BELL POTTER

Analyst

Tanushree Jain 612 8224 2849

Authorisation

TS Lim 612 8224 2810

Recommendation

Buy (unchanged)
Price
\$0.745
Valuation
\$1.10 (unchanged)
Risk
Speculative

GICS Sector

Pharmaceuticals & Biotechnology

Expected Return	
Capital growth	47.7%
Dividend yield	0.0%
Total expected return	47.7%
Company Data & Ratios	
Enterprise value	\$238.3m
Market cap	\$274.6m
Issued capital	368.59m
Free float	100%
Avg. daily val. (52wk)	\$318,565
12 month price range	\$0.59 - \$0.88

Price Performance						
	(1m)	(3m)	(12m)			
Price (A\$)	0.66	0.84	0.66			
Absolute (%)	12.88	-11.31	12.88			
Rel market (%)	11.63	-13.03	-0.87			



SOURCE: IRESS

Starpharma (SPL)

Speculative

See Key risks on Page 6 &
Biotechnology Risk Warning on Page 8
Speculative securities may not be

AstraZeneca advances first DEP oncology candidate towards the clinic

AZN/SPL's DEP cancer drug moves towards the clinic

Pre-clinical studies on the first DEP drug under SPL/AZN's 2015 oncology partnership has been completed which has triggered a US\$2m milestone payment to SPL (in line with our estimates). We expect AZN to advance the candidate into Phase 1 clinical trials in 2HCY17, which would trigger another milestone to SPL (BPe US\$3m). Scale up activities to support clinical trials has also been completed. Under the terms of the Sep'15 deal, SPL received US\$2m upfront and following this US\$2m milestone, remains eligible to receive an additional US\$122m in development, regulatory and sales milestones on the lead product and up to US\$93.3m in milestones on each follow on product and tiered royalties on sale. AZN's endorsement of the DEP technology provides further validation for SPL's broader DEP drug delivery platform.

First DEP drug 'an exciting novel oncology agent'

The head of Oncology of AZN's IMed unit referred to this drug as 'an exciting novel oncology agent'. While nothing has been disclosed so far on it, our analysis of AZN's pre-clinical oncology pipeline leads us to speculate that the candidate in question is AZD0466, a dual BCL-2/xl inhibitor being targeted at a broad range of blood cancers (liquid tumours). This is a well validated target, hampered by a narrow therapeutic window and on-target bone marrow toxicities such as thrombocytopenia and neutropenia. We strongly believe that the inherent toxicity issues seen with this class of drugs, positions it to benefit from SPL's DEP technology which can improve its therapeutic window. If we are correct, then this blood cancer drug has immense potential and broad applicability both as monotherapy and in combination. That fact, along with blood cancers being one of AZN's key oncology focus as evident from their recent US\$4bn acquisition of Acerta, in our view would make this drug very valuable to AZN, especially if we consider the potential for it to be combined with AZN/Acerta's lead candidate acalabrutinib (est. \$5bn+ peak sales potential for AZN) down the road. This bodes well for SPL/AZN's long term collaboration and AZN's interest in SPL.

Retain Buy (speculative) and Valuation of \$1.10

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

Earnings Forecast					
Year end 30th June	2015A	2016A	2017E	2018E	2019E
Revenue (A\$m)	4.3	7.3	9.2	19.3	42.1
EBITDA (A\$m)	-18.6	-22.5	-15.0	4.0	26.6
NPAT (adjusted) (A\$m)	-19.0	-22.7	-15.3	2.6	18.5
EPS (adjusted) (cps)	-6.11	-6.57	-4.15	0.69	4.96
EPS growth (%)	N/A	N/A	N/A	NM	NM
PER (x)	N/A	N/A	N/A	107.5	15.0
EV/EBITDA (x)	-12.8	-10.6	-15.9	59.2	9.0
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 (%)	-50.5%	-45.9%	-42.2%	6.4%	30.7%

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

AZN/SPL's DEP oncology candidate under collaboration moves towards the clinic

Event: Starpharma has achieved a key development milestone under its collaboration with AstraZeneca (AZN). Pre-clinical studies on the first DEP drug under SPL/AZN's September 2015 oncology partnership has been completed which has triggered a US\$2m milestone payment to SPL (in line with our estimates).

Commentary in the announcement also suggests that both SPL and AZN are impressed with how well the DEP candidate is performing and are looking to advance it into the clinic (human trials). AZN also continues to investigate the potential of SPL's DEP technology across its broader oncology portfolio. We believe this includes novel pipeline candidates as well as existing marketed drugs close to patent expiry.

Scale up activities for drug to support clinical trials has also been completed.

Our comments

- We are encouraged by the speedy progress in the partnership. We expect AZN to advance the candidate into Phase 1 clinical trials in 2HCY17, which would trigger another milestone to SPL (BPe US\$3m). We believe this milestone will be paid once the first patient is dosed in the Phase 1 trial.
- AZN's endorsement of the DEP technology provides further validation for SPL's broader DEP drug delivery platform.
- Following the success with the first candidate so far, we continue to expect more candidates to progress into the clinic under the September 2015 partnership. As a reminder, AZN also selected a second oncology molecule to develop using SPL's DEP technology in December 2015. We believe this second candidate is relatively early stage, with a lead DEP enhanced formulation yet to be selected. We expect that AZN could be in a position to select a DEP-enhanced version of this second molecule to progress to scale up and formal pre-clinical toxicology studies within the next 12 months.
- We note that the two companies have also entered into a separate collaboration agreement in July 2016, which we believe is on an existing marketed compound. Given the initial partnership between the companies has progressed well, we remain optimistic that the 2016 collaboration could also progress to a commercial licensing deal (BPe FY18).
- The head of Oncology of AZN's IMed unit referred to this drug as 'an exciting novel oncology agent'. While nothing has been disclosed so far on it, our analysis of AZN's pre-clinical oncology pipeline leads us to speculate that the candidate in question is a blood cancer drug with immense potential and broad applicability both as monotherapy and in combination. If we are correct, blood cancers being one of AZN's key oncology focus as evident from their recent US\$4bn acquisition of Acerta, in our view would make this drug very valuable to AZN and bodes well for the long term collaboration between both the companies. We discuss our speculations around the drug in detail later in the report.

Details of the SPL- AZN Deal inked in September 2015

 The deal is for a preclinical dendrimer enhanced novel oncology molecule in AZN's pipeline which AZN & SPL have been working on since 2014 and related compounds belonging to a defined family of oncology targets.

- AZN paid SPL US\$2m as cash upfront payment on signing of the deal.
- SPL is eligible to receive up to US\$124m in milestones on the lead product alone, including US\$64m in development and launch milestones (includes the US\$2m preclinical milestone just triggered) and US\$60m in sales milestones receivable on annual sales thresholds being met.
- SPL will also be eligible to receive up to US\$93.3m additionally in development, regulatory and sales milestones on each follow on product.
- AZN will bear all future development and commercialization costs related to the products under the agreement.
- SPL will also receive undisclosed royalties on product sales. As per SPL estimates, the
 royalties over the life of the lead drug could amount to ~US\$324m. The company has
 not disclosed the royalty rates under the deal. We estimate royalties to be tiered and in
 the range of low single digits to low double digits.

First DEP drug 'an exciting novel oncology agent'

- The head of Oncology of AZN's IMed (Innovative Medicines Unit) referred to this drug
 as 'an exciting novel oncology agent'. The IMED unit at AZN focuses on scientific
 advances in small molecules. AZN has a different unit which focuses on biologics.
 Therefore although not specified, we believe the deal focuses on small molecule cancer
 drugs.
- While nothing has been disclosed so far around the molecular target of the lead drug, our analysis of AZN's pre-clinical oncology pipeline leads us to speculate that the candidate in question is AZD0466, a dual BCL-2/xl inhibitor being targeted at a broad range of haematologic cancers (liquid tumours or blood cancers).
- AZN has developed a nanomedicine IV (intravenous) formulation of this drug, which has essentially been designed to improve its therapeutic window.
- This is a well validated target, hampered by a narrow therapeutic window and on-target bone marrow toxicities such as thrombocytopenia and neutropenia.
- The B-cell lymphoma-2 (Bcl-2) family of proteins is central to the regulation of apoptosis, which is vital for proper tissue development and cellular homeostasis. Antiapoptotic proteins, members of the Bcl-2 family (BCL-2, BCL-xL, BCL-W and MCL-1), are an important survival factor for many cancers and their overexpression has been associated with tumour initiation, progression and resistance to current anticancer therapies.
- A first in class BCL-2 inhibitor from Abbvie called Venclexta (venetoclax) has already been approved by the FDA last year for a sub group of patients with chronic lymphocytic leukemia (CLL). This provides validation for the target. It is also in clinical trials both as monotherapy and in combination with other drugs including Abbvie's imbruvica (ibrutinib) for other B-cell lymphoid malignancies. Early encouraging data on venetoclax has been seen in follicular lymphoma (FL), diffuse large B-cell lymphomas (DLBCL) and multiple myeloma (MM). We understand that street forecasts are available which puts Abbvie's haematological tumor sales (imbruvica and venclexta) reaching US\$6bn by 2020.
- However, although venclexta looks very promising, the complete response rates are still relatively low and not all people respond to treatment. In case of FL and DBCL monotherapy data has also not been very good and various resistance mechanisms have been highlighted. One of the resistance mechanisms have been the upregulation of the other BCL-2 family of proteins BCL-XL and MCL-1.

AZN with its AZD0466, by dual inhibition of BCL-2 and BCL-XL could increase the responders by targeting cancer cells which express both BCL-2 and BCL-XL, so that cancer cells with high expression of BCL-XL would not be able to escape.

- We note that prior to developing venclexta, Abbvie had tried previous generations of drugs which did target BCL-2, BCL-XL and another BCL-2 family protein. However, the therapeutic potential of those drugs were limited by on-target dose limiting toxicities such as thrombocytopenia, a cause of which was BCL-XL and neutropenia.
- Therefore AZN's AZD0466 has been designed with a broader Bcl2/xL profile, to improve the therapeutic window for thrombocytopenia, which has prevented agents of this profile delivering their full potential previously.
- We strongly believe that the inherent bone marrow toxicity issues seen with this class
 of drugs, positions it to benefit from SPL's DEP technology which can improve its
 therapeutic window. The safety data we have seen with SPL's internal DEP-docetaxel
 program and also with pre-clinical oxaliplatin have shown consistent improved safety
 profile with absence of neutropenia and thrombocytopenia, which supports our belief
 that the DEP technology is well suited for improving the abovementioned class of
 compounds.
- If we are correct, then this blood cancer drug has immense potential and broad applicability both as monotherapy and in combination. That fact, along with blood cancers being one of AZN's key oncology focus as evident from their recent US\$4bn acquisition of Acerta, in our view would make this drug very valuable to AZN, especially if we consider the potential for it to be combined with AZN/Acerta's lead candidate acalabrutinib (est. \$5bn+ peak sales potential for AZN) down the road. Our belief comes from the fact that AZN is doing a head to head trial of its acalabrutinib with Abbvie's Imbruvica and as we noted, Abbvie is also running Imbruvica + venetoclax combo trials to potentially expand the responding patient pool and achieve highly durable responses.
- Given, that we expect AZN's acalabrutinib to become the foundation of its haematological franchise, potential combination of AZD0466 with it in future also bodes well for the prospects of the drug and its value to AZN.
- The potential value of AZD0466 to AZN therefore would bode well for SPL/AZN's long term collaboration and clinical success could potentially increase AZN's interest in SPL.

In summary, we are impressed with the speedy progress of the collaboration between the two companies and view the advancement of the first DEP candidate towards the clinic by AZN as a vote-of-confidence for SPL's DEP technology. We believe AZN as a partner is a good strategic fit for SPL given its focus on oncology and its specific experience and capabilities in drug conjugates. AZN's strong endorsement of the DEP technology, further supported by data from SPL's internal programs, in our view provides validation for the DEP technology and could potentially lead to further partnerships for SPL on similar lines to the AZN deal. Furthermore, if our speculation is correct, the first DEP candidate is potentially valuable to AZN and clinical success could therefore increase AZN's interest in SPL.

Forthcoming Milestones

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

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

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

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

Starpharma Holdings Ltd. (SPL)

COMPANY DESCRIPTION

Starpharma is a Melbourne-based platform company commercialising the science of nanoscale polymers called dendrimers. Its proprietary dendrimer technology is versatile with wide applicability across multiple sectors including pharmaceuticals, agrochemicals and industrial applications. SPL's lead product is VivaGel which is being developed as an anti-microbial coating for Ansell and Okamoto condoms offering protection against Sexually Transmitted Infections, as well as a topical microbicide to prevent the recurrence of the common vaginal infection in women, Bacterial Vaginosis (BV). SPL is also working on improved formulations of leading cancer drugs as well as agrochemicals both internally and with external partners. Substantial shareholders include Allan Gray, M&G and Fidelity. Their combined holdings represent ~31.2%.

INVESTMENT STRATEGY

SPL remains an attractive story with multiple shots on goal. We expect multiple catalysts to play out over the next 12 months which could further de-risk the platform technology and demonstrate its commercial viability. We believe that CY17 will be a watershed year for SPL, with the release of Top-line data from the Phase I DEP docetaxel trial. Positive data from this trial will serve as a proof of concept for SPL's dendrimers to be effective drug delivery agents and substantially de-risk the company. SPL's strong cash position of A\$36.3m underpins its future growth and we expect the company add value in the medium term through commercial revenue from the condom coating asset, the AstraZeneca drug delivery partnership, as well as VivaGel for BV, as well as through progressing clinical trials for DEP docetaxel and VivaGel for prevention of R-BV. We also are encouraged between the deepening ties between AstraZeneca and SPL. We continue to rate SPL as a Buy.

KEY RISKS

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

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



Starpharma as at 21 April 2017

Recommendation Buy, Speculative
Price \$0.745

Valuation \$1.10

Part	Starpharma (SPL)								,	Share price	e (A\$)	\$0.745
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Debt 0.0 0.0 0.0 0.0 0.0 0.0 0.0 Provisions 0.8 0.8 0.8 0.8 0.8 0.8 0.8 0.8 0.8 0.8	Payables	5.9	8.8	4.9	5.1	5.3						
Provisions 0.8 0.8 0.8 0.8 0.8 Other liabilities 0.1 0.0 0.0 0.0 0.0 Total liabilities 6.8 9.6 5.8 6.0 6.2 Shareholders' equity 37.6 49.4 36.1 40.3 60.4 Minorities 0.0 0.0 0.0 0.0 0.0 Total shareholders funds 37.6 49.4 36.1 40.3 60.4 Total funds employed 44.4 59.0 41.9 46.2 66.6												
Other liabilities 0.1 0.0 0.0 0.0 0.0 Total liabilities 6.8 9.6 5.8 6.0 6.2 Shareholders' equity 37.6 49.4 36.1 40.3 60.4 Minorities 0.0 0.0 0.0 0.0 0.0 Total shareholders funds 37.6 49.4 36.1 40.3 60.4 Total funds employed 44.4 59.0 41.9 46.2 66.6												
Shareholders' equity 37.6 49.4 36.1 40.3 60.4 Minorities 0.0 0.0 0.0 0.0 0.0 Total shareholders funds 37.6 49.4 36.1 40.3 60.4 Total funds employed 44.4 59.0 41.9 46.2 66.6												
Minorities 0.0 0.0 0.0 0.0 0.0 Total shareholders funds 37.6 49.4 36.1 40.3 60.4 Total funds employed 44.4 59.0 41.9 46.2 66.6	Total liabilities	6.8	9.6	5.8	6.0	6.2						
Minorities 0.0 0.0 0.0 0.0 0.0 Total shareholders funds 37.6 49.4 36.1 40.3 60.4 Total funds employed 44.4 59.0 41.9 46.2 66.6	Total habilities		10.1	36.1	40.3	60.4						
Total shareholders funds 37.6 49.4 36.1 40.3 60.4 Total funds employed 44.4 59.0 41.9 46.2 66.6		37.6	43.4									
	Shareholders' equity			0.0	0.0	0.0						
W/A shares on issue 310.1 345.0 367.8 370.5 373.4	Shareholders' equity Minorities	0.0	0.0									
	Shareholders' equity Minorities Total shareholders funds	0.0 37.6	0.0 49.4	36.1	40.3	60.4						

Recommendation structure

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

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

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

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

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

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

Biotechnology Risk Warning:

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 6 of this note.

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