

Analyst
Tanushree Jain 612 8224 2849

Authorisation
TS Lim 612 8224 2810

Recommendation
Buy (unchanged)
Price
\$0.685
Valuation
\$1.10 (unchanged)
Risk
Speculative

GICS Sector
Pharmaceuticals & Biotechnology

Expected Return

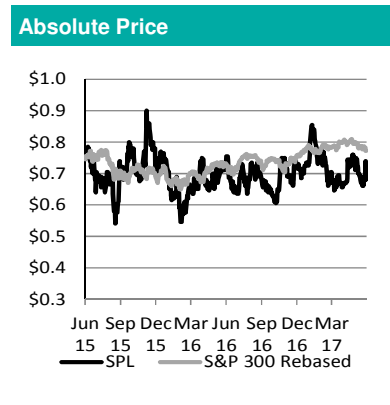
Capital growth	60.6%
Dividend yield	0.0%
Total expected return	60.6%

Company Data & Ratios

Enterprise value	\$222.8m
Market cap	\$252.5m
Issued capital	368.59m
Free float	100%
Avg. daily val. (52wk)	\$310,270
12 month price range	\$0.59 - \$0.88

Price Performance

	(1m)	(3m)	(12m)
Price (A\$)	0.76	0.68	0.71
Absolute (%)	-7.89	2.94	-1.41
Rel market (%)	-5.18	3.92	-7.88



SOURCE: IRESS

Starpharma (SPL)

Speculative
See Key risks on Page 9 &
Biotechnology Risk Warning on Page 11
Speculative securities may not be
suitable for Retail clients

Preclinical data from DEP irinotecan study impresses us

DEP irinotecan shows superior anticancer activity in mice

Mice studies in colon cancer have shown significantly improved activity and survival benefit of treatment with SPL's DEP irinotecan over marketed irinotecan in 2 different cancer cell lines, including one which is known to be resistant to irinotecan. In one study mice treated with SPL's drug had no evidence of tumour (complete regression) on day 29 and the treatment effect was maintained out to 119 days. DEP irinotecan significantly prolonged survival compared to irinotecan ($p < 0.0045$), with 100% of treated mice being alive at day 119. Comparatively mice treated with irinotecan only exhibited a delay in their tumour growth vs. placebo. In the second study DEP irinotecan outperformed irinotecan significantly on both tumour growth inhibition and survival ($P < 0.0001$). This data provides further validation of SPL's DEP platform with similar preclinical activity now seen across various drugs and different animal models.

Improved irinotecan – an attractive commercial opportunity

Irinotecan is a chemotherapy drug which has FDA approval for colorectal cancer, but is also used off label in a range of other cancers including lung cancer. Prior to losing its patent exclusivity, Pfizer's Camptosar (irinotecan) achieved peak sales of US\$1.1bn. Irinotecan's utility has been hampered by dose limiting toxicities which include severe diarrhoea and myelosuppression (including neutropenia). The potential applicability of a better and safer irinotecan across multiple solid tumours beyond colorectal cancer positions it as a multibillion dollar drug and deal values for successful approaches in recent times have been in the range of ~\$1bn-\$2bn. While there are competing and more advanced approaches for a next generation irinotecan, toxicity profile is still not optimal. Given what we have seen with SPL's DEP technology to date, we believe SPL could add value by improving the safety profile of their version of irinotecan. We look forward to additional pre-clinical studies to better characterise the drugs PK and safety profile. If results from further studies continue to be similarly positive, it could open up additional partnering opportunities for SPL.

Retain Buy (speculative) and Valuation of \$1.10

No changes to earnings. We retain Buy (spec.) and DCF valuation of \$1.10/sh.

Earnings Forecast

Year end 30th June	2015A	2016A	2017E	2018E	2019E
Revenue (A\$m)	4.3	7.3	9.2	19.3	42.1
EBITDA (A\$m)	-18.6	-22.5	-15.0	4.0	26.6
NPAT (adjusted) (A\$m)	-19.0	-22.7	-15.3	2.6	18.5
EPS (adjusted) (cps)	-6.11	-6.57	-4.15	0.69	4.96
EPS growth (%)	N/A	N/A	N/A	NM	NM
PER (x)	N/A	N/A	N/A	98.9	13.8
EV/EBITDA (x)	-12.0	-9.9	-14.9	55.4	8.4
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 (%)	-50.5%	-45.9%	-42.2%	6.4%	30.7%

NOTE: REVENUE INCLUDES R&D TAX INCENTIVES. FY17/ FY18/ FY19 REVENUE ALSO INCLUDE POTENTIAL UPFRONT AND MILESTONES FROM VIVAGEL SYMPTOMATIC RELIEF, TREATMENT, PREVENTION OF R-BV AND DEP DOCETAXEL DEALS, MILESTONES FROM AZN AND ROYALTIES. SOURCE: BELL POTTER SECURITIES ESTIMATES

DEP irinotecan demonstrates superior anticancer activity than irinotecan

Event: Starpharma has announced impressive data from preclinical studies in colon cancer of its novel DEP irinotecan. The study was conducted using two colon cancer xenograft models and compared SPL's DEP irinotecan against positive control irinotecan (Camptosar) and a placebo group which was saline. The study was conducted at the Peter MacCallum Cancer Centre, one of the leading cancer research centres.

The data was discussed in meetings with various key stakeholders (Key opinion leaders, clinicians and potential pharma partners) at the high profile oncology conference held recently in the US (ASCO – American Society of Clinical Oncology). We note that there was no formal presentation of this data at ASCO this year.

Data demonstrated the superior anti-cancer activity and survival benefit of DEP irinotecan over marketed irinotecan (original brand name Camptosar marketed by Pfizer) in both the xenograft models, including one which is considered to be less sensitive/resistant to irinotecan. We note that the dose of DEP irinotecan used in the studies was more than 3 times lower than the irinotecan dose used.

In our view, this data provides further validation of SPL's DEP platform with similar preclinical activity now seen across various drugs and across different animal models.

SPL is now expediting the development of this drug, with scale up activities ongoing for drug to support further preclinical studies, ahead of clinical trials. DEP irinotecan could be the third candidate selected by SPL from its internal DEP pipeline (behind DEP docetaxel and DEP cabazitaxel), which is not surprising given its commercial attractiveness and the encouraging preclinical data just released. The key deciding factor in our view would be the safety profile i.e. whether the DEP technology is able to improve the safety profile of irinotecan vs. traditional irinotecan and other irinotecan reformulation approaches.

We discuss the preclinical results and the commercial attractiveness for the drug below.

Next generation irinotecan – an attractive commercial opportunity

Irinotecan is a chemotherapy drug which has been approved by the FDA for colorectal cancer (first line or second line), but is also used off label in a range of other cancers including lung cancer. It is one of the components of first line combination chemotherapy regimen FOLFIRI or is given in combination with other targeted therapies for first line and second-line metastatic colon cancer.

Prior to losing its patent exclusivity, Pfizer's Camptosar (irinotecan) achieved peak sales of US\$1.1bn. While the size of the opportunity makes it commercially attractive for SPL to target, the key reason in our view which makes it particularly attractive for targeting is its dose limiting toxicities. Utility of irinotecan has been somewhat limited due to its narrow therapeutic index. **The drug has severe dose limiting toxicities which include severe diarrhoea and myelosuppression (including neutropenia).**

Irinotecan is a prodrug that needs to be converted in the liver to the active cytotoxic molecule SN38, which has 100 to 1,000 fold more potent cytotoxicity in vitro compared with irinotecan. However SN38 cannot be directly administered systemically since it is highly insoluble and toxic.

There have been various prodrug and nanomedicine approaches used to either make a better version of irinotecan (more efficacious/less toxic) i.e. prodrug of SN38 or find out a way to deliver SN38 directly to cancer cells. Some of these approaches have also been successful and showed promise in several solid tumours. It's interesting to note that some of the more advanced products have chosen to prioritise indications for which irinotecan is not approved by the FDA (such as breast cancer and pancreatic cancer).

The potential applicability of a better and safer irinotecan across multiple solid tumours beyond colorectal cancer positions it as a multibillion dollar drug (blockbuster opportunity) and this view is supported by the deal values for some of these successful approaches in recent years as we have listed in the Table below.

Table 1 - Successful next generation irinotecan's have attracted high value deals given their blockbuster opportunity

Date	Company	Product	Indication	Stage at licensing	Licensee	Total deal value in USDm (upfront plus milestones)	Upfront (USDm)	Milestones (USDm)	Note
Feb-17	Immunomedics	IMMU-132 (antibody drug conjugate anti-Trop-2/SN-38 antibody). It is an ADC composed of an anti-TROP-2 antibody linked to SN-38, the active metabolite of irinotecan.	Metastatic Triple Negative Breast Cancer and other metastatic solid tumours (urothelial, lung NSCLC and SCLC, prostate, endometrial)	Phase 1/2	Seattle Genetics	2000	250	1750	Tiered double digit royalties were also part of the deal and Seattle also purchased stock worth \$15m of Immunomedics. Deal with Seattle Genetics fell through recently on litigation by an activist investor. Has been granted Breakthrough therapy designation for mTNBC. It delivers greater concentrations of SN-38 in tumours. Still has toxicity although manageable with key SAE's Neutropenia, diarrhea and febrile neutropenia, although was found to be lower than irinotecan
Jan-17	Merrimack Pharmaceuticals	Onivyde (irinotecan liposome injection) and doxorubicin hydrochloride liposome injection	Pancreatic Cancer and other indications	Approved for metastatic pancreatic cancer in combination with fluorouracil and leucovorin	Ipsen	1025	575	450	Onivyde is irinotecan encapsulated in a liposome. It has black box warning for severe neutropenia and severe diarrhea. Ipsen acquired Onivyde to get U.S. commercialization rights for Onivyde and took over Merrimack's existing licensing agreements with Shire Plc outside the United States and with PharmaEngine Inc for Taiwan. Deal included manufacturing assets as well.
Jun-16	Nektar Therapeutics	Onzeald (etririnotecan pegol, NKTR-102). This is a pegylated version of irinotecan (PEG conjugate prodrug of irinotecan) designed to provide extended release of irinotecan and therefore increased exposure to SN-38	Advanced Breast Cancer with history of brain metastases. Also in trials for other solid tumours (colorectal, glioma, lung - NCCLC, SCLC and ovarian)	Phase 3	Daichi Sankyo Europe	80	20	60	EU, Switzerland and Turkey rights only. Nektar is also entitled to significant double-digit royalties on net sales in Europe. In a Phase 3 BEACON study in breast cancer while Onzeald had fewer SAE's vs. active control arm they were still quite high and included diarrhea and neutropenia
Sep-14	Merrimack Pharmaceuticals	Onivyde (irinotecan liposome injection)	Pancreatic Cancer and other indications	Phase 3	Baxter/Baxalta (acquired by Shire now)	970	100	870	Ex-US rights only.

SOURCE: BELL POTTER SECURITIES

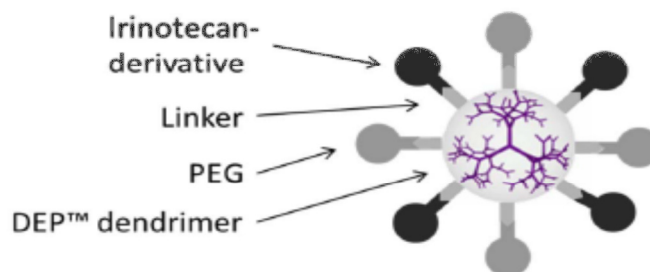
Given the successful approaches above and the high competition in developing next generation irinotecan's **the question arises as to how SPL can differentiate their DEP irinotecan from these approaches and whether there still exists an unmet need.**

On analysis of the data of the 3 drugs listed above we conclude the below:

- **Toxicity profile is still not optimal and given what we have seen with SPL's dendrimer technology platform to date, we believe they can significantly add value by improving the safety profile of their drug.** Most of the above drugs seem to have similar/slightly lower toxicity profile as irinotecan, however with higher levels of exposure of active molecule SN38, which translated to better efficacy than irinotecan.
- Both Merrimack and Nektar Therapeutics drugs are still delivering irinotecan, which means it needs to be converted to the active molecule SN38. Though they are able to get increased SN38 exposure vs. traditional irinotecan, we believe approaches such as SPL's which directly deliver the active molecule SN38 (requiring no conversion from irinotecan) should be able to have more SN38 into the tumour and therefore potentially have better efficacy.
- Immunomedics IMMU-132 (antibody drug conjugate) approach with SN38 being delivered directly is therefore somewhat similar to what SPL is trying to do. Although we note that Immunomedics has an active targeting antibody (anti-TROP-2) while SPL is passively targeting the tumour with its DEP irinotecan taking advantage of the leaky vasculature associated with tumour tissue to enter the tumour cells which is similar to the DEP docetaxel approach. IMMU-132 has a high drug to antibody ratio (Immunogen

claims 7 molecules of drug per antibody) which leads to higher amount of SN-38 being delivered to the blood and tumour (130-fold in animal model vs. irinotecan). We believe the DEP technology has the potential to also deliver a high drug payload with improved homogeneity and stability (dendrimer scaffold with multiple points of attachment).

Figure 1 - SPL's DEP irinotecan incorporates SN-38 the active irinotecan derivative



SOURCE: COMPANY DATA

- We note IMMU-132 in clinical trials had lesser diarrhoea than irinotecan, however still has a high rate of dose limiting neutropenia. It also continues to have grade 3/4 diarrhoea (serious adverse event), however lower than irinotecan. We have in the past seen the DEP technology overcome the bone marrow toxicity issue with interim data from first human clinical trial for DEP docetaxel showing no evidence of neutropenia so far and several preclinical studies across different cancer xenografts consistently showing a favourable safety profile (no neutropenia and other side effects including alopecia and thrombocytopenia).

Improved toxicity profile of a next generation irinotecan would be highly advantageous:

- Since irinotecan generally forms part of a combination chemotherapy regimen in cancer and toxicity profile tends to differ in combination vs. monotherapy, we believe improved tolerability could improve efficacy outcomes for patients in different cancer settings. A large proportion of patients on irinotecan treatment have to reduce their dose below the recommended optimal/most efficacious dose due to tolerability issues. Improving the tolerability profile and having higher proportion of patients remaining on the optimal dose is also likely to improve the efficacy outcomes for these patients.
- Improved safety will also be of advantage in an era where anti-PD1/PD-L1 are now looking to combine with chemotherapy. The first chemotherapy/anti-PD1 combination has also been approved for first line treatment. Chemotherapy remains the cornerstone of treatment for the majority of GI (gastrointestinal) and other cancers. However overlapping bone marrow toxicity or myelosuppression (including neutropenia) complicates attempts to combine them together to improve outcomes for patients. Myelosuppression is already a dose limiting toxicity for traditional irinotecan and when combined with a checkpoint inhibitor could further reduce the treatments tolerability profile. Hence reducing side effects of chemotherapy will position it better in future combination attempts.

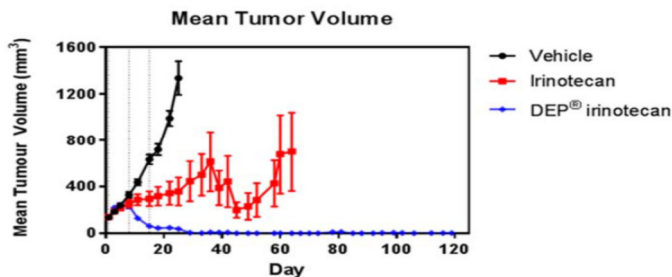
Key findings from the preclinical studies

SW-620 XENOGRAFT (CONSIDERED SENSITIVE TO IRINOTECAN)

- DEP irinotecan significantly inhibited tumour growth compared to irinotecan ($p < 0.0001$).
- Mice treated with SPL's DEP irinotecan had no evidence of tumour (complete regression) on day 29 after first dose, with treatment effect sustained out to 119 days.

- Comparatively mice treated with irinotecan did not induce a regression (i.e. did not reduce the size of tumours from baseline). Irinotecan treated mice however did exhibit a delay in tumour growth vs. placebo treated mice, as seen historically in other studies as well.

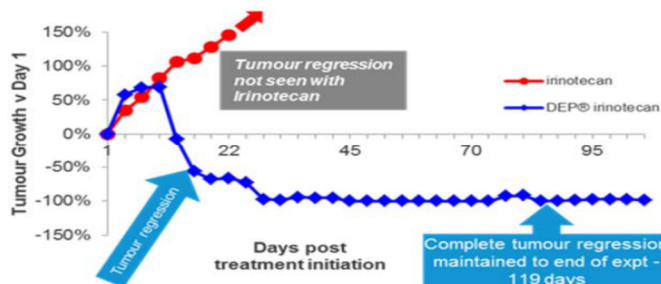
Figure 2 - Improved efficacy with SPL's DEP Irinotecan in SW-620 mice colon cancer model vs. irinotecan (P<0.0001)



MOUSE XENOGRAFT (SW-620 COLON CANCER IN BALB/C NUDE MICE); N= 6 PER GROUP - SALINE, DEP IRINOTECAN (MTD 25MG/KG) AND IRINOTECAN (MTD 90MG/KG); IV DOSE WEEKLY FOR 3 WEEKS (DOSED ON DAY 1,8 & 15)

SOURCE: COMPANY DATA

Figure 3 – Complete tumour regression with SPL's DEP Irinotecan in SW-620 mice colon cancer model vs. no tumour regression for irinotecan (P<0.0001)

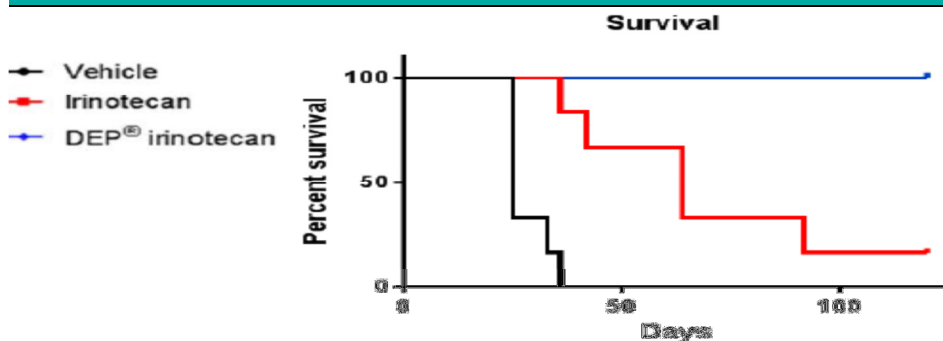


MOUSE XENOGRAFT (SW-620 COLON CANCER IN BALB/C NUDE MICE); N= 6 PER GROUP - SALINE, DEP IRINOTECAN (MTD 25MG/KG) AND IRINOTECAN (MTD 90MG/KG); IV DOSE WEEKLY FOR 3 WEEKS (DOSED ON DAY 1,8 & 15)

SOURCE: COMPANY DATA

- DEP irinotecan significantly prolonged survival compared to irinotecan (p<0.0045), with 100% of the mice treated with SPL's DEP irinotecan being alive at day 119.
- Comparatively only one mouse (16.66%) treated with irinotecan was alive by Day 119.

Figure 4 - Improved survival rate with SPL's DEP irinotecan in SW-620 mice colon cancer model (P<0.0045)

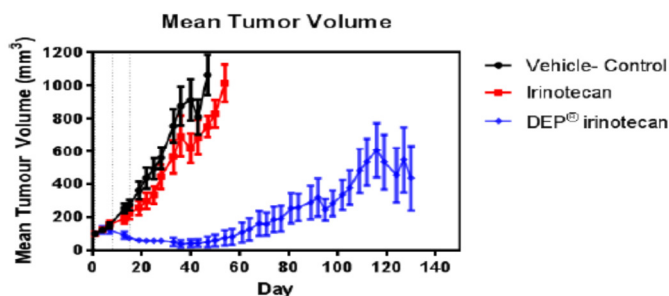


SOURCE: COMPANY DATA

HT-29 XENOGRAFT (CONSIDERED INSENSITIVE/RESISTANT TO IRINOTECAN)

- DEP irinotecan significantly inhibited tumour growth compared to irinotecan (p<0.0001).
- At Day 36 after first dose, tumour growth inhibition vs. placebo was 95% for DEP irinotecan vs. 21% for irinotecan.
- This mice model is considered to be resistant or less sensitive to irinotecan vs. the SW-620 model. In line with that, we saw very little anti-cancer activity of irinotecan in this study. Irinotecan treated mice exhibited only a short delay in tumour growth vs. placebo treated mice.
- Comparatively, DEP irinotecan demonstrated improved anti-cancer activity, implying that it was able to overcome the irinotecan resistance. Mice treated with DEP irinotecan saw a decrease in the size of their tumour (regression) with maximum regression of 62% on Day 36.

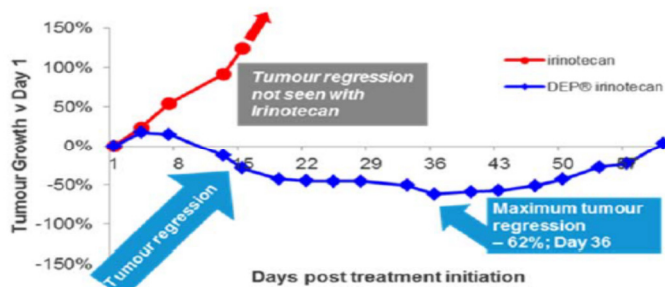
Figure 5 - Improved efficacy with SPL's DEP Irinotecan in HT-29 mice colon cancer model vs. irinotecan (P<0.0001)



MOUSE XENOGRAFT (HT-29 COLON CANCER IN BALB/C NUDE MICE); N= 10 PER GROUP - SALINE, DEP IRINOTECAN (MTD 25MG/KG) AND IRINOTECAN (MTD 90MG/KG); IV DOSE WEEKLY FOR 3 WEEKS (DOSED ON DAY 1,8 & 15)

SOURCE: COMPANY DATA

Figure 6 – Improved tumour regression with SPL's DEP Irinotecan in HT-29 mice colon cancer model vs. no tumour regression for irinotecan (P<0.0001)

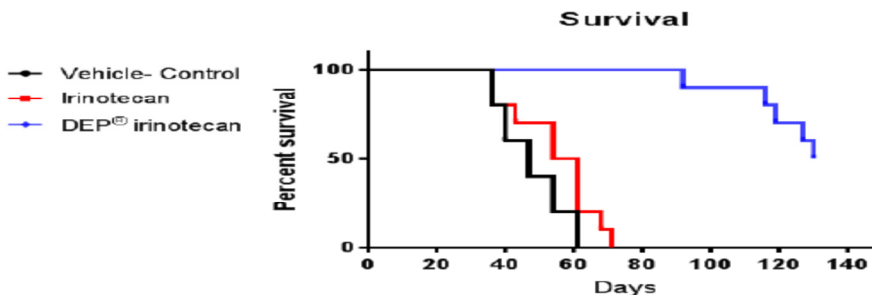


MOUSE XENOGRAFT (HT-29 COLON CANCER IN BALB/C NUDE MICE); N= 10 PER GROUP - SALINE, DEP IRINOTECAN (MTD 25MG/KG) AND IRINOTECAN (MTD 90MG/KG); IV DOSE WEEKLY FOR 3 WEEKS (DOSED ON DAY 1,8 & 15)

SOURCE: COMPANY DATA

- SPL's DEP irinotecan significantly prolonged survival compared to irinotecan (p<0.0001), with 50% of mice treated with DEP irinotecan being alive at day 130. This represented an 11.8x improvement in survival compared to irinotecan.
- Comparatively none of the mice treated with irinotecan were alive by Day 71.
- Irinotecan had a 7 day survival improvement over placebo/saline while DEP irinotecan had a 83 day survival improvement over placebo (saline).

Figure 7 - Improved survival rate with SPL's DEP irinotecan in HT-29 mice colon cancer model (P<0.0001)



SOURCE: COMPANY DATA

We understand that DEP irinotecan was well tolerated in both the models. No other details on the safety profile of DEP irinotecan vs. irinotecan were provided.

Our comments

- We view the significantly improved activity and survival benefit of SPL's DEP irinotecan over marketed irinotecan in 2 different cancer cell lines, including one which is known to be resistant to irinotecan as highly encouraging.
- The SW620 xenograft model has a well-characterised, but modest, response to irinotecan. The fact that treatment with DEP irinotecan caused complete tumour regression and had 100% survival out to 119 days (a considerably long time frame) is remarkable.
- The improved anti-cancer activity and survival benefit in an irinotecan resistant model, in our view suggests the possibility for the drug to be used in irinotecan refractory population, which we view as positive.
- 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.**

- We believe additional in vivo studies to ascertain safety and efficacy across other cancer xenografts and characterisation of the pharmacokinetic profile of the drug candidate pre-clinically are required to build on this positive preliminary data. More information around the plasma half-life, tumour-specific accumulation and exposure, incidence of diarrhoea and neutropenia, release and accumulation from bile and intestine will help to differentiate DEP irinotecan from other competing delivery platforms.
- The key advantage that DEP irinotecan could have over other approaches would be either to improve efficacy without increasing toxicity or improve safety profile with either the same or improved efficacy. We believe the latter would be of greater advantage especially when considering future positioning in chemo/immune-oncology combinations.
- It is too preliminary to make comments around the technology and how it might lend itself to improving the toxicity profile of irinotecan. However so far the DEP technology has been able to reduce the dose limiting toxicities of various toxic compounds and therefore its reasonable to expect it could potentially do that with irinotecan.
- We do however note that based on our analysis the main dose limiting toxicities of irinotecan (diarrhoea and neutropenia) seem primarily related to its metabolism and conversion to active metabolite SN-38 and its elimination from the bile. Since DEP irinotecan directly delivers the active metabolite SN38 (bypassing the liver), its activity is not reliant on the hepatic activation and metabolism. Neutropenia is directly related to the concentration of SN-38 in plasma with higher rates of SN-38 secretion resulting in higher rates of neutropenia. SN-38 also plays a central role in late onset diarrhoea, as it is caused by excessive biliary secretion of SN-38 in the lumen of the intestines. Inherent characteristics of the DEP technology in the past have limited the toxic drugs exposure to healthy cells and tissues, had better targeted delivery into the tumour and greater accumulation of drug in the tumour, increased its half-life and controlled its release and therefore its therapeutic index. We believe all of those characteristics would be applicable to improve the safety profile of irinotecan as well.

In summary, we view the preliminary efficacy data on SPL's DEP irinotecan as highly encouraging. This data provides further validation of SPL's DEP platform with similar preclinical activity now seen across various drugs and across different animal models. 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. Based on the promising data we believe DEP irinotecan is in the running to become SPL's 3rd internal candidate to advance into further development (behind docetaxel and cabazitaxel). The potential applicability of a better and safer irinotecan across multiple solid tumours beyond colorectal cancer positions it as a multibillion dollar drug and as we have seen recently there is no dearth of potential partners willing to pay high value for such an opportunity should it succeed. Therefore DEP irinotecan offers an attractive commercial opportunity if results from further studies continue to be similarly positive, which could open up additional partnering opportunities for SPL.

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:

- 4QFY17 - Results from the two Phase III trials of VivaGel for Prevention of Recurrence of Bacterial Vaginosis;
- 4QFY17/1QFY18 - Licensing deal for VivaGel Treatment for BV for US market and the OTC product for BV for Ex-US markets with upfronts and milestones;
- 4QFY17/1QFY18 – Top-line results from Phase I DEP docetaxel trial (dose escalation and expansion phase);
- 4QFY17/1QFY18 – NDA filing for VivaGel for Treatment of Bacterial Vaginosis (BV) to US FDA for approval in US market;
- 4QFY17/1QFY18- Launch of VivaGel OTC (Over the counter) product for symptomatic relief of BV by Aspen in ANZ;
- 1HFY18 – Potential initiation of Phase I trial with first DEP AstraZeneca drug under partnership triggering a US\$3m milestone payment to SPL;
- 1HFY18 – Potential initiation of Phase II clinical trial for DEP docetaxel;
- 1HFY18 – Potential licensing deal for VivaGel for prevention of recurrence of BV;
- 1HFY18 - Launch of VivaGel coated condom in Japan by Okamoto;

In addition, we expect that over the next 12 months SPL's collaboration with AstraZeneca on the new DEP program announced in July 2016, could advance to a commercial licensing deal.

Also, we note that activities related to obtaining regulatory approval in China for SPL's VivaGel coated condom for the government segment of the Chinese condom market have commenced and are progressing well. The process could take several months and at this stage it is difficult to estimate a timeline for approval and launch. Assuming the entire process takes between 10-18 months, there is a possibility for the approval to be received sometime in CY17.

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 ~31.2%.

INVESTMENT STRATEGY

SPL remains an attractive story with multiple shots on goal. We expect multiple catalysts to play out over the next 12 months which could further de-risk the platform technology and demonstrate its commercial viability. We believe that CY17 will be a watershed year for SPL, with the release of Top-line data from the Phase I DEP 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 A\$29.7m underpins its future growth and we expect 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 BV, as well as through progressing clinical trials for DEP docetaxel and VivaGel for prevention of R-BV. We also are encouraged between the deepening ties between AstraZeneca and SPL. We continue to rate SPL as a Buy.

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 DEP 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 or BV product 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.

Table 2 - Financial summary

Starpharma (SPL)						Share price (A\$)					\$0.685
As at 9 June 2017						Market cap (A\$m)					252.5
Profit and Loss						Valuation data					
Y/e June 30 (A\$m)	2015A	2016A	2017E	2018E	2019E	Y/e June 30	2015A	2016A	2017E	2018E	2019E
Revenue*	4.3	7.3	9.2	19.3	42.1	Net profit (A\$m)	-19.0	-22.7	-15.3	2.6	18.5
EBITDA	-18.6	-22.5	-15.0	4.0	26.6	EPS (c)	-6.1	-6.6	-4.1	0.7	5.0
Depreciation & Amortisation	-1.2	-0.9	-1.0	-1.0	-1.0	EPS growth (%)	N/A	N/A	N/A	NM	NM
EBIT	-19.8	-23.5	-16.0	3.1	25.6	P/E ratio (x)	N/A	N/A	N/A	98.9	13.8
Net interest & Other Income/(Expense)	0.9	0.8	0.7	0.6	0.9	CFPS (c)	-4.4	-5.2	-4.5	1.8	6.2
Pre-tax profit (loss)	-19.0	-22.7	-15.3	3.7	26.5	Price/CF (x)	-15.6	-13.3	-15.2	39.0	11.1
Tax	0.0	0.0	0.0	1.1	7.9	DPS (c)	0.0	0.0	0.0	0.0	0.0
NPAT (adjusted)	-19.0	-22.7	-15.3	2.6	18.5	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	-19.0	-22.7	-15.3	2.6	18.5	EV/EBITDA	-12.0	-9.9	-14.9	55.4	8.4
Reported net profit (loss) to shareholders	-19.0	-22.7	-15.3	2.6	18.5	EV/EBIT	-11.2	-9.5	-14.0	73.0	8.7
* Including R&D tax incentive, milestones and royalties. FY17 Revenue number includes potential upfront from VivaGel BV symptomatic relief deal and from BV treatment (US) deal and milestone from AZN deal, FY18 revenue number includes potential upfront from BV prevention of recurrence and milestone from BV treatment (US) and AZN deals. FY19 revenue number includes potential milestone from BV symptomatic relief, BV recurrence deal and AZN deal and upfront from DEP docetaxel deal.											
Cashflow						Profitability ratios					
Y/e June 30 (A\$m)	2015A	2016A	2017E	2018E	2019E	Y/e June 30	2015A	2016A	2017E	2018E	2019E
Reported NPAT plus discontinued ops.	-19.0	-22.7	-15.3	2.6	18.5	EBITDA/revenue (%)	N/A	N/A	N/A	20.8%	63.1%
Non-cash items	2.0	2.3	2.4	2.3	2.3	EBIT/revenue (%)	N/A	N/A	N/A	15.8%	60.8%
Working capital	3.3	2.7	-3.7	1.6	2.2	Return on assets (%)	-42.7%	-38.4%	-36.4%	5.6%	27.8%
Other operating cash flow	0.0	-0.1	0.0	0.0	0.0	Return on equity (%)	-50.5%	-45.9%	-42.2%	6.4%	30.7%
Operating cashflow	-13.6	-17.8	-16.6	6.5	23.0	Return on funds empl'd (%)	-50.4%	-45.9%	-42.2%	6.4%	30.7%
Capex	-0.7	-0.1	-0.1	-0.1	-0.1	Dividend cover (x)	N/A	N/A	N/A	N/A	N/A
Investments	0.0	0.0	0.0	0.0	0.0	Effective tax rate (%)	0.0%	0.0%	0.0%	30.0%	30.0%
Other investing cash flow	0.0	0.1	0.0	0.0	0.0	Liquidity and leverage ratios					
Investing cashflow	-0.7	0.0	-0.1	-0.1	-0.1	Y/e June 30	2015A	2016A	2017E	2018E	2019E
Change in borrowings	0.0	0.0	0.0	0.0	0.0	Net cash (debt) (A\$m)	30.8	46.0	29.5	36.1	59.2
Equity issued	20.5	32.6	0.0	0.0	0.0	Net debt/equity (%)	N/A	N/A	N/A	N/A	N/A
Dividends paid	0.0	0.0	0.0	0.0	0.0	Net interest cover (x)	N/A	N/A	N/A	NM	NM
Other financing cash flow	0.0	0.0	0.0	0.0	0.0	Current ratio (x)	5.2	5.3	5.9	6.6	9.8
Financing cashflow	20.5	32.6	0.0	0.0	0.0	Interims					
Net change in cash	6.2	14.8	-16.7	6.4	22.9	Y/e June 30 (A\$m)	2H15A	1H16A	2H16A	1H17A	2H17E
Cash at end of period*	30.8	46.0	29.5	36.1	59.2	Revenue*	2.4	5.3	2.1	2.0	7.2
* Includes effect of exchange rate fluctuations on cash balance											
Free cash flow	-14.3	-17.9	-16.7	6.4	22.9	EBITDA	-10.2	-9.8	-12.7	-8.9	-6.1
Balance sheet						Interims					
Y/e June 30 (A\$m)	2015A	2016A	2017E	2018E	2019E	Y/e June 30 (A\$m)	2H15A	1H16A	2H16A	1H17A	2H17E
Cash	30.8	46.0	29.5	36.1	59.2	Revenue*	2.4	5.3	2.1	2.0	7.2
Current receivables	4.0	4.1	4.0	2.6	0.6	EBITDA	-10.2	-9.8	-12.7	-8.9	-6.1
Inventories	0.0	0.0	0.0	0.0	0.0	Depreciation & Amortisation	-0.6	-0.5	-0.5	-0.5	-0.5
Other current assets	0.2	0.2	0.2	0.2	0.2	EBIT	-10.8	-10.3	-13.2	-9.4	-6.6
Current assets	35.1	50.3	33.7	38.9	60.0	Net interest & Other Income (Expense)	0.4	0.3	0.6	0.3	0.4
PPE	0.9	0.7	0.5	0.4	0.1	Pre-tax profit	-10.4	-10.0	-12.6	-9.0	-6.2
Non-current receivables	0.0	0.0	0.0	0.0	0.0	Tax	0.0	0.0	0.0	0.0	0.0
Intangible assets	8.4	8.1	7.6	7.0	6.4	NPAT (adjusted)	-10.4	-10.0	-12.6	-9.0	-6.2
Other non-current assets	0.0	0.0	0.0	0.0	0.0	Less minority interests	0.0	0.0	0.0	0.0	0.0
Non-current assets	9.3	8.8	8.2	7.4	6.5	Net profit to shareholders	-10.4	-10.0	-12.6	-9.0	-6.2
Total assets	44.4	59.0	41.9	46.2	66.6	*Includes R&D Tax incentive					
Payables	5.9	8.8	4.9	5.1	5.3						
Debt	0.0	0.0	0.0	0.0	0.0						
Provisions	0.8	0.8	0.8	0.8	0.8						
Other liabilities	0.1	0.0	0.0	0.0	0.0						
Total liabilities	6.8	9.6	5.8	6.0	6.2						
Shareholders' equity	37.6	49.4	36.1	40.3	60.4						
Minorities	0.0	0.0	0.0	0.0	0.0						
Total shareholders funds	37.6	49.4	36.1	40.3	60.4						
Total funds employed	44.4	59.0	41.9	46.2	66.6						
W/A shares on issue	310.1	345.0	367.8	370.5	373.4						

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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Disclosure: Bell Potter Securities acted as joint lead manager in the December 2015 placement and received fees for that service.

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