	Starpharma ann	ual report 2001

Starpharma: targeting the prevention and treatment of major human diseases using dendrimers...

[Dendrimers are synthetic nanoscale molecules that have precise, defined structures and properties]

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Dear Shareholder,

Over the past twelve months, Starpharma Pooled Development Limited ("the company") group of companies has developed key in-house capabilities required for drug discovery, design, development and commercialisation. Starpharma has a true platform technology and is focused on commercial drug development arising from its research program.

The major milestones outlined in the prospectus issued in September 2000 are being achieved. The company has continued to attract strong interest and funding support for its development projects. As a result of the successful fund raising and subsequent listing on the Australian Stock Exchange in October 2000, the company has a strong cash position.

Significant achievements in the past financial year have been:

- the granting in the U.S. of the broad-based antiviral dendrimer patent;
- successful preclinical development of Starpharma's lead compound to target prevention of sexually transmitted diseases;
- ongoing research success in a wide range of disease applications for dendrimer compounds; and
- the continued expansion of Starpharma's intellectual property.

A more recent achievement was the establishment of Dendritic Nanotechnologies Limited as another company in the Pooled Development Fund structure, and the association of Donald A. Tomalia, Ph.D., the founder of dendrimer chemistry and his team with Starpharma.

The last twelve months have also seen changing sentiment worldwide towards biotechnology stocks. The Board and management of Starpharma believe we are well placed to create shareholder value resulting from our combined focus on product development and maintaining our current dominant intellectual property position relating to dendrimer-based drugs.

I look forward to an exciting future as Starpharma becomes progressively recognised as a focused drug development company with world leading technology.

I thank you for your support as a shareholder.

Richard Oliver AM Chairman

CEO's Report

When Starpharma was established, a key asset was a licence from the Biomolecular Research Institute to commercialise technology in an area described as the use of dendrimers to develop drugs targeting major diseases. Many in the scientific and pharmaceutical communities regarded the area as being of novelty interest. Subsequently there has been a major shift in attention with more dendrimer publications in the last twelve months than in the previous 10 years combined. In the past year, significant changes also occurred at Starpharma. The company has established a team with expertise in key disciplines of commercial drug discovery and development.

Establishment of an In-House Drug Discovery Team

Starpharma has employed a team of scientists including the inventors of Starpharma's original technology, Dr Barry Matthews and Dr George Holan. The team has a with a chemistry focus but with multidisciplinary skills, a critical factor contributing to their success. The team focuses on the development of synthetic structures, called dendrimers. Dendrimers are precise nanoscale molecules, and are significantly larger than traditional synthetic drugs. Starpharma's expertise and intellectual property position in pharmaceutical applications of dendrimers is internationally competitive. Starpharma's dendrimer chemistry capabilities were recently enhanced by the establishment of Dendritic Nanotechnologies Limited and the engagement of Donald A. Tomalia, Ph.D., an international pioneer of dendrimer technology, and his team.

Focused Product Development Expertise

Compounds from Starpharma's drug discovery program are evaluated in disease models by a broadly based group of international collaborators, who are excited by the compounds' activity against a wide range of diseases. New drug candidates must satisfy strict preclinical safety and efficacy testing criteria. Starpharma has established a preclinical development team focused on developing lead drug candidates, and gaining approval from the U.S. regulatory authority for testing in humans. There is limited expertise in preclinical development in Australia making it necessary to assemble a team of international consultants and contractors. This team is coordinated by our Preclinical Development Manager, Tom McCarthy, Ph.D. Starpharma's lead drug candidates, a vaginal microbicide for prevention of sexually transmitted diseases and a topical treatment for genital herpes, represent significant commercial opportunity. Starpharma plans to submit an Investigational New Drug (IND) application for its microbicide product to the U.S. Food and Drug Administration in late 2001. Approval of this application would allow the first synthetic nanoscale drug to be tested in humans.

Establishment of a Commercial Management Infrastructure

The broad strategy of the Starpharma group is to discover new drug opportunities, protect intellectual property and add value to products by developing them to the point where new drugs demonstrate efficacy in humans, before licensing to major pharmaceutical companies





Photo above: The new home of Starpharma, the Baker Medical Research Institue in Prahran, Melbourne. with the resources for later stage development, manufacturing and marketing. This business model is well established in the U.S. and Europe and allows Starpharma to maximise value with minimum resource input. The Starpharma commercial management team, headed by Tim Grogan, has the expertise to effectively manage agreements with collaborators, product licensing and major commercial alliances, winning respect with the successful establishment of Dendritic Nanotechnologies Ltd, an Australian entity which will employ a world-renowned research group.

The Future

In December, Starpharma's team will come together at one site as the first commercial tenant of the new Baker Medical Research Institute in Melbourne. The challenge ahead is to grow the company in order to fully exploit a unique intellectual property position, and the wide range of opportunities arising from our core competency in developing drugs based on dendrimer nanotechnologies. Starpharma will remain focused on the goals described above, and has the people with the expertise necessary to be successful.

Jul 2 Sife John Raff, Ph.D.

CEO

Lead products target STDs

Targeting Major Diseases and Health Issues for Humans

Starpharma's business philosophy is product-focused and has an applied emphasis that targets major human diseases and health issues. As Starpharma grows, the necessary capabilities are being developed within the company to provide for rapid product development and release. Starpharma has been structured to participate in all stages of product development and to manage aspects of licensing with commercial partners or registration with regulatory bodies, with the aim of bringing the benefits of Starpharma's novel drugs to those in need.

A Range of Major Disease Targets

Starpharma's priority disease targets are:

- Sexually transmitted diseases such as HIV, hepatitis B, herpes, genital warts
- Cancer (tumour-related)
- Toxin-related illnesses such as cholera

Starpharma's dendrimer compounds have also shown activity against respiratory illnesses such as influenza and respiratory syncytial virus, exotic viruses such as Ebola and Dengue, and other diseases including malaria.

The Lead Product

Starpharma's lead product in development, SPL7013, is a vaginal microbicide product for the prevention of the transmission of major STDs such as HIV, genital herpes, genital warts, hepatitis B and chlamydia. Preclinical development and testing of the drug is progressing well, with human trials of the product planned for 2002. Another product, also based on SPL7013, is being developed as a topical treatment for genital herpes outbreaks in already infected people. Importantly, recent animal trials of the product for this indication showed positive results, with SPL7013 significantly reducing the severity of sores and swelling caused when mice were infected with herpes simplex virus.



- Angiogenesis inhibition Hepatitis B
- Anti-Toxins
 Bacterial Entero-toxins
- Venoms Exotic Viruses Ebola
- Dengue SexuallyTransmitted Diseases HIV Herpes Simplex Virus Genital Warts (Human papilloma Virus) Chlamvdia

Page 5:

- 1+2 HIV attacks a T-cell.
- 3 HIV infection of a T-cell begins with attachment of a protein on the surface of the virus, gp120, to CD4 receptors on the T-cell.
- 4 Starpharma's dendrimers may prevent HIV infection by preventing binding of viral gp120 proteins to the CD4 receptors on the cell, thus preventing viral attachment and entry into the cell.



Lead Product: Mechanism of Starpharma's compound SPL7013 preventing HIV infection.

Developing Drug Solutions for people

Market Potential for STD Microbicide Therapies

A recent bill introduced into the U.S. Congress, entitled the Microbicide Development Act of 2001, highlighted that in 2002, approximately 15.4 million people in the U.S. will acquire a new STD. Importantly, the risk of acquiring HIV is significantly increased in those with existing STDs. Globally, 36.1 million people live with HIV while another 15,000 new infections occur daily, and more than 26 million people have died from AIDS since it was first detected in 1983. Each year, the estimated direct medical costs of STDs in the U.S. amount to some \$8.4 billion, while indirectly STDs cost the general community in the U.S. alone some \$20 billion. The microbicide bill specifically identifies microbicidal products as a promising new approach, which would kill, or render inactive, STDs including HIV. Starpharma is focused on the development of a broad spectrum vaginal microbicide product to prevent the transmission of STDs such as HIV, herpes and hepatitis B. In the U.S., it is estimated that some 21 million women would be interested in using a microbicidal product, but there is currently no effective microbicide on the market. Therefore, there exists a large potential for novel products such as Starpharma's vaginal microbicide, which is planned to enter trials in humans in 2002, to be a market leader in this area.

Investigational New Drug Application

An investigational new drug (IND) application is planned to be submitted to the U.S. Food and Drug Administration (FDA) later this year. This IND will describe the safety and efficacy profile of the vaginal microbicide product as demonstrated by *in vitro* and animal studies. The approval of the IND application by the FDA is an important milestone in the product development process as it allows for the commencement of Phase 1 clinical trials in humans, to establish the safety and efficacy of the product.

Ongoing liaison with the FDA throughout the drug development process, including during clinical trials, will facilitate successful licensing or registration of a product. The evolving Regulatory Affairs roles and responsibilities within the company will also be of great benefit to Starpharma's product development prospects.

Research and Development Team - Skills and Expertise

Starpharma significantly expanded its research and development team in 2000-2001 to include scientists with significant expertise in the areas of synthetic chemistry, analytical chemistry and pharmacology/toxicology. Many of the synthetic chemists who joined Starpharma this year were previously employed by the Biomolecular Research Institute (BRI) and worked on specific projects for Starpharma. Starpharma's core technical competency is in synthetic chemistry, which allows for the design and synthesis of novel dendrimer compounds with specific biological activity. The research team has been, and



Global Research Network

The Americas Vancouver, Canada Viridae Clinical Sciences Inc. Project: Vaginal Microbicide, Hepatitis B. Antitoxins, Exotic Viruses, Consultant ค Ohio, USA University Medical Centre Project: Vaginal Microbicide Viridae USA Project: Vaginal Microbicide Utah. USA University of Utah Virology Laboratory Project: Respiratory Viruses, Exotic Viruses Pennsvlvania. USA Fox Chase Institute for Cancer Research Project: Hepatitis B/Liver Cancer a Texas, USA Baylor University Medical College Project: Respiratory Viruses 6 Alabama, USA University of Alabama Project: Vaginal Microbicide, CMV ด Maryland, USA NIAID-NIH Project: Administration of US Funds Georgetown University Project: Hepatitis B/Liver Cancer,

US Army Medical Research Institute Project: Exotic Viruses, Antitoxins (3) New York, USA Cornell University Project: Hepatitis B/Liver Cancer

Vaginal Microbicide

continues to be, the foundation of Starpharma's success in creating new intellectual property, in developing and analysing lead compounds for effective disease targeting, and in managing preclinical development of products.

Earlier this year, Starpharma was notified by the U.S. Patent Office that the patent, "Antiviral Dendrimers" was issued as U.S. Patent Number 6,190,650. This patent provides Starpharma with broad patent protection related to the antiviral applications of dendrimer nanotechnologies, such as prevention of sexually transmitted diseases, and other applications. The activities of Starpharma's R&D team in increasing patent coverage led to a further three patent applications being filed in the period from July 1, 2000 to June 30, 2001, and another one in the period after July 1, 2001.

Starpharma employees are encouraged to develop multidisciplinary skills, which strengthen and diversify the research and development team, optimise the use of resources, and help to minimise the time from discovery to product registration or licensing.

In addition to its Australian-based R&D team, Starpharma maintains an extensive global research network which consists of world leaders in fields including HIV/AIDS, hepatitis B, respiratory syncytial virus, influenza and other major diseases.



Dendrimers, Nanotechnology and Starpharma's Leading Position

Starpharma has discovered a large number of dendrimer compounds that have demonstrated efficacy against a range of major diseases. Starpharma's lead vaginal microbicide compound is expected to be the first dendrimer, and perhaps more significantly, the first synthetic nanosized structure, to be used in pharmaceutical products for human use.

Dendrimers are precisely controlled, highly branched, nano-sized materials that provide a platform for the development of products in a wide range of commercial applications, from life sciences to the electronics and materials industries. As opposed to miniaturization of large objects or devices, the synthetic chemistry techniques employed by Starpharma allow for precise, piece by piece construction of nanotech objects in the range of 1 to 100 nanometres in size (1 billionth to 100 billionths of a meter, or around 50,000 times smaller than the thickness of a human hair). While other materials such as natural proteins and polymers exist in the nanoscale size range, no material compares with dendrimers for the level of control over size, shape and functionality of the final compound. As a result, dendrimer-based pharmaceuticals are reproducible, predictable and defined, and can be precisely constructed to specifically target certain diseases, cells or whole organs within the human body.

Nanotechnology is emerging as an exciting new frontier in science. The U.S., Japanese and South Korean governments, for example, recognise nanotechnology as being of major national importance and have made large commitments to nanotechnology development programs. The U.S. federal government, through its National Nanotechnology Initiative, has allocated more than half a billion U.S. dollars in 2001 alone to research projects across various government departments, including the U.S. National Institutes of Health (NIH).

Starpharma's preclinical and early-stage development projects benefit from NIH funding through grants to support U.S. based studies on our compounds, and the company is positioned to participate in the increased U.S. government investment in nanotechnology. Dendrimers were identified in the U.S. National Nanotechnology Initiative as an attractive foundation for nanomedicine products.

Dendrimers as pharmaceuticals are much larger than conventional drug molecules and employ the principle of polyvalent, or multiple receptor-site, binding. Polyvalent interactions are common in many natural biological interactions, including virus-cell interactions within the human body. Through polyvalent interactions with receptors or binding sites, dendrimers may be designed to achieve higher activity than small-molecule drugs. In addition, dendrimers may be constructed and modified to have longer duration of action, reduced side effects and other beneficial effects compared with currently available pharmaceuticals.

Starpharma's work with dendrimers represents the leading edge of global research and development of the biological application of nanotechnology.





Photo 1,2,3: Dendrimers are capable of multiple interactions with cells.

Photo 4: Monovalent binding of a traditional drug to a cell receptor.



Starpharma has a world leading position in the design, development, application and commercialisation of dendrimer based drugs

International Commercial Relationships and Opportunities

Dendritic Nanotechnologies Limited - Major Commercial Development Opportunities

Starpharma recently announced that it is to enter into a venture with the pioneer of dendrimer technology, Donald A. Tomalia, Ph.D., to develop dendrimers as products for life science and other applications. Under the proposed venture, Starpharma Pooled Development Limited (PDL) will invest up to U.S.\$2.18 million over the next three years in Dendritic Nanotechnologies Ltd, a new Australian company, with its head office in Melbourne, Australia, and a branch office and laboratory facilities at Central Michigan University in Mount Pleasant, Michigan, U.S.A. This venture will bring together two of the most advanced groups in dendrimer research and development, and will create important new opportunities with other business partners for commercialising dendrimer products with unique properties.

For shareholders, this venture represents several major benefits to Starpharma as it:

- links Starpharma to the latest advances in leading edge dendrimer technology;
- is consistent with Starpharma's objective of increasing its U.S. presence;
- provides for synergistic research benefits and the exchange of new intellectual property between the two groups, in pharmaceutical and other fields of application;
- provides new drug development opportunities based on novel dendrimer structures.

Starpharma PDL is a Pooled Development Fund structure that, as well as investing in external opportunities, invests in the companies Starpharma Ltd, Angiostar Ltd and Viralstar Ltd. Dendritic Nanotechnologies Ltd represents the fourth entity under the Pooled Development Fund structure.

Profiles

Tim Grogan (*LLB*, *B.Sc.*) Manager, Commercial Development and Intellectual Property Tim plays a crucial role in managing, developing and protecting Starpharma's intellectual property portfolio consistent with strategic corporate and product development objectives, and he is overseeing the implementation of quality assurance systems. Tim is also involved in establishing major collaborations and alliances and recently initiated the formation of the venture with Donald A. Tomalia, Ph.D., which lead to the establishment of Dendritic Nanotechnologies Ltd.

Tom McCarthy Ph.D. Preclinical Development Manager

Tom exemplifies the encouragement by Starpharma management of a multidisciplinary approach to drug development. Tom is a synthetic chemist who is currently overseeing the preclinical development of the vaginal microbicide product. This program includes in vitro and animal safety and efficacy studies on our compound, which are being carried out at centres across the U.S., and the filing of the IND application for the commencement of human clinical trials. Successful management of this program requires a sound understanding of both chemical and biological science, as well as regulatory processes.







Above: Donald A. Tomalia, Ph.D. explains dendrimer chemistry to the press at the official launch of Dendritic Nanotechnologies Limited at Central Michigan University, U.S.A.

Centre: The CEO of Starpharma, John Raff, Ph.D., with Donald A. Tomalia, Ph.D., and the President of Central Michigan University, Michael Rao, Ph.D.

Bottom: Barry Matthews, Ph.D., Starpharma's Director of Research and David Lombard-Harrison, Assistant General Counsel, Central Michigan University, at the press conference.



Left to Right: Prof Peter Colman, Dr Peter Jenkins, Ben Rogers, David O'Keefe, Dr Sue Pallich, Dr John Raff, Dr George Holan, Chris Virgona, Dr Scott Henderson, Suzie Parker-Scott, Peter Karellas, Tim Grogan, Dr Greg Raymond, Dr Jeremy Paull, Lisa Stewart, Richard Oliver, Ross Dobinson, Maria Felsinger, Dr Tom McCarthy, Michael Giannis, Dr Romina Di Florio and Dr Belinda Braggs.

Growing Preclinical Development Capabilities

One of the most important aspects of drug development after the discovery phase is the evaluation of the safety and efficacy of the drug in a series of rigorous laboratory tests and analyses prior to exposure of humans to the drug in clinical trials (preclinical development). Presently, external contractors, based in the U.S., Canada and Australia, conduct much of Starpharma's preclinical drug development and their activities are co-ordinated by Starpharma's Preclinical Development Manager, Tom McCarthy, Ph.D. (see profile). In addition to external activities, Starpharma is developing a GLP standard analytical laboratory, as well as systems such as quality assurance and regulatory affairs to assist in the planning and management of preclinical research activities carried out by contractors and collaborators. Therefore, Starpharma is developing the in-house expertise to deal with the many procedural, quality and regulatory issues faced by pharmaceutical companies during the preclinical stages of drug development.

A Quality Assurance System to Add Value to Products

In an initiative to enhance preclinical development and the management of product development risk, Starpharma is investing significant effort in the implementation of quality systems infrastructure to achieve successful compliance with the requirements of various regulatory bodies including the U.S. FDA. The quality system aims to meet product regulatory requirements to ensure the successful transition of drugs from the discovery stage through to preclinical development, clinical trials, registration and marketing.

Recently, Starpharma retained a pharmaceutical systems consultant to assist in defining the scope and aims of the Starpharma Quality Assurance (QA) Systems. Processes are underway to implement the QA systems throughout the company, beginning with the training of employees and the set-up of company policies, guidelines and procedures documentation. The QA system will encompass all of Starpharma's internal activities, as well as external activities with contractors and consultants, with the aim of increasing productivity and protecting against business risks.



Dendrimers are large compared with traditional drugs, but the nanoscale is small compared to other objects such as the HIV virus, bacteria, red blood cells and human hair.

Shareholder Information

A. Distribution of equity shareholders

Analysis of numbers of equity security holders by size of holding:

	Class of equity security		
	Ordinary shares		
	Shares	Options	
1 - 1,000	55	-	
1,001 - 5,000	551	-	
5,001 - 10,000	486	-	
10,001 - 100,000	666	11	
100,001 and over	100	7	
	1,858	18	

There were 19 holders of less than a marketable parcel of ordinary shares.

B. Equity security holders

Twenty largest security holders

The names of the twenty largest holders of equity securities in a class which is quoted are listed below:

	Ordinary shares		
Name	Number held	Percentage of issued shares	
Peter Malcolm Colman	5,982,482	6.73	
Arran Bay Pty Ltd	4,357,600	4.90	
Gilridge Pty Ltd	4,000,000	4.50	
John William Raff	3,602,581	4.05	
Espasia Pty Ltd	3,505,289	3.94	
Davambros Pty Ltd <the a="" c="" davambros=""></the>	2,470,250	2.78	
UBS Warburg Private Clients Nominees Pty Ltd	2,240,350	2.52	
Ruth Raie Holan	2,051,045	2.31	
Barry Matthews	2,019,045	2.27	
National Nominees Ltd	1,451,469	1.63	
HSBC Custody Nominees (Australia) Limited	1,439,689	1.62	
Natalie Jane Le Sueur	1,200,000	1.35	
Mr Hugo Frijlink	1,095,069	1.23	
Applecross Secretarial Services Pty Ltd <l a="" c="" family="" gorr=""></l>	1,077,000	1.21	
Dapali Pty Ltd	1,070,000	1.20	
Jagen Pty Ltd	1,000,000	1.12	
Sheila Gail Jenkins	880,000	0.99	
Westpac Custodian Nominees Ltd	833,751	0.94	
APV Nominees Pty Ltd	800,000	0.90	
Equity Trustees Limited <jm a="" asset="" c="" management=""></jm>	759,267	0.85	
	41,834,887	47.04	

Unquoted equity securities

	Number on issue	Number of holders
Restricted shares The restriction on these shares will cease on 28 September 2002.	33,834,942	26
Options issued under the Starpharma Pooled Development Limited	00,001,012	20
Executive and Employee Share Option Plan (ASX code SPLAK)	2,360,000	7
Options issued under the Starpharma Pooled Development Limited Employee Share Option Plan (ASX code SPLAM)	300,000	11

C. Substantial holders

Substantial holders in the company are set out below:

	Percentage
5,982,482	6.73
4,705,289	5.29
5,872,100	6.61
4,512,000	5.08
	4,705,289 5,872,100

D. Voting Rights

The voting rights attached to each class of equity securities are set out below:

(a) Ordinary shares

On a show of hands every member present at a meeting in person or by proxy shall have one vote and on a poll each share shall have one vote.

(b) Options

No voting rights.

Financial Statements:

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Company Particulars

Directors	R J D Oliver AM (Chairman) P M Colman BSc (Hons), PhD, FAA, FTSE R Dobinson B Bus (Acc) P J Jenkins MB, BS (Melb), FRACP L Gorr B Juris, LLB, M.Admin J W Raff Dip Ag Sc, BSc, PhD
Chief Executive Officer	J W Raff Dip Ag Sc, BSc, PhD
Secretary	B P Rogers
Registered Office	343 Royal Parade Parkville Victoria 3052 Australia Telephone 61 3 9662 7123 Facsimile 61 3 9662 7129
Notice of annual general meeting	The annual general meeting of Starpharma Pooled Development Limited will be held at: ASX Theatrette (530 Collins Street, Melbourne) Time: 4:00pm Date: Thursday 15 November 2001
Share Register	Computershare Registry Services Pty Ltd Level 12 565 Bourke Street Melbourne Victoria 3000 Australia Telephone: 03 9615 5970 Facsimile: 03 9611 5710
Stock exchange listing	Starpharma Pooled Development Limited's shares are listed on the Australian Stock Exchange (ASX) Level 3, 530 Collins Street Melbourne Victoria 3000 Australia ASX Code: SPL
Auditor	PricewaterhouseCoopers 333 Collins Street Melbourne Victoria 3000 Australia
Solicitors	Blake Dawson Waldron Level 39, 101 Collins Street Melbourne Victoria 3000 Australia
Bankers	Commonwealth Bank of Australia
Website	www.starpharma.com

Directors' Report

Your directors present their report on the consolidated accounts of Starpharma Pooled Development Limited and the entities it controlled at the end of, or during, the year ended 30 June 2001.

Directors

The following persons were directors of Starpharma Pooled Development Limited during the whole of the financial year and up to the date of this report:

R J D Oliver (Chairman) P M Colman R Dobinson L Gorr P J Jenkins J W Raff

Principal activities

During the year the principal activity of the consolidated entity constituted by Starpharma Pooled Development Limited and the entities it controlled consisted of management and funding of pharmaceutical research and development. There were no significant changes in the nature of those activities during the financial year.

Review of operations and consolidated results

Operating Loss

For the year ended 30 June 2001 the consolidated entity incurred an operating loss after income tax of \$3,906,427. Expenditure on direct research activities was \$4,004,525.

Research and Development Programs

The consolidated entity's research and development activities are managed by the controlled entity Starpharma Limited. Activities are directed towards the development of compounds as preventatives or treatments for a range of human diseases and conditions, using technology based on synthetic structures called dendrimers. The priority disease targets are:

- Sexually transmitted diseases such as HIV, hepatitis B, herpes, genital warts;
- Cancer (tumour-related);
- Toxin-related illnesses such as cholera.

During the year Starpharma Limited selected one of its compounds known as SPL7013 for development as a vaginal microbicide product for the prevention of the transmission of major sexually transmitted diseases. Preclinical development and testing of SPL7013 is progressing and human trials of the product are planned for the 2002 calendar year. Another product, also based on SPL7013, is being developed as a topical treatment for genital herpes outbreaks in already infected people.

Intellectual Property

Starpharma Limited received notification from the US Patent Office that the patent "Antiviral Dendrimers" was issued as US Patent No. 6,190,650 on 20 February 2001. This patent provides Starpharma with broad patent protection related to the antiviral applications of dendrimer nanotechnologies, such as prevention of sexually transmitted diseases, and other applications. The activities of Starpharma's R&D team in increasing patent coverage led to a further three patent applications being filed in the period from 1 July 2000 to 30 June 2001.

Capital Raising and ASX Listing

The company issued a Prospectus on 18 August 2000 for the issue of 26,400,000 shares including up to 2,400,000 by oversubscriptions at the issue price of \$0.85 per share. The offer raised \$22.4 million including \$2 million in

oversubscriptions. The company was admitted to the official list of the Australian Stock Exchange Limited and quotation of its shares commenced on 28th September 2000. The company's shares previously traded on an exempt stock market operated by Austock Management Limited, and this market was terminated on 27th September 2000.

Staff

Starpharma Limited has employed a team of scientists with a chemistry focus but with multidisciplinary skills. Staff have also been recruited to form a preclinical development team to take lead drug candidates through the testing and regulatory processes necessary to gain approval to commence trials in humans. At the date of this report a total of twenty staff were employed by Starpharma Limited.

Employee Share Option Plan

At the Annual General Meeting held on 16th November 2000 members approved the introduction of a new Starpharma Employee Share Option Plan, which was drafted to take into account recent amendments to the Corporations Law and the ASX Listing Rules. At the date of this report 300,000 share options had been issued under this plan.

Dividends

No dividend has been paid or declared since the end of the previous financial year, and the directors do not recommend the declaration of a dividend.

Significant changes in the state of affairs

Significant changes in the state of affairs of the consolidated entity during the financial year were as follows:

An increase in share capital from \$12,279,472 to \$33,034,058 as a result of:

	2001
	\$
Issue of 26,400,000 fully paid ordinary shares at \$0.85 each:	22,440,000
Less: Issue costs	(1,685,414)
Net increase in share capital:	20,754,586

In the opinion of the directors there were no other significant changes in the state of affairs of the consolidated entity that occurred during the financial year under review not otherwise disclosed in this report or in the financial statements.

Matters subsequent to the end of the financial year

On 6 August 2001, Starpharma Pooled Development Ltd entered into an agreement with Dr Donald A. Tomalia, to establish a new venture to develop products using dendrimer nanotechnology. Under the proposed venture Starpharma intends to invest up to US\$2.18 million over the next three years in Dendritic Nanotechnologies Limited, a new Australian company which will have its head office in Melbourne and a branch office and laboratory at Central Michigan University, Michigan USA. Dr Tomalia's team of experienced dendritic polymer scientists will be employed by the new company.

Except for the venture discussed above, no other matter or circumstance has arisen since 30 June 2001 that has significantly affected, or may significantly affect:

(a) the consolidated entity's operations in future financial years, or

(b) the results of the operations in future financial years, or

(c) the consolidated entity's state of affairs in future financial years.

Likely developments and expected results of operations

In the opinion of the Directors, the consolidated entity will continue its activities as described. Further information on likely developments in the operations of the consolidated entity and the expected results of operations have not been included in this report because the directors believe it would be likely to result in unreasonable prejudice to the consolidated entity.

Information on Directors

Director	Experience	Special Responsibilities	Particulars of directors' interests in shares and options		
			Shares	Options	
RJD Oliver AM	Non-executive director for 4 years Former Executive Chairman, Willis Corroon International Pty Ltd, and Willis Corroon Richard Oliver Pty Ltd, a global risk management consulting group that he had established in 1972.	Non-executive Chairman. Chairman of Remuneration Committee	4,713,000	360,000	
PM Colman BSc(Hons), PhD FAA, FTSE	Non-executive director for 4 years. Head, Structural Biology Division, The Walter & Eliza Hall Institute of Medical Research. Former Executive Director, Biomolecular Research Institute. Published widely in the field of structural biology. In 1983 his Laboratory determined the structure of the surface proteins of influenza virus, and a major result of that work was the discovery of Relenza. One of the founding directors of Biota Holdings Ltd.	Member of Research Committee	5,982,482	280,000	
R Dobinson B.Bus (Acc)	Non-executive director for 4 years Merchant banker with a background in investment banking and stockbroking. Has acted as corporate director for two leading stockbrokers, and was an executive director of the NAB's corporate advisory subsidiary. Later headed the Corporate Advisory Division of Dresdner Australia Ltd. Managing Director of TSL Group Ltd, a corporate advisory company specialising in establishing and advising biotechnology companies. Also a director of Acrux Ltd, Nutrihealth Pty Ltd, Plantic Technologies Ltd, and Roc Oil Company Ltd.	Chairman of Audit Committee, member of Remuneration Committee	4,775,789	280,000	

Director	Experience	Special Responsibilities	Particulars of c interests in sha	lirectors' ares and options
			Shares	Options
L Gorr, B. Juris LLB, M. Admin	Non-executive director since May 2000. Senior Partner, Herbert Geer & Rundle. 29 years' experience as a solicitor. Extensive experience in providing advice on the negotiation and interpretation of technology licensing agreements. Clients include investors in, and advisors to the biotechnology industry.	Member of Audit Committee.	5,872,100	280,000
PJ Jenkins MB, BS (Melb), FRACP	Non-executive director for 4 years. Consultant physician and gastroenterologist. Holds a number of clinical and research positions with the Alfred Hospital and has held clinical positions with the Baker Medical Research Centre. Foundation director of Anadis Ltd, a listed bio-pharmaceutical company. Judge of the Australian Technology Awards for the past four years.	Chairman of Research Committee	1,874,000	280,000
JW Raff Dip. Ag. Sc., BSc. PhD	Previously General Manager of the Biomolecular Research Institute. Co-founder, director and major shareholder of a technology based agricultural seed company. Also founder and investor in a number of other start-up technology companies.	Chief Executive Officer	4,333,581	600,000

Directors' meetings

The number of meetings of the company's board of directors and of each committee held during the year ended 30 June 2001, and the numbers of meetings attended by each director were:

Full meetings of dir	ectors	Meetings of committees						
			Audit	Remunei	ration	Res	earch	
А	В	A	В	А	В	А	В	
18	18	*	3	1	1	*	5	
13	18	*	3	*	1	5	5	
15	18	3	3	1	1	*	5	
18	18	3	3	*	1	*	5	
17	18	*	3	*	1	5	5	
18	18	*	3	*	1	5	5	
	A 18 13 15 18 17	18 18 13 18 15 18 18 18 17 18	A B A 18 18 * 13 18 * 15 18 3 18 18 3 17 18 *	A B A B 18 18 * 3 13 18 * 3 15 18 3 3 18 18 3 3 17 18 * 3	A B A B A 18 18 * 3 1 13 18 * 3 1 15 18 3 3 1 18 18 * 3 3 * 17 18 * 3 * *	A B A B A B 18 18 * 3 1 1 13 18 * 3 1 1 15 18 3 3 1 1 15 18 3 3 1 1 17 18 * 3 * 1	A B B B	A B B A B B B

A = Number of meetings attended

B = Number of meetings alterided B = Number of meetings held during the time the director held office or was a member of the committee during the year. * = Not a member of the relevant committee.

Retirement, election and continuation in office of Directors

Dr Peter Colman retires by rotation as director at the annual general meeting and, being eligible, offers himself for re-election. Mr Ross Dobinson retires by rotation as director at the annual general meeting and, being eligible, offers himself for re-election.

Directors' and executives' emoluments

The remuneration committee, consisting of two non-executive directors, advises the Board on remuneration policies and practices generally, and makes specific recommendations on remuneration packages and other terms of employment for executive directors, other senior executives and non-executive directors.

Executive remuneration and other terms of employment are reviewed annually against goals set at the start of the year, relevant comparative information and if required independent expert advice. As well as a base salary, remuneration packages include superannuation, retirement and termination entitlements, performance-related bonuses and fringe benefits. Executives are also eligible to participate in the Starpharma Pooled Development Limited Employee Share Option Plan.

Remuneration packages are set at levels that are intended to attract and retain executives capable of managing the consolidated entity's operations.

Remuneration and other terms of employment for the Chief Executive Officer and certain other senior executives are formalised in service agreements.

Remuneration of non-executive directors is determined by the Board within the maximum amount approved by the shareholders from time to time.

The Board undertakes an annual review of its performance and the performance of the Board committees against goals set at the start of the year. Performance related bonuses are available to executives. Bonuses are not payable to non-executive directors.

Details of the nature and amount of each element of the emoluments of each director of Starpharma Pooled Development Limited and each of the 5 officers of the company and the consolidated entity receiving the highest emoluments are set out in the following tables.

Non-executive directors of Starpharma Pooled Development Limited

Name	Base Fee	Committee Fees	Superannuation	Total
Mr Richard Oliver, Chairman	27,133	-	1,121	28,254
Prof Peter Colman	20,374	-	1,630	22,004
Mr Ross Dobinson	20,374	-	1,630	22,004
Mr Leon Gorr	20,374	-	1,630	22,004
Dr Peter Jenkins	20,374	-	1,630	22,004

Executive directors of Starpharma Pooled Development Limited

Name	Base salary	Motor vehicle	Super-annuation	Bonus	Options	Other benefits	Total
	\$	\$	\$	\$	\$	\$	\$
Dr John Raff	175,000	31,719	26,950	-		-	233,669

Other executives of Starpharma Pooled Development Limited

Name	Base salary	Motor vehicle	Superannuation	Bonus	Options	Other benefits	Total
\$	\$	\$	\$	\$	\$	\$	
Dr Barry Matthews Research Director	120,000	17,224	18,480	-	-	-	155,704
Mr Tim Grogan Manager, Intellectual Property and Business Development (From 24/7/00 to 30/6/01)	99,862	20,517	15,379	-	-	-	135,758
Mr Ben Rogers Company Secretary and Finance Manager	85,658	23,388	13,191	-	-	-	122,237
Dr Leigh Hammond Pharmaceutical Manager (From 1/7/2000 to 28/2/2001)	84,922	-	12,183	-	-	8,600*	105,705

*Consultancy fee for work performed during March 2001 following resignation.

Starpharma Pooled Development Limited and the consolidated entity employ no other executive officers.

Share options granted to directors and the most highly remunerated officers

Options over unissued ordinary shares of Starpharma Pooled Development Limited granted during or since the end of the financial year to any of the directors or the 5 most highly remunerated officers of the company and consolidated entity as part of their remuneration were as follows:

	Options Issued
Mr Tim Grogan, Manager, Intellectual Property and Business Development	100,000

The options were granted under the Starpharma Pooled Development Limited Employee Share Option Plan (ASX code SPLAM) on 7th February 2001.

Shares under option

Unissued ordinary shares of Starpharma Pooled Development Limited under option at the date of this report are as follows:

	Number	Issue price of shares	Expiry date
Starpharma Pooled Development Limited Executive and Employee Share Option Plan (ASX code SPLAK)	2,360,000	93.75 cents	28 September 2002
Starpharma Pooled Development Limited Employee Share Option Plan (ASX code SPLAM)	300,000	93.75 cents	31 January 2005

Options issued under Plan SPLAK are exercisable during the period from 1 February 2002 to 28 September 2002. Options issued under Plan SPLAM are exercisable during the period from 1 January 2003 to 31 December 2005. No option holder has any right under the options to participate in any other issue of the company or of any other entity.

Shares Issued on the Exercise of Options

No shares in Starpharma Pooled Development Limited have been issued on the exercise of options.

Insurance of officers

During the financial year Starpharma Pooled Development Limited and officers of the company and related bodies corporate arranged through Willis Australia Ltd for a Directors' and Officers' Liability insurance policy with HIH Casualty and General Insurance Ltd ("HIH") to indemnify certain officers of the company and related bodies corporate.

Following advice from Willis Australia Ltd ("Willis") that HIH represented unacceptable security for the underwriting of Willis' client policies, the company instructed Willis to seek an alternative underwriter. A Directors' and Officers' Liability Insurance policy was subsequently arranged through Willis with Royal and Sun Alliance as the underwriter, with effect from 23 April 2001.

It is a condition of the policy that the company not publish details of the nature of the liabilities insured by the policy or the amount of the premium paid.

The officers of the company covered by the insurance policy include the directors and executive officers.

Agreement to indemnify officers

During the financial year the company entered into agreements to indemnify the directors of the company and its controlled entities (subject to certain qualifications):

(i) against all liabilities incurred in the capacity of an officer of the company or any related body corporate of the company unless liability arises out of conduct involving lack of good faith; and

(ii) for costs and expenses incurred by a director in defending any proceedings in which judgement is given in favour of the director or in which the director is acquitted.

Under the agreements the company must maintain a Directors' and Officers' Liability insurance policy while the director holds office and for a further 7 years after the directors ceases to be a director of the company or of any related bodies corporate.

Environmental regulations

The consolidated entity has complied with all applicable environmental regulations.

Auditor

PricewaterhouseCoopers continues in office in accordance with section 327 of the Corporations Act 2001.

This report is made in accordance with a resolution of the Directors.

R J D Oliver Director

24 September, 2001 Melbourne

Corporate Governance Statement

A description of the company's main corporate governance practices is set out below. All these practices, unless otherwise stated, were in place for the entire year.

The Board of Directors and its committees

The Board is responsible for the overall corporate governance of the company and its controlled entities, including development of corporate strategies, establishing goals for management and monitoring progress towards the achievement of these goals.

Composition of the Board

The constitution of the company requires that one third of directors (or if their number is not a multiple of three then the number nearest to one third) retire at every annual general meeting and be eligible for re-election. The minimum number of directors is three and the maximum is fifteen unless the company passes a resolution varying that number.

The chairman is an independent non-executive director who is elected by the full Board.

At the date of signing the directors' report the board consisted of five non-executive directors and one executive director, Dr J W Raff. Details of the directors at the date of this statement are set out in the directors' report under the heading "Information on Directors".

Independent professional advice

Directors have the right, in connection with their duties and responsibilities as directors, to seek independent professional advice at the company's expense. Prior approval of the Chairman is required, but this will not be unreasonably withheld.

Administrative structure and internal control framework

Board meetings are held on a monthly basis, or more frequently if required. A detailed management report is prepared by senior management and distributed with board papers prior to each meeting. The Chief Executive Officer and the Company Secretary attend all Board meetings.

The Board reviews and approves the investment plans and annual budget for the company and oversees the research & development plans of investee companies.

Ethical standards

The directors are committed to the principles underpinning best practice in corporate governance, with a commitment to the highest standards of legislative compliance and financial and ethical behaviour.

Trading in company securities

The purchase and sale of company securities by directors, executives and employees is only permitted during the thirty day period following the annual general meeting and the release of the half yearly and annual financial results to the market, unless prior approval is given to each transaction by the Chairman.

Committees

The Board has established the following committees to assist in the discharge of its responsibilities:

Audit committee

The Audit committee consists of Mr Ross Dobinson (Chairman) and Mr Leon Gorr. The committee meets at least twice a year, and has direct access to the company's auditors. The charter of the Audit Committee is:

• to review and report to the Board on the annual report and financial statements, and to review the adequacy of external audit arrangements, particularly the scope and quality of the audit;

- to provide assurance to the Board that it is receiving adequate, up to date and reliable information;
- to assist the Board in reviewing the effectiveness of the organisation's internal control environment covering:
 - effectiveness and efficiency of operations
 - reliability of financial reporting
 - compliance with applicable laws and regulations;
- to assist the board in the development and monitoring of risk management, statutory compliance and ethics programs.

Remuneration committee

The Remuneration committee advises the Board on remuneration policies and practices. This committee consists of:

Mr Richard Oliver

Mr Ross Dobinson

Research Committee

This is a committee of the board of the controlled entity Starpharma Limited and was established in September 2000 and consists of Dr Peter Jenkins (Chairman), Prof Peter Colman and Dr John Raff. The Charter of the Research Committee is:

- to ensure that the Board of Starpharma Limited is kept fully informed of developments relating to the company's research activities and development progress against milestones; and
- to advise the Board of Starpharma Pooled Development Limited on scientific matters in relation to the company's continuous disclosure obligations under the listing rules of the Australian Stock Exchange.

The committee members have been chosen on the basis of their expertise and the composition of the committees is reviewed annually by the Board.

Continuous Disclosure

The Company Secretary has been appointed as the person responsible for communications with the Australian Stock Exchange (ASX). This person is also responsible for ensuring compliance with the continuous disclosure requirements in the ASX Listing rules and overseeing and co-ordinating information disclosure to the ASX, analysts, brokers, shareholders, the media and the public.

Statements of Financial Performance for the year ended 30 June 2001

	Consolidated			Pare	Parent Entity	
	Notes	2001	2000	2001	2000	
		\$	\$	\$	\$	
Revenue from ordinary activities	2	1,964,151	1,609,750	964,590	199,464	
Administration Expenses		(1,498,347)	(650,602)	(268,344)	(63,022)	
Occupancy Expenses		(18,496)	(19,062)	-	-	
Research and Development Expenses		(4,004,525)	(2,631,559)	-	-	
Other expenses from ordinary activities		(349,210)	(80,541)	-	-	
Profit (loss) from operating activities before tax	3	(3,906,427)	(1,772,014)	696,246	136,442	
Income tax attributable to ordinary activities	4					
Profit (loss) from ordinary activities						
after income tax	13	(3,906,427)	(1,772,014)	696,246	136,442	
		Cents	Cents			
Basic Earnings per share	24	(4.74)	(3.10)			

The above statements of financial performance should be read in conjunction with the accompanying notes.

Statements of Financial Position as at 30 June 2001

		Co	nsolidated Pa		arent Entity	
	Notes	2001	2000	2001	2000	
		\$	\$	\$	\$	
Assets						
Current Assets						
Cash assets	5	25,412,466	7,225,730	23,886,871	5,431,807	
Receivables	6	305,208	698,237	42,376	3,251	
Other	7	71,541	225,976	4,909	67,804	
Total Current Assets		25,789,215	8,149,943	23,934,156	5,502,862	
Non-Current Assets						
Property, plant and equipment	8	236,240	116,832	-	-	
Other financial assets	9	,		10,000,006	7,000,006	
Total Non Current Assets		236,240	116,832	10,000,006	7,000,006	
Total Assets		26,025,455	8,266,775	33,934,162	12,502,868	
Liabilities						
Current Liabilities			150.054			
Payables	10	1,044,934	159,854	8,305	27,843	
Provisions	11	64,868	39,427	-	-	
Total Current Liabilities		1,109,802	199,281	8,305	27,843	
Total Liabilities		1,109,802	199,281	8,305	27,843	
Net Assets		24,915,653	8,067,494	33,925,857	12,475,025	
Equity						
Contributed Equity	12	33,034,058	12,279,472	33,034,058	12,279,472	
Retained profits (Accumulated losses)	13	(8,118,405)	(4,211,978)	891,799	195,553	
Total Equity		24,915,653	8,067,494	33,925,857	12,475,025	

The above statements of financial position should be read in conjunction with the accompanying notes.

Statements of Cash Flows for the year ended 30 June 2001

	Con		nsolidated Pa		arent Entity	
	Notes	2001	2000	2001	2000	
		\$	\$	\$	\$	
Cash Flows from Operating Activities						
Receipts from trade and other debtors		178,052	-	-	-	
Grant income (Inclusive of GST)		1,354,163	517,141	-	-	
Payments to suppliers and employees						
(Inclusive of GST)		(5,025,504)	(3,437,974)	(292,791)	(61,313)	
Interest received		1,039,554	263,902	925,465	200,108	
Net cash inflows (outflows) from						
operating activities	18	(2,453,735)	(2,656,931)	632,674	138,795	
Cash Flows from Investing Activities						
Payments for the purchase of share						
in controlled entities		-	-	(3,000,000)	(3,000,000)	
Payments for property, plant and equipment		(181,919)	(109,794)	-	-	
Net cash flows from investing activities		(181,919)	(109,794)	(3,000,000)	(3,000,000)	
Cash Flows from Financing Activities						
Proceeds from issue of shares		22,440,000	7,812,500	22,440,000	7,812,500	
Share issue transaction costs		(1,617,610)	(533,028)	(1,617,610)	(533,028)	
Net cash flows from financing activities		20,822,390	7,279,472	20,822,390	7,279,472	
Net Increase in Cash Held		18,186,736	4,512,747	18,455,064	4,418,267	
Cash at the beginning of the financial year		7,225,730	2,712,983	5,431,807	1,013,540	
Cash at the end of the financial year		25,412,466	7,225,730	23,886,871	5,431,807	

The above statements of cash flows should be read in conjunction with the accompanying notes.

Notes to the Financial Statements for the year ended 30 June 2001

Note 1: Summary of Significant Accounting Policies

This general purpose financial report has been prepared in accordance with Accounting Standards, other authoritative pronouncements of the Australian Accounting Standards Board, Urgent Issues Group Consensus Views and the Corporations Act 2001.

It is prepared in accordance with the historical cost convention. The accounting policies adopted are consistent with those of the previous year. As a result of applying the revised Accounting Standard AASB 1018 *Statement of Financial Performance*, revised AASB 1034 *Financial Report Presentation and Disclosures* and AASB 1040 *Statement of Financial Position* for the first time, a number of comparative amounts were presented or reclassified to ensure comparability with the current reporting period.

(a) Principles of consolidation

The consolidated financial statements incorporate the assets and liabilities of all entities controlled by Starpharma Pooled Development Limited (the 'company' or 'parent entity') as at 30 June 2001 and the results of all controlled entities for the year then ended. Starpharma Pooled Development Limited and its controlled entities together are referred to in this financial report as the consolidated entity. The effects of all transactions between entities in the consolidated entity are eliminated in full.

Where control of an entity is obtained during the financial year, its results are included in the consolidated profit and loss account from the date on which control commences.

(b) Income tax

Tax effect accounting procedures are followed whereby the income tax expense in the profit and loss account is matched with the accounting profit after allowing for permanent differences. The future tax benefits relating to tax losses and timing differences are not carried forward unless the benefits are virtually certain of realisation.

(c) Receivables

The debtors comprise grants receivable and they are recognised as they are due for settlement no more than 60 days from the date of recognition.

(d) Acquisition of assets

The cost method of accounting is used for all acquisitions regardless of whether shares or other assets are acquired. Cost is determined as the fair value of the assets given up, shares issued or liabilities undertaken at the date of acquisition plus incidental costs directly attributable to the acquisition.

(e) Revenue recognition

Amounts disclosed as revenue are payments under the Federal Government R&D START grant, interest income on short term deposits and sundry items. Revenue is recognised for the major business activities as follows:

(i) Grant Funding

Grant funding is provided under the consolidated entity's agreements with the Commonwealth of Australia. Grant funding is equivalent to 50% of the consolidated entity's spend on eligible research and is capped at the maximum of approved grants on specific projects. Grant revenue is recognised when eligible research expenditure has been incurred.

(f) Recoverable amount of non-current assets

The recoverable amount of an asset is the net amount expected to be recovered through the net cash inflows arising from its continued use and subsequent disposal. Where the carrying amount of a non-current asset is greater than its recoverable amount, the asset is revalued to its recoverable amount. In assessing recoverable amounts the relevant cash flows have not been discounted to their present value.

(g) Depreciation and amortisation of property, plant and equipment

Depreciation is calculated on a straight line basis to write off the net cost or revalued amount of each item of property, plant and equipment over its expected useful life to the consolidated entity. The expected useful life of items of property, plant and equipment ranges from 4 to 8 years.

(h) Good and services tax systems changes

Costs incurred to update existing systems or to design, develop and implement new system to deal with the GST are charged as expenses as incurred.

(i) Employee entitlements

(i) Wages and salaries, annual leave and sick leave

Liabilities for wages and salaries, annual leave and sick leave are recognised, and are measured as the amount unpaid at the reporting date at current pay rates in respect of employees' services up to that date.

(ii) Superannuation

The consolidated entity contributes to employee superannuation on the basis of legal and contractual requirements, with contributions being charged against income.

(j) Research expenditure

Research expenditure is charged against income when incurred.

(k) Trade and other creditors

These amounts represent liabilities for goods and services provided to the consolidated entity prior to the end of the financial year which are unpaid. These amounts are unsecured and are paid in accordance with supplier terms.

(I) Cash

For the purpose of the statements of cash flows, cash includes deposits at call which are readily convertible to cash on hand and are subject to an insignificant risk of changes in value.

(m) Transaction costs arising in relation to the issue of equity

Transaction costs in relation to the future issue of equity are deferred and recognised directly as a reduction against the proceeds of the future capital raising to which they relate.

(n) Investments

Investments in controlled entities are accounted for in the consolidated financial statements in the manner set out in Note 1(a).

(o) Earnings per share

(i) Basic earnings per share

Basic earnings per share is determined by dividing the net loss after income tax attributable to members of the company, excluding any costs of servicing equity other than ordinary shares, by the weighted average number of ordinary shares outstanding during the financial year, adjusted for bonus elements in ordinary shares issued during the year.

(ii) Diluted earnings per Share

Diluted earnings per share adjusts the figures used in the determination of basic earnings per share to take into account the after income tax effect of interest and other financing costs associated with dilutive ordinary shares and the weighted average number of shares assumed to have been issued for no consideration in relation to dilutive potential ordinary shares.

(p) Foreign currency translation

Foreign currency transactions are initially translated into Australian currency at the rate of exchange at the date of the transaction. At balance date amounts payable and receivable in foreign currencies are translated to Australian currency at rates of exchange at that date. Resulting exchange differences are recognised in determining the profit or loss for the year.

Note 2: Revenue

	Co	onsolidated	Par	rent Entity
	2001	2000	2001	2000
	\$	\$	\$	\$
Revenue from outside operating activities				
Government grants	886,194	1,344,173	-	-
Interest revenue	1,076,553	265,577	964,590	199,464
Other	1,404	-	-	-
	1,964,151	1,609,750	964,590	199,464

Note 3: Operating Profit/Loss

	Consolidated		Parent Entity	
	2001	2000	2001	2000
	\$	\$	\$	\$
(i) Operating expenses				
Profit/loss from ordinary activities before income tax expense includes				
the following specific expenses:				
Depreciation (plant & equipment)	62,511	15,314	-	-
Employee entitlements	25,441	20,538	-	-
Research and development expense	4,004,525	2,631,559	-	-
Rental expense on operating leases	162,957	63,828	-	-
(ii) Auditors' remuneration				
Amounts received, or due and receivable, by the auditor of the consolidated entity for:				
Auditing the financial statements	54,550	23,250	-	-
Taxation services, other support	43,441	44,240	-	-

Note 4: Income Tax

The income tax expense for the financial year differs from the amount calculated on the operating profit/(loss). The differences are reconciled as follows:

	Consolidated		Parent Entity	
	2001 \$	2000 \$	2001 \$	2000 \$
Current				
Profit/(loss) from ordinary activities before income tax	(3,906,427)	(1,772,014)	696,246	136,442
Income tax expense/(benefit) @ 34% (2000: 36%)	(1,328,185)	(637,925)	236,723	49,119
Tax effect of permanent differences:				
Brokerage fees	-	276	-	-
Entertainment	4,034	-	-	-
Legal expenses	-	1,310	-	-
Research and development allowance	(119,000)	-	-	-
Other	272	-	68	-
Income tax expense/(benefit) adjusted for permanent differences	(1,442,879)	(636,339)	236,791	49,119
Under/(over) provision arising in prior year	(93,528)	(84,224)	5,650	
Less loss transferred to controlling entity	-	-	(242,441)	(49,119)
Future income tax benefits written off/not brought to account	1,536,407	720,563	-	
Income tax expense/(benefit) attributable to operating profit/loss	-	-	-	-

Future income tax benefits

Potential future income tax benefits of \$2,622,895 (2000: \$1,262,329) attributable to tax losses carried forward by controlled entities have not been brought to account in the accounts at balance date because the directors do not believe it appropriate to regard the realisation of the future income tax benefits as virtually certain. A net deferred income tax liability attributable to timing differences of \$51,085 (2000: \$225,075) has been netted off against gross tax loss future tax benefits (valued at 30%) of \$2,673,980 (2000: \$1,487,404) on the basis that these timing differences will reverse out in periods in which carried forward tax losses are available.

These future income tax benefits will only be obtained if:

(i) the consolidated entity derives future assessable income of a nature and of an amount sufficient to enable the benefit from the deduction for the loss to be realised; or

(ii) the consolidated entity continues to comply with the conditions for deductibility imposed by the law; and

(iii) no changes in tax legislation adversely affect the consolidated entity in realising the benefit from the deductions for the loss.

Adjustment to deferred income tax balances

Legislation reducing the company tax rate from 36% to 34% in respect of the 2000-2001 income tax year and then to 30% from the 2001-2002 income tax year was announced on 21 September 1999 and received Royal Assent on 10 December 1999. As a consequence, future income tax benefits attributable to carried forward losses, net of a provision for deferred income tax liability, have been revalued at 30% on the basis that the consolidated entity is not expected to be in a tax payable position until the year ended 30 June 2002 at the earliest.

Note 5: Current Assets – Cash Assets

	Co	onsolidated	Pa	rent Entity
	2001	2000	00 2001	2000
	\$	\$	\$	\$
Cash at bank and on hand	3,419,476	3,129,124	1,893,881	1,335,201
Deposits at call	21,992,990	4,096,606	21,992,990	4,096,606
	25,412,466	7,225,730	23,886,871	5,431,807
	C	onsolidated	Pa	rent Entity

	Consonaaca		10	
	2001	2000	2001	2000
	\$	\$	\$	\$
Balance of cash as shown in the				
statements of cash flows	25,412,466	7,225,730	23,886,871	5,431,807

Deposits at call

The deposits are bearing floating interest rates of 4.98% (2000-6.05%)

Note 6: Current Assets - Receivables

	Сс	onsolidated	Pa	arent Entity
	2001	2000	2001	2000
	\$	\$	\$	\$
Interest receivable	49,014	12,015	42,376	3,251
Other receivables	256,194	686,222	-	-
	305,208	698,237	42,376	3,251

Interest receivable

The carrying amount of interest receivable approximates net fair values.

Other receivables

The receivables comprise grant income, and the carrying amounts of the other receivables approximate net fair values and are subject to normal terms of settlement within 60 days.

Note 7: Current Assets - Other

	Co	Consolidated		Parent Entity	
	2001	2000	2001	2000	
	\$	\$	\$	\$	
Prepayments	12,777	158,172	-	-	
Deferred (future) share issue costs	-	67,804	-	67,804	
GST Claimable	58,764	-	4,909	-	
	71,541	225,976	4,909	67,804	

Note 8: Non-Current Assets – Property, Plant and Equipment

	Сс	Consolidated		Parent Entity	
	2001	2000	2001	2000	
	\$	\$	\$	\$	
Plant and equipment (at cost)	322,248	140,329	-	-	
Less: Accumulated depreciation	(86,008)	(23,497)	-	-	
	236,240	116,832	-	-	

Reconciliations

Reconciliations of the carrying amounts of plant & equipment at the beginning and end of the current financial year are set out below.

	Plant & Equipment \$
Consolidated	
Carrying amount at 1 July 2000 Additions Depreciation Expense	116,832 181,919 (62,511)
Carrying amount at 30 June 2001	236,240

Note 9: Non-Current Assets – Other Financial Assets

	Consolidated		Pa	Parent Entity	
	2001	2000	2001	2000	
	\$	\$	\$	\$	
Non-traded Investments					
Shares in controlled entities – at cost (Note 15)	-	-	10,000,006	7,000,006	
Note 10: Current Liabilities - Payables

	Co	onsolidated	Pa	Parent Entity	
	2001 2000		2001	2000	
	\$	\$	\$	\$	
Trade creditors	1,016,493	159,854	8,305	27,843	
GST Payable	28,441	-	-	-	
	1,044,934	159,854	8,305	27,843	

Note 11: Current Liabilities - Provisions

	Сс	onsolidated	Pa	Parent Entity	
	2001	2000	2001	2000	
	\$	\$	\$	\$	
Employee entitlements	64,868	39,427	-	-	

Note 12: Contributed Equity

	Pa	rent Entity	Parent Entity		
	2001	2001 2000		2000	
	Shares	Shares	\$	\$	
(a) Share Capital					
Ordinary shares - fully paid	88,900,000	62,500,000	33,034,058	12,279,472	
Former share premium account included in equity			2,500,000	2,500,000	

Date	Details		Number of shares	Issue Price	\$
1 July 1999	Opening balance		12,500,000		5,000,000
	Rights issue	(c)	3,125,000	\$0.01	31,250
20 Dec 1999	Final call of \$2.49 per share on rights issue			\$2.49	7,781,250
	Issue costs in relation to the rights issue and				
	final call				(533,028)
20 April 2000	Share split of 4 for 1		-		12,279,472
30 June 2000	Balance		62,500,000		12,279,472
20 September 2000	Issue of Fully Paid Ordinary shares	(d)	26,400,000	\$0.85	22,440,000
	Issue costs in relation to share issue				(1,685,414)
30 June 2001	Balance		88,900,000		33,034,058

(b) Movements in ordinary contributed capital of the company during the past two years were as follows:

(c) Rights Issue

On the 15 September 1999 the company invited its shareholders to subscribe to a rights issue of 3,125,000 ordinary shares at an issue price of \$2.50 per share on the basis of 4 shares for every 1 fully paid ordinary shares held.

(d) Ordinary Shares

On the 20 September 2000 the company issued 26,400,000 at an issue price of \$0.85 per share. These shares entitle the holder to participate in dividends and the proceeds on winding up of the company in proportion to the number of and amounts paid on the shares held.

Note 13: Retained Profits (Accumulated Losses)

	Сс	Parent Entity		
	2001 2000		2001	2000
	\$	\$	\$	\$
Retained profits (accumulated losses)				
at beginning of the year	(4,211,978)	(2,439,964)	195,553	59,111
Net profit (loss) for the year	(3,906,427)	(1,772,014)	696,246	136,442
Retained profits (accumulated losses)				
at end of the year	(8,118,405)	(4,211,978)	891,799	195,553

Note 14: Commitments for Expenditure

Сс	onsolidated	Parent Entity	
2001	2000	2001	2000
\$	\$	\$	\$
76,604	74,092	-	-
85,514	40,853	-	-
-	-	-	-
162,118	114,945	-	-
162,118	114,945	-	-
	2001 \$ 76,604 85,514 - 162,118	\$ 76,604 74,092 85,514 40,853 - 162,118 114,945 	2001 2000 2001 \$ \$ \$ \$ \$ \$ 76,604 74,092 - 85,514 40,853 - - - - 162,118 114,945 -

Note 15: Controlled Entities

Wholly-owned Group

The consolidated entity consists of Starpharma Pooled Development Limited and its controlled entities, Starpharma Limited, Angiostar Limited and Viralstar Limited. Ownership interest in these controlled entities is set out below.

Investments in Controlled Entities

	Country of Incorporation	Class of Shares	Equity	Holding	Cost of Parent Enti	ty's Investment
					2001	2000
					\$	\$
Starpharma Limited	Australia	Ordinary	100%		3,400,001	2,400,001
Angiostar Limited	Australia	Ordinary	100%		3,300,005	2,300,005
Viralstar Limited	Australia	Ordinary	100%		3,300,000	2,300,000
					10,000,006	7,000,006
Note 16: Remuneration of Di		Directors of Entities	in the Ecor 2001 \$	nomic Entity 2000 \$	Directors 2001 \$	of Parent Entity 2000 \$
Income paid or payable, or available, to directors of er consolidated entity in conr management of affairs of t or its controlled entities	ntities in the nection with the		349,937	300.006	349,937	300,006

The numbers of parent entity directors whose total income from the parent entity or related parties was within the specified bands are as follows:

\$		\$	2001	2000
10,000	-	19,999	-	5
20,000	-	29,999	5	-
200,000	-	219,999	-	1
230,000	-	239,999	1	-

Note 17: Remuneration of Executives

	Executive Officers of the Consolidated Entity		Executive Officers of the	Parent Entity
	2001	2000	2001	2000
	\$	\$	\$	\$
Remuneration received, or due and receivable from entities in the consolidated entity and related parties by Australian based executive officers (including directors) whose remuneration was at least \$100,000:				
Executive officers of the parent entity	753,073	215,744	491,664	215,744

The numbers of Australian based executive officers (including directors) whose remuneration from entities in the consolidated entity and related parties was within the specified bands are as follows:

			Executive Officers of the Consolidated Entity		Executive Officers of the	Parent Entity	
				2001	2000	2001	2000
				\$	\$	\$	\$
\$		\$					
100,000	-	109,999		1	-	-	-
120,000	-	129,999		1	-	1	-
130,000	-	139,999		1	-	1	-
150,000	-	159,999		1	-	-	-
210,000	-	219,999		-	1	-	1
230,000	-	239,999		1	-	1	-

Options are granted to executive officers under the Starpharma Pooled Development Limited Employee Share Option Plan, details of which are set out in Note 23.

A summary of options granted and exercised by Australian based executive officers (with income of at least \$100,000) during the year ended 30 June 2001 is set out below.

	Granted	Exercised	Outstanding
Australian based executive officers of the parent entity	100,000	-	100,000

The amounts disclosed as remuneration of executive officers in this note include the assessed fair value of the options at the date they were granted to executive officers during the year ended 30 June 2000. On issue of the options, the exercise price was equivalent to the share price on the date of issue. After taking this into account and the earliest date on which the options may be exercised, namely 1 February 2002, the fair value of the options at the date of issue has been assessed as \$nil.

Note 18: Cash Flow Information

Reconciliation of net cash flows from operating activities to operating profit/(loss) after income tax

	Co	onsolidated	Pa	Parent Entity		
	2001	2000	2001	2000		
	\$	\$	\$	\$		
Operating profit/(loss) after income tax:	(3,906,427)	(1,772,014)	696,246	136,442		
Depreciation and amortisation:	62,511	15,314	-	-		
Change in operating assets and liabilities						
(Increase) decrease in receivables and other assets	393,029	(814,256)	(39,125)	28,477		
(Increase) decrease in other operating assets	86,631	-	(4,909)	-		
Increase (decrease) in trade creditors	885,080	(106,513)	(19,538)	(26,124)		
Increase (decrease) in employee provisions	25,441	20,538	-	-		
Net cash inflows/(outflows) from operating activities	(2,453,735)	(2,656,931)	632,674	138,795		

Note 19: Events Subsequent to Balance Date

On 6 August 2001, Starpharma Pooled Development Ltd entered into an agreement with Dr Donald A. Tomalia, to establish a new venture to develop products using dendrimer nanotechnology. Under the proposed venture Starpharma intends to invest up to US\$2.18 million over the next three years in Dendritic Nanotechnologies Limited, a new Australian company which will have its head office in Melbourne and a branch office and laboratory at Central Michigan University, Michigan USA. Dr Tomalia's team of experienced dendritic polymer scientists will be employed by the new company.

Note 20: Related Parties

Directors

The names of persons who were directors of Starpharma Pooled Development Limited at any time during the financial year are as follows: P M Colman, R Dobinson, L Gorr, P J Jenkins, R J D Oliver and J W Raff. All of these persons were also directors during the year ended 30 June 2000.

Details of directors' remuneration are set out in Note 16.

Transactions of Directors and Director-related entities concerning shares or share options

Aggregate numbers of shares of Starpharma Pooled Development Limited issued to and held directly, indirectly or beneficially by directors of the company or the economic entity or their director-related entities at balance date:

	2001	2000
	Number	Number
Acquisitions		
Ordinary shares	1,396,371	8,545,984*
Options over ordinary shares	-	2,080,000*
Disposals		
Ordinary shares	-	8,197,840*
Options over ordinary shares	-	-
Currently held		
Ordinary shares	27,550,952	26,154,581*
Options over ordinary shares	2,080,000	2,080,000*

*Total number of shares or options following a 4 for 1 share split effective from 6 April 2000.

Other transactions with Directors and Director-related Entities

For part of the year a director, Prof P M Colman was the Managing Director of The Biomolecular Research Institute Limited, which has provided contract research and research management services to the consolidated entity. All such dealings with the consolidated entity are in the ordinary course of business and on normal terms and conditions.

Two directors, Mr R Dobinson and Mr L Gorr are directors of the company, Technology Structuring Limited which has rendered consulting services to the consolidated entity. All such dealings with the consolidated entity are in the ordinary course of business and on normal terms and conditions.

A director, Mr L Gorr is a partner of Herbert Geer & Rundle, who have provided legal services to the consolidated entity. All such dealings with the consolidated entity are in the ordinary course of business and on normal terms and conditions.

Aggregate amounts of each of the above types of transactions with directors and their director-related entities are:

	Со	Consolidated		Parent Entity	
	2001	2000	2001	2000	
	\$	\$	\$	\$	
Contract research and research management services	273,208	1,090,039	-	-	
Consulting services	9,000	167,562	9,000	131,562	
Legal fees	22,172	164,501	18,809	150,085	

Apart from the above no director has entered into a material contract with the consolidated entity since the end of the previous financial year and there were no material contracts involving directors' interests subsisting at year end.

Wholly owned group

The wholly-owned group consists of Starpharma Pooled Development Limited and its wholly-owned controlled entities, Angiostar Limited, Starpharma Limited and Viralstar Limited. Ownership interests in these controlled entities are set out in note 15.

Controlling entity

The ultimate parent entity in the wholly owned group is Starpharma Pooled Development Limited.

Note 21: Financial Instruments

(a) Credit risk exposures

The credit risk on the financial assets (limited to interest receivable) of the company and consolidated entity which have been recognised on the balance sheet is generally the carrying amount of those financial assets net of any provisions where raised.

(b) Interest rate risk

The company's and consolidated entity's exposure to interest rate risk is limited to that exposure which arises from the holding of cash balances and bills of exchange. Interest is earned on cash balances at the prevailing floating rate, which at 30 June 2001 was 3% and on bills of exchange at 4.98%. Cash balances are at call and bills of exchange have a maturity of no more than 60 days. All other financial assets and liabilities are non interest bearing.

(c) Carrying amounts and net fair values of financial asset and liabilities

The company's and the consolidated entity's balance sheet reflect net assets. All balances stated in these balance sheets are, respectively, considered to form part of the company's and the consolidated entity's net financial assets and liabilities with the exception of property, plant and equipment assets, other receivables, employee entitlement liabilities and investments in subsidiary companies (where included therein).

The carrying value of financial assets and liabilities as stated in the company's and consolidated entity's balance sheets is equivalent to the net fair value of those financial assets and liabilities.

Note 22: Segment Information

The consolidated entity operates in the pharmaceutical research and development industry and in one geographical segment within Australia.

Note 23: Employee Entitlements

(a) Employee entitlement liabilities

	Сс	Consolidated		Parent Entity	
	2001	2000	2001	2000	
	\$	\$	\$	\$	
Provision for employee entitlements current (Note 11)	64,868	39,427	-	-	
	2001	2000	2001	2000	
	Number	Number	Number	Number	
Employee Numbers					
Number of employees at the reporting date	20	7	-	-	

(b) Employee option plans

(i) Starpharma Pooled Development Limited Executive and Employee Option Plan

The establishment of the Starpharma Pooled Development Limited Executive and Employee Option Plan was approved by members at the annual general meeting held on 25 November 1999.

Under the plan, directors of the parent entity may from time to time determine that an eligible person is entitled to participate in the plan and will determine the number of employee options which may be granted to that person or any

associate of that person. In making these determinations the directors are required to have regard to the person's

- length of service with the consolidated entity;
- record of employment with the consolidated entity;
- potential contribution to the future growth of the consolidated entity; and
- to any other matters which tend to warrant the person's participation in the plan.

Under the plan, eligible persons include employees of the consolidated entity, including directors and consultants acting in management roles.

A total of 590,000 options were issued under the plan to 7 employees. Subsequent to the 4 for 1 share subdivision on 6 April 2000, the number of options on issue was adjusted on a consistent basis, resulting in 2,360,000 options on issue. The options were issued for no consideration and are capable of being exercised no earlier than 1 February 2002. The amount which may be received upon the exercising of these options post 1 February 2002 will be recognised as issued capital at the date of issue of the underlying shares. Following the share subdivision, the exercise price of the options was reduced from \$3.75 to \$0.9375.

(ii) Starpharma Pooled Development Limited Employee Share Option Plan

At the Annual General Meeting held on 16th November 2000 members approved the introduction of a new Starpharma Employee Share Option Plan, which was drafted to take into account amendments to the then Corporations Law and the ASX Listing Rules.

A total of 300,000 options were granted under the plan on the 7 February 2001. These options were issued no consideration and are capable of being exercised no earlier than 1 January 2003.

At 30 June 2001 the total number of unissued shares under these options is 2,660,000. The market selling price per ordinary share at 30 June 2001 was \$0.59.

Note 24: Earnings per Share

	Consolidated	
	2001	2000
	Cents	Cents
Basic Earnings per share	(4.74)	(3.10)

Diluted earnings per share is not materially different to basic earnings per share.

	Co	Consolidated	
	2001	2000	
	Number	Number	
Weighted average number of shares used as the denominator			
in calculating basic earnings per share	82,462,739	57,125,537	

Potential ordinary shares not considered dilutive:

As at the 30 June, the company had on issue:

2,360,000 options over unissued capital exercisable on or before the 28 September 2002 at the price of 93.75 cents per ordinary share. These options are not considered dilutive.

300,000 options over unissued capital exercisable on or before the 31 January 2005 at the price of 93.75 cents per ordinary share. These options are not considered dilutive.

Directors' Declaration

The directors declare that the financial statements and notes set out on pages 24 to 41:

- (a) Comply with Accounting Standards, the Corporations Regulations 2001 and other mandatory professional reporting requirements; and
- (b) Give a true and fair view of the company's and consolidated entity's financial position as at 30 June 2001 and of their performance, as represented by the results of their operation and their cash flows, for the financial year ended on that date.

In the directors opinion:

- (a) the financial statements and notes are in accordance with the Corporations Act 2001; and
- (b) there are reasonable grounds to believe that the company will be able to pay its debts as and when they become due and payable.

This statement is made in accordance with a resolution of the directors.

R J D Oliver Director

24 September, 2001 Melbourne

PRICEWATERHOUSE COOPERS '

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Independent audit report to the members of Starpharma Pooled Development Limited

Scope

We have audited the financial report of Starpharma Pooled Development Limited (the Company) for the financial year ended 30 June 2001 as set out on pages 24 to 42. The Company's directors are responsible for the financial report which includes the financial statements of the Company and the consolidated financial statements of the consolidated entity comprising the Company and the entities it controlled at the end of, or during, the financial year. We have conducted an independent audit of the financial report in order to express an opinion on it to the members of the Company.

Our audit has been conducted in accordance with Australian Auditing Standards to provide reasonable assurance as to whether the financial report is free of material misstatement. Our procedures included examination, on a test basis, of evidence supporting the amounts and other disclosures in the financial report, and the evaluation of accounting policies and significant accounting estimates. These procedures have been undertaken to form an opinion as to whether, in all material respects, the financial report is presented fairly in accordance with Accounting Standards, other mandatory professional reporting requirements and the Corporations Act 2001 in Australia so as to present a view which is consistent with our understanding of the Company's and the consolidated entity's financial position, and performance as represented by the results of their operations and their cash flows.

The audit opinion expressed in this report has been formed on the above basis.

Audit opinion

In our opinion, the financial report of the Company is in accordance with:

- (a) the Corporations Act 2001, including:
 - (i) giving a true and fair view of the Company's and consolidated entity's financial position as at 30 June 2001 and of their performance for the financial year ended on that date; an
 - (ii) complying with Accounting Standards and the Corporations Regulations 2001; and
- (b) other mandatory professional reporting requirements.

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PricewaterhouseCoopers Chartered Accountants

) Richela

Nick Ridehalgh Partner

Melbourne 24 September, 2001

Glossary

Clinical Trials - Studies conducted to investigate in a controlled manner, the safety and efficacy of a drug, compound, device or procedure in living human subjects. There are several distinct phases of clinical trial for a new chemical entity being developed as a new pharmaceutical:

- Phase 1: A small trial in 20-50 healthy volunteers to assess the safety of the new drug.
- *Phase 2:* A restricted (e.g. white only) trial in people of the new drug in 50-200 people belonging to the target population (i.e. females) to assess the efficacy of the new drug.
- *Phase 3:* Large, multi-centre trials in 3,500-50,000 people belonging to the target population to confirm the efficacy, and to determine the complete safety profile, of the new drug.

Dendrimers - Precisely controlled, highly branched, nanoscale materials that provide a platform for the development of products in a wide range of commercial applications from life sciences to electronics.

FDA - United States Food and Drug Administration; the regulatory body that regulates the development, approval and marketing of new and existing pharmaceuticals in the U.S.

GLP - Good Laboratory Practices; the regulations governing the conduct of preclinical safety and efficacy studies for new drugs, which aim to assure the quality and integrity of data submitted in support of an IND or New Drug Approval (NDA) application.

Investigational New Drug (IND) application - An application to the U.S. Food and Drug Administration to commence trials of a drug in humans. The application details the findings of in vitro and animal studies of drug product safety and efficacy prior to human trials.

Nanotechnology - The exploitation of the unique properties and phenomena of matter at the atomic and molecular level, or nanoscale.

Polyvalent - A property or mechanism describing multiple interactions between two single entities. A dendrimer is a compound capable of a polyvalent interaction with a cell by virtue of the many surface active groups on the dendrimer interacting with many receptors on the cell surface.

Preclinical Studies - Studies carried out in vitro or in animals to determine the effect and toxicity of a drug prior to studies in humans. However, preclinical, or better referred to as nonclinical studies may be ongoing throughout clinical trials to determine, for example, the effects of long-term use of a drug in animals.

Quality Assurance System - A system to guarantee the excellence, security and dependability of a process or its product, by monitoring, validating and certifying the steps of the process.

Regulatory Affairs - Applies the meaning of laws, guidelines and policies of regulatory bodies to a product development program, and predicts changes and trends in regulations governing pharmaceutical development, testing and registration that may affect product development.

