

Analyst

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Authorisation

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Starpharma (SPL)

Speculative

See Key risks on Page 11 &
Biotechnology Risk Warning on Page 13
Speculative securities may not be
suitable for Retail clients

Strong Phase 3 BV results improve VivaGel's Commercial prospects

Recommendation

Buy (unchanged)

Price

\$0.835

Valuation

\$1.29 (previously \$1.17)

Risk

Speculative

GICS Sector

Pharmaceuticals & Biotechnology

Expected Return

Capital growth	54.5%
Dividend yield	0.0%
Total expected return	54.5%

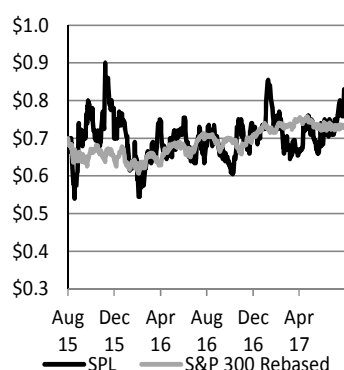
Company Data & Ratios

Enterprise value	\$247.0m
Market cap	\$308.2m
Issued capital	369.09m
Free float	100%
Avg. daily val. (52wk)	\$301,251
12 month price range	\$0.59 - \$0.88

Price Performance

	(1m)	(3m)	(12m)
Price (A\$)	0.74	0.75	0.65
Absolute (%)	12.93	11.41	27.69
Rel market (%)	13.06	14.29	23.77

Absolute Price



SOURCE: IRESS

BELL POTTER SECURITIES LIMITED
ABN 25 006 390 7721
AFSL 243480

Phase 3 R-BV trials demonstrate compelling efficacy

A statistically significant and consistent benefit of treatment with VivaGel vs. placebo was seen across both the prevention of recurrence of bacterial vaginosis (R-BV) trials on the primary efficacy endpoint and across various secondary efficacy endpoints including time to recurrence of BV, patient reported symptoms (vaginal odour and discharge) and other individual efficacy measures of BV (including clinician and bacteriologic assessments). The trial has shown statistically significant results despite accounting for missing data as failure, which further highlights the robustness of these results. The treatment was also found to be safe and well tolerated. The strong results from the R-BV trials and the SPA agreement on trial design with FDA, considerably de-risk the asset and increase the likelihood of marketing approval for VivaGel R-BV.

VivaGel BV now moves towards approval and licensing

A marketing application for BV treatment is expected to be submitted to the FDA in 3QCY17 and for R-BV in 4QCY17. VivaGel also has FDA's Fast Track and Qualified Infectious Disease Product (QIDP) designation for both BV indications, which offer an expedited path to market through rolling NDA submission and priority review (shorter 6 months FDA review time). QIDP also provides an additional five years of market exclusivity to VivaGel, further enhancing its commercial prospects. SPL has engaged a US bank to assist it with a competitive process ongoing on partnering BV. SPL had A\$61.2m cash at the end of June'17. We expect a licensing deal for BV over the next 2-3 months, will lead to further cash injection and allow SPL to focus completely on its core high value add drug delivery business.

Valuation lifted to \$1.29, Retain Buy (speculative)

Following revisions to our model, the net result is a 6% decrease in our net loss forecast for FY17 and a \$6.5m increase in our NPAT forecast for FY19, driven by reduced R&D costs and increased probability of success assigned to VivaGel R-BV (70% vs. 44%). Changes to FY18 NPAT were not material. Our valuation for SPL has lifted to A\$1.29/sh (was A\$1.17/sh). We retain Buy (spec). SPL remains one of our top picks for FY18. **Next catalyst:** Results from Phase 1 DEP docetaxel trial in 3QCY17.

Earnings Forecast

Year end 30th June	2015A	2016A	2017E	2018E	2019E
Revenue (A\$m)	4.3	7.3	6.6	22.9	40.6
EBITDA (A\$m)	-18.6	-22.5	-16.3	6.3	24.9
NPAT (reported) (A\$m)	-19.0	-22.7	10.2	4.9	18.1
NPAT (adjusted) (A\$m)	-19.0	-22.7	-16.8	4.9	18.1
EPS (reported) (cps)	-6.11	-6.57	2.78	1.32	4.84
EPS (adjusted) (cps)	-6.11	-6.57	-4.55	1.32	4.84
EPS (adjusted) growth (%)	N/A	N/A	N/A	NM	266.8%
PER (x)	N/A	N/A	N/A	63.3	17.2
EV/EBITDA (x)	-13.3	-11.0	-15.1	39.0	9.9
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%	-27.7%	7.3%	20.8%

NOTE: REVENUE INCLUDES R&D TAX INCENTIVES AND UPFRONTS & MILESTONES FROM DEALS. 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
DISCLAIMER: THIS REPORT MUST BE READ WITH THE DISCLAIMER ON PAGE 13 THAT FORMS PART OF IT INCLUDING THE FOLLOWING DISCLOSURE.
DISCLOSURE: BELL POTTER SECURITIES ACTED AS JOINT LEAD MANAGER IN THE DECEMBER 2015 PLACEMENT AND RECEIVED FEES FOR THAT SERVICE.

Phase 3 R-BV trials demonstrate compelling efficacy

Starpharma has reported positive Top-line results from its two Phase 3 trials with VivaGel for prevention of recurrence of bacterial vaginosis (R-BV).

Results demonstrate consistent and statistically significant efficacy of VivaGel in preventing recurrence of BV on the primary efficacy endpoint and across various secondary efficacy endpoints.

The strong results from the R-BV trials and the SPA (Special Protocol Assessment) agreement on trial design with FDA, considerably de-risk the asset and increase the likelihood of marketing approval for VivaGel R-BV.

We discuss the trial design and data reported from the trials below.

Phase 3 Trial Summary

Trial Design

- The two double-blind, randomised, multi-centre placebo-controlled trials were identical in design and enrolled 1,223 women (age 18-45 years) who had a history of recurrence of BV. Trial 017 was predominantly conducted in the US with 585 women with a history of R-BV, while Trial 018 was predominantly conducted in Europe with 636 women with a history of R-BV.
- A history of R-BV was defined as at least three episodes of BV in the preceding 12 months (i.e. average of at least one recurrence every 16 weeks).
- After screening, eligible women entered the open-label treatment phase and received a seven-day course of oral metronidazole (500 mg twice daily).
- Women were then randomised to receive either VivaGel or placebo gel administered at bedtime on alternate days for 16 weeks.

The Phase 3 trial design is depicted in the figure below:

Figure 1 - VivaGel Phase 3 R-BV Trial design



SOURCE: COMPANY DATA

Sites: Trial 017 was conducted at 66 clinical sites in the US, Canada, Mexico and Puerto Rico. Trial 018 was conducted at 46 clinical sites in Europe (UK, Bulgaria, Romania, Ukraine, Hungary, Czech Republic), US and Thailand. We note that there were very few US sites in Trial 018.

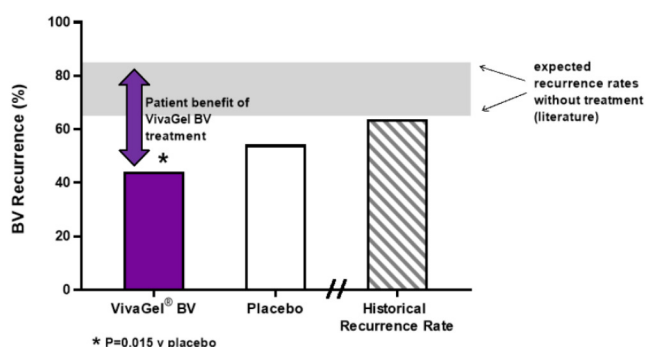
Primary end-point: Recurrence of BV at or by the Week 16 visit as diagnosed by clinical findings (i.e. presence of three out of four Amsel criteria). For the primary efficacy analyses, any patients who failed to attend the Week 16 visit were deemed to have recurred i.e. were imputed to failure (even if in reality they remained BV free).

Secondary end-points:

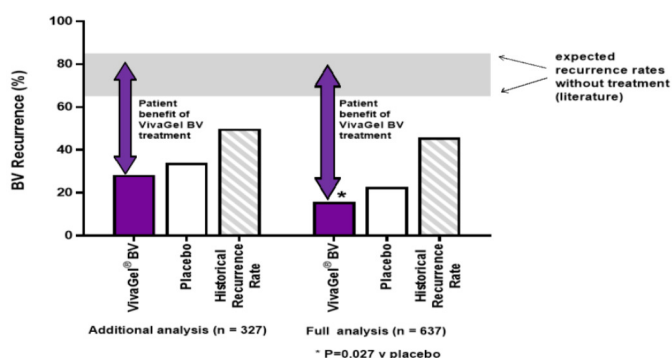
- Time to recurrence of BV according to the primary efficacy endpoint definition.
- Presence of patient-reported BV symptoms (vaginal odour and/or discharge) at or by the Week 16 visit.
- Recurrence of individual Amsel criteria at or by the Week 16 visit.
- Recurrence of BV as determined by presence of a Nugent score of 7-10 at or by the Week 16 visit.
- Recurrence of BV according to the composite definition of at least 3 clinical findings and a Nugent score of at least 4 at or by the Week 16 visit.
- Safety as determined by Adverse events (AEs) during the Double-blind Treatment and Follow-up Phases.

Key result highlights from the Phase 3 trial**Primary efficacy endpoint met**

- The trial met its primary efficacy endpoint, demonstrating statistically significant reduction in rate of recurrence of BV at or by week 16 vs. placebo. Trial 017 (44.2% in VivaGel treated group vs. 54.3% in placebo, $p=0.015$) and Trial 018 (15.7% in VivaGel treated group vs. 22.6% in placebo, $p=0.027$). We note that in the trial, patients who failed to attend week 16 follow up visit were put in the failure pool (i.e. deemed to have a recurrence in BV even if in reality they may have remained BV free). Excluding this missing data in trial 017, rate of recurrence of BV in VivaGel treated arm would have been even lower 34.9% vs. 46.6% in placebo.
- The company also estimated the 16 week historical recurrence rate (HRR) using the trial participants historical BV recurrence rate. HRR in Trial 017 was 65% and in Trial 018 was 50%. Hence, the reduced rate of recurrence in VivaGel treated arm also compares favourably to historical recurrence rates.
- Pooled data from both the trials also showed statistically significant reduction in rate of BV recurrence in VivaGel treated patients vs. placebo ($p=0.002$).
- Another additional analysis was conducted prior to unblinding data on a subset of patients in the EU trial 018 (sites with lower than expected recurrence rates were excluded). Due to smaller sample size (327 patients) while this sub analysis did not have statistical significance on the primary endpoint, it still showed a similar pattern of benefit of treatment with VivaGel (recurrence rate of 28.2% vs. placebo 33.9%, $p=0.266$). However, we did see statistical significance in this sub analysis on the other individual secondary efficacy measures.

Figure 2 – 017 US Trial – Patients with BV Recurrence at or by Week 16

SOURCE: COMPANY DATA

Figure 3 - 018 US Trial – Patients with BV Recurrence at or by Week 16

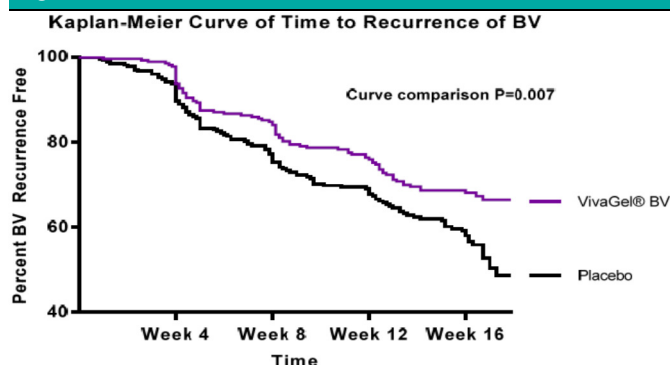
SOURCE: COMPANY DATA

Secondary efficacy endpoints met

Statistically significant benefit of treatment with VivaGel vs. placebo was also seen on 5 additional secondary efficacy endpoints which include patient reported symptoms, clinician assessments and bacteriologic assessments. This further supports VivaGel's mechanism of action.

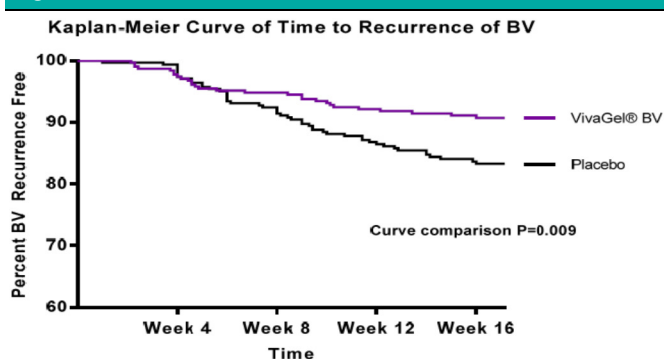
- **Time to recurrence of BV:** 017 US trial $P=0.007$; 018 European trial full analysis $P=0.009$, additional analysis $P=0.055$;

Figure 4 – 017 US Trial – Time to Recurrence of BV



SOURCE: COMPANY DATA

Figure 5 – 018 EU Trial – Time to Recurrence of BV



SOURCE: COMPANY DATA

- **Reduced recurrence of patient reported symptoms of vaginal odour and/or discharge:** 017 US trial $P<0.001$; 018 European trial full analysis $P=0.019$, additional analysis $P=0.032$;

Figure 6 – Recurrence of BV (defined as presence of Vaginal Odour and or discharge) at or by 16 weeks

Secondary Endpoint Analyses Patient Reported Symptoms (Vaginal Odour and/or Discharge)	Recurrence Rate %		p-value
	VivaGel® BV	Placebo	
017 US trial	23.0	36.5	<0.001
018 European trial (full analysis)	14.4	21.7	0.019
018 European trial (additional analysis)	23.8	34.9	0.032

SOURCE: COMPANY DATA

- **Reduced recurrence of BV by Nugent score of 7-10:** 017 US trial $P=0.012$; 018 European trial full analysis $P=0.002$, additional analysis $P=0.016$;

Figure 7 - Reduced recurrence of BV by Nugent score of 7-10 at or by 16 weeks

Secondary Endpoint Analyses Nugent Score 7-10	Recurrence Rate %		p-value
	VivaGel® BV	Placebo	
017 US trial	38.5	49.5	0.012
018 European trial (full analysis)	14.4	24.6	0.002
018 European trial (additional analysis)	18.8	31.1	0.016

SOURCE: COMPANY DATA

- **Reduced recurrence of BV by clinical findings (i.e. 3 out of 4 Amsel criteria) and Nugent score greater than or equal to 4:** 017 US trial $P=0.008$; 018 European trial full analysis $P=0.014$, additional analysis $P=0.045$; and

Figure 8 - Reduced recurrence of BV by clinical findings (i.e. 3 out of 4 Amsel criteria) and Nugent score greater than or equal to 4 at or by 16 weeks

Secondary Endpoint Analyses Clinical Findings and Nugent Score ≥ 4	Recurrence Rate %		p-value
	VivaGel® BV	Placebo	
017 US trial	29.3	40.2	0.008
018 European trial (full analysis)	9.6	16.3	0.014
018 European trial (additional analysis)	17.2	26.7	0.045

SOURCE: COMPANY DATA

- **Reduced recurrence of individual Amsel criteria as assessed by clinicians:** **Discharge** (017 US trial P=0.015; 018 European trial full analysis P=0.011, additional analysis P=0.012), **Positive whiff test** (017 US trial P=0.082; 018 European trial full analysis P=0.010, additional analysis P=0.022) and **Clue cells** (017 US trial P=0.014; 018 European trial full analysis P=0.001, additional analysis P=0.008). **We note that** the impact of VivaGel on reducing clue cells also supports its mechanism of action of disrupting biofilm.

Figure 9 - Recurrence of BV (defined as presence of Amsel criterion for discharge) at or by 16 weeks

Secondary Endpoint Analyses Amsel Criterion - Discharge	Recurrence Rate %		p-value
	VivaGel® BV	Placebo	
017 US trial	35.1	45.3	0.015
018 European trial (full analysis)	9.9	17.0	0.011
018 European trial (additional analysis)	16.6	28.5	0.012

SOURCE: COMPANY DATA

Figure 10 - Recurrence of BV (defined as presence of Amsel criterion for whiff test) at or by 16 weeks

Secondary Endpoint Analyses Amsel Criterion – Whiff Test	Recurrence Rate %		p-value
	VivaGel® BV	Placebo	
017 US trial	35.9	43.1	0.082
018 European trial (full analysis)	10.9	18.3	0.010
018 European trial (additional analysis)	18.5	29.7	0.022

SOURCE: COMPANY DATA

Figure 11 - Recurrence of BV (defined as presence of Amsel criterion for clue cells) at or by 16 weeks

Secondary Endpoint Analyses Amsel Criterion – Clue Cells	Recurrence Rate %		p-value
	VivaGel® BV	Placebo	
017 US trial	38.0	48.4	0.014
018 European trial (full analysis)	10.6	20.0	0.001
018 European trial (additional analysis)	18.5	31.7	0.008

SOURCE: COMPANY DATA

Additional secondary endpoints met

- Results also showed that benefits of treatment was also sustained after stopping treatment in the 12-week follow up period after (i.e. for 3 months after cessation of treatment) in terms of reduced discharge, odour and clue cells.
- The treatment was found to be safe and well tolerated, with adverse event profile largely similar to placebo. Rates of candidiasis was slightly higher than placebo in the 017 US trial, however still considered to be low and manageable.

Figure 12 – VivaGel treatment was safe and well tolerated with low rates of candidiasis

Treatment Related Adverse Events (AEs)	017 US Trial				018 European Trial			
	During Treatment		Off Treatment		During Treatment		Off Treatment	
	VivaGel® BV	Placebo	VivaGel® BV	Placebo	VivaGel® BV	Placebo	VivaGel® BV	Placebo
Non-GU AEs	1.0%	1.4%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
GU AEs	10.9%	10.0%	1.4%	1.0%	1.6%	1.9%	0.3%	0.0%
Candidiasis	5.8%	2.7%	1.0%	0.0%	0.6%	0.9%	0.3%	0.0%

GU = genitourinary; During Treatment = Double-blind treatment phase; Off Treatment = Follow-up phase

SOURCE: COMPANY DATA

In summary, a statistically significant and consistent benefit of treatment with VivaGel was seen across both the trials on the primary efficacy endpoint and across various secondary efficacy endpoints including time to recurrence of BV, patient reported symptoms (vaginal odour and discharge) and various other individual efficacy measures of BV (including clinician assessments and bacteriologic assessments). We are also encouraged that the trial has shown statistically significant results despite accounting for missing data as failure. This further highlights the robustness of these results. The treatment was also found to be safe and well tolerated, with adverse event profile largely similar to placebo.

We also note that SPL has a Special Protocol Assessment (SPA) from the FDA for its R-BV trials. The SPA is a binding written agreement between the FDA and SPL that the design, endpoints and statistical analysis approach of the Phase 3 R-BV trials are acceptable and adequately address all the objectives in support of a regulatory submission for the drug's approval. Given there is no approved R-BV treatments and no precedence for approval, having an SPA decreases the regulatory uncertainty for VivaGel.

We note that for R-BV there is currently no approved treatment. VivaGel offers an effective alternative to antibiotic treatment with a novel mechanism of action, which given the rising antibiotic resistance problem should find support both from regulators and physicians. We also note that for patients the main symptoms they struggle with are odour and discharge and the strong effect of VivaGel treatment on alleviating these symptoms is likely to be a key selling point for women suffering from BV.

The strong results from the R-BV trials and the SPA, considerably de-risk the asset and increase our confidence around the likelihood of marketing approval for VivaGel for R-BV.

Path Forward

We expect a marketing application for BV treatment to be submitted to the FDA in 3QCY17, followed by a marketing application for R-BV in 4QCY17.

FDA has also granted Fast Track and Qualified Infectious Disease Product (QIDP) designation to VivaGel for both BV indications. These designations offer an expedited path to market for VivaGel through rolling NDA submission (marketing application can be submitted in parts) and priority review, which shortens FDA review time to 6 months. The QIDP designation also provides an additional five years of market exclusivity to VivaGel, further enhancing the commercial prospects for VivaGel.

SPL has engaged a US bank to assist it with a competitive process ongoing on partnering BV. We expect a licensing deal for BV over the next 2-3 months.

We currently forecast VivaGel BV (treatment and R-BV) to be licensed in a deal worth up to US\$257m, including US\$50m in upfronts and near term regulatory milestones and the balance in commercial milestones. We also forecast double digit royalties on net sales (BPe 25%).

The company had A\$61.2m cash at the end of June'17, following the recent sale of its agrochemical business. A deal for BV will lead to further cash injection and allow SPL to focus completely on its core high value add drug delivery business.

Earnings and Valuation Changes

We have revisited our assumptions for SPL and made adjustments to our forecasts following the release of the VivaGel R-BV Phase 3 results and SPL's quarterly cash flow statement, which have impacted earnings and valuation.

Key changes to our modelling assumptions

- We have increased the probability of success for VivaGel R-BV to 70% (was 44%).
- We have updated our model with revised BPe USD/AUD currency assumptions for 2017 onwards (0.75-0.77).
- We have increased our capex for FY17 and reduced our estimate on net proceeds from sale of agrochemicals business based on the quarterly cash flow statement.
- We have also reduced our R&D forecasts for FY17 and increased it for FY18 based on the quarterly statement and reallocation of expense related to DEP docetaxel between the two years.
- We have increased our forward G&A forecasts marginally based on an increase in our non-cash share base payment forecasts.
- We have moved our estimated US\$3m milestone receivable from AstraZeneca on start of Phase 1 trial to 3QFY18 (was 2QFY18), given that we expect the trial to start after the companies release pre-clinical data later this year. We believe the data will likely be released at the high profile ASH (American Society of Hematology) conference in December (9th-12th Dec'17).
- With the slower than expected roll out of the VivaGel coated condom (VCC) asset to date, we are assuming a much slower rate of ramp up in revenues from VCC and have also reduced our market penetration forecasts for EX-US markets.
- We have rolled forward our DCF model.

**We value SPL at
\$1.29/sh**

The net result is a decrease in our adjusted net loss forecasts for FY17 driven by reduced R&D costs, offset by a decrease in NPAT for FY18, driven by increase in R&D costs. The increase in our FY19 NPAT forecast was driven by increased probability of success assigned to VivaGel R-BV (70% vs 44%). The short term NPAT adjustments combined with the long term impact of higher probability of success assigned to VivaGel R-BV and rolling forward of our DCF model has lifted our valuation for SPL to A\$1.29/sh (was A\$1.17/sh). **We retain our Buy (Speculative) recommendation.**

Table 1 - Key Changes to our FY17-19 Forecasts

	FY2017E			FY2018E			FY2019E		
	Old	New	Change (%)	Old	New	Change (%)	Old	New	Change (%)
Revenues	6.6	6.6	0%	21.8	22.9	5%	31.2	40.6	29.9%
Interest Income	0.7	0.6	-13%	1.0	1.0	1%	1.2	1.3	4.9%
R&D	19.6	18.2	-7%	10.5	11.7	11%	10.5	10.5	0.0%
G&A	4.6	4.7	3%	4.8	4.9	2%	5.0	5.1	2.4%
EBITDA	-17.6	-16.3	-7%	6.5	6.3	-2%	15.7	24.9	58.5%
EBIT	-18.6	-17.4	-7%	6.1	5.9	-3%	15.4	24.5	59.6%
NPAT (adjusted)	-17.9	-16.8	-6%	5.0	4.9	-2%	11.6	18.1	55.5%
Adjusted Diluted EPS	-4.9	-4.6	-6%	1.4	1.3	-2%	3.1	4.8	55.5%

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 2 - Summary of Valuation

Forecasts	Base case
Enterprise Value from DCF (AUDm)	425.9
Add: Reported Cash (AUDm)	61.2
Less: Debt (AUDm)	0.0
Equity Value (AUDm)	487.1
Total diluted shares (million)	378.6
Value per share (AUD)	\$1.29
Current Share price (AUD)	\$0.84
Expected Capital Growth	54.5%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Table 3 - 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 Treatment (US)	Preparing NDA to file for approval	2018 (US)	20.0%	\$142	70.0%	\$56	\$0.15	11.5%
VivaGel BV Symptomatic Relief	First regulatory approval in Europe received	2018 (Ex-US)	15.0%	\$21	80.0%	\$19	\$0.05	4.0%
VivaGel BV Prevention of Recurrence	Phase III	2019	25.0%	\$642	70.0%	\$247	\$0.65	50.8%
VivaGel Coated Condom - Okamoto	Regulatory certification received	2018 (Japan)	10.0%	\$21	80.0%	\$5	\$0.01	1.0%
VivaGel Coated Condom - Humanwell Healthcare	Regulatory approval received for AU, NZ, Canada	2015 (AU), 2017 (Canada), 2018 (US)	10% (US), 4% (EX US)	\$232	80.0%	\$53	\$0.14	10.9%
DEP Docetaxel (first solid tumour)	Phase I	2022	15.0%	\$564	15.0%	\$59	\$0.15	12.0%
AZN DEP Cancer Drug (lead)	Pre-clinical	2024	NA	NA	NA	\$25	\$0.07	5.2%
Diagnostics/Laboratory Reagents	On-market	NA	NA	NA	NA	\$3	\$0.01	0.5%
Other Pipeline/Non-allocated	NA	NA	NA	NA	NA	-\$41	-\$0.11	-8.4%
Cash (est. at 30th June 2017)	NA	NA	NA	NA	NA	\$61	\$0.16	12.6%
Debt (last reported)	NA	NA	NA	NA	NA	-\$0.0	\$0.00	0.0%
Equity Value						\$487.1	\$1.29	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 VIVAGEL BV TREATMENT 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 4 - 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	2018	25	1.5	NA	23.5	20.0%
VivaGel	BV Treatment (US)	Registration (pre-launch)	TBC	2018	57	1	9	47	25.0%
VivaGel	BV Prevention of Recurrence	Phase III complete	TBC	2018	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 (now Humanwell Healthcare)	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 (BPe speculation blood cancers)	Pre-clinical	AstraZeneca	2016	126	2	64	60	NA

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 Eli Lilly (drug delivery), Elanco (drug delivery), GSK (drug delivery) and from its undisclosed partnerships in drug delivery (partnership with 2 undisclosed companies on antibody-targeted conjugates). 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 existing portfolio (i.e. a marketed compound by AZN). 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 and we understand are progressing at a rapid rate. Approval in China would be a potential upside to our estimates.

At this stage, we do not value SPL's other internal candidates from drug-delivery including DEP cabazitaxel or DEP irinotecan, or its 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. We expect DEP cabazitaxel to move into Phase 1 trials in 1H FY18 and therefore expect to include it in our model in the coming months, which would represent an 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 remainder of CY17, we expect the following announcements to act as catalysts for a potential re-rating of the stock:

- Sep-Nov'17 - Licensing deal for VivaGel for BV (all indications) with upfronts and milestones;
- 1QFY18 – NDA filing for VivaGel for Treatment of Bacterial Vaginosis (BV) to US FDA for approval in US market;
- 2QFY18 – NDA filing for VivaGel for prevention of recurrence of Bacterial Vaginosis (R-BV) to US FDA for approval in US market;
- 1QFY18 – Top-line results from Phase I DEP docetaxel trial (dose escalation and expansion phase);
- 9th-12th Dec'17 – Potential release of pre-clinical data on lead candidate under AZN/SPL partnership at the high profile ASH (American Society of Hematology) conference;
- 3QFY18 – Potential initiation of Phase I trial with first DEP AstraZeneca drug under partnership triggering a US\$3m milestone payment to SPL;
- 2QFY18 – Potential initiation of Phase II clinical trial for DEP docetaxel;

- 1HFY18- 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 DEP Cabazitaxel;
- 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 2HCY17.

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 the pharmaceuticals sector. SPL's lead product is VivaGel which is being developed as an anti-microbial coating for condoms offering protection against Sexually Transmitted Infections, as well as a topical microbicide for treating and preventing the recurrence of the common vaginal infection in women, Bacterial Vaginosis (BV). SPL is also working on improved formulations of leading cancer drugs both internally and with external partners including AstraZeneca. Substantial shareholders Allan Gray, M&G and Fidelity, in combination hold ~31.2% stock.

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\$61.2m and sharpened focus on pharmaceuticals following sale of its agrochemical business 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, VivaGel for BV, as well as through progressing clinical trials for DEP docetaxel and other internal DEP candidates. 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 ongoing 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/Humanwell Healthcare 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 5 - Financial summary

Starpharma (SPL)						Share price (A\$)						\$0.835
As at 8 August 2017						Market cap (A\$m)						308.2
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	6.6	22.9	40.6	Net profit (A\$m)	-19.0	-22.7	-16.8	4.9	18.1	
EBITDA	-18.6	-22.5	-16.3	6.3	24.9	EPS (c)	-6.1	-6.6	-4.6	1.3	4.8	
Depreciation & Amortisation	-1.2	-0.9	-1.0	-0.4	-0.4	EPS growth (%)	N/A	N/A	N/A	NM	266.8%	
EBIT	-19.8	-23.5	-17.4	5.9	24.5	P/E ratio (x)	N/A	N/A	N/A	63.3	17.2	
Net interest & Other Income/(Expense)	0.9	0.8	0.6	1.0	1.3	CFPS (c)	-4.4	-5.2	-4.6	2.2	5.9	
Pre-tax profit (loss)	-19.0	-22.7	-16.8	7.0	25.8	Price/CF (x)	-19.0	-16.2	-18.1	37.4	14.1	
Tax	0.0	0.0	0.0	2.1	7.7	DPS (c)	0.0	0.0	0.0	0.0	0.0	
NPAT (adjusted)	-19.0	-22.7	-16.8	4.9	18.1	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	-16.8	4.9	18.1	EV/EBITDA	-13.3	-11.0	-15.1	39.0	9.9	
Reported net profit (loss) to shareholders	-19.0	-22.7	10.2	4.9	18.1	EV/EBIT	-12.5	-10.5	-14.2	41.5	10.1	
* Including R&D tax incentive, milestones and royalties. FY18 revenue number includes potential upfront from VivaGel BV deal (all indications) and milestone from BV treatment (US) and AZN deals. FY19 revenue number includes potential milestone from BV 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	-19.0	-22.7	10.2	4.9	18.1	EBITDA/revenue (%)	N/A	N/A	N/A	27.6%	61.5%	
Non-cash items	2.0	2.3	-23.5	1.7	1.7	EBIT/revenue (%)	N/A	N/A	N/A	25.9%	60.5%	
Working capital	3.3	2.7	-3.7	1.6	2.2	Return on assets (%)	-42.7%	-38.4%	-25.3%	6.7%	19.5%	
Other operating cash flow	0.0	-0.1	0.0	0.0	0.0	Return on equity (%)	-50.5%	-45.9%	-27.7%	7.3%	20.8%	
Operating cashflow	-13.6	-17.8	-17.0	8.3	22.0	Return on funds empl'd (%)	-50.4%	-45.9%	-27.7%	7.3%	20.8%	
Capex	-0.7	-0.1	-0.6	-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	33.3	0.0	0.0	Liquidity and leverage ratios						
Investing cashflow	-0.7	0.0	32.7	-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	61.2	69.6	91.7	
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	11.5	12.2	15.1	
Financing cashflow	20.5	32.6	0.0	0.0	0.0	Interims						
Net change in cash	6.2	14.8	15.7	8.1	21.9	Y/e June 30 (A\$m)	2H15A	1H16A	2H16A	1H17A	2H17E	
Cash at end of period*	30.8	46.0	61.2	69.6	91.7	Revenue*	2.4	5.3	2.1	2.0	4.6	
* Includes effect of exchange rate fluctuations on cash balance						EBITDA	-10.2	-9.8	-12.7	-8.9	-7.4	
Free cash flow	-14.3	-17.9	-17.6	8.1	21.9	Depreciation & Amortisation	-0.6	-0.5	-0.5	-0.5	-0.6	
Balance sheet						EBIT	-10.8	-10.3	-13.2	-9.4	-8.0	
Y/e June 30 (A\$m)	2015A	2016A	2017E	2018E	2019E	Net interest & Other Income (Expense)	0.4	0.3	0.6	0.3	0.3	
Cash	30.8	46.0	61.2	69.6	91.7	Pre-tax profit	-10.4	-10.0	-12.6	-9.0	-7.7	
Current receivables	4.0	4.1	4.0	2.6	0.5	Tax	0.0	0.0	0.0	0.0	0.0	
Inventories	0.0	0.0	0.0	0.0	0.0	NPAT (adjusted)	-10.4	-10.0	-12.6	-9.0	-7.7	
Other current assets	0.2	0.2	0.2	0.2	0.2	Less minority interests	0.0	0.0	0.0	0.0	0.0	
Current assets	35.1	50.3	65.4	72.3	92.4	Net profit to shareholders	-10.4	-10.0	-12.6	-9.0	-7.7	
PPE	0.9	0.7	1.0	0.7	0.5	*Includes R&D Tax incentive						
Non-current receivables	0.0	0.0	0.0	0.0	0.0							
Intangible assets	8.4	8.1	0.0	0.0	0.0							
Other non-current assets	0.0	0.0	0.0	0.0	0.0							
Non-current assets	9.3	8.8	1.0	0.7	0.5							
Total assets	44.4	59.0	66.3	73.0	92.9							
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	60.6	67.1	86.8							
Minorities	0.0	0.0	0.0	0.0	0.0							
Total shareholders funds	37.6	49.4	60.6	67.1	86.8							
Total funds employed	44.4	59.0	66.3	73.0	92.9							
W/A shares on issue	310.1	345.0	368.1	370.8	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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