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Speculative
See Key risks on Page 8 & Biotechnology Risk Warning on Page 10
Speculative securities may not be suitable for Retail clients

Starpharma (SPL)

Key clinical & commercial milestones are expected in FY17

Recommendation
Buy (unchanged)
Price
\$0.735
Valuation
\$1.05 (previously \$1.07)
Risk
Speculative

GICS Sector
Pharmaceuticals & Biotechnology

Expected Return

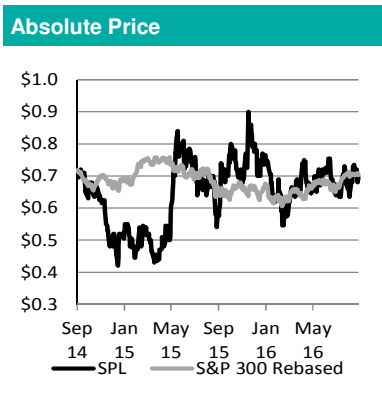
Capital growth	42.9%
Dividend yield	0.0%
Total expected return	42.9%

Company Data & Ratios

Enterprise value	\$223.9m
Market cap	\$269.8m
Issued capital	367.11m
Free float	100%
Avg. daily val. (52wk)	\$329,836
12 month price range	\$0.535 - \$0.98

Price Performance

	(1m)	(3m)	(12m)
Price (A\$)	0.70	0.70	0.58
Absolute (%)	-1.43	-0.72	18.97
Rel market (%)	-1.15	-4.53	8.26



SOURCE: IRESS

FY16- Key highlights

FY16 Net loss of \$22.7m (up 20% y/y) was ~3% ahead of our forecast (BPe \$22.1m), driven primarily by higher G&A costs. Revenue (including commercialization revenue and R&D tax incentive) of \$7.3m (up 71% y/y) was modestly below our forecast (BPe \$7.7m) and was driven by lower royalty and research revenue from commercial partners. R&D costs were in-line but markedly higher over pcp (+30%), due to increased clinical costs related to VivaGel for prevention of recurrent Bacterial vaginosis (R-BV) and DEP docetaxel. Cash of \$46m provides runway for the next 2 years and should allow SPL to progress to the next inflection point on each of its pipeline programs, as well as support its ongoing partnering negotiations.

New partnerships signed on targeted DEP platform

SPL has disclosed that it has recently signed two new partnerships with world-leading antibody-drug conjugate (ADC) companies. It involves the application of SPL's targeted DEP platform to enhance proprietary drugs from these ADC companies. Details are not disclosed. We view the agreements as a source of future cash injection, should they progress to a commercial licensing deal. Estimates project market for ADCs could grow to US\$9bn by 2023. Key players in this space include Roche, AstraZeneca, Celgene, Pfizer, Novartis, Seattle Genetics and Immunogen.

Valuation reduced to \$1.05, Retain Buy

Following changes to our model, the net result is increase in our net loss forecasts for FY17 by +6% and a decrease in our net profit forecasts for FY18 by -10%. The short term NPAT adjustments primarily driven by increase in G&A forecasts, combined with the longer term impact of removal of glyphosate from our model, partially offset by rolling forward of our DCF model has resulted in a modest reduction in our valuation for SPL to A\$1.05/sh (was A\$1.07/sh). We retain Buy. **Key re-rating catalysts include** a) Top line results from Phase I DEP docetaxel trial in 4QCY16, b) Top-line results from Phase III R-BV trials by end 4QCY16/early 1QCY17, c) initiation of Phase I trial (1HCY17) with first DEP AstraZeneca drug and d) launch of BV OTC product by Aspen in ANZ in 2HCY16.

Earnings Forecast

Year end 30th June	2015A	2016A	2017E	2018E	2019E
Revenue (A\$m)	4.3	7.3	19.6	33.3	18.0
EBITDA (A\$m)	-18.6	-22.5	-4.5	18.0	2.5
NPAT (adjusted) (A\$m)	-19.0	-22.7	-4.6	12.6	1.9
EPS (adjusted) (cps)	-6.11	-6.57	-1.24	3.38	0.51
EPS growth (%)	N/A	N/A	N/A	NM	-84.8%
PER (x)	N/A	N/A	N/A	21.7	143.0
EV/EBITDA (x)	-12.0	-9.9	-49.2	12.4	90.4
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%	-9.9%	20.8%	3.0%

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

FY16 – Results Summary

A summary of the reported FY16 result is shown in the Table below:

Table 1 – FY16 result summary						
	Result vs PCP			Result vs Forecast		Comments
	FY15A	FY16A	% change	FY16E	Variance (%)	
Revenues (incl R&D Tax incentive)	4.3	7.3	71%	7.7	-4%	Slightly lower than expected due to lower revenue from commercial partners
R&D	19.7	25.7	30%	26.0	-1%	In-line
G&A	3.2	4.2	33%	3.4	24%	Higher than expected
Operating costs	22.9	29.9	31%	29.4	-2%	Opex slightly higher than expected driven by higher G&A
EBITDA	-18.6	-22.5	21%	-21.7	4%	Higher loss driven by higher opex and lower revenue
Depreciation and Amortisation	-1.2	-0.9	-24%	-1.0	-9%	Slightly lower amortisation expense
EBIT	-19.8	-23.5	18%	-22.8	3%	Higher loss driven by higher opex and lower revenue, partially offset by lower D&A
Net Interest Income/(expense)	0.9	0.7	-23%	0.7	-2%	Lower interest income
Other Income/(expense)	0.0	0.1	NM	0.0	NM	Other income includes \$125k proceeds from sale of financial assets
Pretax Income (Loss)	-19.0	-22.7	20%	-22.1	3%	
Net Income (Loss) after tax	-19.0	-22.7	20%	-22.1	3%	Higher loss due to increased opex and lower interest income
Diluted EPS/Share	-\$0.06	-\$0.07	8%	-\$0.06	2%	

SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

Key result highlights

- Small miss in revenue:** Revenue (including commercialization revenue and R&D tax incentive) of \$7.3m was 4% below our forecast (BPe \$7.7m) and was driven by lower royalty and research revenue from commercial partners. R&D tax incentive of \$3.5m was in line with our estimates. The 71% increase in revenue over pcp was driven by the A\$2.9m upfront payment received from AstraZeneca in 1H16.
- Operating costs were slightly higher than expected:** Opex (including R&D and G&A) of \$29.9m (up 31% y/y) were ~2% ahead of our forecast, driven by higher 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. G&A costs also increased over pcp and were partially driven by higher share based payments.
- Lower interest income:** Interest income was below our forecast and below pcp due to lower interest rates, with the group holding higher cash reserves in USD.
- Net loss was 3% ahead of our forecast:** FY16 Net loss of \$22.7m (up 20% y/y) was ~3% ahead of our forecast (BPe \$22.1m), driven by higher opex, lower revenue and lower interest income, partially offset by lower D&A and other income of \$125,000 related to disposal of SPL's shareholding in Dimerix Limited (ASX:DXB).
- Strong cash position at end of FY16:** Cash balance of \$46m was in-line with our forecasts, given that we had adjusted our numbers last month following SPL's Appendix 4C quarterly cash flow report. SPL has been burning ~A\$2m/month on average over the last 12 months (excluding R&D tax incentive and customer receipts). In our view, SPL's strong cash position provides runway for the next 2 years and should allow it to comfortably progress to the next inflection point on each of its pipeline programs, as well as support its ongoing partnering negotiations.

Key Pipeline Update

SPL has provided an update on its product portfolio as described below:

New development

Two new DEP partnerships signed with world-leading antibody-drug conjugate companies: SPL has disclosed for the first time that it has recently signed two new partnerships with world-leading antibody-drug conjugate (ADC) companies. The partnership is around the application of SPL's targeted DEP platform to enhance proprietary drugs from these ADC companies. The deals are at the back of the positive data seen on SPL's HER2 (antibody)-targeted DEP conjugate (TDC), which the company states generated a significant amount of industry interest. Details around the partnership are not disclosed (including name of the companies, compounds, target indication etc.). While this is not a commercial licensing agreement at this stage, it could translate to a potentially valuable commercial licensing agreement in the future. As we have seen with the deal SPL did with AstraZeneca in drug-delivery, such platform deals not only provide validation of the technology but also have very attractive commercial terms.

We had expected the Targeted DEP platform to provide new partnering opportunities for SPL and we are encouraged with this progress made by the company even though details haven't been disclosed.

Results from a preclinical study in ovarian cancer of SPL's TDC demonstrated improved activity and survival benefit of treatment with SPL's targeted DEP conjugate over the two marketed agents from Roche (Herceptin and Kadcylla). 100% of the mice treated with SPL's TDC were alive at Day 120. Comparatively none of the mice treated with Kadcylla or Herceptin were alive by Day 50. Mice treated with SPL's TDC had no evidence of tumour (complete regression) after last dose and the treatment effect was maintained out to 120 days.

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.

An ADC combines a targeting antibody (specific to a cancer-specific antigen), to a cytotoxic agent. 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 Kadcylla have spurred interest and investment in this space. Both these drugs have combined sales in excess of US\$1bn.

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, in 2014 expanded its partnership to more than \$1bn and took an option to buy Sutro.

Although SPL has not disclosed the name of its partners the key players as mentioned above are Roche, AstraZeneca, Celgene, Pfizer, Novartis, Seattle Genetics and Immunogen. Any of them could be the high quality partners SPL has collaborated with. Given that SPL's pre-clinical study was with Roche's drugs they definitely would be in the front of the pack if we had to guess. Also, would be AZN given they already have existing partnerships in place with SPL.

Other pipeline progress update

- **VivaGel Prevention of recurrence of Bacterial Vaginosis (R-BV) trials nearing completion:** SPL is running two Phase III trials of VivaGel with 620 patients each for the prevention of recurrence of BV (R-BV) after reaching agreement with the FDA under a Special Protocol Assessment (SPA). **The trials are progressing well (now over 90% recruited), with recruitment ongoing at over 100 sites.** We expect top-line results from the trials by end of 4QCY16/early 1QCY17. We expect positive results from these trials would enable SPL to get a lucrative deal (BPe 1HCY17) given the high unmet need and no other approved treatments.
- **DEP docetaxel Phase I trial is in second expansion phase:** DEP docetaxel Phase I trial is in the dose expansion phase where a cohort of patients will be treated at the maximum tolerated dose from the dose escalation phase. A large European site has been added to facilitate rapid recruitment given the competition for patients in Australia so far has slowed the recruitment rate in the trial. We expect this European site would also potentially be one of the first few sites in a follow on Phase 2 trial for DEP docetaxel. There have been no dose limiting toxicities including neutropenia or alopecia (hair loss). **SPL also reports that patients (heavily pre-treated) have shown promising efficacy signals in a range of tumours (including those not typically sensitive to docetaxel) and at a broad range of dose levels, including at levels lower than the usual Taxotere clinical doses.**

Planning for a Phase 2 program is underway. **Product manufacture and site and CRO selection is well advanced to facilitate rapid progression from phase 1 into phase 2. We expect Top-line results from this trial in 4QCY16.** Positive results from this trial will provide proof of concept and will be a crucial de-risking event for the company. We also expect the data to have flow through implications for the rest of the drug delivery pipeline.

- **AstraZeneca drug delivery partnership progressing well:** The company also reported that their partnered program with AstraZeneca is progressing well. Last month **the companies expanded their partnership.** Under the new agreement, SPL's DEP technology will be applied to a compound in AZN's portfolio. This compound is not under the scope of the licensing agreement inked between the two companies in Sep'15 which covered a defined family of oncology targets. We expect that AZN could be in a position to select DEP-enhanced versions of the molecule within the next 12-18 months. We believe that SPL's DEP technology is being applied to a marketed compound, therefore it's likely a lifecycle strategy and if the product is a significant revenue generator, a deal could turn out to be quite valuable for SPL with a much faster path to market. We believe the expanded agreement is also indicative of AZN's deep interest in SPL's DEP technology and also suggests that the initial partnership between the two companies on oncology compounds is progressing well. We view this new agreement as a source of future cash injection, should it progress to a commercial licensing deal.
- **Regulatory and Commercialisation progress made for VivaGel portfolio of products:** The company also reported that they have made progress on the regulatory and commercialisation activities for the VivaGel coated condom (VCC) and the VivaGel OTC (over the counter) product for symptomatic relief of BV. SPL expects to conclude some of these activities in the near future. We expect additional regulatory approvals for VCC in markets under agreement with Ansell over the next 6 months. **We also expect SPL's partner Aspen to launch the OTC BV product in ANZ before the end of Dec 2016. The product is currently under regulatory review in Australia (having benefited from the Australian-EU mutual recognition agreement).** We also expect additional regulatory approvals and licensing deals for the OTC BV product to be finalised over the course of the next 4 months.

Earnings and Valuation Changes

We have revisited our assumptions for Starpharma and made adjustments to our forecasts based on the FY16 results filed on the ASX, which have impacted earnings and valuation.

Key changes to our modelling assumptions

- We have increased our G&A forecasts based on the higher than expected numbers reported in FY16 and to reflect our increased share based payment forecasts for FY17 onwards.
- We now assume that launch of VivaGel coated condom by Ansell in US happens in 1HFY18 (was 2HFY17).
- We have removed dendrimer-glyphosate from our model for now. Sales for this herbicide have been declining and recently contradictory findings on carcinogenic risks have thrust the chemical into dispute with several European countries imposing bans on its use. Proposal has been made to offer a limited extension to allow for time to study it further, however at a recent meeting the proposal did not get the majority votes needed for its adoption. With this uncertainty around, we believe it prudent to remove it from our forecasts for now.
- We have lowered our interest rate forecasts based on FY16 numbers, which has reduced our interest income forecasts going forward.
- We have updated our model with revised BPe USD/AUD currency assumptions for 2017 onwards (0.74-0.75).
- We have rolled forward our DCF model.

The net result is increase in our net loss forecasts for FY17 by +6% and a decrease in our net profit forecasts for FY18 by -10%. The short term NPAT adjustments combined with the longer term impact of removal of glyphosate from our model, partially offset by rolling forward of our DCF model has resulted in a modest reduction in our valuation for SPL to A\$1.05/sh (was A\$1.07/sh). **We retain our Buy (Speculative) recommendation.**

**We value SPL at
\$1.05/sh**

Table 2 - Key Changes to our FY17-18 Forecasts

	FY2017E			FY2018E		
	Old	New	Change (%)	Old	New	Change (%)
Revenues	19.6	19.6	0%	35.1	33.3	-5%
Interest Income	0.9	0.8	-13%	1.1	0.9	-14%
R&D	19.6	19.6	0%	10.5	10.5	0%
G&A	4.2	4.5	7%	4.5	4.8	7%
EBITDA	-4.2	-4.5	9%	20.1	18.0	-10%
EBIT	-5.2	-5.5	6%	19.0	17.0	-11%
NPAT (adjusted)	-4.3	-4.6	6%	14.1	12.6	-10%
Adjusted Diluted EPS	-1.2	-1.2	8%	3.8	3.4	-10%

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)	346.3
Add: Reported Cash (AUDm)	46.0
Less: Debt (AUDm)	0.0
Equity Value (AUDm)	392.3
Total diluted shares (million)	374.9
Value per share (AUD)	\$1.05
Current Share price (AUD)	\$0.74
Expected Capital Growth	42.9%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Table 4 - 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	2017 (Ex-US)	15.0%	\$58	80.0%	\$47	\$0.13	12.0%
VivaGel BV Prevention of Recurrence	Phase III	2018	25.0%	\$647	44.0%	\$177	\$0.47	45.0%
VivaGel Coated Condom - Okamoto	Regulatory certification received	2017 (Japan)	10.0%	\$21	80.0%	\$5	\$0.01	1.4%
VivaGel Coated Condom - Ansell	Regulatory approval received for AU,NZ	2015 (Ex-US), 2018 (US)	10.0%	\$375	80.0%	\$79	\$0.21	20.2%
DEP Docetaxel (first solid tumour)	Phase I	2022	15.0%	\$539	15.0%	\$48	\$0.13	12.4%
AZN DEP Cancer Drug (lead)	Pre-clinical	2024	NA	NA	NA	\$28	\$0.07	7.0%
Priostar-2,4-D	Pre Regulatory Submission	2019 (US)	20.0%	\$62	45.0%	\$3	\$0.01	0.8%
Diagnostics/Laboratory Reagents	On-market	NA	NA	NA	NA	\$3	\$0.01	0.8%
Other Pipeline/Non-allocated	NA	NA	NA	NA	NA	-\$45	-\$0.12	-11.4%
Cash (last reported)	NA	NA	NA	NA	NA	\$46	\$0.12	11.7%
Debt (last reported)	NA	NA	NA	NA	NA	-\$0.0	\$0.00	0.0%
Equity Value						\$392.3	\$1.05	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. PEAK SALES FOR PRIOSTAR -2,4-D IS FOR US MARKET 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 & ANZ)	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	2019	300	15	125	160	15.0%
AZN DEP Cancer Drug (lead)	Unknown	Pre-clinical	AstraZeneca	2016	126	2	64	60	NA
Priostar-2,4-D	Crop protection	Pre Regulatory Submission	Adama (US only)	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 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), 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 assign no value to the new collaboration agreement signed with AstraZeneca in July 2016 on a new DEP program in AZN's portfolio. This compound is not under the scope of the licensing agreement inked between the two companies in Sep'15 which covered a defined family of oncology targets. Should this agreement translate to a commercial licensing deal in future, it will be an 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 a license and supply agreement with Shenyang Sky and Land Latex Co. for its VivaGel coated condom (VCC), for the government segment of the Chinese condom market (estimated market 3bn condoms/year). Activities related to obtaining regulatory approval in China have commenced. Approval in China would be a potential upside to our estimates.

At this stage, we do not value SPL's other internal candidate from drug-delivery including DEP cabazitaxel or DEP 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. 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, SPL 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:

- **2QFY17 – Top-line results from Phase I DEP docetaxel trial (dose escalation and expansion phase);**
- 1HFY17 - Additional regulatory approvals for VivaGel for symptomatic relief of Bacterial Vaginosis (BV) in Ex-US markets;
- **1HFY17- Launch of VivaGel OTC (Over the counter) product for symptomatic relief of BV by Aspen in ANZ;**
- **End 2QFY17/early 3QFY17 - Results from the two Phase III trials of VivaGel for Prevention of Recurrence of Bacterial Vaginosis;**
- **1HFY17 - Completion of pre-clinical studies with first DEP AstraZeneca drug under partnership triggering a milestone payment to SPL;**
- 1HFY17 - Licensing deal for VivaGel OTC product for BV with upfronts and milestones;
- 1HFY17 - Additional regulatory approvals for VivaGel coated condom (VCC) in markets under agreement with Ansell;
- **2HFY17 – Potential initiation of Phase I trial with first DEP AstraZeneca drug under partnership triggering a milestone payment to SPL;**
- **2HFY17 – Potential initiation of Phase II clinical trial for DEP docetaxel;**
- **2HFY17 – Potential licensing deal for VivaGel for prevention of recurrence of BV;**
- 2HFY17 - Launch of VivaGel coated condom in Japan by Okamoto;

In addition, we expect that over the next 12-18 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. The process could take several months and at this stage it is difficult to estimate a timeline for approval and launch. Assuming the process takes between 10-18 months, there is a possibility for the approval to be received sometime in CY17.

We also believe there is a strong likelihood of additional partnerships for the VivaGel Coated condom for regions affected by Zika virus infection and not under agreement with Ansell in FY17.

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 ~30.2%.

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 before the end of the year. 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\$46.0m 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.

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.

Table 6 - Financial summary

Starpharma (SPL)						Share price (A\$)					\$0.735
As at 29 August 2016						Market cap (A\$m)					269.8
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	19.6	33.3	18.0	Net profit (A\$m)	-19.0	-22.7	-4.6	12.6	1.9
EBITDA	-18.6	-22.5	-4.5	18.0	2.5	EPS (c)	-6.1	-6.6	-1.2	3.4	0.5
Depreciation & Amortisation	-1.2	-0.9	-0.9	-1.0	-1.0	EPS growth (%)	N/A	N/A	N/A	NM	-84.8%
EBIT	-19.8	-23.5	-5.5	17.0	1.5	P/E ratio (x)	N/A	N/A	N/A	21.7	143.0
Net interest & Other Income/(Expense)	0.9	0.8	0.9	1.0	1.2	CFPS (c)	-4.4	-5.2	-1.1	5.0	1.2
Pre-tax profit (loss)	-19.0	-22.7	-4.6	18.1	2.7	Price/CF (x)	-16.7	-14.2	-69.1	14.6	59.2
Tax	0.0	0.0	0.0	5.4	0.8	DPS (c)	0.0	0.0	0.0	0.0	0.0
NPAT (adjusted)	-19.0	-22.7	-4.6	12.6	1.9	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	-4.6	12.6	1.9	EV/EBITDA	-12.0	-9.9	-49.2	12.4	90.4
Reported net profit (loss) to shareholders	-19.0	-22.7	-4.6	12.6	1.9	EV/EBIT	-11.3	-9.5	-40.8	13.2	148.9
* Including R&D tax incentive, milestones and royalties. FY17 Revenue number includes potential upfront from VivaGel BV symptomatic relief deal and from BV prevention of recurrence deal and milestone from AZN deal, FY18 revenue number includes potential milestone from BV prevention of recurrence and AZN deals. FY19 revenue number includes potential milestone from BV symptomatic relief deal and upfront from DEP docetaxel deal.											
Cashflow						Share price now					
Y/e June 30 (A\$m)	2015A	2016A	2017E	2018E	2019E	Share price now	\$0.735				
Reported NPAT plus discontinued ops.	-19.0	-22.7	-4.6	12.6	1.9	Valuation:	\$1.05				
Non-cash items	2.0	2.3	2.5	2.6	2.6	Premium (discount) to price	42.9%				
Working capital	3.3	2.7	-1.9	3.6	0.1	Recommendation:	Buy				
Other operating cash flow	0.0	-0.1	0.0	0.0	0.0	Risk Rating	Speculative				
Operating cashflow	-13.6	-17.8	-3.9	18.8	4.6	Profitability ratios					
Capex	-0.7	-0.1	-0.1	-0.1	-0.1	Y/e June 30	2015A	2016A	2017E	2018E	2019E
Investments	0.0	0.0	0.0	0.0	0.0	EBITDA/revenue (%)	N/A	N/A	N/A	54.0%	13.8%
Other investing cash flow	0.0	0.1	0.0	0.0	0.0	EBIT/revenue (%)	N/A	N/A	N/A	51.1%	8.4%
Investing cashflow	-0.7	0.0	-0.1	-0.1	-0.1	Return on assets (%)	-42.7%	-38.4%	-8.5%	18.4%	2.7%
Change in borrowings	0.0	0.0	0.0	0.0	0.0	Return on equity (%)	-50.5%	-45.9%	-9.9%	20.8%	3.0%
Equity issued	20.5	32.6	0.0	0.0	0.0	Return on funds empl'd (%)	-50.4%	-45.9%	-9.9%	20.8%	3.0%
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	20.5	32.6	0.0	0.0	0.0	Liquidity and leverage ratios					
Net change in cash	6.2	14.8	-4.1	18.6	4.5	Y/e June 30	2015A	2016A	2017E	2018E	2019E
Cash at end of period*	30.8	46.0	41.9	60.5	65.0	Net cash (debt) (A\$m)	30.8	46.0	41.9	60.5	65.0
* Includes effect of exchange rate fluctuations on cash balance											
Free cash flow	-14.3	-17.9	-4.1	18.6	4.5	Net debt/equity (%)	N/A	N/A	N/A	N/A	N/A
Balance sheet						Net interest cover (x)	N/A	N/A	N/A	NM	NM
Y/e June 30 (A\$m)	2015A	2016A	2017E	2018E	2019E	Current ratio (x)	5.2	5.3	6.0	7.8	8.2
Cash	30.8	46.0	41.9	60.5	65.0	Interims					
Current receivables	4.0	4.1	4.1	0.7	0.8	Y/e June 30 (A\$m)	2H15A	1H16A	2H16A	1H17E	2H17E
Inventories	0.0	0.0	0.0	0.0	0.0	Revenue*	2.4	5.3	2.1	4.6	15.0
Other current assets	0.2	0.2	0.2	0.2	0.2	EBITDA	-10.2	-9.8	-12.7	-9.0	4.4
Current assets	35.1	50.3	46.2	61.4	66.0	Depreciation & Amortisation	-0.6	-0.5	-0.5	-0.7	-0.3
PPE	0.9	0.7	0.5	0.3	0.1	EBIT	-10.8	-10.3	-13.2	-9.6	4.1
Non-current receivables	0.0	0.0	0.0	0.0	0.0	Net interest & Other Income (Expense)	0.4	0.3	0.6	0.3	0.7
Intangible assets	8.4	8.1	7.5	6.8	6.2	Pre-tax profit	-10.4	-10.0	-12.6	-9.4	4.8
Other non-current assets	0.0	0.0	0.0	0.0	0.0	Tax	0.0	0.0	0.0	0.0	0.0
Non-current assets	9.3	8.8	8.0	7.2	6.3	NPAT (adjusted)	-10.4	-10.0	-12.6	-9.4	4.8
Total assets	44.4	59.0	54.1	68.6	72.3	Less minority interests	0.0	0.0	0.0	0.0	0.0
Payables	5.9	8.8	6.9	7.1	7.3	Net profit to shareholders	-10.4	-10.0	-12.6	-9.4	4.8
Debt	0.0	0.0	0.0	0.0	0.0	*Includes R&D Tax incentive					
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	7.7	7.9	8.1						
Shareholders' equity	37.6	49.4	46.4	60.7	64.2						
Minorities	0.0	0.0	0.0	0.0	0.0						
Total shareholders funds	37.6	49.4	46.4	60.7	64.2						
Total funds employed	44.4	59.0	54.1	68.6	72.3						
W/A shares on issue	310.1	345.0	368.9	373.7	373.1						

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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