# SIRTEX MEDICAL LIMITED ACN 078 166 122

Prospectus

**Underwriter and Financial Advisor** 

KTM Capital Pty Limited ACN 086 281 950

**Broker to the Issue** 

Austock Brokers Pty Limited ACN 053 513 438



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This Prospectus is dated 17 July 2000 and was lodged with the ASIC on 17 July 2000. No responsibility for the contents of this Prospectus is taken by the Australian Securities and Investments Commission or Australian Stock Exchange Limited or their respective officers. This Prospectus does not constitute an offer in any place in which, or to any person to whom, it would not be lawful to make such an offer.

The distribution of this Prospectus in jurisdictions outside Australia may be restricted by law and persons who come into possession of this Prospectus should seek advice on and observe any such restrictions. Any failure to comply with such restrictions may constitute a violation of applicable securities laws.

Before deciding to invest in Sirtex Medical, potential investors should read the entire Prospectus and in particular consider the risk factors that could affect the financial performance of Sirtex Medical.

The price of shares may rise or fall according to a number of factors. You should carefully consider these risks in light of your personal circumstances (including financial and taxation issues) and seek professional advice from your accountant, stockbroker, lawyer or other professional adviser before deciding whether to invest.

No securities will be issued or allotted on the basis of this Prospectus later than 12 months after the date of the issue of this Prospectus. A number of terms and abbreviations used in this Prospectus have defined meanings which appear in the Glossary. All financial amounts shown in this Prospectus are expressed in Australian dollars unless otherwise stated.



# Chairman's Letter



17 July 2000

Dear Investor,

On behalf of the Board of Sirtex Medical, it is with pleasure that I invite you to become a shareholder in the Company. Sirtex Medical was formed to commercialise a portfolio of three products relating to the treatment of liver cancer and aims to become the world leader in liver cancer treatment products. In addition, the Company's third product is based on a new generic technology platform which may develop into a treatment for other forms of cancer, as well as having other applications in medicine.

Sirtex Medical's first product, SIR-Spheres®, is a micro-particle that can be rendered radioactive. Using procedures developed over many years, the micro-particles can be targeted to tumours within the liver tissue. SIR-Spheres® has been evaluated in Phase II and Phase III clinical trials in Australia, New Zealand and Hong Kong. General marketing approval for sale of SIR-Spheres® was granted for Australia by the Therapeutic Goods Administration in 1998 and the Company is now pursuing registration in all other relevant jurisdictions. In particular, Sirtex Medical has recently submitted a Pre-Market Approval Application to the Food & Drug Administration of the US Department of Health and Human Services for US marketing approval of SIR-Spheres®.

Sirtex Medical's second product, Dox-Spheres, involves the use of a patented matrix formulation to transport anticancer drugs to the site of the cancer, where the matrix releases the active drug into the cancer minimising the exposure of the normal tissues to the effects of the drug. The Company has completed an initial Phase I/II clinical trial and will be undertaking further trials in the immediate future.

The Company's third product, Thermo-Spheres, utilises the principle of targeted hyperthermia. Hyperthermia is a technique for treating cancer in which the temperature of the tumour is raised by as little as  $5^{\circ}$ C in order to destroy it. Hyperthermia is an effective concept for cancer therapy, but to date no technology has ever been developed that could target heat to deeply situated tumours in patients with advanced cancer.

Sirtex Medical has developed an innovative method for hyperthermia treatment of cancer using its generic targeted micro-particle technology. Results from treating animals with liver cancer using this new technique are outstanding and the Company is confident that targeted hyperthermia could become a major new form of cancer treatment. In 1999 the Company embarked on a new development program to extend the use of the technology to other forms of cancer. If these experiments prove successful it should open up enormous potential for the management of many forms of cancer.

The Company's product concepts have been developed over an eighteen year period under strict confidentiality. The Company believes that it has the patent and trademark protection to safeguard its intellectual property.

The Company is moving its head office from Perth to Sydney and has recruited a new executive team with the experience and skill to market Sirtex Medical's first product, SIR-Spheres®.

The Company believes the unmet demand for effective treatment of liver cancer provides an opportunity for Sirtex Medical's products.

Sirtex Medical has decided to list on the ASX to raise the additional capital necessary to fund the commercialisation of the Company's products. In recognition of the value of its employees, Sirtex Medical has also established an Employee Share Option Plan to help reward existing employees and attract new qualified staff.

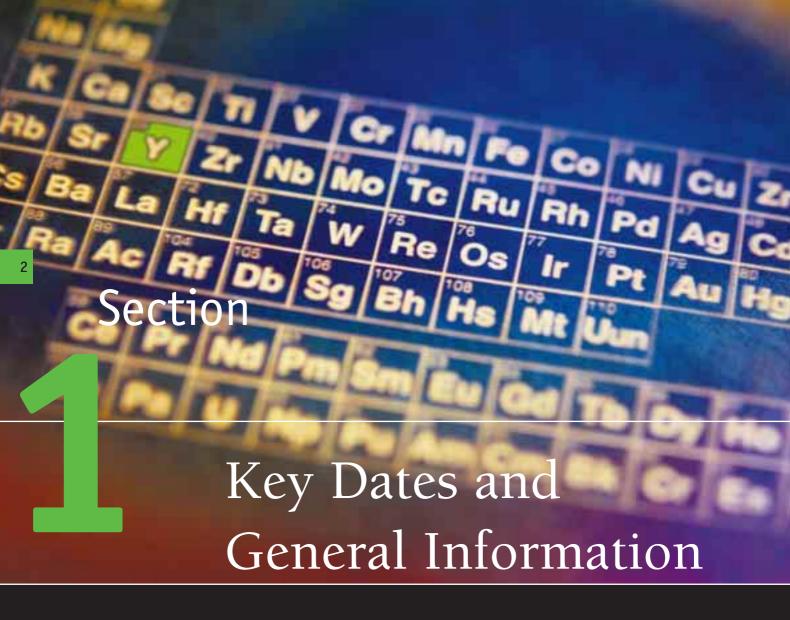
Under this Prospectus, Sirtex Medical is offering for subscription 15 million shares at an issue price of \$1.00 to raise \$15 million. Upon listing on the ASX, Sirtex Medical will have a market capitalisation of \$54 million at the Offer Price.

On behalf of the Board of Sirtex Medical, I commend this Offer to you and look forward to welcoming you as a shareholder in the Company.

Yours sincerely,

Dr. Chris Roberts

Chairman



#### **Key Dates**

Application list opens	Tuesday	25 July 2000
Application list closes	Friday	11 August 2000
Expected date of dispatch		
of holding statements	Thursday	17 August 2000
Expected date of quotation		
of Shares on the ASX	Thursday	24 August 2000

#### **Offer Statistics**

Offer Price \$1.00

Number of Shares on issue following the Offer 54,000,000

Number of Shares being offered by this Prospectus 15,000,000

Gross proceeds from issue available to Sirtex Medical \$15 million

Market Capitalisation at the Offer Price \$54 million

Net assets per Share \$34.6 cents (note 1)

Net tangible assets per Share 28.8 cents (note 1)

#### Notes

1. Based on the pro forma balance sheet (refer Section 3).

Section

- The incidence of cancer is increasing as advances in medical science lead to a decrease in the death rate from other causes of disease. Although the types of cancer that occur in first, second and third world countries varies, cancer remains one of the most important causes of death in all societies.
- At the current time liver cancer is largely untreatable and more than 95% of patients will die due to the disease.
- 3 Sirtex Medical was formed to commercialise a portfolio of three technologies relating to the treatment of liver cancer. The Company has adapted techniques for targeting large numbers of micro-particles into tumours within the liver. These particles can be manufactured from a variety of materials and act as transport vehicles to carry anticancer agents such as ionising radiation, anti-cancer drugs or materials that can generate heat within the cancer.
- 4 The Company's first product, SIR-Spheres® is a micro-particle that can be rendered radioactive and can be targeted to tumours within liver tissue.



# Investment Highlights

- 5 SIR-Spheres® have been evaluated in Phase II and Phase III clinical trials and more than 400 patients in Australia, New Zealand and Hong Kong have been treated. The Phase III clinical trial has demonstrated an increase in the remission times for patients receiving treatment.
- General marketing approval for the sale of SIR-Spheres® was granted in Australia by the Therapeutic Goods Administration in 1998. Regulatory approval has also been obtained for sale of SIR-Spheres® in New Zealand, Hong Kong and Singapore. The Company is now pursuing registration in other relevant jurisdictions. In particular, the Company recently submitted a Pre-Market Approval Application to the Food & Drug Administration of the US Department of Health and Human Services for US marketing approval of SIR-Spheres®.
- 7 Sirtex Medical's second technology for the treatment of cancer involves the use of a patented matrix formulation to transport proven anticancer drugs to the site of the cancer.
- 8 The Company's third technology for the treatment of cancer utilises the principle of targeted hyperthermia to treat cancer by raising the temperature of the tumour in order to destroy it. Sirtex Medical has developed a novel method for hyperthermia treatment of cancer using internally generated heat.
- 9 Sirtex Medical's hyperthermia technology could develop into a new generic treatment platform for many types of cancer.
- With the commercialisation of its technology Sirtex Medical aims to become a world leader in the treatment of cancer.
- 11 The Company expects the amount raised to fund the Company's activities for a period of at least 3 years. The Company does not expect to need to raise any additional capital over this period.



#### **Description of the Offer**

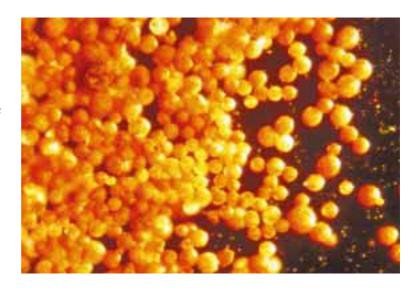
This Prospectus offers a total of 15 million Shares at an Offer Price of \$1.00 per Share, payable in full on application. The Shares being offered under this Prospectus comprise the issue of new Shares by Sirtex Medical.

The new Shares to be issued by Sirtex Medical under the Offer will rank equally in all respects with each other and the existing issued Shares of Sirtex Medical after completion of the Offer. See Section 10 for details of the rights attaching to the Shares.

After the close of the Offer the issued capital of Sirtex Medical will be 54 million fully paid Shares, of which the Existing Security holders will hold 39 million Shares, or 72.2% of the total issued capital. The Existing Security holders, holding a total of 34.35 million Shares, have entered into 24 month escrow arrangements relating to their Shares, details of which are set out in Section 10.

The Company will apply to the ASX for admission to the Official List and to have all of its issued Shares (other than shares classified as restricted securities by the ASX) listed for quotation on the ASX.

The Directors believe that, on completion of the Offer, Sirtex Medical will have enough working capital to carry out its objectives stated in this Prospectus. The proceeds of the Offer are sufficient to fund the Company for over three years.



Sirtex Medical's second generation SIR-Spheres®.

#### **Purpose of the Offer**

The purposes of the Offer are as follows:

- to fund the ongoing development, research and marketing of Sirtex Medical's anti-cancer products for over 3 years (\$13.7 million);
- to assist Sirtex Medical in retaining the services of high calibre employees by providing them with the opportunity to own Shares through an employee share option plan;
- to pay the costs of the Offer (\$1.3 million);
- to increase the public profile of Sirtex Medical; and
- to allow Sirtex Medical easier access to the equity market in order to fund future growth opportunities both through acquisitions and other business opportunities.

Projected cash requirements for Sirtex Medical over the three financial years ending 30 June 2003 are shown in the following table.

#### Projected Cash Requirements for Sirtex Medical

\$'000			
Year ending 30 June	2001	2002	2003
R&D	1,080	1,250	1,500
Marketing	800	1,350	2,300
Property, plant & equipment	1,300	1,100	600
Operating expenses	620	800	1,000
Total Expenditure	3,800	4,500	5,400

# Information Summary

#### **Financial Performance**

Sirtex Medical's results for each financial year from 1997 to 1999 are shown below.

\$	<b>Actual 3 Months</b>	Actual	Actual	Actual 6 months
Year ending 30 June	to 30 June 1997	1998	1999	to 31 Dec 1999
Revenue	19,206	529,384	400,129	308,596
Earnings Before				
Interest & Tax	(201,506)	(553,754)	(1,355,047)	(536,113)

#### Notes

- 1. Where necessary, the financial information has been adjusted to ensure comparability of results (refer Section 8).
- 2. Revenue includes all revenue including grant and interest income. Revenue for the sale of SIR-Spheres® was \$151,444, \$155,554 and \$126,246 for 1998, 1999 and the six months to 31 Dec 1999 respectively.

A summary of Sirtex Medical's Proforma Balance Sheet is set out below, incorporating the audited balance sheet as at 31 December 1999 adjusted for the Offer. The assumptions underlying the summary Proforma Balance Sheet and a detailed Proforma Balance Sheet are set out in the Independent Accountant's Report in Section 8.

	\$'000
Current Assets	15,689
Non-Current Assets	3,149
Total Assets	18,838
Current Liabilities	158
Non-Current Liabilities	_
Total Liabilities	158
Shareholders Equity/Net Assets	18,680

#### **Asset Backing**

Based on the Proforma Balance Sheet annexed to the Independent Accountant's Report in Section 8, Sirtex Medical's proforma net asset backing per Share will be 34.59 cents at the time of its ASX listing. The Sirtex Medical proforma net tangible asset backing will be \$28.8 cents per Share at the time of its ASX listing.

#### **Dividend Policy**

Sirtex Medical does not intend to pay dividends in the foreseeable future.

#### **Business and Investment Risks**

The financial performance of Sirtex Medical may be affected by a number of business risks. Some of these risks apply to companies generally and include changes in the level of interest rates, movements in exchange rates and general economic conditions.

There are also a number of risk factors that are specific to an investment in Sirtex Medical. These include:

- There are long lead times for the development of medical products and therapies;
- The reliance on retaining and attracting highly skilled staff;
- The granting of patent protection may not guarantee complete protection of the Company's intellectual property;
- Competition from parties who could potentially supply products which compete with the Company; and

 The extent of public and private health scheme reimbursement for Sirtex Medical's products will have a large impact on the Company's ability to penetrate the cancer therapy market.

A description of these and other potential business risks is set out in Section 7.

Before deciding to invest in Sirtex Medical, potential investors should read the entire Prospectus and in particular consider the risk factors that could affect the financial performance of the Company.

#### How to Apply for Shares

An application for Shares in the Offer can be made only by completing an Application Form contained in this Prospectus. Detailed instructions on the correct method of completing an Application Form are included at the end of this Prospectus.

The Application Form must be accompanied by a cheque, in Australian Dollars, for the application monies. The minimum Application under this Offer is for 2,000 Shares (being application monies of \$2,000) and thereafter in multiples of 100 Shares. All cheques must be made payable to 'Sirtex Medical Limited-Float Account' and crossed 'Not Negotiable'.

The completed Application Form should be received by:

Registries Limited Level 2 28 Margaret Street Sydney NSW 2000

no later than 5.00pm EST on the Closing Date. The Closing Date is expected to be Friday 11 August, 2000. Payments by cheque will be deemed to be made when the cheque is honoured by the bank on which it is drawn. Applicants are advised to lodge their applications as early as possible after the Offer opens.

Sirtex Medical reserves the right, in consultation with the Underwriter, to close the application list early without prior notice. The Underwriter reserves the right to extend the Offer period in consultation with the Company. The Company does not intend to accept applications received after the Closing Date other than in satisfaction of the Underwriter's obligations to meet any shortfall in Applications.

#### **Acceptance of Applications**

The Company may reject any Application, or accept an Application in respect of a number of Shares less than the number for which the Applicant applies. Acceptance of an Application by the Company creates a legally binding contract between the Applicant and the Company for the number of Shares for which the Application is accepted. Acceptance only takes place on allotment and issue of Shares.

Where an Application is rejected, the Application monies will be returned in full. If the number of Shares allotted to the Applicant is fewer than the number for which the Applicant applies, the surplus Application monies will be returned. Interest will not be paid on the returned Application monies.

The Company will allot the Shares that are the subject of successful Applications as soon as possible after the Closing Date and the grant of ASX permission for official quotation of the Shares unconditionally or on conditions acceptable to the Directors.

Pending the allotment by the Company of Shares offered by this Prospectus, the Company will deposit application monies in a separate bank account and keep them there for so long as those Applications, or any part of them, are liable to be repaid in accordance with the Corporations Law or this Prospectus.

#### **Employee Share Option Plan**

A summary of the Employee Share Option Plan is contained in Section 10.

#### **ASX Listing**

The Company will make an application to the ASX within seven days after the date of issue of this Prospectus for the Company to be admitted to the official list of the ASX and for the official quotation of all Shares (other than the Shares classified as restricted securities by the ASX).

The fact that ASX may admit Sirtex Medical to the official list is not to be taken as an indication of the merits of the Company or the Shares. The ASX, its officers and employees take no responsibility for the contents of this Prospectus.

If granted, the Company will seek quotation of the Shares as soon as is practicable after the issue of statements of holdings to Shareholders.

# **Information Summary**

If the Shares are not admitted for quotation within three months after the date of this Prospectus, any issue of Shares under this Prospectus will be void and the Company will return all application monies as soon as practicable. Interest will not be paid on any application monies refunded.

#### **Clearing House Electronic Subregister System (CHESS)**

The Company will apply to the ASX to participate in the Securities Clearing House Electronic Subregister System, known as CHESS. Under CHESS, the Company will not be issuing share certificates to investors.

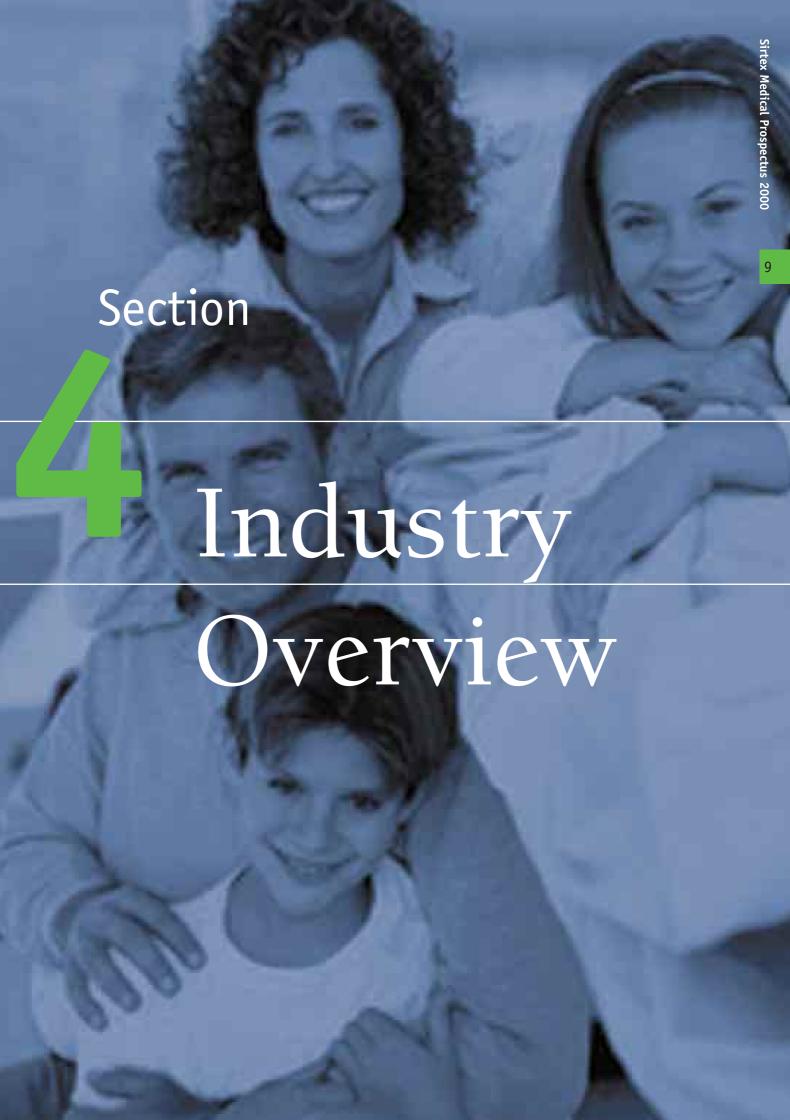
Instead, investors will receive a statement (similar to a bank account statement) that sets out the number of Shares allotted to each of them under this Prospectus. The notice will also advise holders of their Holder Identification Number and explain, for future reference, the sale and purchase procedures under CHESS. Further monthly statements will be provided to holders which reflect any changes in their shareholding in the Company during that month.

#### **Underwriting**

The Offer is fully underwritten by KTM Capital. KTM Capital is entitled to an underwriting commission of 4.5% of the underwritten amount of \$15.0 million, being \$742,500 (including GST), and a management fee of \$75,000. Details of the underwriting agreement, including the circumstances in which the Underwriter may terminate its obligations, are set out in Section 10.

#### **Overseas Investors**

It is the responsibility of investors to obtain all necessary approvals for the subscription for Shares under this Prospectus. This Prospectus does not constitute an offer in any place in which, or to any person to whom, it would not be lawful to make an offer.



# Industry Overview

#### The Incidence of Cancer

Cancer is a major health issue all around the world. Although the types of cancer that occur in first, second and third world countries varies, cancer remains one of the most important causes of death in all societies. There are an estimated 7 million people who develop cancer each year and the number is constantly growing. Furthermore, the majority of these cancers will be fatal.

In Australia, which is similar to all Western societies, approximately 43% of males and 27% of females develop cancer by the age of 75 years, and these figures do not include the simple skin cancers that are extremely common. The Australian statistics show that cancer is now responsible for 37% of all deaths that occur in persons under the age of 70 years (31% for men and 42% for women).

Although medical science has greatly improved the outlook for major health problems such as heart disease and infections, there has been little real progress in controlling most forms of cancer. As a result, the percentage of people dying from cancer has risen dramatically. In Australia during the period 1971 to 1991 the percentage of people dying from cancer approximately doubled and is still rising.

As cancer often occurs in middle aged people, the loss to the community is even more exaggerated when considering the premature person-years of life lost as shown in the following chart. Cancer is clearly the single most important cause of premature mortality in Australia and all Western societies.

Percentage of total person-years of life lost to age 70 – Australia 1991



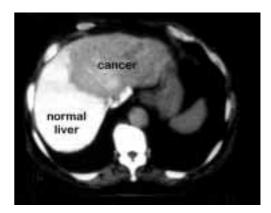
Source: Fritschi, L., Taylor, R. 1991. Cancer the major cause of premature death in Australia. *Cancer Forum.* 19 (2). 151-155.

#### The Incidence of Liver Cancer

Liver cancer is very common and can be considered as two types, primary and secondary. The incidence of liver cancer can be measured from well established cancer incidence and mortality statistics. Together, primary and metastatic (secondary) liver tumours account for the largest cancer-related adult mortality in the world.

Primary liver cancer occurs when the disease starts within the liver. It is particularly common in Asia and Africa, including high wealth Asian countries such as Hong Kong, Japan and Taiwan. In some countries primary liver cancer is more common than any other form of cancer and is driven largely by the very high incidence of Hepatitis endemic in those countries. As illustrated in Table 1, over 400,000 individuals worldwide are affected by primary liver cancer per annum and more than 95% will require palliative care as there is no effective treatment for the vast majority of people.

Approximately a quarter of all cases of primary liver cancer occur in developed countries. Further, the incidence of primary liver cancer is rising in Western societies.



CAT scan of a patient with advanced primary liver cancer. The large and inoperable size of this tumour is typical of the advanced state of cancer that is found when patients are first diagnosed.

Sirtex Medical's micro-particle technology is designed to treat both small and large tumours such as shown in this CAT scan.

El-Serag and Mason (*New England Journal of Medicine 1998*, 340, 745-50) recently reported that the incidence of primary liver cancer in the US had increased by 71% for the period 1991-95 compared to 1976-80. A similar rise in the incidence of primary liver cancer has also been reported in Europe. The rapidly rising incidence is thought to be linked to the increased incidence of Hepatitis B and C.

Secondary liver cancer occurs when a cancer develops within some other organ such as the bowel or breast, and then spreads to the liver. The liver is a common site for secondary tumours of the bowel, stomach, pancreas, melanoma, breast and lung. Secondary liver cancer is a common occurrence in all countries. As about a third of the world's population will develop some form of cancer, the common occurrence of secondary liver cancer can be appreciated. The liver is the most common site of metastases for cancers of the abdominal organs and approximately a third of all cancers ultimately spread to the liver. For instance, more than 40% of all people who develop bowel cancer will end up with secondary liver cancer which will prove fatal. Based only on the incidence of primary bowel cancer, secondary liver cancer will develop in at least 200,000 people each year from bowel cancer alone.

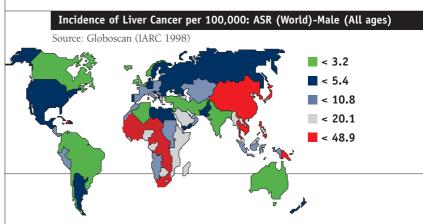
Sirtex Medical's estimates of the incidence of primary liver cancer and secondary liver cancer arising from primary bowel cancer are shown in Tables 1 and 2. Many published medical documents estimate that the true incidence of primary liver cancer is probably more than twice that quoted in Table 1. This larger number reflects the poor reporting mechanisms in developing countries. In these estimates of the total liver cancer market, secondary liver cancer from sources other than primary bowel cancer has been ignored and secondly, the data set is from estimates made in 1990.

In summary, cancer incidence rates have increased due to an aging population, the natural cancer incidence increase as a result of a lesser mortality from other diseases, and as a result of the rising incidence of hepatitis.

**Table 1:** Incidence of Primary Liver Cancer

Region	Incidence
Eastern Asia	278,067
South-East Asia	33,834
South-Central Asia	17,775
Western Asia	3,833
Eastern Africa	12,214
Middle Africa	9,217
Northern Africa	2,923
Southern Africa	3,663
Western Africa	14,933
Caribbean	1,800
Central America	3,190
South America	5,541
Northern America	8,422
Eastern Europe	16,079
Northern Europe	3,030
Southern Europe	13,293
Western Europe	8,682
Australasia	478
Melanesia	460
Total	436,771

Source: Globoscan CD Incidence in 1990



**Table 2:** Incidence of Secondary Liver Cancer Arising from Primary Bowel Cancer

Region	Incidence of Bowel Cancer <sup>1</sup>	Incidence of Secondary Liver Cancer <sup>2</sup>
Eastern Asia	183,731	55,119
South-East Asia	29,837	8,951
South-Central Asia	37,635	11,290
Western Asia	7,788	2,334
Eastern Africa	5,771	1,731
Middle Africa	1,146	343
Northern Africa	4,500	1,350
Southern Africa	2,654	796
Western Africa	4,300	1,290
Caribbean	4,588	1,376
Central America	5,512	1,653
South America	37,130	11,139
Northern America	154,479	46,343
Eastern Europe	89,168	26,750
Northern Europe	47,973	14,391
Southern Europe	53,435	16,030
Western Europe	101,890	30,567
Australasia	10,734	3,220
Melanesia	222	66
Total	782,452	234,739

- 1. Source: Globoscan CD Incidence in 1990.
- 2. Estimated by Sirtex Medical

# Industry Overview

# Current Treatment Regimens for Liver Cancer

At the current time both primary and secondary liver cancers are largely untreatable and more than 95% of these patients will die due to the disease. Based on current statistics, in approximately 7% of patients the cancer can be surgically removed from the liver and another 3% can be treated by other local therapies. Of this 10%, less than half will actually survive more than four years.

Primary liver cancer usually progresses very quickly and the average survival period in Asia from the time the patient is first diagnosed to death is of the order of three months. Most patients receive no active treatment.

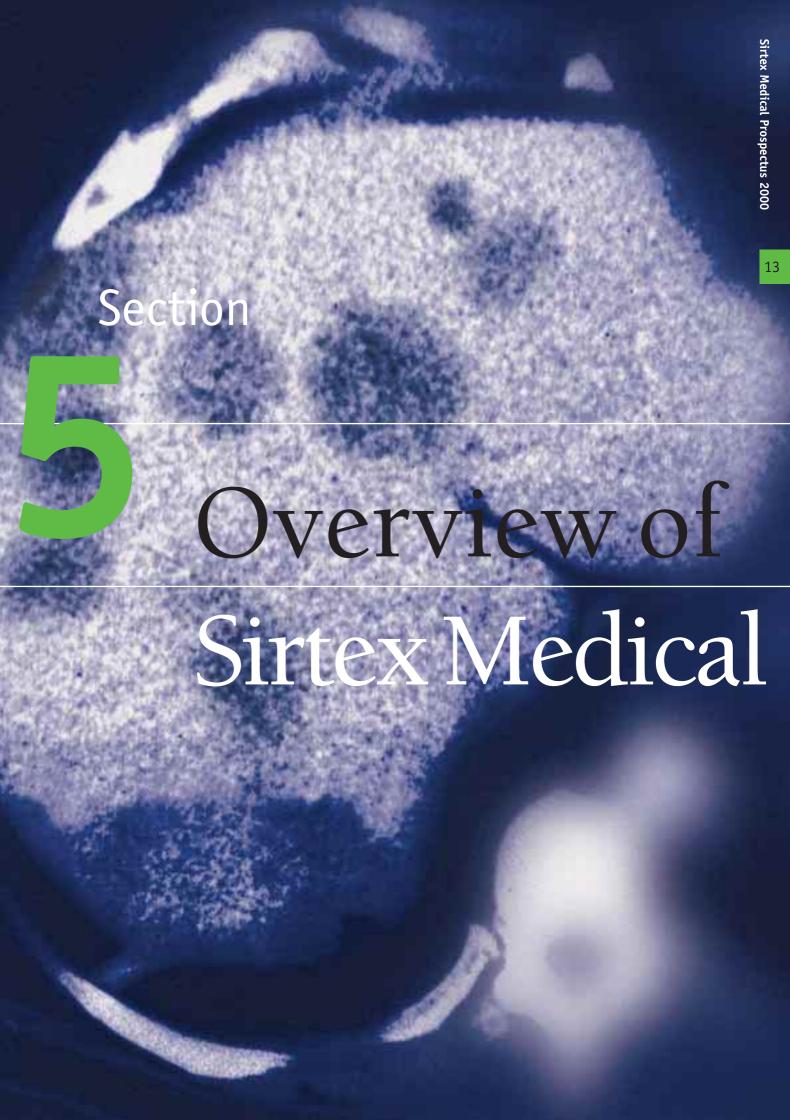
Treatment of secondary liver cancer varies with the underlying disease, the extent of secondary spread in the liver and in other sites, and the availability of effective systemic therapy. Some of the less common cancers such as testicular carcinoma involving the liver can be cured with combination chemotherapy. Breast carcinoma and lung cancer patients will often obtain a partial remission with chemotherapy. Bowel cancer may spread solely or predominantly to the liver making regional treatment a viable option. Traditionally used treatment options include the following:

*Systemic Chemotherapy* – Systemic chemotherapy is frequently used for patients with advanced secondary liver cancer from tumours in the gastro-intestinal tract. Drugs such as 5-fluorouracil plus leucovorin are commonly used. The reported response rate is in the order of 30%. Of this 30%, most responses are relatively short lived and patients are never cured. Patients with secondary tumours from other sites such as melanoma are generally either not treated or given systemic chemotherapy that has a less than 20% chance of having any effect. Systemic chemotherapy is associated with significant side effects in the majority of patients.

Hepatic Artery Chemotherapy ('HAC') -HAC is where the chemotherapy is delivered directly into the hepatic artery. This is of little value in primary liver cancer. HAC is commonly used for patients who have secondary liver cancer from primary tumours in the large bowel that is advanced, but there is no evidence of malignancy at any other site. Hepatic perfusion chemotherapy, usually using the drug floxuridine (FUDR) or fluorouracil (5FU) has now been used for more than 30 years. Response rates are generally in the order of 60%, but this treatment is only beneficial to patients who have no evidence of disease outside the liver. Despite large numbers of clinical trials, the evidence concludes that the survival benefit from HAC is only of the order of months, even for patients who favourably respond to treatment.

Trans-Arterial Chemo-embolisation ('TACE') – TACE therapy consists of inserting a catheter into the hepatic artery and injecting a mixture of lipiodol plus chemotherapy drugs into the hepatic artery. This technique has been widely used for about 15 years and is regarded as the best aggressive treatment option for non-curable primary liver cancer. TACE has been the subject of numerous scientific articles and reviews and although some patients seem to respond to the treatment, there is no evidence that has even demonstrated a survival improvement resulting from this treatment. Consequently in many centres TACE therapy has been discontinued and no treatment offered as an option. If TACE therapy is used it is usually repeated at least three times, with each interval requiring several days admission to hospital for each treatment. TACE therapy has significant side effects in some patients, including fatal liver failure.

Although presently available forms of therapy for advanced primary and secondary liver cancer have only a small chance of improving survival, treatment is still offered to many patients as both the cancer patients and their families often demand some form of treatment. A treatment that has been scientifically proven to be effective is likely to be rapidly adopted.



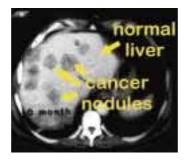
# Overview of Sirtex Medical

The original concepts underpinning the core technology being commercialised by Sirtex Medical was initially developed by Dr. Bruce Gray and the Cancer Research Institute Inc (CRI) and have been published in the scientific literature. The CRI is an independently incorporated research institute, founded in 1990 that is now affiliated with the Centre for Applied Cancer Studies at the University of Western Australia. The CRI has undertaken many research programs investigating cancer over the past decade.

Scan 1

This series of CT scans shows a typical response after treatment with SIR-Spheres®. The patient has advanced secondary liver cancer.

Scan 1 shows the cancer before treatment.



Scan 2

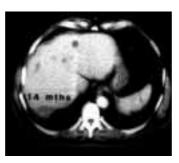
Scan 2,3 and 4 show continual shrinkage of the tumour at 4, 8 and 14 months after treatment with SIR-Spheres®. The majority of patients treated with SIR-Spheres® respond in a similar manner to this patient.



Scan 3



Scan 4



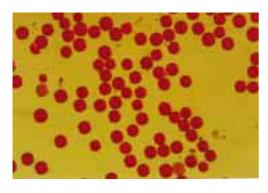
Sirtex Medical was formed in 1997 to acquire and commercialise a portfolio of three technologies relating to the treatment of liver cancer developed by the CRI and Dr Bruce Gray. At that time NJI No. 2 Investment Fund (managed by Nomura/JAFCO Investment (Asia) Ltd) subscribed for equity in the Company to finance development of the technologies. Since its formation, Sirtex Medical has both undertaken its own research and development and also contracted other agencies such as the CRI to further develop the Company's technologies.

To capitalise on the market opportunities for its technologies, Sirtex Medical is moving its corporate head office from Perth to Sydney and employed key executives with experience in establishing and growing an international medical products business.

Sirtex Medical aims to become the world leader in liver cancer treatment products. The Company believes the unmet demand for effective treatment of liver cancer provides an opportunity for Sirtex Medical's products. The Company will also apply its micro-particle technology to other diseases where the Company's intellectual property can provide market opportunities. The Company's products are described below.

#### Sirtex Medical's Cancer 5.1 **Treatment Products**

Sirtex Medical has developed and refined some techniques for targeting large numbers of micro-particles into tumours within the liver. These particles can be manufactured from a variety of different materials and act as transport vehicles to carry anti-cancer agents such as ionising radiation (ie. SIR-Spheres®), anti-cancer drugs (ie. Dox-Spheres) or materials that can generate heat within the cancer (ie. Thermo-Spheres). This has provided Sirtex Medical with a technology platform on which other products can be developed. To date the Company has concentrated on developing its technology in three main areas.



Photograph of radioactive SIR-Spheres®. The micro-particles are approximately 35 micron in diameter. Many millions are injected through a syringe into the blood stream and are targeted to the cancer of the patient.

# Product 1 – Targeted Radiotherapy with SIR-Spheres°

#### **Product Description**

SIR-Spheres® are biocompatible yttrium-90 micro-particles that are rendered radioactive by neutron bombardment. SIR-Spheres® are administered by injection into the blood supply of the liver, whereupon the particles are targeted specifically to the tumours within the liver. The SIR-Spheres® are trapped in the small blood vessels of the tumour. It is not necessary to identify either the number or location of the tumours within the liver, as the SIR-Spheres® will target them regardless of where they are. Once targeted to the tumour, SIR-Spheres<sup>®</sup> irradiate it by a process known as Selective Internal Radiation Therapy (SIRT), leading to the destruction of the tumour, whilst most of the normal liver tissue remains relatively unaffected.

#### **Clinical Data**

SIR-Spheres® have been used to treat more than 400 patients with liver cancer in Australia, New Zealand and Asia in a variety of clinical trials. These human tests have been conducted within the framework of rigid scientific experiments in major teaching hospitals and cancer centres. Phase I, II and III trials have been completed. In Australia and New Zealand most patients had developed secondary (metastatic) liver cancer, whilst in Hong Kong primary liver cancer was predominant. Generally, patients with secondary liver cancer were treated by combining SIR-Spheres® with conventional chemotherapy. The results for both groups of patients have shown response rates higher than other forms of treatment. Further trials are currently underway to extend the clinical use of SIR-Spheres<sup>®</sup>.

In Australia approximately 130 patients have been treated in various Phase I and II trials. The Phase III trial in Perth closed in June 1997 after accruing 74 patients (half treated with SIR-Spheres®). The trial compared treatment using FUDR Hepatic Artery Chemotherapy as the control group against the same chemotherapy plus a single injection of SIR-Spheres®. FUDR Hepatic Artery Chemotherapy is the most aggressive 'state-of-the-art' treatment currently available. The patients that received the single injection of SIR-Spheres® showed substantially better outcomes than those treated with chemotherapy alone, viz:

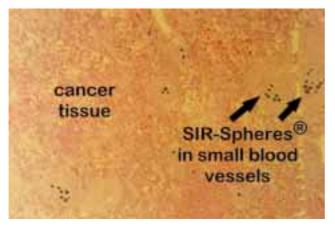
- A highly significant increase in objective response to treatment as measured by decrease in tumour size for patients receiving SIR-Spheres® (from 18% to 44%, p=0.01).
- A highly significant increase in objective response to treatment as measured by decrease in CarcinoEmbryomic Antigen (CEA) for patients receiving SIR-Spheres<sup>®</sup> (from 47% to 72%, p=0.004).
- A highly significant increase in mean percentage fall in CEA for patients receiving SIR-Spheres® (from 53% to 76%, p=0.008).
- A highly significant increase in the average time the liver cancer was kept in remission for patients receiving SIR-Spheres® (from 10.0 months to 19.2 months, p=0.01).
- An increase in 2 year survival from 26% to 39% for patients receiving SIR-Spheres<sup>®</sup>.
- An increase in 3 year survival from 6% to 17% for patients receiving SIR-Spheres<sup>®</sup>.

Note: p value is the probability that an event or series of events occurs randomly. An event that has a p value of less than 0.05 is generally considered to be significant. A p value of 1.0 is 100% probability that the event or events have occurred randomly.

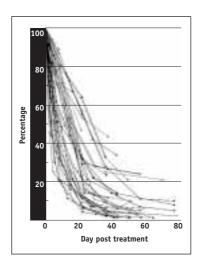
The Phase III trial design was based on ethical considerations whereby every patient was given the most aggressive form of treatment currently available. The fact that SIR-Spheres® plus FUDR Hepatic Artery Chemotherapy showed an improvement over and above FUDR Hepatic Artery Chemotherapy only is significant and will be published in the scientific press in the near future. Early results were first released to the medical community at the annual meeting of the American Society of Clinical Oncology

# Overview of Sirtex Medical

(ASCO) on 16 May, 1999 and caused great interest. Sirtex Medical's presentation at ASCO was one of a small group of new studies that was selected out of more than 2000 presentations by the ASCO Committee for a news conference on 'New Technologies for the Future'.



Photograph of a cancer containing SIR-Spheres®. The SIR-Spheres® have been injected into the blood stream and have lodged in the small blood vessels of the cancer inside the liver.



Alpha-fetoprotein levels in the blood are routinely used as a guide to the success of treatment in patients with primary liver cancer. This graph shows the change in alpha-fetoprotein levels in a group of 46 consecutive patients with primary liver cancer who were treated with SIR-Spheres® by the Prince of Wales Hospital in Hong Kong. A fall in the blood alpha-fetoprotein level in patients with primary liver cancer is widely used to determine whether patients have responded favourably to treatment.

In Hong Kong most patients have been treated outside of trials as SIR-Spheres® are now considered a standard treatment for primary liver cancer. As well as being highly effective, treatment with SIR-Spheres® also has been reported to have considerably fewer side effects than alternate treatments and therefore may well be the preferred treatment option for many patients.

An important observation from both Asian and Australian trials is that some patients with very advanced liver cancer can be down-staged to the point where their tumours can be surgically removed and even cured after treatment with SIR-Spheres<sup>®</sup>. In New Zealand patients are now also treated with SIR-Spheres<sup>®</sup> outside of trials as the treatment is considered standard therapy there also.

#### Manufacturing

SIR-Spheres® are manufactured under an agreement with Australian Radioisotopes ('ARI') which is the commercial arm of the Australian Nuclear Science & Technology Organisation ('ANSTO'). ANSTO is an Australian Government agency that operates Australia's only nuclear reactor. ARI is the major supplier of radiopharmaceutical agents in Australia and is approved by the TGA for the manufacture of radiopharmaceuticals. ARI is actively expanding its presence in Asia where it currently markets a range of products.

#### **Regulatory Approval**

The marketing of medical products requires regulatory approval in each country. Sirtex Medical has obtained regulatory approval for marketing SIR-Spheres® in Australia, New Zealand, Hong Kong and Singapore. Sirtex Medical's application to the FDA in the USA was submitted in October 1999 and is currently being evaluated. The Company proposes to submit an application for marketing approval in the European Union in the near future.

#### **Intellectual Property Position**

The concepts underpinning SIRT technology were developed and refined over more than ten years in a number of public research institutions. Early data was publicly disclosed and therefore it is not possible to obtain patent protection for the first generation SIR-Spheres®. The Directors believe that the lack of patent protection on the first generation SIR-Spheres® will not affect the Company's prospects of commercialising this therapy since the Company now has developed a secondgeneration of SIR-Spheres®, with which it plans to replace the current SIR-Spheres® in the marketplace. Patent protection for the improved SIR-Spheres® has been granted in Australia and the USA. Similar patent applications are currently being assessed in four other relevant markets (see Section 9).

# Sirtex Medical's patented second generation SIR-Spheres®

The second generation SIR-Spheres® is an improved product on the early generation SIR-Spheres® and differs from the early SIR-Spheres® in that they are manufactured from pure yttrium oxide and are microscopic hollow ceramic particles. This new product has many advantages over the early yttrium-90 micro-particles, including the ability to carry higher doses of radiation, better product quality control and improved safety characteristics. The Company plans to test the second generation SIR-Spheres® in patients before the end of the year 2000. It is anticipated that regulatory approval for the second generation SIR-Spheres® will be based on establishing biological equivalence with the first generation product.



Photograph of Sirtex Medical's second generation SIR-Spheres\*. These particles are hollow ceramic microspheres that have improved characteristics over the first generation product.

#### Product 2 - Controlled-Release Therapy with Dox-Spheres

#### **Product Description**

This technology consists of a mechanism for incorporating drugs into a biodegradable matrix and controlling the release of the active drug from the matrix. In the first instance the matrix technology has been developed to transport the drug Doxorubicin (Dox-Spheres). Doxorubicin is a widely used anti-cancer drug that is no longer protected by patents. Dox-Spheres may provide effective treatment for the treatment of solid tumours, particularly tumours in the liver, head and neck.

#### **Clinical Data**

Fifteen patients with liver cancer have been treated with Dox-Spheres in Australia. Results indicate approximately half the patients responded to treatment. Sirtex Medical plans to undertake a series of patient studies in which the Dox-Spheres will be injected directly into tumours. This should have application for the treatment of tumours both within the liver and in other organs.

The Company will also conduct further Phase II trials by combining the Dox-Spheres with both targeted hyperthermia and SIR-Spheres<sup>®</sup>. This makes sound clinical sense as ionising radiation and heat both potentiate the cytotoxic effects of Doxorubicin.

#### **Intellectual Property Position**

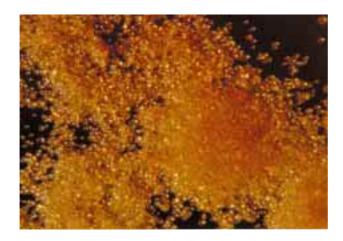
By combining Doxorubicin with Sirtex Medical's novel matrix, a new formulation for the drug (Dox-Spheres) is created. Patent protection for Dox-Spheres has been applied for in a number of countries and patents have already been granted in Australia and the USA (see Section 9).

# Product 3 -Targeted Hyperthermia with Thermo-Spheres

Hyperthermia is a technique for destroying cancer cells by raising the temperature of the cancer in the order of 5°C. The subject has been extensively researched over the past 20 years and numerous heating devices have been produced.

Some hyperthermia devices are available commercially and are based on either focused ultrasound or electromagnetic radiation. None of these devices have been able to accurately deliver high heat loads to deeply situated cancers without also

# Overview of Sirtex Medical



Photograph of biodegradable micro-particles using Sirtex Medical's matrix technology. These micro-particles can be formulated into Dox-Spheres™ which are injected into the blood stream of patients with cancer. The micro-particles are designed to degrade and release their drug payload at a predetermined rate.

destroying the surrounding normal tissues. The single remaining obstacle to clinical application of hyperthermia is a technological one, rather than a biological one.

As the current technology has not overcome the major obstacles for effective heating of cancers, none of the commercially available technologies have gained acceptance and there remains a large potential market for effective hyperthermia technology.

Several companies have developed radiofrequency probes that can be inserted directly into liver tumours. The probes emit radiofrequency waves that heat tissue in the immediate vicinity of the end of the probe. While this technology uses heating to cause effective local tissue destruction, it has limited application in the treatment of liver cancer. Similarly, the direct implantation of metal seeds can also cause local heating in the immediate vicinity of the seed and might have some effect provided it is implanted directly into the tumour. These technologies can only be used to treat small localised tumours that can be directly visualised in order to manually insert the devices into the tumour. These technologies only have the potential to treat approximately 10% of the population of liver cancer patients, as approximately 90% of patients have widespread disease that is well beyond the scope of any form of local treatment.

Not only do these technologies have limited potential applications, but there are already many other technologies that can treat localised small liver tumours including surgery, cryotherapy, alcohol injection and laser ablation.

# Sirtex Medical's Hyperthermia Technology

Sirtex Medical's targeted hyperthermia research program has approached the problem of heating cancer tissues from a different perspective to previous technologies. Sirtex Medical's technology is designed to treat the majority of liver cancer patients that do not have localised tumours and for whom treatment options are limited.

Rather than attempting to focus external heat sources from the exterior, Sirtex Medical has developed a technique whereby small magnetic micro-particles (Thermo-Spheres) can be delivered selectively into the cancer and those particles can then be used to produce localised heating from within the cancer itself.

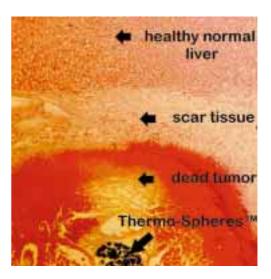
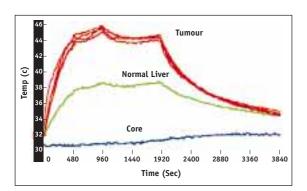


Photo of cancer in liver of an animal following treatment with Hyperthermia. The cluster of micro-particles that generated the hyperthermia are seen at the bottom of the photograph. These are surrounded by an area of dead tissue. At the top is viable liver tissue that has not been affected by the treatment.

This representative graph shows recorded temperatures within the cancer and normal tissues of a rabbit with liver cancer treated by Sirtex Medical's hyperthermia technology. The rabbit has had Thermo-Spheres injected into the blood stream and they have concentrated in the cancer within the liver. The rabbit was then placed in the hyperthermia machine and temperature probes placed in the cancer, the normal healthy liver and the core body of the animal. The temperature of the cancer reached more than 45°C within minutes of placing the animal in the machine, and maintained for more than 30 minutes.



The product concepts have been the subject of a major research program at the Cancer Research Institute Inc over many years. Sirtex Medical established beyond doubt that it is possible to produce high temperature elevations in targeted tissues using specifically designed Thermo-Spheres and an external electromagnetic device. The nature of the micro-particles, their conformity and physical characteristics, their biocompatability and all the parameters of the external electromagnetic device that generates heating in the micro-particles are all within acceptable biological and engineering limits. Recent experiments have shown in live animals with liver cancer that the cancers could be totally destroyed with the hyperthermia technology. This most important finding proves conclusively that the concept is sound and the technique is highly effective in animal studies of liver cancer.

# Advantages of Hyperthermia Therapy

One of the important limiting factors in current cancer therapies is the side-effects of the respective treatments. Chemotherapy drugs have limited effectiveness on most forms of cancer and normally have severe side effects on healthy organs. Conventional radiotherapy can only be applied to limited areas of the body and adversely effects nearby tissues. In contrast heat, by its very nature, can be applied locally with

no systemic effects. Regardless of the source of origin, tumours can be destroyed by heat, thus allowing the development of generic treatments. The reduction in side effects as compared with traditional treatments could lead to hyperthermia becoming an acceptable treatment for various types of cancer. The reason this has not occurred to date is that prior to Sirtex Medical's technology, there has not been a technique for targeting heat to advanced cancers in humans whilst sparing normal adjacent tissues.

As a result of the positive results from treating animals in Sirtex Medical's current hyperthermia program, the Company is investigating the potential to use the technology to treat many different forms of cancer that are not limited to the liver. By attaching Sirtex Medical's magnetic material to anti-cancer antibodies, it may be possible to target cancers wherever they exist. In 1999 Sirtex Medical commenced a new research program to further develop this technology. If this technique proves successful, there is potential for wide application in the treatment of many forms of cancer.

#### **Current Status of the Technology**

Sirtex Medical is in the process of scaling up the hyperthermia technology for application to human patients. The first full sized human prototype of the external electromagnetic device that generates heating of the Thermo-Spheres has been built and clinical trials in patients are planned to begin in late 2000. The encouraging results that have been obtained in animals with cancer indicate the technology should generate a high level of interest from the world medical community.

#### **Intellectual Property Position**

Sirtex Medical has applied for two families of patents to protect the Company's hyperthermia technology. The patent applications cover both the hyperthermia micro-particles and the device used to generate the electromagnetic fields required (see Section 9).

#### **Combination Therapy**

Sirtex Medical's complementary cancer targeting technologies are a major advantage for the Company. It is well established that even small amounts of heat will potentiate the effects of both radiotherapy and chemotherapy. Targeted hyperthermia therapy, used in conjunction with targeted radiotherapy using SIR-Spheres®, should improve even further the efficacy of the SIR-Spheres®. Targeted hyperthermia can

# Overview of Sirtex Medical

also potentially be used together with conventional chemotherapy to increase its effectiveness. Combining Sirtex Medical's hyperthermia technology with conventional treatments should increase the size of the hyperthermia market and has the potential to put the Company at the forefront of cancer treatment technologies. In the long term, and because of its generic nature, targeted hyperthermia may be able to be applied to many types of cancer.

#### 5.2 Competitor Activity

There are existing treatments for both localised and advanced liver cancer.

#### **Localised Liver Cancer**

Several new companies have emerged claiming either new drugs or devices for the treatment of liver cancer. While these claims have validity, their combined potential impact on the liver cancer market is minimal. Without exception, all these new technologies and products are designed to deliver some form of local tumour destruction. In order to apply any of these technologies, the tumour must be small and able to be visualised either at surgery or by radiological imaging. Direct visualisation of the tumour is necessary so the cryoprobes, radiofrequency probes, laser probes or injecting hypodermic needle can be implanted directly into the tumour. This means that each of these technologies can only be applied to tumours in the liver, which are both small in size and very limited in number.

As only approximately 10% of liver cancer patients fit these criteria, all the competing technologies are limited to this small percentage of the target population. None of these technologies can effectively treat the 90% of the patients with advanced primary or secondary liver cancer. Furthermore, all of these technologies are competing with surgery, which is now widely used to remove localised liver tumours and is the preferred treatment option for the 10% of patients with localised liver cancer.

Competition might come from the use of existing or new chemotherapeutic drugs or other controlled-release technology. However, in clinical practice there is limited use of chemotherapy in primary liver cancer and limited use in secondary liver cancer. Therefore, any new therapy with demonstrated effectiveness should find acceptance in the market place.

#### **Advanced Liver Cancer**

There is always potential for other companies to develop and market targeted radioactive micro-particles for the treatment of liver cancer that would compete with Sirtex Medical's SIR-Spheres®. Attempts have been made to use solid glass microspheres to carry yttrium-90 for treating liver cancer, but the clinical results reported in the literature are inferior to those of Sirtex Medical's product. Other radioactive materials that have been used include isotopes of phosphorus, holmium and rhenium. Sirtex Medical believes that the positive clinical trial results from use of the SIR-Spheres® and its superior second generation SIR-Spheres® product should give Sirtex Medical market leadership in this area.

Chemotherapy in a number of different forms has been used to treat liver cancer. The treatment options include systemic chemotherapy, regional hepatic artery chemotherapy and trans-arterial chemoembolisation.

Many clinical trials and meta-analyses have evaluated various chemotherapy treatments for both primary and secondary liver cancer. No form of treatment has ever been proven to increase survival for patients with advanced primary liver cancer. For patients with advanced secondary liver cancer from primary bowel cancer, chemotherapy has been shown to cause regression in one third of patients and increase survival by an average of nine weeks, although no patient is ever cured. Regional chemotherapy results in a higher tumour response rate, but there is no increase in survival when compared to systemic chemotherapy. There is an immediate demand for effective treatment

that has not been met with currently available technology.

# New Treatments Under Development

Liver cancer is such a major problem that many research groups are looking for treatments that will be effective. New treatments under investigation by other groups include:

- 1. Tumour vaccines
- 2. New cytotoxic drugs
- 3. Anti-Angiogenesis factors
- 4. Gene therapy
- 5. Hormone receptor blocking agents

Apart from surgical removal or local destruction of isolated tumours in a small minority of patients, no previous treatment has ever been conclusively shown to prolong the life of patients with liver cancer. Despite decades of research, all of the above mentioned new treatments under investigation have so far failed to make any impact on management of patients with liver cancer.

# **5.3** Balancing the Risks Associated With Medical Research

In medical research there is a high risk that concepts under development will not become marketable products. For example, less than 10% of any new drug candidates at the pre-clinical phase reach commercialisation. Sirtex Medical is managing this risk by having 3 products at different stages of development and by performing early experiments that indicate whether the products can be successfully developed.

The risk associated with Sirtex Medical's new generation SIR-Spheres® is low because the treatment concept underpinning the technology has been evaluated in more than 400 cancer patients in Australia, New Zealand and Asia. Likewise, the risk that the product development program for Dox-Spheres may fail is relatively low because the product combines an already proven anti-cancer drug, Doxorubicin, with a biodegradable matrix. In addition, early trials in humans have produced encouraging results.

Hyperthermia is at an early stage of its development. The technology has been proven in an animal model. The challenge is to scale up the technology to enable the treatment of humans.

#### **5.4** Financial Prospects

#### 5.4.1 Key Drivers to Revenue

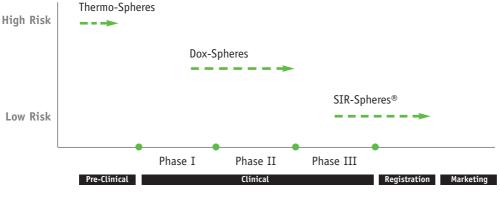
The principal factors determining the revenue generated by the Company will be market acceptance of the products offered by the Company, the influence of government regulation of the business to be conducted by the Company and the impact of the competitive activities undertaken by other market participants.

Up until the present time the sale of SIR-Spheres® has been in the context of clinical trials and test marketing programs.

Part of the proceeds of the Offer will be used to establish the Company's marketing and distribution infrastructure. This will include the establishment of overseas marketing offices and the appointment of distributors in selected markets.

The ability of Sirtex Medical to market its products to potential consumers depends on many factors including the availability of sophisticated health care services, awareness of treatment options, affordability of high cost treatments and market competition. The demand for SIR-Spheres® is expected to be driven by the quality of clinical trial results, the granting of regulatory approval

#### Risk/Development Stages of Sirtex Medical's three products.



Stage of Development

# Overview of Sirtex Medical

by the relevant Government health authorities and the endorsement of the treatment by high profile cancer experts.

Sirtex Medical is adopting a four tiered strategy within each market to position its technologies as the primary choice for liver cancer therapy. The strategy involves the simultaneous targeting of the regulatory authorities, opinion leaders in the medical community, private health funds and potential patients and their families.

The delivery of SIR-Spheres®, similar to other sophisticated medical procedures requires a high level of expertise and can only be performed by a specialist who has received the appropriate training. Initially, Sirtex Medical will sponsor training programs to demonstrate the product and train a pool of specialists. As the number of trained users increases, the need for Sirtex Medical to be responsible for this training activity will diminish.

Except for company sponsored clinical trials, SIR-Spheres® are expected to be administered in private hospitals able to attract patients that are not cost sensitive. Sirtex Medical will also be submitting applications for Government funding of the product in appropriate markets.

#### The internet as a medical information tool

Consumers of healthcare are turning to the internet for medical information. For example, 17.5 million American adults, or 43% of all American web users, used on-line health and medical content in 1998, half of those users sought information on a specific disease condition.

To exploit the interactive 'mass marketing' communication offered by the internet, Sirtex Medical has recently implemented a web site (http://www.sirtex.com) to complement its existing promotion activities. Sirtex Medical has also recently established the web site name liver-cancer.net.

The Sirtex Medical web site is also designed to provide detailed information to general practitioners to enable them to recommend treatment to their patients. The web site provides patients with general

information about liver cancer as well as their treatment options. A unique feature of the site is an information print out that patients can give to their local doctor when requesting SIRT therapy.

A later addition to the web site will be a list a clinics in each country where SIRT therapy is available for administration.

Sirtex Medical's web site has received a large number of inquiries from patients and health professionals from around the world. The web site is allowing Sirtex Medical to build awareness of its products and position itself as a market leader in the development of treatments for liver cancer.

#### **Distribution Strategies**

Sirtex Medical has developed two distribution strategies based on direct and indirect models. Rapid market penetration and legislative requirements are key criteria in selecting the distribution strategy for a target market.

The Company's current, and preferred, distribution strategy is the direct distribution model. In Australia, New Zealand and Hong Kong, Sirtex Medical directly markets to purchasing hospitals. In this 'Direct' model, purchase orders are received by the Company's office in Perth, Western Australia, and production orders forwarded to a third party manufacturer. The manufacturer renders the SIR-Spheres® radioactive and then ships the product to the customer. All invoicing and payments are directly coordinated by Sirtex Medical.

To ensure SIR-Spheres® penetrate each market within the shortest possible time frame and with the broadest possible coverage, Sirtex Medical has developed an additional 'Indirect' distribution model. This strategy is applied to those markets where legislation requires a local agent (such as Singapore or Taiwan) or where regional and multinational radiopharmaceutical companies have an established distribution presence. It is anticipated that where Sirtex Medical uses a local agency, the local agencies will assist Sirtex Medical to obtain product registration for SIR-Spheres® in their respective markets.

#### 5.4.2 Costs of the Business

The projected cash requirements for Sirtex Medical over the three financial years ending 30 June 2003 and the assumptions on which the requirements are based are set out below. The Directors have prepared the projected cash requirements with proper care and attention and consider all assumptions to be reasonable when taken as a whole.

#### Projected Cash Requirements for Sirtex Medical

\$'000			
Year ending 30 June	2001	2002	2003
R&D	1,080	1,250	1,500
Marketing	800	1,350	2,300
Property, plant & equipment	1,300	1,100	600
Operating expenses	620	800	1,000
Total Expenditure	3,800	4,500	5,400

The projected cash requirements are based on a large number of economic and business assumptions. The most material assumptions are set out below. The projected cash requirements are likely to vary from actual cash requirements because the assumptions and the projections are, by their very nature, subject to significant uncertainties and contingencies, many of which are outside the control of the Directors. Accordingly, neither the Company or its Directors can give any assurance that the projected cash requirements will not be exceeded or otherwise varied.

The projected cash requirements should be read together with the assumptions and sensitivity analysis set out in this section and in conjunction with the risk factors described in Section 7 and other information contained in this Prospectus.

The projected cash requirements specifically exclude any potential operating expenses that may arise as a result of new business opportunities. In preparing the projected cash requirements, the following significant assumptions were made:

#### • Competitive environment:

There will be no substantial change in the existing competitive environment in which the Company operates and there will be no material amendment to any material agreement regarding the Company's businesses.

#### • Continuity of operations:

There will be no significant disruption to the research and development or marketing program of the Company.

#### Tax legislation:

The Australian Government has announced its intention to implement major tax reform. While the form of such legislation and its potential impact on the Company cannot be determined with accuracy, it appears unlikely to impact the projected cash requirements. The Company has assumed that there will be no change in the taxation legislation (in Australia or elsewhere) that will have a material impact on the projected cash requirements.

#### • Regulatory environment:

There will be no significant changes in legislation or in the policies and procedures of the regulators in Australia or any other country in which the Company is conducting business or seeking registration for its products and that outstanding issues will be resolved in the manner consistent with the Company's expectations and the regulatory risks set out in this Prospectus.

#### Offering costs:

The Company's estimated costs associated with the Offer will be met out of the equity raised.

#### • Exchange rates:

The value of the Australian dollar will be maintained at the level as at the date of this Prospectus.

#### Full subscription:

The Offer is fully subscribed and no further issues are made prior to 30 June 2003.

# Overview of Sirtex Medical

#### Research and Development:

Expenditure on research and development will be maintained at approximately the present level in real terms. It is assumed that no further research and development is undertaken on the SIR-Spheres and any future clinical trials in this area are contained within the marketing budget. If a major clinical trial to demonstrate the cost effectiveness of SIR-Spheres is required by Health Maintenance Organisation's in the US, additional expenditure above that estimated will be required. Early introduction of Dox-Spheres could increase the rate of expenditure attributable to gaining regulatory approval during the next two years. Hyperthermia will remain the major research and development project area. The costs of building the various prototype hyperthermia units have been included in the Property, Plant and Equipment projected cash requirement. Early clinical acceptance of this technology would bring forward the expenditure in this area and could require the development of a strategy to help hospitals finance the purchase of a hyperthermia unit. The Company will continue to protect its intellectual property in the major markets of USA, Europe, Australia and Japan through patenting. The cost of prosecuting a patent application as been assumed to be \$100,000. No allowance has been made in the projected cash requirements for the costs of defending the patents in the courts.

#### Marketing:

The marketing expenditure levels are dependent on the Company achieving FDA approval for SIR-Spheres before the end of the year 2000. During 2000 and until FDA approval is obtained for SIR-Spheres, the marketing effort will be concentrated on developing clinical publications and reference data from sales to hospitals in the Asia Pacific region. Any delay in obtaining FDA

approval is likely to delay the projected cash requirements in this area. Included in the marketing budgets are the cost of employing three additional marketing staff in 2002 and 2003, running focussed clinical trials and training sessions and conference sponsorship. A major objective of the focussed clinical trials will be to gain data on the health economics and cost effectiveness of SIR-Spheres. This data will be used to apply for re-imbursement to be made available to US patients by US Health Maintenance Organisations.

#### • Property, Plant and Equipment:

The Company is relocating its operations to Sydney from their present location in Perth. This move will provide closer proximity to the larger markets in the Eastern States of Australia and easier access to a larger pool of potential employees with medical industry experience. In addition to staff relocation costs, provision has been made to fit-out new premises with offices, laboratories, prototyping, production, warehouse, training and MIS/EDP systems. It has been assumed that the Company will lease suitable premises in the hi-tech medical zones in the vicinity of Macquarie University. In the event that suitable leasehold premises cannot be located it may be necessary to purchase premises which would require extra funding. It has been assumed that the Company will produce 3 prototype hyperthermia units over the course of 2001 to 2003. The actual number of hyperthermia units or components thereof is dependent on the scientific outcomes achieved. Early success in decreasing the cost and power requirements of the units will decrease the necessary expenditure in this area.

#### • Operating Expenses:

The projected operating expenses are based on the Company's historical expenditure levels and allowances have been made for the employment of a Chief Financial Offer in 2001.

Manufacture of the SIR-Spheres will be sub-contracted to ARI until second generation SIR-Spheres are introduced. At that time the SIR-Spheres will be produced in-house and sent to ARI for activation prior to shipment. No allowance has been made to upgrade existing production equipment at ARI.

The projected cash requirements have been prepared by the Company based on certain economic and business assumptions of future events. The actual events and outcomes may differ in quantum and timing from the assumptions with a material consequential impact (either positive or negative) on the projected cash requirements.

The sensitivity of the projected cash requirements to some of the key assumptions on which it was prepared is set out below. The impact of changes in the assumptions has been calculated in isolation over the full period for the projected cash requirements.

It is likely that future events will result in outcomes different from those in the projected cash requirements and that future requirements will be the product of a variety of factors. For example, it has been assumed that no additional safety and effectiveness data for SIR-Spheres will be needed to meet the requirements of the FDA. If the FDA mandates a long and extensive clinical trial, the cost of such a trial could be as high as \$10,000 per patient. A delay of 12 months in obtaining the FDA approval for SIR-Spheres may produce an approximate \$1,000,000 decrease in marketing expenditure for 2002. The cost of producing an additional hyperthermia prototype unit will increase the Property, Plant and Equipment expenditure by \$300,000. These examples assume no correlation between the variables and any other assumptions or risk factors.

In practice, changes in assumptions may offset each other or may be additive and it is likely that the Company's management would respond to any adverse changes in an assumption by taking action to try to minimise the effect. The variation of the key assumptions shown in the sensitivity analysis is not intended to be indicative of the likely range of variations that may be experienced throughout the three financial years ending 30 June 2003.

The Company expects the gross operating margin on the sale of its products to be greater than 50%. High margins are a

characteristic of the medical therapy market which has to recover substantial investment in research and development.

#### 5.4.3 No Forecasts

Revenue and profitability for the Company is reliant on, among other things, the level of acceptance of the Company's products in international markets, the granting of regulatory approval for sale of the Company's products in key markets (most notably the United States), the activity of competitors in the market and the ability to obtain either government or medical health organisation reimbursement.

To date the Company's product sales have been in the context of clinical trials and test marketing programs. The commercial side of the Company's business is now in the initial stages of its market development program.

In view of these factors, the Directors consider that they are unable to provide potential investors with reliable revenue or profit projections or forecasts.

#### **5.4.4 Contingent Liabilities**

The Directors are not aware of any contingent liabilities which may have an effect on the Company's future financial position.

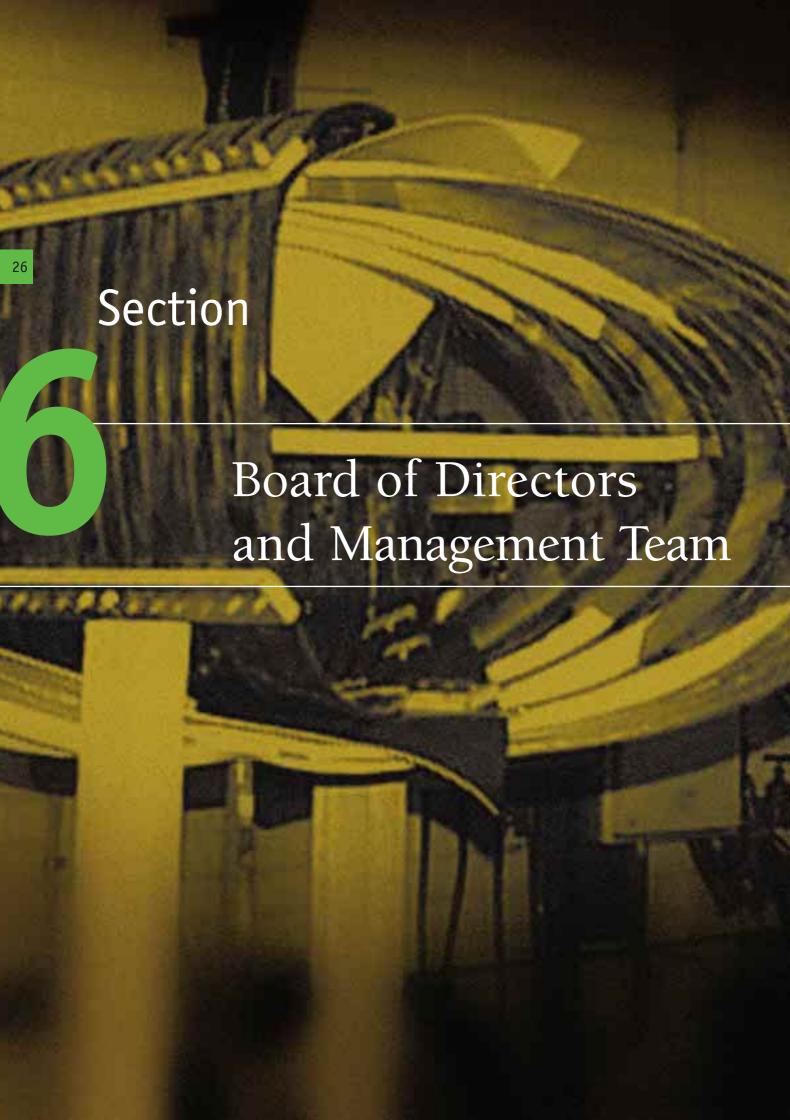
#### 5.4.5 Dividends

The Directors do not anticipate paying any dividends in the foreseeable future.

The Directors intend to give priority to maximising the Company's penetration of the cancer therapy market and to vigorously pursue the Company's anti-cancer product development program. Ultimately, the payment of dividends will depend on the successful financial performance of the Company. The Directors will take into account the funding needs of the Company in determining future dividend policy and the specific level of any dividends. The Directors do not guarantee any dividends will be declared by the Company.

#### 5.4.6 Debt

On completion of the issue the Company will not have any interest bearing debt. The Directors may in the future explore opportunities for securing lease finance in connection with facilities and equipment to be used in the conduct of the Company's business.



#### **Board of Directors**

#### Dr Chris Roberts BE(Hons), MBA, PhD

Non-Executive Chairman, Age 46

Dr Roberts graduated with honours in Chemical Engineering from the University of NSW, obtained an MBA from Macquarie University and completed a PhD at the University of NSW. He has over 24 years of experience in the medical device industry and is currently a Director and Executive Vice President of ResMed Inc, a medical device company listed on the NYSE and ASX. He previously held senior executive positions with Nucleus Ltd, BGS Medical Corporation, Electro-Biology Inc, Telectronics Pty Ltd and Domedica Pty Ltd. He has wide experience in commercialisation and marketing of new medical technology.

# **Dr Bruce Gray** MB BS, MS, PhD, FRACS Medical Director, Age 58

Dr Gray is a graduate of the University of Western Australia, University of Melbourne and Tufts University in Boston. He has held the position of Professor at the University of Western Australia for more than fourteen years and is the Medical Director of the Lions Cancer Institute Inc. and Cancer Research Institute Inc. He has extensive experience in medical research and is a world authority in the area of targeted anti-cancer techniques. He has published widely in the area of cancer treatment and particularly the treatment of liver cancer. He has served in various executive capacities on numerous academic and society boards.

#### Dr Michael Panaccio BSc (Hons), MBA, PhD

Non-Executive Director, Age 38

Dr Panaccio is a graduate of the University of Melbourne. On completion of his PhD, Dr Panaccio joined the Veterinary Research Institute to undertake commercially focussed research and development. During the period 1984-1995, Dr Panaccio developed strong collaborations with a number of multinational pharmaceutical companies and Rural Industry Funds. In 1996 Dr Panaccio joined Nomura/ JAFCO Investment (Asia) Limited, a Singapore based venture capital firm. Dr Panaccio is also a director of Technico Pty Limited, ExGenix Limited and Colloidal Dynamics Group Inc.

#### Dr Colin Sutton BSc, PhD, FAICD

Chief Executive Officer, Age 58

Dr Sutton trained in chemistry and biochemistry at the University of New South Wales. After serving in various technical and marketing positions in 1975 he joined Telectronics Limited, a leading manufacturer of cardiac pacemakers, as a marketing executive. He subsequently held a number of senior positions within Telectronics, including Chief Executive, North America; Chief Executive, Asia Pacific and Chief Executive, Europe. In 1994 Dr Sutton joined Air-Shields Inc., a leading manufacturer of neonatal equipment, responsible for sales in the Asia Pacific region. Following the acquisition by Hill-Rom Inc. of Air-Shields and Medaes in 1998, Dr Sutton was appointed General Manager -South Asia Pacific.

#### **Key Management Team**

#### Mr Grant Boyce B. Comm. ACA

Company Secretary, Age 44

Mr Boyce is a Chartered Accountant who was a partner at Ernst & Young until he established Montrose Partners in 1992. Mr Boyce has been the company secretary since inception, bringing to the Company many years of experience in professional and commercial environments.

#### Dr Monica Hope B.Pharm. PhD

Regulatory Affairs Manager, Age 39

Dr Hope is a Pharmacy graduate of Curtin University who has managed the regulatory affairs issues of the Company for the past two years. She has a detailed knowledge of the international requirements for gaining regulatory approval for Sirtex Medical's current and future product line. Dr Hope is responsible for taking the Company's products through the numerous regulatory bodies that control marketing of medical products in the target markets.

#### Dr Steven Jones B.Sc. (Hons), PhD

Senior Scientist and Project Leader, Age 37

Dr Jones is a physics graduate of the University of Western Australia who has spent the past 14 years in research and development. He has worked for the Cancer Research Institute Inc for many years developing the hyperthermia technology. He is a world expert in this area and brings to the Company an indepth understanding of the requirements for developing the Company's technology to the stage of clinical application in cancer patients.

# Section

# Risk Factors

### Risk Factors

The business activities of Sirtex Medical are subject to risks and there are many factors which may impact on its future performance. Some of these risks can be mitigated by the use of safeguards and appropriate systems and controls, but many are outside the control of the Company and cannot be mitigated. There are also general risks associated with any investment. There are a number of factors which investors should consider before they make a decision whether or not to apply for Shares. The principal factors include, but are not limited to, the following:

#### **Dependence on General Economic Conditions**

Sirtex Medical, in common with other suppliers of health services, is affected by general economic conditions including the level of interest rates, employment rates, inflation and spending by clients on health services. Any changes in government fiscal, monetary and regulatory policies may also affect the Company's business.

#### Reliance on Key Personnel and Need to Attract Qualified Staff

The Company's success will depend in part on the continued services of its key employees. The loss of services of one or more of the Company's key employees could have a material adverse effect on the Company's business, operating results and financial condition. The Company's future success will also depend on its ability to hire and train qualified staff. Competition for such personnel is intense and there can be no assurance that the Company will be successful in attracting and retaining such personnel. The Directors believe that the implementation of the Employee Share Option Plan will assist in attracting and retaining key staff. The continued services of Drs Bruce Gray and Steven Jones are vital to the ongoing success of the Company. This risk is addressed in part by the existence of a five-year service contract with each of these key staff members (see Section 10 for details).

#### Management of Growth

The Company is expected to experience a period of rapid growth and an increase in the number of its employees and offices and the scope of its supporting infrastructure. This growth will result in new and increased responsibilities for management personnel and may place a significant strain on the Company's management. The Company will be required to continue to implement and improve its systems on a timely basis in order to accommodate the increased number of transactions and clients and the increased size of its operation.

#### Medical Research and Development

Medical research and development involves long lead times and Sirtex Medical's hyperthermia program is at an early stage. Sirtex Medical's therapies may fail at any of the stages of research and development, from laboratory studies through to Phase III clinical trials. A failure at any stage may render the costly research and development program obsolete.

#### **Government Regulations**

Sirtex Medical's operations are subject to laws, regulatory restrictions and certain governmental directives, recommendations and guidelines relating to, amongst other things, occupational safety, laboratory practice, the use and handling of hazardous materials, prevention of illness and injury, environmental protection and animal and human testing. There can be no assurance that future legislation will not impose further government regulation, which may adversely affect the business or financial condition of Sirtex Medical. Delays or failure in obtaining regulatory approval, including a Pre-Market Approval from the FDA, for a product would be likely to have a serious adverse effect on the financial performance of Sirtex Medical and a consequent impact on the value of Sirtex Medical.

## Risk Factors

#### **Healthcare Funding Changes**

The growing cost of providing health care has placed financial burdens on Governments, insurers and individuals. In some jurisdictions medical treatments are provided solely by Governments. In other jurisdictions individuals are expected to cover their own costs, sometimes with the assistance of insurers. The level of health care reimbursement for Sirtex Medical's therapies will have a large impact on the Company's ability to penetrate the cancer therapy market. Health care reimbursements and price controls can be amended and Sirtex Medical will, accordingly, be affected favourably or adversely depending on the nature of any such amendments.

#### Competition

Cancer is an enormous problem worldwide and it is not surprising that a large number of companies and research organisations are developing alternative treatments for all types of cancer, including liver cancer. Not only is the market comprised of a large number of participants, it is also subject to rapid change and intense competition. The Company faces competition from other organisations, many of which may have significantly greater financial, technical and marketing resources than Sirtex Medical. The Company has faced, and is expected to continue to face, additional competition from new entrants into its markets. Sirtex Medical will continue to review developments in the treatment of cancer to ensure that its therapies are based on the most up-to-date technology available.

Increased competition could result in price reductions, under-utilisation of employees, reduced operating margins and loss of market share. Any of these occurrences could adversely affect the Company's business, operating results and financial condition. There can be no assurance that the Company will be able to compete successfully against current or future competitors.

The risk exists that one or more of the competitive products in existence now or in development now or in the future will prove more efficacious, more cost effective, more timely or more acceptable to patients than any product arising from Sirtex Medical's research and development program.

#### **Potential Acquisitions**

As part of its business strategy, the Company may make acquisitions of or significant investments in, complementary companies, products or technologies, although no such acquisitions or investments are currently planned. Any such future transactions would be accompanied by the risks commonly encountered in making acquisitions of companies, products and technologies.

#### **Additional Capital Requirements**

Medical research and development activities require a high level of funding over a long period of time and, over the course of its existence, Sirtex Medical intends to develop or acquire other cancer therapies. There is no assurance that additional funding will be available to Sirtex Medical in the future or be secured on acceptable terms. If adequate additional funds are not available, Sirtex Medical may be required to curtail significantly one or more of its research and development projects which may materially and adversely effect Sirtex Medical's future business prospects.

#### **Third Party Contract Risk**

Any default in the performance of obligations by persons with whom Sirtex Medical has contracted or is dependent on may have an adverse effect on Sirtex Medical. In particular, Sirtex Medical is reliant on manufacturers, agents and distributors, in particular the services provided by the Australian Nuclear Science and Technology Organisation in respect of the manufacture of SIR-Spheres® (as described in Section 10). The inability of any of these parties to perform their obligations could have a significant impact on the Company.

#### **Technology and Intellectual Property Rights**

Securing rights to technology and patents is an integral part of securing potential product value in the outcomes of medical research and development. Competition in retaining and sustaining protection of technology and the complex nature of technologies can lead to patent disputes.

### Risk Factors

The granting of a patent does not guarantee that the patent is valid, the rights of others are not infringed or that competitors will not develop technology to avoid such patents. Sirtex Medical's success depends, in part, on its ability to obtain patents, maintain trade secret protection and operate without infringing the proprietary rights of third parties. Because the patent positions of medical companies can be highly uncertain and frequently involve complex legal and factual questions, neither the breadth of claims allowed in medical patents nor their enforceability can be predicted. There can be no assurance that any patents which Sirtex Medical may own or control in the future will afford Sirtex Medical commercially significant protection of its technology or its products or have commercial application.

As indicated elsewhere, as with most new therapeutic agents, many persons and organisations have been involved in creating and developing the technology being exploited by Sirtex Medical. The Directors cannot exclude the possibility that a person may claim in future an ownership interest in the technology, but the Directors are not aware from their investigations of any such claims having been made against the Company.

#### **Risk of Product Liability**

Sirtex Medical's business exposes it to potential liability risks that are inherent in the research and development, preclinical study, clinical trials, manufacturing and use of therapeutic products in humans. Sirtex Medical has obtained product liability insurance (see Section 10 for details). However, there can be no assurance that adequate or necessary insurance coverage will be available at an acceptable cost or in sufficient amounts, in the future, or that a product liability or other claim would not materially and adversely affect the business or financial condition of Sirtex Medical.

Section

# IndependentAccountantsReport

# Independent Accountants Report

[Deloitte Touche Tohmatsu letterhead to come]

17 July, 2000

The Directors Sirtex Medical Limited GPO Box J703 PERTH WA 6000

Dear Sirs

#### **Independent Accountants Report**

#### 1. Introduction

This Independent Accountants Report ("the Report") has been prepared for inclusion in a Prospectus relating to the proposed issue by Sirtex Medical Limited ('Sirtex Medical') of 15,000,000 ordinary shares at an issue price of \$1.00 each to raise approximately \$15,000,000.

#### 2. Basis of Preparation

This Report has been prepared to provide investors with information on historical results and the assets and liabilities of Sirtex Medical. This Report does not address the rights attaching to the shares to be issued in accordance with this Prospectus, nor the risks associated with the investment.

#### 3. Background

The company was incorporated on 21 April 1997 as Paragon Medical Limited and subsequently changed its name to Sirtex Medical Limited.

It was formed to acquire and commercialise three technologies relating to the treatment of liver cancer which had been under development by the Cancer Research Institute Inc, and Dr Bruce Gray. Initial funding for the development of the technology was provided by the investment of \$3.0 million by NJI No. 2 Investment Fund (managed by Nomura/JAFCO Investment (Asia) Limited). Sirtex Medical in the past 3 years has undertaken its own research and development and utilised the expertise of other agencies such as the Cancer Research Institute Inc to further develop the three technologies.

#### 4. Scope Of Examination

You have requested Deloitte Touche Tohmatsu ('Deloitte') to prepare this Report, which is to include the following information:

- (i) the audited consolidated results of Sirtex Medical for the 3 months ended 30 June 1997, the years ended 30 June 1998 and 1999 and the six month period to 31 December 1999;
- (ii) the audited consolidated statement of assets and liabilities of Sirtex Medical as at 30 June 1999 and as at 31 December 1999; and
- (iii) the proforma consolidated statement of assets and liabilities of Sirtex Medical as at 31 December 1999 adjusted to include funds to be raised by the Prospectus and the completion of the transactions referred to in Note 2 of Appendix 3.

During our review of the financial position of the Company we have made such enquiries and performed such procedures, as we considered necessary for the purpose of this Report. Our review included:

- (i) the financial statements of Sirtex Medical for the 3 months ended 30 June 1997, the years ended 30 June 1998 and 1999 and six months ended 31 December 1999 which were audited by Deloitte;
- (ii) discussions with Directors;
- (iii) review of contractual agreements; and
- (iv) a review of publicly available information.

We have not been requested to examine related party transactions as these are disclosed elsewhere in the Prospectus.

We have not valued the intangible asset, being the intellectual property. The value of the intangible asset has been stated at cost in accordance with Australian Accounting Standards. The value of the intellectual property is dependent upon revenues (if any) generated from future trading and/or sale of the contractual rights and related technology.

The proforma balance sheet has been prepared on a going concern basis. Accordingly, the amounts at which the assets and liabilities are disclosed in this Report do not purport to be the amounts which would be realised if such assets were sold at the date of this Report.

## 5. Opinion

In our opinion the proforma statement of assets and liabilities as set out in Appendix 2 presents fairly the proforma assets and liabilities of Sirtex Medical as at 31 December 1999, in accordance with the accounting methodology required by Australian Accounting Standards and with disclosure to the extent considered necessary and on the basis of the assumptions and transactions set out in Appendix 3.

## 6. Other Matters

Deloitte has not made and will not make any recommendation through the issue of this Report to potential investors of Sirtex Medical as to the merits of the investment. The shares offered under the Prospectus should be considered speculative because of the nature of the company's business. The specific risks associated with the investment are detailed in the Prospectus.

Deloitte is the auditor of Sirtex Medical. Neither Deloitte nor any partner or executive employee have any material interest in Sirtex Medical either directly or indirectly, nor in the outcome of the offer except for normal professional fees due for the preparation of this Report and ongoing professional fees received as auditor which have been disclosed in note 13 in Appendix 3.

Deloitte was not involved in the preparation of any other part of the Prospectus and accordingly make no representations or warranties as to the completeness and accuracy of any information contained in any other part of the Prospectus (except the extracts from this Report in Section 3 of the Prospectus).

Yours faithfully

## **DELOITTE TOUCHE TOHMATSU**

## **APPENDIX 1**

**Sirtex Medical Limited** 

## **Profit and Loss Statement**

	Consolidated Audited 3 months 30 Jun 1997 \$	Consolidated Audited 12 months 30 Jun 1998	Consolidated Audited 12 months 30 Jun 1999 \$	Consolidated Audited 6 months 31 Dec 1999 \$
Operating loss before income tax Income tax attributable to operating loss	(201,506)	(553,754) –	(1,355,047)	(536,113)
Operating loss after income tax Accumulated losses at the beginning	(201,506)	(553,754)	(1,355,047)	(536,113)
of the period  Accumulated losses at the end of		(201,506)	(755,260)	(2,110,307)
the period	(201,506)	(755,260)	(2,110,307)	(2,646,420)

**APPENDIX 2** 

**Sirtex Medical Limited** 

## Statement of Assets and Liabilities

		Consolidated Audited 30 Jun 1999	Consolidated Audited 31 Dec 1999	Consolidated Proforma 31 Dec 1999
	Note	\$	\$	\$
Current Assets				
Cash	3	201,411	250,626	13,950,626
Receivables		34,424	52,136	52,136
Inventories		2,523	6,799	6,799
Investments	4	120,000	1,650,000	1,650,000
Other		256	29,464	29,464
Total Current Assets		358,614	1,989,025	15,689,025
N. C. A.A.				
Non-Current Assets Plant and equipment		23,958	23,573	23,573
Intangibles	5	3,216,026	3,125,857	3,125,857
Total Non-Current Assets		3,229,984	3,149,430	3,149,430
Total Assets		3,598,598	5,138,455	18,838,455
Current Liabilities				
Accounts payable	6	60,105	126,016	126,016
Provision for Employee Entitlements		22,032	32,091	32,091
Total Current Liabilities		82,137	158,107	158,107
Non-Current Liabilities				
Borrowings	7	_	1,000,000	_
Total Non-Current Liabilities		_	1,000,000	_
Total Liabilities		82,137	1,158,107	158,107
Net Assets		3,516,461	3,980,348	18,680,348
Equity				
Issued capital	8	5,626,768	6,626,768	21,365,608
Accumulated (losses)		(2,110,307)	(2,646,420)	(2,685,260)
Total Equity		3,516,461	3,980,348	18,680,348

To be read in conjunction with Appendix 3

### **APPENDIX 3**

### **Sirtex Medical Limited**

Notes to the Profit and Loss Statement and Statement of Assets and Liabilities

## 1. Statement of Significant Accounting Policies

## (a) Basis of Accounting

The profit and loss statement and the statement of assets and liabilities (collectively referred to as the 'financial statements') have been prepared in accordance with the Corporations Law, applicable Accounting Standards and Urgent Issues Group Consensus Views, and comply with other requirements of the law.

In addition to the accounting policies prescribed by applicable Accounting Standards and Urgent Issues Group Consensus Views, the following significant accounting policies have been adopted in the preparation and presentation of the financial statements:

## (b) Principles of Consolidation

The consolidated financial statements have been prepared by combining the financial statements of all the entities that comprise the economic entity as defined in accounting standard AASB1024 'Consolidated Accounts'. Consistent accounting policies have been employed in the preparation and presentation of the consolidated financial statements.

The consolidated financial statements include the information and results of each controlled entity from the date on which the company obtains control and until such time as the company ceases to control such entity.

In preparing the consolidated financial statements, all intercompany balances and transactions, and unrealised profits arising within the economic entity are eliminated in full.

### (c) Income Tax

Income tax has been brought to account using the liability method of tax effect accounting whereby income tax expense shown in the profit and loss statement is based on the operating profit before income tax adjusted for any permanent differences.

Timing differences which arise due to different accounting periods in which items of revenue and expense are included in the determination of operating profit before income tax and taxable income, are brought to account as either provision for deferred income tax or an asset described as future income tax benefit at the rate of income tax applicable to the year in which the benefit will be received or the liability will become payable.

Future income tax benefits are not brought to account unless realisation of the asset is assured beyond reasonable doubt. Future income tax benefits in relation to tax losses are not brought to account unless there is virtual certainty of realisation of the benefit.

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 the income taxation legislation and the anticipation of derivation of sufficient future assessable income to enable the benefit to be realised and compliance with the conditions of deductibility imposed by law.

### (d) Inventories

Inventories are measured at the lower of cost and net realisable value. Costs are assigned on a first-in first-out basis and include direct materials, direct labour and an appropriate portion of variable and fixed overhead expenses.

### (e) Receivables

Trade receivables and other receivables are recorded at amounts due less any provision for doubtful debts.

## (f) Plant and Equipment

Plant and equipment are brought to account at cost or at independent or directors' valuation, less, where applicable, any accumulated depreciation or amortisation. The carrying amount of plant and equipment is reviewed annually by directors to ensure it is not in excess of the recoverable amount from those assets. The recoverable amount is assessed on the basis of the expected net cash flows which will be received from the assets employment and subsequent disposal. The expected net cash flows have not been discounted to their present values in determining recoverable amount.

Depreciation is provided on plant and equipment. Depreciation is calculated on a diminishing value basis so as to write off the net cost of each asset over its useful life. The following estimated useful lives are used in the calculation of depreciation:

- Plant and Equipment 2-5 years

## (g) Leases

Leases of fixed assets, where substantially all the risks and benefits incidental to the ownership of the asset, but not legal ownership, are transferred to the company are classified as finance leases. Finance leases are capitalised recording an asset and a liability equal to the present value of the minimum lease payments, including any guaranteed residual value. Leased assets are amortised over their estimated useful lives. Lease payments are allocated between the reduction of the lease liability and the lease interest expense for the period.

Lease payments under operating leases, where substantially all the risks and benefits remain with the lessor, are charged as expenses in the years in which they are incurred.

## (h) Investments

Investments brought to account are at cost or at directors' valuation. The carrying amount of investments is reviewed annually by directors to ensure it is not in excess of the recoverable amount of these investments. The recoverable amount is assessed from the shares' current market value or the underlying net assets in the particular entities. The expected net cash flows from investments have not been discounted to their present value in determining the recoverable amounts, except where stated.

Dividends are brought to account in the profit and loss account when received.

## (i) Employee Entitlements

Provision is made for the liability for employee entitlements arising from services rendered by employees to balance date. Employee entitlements expected to be settled within one year together with entitlements arising from wages and salaries, annual leave and sick leave which will be settled after one year, have been measured at their nominal amount. Other employee entitlements payable later than one year have been measured at the present value of the estimated future cash out flows to be made for those entitlements.

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

## (j) Intellectual Property

The acquisition cost of intellectual property is recorded at cost and amortised on a straight-line basis over the period of the patents.

### (k) Research and Development Costs

Research and development costs are written off as and when they are incurred.

## (l) Accounts Payable

Trade payables and other accounts payable are recognised when the economic entity becomes obliged to make future payments resulting from the purchase of goods and services.

## (m) Borrowings

Convertible notes, bank loans and other loans are recorded at an amount equal to the net proceeds received. Interest expense is recognised on an accrual basis.

## 2. Actual and Proposed Transactions to arrive at Proforma Statement of Assets and Liabilities

The proforma statement of assets and liability reflects the position of Sirtex Medical subsequent to the capital raising. The 31 December 1999 statement of assets and liabilities is adjusted to reflect the effect of the actual and proposed transactions pursuant to the proposed capital raising and assumes no oversubscription of shares. The transactions reflected in the proforma balance sheet are as follows:

- a) Dr Bruce Gray was issued 13,594 shares in lieu of salary.
- b) The existing shares, including the 13,594 shares issued to Dr Gray, were converted to ordinary shares fully paid. Each existing share was converted into 11.225646 new ordinary shares.
- c) The issue of 15,000,000 fully paid ordinary shares at an issue price of \$1.00 each to raise \$15,000,000.
- d) The costs of the capital raising of \$1,300,000 in relation to the Prospectus and share issue which are to be offset against the capital raised.
- e) The conversion of the \$1,000,000 convertible notes to 1,428,571 ordinary shares fully paid.

	Consolidated 12 Months 30/06/99	Consolidated 6 Months 31/12/99	Consolidated Proforma
	\$	\$	\$
Note 3 – Cash			
Cash at bank:			
Cheque account	201,261	250,476	250,476
Petty cash	150	150	150
Proforma adjustments			
2(c) Share placement	_	_	15,000,000
2(d) Share issue costs	_	_	(1,300,000)
	201,411	250,626	13,950,626
Note 4 – Investments			
Current			
Bills endorsed by banks	120,000	1,650,000	1,650,000
	120,000	1,650,000	1,650,000
Note 5 – Intangibles			
Intellectual property			
At cost	3,606,758	3,606,758	3,606,758
Less: Accumulated depreciation	(390,732)	(480,901)	(480,901)
	3,216,026	3,125,857	3,125,857
Note 6 – Accounts Payable			
Current			
Unsecured:			
Trade creditors	52,105	6,266	6,266
Other creditors	8,000	119,750	119,750
	60,105	126,016	126,016

	Consolidated 12 Months 30/06/99	Consolidated 6 Months 31/12/99	Consolidated Proforma
	\$	\$	\$
Note 7 – Borrowings  Non-Current  Unsecured  1,000,000 8% convertible notes were issued on 23 December 1999 at \$1.00 each. The notes must be repaid by the issue of ordinary shares at a 30% discount to the initial public offer price if the ordinary shares are quoted on the ASX before 23 December 2000 when the notes would otherwise mature for repayment in cash together with interest.			
. ,	_	1,000,000	1,000,000
Proforma adjustments 2(e) Conversion of notes to shares	_	_	(1,000,000)
	_	1,000,000	
Note 8 – Share Capital Issued and paid up capital 1 B ordinary subscriber share issued at \$2.00 each.	2	2	-
4 A ordinary subscriber shares issued at \$2.00 each.	8	8	-
1,028,333 A ordinary shares issued on 1 May 1997 for the acquisition of intellectual property and equipment issued at \$2.00 each. 30,000 B ordinary shares issued on	2,056,666	2,056,666	-
1 May 1997 to raise working capital issued at \$0.67 each.	20,100	20,100	-
774,996 B ordinary shares issued on 1 May 1997 for the acquisition of intellectual property and equipment issued at \$2.00 each.	1,549,992	1,549,992	_
499,999 A convertible participating redeemable preference shares issued on 30 May 1997 to raise working capital issued at \$2.00 each.	999,998	999,998	_

	Consolidated 12 Months 30/06/99	Consolidated 6 Months 31/12/99	Consolidated Proforma
	\$	\$	\$
Note 8 – Share Capital (continued)			
1 C convertible participating redeemable preference share issued on 30 May 1997			
to raise working capital issued at \$2.00 each.	2	2	_
500,000 A convertible participating redeemable preference shares issued on 21 May 1998 to			
raise working capital issued at \$2.00 each.	1,000,000	1,000,000	_
500,000 A convertible participating redeemable preference shares issued on 13 September 1999		1 222 222	
to raise working capital at \$2.00 each.	_	1,000,000	_
Proforma Adjustments			
2(a) Issue of 13,594 shares to			
Dr Bruce Gray in lieu of services rendered.	_	_	38,840
2(b) Conversion of 3,346,928 existing shares into 37,571,429 ordinary shares on the basis			
of 11.225646 new ordinary shares fully paid			
for 1 existing share.	_	_	6,626,768
2(c) Issue of 15,000,000 shares fully paid to \$1.00.	_	_	15,000,000
2(d) Payment of associated issue costs.	-	-	(1,300,000)
2(e) Conversion of \$1,000,000 of convertible			
notes to 1,428,571 ordinary shares fully paid.		_	1,000,000
	5,626,768	6,626,768	21,365,608

## Note 9 – Options

As at 31 December 1999 there were 15,500 options on issue under the Employee Share Option Plan exercisable at \$3.50 per share. As a result of the share conversion referred to in note 2(b) above these options will convert into 173,997 options exercisable at \$0.31 per share and have an expiry date of 4 years from the date the company is first listed on the Australian Stock Exchange.

Subsequent to 31 December 1999 and prior to the issue of the shares under the Prospectus a further 1,630,616 options will be issued to directors and other related parties with the following expiry dates and exercise prices:

Number of Options	Expiry Date	Exercise Price
876,616	[1]	\$1.00
377,000	[2]	[2]
377,000	[3]	[3]

- [1] Options exercisable within 5 years from the date the company is first listed on the Australian Stock Exchange provided that if the person leaves the service of the Company, the options have to be exercised within 3 months of their departure date.
- [2] Options exercisable at 1st anniversary of Initial Public Offering. Exercise price is the average share price of the previous 5 trading days on the Australian Stock Exchange.
- [3] Options exercisable at 2nd anniversary of Initial Public Offering. Exercise price is the average share price of the previous 5 trading days on the Australian Stock Exchange.

For further information regarding the Employee Share Option Plan refer to Section 10 of the Prospectus.

## Note 10 – Related Party Disclosure

Details of Directors and other related parties are included in Section 10 of the Prospectus.

## Note 11 – Event Occurring After Balance Date

There are no matters or circumstances that have arisen since the end of the financial year that have significantly affected or may significantly affect the operations of the economic entity, the results of those operations or the state of affairs of the economic entity, in future years.

## Note 12 – Commitments

The parent entity has advised the controlled entity that it will continue to provide financial assistance to allow it to meet its working capital and capital expenditure commitments for at least the next 12 months.

## Note 13 - Auditor's Remuneration

	Consolidated Audited 3 months 30 Jun 1997 \$	Consolidated Audited 12 months 30 Jun 1998	Consolidated Audited 12 months 30 Jun 1999 \$	Consolidated Audited 6 months 31 Dec 1999
Auditing services	2,000	10,742	6,415	6,000
Other services	5,600		1,560	12,000
	7,600	10,742	7,975	18,000

## Section

# Reports on Patents



17 July 2000

The Directors Sirtex Medical Limited 125 Burswood Road Victoria Park East WA 6101

Dear Sirs

## Patent Attorneys' Report

This report has been prepared for inclusion in the Prospectus of Sirtex Medical Limited (hereinafter 'Sirtex').

### **Background**

Wray & Associates is a firm of patent and trade mark attorneys specialising in the law and practice relating to intellectual property. The firm was established in 1920 and has a long history in servicing the intellectual property needs of both Australian and overseas clients.

Each of our partners is a Fellow of the Institute of Patent and Trade Mark Attorneys of Australia. Our professional staff are divided into departments by technology areas, each department being overseen by a partner or associate of the firm. The firm's structure presently contains departments dedicated to the chemical/pharmaceutical, biotechnology, computer/electronic, mechanical engineering and the physics/general mechanical technology areas. Our professional staff each holds a tertiary qualification in the technology field in which he/she practices.

The term 'intellectual property' relates to a group of rights covering patents, trade marks, registered designs, copyright, confidential information/trade secrets, plant breeder's rights and printed circuits. Patents are perhaps the most familiar, and in certain circumstances the most powerful, of these rights. A patent provides the owner with a statutory monopoly for a limited period. This monopoly allows the patent owner to exercise control over use of the technology protected in the patent, including restricting access or allowing its use through grant of licences. Patents may be granted in a wide variety of technology areas, including pharmaceuticals, and chemical compositions and processes.

It should be noted that the granting of a patent does not guarantee that the patentee is entitled to practise the invention claimed in the patent. It may be that working of a patented invention is prevented by the existence of another patent or a patent application which has still to mature to a patent and which has an earlier priority date to the above application.

In addition, the grant of a patent does not guarantee validity of that patent since it may be revoked on the grounds of invalidity at any time during its life. If none of the claims of a granted patent are valid then the patent is unenforceable. For example, relevant prior disclosures may be discovered which may limit the scope of patent protection sought, perhaps to a very narrow field.

## **WRAY & ASSOCIATES**

Patent and Trade Mark Attorneys

6th Floor, 239 Adelaide Terrace, Perth Western Australia 6000 Australia Telephone (+618) 9325 6122 Facsimile (+618) 9325 2883 E-mail wray@wray.com.au

## **Patent Applications**

Sirtex was formerly known as Paragon Medical Limited ('Paragon'). We confirm that Paragon is the patent applicant in respect of a number of patent applications in a variety of countries as described in Schedule A. Similarly, the Company is the applicant in respect of a number of trade mark applications, also in a variety of countries as described in Schedule B. None of these applications have been amended to reflect the change in name of the applicant from Paragon to Sirtex, although documents have been filed at the United States Patent Office to change the name of the assignee from Paragon Medical Limited to Sirtex Medical Limited in respect of United States patent application 09/182,580.

There are essentially three streams of patent applications that may be broadly defined as follows:

## 'Targeted Hysteresis Hyperthermia as a Method for Treating Diseased Tissue'

The patent applications having this title relate to a technique for localised heating of a substance using heat generated by small magnetic particles exposed to a time varying linear alternating magnetic field. This technique can be used but is not limited to treat cancerous growths containing one or more tumours.

All of the applications are presently awaiting examination except for United States patent application 09/180,399 which has been allowed. The next step is to pay the issue fee. The European application will undergo a search before it undergoes examination.

Each of the applications filed in respect of this invention has been filed as national phase entries of International Patent Application PCT/AU99/00287. This international application underwent its own preliminary examination before the Australian Patent Office in its capacity as an International Preliminary Examining Authority, after which that office reported that the invention as claimed in each and every claim satisfied the requirements with regard to novelty and inventive step. It should however be noted that the report issued by the Australian Patent Office is non-binding on member countries of the Patent Cooperation Treaty.

We are not aware at this stage of any prior disclosures which we believe to be detrimental to the patentability of the subject matter of the invention described.

## 'Improved Targeted Hysteresis Hyperthermia as a Method for Treating Diseased Tissue'

The patent applications having this title relate to a technique for the localised heating of a substance using heat generated by small magnetic particles exposed to a time varying rotational magnetic field. This technique can be used but is not limited to treat cancerous growths in tissue which contains one or more tumours.

All the applications are at present generally awaiting examination, except United States patent Application 09/182,580, which has been allowed and ROC Patent Application 87117954 which is undergoing examination. With respect to US 09/182,580, the next step of paying the issue fee has been attended to. We are waiting for the patent to be issued.

We are not aware at this stage of any prior disclosures which we believe to be detrimental to the patentability of the subject matter of the invention described.

### 'Magnetic Material'

The international patent application given this title relates to a magnetic material which has improved magnetic heating characterisation that can be used in diverse methods such as, but not limited to, the treatment of diseased tissue.

Sirtex filed an international patent application under the provisions of the Patent Co-operation Treaty ('international application') designating Australia together with other member States (countries and regions) of the Treaty. This treaty presently covers over 100 countries including Australia and the majority of the developed or industrialised countries. The international application claims priority from Australian provisional application PP8998 filed on 3 March 1999. Filing an international application allows the final due date for filing patent applications in individual countries and regions (referred to as entering the 'national phase'), and the associated cost, to be deferred for a period of up to 30 or 31 months (depending upon the country concerned) from the date of filing of the first priority application for the invention that is the subject of the international application.

After an international application is filed, an international search is conducted by the International Searching Authority (which, in this case, will be the Australia Patent Office). The international search may

or may not reveal prior documentary disclosures relevant to the question of novelty and/or inventiveness of the invention. The international application is published 18 months from its earliest priority date, i.e. the date of filing of the first priority application for the invention. The international search report is published together with the international application. The PCT provisions give the applicant the option of demanding International Preliminary Examination. The applicant must demand International Preliminary Examination if it wishes to proceed down that path, on or before expiry of 19 months from the date of filing of the first priority application. If the applicant elects certain countries and/or regions by filing a demand for International Preliminary Examination and files such demand on or before 19 months from the date of filing of the first priority application, then the applicant is allowed 30 or 31 months (depending on the country concerned) from the date of filing of the first priority application for the invention to enter the international application into the 'national phase'. If the applicant chooses not to file a demand for International Preliminary Examination or files the demand after 19 months from the date of filing of the first priority application it follows that no countries or regions were elected on or before 19 months from the first priority application. Consequently, the applicant is allowed only 20 or 21 months (depending on the country concerned) from the filing date of the first priority application to enter the international application into the 'national phase'.

Entering the 'national phase' in the countries and regions designated in the international application is analogous to filing separate national or regional applications in the individual countries and regions concerned.

The international search has revealed five prior documentary disclosures which the International Searching Authority considers to be relevant to the question of novelty or inventiveness of the invention. One of these documents is a document published prior to the international filing date but later than the priority date

and the international patent application.

## **Trade Mark Applications**

Registered trade marks protect names, words, labels, symbols, or a combination of these, when used to signify the origin of goods or services. Registration of a trade mark provides the owner with a monopoly in respect of the use of the registered mark, which the owner may choose to license to others. The registration allows the owner to take action against those believed to be infringing. Infringement generally includes the use of marks that are held to be substantially identical or deceptively similar to the registered mark when used on the same goods or services, or goods or services of the same description.

## 'SIR-SPHERES'

The 'SIR-SPHERES' US trade mark application has been allowed but is not yet registered.

The 'SIR-SPHERES' European Community trade mark application was published on 19 October 1998, but has not yet been registered. From the date of publication there was a non-extendable period of 8 months within which the application could have been opposed by third parties, or observations filed with the Community Trade Marks Office outlining objections to registration. The opposition period has expired and there are no active oppositions. We expect the application to proceed through to registration.

## Independence

Neither Wray & Associates nor any of its partners has any entitlement to any shares in Sirtex, or has any interest in the promotion of Sirtex. Wray & Associates have acted in the prosecution and filing of the various applications noted herein since 1996. Wray & Associates will be paid its usual professional fee for the preparation of this report.

### Conclusion

Sirtex has worked to protect its intellectual property in a diligent and effective manner, as a result of which it owns a significant patent/patent application and trade mark portfolio. Importantly, it appears from information available to us that these rights are entirely valid and defensible.

Yours faithfully
WRAY & ASSOCIATES



## PATENTS & TRADE MARKS STATUS REPORT

**Sirtex Medical Limited** 

Date: 17 July 2000

Prepared for and on behalf of Sirtex Medical Limited

### **Notes**

The following provides a status report on those files that Wray & Associates are handling on behalf of Sirtex Medical Limited.

In this status report, we have only identified those applications that are currently pending. We have not included applications that have lapsed.

### **Patents**

Patent Series 3 and 4 are presently provisional patent applications. These applications are due for completion at the times mentioned in the report. We will contact you shortly concerning these applications.

Applications corresponding to the provisionals in each of Patent Series 3 and 4 can be filed in all convention countries. Should you require a list of those countries, please do not hesitate in contacting us.

### **Trade Marks**

We have also included a status report on those trade marks that we have filed for and on behalf of Sirtex Medical Limited.

## **WRAY & ASSOCIATES**

Patent and Trade Mark Attorneys

6th Floor, 239 Adelaide Terrace, Perth Western Australia 6000 Australia Telephone (+618) 9325 6122 Facsimile (+618) 9325 2883 E-mail wray@wray.com.au

## Schedule A

### Patent Series 1

'Targeted Hysteresis Hyperthermia as a Method for Treating Diseased Tissue'

## **APPLICATIONS**

**CANADA** 

Application No. 2253963 Filing date 09.05.97

Title Targeted hysteresis hyperthermia as a method for treating diseased tissue.

**CHINA** 

Application No. 97194528.4 Filing date 09.05.97

Title Targeted hysteresis hyperthermia as a method for treating diseased tissue.

**EUROPE** 

Application No. 97917946.2 Filing date 09.05.97

Title Targeted hysteresis hyperthermia as a method for treating diseased tissue.

**JAPAN** 

Application No. 540311/1997 Filing date 09.05.97

Title Targeted hysteresis hyperthermia as a method for treating diseased tissue.

**SOUTH KOREA** 

Application No. 1998-709065 Filing date 09.05.97

Title Targeted hysteresis hyperthermia as a method for treating diseased tissue.

**UNITED STATES OF AMERICA** 

Application No. 09/180399 Filing date 09.05.97

Title Targeted hysteresis hyperthermia as a method for treating diseased tissue.

**DIVISIONAL STATES** Divisional of United States patent application 09/180399

Application No. 09/569788 Filing date 12.05.2000

Title Targeted hysteresis hyperthermia as a method for treating diseased tissue.

## **Patent Series 2**

'Improved Targeted Hysteresis Hyperthermia as a Method for Treating Diseased Tissue'

## **APPLICATIONS**

### **CANADA**

Application No. 2252199 Filing date 29.10.98

Title Improved targeted hysteresis hyperthermia as a method for treating diseased tissue

**CHINA** 

Application No. 98125001.7 Filing date 29.10.98

Title Improved targeted hysteresis hyperthermia as a method for treating diseased tissue

**EUROPE** 

Application No. 98308777.6 Filing date 27.10.98

Title Improved targeted hysteresis hyperthermia as a method for treating diseased tissue

**JAPAN** 

Application No. 306483/1998 Filing date 28.10.98

Title Improved targeted hysteresis hyperthermia as a method for treating diseased tissue

**SOUTH KOREA** 

Application No. 1998-45908 Filing date 29.10.98

Title Improved targeted hysteresis hyperthermia as a method for treating diseased tissue

Notes Request for examination filed 19.03.99

**TAIWAN** 

Application No. 87117954 Filing date 18.11.98

Title Improved targeted hysteresis hyperthermia as a method for treating diseased tissue

## **UNITED STATES OF AMERICA**

Application No. 09/182580 Filing date 29.10.98

Title Improved targeted hysteresis hyperthermia as a method for treating diseased tissue

## **Patent Series 3**

'Magnetic Material'

## **APPLICATION**

Priority Application No. PP8998 Filing date 03.03.99

Title Magnetic material

International Patent

Application No. PCT/AV00/00151 Filing date 03.03.00

Title Magnetic material

## Schedule B

## **Trade Mark Series 1**

'Sir-Spheres'

## **APPLICATIONS**

## **EUROPE**

Application No. 726851
Filing date 16/01/98
Title 'SIR-SPHERES'

## UNITED STATES

Application No. 75/438813
Filing date 23/02/98
Title 'SIR-SPHERES'

## DAVIES COLLISON CAVE PATENT & TRADE MARK ATTORNEYS



17 July, 2000

The Directors Sirtex Medical Limited PO Box 405 Victoria Park WA 6979

Our Ref: JMS:ETC

Re: Report of Australian and Foreign Patents and Patent Applications

Dear Sirs,

This report of Australian and foreign patents and patent applications (hereinafter referred to as the 'Report') has been prepared for inclusion in a prospectus to be issued by Sirtex Medical Limited (hereinafter referred to as 'Sirtex Medical').

Davies Collison Cave is a firm of patent and trademark attorneys. All partners of the firm who are involved in patent matters are Fellows of the Institute of Patent and Trademark Attorneys of Australia

The partners and professional staff of Davies Collison Cave practise in a range of technologies including pharmaceutical and other chemical technologies and biotechnology. The chemical/biotechnology group of Davies Collison Cave comprises four partners and eight experienced assistants. All members of the group have academic qualifications in chemistry, molecular biology, microbiology and/or biochemistry. The partners and professional staff of Davies Collison Cave work closely with a range of intellectual property specialists throughout the world in order to maximise international protection for innovations of clients of the firm.

Intellectual property may be regarded as a collective term for a group of rights which provide varying degrees of exclusivity in relation to products, processes, names, designs and drawings in industry, science or commerce. Patent rights constitute an important component of intellectual property, and provide protection for new, non-obvious and useful inventions for a limited period. Patents may be granted in respect of new or improved products, compositions and processes in almost all areas of current scientific, commercial and industrial activities, including pharmaceuticals.

Patent rights are essentially national rather than transnational and a patent must be obtained in each country where protection of an invention is required. A fundamental requirement of the patent system is that the invention be 'new' at the time of lodging a patent application. Newness in this sense is judged in relation to what was publicly known or used at the date of the application. Another requirement is for a distinct inventive advance over what was previously known. This means that valid patent protection cannot be obtained for trivial or obvious developments.

Pursuant to an International Convention, the filing of an initial patent application establishes a priority date for the invention in Australia and all other countries which are party to this Convention, including countries such as the United States, Canada, New Zealand, Europe and Japan.

The usual steps towards obtaining a patent in Australia and other countries in respect of an invention begin by filing of an application accompanied by a provisional specification in Australia. The filing of a provisional application establishes the priority date in respect of the invention disclosed in the provisional specification. Within twelve months from the date of the filing of the provisional application, a complete application is lodged. At this time, in order to obtain protection in other countries, the applicant may file separate national patent applications in each of the countries in which protection is required. Alternatively, the applicant may file a single International

## Davies Collison Cave

PATENT & THADE MAIR ATTORNEYS

### Melbourne

1 Little Collins Street Melbourne, Victoria Australia, 1000

G.P.O. Box 4387QQ Melbourne, Victoria Australia, 3601

Telephone: +61 3 9254 2777 Facsimile: +61 3 9254 2770

### Other Offices

## Sydney

Level 18 16 Barrack Street Sydney, New South Wales Australia, 2000

G.P.O. Box 3876 Sydney, New South Wales Australia, 2001

Telephone: +61 2 9262 2611 Facsimile: +61 2 9262 1000

## Brisbano

Level 3 303 Coronation Drive Milton, Queensland Australia, 4864

P.O. Bex 2219 Milton Business Centre Milton, Queensland Australia, 4064

Telephone: +61 7 3368 2255 Facsimile: +61 7 3368 2262

### Canberra

Level 11 St George Centre 60 Marcus Clarke Street Canberra City, A.C.T. Austrolia, 2601

Telephone: +61 2 6248 8063 Facultuile: +61 2 6248 6591

e-mail: mail@davies.com.au Web ahr: http://www.davies.com.au

In association with: Durin Collisos Care Solicitors, Intellectual Property Law

application under the provisions of the Patent Cooperation Treaty (generally referred to as a 'PCT' application or an 'International' application) in which it is possible to designate countries or regions in which protection is required. The International application itself does not mature into a worldwide patent, but at the end of the international phase, steps can be taken to file the application into any or all of the countries or regions designated in the original International application.

Regional patent applications, such as a European regional application, may also be filed. A European application may designate any or all countries which are party to the European Patent Convention. These countries currently include Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Liechtenstein, Luxembourg, Monaco, Netherlands, Portugal, Spain, Sweden, Switzerland and the United Kingdom. A European patent application may also be extended to certain other jurisdictions including those which are not full signatories to the European Patent Convention. The European patent application is processed centrally and in a single language and, if ultimately successful, can mature into a granted European patent. The term 'European patent' actually constitutes a bundle of national patent rights, each of which can be enforced separately through national Courts.

In Australia and most other countries, patent rights may be kept in force for a period of 20 years from the date of filing of the complete application on which the patent is granted, and while the patent is in force the owner has the exclusive right to exploit the invention.

Patent specifications prepared by Davies Collison Cave are drafted with due regard to specific requirements in Australia and foreign jurisdictions. This ensures that a specification contains adequate support for any amendments or particular claim language which may be required in a particular jurisdiction. The specifications are also drafted to accommodate improvements to the technology for which protection is sought and with due regard to potential third party competition.

For the purposes of the present prospectus, Sirtex Medical has requested that Davies Collison Cave summarise the status of patents and patent applications in which it has indicated that it has an interest and which fall into several groups.

This Report comprises the following Schedules of patent and patent applications:

## **SCHEDULE I**

Title: 'Controlled Release Preparation'

### Description:

The invention relates generally to controlled release preparations which comprise an ionic polymer matrix loaded with an active compound, particularly a pharmaceutically active compound, the active compound being complexed with a complexing agent to modify the release of the active compound from the polymer matrix. The ionic polymer matrix may be provided in the form of microspheres, such as microspheres of crosslinked albumin/dextran sulphate. Specifically as disclosed are controlled release preparations in which the ionic polymer matrix is loaded with a cytotoxic or cytostatic drug such as doxorubicin, daunorubicin or cisplatin, and the complexing agent is a metal ion such as Fe, or chitosan. The scope of patent protection obtained in respect of the invention will be dependent on the scope of the claims which are granted in each national or regional patent.

- 1 Australian Provisional Patent Application No. PM2492/93, dated 18 November 1993; lapsed, priority application for International Application No. PCT/AU94/00708.
- 2 International Application No. PCT/AU94/00708, dated 17 November 1994; lapsed, proceeding as national/regional applications set out below.
- 3 Australia Patent No. 693821, dated 17 November 1994; granted.
- 4 Canada Application No. 2176933, dated 17 November 1994; pending.
- 5 Europe Application No.95900570.3, dated 17 November 1994; pending.
- 6 Japan Application No. 514111/95, dated 17 November 1994; pending.
- 7 People's Republic of China Application No. 94194617.7, dated 17 November 1994; pending.
- 8 United States of America Patent No. 5932248, dated 3 August 1999; granted.

### SCHEDULE II

Title: 'Particulate Material'

### Description:

The invention relates generally to a particulate material which comprises hollow or cup-shaped ceramic microspheres having a diameter in the range of from 5 to 200 microns. The microspheres may be made radioactive and used in selective internal radiation therapy (SIRT) of various forms of cancer and tumours, including cancer of the liver. Specifically disclosed are radioactive microspheres which consist of yttria or another yttrium-containing compound as base material and in which the radionuclide is beta-radiation emitting yttrium-90. The scope of patent protection obtained in respect of the invention will be dependent on the scope of the claims which are granted in each national or regional patent.

- Australian Patent Application No. 54724/94, dated 21 January 1994; lapsed, priority application for International Application No. PCT/AU95/00027.
- 2 International Application No. PCT/AU95/00027, dated 20 January 1995; lapsed, proceeding as national/regional applications set out below.
- 3 Australia Application No. 690630, dated 20 January 1995; granted.
- 4 Canada Application No. 2181254, dated 20 January 1995; pending.
- 5 Europe Application No. 95906840.4, dated 20 January 1995; pending.
- 6 Japan Application No. 519254/95, dated 20 January 1995; pending.
- 7 People's Republic of China Application No. 95191698.X, dated 20 January 1995; pending.
- 8 United States of America Patent No. 5885547, dated 23 March 1999; granted.
  - Application No. 09/178259, dated 23 October 1998; allowed.
- 9 Hong Kong Application No. 98113874.7, dated 17 December 1998; pending.

Full details of the inventions which are the subject of the patents and patent applications set out in Schedules I and II are described in the relevant patent specifications.

All of the patents and patent applications set out in Schedules I and II are currently in force, although some are subject to the payment of periodic (mainly annual) fees in order to maintain them in force. In most countries, a patent application is subjected to examination for novelty (and often obviousness) before a patent is granted. However, when a patent is granted, there can be no guarantee that the patent is valid and enforceable. Furthermore, there can be no assurance that each of the patent applications set out in Schedules I and II will result in the grant of a patent, or that the scope of protection provided by any patent which is granted will be identical to the scope of the application as originally filed.

To date, there has been no third party challenge to the validity of any of the patents or patent applications set out in Schedules I and II.

Davies Collison Cave acts as Patent Attorneys to Sirtex Medical, and for this reason has prepared this Report for inclusion in the Prospectus to be issued by Sirtex Medical. Davies Collison Cave will be paid its usual professional fees for the preparation of this Report based on commercial rates. It has no other interests in the promotion of Sirtex Medical.

Yours faithfully DAVIES COLLISON CAVE

Section

## 10 Additional Information

## **Share Capital**

The share capital of Sirtex Medical after the issue of the Shares under this Prospectus will be as follows:

	Number of Shares	Percentage of Shares
Existing Securityholders	39,000,000	72.2%
Shares offered under this Prospectus	15,000,000	27.8%
Total issued share capital	54,000,000	100%

## **Details of Existing Securityholders**

The holdings by Existing Securityholders of issued securities in the Company will be as set out below after the issue of the Shares under this Prospectus (assuming that the Existing Securityholders do not apply for Shares under the Offer). It is proposed that some of the Existing Securityholders undertake not to dispose of any interest in or grant any security over some of their Shares or Options. The number of Shares or Options which are proposed to be subject to this escrow requirement and the relevant proposed escrow period is also set out below. Subject

to certain conditions, the escrow restriction will not preclude:

- any the holders of the relevant Shares or Options from accepting a takeover offer provided holders of not less than 50% of the remaining Shares or Options then on issue have accepted the takeover offer; or
- the transfer or cancellation of the relevant Shares or Options as part of a merger by way of scheme of arrangement.

Securityholder	Securities	Number subject to escrow	Escrow period
Dr Bruce Gray	19,438,283 Shares 114,000 Options	19,399,443 Shares 114,000 Options	2 yrs following quotation of Shares 2 yrs following quotation of Shares
Cancer Research Institute Inc	4,864,432 Shares	4,864,432 Shares	2 yrs following quotation of Shares
NJI No. 2 Investment Fund	11,786,928 Shares	8,786,928 Shares	2 yrs following quotation of Shares
Other persons including employees, previous and	2,910,357 Shares	1,303,351 Shares 428,571 Shares	2 yrs following quotation of Shares 1 yr following quotation of Shares
current directors and persons holding convertible notes	1,690,613 Options*	1,690,613 Options**	* 2 yrs following quotation of Shares

<sup>\* 173,997</sup> are exerciseable at \$0.31, 876,616 are exerciseable at \$1.00, 377,000 will be exerciseable at the weighted average trading price on the ASX over the 5 trading days before the first anniversary of quotation of the Shares and 377,000 will be exerciseable at the average trading price on the ASX over the 5 trading days before the second anniversary of quotation of the Shares.

## **Rights Attaching to Shares**

The rights attaching to ownership of the Shares are set out in the Constitution of the Company and are further regulated by the Corporations Law, the Listing Rules, the SCH Business Rules and general law. The following is a summary of certain provisions of the Constitution. This summary is not a complete statement of the rights of Shareholders in the Company or a complete description of the specific provisions referred to in the summary. However, a copy of the Constitution has been lodged with the ASIC. The Company will provide a copy of the Constitution free of charge to anyone who requests a copy during the application period under this Prospectus.

### Voting

Each member is entitled to receive a notice of and generally to attend and vote at general meetings of the Company. A Shareholder may attend and vote in person or may appoint a proxy, attorney or representative to attend and vote on their behalf.

Matters that may be considered and voted on at general meetings of the Company include amendments to the Constitution, changes to the structure of the share capital of the Company, variation of the rights

<sup>\*\*</sup> some or all of these Options may be relieved from escrow depending on the response from the ASX which the Company is awaiting.

attaching to or the terms of issue of a class or classes of shares and the appointment or removal of directors. Resolutions put to the vote at general meetings will not generally relate to the day-to-day management of the Company.

A resolution put to the vote at a general meeting must be decided on a show of hands unless a poll is demanded. A poll may be demanded by:

- · the chairperson of the meeting;
- at least 5 members present and having the right to vote at the meeting; or
- members with at least 5% of the votes that may be cast on the resolution on a poll.

Each member is entitled to one vote if voting is by a show of hands but is entitled to one vote for each fully paid share (or a fraction of a vote for each partly paid Share) where voting is by poll.

### **Dividends**

The board of directors of the Company may pay any interim and final dividends, as in their judgement, the financial position of the Company justifies. A declaration of the directors as to the amount of the net profits of the Company is conclusive.

If the directors decide to pay a dividend then, subject to the rights of shareholders with any special or preferential rights to dividends, each share carries the right to participate in the dividend in the same proportion that the amount paid up (not credited) on the share bears to the total amounts paid and payable (excluding amounts credited).

The directors are not obliged to pay a dividend out of the profits of the Company and may instead:

- carry the profits forward to carry them to a reserve for any purpose for which the profits of the Company may properly be applied;
- pay up unissued shares or other securities of the Company for issue to shareholders in the proportion to which those shareholders would have been entitled were the amounts distributed by way of dividend;
- pay up any unpaid amounts on shares or other securities of the Company held by shareholders in the proportion to which those shareholders would have been entitled were the amounts distributed by way of dividend:
- implement a dividend reinvestment plan on such terms as they think fit under which the whole or any part of any dividend due to shareholders may be applied in subscribing for securities of the Company or a related body corporate; or
- implement a dividend selection plan, on terms as they think fit under which participants may elect to receive a dividend from the Company or to forego a dividend in place of some other form of distribution from the Company or another body corporate or trust.

## **New Issues**

The directors may issue new shares or options in respect of new shares to any person at such times and on such terms and conditions as they think fit provided that the issue complies with the Corporations Law and Regulations, the Listing Rules and general law.

The Company may issue preference shares, including preference shares that are liable to be redeemed, which receive priority payment ahead of the ordinary shares in relation to matters such as:

- participation in profits or dividend payment to the extent of the preference dividend; and
- return of capital and payment of the accrued preference dividend in a winding-up.

A preference dividend payable in respect of a preference share may be at a fixed or variable rate as specified in the relevant certificate for that preference share issued by the Company. Unless otherwise stated in the certificate of the share, a dividend payable in respect of preference shares, will accrue from day to day and is payable in respect of the amount for the time being paid on the preference share.

A preference share does not entitle its holder to vote at any general meeting except in certain circumstances outlined in the Constitution.

### Transfer of shares

Shareholders may generally transfer all or any of their shares by:

- a proper SCH transfer; or
- a written transfer in any usual form or in any other form approved by the directors.

A transferor of shares will remain the holder of the shares until the transfer is:

- effected in accordance with the SCH Business Rules; or
- registered and the name of the transferee is entered in the register of members in respect of the shares.

The directors may refuse to register a transfer of shares where refusal is permitted by the Constitution or the Listing Rules. The grounds upon which the directors are permitted to refuse to register a transfer of shares include where:

- the transfer is not in registrable form; or
- the refusal to register the transfer is permitted under the Listing Rules.

If the directors decline to register a transfer, the Company must give the party lodging the transfer a written notice of the refusal and reason for the refusal.

## Selling non-marketable parcels

The directors may sell less than a marketable parcel of shares (ie less than the minimum number of shares determined by the directors to be a marketable parcel by reference to the Listing Rules) if they following the procedure set out below:

- Once in every 12 month period (except during the offer period of a takeover bid), the directors may send written notice to a shareholder who holds less than a marketable parcel of shares:
  - · explaining the procedure for selling less than a marketable parcel of shares; and
  - advising the shareholder that he or she may choose to be exempt from selling his or her shares in accordance with this procedure.
- If within 6 weeks after the notice is sent, the Company has not received notice from the shareholder choosing to be exempt from this procedure and the shareholder has not increased his or her shareholding to a marketable parcel, the Company may sell the shares constituting less than a marketable parcel and deal with the proceeds of sale in accordance with the Constitution.

In addition to the powers above, the directors may cause the Company to sell shares and may determine that a member's right to vote or receive dividends in respect of those shares is removed or changed where the shares constitute a new holding of less than a marketable parcel which was created by the transfer of less than a marketable parcel.

The procedure for selling less than a marketable parcel of shares does not apply if a takeover bid for the Company is announced after a notice is issued, but before agreement is entered into, for the sale of shares. However, a new notice may be issued after the offer period of the takeover bid closes.

## **Variation of Rights**

Unless the terms of the issue of a class of shares provides differently, the rights and privileges attaching to a class of shares can only be varied if the variation is approved by the holders of 75% of the issued shares of that class in writing or by special resolution passed at a meeting of the holders of shares of that class.

### Winding Up

If the Company is wound up then the assets of the Company would be applied in paying creditors of the Company.

If the company is wound up the surplus assets must be distributed among the members in proportion to the number of shares held and, for this purpose, each partly paid share is treated as a fraction of a share equivalent to the proportion which the amount paid up (not credited) on the share bears to the total amounts paid and payable (excluding amounts credited).

These comments in relation to a winding up are subject to the rights of shareholders who may from time to time hold preferential rights in relation to a winding up.

### **Restricted securities**

Restricted securities cannot be disposed of during the applicable escrow period (and the Company will refuse to acknowledge disposal of restricted securities during the applicable escrow period) except as permitted by the Listing Rules or the ASX.

During a breach of the Listing Rules relating to restricted securities or a breach of a restriction agreement, the holder of restricted securities is not entitled to any dividend or distribution or voting rights in respect of the restricted securities.

### **Directors**

The minimum number of directors is three and the maximum number is to be fixed by the directors but must not be more than 12 unless the Company in general meeting determines otherwise.

A Director may be appoint by resolution of the shareholders or by the other Directors. At each annual general meeting, each Director appointed by the other Directors, one third of the remaining Directors and any other Director who has been in office for 3 years or more since elected or last re-elected to office must retire (although they can offer themselves for re-election). The Chief Executive Officer is not required to retire or be counted for the purpose of determining the number of Directors who must retire.

The shareholders may remove a director from office by resolution in accordance with the Corporations Law.

## **Directors indemnity**

The Company, to the extent permitted by law, indemnifies each director, alternate director or executive officer (and any person who has previously served in any such capacity) against all losses or liabilities incurred by the person as an officer of the Company.

The Company may enter into a deed with a director, alternate director or executive officer (and any person who has previously served in any such capacity) in order to give effect to the rights conferred by the indemnity.

The indemnity is a continuing obligation, even though a director, alternate director or executive officer (and any person who has previously served in any such capacity) may have ceased to be an officer of the Company or related body corporate.

The indemnity applies only to the extent that the loss or liability is not covered by insurance. The Company may also, to the extent permitted by law, purchase or maintain insurance or pay premiums for insurance against any liability incurred by those persons.

## **Employee Share Option Plan**

The Company has established an ESOP which was adopted in 1998. The full terms of the ESOP may be inspected at the registered office of the Company during normal business hours.

### **Objectives**

The objective of the ESOP is to assist in the recruitment, reward, retention and motivation of employees of the Group. Under the ESOP eligible employees are granted options over Shares on terms determined by the Board in accordance with the ESOP. At the time of quotation of the Shares, Options over 173,997 Shares will have been issued under the ESOP. The balance of the Options will have been issued outside of the ESOP but on substantially the same terms as the ESOP.

## **Eligibility - ESOP**

Under the ESOP, the Board has absolute discretion to determine whether certain directors, executive officers, other employees or other persons the Board determines are eligible to participate in the ESOP. The Board may make offers to eligible employees or other persons it declares eligible from time to time. The options are personal to the participant and may not be assigned to, or exercised by, another person or body corporate (except in cases of permanent disability or death).

Once the Company is admitted to the ASX, the number of Shares underlying options that may be granted under the ESOP when aggregated with the Shares that have been issued on exercise of options granted under the plan during the five years preceding the date on which an option is issued must not exceed 5% of the issued Shares in the capital of the Company at the date of issue of the options.

### Consideration

At the time options are granted no payment is required.

### **Exercise price**

The exercise price for options granted under the ESOP will be the price fixed by the Board prior to the grant of the options.

The Company has issued options to employees since the adoption of the ESOP. In accordance with the ESOP rules, as the Company's shares were not listed on the date the options were issued, the exercise price was determined by the Board. Once the Company's shares are listed on the ASX, the exercise price for future options will be determined by the Board and must be at least equal to the Market Price on the day of issue.

The ESOP rules define Market Price on a particular day as:

- (a) if there was at least one transaction on the ASX during the 5 business days before the day, the weighted average of the prices at which Shares were traded during that 5 business day period; or
- (a) if there were no transactions during the 5 business days before the day, the last price at which an offer was made on the ASX in that 5 business day period to buy a Share in the Company.

### **Exercise restrictions**

The options granted under the ESOP may be subject to exercise conditions determined by the Board in its absolute discretion prior to grant of the options. These restrictions could include length of service by the employee and threshold prices at which Shares are traded on the ASX. Any restrictions imposed by the Board must be set out in the offer.

### Term of Options.

Options granted under the ESOP will lapse at the time specified by the Board on issue of the options which will be no more than 10 years after the Option is granted and, unless otherwise determined by the Board, will be 5 years after the Option is granted. The Board has power to extend the date by which options must be exercised

## Participation in Dividends, Rights Issues and Bonus Issues

The options granted under the ESOP do not give any right to participate in dividends or rights issues until Shares are allotted pursuant to the exercise of the relevant option. However, the exercise price may be adjusted to take account of any rights issue. The number of Shares issued on exercise of options will be adjusted for bonus issues made prior to the exercise of the options.

## Subdivision, consolidation or other reconstruction

If the Company, after having granted an option under the ESOP, reduces its issued share capital or subdivides or consolidates its Shares, or engages in any other reconstruction of capital, the number of the Shares issued to the option holder on exercise of an option must be subdivided consolidated or reconstructed, as the case may be, in accordance with the Listing Rules and the exercise price must be correspondingly adjusted.

## **Takeover Bid**

The Board must notify optionholders when the bidder has acquired 30% of the issued shares. The optionholders may exercise their options during the next 30 days irrespective of whether the relevant exercise period has commenced.

The optionholder is given a further opportunity to exercise the options when the bidder has acquired 90% of the shares, but failure to exercise the options in such circumstances will cause the options to lapse. The opportunity to exercise prior to the relevant exercise period does not apply if the exercise price has not at that time been set.

## **Restrictions on transfer**

Options granted under the ESOP are not transferable.

## **Material Contracts Summary**

The Directors consider that the material contracts described below and elsewhere in this Prospectus are the contracts which an investor would reasonably regard as material and which investors and their professional advisers would reasonably expect to find described in this Prospectus for the purpose of making an informed assessment of the Offer. The description below is only a summary of the relevant terms of the material contracts.

## Underwriting Agreement dated 17 July 2000 between Sirtex Medical Limited and KTM Capital Pty Limited

KTM Capital Pty Limited has agreed to underwrite the Offer of 15 million Shares pursuant to this Prospectus.

The Underwriter will receive an underwriting commission equal to 4.5% of the aggregate Offer Price of all Shares offered under the Prospectus and a management fee of \$75,000. The Underwriter will also be entitled to reimbursement from the Company for reasonable costs and expenses incurred by the Underwriter in connection with the Offer or any review of the prospectus undertaken by a regulatory body.

The Underwriter may terminate its obligations to satisfy a shortfall under the Offer if any of the termination events specified in the agreement occur before allotment of the Shares under the Offer. The Underwriter may not terminate for certain events (those which are followed by an asterisk below) unless the Underwriter believes on reasonable grounds acting bona fide that the relevant event has or is likely to have a materially adverse effect on the Company or the outcome of the Offers or could give rise to a material liability of the Underwriter. The events of termination include the following:

- a statement contained in the Prospectus is misleading or deceptive, a matter is omitted from the Prospectus (having regard to the provisions of Sections 710 and 711 of the Corporations Law) or the issue of the Prospectus is misleading or deceptive;\*
- the Prospectus does not contain (having regard, among other things, to the matters set out in Section 710(1) of the Corporations Law) all such information as investors and their professional advisers would reasonably require to make an informed assessment of the assets and liabilities, financial position and performance, profits and losses and prospects of the Company and its group (insofar as the position in relation to an entity in the group will or may affect the overall position of the Company) and the rights and liabilities attaching to the Shares being offered under the Prospectus;
- any information made available by or on behalf of the Company to the Underwriter in relation to the Company, its group, any entity in the group or the Offers is false or misleading or is misleading or deceptive;\*
- any adverse change occurs in the assets, liabilities, financial position and performance, profits, losses or
  prospects of the Company and its group (insofar as the position in relation to an entity in the group will
  or may affect the overall position of the Company) including without limitation any adverse change in
  the assets, liabilities, financial position and performance, profits, losses or prospects of the group from
  those respectively disclosed in the Prospectus or the public statements made by the Company;\*
- there occurs any material adverse change or disruption to the financial markets of Australia, the United
  States of America or other major international financial market, or there occurs any change in national or
  international political, financial or economic conditions, in each case the effect of which is such as to make
  it, in the reasonable judgment of the Underwriter, impracticable to market the Offers or to enforce contracts
  to purchase the Shares or is reasonably likely to materially and adversely affect the success of the Offer;
- at any time after issue of the Prospectus:
  - there occurs a change affecting any matter contained in the Prospectus, as envisaged in Section 719
    of the Corporations Law occasioning the need, in the Underwriter's reasonable opinion, for a
    supplementary or replacement document to be lodged;
  - there arises a significant new matter, the inclusion in the Prospectus of information about which would have been required by Chapter 6D of the Corporations Law if it had arisen when the Prospectus was prepared, as envisaged in Section 719 of the Corporations Law;

- there is a deficiency in the Prospectus within the meaning of Sections 719 of the Corporations Law;
- the Company converts all or any of its shares into a larger or smaller number of shares except a conversion to effect the restructure of the share capital as contemplated in the Prospectus;
- the Company or a subsidiary resolves to reduce its share capital in any way;
- the Company or a subsidiary enters into a buy-back agreement or resolves to approve the terms of a buy-back agreement in accordance with Part 2J.1 Division 2 of the Corporations Law;
- the Company or a subsidiary makes an allotment of or grants an option to subscribe for any of its shares or agrees to make such an allotment or grant such an option except an allotment or grant contemplated in the Prospectus;
- the Company or a subsidiary issues or agrees to issue convertible notes;
- the Company or a subsidiary disposes or agrees to dispose of the whole or a substantial part of its business or property;
- the Company or a subsidiary charges or agrees to charge the whole or a substantial part of its business or property;
- the Company or a subsidiary resolves that it be wound up;
- a provisional liquidator of the Company or a subsidiary is appointed;
- a court makes an order for the winding up of the Company or a subsidiary;
- an administrator is appointed under Sections 436A, 436B or 436C of the Corporations Law to the Company or a subsidiary;
- the Company or a subsidiary executes a deed of company arrangement;
- a receiver or receiver and manager is appointed in relation to the whole or substantial part of the property of the Company or a subsidiary; or
- the Company withdraws the Prospectus;
- hostilities not presently existing commence (whether war has been declared or not) or a major escalation
  in existing hostilities occurs (whether war has been declared or not) involving any one or more of
  Australia, New Zealand, the United States of America, a member nation of the North Atlantic Treaty
  Organisation, a country comprising part of the former Union of Soviet Socialist Republics, Canada, Japan,
  Indonesia, Thailand, Singapore, Malaysia, Hong Kong, North Korea or the Peoples Republic of China;\*
- the All Ordinaries Index of the ASX closes on 3 consecutive trading days at a level that is at least 10% below the level of that Index as at the close of trading on the date of the agreement;
- the Small Ordinaries Index of the ASX closes on 3 consecutive trading days at a level that is at least 10% below the level of that index as at the close of trading on the date of the agreement;
- there is introduced or there is announced a proposal to introduce into the Parliament of Australia or any
  State of Australia a new law or the Reserve Bank of Australia or any Commonwealth or State authority
  adopts or announces a proposal to adopt a new policy, any of which does or is likely to prohibit or
  regulate, in a materially adverse way, the principal business of the Company, the Offer, capital issues
  generally or stock markets generally;
- · a director of the Company is charged with an indictable offence;\*
- there occurs a contravention by the Company or any entity in its group of the Corporations Law, its constitution, any applicable Listing Rules or the SCH Business Rules;\*
- approval to the official quotation of all of the Shares offered under this Prospectus on the ASX is refused, not granted or granted subject to any condition which the Underwriter, on reasonable grounds considers unacceptable on or before the date being 3 months after the date of the Prospectus;

- approval to the official quotation of all of the Shares offered under this Prospectus on the ASX is withdrawn or qualified on a basis which the Underwriter on reasonable grounds considers unacceptable before allotment of all of the Shares offered under this Prospectus;
- the ASIC issues an order or indicates an intention to hold a hearing arising out of or in connection with the Offer under Section 739 of the Corporations Law or the ASIC commences an examination of any person or requires any person to produce documents arising out of or in connection with the Offer or the Company under Sections 19 or 30 to 33 of the Australian Securities and Investments Commission Act and such order is not withdrawn or such hearing or examination is not concluded to the satisfaction of the Underwriter (acting reasonably) within 10 business days;
- an application is made by the ASIC for an order under Section 1324B of the Corporations Law in relation to the Prospectus;
- any person (other than the Underwriter) gives a notice under Section 733(3) of the Corporations Law or any person (other than the Underwriter) who has previously consented to the inclusion of its name in the Prospectus or to be named in the Prospectus withdraws that consent;
- any person gives a notice under Section 730 of the Corporations Law in relation to the Prospectus;\*
- there is a default by the Company in the performance of any of its obligations under the agreement;\*
- a warranty contained in the agreement on the part of the Company is or becomes untrue or incorrect;\*
- any of the material contracts described in this Prospectus are varied without the Underwriter's prior written consent;\*
- any of the material contracts are repudiated, rescinded or terminated without the Underwriter's prior written consent;\*
- any litigation, arbitration or other legal proceeding is commenced against any entity in the group; or\*
- any person commences proceedings or otherwise asserts that the use by the Company of any trademarks, tradenames or logo referred to in the Prospectus infringes that person's intellectual property rights.\*

The Company has agreed to indemnify the Underwriter, its related bodies corporate and each of its officers, employers and advisers from and against all claims, demands, damages, losses, costs, expenses and liabilities suffered or incurred (including costs for which it is entitled to be reimbursed) as a result of:

- any representation or warranty made by the Company under the agreement not being true and correct;
- any breach of the agreement by the Company;
- the distribution of the Prospectus (or any supplementary or replacement document) and the making of the Offer; or
- any advertisement or publicity of the Offer issued with the knowledge and consent of the Company and without the written consent of the Underwriter;

The indemnity provided by the Company does not apply to any claims, demands, damages, losses, costs, expenses or liabilities to the extent that they result from:

- any untrue statement or omission or alleged untrue statement or omission made in reliance upon and in conformity with written information furnished to the Company by an indemnified Party for use in the Prospectus (or any supplementary or replacement document);
- any penalty or fine which the indemnified party is required to pay for any contravention of the Corporations Law which was directly caused by an indemnified party;
- any other amount in respect of which the indemnity would be illegal, void or unenforceable;
- any obligation of the Underwriter to subscribe for the shortfall under the agreement;

- the indemnified party failing (except where caused by the default of the Company) in any material respect to meet any of its obligations to the Company under the agreement or otherwise; and
- any default, fraud, recklessness, wilful misconduct or negligence of an indemnified party.

## **Executive Service Agreements**

The Company has appointed Dr Colin Sutton as Chief Executive Officer and entered into a service agreement with him. As noted in Section 7, the continued services of Drs Bruce Gray and Steven Jones are vital to the ongoing success of the Company. The Company has entered into 5 year service contracts with each of these two key staff. Each of these contracts is summarised below.

## Executive Service Agreement dated 4 May 2000 between Sirtex Medical and Dr Colin Sutton Sirtex Medical has appointed Dr Colin Sutton as Chief Executive Officer reporting to the Board by way of an executive service agreement. The executive service agreement has a term of 5 years from 20 March 2000 unless terminated earlier in accordance with the agreement.

The initial remuneration package for Dr Sutton will have a total cost to Sirtex Medical of \$200,000 per annum (inclusive of superannuation) and subject to review on an annual basis. Dr Sutton will be eligible to participate in the ESOP at the discretion of the Board.

In addition to the remuneration specified in the agreement, Dr Sutton will, on quotation of the Shares, be issued with 377,000 Options exerciseable at \$1.00 (although only 20% of such Options will become available for exercise in each of the 5 years following issue) and 377,000 Options which will be exerciseable at the weighted average trading price on the ASX over the 5 trading days before the first anniversary of quotation of the Shares (although only 20% of such Options will become available for exercise in each of the 5 years following that date) and 377,000 Options which will be exerciseable at the weighted average trading price on the ASX over the 5 trading days before the second anniversary of quotation of the Shares (although only 20% of such Options will become available for exercise in each of the 5 years following that date).

Dr Sutton has undertaken that he will not directly or indirectly carry on or otherwise be concerned with or interested in any business which is competitive with any part of the business of the Company for up to 3 years after termination of his executive service agreement.

The agreement may be terminated by the Company in certain circumstances or by agreement between the Company and Dr Sutton.

## Executive Service Agreement dated 7 July 2000 between Sirtex Medical and Dr Bruce Gray

Sirtex Medical has appointed Dr Bruce Gray as Medical Director reporting to the Board by way of an executive service agreement. The executive service agreement has a term of 5 years commencing on the date the Shares are quoted on the ASX unless terminated earlier in accordance with the agreement.

Dr Gray is a founder of the Company and has been instrumentally involved in the development of the technologies of the Company. Dr Gray will continue to develop and promote the technologies and conduct further medical research in connection with the technologies and other methods for treating patients with liver cancer

The Company will have property in any improvement in the technologies or a new invention or discovery made by Dr Gray during the term of his employment which relates to the business of the Company or is capable of being used by the Company.

Dr Gray has undertaken that he will not directly or indirectly carry on or otherwise be concerned with or interested in any business which is competitive with any part of the business of the Company as it relates to the development and exploitation of medical technology for up to 3 years after termination of his executive service agreement.

The initial remuneration package for Dr Gray will be \$150,000 per annum (inclusive of superannuation) and subject to review on an annual basis and increased at least in line with movements in the All Groups Consumer Price Index published by the Australian Bureau of Statistics. Dr Gray will be eligible to participate in the ESOP at the discretion of the Board.

The agreement may be terminated by the Company in certain circumstances or by agreement between the Company and Dr Gray.

## Executive Service Agreement dated 7 July 2000 between Sirtex Medical and Dr Steven Jones

Sirtex Medical has appointed Dr Steven Jones as Chief Scientist and Project Leader in relation to the hyperthermia technology. The executive service agreement has a term of 5 years commencing on the date the Shares are quoted on the ASX unless terminated earlier in accordance with the agreement.

Dr Jones has worked with the CRI and more recently with the Company in the development of the hyperthermia technology and he is a world expert in this area. Dr Jones will be employed with the Company on a full-time basis to conduct and lead ongoing medical research and further develop the hyperthermia technology [insert more detailed description of the position].

The Company will have property in any improvement in the technologies or a new invention or discovery made by Dr Jones during the term of his employment which relates to the business of the Company or is capable of being used by the Company.

Dr Jones has undertaken that he will not directly or indirectly carry on or otherwise be concerned with or interested in any business which is competitive with any part of the business of the Company as it relates to the development and exploitation of medical technology for up to 3 years after termination of his executive service agreement.

The initial remuneration package for Dr Jones will be \$79,400 per annum (inclusive of superannuation) and subject to review on an annual basis and increased at least in line with movements in the All Groups Consumer Price Index published by the Australian Bureau of Statistics. Dr Jones will be eligible to participate in the ESOP at the discretion of the Board.

The agreement may be terminated by the Company in certain circumstances or by agreement between the Company and Dr Jones.

## Manufacture and Supply Agreement dated 4 February 2000 between Sirtex Medical, Sirtex Medical Products Pty Ltd (a subsidiary of the Company) and the Australian Nuclear Science & Technology Organisation

The Company, Sirtex Medical Products Pty Ltd and the Australian Nuclear Science & Technology Organisation have entered into an agreement under which the Australian Nuclear Science & Technology Organisation (through its Australian Radioisotopes commercial division) has agreed to render radioactive, label, package and deliver the first generation SIR-Spheres® at the direction of Sirtex Medical Products Pty Ltd until 30 June 2000.

The Company has given consent for the Australian Nuclear Science & Technology Organisation to use its technology for this purpose (although each party is subject to obligations of confidentiality) but the Company will have all rights in respect of any new intellectual property relating to the first generation SIR-Spheres®.

Sirtex Medical Products Pty Ltd indemnifies the Australian Nuclear Science & Technology Organisation against all claims and proceedings brought or made by patients (or their dependents or medical practitioners) against it for personal injury (including death) to patients arising out of or related to the administration of the first generation SIR-Spheres®.

Sirtex Medical Products Pty Ltd may only distribute the first generation SIR-Spheres® to trained physicians and must ensure that the physicians and medical institutions administering the product have appropriate certification for the administration of radioactive materials. Sirtex Medical Products Pty Ltd must notify any person who takes possession of the products of the dangerous nature of the products and provide any warning and distribute to such persons any labelling or literature given by the Australian Nuclear Science & Technology Organisation.

The Australian Nuclear Science & Technology Organisation is the only organisation in Australia which has a nuclear reactor that can be used for the production of medical isotopes. If for any reason the Australian Nuclear Science & Technology Organisation is unable or unwilling to provide the manufacturing services as required or to the satisfaction of the Company and Sirtex Medical Products Pty Ltd, then it may take several months to find an alternative manufacturer overseas. In these circumstances, the Company does not expect that the manufacture by an alternative source would significantly impact on the price of or profit margins on the first generation SIR-Spheres®.

## R&D Start Grant Agreement dated 17 June 1998 between Sirtex Medical and the Industry Research and Development Board

The Company has entered into an agreement with the Industry Research and Development Board under which the board is to provide between 14 January 1998 and 30 June 2001 a total grant of up to \$950,000 to assist the Company with the development of the SIR-Spheres® and hyperthermia technologies. The Company acknowledges the financial assistance it has received under the grant up to the date of this prospectus (being \$840,839).

The money is provided on the basis that the Company will spend \$2,752,800 on the project and that the money provided under the grant must not exceed 50% of the total expenditure by the Company on the project. The agreement also specifies milestones. The remaining milestones to be achieved are the completion of testing of a human hyperthermia device on animals and completion of Phase I clinical trials in cancer patients, by 30 June 2001.

The Company is required to use its best endeavours to exploit the results of the SIR-Spheres® and hyperthermia technologies in a manner that will benefit the Australian economy to the satisfaction of the Industry Research and Development Board. The required exploitation is the manufacture in Australia, for sale in Australia and overseas, of the SIR-Spheres®, hyperthermia devices or particles or other products or services developed as a result of the project.

If in the reasonable opinion of the Industry Research and Development Board:

- the Company is not carrying out its obligations to exploit the results of the project to the satisfaction of the Industry Research and Development Board; or
- · one or more persons not resident in Australia takes control of the Company or its business,

the Industry Research and Development Board may require the Company to repay the grant to the Commonwealth together with interest from the time it received the grant payment to the date of repayment or the Industry Research and Development Board may licence an Australian party nominated by the Industry Research and Development Board to exploit the results (such licence may be up to 5 years in duration but must be on fair and reasonable commercial terms having regard to the intention that the results of the project will benefit the Australian economy, the amount of the grant paid to the Company and the total expenditure by the Company on the project). These provisions continue for 5 years after 30 June 2000. The interest rate on repayments is 7.95% per annum.

The Company must not assign or grant any right to the intellectual property in the project to any other person except with the prior written consent of the Industry Research and Development Board (which may not be unreasonably withheld). The Industry Research and Development Board may require repayment of the grant together with interest or payment of 50% of the monetary value of the benefits derived from any unauthorised dealings.

The Industry Research and Development Board may terminate the agreement if, among other things:

- a breach of the agreement (including failure to meet a milestone) has not been remedied by the Company within 14 days of notice being given to the Company;
- the Company breaches its obligations to exploit the results of the project, a representation or warranty in the agreement or its obligations under the Affirmative Action (Equal Employment Opportunity for Women) Act 1986:
- the Company ceases to carry on a project eligible for a grant;
- the Company sells or enters into negotiations to sell sufficient of its assets or resources so that, in the opinion of the Industry Research and Development Board, the Company is unable to fulfil its obligations; or
- the Company becomes insolvent or wound up or liquidation proceedings are commenced against the Company.

In circumstances of termination, the Industry Research and Development Board may require the Company to repay all or part of the grant with interest from the time the Company received the various payments to the date of repayment. If the Company does not pay the amount specified within the time specified, the Industry Research and Development Board may issue a notice to require the Company to assign the intellectual property in the project to the Commonwealth.

## Consents and Disclaimers of Responsibilities

Written consents to the issue of this Prospectus have been given and at the time of this Prospectus have not been withdrawn by the following parties:

Freehill Hollingdale & Page has given and before lodgement of this Prospectus, has not withdrawn its consent to be named as lawyers to the Offer in the form and context in which it is named. Freehill Hollingdale & Page specifically disclaims liability to any person in the event of any omission from or any misleading or deceptive statement in this Prospectus. While Freehill Hollingdale & Page has provided advice to the Directors and the Company in relation to the issue of this Prospectus and the conduct of due diligence enquiries by the Company, the Directors and others, Freehill Hollingdale & Page has not authorised or caused the issue of this Prospectus and takes no responsibility for any part of the Prospectus other than references to its name.

Deloitte Touche Tohmatsu has given and before lodgement of this Prospectus, has not withdrawn its consent to be named as auditors of the Company and the inclusion of extracts of the audited financial statements in Sections 3 and the Independent Accountant's Report in Section 8 in the form and context in which those statements are included. Deloitte Touche Tohmatsu specifically disclaims liability to any person in the event of any omission from or any misleading or deceptive statement included in this Prospectus other than Section 8. Deloitte Touche Tohmatsu has not authorised or caused the issue of this Prospectus and takes no responsibility for any part of the Prospectus other than the audited financial statements referred to in this Prospectus and the Independent Accountant's Report.

Wray & Associates has given and before lodgement of this Prospectus, has not withdrawn its consent to be named as patent attorneys of the Company and the inclusion of its report in Section 9 in the form and context in which it is included. Wray & Associates specifically disclaims liability to any person in the event of any omission from or any misleading or deceptive statement included in this Prospectus other than Section 9. Wray & Associates has not authorised or caused the issue of this Prospectus and takes no responsibility for any part of the Prospectus other than its report in Section 9.

Davies Collison Cave has given and before lodgement of this Prospectus, has not withdrawn its consent to be named as patent attorneys of the Company and the inclusion of its report in Section 9 in the form and context in which it is included. Davies Collison Cave specifically disclaims liability to any person in the event of any omission from or any misleading or deceptive statement included in this Prospectus other than Section 9. Davies Collison Cave has not authorised or caused the issue of this Prospectus and takes no responsibility for any part of the Prospectus other than its report in Section 9.

Registries Limited has given and before lodgement of this Prospectus has not withdrawn its consent to be named as the Share Registry of the Company in the form and context in which it is named. It has had no involvement in the preparation of any part of this Prospectus other than assisting in the design of the Application Form and recording its name as share registrar to the Company. Registries Limited specifically disclaims liability to any person in the event of any omission from or any misleading or deceptive statement in this Prospectus. It has not authorised or caused the issue of this Prospectus and takes no responsibility for any part of the prospectus other than the references to its name.

KTM Capital Pty Limited has given and before lodgement of this Prospectus has not withdrawn its consent to be named as Underwriter of the Issue in the form and context in which it is named. KTM Capital Pty Limited specifically disclaims liability to any person in the event of any omission from, or any misleading or deceptive statement in this Prospectus. It has not authorised or caused the issue of this Prospectus and takes no responsibility for any part of the Prospectus other than the references to its name.

## Expenses of the Offer

The Company will bear the expenses in connection with the Offer. The expenses which are known at the date of this Prospectus are as follows.

Accounting	\$18,000
Legal	\$230,000
Underwriting	\$742,500
Management	\$75,000
Experts Reports	\$4,560
Printing	\$70,000
Other	\$80,000
Total	\$1,220,060

The Company estimates that the total expenses of the Offer will not exceed \$1.3 million.

No form of payment of any kind will be made or agreed to be made to any expert or firm other than for cash.

## **Interests of Experts and Others**

Freehill Hollingdale & Page acted as legal adviser to Nomura/JAFCO Investment (Asia) Ltd in relation to the establishment of the Company, the acquisition of certain intellectual property from Professor Bruce Gray and the Cancer Research Institute Inc and the initial investment by NJI No. 2 Investment Fund in the Company in 1997. Freehill Hollingdale & Page were paid \$28,000 plus disbursements for their services.

Freehill Hollingdale & Page have acted as legal adviser to the Company in connection with the issue of this Prospectus and have or will be paid \$230,000 plus disbursements for their services up to the date of this Prospectus. Further amounts for subsequent services may be charged in accordance with their normal time-based charge out rates. The Company estimates that such further fees may be up to \$10,000.

Deloitte Touche Tohmatsu have acted as auditor of the Company and as Independent Accountant to the Offer and have or will be paid \$35,000 plus disbursements for their services up in the 2 years to the date of this Prospectus. Further amounts for subsequent services as auditor may be charged in accordance with their normal charge out rates.

Davies Collison Cave have acted as patent attorneys of the Company and have prepared a report contained in this Prospectus and have or will be paid \$2,500 plus disbursements for their services up to the date of this Prospectus. Further amounts for subsequent services may be charged in accordance with their normal time-based charge out rates. The Company estimates that such further fees may be up to \$1,000.

Wray & Associates have acted as patent attorneys of the Company and have prepared a report contained in this Prospectus and have or will be paid \$1,000 plus disbursements for their services up to the date of this Prospectus. Further amounts for subsequent services may be charged in accordance with their normal time-based charge out rates.

KTM Capital have acted as agents to a private placement of convertible notes in the Company to raise \$1.0 million. KTM Capital was paid a fee of \$50,000 in connection with the placement. KTM Capital is also entitled to receive fees and commissions under the Underwriting Agreement as described above.

### **Interests of Directors**

Directors are not required under the Constitution of the Company to hold any Shares in the Company.

Directors may apply for Shares under this Prospectus. As at the date of this Prospectus none of the Directors had determined whether or not to apply for Shares under this Prospectus.

Upon completion of the Offer, the Directors of the Company and their Associates will hold interests in the following securities of the Company if they do not apply for any further Shares under the Offer:

	Shares	<b>Options</b>
Dr Chris Roberts	_	151,000
Dr Bruce Gray	19,399,443	114,000
Dr Michael Panaccio	11,786,928*	114,000*
Dr Colin Sutton		1,131,000

\* Dr Panaccio does not hold these Shares or Options. The Shares are held by NJI No.2 Investment Fund and the Options are held by Nomura/JAFCO Investment (Asia) Ltd. Dr Panaccio is an employee of Nomura/JAFCO Investment (Asia) Ltd (which is the manager of NJI No.2 Investment Fund and is a board nominee of NJI No. 2 Investment Fund).

### Remuneration

Each director is entitled to such remuneration out of the funds of the company as the directors determine but the remuneration of non-executive directors may not exceed in aggregate in any financial year the amount fixed by the Company in general meeting for that purpose. As at the date of this Prospectus, the aggregate annual remuneration of the executives referred to in Section 6 is \$590,000 and the aggregate maximum annual amount of remuneration for non-executive directors is \$150,000. The remuneration

# Additional Information

of a director may be a fixed or stated sum or may be a share of a fixed sum. If a director incurs travelling or other expenses or performs extra services in connection with the affairs of the Company, they may be reimbursed for these expenses or services. The remuneration payable to a director must not include a commission on or percentage of profits or operating revenue.

# **Deeds of Indemnity**

The Company has entered into deeds of indemnity with each Director under which the Company:

- indemnifies each Director (in their capacity as an officer of the Company) to the full extent permitted by law for acts and omissions of the Director during the period that the Director was in office (although the indemnity is enforceable even after the Director has ceased to hold office);
- undertakes to provide and, to the extent permitted by law, pay the premium for appropriate directors
  and officers insurance to protect the Director from liability arising from acts or omissions which
  occurred during the period that the Director was in office (although the policy must be maintained
  for 7 years after the Director ceases to hold office); and
- gives each Director access to certain books and records of the Company which relate to the period that the Director was in office for the purpose of participating in legal or administrative proceedings after the Director ceases to hold office (but each Director is under obligations of confidentiality in respect of those documents).

# **Corporate Governance**

The Company policies regarding the terms and conditions for remuneration relating to the appointment and retirement of Board members are approved by the Board following professional advice. The remuneration and terms and conditions of employment for the Chief Executive Officer and other executive Directors and senior executives are also reviewed and approved by the Board after seeking professional advice.

The Board is the vehicle to facilitate the identification of significant areas of business risk, implement procedures to manage such risks and to develop policies regarding the establishment and maintenance of appropriate ethical standards. In relation to these matters, the Board specifically:

- ensures compliance in relation to legal, statutory and ethical matters;
- monitors the business environment;
- · identifies business risk areas;
- · identifies business opportunities; and
- monitors systems established to ensure prompt and appropriate responses to shareholder complaints and enquiries.

The Company does not presently have an audit committee. However, all members of the Board currently participate in matters affecting the auditing requirements of the Company.

# **Consent by Directors**

The Directors have consented to the lodgement and issue of this Prospectus.

Section

# Glossary of Terms and References

# Glossary of Terms and References

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

# **General Terms**

Term/Abbreviation Meaning

\$, A\$ Australian Dollars

Applicant A person who submits an Application

Application A valid application to subscribe for or acquire a specified number of

Shares under the Offer

Application Form The application form which is attached to and forms part of this

Prospectus in relation to the subscription or purchase of Shares

ASIC Australian Securities and Investment Commission
Associate An 'associate' as defined in the Corporations Law

ASX Australian Stock Exchange Limited

ASX Listing Rules or Listing Rules The official listing rules of ASX as amended from time to time

Board The board of Directors of the Company
CHESS Clearing House Electronic Subregister System

Closing Date The date on which the application list closes, being Friday 25 August

2000 unless the Directors, in conjunction with the Underwriter,

exercise their right to vary that date

Company or Sirtex Medical Sirtex Medical Limited

Directors Directors of Sirtex Medical Limited
EBIT Earnings before interest and tax

EBITDA Earnings before interest, tax, depreciation and amortisation
ESOP The Employee Share Option Plan of the Company described

in Section 10

Existing Securityholders Existing Securityholders means the persons who will hold Shares or

Prospectus) on completion of the issue of the Shares under this Prospectus and includes persons who do not hold Shares at the date of issue of this Prospectus but will acquire shares by transfer between shareholders or on conversion of existing convertible notes on

Options in the Company (other than the Shares offered under this

completion of the issue of the Shares under this Prospectus A year commencing on 1 July and ending on 30 June

Group Sirtex Medical Limited and all Subsidiaries

GST Goods and Services Tax

Issue of Shares pursuant to this Prospectus

Sirtex Medical or

Financial Year

the Company Sirtex Medical Limited (ACN 078 166 122)
Offer The offer of Shares under this Prospectus

Offer Price \$1.00 per Share

Offer Shares The Shares to be issued by the Company pursuant to this Prospectus

Option Option means an option to subscribe for and be issued

with a Share

Option Plan The Employee Share Option Plan of the Company described in Section 10

PE price earnings ratio

Prospectus This prospectus dated 17 July 2000 for the offer of 15 million Shares

in Sirtex Medical as modified by any supplementary prospectus made

by the Company and lodged with ASIC from time to time.

Ralph Report The Ralph Report on the Reform of the Australian Taxation System

release in October 1999.

Shares ordinary shares in the Company

Subsidiary A 'subsidiary' as defined in the Corporations Law

Underwriter or KTM Capital KTM Capital Pty Limited

# Glossary of Terms and References

# **Technical Terms**

Carcinoma A medical term for cancer

Chemotherapy The administration of anti cancer drugs to patients with cancer

Cryotherapy Treatment of cancer by freezing in order to destroy it

Doxorubicin An anti-cancer drug that is widely used in the treatment

of cancer patients

FDA Food and Drug Administration of the USA Department

of Health and Human Services

FUDR Floxuridine, a type of anti-cancer drug
Hepatic Artery The main artery supplying blood to the liver

Hyperthermia The treatment of cancer by raising the temperature of the cancer in

order to destroy it

Lipiodol An oily liquid that is used to mix with anti-cancer drugs and which

can be injected into the hepatic artery of patients with liver cancer in

order to concentrate the drug in the cancerous tissues

Metastases Secondary cancers that occur as a result of a cancer at another site

spreading to new tissues of the body

Phase I Trial A clinical experiment in which new therapies are tested predominantly

to determine their safety at different doses

Phase II Trial A clinical experiment in patients that assesses whether

a new treatment has a beneficial effect on the patient

Phase III Trial A clinical experiment in patients in which a new experimental

treatment is compared with what is regarded as 'standard practice'

SIRT Selective Internal Radiation Therapy is the medical procedure in which

SIR-Spheres® is administered to patients in order to treat their cancer

TGA Therapeutic Goods Administration of Australia

TACE Trans Arterial Chemo-Embolisation is the technique used to treat liver

cancer whereby an anti-cancer drug is mixed with lipiodol and

injected into the main artery supplying blood to the live

# References

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# Glossary of Terms and References

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# 12 Application Forms

# **Application Form**

Send to: Registries Limited

# SIRTEX MEDICAL LIMITED ACN 078 166 122

or P.O.Box R67

Firm Stamp

	Level 2, 28 Margaret Street Royal Exchange NSW 1223 Sydney NSW 2000
	Broker Code
Α	I/We apply for
	Shares at \$1.00 per Share
В	I/We lodge full application money
	This amount must equal the number of Shares applied for multiplied by the Offer Price.
C	Applicant 1
	Mr Mrs Ms Miss Given Name or Company Name Surname
	Applicant 2
	Mr Mrs Ms Miss Given Name or Company Name Surname
	Applicant 3
	Mr Mrs Ms Miss Given Name or Company Name Surname
D	Postal Address Number and Street
	Suburb/City or Town State Postcode
Ε	Chess HIN (If Applicable)
F	Area Code Home Telephone Work Telephone Contact Name
G	Tax File Number/Exemption Details
	Applicant 1 Applicant 2 Applicant 3
н	Cheque Details Please make cheque(s) payable to 'Sirtex Medical Limited Share Offer'
	Drawer Bank Branch
	\$ .00
	\$ .00
	Total \$ .00

Declaration

I/We declare that this application is completed according to the declaration/appropriate statements on the reverse of this form and agree to be bound by the Constitution of Sirtex Medical Limited. The return of this Application Form with your cheque(s) for the application monies will constitute your offer to subscribe for ordinary shares in the Company. No signature is required. You should read this Prospectus carefully before completing this Application Form.

# Further information for applications

### TREATMENT OF APPLICATION

The return of an Application Form with your cheque for the application money will constitute your offer to purchase or subscribe for Shares. If your Application Form is not completed correctly, or if the accompanying payment is the wrong amount, it may still be treated as valid.

The decision of the Company and the Underwriter as to whether to treat your Application as valid, and how to construct, amend or complete it, shall be final. The decision on the number of Shares to be allocated or transferred to you shall also be final. You will not, however be treated as having offered to purchase more Shares than is indicated on the Application Form.

Investors applying under the Offer whose applications are not accepted, or are accepted in respect of a lower number of Shares than the number applied for, will receive a refund of all or part of their application money without interest, as applicable.

### WHERE TO SEND YOUR COMPLETED APPLICATION FORM

The completed Application Form should be sent to Registries Limited at Level 2, 28 Margaret Street, Sydney NSW 2000.

### **CORRECT FORMS OF REGISTRABLE NAMES**

Note that ONLY legal entities are allowed to hold Shares. Applications must be in the name(s) of natural persons, companies or other entities acceptable to the Company and the Underwriter. At least one full given name and the surname is required for each natural person. The name of the beneficiary or any other non-registrable name may be included by way of an account designation if completed exactly as described in the examples of correct forms below.

Type of Investor	Correct Form	Examples of Incorrect Form
Individuals	William John Smith	
Give full name – not initials		W.J.Smith
Persons under the age of 18	Peter Robert Jones	
Do not use the name of a minor.	Jenifer Margaret Jones	
use name(s) of parents(s)/guardian(s)	(Michael Jones A/C)	Michael Jones
Companies		P.Johnson Co.
Use company title, not abbreviations	Paul Johnson Pty Ltd.	Paul Johnson P/L
Trusts		
Do not use the name of the trust,	William John Smith	William Smith Family Trust
use trustee(s) personal name(s)	(Smith Family A/C)	
Deceased Estates		
Do not use the name of deceased,	Rosemary Jane Murray	Estate of late Colin Walker
use name(s) of the trustee(s)	(Est Colin Walker A/C)	
Partnerships	Sally Jane Jones	Sally Jones & Son
Do not use the name of the partnership,	David Ashley Jones	
use personal name of partner	(Sally Jones & Son A/C)	
Clubs/unincorporated bodies		
Do not use the name of clubs etc,	William John Smith	Weekend Anglers' Association
use personal names of office bearer(s)	(Weekend Anglers' Association A/C)	
Superannuation Funds		
Do not use the name of the fund,	Madeleine Kelly Pty Ltd	Madeleine Kelly
use name(s) of trustee(s)	(Super Fund A/C)	Pty Ltd Superannuation Fund

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or P.O.Box R67

Firm Stamp

	Level 2, 28 Margaret Street Royal Exchange NSW 1223 Sydney NSW 2000
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	Shares at \$1.00 per Share
В	I/We lodge full application money
	This amount must equal the number of Shares applied for multiplied by the Offer Price.
C	Applicant 1
	Mr Mrs Ms Miss Given Name or Company Name Surname
	Applicant 2
	Mr Mrs Ms Miss Given Name or Company Name Surname
	Applicant 3
	Mr Mrs Ms Miss Given Name or Company Name Surname
D	Postal Address Number and Street
	Suburb/City or Town State Postcode
Ε	Chess HIN (If Applicable)
F	Area Code Home Telephone Work Telephone Contact Name
G	Tax File Number/Exemption Details
	Applicant 1 Applicant 2 Applicant 3
н	Cheque Details Please make cheque(s) payable to 'Sirtex Medical Limited Share Offer'
	Drawer Bank Branch
	\$ .00
	\$ .00
	Total \$ .00

Declaration

I/We declare that this application is completed according to the declaration/appropriate statements on the reverse of this form and agree to be bound by the Constitution of Sirtex Medical Limited. The return of this Application Form with your cheque(s) for the application monies will constitute your offer to subscribe for ordinary shares in the Company. No signature is required. You should read this Prospectus carefully before completing this Application Form.

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Give full name – not initials		W.J.Smith
Persons under the age of 18	Peter Robert Jones	
Do not use the name of a minor.	Jenifer Margaret Jones	
use name(s) of parents(s)/guardian(s)	(Michael Jones A/C)	Michael Jones
Companies		P.Johnson Co.
Use company title, not abbreviations	Paul Johnson Pty Ltd.	Paul Johnson P/L
Trusts		
Do not use the name of the trust,	William John Smith	William Smith Family Trust
use trustee(s) personal name(s)	(Smith Family A/C)	
Deceased Estates		
Do not use the name of deceased,	Rosemary Jane Murray	Estate of late Colin Walker
use name(s) of the trustee(s)	(Est Colin Walker A/C)	
Partnerships	Sally Jane Jones	Sally Jones & Son
Do not use the name of the partnership,	David Ashley Jones	
use personal name of partner	(Sally Jones & Son A/C)	
Clubs/unincorporated bodies		
Do not use the name of clubs etc,	William John Smith	Weekend Anglers' Association
use personal names of office bearer(s)	(Weekend Anglers' Association A/C)	
Superannuation Funds		
Do not use the name of the fund,	Madeleine Kelly Pty Ltd	Madeleine Kelly
use name(s) of trustee(s)	(Super Fund A/C)	Pty Ltd Superannuation Fund

### **Head Office**

125 Burswood Road Victoria Park East WA 6101

# **Board of Directors**

Dr Chris Roberts

(Non-Executive Chairman)

Dr Michael Panaccio

(Non-Executive Director)

Dr Bruce Gray

(Medical Director)

Dr Colin Sutton

(Chief Executive Officer)

# Section

# 2 Corporate Directory

# **Solicitors**

Freehill Hollingdale and Page Level 48 101 Collins Street Melbourne VIC 3000

# **Auditors and Independent Accountants**

Deloitte Touche Tohmatsu Central Park, Level 16 152-158 St Georges Terrace Perth WA 6001

# **Underwriter and Financial Advisor**

KTM Capital Pty Limited Level 2 16 O'Connell Street Sydney NSW 2000

# Brokers to the Issue

Austock Brokers Pty Limited Level 1 350 Collins Street Melbourne VIC 3000

# **Share Registry**

Registries Limited Level 2 28 Margaret Street Sydney NSW 2000 SIRTEX
MEDICAL
LIMITED

Prospectus