

#### AGM - Chairman's and CEO's presentations

**Melbourne; 8 November 2007**: Attached is the Chairman's address together with the CEO's presentation to the Annual General Meeting of Starpharma Holdings Limited (ASX:SPL, OTCQX:SPHRY), to be held at 4.00pm today.

#### About Starpharma:

Starpharma Holdings Limited (ASX:SPL, OTCQX:SPHRY) is a world leader in the development of dendrimer nanotechnology for pharmaceutical, life-science and other applications. SPL is principally composed of two operating companies, Starpharma Pty Ltd in Melbourne, Australia and Dendritic Nanotechnologies, Inc in Michigan, USA. Products based on SPL's dendrimer technology are already on the market in the form of diagnostic elements and laboratory reagents.

The Company's lead pharmaceutical development product is VivaGel<sup>®</sup> (SPL7013 Gel), a vaginal microbicide designed to prevent the transmission of STIs, including HIV and genital herpes.

In February 2007 Starpharma signed an agreement with EMD/Merck Biosciences for laboratory applications of Priofect<sup>™</sup>, an RNAi transfection reagent. Starpharma has retained all therapeutic applications of this siRNA delivery technology and is actively seeking partners to develop products based on it.

In the wider pharmaceutical field Starpharma has specific programs in the areas of Drug Delivery and Drug Optimisation technologies (using dendrimers to control where and when drugs go when introduced to the body) and Targeted Diagnostics (using dendrimers as a scaffold to which both location-signalling and targeting groups are added to allow location of specific cell type, such as cancer cells).

More broadly the company is exploring dendrimer opportunities in materials science with applications as diverse as adhesives, lubricants and water remediation.

SPL has a comprehensive IP portfolio that comprises more than 224 patents/applications issued and pending across 56 patent families - a unique level of IP concentration among nanotechnology companies.

**Dendrimers:** A type of precisely-defined, branched nanoparticle. Dendrimers have applications in the medical, electronics, chemicals and materials industries.

**Microbicides:** A microbicide inactivates, kills or destroys microbes such as viruses and bacteria. Microbicides may be formulated as gels, creams, sponges, suppositories or films with the purpose of reducing significantly the incidence of STIs. They are intended for vaginal or rectal use to afford protection for varying periods, from several hours up to days. Microbicides may also be designed to have a contraceptive function.

American Depositary Receipts (ADRs): Starpharma's ADRs trade under the code SPHRY (CUSIP number 855563102). Each Starpharma ADR is equivalent to 10 ordinary shares of Starpharma as traded on the Australian Stock Exchange. The Bank of New York Mellon is the depositary bank. Starpharma's ADRs are listed on International OTCQX (<u>www.otcqx.com</u>), a premium market tier in the U.S. for international exchange-listed companies, operated by Pink Sheets, LLC.

#### **Forward Looking Statements**

This document contains certain forward-looking statements, relating to Starpharma's business, which can be identified by the use of forward-looking terminology such as "promising", "plans", "anticipated", "will", "project", "believe", "forecast", "expected", "estimated", "targeting", "aiming", "set to", "potential", "seeking to", "goal", "could provide", "intends", "is being developed", "could be", "on track", or similar expressions, or by express or implied discussions regarding potential filings or marketing approvals, or potential future sales of product candidates. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no assurance that any existing or future regulatory filings will satisfy the FDA's and other health authorities' requirements regarding any one or more product candidates nor can there be any assurance that such product candidates will be approved by any health authorities for sale in any market or that they will reach any particular level of sales. In particular, management's expectations regarding the approval and commercialization of the product candidates could be affected by, among other things, unexpected clinical trial results, including additional analysis of existing clinical data, and new clinical data; unexpected regulatory actions or delays, or government regulation generally; our ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing pressures; and additional factors that involve significant risks and uncertainties about our products, product candidates, financial results and business prospects. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. Starpharma is providing this information as of the date of this document and does not assume any obligation to

update any forward-looking statements contained in this document as a result of new information, future events or developments or otherwise.

#### For further information:

Media	Starpharma ( <u>www.starpharma.com</u> )		
Rebecca Wilson Buchan Consulting Tel: +61 2 9237 2800 Mob: +61 417 382 391 rwilson@bcg.com.au	<b>Dr Jackie Fairley</b> Chief Executive Officer +61 3 8532 2704	Ben Rogers Company Secretary +61 3 8532 2702 ben.rogers@starpharma.com	



#### **Chairman's Address**

#### **Annual General Meeting**

of

#### Starpharma Holdings Limited, 14 November, 2007

Welcome to the 2007 Starpharma AGM. This is my fifth AGM as Chairman of the Starpharma Board, and, as for the previous 4 years, we have plenty of significant new developments on which to report. Where 'change' was the theme of my address in 06-07, 'consolidation' could be the appropriate theme today.

At our last AGM I pre-empted this year's address somewhat by talking about the acquisition of US-based investee company Dendritic Nanotechnologies by Starpharma Holdings, even though it took place outside that reporting period.

It was a defining moment for the company and has been a significant focus of our activities of the past year. The combined entity has access to many new commercial opportunities as a result of an expanded pipeline, reflecting the versatility of the company's platform technology. I'm pleased to say that the consolidation of both companies was smooth and completed on time.

We have added programs in drug delivery and optimisation to our VivaGel development program. Some of our research reagents for transferring DNA and related molecules into cells are already on the market, while others in the new area of gene-silencing via siRNA technology are at the late pre-launch stage.

These involve commercial agreements for our dendrimer products with global pharmaceutical companies such as Sigma Aldrich and EMD Biosciences (part of Merck kGA) in addition to the discussion across a range of sectors as diverse as manufacturing, automotive lubricants, pharmaceutical and cosmetic ingredients.

For example, Starpharma signed a deal with the US Centre for Defence to use our dendrimer technology to purify water on a number of army bases contaminated by jet fuel. We are also exploring with global pharmaceutical companies applying our technology to improve the solubility of drugs.

The acquisition has enhanced our international profile on which we intend to build.

DNT is an excellent fit for Starpharma – not only because of its focus on dendrimer-related nanotechnology. It serves to increase our investor profile in the US and so its location there is a clear advantage.

As I noted in the annual report, the successful resolution of negotiations and DNT's smooth integration was a credit to the company's Board and senior management team.

Not surprisingly, changes in the nature of the company led to changes in the composition of the Board.

Richard Hazleton, who was Chairman of the DNT Board at the time of the acquisition, accepted our offer to join Starpharma's Board.

As Chairman, I cannot over-emphasise what it means to Starpharma to welcome as a director a person of Richard's calibre. With a list of credentials that includes retired Chairman

and CEO of the Dow Corning Chemical Company, Richard's skills in the areas of technology commercialisation and international management both supplement, and complement, those of other Board members.

Our lead product VivaGel has also made solid progress. Having successfully completed the first safety studies in healthy women and men, our program has now moved into expanded safety, tolerability and acceptability studies in the US, and Kenya.

Starpharma has for some time been exploring the potential of VivaGel as a condom coating and last month signed a second agreement for a co-development program with SSL International, the world's largest marketer of condoms. This deal alone, represents a major opportunity for the company and significantly enhances our commercialisation options for VivaGel as a condom coating in parallel with its development as a stand alone product. Our partner SSL International manufactures Durex, the world's leading condom brand with a market share of more than 30% and we will therefore be exposed to this market through our condom coating agreement.

I am aware that the biotechnology sector is still unfairly rated in Australia and that we have an obligation to both our shareholders and the sector to provide clear, relevant information that underscores our achievements.

The topic of dendrimer technology can be challenging even to scientists, especially in relation to research applications. When the rigorous process of clinical trials of dendrimers for potential human therapies and preventive measures is factored in, it's not surprising that our situation is not well understood by all.

It is often noted that investors in the US are generally better informed about the potential for biotech sector than those in Australia. I believe the situation is changing, but we need to continue contributing to that change.

Certainly the investor and corporate interest in Starpharma in the US has taken off with the launch of our level one ADRs last March on the new OTCQX International market tier. Starpharma was the first Australian company, and first biotechnology company globally to be invited to join the OTCQX, which is a validation of the tremendous potential of our technology to a global audience.

In the present year, the clinical development of VivaGel remains a high priority of our commercialisation strategy, supported by revenues from our products on the market and continued funding from the US National Institutes of Health.

In my concluding remarks of my 2005-06 address I said "there is plenty of good news and also plenty of hard work ahead for the Board and management of Starpharma".

Some things don't change. As I see it, 'good news' and 'plenty of hard work ahead' is a hallmark of a company going places. I look forward to the journey during 2007-08.

It only remains for me to thank once again the Starpharma Board; Jackie and her management team for their sterling efforts in taking the company to a new level of maturity and of course all the staff in Australia and the US.

I know that, like me, they anticipate big achievements for the company and its shareholders.

Thank you.

Peter T. Bartels Chairman



Starpharma Holdings Limited Annual General Meeting CEO Presentation

> ASX:SPL OTCQX:SPHRY

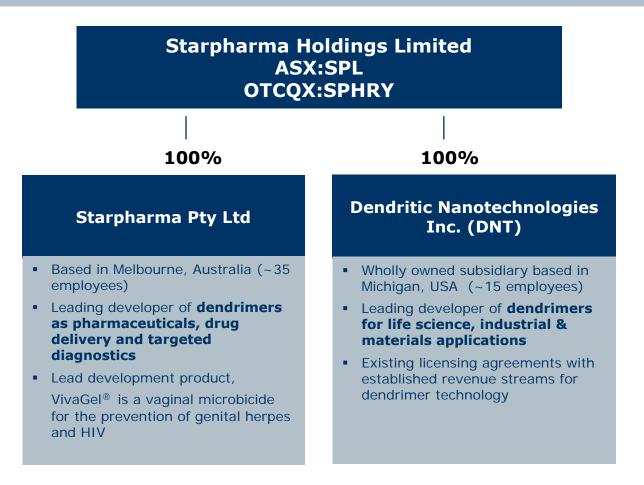
Dr Jackie Fairley CEO 14 November 2007



This document contains certain forward-looking statements, relating to Starpharma's business, which can be identified by the use of forward-looking terminology such as "promising", "plans", "anticipated", "will", "project", "believe", "forecast", "expected", "estimated", "targeting", "aiming", "set to", "potential", "seeking to", "goal", "could provide", "intends", "is being developed", "could be", "on track", or similar expressions, or by express or implied discussions regarding potential filings or marketing approvals, or potential future sales of product candidates. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no assurance that any existing or future regulatory filings will satisfy the FDA's and other health authorities' requirements regarding any one or more product candidates nor can there be any assurance that such product candidates will be approved by any health authorities for sale in any market or that they will reach any particular level of sales. In particular, management's expectations regarding the approval and commercialization of the product candidates could be affected by, among other things, unexpected clinical trial results, including additional analysis of existing clinical data, and new clinical data; unexpected regulatory actions or delays, or government regulation generally; our ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing pressures; and additional factors that involve significant risks and uncertainties about our products, product candidates, financial results and business prospects. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. Starpharma is providing this information as of the date of this presentation and does not assume any obligation to update any forward-looking statements contained in this document as a result of new information, future events or developments or otherwise.



#### **Company Structure**





## Starpharma: 06/07 Highlights

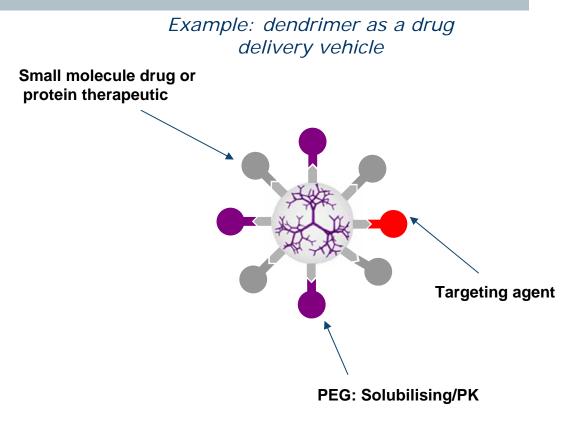
Drivers	Goal	Status
<u>Strategic</u>	Acquisition of DNT	<ul> <li>Integration complete</li> </ul>
	Greater commercial focus	<ul> <li>3 commercial deals; aggressive business development effort</li> </ul>
Products	Advance VivaGel <sup>®</sup> Development	<ul> <li>2 US/international trials initiated under INDs</li> <li>Male Study Completed &amp; reported at IAS 2007</li> <li>Non clinical program significantly advanced</li> </ul>
	Partner Condom Coating	2 deals signed with market-leading companies
<u>Pipeline</u>	PrioFect <sup>®</sup> siRNA transfection reagent	Deal signed with EMD Biosciences; Launch 2007
	MRI imaging agent - cardiovascular disease & cancer	<ul> <li>Funding awarded by NHMRC and in-vitro proof of concept; NCI funding for cancer program</li> </ul>
	Drug Delivery	Significant progress in cancer and protein programs
<u>Corporate</u>	Build international base to increase shareholder value	<ul> <li>Dow becomes a major shareholder</li> <li>Launch on OTCQX; US Analyst coverage</li> <li>R. Hazleton joins Board</li> </ul>
	Organization Development	<ul> <li>Streamline Management Team</li> <li>Strengthen development expertise</li> </ul>



#### Technology Overview

#### **Commercial Advantages of Dendrimers:**

- Key enabling nano-scale technology
- Synthetic macromolecules (1-15nm)
- Highly versatile technology:
  - drugs e.g. VivaGel<sup>®</sup> active SPL7013
  - drug delivery
  - siRNA/DNA delivery
  - diagnostics & materials applications
- Scalable chemical manufacturing process
- Can tailor features for tissue targeting
- Competitive Cost Of Goods
- Well tolerated





#### **Pipeline Pharmaceutical & Medical Products** Proof of Concept **Clinical Trials** Lead Sales **VivaGel**® HSV-2 prevention HIV prevention Condom coating **ADME Engineering** Therapeutic protein PK optimization **Drug Delivery – Small Molecules** Cancer therapeutic **Drug Optimization** Enhanced solublisation In-vivo and in vitro Diagnostics DADE BEHRING Stratus CS<sup>®</sup> (Cardiac Diagnostic) MRI imaging (Ovarian cancer & cardiovascular disease) **Life-science Products Proof of Concept** Prototype **Pre-launch** Sales **Gene Transfection Reagents** SuperFect<sup>®</sup> QIAGE siRNA/DNA Transfection Reagents MERCK PrioFect <sup>®</sup>



#### VivaGel<sup>®</sup> - Lead Product for Prevention of Sexually Transmitted Infections (STIs)

- VivaGel<sup>®</sup> is a topical vaginal microbicide being developed under two INDs for the prevention of HIV and genital herpes (HSV-2) in women
- Gel-based formulation with a nanotech dendrimer active (SPL7013), delivered via a vaginal applicator ; VivaGel<sup>®</sup> inactivates HIV and HSV-2 by binding to the virus preventing it attaching to the host
- Potent contraceptive activity in animal models

Herpes represents a major health issue:

- Affects 22% sexually active adults in the USA and 15-20% in Europe
- 40-50% of women in the U.S. by 2025 (estimated)
- Major risk factor for HIV: 38-69% new HIV infections in females attributable to HSV-2

Alternative prevention options are limited:

Prevention Options	Condoms	Abstinence	Vaccines	Microbicides (in development)
HIV	$\checkmark$	$\checkmark$	x	$\checkmark$
Genital Herpes	$\checkmark$	$\checkmark$	X	VivaGel <sup>®</sup>



#### VivaGel<sup>®</sup> Update - November 2007

- Male tolerance study complete: VivaGel® safe and well tolerated; presented at IAS July 2007
- Herpes study (San Francisco and Kenya) near completion
- Collaboration with Microbicide Trials Network established

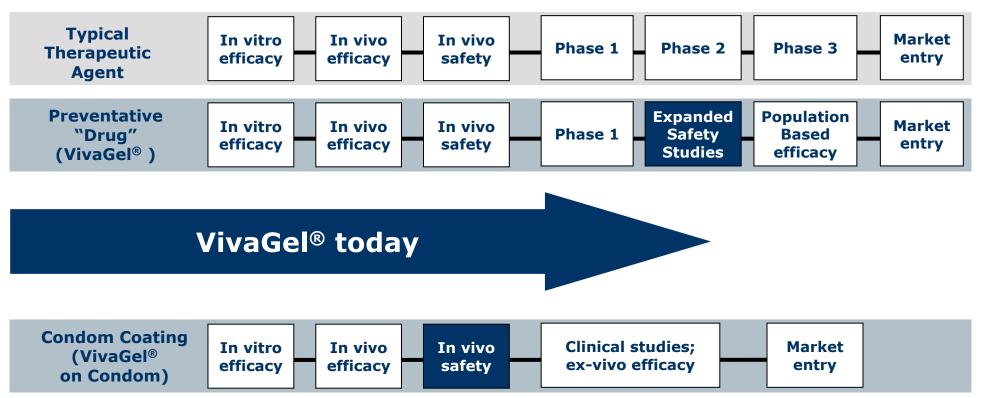


- Expanded safety study in sexually active women initiated (Florida and Puerto Rico); 7/40 participants enrolled
- Carcinogenicity studies in animals initiated and ongoing; Chronic toxicology and Genetic toxicity programs complete: well tolerated
- API scaled up to ~10kg scale; scale up to PIII/commercial scale underway
- VivaGel<sup>®</sup> Contraceptive mechanism of action elucidated further; fertilization inhibitor



#### VivaGel<sup>®</sup> - Development stage and plan

#### **PRODUCT TYPE**

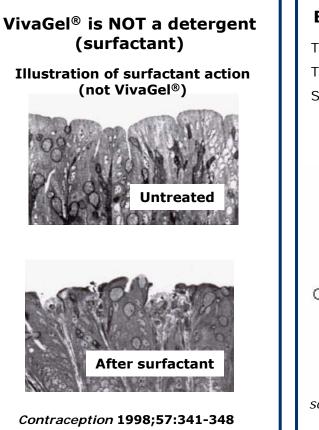




## **VivaGel® – The Condom Coating Opportunity**

#### **The Opportunity**

- Condom manufacturers have long recognised a demand for premium condoms with added protection
- Historically N9 (a surfactant) has been used
- N9 has been shown to <u>increase</u> risk of HIV and HPV (Human Papilloma Virus)
- N9 is thought to disrupt the vaginal wall, allowing entry to these viruses
- Condom manufacturers and regulators are actively seeking an N9 replacement
- VivaGel<sup>®</sup> may be the replacement of choice given it is not cytotoxic and its activity: antiviral (HSV-2/HIV) and contraceptive



#### **Branded Condom Market** Total Sales: US\$3.26B (2006) Top 4 sales: 70% of total Sales Growth: 4-5% annually **Chief Factor in growth:** awareness of AIDS and STIs others SSL 30% 35% Okamoto 9% Ansell Church & 15% Dwight 11%

source: "Condoms - a global strategic business report 2005"

Condoms represent a US\$3.26B market; VivaGel® offers a potential premium product



**VivaGel<sup>®</sup> – The Condom Coating Opportunity** 

- Co-development Agreement signed in October 2007 with SSL Plc (LSE:SSL), the makers of Durex, the market leading condom brand
- Retail branded condom sales are estimated as \$3.2Bi USD growing at 4-5% annually#
- SSL holds ~ 30% market share globally#
- Durex have an extensive range of condom types including other coated condoms and a range of lubricants marketed under the Play brand
- Agreement includes undisclosed milestone payments and sets out a co-development program for VivaGel<sup>®</sup> coated Durex condoms including regulatory and market development activities
- Another (unnamed) regional condom-coating deal announced in July 2007







*# source: Condoms - a global strategic business report 2005* 



#### Portfolio: siRNA Delivery – PrioFect®

**Concept:** Overcome the principal obstacle to the development of RNAi-based drugs ... delivery

#### Commercial opportunities for PrioFect®:

#### 1. Research reagent market(\$200 million)

- Licensed globally to EMD Biosciences\*
- Agreement includes royalties, supply and milestones
- First products to market in 2007

## 2. Therapeutic/delivery application

- Rights retained
- Significant commercial potential for an effective delivery agent
- Opportunity for multiple deals

#### Merck buys Sirna Therapeutics

By Bioperform Web Watch Posted 10/31/2006 11:01:00 AM

**The Associated Press** reports that Merck & Co. ha agreed to pay \$1.1 billion to buy Sirna Therapeutics Inc. Merck's \$13-per-share offer for the San

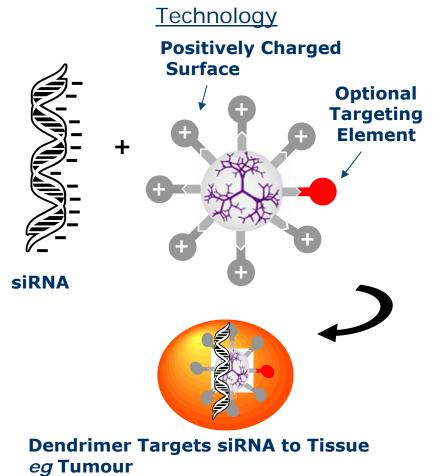


\* **EMD Biosciences, Inc**. is part of the Performance and Life Science Chemicals (PLS) division of **Merck KGaA**, a global pharmaceutical and chemical company with sales of EUR 6.3 billion in 2006.



## Portfolio: Dendrimer-Based Delivery of Nucleic Acids (eg. siRNA and DNA)

Concept: Targeted dendrimer delivers siRNA into specific tissues as a molecular therapeutic



## <u>Significance</u>

siRNA is a powerful novel method for specific gene silencing which is revolutionizing medical therapeutics.

One of the most critical factors for a successful siRNA mediated therapeutic is the ability to deliver the siRNA specifically to the target tissue.

Advantages of Starpharma Dendrimers:

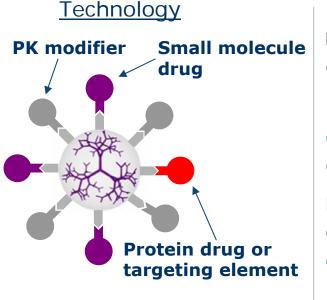
- Significant *in vitro* activity and acceptable toxicity profile.
- Non-interference with serum components.
- Ability to take advantage of passive or active targeting to specific tissues.
- Ability to produce at scale, to cGMP quality.
- Ability to control Pharmacokinetic properties.

Signed worldwide exclusive license and supply agreement for the *in vitro* research market with EMD Biosciences



## **Portfolio: Drug/Protein Delivery**

## **Concept:** Conjugation of drug to dendrimer to improve targeting and PK properties



**Potential surface groups:** 

- Small molecule or protein therapeutic
- Pharmacokinetic (PK) modifier
- Targeting element

## **Significance**

Potential for:

- Targeting to specific tissues, reducing offtarget effects to improve efficacy/ reduce toxicity/improve dosing.
- Improved PK and solubility of drugs.
- Product lifecycle management.

Especially applicable for protein therapeutics:

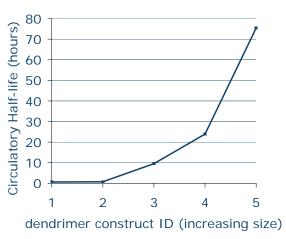
- Which have very short half life *in vivo*.
- Which are expensive, therefore desirable to reduce amount needed.

Opportunity for multiple deals.

Significant interest from potential pharmaceutical partners.

## Results

Addition of PK modifying units to the dendrimers surface significantly extends drug half life *in vivo*.



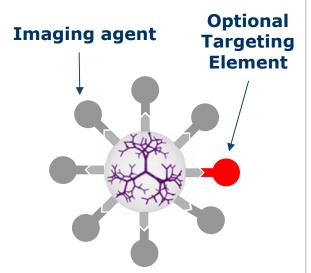
The global protein therapeutics market was valued at US\$57 billion in 2005



## Portfolio: Dendrimer-Based Targeted Imaging

**Concept:** Targeted magnetic resonance (MRI) imaging agent for detection and monitoring of diseased tissue

<u>Technology</u>



#### **Significance**

- Dendrimer loaded with MRI-contrast agent provides significantly better imaging resolution than contrast agent alone.
- Dendrimer scaffold also provides ability to link on specific targeting groups (e.g. Antibodies).

#### **Cardiovascular Application**

Improved product for the early detection of unstable atherosclerotic plaques in arterial walls.

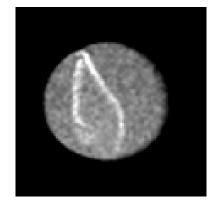
Funded by the NHMRC (\$327k) in collaboration with the Baker Heart Research Institute.

#### **Cancer Application (NCI funded)**

Improved MRI product for detection and monitoring of cancerous tissue.

#### **Results**

Dendrimer/MRI agent coupled to Thrombus (clot) Specific Antibody





#### DNT's Priostar<sup>®</sup> Dendrimers: significant progress in 2007

#### **Priostar® Life Science Reagent Products**

- Two product lines established:
  - PrioFect<sup>®</sup> transfection reagents licensed to EMD Merck
  - Priostar<sup>®</sup> life science reagents
- Materials under evaluation with several large life science reagent suppliers for signal amplification, solubilization, protein separation, and coatings/biosensors

#### **Priostar® Specialty Additives Products**

- Five product lines established
- Materials in product development evaluation with several major corporations as additives in such diverse fields as cosmetics, inks, household products, and plastics





#### Starpharma's existing commercial agreements for dendrimers

**Stratus CS®** Cardiac marker diagnostic licensed to Dade Behring

SuperFect<sup>®</sup> Gene transfection technology licensed to Qiagen



#### **STARBURST®**

Dendrimers commercially available via Sigma Aldrich

#### Priofect®

siRNA & DNA transfection reagents

# MD MERCK

#### VivaGel®

Co-development deal for Condom Coating

Co-development deal for Condom Coating (unnamed company)





SSL International plo



## **Key Financials**

	Year Ended 30 June (A\$M)			
	2006	2007#		
Revenue (excluding grants)	0.6	1.5		
Grant Income	6.4	8.1		
Net Loss after tax	(7.5)	(7.2)		
Net Increase (decrease) in Cash	6.1	(3.8)		
Cash Burn	(8.1)	(4.2)		
Cash Balance	14.3	10.1		
# 2007 includes DNT results as a wholly owned subsidiary from 20th October 2006				



#### Priority areas of focus for 07/08

- **1.** Progress VivaGel<sup>®</sup> clinical trial program towards efficacy trials for HIV & Genital Herpes and proof of concept for contraception. Complete other NDA requirements
- 2. Support the rapid development of the condom coating product with our 2 partners
- **3.** Increasing near term revenue from dendrimer products through:
  - Deals with life science reagent suppliers for signal amplification, solubilisation, and surface coatings/biosensors.
  - Deals with corporations as additives in fields such as cosmetics, inks, household products, and plastics.

# 4. Internal development and establish commercial partnerships - Drug Delivery, MRI and siRNA delivery

#### 5. Improving market engagement and price performance

- Parallel US and Australian investor engagement.
- Utilisation of major milestones for revaluation.



#### **Investment Summary**

- VivaGel<sup>®</sup> Vaginal Microbicide ; "first in class" for herpes prevention
- VivaGel<sup>®</sup> has already achieved significant milestones and support:
  - FDA Fast track status granted for HIV
  - >US\$26M of NIH funding for microbicide development
  - Only microbicide with NIH funding for genital herpes indication
- Commercially attractive condom coating opportunity 2 deals in place
- Deep pipeline of drug delivery, siRNA delivery and life science programs
- Generating revenue through existing royalties with launch of further licensed products due 2007/08
- US operations, growing US shareholder base and increasing profile



**Starpharma Holdings Limited** ASX: SPL OTCQX: SPHRY

Dr Jackie Fairley President and CEO +613 85322704

Further information: www.starpharma.com info@starpharma.com







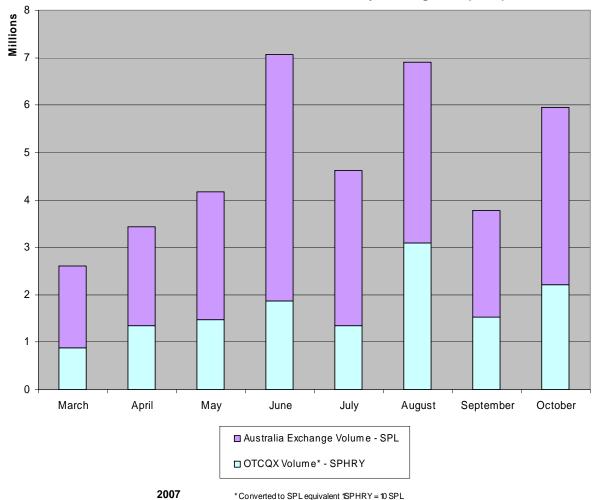
## **Supplementary Information**



Key Management	
Dr Jackie Fairley, President and CEO	<ul> <li>Over 17 years international business development and general management experience in pharmaceuticals and biotechnology</li> <li>Former senior roles with CSL and Faulding (Mayne Pharma)</li> </ul>
Dr Paul Barrett, VP Business Development	<ul> <li>Significant experience in marketing and business development in Australia and UK</li> <li>Broad life-science experience; competitive intelligence</li> </ul>
Dr David Owen, VP Research	<ul> <li>Extensive experience in medicinal chemistry and biochemistry</li> <li>Managing teams focussed on commercially directed drug discovery</li> </ul>
Dr Jeremy Paull, VP Development & Reg. Affairs	<ul> <li>Integral role to advancement of VivaGel clinical program</li> <li>Extensive NIH liaison, regulatory and product development experience</li> </ul>
Dr Robert Berry, President, DNT Inc.	<ul> <li>Founder of four technology companies and consortia</li> <li>Previously President and CEO of CMU Research Corporation</li> </ul>
Ben Rogers, Company Secretary & CFO	<ul> <li>Extensive experience in finance, corporate governance and HR management</li> <li>Member of Starpharma's start-up/IPO management team</li> </ul>
Nigel Baade, Financial Controller	<ul> <li>CPA qualified accountant</li> <li>Experience in the pharmaceutical and biotechnology industries</li> </ul>



## Monthly Trading Data (October 2007) ASX: SPL and OTCQX : SPHRY



ASX: SPL and OTCQX : SPHRY Monthly Trading Data (2007)



## **VivaGel®– Product Features and Performance**

VivaGel <sup>®</sup> Offers Several Key Advantages	<ul> <li>Market research indicates significant (international) user and payor demand for microbicide gels</li> <li>VivaGel<sup>®</sup> : "first in class" for Herpes</li> <li>Compelling HSV-2 &amp; HIV efficacy and potent contraceptive activity in animal models</li> <li>Significant NIH support for development</li> <li>Viruses appear not to develop resistance to VivaGel<sup>®</sup></li> </ul>
Excellent Results in Human and Animal trials	<ul> <li>Successfully trialled in both men and women under IND</li> <li>VivaGel<sup>®</sup> is currently in expanded safety human studies (PhaseI/IIa) in USA &amp; Africa</li> <li>VivaGel<sup>®</sup> shows excellent activity in relevant HIV &amp; HSV-2 strains in very stringent anima models</li> <li>Well tolerated in male and female subjects</li> </ul>
Excellent Drug Characteristics	<ul> <li>Lower development risk : Topical gel, external to body</li> <li>Full development package; well defined chemical entity, scalable</li> <li>Affordable - Low manufacturing cost</li> <li>Excellent IP position</li> </ul>



## **VivaGel<sup>®</sup> - Clinical Trial Status**

Study	No. Participants	Site(s)	IND Application	Status
Safety, tolerability and pharmacokinetic study of escalating doses of VivaGel in healthy women when administered vaginally, once daily for 7 days	37	Adelaide, Australia	Prevention of HIV	Complete
Safety and acceptability study of VivaGel when administered to the penis of healthy male volunteers once daily for 7 days	37	Melbourne, Australia	Prevention of HIV	Complete
Expanded safety and tolerability study of VivaGel in healthy young, sexually abstinent women when administered twice daily for 14 days	60	San Francisco, USA and Kisumu, Kenya	Prevention of genital herpes	Ongoing
Expanded safety and acceptability study of VivaGel in healthy young, sexually active women when administered twice daily for 14 days	40	Tampa, USA and San Juan, Puerto Rico	Prevention of HIV	Ongoing



## **VivaGel® : Significant Advantages Over Competitors**

	Competitor Category	Key Disadvantages	VivaGel <sup>®</sup> Advantages			
HSV-2	VivaGel $^{ extsf{w}}$ is the only microbicide being developed to prevent genital herpes					
	Surfactants/Detergents	<ul> <li>Ulceration possible</li> <li>Potential increased risk of infection</li> </ul>	<ul> <li>No surfactant properties</li> <li>Non-irritant</li> <li>Does not increase infection risk</li> </ul>			
	Sulphated Carbohydrates	<ul> <li>Not active against clinical HIV strains</li> </ul>	<ul> <li>Highly active against all HIV strains tested</li> </ul>			
HIV	Reverse Transcriptase Inhibitors and other anti-viral drugs	<ul> <li>Drug resistance is an issue</li> <li>Primary mode of action requires infection process to have begun</li> <li>Not active against HIV</li> </ul>	<ul> <li>Very high barrier to development of viral resistance</li> </ul>			
	Sulphated Polymers	<ul> <li>High cost of synthesis</li> <li>Poor characterisation of the drug substance likely to present regulatory issues</li> </ul>	<ul> <li>Excellent drug characteristics</li> <li>Low manufacturing costs</li> <li>Stable, well defined entity</li> </ul>			
	Acidity Control Agents	<ul> <li>Is acidity control sufficient protection as mono-therapy?</li> </ul>	<ul> <li>Potent activity against HIV and HSV-2 in animal models</li> <li>Non-irritant</li> </ul>			
	VivaGel <sup>®</sup> has significant competitive advantages					

Sector	Current Discussions with	Application	Market Size USD /Region
Research Reagents	Major Reagent manufacturers Major Reagent manufacturers	Fluorescent dye conjugate Dyes for <i>in vitro</i> diagnostics	\$100M /US \$2.5B /US
Automotive Lubricants	"Top 5" US Oil Company	Lubricant additive	\$1.7B /US
Specialty Additives	Large Construction Material Supplier	Plastics additive	\$5.5B /US
	Major Technology Company	Medical and dental adhesives and sealants	\$1.3B /US
Manufacturing	Multiple avenues of exploration	Specialty Adhesives	\$2.2B /US
	"Top 5" European electronics manufacturer	Electronics chemicals	\$3.7B /US
Pharmaceutical	Global Healthcare Company	Solublisation/Excipient	\$1.4B /Europe
Cosmetic Ingredients	Cosmetic Ingredient Suppliers	Solubilisation	\$6.2B /US
Water Treatment Chemicals	Water quality specialists	Water filtering/ remediation	\$3.1B /US