

sienna  
CANCER DIAGNOSTICS

# PROSPECTUS

Sienna Cancer Diagnostics Limited

ACN 099 803 460

**OFFER OF 30 MILLION NEW SHARES IN SIENNA CANCER DIAGNOSTICS LIMITED  
AT \$0.20 PER SHARE TO RAISE A MINIMUM OF \$4 MILLION AND  
A MAXIMUM OF \$6 MILLION**

**THIS OFFER IS NOT UNDERWRITTEN**

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#### IMPORTANT INFORMATION:

This is an important document and it should be read in its entirety. If after reading this Prospectus, you do not fully understand it or the rights attaching to the Shares offered by it, you should consult an accountant, solicitor or other professional adviser for assistance. The Shares offered by this Prospectus should be considered speculative.



LEAD MANAGER



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# SECTION 1

## IMPORTANT NOTICES



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## SECTION 1

### IMPORTANT NOTICES

#### Offer

The Offer contained in this Prospectus is an invitation to acquire fully paid ordinary shares ("**Shares**") in Sienna Cancer Diagnostics Limited ACN 099 803 460 ("**Sienna**" or "**Company**").

#### Lodgement and listing

This Prospectus is dated 25 May 2017 ("**Prospectus Date**") and a copy was lodged with the Australian Securities and Investments Commission ("**ASIC**") on that date. The Company will apply to ASX Limited ("**ASX**") within seven days after the Prospectus Date for admission of the Company to the official list of the ASX and quotation of its Shares on the ASX. Neither ASIC, ASX nor their officers take any responsibility for the content of this Prospectus or for the merits of the investment to which this Prospectus relates.

#### Note to Applicants

The information in this Prospectus is not financial product advice and does not take into account your investment objectives, financial situation or particular needs. It is important that you read this Prospectus carefully and in its entirety before deciding whether to invest in the Company. In particular, you should consider the risk factors that could affect the performance of Sienna. You should carefully consider these risks in light of your personal circumstances (including financial and tax issues) and seek professional guidance from your stockbroker, solicitor, accountant or other independent professional adviser before deciding whether to invest in Shares. Some of the key risk factors that should be considered by prospective investors are set out in Section 14. There may be risk factors in addition to these that should be considered in light of

your personal circumstances. You should also consider the assumptions underlying the financial information and the risk factors that could affect Sienna's business, financial condition and results of operations. No person named in this Prospectus, nor any other person, guarantees the performance of Sienna or the repayment of capital or any return on investment made pursuant to this Prospectus.

#### No offering where offering would be illegal

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. No action has been taken to register or qualify the new Shares or the Offer, or to otherwise permit a public offering of the new Shares in any jurisdiction outside Australia and New Zealand. The distribution of this Prospectus outside Australia and New Zealand may be restricted by law and persons who come into possession of this Prospectus outside Australia and New Zealand should seek advice on and observe any such restrictions. Any failure to comply with such restrictions may constitute a violation of applicable securities laws. This Prospectus has been prepared for publication in Australia and New Zealand and may not be released or distributed in the United States. This Prospectus does not constitute an offer to sell, or a solicitation of an offer to buy, securities in the United States. The new Shares and Existing Shares have not been, and will not be, registered under the US Securities Act or the securities laws of any state of the United States, and may not be offered or sold in the United States, or to or for the account or benefit of a US Person, except in a transaction exempt from the registration requirements of the

US Securities Act and applicable United States state securities laws. The Offer is not being extended to any investor outside Australia or New Zealand, other than to institutional investors as part of the Offer.

#### Important notice to New Zealand Investors

This Offer to New Zealand investors is a regulated offer made under Australian and New Zealand law. In Australia, this is Chapter 8 of the Corporations Act and regulations made under the Corporations Act. In New Zealand, this is subpart 6 of Part 9 of the Financial Markets Conduct Act 2013 and Part 9 of the Financial Markets Conduct Regulations 2014. This Offer and the contents of the Prospectus are principally governed by Australian rather than New Zealand law. In the main, the Corporations Act and the regulations made under the Corporations Act set out how the offer must be made.

There are differences in how financial products are regulated under Australian law. For example, the disclosure of fees for managed investment schemes is different under the Australian regime. The rights, remedies, and compensation arrangements available to New Zealand investors in Australian financial products may differ from the rights, remedies, and compensation arrangements for New Zealand financial products. Both the Australian and New Zealand financial markets regulators have enforcement responsibilities in relation to this Offer. If you need to make a complaint about this Offer, please contact the Financial Markets Authority, New Zealand (<http://www.fma.govt.nz>). The Australian and New Zealand regulators will work together to settle your complaint.

The taxation treatment of Australian

financial products is not the same as for New Zealand financial products. If you are uncertain about whether this investment is appropriate for you, you should seek the advice of an appropriately qualified financial adviser. The Offer may involve a currency exchange risk. The currency for the financial products is not New Zealand dollars. The value of the financial products will go up or down according to changes in the exchange rate between that currency and New Zealand dollars. These changes may be significant. If you expect the financial products to pay any amounts in a currency that is not New Zealand dollars, you may incur significant fees in having the funds credited to a bank account in New Zealand in New Zealand dollars. If the financial products are able to be traded on a financial product market and you wish to trade the financial products through that market, you will have to make arrangements for a participant in that market to sell the financial products on your behalf. If the financial product market does not operate in New Zealand, the way in which the market operates, the regulation of participants in that market, and the information available to you about the financial products and trading may differ from financial product markets that operate in New Zealand.

### **Financial information presentation**

Section 10 sets out in detail the financial information referred to in this Prospectus. The basis of preparation of that information is set out in Section 10.7. All financial amounts contained in this Prospectus are expressed in Australian dollars unless otherwise stated. Any discrepancies between totals and sums of components in tables contained in this Prospectus are due to rounding.

This Prospectus contains forward looking statements which are identified by words such as “may”, “could”, “believes”, “estimates”, “expects”, “intends” and other similar words that involve risks and uncertainties. Any forward looking statements are subject to various risk factors that could cause Sienna’s actual results to differ materially from the results expressed or anticipated in these statements. Forward looking statements should be read in conjunction with risk factors as set out in Section 14 and other information in this Prospectus.

### **Disclaimer**

No person is authorised to give any information or to make any representation in connection with the Offer described in this Prospectus which is not contained in this Prospectus. Any information not so contained may not be relied upon as having been authorised by the Company or any other person in connection with the Offer. You should rely only on information in this Prospectus.

It is expected that the Shares will be quoted on the ASX initially on a deferred settlement basis. Sienna, the Lead Manager, and the Share Registry disclaim all liability, whether in negligence or otherwise, to persons who trade Shares before receiving their holding statement.

### **Exposure Period**

The Corporations Act prohibits Sienna from processing Applications in the seven day period after the date of Prospectus Lodgement (“**Exposure Period**”). The Exposure Period may be extended by ASIC by up to a further seven days. The purpose of the Exposure Period is to enable the Prospectus to be examined by market participants prior to the raising of funds. Applications received during

the Exposure Period will not be processed until after the expiry of the Exposure Period. No preference will be conferred on any Applications received during the Exposure Period.

### **Obtaining a copy of this Prospectus**

A copy of the Prospectus is available free of charge to Australian and New Zealand resident investors during the Offer Period:

- By calling Sienna on 03 8288 2141 (within Australia) or +61 3 8288 2141 (outside Australia) from 9.00am until 5.00pm AEST, Monday to Friday, during the Offer Period.
- Via email request to [info@siennadiagnostics.com.au](mailto:info@siennadiagnostics.com.au).
- In electronic format at the Offer website: [siennadiagnostics.com.au/ipo](https://siennadiagnostics.com.au/ipo)  
The Offer constituted by this Prospectus in electronic form is available only to Australian or New Zealand residents accessing the website from Australia or New Zealand. It is not available to persons in the United States. Persons who access the electronic version of this Prospectus should ensure that they download and read the entire Prospectus.

Applications for new Shares may only be made on the appropriate Application Form attached to, or accompanying, this Prospectus in its paper copy form, or in its electronic form. By making an Application, you declare that you were given access to the Prospectus, together with an Application Form. The Corporations Act prohibits any person from passing the Application Form on to another person unless it is attached to, or accompanied by, this Prospectus in its paper copy form or the complete and unaltered electronic version of this Prospectus.

## SECTION 1 IMPORTANT NOTICES

### Defined terms and abbreviations

Defined terms and abbreviations used in this Prospectus are explained in Section 17 – Glossary. Unless otherwise stated or implied, references to times in this Prospectus are to AEST.

### Privacy

By completing an Application Form, you are providing personal information to the Company, and the Share Registry which is contracted by the Company to manage Applications. The Company, and the Share Registry on their behalf, collect, hold and use that personal information to process your Application, service your needs as a Shareholder, provide facilities and services that you request and carry out appropriate administration.

Once you become a Shareholder, the Corporations Act and Australian taxation legislation require information about you (including your name, address and details of the Shares you hold) to be included in Sienna's public register. The information must continue to be included in Sienna's public register if you cease to be a Shareholder. If you do not provide all the information requested, your Application Form may not be able to be processed. The Company and the Share Registry may disclose your personal information for purposes

related to your investment to their agents and service providers including those listed below or as otherwise authorised under the Privacy Act 1988 (Cth):

- The Share Registry for ongoing administration of the Shareholder register;
- The Lead Manager in order to assess your Application;
- Printers and other companies for the purpose of preparation and distribution of documents and for handling mail;
- Market research companies for the purposes of analysing the Company's shareholder base and for product development and planning; and
- Legal and accounting firms, auditors, management consultants and other advisers for the purpose of administering, and advising on, the Shares and for associated actions.

You may request access to your personal information held by or on behalf of the Company. You can request access to your personal information or obtain further information about Sienna's privacy practices by contacting the Share Registry or Sienna. Sienna aims to ensure that the personal information it retains about you is accurate, complete and up-to-date. To assist with this, please contact Sienna

or the Share Registry if any of the details you have provided change. In accordance with the requirements of the Corporations Act, information on the Shareholder register will be accessible by members of the public.

### Syndicate structure

Sequoia Corporate Finance Pty Ltd ("**Sequoia Corporate Finance**") is the Lead Manager to the Offer.

### Photographs and diagrams

Photographs used in this Prospectus which do not have descriptions are for illustration only and should not be interpreted to mean that any person endorses this Prospectus or that assets shown in them are owned by the Company. Diagrams used in this Prospectus are illustrative only and may not be drawn to scale. Unless otherwise stated, all data contained in graphs, charts and tables is based on information available as at the date of this Prospectus.

### If you have any questions

If after reading this Prospectus, you do not fully understand it or the rights attaching to the new Shares offered by it, you should consult an accountant, solicitor or other professional adviser for assistance. The Company is unable to advise applicants on the suitability or otherwise of an investment in the Company.

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THIS DOCUMENT IS  
IMPORTANT AND SHOULD  
BE READ IN ITS ENTIRETY

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# SECTION 2

## KEY OFFER INFORMATION



## SECTION 2

### KEY OFFER INFORMATION

#### The Offer

Sienna Cancer Diagnostics Limited ACN 099 803 460 is seeking to raise up to \$6 million by the issue of up to 30 million new Shares at an Offer Price of \$0.20 per Share.

Following the completion of the Offer the shareholding structure\* in Sienna will be as follows:

Category	Based on the Maximum Subscription of \$6 million
Existing Shares	<b>157,274,327</b>
New Shares offered under this Prospectus	<b>30,000,000</b>
Total number of Shares on completion of the Offer**	<b>187,274,327</b>
Offer Price	<b>\$0.20</b>
Gross proceeds from the Offer	<b>\$6,000,000</b>
Indicative market capitalisation at the Offer Price	<b>\$37,454,865</b>

\* Sienna had 2,273,314 shareholder options on issue at the date of this Prospectus. Further details of shareholder options are provided at Section 16 (b). The Company also operates an Employee Share Option Plan (ESOP). There were 10,530,000 options on issue under this ESOP at the date of the Prospectus. Details of the ESOP are provided at Section 16 (i).

\*\* The percentage of Shares in the total share capital of the Company available at Listing for investors to freely trade in the public market (i.e. "free float") will be at least 20% based on the Minimum Subscription and Maximum Subscription.

#### Indicative Key Dates\*\*\*

Prospectus lodged with ASIC	<b>25 May 2017</b>
Exposure Period	<b>25 May to 8 June 2017</b>
Opening Date	<b>9 June 2017</b>
Closing Date	<b>17 July 2017</b>
Expected date for allocation of Sienna Shares	<b>31 July 2017</b>

\*\*\* These dates are indicative only and may change. The Company reserves the right to amend any and all of the above dates without notice to you including (subject to the ASX Listing Rules and the Corporations Act), to close the Offer early, to extend the Offer, to accept late Applications, either generally or in particular cases, or to withdraw the Offer before settlement. If the Offer is withdrawn before the issue of the Shares, then all Application monies will be refunded in full (without interest) as soon as practicable in accordance with the requirements of the Corporations Act.

# SECTION 3

## MESSAGE FROM THE CHAIRMAN



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### SECTION 3

#### MESSAGE FROM THE CHAIRMAN



**Dr Geoffrey Cumming**  
Non-executive Chairman

Dear Investor

On behalf of the Board of Directors, it is with great pleasure that I present this Prospectus and invite you to become a shareholder in Sienna Cancer Diagnostics Limited (Company or Sienna).

This Prospectus offers subscription Shares in the Company at \$0.20 per share to raise a minimum of \$4 million and up to a maximum of \$6 million.

Sienna is a public company, with its head office in Melbourne, Australia and in-country operations in Australia and the United States. The Company's focus is on the development and commercialisation of innovative products that address unmet clinical needs for the characterisation or evaluation of samples being investigated for the presence of cancer, to aid in the diagnosis or monitoring of disease. The recent commercialisation of the Company's novel in vitro diagnostic (IVD) to detect the hTERT component of telomerase is a validation of the Company's core competency. With initial application as an adjunct test to urine cytology to assist bladder cancer diagnosis, the test has well defined clinical utility. Sienna intends to continue to develop and commercialise the Company's intellectual property using its internal resources and expertise, and a network of global strategic partners.

This Prospectus highlights the intellectual property owned and licensed by the Company (in the Patent Report contained in Section 13) and its potential portfolio of products.

As is commonly the case with biotechnology companies, an investment in Sienna carries significant risks. In addition to commercialisation risks and intellectual property risks, there are other material risks associated with investing in the Company. The main risk factors associated with an investment pursuant to this Prospectus are highlighted in Section 14. I encourage you to read the Prospectus in its entirety before making an investment decision.

The closing date for application and payment is 5:00pm AEST on 17 July 2017, unless the target subscription is reached earlier, or later as determined by the Directors.

On behalf of the Directors, I look forward to your support and participation as a shareholder.

Yours faithfully

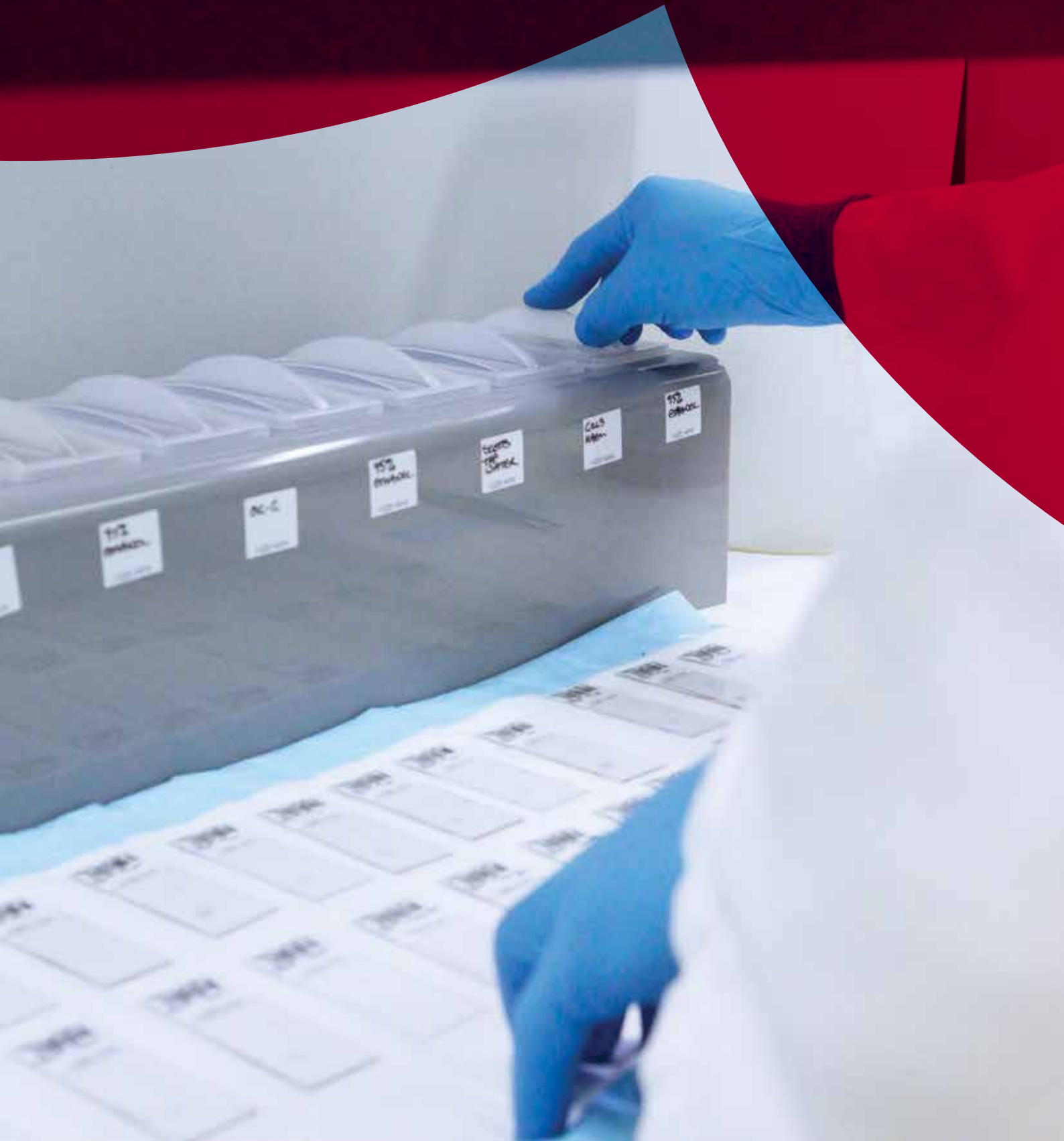
A handwritten signature in dark ink, appearing to read 'G. Cumming', written in a cursive style.

**Dr Geoffrey Cumming**  
Non-executive Chairman



# SECTION 4

## INVESTMENT OVERVIEW



## SECTION 4 INVESTMENT OVERVIEW

This section is a summary only of the information contained in this Prospectus. Investors should consider this Prospectus in its entirety.

Topic	Details	Where to find more information
<b>A. Introduction</b>		
<b>Who is Sienna?</b>	<p>Sienna is an Australian company whose goal is identifying, developing and commercialising innovative and novel diagnostic technologies which satisfy an unmet clinical and market need in the detection, characterisation and monitoring of cancer.</p> <p>Diagnostics tests can provide early detection of a number of diseases or conditions, which can lead to better patient outcomes following treatment. Sienna has developed an in vitro diagnostic (“IVD”) test to detect human <u>T</u>elomerase <u>R</u>everse <u>T</u>ranscriptase (“hTERT”) in clinical samples. hTERT is a component of the telomerase enzyme complex which acts to extend and maintain telomeres in cells, and thereby plays a fundamental role in cell proliferation and cellular ageing.</p> <p>Importantly, telomerase is up-regulated in nearly all epithelial cancer cells<sup>1,2</sup> and it is this fact that underlies Sienna’s first IVD product. Sienna has registered with the Food &amp; Drug Administration (FDA) in the USA, an antibody called “Anti-hTERT Antibody (SCD-A7)”, which is being used by pathology laboratories to identify the presence of hTERT. The first application of this technology is addressing an unmet clinical need in the assessment of urine samples being investigated for bladder cancer.</p>	Section 5
<b>What is the Offer Price and total to be raised?</b>	The Offer Price is \$0.20 per Share, with a target raise of a minimum of \$4 million and a maximum of \$6 million.	Section 2
<b>What is the purpose of the Offer and how will the proceeds of the Offer be used?</b>	<p>The primary purpose of the Offer is to raise funds to:</p> <ul style="list-style-type: none"> <li>• support the Company’s Expenditure Program;</li> <li>• achieve listing on the ASX, to broaden the shareholder base and provide a market for the Shares;</li> <li>• provide working capital;</li> <li>• pay the expenses of the Offer.</li> </ul>	

Topic	Details	Where to find more information	
Use of funds	It is intended that the funds raised under this Offer will be used with the objectives being to grow revenues, advance the development of additional clinical applications for the hTERT antibody and source/develop additional technologies for the Sienna product pipeline.		

Topic	Details	Where to find more information
<b>Working capital</b>	On completion of the capital raising under this Prospectus, Sienna Cancer Diagnostics will have sufficient working capital to carry out its stated objectives as detailed in this Prospectus.	
<b>Is the Offer underwritten?</b>	The Offer is not underwritten.	
<b>Dividend policy</b>	<p>The Directors do not envisage that the Company will be in a position to declare any dividends in the foreseeable future.</p> <p>The financial prospects of the Company are dependent on several factors, including without limitation successful completion of its product development, clinical/scientific trials, regulatory filings and market penetration of its lead products.</p> <p>There is no guarantee in regards to the rate of market uptake of Sienna's initial product offering, or that the Company's development work will result in any further commercial applications utilising Sienna's intellectual property. In light of these factors and having regard to ASIC Regulatory Guide 170, the Directors consider at this stage the Company is unable to provide potential investors with reliable revenue or profit forecasts, and no dividends should be expected in the short term.</p>	
<b>Taxation considerations</b>	The tax treatment and consequences of the Offer will vary depending on the particular circumstances of the Applicant. The Company accepts no liability or responsibility in relation to any taxation consequences connected to the Offer. Therefore, regarding the appropriate tax treatment that applies to the Offer, it is the responsibility of Applicants who make an Application to satisfy themselves by consulting their own professional tax advisers prior to investing in the Company.	Section 15
<b>ASX listing application</b>	<p>Not later than 7 days after the date of this Prospectus, an application will be made to the ASX for Sienna to be admitted to the Official List of the ASX and for the Official Quotation of the Shares. The fact that the ASX may admit Sienna to its Official List is not to be taken in any way as an indication of the value or merits of Sienna or of the Shares offered under this Prospectus.</p> <p>Official Quotation, if granted, will commence as soon as practicable after the issue of transaction holding Statements to successful Applicants. If permission for quotation of the Shares is not granted within 3 months after the date of this Prospectus, all Application money will be refunded without interest.</p>	



Topic	Details	Where to find more information																		
B. Key Financial Information																				
What is the key financial information of the Company?	The summarised pro forma statement of financial position of Sienna after the Offer, assuming a maximum subscription, is set out below:	Section 11																		
	<table><tr><th>As at 31 December 2016</th><th>Pro forma \$</th></tr><tr><td>Total Current Assets</td><td>7,033,833</td></tr><tr><td>Total Non-Current Assets</td><td>2,350,471</td></tr><tr><td><b>Total Assets</b></td><td><b>9,384,304</b></td></tr><tr><td>Total Current Liabilities</td><td>492,853</td></tr><tr><td>Total Non-Current Liabilities</td><td>15,166</td></tr><tr><td><b>Total Liabilities</b></td><td><b>508,019</b></td></tr><tr><td><b>Net Assets</b></td><td><b>8,876,285</b></td></tr><tr><td><b>Total Equity</b></td><td><b>8,876,285</b></td></tr></table>	As at 31 December 2016	Pro forma \$	Total Current Assets	7,033,833	Total Non-Current Assets	2,350,471	<b>Total Assets</b>	<b>9,384,304</b>	Total Current Liabilities	492,853	Total Non-Current Liabilities	15,166	<b>Total Liabilities</b>	<b>508,019</b>	<b>Net Assets</b>	<b>8,876,285</b>	<b>Total Equity</b>	<b>8,876,285</b>	
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	<b>Net Assets</b>	<b>8,876,285</b>																		
<b>Total Equity</b>	<b>8,876,285</b>																			

Topic	Details	Where to find more information
C. Key Strengths and Opportunities		
Investment highlights	<p>Key investment highlights:</p> <p><b>Established Business</b></p> <ul style="list-style-type: none"> <li>• Immediate access to market for Sienna’s existing IVD test in the bladder cancer application via distribution partners (in the United States of America (USA), the United Kingdom and Switzerland) to pathology laboratories</li> <li>• Patient healthcare reimbursement already established in the USA for Sienna’s IVD test</li> <li>• Experienced Board and management team</li> </ul> <p><b>Commercialised Intellectual Property</b></p> <ul style="list-style-type: none"> <li>• Sienna’s existing intellectual property and technology is already being utilised in a limited number of commercial laboratories</li> <li>• Patent protected technology</li> </ul> <p><b>Existing Revenue</b></p> <ul style="list-style-type: none"> <li>• Existing revenue with the opportunity for incremental growth in the near term</li> </ul> <p><b>Growth Opportunities</b></p> <ul style="list-style-type: none"> <li>• Large addressable global market</li> <li>• Platform technology with potentially broad utility</li> <li>• Alignment of business model with current market dynamics, driving a low threshold for adoption: <ul style="list-style-type: none"> <li>– Revenue and profit driver for pathology laboratories</li> <li>– Complementary rather than competitive to existing products marketed by diagnostics companies</li> </ul> </li> </ul> <p><b>Regulatory Approvals</b></p> <ul style="list-style-type: none"> <li>• Major regulatory milestones achieved with existing registration in the USA, the EU and Australia</li> </ul>	Section 6

Topic	Details	Where to find more information
<b>Market</b>	<p>Sienna's product is positioned for the global IVD market for use in pathology laboratories.</p> <ul style="list-style-type: none"> <li>The revenue for cancer diagnostics in the USA in 2014 was \$5.6 billion.<sup>3</sup></li> <li>Sienna's initial target segment is the urine cytology market. Once the Company is further established in this market it intends, subject to available funding, to expand into the broader cytology market. Sienna believes there are between 1.3 and 1.6 million urine cytology tests performed each year in the United States alone.<sup>4</sup> Each of those tests is a target for an adjunct test using Sienna's product. At an average reimbursement price to the laboratory customer of USD108.38 for each adjunct test performed, Sienna has the ability to participate in a market valued over USD140 million in the USA in the application of bladder cancer. Sienna's business model is to receive a proportion of the reimbursement through product sales (via its distribution partner) to the laboratory performing the test.</li> <li>With the USA representing approximately 42% of the global cytology based IVD market,<sup>5</sup> Sienna estimates there are approximately 3.5 million urine cytology tests performed globally<sup>3,4</sup> which further expands the opportunity for increased sales.</li> <li>If Sienna successfully develops and validates additional cytology applications for its telomerase based product, the global market opportunity will expand.</li> <li>Sienna intends (subject to available funding) to research further expansion of its telomerase technology into immunohistochemistry (IHC) tissue based applications, which has the potential to significantly expand the market opportunity.</li> <li>Sienna intends to pursue additional technologies, such as new biomarkers, with a view to in-licensing or directly acquiring these technologies, enabling product pipeline and portfolio expansion.</li> </ul>	Section 6

Topic	Details	Where to find more information
<b>Experienced executive team</b>	<p>Sienna's executive management team has a depth of experience in biotechnology:</p> <p><b>Matthew Hoskin, Chief Executive Officer (CEO)</b> – Over 20 years' experience leading business in the biotech and healthcare sectors. Direct experience in the pathology diagnostics industry with Vision Biosystems and Leica Biosystems.</p> <p><b>Tony Di Pietro, Chief Financial Officer (CFO) and Company Secretary</b> – Formerly CFO of an ASX listed entity, a CPA with over 15 years of corporate accounting experience.</p>	Section 9
<b>D. Key Risks</b>		
<b>Speculative nature of investment</b>	<p>The new Shares to be issued pursuant to the Prospectus carry no guarantee with respect to the payment of dividends, return of capital or the market value of those Shares. Sienna applies its cash reserves to the development and commercialisation of its technology, and the Company's success will be largely dependent on the results of that development and commercialisation. An investment in Sienna's Shares should therefore be considered speculative with the risk of loss of capital.</p>	Section 14
<b>Sufficiency of funding</b>	<p>Sienna believes that with the minimum raising of \$4M from this Initial Public Offering (IPO), the Company will have sufficient capital resources to fulfil the requirements for funding over the next 18 months.</p> <p>It should be noted, however, that Sienna may need to raise additional funds from time to time. In certain circumstances, the Company's ability to successfully operate may be subject to its ability to raise additional funds, which will be subject to factors beyond the control of the Company and its Directors (including without limitation cyclical factors affecting the economy and financial and share markets generally).</p>	Section 14.2 (a)
<b>Expenditure Program</b>	<p>Sienna has not entered into contracts for a number of the material items covered by the Expenditure Program nor does it have binding quotations in relation to such items. Rather the Directors have determined that following the successful close of the Offer, Sienna will be well positioned to negotiate the exact terms for such contracts. Sienna has some indicative quotations for major expenditure items. The Directors and management team have extensive experience in the diagnostics and healthcare industry and have prepared the anticipated expenditure based on discussions with potential suppliers of those services, and their own experience of the likely costs for those expenditure items. While the Directors are confident Sienna will be able to source suitable suppliers, there is a risk that the Company may not be able to source those suppliers at the estimated expenditure.</p>	Section 14.2 (b)



Topic	Details	Where to find more information
<b>Intellectual property</b>	<p>As noted in the Patent Report in Section 13, certain of Sienna's patent applications are subject to review and may not be granted. The examiner has queried whether there is an inventive step in developing the subject matter of the patent application (which is a critical component in determining whether to grant a patent application). Sienna has intellectual property in the form of a licence from Geron Corporation for the use of hTERT in human diagnostics, plus a licence from Dana-Farber Cancer Institute to biological materials used by Sienna in the production of its product.</p> <p>There is no guarantee that the Company's patent applications will be granted or that the Company's owned and licensed patent rights comprise all the rights that the Company ought to have acquired to be entitled to freely use and commercialise its products. Further, there may be a legal challenge to any patent within the Sienna intellectual property portfolio. A loss of any material part of Sienna's intellectual property portfolio (for example where there is a challenge to Sienna's intellectual property rights) could adversely impact Sienna's development and commercialisation activities.</p>	Section 14.3
<b>Regulatory requirements</b>	<p>Regulatory bodies and the requirements they impose on the registration of medical devices, including IVD tests, are complex and vary by region. Registration can be a lengthy process, where for example prior determinations made by other regulatory bodies are not determinative of the decision reached by a new regulatory authority.</p> <p>Sienna has registered its first in-market product as a Class 1 IVD in the USA, a CE marked / General Class IVD in the EU, and a Class 2 IVD in Australia. There is no guarantee that regulatory approval or registration in these countries will not be revoked at some future time.</p> <p>Despite registration in the USA, commercial success significantly depends on the uptake of the IVD test (its use in laboratories) in the USA.</p>	Section 14.2 (c)
<b>Key personnel</b>	<p>Sienna currently employs, or engages as consultants, several key members of its management and scientific team. The loss of any of these people's services could materially and adversely affect the Company and may impede the achievement of its research, product development and commercialisation objectives.</p> <p>The successful development of the Company will require the services of additional staff. There can be no assurance that the Company will be able to attract appropriate additional staff and this may adversely affect the Company's prospects for success.</p>	Section 14.2 (d)
<b>No independent valuation</b>	<p>No independent valuation of the Company's intellectual property, or generally the Company's Shares, has been carried out for the purposes of this Prospectus.</p>	Section 14.4 (a)

## SECTION 4 INVESTMENT OVERVIEW

Topic	Details	Where to find more information
<b>E. Summary of the Offer</b>		
<b>Opening and closing of the Offer</b>	Applications may be lodged at any time after the Opening Date until 5.00 pm (AEST) on the Closing Date.	Section 2
<b>Minimum subscription</b>	Sienna has determined that the minimum amount to be raised under this Prospectus is \$4 million (being 20 million ordinary Shares at 20 cents). If this minimum amount is not raised all Application money will be refunded in full (without interest).	Section 2
<b>Allocation policy</b>	<p>The Company reserves the right to authorise the issue of a lesser number of Shares than those for which Application has been made or to reject any Application. Where no issue or allocation is made, or the number of Shares issued is less than the number applied for, surplus Application money will be refunded (without interest).</p> <p>If an Application Form is not completed correctly, or if the accompanying payment is for the wrong amount, it may still be treated as valid. The Company's decision as to whether to treat an Application as valid, and how to construe, amend or complete it, will be final. The Company's decision on the number of Shares to be allocated to an Applicant will also be final.</p>	
<b>What are the costs of the Offer?</b>	The maximum costs of the Offer are estimated to be \$723,000 (exclusive of any applicable GST) based on the maximum raising under this Prospectus. These costs will be paid by the Company out of the proceeds of the Offer and existing cash reserves.	
<b>Are there additional costs payable by the Applicant?</b>	No brokerage, commission, stamp duty or any other costs are payable by Applicants on acquisition of the Shares under the Offer.	
<b>F. Non-executive Directors</b>		
<b>Who are the Directors of Sienna?</b>	Dr Geoffrey Cumming – Non-executive Chairman Dr David Earp – Non-executive Director Mr Carl Stubbings – Non-executive Director Dr John Chiplin – Non-executive Director	Section 9
<b>What are the interests of the Directors or related parties in Sienna?</b>	The interests of the Directors of Sienna (both direct and indirect) in the Company's securities, at the date of this Prospectus, and after the completion of the Offer, are outlined in Section 16.	Section 16 (k)

Topic	Details	Where to find more information
<b>G. Applications</b>		
<b>How do I apply for the new Shares?</b>	<p>By completing and submitting the valid Application Form accompanying this Prospectus. All Application money will be held on trust, in a separate bank account that has been opened only for this purpose, until the Shares to be issued under the Offer are issued and allotted, or the Application money is refunded to unsuccessful Applicants.</p> <p>Applications must be for at least 10,000 Shares at a subscription price of \$0.20 per Share or a greater number in multiples of 2,500 Shares at a subscription price of \$0.20 per Share. The Offer Price of \$0.20 per Share is payable in full on Application.</p> <p>Cheques must be in Australian currency and made payable to <b>"Sienna Cancer Diagnostics Limited – IPO Trust Account"</b> and crossed <b>"Not Negotiable"</b>.</p>	
<b>Lodgement of Applications</b>	<p>Applicants should return their completed Application Forms, and if paying by cheque, their cheque for the Application money to:</p> <p><b>For existing Shareholders</b></p> <p>Mailing Address: Sienna Cancer Diagnostics Limited C/- Link Market Services Limited GPO Box 3560, Sydney NSW 2001</p> <p>Hand Delivery: Sienna Cancer Diagnostics Limited C/- Link Market Services Limited 1A Homebush Bay Drive, Rhodes NSW 2138</p> <p><b>For new investors:</b></p> <p>Mailing Address Sienna Cancer Diagnostics Limited C/- Link Market Services Limited Locked Bag A14, Sydney South NSW 1235</p> <p>Hand Delivery Sienna Cancer Diagnostics Limited C/- Link Market Services Limited 1A Homebush Road Bay Drive, Rhodes NSW 2138</p>	
<b>Where can I find more information about this Prospectus or the Offer?</b>	<p>Further information can be obtained by reading this Prospectus in its entirety. For advice on the Offer you should speak to your stockbroker, accountant or other professional adviser. If you require assistance or additional copies of this Prospectus please contact the Company on (03) 8288 2141 (within Australia) or +61 3 8288 2141 (outside Australia).</p>	





# SECTION 5

## COMPANY OVERVIEW AND TECHNOLOGY



## 5.1 High Level Summary

Telomerase is recognised as an important biomarker in cancer. Approximately 85% of all human epithelial cancers (arising from tissue that lines the inner or outer surfaces of the body) up-regulate telomerase<sup>1,2</sup> as a mechanism to avoid cellular senescence (leading to death) and allow sustained cellular division and cancer growth.

Sienna believes that its IVD test is the first IVD registered test to detect the presence of hTERT (a component of the telomerase complex) in a range of cytology (the study of the structure or morphology of cells) samples. This test has been registered with the FDA (USA regulatory authority), the Medicines and Healthcare products Regulatory Agency (MHRA – a European regulatory authority) and the Therapeutic Goods Administration (TGA – Australian regulatory authority) for human clinical use.

The first application Sienna has commercialised for the telomerase test is as an adjunct to urine cytology to assist in the diagnosis of bladder cancer. Telomerase is up-regulated in 90% of bladder cancers.<sup>1,6</sup> This application was chosen as an initial target because of the high number of urine cytology tests performed each year and the significant unmet clinical need (urine cytology has traditionally had poor sensitivity in detecting bladder cancer, especially in low grade cancer<sup>7</sup>).

Sienna's IVD product was developed with the following key attributes to enable rapid access to the diagnostics market:

- It uses existing samples already being collected and sent to the laboratory (for example; urine samples are collected from patients being investigated for bladder cancer for urine cytology testing).
- It has been designed as an adjunct to existing non-invasive tests, providing further clinical evidence and therefore adding information to the testing already being undertaken, while not competing with those tests.
- The test does not require dedicated equipment. The format in which the test is provided allows it to be used on existing laboratory automated platforms, without the need to purchase expensive specialist equipment.
- It uses existing reimbursement codes in the USA related to immunohistochemistry (IHC)/immunocytochemistry (ICC) antibody testing.

The first commercial validation of Sienna's technology was through Bostwick Laboratories Inc. (Bostwick), a

large private pathology laboratory in the USA. Sienna signed a license agreement with this laboratory which allowed them to develop an in-house ICC stain, which has been in use since January 2015.

The registration of the new IVD product provides a significant market opportunity for Sienna. The Company believes that the USA bladder cancer detection market accounts for approximately 1.3 to 1.6 million urine cytology tests per year. This is only one clinical application for the test.

Supply and distribution agreements have been executed with partners in the USA, the UK and Switzerland, with additional partnerships being explored in a number of other countries.

Revenue growth may be achieved through:

- increased market penetration in the countries in which the product was recently launched.
- geographical expansion into additional countries across Europe, Asia and the rest of the world.
- expanding the clinical applications of the product into other cytology based samples for investigation of additional cancer types.
- research into further applications in the area of histology (the study of the structure of tissues as seen under a microscope) based samples.
- adding new products to the pipeline through in-license or acquisition of new biomarkers or other cancer related technologies.

Sienna has a skilled and capable team with strong internal resources which, when combined with the Company's partners, has the ability to deliver on our strategy.

## 5.2 Company Focus

Sienna's primary business focus is on innovative diagnostic technologies that can satisfy unmet clinical needs for the detection, characterisation or monitoring of cancer. Diagnostic products can provide vital clinical information, including early detection of diseases or conditions, and are the first step for clinicians in the patient care process.

Through its first product, Sienna believes that it is the first company to commercialise a clinical diagnostic technology for telomerase detection. Telomerase, an enzyme which is found in nearly all epithelial cancer cells, and whose discovery was the subject of a Nobel Prize in 2009<sup>8</sup>, is the basis of a unique biomarker used by Sienna to aid bladder cancer diagnosis.

### 5.3 Sienna's Technology and its Use

Sienna has achieved regulatory registration in the USA, Europe and Australia for a product called "Anti-hTERT Antibody (SCD-A7)", which can be used by pathology laboratories to identify the hTERT component of telomerase. Telomerase has an important role in cancer, which is outlined in Section 5.4 and 5.5.

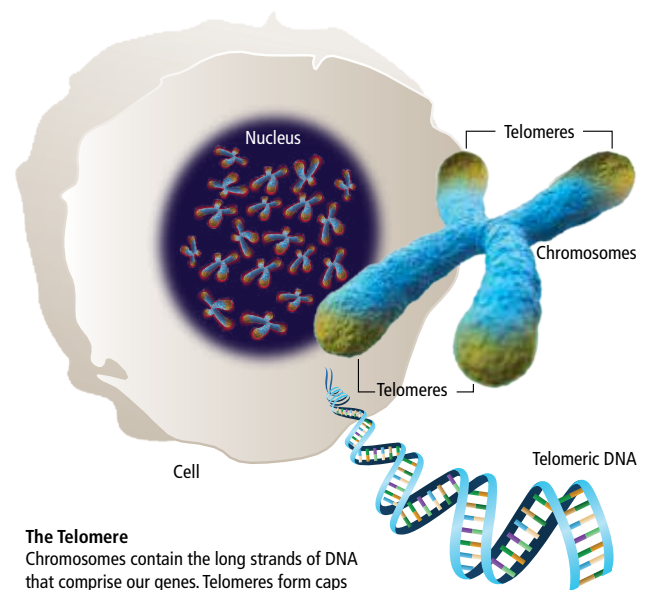
The Anti-hTERT Antibody and its use are part of the Company's proprietary technology and form the backbone of the telomerase diagnostic platform and intellectual property protections. This technology is subject to the intellectual property rights detailed in Section 13.

Sienna's antibody can detect the presence of hTERT in a range of cell types, including malignant (cancer) cells. A pathology laboratory uses the antibody in performing an assay to stain cells. This technique, known as immunocytochemistry (ICC), is a cell staining process used to detect the presence of a biomarker (in Sienna's case, the protein hTERT), thereby allowing visualisation and examination under a microscope. ICC is a valuable tool, routinely used by diagnostic laboratories for the determination of cellular contents. Samples that can be analysed include smears, aspirates, swabs, urine, cultured cells, and cell suspensions.

By utilising this technique, the laboratory clinician can evaluate whether or not cells in a particular sample contain the biomarker in question, hTERT. In cases where a positive signal is found, the test shows subcellular localisation, potentially assisting the referring physician in their diagnostic determination. Laboratory technicians use Sienna's test to detect the presence of hTERT in the cell nucleus of epithelial cells, which provides an indication that the cell is potentially cancerous.

### 5.4 Telomeres and Telomerase

Telomeres are DNA structures at the ends of chromosomes that act as protective caps. In humans, telomeres are involved in the stabilisation and protection of chromosomal ends, and the regulation of a cell's capacity to replicate. Telomeres shorten with each round of normal cell division. After several cell divisions, telomeres reach a critical length, forcing the cells to undergo senescence, which is correlated to physiological cell death. This system provides a "counting" mechanism to limit the number of times a normal cell can divide.



**The Telomere**  
Chromosomes contain the long strands of DNA that comprise our genes. Telomeres form caps at the end of the chromosomes.

Under some circumstances cells are able to divide without the penalty of progressive telomere shortening. In these situations, an enzyme called telomerase can catalyse the extension of telomeres by the addition of new DNA.

While studies have established modest levels of telomerase activity in normal proliferative tissues (such as bone marrow, tissue from the gastrointestinal tract and uterine endometrium), it is absent in normal somatic cells that do not need multiple cycles of cell division. In contrast, most malignant cancer cells of human cell populations contain high levels of telomerase activity;<sup>1</sup> this knowledge led Sienna to develop an IVD product that uses an anti-hTERT antibody to detect the presence of telomerase.

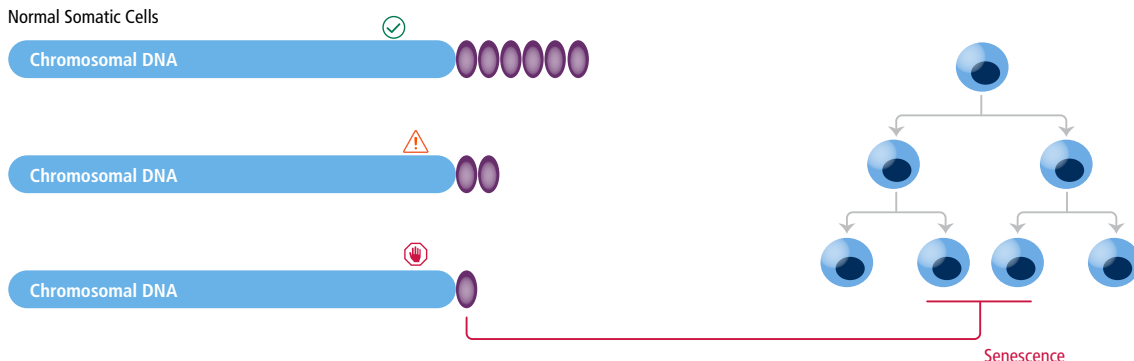
## 5.5 Telomerase in Cancer

Telomerase is well recognised as a remarkable molecule used by 80-90% of cancers<sup>1,9</sup> to enable immortal cell replication.

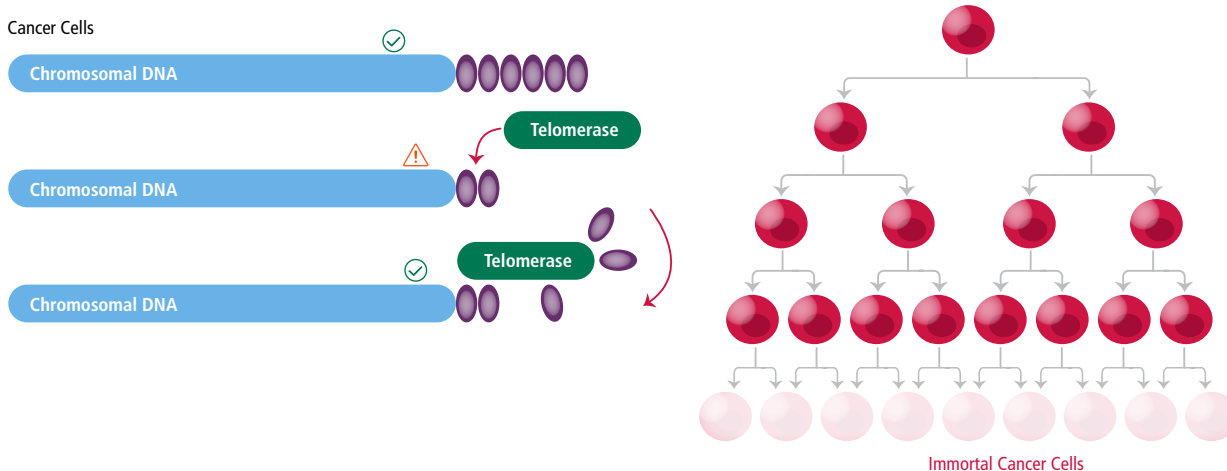
Telomere maintenance is regarded as an important mechanism by which tumour cells evade senescence (or cell death), and in most cases it is achieved by reactivating or up-regulating telomerase activity. Although the presence of telomerase is not necessarily the cause of cancer, its role in maintaining telomere length is thought to play a vital role in allowing the cancer to grow.<sup>10</sup>

### Regulation of telomere length in normal and cancer cells by telomerase<sup>11</sup>

#### a. Normal Somatic Cells



#### b. Cancer Cells



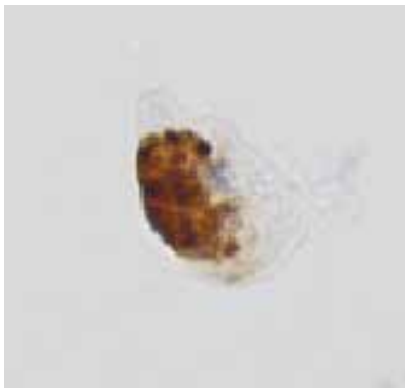
## 5.6 Antibodies and Immunocytochemistry (ICC)

The immune system identifies and neutralises foreign invaders such as bacteria and viruses, and this function is carried out by specialised white blood cells, called lymphocytes. A subset of these, B lymphocytes, have Y-shaped proteins called antibodies on their cell surface that bind pathogens and facilitate their elimination. Because antibodies have exquisite specificity for unique target molecules, this can be exploited as a tool to locate molecules of interest in biological specimens. In a diagnostic laboratory, antibody reagents are used to indicate the presence of molecules associated with various characteristics that may include disease processes within patient specimens.

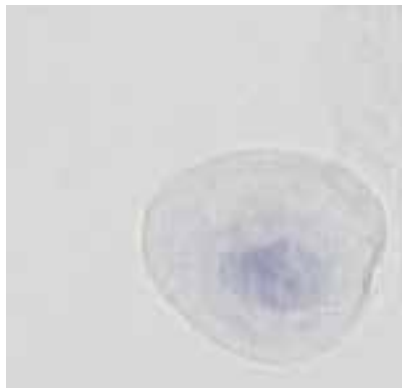
Immunocytochemistry (ICC) is a laboratory technique that uses antibodies to test for certain antigens (biomarkers) in a sample of cells. The antibodies are usually linked to an enzyme or a fluorescent dye. When the antibodies bind to the antigen in the cell sample, the enzyme or dye is activated, and the antigen can then be observed under a microscope. ICC is used to help diagnose diseases, such as cancer. It may also be used to help tell the difference between different types of cancer.

Sienna's test for telomerase, through the identification of hTERT, is conducted via this ICC technique.

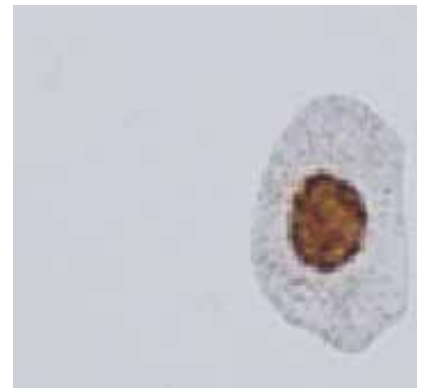
### Examples of stained cells viewed under a microscope:



A malignant cell with abnormal morphological appearance including irregular shape and an enlarged nucleus relative to the size of the cell. This cell has also stained positive for hTERT (indicated by the brown nucleus) using the Sienna antibody.



A normal cell with normal morphological appearance that is negative for hTERT using the Sienna antibody (indicated by the unstained nucleus).



A cell that appears to be normal from a morphological perspective but staining positive for the presence of telomerase using the Sienna antibody (indicated by the brown stained nucleus).





# SECTION 6

## MARKET OVERVIEW



## 6.1 Overall Market - Introduction

Cytology (cell) and histology (tissue) diagnostics is a large market (\$7.4 billion in 2013) for in vitro diagnostic (IVD) and other reagents used by clinical laboratories.<sup>12</sup> Cancer represents the largest disease application for which cytology and histology diagnostics are used.

Sienna's products are developed for the global cancer IVD market for use in pathology laboratories. The cancer IVD market is expected to reach USD8.3 billion by 2019 with a Compound Annual Growth Rate (CAGR) of approximately 8%.<sup>3</sup> The USA represents the single largest share of this market, followed by Europe, Japan, and then rest of world.<sup>3</sup>

Investors should note there is no guarantee as to what market share Sienna's existing IVD product may achieve or that Sienna will be able to commercialise IVD products in other cancer modalities. This reflects the commercialisation risk in investing in an early stage company.

## 6.2 Cytology and Histology Diagnostics Markets

Cytology and histology have been established segments of the in vitro diagnostics industry and clinical laboratory market for decades. Advances in research, and in drug discovery and development, are fuelling growth in clinical applications of cytology and histology diagnostics. Research is being undertaken to better understand the biological mechanisms and processes of disease. The results of this research are used to develop:

- new tests for diagnosis or prognosis
- new targeted therapies
- companion diagnostic tests to identify which patients will benefit from treatment with these new targeted therapies

Cytology and histology use assays for the identification of specific proteins, genes or mutations, or other molecules. These assays provide critically important information about:

- whether or not the specific protein or nucleic acid sequence is present
- whether a patient is infected with a specific pathogen
- whether biomarkers associated with malignancies are present
- whether tissue is diseased
- what type of disease may be present
- whether a tumour is benign or malignant

New platforms and assays, combined with an ageing population and increasing number of patients with cancer, will continue to fuel growth in the tissue and cell based diagnostic market.

## 6.3 Cytology and Histology Diagnostics Markets for Cancer

Cancer is an important area of cell and tissue diagnostics. Cancer testing makes up the majority of the overall IVD cell and tissue diagnostics market.<sup>12</sup> Examination of cells and tissue under a microscope to determine whether they are abnormal is a key part of the diagnosis of cancer. The role of cell and tissue diagnostics in oncology may be even more important in the future as tumour tissues are evaluated not just by the traditional histology tests used to diagnose cancer, but also for an increasing number of biomarkers to determine whether a patient's tumour expresses the protein target for new cancer therapies. Tissue diagnostic assays are also being developed and performed to address questions such as how aggressive a patient's cancer is likely to be, and the risk of recurrence.

Cancer immunoassays (tests to measure or identify tumour markers) play an important part in cancer testing. They detect proteins in the blood, urine, or other body fluids such as sputum, nipple aspirate, and semen. The presence of these proteins, or higher/lower than normal levels of the protein, may indicate an abnormal process in the body, such as cancer, and can provide further information if cancer is diagnosed. Doctors use tumour marker tests at various stages in patient care: for diagnosis, treatment monitoring and disease recurrence. Immunoassays play a major role in cancer IVD's, and with advances in protein research, are poised to increase in importance.

## 6.4 Cancer Rates

According to the World Health Organisation, non-communicable diseases (NCDs), such as cancer, heart disease and diabetes, kill 40 million people each year, claim more lives every year and account for approximately 70% of the world's deaths.<sup>13</sup>

Within the following westernised countries of the world: France, Germany, Italy, Japan, Spain, the UK and the USA, millions of people are diagnosed with cancer each year. Sales of cancer diagnostic products in these countries account for the majority of total worldwide sales. Thus the market for cancer tests is concentrated in the developed world, with the USA and Canada making up 50%, EU countries 18% and Japan 15%. The market



outside of these countries is a rapidly growing one, particularly in Asia.<sup>14</sup>

Cancer is generally considered to be a disease of ageing. With a greater proportion of the worldwide population moving into higher age brackets, particularly in westernised countries, and unhealthy lifestyle factors (such as reduced physical activity), the incidence of cancer is expected to rise. Some forecasters are expecting the current number of cancer-related cases to double by 2020.<sup>14</sup>

## 6.5 Our Current Business – Access to Market

Sienna secured its first commercial contract in 2014 with Bostwick, a strategically targeted uropathology laboratory in the United States. This laboratory purchased the Company's first product, SCD-A7, as an analyte specific reagent (ASR) for use in its own ICC stain. A significant number of stains have been performed since it was first offered in January 2015.

Sienna subsequently developed a new format for the reagent, making the product simpler to implement and use for the laboratory customer, deploying a manufacturing process that is more scalable from a volume production perspective, and compliant with anticipated future regulatory changes in Europe.

The new product format has now been registered for sale as an IVD product in the USA, Europe and Australia. This registration means any laboratory with the necessary equipment to perform IHC/ICC staining can purchase and use the product.

As SCD-A7 is an antibody for clinical diagnostic use, USA pathology laboratories which use the Sienna antibody in an ICC test are able to claim payment for the test via existing reimbursement codes within the USA healthcare system. This simplifies payment for the laboratory and facilitates the uptake of Sienna's new IVD product by more laboratories.

## 6.6 Further Business Opportunities – Expanding Our Markets

From the funds raised under this Prospectus, the Company intends to expand market opportunities by:

- Working with external clinical / scientific partners to complete and publish studies demonstrating the clinical utility of the IVD product as an adjunct to urine cytology for assisting bladder cancer diagnosis and monitoring.

- Carrying out sales and marketing activities to increase uptake in the USA, UK and Australian markets, where registration and channels to market already exist.
- Conducting research and development activities to expand the clinical utility of the product in different sample types to detect other cancers.
- Identifying and securing business development opportunities for:
  - Geographical expansion into additional countries with new distribution partners.
  - Technology expansion with additional intellectual property introduced into Sienna's pipeline through in-licensing or acquisition.

## 6.7 Clinical Use in an Existing Laboratory

A uropathology laboratory in the United States is currently performing hTERT testing on urine samples as an adjunct test to routine urine cytology for the identification and investigation of bladder cancer. In urine cytology there are a number of indeterminate or inconclusive tests (approximately 23%<sup>7</sup>), and the rate of detection for low grade malignancy is relatively poor,<sup>7</sup> representing an unmet medical need.

The recently launched IVD version of the Sienna antibody may be taken up by the pathology laboratory testing market as a tool for providing useful diagnostic information that is adjunctive to routine cytology testing.

## 6.8 The Business Model for Most US Pathology Laboratories

The core business model of US commercial pathology laboratories is based on the payment they receive for the testing services they perform. Competition is strong amongst pathology laboratories, with laboratories attempting to differentiate from their competition in areas such as:

- Quality of service
- Turnaround time
- Breadth of tests performed
- Ease of sample collection logistics and diagnostic report access

Pathology laboratories that adopt Sienna's product are offered the following advantages:

- Ability to provide additional information in the clinical report to the referring physician, over and above that reported from a regular cytology examination alone. This improved clinical report has the potential to drive

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## SECTION 6

### MARKET OVERVIEW

increased referrals for other tests performed by the laboratory.

- For each test performed using the Sienna IVD antibody, the laboratory receives additional revenue through reimbursement from payers (e.g. medical insurance providers). It does not replace an existing test, but forms an adjunct test that helps to grow the business of the laboratory.
- The Sienna IVD product is used on existing samples that are already collected for routine testing, so there are no additional collection costs or changes in clinical paradigm related to the acquisition of the sample.
- The Sienna IVD product uses existing laboratory equipment and ancillary reagents, utilising existing testing processes already in place with the laboratory.
- Better quality of service to referring physicians who are the laboratory's customers.

For these reasons, it is anticipated that the adoption of the Sienna IVD product by pathology laboratories will help them offer improved clinical information to their customers (the referring physicians) and in turn generate revenue and profit for the laboratory.

#### 6.9 Competitive Advantage

While there are several anti-hTERT antibodies available for use in research laboratories, Sienna believes it is the first and only company to register an anti-hTERT antibody for commercial use as an IVD product in clinical diagnostic laboratories. Sienna selected the antibody used in its product after evaluating other anti-hTERT antibodies, and secured an exclusive license to use this antibody for diagnostic purposes. Sienna invested significant resources into the development and optimisation of the staining process for this antibody on different staining platforms. Together with Sienna's patent position, this investment in technology development provides Sienna with the potential to achieve a strong market position for its IVD product.

Launching first as an ASR registered product then following with an IVD registered product provided Sienna with several significant advantages:

- The time to market for the first product was substantially shortened, and hence the commencement of first product revenues.
- It allowed valuable customer feedback on the use of the product in a working clinical laboratory environment, providing useful input for the design and specification of the future product format that was subsequently registered as an IVD.
- The value of the antibody as a clinical diagnostic adjunct to existing diagnostic tests was established by a large pathology laboratory operating in the competitive field of commercial pathology.
- Validation of the clinical utility of the Sienna ASR product by a leading uropathology laboratory has resulted in significant interest from other pathology laboratories seeking information on how they might gain access to the product.

In summary, Sienna's earlier ASR product not only generated early revenues for Sienna, but helped to prime the market for Sienna's IVD product, which is expected to assist penetration into the broader pathology market.

As Sienna's product fits into existing pathology laboratory workflows, it provides some significant advantages in the market:

- The Sienna antibody is designed to be compatible with existing automated-staining systems, such as the market-leading Roche Ventana platform. Running the Sienna test increases the use of these instruments along with their ancillary reagents, thereby increasing the revenue streams for the diagnostic companies that sell them. Tests using the Sienna antibody are seen as a value-adding adjunct, not a competitive threat to these diagnostic companies. This scenario creates an opportunity for leveraging the sales forces of the major diagnostic companies to help spread awareness of Sienna's product.
- The test uses a common technique (ICC) that pathology laboratories widely use, and therefore have equipment, staff expertise, and processes in place, making adoption of the new test easier.
- The test is performed on samples that are already being collected and sent to the laboratory for analysis via routine urine cytology. No new or additional sample collection is required, and no additional sample shipment is needed.
- The test does not disrupt other testing currently done in the laboratory. Referring physicians will still receive the same information they did previously, but it will be supplemented with additional useful clinical data. The existing revenue stream for the laboratory is maintained, and a new revenue stream for the additional test is established.
- The test makes use of an existing reimbursement code for IHC/ICC testing, so the purchasing laboratory can use established channels for payment.

## 6.10 Barriers to Market Entry for Directly Competitive Products

Translating telomerase into a biomarker of clinical utility is multifaceted. The telomerase enzymatic complex comprises:

- An RNA component (hTR), which acts as a template for DNA replication
- The human telomerase reverse transcriptase (hTERT), which is responsible for catalytic activity
- Accessory proteins, including dyskerin

Of the various telomerase components, Sienna has found that assaying for the hTERT subunit is the most practical and efficient way of detecting the telomerase enzymatic complex for clinical diagnosis. However, there are hurdles that any competitor would need to overcome in order to translate this into a commercially viable product:

**Patents** – Besides the in-licensing of global intellectual property protecting the use of telomerase detection in the field of clinical diagnosis, Sienna has filed its own patent for a method of use in clinical diagnostics for the resolution of indeterminate cytology results. Furthermore, Sienna has filed additional method-of-use patents to secure protection across an even broader field of diagnostic use. Competitors wishing to enter this space would face potential infringement of intellectual property licensed to or owned by Sienna.

**Clinical sample acquisition** – This is a complex, time consuming and slow process, but is necessary to producing a working antibody in the desired application. For samples to be collected for testing and research and development work, detailed research agreements and ethics applications are required, as are close partnerships with clinical entities (hospitals or pathology laboratories).

**cGMP production** – The proprietary process for the generation of SCD-A7 antibodies. For an antibody to be used in clinical diagnostics, it must be manufactured with full compliance to cGMP requirements and regulations. Many companies that supply Research Use Only (RUO) antibodies do not have the manufacturing capability or quality systems infrastructure to achieve cGMP compliance.

**Know-how** – To create a reproducible result for the antibody in a clinical environment. Different fixatives and different liquid based cytology (LBC) methods have significant impacts on clinical performance and must be thoroughly investigated. Similarly, developing the exact staining protocol required to produce reliable ICC results takes significant expertise and a substantial period of

time. Sienna has had to develop significant proprietary know-how in its work to bring the Sienna IVD to market.

**Regulatory approval** – To produce an IVD product, a company and the product must be fully compliant with multiple regulatory requirements and must go through a rigorous process of validation followed by registration/approval of the product by the regulatory authorities.

**Technical barriers** – Monoclonal antibody production involves a complex series of steps, including the screening of large numbers of candidate clones with each antibody being unique in both structure and function. A new anti-hTERT antibody would need to fulfil the following criteria:

- Specificity: Due to the unique characteristics of the hTERT molecule, the generation of highly specific antibodies has proven to be particularly challenging in the telomerase field.<sup>15</sup>
- Performance: All antibodies perform differently in a range of applications, including IHC, ICC, quantitative immunoassays, flow cytometry, Western blot and immunoprecipitation. A suitable candidate for ICC diagnosis would have to successfully identify the correct cell types in an ICC test.

## 6.11 Sienna's Target Market

Of the global cancer diagnostics market, the immunoassay and histology/cytology segments are the ones in which Sienna's product is anticipated to be utilised. These segments represent approximately 70% of the total market, or approximately USD5 billion per year.<sup>14</sup> This broader market segment in which Sienna will sell its products is a large, well established market.

As previously mentioned, an important initial application for Sienna's IVD product is as an adjunct to urine cytology in the bladder cancer testing market. Sienna believes there are 1.3 to 1.6 million urine cytology tests performed each year in the USA alone,<sup>4</sup> with a reimbursement of approximately USD108 per test.<sup>16</sup> This represents the urine cytology market for just one cancer type, bladder cancer, in one country, the USA. Given the prevalence of other cancer types relative to bladder cancer,<sup>17</sup> Sienna estimates the global cytology testing market, across all sample types, to be many times greater than that of urine cytology/bladder cancer testing alone.

Sienna's hTERT antibody has the required regulatory status for product sales in the USA, EU and Australia. Expansion of the potential market for the product into additional sample / cancer types beyond urine / bladder cancer in those regions requires further research and development, including protocol development, and the generation of supporting clinical data.





# SECTION 7

## REIMBURSEMENT AND REGULATORY STRATEGY



## 7.1 The US Reimbursement Model

In the USA, healthcare is paid for either by the consumer directly, or more commonly the payer is a third-party private or governmental insurer. Before approving a new medical technology for reimbursement, private and governmental payers analyse clinical and economic data to determine the clinical value and cost-effectiveness as compared to other available products and procedures. Coding systems are assigned and used by payers to track products and procedures and are used as a payment mechanism for reimbursement to the healthcare provider.

Within the USA, there is an existing reimbursement mechanism for specimen examination via ICC. For a single antibody test via ICC or IHC, code 88342 is used and attracts the following average reimbursement amount:

- Immunohistochemistry (1st stain) – Global (combined Technical Component (TC) and Professional Component (PC)) = USD108.38, (Exact amount of reimbursement for this code varies by state, but the above figure is the national average)<sup>16</sup>

## 7.2 Regulatory Landscape

Regulatory bodies and the requirements they impose on the registration of medical devices including IVD tests, vary by region.

Most countries have their own specific regulatory systems that take little heed of other country regulations or the status of products registered in other regions. The USA, China and Japan are examples of these independent regulatory environments.

Countries within the EU adhere to a single, common set of regulatory requirements, with translational requirements being the main difference between countries.

Australia, New Zealand, Canada and several Asian countries have their own regulatory authorities and sets of requirements, but recognise the registration of medical devices in other regions, namely the EU, as acceptable evidence and grounds for registration, usually with minimal additional requirements.

## Sienna Regulatory Pathway Summary

- a. USA: Any product sold for clinical use in the USA must be listed with the FDA as a medical device and its manufacture must comply with the FDA's 21CFR820 Quality System Regulation, intended to ensure safe and effective devices. For diagnostic reagent products used in pathology laboratories, there are several classifications under which such devices may be registered, depending on their intended use.<sup>18</sup>

ASR (Analyte Specific Reagent)<sup>18</sup>

- Intended for use in a diagnostic application for identification and quantification of an individual chemical substance or ligand in biological specimens
- An ASR is typically a component for a Laboratory Developed Test (LDT) developed by an appropriately registered laboratory. The test is then registered as an IVD for use by that specific laboratory (or group)

IVD (in vitro diagnostic)<sup>18</sup>

- Intended use is to identify, by immunological techniques, antigens in tissues or cytologic specimens

Class I IVD

- Intended to provide the pathologist with adjunctive diagnostic information that may be incorporated into the pathologist's report, but that is not ordinarily reported as an independent finding

Sienna's initial entry to the USA market was accelerated through the targeted launch of an ASR registered product with the FDA. This allowed initial product revenues to commence with limited cost to Sienna, albeit in a small, strategically targeted subset of the total addressable pathology laboratory market.

Subsequently, the IVD-listed version has been released by Sienna, allowing pathology laboratories across the USA to take up the test for routine clinical use.

- b. Europe: Within the EU regulatory framework, IVD medical devices are governed by Directive 98/79/EC, and compliance facilitates free trade with the 28 EU member states. The Directive lists “Essential Requirements” to which all IVDs must comply before being placed on the market, including design, production, labelling, and instructions for use.

Compliance with these Essential Requirements can be achieved through meeting the harmonised standard ISO 13485 for Quality Management Systems.

Medical devices are classified into four categories on a risk-based system, based on the relative danger to public health and/or patient treatment, as established in Annex II of the Directive.

These classifications include:

- List A – High Risk (HIV, Hepatitis B, C, and D);
- List B – Moderate Risk (Rubella, PSA, etc);
- Self-Test (Pregnancy, Cholesterol Home Tests);
- General (Tests for Hormones, Cardiac Markers, Haematology and Clinical Chemistry Tests).

Note: soon to be introduced new IVD Regulation will classify IVDs into four risk-based levels (A, B, C, D) with D being the highest risk.

The CE-mark is a requirement for selling medical products and equipment in the EU. CE Marking signifies that the product complies with the essential health, safety and environmental protection requirements of the European in vitro Device Directive.

Sienna’s IVD product has been registered as a ‘General Class IVD’, allowing it to self-certify its CE Mark.

- c. Australia: Marketing an IVD device in Australia requires approval by the TGA and registration in the Australian Register of Therapeutic Goods (ARTG).

The TGA has a four-tier classification system for IVD products – Class I, II, III, and IV (IV being the highest risk) – based on perceived risk to users and public health.

Sienna’s IVD product has been registered as a Class II device, is listed in the Australian Register of Therapeutic Goods (ARTG), and is based on ISO13485 Certification and compliance with Essential Principles for medical devices.







# SECTION 8

## SALES / COMMERCIALISATION STRATEGY



## USA

Sales, service and support in the USA will be through a supply and distribution partner, as it will be in most countries throughout the world. The use of a distribution partner that already supplies complementary products to the pathology laboratories who will potentially become customers of the Sienna product, has many advantages over building a direct sales force:

- Relationships with customers are already established
- Detailed market and customer knowledge already exist
- Customer supply and support infrastructure is already in place
- Avoidance of large setup costs to establish USA based marketing, sales and support personnel and infrastructure.

To support the distribution partner and enhance its ability to achieve maximum revenue growth in the territory, Sienna has engaged a USA based Commercial Manager to drive USA operations.

StatLab Medical Products have been appointed as supply and distribution partner for the USA. StatLab is a pathology supply company that has significant presence in the market and a focus on growing its advanced staining business, of which Sienna's product will be an integral part.

Sienna's IVD product is now registered with the FDA and available for sale in the USA. This registered IVD status means the product may be used by pathology laboratories throughout the USA for the purpose of identifying the presence of hTERT in cytology samples. Although the potential utility for hTERT detection in cytology samples is broad, the initial application for which data is currently available is as an adjunct to urine cytology testing for assisting in the diagnosis of bladder cancer.

Sienna's sales model in the USA is to use sales representatives of StatLab to promote sales of the Sienna product to pathology laboratories. These targeted pathology laboratories will then use their own marketing/sales forces to promote the test to specialist urologists and other referring physicians.

By partnering with an established distributor in the USA, with existing products already being sold to pathology laboratories, Sienna expects to minimise sales and distribution costs while still achieving effective sales growth. Local distribution partners who already have good penetration into pathology laboratories

should allow geographical reach into all the regional laboratories capable of implementing the IVD product. Sienna's Commercial Manager will remain focused on relationship management with the larger laboratories, and provide support, training and assistance to the external distributor sales force, as well as reporting and forecasting back to head office.

## EU Strategy Summary

Taking advantage of the single regulatory registration system in the EU, Sienna's strategy is to sign agreements with distribution partners for launch of the IVD product. Agreements are already in place for the UK and Switzerland for the commencement of the roll out of the IVD product.

Launch will be in the form of a CE-marked IVD registered product. The strategy will be to initially target the higher volume laboratories and reputable clinical/scientific reference sites. Wherever possible, a "follow the customer" strategy will be leveraged through business development relationships with large multinational diagnostic companies, in order to gain maximum traction in any newly entered region where these global laboratory partners operate.

As scientific studies are published to support the use of hTERT detection for a wider number of sample types and diagnostic panels, laboratories where the Sienna assay is already being used for a subset of sample types/diagnostic panels will broaden their use of the IVD product and increase the overall market penetration.

Sienna has established a presence in Europe in the form of a consultant business development partner, who will have responsibility for conducting ongoing market analysis, building relationships with key laboratory reference sites, providing real time (same time zone) sales support, attending trade shows, supporting the European distributor organisation(s) and undertaking general product marketing.

## Rest of World Summary

Part of the funds from the capital raised under this Prospectus will be used to employ a resource whose task it will be to drive market expansion into regions outside the USA, EU and Australia.

These markets are rapidly growing, particularly in Asia. Sienna is likely to implement the same strategy as for the USA and EU, by establishing distribution partnerships in various countries to tap into their local market knowledge and networks.

# SECTION 9

## BOARD AND MANAGEMENT



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## SECTION 9

### BOARD AND MANAGEMENT

The Sienna Cancer Diagnostics Board and management team have proven skills and experience in navigating the complex clinical diagnostics commercialisation pathway. This includes experience in developing test formats that fit existing clinical paradigms and pathology workflows, utilising existing automation equipment, accessing existing reimbursement pathways and optimising regulatory strategies; all focussed on selling diagnostics products to a broad market in a timely and cost efficient manner.

#### 9.1 Sienna's Board

**Dr Geoffrey  
Cumming:  
Non-executive  
Chairman**



Geoff has held senior roles in the global healthcare and biotechnology sector for more than 20 years. As Managing Director, Roche Diagnostic Systems (Oceania), Geoff transformed the loss-making entity the Swiss parent was intending to divest, into the fastest growing and most profitable affiliate in the Roche group. In his role as Managing Director/CEO of Biosceptre International Ltd, Geoff was successful in designing and securing key funding arrangements through a skilful range of capital raising initiatives, including large government grants, partnering and co-development deals. His most recent executive role was as Managing Director / CEO of Anteo Diagnostics Ltd (ASX: ADO). He is currently a Non-executive Director of Anteo Diagnostics Ltd and Medical Australia Ltd (ASX: MLA). Geoff is an independent director as in the Board's view he is free from any business or other relationship that could materially interfere with or reasonably be perceived to materially interfere with the independent exercise of his judgement.

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**Mr Carl Stubbings:  
Non-executive  
Director**



Carl joined Sienna's Board in December 2011 and held the role of Acting CEO from August 2016 to March 2017. Carl has considerable experience commercialising diagnostic products, both locally and globally. Based in the USA for 13 years, he served as Senior Vice President for Panbio USA Ltd and Vice-President of Sales and Marketing for Focus Diagnostics, a subsidiary of Quest Diagnostics, one of world's largest pathology laboratories. In July 2012, Carl moved back to Australia and has held roles at Benitec Biopharma Limited (ASX:BLT, NASDAQ:BNTC), where he was Chief Business Officer, and more recently as Head of Commercialisation at BCAL Diagnostics, a start-up company developing a blood test for breast cancer. In addition to his executive roles, Carl is also a Non-executive Director of ASX listed medical device company Analytica Medical Limited (ASX:ALT) and Otakaro Pathways, a New Zealand based company developing a diagnostic test for Crohn's disease. Carl is an independent director as in the Board's view he is free from any business or other relationship that could materially interfere with or reasonably be perceived to materially interfere with the independent exercise of his judgement.

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**Dr David Earp:  
Non-executive  
Director**



David was a partner in an intellectual property law firm, advising life science clients, prior to taking senior roles in a number of biotechnology companies. From 1999 until 2012, David served in various roles at Geron Corporation (NASDAQ:GERN), including Chief Patent Counsel, Chief Legal Officer and Senior Vice President of Corporate Transactions. From 2005 to 2010, David was a Board member of TA Therapeutics Ltd. (Hong Kong, PRC). He served on the Board of ViaGen Corporation (Austin, Texas) from 2008-2012, including as Executive Chairman from 2010 until the company was acquired in a trade sale. He is currently the President, CEO and a Director of Circle Pharma, an early stage biotechnology company located in San Francisco, California. David holds a BSc with First Class Honours from Leeds University (UK), a PhD in biochemistry from Cambridge University (UK) and a JD from Lewis and Clark Northwestern School of Law (Portland, Oregon). David is an independent director as in the Board's view he is free from any business or other relationship that could materially interfere with or reasonably be perceived to materially interfere with the independent exercise of his judgement.

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**Dr John Chiplin:  
Non-executive  
Director**



John is an experienced healthcare executive who brings considerable capital markets experience to the Sienna Board. His most recent executive position was CEO of Polynoma LLC, a US based cancer immunotherapy company, and he was formerly the founding CEO of ASX listed Arana Therapeutics Limited prior to that company's acquisition by Cephalon (now Teva). Before his appointment at Arana, Dr Chiplin was head of the UK's \$300M ITI Life Science investment fund. He is currently a Non-executive Director of ASX listed biotechnology companies Benitec Biopharma Limited (ASX:BLT, NASDAQ:BNTC), Cynata Therapeutics Limited (ASX:CYP) and Adalta Limited (ASX:1AD). He is the Chairman of UK AIM listed company Scancell Holdings Plc (AIM:SCLP). Dr Chiplin is also the founder and Managing Director of Newstar Ventures, an early stage investment fund. John is an independent director as in the Board's view he is free from any business or other relationship that could materially interfere with or reasonably be perceived to materially interfere with the independent exercise of his judgement.



## 9.2 Sienna's Management Team

**Matthew Hoskin:**  
**Chief Executive**  
**Officer**



Matthew joined Sienna as Chief Operating Officer in February 2014, before being promoted to the role of CEO in April 2017. He has over 20 years' experience leading business in the biotech and healthcare sectors, including Siemens Medical, Leica Biosystems and Hospira. Matthew played a key role in driving growth at Vision Biosystems, which became one of Australia's most profitable biotechnology companies and ultimately sold for approximately AUD800 million.

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**Tony Di Pietro:**  
**Chief Financial**  
**Officer and**  
**Company Secretary**



Tony is a CPA accredited accountant with over 15 years of corporate accounting experience, gained both in Australia and the UK. He also holds a Graduate Diploma of Applied Corporate Governance from the Governance Institute of Australia. Tony was previously at Acrux Limited, where he was a key member of management for more than 10 years. During this period, Acrux transitioned from a small loss-making public company to an ASX listed company generating significant profits.

# SECTION 10

## FINANCIAL INFORMATION



## **10.1 Introduction**

A summary of the Company's financial information is provided within this section from the audited financial statements for the years ended 30 June 2015 and 30 June 2016, and the financial statements of the half-year to 31 December 2016, which have been reviewed by the Company's auditor, Walker Wayland NSW, Chartered Accountants. All financial information has been prepared in Australian Dollars, unless otherwise stated.

This financial information has been prepared in accordance with the Australian Accounting Standards and Interpretations issued by the Australian Accounting Standards Board and the Corporations Act 2001.

The Company's financial information should be read together with:

- the Investigating Accountant's Report set out in Section 12;
- management's discussion and analysis set out in Section 10.6;
- the risk factors described in Section 14; and
- the other information contained in this Prospectus.

## **10.2 Audited Financial Statements**

The historical financial information has been extracted from the financial reports of Sienna for the years ended 30 June 2015 and 30 June 2016, and the half-year ended 31 December 2016. The financial reports for the financial years ended 30 June 2015 and 30 June 2016 were audited by Walker Wayland NSW, Chartered Accountants, in accordance with Australian Auditing Standards. The financial reports for the 6 months to 31 December 2016 were reviewed by Walker Wayland NSW, Chartered Accountants.

The historical financial information is presented in an abbreviated form and does not contain all the disclosures, statements or comparative information required by Australian Accounting Standards applicable to financial reports prepared in accordance with the Corporations Act.

The principal accounting policies adopted in the preparation of the financial statements are set out in Section 10.7 of this Prospectus. These policies have been consistently applied to the financial period presented, unless otherwise stated.

For the 2015 and 2016 financial reports, Walker Wayland NSW Chartered Accountants, without qualifying their audit opinion, included an Emphasis of Matter paragraph addressing the uncertainty of ongoing viability without the receipt of funds from capital raising initiatives. During the 2016 financial year the Company raised capital from the exercise of shareholder options and the placement of Shares to new and existing shareholders. Since the end of the 2016 financial year Sienna received \$637,523 from the refund of the 2016 Research and Development Tax Incentive. With the funds received from the minimum subscription (\$4 million) sought through this Prospectus, the Directors are confident that the Company will have sufficient working capital to meet its debts as they fall due, and to continue trading as a going concern.

### 10.3 Historical Statement of Profit or Loss and Other Comprehensive Income

The table below sets out a summary of the Company's historical statement of profit and loss and other comprehensive income for 2015 and 2016 financial years and the half-year to 31 December 2016.

	6 Months Half-year FY2017 Reviewed (\$)	12 Months FY2016 Audited (\$)	12 Months FY2015 Audited (\$)
<b>REVENUE FROM ORDINARY ACTIVITIES</b>			
Revenue	931,247	1,326,301	931,435
Interest Income	4,546	17,697	38,757
	<b>935,793</b>	<b>1,343,998</b>	<b>970,192</b>
<b>EXPENSES</b>			
Employee and contractor costs	(394,872)	(1,198,888)	(1,563,881)
Administration	(85,884)	(230,441)	(172,093)
Research and development	(43,099)	(215,212)	(134,316)
Insurance	(22,599)	(47,030)	(42,032)
Travel and meetings	(21,332)	(110,609)	(80,894)
Other expenses from ordinary activities	(377)	(701)	(1,117)
	<b>(568,163)</b>	<b>(1,802,881)</b>	<b>(1,994,333)</b>
<b>Profit/(Loss) Before Impairment, Depreciation and Amortisation</b>	<b>367,630</b>	<b>(458,883)</b>	<b>(1,024,141)</b>
Impairment of intangibles	-	-	(19,894)
Depreciation and amortisation	(12,928)	(17,817)	(37,906)
<b>Profit/(Loss) Before Income Tax</b>	<b>354,702</b>	<b>(476,700)</b>	<b>(1,081,941)</b>
Income tax expense	-	-	-
<b>Total Comprehensive Profit/(Loss) for the Year</b>	<b>354,702</b>	<b>(476,700)</b>	<b>(1,081,941)</b>

## 10.4 Historical Statement of Cash Flows

The table below sets out a summary of the Company's historical statements of cash flows for the 2015 and 2016 financial years and the half-year to 31 December 2016.

	6 Months Half-year FY2017 Reviewed (\$)	12 Months FY2016 Audited (\$)	12 Months FY2015 Audited (\$)
<b>CASH FLOW FROM OPERATING ACTIVITIES</b>			
Receipts from operating activities	997,593	1,425,674	800,364
Interest received	4,851	17,897	37,854
Payments to suppliers and employees	(808,256)	(1,511,740)	(1,870,288)
<b>Net Cash Provided by/(Used in) Operating Activities</b>	<b>194,188</b>	<b>(68,169)</b>	<b>(1,032,070)</b>
<b>CASH FLOW FROM INVESTING ACTIVITIES</b>			
Purchase of intangibles	(49,481)	(10,220)	(15,142)
Purchase of property, plant and equipment	(2,329)	(6,057)	(92,909)
Payment for capitalised development costs	(655,609)	(880,642)	(690,337)
<b>Net Cash Used in Investing Activities</b>	<b>(707,419)</b>	<b>(896,919)</b>	<b>(798,388)</b>
<b>CASH FLOW FROM FINANCING ACTIVITIES</b>			
Net proceeds from issue of ordinary Shares	1,082,070	1,242,809	2,032,988
<b>Net Cash Provided by Financing Activities</b>	<b>1,082,070</b>	<b>1,242,809</b>	<b>2,032,988</b>
<b>Net Increase in Cash Held</b>	<b>568,839</b>	<b>277,721</b>	<b>202,530</b>
Cash and cash equivalent at beginning of financial year	1,080,657	791,338	589,479
Effects of exchange rate changes on the balance of cash held in foreign currencies	4,587	11,598	(671)
<b>Cash and Cash Equivalent at End of Financial Year</b>	<b>1,654,083</b>	<b>1,080,657</b>	<b>791,338</b>



## 10.5 Historical Statement of Financial Position

The table below sets out a summary of the Company's statement of financial position as at 30 June 2015, 30 June 2016 and 31 December 2016.

	Half-year FY2017 Reviewed (\$)	FY2016 Audited (\$)	FY2015 Audited (\$)
<b>CURRENT ASSETS</b>			
Cash assets	1,654,083	1,080,657	791,338
Receivables	76,511	127,619	182,972
Other Assets	26,239	50,173	35,381
<b>Total Current Assets</b>	<b>1,756,833</b>	<b>1,258,449</b>	<b>1,009,691</b>
<b>NON-CURRENT ASSETS</b>			
Intangibles	2,314,362	1,612,627	721,765
Property, plant and equipment	36,109	43,352	55,112
<b>Total Non-Current Assets</b>	<b>2,350,471</b>	<b>1,655,979</b>	<b>776,877</b>
<b>Total Assets</b>	<b>4,107,304</b>	<b>2,914,428</b>	<b>1,786,568</b>
<b>CURRENT LIABILITIES</b>			
Payables	427,185	614,582	353,129
Provisions	65,668	105,971	66,837
<b>Total Current Liabilities</b>	<b>492,853</b>	<b>720,553</b>	<b>419,966</b>
<b>NON-CURRENT LIABILITIES</b>			
Provisions	15,166	10,578	14,296
<b>Total Non-Current Liabilities</b>	<b>15,166</b>	<b>10,578</b>	<b>14,296</b>
<b>Total Liabilities</b>	<b>508,019</b>	<b>731,131</b>	<b>434,262</b>
<b>Net Assets</b>	<b>3,599,285</b>	<b>2,183,297</b>	<b>1,352,306</b>
<b>EQUITY</b>			
Contributed Equity	16,670,997	15,588,927	14,346,118
Reserves	113,928	140,911	76,029
<b>Accumulated Losses</b>	<b>(13,185,640)</b>	<b>(13,546,541)</b>	<b>(13,069,841)</b>
<b>Total Equity</b>	<b>3,599,285</b>	<b>2,183,297</b>	<b>1,352,306</b>

## **10.6 Management's Discussion and Analysis of the Historical Financial Information**

### **Statement of Profit and Loss and other Comprehensive Income**

#### ***Revenue***

Sienna received first product revenues during the 2015 financial year. Total revenue for the half-year to 31 December 2016 was \$935,793, including \$291,588 of product revenue and \$637,523 received from the Australian Government's Research and Development Tax Incentive program. Total revenue recorded for the 2016 financial year was \$1,343,998 (2015: \$970,192) and included \$640,664 (2015: \$304,634) from product commercialisation agreements and \$682,921 (2015: \$274,724) received from the Research and Development Tax Incentive program. During the 2015 financial year, Sienna received \$333,228 in grant income from the Federal Government's Commercialisation Australia Early Stage Commercialisation grant program.

#### ***Employee and contractor costs***

Employee and contractor costs includes expenditure for Sienna employees and Directors. Sienna currently employs 9.3 full-time equivalent employees (10 staff members) and 4 Non-executive Directors. Of the total number of employees, 6 are engaged directly in research and development, with the remaining staff employed in corporate and administrative support roles.

Employee and contractor costs from the 2015 financial year included the payment and recognition of amounts payable to Directors for fees outstanding for the period from 1 July 2011 to 30 June 2014, the payment of amounts due to the Managing Director/Chief Executive Officer at cessation of employment, and the employment of four new staff members: Sienna's inaugural Chief Financial Officer, a Quality Assurance Manager, a Senior Scientist and an additional Research Technician/Scientist to aid further development and commercialisation of SCD-A7. The irregular nature and recognition of the costs described above resulted in the reduction of employee expenditure recorded for the 2016 financial year

Employee and contractor costs are expected to increase in the 2018 financial year, as the Company employs marketing and business development staff to further penetrate worldwide markets for Sienna's products.

#### ***Administration expenditure***

Administration expenditure accounts for corporate overheads (including lease payments incorporating laboratory space), accounting and audit fees, corporate advisers' fees and legal fees. Expenditures unique to an ASX listed organisation, such as ASX listing fees, increased share registry fees and governance advice, are expected to increase administration expenditure once the Company is admitted to the official list.

#### ***Research and development expenditure***

This category includes all expenditure on product research and development, which is guided by the Company's commercialisation strategies. Expenditure includes clinical sample acquisition, external research, regulatory advice and laboratory consumables.

Following the receipt of funds from the IPO, the Company expects a similar level of expenditure to be incurred over the coming financial years. Further research is to be conducted into the application of Sienna's intellectual property to detect other cancer types in different cytology and histology (tissue) samples.

For the 2015 and 2016 financial years, as well as the half-year to 31 December 2016, employee and contractor costs, administration, and research and development categories of expenditure have been reduced by the capitalisation of development expenditure for SCD-A7, required by accounting standard AASB 138 – Intangible Assets. SCD-A7 (referred to as the IVD) became available for use by third party laboratories in December 2016, which triggered the commencement of the amortisation of accumulated capitalised development expenditure.

### **Statement of Cash Flows**

#### ***Cash flow from operating activities***

Receipts from operating activities represents product revenue receipts and payments received from the Research and Development Tax Incentive program and government grants. Product revenues were first received during the 2015 financial year.

If not for the payment of amounts due to Directors for fees outstanding for prior financial years, and the payment of amounts due to the outgoing Managing Director/Chief Executive Officer during the 2015 financial year, payments to suppliers and employees would show a steady increase over the prior three financial years, as Sienna progressed research and development of SCD-A7.

***Cash flow from investing activities***

Payment for intangibles related to patent legal fees.

The payments for property, plant and equipment during the half-year to 31 December 2016 and the 2016 financial year were modest, however during the 2015 financial year a significant sum was invested in scientific equipment necessary for the continued development of SCD-A7.

Payments for capitalised development costs represent SCD-A7 expenditure required to be capitalised by the provisions of accounting standard AASB 138 – Intangible Assets.

***Cash flow from financing activities***

Net proceeds from the issue of ordinary Shares represents the net receipt of funds from the exercise of shareholder options and the issue of Shares to new and existing shareholders.

**Statement of Financial Position**

***Receivables***

The balance of receivables at 31 December 2016, \$76,511, is made up of \$66,937 being trade and other debtors, \$791 for accrued interest revenue and \$8,783 of refundable GST input tax credits.

***Intangibles***

The balance at 31 December 2016 for intangibles, \$2,314,362, consists of \$91,128 for capitalised patent fees and \$2,223,234 for accumulated capitalised development expenditure for SCD-A7. The accumulated capitalised development expenditure began the gradual process of amortisation to the Statement of Profit and Loss and Comprehensive Income in December 2016. While the capitalised patent fees represent patents that are yet to be granted, the granting of these patents will trigger the commencement of the amortisation process.

***Payables***

The balance of payables at 31 December 2016, \$427,185, is made up of trade and other creditors, \$297,833 and accrued expenditure, \$129,352. Sienna had no short or long term debt at 31 December 2016.

***Provisions***

Represents the balance of employee entitlements for annual and long service leave.

***Reserves***

The employee share option reserve is the sole reserve represented by the balance. Accounting standard AASB 2 Share-based Payment mandates the recognition of a non-cash expense for share options granted to employees.

**After Balance Date Events**

On 16 March 2017, Sienna became aware that Bostwick, a significant customer of the Company, had filed for chapter 11 bankruptcy protection in the United States on 15 March 2017. As part of an auction and sale process facilitated by the bankruptcy courts, Poplar Healthcare PLLC completed the acquisition of the assets of Bostwick on 4 May 2017. Sienna has registered invoices for product incomes earned in December 2016, January 2017, February 2017 and the first 15 days of March 2017, representing USD155,370 of revenue, with the courts as an unsecured creditor of the chapter 11 filing. The Company has since received payment of invoices for product incomes earned post the chapter 11 filing date and has also received an offer to purchase part of its chapter 11 claim from a third party. In light of these developments, product revenue for December 2016 was not recognised in the financial report for the half-year ended 31 December 2016.

Sienna's Board and management anticipate ongoing sales to the customer in its new ownership structure, as, at the date of this Prospectus, the customer continues to use Sienna's product.

## 10.7 Significant Accounting Policies

### **Basis of Preparation**

The financial information provided in Section 10 has been extracted from the financial statements of Sienna Cancer Diagnostics Limited, which are prepared in accordance with Australian Accounting Standards and Interpretations and the Corporations Act 2001. Compliance with Australian Accounting Standards ensures that the financial statements comply with International Financial Reporting Standards. For the purposes of preparing Sienna's financial statements the Company is a for-profit entity.

Material accounting policies adopted in the preparation of these financial reports are presented below. They have been consistently applied unless otherwise stated. The financial reports have been prepared on an accruals basis and are based on historical costs, modified (where applicable) by the measurement at fair value of selected non-current assets, financial assets, and financial liabilities.

### **Accounting Policies**

#### **a. Going Concern**

The financial reports have been prepared on a going concern basis.

#### **b. Income Tax**

Income tax expense represents the sum of the tax currently payable and deferred tax.

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 in 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. No deferred tax assets have been recognised on the balance sheet as at 30 June 2016, as the probability of deriving a benefit is uncertain.

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 expectation that the Group 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. Revenue Recognition**

Revenue is recognised at the fair value of the consideration received net of the amount of goods and services tax (GST) payable to the taxation authority.

##### *Interest income*

Interest income is recognised as it accrues, taking into account the effective yield on the financial asset.

##### *Product revenue*

Revenue from product agreements is made up of:

- Royalties based on the number of laboratory tests conducted by commercial partners. Royalty revenue is recognised in the period in which the laboratory tests occur.
- Revenue from the supply of product. Revenue from the supply of product is recognised in the period in which the product is supplied.
- Revenue arising as the result of a milestone (such as the signing of a commercial agreement). Revenue relating to milestones is recognised upon achievement of the milestone, which is the trigger point for the right to receive the revenue.

#### **Grant income**

Revenue from the receipt of contracted grants is recognised in the period monies associated with the grants are expensed.

Other revenue is recognised as received or over the time period to which it relates.

#### **d. Goods and Services Tax**

Revenue, expenses and assets are recognised net of the amount of goods and services tax (GST), except where the amount of GST incurred is not recoverable from the taxation authority. In these circumstances the GST is recognised as part of the cost of acquiring the asset or as part of an item of expense.

Receivables and payables are stated with the amount of GST included.

The net amount of GST recoverable from, or payable to, the taxation authority is included as a current asset or liability in the statement of financial position.

Cash flow is included in the statement of cash flow on a gross basis. The GST components of cash flow arising from investing and financing activities, which are recoverable from, or payable to, the taxation authority, are classified as operating cash flow.

#### **e. Property, Plant and Equipment**

Each class of property, plant and equipment is carried at cost or fair value less, where applicable, any accumulated depreciation and impairment.

##### **Plant and equipment**

The carrying amount of plant and equipment is reviewed annually by Directors to ensure it is not in excess of the recoverable amount from these assets. The recoverable amount is assessed on the basis of the expected net cash flows that will be received from the assets' employment and subsequent disposal. The expected net cash flows have been discounted to their present values in determining recoverable amounts.

Subsequent costs are included in the asset's carrying amount or recognised as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to the Group and the cost of the item can be measured reliably. All other repairs and maintenance are charged to the income statement during the financial period in which they are incurred.

##### **Depreciation**

The depreciable amount of all fixed assets, including building and capitalised lease assets but excluding freehold land, is depreciated on a straight-line basis over their useful lives to the Group commencing from the time the asset is held ready for use. Leasehold improvements are depreciated over the shorter of either the unexpired period of the lease or the estimated useful lives of the improvements. Items of property, plant and equipment, are depreciated over their estimated useful lives.

The depreciation rates for each class of asset are:

Class of Non-Current Asset	Depreciation Rate
Office Furniture and Equipment	5% - 100% straight line
Research Equipment	14.29% - 100% straight line

The assets' residual values and useful lives are reviewed, and adjusted if appropriate, at each end of reporting period.

An asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount.

Gains and losses on disposals are determined by comparing proceeds with the carrying amount. These gains or losses are included in the income statement. When revalued assets are sold, amounts included in the revaluation reserve relating to that asset are transferred to retained earnings.



**f. Impairment of Assets**

At each reporting date the carrying values of its tangible and intangible assets are reviewed to determine whether there is any indication that those assets have been impaired. If such an indication exists, the recoverable amount of the asset, being the higher of the asset's fair value less costs to sell and value in use, is compared to the asset's carrying value. Any excess of the asset's carrying value over its recoverable amount is expensed to the statement of comprehensive income.

Impairment testing is performed annually for intangible assets with both finite and indefinite lives.

Where it is not possible to estimate the recoverable amount of an individual asset, an estimate of the recoverable amount of the cash-generating unit to which the asset belongs is calculated.

**g. Cash and Cash Equivalents**

Cash and cash equivalents include cash on hand and deposits held at call with banks.

**h. Investments**

Non-current investments are measured at cost. The carrying amount of non-current investments is reviewed annually by Officers of the Company to ensure it is not in-excess of the recoverable amount of these investments. The recoverable amount is assessed from the underlying net assets of the investment. The expected net cash flows from investments have not been discounted to their present value in determining the recoverable amounts.

**i. Intangibles**

*Licences*

Licences are valued in the accounts at cost of acquisition. Licences have a finite life and are amortised over the period in which their benefits are expected to be realised.

*Patents*

Patents are recognised at cost of acquisition. Patents have a finite life and are carried at cost less any accumulated amortisation and any impairment losses. Patents are amortised on a straight-line basis over the term of the patent commencing from the time the patent is registered.

*Research and development*

Research and development expenditure during the research phase of a project is recognised as an expense when incurred. Product development costs are capitalised only when each of the following specific criteria has been satisfied:

1. Technical feasibility of completing development of the product and obtaining approval by regulatory authorities.
2. Ability to secure a commercial partner for the product.
3. Availability of adequate technical, financial and other resources to complete development of the product, obtain regulatory approval and secure a commercial partner.
4. Reliable measurement of expenditure attributable to the product during its development.
5. High probability of the product entering a major diagnostic market.

Capitalised development costs have a finite life and are amortised on a systematic basis over the period from when the product becomes available for use and ceases at the earlier of the date the asset is expected to exit the market or that the asset is classified as held for sale (or included in a disposal group that is classified as held for sale) in accordance with AASB 5.

**j. Payables**

Liabilities are recognised for amounts to be paid in the future for goods or services received. Trade accounts payable and other creditors are normally settled within 60 days.

**k. Employee Entitlements**

*Short-term and long-term employee benefits*

A liability is recognised for benefits accruing to employees in respect of wages and salaries, annual leave and sick leave in the period the related service is rendered.

Liabilities recognised in respect of short-term employee benefits, are measured at their nominal values using the remuneration rate expected to apply at the time of settlement. Liabilities recognised in respect of long-term employee benefits are measured as the present value of the estimated future cash outflows to be made by the Group in respect of services provided by employees up to the reporting date.

Contributions are made to employee superannuation funds and are charged as expenses when incurred.

*Equity-settled compensation*

Sienna operates a share-based compensation plan, in the form of an Employee Share Option Plan (ESOP). The total amount to be expensed over the vesting period is determined by reference to the fair value of the shares of the options granted.

**l. Financial Instruments**

*Recognition*

Financial instruments are initially measured at cost on transaction date, which includes transaction costs, when the related contractual rights or obligations exist. Subsequent to initial recognition these instruments are measured as set out below.

*Loans and receivables*

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market and are stated at amortised cost using the effective interest rate method.

*Financial liabilities*

Non-derivative financial liabilities are recognised at amortised cost, comprising original debt less principal payments and amortisation.

*Impairment*

At each reporting date, financial instruments are assessed as to whether there is objective evidence that the instrument has been impaired. In the case of available-for-sale financial instruments, a prolonged decline in the value of the instrument is considered to determine whether impairment has arisen. Impairment losses are recognised in the statement of comprehensive income.

**m. Comparative Figures**

When required by Accounting Standards, comparative figures have been adjusted to conform to changes in presentation for the current financial year.

**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 Group.

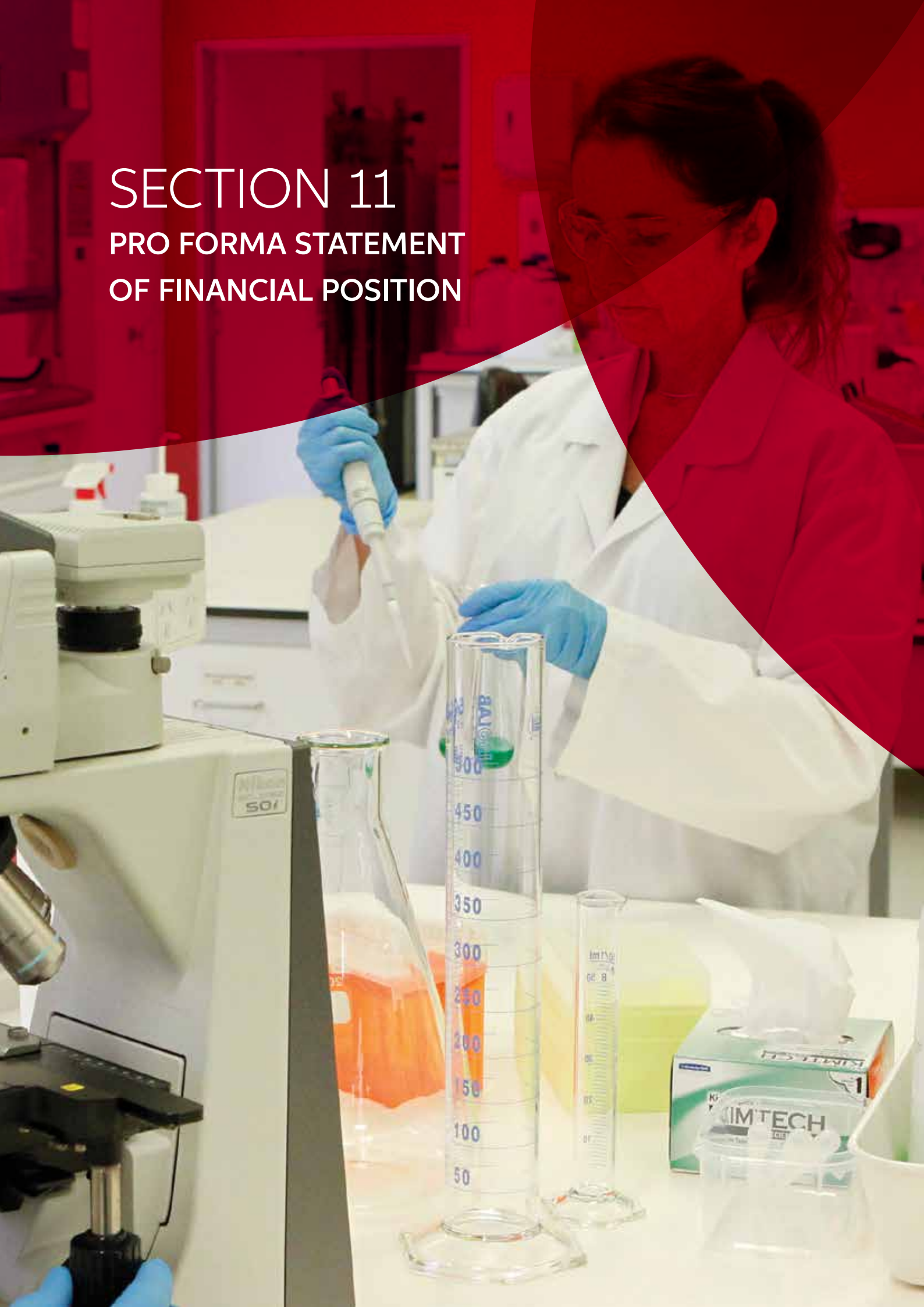
*Key estimates – impairment*

At each reporting date assessments of impairment are undertaken by evaluating conditions specific to Sienna that may lead to impairment of assets. Where an impairment trigger exists, the recoverable amount of the asset is determined. Value-in-use calculations performed in assessing recoverable amounts incorporate a number of key estimates.



# SECTION 11

## PRO FORMA STATEMENT OF FINANCIAL POSITION





## SECTION 11

### PRO FORMA STATEMENT OF FINANCIAL POSITION

The pro forma statement of financial position as at 31 December 2016 has been prepared to illustrate the effects of the IPO's financial transactions (the capital raised and associated costs) on the Company's financial position.

As at 31 December 2016	Minimum Subscription			Maximum Subscription	
	Reviewed (\$)	Adjustments (\$)	Pro forma (\$)	Adjustments (\$)	Pro forma (\$)
<b>CURRENT ASSETS</b>					
Cash assets	1,654,083	3,419,000	5,073,083	5,277,000	6,931,083
Receivables	76,511	–	76,511	–	76,511
Other assets	26,239	–	26,239	–	26,239
<b>Total Current Assets</b>	<b>1,756,833</b>	<b>3,419,000</b>	<b>5,175,833</b>	<b>5,277,000</b>	<b>7,033,833</b>
<b>NON-CURRENT ASSETS</b>					
Intangibles	2,314,362	–	2,314,362	–	2,314,362
Property, plant and equipment	36,109	–	36,109	–	36,109
<b>Total Non-Current Assets</b>	<b>2,350,471</b>	<b>–</b>	<b>2,350,471</b>	<b>–</b>	<b>2,350,471</b>
<b>Total Assets</b>	<b>4,107,304</b>	<b>3,419,000</b>	<b>7,526,304</b>	<b>5,277,000</b>	<b>9,384,304</b>
<b>CURRENT LIABILITIES</b>					
Payables	427,185	–	427,185	–	427,185
Provisions	65,668	–	65,668	–	65,668
<b>Total Current Liabilities</b>	<b>492,853</b>	<b>–</b>	<b>492,853</b>	<b>–</b>	<b>492,853</b>
<b>NON-CURRENT LIABILITIES</b>					
Provisions	15,166	–	15,166	–	15,166
<b>Total Non-Current Liabilities</b>	<b>15,166</b>	<b>–</b>	<b>15,166</b>	<b>–</b>	<b>15,166</b>
<b>Total Liabilities</b>	<b>508,019</b>	<b>–</b>	<b>508,019</b>	<b>–</b>	<b>508,019</b>
<b>Net Assets</b>	<b>3,599,285</b>	<b>3,419,000</b>	<b>7,018,285</b>	<b>5,277,000</b>	<b>8,876,285</b>
<b>EQUITY</b>					
Contributed Equity	16,670,997	3,702,000	20,372,997	5,554,000	22,224,997
Reserves	113,928	–	113,928	–	113,928
Accumulated losses	(13,185,640)	(283,000)	(13,468,640)	(277,000)	(13,462,640)
<b>Total Equity</b>	<b>3,599,285</b>	<b>3,419,000</b>	<b>7,018,285</b>	<b>5,277,000</b>	<b>8,876,285</b>



This Prospectus contemplates the following transactions and events, referred to as the pro forma adjustments, which are to take place on or before the completion of the Offer. They are presented as if they, together with the Offer, had occurred on or before 31 December 2016 and are set out below:

### **Subscription Amount**

The Minimum Subscription is the issue of 20,000,000 new fully paid ordinary Shares at \$0.20 each amounting to \$4 million. Cash expenses associated with the Offer (including offer management, advisory, legal, accounting, administrative and other expenses) are estimated to be \$581,000 (exclusive of GST).

The Maximum Subscription is the issue of a further 10,000,000 Shares at \$0.20 each to raise a further \$2 million, bringing the total amount raised to \$6 million. Costs associated with raising the \$6 million are estimated at \$723,000 (exclusive of GST).

### **Pro Forma Cash Assets**

Cash assets at 31 December 2016, set out below, includes the proceeds from both the minimum \$4 million and maximum \$6 million capital raising scenarios after costs of the Offer:

	Pro Forma Minimum Subscription (\$)	Pro Forma Maximum Subscription (\$)
Cash assets at 31 December 2016	1,654,083	1,654,083
Proceeds from the Shares issued under the Offer	4,000,000	6,000,000
Payment of the Offer Costs	(581,000)	(723,000)
<b>Total Cash Assets</b>	<b>5,073,083</b>	<b>6,931,083</b>

### **Pro Forma Share Capital**

The pro forma share capital as at 31 December 2016, set out below, reflects both the minimum \$4 million and maximum \$6 million capital raising scenarios after deducting the costs of the Offer that are directly attributable to equity:

	Pro Forma Minimum Subscription (\$)	Pro Forma Maximum Subscription (\$)
Share Capital at 31 December 2016	16,670,997	16,670,997
Proceeds from the Shares issued under the Offer	4,000,000	6,000,000
Offer costs that are directly attributable to equity	(298,000)	(446,000)
<b>Total Share Capital</b>	<b>20,372,997</b>	<b>22,224,997</b>

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## SECTION 11

### PRO FORMA STATEMENT OF FINANCIAL POSITION

#### Pro Forma Accumulated Losses

The pro forma accumulated losses as at 31 December 2016, set out below, reflects both the minimum \$4 million and maximum \$6 million capital raising scenarios after including the costs of the Offer that are expensed to the Profit or Loss and Other Comprehensive Income statement:

	Pro Forma Minimum Subscription (\$)	Pro Forma Maximum Subscription (\$)
Accumulated losses at 31 December 2016	(13,185,640)	(13,185,640)
Offer costs that are expensed to the profit or loss and other comprehensive income statement	(283,000)	(277,000)
<b>Total Accumulated Losses</b>	<b>(13,468,640)</b>	<b>(13,462,640)</b>

# SECTION 12

## INVESTIGATING ACCOUNTANTS' REPORT





**Walker Wayland NSW**  
Chartered Accountants

ABN 55 931 152 366

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SYDNEY NSW 2000

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24 May 2017

The Board of Directors  
Sienna Cancer Diagnostics Limited  
1 Dalmore Drive  
SCORESBY VIC 3179

Dear Directors

## **INDEPENDENT LIMITED ASSURANCE REPORT ON THE HISTORICAL AND PRO FORMA FINANCIAL INFORMATION**

### **Introduction**

We have been engaged by Sienna Cancer Diagnostics Limited ("Sienna" or the "Company") to report on the Historical and Pro Forma Financial Information of the Company for inclusion in a Prospectus to be dated on or about 24 May 2017 ("the Prospectus") to be issued by Sienna in respect to the offer of new shares in the Company ("Public Offer").

This report is an Independent Limited Assurance Report, the scope of which is set out below.

Expressions defined in the Prospectus have the same meaning in this report, unless otherwise specified.

### **Scope**

You have requested Walker Wayland NSW, Chartered Accountants to review the following Historical and Pro Forma Financial Information included in the Prospectus.

The Historical and Pro Forma Financial information is presented in an abbreviated form insofar as it does not include all of the presentation and disclosures required and other mandatory professional reporting requirements applicable to general purpose financial statements prepared in Australia in accordance with the Corporations Act 2001.

Our limited assurance engagement has not been carried out in accordance with auditing or other standards and practices generally accepted in any jurisdiction outside of Australia and accordingly should not be relied upon as if it had been carried out in accordance with those standards and practices.

### **Historical and Pro Forma Financial Information**

The Historical and Pro Forma Financial Information of Sienna, as set out in the Prospectus comprises:

- The historical statement of profit or loss and other comprehensive income for Sienna for the 12 months ended 30 June 2015 ("FY2015"), the 12 months ended 30 June 2016 ("FY2016") and the 6 months ended 31 December 2016 ("HY 2017");



- The historical statement for cash flows of Sienna for FY2015, FY2016 and HY2017;
- The reviewed historical and pro forma statement of financial position of Sienna as at HY 2016; and
- The audited historical statement of financial position of Sienna as at FY2015 and as at FY2016.

(Hereafter the “Historical and Pro Forma Financial Information”)

The Historical Financial Information set out in Section 10 of the Prospectus has been extracted from the reviewed financial statements of Sienna Cancer Diagnostics Limited as at HY2016 and the audited financial statements of Sienna Cancer Diagnostics Limited for the years ended FY2015 and FY2016. No other pro forma adjustments have been made to the historical audited financial statements for FY2015 and FY2016.

Sienna Cancer Diagnostics was incorporated on 11 April 2002. The Company incorporated Melbourne Diagnostics Pty Limited on 06 April 2006 and owns 100% of the equity.

The Historical Financial Information for FY 2015 and FY2016 has been audited by Walker Wayland NSW, Chartered Accountants. An unqualified audit opinion was issued for FY2015 and FY2016 respectively with an emphasis of matter paragraph included in both years audit reports for significant uncertainty regarding ongoing viability.

The historical pro forma statement of financial position as at FY2016 assumes completion of the proposed transactions outlined in Section 11 of the Prospectus which includes the Offer and the event occurring subsequent to HY2016 (the “Pro Forma Transactions”) as though they had occurred on that date.

The stated basis of preparation is the recognition and measurements principles contained in the International Financial Reporting Standard (“IFRS”) and Sienna Cancer Diagnostics Limited’s adopted accounting principles applied to the Historical and Pro Forma Financial Information

This report has been prepared for inclusion in the Prospectus. Walker Wayland NSW, Chartered Accountants disclaim any assumption of responsibility for any reliance on this report or on the Financial Information to which this report relates for any purpose other than the purposes for which it was prepared. This report should be read in conjunction with the Prospectus.

#### **Directors’ Responsibility**

The Directors of Sienna are responsible for the preparation and presentation of the Historical and Pro Forma Financial Information. The Directors are also responsible for the determination of the Pro Forma transactions set out in Section 11 of the Prospectus and the basis of preparation of the Historical and Pro Forma Financial Information.

This responsibility also includes compliance with applicable laws and regulations and for such internal controls as the Directors determine necessary to enable the preparation of the Historical and Pro Forma Financial Information that are free from material misstatement.





### **Our Responsibility**

Our responsibility is to express a limited assurance conclusion on the Historical and Pro Forma Financial Information based on the procedures performed and evidence we have obtained. We have conducted our engagement in accordance with the Standard on Assurance Engagements ASAE 3420: "Assurance Engagements to Report on the Compilation of Pro Forma Historical Pro Forma Financial Information" and ASAE 3450: "Assurance Engagements involving Corporate Fundraisings and/ or Prospective Historical Pro Forma Financial Information". Our procedures consisted of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and review procedures applied to the accounting records in support of the Historical and Pro Forma Financial Information.

These procedures are substantially less in scope than an audit conducted in accordance with Australian Auditing Standards, and consequently do not enable us to obtain reasonable assurance that we would become aware of all significant matters that might be identified in an audit. We have not performed an audit and, accordingly, we do not express an audit opinion on the Historical and Pro Forma Financial Information.

Our engagement did not involve updating or re issuing any previously issued audit reports on any Historical and Pro Forma Financial Information used as a source of the Historical and Pro Forma Financial Information.

### **Conclusion**

#### **Historical and Pro Forma Financial Information**

Based on our independent review, which is not an audit, nothing has come to our attention which causes us to believe that the Historical and Pro Forma Financial Information of Sienna as described in Section 10 and Section 11 of the Prospectus does not present fairly:

- The historical statement of profit or loss and other comprehensive income for Sienna FY2015, FY2016 and HY2017;
- The historical statement of cash flows for Sienna for FY2015, FY2016 and HY2017;
- The reviewed historical and pro forma statement of financial position as at HY2017;
- The audited historical statement of financial position of Sienna as at FY2015 and FY2016; and
- The pro forma transactions set out in Section 11 of the Prospectus are a reasonable basis for the historical pro forma statement of financial position as at HY 2017;

In accordance with the measurement and recognition requirements (but not all of the presentation and disclosure requirements) of applicable Accounting Standards and other mandatory professional reporting requirements under IFRS as if the pro forma transactions set out in Section 11 had occurred at HY2017

We have assumed, and relied on representations from certain members of management of Sienna, that all material information concerning the historical operations of Sienna has been disclosed to us and that the information provided to us for the purpose of our work is true, complete and accurate in all respects. We have no reason to believe that those representations are false.



#### **Restriction on Use**

Without modifying our conclusion, we draw your attention to Section 10 which describes the purpose of the Historical and Pro Forma Financial Information being for inclusion in the Prospectus. As a result, the Historical and Pro Forma Financial Information may not be suitable for use for another purpose.

#### **Consent**

Walker Wayland NSW, Chartered Accountants has consented to the inclusion of this Independent Limited Assurance Report in the Prospectus in the form and context in which it is included.

#### **Liability**

The liability of Walker Wayland NSW, Chartered Accountants is limited to the inclusion of this report in the Prospectus. Walker Wayland NSW, Chartered Accountants makes no representation regarding, and has no liability, for any other statements or other material in, or omissions from the Prospectus.

#### **Independence or Disclosure of Interest**

Walker Wayland NSW, Chartered Accountants does not have any pecuniary interests that could reasonably be regarded as being capable of affecting its ability to give an unbiased conclusion in this matter. Walker Wayland NSW, Chartered Accountants will receive a professional fee for the preparation of this Independent Limited Assurance Report.

Yours faithfully,

**Walker Wayland NSW**  
**Chartered Accountants**

A handwritten signature in black ink, appearing to be 'Wali Aziz', written over a light grey circular stamp.

**Wali Aziz**  
**Principal**



# SECTION 13

## PATENT REPORT



### 13.1 Executive Summary

Set out below is our report (the “Report”) detailing the current status of intellectual property being handled by FB Rice on behalf of Sienna Cancer Diagnostics Ltd. for inclusion in a Prospectus to be lodged at the Australian Securities and Investments Commission.

The Report provides a general summary of intellectual property in Section 13.3 and summarises the details and status of the granted patents and pending patent applications owned, or licensed by, Sienna Cancer Diagnostics Ltd. Trade mark applications are also summarised in Section 13.4.

Section 13.5 explains that we are not aware of any issues that affect proprietorship of the relevant patent families in the portfolio.

Section 13.6 provides general comments on Validity of Patents. Limitations and Qualifications of this Report are outlined in Section 13.7.

### 13.2 Background and Scope

FB Rice has been instructed by Sienna Cancer Diagnostics Ltd to prepare this Report for inclusion in a Prospectus to be issued by Sienna Cancer Diagnostics Ltd. FB Rice has been instructed to provide the details and status of patent matters in the intellectual property portfolio referred to in this Report.

To the best of our knowledge the Report is accurate as at its date, subject to the limitations and qualifications set out in Section 13.7. FB Rice is not aware of any material changes expected to occur to the status of the matters outlined below prior to the expected date for allocation of Sienna Shares, except where indicated.

### 13.3 Intellectual Property

#### 13.3.1 Meaning of Intellectual Property

The term “intellectual property” refers to a group of registrable and non-registrable rights, including rights in patents, designs, trade marks, plant varieties, copyright, confidential information and trade secrets. Intellectual property has many of the characteristics possessed by real and personal property. In particular, intellectual property is an asset, which may be bought, sold, licensed, exchanged, or otherwise transferred as other forms of property. Accordingly, an intellectual property owner has the right to prevent the unauthorised use or sale of its property.

This Report is only directed to intellectual property which is in the form of patents, patent applications and trade mark applications.

#### 13.3.2 Patents

Patents cover inventions and provide a temporary monopoly in exchange for an inventor’s full disclosure of the invention to the public. A patent provides protection for novel (new), inventive (non-obvious) and useful inventions for a fixed period, which is typically up to 20 years. For certain inventions, this period may be extended. In addition, to maintain a pending application or patent, it is necessary to pay renewal fees, usually on an annual basis. Patents may be granted in relation to a wide range of subject matter, such as new or improved products, new uses for products and methods. Such subject matter must, however, be industrially applicable.

A patent cannot be granted on a worldwide basis. Rather, patents must be obtained in every country where protection is required. Although there is a certain amount of harmonisation between the patent granting procedures and standards throughout the world, there are differences regarding the test for patentability. Accordingly, patent scope may vary from country to country and indeed a patent may not be granted in a particular country for failure to comply with the relevant standards.

#### 13.3.3 Patenting Process

In most countries, the process of protecting patent rights begins with the submission of a patent application comprising a patent specification describing the invention. Filing an Australian patent application (provisional or complete) or other initial patent application in a foreign country which permits such a filing, satisfies this requirement.

A fundamental requirement of the patent system is that the invention is novel and inventive at the time of filing, relative to what was publicly known or used at the date of the application. Accordingly, it is imperative that the



specification contains a full disclosure of the invention. A patent specification generally consists of a description of the invention and so-called claims which define the scope of the invention.

Once the initial application has been filed, further applications in foreign countries must be filed within twelve (12) months, pursuant to an international Treaty called the Paris Convention, otherwise rights to the invention may be lost in those countries. In this regard, the Paris Convention provides that the filing of an initial patent application establishes a priority date for the invention in all other countries which are party to this Convention, including countries such as the USA, Japan and Australia, as well as regions such as Europe and Eurasia.

The filing of further patent applications in foreign countries may be pursued individually or in some instances by filing an application with a regional patent office that does the work for a number of countries, such as the European Patent Office and the African Regional Industrial Property Organisation. The Patent Cooperation Treaty ("PCT") may also be utilised for the filing of a single international patent application. The PCT allows applicants to request patent protection in as many signatory states as needed at a later date.

Once a PCT application has been filed it is subjected to what is called an "international search", carried out by one of the major patent offices. The search results are then communicated to the patent applicant in an "international search report", which is a listing of published documents that might affect the patentability of the invention claimed in the international application. On the basis of the international search report the applicant may decide to withdraw the application. However, if the PCT application is not withdrawn, it is, together with the international search report, published by the International Bureau.

If the applicant decides to continue with the international application, then within thirty (30) months of the provisional patent application filing date, national patent applications need to be filed. In some countries such as Australia and regions such as Europe, the deadline is thirty-one (31) months.

Once the PCT process has been completed then the national or regional phase is undertaken, as the PCT application itself does not mature into patents. The standard documentation and fee requirements will need to be satisfied in each country, and in non-English speaking countries that will include translating the PCT specification into the language of the relevant country. Failure to enter the national phase within the thirty (30) month period will result in abandonment of the ability to secure patent protection in most PCT countries.

The national or regional applications progress under the jurisprudence and legislation of each country or region. In most jurisdictions, such as Australia, Europe, United States and Japan, examination by the relevant patent office comprises an examination of the art from which the invention pertains as it existed at the priority date of the application. Examination establishes what is referred to as the "state of the art". The patent application is measured against the state of the art and an assessment is made regarding whether the invention described in the application is novel, inventive, useful and relates to patentable subject matter in that jurisdiction. Therefore, the time required to complete the process of examination differs from country-to-country and the scope of protection may differ depending upon the law of each country. In general, it will take several years from the date of application until the patent is actually granted. With respect to regional applications, like the European application, this involves filing a single application designating any of the countries that are signatories to the Convention covering that region. The single application is subjected to examination, and assuming that the application is allowed, it will proceed to the grant phase. The applicant can then elect to have patents validated in all or some of the originally designated countries, and the individual patents then function as though they were patents granted under standard national procedures.

#### **13.3.4 Granted Patents: Renewal Fees, Validity, Exploitation and Enforcement**

Once a patent has been granted renewal fees will need to be paid, otherwise the patent will cease.

A patent owner has the exclusive rights to use the patented technology throughout the lifetime of a patent. This means that the owner can decide to exclusively use it for their own benefit and prevent others from using it. Alternatively, they can allow others to use it under the terms of a license agreement. The terms of the license agreement generally define the limited scope of the use of the patent and the consideration to be paid for the use of it.

Enforcement of patent rights varies from country-to-country. The remedies for unauthorised use (patent infringement) available to the patent owner often include an injunction, which effectively stops further infringement of the patent, damages or account of profits, and costs.

### 13.3.5 Trade Marks

A trade mark distinguishes the owner's products and services from those of competitors and is an indicator of the source of the products and services. A trade mark may be a word, device, packaging get-up, product shape, combinations of these, or indeed, almost any aspect of branding that serves to differentiate the owner's products and services from those of competitors.

Trade mark registration provides the owner or its authorised users the right to exclusive use of the trade mark in those countries where registration is achieved, and precludes others from using or registering the same or a similar trade mark in the same field of business. It also provides an enforceable right against misuse by competitors, and is an asset and property right which may be licensed or sold.

### 13.3.6 Registration of Trade Marks Internationally

It is possible to file trade mark applications in foreign countries using a number of systems and it is a matter of deciding, in each case, which system is preferable, but the rights granted by registration are the same irrespective of the system used. The three systems are:

1. International registration under the Madrid Protocol system - This is an "international registration" allowing the filing of a single application designating the country or countries of interest. There are over 50 countries in the Madrid Protocol system and the whole of Europe can be designated as a single region. To file an international application the trade mark owner must have either a trade mark registration or a pending application in the home country of the business entity. The international filing undergoes preliminary examination for formalities at the central office called the International Bureau in Geneva and then undergoes examination based on the law of each designated country.
2. European Community Trade Mark (CTM) - The CTM regime is a single registration covering all member countries of Europe.
3. National Registrations – In most countries it is possible to register a trade mark directly in the country of interest and for those countries that are not members of the Madrid Protocol such as Canada, South Africa, some Asian countries, and some South American countries.

### 13.3.7 Maintenance of Trade Mark Registrations

In some countries, such as Canada, it is necessary to prove use of a trade mark before registration is granted. In other countries, such as USA it is necessary to prove use of a trade mark after registration so as to maintain a valid registration, and if proof of use is not provided the registration is deemed to be abandoned.

In most countries, a registered trade mark is vulnerable to cancellation by application by a third party if it is unused during the life of the registration. The non-use period which will trigger the risk of cancellation proceedings varies from country to country, but is usually a three or five year period during which there has been no commercial use of the trade mark for the goods or services of the registration, in which the trade mark is registered.

There is also the requirement to maintain the registration by paying registration fees by the relevant date, usually every ten years after registration.

## 13.4 Sienna Cancer Diagnostics Ltd Intellectual Property Patent Portfolio

### 13.4.1 Overview

Sienna Cancer Diagnostics Ltd. telomerase based cancer detection platform and products are protected by a number of patents. Sienna Cancer Diagnostics Ltd. has obtained a license to broad overarching patent protection for human telomerase reverse transcriptase (hTERT) protein and anti-hTERT antibodies and is currently pursuing more focused applications directed towards the use of anti-hTERT antibodies in various methods of cancer detection.

Sienna Cancer Diagnostics Ltd is also pursuing trade mark protection for its business name and the name of its lead anti-hTERT antibody.

### 13.4.2 Intellectual Property Owned by Sienna Cancer Diagnostics Ltd

#### Patents

##### (i) Patent Family 1: Method of Detecting Cancer

Owner	Sienna Cancer Diagnostics Ltd
Inventors	LALLA, Minesh; TURATTI, Fabio; WILSON, Sharyn
Priority Data	AU 2014900494
Earliest Priority Date	17 February 2014
International Application PCT No	PCT/AU2015/050060
[Publication Number]	[WO2015/120523]
International Application Filing Date	17 February 2015

#### Ownership

This patent family is owned by Sienna Cancer Diagnostics Ltd.

#### Brief Summary of the Invention

This patent family is directed towards use of anti-telomerase antibodies in methods of resolving inconclusive cytology to detect cancer. The pending claims are focused towards the current commercial activities of Sienna Cancer Diagnostics Ltd which include licensing its telomerase detection platform to pathology laboratories for use in resolving inconclusive cytology to detect cancers such as bladder cancer.

#### Summary

- The application published on 20 August 2015 as WO2015/120523 with an international search report (ISR).
- The ISR indicates that all pending claims are novel. However, the International Examiner asserts that the claims lack an inventive step. Arguments rebutting the Examiner's assertions have been formulated in consultation with Sienna Cancer Diagnostics Ltd.
- Applications are pending in USA, Europe, Japan, China, Israel and Australia. Patentability will ultimately be judged on a country by country basis during Examination.

#### Status

The Table below summarises the status of this patent family.

Country	Official No	Status	Predicted Expiry
International	PCT/AU2015/050060	Pending	17 February 2035
USA	15/116182	Pending	17 February 2035
Europe	15748774.5	Pending	17 February 2035
Japan	2016-550860	Pending	17 February 2035
China	2.0158E+11	Pending	17 February 2035
Israel	247270	Pending	17 February 2035
Australia	2015218188	Pending	17 February 2035

(ii) Patent Family 2: Cancer Detection Method

Owner	Sienna Cancer Diagnostics Ltd
Inventors	HOSKIN, Matthew; LALLA, Minesh; TURNBULL, Shannon
Priority Data	AU 2015903361
Earliest Priority Date	19 August 2015
International Application PCT No	PCT/AU2016/050764
[Publication Number]	[WO2017/027928]
International Application Filing Date	18 August 2016

**Ownership**

This patent family is owned by Sienna Cancer Diagnostics Ltd.

**Brief Summary of the Invention**

This application is also directed towards use of anti-telomerase antibodies in cancer detection methods.

**Summary**

- The application published on 23 February 2017 as WO2017/027928 with an international search report (ISR).
- The ISR initially indicates that all pending claims are novel. However, the International Examiner asserts that the claims lack an inventive step. They also assert that the priority document of family 1 may be relevant for considerations of novelty. Arguments rebutting the Examiner's assertions have been formulated in consultation with Sienna Cancer Diagnostics Ltd.


**Status**

The Table below summarises the status of this patent family.

Country	Official No	Status	Predicted Expiry
International	PCT/AU2016/050764	Pending	18 August 2036

**Trade Marks**

The Table below summarises the status of the Sienna Cancer Diagnostics Ltd. trade mark portfolio.

Trade Mark	Country	Official No	Filing Date	Case Status
	Australia	1824912	9 February 2017	Filed, 1st Examination Report Issued
SCDA7	Australia	1824911	9 February 2017	Filed, 1st Examination Report Issued

## Ownership

The trade marks in the above table are owned by Sienna Cancer Diagnostics Ltd.

### 13.4.3 Licensed Technology

Sienna Cancer Diagnostics Ltd has a licence to several patents owned by Geron Corporation. The patents are directed towards human telomerase transcriptase (hTERT) protein and anti-hTERT antibodies.

#### (i) Patent Family 1: Human Telomerase Catalytic Subunit

Owner	Geron Corporation
Inventors	CECH, Thomas; LINGNER, Joachim; NAKAMURA, Toru; CHAPMAN, Karen; MORIN, Gregg; HARLEY, Calvin; ANDREWS, William
Priority Data	US 08/724,643; US 08/844,419; US 08/846,017; US 08/851,843; US 08/854,050; US 08/911,312; US 08/912,951; US 08/915,503
Earliest Priority Date	1 October 1996
International Application PCT No	PCT/US1997/017885
International Application Filing Date	1 October 1997

## Ownership

This patent family is owned by Geron Corporation. Sienna Cancer Diagnostics Ltd has obtained a license to the patent family from Geron Corporation.

### Brief Summary of the Invention

This patent family is directed towards human telomerase transcriptase (hTERT) protein and anti-hTERT antibodies.

### Status and Claim Scope

The Table below summarises the status of this patent family.

Country	Official No	Status	Predicted Expiry
Austria	ATE245194T1	Granted	1 October 2017
Australia	734089	Granted	1 October 2017
Brazil	PI9712254.8	Pending	1 October 2017
Canada	2267664	Granted	1 October 2017
China	1291231	Granted	1 October 2017
Europe	2213740 (09176870.5)	Pending	1 October 2017
Europe	841396	Granted	1 October 2017
Belgium	841396	Granted	1 October 2017
France	841396	Granted	1 October 2017
Germany	841396	Granted	1 October 2017



## SECTION 13

### PATENT REPORT

Country	Official No	Status	Predicted Expiry
Great Britain	841396	Granted	1 October 2017
Ireland	841396	Granted	1 October 2017
Italy	841396	Granted	1 October 2017
Luxembourg	841396	Granted	1 October 2017
Spain	841396	Granted	1 October 2017
Sweden	841396	Granted	1 October 2017
Switzerland	841396	Granted	1 October 2017
Great Britain	2317891	Granted	1 October 2017
Hong Kong	1038585	Granted	1 October 2017
Israel	129103	Granted	1 October 2017
Japan	3869092	Granted	1 October 2017
Korea	10-0530483	Granted	1 October 2017
New Zealand	334709	Granted	1 October 2017
Norway	319982	Granted	1 October 2017
Singapore	64216	Granted	1 October 2017
Switzerland	689672	Granted	1 October 2017
USA	7285639	Granted	21 June 2018
USA	7413864	Granted	4 February 2018
USA	7750121	Granted	4 February 2018

### 13.5 Proprietorship

Typically, a patent for an invention may only be granted to the inventor(s) or to a person who has entitlement to the invention by way of assignment, employment contract or other means.

FB Rice understands that Sienna Cancer Diagnostics Ltd is entitled to be recorded as the owner of the applications listed in Section 13.4.2 discussed above.

It is important to note that there are legal mechanisms by which third parties can bring evidence that they have sole or joint entitlement to an invention and any patent application or patent obtained for that invention. We are not aware of any issues regarding the ownership or entitlement with respect to the patents or patent applications listed in Section 13.4.

### 13.6 Validity of Patents

The ultimate validity of the claims of a patent cannot be guaranteed. Various legal mechanisms exist to challenge the validity of patents and patent applications. For example, validity of a patent application may be challenged in the following ways:

- a. during examination;
- b. in opposition proceedings once the application has been examined and found allowable;
- c. in court during revocation proceedings brought by a third party; or
- d. during infringement proceedings initiated against an alleged infringer.

As at the date of this Report, we are not aware of any litigation being commenced in respect to any patent or patent application referred to in this Report.

As some of the patent rights set out in this Report are still pending patent applications and will undergo examination, it cannot be assumed that these applications (or any applications stemming from them) will proceed to grant or, if grant is achieved, that the claims will remain in their present form. It is possible, for example, that the scope of the claims of these patent applications may be restricted during examination of the applications.

## **13.7 Limitations and Qualifications**

### **13.7.1 Information Sources**

In preparing this Report, in addition to reviewing our internal databases, we relied upon information contained in relevant publicly available databases and the searches conducted by the appropriate national and international patent and trade mark offices with respect to the patents, patent applications and trade mark applications in Section 13.4. FB Rice is not responsible for the accuracy of the information available in public databases and accordingly cannot guarantee the accuracy of this information.

### **13.7.2 Jurisdictional Requirements**

Each jurisdiction has its own laws and particular requirements that need to be met for the grant and maintenance of a patent. Accordingly, the assessment of patentability varies from jurisdiction-to-jurisdiction, and inventions, which may be granted and registrable in one jurisdiction, may be excluded from grant and registration in another. Moreover, the different jurisdictional requirements may result in variation of the scope of patent protection obtained for the same patent in different jurisdictions. The outcome of examination of the patent application by the office of one jurisdiction is not binding on the office of any other jurisdiction. Similarly, international PCT searches and examination reports are not binding on national patent applications during examination in the national phase.

In some jurisdictions there is a duty to disclose certain information to the relevant patent office. This information can include relevant prior art information known to the applicant or its agents, or search results issued in respect of corresponding foreign applications. Failure to disclose such information may adversely affect the validity and/or enforceability of the patent.

We further note that there may be changes to patent and/or trade mark law and its interpretation by the courts in a particular jurisdiction from time-to-time, which may have an impact on patents and/or trade marks in the relevant jurisdiction. For example, the Australian Government recently enacted the Intellectual Property Law Amendments (Raising the Bar) Act 2012 (Cth), which represents a significant amendment to Australian patent law. In particular, the Act raises the requirement for patentability and the description requirements for patent specifications. It applies to all Australian patent applications for which a request for examination was filed on or after 15 April 2013. Other examples include relatively recent decisions of the US Supreme Court which have increased the threshold for what constitutes patentable subject matter in the USA.

### **13.7.3 Patentability Search Limitations**

A patentability search, such as international searches carried out by various patent offices under the PCT procedure, cannot be guaranteed to locate all prior art that may exist which is potentially relevant to the assessment of novelty and inventive step of a claimed invention. Such searches are generally computer-based searches and are dependent on the database search strategy and the coverage provided by the databases used. For example, the databases may not cover older published documents and/or certain jurisdictions. Further, all patentability searches are subject to the accuracy of records, as well as the indexing and classification of the subject matter comprising the records. The scope of each search is also dependent on the search strategy utilised and, for example, the keyword(s) selected for the search.

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## SECTION 13

### PATENT REPORT

Besides documentary prior art, commercialisation or secret use of an invention by, or with the authority of, a patent applicant (or their predecessor in title), public use of an invention and non-confidential oral disclosures before the priority date of a patent application may also be relevant to the assessment of patentability. As patentability searches are conducted on published documents, they would not locate such other forms of prior art disclosures.

Accordingly, although patentability searches provide a reasonable indication of patentability, it is not possible to guarantee that every relevant prior art record has been located and considered. As a result, any conclusions regarding the validity of the claims of a particular patent based on patent office searches should be regarded as indicative rather than conclusive.

Further, non-provisional patent applications are not normally published until at least 18 months from the earliest acceptable priority date. Accordingly, a patentability search would not normally identify any third party patent application that is potentially relevant to the assessment of patentability that has a priority date which is less than 18 months prior to the date of the patentability search. Delays between official publication and the incorporation of information into the relevant database can also occur, which means that some documents may not be located in a patentability search.

#### 13.7.4 Freedom to Operate

There is no guarantee that the patent rights referred to in this Report comprise all of the rights that are required for Sienna Cancer Diagnostics Ltd. to be entitled to freely use and commercialise its products. If third party patents or patent applications contain claims infringed by Sienna Cancer Diagnostics Ltd. technology and these claims are valid, Sienna Cancer Diagnostics Ltd. may be unable to obtain licenses to these patents at a reasonable cost, if at all, and may also be unable to develop or obtain alternative technology. If such licenses cannot be obtained at a reasonable cost, the business could be significantly impacted.

#### 13.7.5 Entitlement to Claimed Priority Date

In Australia, for subject matter contained in a non-provisional patent application to be entitled to the priority date established by a corresponding priority patent application or provisional patent application, there must be a “real and reasonably clear disclosure” of the subject matter in the priority application. Similar provisions apply in other jurisdictions. Subject matter disclosed in a non-provisional patent application that is not contained in a corresponding priority application is generally only entitled to the filing date of the non-provisional application as a priority date.

### 13.8 Statement of Independence

FB Rice is a firm of patent and trade mark attorneys that provide advice in relation to all aspects of intellectual property. FB Rice has extensive experience protecting and defending intellectual property rights and commercialising products and services. FB Rice provides a comprehensive intellectual property service through its patent and trade mark attorney practices, consultancy arm and through its partnership with a major international renewal service.

FB Rice has no interest in Sienna Cancer Diagnostics Ltd, other than fees for professional work done.

FB Rice has no involvement in the preparation of the Prospectus by Sienna Cancer Diagnostics Ltd, other than the preparation of this Report. FB Rice is therefore considered independent of Sienna Cancer Diagnostics Ltd. for the purpose of preparing this Report and gives its consent for inclusion of this Report in the Prospectus.

The persons responsible for preparing this Report are Dr Ian Rourke, Partner in FB Rice and Dr Cameron Smith, Associate in FB Rice.

# SECTION 14

## RISK FACTORS



### 14.1 Introduction

This section identifies some of the major risks associated with an investment in the Company. Intending Applicants should consider the risk factors described below, together with information contained elsewhere in this Prospectus, before any decision is made to subscribe for Shares.

There are numerous risks which could materially and adversely affect the financial and operating performance of the Company, which in turn could impact the value of the Shares. The Directors and management have implemented internal controls and processes to mitigate some of these risks. There are however risks over which the Company, the Directors and management will be unable to exert significant influence.

Any potential investor should be aware that subscribing for Shares involves various risks. The Shares to be issued pursuant to the Prospectus carry no guarantee with respect to the payment of dividends, return of capital or the market value of those Shares. An investment in Shares of the Company should therefore be considered speculative.

### 14.2 Business Risks Associated With The Company

- a. Sufficiency of Funding:** The funding proposal set forth in this Prospectus is based on the Company's best estimation of cash flow projections and estimated expenditures for either an 18 or 23 month period, depending on the amount raised. The Directors and management believe that, on receipt of funds from the Prospectus, Sienna will have sufficient working capital to carry out its stated objectives. However, financial resources are limited and the Company may never achieve profitability. The Company may be required to raise additional funds from time to time to finance completion of the development and commercialisation of its products and other longer-term objectives. The ability to raise additional funding is subject to factors beyond the control of the Company and its Directors, including cyclical factors affecting the economy and share markets generally. The Directors can give no assurance that future funds can be raised by the Company on favourable terms, if at all.
- b. Expenditure Program:** Contracts, or binding quotations, for a number of the material items covered by the Expenditure Program have yet to be entered into/sought. The Directors believe the

Company will be well positioned to negotiate terms of such contracts following the receipt of funding from the Offer. The Directors and management team have extensive experience in the diagnostics and healthcare industry and have prepared the anticipated expenditure detailed in Section 4 based on some indicative quotations, discussions with potential suppliers and their own experience of the likely costs for those expenditure items. While the Directors and management are confident Sienna will be able to source suitable suppliers at the estimated expenditure, there is a risk that the Company will be unable to.

- c. Regulatory Requirements:** Regulatory bodies and the requirements they impose on the registration of medical devices, including IVD tests, are complex and vary by region. Registration can be a lengthy process, where for example prior determinations made by other regulatory bodies are not determinate of the decision reached by a new regulatory authority. Most countries have their own specific regulatory systems that take little heed of other country regulations or the status of products registered in other regions. The USA, China and Japan are examples of these independent regulatory environments.

Countries within the EU adhere to a single, common set of regulatory requirements, with translational requirements being the main difference between countries.

Australia, New Zealand, Canada and several Asian countries each have their own regulatory authorities and sets of requirements, but recognise the registration of medical devices in other regions, namely the EU and its CE marking, as acceptable evidence and grounds for registration, usually with minimal additional requirements.

Sienna has registered its first in-market product as a Class 1 IVD in the USA, a CE marked / General Class IVD in the EU, and a Class 2 IVD in Australia. There is no guarantee that regulatory approval or registration in these countries will not be revoked at some future time.

Additional country-specific regulatory approvals or registrations will be sought as required, as Sienna's geographical expansion program is executed. There is no guarantee that registration or approval by the relevant regulatory authorities in any future targeted countries will be achieved.



Despite registration in the USA, commercial success significantly depends on the uptake of the IVD test (its use in laboratories) in the USA.

- d. Key Personnel:** The Company currently employs a number of key management and scientific personnel. Sienna will also require the services of additional staff to further develop the Company's products and implement marketing strategy. The Company's future success depends on retaining and attracting suitably qualified personnel. The Company has implemented a short-term incentive program as well as a long-term incentive plan in the form of employee share options aimed at assisting the recruitment and retention of personnel. Despite these measures there is no guarantee that the Company will be able to attract and retain suitably qualified personnel, and a failure to do so could materially and adversely affect the business, its operating results and financial prospects.
- e. Competition:** The Company operates in the competitive diagnostics industry. There are companies within the industry with significantly greater financial, technical, human, research and development, and marketing resources than the Company. The Company's competitors may develop products in advance of Sienna's and/or produce products that are more effective than those developed by the Company. If this was to occur, the Company's current and future products may become obsolete or uncompetitive, resulting in adverse effects on cash flows and profitability.
- f. Innovative Technological Commercialisation:** The Company's IVD product is relatively unproven in the market place in that only a limited number of laboratories in the USA are currently using the Company's IVD test. Notwithstanding that commercialisation of the Company's technology has already been conducted in the form of their ASR product, if the Company's IVD product is ultimately taken up in the market at a lower rate than anticipated, the Company's business and resulting value may be materially harmed.
- g. Manufacturing/Production Risks:** Production of a diagnostic antibody is a low risk undertaking for an experienced and capable manufacturer. Nonetheless there is some risk that batches manufactured for sale do not pass acceptance testing or are rejected for quality control reasons, leading to an inability to supply product to the market.
- h. Dependence on Service Providers:** The Company intends to operate a significant amount of its key activities through a series of contractual relationships with licensees, independent contractors and suppliers. All of the Company's contracts carry a risk that the third parties do not adequately or fully comply with its or their respective contractual rights and obligations. Such failure could lead to termination and/or significant damage to the Company's product development efforts.
- i. Third Party Licensees:** The Company's strategy for the development and commercialisation of its products depends on the formation of licensing or other commercial relationships with third parties that have complementary capabilities. The Company intends to establish licensing or other commercial relationships to achieve its product development and commercial objectives. The Company may not have all the resources that it needs to internally develop its products through to market launch, and intends to rely on its ability to enter into licensing or other commercial relationships to achieve this objective and on its commercial partner's abilities to fulfil their respective contractual responsibilities. Any failure by the Company's collaborators and commercial partners to fulfil their responsibilities could adversely impact the value of the Company.
- j. Product Liability:** As with all new products, even after regulatory product registration or approval, there is no assurance that unforeseen performance characteristics or manufacturing defects will not arise. Such events could expose the Company to product liability claims or litigation, resulting in the removal of the regulatory registration or approval and/or monetary damages. The Company maintains product liability insurance however there is no guarantee that liabilities arising out of any claim will remain within Sienna's insurance coverage. There is also no guarantee that adequate product liability insurance will continue to be available or available at a reasonable cost. Product liability claims have the potential to damage the Company's reputation and ongoing viability.
- k. Healthcare Insurers and Reimbursement:** In both domestic and foreign markets, sales of products are likely to depend in part upon the availability and amounts of reimbursement from third party healthcare payer organisations, including government agencies, private healthcare insurers, self-insured employee plans and other healthcare payers such as health maintenance organisations. In most major markets, there is considerable pressure to reduce the cost of healthcare. No assurance can be given

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## SECTION 14

### RISK FACTORS

that reimbursement will continue to be provided by such payors at all, or without substantial delay, or that reimbursement amounts will be sufficient to enable the Company to sell products developed on a profitable basis.

**I. Currency Risk:** While the Company's financial reports are prepared in Australian dollars, a proportion of revenues and expenditures are earned and incurred in overseas jurisdictions. These revenues and expenditures are subject to the risk of fluctuations in foreign exchange markets. The Company currently receives product revenues in US dollars and has US payment obligations under intellectual property licensing agreements. To facilitate the receipt of US funds and payment of US liabilities, Sienna maintains a US dollar account. The account acts as a natural hedge for Sienna's exposure to the US currency. The Company has, and expects future, Great British Pound expenditures and anticipates future exposures to the EURO and some Asian currencies. As a result of fluctuations in foreign currency markets, transactions made in all foreign currencies may exceed budgeted amounts. Other than the natural hedge discussed, the Company has no plans to hedge its foreign currency payments.

**m. Changes in Australian Government Research and Development Incentives:** The use of funds and the Expenditure Program outlined in this Prospectus includes the anticipated receipt by the Company of tax refunds based on the Company's actual research and development spending. There is no guarantee that the Australian Federal Government will not change its Research and Development Tax Incentive program. If the program ceases or a material adverse change is made to the refundable component of the program, a significant funding gap would result, jeopardising the achievement of the product development and commercialisation objectives outlined within the Prospectus.

### 14.3 The Company's Intellectual Property

**a. Patent Protection:** As noted in the Patent Report in Section 13, certain of Sienna's patent applications are subject to review and may not be granted. The examiner has queried whether there is an inventive step in developing the subject matter of the patent application (which is a critical component in determining whether to grant a patent application). Sienna has intellectual property in the form of a global licence from Geron for the use of hTERT in human diagnostics, plus a licence to use certain biological

materials (as outlined in Section 16 f. ii.). There is no guarantee that the Company's patent applications will be granted or that the Company's owned and licensed patent rights comprise all the rights that the Company ought to have acquired to be entitled to freely use and commercialise its products. Further, there may be a legal challenge to any patent within the Sienna intellectual property portfolio. A loss of any material part of Sienna's intellectual property portfolio (for example where there is a challenge to Sienna's intellectual property rights) could adversely impact Sienna's development and commercialisation activities.

**b. Trade Secrets:** The Company relies on its trade secrets, which include information relating to the manufacture, development and deployment of its diagnostic products. The protective measures that the Company employs may not provide adequate protection for its trade secrets. This could erode the Company's competitive advantage and materially harm its business. The Company cannot be certain that others will not independently develop the same or similar technologies on their own or gain access to trade secrets or disclose such technology, or that the Company will be able to meaningfully protect its trade secrets and unpatented know-how and keep them secret.

**c. Infringement of Third Party Intellectual Property:** If a third party accuses the Company of infringing its intellectual property rights, or if a third party commences litigation against the Company for the infringement of patent or other intellectual property rights, the Company may incur significant costs in defending such action, whether or not it ultimately prevails. Typically, patent litigation in the healthcare industry is expensive. Costs that the Company may incur in defending third party infringement actions would also include diversion of management's and technical personnel's time. In addition, parties making claims against the Company may be able to obtain injunctive or other equitable relief that could prevent the Company from further developing discoveries or commercialising its products. In the event of a successful claim of infringement against the Company, it may be required to pay damages and obtain one or more licenses from the prevailing third party. If it is not able to obtain these licenses at a reasonable cost, if at all, it could encounter delays in product introductions and loss of substantial resources while it attempts to develop alternative products. Defence of any lawsuit

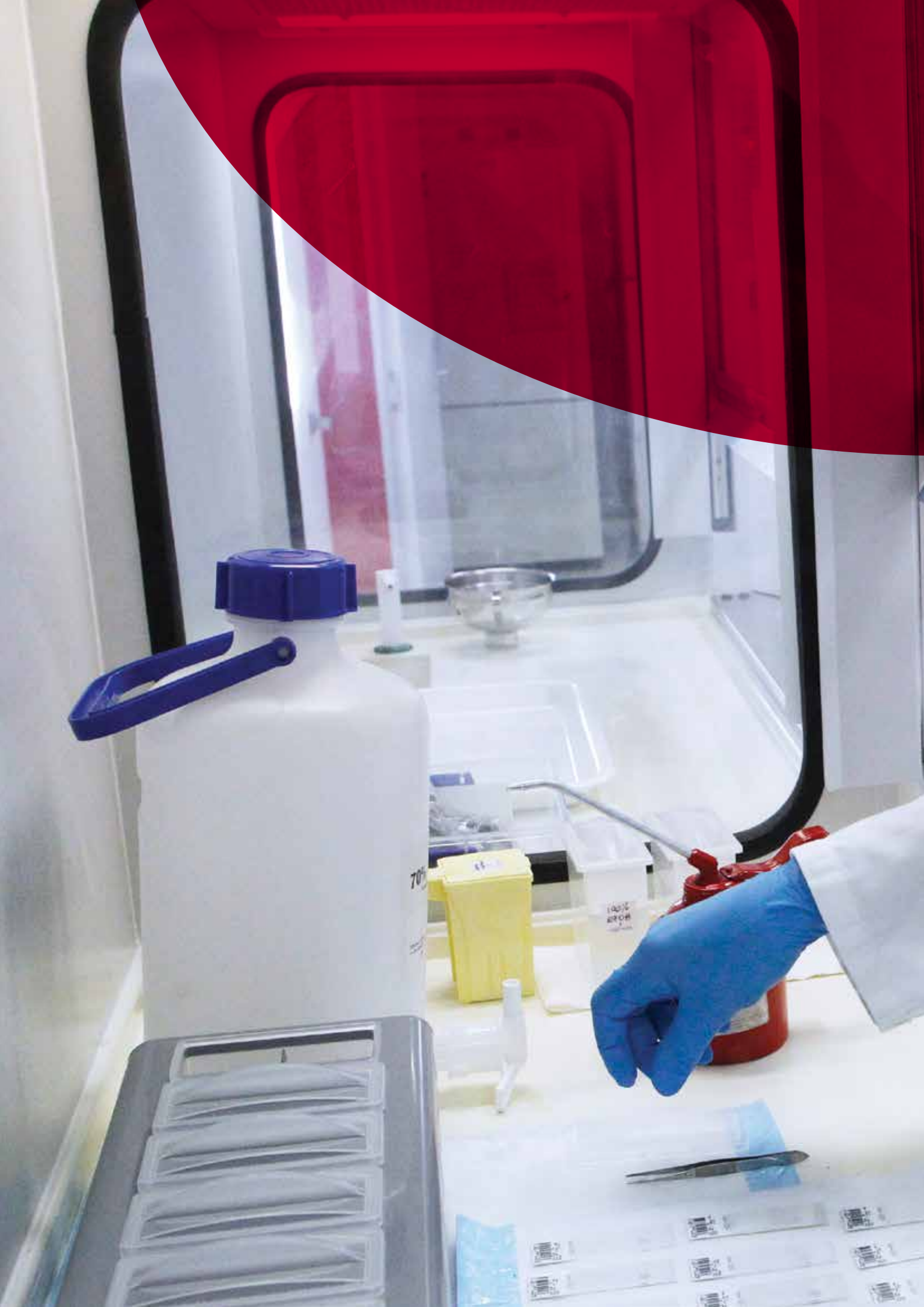
or failure to obtain any of these licenses could prevent the Company or its partners from commercialising available products and could cause it to incur substantial expenditure.

#### 14.4 Investment and General Risk Factors

- a. No Independent Valuation:** No independent valuation of Sienna has been undertaken for the purposes of the listing. Valuations of biotechnology companies before significant commercial use of the Company's products can be imprecise. The Directors do not believe that an independent valuation would be meaningful, given the likely qualifications and limitations in such valuations, and the difficulties and high cost of determining the likely commercial success of the Company, its technologies and products given the further development work required.
- b. Market for Shares:** Prior to the Offer there has been no public market for the Shares. No assurance can be given that an active market will develop in the Shares, or that the Shares will trade at or above the Offer Price after the Shares have been listed on the Official List and after Official Quotation.
- c. Stock Market Volatility:** The Company's achievements, the day to day performance of the share market, and general market/economic conditions may impact the Company and the price at which its Shares trade on the ASX. The share market has in the past and may in the future be affected by a number of factors, including:
  - i. general economic conditions
  - ii. investor sentiment towards a particular industry sector
  - iii. interest rates
  - iv. market confidence
  - v. trading activities including short selling
  - vi. the supply of capital
  - vii. currency exchange rates
  - viii. force majeure events
  - ix. political instability
  - x. changes in government policy

#### 14.5 Concluding Comment

The Risks discussed in this section are not a complete list of risks potentially impacting the Company's financial performance or the value of the Shares offered under this Prospectus. The Shares to be issued pursuant to this Prospectus carry no guarantee with respect to the payment of dividends, return of capital or the market value of those Shares. The Company, its Directors or any other party associated with the preparation of this Prospectus cannot guarantee that any objectives of the Company will be achieved, or that any particular performance of the Company or of the Shares, including those offered by this Prospectus, will be achieved.







# SECTION 15

## TAXATION



The Australian taxation summary provided in this section provides a general overview of the tax implications for Australian residents who acquire and hold the Shares under the offer contained in this Prospectus. This summary is based on the tax laws of Australia at the date of this Prospectus. If Australian tax laws were to change following the issuance of this Prospectus, the tax consequences discussed may alter.

Australian tax laws are complex. What is discussed here is not intended to cover all of the possible taxation implications for investors. Shareholders are advised to seek independent professional advice regarding the tax consequences of holding and disposing of their Shares, taking into account their specific circumstances.

The commentary that follows assumes shareholders hold their Shares on capital account. If the Shares are considered to be held on revenue account (which may be applicable to share traders for example) a different treatment for taxation may apply.

### **Australian Investors**

#### **i. Capital Gains Tax**

Under the capital gains tax (CGT) regime of the Australian tax legislation, shareholders who hold Shares on capital account are subject to the CGT regime on disposal of those Shares. A shareholder will make a capital gain where the capital proceeds received exceed the cost base of those Shares. Conversely, a shareholder incurs a capital loss where the capital proceeds received on disposal are less than the reduced cost base of the Shares. Broadly, the cost base, and reduced cost base, of Shares acquired is the amount you pay to acquire the Shares plus any incidental costs of acquisition and disposal of the Shares. For CGT purposes, you acquire your Shares on the date the Shares are issued or allotted to you.

Capital losses made in the same or prior income years can typically be offset against any capital gains made in the current year. Any remaining net capital gain is included in assessable income and taxed. Where a net capital loss is incurred it may be carried forward indefinitely and offset against future capital gains subject to the loss recoupment rules.

Shareholders who are individuals, trusts or superannuation entities may be entitled to a 50% discount on capital gains if the Shares have been held for 12 months or more. Complying superannuation

funds and life insurance companies holding the Shares as virtual pooled superannuation trust assets are entitled to a discount of 33.3%. Companies are not entitled to the discount.

#### **ii. Stamp Duty**

While the Shares remain quoted on the ASX no stamp duty is payable on the issue or transfer of Shares.

#### **iii. Taxation of Dividends**

##### ***Australian resident individuals***

Dividends paid to Shareholders will constitute assessable income in the income year they are received. Dividends you receive may be franked or unfranked. Franked dividends have “franking credits” attached and represent the Australian corporate tax paid by the Company. Franking credits should be added to the dividend received and included in your assessable income.

Shareholders are entitled to a tax offset against tax payable for the income year equal to the franking credits received, if two tests are satisfied. The two tests are the “holding period rule” and the “related payments rule”. These rules will, in broad terms, be met where you have held the Shares at risk for at least 45 continuous days (excluding the dates of acquisition and disposal).

##### ***Australian resident trusts***

The ultimate Australian resident beneficiaries of Australian resident trusts who receive dividends are generally entitled to a tax offset based on their share of the franking credit attached to distributed dividends. However, the tax treatment of the dividend depends on the type of beneficiary receiving the distribution (is the beneficiary an individual, a corporate entity or a trustee?). Where the trust itself is subject to tax on the dividend, then it may be entitled to offset the tax payable against the franking credit. A franking credit is unable to be utilised where the trust records a net loss or does not have any net income. However, if the trust records at least \$1 of net income for the income year, the franking credits are able to be passed through to beneficiaries entitled to income of the trust.

For non-fixed trusts, the trustee may be required to make a family trust election in order to enable beneficiaries to utilise the franking credits.

# SECTION 16

## ADDITIONAL INFORMATION



## SECTION 16

### ADDITIONAL INFORMATION

#### a. Company Information

The Company was incorporated on 6 March 2002 under the Corporations Act 2001 as a public company limited by shares. The Company is taxed as a public company and its statutory accounts reported to 30 June annually.

#### b. Share Capital Structure

Following the completion of the Offer the shareholding structure\* in Sienna will be as follows:

Category	Number of Shares at the Minimum Subscription	% Ownership interest	Number of Shares at the Maximum Subscription	% Ownership interest
Existing Shares	157,274,327	88.7%	157,274,327	84.0%
New Shares offered under this Prospectus	20,000,000	11.3%	30,000,000	16.0%
<b>Total</b>	<b>177,274,327</b>	<b>100%</b>	<b>187,274,327</b>	<b>100%</b>

\* Sienna had 2,273,314 shareholder options on issue at the date of this Prospectus. These options become exercisable on or after 2 April 2018, expire 2 October 2018 and are exercisable at \$0.22 cents. The Company also operates an Employee Share Option Plan (ESOP). There were 10,530,000 options on issue under this ESOP at the date of the Prospectus. Details of the ESOP are provided below at Section 16 (i).

#### c. Rights Attaching to Shares

The Shares offered under this Prospectus are fully paid ordinary Shares in the capital of Sienna. A summary of the more significant rights attaching to the Shares, detailed in the Company's Constitution, is set out below. This summary is not exhaustive nor does it constitute a definitive statement of the rights and liabilities of Sienna members.

- **Ranking** – The Shares will be ordinary Shares and will rank equally in all respects with the ordinary Shares in Sienna on issue prior to the date of this Prospectus.
- **Reports and Notices** – Members are entitled to receive all notices, reports, accounts and other documents required to be furnished to members under the Constitution of Sienna and the Corporations Act.
- **General Meetings** – Subject to any preferential or special rights attaching to any Shares that may be issued by Sienna in the future, members are entitled to be present in person, or by proxy, attorney or, where the member is a body corporate, by representative to speak and to vote at general meetings of Sienna. Members may requisition general meetings in accordance with the Corporations Act and the Constitution of Sienna.
- **Voting** – At a general meeting of Sienna every ordinary member present in person, or by proxy, attorney or representative shall, on a show of hands have one vote, and upon a poll have one vote, for every Share held.
- **Reduction of Capital** – Subject to the Corporations Act and Listing Rules, Sienna may resolve to reduce its share capital by any lawful manner as the Directors or shareholders may approve.
- **Winding Up** – Members will be entitled in a winding up to share in any surplus assets of Sienna in proportion to the capital paid up, or which ought to have been paid up, at the commencement of the winding up on the Shares held by them respectively.
- **Transfer of Shares** – Shares in Sienna may be transferred in any form authorised by the Corporations Act or approved by the Directors and in the manner prescribed by the Constitution of Sienna, the Corporations Act, the Listing Rules or the ASX Settlement and Operating Rules. The Directors may, subject to the Listing Rules and the ASX Settlement and Operating Rules, request an ASX approved clearing and settlement facility to apply a holding lock to prevent any transfer of Shares. The Directors may refuse to register a paper based transfer of a Share in particular circumstances.
- **Issue of Further Shares** – The Directors control the allotment, issue, grant of options in respect of, and disposal of Shares. Subject to restrictions on the allotment of Shares and grant of options to Directors or their associates under the Company's Constitution and the Corporations Act, the Directors may allot, grant options or otherwise dispose of Shares on such terms and conditions as they see fit.

- **Takeover Approval Provisions** – Any proportional takeover scheme must be approved by those members holding Shares included in the class of Shares in respect of which the offer to acquire those Shares was first made. The registration of the transfer of any Shares following the acceptance of an offer made under a scheme is prohibited until that scheme is approved by the relevant members.
- **Application of Listing Rules** – On admission to the Official List of the ASX, if the Listing Rules prohibit an act being done, the act must not be done, despite anything in the Constitution of Sienna. Likewise, nothing in the Constitution 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 (as the case may be). If the Listing Rules require a Constitution to contain a provision or not to contain a provision, the Constitution is deemed to contain that provision or not to contain that provision (as the case may be). If a 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 that inconsistency.

**d. CHESS**

The Company will apply to be admitted to participate in CHESS, in accordance with the ASX Listing Rules and the ASX Settlement and Operating Rules. On admission to CHESS, the Company will operate an electronic issuer-sponsored sub-register and an electronic CHESS sub-register. The two sub-registers together will make up the Company's principal register of Shares.

The Company will not issue certificates to Shareholders. Shareholders who elect to hold Shares on the issuer-sponsored sub-register will be provided with a holding statement (similar to a bank account statement), which sets out the number of Shares allotted to the Shareholder under this Prospectus. For Shareholders who elect to hold the Shares on the CHESS sub-register, the Company will issue an advice that sets out the number of Shares allotted to the Shareholder under this Prospectus. At the end of the month of allotment, CHESS (acting on behalf of the Company) will provide Shareholders with a holding statement that confirms the number of Shares held.

A holding statement (whether issued by CHESS or the Company) will also provide details of a Shareholder's Holder Identification Number in the case of a holding on the CHESS sub-register or Shareholder Reference Number in the case of a holding in the issuer-sponsored sub-register. Following distribution of these initial holding statements to all Shareholders, a holding statement will also be provided to each Shareholder at the end of any subsequent month during which the balance of that Shareholder's holding of Shares changes.

**e. Restricted Securities and Escrow Arrangements**

The ASX may, as a condition of granting the Company's application for Official Quotation of its Shares, classify certain Existing Shares as restricted securities. Any such classification will restrict the transfer of effective ownership or control of any restricted securities without the written consent of the ASX and for such period as the ASX may determine. The terms of any such restriction or escrow arrangements will be determined by the ASX in accordance with the ASX Listing Rules. Details of any such restriction or escrow arrangements will be disclosed prior to commencement of Official Quotation of the Company's Shares.

**f. Material Contracts**

The following contracts are considered by the Directors to be material for the purposes of this Prospectus or may be relevant to a potential investor:

- i. **Material Contract – Geron Licence Agreement** - Sienna's intellectual property licence with respect to the use of hTERT as a diagnostic in commercial applications.

Sienna has entered into a Licence Agreement with Geron Corporation dated 28 November 2011 and amended on 1 June 2012 and 23 December 2014 ("Geron Licence").

The Geron Licence grants the Company a global licence to certain technology (including a number of patents) relating to hTERT protein and anti-hTERT antibodies ("**Geron Technology**"). The Geron Technology is licensed to the Company for use within the "field of use" of assays for the detection or measurement of the telomerase protein, using antibodies or antibody fragments against telomerase for the purpose of detecting cancer or susceptibility to cancer.

The term of the Geron Licence continues until the later of: (i) conclusion of sales of products which incorporate Geron know-how or are covered by a Valid Claim of the Geron Patents; or (ii) expiry of all "Valid Claims of the Geron Patents". The "Geron Patents" comprise a list of 32 patents (the latest expiring 21 June 2018), but the Company envisages continuing to sell its products after this date.

Under the Geron Licence the Company has financial obligations to pay regulatory milestones if triggered, as well as royalties (based on commercial sales by Sienna at a negotiated commercial rate); and sublicense revenue share payments where Sienna sub-licences the Geron Technology to a third party prior to the later of (i) 5 years from the last valid claim of the Geron Patents to expire, or (ii) 10 years from the first commercial sale by Sienna.

ii. **Material Contract – Dana-Farber Cancer Institute (DFCI) Agreement**

The Company has entered into an exclusive licence agreement dated 14 February 2014 with DFCI under which the Company has obtained access to certain intellectual property rights (including biological materials and technical information). The licence is exclusive to the Company in the field of in vitro diagnostic (IVD) assays for the measurement of the telomerase protein for the purpose of detecting cancer or susceptibility to cancer, but excludes the right to commercial sales for research purposes and common reserved rights (for example to the US military).

Under the DFCI licence agreement the Company has reporting obligations, diligence obligations, insurance obligations and has to pay a royalty to DFCI on both commercial sales by the Company and any sub-licensing fees received by the Company relating to the DFCI intellectual property (at arm's length commercial rates).

Further the Company have given commercial indemnities in favour of DFCI for liabilities incurred by DFCI from the sale by the Company of its products incorporating the DFCI intellectual property. The DFCI licence, subject to usual provisions for early termination (for example non-payment of royalties or breach of the licence agreement), is for a term of 20 years.

iii. **Material Contract – Statlab Medical Distribution Agreement - Sienna's USA sales distribution arrangement.**

On 16 September 2016, the Company entered into a non-exclusive distribution agreement ("**Distribution Agreement**") with SLMP LLC (also known as Statlab Medical) ("**Distributor**") for the distribution of 1ml single vials of Anti-hTERT antibody (SCD-A7) ("**Product**") in the United States of America ("**Territory**"). The Distribution Agreement has an initial twelve month term and will be automatically renewed for successive twelve month periods unless terminated by either party in accordance with the terms of the Distribution Agreement.

The Distribution Agreement contains certain standard representations, and warranties by Sienna to the Distributor. These include but are not limited to representations and warranties relating to product defects, and indemnities relating to breach of warranties, and specifications. Sienna must obtain and maintain product liability insurance with bodily injury, death and property limits of at least USD1 million per occurrence and USD5 million in aggregate.

iv. **Material Contract – Sequoia Engagement Letter – Sienna's Lead Manager and Corporate Adviser.**

Sienna has engaged Sequoia to act exclusively as its corporate adviser in connection with the Offer pursuant to the terms of a letter of engagement dated 4 April 2017 (Engagement Letter). Sienna has also granted a right of first refusal to Sequoia for a limited period to be engaged as financial adviser to the Company for mergers and acquisitions actions, including in the event that the Company receives a takeover offer or offer for the purchase of the Company's assets.

The Company has agreed to pay Sequoia the following fees and reimbursements (exclusive of GST) in consideration for the following Services:

- **Retainer fee:** a monthly retainer fee of \$10,000 per month commencing on the date of the Engagement Letter;
- **Ongoing corporate advisory fees:** a fixed payment of \$50,000 for corporate advisory services to be provided by Sequoia to Sienna for a period of 12 months from listing;



- **Brokerage fee:** brokerage fees totalling 7% of funds raised under the Offer (excluding funds raised as part of the Chairman's List). The Company will pay Sequoia 2% of funds raised through Chairman's List investors;
- **DvP establishment costs:** the sum of \$10,000 for the establishment and execution of the DvP settlement function; and
- **Out-of-pocket expenses:** the Company will from time to time reimburse Sequoia for reasonable costs and expenses it incurs in connection with the engagement.

Sienna has agreed to indemnify Sequoia and certain affiliated entities and persons against all losses, claims, and liabilities which any of them suffer in connection with, directly or indirectly, the Offer or the Engagement Letter (Indemnity). The Indemnity is subject to certain exceptions, including wilful misconduct, fraud, or gross negligence.

#### **g. Agreements: Staff and Consultants**

The Company has entered into agreements with staff and consultants. Each of these agreements contains a confidentiality clause. The terms of these agreements with regards to confidentiality are standard in that they impose restrictions on the disclosure of confidential information and restrictions on the use of confidential information, except for the purposes for which it has been disclosed. The agreements are subject to the usual exclusions in relation to information that was in the public domain when disclosed, that comes into the public domain after disclosure, other than as a result of the recipient's breach of the agreement or was in the recipient's possession when disclosed. Some agreements contain other exclusions relating to disclosure required by law to the extent required to be disclosed.

#### **h. Directors' and Officers' Deeds of Indemnity, Insurance and Access**

The Company has entered into a deed of indemnity, insurance and access with each of its Directors and Officers. The key features of the deed may be summarised as follows:

- i. to the extent permitted by law, the Company:
  1. indemnifies each of the Directors and Officers against any liability incurred by the Director or Officer or former Director or Officer of the Company;
  2. indemnifies the Director or Officer against any reasonable legal costs incurred as a result of the Director or Officer defending an action for any liability incurred by the Director or Officer as a Director or Officer or former Director or Officer of the Company;
  3. releases the Director or Officer from any present, future or contingent claims that arise directly or indirectly from the Director's or Officer's position, acts or omissions as a Director or Officer or former Director or Officer of the Company, other than in respect 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.
- ii. the Company must, where possible, maintain appropriate insurance cover in favour of the Director or Officer during the term of the Director's or Officer's appointment and for at least a period of seven years after the Director or Officer ceases to be a Director or Officer of the Company on terms that are reasonably prudent to the Company;
- iii. the Director or Officer, during his or her appointment and for a period of seven years after the Director or Officer ceases to be a Director or Officer of the Company, may inspect any books and records of the Company in certain circumstances and for particular purposes; and
- iv. the Director or Officer is entitled to retain any board documents, including minutes of board meetings or committees. These documents will become the property of the Director or Officer at the time they are supplied to the Director or Officer. Notes of board meetings or other communications made by the Director or Officer will remain the property of the Director or Officer. Upon request the Director or Officer agrees to provide the Company with a copy of these documents.

#### **i. Employee Share Option Plan (ESOP)**

The Company has adopted an ESOP to foster an ownership culture within the Company and to motivate Directors and staff to achieve performance targets. All employees and Directors are eligible to participate in the ESOP at the absolute discretion of the Board.

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Shares allotted and issued on exercise of options granted under the ESOP rank equally in all respects with other Shares from the date of allotment and issue, subject to satisfaction of any applicable disposal restrictions.

The aggregate number of Shares which may be issued pursuant to the ESOP (when aggregated with all Shares that may be issued under any other employee incentive plans), shall not at any time exceed 15% of the total number of issued Shares. The Company may offer with an invitation to participate in the ESOP, an interest free limited recourse loan to assist in funding the issue price in respect of the relevant Shares.

The issue price of Shares purchased on exercise of options issued, and to be issued, under the ESOP is set at the time of granting options and is determined by the Board.

At the date of this Prospectus the Company has 10,530,000 Options on issue under this ESOP, 8,030,000 exercisable at \$0.22 and the balance of 2,500,000 exercisable at \$0.243, with varying vesting and expiry dates (the last expiry date being 1 April 2022). From this pool of 10,530,000 Options, the CEO Matthew Hoskin has been granted 1,500,000 Options exercisable at \$0.22 with an expiry date of 3 February 2018 and 2,500,000 options exercisable at \$0.243 with an expiry date of 1 April 2022.

#### **j. Corporate Governance**

The Directors are responsible for the strategic direction of the Company, the identification and implementation of corporate policies and goals, and monitoring of the business and affairs of the Company on behalf of its members.

The Company is cognisant of the Corporate Governance Principles and Recommendations (3rd Edition), ("**Corporate Governance Principles**") as published by the ASX Corporate Governance Council and acknowledges that the 8 principles set out therein are fundamental to good corporate governance.

The Board believes that the structure of the Company, its management and business practices provide a basis of governance which meets the essential corporate governance principles articulated by the ASX in the abovementioned publication. The Board intends to formally adopt a Corporate Governance Policy for the Company which will be available on the Company's website in due course.

One of the key objectives of the Board is to ensure timely, transparent and accurate communication with all members and compliance with all regulatory requirements. To this effect the Board has established the following Committees:

- i. An Audit and Risk Committee whose primary function is to give additional assurance regarding the quality and reliability of financial information used by the Board and financial information provided by the Company pursuant to its statutory reporting requirements.
- ii. A Remuneration Committee whose primary function is to review and report to the Board the matters concerning executives' and Directors' remuneration.

While the ASX Corporate Governance Principles and Recommendations are not compulsory, the Company will and in accordance with Listing Rule 4.10, advise the market whether it meets the ASX Corporate Governance Principles and Recommendations and if not, state why not. Please find below a high level summary of the Company's current departures from the ASX Corporate Governance Principles and Recommendations:

Departure from ASX Corporate Governance Principles and Recommendations	Reason for Departure
<p><b>Corporate Governance Principle 1.5</b> A listed entity should:</p> <ul style="list-style-type: none"> <li>a. have a diversity policy which includes requirements for the Board or a relevant committee of the Board to set measurable objectives for achieving gender diversity and to assess annually both the objectives and the entity's progress in achieving them;</li> <li>b. disclose that policy or a summary of it; and</li> <li>c. disclose as at the end of each reporting period the measurable objectives for achieving gender diversity set by the Board or a relevant committee of the Board in accordance with the entity's diversity policy and its progress towards achieving them.</li> </ul>	<p>Due to the size of the of Company and the number of employees as at the date of this Prospectus, the Board is yet to implement a formal diversity policy or set objectives for gender diversity. When a position becomes available, the Company seeks to employ the best candidate available and does not discriminate on the basis of age, gender, ethnicity, sexual orientation, religion or on any other grounds. The Company recognises the importance of building a strong female presence across all tiers of the business.</p> <p>As at the date of this Prospectus, the Company employs 10 people, 4 of whom are female. The Board is made up of 4 male Non-executive Directors.</p>
<p><b>Corporate Governance Principle 1.6</b> A listed entity should:</p> <ul style="list-style-type: none"> <li>a. have and disclose a process for periodically evaluating the performance of the Board, its committees and individual Directors; and</li> <li>b. disclose, in relation to each reporting period, whether a performance evaluation was undertaken in the reporting period in accordance with that process.</li> </ul>	<p>As at the date of the Prospectus and due to the Company's size and resources, the Board has not adopted a formal process for periodically evaluating the performance of the Board, its committees and individual Directors. However, once Listed, the Board will consider (taking into account the Company's financial and human resources) whether a formal process of evaluation should be adopted.</p>
<p><b>Corporate Governance Principle 1.7</b> A listed entity should:</p> <ul style="list-style-type: none"> <li>a. have and disclose a process for periodically evaluating the performance of its senior executives; and</li> <li>b. disclose, in relation to each reporting period, whether a performance evaluation was undertaken in the reporting period in accordance with that process.</li> </ul>	<p>As at the date of the Prospectus and due to the size of the Company, the Board has not adopted a formal process whereby it periodically evaluates the performance of its senior executives. However, once Listed, the Board will consider (taking into account the Company's financial and human resources) whether a formal process of evaluation should be adopted.</p>

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**SECTION 16**  
**ADDITIONAL INFORMATION**

<p><b>Corporate Governance Principle 2.1</b> The Board of a listed entity should:</p> <p>a. have a nomination committee which:</p> <ol style="list-style-type: none"><li>1. Has at least three members, a majority of whom are independent Directors; and</li><li>2. is chaired by an independent Director, and disclose:<ul style="list-style-type: none"><li>• the charter of the committee;</li><li>• the members of the committee; and</li><li>• as at the end of each reporting period, the number of times the committee met throughout the period and the individual attendances of the members at those meetings; or</li></ul></li></ol> <p>b. if it does not have a nomination committee, disclose that fact and the processes it employs to address Board succession issues and to ensure that the Board has the appropriate balance of skills, knowledge, experience, independence and diversity to enable it to discharge its duties and responsibilities effectively.</p>	<p>As at the date of this Prospectus, the Board does not consider it necessary to establish a Nomination Committee.</p> <p>The tasks of director and executive succession planning and the identification of Directors for appointment are currently carried out by the Board. The Board may engage an external consultant to help identify potential Board members and executives. Only those Directors with the relevant experience to fill the gaps of representation on the Board are considered for Shareholder approval of their appointment to the Board. All existing Directors interview potential Board members. Shareholders are provided with all the relevant information, including biographical details, pertaining to the director/s put forward for election/ re-election.</p>
<p><b>Corporate Governance Principle 2.6</b> A listed entity should have a program for inducting new Directors and provide appropriate professional development opportunities for Directors to develop and maintain the skills and knowledge needed to perform their role as Directors effectively.</p>	<p>As at the date of this Prospectus, the Company has not adopted a formal induction program for new Directors. The Board will consider adopting a formal induction process once Listed.</p>
<p><b>Corporate Governance Principle 4.2</b> The Board of a listed entity should, before it approves the entity's financial statements for a financial period, receive from its CEO and CFO a declaration that, in their opinion, the financial records of the entity have been properly maintained and that the financial statements comply with the appropriate accounting standards and give a true and fair view of the financial position and performance of the entity and that the opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.</p>	<p>The Company is aware of all financial reporting requirements and the ASX recommendation outlined in Corporate Governance Principle 4.2. The Board intends to implement this process once Listed.</p>

<p><b>Corporate Governance Principle 6.1</b> A listed entity should provide information about itself and its governance to investors via its website.</p>	<p>As a formal corporate governance policy is yet to be adopted by the Board, there is no information on the Company's website about its governance. At the date of this Prospectus however, a draft Corporate Governance Policy is being considered by the Board and a corporate governance policy will be adopted before the Company is Listed. Sienna intends to disclose the policy on its website.</p>
<p><b>Corporate Governance Principle 7.2</b> The Board or a committee of the Board should:</p> <ol style="list-style-type: none"> <li>review the entity's risk management framework at least annually to satisfy itself that it continues to be sound; and</li> <li>disclose, in relation to each reporting period, whether such a review has taken place.</li> </ol>	<p>As at the date of this Prospectus, the Company is yet to formally implement a risk management framework. However, risk management strategies are discussed at length at Board level.</p> <p>As the Company matures, it is anticipated that a formal risk management framework will be adopted. The Audit and Risk Committee will be expected to report against the risk management framework.</p>
<p><b>Corporate Governance Principle 7.3</b> A listed entity should disclose:</p> <ol style="list-style-type: none"> <li>if it has an internal audit function, how the function is structured and what role it performs; or</li> <li>if it does not have an internal audit function, that fact and the processes it employs for evaluating and continually improving the effectiveness of its risk management and internal control processes.</li> </ol>	<p>Due to the relatively small size of the Company's operations and its financial resources, Sienna does not have an internal audit function.</p> <p>Walker Wayland NSW Chartered Accountants conducts the Company's annual external audit at the end of each financial year.</p>
<p><b>Corporate Governance Principle 8.2</b> A listed entity should separately disclose its policies and practices regarding the remuneration of Non-executive Directors and the remuneration of Executive Directors and other senior executives.</p>	<p>Once Listed, the specific details of the Company's policies and practices regarding remuneration will be outlined within the Directors' Report of the annual statutory accounts.</p>

**k. Directors' Share Qualifications, Remuneration and Interests**

Except as disclosed in the Prospectus, no Director or proposed Director of the Company, or firm in which a Director or proposed Director is a partner, has any interest, nor has had any interest for registration, or has received or is entitled to receive any sum for services rendered by either him or the firm to induce him to become or qualify him as a Director, or otherwise in connection with the promotion or formation of the Company or in the property proposed to be acquired by the Company in connection with its promotion or formation.

**i. Shareholding Qualifications and Remuneration**

The Directors are not required under the Constitution of the Company to hold any Shares in order to qualify as Directors.

The Constitution provides that the Directors are entitled to remuneration for their services as Directors as determined by the Company in general meeting. A Director may be paid fees or other amounts as the Directors determine, where a Director performs special duties or otherwise performs services outside the scope of the ordinary duties of a Director. A Director may also be reimbursed for any disbursements or any other out of pocket expenses incurred as a result of the directorship or any special duties.



## SECTION 16

### ADDITIONAL INFORMATION

#### ii. Directors' Interests and Annual Remuneration

Set out below are details of the interests of the Directors in the Shares and other securities of the Company, and annual remuneration, immediately prior to lodgement of the Prospectus with ASIC for registration. Interests include those held directly and indirectly.

Name	Position	Annual Remuneration	Shares Directly Held <sup>#</sup>	Options Held	Option Valuation <sup>*</sup>
Dr Geoffrey Cumming	Non-executive Chairman	\$54,750	823,860	600,000	\$9,900
Dr David Earp	Non-executive Director	\$27,375	133,334	400,000	\$6,080
Mr Carl Stubbings	Non-executive Director	\$27,375	113,975	400,000	\$6,080
Dr John Chiplin	Non-executive Director	\$27,375	-	-	-

<sup>#</sup> All Shares held by Directors were paid for by the Directors; no Shares have been issued in lieu of services provided.

<sup>\*</sup> Option Valuation Assumptions:

The fair value of options is determined using a modified binomial option pricing model that takes into account the issue price, the term of the options, the Share price at issue date and expected price volatility of the underlying Share, the expected dividend yield and the risk free interest rate. The Directors options shown in the above table were valued using the following information and inputs:

Directors	Dr Geoffrey Cumming	Dr David Earp	Mr Carl Stubbings
Issue price of option	\$0.00	\$0.00	\$0.00
Exercise price	\$0.22	\$0.22	\$0.22
Issue date	13 July 2015	18 June 2015	22 June 2015
Term (years)	4 years	4 years	4 years
Expected dividend yield	0%	0%	0%
Risk free rate	5.75 %	5.75 %	5.75 %
Estimated volatility	20.06 %	20.06 %	20.06 %

#### I. Interests and Consents of Experts

Except as disclosed in this Prospectus:

- No expert, or firm in which any expert is a partner, has any interest that existed when a copy of the Prospectus was lodged with ASIC for registration, nor had any such interest within 2 years before lodgement of the Prospectus for registration, in the promotion of the Company or has received or is entitled to receive any sum for services rendered by the expert or the firm in connection with the promotion or formation of the Company, or in any property proposed to be acquired by the Company in connection with the promotion or formation.
- No amounts have been paid or agreed to be paid to any expert, or any firm in which any expert is a partner, for services rendered in connection with the promotion or formation of the Company.

In accordance with the terms of its engagement Walker Wayland NSW Chartered Accountants has prepared the Independent Accountant's Report (which forms part of this Prospectus). Walker Wayland will be paid \$8,000 (plus GST) for services provided in connection with this Offer and may receive further payments in accordance with its normal time based charges.

In accordance with the terms of its engagement, K&L Gates as Australian legal advisers for the Company will be paid \$100,000 (plus GST) for services provided in connection with this Offer and may receive further payments in accordance with its normal time based charges.

In accordance with the terms of its engagement, FB Rice as patent attorneys for the Company will be paid \$3,000 (plus GST) for the provision of its Patent Attorney Report (which forms part of this Prospectus) and may receive further payments in accordance with its normal time based charges.

In accordance with the terms of its engagement, Sequoia Corporate Finance as Lead Manager will be paid aggregate fees between \$320,000 and \$460,000 (plus GST) (depending upon the amount raised pursuant to the Offer) for acting as corporate advisor in connection with this Offer.

i. **Walker Wayland NSW Chartered Accountants – Independent Accountant – Wali Aziz**

Walker Wayland NSW, Chartered Accountants has given and not withdrawn its written consent to being named as Independent Accountant for Sienna in the Prospectus in the form and context in which it is named and the issue of the Prospectus with its Independent Accountant's Report dated 24 May 2017 in the form and context in which it is included and to all references to that report in the Prospectus in the form and context in which those references are included.

Walker Wayland NSW, Chartered Accountants in its capacity as an Independent Accountant has only participated in the preparation of the Prospectus to the extent of preparing its Independent Accountant's Report. Walker Wayland was not involved in the preparation of any other part of the Prospectus and did not authorise or cause the issue of any other part of the Prospectus.

Except as provided above Walker Wayland NSW, Chartered Accountants does not make, or purport to make, any statement in this Prospectus and is not aware of any statement in this Prospectus which purports to be based on a statement made by it and makes no representation, express or implied, regarding and takes no responsibility for, any statement in or omissions from this Prospectus.

ii. **Walker Wayland NSW Chartered Accountants – Auditor – Richard Woods**

Walker Wayland NSW, Chartered Accountants has given and not withdrawn its written consent to being named as Auditor for Sienna in the Prospectus in the form and context in which it is named.

Walker Wayland NSW, Chartered Accountants in its capacity as Auditor was not involved in the preparation of any part of the Prospectus and did not authorise or cause the issue of any other part of the Prospectus.

Walker Wayland NSW, Chartered Accountants does not make, or purport to make, any statement in this Prospectus and is not aware of any statement in this Prospectus which purports to be based on a statement made by it and makes no representation, express or implied, regarding and takes no responsibility for, any statement in or omissions from this Prospectus.

iii. **K&L Gates – Legal Advisers**

K&L Gates has given and not withdrawn its written consent to be named herein as Australian Legal Advisers to Sienna in the form and context in which it is so named. K&L Gates does not make, or purport to make, any statement in this Prospectus and is not aware of any statement in this Prospectus which purports to be based on a statement made by it and makes no representation, express or implied, regarding and takes no responsibility for, any statements in or omissions from this Prospectus.

iv. **FB Rice – Patent Attorney**

FB Rice has given and not withdrawn its written consent to be named herein as Patent Attorneys to Sienna in the form and context in which it is so named. Other than the expert report contained in Section 13, FB Rice does not make, or purport to make, any statement in this Prospectus and is not aware of any statement in this Prospectus which purports to be based on a statement made by it and makes no representation, express or implied, regarding and takes no responsibility for, any statements in or omissions from this Prospectus.

v. **Link Market Services Limited – Share Registry**

Link Market Services Limited has given and not withdrawn its written consent to be named herein as the share registry to Sienna in the form and context in which it is so named. Link Market Services does not make, or purport to make, any statement in this Prospectus and is not aware of any statement in this Prospectus which purports to be based on a statement made by it and makes no representation, express or implied, regarding and takes no responsibility for, any statements in or omissions from this Prospectus.

## SECTION 16

### ADDITIONAL INFORMATION

#### vi. Sequoia Corporate Finance – Lead Manager

Sequoia Corporate Finance Pty Ltd, a corporate authorised representative (No. 469074) of D2MX Pty Ltd (AFSL No. 297950) is named in the Corporate Directory as Lead Manager to the Offer. Each of D2MX Pty Ltd and Sequoia Corporate Finance Pty Ltd (together, “Sequoia”) have given their written consent to be named as Lead Manager to the Company in the form and context in which they are named and have not withdrawn their consent prior to lodgement of this Prospectus within ASIC.

Sequoia was not involved in the preparation of any part of this Prospectus and did not authorise or cause the issue of this Prospectus. Sequoia makes no express or implied representation or warranty in relation to Sienna, this Prospectus or the offer and does not make any statement in this Prospectus, nor is any statement in it based on any statement made by Sequoia. To the maximum extent permitted by law, Sequoia expressly disclaims and takes no responsibility for any material in, or omission from, this Prospectus other than the reference to its name.

#### m. Substantial Existing Interests in Shares

The substantial shareholders (holding more than 5% of the issued capital) in the Company as at the date of this Prospectus are as follows:

Shareholder	Number of Shares	% of Issued Capital
David Neate	17,002,970	10.81%
TRAOJ P/L	14,546,664	9.25%
Geron Corporation	13,842,625	8.80%

#### n. Costs of the Offer

If the Offer proceeds, the total estimated costs of the Offer, including legal fees incurred, registration fees, fees for other advisers, prospectus design, printing and advertising expenses and other miscellaneous expenses, will be approximately \$581,000 (excluding GST) if \$4 million is raised and \$723,000 (excluding GST) if \$6 million is raised.

#### o. Legal Proceedings

So far as the Directors are aware, at the Prospectus date, there is no litigation of a material nature, existing or threatened, which may significantly affect the Company or its activities.

#### p. Governing Law

This Prospectus and the contracts that arise from the acceptance of Applications are governed by the law applicable in Victoria and each Applicant submits to the exclusive jurisdiction of the courts of Victoria.

#### q. Authorisation

This Prospectus is issued by the authority of the Board of the Company.

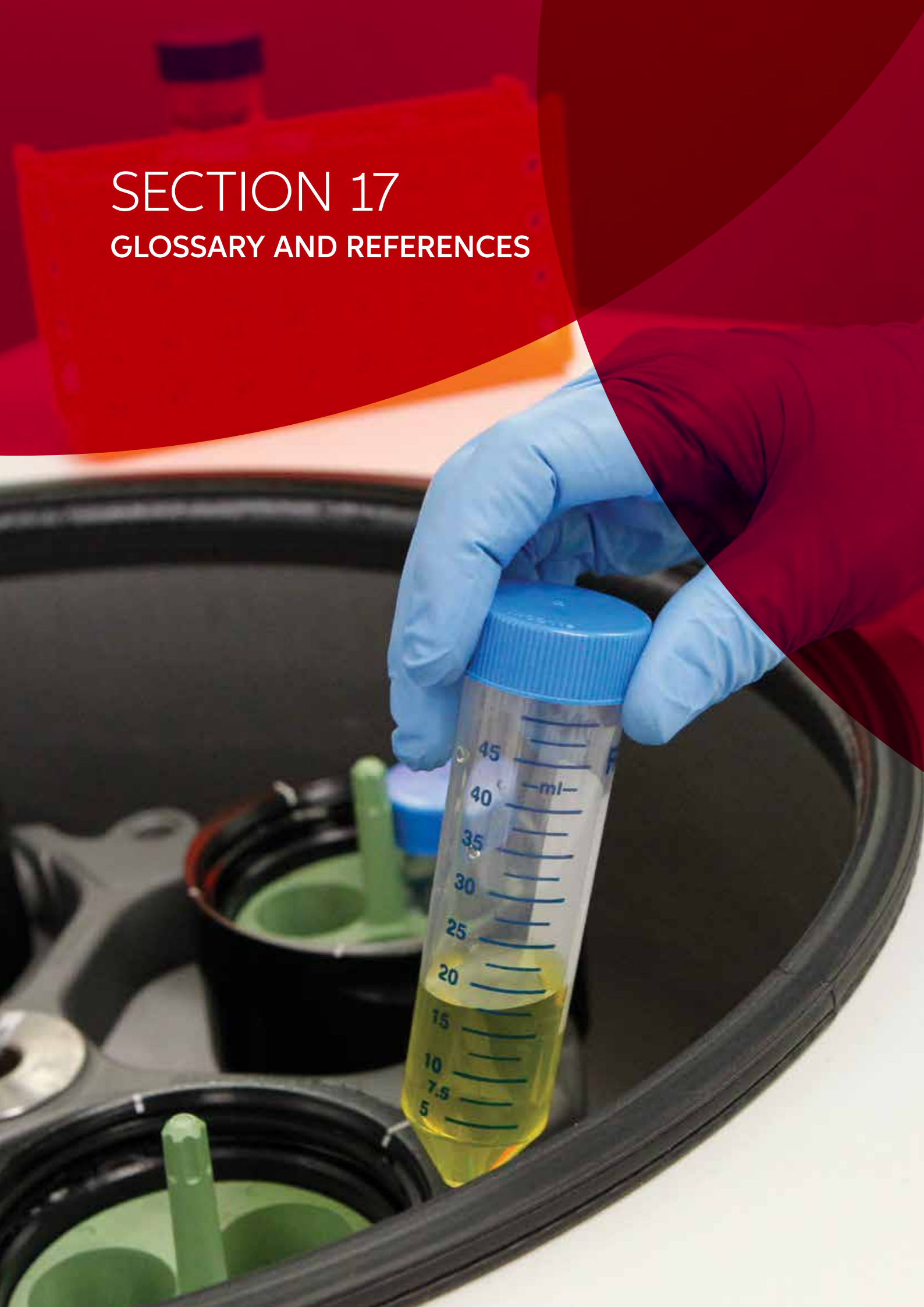
Dated: 25 May 2017



**Geoffrey Cumming**  
**Non-executive Chairman**  
**Sienna Cancer Diagnostics Limited**

# SECTION 17

## GLOSSARY AND REFERENCES



In this Prospectus, unless the context otherwise requires:

**\$** means Australian dollars.

**AEST** means Australian Eastern Standard Time.

**ASR: Analyte Specific Reagent** means the active ingredient of an in-house test. ASRs are raw materials and components used to develop laboratory assays.

**Applicant** means a person who makes an application for Shares.

**Application** means an application for Shares under this Prospectus made by an Applicant via an Application Form.

**Application Form** means the form accompanying or attached to this Prospectus by which an Applicant may apply for Shares.

**ASIC** means the Australian Securities and Investments Commission.

**ASX** means ASX Limited ACN 008 624 691 or the financial market operated by it as the context requires.

**ASX Listing Rules** means the official listing rules of the ASX exchange.

**ASX Settlement and Operating Rules** means the rules established under the Corporations Act for settlement of transactions of securities of a company for which Clearing House Electronic Sub-Register System (CHES) approval has been given.

**Board** means the board of Directors of the Company.

**Business Day** means a day that is not a Saturday or Sunday or a public holiday in Victoria.

**CAGR: Compound Annual Growth Rate**

**cGMP: Current Good Manufacturing Practice** means the FDA's regulations ensuring that products are consistently produced in a controlled environment with quality standards guiding their intended use.

**CHES** means the Clearing House Electronic Sub-register System.

**Closing Date** means the date on which the Offer closes, as outlined in Section 2 of this Prospectus.

**Company** means Sienna Cancer Diagnostics Limited ACN 099 803 460.

**Constitution** means the constitution of the Company.

**Corporations Act** means the Corporations Act 2001 (Cth).

**Cytology** means the study of cells, focusing on the structure or morphology of cells.

**Cytopathology** means the study or evaluation of changes in cells as the result of disease.

**DNA: Deoxyribonucleic Acid** means the molecule that carries the genetic instructions for growth, development, functioning and reproduction of living cells.

**Directors** means the Directors of the Company.

**Epithelial cancers** (or carcinomas) means cancers that begin in one of the tissues that line the entire inner or outer surfaces of the body. They are the most common type of cancer in adults.

**Existing Shares** means the issued Shares immediately prior to the allotment of Shares under the Offer.

**Expenditure Program** means the anticipated expenditures to be incurred by the Company and funded by the capital raising under this Prospectus as detailed in Section 4, under Use of Funds.

**Exposure Period** means the period of 7 days (or 14 days if extended by ASIC) after the lodgement of the Prospectus with ASIC during which the Company may not accept Applications.

**FDA: Food and Drug Administration** means the USA regulatory body.

**Histology** means the study of tissues, and more specifically the study of the structure of tissues as seen under a microscope.

**Histopathology** means the study or examination of the structure of diseased tissue.

**hTERT** means human Telomerase Reverse Transcriptase.

**Immunocytochemistry (ICC)** means the cell staining process used to detect the presence of a biomarker in cells, by use of a specific antibody which binds to the biomarker in question, thereby allowing visualisation and examination under a microscope.

**Immunohistochemistry (IHC)** means the tissue staining process used to detect the presence of a biomarker in tissue, by use of a specific antibody which binds to the biomarker in question, thereby allowing visualisation and examination under a microscope.

**IVD: In Vitro Diagnostic** means a medical device which is intended by the manufacturer for the in vitro examination of specimens derived from the patient to provide information for diagnostic, monitoring or compatibility purposes.



**Lead Manager or Sequoia** means Sequoia Corporate Finance Pty Ltd ACN 602 219 072.

**Listing or Listed** means the admission of the Shares to quotation on the ASX in accordance with the ASX Listing Rules.

**Listing Date** means the date Listing occurs.

**MHRA: Medicines and Healthcare products Regulatory Agency** means the European regulatory authority.

**Offer** means the offer of up to 30 million ordinary Shares under this Prospectus.

**Offer Price** means \$0.20 per Share.

**Official List** means the official list of the ASX.

**Official Quotation** means official quotation of the Shares on the Official List.

**Opening Date** means the date the Offer opens, as outlined in Section 2 of this Prospectus.

**Prospectus** means this document dated 25 May 2017.

**Registrar** means Link Market Services Limited.

**Share** means a share in the issued capital of the Company.

**Shareholder** means a person who holds Shares.

**TGA: Therapeutic Goods Administration** means the Australian regulatory authority.

**USD** means United States Dollars.

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## SECTION 17

### REFERENCES

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18. United States Food & Drug Administration (FDA) *Code of Federal Regulations, Title 21, Part 864, Sections 864.1860 & 864.4020*.

## Directors

Dr Geoffrey Cumming – Non-executive Chairman  
Dr David Earp – Non-executive Director  
Dr John Chiplin – Non-executive Director  
Mr Carl Stubbings – Non-executive Director

## Chief Executive Officer

Mr Matthew Hoskin

## Chief Financial Officer and Company Secretary

Mr Tony Di Pietro

## Registered Office

1 Dalmore Drive  
Scoresby VIC 3179

## Lead Manager and Corporate Adviser

Sequoia Corporate Finance Pty Ltd  
Level 4, ANZAC House  
4 Collins Street  
Melbourne VIC 3000

## Auditors

Walker Wayland NSW, Chartered Accountants  
Richard Woods  
Suite 11.01, Level 11  
60 Castlereagh Street  
Sydney NSW 2000

## Australian Legal Advisers

K&L Gates  
Level 25  
525 Collins Street  
Melbourne VIC 3000

## Share Registry

Link Market Services Limited  
Tower 4  
727 Collins Street  
Melbourne VIC 3008

## Patent Attorneys

FB Rice  
Level 14  
90 Collins Street  
Melbourne VIC 3000

## Independent Accountants

Walker Wayland NSW, Chartered Accountants  
Wali Aziz  
Suite 11.01, Level 11  
60 Castlereagh Street  
Sydney NSW 2000

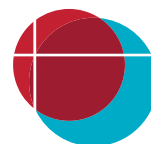
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Telephone +61 3 8288 2141

[www.siennadiagnostics.com.au](http://www.siennadiagnostics.com.au)

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CANCER DIAGNOSTICS