

ASLAN Pharmaceuticals

Additional clinical support for varlitinib

Clinical update

Pharma & biotech

7 June 2018

Price **\$9.86**

Market cap **\$324m**

NT\$30.06/US\$

Net cash (\$m) at March 2018
+ IPO + greenshoe 70.2

ADSs in issue 32.9

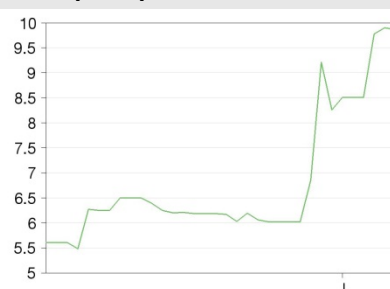
Free float 67%

Code ASLN

Primary exchange Taipei

Secondary exchange NASDAQ

Share price performance



% 1m 3m 12m

Abs N/A N/A N/A

Rel (local) N/A N/A N/A

52-week high/low N/A N/A

Business description

ASLAN Pharmaceuticals is a Singapore-based drug developer targeting Asia-prevalent diseases. It has varlitinib in pivotal clinical trials for biliary tract cancer and gastric cancer, and will be advancing ASLAN003 to Phase II trials for acute myeloid leukaemia.

Next events

ASLAN004 Phase I initiation Q318

Varlitinib first-line BTC results Late 2018

Varlitinib GC interim results H218

Varlitinib Chinese BTC results Late 2018

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ASLAN presented data at ASCO from a Phase Ib dosing study examining varlitinib in combination with carboplatin, paclitaxel and Herceptin. Patients were enrolled across a range of cancers, but the majority (20/37) were HER2+ metastatic breast cancer patients. The drug demonstrated efficacy across the study and the addition of Herceptin at the optimal dose did not induce toxicity, suggesting the potential of future combinations.

Year end	Revenue (\$m)	PBT* (\$m)	EPS* (\$)	DPS (\$)	P/E (x)	Yield (%)
12/16	11.5	(7.6)	(0.07)	0.0	N/A	N/A
12/17	0.0	(38.8)	(0.31)	0.0	N/A	N/A
12/18e	0.0	(38.9)	(0.25)	0.0	N/A	N/A
12/19e	0.7	(62.0)	(0.35)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments. Note the functional currency of the company is US dollars.

Tolerable dose combination with Herceptin found

The study examined 37 patients with a median three prior therapies. It was structured as a dose de-escalation study, so the rate of dose-limiting toxicities were high by design, but largely in line with other chemotherapy combination regimens. These events included neutropenia and electrolyte disorders. Carboplatin combinations were not tolerated, but Herceptin had no effect in the arm in which it was tested.

More evidence of varlitinib efficacy

The evaluation of efficacy in this study is difficult given the advanced stage of these patients and the high degree of variability in the study protocol. However, a disease control rate (stable disease + partial response + complete response) of 81% in evaluable patients and 56% on an intent to treat basis was observed. Among the patients with HER2+ breast cancer, six were able to be controlled on single agent varlitinib for a median of seven months, which is comparable to the progression free survival seen with Herceptin + paclitaxel in the front line (7.1 months).

ASLAN uplists to NASDAQ

In May 2018, ASLAN completed an offering of 6m ADSs (each representing five ordinary shares) on NASDAQ at a price of \$7.03. Proceeds were \$42.2m gross/\$36.8m net and an additional 0.9m ADSs will be offered in the underwriter's greenshoe. We expect this to provide a runway through the major clinical catalysts of 2018 and 2019.

Valuation: Increased to \$364m from \$308m

We have increased our valuation to \$364m (NT\$11.0bn) from \$308m (NT\$9.3bn), although it is lower on a per-share basis: \$11.04 per ADS (NT\$66.68 per ordinary share) compared to \$11.83 (NT\$71.85) previously. We arrive at estimated net cash (Q118 + offering + greenshoe) of \$70.2m. We expect the company to require \$60m in additional capital to reach profitability in 2021.

New data presented at ASCO

The company presented two posters at the American Society of Clinical Oncology (ASCO) annual conference in June 2018. The first was a description of the company's ongoing pivotal TREETOP study of varlitinib in biliary tract cancer (BTC), which did not provide any new clinical data. However, the company also presented data from an ongoing Phase Ib varlitinib combination dosing study. The trial is designed to examine varlitinib with and without Herceptin (trastuzumab, Roche) in combination with carboplatin and paclitaxel. The combination of Herceptin with a platinum drug and a dose of Taxol (such as carboplatin and paclitaxel respectively) is a common treatment for HER2+ breast cancer, which formed the majority of patients (20/37) in the study.

Interpreting the results of the study is complex given the multiple doses and four different active molecules being studied (Exhibit 1). The study was structured as a dose de-escalation, such that initial cohorts were at drug concentrations that were likely to cause dose limiting toxicities (DLTs). These DLTs included neutropenia (febrile and otherwise), as well as a number of electrolyte disorders (hypophosphatemia, hyponatremia and hypokalemia) among others. The latter are not uncommon in cancer patients undergoing chemotherapy, but are typically secondary to gastrointestinal distress (vomiting, diarrhea, etc). Diarrhea (of any grade) was the most common adverse event (69%), followed by fatigue (67%). The study identified 300mg dosed twice a day, intermittently (four days on, three days off) in combination with paclitaxel as the optimal dose combination and that addition of Herceptin did not increase toxicity.

Exhibit 1: Safety results from Phase 1b dosing study

Varlitinib dosing	Other drugs	N	DLT
500mg BD cont.	CP	3	3
400mg BD cont.	CP	5	3
400mg BD int.	CP	4	2
300mg BD int.	CP	6	2
300mg BD int.	P	6	0
400mg BD int.	P	4	2
300mg BD cont.	P	6	4
300mg BD int.	PT	3	0

Source: ASCO abstracts. Notes: cont.=continuous dosing, int.=intermittent dosing, C=carboplatin, P=paclitaxel, T=trastuzumab, DLT=dose limiting toxicity, PR=partial response, SD=stable disease.

These data build on the previously available evidence that varlitinib is clinically active in a range of tumor types. 26 of the 37 patients were evaluable for efficacy of which there was one complete response (CR), nine partial response (PR) and eleven stable diseases (SD). The disease control rate (CR+PR+SD) across among these was 81%, and 57% on an intent to treat basis. Two partial responses and two stable diseases were seen at the optimal dose (out of six). For comparison, disease control using Herceptin and paclitaxel in the first line is 79%,¹ so we find the results from this study to be a compelling response given the number of prior therapies in these patients (median three), and the general variability in the study protocol. The company also noted that of the 10 breast cancer patients that achieved disease control, six maintained it with varlitinib alone for a median of seven months. This is comparable to the progression-free survival seen with Herceptin and paclitaxel in the first line (7.1 months). Varlitinib was not found to be tolerable in the triple combination including carboplatin, which further improves PFS in the Herceptin combination (to 10.7 months), although we do not find this immediately limiting given the multiplicity of treatment options. However, it does speak to the differences between varlitinib and Herceptin, which is generally tolerable in this combination. The ability to combine varlitinib with Herceptin opens up a

¹ Robert N, et al. (2004) Randomized Phase III Study of Trastuzumab, Paclitaxel, and Carboplatin Compared With Trastuzumab and Paclitaxel in Women With HER-2–Overexpressing Metastatic Breast Cancer. *J Clin. Oncol.* 24, 2786-2792.

range of different potential treatment algorithms to be explored, although at this time more data are needed to draw any conclusions.

ASLAN uplists to NASDAQ

In March 2018, ASLAN announced the intent to uplist to the NASDAQ exchange, and subsequently in May priced an offering of ADSs: 6m ADSs (each representing five ordinary shares) at an offering price of \$7.03, for proceeds of \$42.2m gross/\$36.8m net. An additional 0.9m ADSs will be offered in the underwriter's greenshoe (and we have included this in our valuation, see Exhibit 3) . The proceeds will be used to support the ongoing clinical development of varlitinib, ASLAN003 and ASLAN004. The current financing should allow the company to progress through all its major clinical catalysts in 2018 and 2019. The company provided an updated timeline for these events, largely in line with our estimates (Exhibit 2).

Exhibit 2: Clinical catalyst timing

Drug	Program	Catalyst	Timing
Varlitinib	Second-line BTC	Pivotal top-line data	2019
		China pivotal top-line data	Late 2018
	First-line BTC	Phase I/II data	Late 2018
		Phase II top-line data	H218
ASLAN003	AML	Interim data	H218
ASLAN004	Asthma	IND	Q318
	Atopic dermatitis	IND	Q318

Source: ASLAN

Valuation

We have increased our valuation to \$364m (NT\$1.0bn) from \$308m (NT\$9.5bn), although it is lower on a per share basis: \$11.04 per ADS (NT\$66.68 per ordinary share) compared to \$11.83 (\$71.85) previously, as result of dilution from the recent NASDAQ IPO. The increase in the total valuation is driven by increased cash following the IPO (estimated \$42m net including the greenshoe bringing total cash to \$70m), as well as advancing our model to the most recent period.

Exhibit 3: Valuation of ASLAN

Program	Indication	Region	Clinical stage	Prob. of success	Launch year	Peak sales (\$m)	Margin/Royalties	rNPV (\$m)
Varlitinib	Second line BTC	US + Europe	Phase II/III	30%	2020	277	59%	121.6
		East Asia	Phase II/III	30%	2019-2020	195	53-58%	73.9
		R&D						-7.2
	First line GC	US + Europe	Phase II/III	20%	2021	182	57%	31.8
		East Asia	Phase II/III	20%	2021	302	54-60%	51.5
		R&D						-7.7
		Upfront and sales milestones payable						
ASLAN003	First line AML	US + Europe	Phase II ready	10%	2022	308	59%	38.0
		R&D						-4.0
ASLAN002 royalties	First line BC + GC	US + Europe	Phase II	15%	2022	909	5%	16.9
Unallocated costs								-11.8
Total								293.4
Net cash and equivalents (Q118+ IPO + greenshoe) (\$m)								70.2
Total firm value (\$m)								363.7
Total basic ADSs (m)								32.9
Value per ADS (\$)								11.04

Source: ASLAN reports, Edison Investment Research



Financials

The company reported a loss of \$8.6m (NT\$255m) from Q118, of which \$5.1m was attributable to R&D spending. We forecast R&D spending of \$30.5m for the year, increasing to \$34.3m in 2019 with the advancement of the ongoing clinical programs. The company recorded a \$12m payment in the first quarter for the new license agreement with Array Pharma for varlitinib, and it will owe another \$12m on the first anniversary. The company ended Q118 with \$27.9m in cash. If we include expected net proceeds from the NASDAQ IPO including the greenshoe (\$42.3m), we arrive at an estimated net cash of \$70.2m. We expect the company to require additional capital in 2019 to finance the launch of varlitinib, which we record as \$60m in illustrative debt (Exhibit 4).

Exhibit 4: Financial summary

	\$'000s	2016	2017	2018e	2019e
31-December		IFRS	IFRS	IFRS	IFRS
INCOME STATEMENT					
Revenue		11,547	0	0	743
Cost of Sales		(125)	0	0	(111)
Gross Profit		11,422	0	0	631
R&D		(13,165)	(30,001)	(30,526)	(34,313)
SG&A		(6,956)	(9,139)	(10,966)	(31,260)
EBITDA		(7,204)	(37,803)	(38,308)	(61,613)
Normalised operating profit		(7,280)	(38,013)	(38,533)	(61,837)
Amortisation of acquired intangibles		0	0	0	0
Exceptionals		0	0	0	3
Share-based payments		(1,420)	(1,127)	(2,959)	(3,107)
Reported operating profit		(8,700)	(39,140)	(41,492)	(64,941)
Net Interest		(477)	(54)	(198)	(124)
Joint ventures & associates (post tax)		0	0	0	0
Exceptionals		127	(699)	(197)	0
Profit Before Tax (norm)		(7,629)	(38,765)	(38,929)	(61,960)
Profit Before Tax (reported)		(9,049)	(39,892)	(41,888)	(65,065)
Reported tax		0	0	0	0
Profit After Tax (norm)		(7,629)	(38,765)	(38,929)	(61,960)
Profit After Tax (reported)		(9,049)	(39,892)	(41,888)	(65,065)
Minority interests		0	0	0	0
Discontinued operations		0	0	0	0
Net income (normalised)		(7,629)	(38,765)	(38,929)	(61,960)
Net income (reported)		(9,049)	(39,892)	(41,888)	(65,065)
Basic average number of shares outstanding (m)		105	124	157	175
EPS - basic normalised (\$)		(0.07)	(0.31)	(0.25)	(0.35)
EPS - diluted normalised (\$)		(0.07)	(0.31)	(0.25)	(0.35)
EPS - basic reported (\$)		(0.09)	(0.32)	(0.27)	(0.37)
Dividend (\$)		0.00	0.00	0.00	0.00
BALANCE SHEET					
Fixed Assets		593	689	21,615	19,561
Intangible Assets		84	84	21,053	18,999
Tangible Assets		384	444	405	405
Investments & other		125	161	158	158
Current Assets		53,121	50,645	41,128	34,137
Stocks		0	0	0	27
Debtors		1,294	0	0	122
Cash & cash equivalents		51,737	50,573	41,047	33,905
Other		90	72	82	82
Current Liabilities		(3,804)	(5,979)	(14,608)	(7,078)
Creditors		(3,804)	(5,979)	(14,608)	(7,078)
Tax and social security		0	0	0	0
Short term borrowings		0	0	0	0
Other		0	0	0	0
Long Term Liabilities		(8,336)	(9,841)	(10,524)	(70,966)
Long term borrowings		(8,336)	(9,679)	(10,099)	(70,541)
Other long term liabilities		0	(162)	(425)	(425)
Net Assets		41,575	35,513	37,611	(24,346)
Minority interests		0	0	0	0
Shareholders' equity		41,575	35,513	37,611	(24,346)
CASH FLOW					
Op Cash Flow before WC and tax		(7,204)	(37,803)	(38,308)	(61,613)
Working capital		1,524	3,274	(2,325)	4,122
Exceptional & other		(109)	(5)	1,320	1,933
Tax		0	0	0	0
Net operating cash flow		(5,789)	(34,534)	(39,313)	(55,558)
Capex		(374)	(291)	(195)	(224)
Acquisitions/disposals		(81)	(9)	(11,801)	(11,801)
Net interest		0	0	0	0
Equity financing		31,364	33,061	42,320	0
Dividends		0	0	0	0
Other		(68)	(36)	0	0
Net Cash Flow		25,052	(1,809)	(8,989)	(67,583)
Opening net debt/(cash)		0	(25,052)	(22,544)	(12,598)
FX		0	0	(979)	0
Other non-cash movements		0	(699)	22	0
Closing net debt/(cash)		(25,052)	(22,544)	(12,598)	54,985

Source: ASLAN reports, Edison Investment Research

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