



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

**Melbourne; 14 November 2008:** 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.

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### 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® (SPL7013 Gel), a vaginal microbicide designed to prevent the transmission of STIs, including HIV and genital herpes.

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 with around 200 patents granted and applications pending - 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.

**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 Securities Exchange (ASX). The Bank of New York Mellon is the depositary bank. Starpharma's ADRs are listed on International OTCQX ([www.otcqx.com](http://www.otcqx.com)), a premium market tier in the U.S. for international exchange-listed companies, operated by Pink OTC Markets, Inc.

### 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.

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## **Chairman's Address**

### **Annual General Meeting**

**of**

### **Starpharma Holdings Limited, 14 November, 2008**

Welcome to the Starpharma AGM for the fiscal year 2007–2008, which marks my sixth as Chairman of the Board.

I am very pleased to be able to once again address you – our Company's shareholders - on the key highlights and milestones achieved throughout the year.

Three pursuits in particular have formed the focus of the Company's activities to great success. These are:

- the commercialisation of Starpharma's technology;
- the clinical development of VivaGel® as both a condom coating and a vaginal microbicide for the prevention of sexually transmitted infections; and
- the advancement of drug delivery applications of dendrimers.

Last year we were excited to report the early stages of Starpharma's partnering with SSL International - the world's leading marketer of condoms. Starpharma signed a co-development agreement for a VivaGel-coated condom which this year was progressed to a full stage licensing deal.

This was a significant achievement. The agreement secures SSL marketing rights to the VivaGel coated condom in most of the world including Europe and the USA, concurrently providing Starpharma with significant global coverage and an opportunity to build VivaGel brand awareness.

We estimate the deal will deliver the Company more than A\$100m in royalties, further milestone payments and development support, and is a relatively near-term opportunity. I'd like to congratulate Jackie and her team as I know the time that went in to converting the deal into a long term commercial opportunity.

As well as commercial success the clinical development of Starpharma's technology also produced favourable results during the year with the Company's researchers showing that the active ingredient of VivaGel - SPL7013 - already well into clinical development for HIV and genital herpes applications, is also active against human papillomavirus or HPV. This is an important development for human health as most cases of cervical cancer are caused by previous infection with HPV.

To date, all programs involving VivaGel have shared the underlying goal: To prevent the initial invasion by an infectious virus. Last year marked the first move from prevention to treatment of an existing infection, with the finding that VivaGel was active against bacterial vaginosis, a common cause of infection caused by the overgrowth of certain bacteria.

As our clinical research continues we are excited to see new possibilities for additional applications of VivaGel emerge, serving to further validate the widespread potential of Starpharma's technology.

We continue to investigate the research activities of for DNT to ensure an avenue to exploit the non-pharmaceutical applications of dendrimers. Whereas SPL7013 or similar molecules

are the basis of most of our pharmaceutical applications programs, the programs under way at DNT are using different members of the dendrimer class of molecules.

Our programs are wide-ranging, giving some idea of the versatility provided by the unique structure and properties of dendrimers. For example a contract with the US Department of Defence and in collaboration with the Central Michigan University Research Corporation has allowed us to undertake a program in which dendrimers are used to clean up contamination from ground water and to improve the properties of inks and cosmetics - highlighting the potential for our dendrimer technology to be used outside the realm of strictly medical applications.

Before closing, I can't ignore the current volatility of the domestic and global markets. We are operating in a financial market environment unprecedented in our lifetimes and certainly in the life of Starpharma. We are certainly not immune to the devastating effects this environment is having on company values. However whilst the public markets remain uncertain, we remain very certain about what we need to achieve with the company and VivaGel in the near future and we remain committed to the rapid pursuit of our commercial goals. I am confident the year ahead will be a significant one for Starpharma as we near the launch of our first VivaGel product.

Finally, I wish to thank the Starpharma directors, Jackie Fairley and her management team for their extraordinary efforts towards achieving our business goals. Their hard work has enabled Starpharma to achieve significant milestones this past year through the individual programs that are well under-way.

I also thank all members of the wider Starpharma team. We have confidence that the Company's progress will continue and prosper into the next fiscal year under their guidance and endeavour.

Thank you.

Peter T. Bartels  
Chairman



**Starpharma Holdings Limited  
Annual General Meeting  
CEO Presentation**

**ASX:SPL  
OTCQX:SPHRY**

**Dr Jackie Fairley  
CEO  
14 November 2008**



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## Achievements 2007-2008

### ▪ **Commercial Development**

- Signing of Durex® /VivaGel® Condom Coating Full Licence Agreement
- Signing of drug delivery research collaboration with Stiefel – world's largest privately-owned dermatology pharmaceutical company
- First commercial product launch of Starpharma's DNT Priostar® Dendrimers

### ▪ **Vivagel®: Clinical Development and New Indications**

- Clinical trial results: safe and well-tolerated in sexually abstinent women when administered twice daily for 14 days
- Commencement of VivaGel® Clinical Trial investigating surrogate for anti-viral efficacy (HIV&HSV-2)
- Expanded potential VivaGel® applications to prevention of HPV and Bacterial Vaginosis treatment

### ▪ **Pipeline and Application Development**

- Filed patents for new applications of SPL7013 - arthritis and cosmetic treatment
- Water purification technology contract for Priostar® with US Department of Defense
- Funding awarded for joint project with Baker/ IDI to co-develop arterial imaging agent
- Priostar® applications expanded to food science with Unilever agreement

## Starpharma's Commercial Partnerships

### DADE BEHRING

#### Stratus CS®

Cardiac marker diagnostic licensed to Dade Behring



#### SuperFect®

Gene transfection technology licensed to Qiagen



#### STARBURST®

Dendrimers commercially available via Sigma Aldrich



#### Priofect®

siRNA & DNA transfection reagents



#### VivaGel®

Co-development deal for Condom Coating

Co-development deal for Condom Coating (unnamed company)



#### Dendrimers

Stiefel: Drug delivery research collaboration



Unilever: Research Collaboration in Food Quality



## 2007/2008 Financials

	Year Ended 30 June (A\$M)		
	2006	2007 <sup>1</sup>	2008 <sup>1</sup>
Revenue (excluding grants)	0.6	1.5	1.7
Grant Income	6.4	8.1	8.2
Net Loss after tax	(7.5)	(7.2)	(7.5)
Net increase (decrease) in cash	6.1 <sup>#</sup>	(3.8)	(2.0) <sup>#</sup>
Operating Cash Outflow	(7.5)	(3.4)	(5.4)
Cash Balance	14.3	10.1	7.5

<sup>1</sup> Includes DNT results as a wholly owned subsidiary from 20 October 2006

<sup>#</sup> includes financing

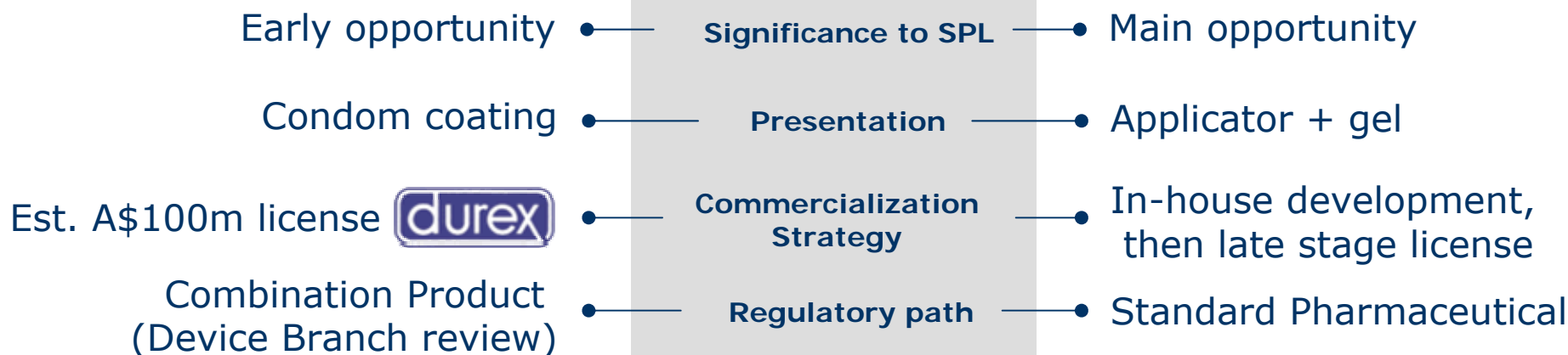




***“ An HIV vaccine may never be found ”***  
 Professor Baltimore, Nobel Prizewinner and authority on HIV.  
*The Times* February 2008

## VivaGel® - for the Prevention of Sexually Transmitted Infections (STIs)

### Two Products in Development





## VivaGel® Condom Coating License Agreement with Durex® - September 2008

Estimated total receipts in excess of A\$100m

### ▪ Starpharma to receive:

- royalties on SSL sales
- milestones
- development assistance

### ▪ Value to Starpharma:

- Estimated receipts in excess of A\$100m
- Nearer term revenue potential (device route)
- Enhancement of VivaGel® brand
- Commercial validation of VivaGel® and microbicides

### ▪ SSL International plc to market near-globally

- Durex® brand (#1 globally)
- >30% share of global market,
- Sell in more than 100 countries,
- Experience with other coated condoms regulatory approval

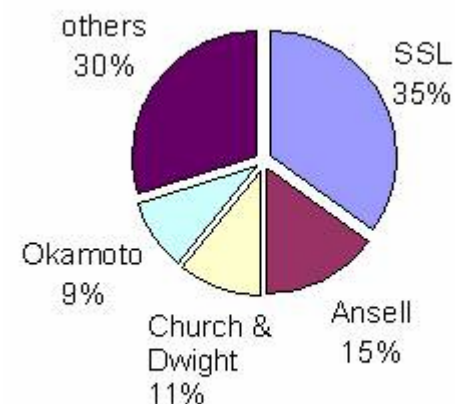
### Condom Market at a Glance

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



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

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



## VivaGel® Coated Condoms

Sample  
VivaGel® coated condoms  
from SSL's manufacturing  
line





## VivaGel® Clinical Trial Status – November 2008

Study	No. Subjects	Site(s)	IND Application	Status
Objectives: Safety, tolerability and PK Schedule: Administered vaginally, once daily for 7 days	37	Adelaide, Australia	Prevention of HIV	Complete
Objectives: Safety and acceptability Schedule: Administered to the penis once daily for 7 days	37	Melbourne, Australia	Prevention of HIV	Complete
Expanded safety and tolerability study Schedule: Administered twice daily for 14 days - sexually abstinent women	54	San Francisco, USA and Kisumu, Kenya	Prevention of genital herpes	Complete
Expanded safety and acceptability study Schedule: Administered twice daily for 14 days - sexually active women	60	Tampa, USA and San Juan, Puerto Rico	Prevention of HIV	Ongoing
Objectives: Assessment of local retention of SPL7013 and timescale over which the product retains antiviral (HIV, HSV-2) activity after (0-24 hours) vaginal administration	12	Melbourne, Australia	Prevention of HIV	Ongoing



## VivaGel®: Human Papilloma Virus (HPV) Activity

	HPV-5	HPV-6	HPV-11	HPV-16	HPV-18	HPV-31	HPV-45
<b>Genital warts</b>	Cutaneous infection	✓	✓				
<b>Carcinoma</b>				✓	✓	✓	✓
<b>Gardasil®</b>	✗	✓	✓	✓	✓	✗	✗
<b>Cervarix®</b>	✗	✗	✗	✓	✓	✗	✗
<b>VivaGel® SPL7013*</b>	✓	✓	TBD#	✓	TBD#	TBD#	✓

\*In-vitro results obtained at NCI and University of Queensland  
 #To be determined - further testing underway

**Activity in HPV strains not currently addressed by existing vaccines**



## VivaGel® :Treatment of Bacterial Vaginosis

### The Market Opportunity

- The most common vaginal infection worldwide
- Causes unpleasant discharge and linked to preterm birth and increased STIs
- Global market for topical vaginal treatments for BV: approx. US\$300M (~4m US R<sub>x</sub>)
- Shortcomings amongst current treatments:
  - Therapeutic Cure Rates  $\leq$  50% with high recurrence
  - Adverse effects: reaction with alcohol consumption; risk of antibiotic resistance; mutagenic effects observed; incompatibility with condoms
- VivaGel® clinical safety trials showed BV resolution in a number of human participants
- Lab tests show desirable differential action on bacterial strains

#### Proposed Development Plan:

Trial Description	Treatment period	Participants
Phase II (PoC)	7 day	~80-110
Phase III	7 day	~400

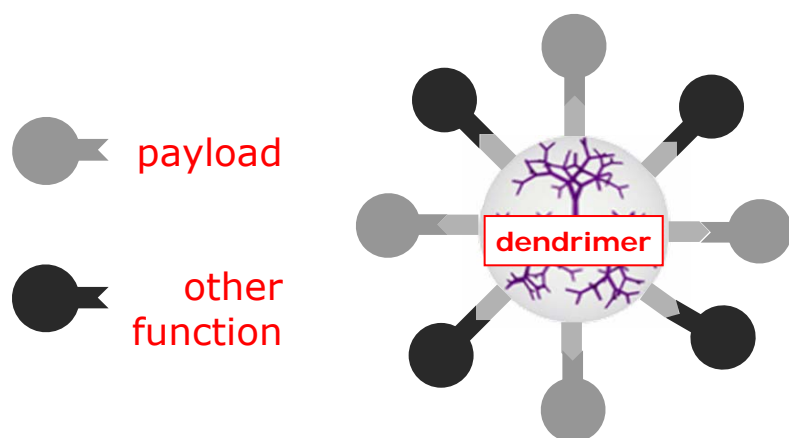


## VivaGel® Opportunities by Indication

Indication/ Product	Mode	Regulatory Approach	Current Stage
<b>HIV Gel</b>	Prevention	Drug	Phase IIa : existing clinical data applies across all indications
<b>HSV-2 Gel (genital herpes)</b>	Prevention	Drug	
<b>HPV</b>	Prevention	Drug	
<b>Contraception</b>	Prevention	TBD: Drug or device	
<b>Bacterial Vaginosis</b>	Treatment	Drug	
<b>Condom Coating</b>	Prevention	Combination Product (Device Designation)	Generation of combination data



## Small Molecule Drug Delivery



### Approach

Improve partner's existing small molecule drugs by attaching to dendrimer

### Benefit

Control drug **destination**

Control drug **duration of action**

Improve **dosing regimen**

Management of **product life cycle**

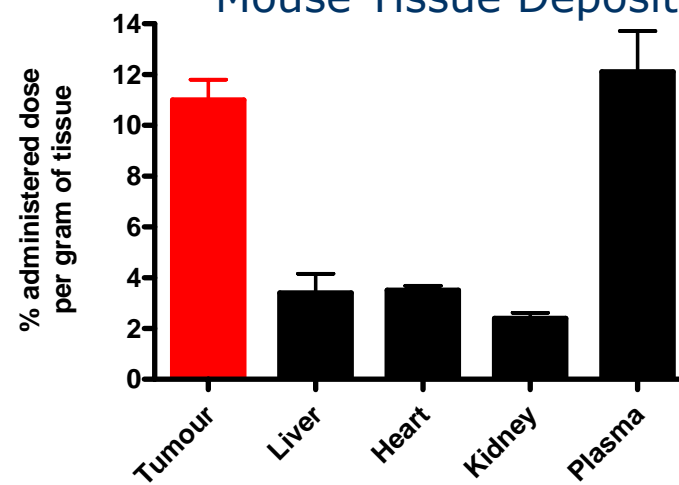
### Status

Proof of concept in Cancer **completing**

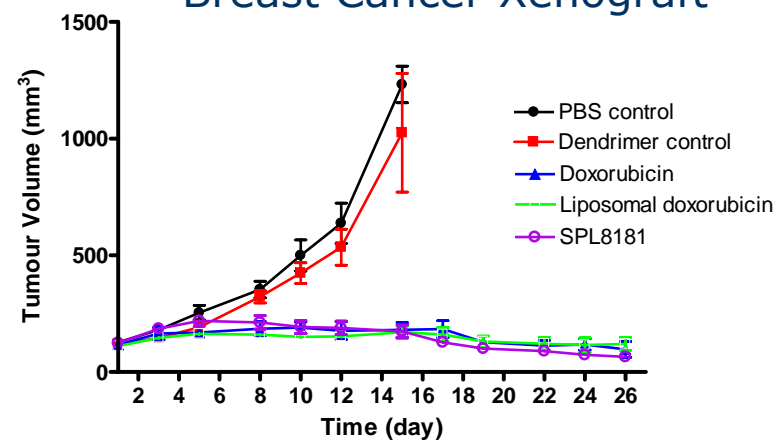
Dermal Partnership



### Mouse Tissue Deposition

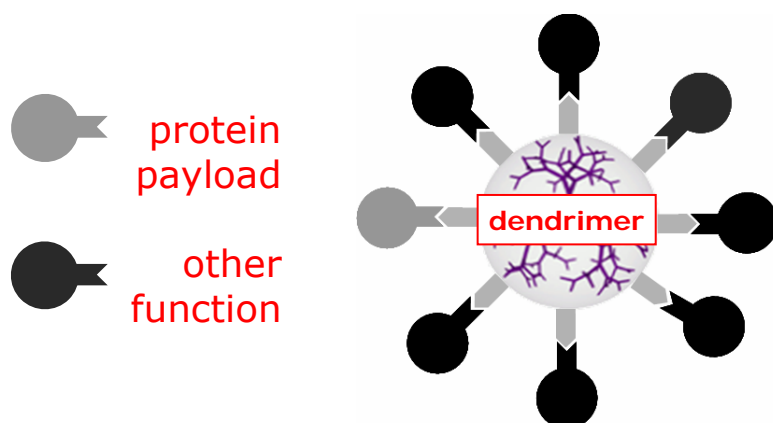


### Breast Cancer Xenograft





## Protein and Peptide Drug Delivery (ADME Engineering)



### Approach

Conjugate protein or peptide to functionalised dendrimer

### Benefit

**Control half life** of protein or peptide therapeutics

**Improve dosing regimen**

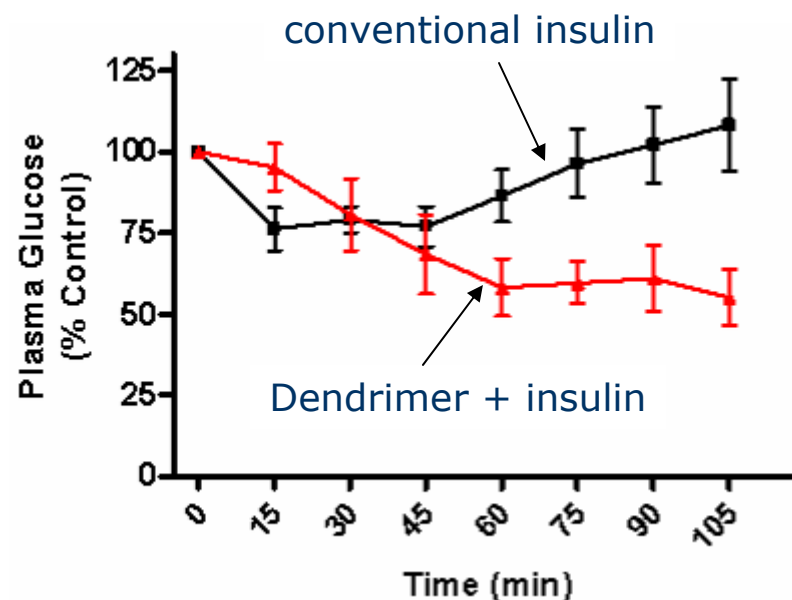
**Reduce protein metabolism**

### Status

*in vivo* using insulin for proof of concept **achieved**

Co-development program with undisclosed partner

### *In vivo* mouse model



**Dendrimer insulin shows prolonged suppression of blood glucose *in vivo***



## Portfolio: siRNA Delivery – PrioFect®

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

### PrioFect® : a delivery agent for siRNA (“Transfection”)

#### siRNA : a means to achieve RNAi

- ...potential foundation for a whole new class of specific and potent drugs against diseases that are difficult to treat.
- ...a natural mechanism that the body uses to inhibit expression of certain genes.

#### Commercial opportunities for PrioFect®:

1. Research reagent market(\$200 million)  
Licensed globally to EMD Biosciences\*



Agreement includes royalties, supply and milestones

**First product launched April 2008**

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. has agreed to pay \$1.1 billion to buy Sirna Therapeutics Inc. Merck's \$13-per-share offer for the San

#### Alnylam:

**“The alliance could be valued at over 1 billion US dollars.....”**

Roche website 2007



#### “Roche acquires Mirus...for RNAi delivery”

Transaction: USD125 million

Source: roche.com



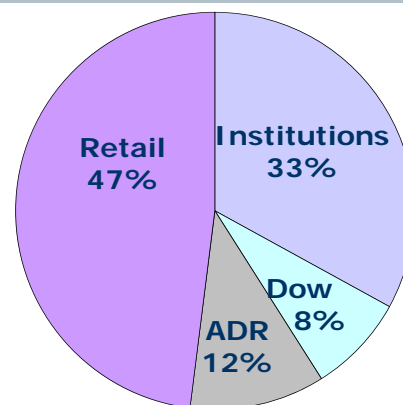
\* EMD Biosciences, Inc. is part of Merck KGaA, a global pharmaceutical and chemical company with sales of EUR 6.3 billion



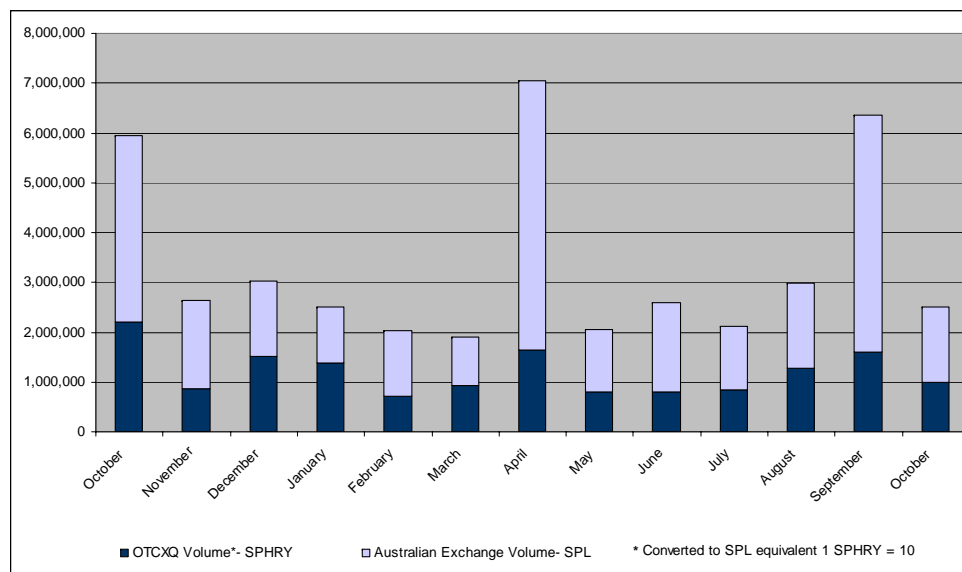
## US Share Trading and Ownership

- ~ 25% US shareholding
- Major shareholders include:
  - Acorn Capital
  - The Dow Chemical Company
  - Platinum Partners LLC
  - GoldmanSachs-JBW /Irrewarra
- OTCQX
  - Premium market tier for Level 1 ADRs
  - ~12% of issued capital
  - Monthly volumes ~1.7M shares\*
  - 15 market makers including Merrill, Merriman, UBS, Jefferies,
  - Most heavily traded Australian biotech Level-1 ADR

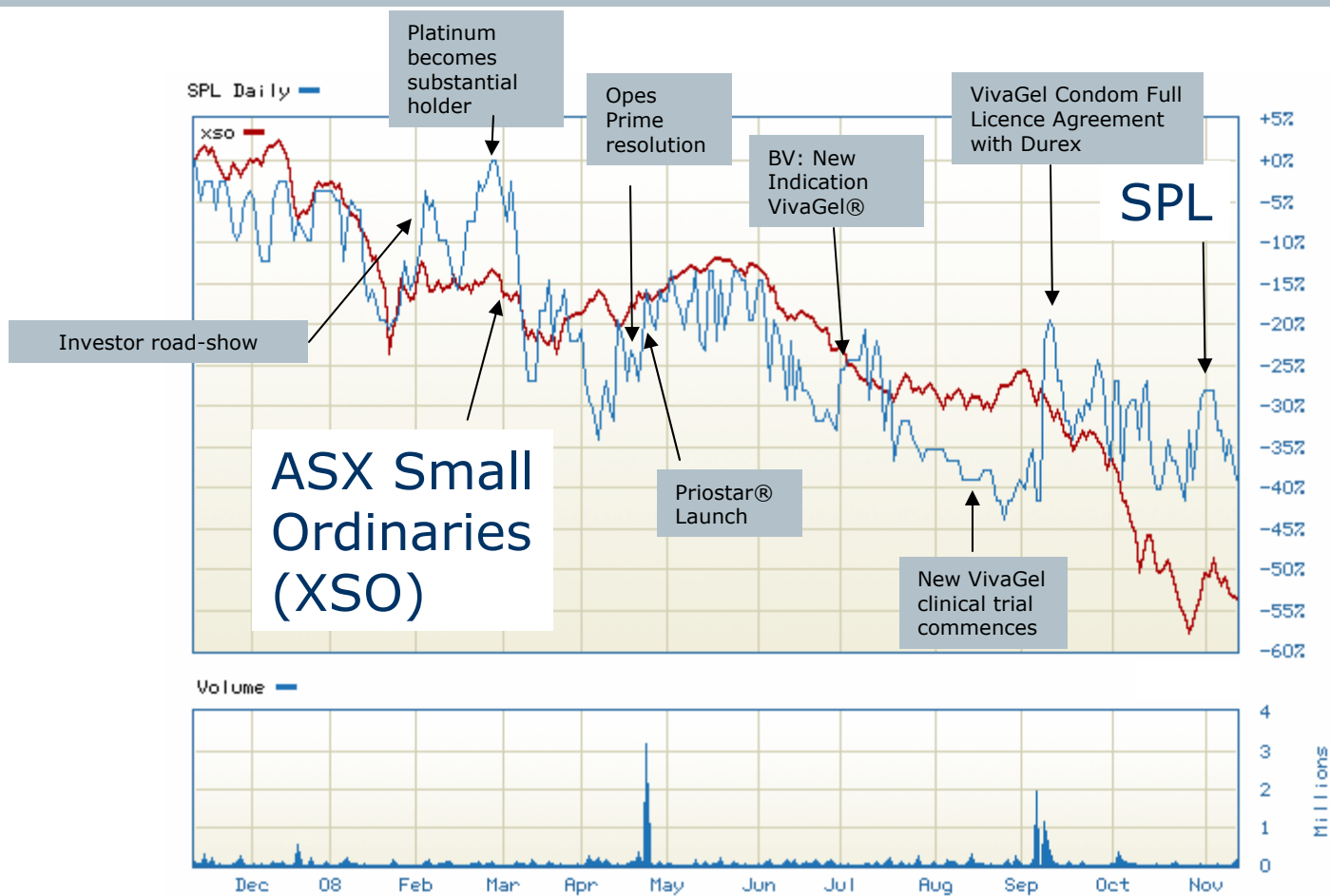
\* 1 ADR = 10 SPL shares



THE BANK OF NEW YORK MELLON



## Share Performance v's ASX Small Ordinaries (XSO) – 1 year





## Value Drivers for Starpharma 2008 and 2009

### **VivaGel®**

- ✓ Report positive results of UCSF/Kenya Expanded Safety/IIa trial
- ✓ Investigate other potential applications e.g. Bacterial vaginosis
  - Submit IND; Commence Phase II trial in Bacterial Vaginosis (BV)
  - Complete Expanded Safety/IIa trial trials and advance program to HIV & Herpes efficacy trials
  - Complete HPV activity spectrum
  - Complete VivaGel® Clinical Trial investigating surrogate for anti-viral efficacy (HIV&HSV-2)

### **VivaGel® Condom coating**

- ✓ Confirm regulatory designation
- ✓ Execute full license agreement
  - Complete development VivaGel® condom coating
  - Submit file for VivaGel® condom coating



### **Expand Dendrimer-based Commercial Relationships**

- ✓ Launch of PrioFect® products under the EMD deal
- ✓ Execute partnerships for pharmaceutical/delivery applications
- ✓ Investigate commercial potential for SPL7013 as hyaluronidase inhibitor
  - Execute further deals: drug delivery, siRNA delivery, life science/diagnostics.





## Starpharma Holdings Limited

ASX:SPL

OTCQX:SPHRY

**Dr Jackie Fairley**

**CEO**

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Further information:

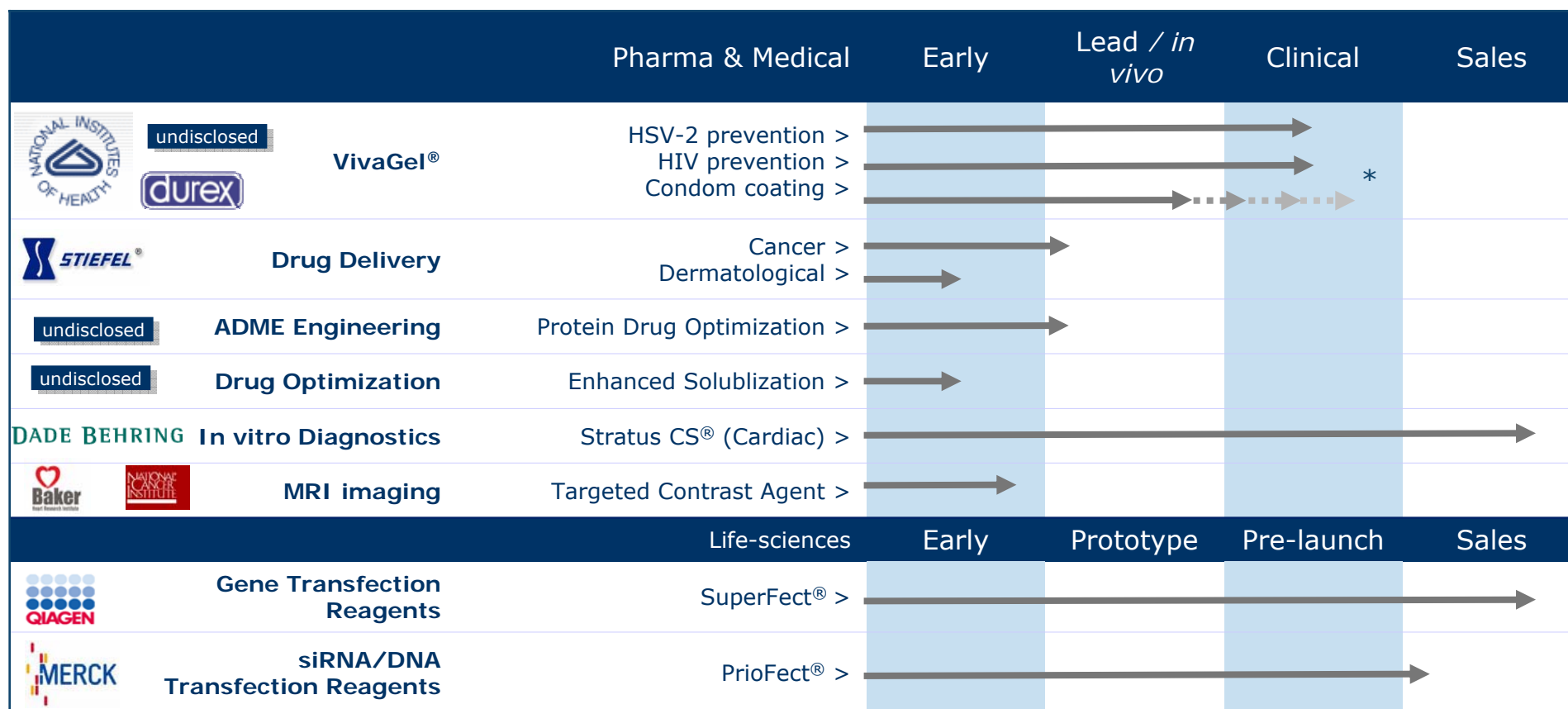
[www.starpharma.com](http://www.starpharma.com)

[info@starpharma.com](mailto:info@starpharma.com)



## Supplementary Information

## Pharmaceutical and Life Sciences Product Pipeline



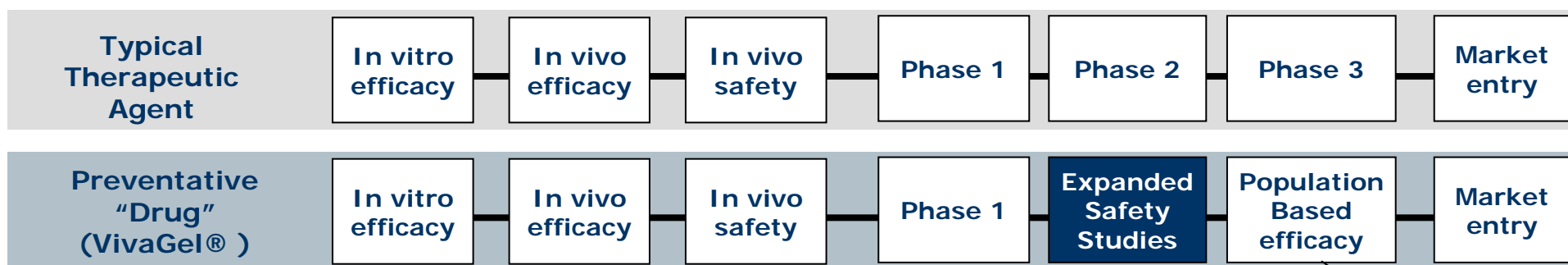
\*Condom coating: accelerated development program





## VivaGel® - Development stage and plan

### PRODUCT TYPE



**VivaGel® today**

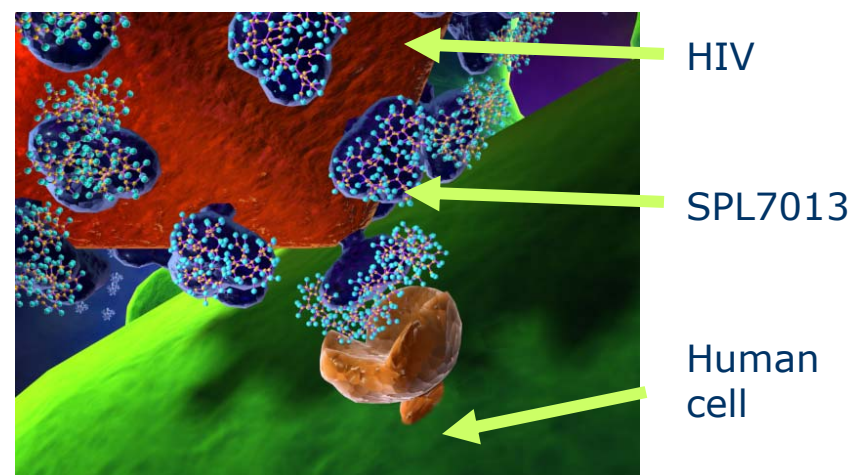
Trial design:  
Placebo, double blind  
HSV-2: 1500-2000  
HIV : ~4000





## VivaGel® - Microbicide for the Prevention of HIV and Genital Herpes

Product	Topical vaginal microbicide (+ condom coating)
Indications:	Under development: Prevention of STIs in women Two INDs - HIV and genital herpes (HSV-2)
Presentation:	Applicator delivered Gel (or coating for condoms)
Active:	Pharmaceutical grade Dendrimer (SPL7013)
Mechanism:	Dendrimer inactivates HIV and HSV-2 Binds to receptors on the virus; blocks cell entry
Motivation:	Vaccines & condoms ineffective; Significant and growing recognition that microbicides offer best prevention option
Other:	Fast Track Status; >\$26M NIH support Highly active in HIV & Herpes in stringent animal models Potent contraceptive activity in animals Activity shown in HPV; other pathogens under investigation



## Commercial Opportunity for Microbicides – HSV-2

### Genital Herpes represents a major health issue:

- Recurrent, lifelong viral infection
- Affects 22% sexually active adults in the USA and 15-20% in Europe
- 40-50% of women in the U.S. by 2025 (estimated)
- Existing prevention methods have proven ineffective and developmental vaccines disappointing
- Major risk factor for HIV: 38-60%\* new HIV infections in females attributable to HSV-2
- Alternative prevention options are limited
- VivaGel® is the only microbicide being developed for Herpes prevention



**70%**

Percentage of female US college students who would buy a microbicide with STI and contraceptive properties

**>20 million**

Women in US who would use a microbicide

Independent Microbicide market estimates > \$1.5-3 Billion

## Excerpt: Microbicide toxicities and efficacies in human cervical explant cultures \*

\*Comparing SPL7013 (VivaGel® active) and placebo against other microbicide candidates

Product	Toxicity <sup>a</sup>	Efficacy (%) <sup>b</sup>
Carraguard	No	1/2 (50)
N9	Yes	2/2 (100)
SPL7013 (VivaGel®)	No	2/2 (100)
Hydroxyethyl cellulose placebo	No	0/3 (0)

\* Cummins et al , Microbicide Testing in Cervical Explants  
**Antimicrobial Agents and Chemotherapy,**  
 May 2007, p.1770-1779: Vol. 51, No.5

<sup>a</sup> Histology was used to evaluate tissue sections. Products were considered toxic if damage (necrosis) to the epithelium or submucosa was observed.

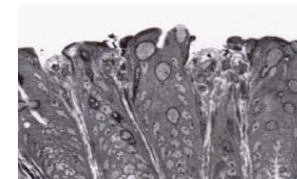
<sup>b</sup> Products were considered efficacious if tissues tested negative for p24 antigen by IHC. Values represent numbers of tissue explants with no detectable p24+ cells per number of explants tested.

### Advantage: VivaGel® is **NOT** a surfactant

Surfactants such as N9 have been shown to damage epithelial cells INCREASING the chance of HIV transmission. VivaGel is NOT a surfactant and has been found not to damage epithelial cells in human trials.



**Normal**



**After surfactant**

*Contraception 1998;57:341-348*



## Commercial Opportunity for Microbicides

### Estimated Market\* for Microbicides in Developed Countries

Market Penetration	Average Frequency of Use Per Annum		
	25x US\$M	50x US\$M	100x US\$M
2.5%	365	730	1,460
5.0%	725	1,450	2,900
10.0%	1,450	2,900	5,800

**\* Key assumptions**

291m women of reproductive age (15-49) in developed countries  
Unit sale price ~ US\$2; Usage rates according to published data

**Source:** World Bank; UNAIDs; EC AIDS survey; BCG analysis, various analyst and microbicide publications

### Industry surveys confirm strong consumer demand

**30 - 40%**

Percentage of female US college students who would buy a microbicide (without contraceptive properties)

**70%**

Percentage of female US college students who would buy a microbicide (with contraceptive properties)

**>20 million**

Women in US who would use a microbicide

Independent Microbicide market estimates > \$1.5-3 Billion

## VivaGel®: Significant Advantages Over Competitors

<b>HSV-2</b>	<b>VivaGel® is the only microbicide being developed to prevent genital herpes</b>
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	<b>Competitor Category</b>	<b>Key Disadvantages</b>
<b>HIV</b>	<b>Naturally Occurring Carbohydrates</b>	<ul style="list-style-type: none"> <li>Limited activity against clinical HIV strains</li> <li>Manufacture / scale up challenge</li> </ul>
	<b>Reverse Transcriptase Inhibitors and other anti-viral drugs</b>	<ul style="list-style-type: none"> <li>Drug resistance is a risk</li> <li>Not active against HSV-2</li> <li>May be absorbed into body</li> </ul>
	<b>Linear Polymers</b>	<ul style="list-style-type: none"> <li>High cost of synthesis/purification</li> <li>Poor characterisation of the drug substance likely to present regulatory issues</li> <li>Additional non-clinical studies required prior to NDA filing</li> </ul>
	<b>Acidity Control Agents</b>	<ul style="list-style-type: none"> <li>Is acidity control sufficient protection as mono-therapy?</li> <li>Additional non-clinical studies required prior to NDA filing</li> </ul>

<b>VivaGel® Advantages</b>
<ul style="list-style-type: none"> <li>Being developed to prevent both HIV and HSV-2</li> <li>Highly active against clinically relevant HIV and HSV-2 strains</li> <li>Very high barrier to the development of viral resistance</li> <li>Potent activity against HIV and HSV-2 in animal models</li> <li>Safe and well tolerated in human trials - males and females</li> <li>Excellent drug characteristics (cost, stability, well defined)</li> <li>Required (NDA) non-clinical studies are well advanced</li> <li>Invitro/in-vivo activity in other STIs – HPV and Chlamydia</li> </ul>

## RNAi Deals: Alnylam - Takeda 27 May 2008 (\$150M+)

### THE WALL STREET JOURNAL.

May 27, 2008, 9:34 am

#### Alnylam Deal With Takeda Embodies Two Trends In One

Posted by Jacob Goldstein



A drug licensing pact announced this morning has not one but two hot trends in drug deals these days: Japanese Pharma players making deals with U.S. companies, and big drug makers lining up to invest in biotech shops developing RNA-based drugs.

In today's deal, Takeda will pay Alnylam \$100 million upfront, plus another \$50 million in "near-term technology transfer payments." The deal gives Takeda exclusive Asia rights to most of what Alnylam is working on, and it gives Alnylam an option on a 50-50 partnership between the two companies in the U.S.

Facing some looming patent expirations and a tough regulatory environment at home, Takeda has been trying to buy its way into newer drugs and expand its presence in foreign markets. Just last month, the company announced a **\$9 billion deal for Millennium Pharmaceuticals**, a U.S. biotech that makes the cancer drug Velcade.

Last week, **Daiichi Sankyo** spent more than \$200 million on German drugmaker U3 Pharma; late last year, Eisai, another big pharma player in Japan, spent nearly \$4 billion to buy **MGI Pharma** of Minnesota.

Meanwhile, Alnylam has been getting lots of attention from Big Pharma players around the world who are hoping that **RNA drugs will be the next big thing**. Novartis already owns 13% of the company, the **WSJ** notes. And last year, **Roche** also cut a big deal with Alnylam. **GlaxoSmithKline** last month partnered with **Regulus**, a JV between Alnylam and Isis, another RNA-focused company.

Image: iStockphoto

### FierceBiotech

THE BIOTECH INDUSTRY'S DAILY MONITOR

#### Is Alnylam Roche's 'second Genentech'?

July 23, 2007

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The **incoming CEO of Roche** says he hopes that the company's partnership with Alnylam will create a "**second Genentech**" in the U.S. for the pharma giant. Alnylam opens up a "new front" in biotech, says Severin Schwan. Roche **is paying \$331 million up front** to gain access to Alnylam's drug discovery technology. It's another sign of the steady convergence of biotech and pharma, with a product-hungry pharma world looking to biotechnology companies to supply the products of the future. It's also a key indicator of the thriving market for new deals.

## Investment Summary

**VivaGel®**

**Development Stage:** Clinical – Expanded safety / Phase IIa

**Indications:** Prevention of transmission of HIV & HSV-2 (genital herpes)

**Two products:** Vaginal Gel + condom coating

**Forecast Market Size:** \$1.5B – \$3B p.a, untapped today; branded + public health

**Commercialisation:** Gel –license agreement during Ph III; Condom – 2 deals now

**Competitive Position:** No competitor on market; HIV/ HSV-2 combo leader

**External validation:** >US\$26M of NIH development funding;  
FDA Fast track (HIV)  
Licence and co-development deal with SSL



**Pipeline**

**siRNA (Priofect):** Enabling technology for RNAi - major new pharma area

**Drug Delivery:** Cancer; dermal; both small and protein drugs; imaging



DADE BEHRING

**Revenues**

**Royalties&milestone:** Dade (Siemens), Qiagen, Merck KgA and SSL plc.



**USA Presence**

**US ADR Listing; US operations; 25% US investors**



Existing Sales + Established Lead Development Product + Pipeline