

Hutchison China MediTech

Update

Bringing Global Innovation and China Oncology into focus

21 March 2019

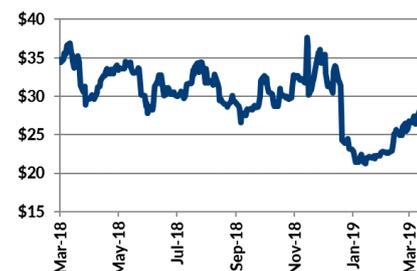
Hutchison China MediTech's (Chi-Med's) noteworthy achievements in FY18 include the landmark approval and launch of Elunate (fruquintinib) in China in 3L mCRC; the continued maturation of the tyrosine kinase inhibitor (TKI) pipeline with multiple assets either in, or approaching, China or Global registrational trials; and significant investment in building the US infrastructure to support the Global Innovation pipeline. 2019 should bring further progress, with a steady stream of clinical catalysts. Next up will be savolitinib NSCLC data at AACR (March 29-April 3). We continue to value Chi-Med at \$33.49/ADS or £51.52/share.

Year-end: December 31	2017	2018	2019E	2020E
Sales (US\$m)	241.2	214.1	168.6	207.6
Adj. PBT (US\$m)	(53.5)	(86.7)	(205.6)	(204.5)
Net Income (US\$m)	(23.0)	(71.3)	(170.6)	(166.9)
Earnings per ADS (US\$)	(0.22)	(0.57)	(1.31)	(1.28)
Cash (US\$m)	358.3	301.0	150.8	11.3
Adj. EBITDA (US\$m)	(17.2)	(69.7)	(163.9)	(159.5)

Source: Trinity Delta Note: Adjusted PBT excludes exceptionals, Cash includes short-term investments, Adjusted EBITDA includes equity in earnings of equity investees.

- Elunate (fruquintinib), a pioneering product** Elunate was launched with partner Eli Lilly in November, generating revenue of \$3.6m in its first five weeks. Solid early signs of clinical acceptance should be boosted by confirmation of reimbursement; negotiations to secure potential National Drug Reimbursement List (NDRL) inclusion in the 2019 update will be pursued. On the development front, the Phase III FRUTIGA gastric cancer interim analysis is imminent, and PD-1/PD-L1 combination studies are planned. The December Eli Lilly deal amendment provides Chi-Med with greater control over R&D plans (including life cycle initiatives), increasing the potential Elunate market opportunity, and its share of deal economics.
- Savolitinib to take centre stage for Chi-Med at AACR** Mature data from the Phase Ib/II global TATTON savolitinib and osimertinib combination NSCLC trial are scheduled for presentation at AACR on March 31, in a plenary session that also includes interim data from the China registration study of savolitinib monotherapy in exon 14m/del NSCLC. This latter study should complete enrolment in H219 and, subject to a positive result, will enable China NDA filing in 2020. Outside of China, the SAVANNAH Phase II savolitinib and osimertinib combination trial in c-Met+ 2L EGFR/T790M refractory NSCLC is due to read out in 2021 and further potentially pivotal NSCLC combination trials should be announced later in 2019.
- R&D investment to grow with portfolio progress** FY18 results met or exceeded expectations. FY19 guidance is centred on R&D spend (\$160m to \$200m) and adjusted non-GAAP net cash flows (-\$120m to -\$150m). This reflects growing investment in the Innovation Pipeline, which is the driver of Chi-Med's future growth, initially through addressing the China Oncology opportunity and longer-term through the Global Innovation pipeline.
- We maintain our \$33.49/ADS or £51.52/share valuation** We value Chi-Med using a DCF-based SOTP approach, which includes an rNPV model of the clinical pipeline. Our current valuation of \$4.5bn (\$33.49/ADS) or £3.4bn (£51.52/share) will be influenced by various share price catalysts over the next 18 months.

Price (US ADS) (UK share)	\$29.35 4,390p
Market Cap	\$3.91bn £2.93bn
Enterprise Value	\$3.61bn £2.70bn
Shares in issue (ADS) (shares)	133.3m 66.7m
12 month range	\$20.83-\$39.68 3,180p-5,668p
Free float	32%
Exchanges	NASDAQ AIM
Sector	Healthcare
Company codes	HCM HCM.L
Corporate client	Yes



Company description

Hutchison China MediTech is a Hong Kong headquartered biopharma with an established Commercial Platform in China, and a diverse pipeline of first-in-class/best-in-class selective oral tyrosine kinase inhibitors (Innovation Platform). Its pipeline, discovered in-house, is in development for the China and global oncology markets.

Analysts

Franc Gregori

fgregori@trinitydelta.org
+44 (0) 20 3637 5041

Mick Cooper PhD

mcooper@trinitydelta.org
+44 (0) 20 3637 5042

Lala Gregorek

lgregorek@trinitydelta.org
+44 (0) 20 3637 5043

Chi-Med: a wealth of opportunity

2018 marked several important achievements for Hutchison China MediTech (Chi-Med), and 2019 will be another critical year for the company with a rich vein of news flow (Exhibit 1). Several clinical studies are due to produce both interim and mature results, and various new trials will initiate, including global proof of concept studies for Syk inhibitor HMPL-523 and PI3K δ inhibitor HMPL-689. However, the focus for investors will largely be on Chi-Med's two most valuable assets - fruquintinib (Elunate) and savolitinib - and on the burgeoning US infrastructure and Global Innovation pipeline. We continue to value Chi-Med at \$4.5bn (\$33.49/ADS) or £3.4bn (£51.52/share) but expect to revisit our assumptions as clinical, regulatory, and commercial catalysts unlock further value.

Exhibit 1: Key near-term Hutchison China MediTech newsflow

Date	Programme	Event
AACR 2019	Savolitinib	Preliminary Phase II monotherapy data in c-Met exon 14 mutations/deletions NSCLC (China) Full Phase II data from global TATTON study (global) at AACR
H119	Fruquintinib	Interim Phase III FRUTIGA analysis (futility): fruquintinib + paclitaxel combo in 2L gastric cancer (China). Top line data in 2020
	HMPL-523	Initiation of Phase I/Ib study in indolent NHL (US/EU)
	HMPL-689	Initiation of Phase I/Ib study in indolent NHL (US/EU)
	Surufatinib	Initiation of Phase II/III in 2L chemo-refractory biliary tract cancer (China)
Mid-2019	Savolitinib	Preliminary Phase II VIKTORY data: savolitinib + docetaxel combo in c-Met mutated gastric cancer (South Korea)
	Surufatinib	Interim analysis of Phase III SANET-ep (China) in non-pancreatic NET
	HMPL-523 / HMPL-689	Phase I/Ib proof of concept data in indolent NHL (China)
H219	Savolitinib	1L exon 14 NSCLC registration study fully enrolled
	Surufatinib	Interim analysis of Phase III SANET-p (China) in pancreatic NET
	Fruquintinib	Initiation of Phase II/III trial in 3L/4L colorectal cancer (US) Release of prescription and sales performance data for 3L mCRC (China) at interim results
2019	Savolitinib	Plans for further Phase II/III studies in lung cancer to be announced (Global)
	PD-1 combos	Initiation of US development of fruquintinib and surufatinib PD-1 combinations

Source: Trinity Delta, Hutchison China MediTech

Fruquintinib: early commercial traction

Promising Elunate uptake, albeit still early in the launch phase

Elunate (fruquintinib) was the first domestically discovered and developed innovative oncology compound approved in China. Following launch in 3L mCRC last November, Elunate is showing solid early signs of clinical acceptance. In the first five weeks on the market, it generated revenue of \$3.6m for Chi-Med, broken down as \$3.3m from product purchases (manufacturing) and royalties of \$0.3m (15% of c\$2m in end-user sales) from partner Eli Lilly. Management also

confirmed that by end-January (ie the first nine weeks on market), over 1,000 patients had received Elunate therapy.

Patient Access Programme means patient only pay for 3 cycles

Elunate is currently an out-of-pocket drug, priced at RMB 21,960 per 4-week cycle (equivalent to US\$3,300), although a domestic Patient Access Programme (PAP) essentially limits the patient's cost of treatment to a maximum of three cycles. The PAP is designed to ensure broad availability while reimbursement discussions are ongoing.

Potential inclusion on the NRDL should catalyse patient access and drive higher volumes

Eli Lilly and Chi-Med have focused on ensuring patient access to increase penetration into the 3L mCRC setting, and drive sales through volume rather than solely price. Negotiations to secure National Drug Reimbursement List (NDRL) inclusion in a potential 2019 update will be pursued. We believe there is strong potential for Elunate's future inclusion on the NDRL given the precedent set by the listing of domestically developed drugs such as apatinib (in gastric cancer) and anlotinib (in NSCLC).

Eli Lilly deal amendment secures Elunate long-term commercial potential in China

On the development front, an interim analysis for futility for the Phase III FRUTIGA trial in 2L gastric cancer is imminent, and PD-1/PD-L1 combination studies are planned as part of the first wave of life cycle indications (LCIs). Chi-Med's pursuit of LCI development is facilitated by the amendment to the Eli Lilly collaboration announced in December. This amendment provides Chi-Med with greater control over China R&D plans (including LCIs) in exchange for assuming R&D funding. Amended terms are shown in Exhibit 2.

Exhibit 2: Chi-Med/Eli Lilly fruquintinib deal terms – 2013 vs 2018

	Original 2013 deal	December 2018 Amendment
LCI Development Costs – Paid by Lilly	70%	0%
LCI Development Costs – Paid by Chi-Med	30%	100%
LCI Regulatory Approval Milestones (\$m) – Paid to Chi-Med ¹	12.5	20.0
Royalty Payments – Paid to Chi-Med ²	15-20%	15-29%
Co-Promotion Rights in China (% of provinces) ³	0%	30-40%
Co-promotion Service Fees – Paid to Chi-Med (% net sales)	0%	Not disclosed

Source: Hutchison China MediTech Note: 1 = Per LCI in China, up to 3 LCIs; 2 = Based on total Elunate sales in China, triggered by first LCI launch; 3 = Not expected before 2021 as it will be triggered by China launch of Eli Lilly's anti-VEGF mAb Cyramza (ramucirumab).

Elunate (fruquintinib) is core to both China Oncology and Global Innovation franchises

Fruquintinib is a core asset in both China Oncology and Global Innovation. The deal amendment expands the potential Elunate market opportunity in China, which coupled to potential co-promotion rights (from 2021+), significantly improves Chi-Med's share of deal economics. It also leverages Chi-Med's commercial acumen and provides a cornerstone product for the nascent Oncology Commercial organisation (currently c30-strong but expanding to 200 by end-2021). Fruquintinib is also one of five Global Innovation clinical assets, which, excepting savolitinib (partnered with AstraZeneca), will be sold through the global marketing organisation.

Elunate is currently Chi-Med's most valuable China asset, contributing \$8.51/ADS (\$1,132m) or £13.09/share (£871m) to our Chi-Med valuation.

Significant clinical data presentations at AACR this month

Potential for first China approval in MET exon 14m/del NSCLC in 2021

TATTON data will inform global registration strategy in NSCLC

AACR abstracts are currently embargoed

Savolitinib: clinical data to determine direction

Savolitinib development has been prioritised in non-small cell lung cancer (NSCLC) by Chi-Med and partner AstraZeneca. Data from two key NSCLC trials will be presented at AACR. These trials are critical in determining the potential for accelerated launch in China (as monotherapy in 1L MET exon 14m/del NSCLC), and the global development timeline and positioning of the savolitinib/osimertinib combination in EGFR/T790M refractory NSCLC.

Read out of the complete data set from the China 92-pt single arm [Phase II study](#) in MET exon 14m/del NSCLC will establish potential for accelerated approval of savolitinib monotherapy in this indication. Enrolment is on track to complete in H219, data read out is expected in 2020. Should an agreed efficacy threshold be met, an NDA could be filed in 2020 with potential for China approval in 2021.

Data review from the dose expansion parts of the [Phase Ib/II TATTON](#) study (TATTON B and D) coupled to the outcome of regulatory discussions will determine pivotal trial design and dosing for global savolitinib + osimertinib combination studies. [SAVANNAH](#), a global Phase II study evaluating savolitinib + osimertinib in c-Met+ 2L EGFR/T790M refractory NSCLC, which could enable US approval, was initiated in December 2018 and should read out in 2021. However, Chi-Med/AstraZeneca have indicated that they anticipate announcing plans for further potentially pivotal combination trials later this year. This strategy of running two global trials in parallel in two NSCLC target patient populations with breakthrough therapy designation (BTD) potential should increase the probability that the combination reaches the market rapidly. We believe savolitinib could receive FDA approval in combination with osimertinib by 2022, if not earlier.

Initial data from the China [Phase II study](#) in exon 14m/del NSCLC and mature data from the B cohort of the global [Phase Ib/II TATTON](#) combination study will be presented orally on March 31 in a plenary session entitled 'Can the challenge of NSCLC resistance be MET or will we not MEK it?'. Abstracts are currently embargoed, but titles have been released:

- Preliminary efficacy and safety results of savolitinib treating patients with pulmonary sarcomatoid carcinoma (PSC) and other types of NSCLC harbouring MET exon 14 skipping mutations ([CT031](#));
- TATTON Phase Ib expansion cohort: Osimertinib plus savolitinib for patients with EGFR-mutant, MET-amplified NSCLC after progression on prior first/second-generation epidermal growth factor receptor (EGFR) TKI ([CT032](#));
- TATTON Phase Ib expansion cohort: Osimertinib plus savolitinib for patients with EGFR-mutant, MET-amplified NSCLC after progression on prior third-generation EGFR TKI ([CT033](#)).

In addition, a biomarker analysis of the TATTON study will be presented in a poster on April 3: Detection of MET-mediated EGFR tyrosine kinase inhibitor (TKI) resistance in advanced non-small cell lung cancer (NSCLC): biomarker analysis of the TATTON study ([4897/20](#)).

We currently value savolitinib at \$5.61/ADS (\$746m) or £8.63/share (£574m).

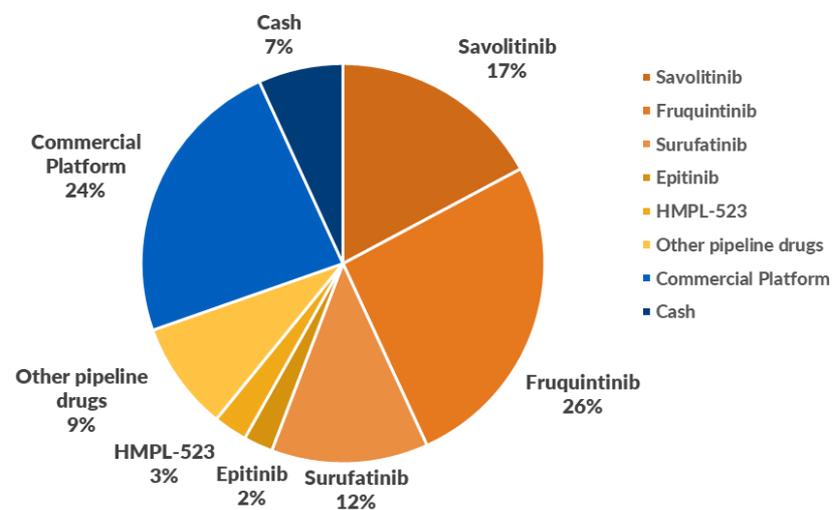
Valuation

Conservative assumptions employed throughout give a valuation of \$4,456m or £3,428m

We value Chi-Med using a sum-of-the-parts methodology, incorporating an earnings-based multiple for the Commercial Platform and an rNPV model for the Innovation Platform. Our valuation remains \$4,456m (equivalent to \$33.49 per ADS) or £3,428m (£51.52 per share).

Exhibit 3 provides a high-level overview of the relative importance of the various assets to the valuation; a detailed breakdown of our valuation can be found in our February 2019 [initiation](#). Our valuation is broadly split between the Innovation Platform which contributes \$3,029m or £2,330m, and the Commercial Platform which adds \$1,131m or £870m.

Exhibit 3: Relative contributions of Chi-Med programmes to valuation



Source: Trinity Delta

Scope for material uplifts in our valuation if progress continues

We employ conservative assumptions throughout our modelling; therefore, any number of incremental improvements on our base case scenarios (notably within the Innovation Platform) could result in sizeable uplifts in our valuation. Additionally, visibility on the late-stage clinical programmes is increasing, with a rich news flow over the coming years. This suggests that there is significant upside potential, with multiple catalysts expected over the coming 24 months.

Financials

FY18 results at least in line with expectations

Chi-Med reported FY18 results that met or beat expectations. Group revenues were \$214.1m, down 11.2% (FY17: \$241.2m) due to the implementation of the 'two-invoice' accounting/booking system which altered how domestic China sales are reported. Revenue growth at the JVs of 13.4% to \$491.5m (from \$433.3m) provides a better reflection of the Commercial Platform's performance. R&D spend in the Innovation Platform of \$142.2m, up 61.6% from \$88.0m, rose in line with the increasing number of later-stage clinical studies that are underway. This translated into an attributable net loss rising at the Group level to \$74.8m, against \$26.7m last year.

Sufficient cash resources to fund all activities through to 2020

Cash resources remained strong, with \$420.3m available at December 2018, vs \$479.6m at end-2017. This consists of cash, cash equivalents, and short-term investment of \$301m, and unutilised bank facilities of \$119m. An additional \$42m in available cash resources is held within the non-consolidated JVs. Management are confident this should support the increased spending in R&D through to at least 2020. We believe, given the clinical opportunities, that it would be judicious to issue some additional debt (c \$30m in FY20 in our modelling), in the absence of an additional capital raise. Debt financing for Chi-Med could be an attractive option for the company, given the strength of its commercial operations, broad pipeline and backing (implicit and explicit) from CK Hutchison.

FY19 guidance focused on key metrics: R&D spend and adjusted net cash flows

For FY19, Chi-Med has streamlined its financial guidance, focusing on the most important guidance metrics: R&D investment and adjusted Group net cash flows.

- R&D expenses are expected to fall within the \$160-200m range;
- Adjusted net cash outflows (non-GAAP), excluding any financing activity, are anticipated to be between \$120m-\$150m.

We estimate that Chi-Med will be investing \$200.5m and \$220.6m in R&D in FY19 and FY20, respectively, to support the growing number of pivotal studies and increased investment in Global Innovation.

We have revised our estimates as indicated in Exhibit 4, to take into account the FY18 results and management guidance; and our financial forecasts are shown in Exhibit 5 overleaf.

Exhibit 4: Summary of changes to estimates

	Sales (\$m)			EBITDA (\$m)			Earnings per ADS (\$)		
	Old	New	Change	Old	New	Change	Old	New	Change
2019E	177.2	168.6	(4.9%)	(170.8)	(203.8)	N/A	(1.06)	(1.31)	N/A
2020E	190.1	207.6	9.2%	(188.0)	(201.9)	N/A	(1.17)	(1.28)	N/A

Source: Trinity Delta

Exhibit 5: Summary of financials

Year-end: December 31	\$'000s	2016	2017	2018	2019E	2020E
INCOME STATEMENT						
Revenues		216,080	241,203	214,109	168,560	207,569
Cost of goods sold		(156,328)	(175,820)	(143,944)	(126,753)	(140,319)
Gross Profit		59,752	65,383	70,165	41,807	67,250
R&D expenses		(66,871)	(75,523)	(114,161)	(200,513)	(220,565)
Selling expenses		(17,998)	(19,322)	(17,736)	(13,419)	(14,416)
G&A expenses		(21,580)	(23,955)	(30,909)	(35,011)	(38,150)
Underlying operating profit		(46,697)	(53,417)	(92,641)	(207,137)	(205,880)
Other revenue/expenses		0	0	0	0	0
EBITDA		(44,356)	(50,839)	(89,051)	(203,748)	(201,882)
Operating Profit		(46,697)	(53,417)	(92,641)	(207,137)	(205,880)
Interest income/expense		(1,129)	(235)	4,969	555	359
Other income/expense		470	116	1,017	1,017	1,017
Profit Before Taxes		(47,356)	(53,536)	(86,655)	(205,565)	(204,505)
Adj. PBT		(47,356)	(53,536)	(86,655)	(205,565)	(204,505)
Current tax income		(4,331)	(3,080)	(3,964)	(4,839)	(4,805)
Equity in earnings of equity investees, net of tax		66,244	33,653	19,333	39,838	42,391
Net Income		14,557	(22,963)	(71,286)	(170,565)	(166,918)
Minority interests		(2,859)	(3,774)	(3,519)	(3,695)	(3,880)
Net income attributable to equityholders		11,698	(26,737)	(74,805)	(174,260)	(170,798)
EPS (\$)		0.20	(0.43)	(1.13)	(2.61)	(2.56)
Earnings per ADS (\$)		0.10	(0.22)	(0.57)	(1.31)	(1.28)
DPS (\$)		0.00	0.00	0.00	0.00	0.00
Average no. of shares (m)		59.7	61.7	66.4	66.7	66.7
<i>Gross margin</i>		28%	27%	33%	25%	32%
<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		167,380	432,195	370,541	210,736	80,745
Cash and cash equivalents		79,431	85,265	86,036	35,871	11,316
Short-term investments		24,270	273,031	214,915	114,915	0
Accounts receivable		45,035	42,270	42,958	36,945	45,495
Inventories		12,822	11,789	12,309	8,682	9,611
Other current assets		5,822	19,840	14,323	14,323	14,323
Non-current assets		175,057	165,737	161,577	170,534	177,792
Property, plant & equipment		9,954	14,220	16,616	19,923	22,955
Intangible assets		3,606	3,738	3,533	3,519	3,506
Investments in equity investees		158,506	144,237	138,318	143,982	148,221
Other non-current assets		2,991	3,542	3,110	3,110	3,110
Current liabilities		(95,119)	(104,600)	(85,479)	(95,218)	(128,926)
Short-term debt		(19,957)	(29,987)	0	0	(30,000)
Accounts payable		(35,538)	(24,365)	(25,625)	(34,727)	(38,443)
Other current liabilities		(39,624)	(50,248)	(59,854)	(60,491)	(60,483)
Non-current liabilities		(43,258)	(8,366)	(34,384)	(34,384)	(34,384)
Long-term debt		(26,830)	0	(26,739)	(26,739)	(26,739)
Other non-current liabilities		(16,428)	(8,366)	(7,645)	(7,645)	(7,645)
Equity		204,060	484,966	412,255	251,668	95,226
CASH FLOW STATEMENTS						
Operating cash flow		(9,569)	(8,943)	(32,847)	(143,482)	(162,454)
Net income		14,557	(22,963)	(71,286)	(170,565)	(166,918)
Non-cash adjustments & other operating cash flow		(27,557)	28,525	31,276	8,340	10,227
Change in working capital		3,431	(14,505)	7,163	18,742	(5,762)
Investing cash flow		(33,597)	(260,780)	43,752	93,318	107,899
CAPEX		(4,327)	(5,019)	(6,364)	(6,682)	(7,016)
Change in short term investments		(24,270)	(248,761)	58,116	100,000	114,915
Investment in an equity investee		(5,000)	(7,000)	(8,000)	0	0
Financing cash flow		92,435	273,196	(8,231)	0	30,000
Proceeds from equity		97,076	291,737	(2,322)	0	0
Increase in loans		(4,077)	(16,947)	(4,627)	0	30,000
Other financing cash flow		(564)	(1,594)	(1,282)	0	0
Net increase in cash		49,269	3,473	2,674	(50,165)	(24,555)
Exchange rate effects		(1,779)	2,361	(1,903)	0	0
Cash at start of year		31,941	79,431	85,265	86,036	35,871
Cash at end of year		79,431	85,265	86,036	35,871	11,316
Net cash at end of year		56,914	328,309	274,212	124,047	(45,423)

Source: Company, Trinity Delta Note: Adjusted numbers exclude exceptionals

Mick Cooper PhD CFA

mcooper@trinitydelta.org

+44 20 3637 5042

Lala Gregorek

lgregorek@trinitydelta.org

+44 20 3637 5043

Franc Gregori

fgregori@trinitydelta.org

+44 20 3637 5041

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