### **BELL POTTER**

### **Analyst**

Tanushree Jain 612 8224 2849

#### **Authorisation**

TS Lim 612 8224 2810

### Recommendation

Buy (unchanged)
Price
\$0.665
Valuation
\$1.11 (previously \$1.12)

Speculative

### GICS Sector

Risk

Pharmaceuticals & Biotechnology

<b>Expected Return</b>	
Capital growth	66.9%
Dividend yield	0.0%
Total expected return	66.9%
Company Data & Ratio	os
Enterprise value	\$189.5m
Market cap	\$244.1m
Issued capital	367.11m
Free float	100%
Avg. daily val. (52wk)	\$344,284
12 month price range	\$0.425 - \$0.98

Price Performance						
	(1m)	(3m)	(12m)			
Price (A\$)	0.63	0.80	0.52			
Absolute (%)	3.17	-18.75	26.21			
Rel market (%)	2.19	-17.35	40.48			



SOURCE: IRESS

### Starpharma (SPL)

### **Speculative**

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

## SPL inks first commercial deal for VivaGel RV

### SPL collaborates with Aspen on VivaGel BV for ANZ

SPL has signed a license and supply agreement with Aspen Pharmacare for its VivaGel OTC (Over the Counter) product for Bacterial Vaginosis (BV). The agreement covers sales and marketing rights for Australia and New Zealand (ANZ). South-Africa based Aspen is one of the leading OTC companies in AU (in Top 5) with several marketed products in the women's health care segment, which makes it an ideal partner for SPL. Financial terms of the deal were not disclosed. SPL will supply product to Aspen (at a transfer price) and also receive royalties on net sales. Aspen will be responsible for all marketing, promotion and distribution costs in ANZ. The product is under review by the Australian Therapeutic Goods Administration (TGA). With the product already approved in Europe, we expect the approval process in AU to be relatively fast. We understand plans for filing in NZ are also underway. SPL expects the product to be launched in CY16 (BPe 2HCY16).

### First commercial deal for BV, more deals to follow

The Aspen deal is an important milestone for SPL being its first commercial deal for VivaGel for BV application. On launch, VivaGel for BV will become SPL's second commercial product after the VivaGel coated condom and will serve to further de-risk SPL's VivaGel portfolio. Partnering negotiations are ongoing for other Ex-US jurisdictions including Europe. In our view, this deal is the first of many more VivaGel BV deals to come. We also see the potential for the partnership between the two companies to be expanded in future to include other jurisdictions as well.

### Valuation largely unchanged at \$1.11, Retain Buy

Our revised assumptions regarding the timing of first sales from VivaGel OTC BV product and increased R&D costs, with positive offsets in reduced G&A costs and rolling forward of our DCF model has resulted in our valuation for SPL being largely unchanged at \$1.11/sh (was \$1.12/sh). Our NPAT est. changed as follows -50% FY16, -5% FY17 and -11% FY18. We retain Buy. Key catalysts: clinical data from ongoing Phase I DEP docetaxel trial (1HCY16) and the two Phase III R-BV trials (2HCY16).

Earnings Forecast					
Year end 30th June	2014A	2015A	2016E	2017E	2018E
Revenue (A\$m)	4.5	4.3	7.7	36.7	42.6
EBITDA (A\$m)	-14.5	-18.6	-21.8	18.0	28.6
NPAT (adjusted) (A\$m)	-14.6	-19.0	-22.1	12.7	20.5
EPS (adjusted) (cps)	-5.15	-6.11	-6.43	3.40	5.49
EPS growth (%)	N/A	N/A	N/A	NM	61.5%
PER (x)	N/A	N/A	N/A	19.6	12.1
EV/EBITDA (x)	-13.1	-10.2	-8.7	10.6	6.6
Dividend (¢ps)	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%	-44.2%	19.8%	23.9%

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

# SPL inks first commercial deal for VivaGel BV

SPL has signed a license and supply agreement with Aspen Pharmacare for its VivaGel OTC (Over the Counter) product for symptomatic relief of Bacterial Vaginosis (BV). The agreement covers sales and marketing rights for Australia and New Zealand (ANZ).

Being an OTC product, women will not need to see a doctor to get a prescription for the product. They will be able to purchase this off-the-shelf in stores.

Aspen Pharmacare Australia is part of the South-Africa based Aspen Group. It is one of the leading OTC companies in AU (in Top 5) with several marketed products in the women's health care segment, which makes it an ideal partner for SPL. Its current annualised sales are close to \$900m in ANZ across its 3 sales divisions: Branded Prescription, Generics, and OTC/Consumer.

In our view, this deal is an important milestone for SPL given that it is the first commercial deal for VivaGel for BV application. We also believe this deal is the first of many more VivaGel BV deals to come.

### Terms of the SPL-Aspen deal

- · Financial terms of the deal were not disclosed.
- SPL will supply product to Aspen (at a transfer price) and also receive undisclosed royalties on net sales. We assume that the effective royalty rate will be around 20%.
- Aspen will be responsible for all marketing, promotion and distribution costs in ANZ.
- SPL expects that Aspen will target to launch the product in CY16 (BPe 2HCY16).
- SPL maintains the manufacturing rights to VivaGel BV and will have the right to commercialise the product in all other territories.
- The product is under review by the Australian Therapeutic Goods Administration (TGA).
   With the product already approved in Europe, we expect the approval process in AU to be relatively fast under the applicable Australia-EU Mutual Recognition Agreement.
- We understand plans for filing in NZ are also underway.

### **Our comments**

- Important milestone for SPL: In our view, SPL's deal with Aspen is an important
  milestone for the company. It is SPL's first commercial deal for VivaGel for BV
  application.
- Becomes second commercial product from SPL's VivaGel Portfolio: On launch,
   VivaGel for symptomatic relief of BV will become SPL's second commercial product
   after the VivaGel coated condom. We believe that launch of the product (first launch
   BPe 1HFY17), as well as additional commercial deals for it will serve to further de-risk
   SPL's VivaGel portfolio.
- Further deals for other jurisdictions to follow: SPL is in active partnering negotiations with various parties for other Ex-US jurisdictions (including Europe) for the OTC BV product. In our view, the Aspen deal is the first of many more VivaGel BV deals to come. We expect the deals for the OTC BV product to primarily be royalty based (as seen with Aspen), with modest commercial milestones. At this stage we assume SPL to license the product for Ex-US markets (especially Europe) for US\$25m including US\$1.5m in upfront, US\$23.5m in sales milestones on certain sales

thresholds being met and double digit royalties (BPe 20%). We estimate peak sales of US\$58m (assuming 15% market penetration).

- There is potential for Aspen-SPL deal to expand in future: Aspen Pharmacare
   Australia is part of the South-Africa based Aspen Group. Aspen has presence in more
   than 150 countries across the world including Europe. We see the potential for the
   partnership between the two companies to be expanded in future to include other
   jurisdictions as well.
- More regulatory approvals in other jurisdictions to follow: SPL already has
  marketing approval for its VivaGel OTC BV product in Europe for the treatment and
  rapid relief of BV including its symptoms. We expect marketing approvals in other ExUS jurisdictions to follow over the course of the next few months including Australia.
  SPL expects the EU approval to facilitate faster regulatory approvals in other countries
  which formally recognise the EU approval such as Australia.

In summary, we view the deal with Aspen as an important milestone for SPL, being its first commercial deal for VivaGel for BV application. On launch, VivaGel for BV will become SPL's second commercial product after the VivaGel coated condom and will serve to further de-risk SPL's VivaGel portfolio. Partnering negotiations are ongoing for other Ex-US jurisdictions including Europe. In our view, this deal is the first of many more VivaGel BV deals to come. We also see the potential for the partnership between the two companies to be expanded in future to include other jurisdictions as well. We expect first sales from the OTC BV product in 2HCY16.

### Overview of Bacterial Vaginosis infection

Bacterial Vaginosis (BV) is the most common vaginal infection in women of childbearing age (14-49). It is associated with an imbalance in the 'good' and 'harmful' bacteria that are normally found in a women's vagina. Specifically in BV patients the *Lactobacillus* species of bacteria loses its predominance to other bacteria such as those of the *Gardnerella*, *Mobiluncus* and other anaerobic species. The lactobacilli are largely responsible for maintaining the acidic pH of the vagina.

**Disease Prevalence:** 29% of US women aged 14-49 have had BV. 30% of BV patients in US have recurrence of symptoms within 3 months of therapy and more than 50% experience a recurrence within 12 months. **Recurrent BV is defined as episodes of 3 BV or more in 12 months.** As an indication BV is an underdiagnosed and undertreated disease.

**Symptoms and Risks:** The disease is linked to complications like premature delivery, increased risk of sexually transmitted infections (STIs) like HIV and genital herpes, development of pelvic inflammatory disease (PID) and in pregnant women undergoing abortion, it is linked to an increased risk of infection.

Many women with BV have no symptoms. For women with symptomatic BV, the disease affects the quality of life especially if they have chronic and repeated episodes of BV. Common symptoms of BV include:

- · Abnormal vaginal discharge
- Unpleasant odour
- · Burning during urination
- · Itching around outside of vagina

**Standard of Care and its quality:** There is currently no treatment approved for prevention of recurrence of BV. Current acute treatment options for BV are also few. There exists an unmet need for safe and effective treatments and therapies that can prevent the recurrence of the infection.

Current standard of care for BV acute treatment are the antibiotics metronidazole and clindamycin. They are administered either as a pill or applied topically intra-vaginally. They are not optimal since they have high relapse rates and are also associated with side effects including increased risk of thrush (candidiasis), gastrointestinal side effects, adverse reactions with alcohol consumption and are incompatible with condom use.

The high side effects of antibiotics sometimes lead to non-compliance and incomplete treatment which in turn may lead to development of resistance by the bacteria for the antibiotic therapy. Frequent use of antibiotics is also considered to lead to development of resistance. We note that the high side effects and resistance issues associated with existing antibiotic treatments make them unsuitable for long-term or preventative use.

### VivaGel for managing BV Symptoms

In Ex-US markets only, SPL is pursuing regional approvals of VivaGel for rapid relief of BV symptoms. This is an OTC (over the counter) consumer product. This means that women will <u>not</u> need to see a doctor to get a prescription and will be able to purchase this off-the-shelf in stores. Given that it is women with Symptomatic BV who generally seek treatment, an effective solution for women to reduce or relieve these symptoms is likely to be well received.

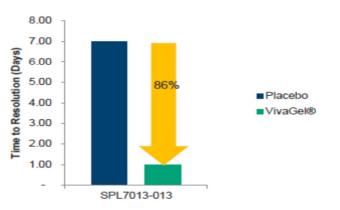
Women, who get symptoms of BV for the first time, are more likely to self-medicate (buying an OTC product) rather than going to a doctor for diagnosis. These women would generally consult a doctor if their symptoms persist after self-treatment.

All the clinical trials so far have demonstrated the strong BV symptom resolution effect of VivaGel compared to the placebo gel as long as women remained on treatment. In 3 separate VivaGel trials, VivaGel was shown to provide statistically significant results showing greater odour resolution as compared to placebo (See Figure 1 & 2).

Figure 1 - VivaGel - Resolution of Odour in BV patients

Figure 2 - VivaGel - Rapid resolution of BV related odour





SOURCE: COMPANY DATA

SOURCE: COMPANY DATA

### Competitive landscape

For symptomatic relief, SPL is targeting the OTC market in Ex-US jurisdictions.

Indirectly, the company will face some competition from the approved antibiotics such as Metronidazole and Clindamycin for acute treatment of BV.

However, its direct competition will be OTC products which can be clubbed broadly under the heading 'Vaginal pH correction treatments'. The 'vaginal pH correction' OTC products are intravaginal gels or washes which change the acid balance of the vagina, making it a less hospitable environment for harmful bacteria. There are quite a few of these products available however, most don't have the extent of clinical trials data as SPL has to back their effectiveness claims.

In the OTC market, awareness and brand building efforts play a significant role in driving product adoption. Therefore, VivaGel's success in the OTC market will depend on the marketing and distribution capabilities of its licensee.

### 1H16 – Results Summary

A summary of the reported 1H16 result is shown in the Table below:

Table 1 – 1H16 result summary									
	Result vs PCP Result vs F		s Forecast	Comments					
	1H15A	1H16A	% change	1H16E	Variance (%)				
Revenues (incl R&D Tax incentive)	1.9	5.3	186%	4.8	11%	Higher than expected due to higher collaboration revenue			
R&D	8.7	13.5	55%	8.8	53%				
G&A	1.6	1.6	2%	1.9	-15%				
Operating costs	10.3	15.1	47%	10.7	-29%	Higher than our forecast. Higher R&D partially offset by lower G&A			
EBIT	-9.0	-10.2	14%	-6.5	57%				
Net Interest Income/(expense)	0.5	0.2	-58%	0.7	-70%	Lower interest income			
Pretax Income (Loss)	-8.5	-10.0	18%	-5.9	71%				
Net Income (Loss) after tax	-8.5	-10.0	18%	-5.9	71%	Higher loss due to increased opex and lower interest income			
Diluted EPS/Share	-\$0.03	-\$0.03	9%	-\$0.02	81%				

SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

### Key result highlights

- Revenue higher than expected: Revenue (including commercialization revenue and R&D tax incentive) of \$5.3m was ahead of our forecast (BPe \$4.8m). This was due to higher revenue from commercial partners. R&D tax incentive of \$1.8m was in line with our estimates. The increase in revenue over pcp was primarily due to higher revenue from commercial partners including the A\$2.9m upfront payment received from AstraZeneca in 1H16.
- Operating costs were higher than expected: Opex (including R&D and G&A) of \$15.1m (up 47% y/y) were ~29% above our forecast driven by higher R&D costs partially offset by lower G&A costs. The increase over pcp was related to increase in R&D costs in particular for the two Phase III trials for VivaGel for prevention of recurrence of Bacterial Vaginosis (R-BV) and the Phase I trial for DEP docetaxel.
- Lower interest income: Interest income was below our forecast and lower than pcp due to lower interest rates and lower cash balance than our forecast.
- **Higher Net loss driven by higher opex:** 1H16 Net loss of \$10.0m (up 18% y/y) was 71% higher than our forecast (BPe \$5.9m), driven by higher opex and lower interest income.
- Strong cash position at end of 1H16: Cash balance of \$54.7m was slightly below our forecasts (BPe \$58.2m). SPL has burned ~\$2.0m/month on average over the last 12 months. This should provide a cash runway beyond CY17 based on current burn rates.

### **Earnings and Valuation Changes**

We have revisited our assumptions for Starpharma and made adjustments to our forecasts based on the 1H16 results filed on the ASX and the Aspen deal for VivaGel BV, which have impacted earnings and valuation.

### Key assumption changes

- We have updated our model for the A\$1.9m cash injection through the SPP. We had earlier assumed A\$3m raising through the SPP.
- We have increased our R&D forecasts based on the higher than expected costs in 1H16, higher share based payment forecasts and revised currency estimates. This was partially offset by reduced G&A forecasts.
- We have revised our assumptions regarding the timing of first sales from VivaGel OTC BV product to 1HFY17 (was 2HFY16).
- We now assume that a licensing deal with ~US\$1.5m upfront for the VivaGel OTC BV product (potentially for Europe) is signed in 1HFY17 (previously 3QFY16). Accordingly our upfront payment has shifted to 1HFY17.
- We have updated our model with revised BPe USD/AUD currency assumptions for 2016.
- We have rolled forward our DCF model.
- We now forecast SPL to end FY16E with \$41.2m cash.

Our revised assumptions regarding the timing of first sales from VivaGel OTC BV product and increased R&D costs, with positive offsets in reduced G&A costs and rolling forward of our DCF model has resulted in our valuation for SPL being largely unchanged at \$1.11/sh (was \$1.12/sh). Our NPAT est. changed as follows -50% FY16, -5% FY17 and -11% FY18. We retain our Buy (Speculative) recommendation.

#### Table 2 - Key Changes to our FY16-18 Forecasts FY2017E FY2016E FY2018E Revenues 9.2 35.9 36.7 -26% R&D 20.0 26.0 -30% 12.5 14.5 -16% 9.5 9.5 0% G&A 3.8 3.5 8% 12% 5.0 10% FRITDA -14.6 -21.8 -49% 18.6 18.0 32.0 28.6 -11% -15.9 -22.9 -44% 17.4 16.9 -3% 30.7 27.6 -10% NPAT (adjusted) -14.7 -22.1 -50% 20.5 -11%

ALL AMOUNTS IN AUD IN MILLIONS EXCEPT EPS. SOURCE: BELL POTTER SECURITIES ESTIMATES

Our DCF valuation model is based on a WACC of 16.0% and a terminal growth rate of 1%.

Table 3 - Summary of Valuation						
Forecasts	Base case					
Enterprise Value from DCF (AUDm)	374.8					
Add: Cash at end FY16E (AUDm)	41.2					
Less: Debt at end FY16E (AUDm)	0.0					
Equity Value (AUDm)	415.9					
Total diluted shares at end FY16E (million)	375.1					
Value per share (AUD)	\$1.11					
Current Share price (AUD)	\$0.67					
Expected Capital Growth	66.9%					

SOURCE: BELL POTTER SECURITIES ESTIMATES

SPL reported A\$54.7m cash at the end of 1H16

We value SPL at \$1.11/sh

Table 4 - SPL- Probability-Weighted Sum-of-parts Valuation Summary Probability adjusted NPV Peak Sales First Fiscal Year of sales Value per Peak Market Probability of Global Asset Stage % Mix share (A\$) (Est.) share success (US\$m (A\$m) 2017 (Ex-US) \$0.12 VivaGel BV Symptomatic Relief First regulatory approval in Europe received 15.0% \$58 80.0% 11.0% VivaGel BV Prevention of Recurrence \$647 \$192 46.1% 2018 25.0% 44.0% \$0.51 Phase III VivaGel Coated Condom - Okamoto Regulatory certification received 2017 (Japan) 10.0% \$21 80.0% \$5 \$0.01 1.3% VivaGel Coated Condom - Ansell Regulatory approval received for AU,NZ 2015 (Ex-US), 2017 (US) 10.0% \$309 80.0% \$83 \$0.22 20.1% DEP Docetaxel (first solid tumour) 2021 15.0% \$511 15.0% \$63 \$0.17 15.1% AZN DEP Cancer Drug (lead) Pre-clinical 2024 NA NA NA \$28 \$0.08 6.8% Dendrimer-Glyphosate Field Trials ongoing 2017 10.0% \$763 15.0% \$21 \$0.05 5.0% Diagnostics/Laboratory Reagents On-market NA \$5 \$0.01 1.2% NA NA NA Other Pipeline/Non-allocated NA NA NA NA Cash (EOY 2016E) 9.9% NA \$41 \$0.11 Debt (EOY 2016E) NA NA NA NA Equity Value \$415.9 \$1.11 100.0%

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 5 - 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	2017	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%
DEP Docetaxel	First Solid tumour	Phase II complete	TBC	2018	300	15	125	160	15.0%
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 DEP 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 BY 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 including the second molecule selected by AZN 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 assign any value to SPL's commercial opportunity for the VivaGel Coated Condom in China. SPL has signed an MOU with a Chinese company to potentially manufacture and sell the VCC to the government segment of the Chinese market (estimated market 3bn condoms/year). SPL will work with the Chinese company towards getting regulatory approval in China ahead of launch in that market and finalisation of a binding commercial agreement. Approval and finalisation of this license agreement for China 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 DEP docetaxel, which demonstrated that DEP 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 DEP 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 DEP docetaxel could lead to upgrades in our numbers.** We will revisit our assumptions on the basis of the Phase I DEP 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:

- 3QFY16 Results from the first dose escalation phase of Phase I DEP docetaxel trial on the MTD (maximum tolerated dose);
- 4QFY16- Results from second expansion phase of DEP docetaxel Phase I trial;
- 2HFY16 Potential licensing deal for agrochemicals program dendrimer-glyphosate;
- 2HFY16 Additional regulatory approvals for VivaGel for symptomatic relief of Bacterial Vaginosis (BV) in Ex-US markets;
- 1HFY17 Licensing deal for VivaGel for symptomatic relief of BV with upfronts and milestones;
- 2HFY16/1HFY17 Additional regulatory approvals for VivaGel coated condom (VCC) in markets under agreement with Ansell;
- 1HFY17 Potential initiation of Phase II clinical trial for DEP docetaxel;
- 1HFY17 Results from the two Phase III trials of VivaGel for Prevention of Recurrence of Bacterial Vaginosis;
- 1HFY17 Launch of VCC in second market (potentially New Zealand) by Ansell;
- 1HFY17 Launch of VivaGel coated condom in Japan by Okamoto;

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 ~29.2%.

### **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 CY16 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\$54.7m 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 DEP 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
  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 OTC 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.



# **Starpharma** as at 7 March 2016

Recommendation Buy, Speculative
Price \$0.665

Valuation \$1.11

Starpharma (SPL)									Share pric		\$0.665
As at 7 March 2016									Market cap	) (A\$M)	244.1
Profit and Loss						Valuation data					
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	7.7	36.7	42.6	Net profit (A\$m)	-14.6	-19.0	-22.1	12.7	20.5
EBITDA	-14.5	-18.6	-21.8	18.0	28.6	EPS (c)	-5.1	-6.1	-6.4	3.4	5.5
Depreciation & Amortisation  EBIT	-1.1	-1.2	-1.0	-1.1	-1.1	EPS growth (%) P/E ratio (x)	N/A N/A	N/A N/A	N/A	NM 10.6	61.5%
Net interest & Other Income/(Expense)	<b>-15.6</b> 1.0	<b>-19.8</b> 0.9	<b>-22.9</b> 0.8	<b>16.9</b> 1.3	<b>27.6</b> 1.8	CFPS (c)	-3.5	-4.4	N/A -6.7	19.6 4.8	12.1 5.9
Pre-tax profit (loss)	-14.6	-19.0	-22.1	18.2	29.3	Price/CF (x)	-19.3	-15.1	-10.0	13.8	11.3
Tax	0.0	0.0	0.0	5.4	8.8	DPS(c)	0.0	0.0	0.0	0.0	0.0
NPAT (adjusted)	-14.6	-19.0	-22.1	12.7	20.5	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	-14.6	-19.0	-22.1	12.7	20.5	EV/EBITDA	-13.1	-10.2	-8.7	10.6	6.6
Reported net profit (loss) to shareholders	-14.6	-19.0	-22.1	12.7	20.5	EV/EBIT	-12.1	-9.6	-8.3	11.2	6.9
Including R&D tax incentive and royalties. F? VivaGel symptomatic relief deal and potential deal and milestone from AZN deal and FY 18 re docetaxel deal, milestone from BV symptomat	upfront & n evenue numb	nilestone fro er includes p	m BV preve	ntion of rec	urrence						
Cashflow											
Y/e June 30 (A\$m)	2014A	2015A	2016E	2017E	2018E	Share price now	\$0.665				
Reported NPAT plus discontinued ops.	-14.6	-19.0	-22.1	12.7	20.5	Valuation:	\$1.11				
Non-cash items	2.5	2.0	1.7	1.7	1.7	Premium (discount) to price	66.9%				
Working capital	2.3	3.3	-2.5	3.6	-0.2	Recommendation:	Buy				
Other operating cash flow	0.0	0.0	0.0	0.0	0.0		Speculative				
Operating cashflow	-9.8	-13.6	-22.9	18.0	22.1	Profitability ratios Y/e June 30	2014A	2015A	2016E	2017E	2018E
Capex	-0.3	-0.7	-0.2	-0.2	-0.2	EBITDA/revenue (%)	N/A	N/A	N/A	49.0%	67.1%
Investments	0.0	0.0	0.0	0.0	0.0	EBIT/revenue (%)	N/A	N/A	N/A	46.1%	64.6%
Other investing cash flow	0.0	0.0	0.1	0.0	0.0	Return on assets (%)	-39.7%	-42.7%	-40.7%	18.5%	22.6%
Investing cashflow	-0.3	-0.7	-0.1	-0.2	-0.2	Return on equity (%)	-44.4%	-50.5%	-44.2%	19.8%	23.9%
						Return on funds empl'd (%)	-44.3%	-50.4%	-44.2%	19.8%	23.9%
Change in borrowings	0.0	0.0	0.0	0.0	0.0	Dividend cover (x)	N/A	N/A	N/A	N/A	N/A
Equity issued	0.2	20.5	32.6	0.0	0.0	Effective tax rate (%)	0.0%	0.0%	0.0%	30.0%	30.0%
Dividends paid Other financing cash flow	0.0	0.0 0.0	0.0	0.0 0.0	0.0	I invidite and law are patient					
Financing cashflow	0.0 <b>0.2</b>	20.5	0.0 <b>32.6</b>	0.0 <b>0.0</b>	0.0 <b>0.0</b>	Liquidity and leverage ratios Y/e June 30	2014A	2015A	2016E	2017E	2018E
Tillationing dubition	0.2	20.5	32.0	0.0	0.0	Net cash (debt) (A\$m)	24.0	30.8	41.2	59.7	82.4
Net change in cash	-9.9	6.2	9.6	17.8	22.0	Net debt/equity (%) Net interest cover (x)	N/A N/A	N/A N/A	N/A N/A	N/A NM	N/A NM
Cash at end of period*  * Includes effect of exchange rate fluctuations on cash balance	24.0	30.8	41.2	59.7	82.4	Current ratio (x)	7.4	5.2	10.6	13.6	17.9
Free cash flow	-10.1	-14.3	-23.1	17.9	22.0						
Balance sheet						Interims					
Y/e June 30 (A\$m)	2014A	2015A	2016E	2017E	2018E	Y/e June 30 (A\$m)	1H15A	2H15A	1H16A	2H16E	1H17E
Cash	24.0	30.8	41.2	59.7	82.4	Revenue*	1.9	2.4	5.3	2.3	4.1
Current receivables	4.4	4.0	4.1	0.7	1.0	EBITDA	-8.4	-10.2	-9.8	-12.1	-6.3
Inventories Other current assets	0.0	0.0	0.0	0.0	0.0	Depreciation & Amortisation  EBIT	-0.6	-0.6	-0.5	-0.6	-0.7
Current assets	0.2 <b>28.6</b>	0.2	0.2 <b>45.4</b>	0.2 <b>60.6</b>	0.2 <b>83.7</b>	Net interest & Other Income (Expense)	-9.0	-10.8	-10.2	-12.6	-7.0
ourrent assets	28.6	35.1	45.4	60.6	83.7	Pre-tax profit	0.5 -8.5	0.4 -10.4	0.2 -10.0	0.6 -12.0	0.4 -6.6
PPE	0.5	0.9	0.8	0.7	0.6	Tax	0.0	0.0	0.0	0.0	0.0
	0.0	0.0	0.0	0.0	0.0	NPAT (adjusted)	-8.5	-10.4	-10.0	-12.0	-6.6
Non-current receivables						Laga minarity interests	0.0	0.0	0.0	0.0	0.0
	7.8	8.4	8.0	7.3	6.5	Less minority interests				-12.0	-6.6
Intangible assets			8.0 0.0	7.3 0.0	6.5 0.0	Net profit to shareholders	-8.5	-10.4	-10.0	12.0	0.0
Intangible assets Other non-current assets	7.8	8.4				-		-10.4	-10.0	12.0	0.0
Intangible assets Other non-current assets Non-current assets	7.8 0.0	8.4 0.0	0.0	0.0	0.0	Net profit to shareholders		-10.4	-10.0	12.0	0.0
Intangible assets Other non-current assets Non-current assets Total assets	7.8 0.0 <b>8.3</b>	8.4 0.0 <b>9.3</b>	0.0 <b>8.9</b>	0.0 <b>8.0</b>	0.0 <b>7.0</b>	Net profit to shareholders		-10.4	-10.0	72.0	0.0
Intangible assets Other non-current assets Non-current assets Total assets Payables	7.8 0.0 <b>8.3</b> 36.9	8.4 0.0 <b>9.3</b> 44.4	0.0 <b>8.9</b> <b>54.3</b>	0.0 <b>8.0</b> <b>68.6</b>	0.0 <b>7.0</b> <b>90.7</b>	Net profit to shareholders		-10.4	-10.0	72.0	0.0
Intangible assets Other non-current assets Non-current assets Total assets Payables Debt	7.8 0.0 <b>8.3</b> <b>36.9</b>	8.4 0.0 <b>9.3</b> <b>44.4</b> 5.9	0.0 <b>8.9</b> <b>54.3</b> 3.5	0.0 <b>8.0</b> <b>68.6</b> 3.7	0.0 <b>7.0</b> <b>90.7</b> 3.9	Net profit to shareholders		-10.4	-10.0	12.0	0.0
Intangible assets Other non-current assets Non-current assets Total assets Payables Debt Provisions	7.8 0.0 <b>8.3</b> <b>36.9</b> 3.1 0.1	8.4 0.0 <b>9.3</b> <b>44.4</b> 5.9 0.0	0.0 <b>8.9</b> <b>54.3</b> 3.5 0.0	0.0 <b>8.0</b> <b>68.6</b> 3.7 0.0	0.0 <b>7.0</b> <b>90.7</b> 3.9 0.0	Net profit to shareholders		-10.4	-10.0	12.0	0.0
Intangible assets Other non-current assets Non-current assets Total assets Payables Debt Provisions Other liabilities	7.8 0.0 <b>8.3</b> <b>36.9</b> 3.1 0.1 0.7	8.4 0.0 <b>9.3</b> <b>44.4</b> 5.9 0.0 0.8	0.0 <b>8.9</b> <b>54.3</b> 3.5 0.0 0.8	0.0 <b>8.0</b> <b>68.6</b> 3.7 0.0 0.8	0.0 7.0 90.7 3.9 0.0 0.8	Net profit to shareholders		-10.4	-10.0	12.0	0.0
Intangible assets Other non-current assets Non-current assets  Total assets  Payables Debt Provisions Other liabilities Total liabilities	7.8 0.0 <b>8.3</b> <b>36.9</b> 3.1 0.1 0.7 0.0 <b>3.9</b>	8.4 0.0 9.3 44.4 5.9 0.0 0.8 0.1 6.8	0.0 8.9 54.3 3.5 0.0 0.8 0.0 4.3	0.0 8.0 68.6 3.7 0.0 0.8 0.0 4.5	0.0 7.0 90.7 3.9 0.0 0.8 0.0 4.7	Net profit to shareholders		-10.4	-10.0	12.0	
Intangible assets Other non-current assets Non-current assets  Total assets  Payables Debt Provisions Other liabilities Total liabilities Shareholders' equity	7.8 0.0 8.3 36.9 3.1 0.1 0.7 0.0 3.9	8.4 0.0 9.3 44.4 5.9 0.0 0.8 0.1 6.8	0.0 8.9 54.3 3.5 0.0 0.8 0.0 4.3	0.0 8.0 68.6 3.7 0.0 0.8 0.0 4.5	0.0 7.0 90.7 3.9 0.0 0.8 0.0 4.7	Net profit to shareholders		-10.4	-10.0	12.0	
Intangible assets Other non-current assets Non-current assets Total assets  Payables Debt Provisions Other liabilities Total liabilities Shareholders' equity Minorities	7.8 0.0 8.3 36.9 3.1 0.1 0.7 0.0 3.9 33.0 0.0	8.4 0.0 9.3 44.4 5.9 0.0 0.8 0.1 6.8 37.6 0.0	0.0 8.9 54.3 3.5 0.0 0.8 0.0 4.3 50.0 0.0	0.0 8.0 68.6 3.7 0.0 0.8 0.0 4.5 64.1	0.0 7.0 90.7 3.9 0.0 0.8 0.0 4.7 86.0 0.0	Net profit to shareholders		-10.4	-10.0	12.0	
Other non-current assets Non-current assets  Total assets  Payables Debt Provisions Other liabilities Total liabilities Shareholders' equity Minorities Total shareholders funds	7.8 0.0 8.3 36.9 3.1 0.1 0.7 0.0 3.9 33.0 0.0	8.4 0.0 9.3 44.4 5.9 0.0 0.8 0.1 6.8 37.6 0.0 37.6	0.0 8.9 54.3 3.5 0.0 0.8 0.0 4.3 50.0 0.0 50.0	0.0 8.0 68.6 3.7 0.0 0.8 0.0 4.5 64.1 0.0 64.1	0.0 7.0 90.7 3.9 0.0 0.8 0.0 4.7 86.0 0.0 86.0	Net profit to shareholders		-10.4	-10.0	12.0	
Intangible assets Other non-current assets Non-current assets Total assets  Payables Debt Provisions Other liabilities Total liabilities Shareholders' equity Minorities	7.8 0.0 8.3 36.9 3.1 0.1 0.7 0.0 3.9 33.0 0.0	8.4 0.0 9.3 44.4 5.9 0.0 0.8 0.1 6.8 37.6 0.0	0.0 8.9 54.3 3.5 0.0 0.8 0.0 4.3 50.0 0.0	0.0 8.0 68.6 3.7 0.0 0.8 0.0 4.5 64.1	0.0 7.0 90.7 3.9 0.0 0.8 0.0 4.7 86.0 0.0	Net profit to shareholders		-10.4	-10.0	12.0	

### **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 lead manager in the October 2011 and September 2014 placement and joint lead manager in the December 2015 placement and received fees for that service.

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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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