

Analyst

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Authorisation

TS Lim 612 8224 2810

Recommendation
Buy (unchanged)
Price
\$0.845
Valuation
\$1.15 (unchanged)
Risk
Speculative

GICS Sector
Pharmaceuticals & Biotechnology

Expected Return

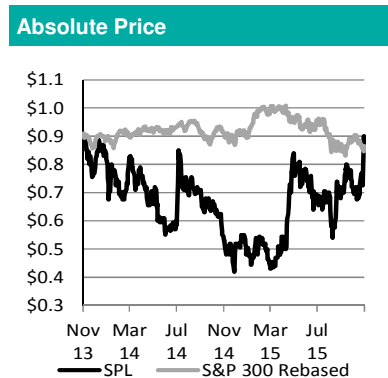
Capital growth	36.1%
Dividend yield	0.0%
Total expected return	36.1%

Company Data & Ratios

Enterprise value	\$244.7m
Market cap	\$270.8m
Issued capital	320.48m
Free float	100%
Avg. daily val. (52wk)	\$289,483
12 month price range	\$0.41- \$0.98

Price Performance

	(1m)	(3m)	(12m)
Price (A\$)	0.75	0.67	0.59
Absolute (%)	13.33	27.82	45.30
Rel market (%)	14.74	32.51	51.33



SOURCE: IRESS

Starpharma (SPL)

Speculative
 See Key risks on Page 10 &
 Biotechnology Risk Warning on Page 12
 Speculative securities may not be
 suitable for Retail clients

DEP platform Expanded, SPL offers a next generation targeted cancer drug

DEP platform expands to active targeting in hot ADC space

With its lead drug dendrimer-docetaxel, SPL has used its DEP technology to 'passively target' the tumour. Similar passive target approach is being used for compounds under its deal with AstraZeneca. SPL is now using an 'active target' approach with its DEP technology to develop antibody-drug conjugates (ADCs). ADCs are also called 'armed antibodies' and promise to deliver cytotoxic drugs directly to the target disease tissue, avoiding healthy tissue and therefore minimising side effects.

With its new Herceptin (antibody)-targeted DEP conjugate (TDC), SPL expands its DEP platform and joins the list of the companies working to improve cancer therapies by developing ADCs. ADCs are currently one of the hottest fields in drug research as apparent from the investment in this space and numerous deals over the last 3-5 years. Estimates project market for ADCs could grow to US\$9bn by 2023.

SPL offers a potentially improved next generation ADC

A mice study in ovarian cancer showed improved activity and survival benefit of treatment with SPL's Herceptin-targeted DEP conjugate over the two marketed agents from Roche (Herceptin and Kadcyła). We view the improved activity of SPL's TDC over the marketed agents as highly encouraging. It opens up additional partnering opportunities for the company. However, we view this as a first step for the company towards validating this candidate and its antibody-targeted DEP platform. We believe additional in vivo studies to characterise the safety & pharmacokinetic profile of the drug candidate are required to build on this positive preliminary data. SPL's approach promises to offer a differentiated approach from other traditional ADC platforms. However, its success will ultimately be dependent on clinical activity. Partnering discussions are underway. Additional validation through a partnership deal and through human clinical trials will help to realise the value of this opportunity.

Maintain Buy and Valuation of \$1.15

No changes to earnings. We retain our Buy recommendation and DCF valuation of A\$1.15/sh. Key catalyst - Results from Phase I DEP docetaxel trial (FY16).

Earnings Forecast

Year end 30th June	2014A	2015A	2016E	2017E	2018E
Revenue (A\$m)	4.5	4.3	9.3	54.6	45.4
EBITDA (A\$m)	-14.5	-18.6	-13.5	43.2	34.4
NPAT (adjusted) (A\$m)	-14.6	-19.0	-14.0	30.1	24.6
EPS (adjusted) (cps)	-5.15	-6.11	-4.32	9.28	7.57
EPS growth (%)	N/A	N/A	N/A	NM	-18.4%
PER (x)	N/A	N/A	N/A	9.1	11.2
EV/EBITDA (x)	-16.9	-13.1	-18.2	5.7	7.1
Dividend (cps)	0.0	0.0	0.0	0.0	0.0
Yield (%)	0.0%	0.0%	0.0%	0.0%	0.0%
Franking (%)	N/A	N/A	N/A	N/A	N/A
ROE (%)	-44.4%	-50.5%	-56.4%	53.5%	29.9%

NOTE: REVENUE INCLUDES R&D TAX INCENTIVES. FY16 & FY17 REVENUE ALSO INCLUDE POTENTIAL UPFRONT FROM DOCETAXEL, VIVAGEL SYMPTOMATIC RELIEF AND PREVENTION OF R-BV DEALS AND ROYALTIES. SOURCE: BELL POTTER SECURITIES ESTIMATES

New antibody DEP conjugate Expands DEP platform

Event: Starpharma has announced encouraging data from a preclinical study of its novel antibody-targeted DEP conjugate (TDC). The study was conducted in an ovarian cancer xenograft model and compared SPL's targeted DEP conjugate (using Herceptin as the antibody) against two positive controls Herceptin and Kadcyla and a placebo group which was saline.

DEP platform expanded

So far SPL has used its dendrimers/DEP technology to 'passively target' the tumour, taking advantage of the leaky vasculature associated with tumour tissue to enter the tumour cells. Both its lead drug DEP docetaxel (a dendrimer enhanced version of docetaxel currently in Phase I trial) and compounds under its deal with AstraZeneca (dendrimer enhanced novel oncology molecule from AstraZeneca and related compounds currently in pre-clinical studies) follow the 'passive target' approach.

The new candidate from SPL is different from the above because in this case SPL is using its DEP technology to actively target the tumour by attaching a targeting molecule (in this case an antibody called Herceptin) to the dendrimer construct.

Hence, with this new antibody-targeted DEP conjugate, SPL expands its DEP platform and joins the list of the numerous companies working to improve cancer therapies by developing antibody drug conjugates or ADCs.

ADCs or armed antibodies development – A hot space

ADCs are currently one of the hottest fields in drug research as apparent from the investment in this space and numerous deals over the last 3-5 years.

An ADC combines a targeting antibody (specific to a cancer-specific antigen), to a cytotoxic chemotherapeutic agents. ADCs promise to deliver cytotoxic drugs to the target disease tissue, avoiding healthy tissue and therefore minimising side effects.

The approval and subsequent success of two targeted ADC's Seattle Genetics' Adcetris and Roche/Immunogen's Kadcyla have spurred interest and investment in this space. Both these drugs had combined sales in excess of US\$1bn last year. Estimates project market for ADCs could grow to US\$9bn by 2023.

Roche, Immunogen and Seattle Genetics are currently the most advanced players in this space, with several multi-million dollar partnerships in place. Pfizer, Novartis, Celgene, AstraZeneca are all building their ADC pipeline through partnering.

AstraZeneca bought Spirogen an ADC developer for \$440m in 2013. Celgene after 2 years of partnering with Sutro Biopharma, last year expanded its partnership to more than \$1bn and took an option to buy Sutro.

SPL's DEP technology offers a potentially improved next generation ADC

Several new ADC technologies in development are focused on trying to revolutionize how the antibody is attached to the chemical linker and how the drug payload is bound to the targeting antibody. We believe SPL's DEP technology ticks off on some of the key

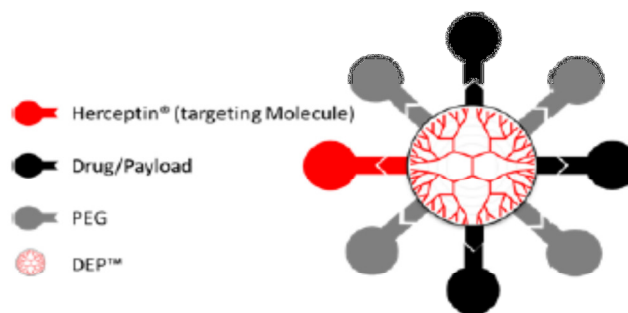
characteristics required for an improved next generation ADC and serves to differentiate it from other ADC platforms currently in clinical development:

- **More drug loading with improved homogeneity and stability:** Most traditional ADC approaches conjugate or link the antibody and the cytotoxic drug payload directly, which limits the amount of drug payload, impacts antibody stability and also results in heterogeneity. This is also the reason that traditional ADC approaches have been known to lack product homogeneity. SPL's approach on the other hand uses its dendrimer scaffold which has multiple points of attachment and instead of linking the antibody and payload directly, acts as a backbone to which both antibody and the drug payload are loaded. This approach makes it possible for SPL to have a higher drug loading per antibody without compromising the PK and physiochemical properties of the ADC and therefore to create a homogeneous drug. Dendrimers are synthesised using standard chemical processes. Since the synthesis process is controlled, dendrimers have a high degree of uniformity. The spherical structure of the dendrimers vs. some of the linear polymer approaches also removes the possibility of interference in binding due to potential overlap of conjugation sites;
- **More choices in drug payload and potential application beyond cancer:** By not attaching the drug payload directly to the antibody chemically, the dendrimer scaffold approach putting the dendrimer scaffold between the payload and the antibody allows greater flexibility to SPL in its choice of drug payload. It also opens up the possibility of SPL's ADCs being used for indications beyond cancer;
- **Flexibility in targeting moiety choice:** SPL's DEP technology is also not limited to full size monoclonal antibodies. It can be conjugated to almost any targeting moiety, such as an antibody fragment or other biologics.
- **Possible for combination drug loading:** According to SPL it can scale up the number of active payload molecules based on the size of the dendrimer as required. This fact along with the antibody not being directly linked to the drug payload, makes it possible for SPL in our view to explore targeted delivery of combination chemotherapy agents.

Summary of the pre-clinical study with SPL's TDC

- SPL's proprietary targeted DEP conjugate in this animal study consists of a dendrimer scaffold which is made of the amino acid lysine. The targeting group (the monoclonal antibody trastuzumab /Herceptin) and an anti-cancer drug (referred to as payload) is conjugated to the poly-lysine dendrimer scaffold. The anti-cancer drug or payload used by SPL in its antibody TDC is not in the public domain. We understand that SPL considers it an important part of its IP. We note that the choice of the cytotoxic agent is a crucial aspect of an ADC and can determine and differentiate its efficacy.
- SPL uses a linker between the dendrimer scaffold and the pharmaceutical drug and the antibody to control the distribution and delivery of the anti-cancer drug to the target tumour cell. The linker used by SPL in its antibody TDC is not in the public domain. We understand that SPL considers it an important part of its IP. We note that the type of linker is a crucial aspect of developing an antibody drug conjugate (ADC). The linker plays an important role in stabilizing the ADC in circulation and therefore determining the therapeutic index of the drug and in controlling its side effects or off-target toxicities.
- Polyethylene glycol (PEG) is also attached to the dendrimer scaffold. It helps the scaffold from escaping detection by the immune system.
- SPL's TDC is armed with multiple number of active payloads per antibody per DEP molecule. According to SPL it can scale up the number of active payload molecule based on the size of the dendrimer as required. This provides it flexibility as well as higher drug loading capacity. Higher drug loading is likely to increase the potency of SPL's TDC and could be an important advantage over standard ADCs.

Figure 1 - SPL's targeted DEP conjugate with full length antibody (Herceptin) used in the study



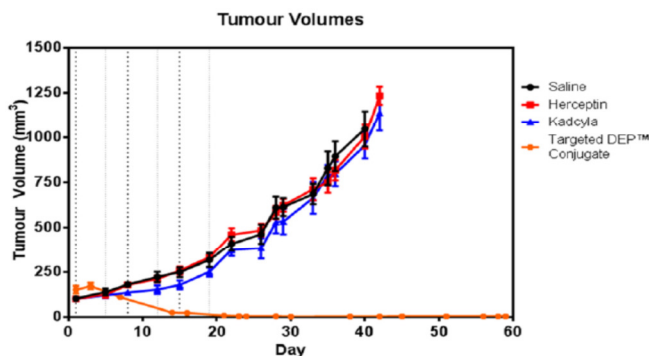
SOURCE: COMPANY DATA

- SPL's TDC is thought to work in a similar fashion to Roche's ADC Kadcyla with the added advantage of passive targeting through tailoring the size and chemical properties of the dendrimer allowing it to reach a specific tissue. SPL's dendrimer scaffold is used as a carrier of the antibody and anti-cancer drug to the tumour tissue. The targeting antibody Herceptin finds HER2-positive or HER2-expressing cells. It then binds to the HER2 receptors on the surface of cells, blocking signals which cause the cell to grow and calling on the body's immune system to destroy the cells. The cancer cells then also absorb the scaffold along with the antibody and the anticancer drug. The anticancer drug is then released inside the tumour which kills the cell.
- In this study NOD-SCID (non-obese diabetic severe combined immunodeficiency) mice model was used. This strain of mice are immune compromised or immunodeficient. These mouse strains exhibit very high take rates for xenografts.
- SKOV-3 a human ovarian cancer cell line with epithelial-like morphology known to overexpress HER2 protein was injected subcutaneously into the flank of the mice and the tumour was allowed to grow to a particular size. We note that the SKOV-3 human ovarian carcinoma cell line is one of a few distinct ovarian preclinical models with HER2 gene amplification, p185HER2 overexpression and sensitivity to the effects of trastuzumab.
- In this SKOV-3 ovarian cancer xenograft model, 5 to 6 mice per group were dosed with Saline or 10 mg/kg dose of Kadcyla (Roche's Herceptin targeted ADC) or 20mg/kg dose of Roche's Herceptin or SPL's targeted DEP conjugate (dose not revealed by SPL).
- The dosing was once weekly for 3 weeks for all groups except for the Herceptin group which was dosed twice weekly for 3 weeks.
- The mice have been followed up to 60 days, with additional follow up ongoing for the mice still surviving.
- The study was conducted at the Peter MacCallum Cancer Centre, one of the leading cancer research centres.

Key findings from the preclinical study

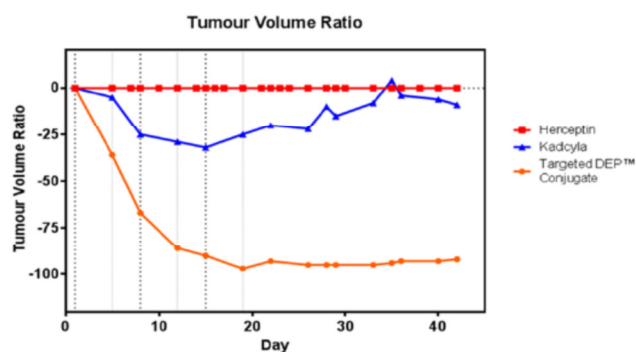
- Mice treated with SPL's targeted DEP Herceptin Conjugate had no evidence of tumour (complete regression) after last dose, with treatment effect maintained out to 60 days. Comparatively in mice treated with Kadcyla, only tumour stasis was observed during treatment with maximum inhibition of 32% at day 12. As soon as treatment was stopped the tumour started regrowing. Herceptin was found to be almost inactive in this mouse model, with a maximum inhibition of 10% at Day 5.

Figure 2 - Improved efficacy with SPL's targeted DEP Herceptin Conjugate in mice ovarian cancer model



MOUSE XENOGRAFT (SKOV-3 OVARIAN CANCER IN NOD-SCID MICE); N= 5/6 PER GROUP ; P= 0.0011
SOURCE: COMPANY DATA

Figure 3 – Higher tumour regression with SPL's targeted DEP Herceptin Conjugate in mice ovarian cancer model

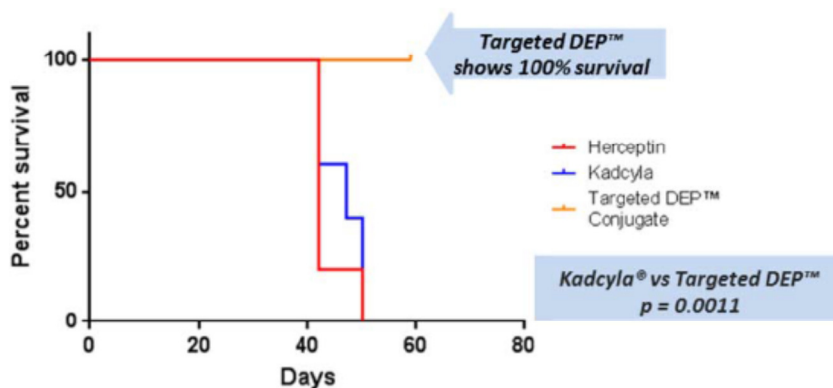


MOUSE XENOGRAFT (SKOV-3 OVARIAN CANCER IN NOD-SCID MICE); N= 5/6 PER GROUP
SOURCE: COMPANY DATA

- 100% of the mice treated with SPL's targeted DEP Herceptin Conjugate were alive at Day 60. We understand the mice which are still surviving are being followed up beyond 60 days to ascertain the length of time the treatment effect is maintained.

Comparatively none of the mice treated with Kadcylla or Herceptin were alive by Day 50 (See Figure 4 below).

Figure 4 - Improved survival rate with SPL's targeted DEP Herceptin Conjugate in mice ovarian cancer model



SOURCE: COMPANY DATA

Our comments on the study and its findings

We view the improved activity of SPL's targeted DEP Herceptin Conjugate over the two marketed agents from Roche (Herceptin and Kadcylla) as highly encouraging. However, we view this as a first step for the company towards validating this candidate and its antibody-targeted DEP platform. We believe additional in vivo studies and characterisation of the pharmacokinetic profile of the drug candidate pre-clinically are required to build on this positive preliminary data. Additional validation through a partnership deal and through human clinical trials will help to realise the value of this opportunity.

The SPL release mentions the following statement 'We are very excited by these latest results for our targeted DEP™ conjugates and feedback from commercial parties on this new data has been very positive indeed. Discussions are now underway with a number of pharmaceutical companies in relation to this targeted DEP™ conjugate and the application of Starpharma's targeted DEP™ platform to their proprietary drugs.'

The above statement suggests that SPL has shared the details of this study and data with potential partners and received encouraging feedback. It also implies that SPL has already

initiated partnering discussions around both the Herceptin -targeted DEP conjugate and also around the application of its targeted DEP technology. Hence, we may see another AstraZeneca type of deal for the TDC technology as well as a potential collaboration on the specific Herceptin-TDC drug.

In our view, for the specific candidate SPL is likely to conduct additional preclinical studies to add more substance to the licensing package and perhaps adopt the same approach as the dendrimer-docetaxel drug, moving it into the clinic before partnering to realise better value.

We discuss some aspects of the study design and findings below:

- **Lower response to treatment seen in this study with Herceptin and Kadcylla compared to some published studies:** In some published historical studies in SKOV-3 xenografts in mice, both Herceptin and Kadcylla have shown to reduce tumor progression.

One study¹ which used 2 doses of Kadcylla (30 mg/kg and 10 mg/kg) in a subcutaneous SKOV-3 xenograft model also indicated significant anticancer effects of Kadcylla. In this study notably tumors were completely eradicated in the 30 mg/kg group and no regrowth was observed after the termination of the treatment. We note however that this study possibly uses a different nude mice strain than what SPL has done. There is also variability in the dosing of Kadcylla.

There are 5-6 different histological subtypes of the ovarian cancers from which the SKOV-3 xenograft is derived. We do not know what histological subtype was used in SPL's study. **The difference in the histological subtypes used in SPL's study and those in published studies may account for the difference in efficacy seen with Herceptin and Kadcylla.**

In SPL's study however, we understand that the cell line used in between treatment groups was the same. Given the antibody across all 3 treatment groups was the same i.e. Herceptin and we did see better efficacy in the Kadcylla group vs. the Herceptin group, **the likely improvement in efficacy seen with SPL's targeted DEP conjugate over Kadcylla is likely due to the cytotoxic drug payload.** Kadcylla has the cytotoxic agent DM1 while the drug payload of SPL's TDC is not in the public domain.

- **Herceptin and Kadcylla both are not approved for ovarian cancer indication:** We note that both Herceptin and Kadcylla are unapproved for ovarian cancer. They are only approved for breast cancer and gastric cancer indications.

Hence, while the data from the study released by SPL is very encouraging, we believe that this is the first step and the likely course for SPL should be to try its Herceptin-TDC in multiple other indications in vivo including those that the two marketed drugs are approved for, in order to further validate the superior efficacy of its drug over the 2 marketed agents.

- **Pharmacokinetic (PK) profile undisclosed as yet, characterisation will build value:** Based on the favourable PK profile seen in-vivo with the dendrimer-docetaxel candidate, we believe PK characterisation of SPL's Herceptin-TDC will help to understand and differentiate its properties from other competing ADC platforms. We believe this data will add value to SPL's partnering discussions around the platform and this particular TDC candidate. Specifically we are looking for more information around the plasma half-life, tumor-specific accumulation, therapeutic index etc.
- **Safety profile to be characterised:** One of the significant attraction for SPL's dendrimer-docetaxel drug is its lack of dose limiting side effects compared to traditional docetaxel reported so far from both pre-clinical and interim Phase I data. One of the

¹ Eradication of growth of HER2-positive ovarian cancer with trastuzumab-DM1, an antibody-cytotoxic drug conjugate in mouse xenograft model. Yu L, Wang Y, Yao Y, Li W, Lai Q, Li J, Zhou Y, Kang T, Xie Y, Wu Y, Chen X, Yi C, Gou L, Yang J.

challenges that ADCs suffer from is off target toxicity. Hence, we look forward to seeing more details on the safety profile of SPL's Herceptin-TDC, which could help us to differentiate SPL's product with some other approaches. We also look to get more visibility on the dose used in the present study.

In summary, we view the preliminary data on SPL's new Herceptin-targeted DEP conjugate as encouraging. It expands SPL's DEP platform and opens up additional partnering opportunities for the company. SPL's approach promises to offer a differentiated approach from other traditional ADC platforms. However, its success will ultimately be dependent on clinical activity. We look forward to additional pre-clinical studies to better characterise the drugs PK and safety profile and ultimately translation of the preliminary anti-cancer activity seen in-vivo in the clinic. With partnering discussions underway, we also look forward to further validation through a partnership deal. There is no change to our forecasts and valuation for Starpharma.

Valuation

We value Starpharma using a risk-weighted DCF. Our DCF model uses risk-adjusted revenue numbers based on the probability of success (of reaching the market) assigned to Starpharma's pipeline products. The probability of success we attribute to each drug candidate is dependent on its development phase. Our DCF valuation model is based on a WACC of 16.0% and a terminal growth rate of 1%.

Table 1 - Summary of Valuation

Forecasts	Base case
Enterprise Value from DCF (AUDm)	357.8
Add: Cash at end FY16E (AUDm)	16.2
Less: Debt at end FY16E (AUDm)	0.0
Equity Value (AUDm)	374.0
Total diluted shares at end FY16E (million)	325.3
Value per share (AUD)	\$1.15
Current Share price (AUD)	\$0.85
Expected Capital Growth	36.1%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Table 2 - SPL- Probability-Weighted Sum-of-parts Valuation Summary

Asset	Stage	First Fiscal Year of sales (Est.)	Peak Market share	Peak Sales Global (US\$m)	Probability of success	Probability adjusted NPV (A\$m)	Value per share (A\$)	% Mix
VivaGel BV Symptomatic Relief	First regulatory approval in Europe received	2016 (Ex-US)	15.0%	\$56	80.0%	\$50	\$0.15	13.3%
VivaGel BV Prevention of Recurrence	Phase III	2017	25.0%	\$647	44.0%	\$198	\$0.61	52.8%
VivaGel Coated Condom - Okamoto	Regulatory certification received	2016 (Japan)	10.0%	\$21	80.0%	\$6	\$0.02	1.6%
VivaGel Coated Condom - Ansell	Regulatory approval received for AU,NZ	2015 (Ex-US), 2017 (US)	10.0%	\$309	80.0%	\$74	\$0.23	19.8%
Dendrimer-Docetaxel (first solid tumour)	Phase I	2021	15.0%	\$511	15.0%	\$45	\$0.14	12.0%
AZN DEP Cancer Drug (lead)	Pre-clinical	2024	NA	NA	NA	\$25	\$0.08	6.8%
Dendrimer-Glyphosate	Field Trials ongoing	2017	10.0%	\$763	15.0%	\$19	\$0.06	5.2%
Diagnostics/Laboratory Reagents	On-market	NA	NA	NA	NA	\$4	\$0.01	1.1%
Other Pipeline/Non-allocated	NA	NA	NA	NA	NA	-\$63	-\$0.19	-16.9%
Cash (EOY 2016E)	NA	NA	NA	NA	NA	\$16	\$0.05	4.3%
Debt (EOY 2016E)	NA	NA	NA	NA	NA	-\$0.0	\$0.00	0.0%
Equity Value						\$374.0	\$1.15	100.0%

GLOBAL PEAK SALES ARE PRE-RISK ADJUSTMENT AND ROYALTIES. BV = BACTERIAL VAGINOSIS. PEAK SALES FOR COATED CONDOM FOR OKAMOTO AND ANSELL ARE BASED ON REGIONS UNDER AGREEMENT WITH THEM. PEAK SALES FOR VIVAGEL SYMPTOMATIC RELIEF IS FOR EX-US MARKETS ONLY. AZN DEP CANCER DRUG ONLY INCLUDES UPFRONT, DEVELOPMENT AND LAUNCH MILESTONES FROM LEAD DRUG UNDER AGREEMENT. SOURCE: BELL POTTER SECURITIES ESTIMATES

Table 3 - Deal Assumptions for SPL

Asset	Indication	Stage at Licensing	Licensee	Fiscal Year Timing of deal (Est.)	Total Deal Value in USDm (upfront plus milestones)	Upfront (USDm)	Developmental & regulatory Milestones (USDm)	Commercial Milestones (USDm)	Royalty Rate (%)
VivaGel	BV Symptomatic Relief (EX-US)	Registration (pre-launch)	TBC	2016	25	1.5	NA	23.5	20.0%
VivaGel	BV Prevention of Recurrence	Phase III complete	TBC	2017	200	5	35	160	25.0%
VivaGel	Coated Condom (Japan)	Pre Regulatory Approval	Okamoto	2011	0	NA	NA	NA	12.0%
VivaGel	Coated Condom (Ex-Japan)	Pre Regulatory Approval	Ansell	2012	0	NA	NA	NA	12.0%
Dendrimer-Docetaxel	First Solid tumour	Phase II ongoing	TBC	2017	200	10	90	100	12.0%
AZN DEP Cancer Drug (lead)	Unknown	Pre-clinical	AstraZeneca	2016	126	2	64	60	NA
Dendrimer-Glyphosate	Crop protection	Pre Regulatory Submission	TBC	2016	0	NA	NA	NA	5.0%

NOTE: OUR DENDRIMER-DOCETAXEL DEAL ASSUMPTIONS ARE CONSERVATIVE REFLECTING ITS EARLY STAGE. IT COULD POTENTIALLY HAVE ADDITIONAL VALUE FOR EACH ADDITIONAL INDICATION THAT THE LICENSEE PURSUES. WE DO NOT INCLUDE COMMERCIAL MILESTONES IN OUR MODEL AT THIS STAGE FOR DOCETAXEL DEAL OR FOR BV PREVENTION OF RECURRENCE. ROYALTIES ARE LIKELY TO BE TIERED FOR EACH DEAL. WE ASSUME FLAT RATE AT MID POINT OF RANGE FOR NOW. AZN DEP CANCER DRUG ONLY INCLUDES UPFRONT, DEVELOPMENT AND LAUNCH MILESTONES FROM LEAD DRUG UNDER AGREEMENT. SOURCE: BELL POTTER SECURITIES ESTIMATES

Upside Risk to our valuation

We have not modelled SPL's potential revenue flow from its partnerships with Nufarm (agrochemicals), Gowan Company (agrochemicals), Makhteshim Agan (agrochemicals), Eli Lilly (drug delivery), Elanco (drug delivery), GSK (drug delivery) and from its multiple undisclosed partnerships both in drug delivery and agrochemicals. These partnerships becoming substantial in future and converting to a commercial licensing deal with financial terms would lead to an upside to our estimates.

At this stage we do not model royalties and sales milestones attached to the lead cancer drug under the AstraZeneca (AZN) partnership. Sales milestones are estimated to be US\$60m and SPL estimates that royalties over the life of the lead drug could amount to ~US\$324m. We also do not include any value for the follow on compounds under the AZN agreement which are each worth up to US\$93.3m in milestones. Clarity on the molecular target and targeted indication on lead drug will allow us to model royalties and sales milestones. Other follow on compounds moving into the clinic would be a potential upside to our estimates.

At this stage, we do not value SPL's second internal candidate from drug-delivery Dendrimer-Oxaliplatin, or its latest Herceptin-targeted DEP conjugate given the early nature of these programmes. These programmes moving ahead into the clinic would be a potential upside to our estimates.

Also, we note that docetaxel (Taxotere) made by Sanofi Aventis is currently approved for multiple indications including breast cancer, head and neck cancer, gastric cancer, prostate cancer and non-small cell lung cancer (NSCLC). SPL has previously reported results from animal studies of dendrimer-docetaxel, which demonstrated that dendrimer-docetaxel has superior efficacy to docetaxel alone across a wide range of tumours namely prostate, lung, ovarian and breast. SPL's closest competitor BIND Therapeutics, which has an improved docetaxel formulation in development, is pursuing NSCLC and prostate cancer indications. At this stage for SPL, we model dendrimer-docetaxel's opportunity for the first solid tumour indication the company may pursue. However, depending on the results from the Phase I trial, which is recruiting patients with various solid tumours, SPL or a potential licensee, may decide to pursue more than one indication in parallel. This could considerably increase the market opportunity for this asset. **Expanded indications for dendrimer-docetaxel could lead to upgrades in our numbers.** We will revisit our assumptions on the basis of the Phase I dendrimer-docetaxel trial results.

Forthcoming Milestones

In terms of news flow over the next 12 months, we expect the following announcements to act as catalysts for a potential re-rating of the stock:

- **1HFY16 - Interim data from the first dose escalation phase of Phase I dendrimer-docetaxel trial on the MTD (maximum tolerated dose);**
- 1HFY16 - Licensing deal for VivaGel for symptomatic relief of BV;
- 1HFY16 - Launch of VivaGel Coated Condom in New Zealand by Ansell and their distributor EBOS group;
- FY16 - Additional regulatory approvals for VivaGel for symptomatic relief of Bacterial Vaginosis (BV) in Ex-US markets;
- FY16 - Additional regulatory approvals for VivaGel coated condom in markets under agreement with Ansell;
- 1HFY16 – Potential licensing deal for agrochemicals program dendrimer-glyphosate;
- **2HFY16- Top line results from dendrimer-docetaxel Phase I trial including the expansion phase of trial;**
- 2HFY16 - Launch of VivaGel coated condom in Japan by Okamoto;
- Early 2HFY16 - Results from the two Phase III trials of VivaGel for Prevention of Recurrence of Bacterial Vaginosis;

In addition, we expect that over the next 6-12 months one or more of SPL's various disclosed or undisclosed partnerships in agrochemicals and drug delivery to expand further, potentially converting to a commercial licensing deal with financial terms attached.

Starpharma Holdings Ltd. (SPL)

COMPANY DESCRIPTION

Starpharma is a Melbourne-based platform company commercialising the science of nanoscale polymers called dendrimers. Its proprietary dendrimer technology is versatile with wide applicability across multiple sectors including pharmaceuticals, agrochemicals and industrial applications. SPL's lead product is VivaGel which is being developed as an anti-microbial coating for Ansell and Okamoto condoms offering protection against Sexually Transmitted Infections, as well as a topical microbicide to prevent the recurrence of the common vaginal infection in women, Bacterial Vaginosis (BV). SPL is also working on improved formulations of leading cancer drugs as well as agrochemicals both internally and with external partners. Substantial shareholders include Allan Gray, M&G and Fidelity. Their combined holdings represent ~32.5%.

INVESTMENT STRATEGY

SPL remains an attractive story with multiple shots on goal. We expect multiple catalysts to play out over the next 6 -12 months which could further de-risk the platform technology and demonstrate its commercial viability. We believe that FY16 will be a watershed year for SPL, with the release of Top-line data from the Phase I dendrimer-docetaxel trial. Positive data from this trial will serve as a proof of concept for SPL's dendrimers to be effective drug delivery agents and substantially de-risk the company. SPL's strong cash position of \$26.1m underpins its future growth and we expect to see the company add value in the medium term through commercial revenue from the condom coating asset, the AstraZeneca drug delivery partnership, as well as VivaGel for Symptomatic relief for BV (Ex-US), as well as through progressing clinical trials for dendrimer-docetaxel and VivaGel for prevention of R-BV. We continue to rate SPL as a Buy (speculative).

KEY RISKS

We see the following key stock specific risks to our investment thesis on Starpharma:

- **Clinical risk:** SPL's clinical trials primarily the Phase III R-BV trials and the Phase I dendrimer-docetaxel trial may fail to demonstrate meaningful safety and efficacy. This may jeopardise the potential for SPL to license the products and/or pursue further clinical development.
- **Technology risk:** SPL is a platform company, with its entire pipeline based on its proprietary dendrimer technology. Any setback clinically or commercially is likely to put the viability of the company's technology at risk.
- **Regulatory risk:** Delays in receiving marketing approval or launch for VivaGel coated condom will negatively impact our revenue forecasts. This risk also extends to other pipeline products in terms of getting regulatory agreement to conduct clinical trials and marketing approval for launch in various markets.
- **Partnering risk:** The basic premise behind our investment thesis for SPL is that all its major products get licensed at attractive terms with the partner being responsible for all commercialisation and any further development as required. If SPL fails to secure partnerships at attractive terms, our forecasts will be negatively impacted. Furthermore, if any of SPL's existing collaborations should be terminated, it is likely to shake the markets confidence in SPL's technology and its commercial viability.
- **Commercial risk:** The VivaGel coated condom sales and revenue from partnerships with Okamoto/Ansell could fail to meet our expectations due to poor commercialization effort, delays in launch, unfavourable experience of consumers with the product, better performance of a competing product etc.
- **Funding risk:** Delays in partnering of products and/or increase in costs of trials beyond what we currently estimate may impact SPL's funding position.

SPL has \$26.1m cash at the end of 1QFY16 and has burned ~\$1.8m/month on average over the last twelve months

Table 4 - Financial summary

Starpharma (SPL)						Share price (A\$)					\$0.845
As at 18 November 2015						Market cap (A\$m)					270.8
Profit and Loss											
Y/e June 30 (A\$m)	2014A	2015A	2016E	2017E	2018E	Y/e June 30	2014A	2015A	2016E	2017E	2018E
Revenue*	4.5	4.3	9.3	54.6	45.4	Net profit (A\$m)	-14.6	-19.0	-14.0	30.1	24.6
EBITDA	-14.5	-18.6	-13.5	43.2	34.4	EPS (c)	-5.1	-6.1	-4.3	9.3	7.6
Depreciation & Amortisation	-1.1	-1.2	-1.2	-1.3	-1.3	EPS growth (%)	N/A	N/A	N/A	NM	-18.4%
EBIT	-15.6	-19.8	-14.7	42.0	33.1	P/E ratio (x)	N/A	N/A	N/A	9.1	11.2
Net interest & Other Income/(Expense)	1.0	0.9	0.7	1.0	1.9	CFPS (c)	-3.5	-4.4	-4.4	11.0	8.3
Pre-tax profit (loss)	-14.6	-19.0	-14.0	43.0	35.1	Price/CF (x)	-24.5	-19.2	-19.1	7.7	10.1
Tax	0.0	0.0	0.0	12.9	10.5	DPS (c)	0.0	0.0	0.0	0.0	0.0
NPAT (adjusted)	-14.6	-19.0	-14.0	30.1	24.6	Yield (%)	0.0%	0.0%	0.0%	0.0%	0.0%
Less minority interests	0.0	0.0	0.0	0.0	0.0	Franking (%)	N/A	N/A	N/A	N/A	N/A
Net profit (loss) to shareholders	-14.6	-19.0	-14.0	30.1	24.6	EV/EBITDA	-16.9	-13.1	-18.2	5.7	7.1
Reported net profit (loss) to shareholders	-14.6	-19.0	-14.0	30.1	24.6	EV/EBIT	-15.7	-12.3	-16.6	5.8	7.4
* Including R&D tax incentive and royalties.											
FY16 Revenue number includes potential											
upfront from VivaGel symptomatic relief											
deal. FY17 revenue number includes											
potential upfront & milestone from BV											
prevention of recurrence and docetaxel deal											
Cashflow											
Y/e June 30 (A\$m)	2014A	2015A	2016E	2017E	2018E	Share price now	\$0.845				
Reported NPAT plus discontinued ops.	-14.6	-19.0	-14.0	30.1	24.6	Valuation:	\$1.15				
Non-cash items	2.5	2.0	2.5	2.6	2.6	Premium (discount) to price	36.1%				
Working capital	2.3	3.3	-2.8	3.2	-0.1	Recommendation:	Buy				
Other operating cash flow	0.0	0.0	0.0	0.0	0.0	Risk Rating	Speculative				
Operating cashflow	-9.8	-13.6	-14.3	35.8	27.0	Profitability ratios					
Capex	-0.3	-0.7	-0.3	-0.3	-0.3	Y/e June 30	2014A	2015A	2016E	2017E	2018E
Investments	0.0	0.0	0.0	0.0	0.0	EBITDA/revenue (%)	N/A	N/A	N/A	79.2%	75.8%
Other investing cash flow	0.0	0.0	0.0	0.0	0.0	EBIT/revenue (%)	N/A	N/A	N/A	76.9%	73.0%
Investing cashflow	-0.3	-0.7	-0.3	-0.3	-0.3	Return on assets (%)	-39.7%	-42.7%	-48.4%	49.7%	28.4%
Change in borrowings	0.0	0.0	0.0	0.0	0.0	Return on equity (%)	-44.4%	-50.5%	-56.4%	53.5%	29.9%
Equity issued	0.2	20.5	0.0	0.0	0.0	Return on funds empl'd (%)	-44.3%	-50.4%	-56.4%	53.5%	29.9%
Dividends paid	0.0	0.0	0.0	0.0	0.0	Dividend cover (x)	N/A	N/A	N/A	N/A	N/A
Other financing cash flow	0.0	0.0	0.0	0.0	0.0	Effective tax rate (%)	0.0%	0.0%	0.0%	30.0%	30.0%
Financing cashflow	0.2	20.5	0.0	0.0	0.0	Liquidity and leverage ratios					
Net change in cash	-9.9	6.2	-14.6	35.5	26.8	Y/e June 30	2014A	2015A	2016E	2017E	2018E
Cash at end of period*	24.0	30.8	16.2	51.8	78.6	Net cash (debt) (A\$m)	24.0	30.8	16.2	51.8	78.6
* Includes effect of exchange rate fluctuations on cash balance											
Free cash flow	-10.1	-14.3	-14.6	35.6	26.8	Net debt/equity (%)	N/A	N/A	N/A	N/A	N/A
Balance sheet											
Y/e June 30 (A\$m)	2014A	2015A	2016E	2017E	2018E	Net interest cover (x)	N/A	N/A	N/A	NM	NM
Cash	24.0	30.8	16.2	51.8	78.6	Current ratio (x)	7.4	5.2	5.1	12.6	18.1
Current receivables	4.4	4.0	4.2	1.2	1.5	Interims					
Inventories	0.0	0.0	0.0	0.0	0.0	Y/e June 30 (A\$m)	2H14A	1H15A	2H15A	1H16E	2H16E
Other current assets	0.2	0.2	0.2	0.2	0.2	Revenue*	1.7	1.9	2.4	6.5	2.9
Current assets	28.6	35.1	20.6	53.2	80.3	EBITDA	-8.9	-8.4	-10.2	-4.8	-8.6
PPE	0.5	0.9	0.9	0.9	0.8	Depreciation & Amortisation	-0.6	-0.6	-0.6	-0.6	-0.6
Non-current receivables	0.0	0.0	0.0	0.0	0.0	EBIT	-9.5	-9.0	-10.8	-5.5	-9.2
Intangible assets	7.8	8.4	7.4	6.5	5.5	Net interest & Other Income (Expense)	0.4	0.5	0.4	0.4	0.3
Other non-current assets	0.0	0.0	0.0	0.0	0.0	Pre-tax profit	-9.1	-8.5	-10.4	-5.0	-9.0
Non-current assets	8.3	9.3	8.3	7.3	6.3	Tax	0.0	0.0	0.0	0.0	0.0
Total assets	36.9	44.4	28.9	60.5	86.6	NPAT (adjusted)	-9.1	-8.5	-10.4	-5.0	-9.0
Payables	3.1	5.9	3.2	3.4	3.6	Less minority interests	0.0	0.0	0.0	0.0	0.0
Debt	0.1	0.0	0.0	0.0	0.0	Net profit to shareholders	-9.1	-8.5	-10.4	-5.0	-9.0
Provisions	0.7	0.8	0.8	0.8	0.8	*Includes R&D Tax incentive					
Other liabilities	0.0	0.1	0.1	0.1	0.1						
Total liabilities	3.9	6.8	4.1	4.3	4.5						
Shareholders' equity	33.0	37.6	24.8	56.2	82.1						
Minorities	0.0	0.0	0.0	0.0	0.0						
Total shareholders funds	33.0	37.6	24.8	56.2	82.1						
Total funds employed	36.9	44.4	28.9	60.5	86.6						
W/A shares on issue	284.4	310.1	324.4	324.5	324.5						

SOURCE: BELL POTTER SECURITIES ESTIMATES

Recommendation structure

Buy: Expect >15% total return on a 12 month view. For stocks regarded as 'Speculative' a return of >30% is expected.

Hold: Expect total return between -5% and 15% on a 12 month view

Sell: Expect <-5% total return on a 12 month view

Speculative Investments are either start-up enterprises with nil or only prospective operations or recently commenced operations with only forecast cash flows, or companies that have commenced operations or have been in operation for some time but have only forecast cash flows and/or a stressed balance sheet.

Such investments may carry an exceptionally high level of capital risk and volatility of returns.

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The stocks of biotechnology companies without strong revenue streams from product sales or ongoing service revenue should always be regarded as speculative in character. Since most biotechnology companies fit this description, the speculative designation also applies to the entire sector. The fact that the intellectual property base of a typical biotechnology company lies in science not generally regarded as accessible to the layman adds further to the riskiness with which biotechnology investments ought to be regarded. **Stocks with 'Speculative' designation are prone to high volatility in share price movements.** Clinical and regulatory risks are inherent in biotechnology stocks. Biotechnology developers usually seek US FDA approval for their technology which is a long and arduous three phase process to prove the safety, effectiveness and appropriate application or use of the developed drug and even after approval a drug can be the subject of an FDA investigation of subsequently discovered possible links between the drug and other diseases not previously diagnosed. Furthermore, the Australian exchange listed biotechnology sector is subject to influence by the global biotechnology sector, particularly that in the USA. Consequently, Australian exchange listed biotechnology stocks can experience sharp movements, both upwards and downwards, in both valuations and share prices, as a result of a re-rating of the sector both globally and in the USA, in particular. Investors are advised to be cognisant of these risks before buying such a stock including **Starpharma**. For a list of risks specific to Starpharma please refer to Page 10 of this note.

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