

Hutchison China MediTech

Update

ESMO 2020: SANET-p delivers further positive suru data

22 September 2020

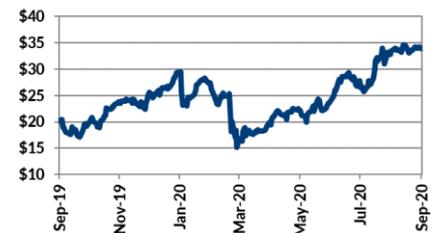
Data from China Phase III SANET-p study of surufatinib in pancreatic neuroendocrine tumours (pNET) was presented at the European Society of Medical Oncology (ESMO) 2020 virtual meeting. SANET-p was terminated early (January 2020) having already met its progression-free survival (PFS) primary endpoint at the planned interim analysis. At ESMO this was revealed to be an investigator assessed PFS of 10.9 months for surufatinib vs 3.7 months for placebo (hazard ratio = 0.49, p=0.0011). The China NDA for pNET, surufatinib's second indication, has been accepted for review with a 2021 approval decision anticipated. First China approval, in extra-pancreatic NET (epNET), is expected this year. Surufatinib will be Hutchison China MediTech's (Chi-Med's) first unpartnered oncology drug launch in China, and likely also in the US as NDA filing should start by end-2020. Our valuation is £5.87/share or \$38.17/ADS.

Year-end: December 31	2018	2019	2020E	2021E
Sales (US\$m)	214.1	204.9	214.8	318.7
Adj. PBT (US\$m)	(86.7)	(141.1)	(202.6)	(188.3)
Net Income (US\$m)	(71.3)	(103.7)	(132.9)	(141.3)
Earnings per ADS (US\$)	(0.57)	(0.80)	(1.00)	(1.02)
Cash (US\$m)	301.1	217.2	279.7	217.0*
Adj. EBITDA (US\$m)	(69.7)	(100.7)	(121.7)	(125.2)

Source: Trinity Delta Note: Adjusted PBT excludes exceptionals, Cash includes short-term investments, Adjusted EBITDA includes equity in earnings of equity investees. *2021E cash includes \$100m from assumed warrant exercise.

- Back of the NET for surufatinib** Two China NDAs for surufatinib have been filed and accepted. The approval decision for the first indication, epNET, is imminent, and assuming it is positive, surufatinib will be launched by Chi-Med's dedicated China Oncology commercial team. We expect it to be positioned as an effective treatment option for NET irrespective of tumour origin given that broad utility has been demonstrated in both Phase III NET trials. Results of the two pivotal trials were recently published in The Lancet Oncology ([SANET-ep](#); [SANET-p](#)).
- SANET-p ESMO data corroborates earlier findings** [SANET-p](#) showed a statistically significant and clinically meaningful difference in investigator assessed PFS vs placebo (10.9 months vs 3.7 months) in a pNET patient population with heavy tumour burden (>80% Grade 2 disease; >90% liver mets). The objective response rate (ORR) was 19.2% in the surufatinib group vs 1.9% for placebo, with a disease control rate (DCR) of 80.8% vs 6.6%. Safety was consistent with observations in prior clinical studies, including SANET-ep ([October 2019 Update](#)).
- Global momentum also building** Chi-Med will begin a rolling NDA submission with the FDA for surufatinib in NETs in late-2020, supported by China Phase III and US bridging data. This should be followed by an MAA filing with the EMA in 2021. FDA acceptance of the NDA is subject to review of the complete application, although planning for a potential late-2021 US launch is underway.
- £5.87/share or \$38.17/ADS valuation** We value Chi-Med using a DCF-based sum-of-the-parts model that includes a clinical pipeline rNPV. China approval of the surufatinib NDA(s) and initiation of NDA and MAA submissions would prompt us to upgrade our valuation. We anticipate multiple other clinical, regulatory, and commercial catalysts that will unlock further value in the coming 12 months.

Price (UK share)	514p
(US ADS)	\$33.85
Market Cap	£3.65bn \$4.81bn
Enterprise Value	£3.38bn \$4.45bn
Shares in issue (shares)	710.6m
(ADS)	142.1m
12 month range	249p-528p \$14.74-\$34.90
Free float	53.2%
Exchanges	AIM NASDAQ
Sector	Healthcare
Company codes	HCM.L HCM
Corporate client	Yes



Company description

Hutchison China MediTech is a Hong Kong headquartered biopharma focused on discovering, developing and commercializing innovative targeted therapeutics and immunotherapies to treat cancer and autoimmune diseases. It has a diverse pipeline of first-in-class/best-in-class selective oral tyrosine kinase inhibitors in development for the China and global markets.

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Exhibit 1: Summary of financials

Year-end: December 31	\$'000s	2017	2018	2019	2020E	2021E
INCOME STATEMENT						
Revenues		241,203	214,109	204,890	214,825	318,711
Cost of goods sold		(175,820)	(143,944)	(160,152)	(164,035)	(212,608)
Gross Profit		65,383	70,165	44,738	50,791	106,103
R&D expenses		(75,523)	(114,161)	(138,190)	(194,554)	(223,819)
Selling expenses		(19,322)	(17,736)	(13,724)	(14,736)	(19,597)
G&A expenses		(23,955)	(30,909)	(39,210)	(43,587)	(50,959)
Underlying operating profit		(53,417)	(92,641)	(146,386)	(202,086)	(188,271)
Other revenue/expenses		0	0	0	0	0
EBITDA		(50,839)	(89,051)	(141,444)	(196,558)	(178,606)
Operating Profit		(53,417)	(92,641)	(146,386)	(202,086)	(188,271)
Interest income/expense		(235)	4,969	3,914	250	714
Other income/expense		116	1,017	1,367	(758)	(758)
Profit Before Taxes		(53,536)	(86,655)	(141,105)	(202,595)	(188,316)
Adj. PBT		(53,536)	(86,655)	(141,105)	(202,595)	(188,316)
Current tax income		(3,080)	(3,964)	(3,274)	(5,204)	(6,370)
Equity in earnings of equity investees, net of tax		33,653	19,333	40,700	74,888	53,356
Net Income		(22,963)	(71,286)	(103,679)	(132,911)	(141,329)
Minority interests		(3,774)	(3,519)	(2,345)	(8,960)	(4,360)
Net income attributable to equityholders		(26,737)	(74,805)	(106,024)	(141,870)	(145,689)
EPS (\$)		(0.04)	(0.11)	(0.16)	(0.20)	(0.20)
Earnings per ADS (\$)		(0.22)	(0.57)	(0.80)	(1.00)	(1.02)
DPS (\$)		0.00	0.00	0.00	0.00	0.00
Average no. of shares (m)		617.2	664.3	665.7	697.9	714.7
<i>Gross margin</i>		27%	33%	22%	24%	33%
<i>EBITDA margin</i>		N/A	N/A	N/A	N/A	N/A
<i>Underlying operating margin</i>		N/A	N/A	N/A	N/A	N/A
BALANCE SHEET						
Current assets		432,195	370,541	317,022	377,543	342,947
Cash and cash equivalents		85,265	86,036	121,157	98,664	60,975
Short-term investments		273,031	214,915	96,011	181,074	156,074
Accounts receivable		42,270	42,958	43,254	47,085	69,854
Inventories		11,789	12,309	16,208	17,976	23,300
Other current assets		19,840	14,323	40,392	32,744	32,744
Non-current assets		165,737	161,577	148,100	171,418	192,661
Property, plant & equipment		14,220	16,616	20,855	34,745	47,985
Intangible assets		3,738	3,533	3,387	0	0
Investments in equity investees		144,237	138,318	98,944	113,644	121,648
Other non-current assets		3,542	3,110	24,914	23,028	23,028
Current liabilities		(104,600)	(85,479)	(113,101)	(121,051)	(134,992)
Short-term debt		(29,987)	0	0	0	0
Accounts payable		(24,365)	(25,625)	(23,961)	(26,965)	(40,774)
Other current liabilities		(50,248)	(59,854)	(89,140)	(94,086)	(94,218)
Non-current liabilities		(8,366)	(34,384)	(39,118)	(39,127)	(39,127)
Long-term debt		0	(26,739)	(26,818)	(26,839)	(26,839)
Other non-current liabilities		(8,366)	(7,645)	(12,300)	(12,288)	(12,288)
Equity		484,966	412,255	312,903	388,783	361,489
CASH FLOW STATEMENTS						
Operating cash flow		(8,943)	(32,847)	(80,912)	(113,143)	(139,784)
Net income		(22,963)	(71,286)	(103,679)	(132,911)	(141,329)
Non-cash adjustments & other operating cash flow		28,525	31,276	6,662	17,207	15,829
Change in working capital		(14,505)	7,163	16,105	2,561	(14,283)
Investing cash flow		(260,780)	43,752	119,028	(105,631)	2,095
CAPEX		(5,019)	(6,364)	(8,565)	(20,568)	(22,905)
Change in short term investments		(248,761)	58,116	118,904	(85,063)	25,000
Investment in an equity investee		(7,000)	(8,000)	8,689	0	0
Financing cash flow		273,196	(8,231)	(1,493)	196,343	100,000
Proceeds from equity		291,737	(2,322)	(95)	197,574	100,000
Increase in loans		(16,947)	(4,627)	(116)	0	0
Other financing cash flow		(1,594)	(1,282)	(1,282)	(1,231)	0
Net increase in cash		3,473	2,674	36,623	(22,430)	(37,689)
Exchange rate effects		2,361	(1,903)	(1,502)	(63)	0
Cash at start of year		79,431	85,265	86,036	121,157	98,664
Cash at end of year		85,265	86,036	121,157	98,664	60,975
Net cash at end of year		328,309	274,212	190,350	252,899	190,210

Source: Company, Trinity Delta Note: Adjusted PBT excludes exceptionals, Cash includes short-term investments, Adjusted EBITDA includes equity in earnings of equity investees. *2021E cash figure includes assumed receipt of \$100m in new funds from warrant exercise

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