starpharma

# SHAREHOLDER Update

JULY 2017

## Starpharma sells Agrochemicals business to Agrium for $35M cash

Starpharma recently announced the sale of its agrochemicals and Priostar® business (Starpharma Agrochemicals) to Agrium, one of the largest agribusinesses in the world, for A$35M cash consideration. Agrium is listed on the NYSE and TSE and has a market capitalisation of ~US$13 billion and 1,500 ag-retail outlets globally.

Starpharma Agrochemicals comprised key patents and technical know-how, and a small number of Starpharma staff dedicated solely to Priostar® dendrimers and agrochemicals operations. The sale was part of a planned strategy to maximise the value of, and monetise, Priostar® technology and does not impact on VivaGel® or DEP® IP or product opportunities. Starpharma had developed a range of value-added formulations utilising Priostar® to a stage where those products had high attraction value as differentiated products for a market-facing third party such as Agrium. With the net proceeds from the transaction, Starpharma's cash balance was greater than $60 million at 30 June 2017.

This sale enables Starpharma to focus resources and activities on its core pharmaceutical development programs, and places the company in an excellent financial position to expand and accelerate the development of its internal DEP® programs.

**Analyst view**

*"We believe the company is in a much stronger position to generate value from its assets as a result of this transaction."*

***Canaccord Genuity Analyst, Matthijs Smith***

*"This acquisition represents an exciting strategic technology platform for Loveland Products that will serve to further differentiate our proprietary product line and open new product development partnership opportunities".*

***Chuck Magro, President & CEO of Agrium***

*"This one is special. It's hard to find good technology that works… This is fairly unique because it will help us make considerable gains with product formulation and give farmers noticeably better results in the paddock."*

***Brent Smith, President of Loveland Products & Vice President of Proprietary Technology & Innovation of Agrium***

### Key transaction details

- A$35M cash consideration
- Sale amount is >4x book value of A$7.5M
- No conditions precedent
- No income tax payable
- No impact on VivaGel® or DEP® IP
- Advised by Macquarie Capital

*Left to right: Matthew Marshall, Agrium Corporate Development & Strategy Manager, Brent Smith, President Loveland Products & Agrium VP of Proprietary Technology & Innovation, Dr Jackie Fairley, Starpharma CEO, Nigel Baade, Starpharma CFO.*

## DEP® irinotecan outperforms irinotecan in multiple cancer models

Starpharma's proprietary DEP® irinotecan has demonstrated significantly improved anti-tumour activity and increased survival compared with irinotecan in a variety of human colon cancer models.

DEP® irinotecan is Starpharma's dendrimer enhanced version of the already marketed major cancer drug, irinotecan (marketed by Pfizer under the brand name Camptosar®).

Irinotecan is primarily used to treat colorectal cancer, which is a significant unmet need and attractive market. Camptosar® achieved peak sales of US$1.1 billion prior to losing patent exclusivity despite having a US FDA "Black Box" warning for severe diarrhoea and myelosuppression (including neutropenia).

In Starpharma's studies, a single treatment cycle of DEP® irinotecan administered on days 1, 8 and 15 significantly improved anti-tumour activity and enhanced survival compared to irinotecan (Camptosar®) in all cancer models tested.

In the **SW-620 colon cancer model**, DEP® irinotecan resulted in complete tumour regression and 100% survival in animals treated.

INTERNAL DRUG DELIVERY

## DEP® irinotecan

*(continued)*

Figures 1 and 2 show the efficacy (anti-tumour effect – mean tumour volume) and survival curves comparing DEP® irinotecan to irinotecan and vehicle control. DEP® irinotecan demonstrated markedly enhanced efficacy and survival rates compared to irinotecan and the differences were highly statistically significant ($P<0.0001$ and $P<0.0045$, respectively).

DEP® irinotecan was also shown to be very effective in another model – a colon cancer (HT-29) tumour model, which typically responds poorly to irinotecan (and did so in this study). In this model DEP® irinotecan treatment resulted in an 11.8-fold improvement in survival compared with irinotecan.

In this model, irinotecan did not achieve appreciable anti-cancer activity compared to vehicle (saline), whereas DEP® irinotecan exhibited a significant anti-cancer effect. DEP® irinotecan was significantly more effective than irinotecan ($P<0.0001$) for both enhanced efficacy and survival. DEP® irinotecan was also well tolerated in the HT-29 model.

Figures 3 and 4 show efficacy (anti-tumour effect – mean tumour volume) and survival curves comparing DEP® irinotecan to irinotecan and vehicle control. DEP® irinotecan demonstrated enhanced efficacy and survival rates compared with irinotecan and the differences were highly statistically significant ($P<0.0001$ and $P<0.0001$, respectively).

These impressive results for DEP® irinotecan are very promising and entirely consistent with the performance of other DEP® candidates from Starpharma's internal and partnered programs.

**Analyst view**

*"Preclinical data from [the] DEP irinotecan study impresses us… In our view, this data provides further validation of SPL's DEP platform. What is remarkable for us is that we have now seen similar results (preclinical improved efficacy outcomes) across various drugs and across different animal models."*

***Bell Potter Analyst, Tanu Jain***

***How does the DEP® technology work?***

*Starpharma uses its dendrimer technology to improve the performance of drugs through delivery. DEP® technology enables the drug to 'get to right place' and a formulation that is more 'patient friendly'. Starpharma's DEP® versions of anti-cancer drugs have been shown to reduce the toxicity and side effects of existing drugs such as neutropenia, and hair loss – which has been reported by chemotherapy patients as the most feared side effect of their treatment.*

**SW-620 Xenograft**

Figure 1

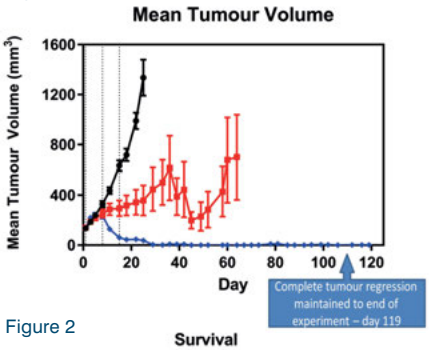
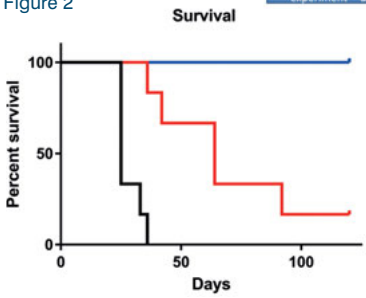



Figure 2




**HT-29 Xenograft**

Figure 3

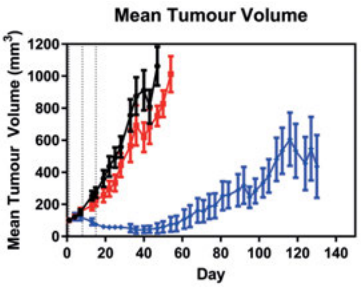
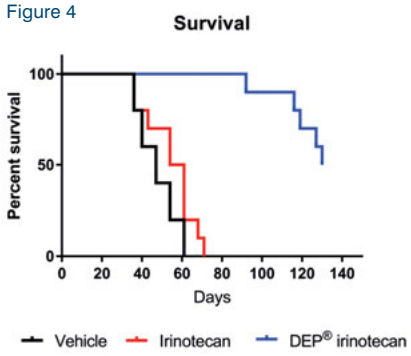



Figure 4




## DEP® docetaxel, DEP® cabazitaxel and scale-up facilities

Starpharma is developing several anti-cancer DEP® products internally (in addition to DEP® irinotecan). These products include DEP® docetaxel, Starpharma's most advanced internal DEP® program, which is currently in the late stages of a phase 1 clinical trial and will soon enter phase 2, and DEP® cabazitaxel, which is due to enter a clinical trial later this year.

DEP® docetaxel is a dendrimer-enhanced version of docetaxel (Taxotere®). DEP® docetaxel continues to show promising efficacy signals, with no neutropenia among patients in the final expansion phase of the phase 1 clinical trial. Starpharma plans to utilise an adaptive trial design to facilitate rapid transition into phase 2 following completion of the final few patients in the phase 1 cohort. Key preparations, such as product manufacture, and CRO selection, are already complete for a seamless transition to the DEP® docetaxel phase 2 trial.

Major progress has also been made in the DEP® cabazitaxel program with product manufacture, site and CRO selection now in the final stages ahead of phase 1 trial start later this year.

### DEP® Scale-up facilities

Starpharma has recently invested in in-house DEP® scale-up capabilities and facilities to accelerate the development of its internal candidates, such as DEP® cabazitaxel and DEP® irinotecan, as well as its partnered DEP® programs. The expansion of these facilities enables the rapid manufacture of preclinical and clinical grade materials, and greater flexibility in managing the costs and faster turnaround than with third-party manufacture. The new facilities have already been used to manufacture DEP® cabazitaxel for upcoming trials and further campaigns are underway.

INTERNAL DRUG DELIVERY

## » AstraZeneca pays US$2M DEP® milestone to Starpharma

In April, Starpharma announced the achievement of a key development milestone for its DEP® drug delivery technology in combination with an exciting proprietary oncology molecule from AstraZeneca, triggering a milestone payment of US$2 million.

This important milestone provides further validation of the utility and consistent performance of the DEP® platform and was achieved under the company's multiproduct DEP® license with AstraZeneca. Starpharma received the payment in June.

This is the final preclinical milestone prior to advancing the first AstraZeneca DEP® candidate to clinical trials and follows the completion of extensive testing and scale up activities.

**AstraZeneca DEP® license**

- First defined family of targets est. US$450M (US$126M + royalties)
- Subsequent products US$93M + royalties
- Tiered royalties on net sales on the resultant AstraZeneca DEP® products
- AstraZeneca funds all development and commercialisation costs.

*"…This important development milestone is indicative of the success we have seen in our DEP® program in partnership with Starpharma.*

*...DEP® technology has enabled us to advance a very exciting novel oncology agent towards the clinic. We're continuing to investigate the potential of DEP® more broadly across molecules within our oncology portfolio."*

***Dr Susan Galbraith, SVP, Head of the Oncology Innovative Medicines Unit at AstraZeneca***

Additionally, this Starpharma collaboration has been featured in AstraZeneca's *Innovation Medicine & Early Development (IMED) Unit 2016 Year in Review* report.

The report highlights this as a key collaboration that aims to:

*"...explore the benefits of Starpharma's dendrimer technology to improve the therapeutic index of drugs in AstraZeneca's Oncology portfolio and pipeline"…*

*"A number of targets in our Oncology portfolio are currently being evaluated with this technology."*

***AstraZeneca IMED Unit 2016 Year in Review***


VIVAGEL®

## » VivaGel® BV phase 3 results timing and commercialisation

Starpharma has completed its international, multicentre, Phase 3 clinical trials evaluating VivaGel® BV for the prevention of recurrent bacterial vaginosis (rBV).

The two double-blind, randomised, placebo-controlled pivotal trials were conducted at sites across the US, Europe, Canada, Mexico and Asia. The completion of these pivotal phase 3 trials is a significant milestone for Starpharma given the market for prevention of rBV is estimated at more than US$1 billion, there are currently no approved products and the company secured both Fast Track and Qualified Infection Disease Product (QIDP) designation for the product.

The phase 3 trial results are now expected to be available in late July/early August 2017. This timing has allowed for additional confirmation from the US FDA on the statistical analysis plan to ensure consistency of the trial data analyses with Starpharma's Special Protocol Agreement (SPA), prior to un-blinding and analysis of the data. The SPA granted by the FDA provides binding FDA agreement on the phase 3 trial design including the primary endpoint.

Following completion of the trials, data collation and routine blinded quality control review were undertaken and are now complete. The statistical analysis plan and bio-statistical programming are now being finalised, prior to the unblinding of the data.

Starpharma is also leveraging the FDA's recently granted QIDP designation and Fast Track status throughout this process. These designations carry significant benefits for regulatory approval and commercialisation, including increased dialogue with the FDA, priority regulatory review and an additional five years of market exclusivity.

In parallel, Starpharma is well-advanced in its preparation of the New Drug Application (NDA) submission for VivaGel® for the treatment and symptomatic relief of BV. This NDA is planned for as early as possible in the second half of 2017, with final pre-submission discussions with the FDA to be held in July 2017.

### Healthcare Investment Bank appointed for VivaGel® BV

Starpharma is also actively engaged in both global and regional negotiations for commercial rights to VivaGel® BV, with a number of term sheets under discussion. Negotiations have been positively impacted by the FDA recently granting Starpharma QIDP and Fast Track designations for both indications which has attracted further significant commercial interest in VivaGel® BV.

As part of this process, the Company has appointed a leading global healthcare investment bank to support the competitive process for negotiating commercial terms with potential partners for VivaGel® BV.

VIVAGEL®

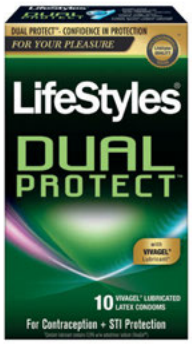
## VivaGel® condom launched in Canada

The VivaGel® condom was launched in April in Canada by Ansell under the LifeStyles® Dual Protect™ brand. This launch marks a major commercial milestone for the product given it is the first commercial launch in North America. The condoms carry the VivaGel® brand and Starpharma will receive royalties based on sales.

The VivaGel® condom is a world-first product based on innovative Australian technology and is the only condom of its type, providing barrier protection and incorporating Starpharma's proprietary antiviral compound, VivaGel®, in the condom lubricant. VivaGel® has been proven in laboratory studies to inactivate HIV (human immunodeficiency virus), HSV (herpes simplex virus) and HPV (human papillomavirus).

*"…a great example of a new and ground-breaking sexual-health product developed and commercialised by two Australian companies."*

***Jeyan Heper, Ansell's President & GM, Sexual Wellness Global Business Unit***




*The launch of LifeStyles® Dual Protect™ condom in Canada follows regulatory and marketing approval in Australia and New Zealand. Further approvals and launch are expected in the coming months, in other regions where licensing deals are in place.*

## Sale of Ansell's Sexual Wellness division

In May, Ansell announced it will sell its Sexual Wellness division (condoms, lubricants, devices, manufacturing sites) to a buyer consortium: Humanwell Healthcare, a multi-billion dollar listed Chinese pharmaceutical and healthcare company with diversified global operations (market cap approx. US$4B) and Citic, a well-known global venture capital firm.

Ansell has confirmed Humanwell has the ability to invest aggressively in the condom business and provide greater focus in this area. The strong Asian market presence of Humanwell will also add additional strategic opportunities for the continued market penetration of the VivaGel® condom in this fast-growing region and will complement Starpharma's existing deal with Shenyang Sky & Land Co for the Chinese Government sector.

CORPORATE NEWS

## Starpharma News & Events

### Agrium fast-tracks new ag-chem super polymer to boost herbicide firepower

Stock Journal


Herald Sun

CHEMISTRY RIGHT FOR $35M SALE

sky NEWS BUSINESS

Sky Business News' James Daggar-Nickson interviewed Dr Jackie Fairley regarding Starpharma's recent sale of its Agrochemicals business. Watch the full interview here: http://www.starpharma.com/starpharma_tv


Sky Business News' Ticky Fullerton interviewed Dr Jackie Fairley who highlighted the Company's VivaGel® portfolio and the DEP® drug delivery technology. Watch the full interview here: http://www.starpharma.com/starpharma_tv


CommSec's Tom Piotrowski interviewed Dr Jackie Fairley on the Company's recent highlights and upcoming milestones. Watch the interview here: http://www.starpharma.com/starpharma_tv

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