National Cervical Cancer Coalition website: <http://www.nccc-online.org/>;

³⁻⁴Innovation Dynamics Expert Report, November 2008;





simultaneous detection and genotyping of high risk strains of HPV.

If the test is used as directed without the use of contraceptive gels or antifungal creams, cells and HPV viral particles from the vaginal wall will transfer to the tampon. Cells and HPV viral particles may still transfer and the test may still work if, contrary to direction, contraceptive gels or antifungal creams are used, but in that case Cellscreen can not be confident that any negative result does not represent a false-negative result. The tampon will then be sent following clear consumer instructions, in a sealable, secure and bar coded identification satchel to the Cellscreen laboratory medicine partner, (Symbion Pathology or other licensed laboratory). The presence of human cells

on the tampon is confirmed by a beta-actin detection step. A PCR based DNA test can reliably reveal the presence of HPV and of any high risk HPV genotype.

As the results of pap smear tests can be ambiguous, a doctor may also request an HPV test. A woman may also wish to acquire her own “peace of mind”. As such, either the doctor can issue the patient with a test kit or, in countries where regulations permit, a woman herself can order the test kit, from the internet or by contacting Cellscreen Direct. The test kit can be easily utilised at home any time other than during the woman’s menstrual cycle.

At the pathology laboratory a technician will remove the tampon from the sealed bag and carefully record the patient’s

details on the laboratory database prior to extracting the DNA from the tampon. The sample is then analysed for the presence or likelihood of high risk strains of HPV.

HPV DNA is only present in small amounts. The DNA must therefore be amplified using standard DNA amplification processes to provide sufficient DNA to yield interpretable results.

The result from the Tam Pap Test is returned to the patient’s doctor, who will advise of the outcome. In some jurisdictions results may be delivered to the patient via a third party clinical practitioner. A high risk HPV positive result may require the patient to undertake further examinations which could ultimately involve surgical

HPV is the most common sexually acquired disease and the cause of 99.7% of incidences of cervical cancer worldwide.



intervention pending the advice of the patient's doctor.

An HPV negative result would most usually mean a patient would not require any further follow up until the next test was undertaken. Research has shown that a negative HPV result means that a woman will be highly unlikely in the short term to contract any form of cervical cancer. The Company would recommend that women perform a Tam Pap home-based Test at regular intervals to ensure the continued absence of high risk HPV infection.

The Company commissioned an initial independent market survey in Australia of 1,010 women undertaken by a leading Australian research organisation to determine womens' general awareness of HPV and casual linkages to cervical cancer. The survey also explored a woman's propensity to utilize a relatively non-invasive process to pre-screen for

the presence of HPV, particularly if the test could be performed in the privacy of the woman's own home. The likely price level was also mentioned. Results of this are indicated below. They indicate a high level of market acceptance for the Tam Pap Test. The Company believes that this survey result would be a predictor for other target market regions such as the USA and Western Europe.

The Company has already received a number of proposals from reputable market survey organizations to conduct further analyses in target markets prior to entry in those markets. Cellscreen intends to initiate market surveys as and when required.

The Australian research was conducted as an on-line survey which solicited responses to 7 structured questions to women between the ages of 25 and 69. The sample was equally divided between Melbourne and Sydney residents.

Table 3: Australian Survey Results
(Number of female respondents = 1,010)

Basis of Question	Positive Response Recorded
Level of worry about contracting cervical cancer;	67%
Do you know somebody who has or had cervical cancer;	29%
Do you know what HPV is?	50%
Have you had a pap smear in the last 2 years;	69%
Did you find the pap smear process degrading, unpleasant or painful?	52%
Top three reasons for not having a pap smear in the last 2 years:	
Hysterectomy;	39%
Invasive;	28%
Lack of Time;	27%
If you could accurately find out whether you have HPV by simply inserting one of your own tampons in the privacy of your own home, would you do it?	90%



5. The Company

5.1 Introduction

The Company was established in October 2008 as the holding company of Tam Pap Pty Ltd and other related companies. The Company's subsidiary, Tam Pap Pty Ltd was incorporated in 2006 to commercialize the Tam Pap Test kit which utilizes a unique technology process that was originally developed by SDS Laboratories to detect Human Papillomavirus. The Test uses a DNA molecular analytical process to reveal potential cell changes that can lead to cervical cancer.

The Company has a vision to become a market leader in the home based molecular test and diagnostic market using "in-house" expertise to generate high levels of market awareness and novel direct to public marketing techniques, which are expected to encourage significant sales volumes of the Test. The Company has access to skilled consultants in the field of direct marketing. Most importantly however, is the fact that the Company will have the HPV Intellectual Property that is expected to position the Company as a premier bio-development and marketing enterprise. The Company will apply sophisticated direct to market retailing methodologies for the first time to a biotechnological process that will seek to gain significant and rapid traction in the marketplace.

The Company's Tam Pap Test kit is currently being commercialized in Australia. The Australian market will continue to be utilised as a "beta-test" bed for the test to reveal reactions, potential improvements to process and to document test efficacy. The Tam Pap

business model is internationally replicable and scalable for sustained revenue generation.

The model itself has been developed with one objective: make it easily scalable to accommodate worldwide distribution. This will be achieved by developing an "online" system to manage and track the entire workflow of orders which may eventuate within any country in the world.

Where it may be necessary to have laboratories other than Symbion analyse the test applicable licensing rights can be granted by Cellscreen to other appropriately accredited laboratories.

Whilst Cellscreen will continue to focus on activities currently being undertaken in Australia, it has also commenced due diligence to implement a US and European market implementation strategy. The US market is the most sophisticated medical diagnostic market in the world with an educated population becoming

increasingly willing to take control of their personal health wherever possible. The Tam Pap Test is ideally positioned for such a market.

In the USA over 60 million women are screened annually for cervical cancer using a pap smear test.⁵ Cellscreen therefore believes that this region will become a primary focus of its commercial activity after the receipt of appropriate statutory approvals. The Company has also commenced in depth due diligence with regard to the exploration of other potential market sectors acquiring substantial health, wellness and preventative screening data to assist and inform its strategic orientation post listing.

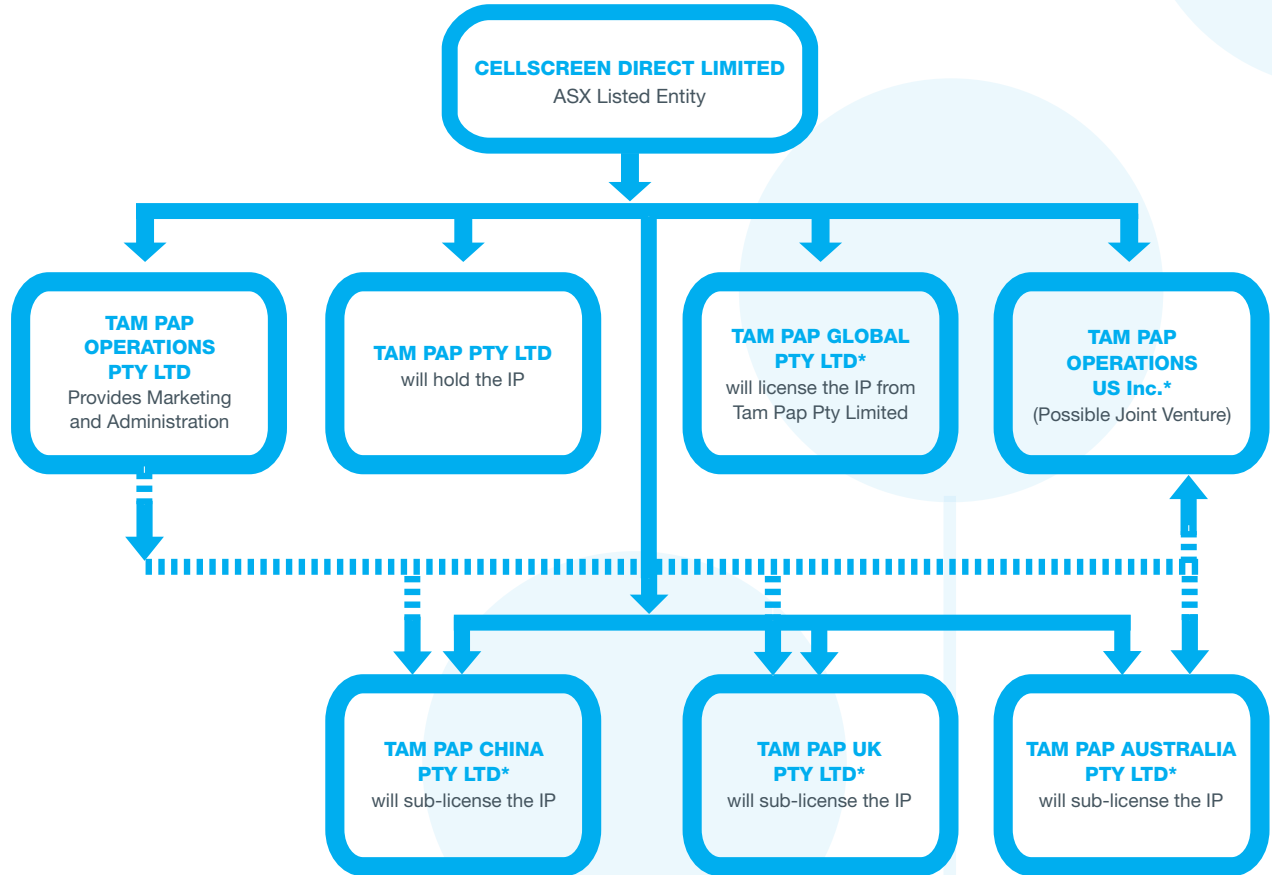
Cellscreen is in the process of implementing a corporate structure (see below) to both protect its intellectual property and allow it to operate effectively within selected regions without undue exposure.



⁵SpectRx, Inc. (2006) Press Release: Two Clinical Studies Indicate SpectRx Non Invasive Cervical Cancer Detection Device Accurately Detects Disease While Reducing False Positive results. Released 16/03/2006;



Table 4: Corporate Structure



- ||| The marketing company provides services to the various entities in Tam Pap
- Shareholding
- * To be established

5.2 Cellscreen’s Technology Framework

5.2.1 Tam Pap Test Kit Platform

Cellscreen’s subsidiary, Tam Pap Pty Limited will acquire on the Company



listing on the ASX, the HPV Intellectual Property (including all patent applications) on which the unique home test for the Human Papillomavirus is based. The processes inherent within the technology platform may enable Cellscreen to

develop further novel diagnostic test products such as the detection and analysis of syphilis, gonorrhoea and chlamydia.

5.2.2 Tam Pap Test Kit

The Company’s Tam Pap Test kit process is fast, efficient and painless. It does not involve the use of a speculum or a cervical scrape. A woman can easily order the Tam Pap self sampling test kit either through her General Practitioner as in Australia or in other countries where regulations permit on-line, by mail or telephone.

Once ordered a kit will be sent directly to the consumer by mail where the woman will receive the following:

- A Specimen Bag;

- A reply paid secure envelope;
- An Explanatory terms and conditions sheet;
- An easy to follow instruction brochure; and
- Barcoded stickers for secure identification.

A woman will self sample in the privacy of her own home by inserting a tampon into the vaginal canal for a period of approximately ten seconds. The tampon will then be removed and placed in the specimen bag which in turn will be secured within the reply paid barcoded envelope.

The reply paid envelope will be forwarded to a pathology laboratory for analysis. Cellscreen will transfer the woman's coded results back to her nominated medical practitioner or to her via a third party clinical practitioner.

For Tests conducted in Australia Cellscreen can transport and handle the samples through the Australian Post system, however the transport and handling of samples will vary in each jurisdiction.

In Australia a Test must be ordered and results delivered through a medical practitioner. In the USA, regulations require test results to be delivered by a medical practitioner or via a third party clinical practitioner. Regulations may vary as to the transfer of results in other jurisdictions.

The Cellscreen screening assay uses biphasic real time polymerase chain reaction (RT-PCR) to detect the presence of human papillomavirus DNA. This RT-PCR screening utilises a variation of SPF primer sets published a decade ago⁶,

and Syto9 dye to show a simple positive / negative result. The typing process can then identify which, if any, of the fifteen high risk HPV genotypes (namely 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68, 73 and 82) and two moderate-high risk types (66 and 70) are present in a sample. This process can identify multiple HPV genotypes, if present in a single sample. The Company's HPV Test has been validated for use on a variety of sampling types, including thin prep, cervical swabs and tampons.

5.3 Market Scope and Growth Opportunities

5.3.1 Introduction

There is now irrefutable evidence establishing the link between infection with high risk HPV genotypes and cervical cancer. Human Papillomavirus is the most common sexually transmitted disease (STD) in the world with 50-80% of all women in western societies infected at some point in their lives. There are around 40 different strains of the virus that can infect the genital region, but most people who become infected are not aware of their condition. In over 90% of cases, the infection will be cleared naturally by the body's immune system within two years.

Different HPV types are often referred to as low or high risk. Low risk types (lrHPV) cause visible genital warts. Whilst this condition is highly contagious and can be uncomfortable for sufferers, it is not a major health concern. High risk HPV types (hrHPV) are known to cause cancer, predominately of the cervix. There are 15 high risk HPV genotypes. In cases

when a patient does not clear an HPV infection and it persists, there is a higher risk that they will develop some form of anogenital cancer.

A recent study has reported that women between the ages of 40-50 years who test positive for HPV have a greater than 20% chance of developing cervical cancer within 10 years.⁷ Whilst being infected with HPV does not mean that a woman will develop cervical cancer, it is known that over 99% of cervical cancer cases develop after infection with hrHPV. Studies have determined that a sensitive HPV test has the potential to eliminate 80-90% of women over the age of 30 from being considered at risk for cervical cancer at that time.⁸

Cellscreen's Tam Pap home-based test kit process has been developed to minimise the time taken to secure necessary DNA and to analyse the sample. The process also is complementary to the work of the medical practitioner who now is no longer required to perform an invasive and time consuming cervical scrape to test for HPV.

5.3.2 HPV and Cervical Cancer

Cervical cancer is the second most common form of cancer in women, with over 470,000 new diagnoses and 280,000 deaths annually worldwide (See Table 5 for breakdown).⁹ Cervical cancer has a much higher prevalence in developing countries with 80% of all cases located in these regions. The higher prevalence can be attributed in part to the lack of widespread screening. Only about 5% of women in developing countries are regularly screened for

⁶SPF Primers are a multiple set of consensus primers that amplify a fragment, around 65 base pairs, of the L1 gene. (Kleeter et al., 1998);

⁷Cancer News. (2005) Study shows HPV test is better predictor of cervical cancer in older women;

⁸Stoller M (2005) *op cit*;

⁹SensiGen LLC. (2007) Press Release: SensiGen Exercises Option to Ultra-Sensitive Human Papillomavirus (HPV) Test. Released 22/2/2007;



cervical cancer, compared to 40-50% of women in developed countries.¹⁰

Research has also shown that women who contract genotype 16 and 18 HPV are potentially 4 to 5 times more likely to develop cervical cancer than those who contract other high risk strains.

Women who are diagnosed with genotype 16 and 18 HPV would generally be immediately referred for a colposcopy, whilst other women diagnosed with other

high risk strains of HPV would be advised to have a pap smear test.

The Australian National Cervical Screening Program was implemented in 1991 and cervical cancer deaths in Australian women have decreased significantly as a result. A total of 3.8 million women were screened as part of the program in 2004 detecting 30,000 abnormalities requiring further follow up, but less than 1,000 cases of cancer.¹¹

Most cervical screening guidelines generally recommend that all women over the age of 18 who have been sexually active should have a pap smear every 2 years until the age of 70.¹²

Although the pap smear has been successful in reducing the incidence of cervical cancer, not all women are taking advantage of the screening programs, as demonstrated in the USA where 50% of women diagnosed with cervical cancer have never been screened and 10-20% have not been screened in the last 5 years. Additionally, 30% of women with cervical cancer were screened but returned a false negative result from their pap test.¹³

HPV Test Market

Globally, HPV has a prevalence of around 9-13% of the total population (male and female), equating to approximately 725 million infected people. In the USA alone there are 6.2 million new cases each year, and 15-20 million American women are infected with HPV at any one time.¹⁴ (See Table 6 below).

Table 5: Global cervical cancer statistics, 2007

	Diagnoses of Cervical Cancer	Deaths due to cervical cancer	Screening coverage
UAE	73	36	-
USA	11,000	4000	85%
Australia	840	330	62%
Japan	8,000	4000	24%
China	46,000	25,500	-
Europe*	60,000	30,000	-
India	133,000	74,200	-

Source: WHO/ICO Information Centre on HPV and Cervical Cancer (2007);

*Eastern and Western Europe;

Table 6: Global Human Papillomavirus Statistics

Region	Prevalence of HPV	Cases of HPV per annum (Women)	Female Population > 15 years
USA	13.1%	15.9 million	121 million
Western Europe	6.1%	4.9 million	80 million
Eastern Europe	29.1%	39.4 million	135 million
Northern Europe	8.0%	3.2 million	41 million
Southern Europe	5.7%	3.7 million	66 million
Japan	7.5%	4.3 million	57 million
China	13.6%	68.9 million	507 million
India	6.6%	24.1 million	366 million

Source: WHO/ICO Information Centre on HPV and Cervical Cancer (2007).

¹⁰Qiagen N.V. (2008) Press Release: Study finds Qiagen's HPV test offers greater long term protection from cervical diseases than the pap. Released 20/05/2008;

¹¹Australian Government. (2008) Australian Institute of Health and Welfare, Cervical Screening;

¹²Australian Government. (2008) Australian Institute of Health and Welfare, Cervical Screening;

¹³Stoler M. (2006) Cervical cancer screening in the HPV era: What is the standard of care? Pathology Today: American Society for Clinical Pathology 2005 Annual Meeting;

¹⁴Bruderlin-Nelson C. (2007) HPV test market expected to boom, IVD Technology;



“The current global HPV diagnostic market is estimated to be worth US\$4.0 billion.”

It is noted that:

- The implementation of a more effective screening program is paramount in reducing the incidence of cervical cancer. WHO data suggests that China has a cervical cancer incidence rate of 3.6 per 100,000 compared to the incidence rate of 14.3 per 100,000 in India. It is possible that China may have a more extensive cervical cancer screening or educational program than India. Cultural and religious beliefs could also impact on discrepancies in certain regions.
- Japan has a much lower diagnosis of cervical cancer than China and India and yet has a HPV prevalence rate of 7.5%, which is greater than India. Japan has an established screening program that captures 24% of the population. This may reduce the incidence of cervical cancer, notwithstanding a higher percentage of women with HPV infection.

The current global viral and molecular diagnostic test market has been estimated to be worth approximately US\$34 billion with the global infectious diseases market worth approximately US\$2.5 billion.¹⁵ The current global HPV diagnostic market is estimated to be worth US\$4.0 billion.¹⁶ The USA makes up the majority of this market, demonstrating annual growth of 40%

since 2003 and continuing growth projected at 25% per annum.¹⁷ The Tam Pap self sampling test kit is expected to sit inside the HPV diagnostic market. Cellscreen aims to make the Tam Pap Test the option of first choice for women. Even in the USA market there is still room for growth in the HPV testing market as only around 20% of targeted women are currently screened for HPV infection in conjunction with a pap smear test.¹⁸

The USA has the highest rates of HPV testing, having introduced optional HPV testing in combination with pap smear tests in 2002.

However the uptake rate may soon be greater in Italy, which in 2007 announced the trial of a government sponsored cervical cancer screening program utilising HPV testing as the primary diagnostic tool.¹⁹ The Italian government will specifically be targeting 26,000 women between the ages of 25 and 30 in the initial pilot trial. HPV DNA tests will only be followed with a pap smear test for those women who test positive to high risk HPV strains.

Competition

There are several HPV tests on the market at present with the most successful being the Digene Inc Hybrid Capture, 2-High Risk HPV DNA test, the only HPV test that has obtained USA FDA Approval, and the PapilloCheck and Amplicor tests in Europe.

The majority of the products that are in development and on the market utilise

samples taken during a normal pap smear test where cells are taken from the cervix using a speculum and brush technique and the sample stored in a thin prep liquid based preserver and are only available through a medical practitioner (liquid based cytology). Approximately 92% of the annual 60m pap smear tests conducted in the USA today are completed using liquid based cytology. In Europe there are approximately 45-55million pap smear tests conducted annually which is expected to grow with the increasing emphasis on screening and prevention techniques.

Two self sampling HPV tests are also available – CerviScreen and Fournier's Feminine Multi-Test. The major competing technologies are identified below:

Qiagen Inc

Qiagen Inc acquired Digene Corporation, the inventor of the Digene HPV hybrid capture assay in 2007. The Digene HPV test is currently the only test approved in the USA for the detection of high risk HPV.²⁰ In 2003 Digene was granted FDA approval for the test to be used in conjunction with Pap Tests, for women over thirty. Sales of the Digene HPV test were US\$135.2 million in FY 2007, an increase of 42% on the previous year.²¹ Qiagen is currently developing a low cost HPV test for sale in developing countries with the company expecting to gain regulatory approvals in China and India in 2008.²² Digene was sold in July 2007 to Qiagen Inc for US\$1.6 billion representing a multiple of 7.3 x projected revenue for 2008.

¹⁵Gen-Probe Corporate Presentation: An Innovative Growth Company in Molecular Diagnostics, January 2008;

¹⁶ValiRx (2008) Press Release: ValiRx and Clarity Imaging sign letter of intent for the distribution of HPV genotype diagnostic test kit. Released 13/02/2008;

¹⁷Wisconsin Technology News. (2008) Third Wave's HPV clinical trial hits key goals. March 11, 2008;

¹⁸Bruderlin-Nelson. (2007) *op cit*;

¹⁹Medical News Today. (2007) Italy is the first country to launch government sponsored cervical cancer screening program using HPV testing as a primary diagnostic, June 14, 2007;

²⁰The Digene HPV test (2008) Homepage <http://www.thehpvtest.com/learn-about-HPV-test.html> Viewed 3/06/08;

²¹Genera Prospectus. (2008);

²²Qiagen. (2007) Sample & Assay Technology brochure;



Roche Ltd

Roche Ltd launched “Amplicor HPV” into the European market in 2004.²³ Amplicor detects 13 strains of high risk HPV from a cervical smear using PCR.²⁴ Amplicor has CE Marking but Roche has yet to gain FDA approval for the Amplicor HPV test.

Greiner Bio-one International AG

Greiner Bio-one International AG, headquartered in Austria has developed “PapilloCheck” an HPV test capable of detecting and typing 24 HPV genotypes (6 low risk and 18 high risk strains) from a cervical smear.²⁵ The detection process uses DNA microassays and is electronically automated for rapid results. PapilloCheck is sold throughout Europe.

Third Wave Technologies Inc

Third Wave Technologies Inc has developed two HPV genotyping tests, one for HPV genotypes 16 and 18 and the other for 14 high risk HPV strains. The 16/18 genotyping test is used to determine if women with abnormal pap smear tests should undergo further treatment (ie: colposcopy).²⁶ The other high risk HPV test is to be used in conjunction with Pap tests in order to provide women over 30 with more accurate clinical diagnoses. Third Wave announced in April 2008 that they have submitted an application for pre-market approval to the US Food and Drug Administration (FDA) for both tests.²⁷

Third Wave have recently been sold to Hologic Inc for US\$580 million.

Innogenetics NV

Innogenetics NV developed the INNO-LiPA HPV Extra assay, which is a line probe assay based on the reverse hybridisation principle and designed to identify 28 types of HPV.²⁸ The test utilises Innogenetics’ proprietary SPF primer and is used in complement to pap smear tests and other DNA based HPV tests. In 2007 Innogenetics’ diagnostic sales in Europe totalled €47 million.²⁹

Gen-Probe Inc

Gen-Probe Inc develops, markets and manufactures nucleic acid tests primarily for the diagnosis of human diseases³⁰ and is developing a test for the detection of HPV.³¹ The APTIMA HPV assay is based on the detection of mRNA of genes known to contribute to cancer advancement. Gen-Probe has entered into a purchase agreement with Roche Molecular Systems, under which Roche will manufacture the DNA probes required for the APTIMA assay.³² Gen-Probe plans to begin clinical trials for the APTIMA HPV assay in the USA and to have a product on the European market in 2008.³³

Polartech Limited

Polartech Limited is a listed Australian company (ASX:PLT) specialising in the development and manufacture of diagnostic devices for pre-cancer and

cancer. CerviScreen comprises a self sampling device and PCR based assay for the detection of HPV³⁴ and has CE Marking and is in the process of gaining TGA approval.³⁵ Polartech has developed Truscreen, a real time cervical screening device, which has both TGA approval and a CE Mark and is achieving some sales in the Asia Pacific region. It has a wand and a disposable tip which is inserted to examine the cervix, picking up electrical and light signals and analysing them against a databank to identify any “abnormal” cervical tissue.³⁶

Genera Biosystems Ltd

Genera Biosystems Ltd is a listed Australian biotechnology company (ASX: GBI), that has developed PapType, an HPV diagnostic utilising cervical smear samples. The PapType technology involves the amplification of DNA gathered in a sample and combination with the PapType beads, which glow red in the presence of HPV.³⁷

The beads are then analysed with a flow cytometer. The PapType test is performed in conjunction with a Pap test. Genera announced in June 2008 the signing of a distribution agreement to supply their HPV diagnostic tests to Gribbles Pathology, one of the largest pathology providers in Australia.³⁸ In September 2008 Genera entered into an agreement with Polartech (ASX:PLT) to explore

²³Roche. (2004) Press Release: Amplicor HPV, new diagnostic test to detect cancer causing viruses, launched in Europe;

²⁴Roche. (2004) *op cit*;

²⁵Greiner Bio-one. (2008) PapilloCheck HPV-screening brochure;

²⁶Third Wave Technologies. (2008) Press Release: Third Wave Completes FDA Submissions for its two HPV Products. Released 28/04/2008;

²⁷Third Wave Technologies; (2008) *op cit*;

²⁸Innogenetics. (2008) Inno-LiPA HPV Genotyping Extra <http://www.innogenetics.com/infectiousdiseases.html?id=59> Viewed 3/6/2008;

²⁹Innogenetics. (2008), Homepage <http://www.innogenetics.com> Viewed 3/6/2008;

³⁰Gen-Probe. (2005) Press Release: Gen-Probe Signs Agreement with Roche to purchase products for APTIMA Human Papillomavirus Assay. Released 15/02/2005;

³¹Gen-Probe. (2008) Product Pipeline <http://www.gen-probe.com/pipeline> Viewed 3/06/2008;

³²Gen-Probe. (2005) *op cit*;

³³Gen-Probe. (2008) *op cit*;

³⁴Polartech. (2008) Cerviscreen-Introduction <http://www.polartech.com.au> Viewed 04/06/2008;

³⁵Polartech Ltd (2008) Press Release: On track to deliver commercialization strategy. Released 25/02/2008;

³⁶Polartech Ltd. (2008) Truscreen <http://www.truscreen.com/index.html> Viewed 28/05/2008;

³⁷Genera Biosystems Prospectus (2008) *op cit*;

³⁸Genera Biosystems (2008) Press Release: First Sales of PapType HPV test to Healthscope, 20/06/2008;



the potential of developing a home-based self sampling test for HPV.

Other Competitors

Other companies currently developing HPV DNA tests that are in development and expected to be released onto the market in the next two years are SensiGen, ValiRX and NorChip. Fournier's Feminine Multi-test is a self sampling test that utilises a tampon like device to collect cells from the cervix. This test is designed to be undertaken in a supervised environment to achieve cell samples that are of a higher quality.³⁹

5.4 The Cellscreen Competitive Advantage

In comparison to other tests available in the market Cellscreen's Tam Pap self sampling home based test has the following competitive advantages:

- The Tam Pap Test can successfully and simultaneously detect and genotype high risk strains of HPV (particularly 16 and 18) using a minimally invasive, private and painless technique, whereas other tests (including the only current FDA approved test) rely on pap smear type procedures to take cervical swabs and are more limited in the number of HPV genotypes they detect;
- The Tam Pap Test can also successfully detect low risk strains of HPV (including types 6 and 11) which can cause genital warts and other infections;
- The Tam Pap Test does not require the initiation of a pap smear to collect cells for analysis. The Tam Pap Test uses a simple tampon to collect DNA that can



be 100% accurately analysed for the presence of HPV;

- The Tam Pap Test will be positioned in the market place for women as an affordable and cost effective test making it a practical alternative for women;
- The Tam Pap process can be implemented without access to a physician in areas where immediate availability is difficult to obtain;
- The Tam Pap process is secure and safe to use and will potentially promote increased levels of usage due to the important fact that privacy can be maintained;

5.5 Commercial Arrangements

Set out below is a brief summary of the material commercial arrangements which have been entered into by the

Company. These agreements have been summarised in more detail in Section 11.

Commercialisation Agreement

Symbion and SDS are major subsidiaries of Primary Health Care Limited, an Australian Company listed on the Australian Stock Exchange.

SDS and Symbion and its related companies provide a comprehensive range of services and facilities to general practitioners, specialists and other health care providers who conduct their own practices and businesses from Primary Health Care's medical centers, licensed day surgeries, specialist and dental clinics and elsewhere.

SDS took the lead role in developing the HPV test platform that Cellscreen will utilize to analytically detect the presence of HPV in samples undertaken. That HPV

³⁹Innovation Dynamics Expert Report, November 2008;



test platform was transferred by SDS to Symbion in October 2008.

Cellscreen via Tam Pap Pty Ltd entered into a Commercialisation Agreement with SDS in October 2007. SDS assigned its rights under that agreement to Symbion under a Deed of Amendment on 27 November 2008. Under the Commercialisation Agreement as amended, on the listing of Cellscreen, Tam Pap Pty Limited will be assigned the HPV Intellectual Property by Symbion, in exchange for 15% of the fully-diluted share capital of Cellscreen as at listing. In addition Symbion will be entitled to fees for each test conducted by it on behalf of Tam Pap or its sub-licensees or if the tests are conducted by another laboratory.

The Commercialisation Agreement as amended provides for continuing collaboration by Cellscreen and Symbion in the growth of test product development applications using the Tam Pap Test platform and collection methodology for continued mutual benefit. Symbion will also continue to assist Cellscreen to achieve FDA approval

in the USA and a CE approval within the European Union.

License Agreements

The Company has negotiated licensing agreements for the marketing of the Tam Pap Test kit in Lebanon, India as well as New Zealand and the Pacific Islands. No agreements for the licensing of laboratories outside Australia have yet been entered into.

5.6 The Regulatory Environment

The regulatory approval process can be a complex environment to navigate however Cellscreen considers that it is essential that appropriate regulatory approvals are obtained in various key jurisdictions to ensure that compliance with relevant codes, health authority frameworks, ethical considerations and safety and security concerns are observed.

Cellscreen through Tam Pap Pty Ltd currently holds:

- A Certificate of Exemption From Entry on the Australian Register of Therapeutic Goods (TGA) dated 2 May 2007 for the Test kit;

The Test also has TGA approval as a diagnostic test.

The Company is in the process of making an application for an FDA approval (USA) and has recently met with the authority to determine the extent of outstanding issues and the timeframe to achieve approval.

The Company has also engaged a lead consultant to assist with the attainment of a CE Mark approval in Europe and the implementation of a quality assurance system that aligns with regulatory requirements (ISO 13485). It is the understanding of the Company that the securement of a CE Mark will be obtained relatively shortly after the Company's listing based upon interactions which have occurred to date.

The Company has also sought and received a number of proposals from skilled regulatory consultants in targeted geographic regions and intends to formally engage a number of these organizations to assist with obtaining required approvals for the Tam Pap Test process after the completion of the Company's listing.

Cellscreen's Tam Pap home-based test kit process has been developed to minimise the time taken to secure necessary DNA and to analyse the sample.



6. Innovation- Dynamics Expert Report



8th November 2008

Ms Alison Coutts
Chairperson
Cellscreen Direct Limited
Suite 40, 112 McEvoy Street
Alexandria NSW 2015

Dear Ms Coutts,

This report has been prepared for the Directors of Cellscreen Direct Limited ("Cellscreen" or "the Company") to provide an independent opinion on the technology for detecting human papillomavirus (HPV) infections in women. The report may be included in the Prospectus to be issued by Cellscreen in connection with an initial public offering ("IPO") of a minimum of 15,000,000 shares at a price of AU\$0.50 to raise a minimum of AU\$7.5 million and also apply for quotation of its shares on the Australian Securities Exchange Limited (ASX).

Cellscreen is focussed on the international marketing and licensing of a novel self-sampling HPV test called Tam-Pap®. This test comprises a method for screening cervical samples for the presence of particular HPV infections and direct consumer marketing aimed to facilitate a high level of participation whilst at the same time meeting national regulatory approvals. The major advantages of the test are the testing process and selection of genotypes included in the screen, its unique and user-friendly home sampling kit and the range of marketing avenues being pursued to facilitate consumer access.

Test results are determined by laboratory-based detection of HPV viral DNA using polymerase chain reaction (PCR). The HPV detection technologies are currently licensed by Tam Pap Pty Ltd (a wholly owned subsidiary of Cellscreen) from Symbion Pathology Pty Limited under a Commercialisation Agreement. Upon Cellscreen listing on the Australian Securities Exchange the intellectual property will be assigned to Tam Pap Pty Limited in consideration for the issue of 15% of the capital of Cellscreen. The test development laboratory will be based in Australia and operated by Symbion Pathology Pty Limited. The product has been approved for distribution in Australia and New Zealand and is currently sold in Australia through clinical practitioners. The test is the subject of a PRE-IDE application to the US Food and Drug Agency for sale in the US.

The stated strategy and business model for the Company is to license the test system to various marketers/distributors in international markets and receive revenue through royalties or direct sales. Cellscreen already markets the test in Australia and intends to enter the US market separately, through a joint venture with a local partner.


To complete our analysis we have assessed the technologies to be assigned to Cellscreen, its business strategy, the markets addressed by the technologies and the Company's ability to access these markets and satisfy their needs within a reasonable time. A separate report on the intellectual property held by Cellscreen is included elsewhere in this prospectus.

Cervical Cancer Testing

Cervical cancer is a slowly-progressing disease that takes up to ten years to develop from early cellular changes into a malignant condition. It is also one of the most treatable cancers when diagnosed early and those patients have a higher survival rate. However cervical cancer usually does not cause identifiable symptoms of the disease until it is quite advanced and prognosis is poor. Regular screening for early warning is therefore very effective for reducing the prevalence and death rate of the disease.

The most common test currently used for cervical cancer screening is the Papanicolaou smear, or "Pap test" which was first developed in the 1920's and requires the collection of sample cells from the cervix using a small brush or spatula. The cells in the sample are assessed microscopically by a trained technician. The process is painless but uncomfortable for most women, with results generally available within one week. The Pap test is the Gold Standard used in many government-sponsored programs that





recommend regular (annual, biannual or tri-annual) cervical screening of sexually active women. The Pap test has been responsible for limiting deaths from cervical cancer and reducing associated healthcare expenditure.

The major advantage of the Pap test is that it directly identifies, at low cost, the majority of cervical cancers in their early stages, when treatment offers a good chance of patient survival. However, the sampling process is uncomfortable for many women, and, importantly, the Pap test is not highly accurate. Some women are misdiagnosed. It is considered to have a specificity of approximately 99% but sensitivity ranging from 40 – 70%. Sensitivity is lower for early stage cell changes, in part due to the test's inability to distinguish between pre-cancerous and other cells and lesions. The Pap test produces false negative results in approximately 15 – 25% of cases. The test is consequently not utilised by all at-risk women with access to screening services.

More advanced cytology based tests have been developed to screen for cervical cancer include the ThinPrep® test marketed by Cytec Corporation, which uses a modified sample collection technique and liquid based cytology allowing for automated image analysis. It is usually employed as a secondary option if the Pap test returns an inconclusive result.

The main disadvantages of the Pap test which limits its effectiveness and uptake are:

1. The low predictive value of the test leading to misdiagnosis
2. The need for clinical examination to collect the sample
3. The overall cost of the test in screening

High risk HPV as a diagnostic test for cervical cancer

There is now irrefutable evidence for the link between infection with certain high risk HPV genotypes and cervical cancer and the 2008 Nobel Prize for Medicine was awarded to Harald zur Hausen of Germany for identifying this link over 30 years ago. Human papillomavirus is one of the most common sexually-transmitted diseases in the world with 50-80% of all women in western societies infected at some point in their lives. There are around forty different strains of the virus that can infect the genital region, but most are usually benign. In around 90% of cases, the infection will be cleared naturally by the body's immune system within two years.

Different HPV types are often referred to as low or high risk for cancer. Low risk types (lrHPV) cause visible genital warts. Whilst this condition is highly contagious and can be uncomfortable, it is not a major health concern. High risk HPV types (hrHPV) are known to cause cancer, predominantly of the cervix. There are approximately fifteen known high risk HPV genotypes. In cases when a patient does not clear an HPV infection and it persists, there is a higher risk that they will develop some form of anogenital cancer.

Young women in their early twenties pose the highest risk of infection. This decreases in women over thirty, but these older women tend to suffer more persistent infections and have increased chance of developing cervical cancer. A recent study has reported that women aged between 40-50 years who test positive for HPV have a greater than 20% chance of developing cervical cancer within 10 years¹. Whilst being infected with HPV does not mean that a woman will develop cervical cancer, it is known that over 99% of cervical cancer cases develop after infection with hrHPV. Studies have determined that a sensitive HPV test has the potential to eliminate 80-90% of women over the age of 30 from being considered at risk for cervical cancer at that time.²

HPV DNA tests are generally more sensitive than the Pap test as an indicator of cervical cancer status, and some sampling procedures for HPV tests are more patient-friendly. However, it is a test for HPV infection and, unlike Pap, not a direct test for cancer and cannot replace the need for cytology-based tests. Using both tests together, or with Pap smear cytology as a confirmatory test however, increases the specificity of the diagnosis and this offers women more reliable results together with personalised screening schedules.

The US has the highest rates of HPV testing; having introduced optional HPV testing in combination with Pap tests in 2002 and women aged over 30 years can purchase an HPV test in parallel to their regular government-sponsored Pap test. HPV testing has also been recommended as the current standard of care for triage of abnormal Pap smears. However the uptake rate may soon be greater in Italy, which in 2007 announced the trial of a government-sponsored cervical cancer screening program utilising HPV testing as the primary diagnostic tool.³ HPV DNA tests will only be followed up with a Pap test for those women who test positive to hrHPV strains.

¹Cancer News (2005) Study shows HPV test is better predictor of cervical cancer in older women, <<http://cancer.immunodefence.com/2006/11/>>

²Stoler M. (2006) Cervical cancer screening in the HPV era: What is the standard of care? Pathology Today: American Society for Clinical Pathology 2005 Annual Meeting.

³Medical News today (2007) Italy is first country to launch government-sponsored cervical cancer screening program using HPV test as primary diagnostic, 14/06/2007

The Italian government will specifically be targeting 26,000 women between the ages of 25 and 30 in the initial pilot trial.

Market Dynamics

Community awareness of HPV and the link to cervical cancer has risen recently due to the release by Merck & Co, Inc. of the locally developed HPV vaccine, Gardasil® and similar cervical cancer vaccine Cervarix®. This awareness will likely help to create interest in HPV testing, but may also lead women to the false belief that vaccination will mean they do not require further testing. The vaccines only protect against hrHPV types 16 and 18 and, whilst these two genotypes account for 70% of all cases of cervical cancer, there are other factors, including other hrHPV genotypes that cause the other 30% of cases. There is uncertainty about the duration of protection from the vaccine and the degree of uptake and acceptance of such a vaccine by women with various cultural backgrounds. HPV testing will still have a major role (as will the Pap test) even as the proportion of vaccinated women rises over the next decade.

The highest rate of HPV infection is found in the early twenties age group, but there is general consensus (and reflected in regulatory approvals) that there is little benefit to testing women under 25 years of age. It is expected that most national screening programs would only employ HPV testing in women aged 25 to 70 (the US HPV testing program targets women thirty and older). The likelihood of gaining approval to market an HPV testing product outside this age range is considered to be minimal.

The Pap test is uncomfortable and embarrassing for many women, and does not have 100% uptake, even in communities where screening is free and widely available. Cultural or religious beliefs or limited access to a clinician in remote areas may also prevent women from being screened, due to the nature of sample collection. As HPV testing can be adapted to various specimen types, it does have potential for attracting a wider market. Self sampling, as recommended for Tam-Pap®, would be more suitable for women in such circumstances.

There is a need for tests that provides wide, separate, specific identification of all HPV genotypes that are associated with cancer risk and to deliver this test in a format and procedure that provides a high level of access and participation by women worldwide. We believe that the Tam-Pap® test is designed to meet these requirements and correctly anticipates a growing demand and acceptance of choice in population screening for high risk HPV.

Market Opportunity for HPV testing

Cervical cancer is the second most common form of cancer in women, with over 500,000 new diagnoses and 280,000 deaths annually worldwide (see Table 1 for breakdown).⁴ Cervical cancer has a much higher prevalence in developing countries with 80% of all cases located in these regions.

This higher prevalence can be attributed in part to the lack of widespread screening. Only about 5% of women in developing countries are regularly screened for cervical cancer, compared to 40-50% of women in developed nations.⁵

In America, 60 million women are screened for cervical cancer annually using the Pap test.⁶ Despite these efforts approximately 11,000 women are diagnosed with cervical cancer every year and 4,000 die of the disease.⁷ The Australian National Cervical Screening Program was implemented in 1991 and cervical

	Diagnoses of Cervical Cancer	Deaths due to cervical cancer	Screening coverage
UAE	73	36	-
USA	11,000	4000	85%
Australia	840	330	61.8%
Japan	8,000	4000	24%
China	46,000	25,500	-
Europe*	60,000	30,000	-
India	133,000	74,200	-

Table 1: Global cervical cancer statistics, 2007

Source: WHO/ICO Information Centre on HPV and Cervical Cancer (2007)

*Eastern and Western Europe

⁴SensiGen, LLC (2007) Press Release: SensiGen Exercises Option to Ultra-Sensitive Human Papillomavirus (HPV) Test, 2/22/2007;

⁵Qiagen N.V (2008) Press release: Study finds QIAGEN's HPV test offers greater long-term protection from cervical diseases than the pap, 20/05/2008;

⁶SpectRx, Inc. (2006) Press Release: Two Clinical Studies Indicate SpectRx Non-Invasive Cervical Cancer Detection Device Accurately Detects Disease While Reducing False Positive results, 16/03/2006;

⁷American Cancer Society (2008) Cancer Facts & Figures;



cancer deaths in Australian women have since decreased significantly. A total of 3.8 million women were screened as part of the Program in 2004, detecting 30,000 abnormalities requiring further follow-up, but less than 1,000 cases of cancer.⁸

Most cervical cancer screening guidelines generally recommended that all women aged 18 or over who are or have been sexually active, should have a Pap smear every 2 years until the age of 70. Although the Pap smear has been successful in reducing the incidence of cervical cancer, not all women are taking advantage of screening programs, as demonstrated in the US where 50% of women diagnosed with cervical cancer have never been screened and 10-20% had not been screened in the last 5 years. Additionally, 30% of women were screened but returned a false negative result from their Pap test.⁹ Considering the known association between cervical cancer and HPV infection, there is clearly an opportunity to provide better diagnosis and predictive risk of cancer if HPV testing were more widely used.

The adoption of HPV testing has been slow to date; attributed to a number of factors, including; existing clinical prejudice, increased patient expense (without government sponsorship) and a lack of public understanding regarding the HPV/cervical cancer risk and the benefits of having both tests done.

As noted earlier, current HPV testing is likely to be used together with Pap testing, not as a replacement, as Pap tests will continue to be used to follow up to positive hrHPV test results to confirm a patient's actual cervical cancer status. However there may be a significant opportunity for more patient-friendly HPV tests, for example less invasive, self-sampling or at home test/sampling kits, to be used in primary screening. This type of test procedure would allow women with no hrHPV infection to avoid the discomfort of a Pap for another 2-3 years, and perhaps encourage more women to participate in regular screening.

HPV test market size

Globally, HPV has a prevalence of around 9-13% of the total (men and women) population, equating to approximately 725 million infected people (see Table 2 for breakdown). In the US alone there are 6.2 million new cases each year, and 15-20 million American women are infected with HPV at any one time.¹⁰

The current global HPV diagnostic market is estimated to be worth US\$200 million.¹¹ The US makes up the majority of this market, demonstrating annual growth of 40% since 2003 and continuing growth projected at 25% per annum.¹² Even in the prime US market there is still room for growth in the HPV testing market, as only around 20% of targeted women are currently screened for HPV infection in conjunction with their Pap test.¹³

Tam-Pap® test system

Cellscreen has licensed a HPV assay system and has a marketing platform to provide women with a way to test their HPV status conveniently and with high surety. The introduction of the test is timely and anticipates broad acceptance of testing of high risk HPV genotypes as a first line indicator of the risk and presence of cervical cancer.

Table 2: Global human papillomavirus statistics, 2007

	Prevalence of HPV	Cases of HPV HPV p.a (women)	Female Population >15 years
USA	13.1%	15.9 million	121 million
Western Europe	6.1%	4.9 million	80 million
Eastern Europe	29.1%	39.4 million	135 million
Northern Europe	8.0%	3.2 million	41 million
Southern Europe	5.7%	3.7 million	66 million
Japan	7.5%	4.3 million	57 million
China	13.6%	68.9 million	507 million
India	6.6%	24.1 million	366 million

Source: WHO/ICO Information Centre on HPV and Cervical Cancer (2007)

⁸Australian Government (2008) Australian Institute of Health and Welfare, Cervical screening;


⁹Stoler, M. (2006) Cervical cancer screening in the HPV era: What is the standard of care? Pathology Today: American Society for Clinical Pathology 2005;

¹⁰Bruderlin-Nelson C. (2007) HPV test market expected to boom, IVD Technology;

¹¹ValiRx. (2008) Press release: ValiRx and Clarity Imaging sign letter of intent for the distribution of HPV genotype diagnostic test kit, 13/02/2008;

¹²Wisconsin Technology News. (2008) Third Wave's HPV clinical trial hits key goals 11/03/2008;

¹³Bruderlin-Nelson. (2007) *op cit*;



The Cellscreen screening assay uses biphasic real time polymerase chain reaction (RT-PCR) to detect the presence of human papillomavirus DNA. This RT-PCR screening utilises a variation of primer sets published a decade ago¹⁴, and a dye to show a simple positive/negative result. A second step to confirm and type the HPV is then performed. The typing process can identify which of fifteen high risk HPV genotypes (namely 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68, 73 and 82) and two moderate-high risk types (66 and 70) are present in a sample. This process can identify multiple HPV genotypes, if present, in a single sample. The Tam-Pap® test has been validated for use on a variety of sampling types, including thin-prep, cervical swabs and tampons and compared with the Digene Hybrid Capture test and other leading HPV assays.

Initially, Cellscreen intends to commercialise this testing technology through the distribution of self-sampling kits that allow women to use an ordinary store-bought tampon to take their own cervicovaginal sample and post it to the Symbion Pathology Pty Ltd laboratory for analysis. The 'secure collection pack' kit includes a sample bag, reply paid envelope, instruction brochure, set of barcodes for laboratory identification, and a terms and conditions sheet for signature. The woman requests a kit, inserts and removes the tampon, attaches a barcode sticker and places it in the provided collection pack, then attaches a barcode sticker to the envelope, seals and mails the package to the laboratory. Symbion Pathology Pty Ltd, based in Australia and owned by Primary Healthcare Limited, has been assigned as the test development laboratory.

Symbion Pathology Pty Ltd is a NATA (National Association of Testing Authorities) approved laboratory and pathology service provider. It is envisaged that, in first instance, test samples will be sent to this laboratory from other world-wide collection sites or posted directly by the client. However in the longer term, separate, local, laboratory facilities in other countries will be set up under licenses. Cellscreen has been approved by Australia Post for mailing through its system. In some markets regulations stipulate that test results must be delivered via a nominated clinical practitioner, whilst in others Cellscreen plans to mail the results directly to each woman.

Regulatory Considerations

The US FDA has only approved one test, the Digene HPV test, for use in conjunction with the Pap-test. Other regulators appear to be cautious in approving HPV screening tests where sampling is not done by a medical practitioner or the test is conducted independent of Pap smears. Part of this caution is due to the risk that women will be reticent to have the Pap test which has been shown to be so successful in reducing cancer and may cause a decrease in women having the appropriate follow up. However, the majority of recommendations from regulatory bodies and professional organisations, such as the American College of Obstetricians and Gynecologists, are that HPV testing can be of benefit to women over the age of 30, where HPV incidence is lower but the risk of persistent infection is greater. Several major clinical trials have shown increased sensitivity of cancer detection using HPV over cytology with only a small loss in positive predictive value, especially in women over 30-35 years.^{15 16} The specificity of the test increases substantially when cytology is used as a follow up.

Cellscreen has completed validation of the sampling and testing procedures and the Tam-Pap® test has been approved by the Australian Therapeutics Goods Administration (TGA) and New Zealand Medsafe for distribution through medical practitioners in these countries. Cellscreen is currently seeking approval from the US FDA for distribution of the Tam-Pap® format as a first line test within the US using a wider direct marketing approach.

In our opinion, due to the increasing uptake of HPV testing in conjunction with Pap tests in major markets and the rising awareness of the benefits in the use of this test as a low cost, first line diagnostic, we expect to see an increase in acceptance by governments to support HPV screening. The decision of the Italian Government to trial HPV screening as a first line test is likely to lead to other countries following this approach as data accumulates. This should lead to approval for registration of even more accessible tests and in government reimbursement. We believe that uptake in countries where home sampling would be culturally more acceptable or desirable would also provide market opportunities for Cellscreen.

¹⁴Kleter et al. (1998) Novel Short-Fragment PCR Assay for Highly Sensitive Broad-Spectrum Detection of Anogenital Human Papillomaviruses, American Journal of Pathology, 153:1731-1739;

¹⁵Mayrand M-H et al. (2007) Human Papillomavirus DNA versus Papanicolaou Screening Tests for Cervical Cancer, NEJM, 357:1579-1588;

¹⁶Ronco, G. et al. (2008) Results at Recruitment From a Randomized Controlled Trial Comparing Human Papillomavirus Testing Alone With Conventional Cytology as the Primary Cervical Cancer Screening Test, J. Nat. Cancer Inst; 100(7):492-501;



Once greater access to HPV testing is accepted, competition for the market will be intense. Success in these markets will depend on strong marketing and distribution channels and a well developed mechanism for sampling, test development, notification and follow up. Cellscreen has shown this capability in current marketing strategies within the confines of government regulations in Australia and has the expertise to deliver the test widely.

Market Access

Tam-Pap® is targeted at women over the age of 25. The test is now available in the Australian market and forms to request a test are available on-line, via phone and through doctors. Marketing by Cellscreen in Australia has been limited to general practitioners who then recommend it to patients and customers.

Cellscreen plans to enter international markets including Europe, India, Middle East, China and the US. The Company intends to enter these markets during 2009. Market entry strategies will differ, seeking marketing and distribution partners in most regions and a joint venture in the US market.

The Company's marketing strategy includes a mix of direct-to-consumer marketing, product association, celebrity endorsement and GP/pharmacist promotion. Cellscreen will distribute informative flyers throughout large retailers, and will advertise on items such as feminine hygiene products, and food packaging. The Cellscreen management and consultants have significant marketing experience on which to draw.

Cellscreen capability

Cellscreen brings together companies and individuals with experience in the delivery of pathology services and in marketing. Symbion Pathology Pty Ltd is owned by Primary Health Care Limited which is listed on the ASX (code: PRY) and the largest pathology service provider in Australia with pathology and radiology businesses, medical centres and health technology. In a major industry consolidation in April 2008, Primary Health Care acquired Symbion Health Limited for A\$3.56 billion giving a reported combined enterprise value of A\$5.1 billion.

Cellscreen CEO, Dr Peter Hughes, was formerly Executive Director of the Epworth Eastern Hospital, Melbourne, and has extensive experience in the provision of integrated health services. Mr Nick Diamond and David Hammer are founders of Cellscreen and have operational and marketing experience. Mr Mathieu Briere is the European Business Development Manager. The Medical and Scientific Advisory Board comprises Professor Brian Morris, University of Sydney and an expert in HPV testing and cervical cancer; Dr Philip Tynan, Clinical Chemistry registrar at the John Hunter Hospital in Newcastle with experience in clinical medicine; Dr Agustin Franco, Head of Molecular Biology at SDS Pathology; Dr Ivan Cotton, Director of Pathology at Hornsby and Ku-ring-gai hospitals and also of SDS Pathology; Professor Michael Quinn from the Department of Obstetrics and Gynaecology at the University of Melbourne and Clinical Director of the Oncology/Dysplasia Unit at the Royal Womens Hospital in Melbourne, and Professor Kerryn Phelps, medical practitioner, former Director of the Australian Medical Association and an active commentator on medical practice and public health issues. Dr Tynan and Dr Franco invented the test used by Cellscreen.

Competition

Currently there are only a few HPV tests on the market, the Qiagen HPV (Digene) test, which dominates the US market and available worldwide, and the PapilloCheck and Amplicor tests available in Europe. However, there are many products in development that are close to completion and are expected to be on the market within the next two years. Due to the expectation that the competition within this market will increase substantially in the near future, Cellscreen will need to aggressively pursue speed to market strategies in order to gain substantial market share.



The major competing technologies are summarised below.

- **QIAGEN, Inc.**, headquartered in the Netherlands, is a publicly listed company which acquired Digene Corporation, the inventor of the Digene HPV hybrid capture assay for US\$1.6 billion in cash and stock in June 2007.¹⁷ The Digene HPV test is currently the only test approved test in America for the detection of hrHPV genotypes and therefore currently monopolises the HPV testing market there.¹⁸ The US FDA approval in 2003 was for its use as a co- test in conjunction with Pap tests or as a follow up for inconclusive results for women over the age of twenty nine. Sales of the Digene HPV test were US\$135.2 million in the first nine months of FY2007, an increase of 42% on the previous year.¹⁹ QIAGEN is currently developing a low cost HPV test for sale in developing countries and they are expecting to gain regulatory approvals in China and India in 2008.²⁰ New technology not utilising the Digene genotype patents has opened up this market. In 2007 Digene filed an infringement suit against Third Wave Technologies, for alleged infringement on one of their HPV patents.
- **Roche Ltd**, launched 'Amplicor HPV' into the European market in 2004.²¹ Amplicor detects 13 strains of hrHPV from a cervical smear using PCR. Amplicor has CE Marking but Roche has yet to gain FDA approval for the Amplicor HPV test.
- **Greiner Bio-one International AG**, headquartered in Austria has developed 'PapilloCheck', an HPV test capable of detecting and typing 24 HPV genotypes (6 low risk and 18 high risk types) from a cervical smear.²² The detection process uses DNA microarrays and is electronically automated for rapid results. Papillocheck is sold throughout Europe.
- **Third Wave Technologies**,²³ Inc. has developed two HPV genotyping tests, one for HPV genotypes 16 and 18 and the other for 14 hrHPV strains. The 16/18 genotyping test is used to determine if women with abnormal Pap tests should undergo further treatment (i.e. colposcopy).²⁴ The other hrHPV test is to be used in conjunction with Pap tests in order to provide women over 30 with more accurate clinical diagnoses. Third Wave announced in April 2008 that they have submitted an application for pre-market approval to the US Food and Drug Administration (FDA) for both tests. In June 2008 Third Wave agreed to its acquisition by Hologic Inc. for US\$580 million.
- **Innogenetics NV** developed the INNO-LiPA HPV Extra assay, which is a line probe assay based on the reverse hybridisation principle and designed to identify 28 types of HPV.²⁵ The test utilises Innogenetics' proprietary SPF10 primer and is used in complement to Pap tests and other DNA-based HPV tests. In 2007 Innogenetics' diagnostic sales in Europe totalled €47 million and they have entered into a licensing agreement with Invitrogen.
- **Gen-Probe, Inc.** develops, markets and manufactures nucleic acid diagnostic tests and is developing a test for the detection of HPV.²⁶ The APTIMA HPV assay is based on the detection of mRNA of genes known to contribute to cancer advancement. Gen-Probe has entered into a purchase agreement with Roche Molecular Systems, under which Roche will manufacture the DNA probes required for the APTIMA HPV assay. Gen-probe plans to begin clinical trials for the APTMA HPV assay in the US and to have a product on the European market in 2008.
- **Polartechnics Limited** is a listed Australian company (ASX: PLT) specialising in the development and manufacture of diagnostic devices for pre-cancer and cancer. CerviScreen comprises a self-sampling device and PCR-based assay for the detection of HPV²⁷ and has CE Marking and is in the process of gaining TGA approval. Polartechnics has also developed TruScreen, a real time optoelectric screening device for cervical cancer tissue, which has both TGA approval and a CE Mark and is already achieving sales in the Asia Pacific region. It has a wand with a disposable tip which is inserted to examine the cervix, picking up electrical and light signals and analysing them against a databank to identify any 'abnormal' cervical tissue.
- **Genera Biosystems Ltd**, a listed Australian biotechnology company (ASX:GBI), that has developed PapType, an HPV diagnostic utilising cervical smear samples. The PapType technology involves the amplification of DNA gathered in a sample

¹⁷Miller C. (2008) The cancer that shouldn't be, www.forbes.com 28/01/2008;

¹⁸The Digene HPV Test (2008) www.thehpvtest.com/ Viewed 3/6/2008;

¹⁹Genera Biosystems Prospectus. (2008);

²⁰Qiagen. (2007) Sample & Assay Technology brochure, Company Website;

²¹Roche. (2004) Press Release: Amplicor HPV, new diagnostic test to detect cancer causing viruses, launched in Europe;

²²Greiner Bio-one. (2008) Company website;

²³Wisconsin Technology News. (2008) *op cit*;

²⁴Third Wave Technologies. (2008) Press Release: Third Wave Completes FDA Submissions for its two HPV products., 28/04/2008;

²⁵Innogenetics. (2008) Inno-LiPA HPV Genotyping Extra, Company website;

²⁶Gen-Probe. (2008) Company website;

²⁷Polartechnics. (2008) Company website;



and combination with the PapType beads, which glow red in the presence of HPV.²⁸ The beads are then analysed with a flow cytometer. The PapType test is performed in conjunction with a Pap test. Genera announced in June 2008 the signing of a distribution agreement to supply their HPV diagnostic tests to Gribbles Pathology, one of the largest pathology providers in Australia.²⁹

Other competitors

Other companies currently developing HPV DNA tests that are expected to be released onto the market in the next two years are SensiGen, ValiRX, and NorChip. The majority of the products that are in development and on the market utilise samples taken during a normal Pap test. Current self-sampling HPV tests include CerviScreen and Fournier's Feminine Multi-Test. The Feminine Multi-Test, is a self sampling test that utilises a tampon like device to collect cells from the cervix. This test is designed to be undertaken in a supervised environment to achieve cell samples that are of a higher quality.

Comparative Advantages of the Cellscreen Technology

In our view, Tam-Pap[®] has several advantages over available HPV test products and methodologies in particular markets:

- Tam-Pap[®] is a low cost and competitive HPV diagnostic test system that is performed to the highest technical and laboratory standards. To the consumer, the Tam-Pap[®] test is a simple, low cost procedure and, coupled to a direct consumer marketing program, could reach a greater proportion of the highest at-risk population. Due to its robustness, Tam-Pap[®] could potentially be utilised in developing countries, which have 80% of all cervical cancer cases, mainly due to the lack of participation in cervical screening programs.
- Technically, Tam-Pap[®] is a sophisticated, proprietary procedure that operates in two steps and provides a high level of test performance. The first step screens for the presence of high risk HPV strains and a second step specifically identifies the individual HPV type present. The advanced format of the Tam-Pap[®] test and the specific DNA primers used allow the test to detect individual HPV types that co-exist in the sample with high sensitivity. This overcomes a limitation of the Digene test that will not detect whether persistent infections are by the same or by different HPV types. The test allows women and their physicians to monitor the persistence of specific infections, calculate the cervical cancer risk and provide a better source of information for use in epidemiological studies.
- The self sampling procedure recommended for Tam-Pap[®] uses a tampon which offers more private, convenient and comfortable screening. Women are already familiar with the use of tampons and have ready access to them. Sampling compliance is therefore high, decreasing the level of misuse and unusable samples. After the sample is taken the tampon is sealed in a secure package and forwarded by regular post to the development laboratory. We believe this testing format is attractive and should appeal to women who do not currently undergo regular Pap test screening for a number of reasons such as personal preferences, cultural beliefs, remoteness or inconvenience.
- The Cellscreen HPV laboratory assay has been designed to accept samples from a wide range of specimen types including Thin Prep solutions, cervical swabs, urine and tampons. This ability gives the assay greater flexibility than currently available HPV testing methods and provides access to all markets.

Risks


There are a number of risks in delivering the Tam-Pap[®] test to the market, in addition to operational and financial risks associated with businesses in this market.

- Government regulatory approval and market acceptance may be slower than anticipated or may not be gained in some countries and this may limit Cellscreen's timing and access to some markets. The Pap test is established as a successful national screening program in many countries and the HPV test may continue to be regarded as a follow up indication of infection rather than as a first line diagnostic for cervical cancer. This view is expected to be transient with publication of

²⁸Genera Biosystems Prospectus (2008);

²⁹Genera Biosystems (2008) Press Release: First sales of PapType HPV test to Healthscope, 20/06/2008;





results from further clinical trials and from the use of the newly released vaccines and tests, increasing awareness of the causal link between HPV and cancer. Cellscreen also intends to market outside the main developed countries, with more direct focus on cost and convenience.

- Supply of the test kit and test results direct to consumers will require close relationships between Cellscreen and doctors, who might not be supportive in some countries, especially without government or other reimbursement such as health insurers and managed care organisations. If the screening test is not reimbursed by third parties, support by local clinicians and opinion leaders, together with strong direct marketing will be essential to gain significant market share. Further clinical studies with Tam-Pap® should reinforce the view of the performance of the test.
- Competition from other test providers will intensify in the next few years and Cellscreen will face strong market challenges, especially from large distribution organisations with key strategic partnerships having access to consumer groups. Cellscreen may also face increased costs to bring the product to more overseas countries. Although now regarded as a low priced product this could be challenged by other suppliers with greater volume and cost/scale benefits. Cellscreen has strong direct marketing experience to reduce this risk somewhat and is partnered by the largest pathology service provider in Australia. They intend to partner further with well placed companies in major markets.
- The use of an Australian laboratory, SDS Pathology, for test development and receipt of samples, especially into Australia from other countries, raises questions of sample viability and integrity, quarantine and safety, test cost and privacy of personal data. We understand that, as the Tam-Pap® test is distributed to other countries by licensees, additional regional or country development laboratories will be established and validation protocols enacted.
- Cellscreen has patent applications covering the diagnostic system and primers used in the test. There is no guarantee that these patents will be granted or have the same scope of claims that have been filed. There is also a risk that Cellscreen has infringed other patents in the area. Cellscreen is aware of the risk and is managing this through its patent attorney and through patent surveillance. A separate patent attorney's report is included in this prospectus.
- Factors unrelated to HPV testing, such as development of newer vaccines or drug treatments for cervical cancer or HPV could reduce the demand and the market for testing and limit this to high risk groups. The size of the market for HPV testing is very large and there is currently an unmet need for better and more convenient test procedures to increase compliance.

Conclusions

Cellscreen has a proprietary, integrated test system, Tam-Pap®, to detect and identify high risk types of HPV in cervical samples as a diagnosis of precancerous lesions and cervical cancer. The present initiative by Cellscreen is timely as the market for cervical cancer screening is shifting from the use of primary Pap tests to HPV testing as first line screening followed by confirmatory cytology.

Overall, the test is robust, user friendly and sensitive, and will be suitable for screening in major markets. Cellscreen recommends self collection of the sample using a tampon and posting to a laboratory, and this provides convenience and privacy which will encourage compliance. The Australian laboratory is operated by SDS Pathology, the developer of the technology and owned by Australia's largest pathology provider, Primary Healthcare Limited. Cellscreen is targeting major world markets and is establishing strategic distribution and joint venture partnerships with key companies.

The major commercial risks to the company are associated with market access governed by regulatory approval and third part reimbursement. Clinical evidence and interest in HPV screening as a first line test for cervical cancer is increasing and wider acceptance is predicted. The market size, and also the competition, will consequently increase substantially.

In our assessment of the company and technology we conclude that Cellscreen has the capability to deliver the diagnostic internationally using a range of approaches, including direct consumer marketing.



Disclaimer

This report is provided solely for inclusion in the prospectus issued by Cellscreen on or about 14th November 2008. All comments, forecasts and recommendations made in this report are made in good faith on the basis of information available to the consultants at the time including information from Cellscreen. This report does not make any recommendations regarding purchase of shares in Cellscreen. Innovation Dynamics has prepared this independent report according to the Regulatory Guides from the Australian Securities and Investments Commission (ASIC) and the ASX Listing Rules. Innovation Dynamics holds an Australian Financial Services Licence from ASIC (No. 295107).

There are multiple risks in bringing Cellscreen's technologies to market where they can generate revenues. Innovation Dynamics does not guarantee that the actions noted here will actually come to pass because of possible changes in the markets and general business environment and actions by Cellscreen, which occur subsequent to this report and are outside our control to know. Innovation Dynamics has not audited any financial forecasts of Cellscreen and has not analysed the legal status of agreements Cellscreen has entered into or patents filed. However, we have not identified anything that would indicate that this is materially misstated. A draft report was issued to the due diligence committee of Cellscreen to confirm factual accuracy and changes were made in the final report in consideration of points raised.

Innovation Dynamics has given written consent to the inclusion of this report as appearing in the Prospectus in the form and context in which it appears, and the references to this report and the inclusion of quotes from this report elsewhere in this Prospectus. Innovation Dynamics has been involved only in the preparation of this Report and not in any other part of this Prospectus, and specifically disclaim liability to any person in respect of any statements included elsewhere in this Prospectus other than references or quotes from this report. Innovation Dynamics has not, other than as set out above, authorised or caused the issue of, this Prospectus.

Innovation Dynamics has acted independently in preparing this report and neither its directors nor staff has any pecuniary or other interest in Cellscreen, or their associates, that could reasonably be regarded as affecting its ability to give an unbiased opinion. Innovation Dynamics will receive normal professional fees for the due diligence and preparation of this report, irrespective of whether or not the IPO is successful. With the exception of these fees, Innovation Dynamics will not receive any other benefits, either directly or indirectly, from the preparation of the report.

INNOVATIONS DYNAMICS PTY LTD



Kelvin Hopper PhD
Executive Chairman



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7. Financial Information

General Assumptions

The Offer is fully subscribed and the gross proceeds of \$7,500,000 before float costs are received by no later than 23rd December 2008. In the event that a Minimum Subscription of \$7,500,000 is not received the Offer will not proceed.

7.1 Historical and Pro forma Financial Information

This section contains the following financial information for the Company prepared by the Directors:

Historical Financial Information

- The Historical Consolidation Balance Sheet as at 30th September 2008, the Historical Consolidated Income Statement, the Historical Consolidated Statement of Changes in Equity and the Historical Consolidated Cash Flow Statement for the period 1 July 2008 to 30th September 2008; and
- The Historical Consolidated Balance Sheet as at 30 June 2008, the Historical Consolidated Income Statement, the Historical Consolidated Cash Flow Statement and the Historical Consolidated Statement of Changes in Equity for the year ended 30 June 2008, (collectively the 'Historical Financial Information').

Pro forma Financial Information

- The Pro forma Consolidated Balance Sheet as at 30 September 2008 ('Pro forma Balance Sheet').

The Directors are responsible for the inclusion of all financial information in this Prospectus.

The Historical Financial Information and the Pro forma Balance Sheet has been reviewed by Weston Woodley & Robertson whose Independent Accountant's Report is contained in Section 8.

7.2 Basis of Preparation & Presentation of the Historical Financial Information & Pro forma Balance Sheet

The Historical Financial Information has been extracted from the reviewed interim financial statements of the Company for the period 1 July 2008 to 30 September 2008 and the audited financial statements of the Company for the year ended 30 June 2008.

The 30 June 2008 financial statements were audited by Weston Woodley & Robertson.

The interim financial statements for the period 1 July 2008 to 30 September 2008 were reviewed by Weston Woodley & Robertson.

The Pro forma Balance Sheet has been based on the reviewed balance sheet of the Company as at 30 September 2008.

Pro forma Adjustments, as set out in Note 2, have been made to the reviewed balance sheet of the Company as at 30 September 2008 to compile the Pro forma Balance Sheet of the Company at that date.

Two Pro forma Balance Sheets have been presented on the basis of a Minimum \$7,500,000 under the Offer (15,000,000 Shares), and maximum subscriptions of \$10,000,000 (20,000,000 Shares).

The financial information set out in the Prospectus has been prepared in accordance with the recognition and measurement principles (but not all the disclosure requirements) prescribed in Australian Accounting Standards and other pronouncements of the Australian Accounting Standards Board. The financial information contained in this Prospectus is presented in an abbreviated form and does not contain all the disclosures required by the Australian Accounting Standards applicable to annual reports prepared in accordance with the Corporations Act.

The financial information in this section should be read in conjunction with:

- The summary of significant accounting policies and additional financial disclosures set out in Note 1;
- The Pro forma Balance Sheet assumptions set out in Note 2;
- The risk factors set out in Section 10 of this Prospectus; and
- Other information contained within this Prospectus.



7.3 Historical and Pro forma Information

HISTORICAL CONSOLIDATED INCOME STATEMENTS

	Historical for 3 months ended 30 September 2008 \$	Historical for year ended 30 June 2008 \$
Revenue	852	3,603
Advertising & marketing expense	(5,968)	(71,306)
Amortisation	(829)	(3,912)
Audit and accountancy	(6,205)	(21,067)
Consulting and professional fees	(24,984)	(64,985)
Employee benefits expense	(71,300)	(29,650)
Finance costs	(8,349)	-
Printing and reproduction	(56)	(23,701)
Rent	(13,200)	(52,000)
Travel	(33,223)	(26,549)
Other expenses	(1,629)	(23,511)
(Loss) before income tax	(164,891)	(313,078)
Income tax expense	-	-
(Loss) for the year	(164,891)	(313,078)





HISTORICAL & PRO FORMA CONSOLIDATED BALANCE SHEETS

	Note	Historical as at 30 June 2008 \$	Historical as at 30 September 2008 \$		Pro forma (minimum subscriptions \$7.5M) as at 30 September 2008 \$	Pro forma (maximum subscriptions \$10M) as at 30 September 2008 \$
				Note 2		
Current assets						
Cash and cash equivalents	2.1	3,750	122,654	a, b, c, e,f,h	6,135,711	8,458,365
Trade and other receivables		17,538	6,062		6,062	6,062
Other assets	2.2	40,476	111,934	b	-	-
Total current assets		61,764	240,650		6,141,773	8,464,427
Non-current assets						
Intangible assets	2.3	33,010	32,181	e,g	4,379,120	4,820,297
Total non-current assets		33,010	32,181		4,379,120	4,820,297
Total assets		94,774	272,831		10,520,893	13,284,724
Current liabilities						
Trade and other payables	2.4	487,854	550,802	b,c, d, f	57,140	57,140
Borrowings	2.5	-	280,000	c	-	-
Total current liabilities		487,854	830,802		57,410	57,410
Non-current liabilities		-	-		-	-
Total liabilities		487,854	830,802		57,410	57,410
Net (liabilities) assets		(393,080)	(557,971)		10,463,753	13,227,584
Equity						
Issued capital	2.6	2	2	a, b, c, d, e, g h, i, j, k	12,315,688	15,079,519
Accumulated losses	2.7	(393,082)	(557,973)	c, h, i, j, k	(1,851,935)	(1,851,935)
(Net deficiency) Total equity		(393,080)	(557,971)		10,463,753	13,227,584



HISTORICAL CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

	Issued Capital \$	Accumulated Losses \$	Total \$
Balance at 1 July 2007	2	(80,004)	(80,002)
(Loss) for the year	-	(313,078)	(313,078)
Balance at 30 June 2008	2	(393,082)	(393,080)
(Loss) for the year	-	(164,891)	(164,891)
Balance at 30 September 2008	2	(557,973)	(557,971)

HISTORICAL CONSOLIDATED CASH FLOW STATEMENTS

	Historical for 3 months ended 30 September 2008 \$	Historical for year ended 30 June 2008 \$
CASH FLOWS FROM OPERATING ACTIVITIES		
Receipts from customers	395	3,629
Payments to suppliers and employees	(189,427)	(156,803)
Interest received	493	235
Net cash provided by (used in) operating activities	(188,539)	(152,939)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of intangible assets	-	(12,422)
Net cash provided by (used in) investing activities	-	(12,422)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from loans and borrowings	307,443	166,784
Net cash provided by financing activities	307,443	166,784
Net increase in cash held	118,904	1,423
Cash and cash equivalents at beginning of financial period	3,750	2,327
Cash and cash equivalents at end of financial period	122,654	3,750



NOTE 1: SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The Historical Financial Information of the Company has been presented in this special purpose financial report on a basis which is considered by the Directors to be the most relevant information to potential investors. It is presented in a summarised form insofar as it does not include all the disclosure required by Australian equivalents to International Reporting Standards ("AIFRS") applicable to annual financial reports prepared in accordance with the Corporations Act 2001. In the view of the Directors of the Company, the omitted disclosures would provide no further relevant information to potential investors.

The significant accounting policies adopted in the presentation of the Historical Financial Information and Pro forma Balance Sheet are set out below.

The accounting policies adopted are the same adopted in the financial statements of the Company for the year ended 30 June 2008 and include all of the measurement requirements of AIFRS. The financial report has been prepared on an accrual basis and is based on historical costs. The financial information is presented in Australian dollars.

(a) Basis of Consolidation

Cellscreen Direct Limited was incorporated on 20 October 2008. On 27 November 2008 the Company acquired all of the issued shares of Tam Pap Pty Limited. AASB 3: Business Combinations requires the acquisition to be reported as a reverse acquisition because Tam Pap Pty Limited has arranged to have itself acquired by Cellscreen Direct Limited as a means of obtaining a listing on the Australian Securities Exchange. Accordingly the Historical Financial Information and Pro forma Balance Sheet represent a continuation of the financial statements of Tam Pap Pty Limited.

All inter-group transactions, balances, income and expenses have been eliminated.

(b) Income Tax

The charge for current income tax expense is based on the Company's profit for the year adjusted for any non-assessable or disallowed items. It is calculated using the tax rates that have been enacted or are substantially enacted by the balance sheet date.

Deferred tax is accounted for using the balance sheet liability method in respect of temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the financial statements. No deferred income tax will be recognised from the initial recognition of an asset or liability, excluding a business combination, where there is no effect on accounting or taxable profit or loss.

Deferred tax is calculated at the tax rates that are expected to apply to the period when the asset is realised or liability is settled. Deferred tax is credited in the income statement except where it relates to items that may be credited directly to equity, in which case the deferred tax is adjusted directly against equity.

Deferred income tax assets are recognised to the extent that it is probable that future tax profits will be available against which deductible temporary differences can be utilised.

The amount of benefits brought to account or which may be realised in the future is based on the assumption that no adverse change will occur in income taxation legislation and the anticipation that the Company will derive sufficient future assessable income to

enable the benefit to be realised and comply with the conditions of deductibility imposed by the law.

(c) Cash and Cash Equivalents

Cash and cash equivalents include:

- cash on hand and at call deposits with banks or financial institutions
- short-term highly liquid investments with original maturities of three months or less.

For the purposes of the cash flow statement, cash includes cash and cash equivalents, net of bank overdrafts.

(d) Impairment

Financial Assets

At each balance sheet date, the Company assesses whether there is objective evidence that a financial asset has been impaired. Impairment losses are recognised in the income statement.

Non-financial Assets

The carrying amounts of the Company's non-financial assets are reviewed at each reporting date to determine whether there is any indication of impairment. If such an indication exists then the asset's recoverable amount is estimated and compared to the asset's carrying value. Any excess of the asset's carrying value over its recoverable amount is expensed to the income statement.

(e) Intangible Assets

The useful lives of intangible assets are assessed to be either finite or indefinite. Identifiable intangible assets with a finite life are tested annually for impairment, where an indicator of impairment exists. Intangible assets with an indefinite life are tested at least

annually for impairment. Useful lives are also examined on an annual basis and adjustments, where applicable, are made on a prospective basis.

Goodwill

Goodwill represents the excess of the cost of an acquisition over the fair value of the Group's share of the net identifiable assets of the acquired subsidiary at the date of acquisition. Goodwill is not amortised but tested annually for impairment or more frequently if events or circumstances indicate that it may be impaired. Goodwill is carried at cost less accumulated impairment losses.

Trademarks

Trademarks are recognised at cost of acquisition. Trademarks have a finite life and are carried at cost less any accumulated amortisation and any impairment losses.

Website

Website development costs are recognised at cost of acquisition. The website has a finite life, and is carried at cost less any accumulated amortisation and any impairment losses.

Intellectual Property – Patent

A patent application for the PCR HPV test, known as the Human Papillomavirus screening method is to be assigned by Symbion Pathology Pty Ltd on the successful listing of the Company's shares on the ASX. The patent is expected to have a useful life of 20 years.

Intangible assets have the following assessed useful life:

Goodwill – indefinite
Trademarks – 15 years
Website development costs – 4 years
Patent – 20 years

(f) Trade and Other Payables

Trade and other payables are recognised when the Company

becomes obliged to make future payments resulting from the purchase of goods and services. These amounts are unsecured and have 30-60 day payment terms.

(g) Employee Benefits

Provision is made for the Company's liability for employee benefits arising from services rendered by employees to balance date. Employee benefits that are expected to be settled within one year have been measured at the amounts expected to be paid when the liability is settled. Employee benefits payable later than one year have been measured at the present value of the estimated future cash outflows to be made for those benefits. Those cashflows are discounted using market yields on national government bonds with terms to maturity that match the expected timing of cashflows.

(h) Provisions

Provisions are recognised when the Company has a legal or constructive obligation, as a result of past events, for which it is probable that an outflow of economic benefits will result and that outflow can be reliably measured.

(i) Borrowings

Borrowings are initially measured at fair value and subsequently measured at amortised cost. Related party financial liabilities are recognised at amortised cost, comprising original debt less principal payments and amortisation.

(j) Leases

Leases of plant and equipment where substantially all the risks and benefits incidental to the ownership of the leased item are classified as finance leases. All other leases are classified as operating leases. The Company had no finance leases during the period.

Lease payments for operating leases are charged as an expense in the income statement on a straight line basis over the term of the lease.

(k) Revenue

Revenue from the rendering of a service is recognised upon the delivery of the service to the customer.

Interest revenue is recognised using the effective interest rate method, which for floating financial assets is the rate inherent in the instrument.

(l) Share Based Payments

The Company provides benefits to its directors and employees (including Key Management Personnel) in the form of share-based payments, whereby directors and employees render services in exchange for shares or rights over shares (equity-settled transactions). The fair value of the equity to which the employee becomes entitled to is measured at grant date and recognised as an expense over the vesting period, with a corresponding increase to an equity account. The fair value of shares is ascertained as the market bid price.

Equity-settled share based payments with parties other than employees are measured at the fair value of the goods and services received. Where a market value cannot be determined, the cost of these equity-settled transactions is measured by reference to the fair value of the equity instruments as at the date which they are granted.

(m) Goods and Services Tax (GST)

Revenues, expenses and assets are recognised net of the amount of GST, except;

- where the GST incurred on purchase of goods and services are not recoverable from the taxation authority in which case the GST is



recognised as part of the cost of acquisition of an asset or as part of the expense; and

- receivables and payables are stated with the amount of GST included.

Cash flows are presented in the cash flow statement on a gross basis, except for the GST component of investing and financing activities, which are disclosed as operating cash flows.

Commitments and contingencies are disclosed net of the amount of GST recoverable from, or payable to, the taxation authority.

(n) Critical Accounting Estimates and Judgments

The Directors evaluate estimates and judgments incorporated into the financial report based on historical knowledge and best available current information. Estimates assume a reasonable expectation of future events and are based on current trends and economic data, obtained both externally and within the Company.

NOTE 2: BASIS OF PREPARATION OF PRO FORMA BALANCE SHEET

- (a) The receipt of \$7,500,000 in proceeds from the issue of 15,000,000 ordinary shares (maximum \$10,000,000 from the issue of 20,000,000 ordinary shares) at 50 cents each as contemplated in this Prospectus.
- (b) Payment of the estimated capital raising costs of \$1,031,386 (\$1,208,732 for maximum subscription) which are to be offset against share capital. The capital raising costs are to be paid in cash \$856,386 (\$1,033,732 maximum subscription) and via the issue of 350,000 ordinary shares. The shares are to be issued to Martin Place Securities Pty

Limited as part of its fees as Sponsoring Broker. As at 30 September 2008 capital raising costs of \$111,934 had been incurred of which \$84,822 had been paid. The balance of the capital raising costs to be paid in cash is \$771,564 (\$948,910 maximum subscription).

- (c) Loan funds totalling \$430,000 have been advanced to the Company under binding loan agreements, of which \$280,000 had been advanced as at 30 September 2008. The principal amounts (\$430,000) are to be repaid within 30 days of the shares being listed on the Australian Securities Exchange (ASX). The loans incur interest and the amount of interest is to be paid by way of issue of 300,000 ordinary shares. The interest cost of \$150,000 is expensed in full of which \$8,349 had been accrued to 30 September 2008.

- (d) On 27 November 2008, Tam Pap Pty Limited:
- undertook a share split to split the 2 ordinary issued shares of Tam Pap Pty Limited into 28,182,373 ordinary shares
 - issued 1,043,629 ordinary shares to Sportzcom Australia Pty Ltd (a trustee of the Cadaecus Discretionary Trust) a company associated with Dr Peter Hughes, for nil consideration in accordance with an agreement entered into with the Company in around April 2007
 - issued 1,125,000 ordinary shares for \$150,000 to MLVS Properties Pty Ltd (as trustee for The Marcus and Vanessa Family Trust) as part of an agreement entered into with the Company on 24 October 2007. The funds in respect of the share issue had

been advanced to the Company on 7 November 2007.

- (e) On 27 November 2008 Cellscreen Direct Limited acquired all the issued shares in Tam Pap Pty Limited and issued 30,351,002 ordinary shares to its shareholders as consideration. Stamp duty of approximately \$91,053 is payable on the acquisition.
- (f) Repayment of \$308,201 of loans advanced to the Company to 30 September 2008 by existing shareholders.
- (g) Issue of 8,511,772 ordinary shares valued at \$4,255,886 (maximum 9,394,125 ordinary shares valued at \$4,697,063) to Symbion Pathology Pty Ltd (“Symbion”) in consideration for the assigning of its patent application for the PCR HPV test, known as the Human Papillomavirus screening method on the successful listing of the Company’s shares on the ASX.
- (h) Issue of 132,000 ordinary shares valued at \$66,000 and the payment of cash of \$36,125 for services by parties other than employees of the Company. These services include corporate consultancy, legal and marketing services.
- (i) Issue of 288,000 ordinary shares valued at \$144,000 to Dr Phillip Tynan (144,000 shares) and Dr Victor Agustin Franco (144,000 shares) in respect of consulting services.
- (j) Issue of 316,000 ordinary shares valued at \$158,000 to members of the Medical and Scientific Advisory Board.
- (k) Issue of 1,496,371 ordinary shares valued at \$748,186 to the Directors. The shares are to be issued from the Company’s Employee Share Plan.





2.1 CASH AND CASH EQUIVALENTS

	Historical as at 30 September 2008 \$	Pro forma (minimum subscriptions \$7.5M) as at 30 September 2008 \$	Note 2	Pro forma (maximum subscriptions \$10M) as at 30 September 2008 \$
Cash at bank	122,654	6,135,711		8,458,365
Reconciliation of Pro forma Adjustment to Cash				
Balance as at 30 September 2008				122,654
Adjustments:				
Funds raised for the minimum issue of 15,000,000 Shares under this Prospectus			(a)	7,500,000
Capital raising costs under this Prospectus			(b)	(771,564)
Loan funds received post 30 September 2008 and repayment of loans to third parties			(c)	(280,000)
Stamp duty on acquisition of Tam Pap Pty Ltd			(e)	(91,053)
Repayment of shareholder loans			(f)	(308,201)
Payment for services			(h)	(36,125)
Pro forma balance as at 30 September 2008				6,135,711
Adjustments (including maximum subscriptions):				
Funds raised from issue of a further 5,000,000 Shares @ \$0.50 under this Prospectus			(a)	2,500,000
Additional capital raising costs under this Prospectus			(b)	(177,346)
Pro forma balance (including maximum subscriptions) as at 30 September 2008				8,458,365





2.2 OTHER CURRENT ASSETS

	Historical as at 30 September 2008 \$	Pro forma (minimum subscriptions \$7.5M) as at 30 September 2008 \$	Note 2	Pro forma (maximum subscriptions \$10M) as at 30 September 2008 \$
Deferred Costs – float expenses	111,934	-		-
Reconciliation of Pro forma Adjustment to Other Assets				
Balance as at 30 September 2008				111,934
Adjustments:				
Capital raising costs under this Prospectus			(b)	(111,934)
Pro forma balance as at 30 September 2008				-

2.3 INTANGIBLE ASSETS

Goodwill	-	91,053		91,053
Patents, licences and computer software	32,181	4,288,067		4,729,244
	32,181	4,379,120		4,820,297
Reconciliation of Pro forma Adjustment to Intangible Assets				
Balance as at 30 September 2008				32,181
Adjustments:				
Goodwill on consolidation			(e)	91,053
Patent acquired – share based payment			(g)	4,255,886
Pro forma balance as at 30 September 2008				4,379,120
Adjustments (including maximum subscriptions):				
Patent acquired – share based payment			(g)	441,177
Pro forma balance (including maximum subscriptions) as at 30 September 2008				4,820,297





2.4 TRADE AND OTHER PAYABLES

	Historical as at 30 September 2008 \$	Pro forma (minimum subscriptions \$7.5M) as at 30 September 2008 \$	Note 2	Pro forma (maximum subscriptions \$10M) as at 30 September 2008 \$
Trade and other payables	550,802	57,140		57,140
Reconciliation of Pro forma Adjustment to Trade and Other Payables				
Balance as at 30 September 2008				550,802
Adjustments:				
Capital raising costs under this Prospectus			(b)	(27,112)
Issue of Shares in lieu of interest			(c)	(8,349)
Issue of Shares			(d)	(150,000)
Repayment of shareholder loans			(f)	(308,201)
Pro forma balance as at 30 September 2008				57,140

2.5 BORROWINGS

Unsecured loans	280,000	-		-
Reconciliation of Pro forma Adjustment to Borrowings				
Balance as at 30 September 2008				280,000
Adjustments:				
Loan funds received post 30 September 2008 and repayment of loans to third parties			(c)	(280,000)
Pro forma balance as at 30 September 2008				-





2.6 ISSUED CAPITAL

	Number of shares	Historical as at 30 September 2008 \$	Pro forma (minimum subscriptions \$7.5M) as at 30 September 2008 \$	Note 2	Pro forma (maximum subscriptions \$10M) as at 30 September 2008 \$
Ordinary shares	2	2	12,315,688		15,079,519

Reconciliation of Pro forma Adjustment to Issued Capital

Balance as at 30 September 2008	2				2
Adjustments:					
Share split (additional Shares)	28,182,373			(d)	-
Issue of 2,168,629 Shares	2,168,629			(d)	150,000
Issue of 300,000 Shares for interest due on borrowings	300,000			(c)	150,000
Issue of 8,511,772 Shares for patent	8,511,772			(g)	4,255,886
Issue of 132,000 Shares to non-employees for services	132,000			(h)	66,000
Issue of 144,000 Shares each to Dr Tynan and Dr Franco for services	288,000			(i)	144,000
Issue of 316,000 Shares to members to the Medical and Scientific Advisory Board	316,000			(j)	158,000
Issue of 1,496,371 Shares to Directors	1,496,371			(k)	748,186
Funds raised from issue of 15,000,000 Shares @ \$0.50 under this Prospectus	15,000,000			(a)	7,500,000
Capital raising costs - under this Prospectus (net of share based payment)	350,000			(b)	(856,386)
Pro forma balance as at 30 September 2008	56,745,147				12,315,688
Adjustments (including maximum subscriptions):					
Issue of additional 882,353 Shares for licence	882,353			(g)	441,177
Funds raised from issue of a further 5,000,000 Shares @ \$0.50 under this Prospectus	5,000,000			(a)	2,500,000
Capital raising costs - under this Prospectus	-			(b)	(177,346)
Pro forma balance (including maximum subscriptions) as at 30 September 2008	62,627,500				15,079,519





2.7 ACCUMULATED LOSSES

	Historical as at 30 September 2008 \$	Pro forma (minimum subscriptions \$7.5M) as at 30 September 2008 \$	Note 2	Pro forma (maximum subscriptions \$10M) as at 30 September 2008 \$
Accumulated losses as at 30 September 2008	(557,973)	(1,851,935)		(1,851,935)

Reconciliation of Pro forma Adjustment to Accumulated Losses

Balance as at 30 September 2008				(557,973)
Adjustments:				
Share based payments for interest on loans (net of accrued expense to 30 September 2008)			(c)	(141,651)
Share based payments for services			(h), (i)	(210,000)
Payment for services			(i)	(36,125)
Share based payments to Scientific and Advisory Board members			(j)	(158,000)
Share based payments to Directors			(k)	(748,186)
Pro forma balance as at 30 September 2008				(1,851,935)

2.8 Subsequent Events

The company has adopted an Employee Share Option Plan and an Employee Share Plan. As at the date of this Prospectus, no options have been issued under the Employee Share Option Plan. On listing, the 1,496,371 shares to be issued to Directors (refer Note 2(k)) will be issued from the Employee Share Plan.

2.9 Commitments

The company leases office space from Luminex Pty Limited (a shareholder controlled company). The lease agreement was signed on 1 October 2006 and the company is on a month to month lease term. The current rent is \$1,000 per week plus GST.



8. Independent Accountant's Report



27 November 2008

The Directors
Cellscreen Direct Limited
Unit 40, 112 McEvoy Street
ALEXANDRIA NSW 2015

**WESTON
WOODLEY
& ROBERTSON**
*Chartered Accountants
& Consultants*

IMC-IMC-TAM06-SPE-COR

Dear Sirs,

INDEPENDENT ACCOUNTANT'S REPORT ON REVIEWED HISTORICAL FINANCIAL INFORMATION AND PRO FORMA BALANCE SHEET

1. Introduction

We have prepared this Independent Accountant's Report ("Report") at the request of the Directors of Cellscreen Direct Limited and its controlled entities ("the Company") for inclusion in a Prospectus to be dated on or about 27 November 2008 ("the Prospectus") relating to the offer (the "Offer") by the Company of 15,000,000 ordinary shares at \$0.50 per share amounting to \$7,500,000, before capital raising costs ("Minimum Subscription"). The Company has reserved the right to accept oversubscriptions of up to 20,000,000 ordinary shares at \$0.50 per share to raise an additional \$2,500,000 which would take the total amount raised under the Offer to \$10,000,000, before capital raising costs ("Maximum Subscription").

All amounts are payable in full on application.

Expressions defined in the Prospectus have the same meaning in this Report.

2. Scope

You have requested Weston Woodley & Robertson prepare an Independent Accountant's Report covering the following financial information:

Historical Financial Information

- The Historical Consolidated Balance Sheet as at 30 September 2008 and the Historical Consolidated Income Statement, the Historical Consolidated Statement of Changes in Equity and the Historical Consolidated Cash Flow Statement for the period 1 July 2008 to 30 September 2008 as set out in Section 7 of the Prospectus; and
- The Historical Consolidated Balance Sheet as at 30 June 2008 and the Historical Consolidated Income Statement, the Historical Consolidated Statement of Changes in Equity and the Historical Consolidated Cash Flow Statement for the year ended 30 June 2008 as set out in Section 7 of the Prospectus;

The above are collectively referred to herein as the 'Historical Financial Information'.

Pro forma Balance Sheet

The pro forma Consolidated balance sheet as at 30 September 2008 (the "Pro forma Balance Sheet"), which assumes completion of the contemplated transactions ("pro forma adjustments") as at that date as disclosed in Section 7 of the Prospectus.





The Historical Financial Information and Pro forma Balance Sheet comprises the financial information for each of the following companies:

- Cellscreen Direct Limited (“Cellscreen”)
- Tam Pap Pty Limited (“Tam Pap”)
- Tampap Operations Pty Limited (“Operations”)

Cellscreen was incorporated on 20 October 2008 and Operations (a wholly owned subsidiary of Cellscreen) was incorporated on 23 October 2008. On 27 November 2008 Cellscreen acquired all the issued shares of Tam Pap, issuing 30,351,002 ordinary shares to Tam Pap shareholders as consideration. AASB 3: Business Combinations requires the acquisition to be reported as a reverse acquisition because Tam Pap has arranged for itself to be acquired by Cellscreen as a means of obtaining a listing on the Australian Securities Exchange. Accordingly, the Consolidated Historical information and Pro forma Balance Sheet represent a continuation of the financial statements of Tam Pap.

The Historical Financial Information has been extracted from:

- The audited financial report of the Company for the year ended 30 June 2008. Weston Woodley & Robertson issued an unqualified audit opinion in respect of the 30 June 2008 financial report. The aforementioned audit opinion included an emphasis of matter in respect of the Company’s ability to continue as a going concern and the consequential need for the Company to seek additional funding via an Initial Public Offering (“IPO”) or other means in order to achieve its stated business objectives. It is our understanding that the Director’s are confident this capital can be accessed via the Offer;
- The reviewed financial report of the Company for the period 1 July 2008 to 30 September 2008 on which an unqualified review conclusion was issued by Weston Woodley & Robertson. The aforementioned review conclusion included an emphasis of matter in respect of the Company’s ability to continue as a going concern and the consequential need for the Company to seek additional funding via an IPO or other means in order to achieve its stated business objectives. It is our understanding that the Director’s are confident this capital can be accessed via the Offer.

The Directors of the Company are responsible for the preparation of the Historical Financial Information, including determination of the pro forma adjustments and accounting policies and assumptions as set out in Section 7 of the Prospectus.

3. Review of Historical Financial Information and Pro forma Balance Sheet

We have conducted our review of the Historical financial Information and Pro-forma Balance Sheet in accordance with the Australian Auditing Standards applicable to review engagements. We have made inquiries and performed procedures as we, in our professional judgement, considered reasonable and these were limited to:

- Reading relevant Board minutes;
- Inquiries of management personnel and of the Company’s Directors;
- Analytical procedures applied to the financial data and certain limited verification procedures;
- A review of the pro forma adjustments and supporting documentation used to compile the Pro forma Balance Sheet;
- A comparison of consistency in application of the recognition and measurement principles prescribed in applicable Accounting Standards and other mandatory professional reporting requirements in Australia and the accounting policies adopted by the Company.

These procedures do not provide all the evidence that would be required in an audit, thus the level of assurance provided is less than given in an audit. We have not performed an audit and, accordingly, we do not express an audit opinion.

4. Conclusions

Historical Financial Information

Based on our review, which is not an audit, nothing has come to our attention, which causes us to believe that the Historical Financial Information, as set out in Section 7 of the Prospectus, does not present fairly, in all material respects, in accordance with





the measurement and recognition requirements (but not all the disclosure requirements) of applicable Accounting Standards and other mandatory professional reporting requirements in Australia:

- (a) the financial position of the Company as at 30 September 2008 and 30 June 2008; and
- (b) the Company's financial performance as represented by the results of its operations and its cash flows for the three month period ended 30 September 2008 and for the year ended 30 June 2008.

Pro forma Balance Sheet

Based on our review, which is not an audit, nothing has come to our attention, which causes us to believe that the Pro forma Balance Sheet as set out in Section 7 of the Prospectus:

- (a) has not been prepared in accordance with the pro forma adjustments, and the policies and assumptions as set out in Section 7 of the Prospectus; and
- (b) did not apply the measurement and recognition requirements (but not all the disclosure requirements) of applicable Accounting Standards and other mandatory professional reporting requirements in Australia.

5. Subsequent Events

Apart from the matters dealt with in this report, and having regard to the scope of our Report, to the best of our knowledge and belief, no material transactions or events outside of the ordinary course of business of the Company have come to our attention that would require comment on, or adjustment to, the information referred to in our Report or that would cause such information to be misleading or deceptive.

6. Disclosure

Weston Woodley & Robertson does not have any interest in the outcome of this offer other than in connection with:

- the preparation of this Report;
- the participation in due diligence procedures; and
- acting as statutory auditor for the Company

for which normal professional fees will be received.

Weston Woodley & Robertson has consented to the inclusion of this Independent Accountant's Report in the Prospectus in the form and context in which it is included. At the date of this Report this consent has not been withdrawn.

In accordance with the terms of our engagement, this Report does not address the future prospects or forecasts of the Company, nor risks associated with an investment in the Company. We disclaim any responsibility for any reliance on this Report or on the financial information to which it relates for any purpose other than that for which it was prepared. This Report should be read in conjunction with the full Prospectus.

Yours faithfully

Weston Woodley & Robertson

Ian M Cooper
Partner

9. Directors and Corporate Matters

9.1 Corporate Structure

Cellscreen Direct Ltd has been established as the corporate holding company and is a 100% owner of the following subsidiary entities:

- Tam Pap Pty Ltd (Owner of the Intellectual Property Licenses);
- Tam-Pap Operations Pty Ltd (Administrative Service Company);

Cellscreen has appointed Dr Peter Hughes as its inaugural Managing Director. Dr Hughes has extensive experience in the foundation, development, operationalisation and growth of privately and publicly held enterprises. Dr Hughes has developed a significant career in healthcare innovations and will lead Cellscreen through its initial and on-going maturity cycle to ensure that all key objectives are reasonably satisfied.

9.2 Board of Directors

Cellscreen's Board consists of:



Ms Alison Coutts
(Non-Executive Chairperson)

Alison has over 25 years' experience in international engineering project management, strategy consulting and executive search. Since the mid 1990's, Alison has been involved in the financial markets; in venture capital, stockbroking and investment banking. Alison is a Non Executive Director of Clear Global Energy, a private company involved in underground coal gasification.

Alison also chairs the external advisory council for all of CSIRO's Health Sector projects. Alison was a member of the advisory panel which worked with the ASX to draft the latest code of best practice for reporting by biotechnology and life science companies.

Alison has a degree in Chemical Engineering, a Masters Degree in Business Administration and a Graduate Diploma in Biotechnology and was a co-founder of EG Capital (a full-service financial advisory and securities dealing firm focussed on biotechnology and life science companies). Alison currently serves as the Director of Corporate Advisory for Martin Place Securities Limited.



Dr Adrian Cachia
(Non-Executive Director)

Adrian is passionately committed to Quality Assurance, scientific excellence and accountability in the delivery of medical services to the public. He is currently the Medical Director of SDS Pathology and the Deputy Medical Director of Symbion Laverty Pathology in Sydney. Both laboratories are subsidiaries of Primary Health Care Limited, which following its recent acquisition of Symbion Health Limited, is now one of the two largest providers of pathology services in Australia.

Adrian is a specialist Histopathologist and Cytopathologist. He is widely regarded as being at the forefront of his speciality. Adrian graduated in Medicine from the University of Sydney in 1989. He has been a Fellow of the Royal College of Pathologists of Australasia since 1996. He is currently the Honorary Secretary of the Australasian Dermatopathology Society; the peak continuing medical educational organisation in Australasia for medical specialists practicing in skin pathology. Adrian is also a voluntary assessor for the National Association of Testing Authorities (NATA); the government-approved body responsible for



accrediting pathology laboratories throughout Australia.

Adrian regularly writes pathology reports on conventional and Thin-Prep pap smears. He has a firm grasp of the known pathogenesis of cervical cancer and has conducted and published PCR-based molecular biology research using a grant obtained from the Medical Research Council (UK). One of Adrian's maternal aunts died of cervical cancer in her 50's.

Adrian also holds a First Class Honours degree in Law from the University of New England. He has particular knowledge of and expertise in large and complex legal and medical systems, processes and laboratory management. Adrian is a Fellow of the Australian College of Legal Medicine. His interests in law include corporate governance and fiduciary duty.



Mr Russell Tate
(Non-Executive Director)

Russell continues to develop a distinguished corporate career where he most recently served as the Executive Chairman and CEO of the ASX listed STW Communications Group, a position held for over 14 years. During this time, STW evolved into the largest and most profitable marketing communications group in Australasia and ranked in the top 10 globally by revenue and profit. The Group today comprises over 70 specialist operating companies including leading international brands such as Ogilvy and Mather. Russell stepped down from this position in July 2008 but still serves as Deputy Chairman of the Group.

Prior to this role, Russell held executive positions with large corporate entities such as Rheem, Ampol Ltd, Heuga Australia Pty Ltd and the Dairy Promotions Council of NSW before establishing his own marketing consultancy – Russell Tate and Associates which eventually evolved into Mainstay Communications where he served as the Managing Director.

Since stepping down from full time executive duties with STW Communications Group Russell has established a new consulting business (Russell Tate Corporate Advisory) which provides businesses with marketing and re-structuring advice. Russell also currently serves as the Chairman of Pleasure State Pty Ltd a leading lingerie entity and Chairman of Central Coast Stadium Pty Limited. Russell has academic qualifications in Commerce and Economics from the University of New South Wales.



Dr Michael Wooldridge
(Non-Executive Director)

Dr Michael Wooldridge attended Melbourne and Monash Universities and has bachelor's degrees in Science and Medicine and a Master of Business Administration. He has served as the Chairman of UNAIDS (Geneva) 1998-1999 and Chairman of the World Health Organisation East Asia/Western Pacific Region. In 2000, he was the inaugural recipient of the Novo Nordisk International Health Policy Award, chosen by an international selection panel as the individual internationally who had most advanced the cause of diabetes policy.

Dr Wooldridge was Australia's Federal Minister for Health from 1996 to 2001, during which time he was widely acknowledged for his commitment to public health, community pharmacy, and biomedical research. He was instrumental in negotiating a previous agreement between the Pharmacy Guild of Australia and the Federal Government which cemented Australian's access to high quality health and pharmacy services.

Dr Wooldridge is an Honorary Fellow of the Australasian Faculty of Public Health Medicine. He is currently Chairman of Resonance Health, Chairman of Dia-b Tech and a Director of Cogstate Ltd and API Ltd.



Mr Warwick Doughty
(Non-Executive Director)

Warwick has served as a Finance and Administration Manager and Director for numerous companies over the last 21 years, inclusive of acting as a financial accountant for Sony Music (UK) for 4 years, and an audit manager for Coopers and Lybrand for 7 years.

Warwick was a founding Director of Demtel International Pty Limited which became Australia's largest television direct response marketing companies. Warwick was also a key member of a consortium that located a Russian submarine at the National Maritime Museum (now located at Long Beach, California) and now currently is a co-owner and Director of Luna Park in Sydney Australia. Warwick is a Foundation Fellow of the Australian Institute of Company Directors.



Dr Peter Hughes
(Managing Director)

Peter was most recently the Executive Director / CEO of Epworth Eastern (the largest not-for-profit private hospital in Melbourne's Eastern Corridor) and has extensive experience in health planning, health systems analysis, facility development, health financing and asset placement.

Peter's career commenced as a practicing architect prior to the planning and project management of major health facility developments. Peter became the general manager of Richard Glenn and Associates, a major health planning consultancy before moving to eventually become the Global CEO of the Bovis Lend Lease Health Business Unit based out of Maryland USA. The Health Business Unit attracted both major individual redevelopment projects and a number of private finance initiative projects in the UK.

Upon returning to Australia in 2001, Peter completed two turn around assignments with major not for profit health enterprises and was also appointed as the Chief Operating Officer of a highly successful publicly listed technology company in Queensland.

Peter has founded and operationalised a number of privately owned Companies and currently serves on the Board of HealthCare Villages Australia Ltd and up until recently served as a board member of the Victorian Cytology Service and Nutrition Australia (Vic Division Chair) as well as frequently lecturing at the RMIT Graduate School of Business in Corporate Strategy, Mergers and Acquisitions.

Peter has academic qualifications in Environmental Science and Architecture and holds both a Masters Degree and Doctorate in Business Administration.

9.3 Medical and Scientific Advisory Board

Cellscreen has constituted a Medical and Scientific Advisory Board to assist it in its continued pursuit of appropriate regulatory approvals, product and technology research and development, licensee selection and clinical sampling and trials. The members of the Scientific Advisory Board (and relevant biographical details) which will report directly to the Board of Directors via the Managing Director are listed below:



Dr Ivan Cottom
(Chair)

Dr Cottom graduated from the University of Sydney in 1968 and completed his training in general pathology in 1975. He was the Director of Pathology at Hornsby and Ku-ring-gai Hospital between 1980-1995 and Sydney Adventist Hospital between 1980-1997.

In 1987 Dr Cottom joined SDS pathology and was appointed as a VMO in Pathology at Ryde Hospital in 1989. Ivan had a long involvement with the Pathology Advisory Committee, the Pathology Services Table Committee and the Australian Association of Pathology Practices including two years as President.



Dr Cottom has also been on the Federal Executive of the AMA, as well as chairman of the staff council and a member of the board and the Medical Advisory Council at St Lukes Hospital. He was also a member of the Medical Advisory Council at Sydney Adventist Hospital and has held a similar position at Hornsby and Ku-ring-gai Hospital. He retains a keen interest in all facets of pathology.



Professor Kerryn Phelps
(Clinical Spokesperson)

Professor Phelps graduated from the University of Sydney medical school in 1981 and completed post graduate training at Sydney's Royal North Shore Hospital. She is a Fellow of the Royal Australian College of General Practitioners and is Founder and Principal of Uclinic Integrative Health Clinic In Sydney as well as Principal and founder of the Cooper Street Clinic also in Sydney.

Professor Phelps is an Adjunct Professor at the University of Sydney's Faculty of Medicine, School of Public Health and Discipline of General Practice and was President of the Australian Medical Association between 2000-2003 being the first woman to hold this position. Professor Phelps serves and has served on a number of Medical and Associated Clinical Advisory Boards and Health Promotion Councils and also acts as a medical consultant to various companies.

Professor Phelps has worked as a medical journalist and media spokesperson on health matters for over 25 years in both television and on radio bringing important health issues to the attention of the Australian public. She is one of Australia's most respected health commentators. Professor Phelps has chaired and delivered numerous papers at national and international seminars on a wide range of health related topics and is an advocate for the development of all areas of health having a special interest in women's health and an integrative approach to the management of the health in general.



Professor Brian Morris

Professor Brian Morris has written the majority of the research papers on which the Tam Pap technology is based. He is a leading expert in cervical cancer screening programs and was the first to patent HPV PCR technologies. He has over 250 publications in peer reviewed journals, including Cervical Screening in the 21st Century: the case for human papillomavirus testing of self-collected specimens.

Brian Morris is Professor of Molecular Medical Sciences in the School of Medical Sciences and Bosch Institute of the Faculty of Medicine at The University of Sydney. He graduated with first class Honours in Science at The University of Adelaide, South Australia in 1972, completed his PhD in the Departments of Medicine at Monash and Melbourne Universities in 1975 when he was awarded a CJ Martin Fellowship by the NHMRC to further his studies in the USA, first at The University of Missouri, Columbia for a year and then at The University of California, San Francisco for two years.

During his second year at the latter he was made an Advanced Fellow of the American Heart Association. He returned to Australia to take up a Lectureship in the (then) Department of Physiology at The University of Sydney in 1978 and set up the first recombinant DNA laboratory on campus. In 1988 he was promoted to Reader and in 1998 to Professor. Distinctions include the award of the Edgeworth David Medal for Science in 1985 and in 1993 a DSc for his contributions to molecular studies of hypertension.

Brian Morris won the 2006 Faculty of Medicine Award for Excellence in Postgraduate Research Supervision. He is a Fellow of the American Heart Association (Council for High Blood Pressure Research) and Member of the Executive Committee of the High Blood Pressure Research Council of Australia (as

Treasurer). He is also a member of the Editorial Board of the two premier journals in hypertension, namely 'Hypertension' and 'Journal of Hypertension'. His research has also led to the earliest priority date for use of PCR in human papillomavirus detection for cervical screening.

Brian is interested in the application of medical research findings to lifestyle and dietary modifications for prevention of disease. This includes optimal 'healthy' diet, exercise, and avoidance of drugs (alcohol, tobacco, etc) and the promotion of male circumcision (www.circinfo.net). He instigated several very successful national symposia on life extension in 2002 and 2003 and this theme has been extended by others leading to the International Conference on Healthy Ageing and Longevity (ICHAL) in 2004, 2005, 2006, and beyond, involving the top names in the field internationally. He is closely associated with the organization and promotion of these conferences.



Dr Philip Tynan

Dr Tynan is a co-inventor of the Tam Pap HPV DNA test process.

Dr Tynan completed an Honours degree in Reproductive Biochemistry in 1981, an experience which subsequently convinced him to study medicine at the University of Newcastle. Upon completion he has worked in various hospitals in the Hunter Region as well as at Tamworth and Sydney.

Dr Tynan has been Clinical Chemistry registrar at the Hunter Area Pathology Service and at Prince of Wales Hospital in Sydney and received his FRCPA in Clinical Chemistry in 1996. Previously he was a staff specialist at John Hunter Hospital and his principal interest in Pathology includes TPN, endocrinology and metabolic diseases.



Dr Victor Agustin Franco

Dr Franco is also a co-inventor of the Tam Pap HPV DNA test process with Dr Tynan. Dr Franco is currently Head of the Molecular Biology Department of SDS Pathology. Dr Franco's primary skill is the development of new diagnostic tests (homemade tests).

Dr Franco specialized in molecular oncology and was once employed as Senior Research Officer for the Children's Cancer Institute Australia and The Newcastle Misericordiae Mater Hospital.

Dr Franco was appointed Development manager at BTF (Biotechnology Frontiers) where he played a crucial role in the development of Precise Reference microbiological standards (2001-2002).

His most recent academic appointment record includes a position as Conjoint Lecturer in the Department of Medicine of the School of Women's and Children's Health, UNSW.

Dr Franco has academic qualifications including a Doctorate of Philosophy, Molecular Microbiology (University of Sydney, 1998) and a Master of Science (Long Island University, Brooklyn, N.Y., 1998).

Dr Franco was awarded Research Grants for the following investigations: Transcriptional regulation of the tumour suppressor gene, retinoic acid receptor beta (2002-2004); The role of TRAIL in induction of apoptosis in human melanoma and in T cell responses to melanoma. N.S.W. Cancer Council (1999-2001).



Professor Michael Quinn

Professor Michael Quinn has a current academic appointment within the Department of Obstetrics and Gynaecology at the University of Melbourne and is a Consultant Gynaecological Oncologist at the Royal Women's Hospital and Peter MacCallum Clinic in Melbourne.

Michael has produced in excess of 190 peer reviewed published papers, 3 books, 8 book chapters and 2 monographs. Michael serves as the Chairman of the Australian and New Zealand Gynaecologic Oncology Trials Group and is a member of the Advisory Board of the National Centre for Gynaecological Cancer.



Michael was the former Chair of the Boards of the Victorian Cytology Service and the National Cancer Control Initiative.

Michael sits on a number of editorial boards and is one of Australia's leading clinical practitioners in gynaecological oncology. Michael completed a medical degree at Glasgow University in 1973 and an MGO at Melbourne University in 1980.

9.4 International Medical and Scientific Advisory Consultants

Cellscreen has secured the services of leading internationally recognized clinical research fellows including Professor Albert Singer whose details are below.

Professor Albert Singer

Professor Albert Singer is a Professor of Gynaecological Research and Molecular Pathology at the University College London.

He is a co-founder of the British Society for Colposcopy and Cervical pathology (1972) and co-founder of British Gynaecological Cancer Group, the forerunner of the British Society for Gynaecological Cancer.

For over forty years he has had a major interest in gynaecological cancer especially the cervix and in the teaching of gynaecological surgery. In relation to the cervix he has maintained a research unit both in London and before in Sheffield. Major interests have been in cervical cancer, particularly in relation to human papillomavirus.

On an international level he is a founding member and board member of the EUROGIN Society (European Research Gynaecological Infection and Neoplasia). He has served as President of the British Colposcopy and Cervical Pathology Society as well as a board member of many other societies. He was the President of the 8TH EUROGIN Congress in Paris in April 2006. He is a member of the editorial board of a number of major international journals and national journals.

Over the last forty years he has produced and co-authored over three hundred publications, many of which were in relation to human papillomavirus (HPV) and the use of HPV in the management of pre-malignant cervical cancer.

9.5 Senior Executive Team

Details of Cellscreen's senior executive team are as follows:



Dr Peter Hughes (Managing Director)

Peter was most recently the Executive Director / CEO of Epworth Eastern (the largest not-for-profit private hospital in Melbourne's Eastern Corridor) and has extensive experience in health planning, health systems analysis, facility development, health financing and asset placement.

Peter's career commenced as a practicing architect prior to the planning and project management of major health facility developments. Peter became the general manager of Richard Glenn and Associates, a major health planning consultancy before moving to eventually become the Global CEO of the Bovis Lend Lease Health Business Unit based out of Maryland USA. The Health Business Unit attracted both major individual redevelopment projects and a number of private finance initiative projects in the UK.

Upon returning to Australia in 2001, Peter completed two turn around assignments with major not for profit health enterprises and was also appointed as the Chief Operating Officer of a highly successful publicly listed technology company in Queensland.

Peter has founded and operationalised a number of privately owned Companies and currently serves on the Board of HealthCare Villages Australia Ltd and up until recently served as a board member of the Victorian Cytology Service and Nutrition Australia (Vic Division Chair) as well as frequently lecturing at the RMIT Graduate School of Business in Corporate Strategy, Mergers and Acquisitions.

Peter has academic qualifications in Environmental Science and Architecture and holds both a Masters Degree and Doctorate in Business Administration.



Mr Nick Diamond
(Business Development Director)

Nick Diamond is a founder of the Cellscreen Direct business and has an in-depth understanding of the Company and its market potential. For the past 3 years Nick has been responsible for all in-house legal matters, relationships with SDS Pathology, key opinion leaders, marketing partners and international licensees as well as dealing with regulatory authorities both within Australia and abroad.

Nicks' previous employment includes practicing as a solicitor at Landerer and Company and Clayton Utz.

Nick comes from a family with a history of involvement in the practice of medicine. His late father, Dr Robert Diamond, was one of Australia's distinguished gynaecologists and obstetricians who earned a science degree from Oxford University for his pioneering attempt with Vickers Engineering to develop an automated Papanicolaou smear test. Nick felt it was a tribute to the legacy of his father to continue his work.

Nick holds a Bachelor of Laws (Honours), Master of Laws (Dispute Resolution) and a Postgraduate Diploma in Legal Practice.



Mr David Hammer
(Global Marketing Director)

David Hammer has been appointed as consultant Global Marketing Director in November 2008 to enable the Company to be the recipient of expert strategic and operational marketing advice, particularly in the fields of direct to consumer product placement. David is a founder of the Cellscreen business and as such already possesses an intimate knowledge of the product portfolio, its capacities, regulatory requirements and global market potential.

David has spent a lifetime marketing unique activities after spending 10 years in retail for Waltons Group in the 1970's prior to serving as a general product manager for K-Tel International. David jointly founded Demtel International during the 1980's. Many of David's catch phrases have become household sayings. He has written and produced over 2,000 television commercials and placed over \$100m in TV airtime.

David and his partner sold Demtel to a public company in 2000 and went on to assist in the establishment of the Metro Theatre, Luna Park Sydney and the Russian Foxtrot submarine exhibition at Darling Harbour. David is a consultant to the Jacque Bougart Group in Paris and created a marketing strategy that developed the world's largest distribution of hair removal machines (3054 sites worldwide).

David is a foundation fellow of the Australian Institute of Company Directors, and a fellow of the Australian Marketing Institute. David holds degree qualifications in Economics and Applied Psychology and a graduate certificate in Marketing.



Mr Mathieu Briere
(European Business Development Manager)

Mathieu was appointed as the Company's Consultant European Business Development Manager in September 2008 and is based in Paris. Mathieu was educated at ESC Marseille Province in the Graduate School of Business, majoring in international trade.

Professionally Mathieu spent 3 years working in the USA for a consumer packaged goods consultancy prior to an appointment with "A French Paradox Inc" based in Chicago Illinois between 2002-2005.

Mathieu then served for 3 years as an export manager for the Starvac Group with a product portfolio encompassing medical and beauty equipment. In this role Mathieu had dealings in approximately 50 countries over 5 continents. Until recently Mathieu worked exclusively for the Karpati Group (a major integrated health and beauty chain) but now devotes a significant proportion of his time working for Cellscreen.





Mr Nick Geddes
(Company Secretary)

The Company has engaged Mr Nick Geddes through his Company, Australian Company Secretaries Pty Ltd to provide corporate secretarial services to Cellscreen Direct Ltd.

Nick Geddes is an experienced Company Secretary who has acted in the capacity for Companies during a float process and beyond. Nick has a career which commenced as a chartered accountant and worked in the UK, Saudi Arabia and Kuwait for a number of multi-national companies during 1968-1976. Nick spent 11 years with the Commonwealth Development Corporation (CDC), a British based investment group, also spending time in CDC's Jakarta office.

Between 1985-1988 Nick was the Investment Manager, Financial Controller and Company Secretary for BT Innovation Ltd before an appointment as the General Manager – Finance and Administration for BLE Capital, a member of the Westpac Group during 1988-1993. During this time Nick was responsible for a \$260m capital raise for this subsidiary. From 1993 to the present time Nick has been a Director of his own Company, Australian Company Secretaries Pty Ltd. Nick is a Fellow of the ICAEW and a Fellow of the Chartered Institute of Company Secretaries in Australia.

The Company once listed will move to appoint a qualified person as Chief Financial Officer. Mr Geddes will fulfil this role in the interim.

9.6 Corporate Governance

The Board of Directors of Cellscreen will be responsible for the corporate governance of the Company including its strategic development. The Board will be accountable to the Shareholders for the performance of the Company and will have overall responsibility for its operations. Day to day management of the Company's affairs, and the implementation of the corporate strategy and policy initiatives, will be formally delegated by the Board to the Managing Director. The key responsibilities of the Board will include:

- Approving the strategic direction and related objectives of the Company and monitoring management performance in the achievement of these objectives;
- Adopting budgets and monitoring the financial performance of the Company;
- Reviewing the performance of the Managing Director;
- Overseeing the establishment and maintenance of adequate internal controls and effective monitoring systems;

- Overseeing the implementation and management of effective safety and environmental performance systems;
- Ensuring all major business risks are identified and effectively managed; and
- Ensuring that the Company meets its legal and statutory obligations.

For the purposes of the proper performance of their duties, the Directors are entitled to seek independent professional advice at the Company's expense, unless the Board determines otherwise. The Board schedules meetings on a regular basis and other meetings as and when required.

The ASX Corporate Governance Council has issued best practice recommendations for corporate governance. These recommendations are not mandatory with companies being required to report if they comply with the recommendations or not and if not, why not. Set out below is the Company's position in relation to each of the recommendations.

Principle 1: Lay solid foundations for management and oversight;

The Board have developed a charter that delegates day to day responsibility for the Company's operations to the Managing Director and senior management team. The Board will effectively monitor, review and oversee the performance of the management team and maintain and where appropriate amend the Board charter from time to time to reflect the maturity level of the Company. The Company has assembled an approved Delegated Limits of Authority framework for all senior executive employees.

Principle 2: Structure the Board to add value;

Cellscreen has appointed an independent Board chairperson and three further independent non-executive directors. There is also 1 non-independent executive director and 1 non-independent non-executive director on the Board. As such the Company does at this time have a majority of independent non-executive directors. At this stage of the Company's development the Board believes it is

important not to limit the class of potential board members and it has not adopted a policy that over half of its directors be independent non-executive directors.

The Company considers industry experience and specific expertise to be important attributes of its Board members and therefore believes that the composition of the Board is appropriate given the size and development of the Company at the present time.

The Company has established a Nomination and Remuneration Committee which will initially be comprised of:

Mr Russell Tate (Chair); and
Dr Michael Wooldridge.

The membership of the committee will be reviewed at least annually.

The Committee is responsible for providing an oversight of the Company's broad remuneration plans, policies and practices, with a view to assisting the Board to ensure that:

- The level and composition of remuneration of executives and Directors is sufficient and reasonable and linked to Company and individual performance;
- The integrity of the Company's remuneration strategies and practices is safeguarded;
- Shareholder interests and employee interests are aligned;
- Independent reviews of remuneration proposals are undertaken; and
- The Company complies with legislative requirements related to remuneration practices.

The committee is also responsible for

reviewing and making recommendations to the Board on the Composition, size and commitment of the Board, to ensure that the Board:

- Efficiently discharges the duties of the Directors and adds value to the Company;
- Has a variety of relevant perspectives and skills and a proper understanding of the current and emerging issues of the business;
- Can effectively review and challenge the performance of management and exercise independent judgment; and
- Has the necessary competencies, expertise and experience to enable it to discharge its mandate effectively.

Principle 3: Promote ethical and responsible decision making;

In alignment with the adoption of a Corporate Governance Charter the Board has also agreed and adopted a detailed Delegations of Authority framework and Code of Conduct and Share Trading Policy. The purpose of these is to ensure that Board members remain cognisant at all times of their duties and performance and when they, management and associates of the Company can effectively deal in securities.

Cellscreen Board charters and policies are designed to promote the highest levels of corporate governance, ethical and moral behaviour as well as compliance with all statutory and legal obligations.

Company policy prohibits Directors and senior management from dealing the Company's securities at any time whilst in

possession of price sensitive information and for 24 hours after:

- Any major announcements;
- The release of the Company's annual financial results to the ASX; and
- The annual general meeting.

Directors must advise the Chairperson of the Board before buying or selling securities in the Company. All such transactions are reported to the Board.

In accordance with the provisions of the Corporations Act and the Listing Rules, the Company advises ASX of any transaction conducted by Directors in the securities of the Company.

Principle 4: Safeguard integrity in financial reporting;

The Board has established an Audit and Risk Committee with its own terms of reference to review and ensure the financial integrity and maintenance of a risk mitigation framework for the Company. All members of this Committee are financially literate and well versed in the identification and diminishment of latent and other risks.

The audit, risk and compliance committee will initially be comprised of:
Mr Warwick Doughty (Chair);
Ms Alison Coutts; and
Dr Adrian Cachia.

The primary responsibilities of the committee are to:

- assess whether the Company's external reporting is legally compliant, consistent with committee members' information and knowledge and suitable for Shareholder needs;
- assess the management processes



- supporting external reporting;
- liaise with the external auditors and ensure that the audit review is conducted in an effective manner;
- make recommendations for the appointment or removal of auditors;
- on an annual basis, assess the performance and independence of the external auditors;
- on an annual basis, assess the performance and independence of the internal auditors (if any);
- monitor the co-ordination of the internal (if any) and external audits in so far as they relate to the responsibilities of the committee;
- recommend to the Board and then promulgate clear standards of ethical behaviour required of Directors and key executives and encourage observance of those standards;
- recommend to the Board and then promulgate and maintain a sound system of risk oversight and management and internal control which:
 - identifies, assesses, manages and monitors risk; and
 - informs investors of material changes to the Company's risk profile; and
 - recommend to the Board and then promulgate and maintain a system to ensure compliance with all environmental and occupational health and safety regulations and legislation.

Principle 5: Make timely and balanced disclosure;

Cellscreen's current practice in relation to disclosure is consistent with the Principle.

The Company has enshrined policies and procedures for ASX and ASIC compliance in the Company's Corporate Governance Charter.

Principle 6: Respect the rights of Shareholders;

The Board of Cellscreen intends to communicate on a regular basis with its shareholders either in electronic format or by other means including media and website. Shareholders will be encouraged to attend Company meetings and announcements and Company auditors will be available at the Annual General Meeting to answer queries which may arise. The Company's policies comply with the Principles in relation to the rights of shareholders.

Information is communicated to Shareholders through:

- Annual and half-yearly financial reports and quarterly reports;
- Annual and other general meetings convened for Shareholder review and approval of Board proposals;
- Continuous disclosure of material changes to ASX for open access to the public; and
- The Company maintains a website where all ASX announcements, notices and financial reports are published as soon as possible after release to ASX.

The Company's auditor will be invited to attend the annual general meeting of Shareholders. The Chairperson will permit Shareholders to ask questions about the conduct of the audit and the preparation and content of the audit report.

Copies of all Corporate Governance Charters and policies and

announcements will be placed on the Company's website www.cellscreeendirect.com following listing.

Principle 7: Recognise and manage risk;

The Board in conjunction with the Senior Management team has put in place a framework and process to identify and manage risk. Risk management is clearly identified within the Board's Governance Charter and all Board members are aware of their responsibility to monitor and regularly review matters of importance.

The Board reviews and monitors the parameters under which such risks will be managed. Management accounts will be prepared and reviewed with the Managing Director at subsequent Board meetings. Budgets are prepared and compared against actual results.

Principle 8: Remunerate fairly and responsibly;

Cellscreen's remuneration practices are reviewed regularly and will comply with the Principles. All Board and Senior Executive remuneration will be fully disclosed in the Company's annual report. Details of the Company's Remuneration and Nominations Committee are set out above.

All Board members in alignment with senior management team members will be subjected to regular reviews and an evaluation on an annual basis. Review processes are highlighted within the Board's Governance Charter. The Board will focus on improving the input, expertise and performance of its members through continuous education and attendance at appropriate seminars.

9.6.1 Size and Composition of Board

The Directors consider the size and composition of the Board are appropriate given the size and status of the Company. However the composition of the Board will be subject to review in a number of ways:

- The Constitution provides that at every annual general meeting, one third of the Directors shall retire from office but may stand for re-election.
- Board composition will be also reviewed periodically either when a vacancy arises or if it considered the Board would benefit from the services of a new Director, given the existing mix of skills and experience of the Board, which should match the strategic demands of the Company. Once it has been agreed that a new Director is to be appointed, a search will be undertaken. Nominations would then be received and reviewed by the Board.

9.6.2 Ethics and Independence – Code of Conduct

The Board recognises the need for Directors and employees to observe the highest standards of behaviour and business ethics when engaging in corporate activity. The Company intends to maintain a reputation for integrity. The Company's officers and employees are required to act in accordance with the law and with the highest ethical standards.

The Board is conscious of the need for independence and ensures that where a conflict of interest may arise, the relevant

Director(s) leave the meeting to ensure a full and frank discussion of the matter(s) under consideration by the rest of the Board. Those Directors who have interests in specific transactions or potential transactions do not receive Board papers related to those transactions or potential transactions, do not participate in any part of a Directors' meeting which considers those transactions or potential transactions, are not involved in the decision making process in respect of those transactions or potential transactions, and are asked not to discuss those transactions or potential transactions with other Directors.

Corporate Governance Council Recommendation 2.1 requires a majority of the Board to be independent directors. In addition, Recommendation 2.2 requires the chairperson of the Company to be independent. The Corporate Governance Council defines independence as being free from any business or other relationship that could materially interfere with, or could reasonably be perceived to materially interfere with, the exercise of unfettered and independent judgement.

In accordance with this definition, four Directors are independent. The following Directors and proposed Directors are not considered to be independent.

Name	Position
Dr Peter Hughes	Managing Director
Dr Adrian Cachia	Non-Executive Director

The Company considers industry experience and specific expertise to

be important attributes of its Board members and therefore believes that it is appropriate that Dr Peter Hughes and Dr Adrian Cachia both serve as members of the Board given the size and development of the Company at the present time.

9.6.3 Identification and Management of Business Risk

The Board has identified the significant areas of potential business and legal risk of the Company. The identification monitoring and, where appropriate, the reduction of significant risk to the Company will be responsibility of the Managing Director and the Board.

The Board reviews and monitors the parameters under which such risks will be managed. Management accounts will be prepared and reviewed with the Managing Director at subsequent Board meetings. Budgets are prepared and compared against actual results.

9.6.4 Remuneration

The Chairperson and the non-executive Directors are entitled to draw Directors fees and receive reimbursement of reasonable expenses for attendance at meetings. The Company is required to disclose in its annual report details of remuneration to Directors. The maximum aggregate annual remuneration which may be paid to non-executive Directors is \$350,000.00. This amount cannot be increased without the approval of the Company's shareholders. A detailed explanation of the basis and quantum of Directors remuneration is set out in Section 11.4.2 of this Prospectus.



10. Risks

10.1 Introduction

The investment offered is speculative. The operations of Cellscreen Direct Ltd will be subject to a number of risk factors associated with business activities and prevailing market conditions. These factors can ultimately affect that performance of the Company and its prevailing valuation.

The Board wish to state that there is no guarantee that Cellscreen can fulfil its intended objectives or deliver future aspirations and as such any investment within the Company should carefully consider both latent and specific risks associated with a Company of this type. The Board has identified below a number of risks which could have a material and adverse impact on the performance of the Company.

There are numerous widespread risks associated with investing in any form of business and with investing in the share market generally. There is also a range of specific risks associated with the Company's business and its involvement in the marketing and distribution of medical diagnostic tests. These risk factors are largely beyond the control of the Company and its Directors because of the nature of the business of the Company.

Persons considering whether or not to invest in the Company should read the whole of this Prospectus in order to fully appreciate such matters and the manner in which the Company intends to operate, before any decision is made to apply for the Shares offered. Prospective investors should consider whether the Shares offered are a suitable investment

for them having regard to their own personal investment objectives and financial circumstances, and the risk factors set out below. If in any doubt, they should consult with their professional advisers before deciding whether to apply for Shares.

The following, which is not exhaustive, identifies some of the major risks associated with an investment in the Company, of which potential investors needs to be aware before making a decision whether or not to invest in the Company's Shares.

10.2 General Risks

The Board advise that prior to this Offer there has been no public market for the Shares. It is relevant to consider that once the Shares list on the ASX there is a potential for the value of the Shares to rise or fall above or below the Offer Price.

The future performance of the Company and the future investment performance of the Shares may be influenced by a range of factors including domestic and international economic conditions. Some of these factors can be mitigated. However, many are outside the control of the Board and the Company. Prior to making any decision to accept the Offer, investors should carefully consider the following general and specific risk factors applicable to the Company:

10.2.1 Government

The introduction of new legislation or amendments to existing legislation by governments, and the decisions of courts and tribunals, can impact adversely on the assets, operations and, ultimately, the financial performance of the Company

and its Shares.

10.2.2 Taxes

Industry profitability can be affected by changes in government taxation policies or in the interpretation or application of those policies.

10.2.3 Economic Factors

Factors such as inflation, currency fluctuation, interest rates, supply and demand and industrial disruption have an impact on operating costs, commodity prices and stock market processes. Both domestic and world economic conditions may affect the performance of the Company. Factors such as rising or slowing demand for goods, inflation or interest rates could impact on sales, revenues and costs. In addition, exchange rate movements will affect revenues and expenses incurred in other currencies. The Company's future possible revenues and the price of its Shares can be affected by these factors which are beyond the control of the Company and its Directors.

10.2.4 Market Acceptance

Up until recently, there has been slow acceptance by both regulators and clinicians to use a HPV test as a first line diagnostic for cervical pre-cancer. Although this position is expected to be transient and with Cellscreen intending to focus on its proprietary based marketing campaign positioning the test as a "pre-screening" mechanism, a significant immediate impact is not expected. With the advent of further clinical trial results and with greater awareness of the relationship between HPV testing and cervical cancer higher levels of acceptance

may gradually occur.

Non-invasive HPV testing may become more sought after given recent media reports highlighting allegations that the Gardasil vaccine may be the cause of significant side effects to younger women, potentially slowing a vaccination regime and in the process enhancing exposure to HPV.⁴⁰

10.2.5 Accounting Standards

Accounting Standards in Australia are established by the Australian Accounting Standards Board (AASB) and are unable to be influenced or controlled by the Directors of Cellscreen. Changes to accounting standards issued by the AASB, could materially and adversely affect the financial performance of the Company and the position reflected within financial statements.

10.2.6 Share Market

Share market conditions may affect listed securities regardless of operating performance. Share market conditions are affected by many factors such as:

- General economic outlook;
- Movements in, or outlook on, interest rates and inflation rates;
- Currency fluctuations;
- Commodity prices;
- Changes in investor sentiment towards particular market sectors; and
- The demand for, and supply of, capital.

Investors should recognise that once the Shares are listed on ASX, the price of the Shares may fall as well as rise. Many other factors will also affect the price of the Shares, including general fluctuations in the performance of local and

The Directors will work to ensure Cellscreen's systems are robust and highly secure against attack from an internal or external source.

international stock markets, movements in interest rates and exchange rates, general economic conditions and investor sentiment.

10.3 Specific Investment Risks

10.3.1 Intellectual Property Risks

Cellscreen's success is contingent upon the efficacy and protection of its intellectual property, including the HPV Intellectual Property, through continual patent and commercial methodologies and Cellscreen's ability to operate without infringing proprietary rights of other third parties.

Cellscreen may therefore at times face a number of risks, costs and uncertainties with respect to a patent prosecution. There is a risk that patent authorities in some jurisdictions may not grant the HPV test patent protection and therefore no assurance can be given that the current patent or any future issued patents can maintain a competitive advantage for Cellscreen. The patent application and responsibility for maintenance and protection of this asset rests with Cellscreen.

There are also risks involving Cellscreen competitors filing objections to SDS's patent applications which may indirectly involve the organization in untimely and expensive litigation resulting in delays to product release in certain markets. The

Company notes SDS received a letter in July 2007 from Polartechnics Limited requesting information regarding the HPV Intellectual Property but to date no action has arisen. The Board has considered this letter having taken advice from representatives of its scientific advisory panel. The Board notes the disclosed Polartechnics Limited patent lapsed in early 2008. The Board has formed the view that Cellscreen's processes are unlikely to have infringed the disclosed Polartechnics Limited's intellectual property rights.

10.3.2 Product Development Risk

The development of Cellscreen's current technology and future product portfolio will be subject to risks of failure due to a number of constraints including capital availability and regulatory issues.

The Cellscreen business model also exposes the Company to product liability risks inherent in research, development and analytical assessments. The Company intends to take out adequate product liability and professional indemnity insurances to mitigate potential loss of financial performance.

10.3.3 Key Resource Availability

The Board of Cellscreen considers that its human capital is its most valuable resource. It is fundamental to the success of the Company that sufficiently skilled

⁴⁰Fox News Report, Tuesday the 8th July 2008, and CBC News Report, Monday the 7th July 2008;



resources in niche specialists' areas are available to continue with driving operational development and growth and ensure that appropriate research and clinical development continues with regard to the Company's portfolio of diagnostic test products.

Should any key resource leave the employment of the Company, they may be difficult to replace. Such loss may restrict the ability of the Company to achieve its objectives.

If a key Cellscreen resource was to take employment with a competitor organization, this may also adversely affect the Company. Cellscreen's ability to recruit both its own resource base and attract and secure licensees will likely impact on the performance of the Company.

10.3.4 Technology Platform

Cellscreen intends to invest in the development of a transactional and consumer information website that can also transmit and store vital data relating to test applications. To effectively operate within a global environment, the Company believes a sophisticated technology platform is essential. The Company must also adhere to a program of regular technology updates.

There is a risk that intended software and technology systems may fail or not operate as intended. The Company must also adhere to a program of regular technology updates.

10.3.5 Progressive Growth

There is a risk that the Company may not be able to efficiently process the significant volumes of test requests and results in a timely manner. The ability



to hire appropriately skilled resources and retain and train them to effectively implement the Company's technology framework will be essential to success. It will also be incumbent upon Cellscreen to effectively and pro-actively manage the SDS and Symbion relationship to ensure that laboratory based resourcing requirements are satisfactorily fulfilled.

10.3.6 Data Security and Storage

Patient and consumer credit data will be held to high levels of privacy and security to induce loyalty and confidence in the Company. The Directors will work to ensure Cellscreen's systems are robust and highly secure against attack from an internal or external source. However there remains a risk that data may be subject to penetration by a third party which may compromise Company performance.

10.3.7 Competitors

Competitors who emerge to provide similar products and services may affect the performance of the Company. Cellscreen will ultimately compete with other organizations who may possess advantages of deep financial resources, size, sophisticated and extensive

distribution networks and capacity to develop other products. Competitors may also be experienced in obtaining necessary regulatory approvals and getting their products to market in an expedient manner.

If a Competitor fears that their market share may become diminished due to the presence of Cellscreen, they may also develop combative strategies to mitigate any potential loss, which Cellscreen will need to counter.


As the biotechnology and viral diagnostic market space gains increasing focus and continual research advances product placement, there can be no assurances provided to investors that Cellscreen can continue to be effective and have a product of choice for its target market. Further development of a new vaccine or drug therapy treatment for HPV may also reduce the market for testing to high risk groups.

Any failure of the Company to compete effectively and produce value propositions of merit will diminish its capacity to meet financial performance targets.

10.3.8 Commercialisation

Although Cellscreen, through Tam-Pap, has "beta-tested" and sold its test kit product in the Australian market place, it is yet to fully commercially exploit the market offering.

The Company's future performance is subject to its ability to drive sales volumes, manage costs, obtain regulatory approvals and stakeholder support, execute its development and growth strategies and source and appoint appropriate license partners who can effectively market and distribute the



product within selected geographies. The Company's success will also largely depend upon its novel marketing and positioning strategies particularly within the USA and the European Union.

There is no assurance that potential customers will utilise the Company's product or subsequently whether the Company can derive sufficient revenues to achieve profitable performance.

10.3.9 Licensee Performance

Cellscreen's growth and sales volume strategy will depend to an extent on the appointment of skilled license partners who can market and distribute the test kit product through agreed sales channels. The Company can offer no guarantee that it will or can appoint appropriate strategic partners despite the in-depth selection criteria applied to each considered partner applicant.

Each license agreement will stipulate expected performance metrics; however the Company cannot guarantee that these objectives will be continually fulfilled.

10.3.10 Funding Risk

Cellscreen may need to raise additional capital to fund and establish initial operations and expand growth potential. The Company will assess the merit of either a new share issue, securement of debt funding or a combination of both to

satisfy on-going needs.

The timing and amounts of any additional capital requirements are not known at this stage and will depend upon a number of factors. There is a risk that the Company may not be able to raise additional capital when required. If adequate funds cannot be accessed Cellscreen may:

- Need to delay or cease further product development;
- Be forced to license its technologies at reduced rates of return;
- Reduce or cease operations;

If the Company raises further capital via a share placement offering, or enters into a lending arrangement, the terms and conditions may not be favourable and may dilute the shareholding of other investors. A debt finance facility may contain restrictive covenants and if a default occurs the financier may have rights to step in and acquire Company assets.

10.3.11 Laboratory Performance

In any diagnostic process there will always be performance risks associated with human error and sample quality. Test performance may be compromised if the sample is not conducted in accordance with the instructions provided and incorrect interpretation of results could occur if data entry is not carried out

appropriately. Cellscreen's laboratory partner Symbion Pathology has developed an accredited quality assurance process to mitigate these risks through a detailed audit and compliance program.

10.4 Summary

This investment should be regarded as speculative. Neither the Company nor its Directors nor any other party associated with the preparation of this Prospectus warrants that any specific objective of the Company will be achieved or that any particular targets of the Company will be achieved.

In addition, to the extent that statements in this Prospectus constitute forward looking statements, these statements involve known and unknown risks, uncertainties and other factors that may cause the Company's actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward looking statements. Although the Company believes that the expectations reflected in the forward looking statements are reasonable, it cannot guarantee future results, levels of activity, performance or achievements and the Company does not assume responsibility for the accuracy and completeness of the statements.

Patient and consumer credit data will be held to high levels of privacy and security to induce loyalty and confidence in the Company.



11. Additional Information

11.1 Incorporation

Cellscreen Direct Limited was incorporated as a public company on 20 October 2008.

11.2 Tax Status and Financial Year

Cellscreen Direct Ltd will be taxed in Australia as a public company at the prevailing corporate tax rate which is currently 30%. The financial year of the Company will end on 30 June annually.

11.3 Litigation

The Directors are not aware of any legal proceedings which have been threatened or actually commenced against the Company.

11.4 Directors' Relevant Interests

11.4.1 Interest of Directors

Except as disclosed in this Prospectus, no Director (whether individually or in consequence of a Director's association with any company or firm or in any material contract entered into by the Company) has now, or has had, in the 2 year period ending on the date of this Prospectus, any interest in:

- The formation or promotion of the Company; or
- Property acquired or proposed to be acquired by the Company in connection with its formation or promotion or the Offer of the Shares; or
- The Offer of the Shares.

Except as disclosed in this Prospectus, no amounts of any kind (whether in cash, shares, options or

otherwise) have been paid or given or agreed to be paid or given to any Director or to any company or firm with which a Director is associated to induce him or her to become, or to qualify as, a Director, or otherwise for services rendered by him or her or any company or firm with which the Director is associated in connection with the formation or promotion of the Company or the Offer of the Securities.

The Directors will have the following interests upon the Company listing on the ASX at the Minimum Subscription level.

Table 7: Non-Executive Directors Fees

Name	No of Shares
Alison Coutts*	230,000
Dr Peter Hughes**	2,150,000
Dr Michael Wooldridge	40,000
Russell Tate	40,000
Dr Adrian Cachia***	40,000
Warwick Doughty	40,000

*Alison Coutts is the Director - Corporate Advisory of MPS Securities which is acting as Sponsoring Broker.

**Dr Peter Hughes holds 1,043,629 of the Shares through Sportzcom Australia Pty Limited and the remaining 1,106,371 Shares will be held personally.

***Dr Adrian Cachia is an employee of Symbion Pathology which has assigned the HPV Test to Tam Pap.

Dr Peter Hughes through Sportzcom Australia Pty Limited will receive consultancy fees of approximately \$90,000 in relation to the formation of the

Company and the Offer of the Shares.

11.4.2 Remuneration of Directors

Directors are entitled to remuneration out of the funds of the Company but the remuneration of the non-executive Directors may not exceed in any year the amount fixed by the Company in general meeting for that purpose. The aggregate remuneration of the non-executive Directors has been fixed at a maximum of \$350,000.00 per annum (allowing for the appointment of future Directors) to be apportioned among the non-executive Directors in such manner as they determine. Each non-executive director will receive Director's fees of \$40,000.00 per annum (exclusive of GST) with Alison Coutts as Chair receiving \$55,000 per annum. Directors are also entitled to be paid reasonable travelling, accommodation and other expenses incurred in consequence of their attendance at Board meetings and otherwise in the execution of their duties as Directors.



Table 8: Non-Executive Directors' Remuneration

Name	Position	Amount \$ pa
Ms Alison Coutts	Non-Exec Chairperson	\$55,000.00
Dr Adrian Cachia	Non-Exec Director	\$40,000.00
Mr Russell Tate	Non-Exec Director	\$40,000.00
The Hon Dr Michael Wooldridge	Non-Exec Director	\$40,000.00
Mr Warwick Doughty	Non-Exec Director	\$40,000.00

In addition, the Directors are entitled to be remunerated or receive benefits from the Company as follows:

- If a Director undertakes any work additional to that usually required of Directors of a Company similar to this Company, the Directors may award such special remuneration and fix the amount hereof at any time during or after the rendering of such special service or the undertaking of such additional work.
- Directors are also entitled to travelling expenses for or in connection with any journeys undertaken by them on the Company's business.
- The performance and remuneration of any managing director or executive director for his services shall be reviewed and determined by the Directors from time to time but on at least an annual basis.

11.4.3 Deeds of Indemnity and Access

The Company has entered into Deeds of Access and Indemnity with each of the Directors. Details of the Deeds of Access and Indemnity are set out in Section

11.9.12 of this Prospectus.

11.4.4 Insurance

The Company has initiated a process to implement the following insurance policies as protection against relevant categories of risk:

- Directors' and Officers' Liability Insurance;
- Public Liability Insurance;
- Product Liability Insurance;
- Professional Indemnity Insurance;

Policy quotations have been arranged through Jardine Lloyd Thompson Pty Limited via the Insurance Company Vero Insurance Limited and Dual Australia and will be converted to executed contracts upon the Company listing on the ASX.

11.4.5 Executive Service Contracts

The Company through its wholly owned subsidiary Tam Pap Operations Pty Ltd ("TPO") has entered into a Senior Executive Employment Agreements with each of Dr Peter Hughes and Mr Nicholas Diamond ("Executives").

Dr Hughes is solely responsible to the Board whilst Mr Diamond is solely responsible to the Managing Director. The Executives must each work, including any additional hours required, an average of

37.5 hours per week.

Dr Hughes' position of director held with HealthCare Villages Australia Limited is acknowledged and his agreement does not limit his ability to perform the requirements of this director's position.

The Executives are required to keep informed of general business developments and develop a professional knowledge in respect of the business activities of TPO and its group companies.

Dr Hughes is to be paid an annual base remuneration of \$350,000 per annum whilst Mr Diamond is to be paid an annual base remuneration of \$178,900 per annum which is inclusive of a car allowance. Mr Diamond is also to be paid a living away from home allowance for accommodation costs when he is required by TPO to be resident overseas up to a maximum of \$50,000 per annum.

The annual base remunerations are to be reviewed each year in the month the agreements commence. TPO will provide the Executives with all necessary equipment, including computers and mobile telephones and other cash and non-cash benefits such as agreed travel arrangements and travel insurance to assist them in performing their roles. TPO is also required to reimburse the executives for all out-of-pocket expenses reasonably incurred in the performance of their duties.

The Executives are entitled to participate in Cellscreen's annual performance related bonus scheme. Any bonuses awarded will be provided equally in cash and shares in Cellscreen unless otherwise agreed. Any share options issued will be subject to the terms and conditions stipulated within Cellscreen's employee



share option plan.

Dr Hughes is also entitled to participate in Cellscreen's long-term incentive plan with long-term incentives to be paid to Dr Hughes in the form of options with a strike price established in accordance in accordance with the terms of his agreement.

The Executives and the board of TPO must discuss appropriate performance measures at the end of each financial year for the following financial year. TPO must also review the Executives performance by reference to the agreed determined measures and targets and must discuss the assessments with them.

The Executives are entitled to four weeks paid annual leave for each 12 months of continuous service in addition to public holidays, along with personal/carer's leave, compassionate leave and parental leave.

TPO may terminate the employment of the Executives by notice in writing if the Executives engage in any act or omission which constitutes serious misconduct, in the reasonable opinion of the board/managing director fail and neglect to perform or carry out their duties in a satisfactory manner, commit a serious or persistent breach or non-observance of a term of the agreement, are convicted of a criminal offence which might injure the reputation of the business or of the Company or the group, refuse or neglect to comply with any lawful and reasonable order given by the board/managing director, are bankrupt or suspend payment or compound or assign their estate for the benefit of their creditors, or provide TPO with information about their qualifications experience or character which is misleading or intended to be

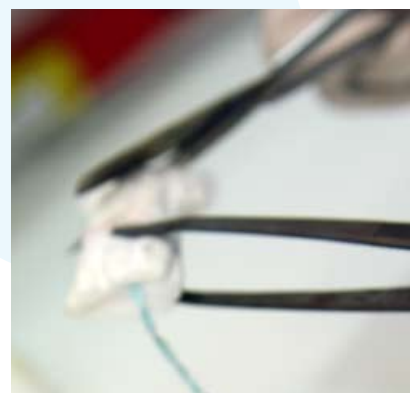
false and misleading.

Mr Diamond's agreement is for a 3 year term, subject to termination provisions.

If the Company terminates the employment of the Executives for any reason apart from those noted above TPO must provide Dr Hughes with 6 months notice of termination and must provide Mr Diamond with 3 months notice of termination. TPO may require the Executives to work through all or part of the notice period or make a payment of remuneration in lieu of such period less any applicable tax. Dr Hughes may terminate his employment by giving 6 months notice and Mr Diamond may terminate his employment by giving 3 months notice in writing to TPO whereby TPO may require the Executives to work through all or only part of the notice period or may make a payment in lieu of the whole or part of the notice period.

On cessation of their employment with TPO the Executives are restrained from being either directly or indirectly involved in any activity or business of a like or similar kind to that engaged by TPO or its group companies anywhere in the world for a period of 12 months. The Executives are also prohibited for a period of 12 months after cessation of their employment from attempting to directly or indirectly solicit or induce any of TPO or its group companies' employees officers or contractors etc to engage in any activity which the Executives are prohibited from engaging in or to have them cease offering their services to TPO or its group companies.

The Executives have agreed that all intellectual property rights in the product of their services are owned by TPO or



any group companies nominated by TPO's board and they will assign to TPO all credit and future intellectual property rights in the products of their services.

The Company has also entered into a consultancy agreement with Revenel Pty Limited for the provision of consultancy services by Mr David Hammer to act as its global marketing director. Revenel Pty Limited will be paid \$200,000 per annum under the agreement.

The consultancy is for a period of 3 years and is terminable by either party on 3 months notice. Upon termination Revenel Pty Limited and Mr Hammer will not solicit customers or employees of the Company for a period of 12 months.

11.5 Interests of Named Persons

Except as disclosed in this Prospectus, no expert, promoter or any other person named in this Prospectus as performing a function in a professional advisory or other capacity in connection with the preparation or distribution of this Prospectus, nor any firm in which any of those persons is or was a partner, nor any company in which any of those persons is or was associated with, has now, or has had, in the 2 year period ending on the

date of this Prospectus, any interest in:

- The formation or promotion of the Company; or
- Property acquired or proposed to be acquired by the Company in connection with its formation or promotion or the Offer under this Prospectus; or
- The Offer under this Prospectus.

Except as disclosed in this Prospectus, no amounts of any kind (whether in cash, Shares, options or otherwise) have been paid or given or agreed to be paid or given to any expert, promoter or any other person named in this Prospectus as performing a function in a professional advisory or other capacity in connection with the preparation or distribution of the Prospectus, or to any firm in which any of those persons is or was a partner or to any company in which any of those persons is or was associated with, for services rendered by that person in connection with the formation or promotion of the Company or the Offer under this Prospectus.

Weston Woodley & Robertson have acted as independent accountants in relation to the Offer. As independent accountants, Weston Woodley & Robertson have been

involved in undertaking due diligence in relation to financial and taxation matters and have prepared the Independent Accountant's Report on the Proforma Accounts which have been included in this Prospectus. In respect of this work the Company has agreed to pay Weston Woodley & Robertson a total of \$30,000 for these services.

Holman Webb, Lawyers have acted as the solicitors to the Company in relation to the Offer, and in that capacity and otherwise assisting the Company with the preparation of this Prospectus, Holman Webb, Lawyers have been involved in undertaking certain due diligence enquiries in relation to legal matters and providing legal advice to the Company in relation to the Offer. In respect of this work, the Company has agreed to pay Holman Webb \$130,000 for these services up to the date of this Prospectus. Holman Webb has or may receive professional fees at their normal rates for other legal work for the Company.

Computershare has agreed to provide share registry services to the Company in accordance with a detailed schedule of fees listed in its proposal dated 27

October 2008 for IPO and Essential Registry Services.

Innovation Dynamics have acted as an Independent Expert in the form and context set out in this Prospectus. Innovation Dynamics have received \$33,000 in respect of the preparation of their report.

Each of the amounts set out above are exclusive of goods and services tax.

11.6 Expenses of the Offer

Actual and estimated expenses connected with the Offer are payable by the Company, these expenses are set out in Table 9 below.

11.7 Consents

Each of the parties referred to in this Section 11:

- Does not make, or purport to make, any statement in this Prospectus or on which a statement made in the Prospectus is based, other than as specified in this Section 11; and
- To the maximum extent permitted by law, expressly disclaims and takes no responsibility for any part of this Prospectus other than a

Table 9: Expenses of the Offer

Expenses of the Offer	Minimum Subscription		Maximum Subscription	
		\$		\$
Legal Expenses		130,000		130,000
Independent Accountant's Report		30,000		30,000
Printing, posting, Share Registry & other miscellaneous		36,224		36,224
ASX listing fee		46,662		49,008
Brokers		720,000		895,000
Consultants		68,500		68,500
TOTAL		1,031,386		1,208,732



reference to its name and a statement included in this Prospectus with the consent of that party as specified in this Section 11.

Weston Woodley & Robertson have given their written consent to the inclusion in Section 8 of this Prospectus of their Independent Accountant's report on the Proforma Accounts and to all statements referring to these reports in the form and context in which they appear and have not withdrawn such consent before lodgement of this Prospectus with ASIC.

Computershare has given and, as at the date hereof, has not withdrawn its written consent to be named as Share Registrar in the form and context in which it is named. Computershare had no involvement in the preparation of any part of this Prospectus other than being named as Share Registrar to the Company. Computershare has not authorised or caused the issue of, and expressly disclaims and takes no responsibility for, any part of this Prospectus.

Holman Webb, Lawyers has consented in writing to being named in the Prospectus as the Solicitors to the Company and has not withdrawn such consent prior to the lodgement of this Prospectus with ASIC. Holman Webb, Lawyers has not caused the issue of the Prospectus, and expressly disclaims and takes no responsibility for, any part of this Prospectus.

Innovation Dynamics has given and not withdrawn its consent to being named in this Prospectus as an Independent Expert, in the form and context in which it is so named. In addition Innovation Dynamics has given and not withdrawn its consent to the dispatch of this Prospectus with references to its report. Innovation Dynamics has had no involvement in the preparation of this

Prospectus other than the inclusion of references to its report and have not given any professional or other advice in respect of any part of this Prospectus. Innovation Dynamics do not accept any liability to any person in respect of any false or misleading statement in, or omission from, any other part of this Prospectus.

There are a number of other persons referred to in this Prospectus who are not experts and who have not made statements included in this Prospectus nor are there any statements made in this Prospectus on the basis of any statements made by those persons. These persons did not consent to being named in the Prospectus and did not authorise or cause the issue of the Prospectus.

Copies of the consents to the issue of this Prospectus are available for inspection, without charge, at the registered office of the Company.

11.8 Details of the Existing Shareholders

Assuming Minimum Subscription the top 10 holders of Shares in the Company prior to the allocation of Shares under this Offer are as follows:

Table 10: Top 10 Shareholders


	Shareholder	Number of Shares	% Issued Capital
1.	Revenel Pty Limited	14,091,188	33.75
2.	Gamog (No. 1) Pty Ltd	14,091,187	33.75
3.	Symbion Pathology	8,511,772	20.39
4.	MLVS Properties Pty Ltd	1,125,000	2.69
5.	Peter Hughes	1,106,371	2.60
6.	Sportzcom Australia Pty Ltd	1,043,629	2.50
7.	Martin Place Securities Pty Ltd	350,000	0.84
8.	Alison Coutts	230,000	0.48
9.	Philip Tynan	144,000	0.35
10.	Agustin Franco	144,000	0.35

11.9 Material Contracts

Set out below is a brief summary of the material contracts which have been entered into by the Company or its subsidiary Tam Pap Pty Ltd, all of which have been identified as material and relevant to an investor. To fully understand all rights and obligations of a material contract it is necessary to review it in full and these summaries should be read in that light. A copy of each of these contracts may be inspected during normal business hours at the registered office of the Company.

11.9.1 Commercialisation Agreement

In October 2007 Tam Pap entered an Intellectual Property Assignment and Licence Deed with Specialist Diagnostic Services Pty Limited (ACN 003 417 605) as trustee of the Sydney Diagnostic Services Unit Trust ("SDS"). The agreement was amended on 27 November 2008 and Symbion Pathology Pty Limited ACN 007 190 043 replaced SDS as a party to the agreement. These two documents together form the Commercialisation Agreement between Tam Pap and Symbion Pathology. Under the Commercialisation Agreement



in consideration for the issue of the equivalent of 15% of the total issued capital on a fully diluted basis of the Company to Symbion, Symbion is to assign unencumbered to Tam Pap all its right, title and interest in the Project Intellectual Property – which includes any intellectual property that the parties together or alone developed or develop for the purposes of marketing and commercialising the Tam Pap Process; and is to assign to Tam Pap the HPV Intellectual Property – which includes the matters encompassed by the SDS Patents and the rights in the Tests. As at the date of this Prospectus the HPV Intellectual Property is subject to a charge over the assets of Symbion. However the Directors understand that arrangements for discharge are in hand and are confident the HPV Intellectual Property will be transferred unencumbered.

Tam Pap has agreed to provide a perpetual non-revocable licence to use the HPV Intellectual Property to Symbion and its related bodies corporate for purposes other than in relation to the Tam Pap Process unless requested by Tam Pap to do so.

Tam Pap has agreed that all Tests using or derived from the Tam Pap Process shall be undertaken at a Symbion laboratory until such time as Symbion notifies that it is unable to cope with the number of such Tests. Symbion is required to provide such notice if at any time 1,000 Tests are not conducted and reported upon within agreed time frames and the situation is unable to be satisfactorily rectified. At such time Tam Pap shall consider appointing other laboratories to undertake Tests using the Tam Pap Process.

Under the Agreement SDS nominated Dr Adrian Cachia to the board of directors of the Company.

Under the terms of the Commercialisation Agreement:

- Where Symbion conducts the Tests, Tam Pap will pay Symbion to conduct the Tests at agreed rates per Test from moneys received from customers within 14 days of the date Tam Pap receives an invoice from Symbion. The Commercialisation Agreement provides a mechanism for the alteration of the rates or otherwise on the basis of good faith negotiations between the parties.
- Where Symbion does not conduct the Tests Symbion is entitled to 5% on all sales or other revenues that are related directly or indirectly to the conduct of the Tests using the Tam Pap Process.
- Tam Pap will obtain (at its cost) all approvals required by any government department or similar regulatory authority in respect of the marketing, sale, distribution or conduct of the Tests which will be held in the name of the Company or other Tam Pap Group Company as elected by Tam Pap. Symbion agrees to provide all reasonable assistance to Tam Pap in obtaining and maintaining the approvals.
- Tam Pap will be responsible for all costs in respect of the maintenance and prosecution of the patent applications relating to the HPV Intellectual Property from the date of the assignment.
- Tam Pap has agreed to indemnify

Symbion in respect of any claim for breach of third party intellectual property rights in respect of the HPV Intellectual Property, no matter when such breaches occurred.

Symbion have represented that other than as questioned by Polartechnics Limited in their letter referred to in Section 10.3.1 of this Prospectus that Symbion is unaware of any infringement or any claim of infringement as at November 2008.

- Tam Pap shall keep itself insured in the amount of \$20 million against any third party claims which may be brought against it with SDS named as an interested party.

Cellscreen has guaranteed the payment of all monies due to Symbion and Tam Pap's obligations under the Commercialisation Agreement.

Symbion acknowledges that it has no right in or to use Tam Pap's unregistered or registered trade marks, including the TAM-PAP trade mark.

Either party may terminate the Commercialisation Agreement by giving notice to the other party if:

- the other party breaches any material term of the Commercialisation Agreement capable of remedy (including an obligation to pay) and fails to remedy the breach within 30 days of receiving notice of the breach;
- the other party takes any steps to enter into any arrangement with its creditors, ceases to be able to pay its debts as they become due, ceases to carry on business or steps are taken by a



mortgagee to enter into possession or dispose of the whole or any part of its assets or business or any steps are taken to appoint a receiver, a receiver and manager, a trustee in bankruptcy, a liquidator, a provisional liquidator, an administrator or other like person of the whole or any part of its assets or business.

Neither party may encumber or assign its right, title or interest in or under the Commercialisation Agreement without the prior written consent of the other party which consent shall not be unreasonably withheld if a proposed assignee is demonstrated to be of good reputation and financial standing, solvent, capable of and prepared to undertake all of the obligations of the party who is the proposed assignor.

11.9.2 Intellectual Property and Services Deed

Luminex Pty Ltd, Tam Pap and Brian James Morris have entered into an intellectual property and services deed, pursuant to which Luminex and Morris assigned to Tam Pap their rights, title and interest in the intellectual property in the project relating to the collection and testing of cervical samples including the TAM PAP and TAM-PAP trade marks and associated logos (“**Project Intellectual Property**”). Morris and Luminex contributed to the development of the Project Intellectual Property.

Pursuant to the deed, all parties agreed that all right, title and interest in and to the Project Intellectual Property is now owned by Tam Pap. Tam Pap wishes to extend the commercialisation of the project relating to the collection and testing of cervical samples.

Until the deed is terminated, Morris will provide the following services to Tam Pap:

- lead on-going development of the Tam Pap process, including providing advice and assistance with respect to the selection of where to offer the Test;
- research and collate support data to validate the efficacy and use of the Test in selected geographic regions around the world;
- attend meetings and negotiate with regulatory authorities to gain approval to use and distribute the Test within selected geographic regions;
- assist with supervision of sample populations to validate the efficacy of the Test in selected geographic regions;
- provide advice on and review marketing materials;
- assist with media and other stakeholder inquiries to position the Test appropriately within selected markets;
- assist with the formation of a Scientific Advisory Panel;
- ensure quality standards and appropriate control methods are in place to protect the use and effectiveness of the Test;
- participate as a member of the Scientific Advisory Panel;
- provide advice and assistance to ensure the Test results are effectively captured, secured and returned to a nominated source in a timely matter; and
- provide leadership devoted towards additional required research and validation methodologies to expand the use

of the Test and its effectiveness.

The deed can be terminated by either Tam Pap or Morris for a breach of obligation, or in the case of winding up or bankruptcy proceedings commenced against a party.

Under the deed the Company is required to issue 100,000 Shares to Morris, half on the Company listing on the ASX and half 12 months after listing, but only if Morris is a member of the Scientific Advisory Panel at that time.

Morris and Luminex warrant that no third party has any right or interest in the intellectual property transferred to Tam Pap pursuant to the deed or another other agreement between the parties.

11.9.3 Luminex - Deed of Assignment

Tam Pap and Luminex Pty Ltd exchanged letters on 2 November 2006 regarding the assignment of Australian Trade Mark Registration no. 1041857 TAM-PAP (“**Trade Mark**”). Luminex agreed to and did assign and transfer to Tam Pap the Trade Mark on 2 November 2006. In consideration for the assignment of the Trade Mark, Tam Pap undertook to pay to the Assignor the sum of \$20,000 when sufficient funds were available.

Tam Pap has entered into a confirmatory deed of assignment with Luminex pursuant to which Luminex confirmed the assignment to Tam Pap of its full right, title and interest in and to the Trade Mark on and from 2 November 2006, including the right to take action and recover remedies, including damages and an account of profits against third parties for infringement of the Trade Mark and/or passing off and/or misleading or deceptive conduct in relation to the Trade Mark.

11.9.4 Heads of Agreement – Service Agreements with Dr Philip Tynan and Dr Victor Agustin Franco

Tam Pap entered into heads of agreement with Dr Philip Tynan (“**Tynan**”) and Dr Victor Agustin Franco (“**Franco**”) in April 2008, pursuant to which each agreed to provide the following services to Tam Pap:

- ongoing development of the Test and provide advice and assistance with respect to the placement of the Test based on the analysis of specimens obtained through a collection device either via or substantially similar to a tampon (“**Tam Pap Test**”);
- advice and assistance to place the Tam Pap Test in selected geographic regions, and to meet and negotiate with regulatory authorities to approve use and distribution of the Tam Pap Test within those regions;
- facilitation and supervision of sample populations to validate the efficacy of the Tam Pap Test in selected geographic regions, and provide advice and assistance to ensure Tam Pap Test results are effectively captured, secured and returned to the nominated source in a timely manner;
- assistance to identify and secure preferred licensees who can distribute the Tam Pap Test and assist with the formation of a Scientific Advisory Panel; and
- advice and review of marketing materials and assistance with media and interested stakeholder inquiries.

In return for services, Tynan and Franco will each receive on the listing of the Company on the Australian Stock Exchange 144,000 fully paid Shares in the Company.

A further \$4,000 worth of Shares will be issued to each at the then prevailing market price for the Shares for each international license that obtains appropriate regulatory approval to enable distribution and sale of the Test upon listing, or in the event of a trade sale an equivalent amount in the form of a cash payment upon settlement.

11.9.5 Agreements – Scientific Advisory Board Members

Tam Pap has entered into various agreements with members of the Scientific Advisory Board, being Dr Ivan Cottom, Professor Kerryn Phelps, Professor Brian Morris and Professor Michael Quinn whereby they agreed to provide the various services to Tam-Pap including:

- assist with ongoing development of the Test within selected geographic regions;
- assemble required research and support data to validate the efficacy and use of the Test in selected geographic regions;
- meet and negotiate with regulatory authorities as required;
- oversee facilitation and supervision of required sample populations to validate the efficacy of the Test in selected geographic regions;
- advise and review applicable marketing materials and other collateral that supports use of the Test in selected geographic regions;

- assist with media and other interested stakeholder inquiries and act as a clinical spokesperson for Tam Pap; and
- assist with the formation of a Scientific Advisory Panel.

Each agreement is for between a one to three year period. The term may be extended by mutual agreement between the parties.

In return for services provided, the members of the Scientific Advisory Board will receive in total 316,000 fully paid Shares issued upon the Company being listed on the ASX.

Doctor Philip Tynan and Dr Victor Franco are also members of the Scientific Advisory Board. The remuneration for these services is set out in the agreements referred to in 11.9.4.

11.9.6 Heads of Agreement – Sportzcom

In May 2008 Tam Pap entered into a Remuneration, Share and Options Transfer Agreement with Sportzcom Australia Pty Ltd a company associated with Dr Peter Hughes as the Trustee of the Cadaecus Discretionary Trust (“**Sportzcom**”).

Sportzcom agreed to provide professional input into the development of the Company and to assist the Company in respect of the Offer of Securities.

In return for services provided, the following commercial particulars will apply:

- Sportzcom was paid on a monthly retainer of AUD\$5,000 per month plus applicable statutory costs up until completion of an initial public offer.
- Dr Peter Hughes will be engaged



by the Company under a separate agreement to act as Managing Director.

- For any work performed outside Dr Hughes' role of Managing Director, Dr Hughes may receive additional fees on a pro-rata basis with other Company directors.

11.9.7 License Agreements

The Company has entered into License Agreements for the sale and marketing of the Tam Pap Test with licensees in India and Lebanon and New Zealand and the Pacific Islands.

Each of the agreements is for a 3 year period unless extended by mutual agreement of the parties. Under each agreement Tam Pap will receive a set amount per test for the supply of the test kit together with a royalty for each test ordered.

11.9.8 Bob Pritchard – Marketing Services

The Company has entered into an agreement with Bob Pritchard for the provision of marketing consultancy services. Mr Pritchard will receive 40,000 Shares upon the successful listing of the Company and will receive an additional 40,000 Shares issued at \$0.50 each upon the Company entering into a marketing licensing agreement with a person introduced by him where the licensee obtains appropriate regulatory approval for the sale and distribution of the sale of the Tam Pap Test in a particular jurisdiction or where the licensee can visibly or quantifiably provide Tam Pap with additional market exposure that may lead to the sale of the Test.

11.9.9 Matkan Sarl – European Business Development Manager

The Company has entered into an agreement with Matkan Sarl whereby that company will act as the European Business Development Manager for the Company.

Matkan Sarl shall provide its services for at least 16 hours per week. The initial term of the Agreement is 24 months commencing 5 September 2008. Matkan Sarl shall be entitled to an annual retainer of Euro 33,600 for these services.

11.9.10 Investor Loans

Tam Pap Pty Ltd ("**Tam Pap**") has borrowed a total of \$430,000 pre the initial public offering of the Company from various parties, some of whom are related to the promotion of the Company.

The terms of the loans are as follows:

- The loans are to be repaid by Tam Pap within thirty (30) days of the Shares in the Company being listed on the ASX ("**Repayment Date**").
- Tam Pap may repay the loans in full, without penalty, at any time prior to the Repayment Date as long as the repayments are made in one lump sum, with such early repayments being at the discretion of Tam Pap.
- The loans incur interest and the amount of interest is to be paid by way of issue of 300,000 ordinary shares.

11.9.11 Martin Place Securities – Letter of Offer of Services

On 2 September 2008 Tam Pap was offered services by Martin Place

Securities Pty Limited ("**MPS**") to assist in raising capital and progressing towards an ASX listing through an initial public offering ("**IPO**"). Alison Coutts, is currently the Director - Corporate Advisory of MPS.

In acting as broker to the share issue for the Company, MPS agrees to use its best and reasonable endeavours to:

- procure successful applications for Shares under the IPO;
- maximise the ability for the Company to satisfy the ASX spread requirements; and
- seek to ensure the successful completion of the IPO and to act in the best interests of the Company at all times, however MPS has no obligation to subscribe for shares offered under the IPO.

In return for providing services as broker to the Share issue MPS is entitled to the following IPO fee structure:

- Management Fee - 1% of funds raised;
- Commitment Fee - \$20,000 (non-refundable) payable on signing of the letter of offer, being part of the Management Fee;
- Placing Fee - 6% on all funds raised; and
- Success Fee - 350,000 Shares on achievement of Minimum Subscription.

Subject to the priority allocation (whereby the Company agrees to afford a priority allocation to applicants for shares under the IPO whose applications bear the stamp of MPS), MPS will make payable a fee of 4% to any application bearing the stamp of Dealer with an AFS Licence.

All fees (other than the Commitment



Fee) are only payable if the Company is admitted to the official list of the ASX.

MPS may terminate this agreement without costs or liability, at any time, if one or more of the following occur before the Company is admitted to the official list of the ASX:

- the Company is in breach of the agreement;
- there is any material adverse change in the condition or financial or trading position of the Company;
- the Company commits a material breach of the ASX Listing Rules or its continuous disclosure obligations under the Corporations Act; or
- ASIC issues or threatens to issue proceedings in relation to the IPO.

The Company may terminate this agreement without costs or liability, at any time, if MPS is in breach of any of its obligations under the agreement.

Either party may terminate the agreement if the Company has not been unconditionally admitted to the official list of the ASX on or before 31 January 2009.

11.9.12 Deeds of Indemnity and Access

Under a Deed of Indemnity and Access executed by the Company and each of the Directors, the Company must, to the extent permitted by law, indemnify each Director against any liability incurred by that person, except where the liability arises out of conduct involving a lack of good faith or the liability is for a pecuniary penalty or compensation order under the Corporations Law. The indemnity extends to legal costs and expenses unless they are incurred in defending criminal proceedings in which the person

is found guilty, in defending proceedings brought by ASIC or a liquidator if the grounds for making the order sought by ASIC or the liquidator are found to have been established, or in instituting and maintaining proceedings in which the court denies relief to the person.

The Company may also maintain in favour of each Director of the Company a Directors' and Officers' policy of insurance for the period that they are a Director and for a period of seven years after they cease to be a Director.

The Company must also make available to each Director the records of the Company in various circumstances. This requirement is in addition to the minimum access to records permitted to the Directors under the Corporations Act. The Directors may in certain circumstances refuse such additional access in the event that they do not consider such access to be in the interests of the Company.

11.9.13 Employee Share Plan Rules

The Company has established the Employee Share Plan for the benefit of Directors, employees and consultants of the Company.

The Board may at its discretion determine the criteria to apply for participation in the ESP including a minimum period of service required by employees.

Offers to participants under the ESP can be for them to acquire Shares by subscription or purchase or otherwise be allocated Shares. The price of Shares offered under the ESP (if any) shall be determined by the Board from time to time. The Board may also determine in respect of each offer the method by which Shares may be acquired for the

purposes of the ESP including, through either allotment and issue of Shares in the Company, acquiring Shares in the ordinary course of trading or otherwise on the ASX, or by acquiring Shares by off market purchases.

The Board may determine that the purchase price of Shares under the ESP may be satisfied through a salary sacrifice arrangement.

Subject to the Corporations Act, the Company may make or procure its subsidiaries or related bodies corporate to make a contribution for the purchase of shares on behalf of a participant in the ESP.

Shares may not be issued under the ESP if the total number of Shares issued under the ESP, or any other Director or employee incentive plan would exceed 15% of the then current number of Shares on issue.

Shares acquired under the ESP may not be disposed of or dealt with in any manner until the end of the period (if any) determined by the Board when making the offer.

The Plan will be administered by the Board in accordance with the Plan Rules. The Board may make rules and regulations for the operation of the Plan which are consistent with the Plan Rules. Subject to the Listing Rules and a requirement that no amendment of the Plan Rules will reduce the rights of any participant in respect of Shares acquired under the ESP, the Board may amend all or any of the provisions of the ESP.

11.9.14 Employee Share Option Plan Rules

The Company has established Employee



Share Option Plan (ESOP) for the benefit of Directors, employees and consultants of the Company.

The Board may at its discretion determine the criteria to apply for participation in the ESOP including a minimum period of service required by employees.

The price of options offered under the ESOP (if any) shall be determined by the Board from time to time.

The Board may determine that the purchase price of options under the ESOP or the exercise price of those options may be satisfied through a salary sacrifice arrangement.

Subject to the Corporations Act, the Company may make or procure its subsidiaries or related bodies corporate to make a contribution for the purchase of options or the underlying Shares following exercise of the Options on behalf of a participant in the ESOP.

The total number of options available for grant to eligible participants under the ESOP may not exceed 5% of the total number of Shares on issue as at the date of grant.

Options acquired under the ESOP or the underlying Shares following exercise of the options may not be disposed of or dealt with in any manner until the end of the period (if any) determined by the Board when making the offer.

The Plan will be administered by the Board in accordance with the Plan Rules. The Board may make rules and regulations for the operation of the Plan which are consistent with the Plan Rules. Subject to the Listing Rules and a requirement that no amendment of the Plan Rules will reduce the rights of any participant in respect of Shares acquired

under the ESOP, the Board may amend all or any of the provisions of the ESOP.

11.10 Rights attaching to Shares

Immediately after issue and allotment, the Shares will be fully paid ordinary shares.

There will be no liability on the part of shareholders for any calls and the Shares will rank *pari passu* with the Shares currently on issue.

The rights attaching to ownership of the Shares are detailed in the Company's Constitution, which may be inspected during normal business hours at the Company's registered office.

A summary of certain rights attaching to the Shares are as follows:

Voting: At a general meeting, every holder of Shares present in person or by proxy, attorney or representative will have one vote on a show of hands and on a poll, one vote for each Share held.

General Meeting: Each holder of Shares is entitled to receive notice of, and to attend and vote at general meetings of the Company and receive all financial statements, notices and other documents required to be sent to members under the Constitution or the Corporations Act.

Dividends: The profits of the Company which the Directors from time to time determine by way of dividend are divisible amongst the members in proportion to the number of Shares held by them and to the percentage of the issue price paid up on the Shares held by them respectively.

Issue of further Shares: The Directors may (subject to any restrictions on the allotment of shares imposed by the Constitution, the Listing Rules and the Corporations Act) allot further Shares on

such terms and conditions as they see fit and issue preference shares on the terms set out in the Constitution.

Transfer of Shares: Holders of Shares may transfer them by a transfer effected in accordance with the ASTC Settlement Rules and the ASX and as otherwise permitted by the Corporations Act.

The Directors may decline to register a transfer of Shares where the transfer is not in registrable form or where the refusal to register the transfer is permitted under the ASX Listing Rules. If the Directors decline to register a transfer the Company must give the party lodging the transfer written notice of the refusal and the reason for refusal.

Winding up: If the Company is wound up, the liquidator may, with the authority of a special resolution, divide among the shareholders the assets and property of the Company and may determine how the division is to be carried out as between the shareholders or different classes of shareholders.

Without prejudice to the rights of the holders of Shares issued upon special terms and conditions, the assets and property available for distribution among the shareholders shall be distributed amongst the shareholders entitled to the assets and property in proportion to the number of Shares held by them irrespective of the amounts paid up on the Shares.

Number and changes in Directors: The number of Directors, excluding any managing director, must not be less than three and the maximum is to be determined by the Company but may not be more than ten unless the Company passes a resolution varying that number.

The Company may by resolution appoint new Directors, increase or reduce the maximum number of Directors, remove any Director before the end of the Director's term of office, and appoint another person in place of a Director who has been removed from office.

At each annual general meeting one-third of the Directors (apart from the Managing Director) will retire and each retiring Director is eligible for re-election.

Directors appointed by the Directors to fill casual vacancies or as an addition to their number shall retire at the Annual General Meeting after they are appointed, and be eligible for election at that Annual General Meeting.

Remuneration of Directors: The Directors (other than the Managing Director or a Director occupying an executive position) may in aggregate be paid as remuneration for their services the maximum sum from time to time

determined by the Company in general meeting (currently a pool of \$350,000). The remuneration will be divided between the non-executive Directors in such proportion and manner as they agree and in default of agreement equally.

The remuneration of a Managing Director or of a Director occupying an executive position may from time to time be fixed by the Directors.

The Directors are entitled to be reimbursed for all reasonable travel and related expenses.

Directors' indemnity: The Company must, to the extent permitted by law, indemnify every Director against the liability incurred as a Director other than a liability owed to the Company or a related body corporate, a liability for a pecuniary penalty order or a compensation order under the Corporations Act, or a liability that is owed to someone other than the Company or a related body corporate and did not arise

out of conduct in good faith.

Auditors and other officers or employees of the Company may by resolution of the Directors be indemnified by the Company against the liability incurred in their role other than a liability owed as above.

Every Director, auditor and other officer or employee of the Company may be resolution of the Directors be indemnified out of the assets of the Company against the liability for legal costs incurred in defending an action for liability incurred in that capacity unless the costs arise in defending or resisting proceedings in which the person is found to have a liability for which they could not be indemnified, in defending or resisting criminal proceedings in which the person is found guilty, in defending or resisting proceedings brought by ASIC or a liquidator for a court order if the grounds for making the order are found by the court to have been established, or in

Cellscreen's Tam Pap Test process is a world first. The process utilises a highly accurate detection test, enabling women to self-sample for HPV in their own home.



connection with proceedings for relief to the person under the Corporations Act in which the court denies the relief.

The Company or a related body corporate may by resolution of the Directors pay, or agree to pay, a premium in respect of a contract insuring a person who is or has been a Director, auditor or other officer or employee of the Company against a liability for costs or any other liability except a liability incurred by that person which arose out of conduct involving a wilful breach of duty in relation to the Company or a contravention of sections 182 or 183 of the Corporations Act.

Divestment of Small Holdings: The Company may give a shareholder a notice that the shareholder is a small holding shareholder and the Company intends to sell, and account to the shareholder for the proceeds of sale, the shareholder's Shares at the end of the period of the notice. The Company may not sell the Shares if the shareholder notifies the Company within the time stipulated in the notice that the shareholder wishes to remain a shareholder.

Share Buy Backs: The Company may buy Shares in itself in any manner permitted by the Corporations Act.

Alteration of the Constitution: The constitution can only be amended by a special resolution passed by at least three-quarters of shareholders present and voting at a general meeting of the Company.

The Company must give at least 28 days written notice to the shareholders (unless consent to short notice is obtained in accordance with the provisions of the

Corporations Act) to propose a special resolution.

Appendix 15A: The constitution contains a provision consistent with Appendix 15A of the ASX Listing Rules which provides that if the Listing Rules prohibit an act, the act shall not be done; prevents an act being done that the Listing Rules require to be done; if the Listing Rules require an act to be done or not to be done authority is given for that act to be done or not to be done; if the Listing Rules require the constitution to contain a provision and it is not contained in the constitution, the constitution is deemed to contain that provision; if the Listing Rules require the constitution not to contain a provision and it contains such a provision the constitution is deemed not to contain that provision and if any provision of the constitution is or becomes inconsistent with the Listing Rules the constitution is deemed not to contain that provision to the extent of the inconsistency.

11.11 Restricted Securities

In accordance with the ASX Listing Rules certain existing shareholders are required to enter into agreements that restrict dealings in the securities held by them. These agreements will be entered into in accordance with the Listing Rules.

Director's Consent

The Directors of the Company report that for the purposes of Section 731 of the Corporations Act, they state that they have made all enquiries that were reasonable in the circumstances and have reasonable grounds to believe that any statements by them in this Prospectus

are true and not misleading or deceptive, and that with respect to any other statements made in this Prospectus by persons other than the Directors, the Directors have made reasonable enquiries and have reasonable grounds to believe that persons making the statement or statements were competent to make such statements, those persons have given the consent required by Section 716(2) of the Corporations Act and have not withdrawn that consent before lodgement of this Prospectus with ASIC.

Each Director of the Company consents to the lodgement of this Prospectus with ASIC, and has not withdrawn that consent prior to this Prospectus being lodged.

This Prospectus is prepared on the basis that:

- certain matters may be reasonably expected to be known to professional advisers of the kind with whom applicants may reasonably be expected to consult; and
- information is known to Applicants or their professional advisers by virtue of any Acts or laws of any State or Territory of Australia or the Commonwealth of Australia.

This Prospectus is dated 1 December 2008.



Signed on behalf of Celscreen Direct Limited

12. Glossary of Terms

The following terms and abbreviations used in this Prospectus have the following meanings:

ADST	means Australian Daylight Savings Time
AEST	means Australian Eastern Standard Time
Applicants	means persons subscribing for Shares under this Prospectus
Application/Application Form	means an application for Shares attached to or accompanying this Prospectus
Application Price	means \$0.50 per share
Application Monies	means funds raised under this Prospectus
AQIS	means the Australian Quarantine and Inspection Service, an agency of the Australian Government
ASIC	means the Australian Securities and Investments Commission
ASX	means ASX Limited ABN 98 008 624 691
Board	means the board of Directors of the Company
CHESS	means the Clearing House Electronic Sub-register System
Closing Date	means 23 December 2008
Company	means Cellscreen Direct Limited ACN 133 796 488 and/or its subsidiaries as the context requires
Constitution	means the constitution of the Company
Corporations Act	means the <i>Corporations Act 2001 (Cth)</i>
Directors	means the directors of the Company from time to time
DNA	means deoxyribonucleic acid
ESOP	means the Cellscreen Direct Employee Share Option Plan
ESP	means the Cellscreen Direct Employee Share Plan
FDA	means the United States Food and Drug Administration, an agency of the United States Department of Health and Human Services



HPV	means the Human Papillomavirus which is an organism that is the primary cause of cervical cancer
HPV Intellectual Property	means the intellectual property in International Patent Application (PCT/AU2008/000087)
Listing Rules	means the ASX rules regulating the Official List
NATA	means National Association of Testing Authority (Australia)
Offer	means an offer for Shares under this Prospectus
Offer Period	means the period that Applications can and will be processed
Official List	means the official list of companies whose securities are listed on the ASX
Opening Date	means 4 December 2008
PCR	means Polymerase Chain Reaction
Plan	means either the ESP or ESOP
Plan Rules	means the rules of either the ESP or ESOP
Prospectus	means this Prospectus for the issue or transfer of Shares in the Company
Quotation	means the quotation of Shares on the Official List of the ASX
RNA	means ribonucleic acid
SDS	means Specialist Diagnostic Services Pty Limited ACN 003 417 605
Share Registrar or Computershare	means Computershare Investor Services Pty Limited
Shareholder	means a holder of Shares in the Company from time to time
Shares	means fully paid ordinary shares in the Company
Symbion	means Symbion Pathology Pty Limited ACN 007 190 043
Tam Pap Test or Test	means the Human Papillomavirus (“ HPV ”) genotyping real-time PCR based test that can be used to detect certain strains of the HPV that has strong correlations to cervical cancer which is based upon the HPV Intellectual Property
TGA	means the Therapeutic Goods Association, an agency of the Australian Government’s Department of Health and Ageing
WHO	means the World Health Organization



Guide to the Application form

YOU SHOULD READ THE PROSPECTUS CAREFULLY BEFORE COMPLETING THIS APPLICATION FORM.

Please complete all relevant sections of the appropriate Application Form using BLOCK LETTERS.

These instructions are cross-referenced to each section of the Application Form.

Instructions

- A. If applying for Securities insert the **number** of Shares for which you wish to subscribe at Item **A** (not less than **4,000** and then in multiples of 200. Multiply by **\$0.50** AUD to calculate the total for Shares and enter the **\$amount** at B. Options are granted for nil additional consideration on the basis of one option for every two shares.
- C. Write your **full name**. Initials are not acceptable for first names.
- D. Enter your **postal address** for all correspondence. All communications to you from the Company will be mailed to the person(s) and address as shown. For joint Applicants, only one address can be entered.
- E. If you are sponsored in CHES by a stockbroker or other CHES participant, you may enter your CHES HIN if you would like the allocation to be directed to your HIN.
- NB: your registration details provided must match your CHES account exactly.**
- F. Complete **cheque details** as requested. Make your cheque payable to “**Cellscreen Direct Limited Float Account**”, cross it and mark it “**Not negotiable**”. Cheques must be made in Australian currency, and cheques must be drawn on an Australian Bank.
- G. Enter your **contact details** so we may contact you regarding your Application Form or Application Monies.
- H. Enter your **email address** so we may contact you regarding your Application Form or Application Monies or other correspondence.

Correct Forms of Registrable Title

Note that **ONLY** legal entities can hold the Shares. The Application must be in the name of a natural person(s), companies or other legal entities acceptable to the Company. At least one full given name and surname is required for each natural person.

Examples of the correct form of registrable title are set out below.

Type of Investor	Correct Form of Registrable Title	Incorrect Form of Registrable Title
Individual	Mr John David Smith	J D Smith
Company	ABC Pty Ltd	ABC P/L or ABC Co
Joint Holdings	Mr John David Smith & Mrs Mary Jane Smith	John David & Mary Jane Smith
Trusts	Mr John David Smith <J D Smith Family A/C>	John Smith Family Trust
Deceased Estates	Mr Michael Peter Smith <Est Lte John Smith A/C>	John Smith (deceased)
Partnerships	Mr John David Smith & Mr Ian Lee Smith	John Smith & Son
Clubs/Unincorporated Bodies	Mr John David Smith <Smith Investment A/C>	Smith Investment Club
Superannuation Funds	John Smith Pty Limited <J Smith Super Fund A/C>	John Smith Superannuation Fund

Lodgement

Mail your completed Application Form with cheque(s) attached to the following address:

Computershare Investor Services Pty Limited

GPO Box 2115

Melbourne VIC 3001

It is not necessary to sign or otherwise execute the Application Form.

If you have any questions as to how to complete the Application Form, please contact **Martin Place Securities Pty Ltd** on **(02) 9222 9111**.

Privacy Statement:

Cellscreen Direct Limited advises that Chapter 2C of the Corporations Act 2001 (Cth) requires information about you as a shareholder (including your name, address and details of the shares you hold) to be included in the public register of the entity in which you hold shares. Information is collected to administer your share holding and if some or all of the information is not collected then it might not be possible to administer your share holding. Your personal information may be disclosed to the entity in which you hold shares. You can obtain access to your personal information by contacting us at the address or telephone number shown on the Application Form.

Our privacy policy is available on our website (<http://www.cellscreeendirect.com>).

Guide to the Application form

YOU SHOULD READ THE PROSPECTUS CAREFULLY BEFORE COMPLETING THIS APPLICATION FORM.

Please complete all relevant sections of the appropriate Application Form using BLOCK LETTERS.

These instructions are cross-referenced to each section of the Application Form.

Instructions

- A. If applying for Securities insert the **number** of Shares for which you wish to subscribe at Item **A** (not less than **4,000** and then in multiples of 200. Multiply by **\$0.50** AUD to calculate the total for Shares and enter the **\$amount at B**. Options are granted for nil additional consideration on the basis of one option for every two shares.
- C. Write your **full name**. Initials are not acceptable for first names.
- D. Enter your **postal address** for all correspondence. All communications to you from the Company will be mailed to the person(s) and address as shown. For joint Applicants, only one address can be entered.
- E. If you are sponsored in CHESS by a stockbroker or other CHESS participant, you may enter your CHESS HIN if you would like the allocation to be directed to your HIN.
- NB: your registration details provided must match your CHESS account exactly.**
- F. Complete **cheque details** as requested. Make your cheque payable to “**Cellscreen Direct Limited Float Account**”, cross it and mark it “**Not negotiable**”. Cheques must be made in Australian currency, and cheques must be drawn on an Australian Bank.
- G. Enter your **contact details** so we may contact you regarding your Application Form or Application Monies.
- H. Enter your **email address** so we may contact you regarding your Application Form or Application Monies or other correspondence.

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cellscreendirect

Cellscreendirect Limited ACN 133 796 488
Unit 40, 112 McEvoy Street Alexandria, NSW, 2015

www.cellscreendirect.com

This is a replacement prospectus dated 1 December 2008. It replaces a prospectus dated 27th November 2008, relating to shares of Cellscreendirect Limited.