Trinity Delta

Hutchison China MediTech

Update

Carrying momentum into H219

13 August 2019

Hutchison China MediTech (Chi-Med) H119 results highlight ongoing financial and operational progress. First China NDA filings for surufatinib and savolitinib are on track for H219 and H120 respectively, following in the footsteps of Elunate's November 2018 launch. Global registration studies of surufatinib and fruquintinib will also initiate in H120. Investment into the maturing China Oncology and Global Innovation pipelines means future R&D spend will continue to grow, but Chi-Med is well-funded with flexibility surrounding future funding options. These are not limited to a future Hong Kong IPO, but include prospects of enhanced revenues from Elunate (post potential NRDL inclusion in Q4) and near-term China approvals/launches, plus possible non-dilutive finance from non-core asset divestment (eg OTC). Our valuation remains $38.55/ADS ($5.14bn) or £5.93/share (£3.95bn).

Year-end: December 31	2017	2018	2019E	2020E
Sales (US$m)	241.2	214.1	183.1	206.9
Adj. PBT (US$m)	(53.5)	(86.7)	(172.1)	(191.1)
Net Income (US$m)	(23.0)	(71.3)	(135.9)	(153.9)
Earnings per ADS (US$)	(0.22)	(0.57)	(1.05)	(1.18)
Cash (US$m)	358.3	301.0	179.3	271.0*
Adj. EBITDA (US$m)	(17.2)	(69.7)	(128.8)	(146.9)

Source: Trinity Delta Note: Adjusted PBT excludes exceptionals, Cash includes short-term investments, Adjusted EBITDA includes equity in earnings of equity investees. *2020E cash figure includes assumed raise of $250m.

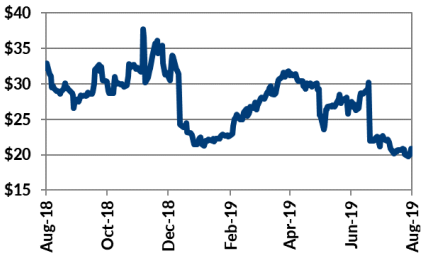
- **Near-term filings for second and third China Oncology products** Surufatinib's China NDA in non-pancreatic NET will be filed by year-end, with potential for 2020 approval/launch. Savolitinib NDA filing is not far behind; enrolment is complete in the ex14 del NSCLC China registration study. Fruquintinib (Elunate), Chi-Med's first launched product in China, generated $4.7m of royalty/manufacturing revenues in H119 on $11.4m of in-market sales by partner Eli Lilly. Potential NRDL inclusion in Q419 should significantly boost market penetration and future Elunate revenues.

- **Further Global Innovation registration studies pending** Savolitinib (partnered with AstraZeneca) is likely to be the first drug approved for the global market. Read out of the SAVANNAH NSCLC Phase II (savolitinib + osimertinib) in 2021 could support accelerated FDA approval. Unpartnered assets surufatinib (pancreatic NET) and fruquintinib (3L/4L CRC) are poised to start global registration studies in H120.

- **Flexibility on funding options** Ongoing pipeline investment will be partially offset by growing China Oncology revenues; other options (eg non-core asset disposals) mean Chi-Med is not dependent on the proposed Hong Kong IPO and global raise. RMB/USD weakening benefits China R&D and with 2020 starts for Global Phase IIb/III studies, FY19 guidance is updated to R&D spend of $130-170m (vs $160-200m) and adj. non-GAAP group net cash outflows of $90-120m (vs $120-150m).

- **Valuation maintained at £5.93/share and $38.55/ADS** Our DCF-based SOTP model includes an rNPV of the clinical pipeline. Our pre-money remains $5.14bn ($38.55/ADS) or £3.95bn (£5.93/share), and we continue to anticipate multiple clinical, regulatory, and commercial catalysts that will unlock further value over the next 12 months.

Price (US ADS)	$20.20
(UK share)	340.5p
Market Cap	$2.75bn
	£2.27bn
Enterprise Value	$2.51bn
	£2.07bn
Shares in issue (ADS)	133.3m
(shares)	666.6m
12 month range	$19.37-$39.68
	312p-567p
Free float	40%
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.

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Chi-Med: pipeline to deliver near-term catalysts

Hutchison China MediTech (Chi-Med) has made significant progress over H119 in advancing its proprietary Global Innovation and China Oncology pipelines. In China, NDAs for the first indications for surufatinib and savolitinib will be filed with the NMPA within the next 12 months. Potential NRDL inclusion of Elunate in Q419 should increase market penetration and catalyse revenue generation potential from the China Oncology franchise. Chi-Med's Global Innovation ambitions are also progressing. The most advanced asset, savolitinib is currently enrolling in the registration-intent SAVANNAH trial for the global market; results from an interim analysis in H120 will determine whether conditional approval could be sought. Two other assets, surufatinib and fruquintinib are also on the cusp of initiating US/EU Phase IIb/III studies (H120). Near-term, these, clinical, regulatory, and commercial catalysts will unlock further pipeline value.

Anticipating pipeline progress

Rich newsflow expected from R&D pipeline…. over 30 trials ongoing

Continued pipeline progress (Exhibit 1) is expected over the coming 12 months as various clinical trials initiate and ongoing studies render data. In total eight assets are under evaluation in over 30 clinical trials, not including a newly disclosed China IND filing (IDH 1/2 inhibitor HMPL-306). An overview of anticipated news is shown in Exhibit 2, and we highlight the following as key catalysts:

Elunate sales should materially benefit from possible Q419 China reimbursement decision

- **Elunate (fruquintinib) potential NRDL inclusion (Q419):** NRDL (National Reimbursement Drug List) inclusion would increase Elunate penetration as it automatically grants access and distribution to all hospital pharmacies across China. Listing is associated with a yet-to-be-negotiated discount to the launch price (US$3.26k/cycle, or a total out of pocket cost of US$9.8k under the patient assistance programme) but this will be more than compensated by greater volumes. Elunate H119 in-market sales were $11.4m; we forecast a $122m peak sales opportunity in China 3L CRC, and a potential $500m-1bn China sales opportunity across multiple indications, with Chi-Med eligible for minimum royalties of 15%.

Surufatinib China NDA filing on track by year-end…. and full data to be presented soon

- **Surufatinib China NDA filing in non-pancreatic NET (H219):** The positive outcome of the interim analysis of the SANETep trial enables China NDA filing earlier than anticipated (see June Update; full data will be presented at a forthcoming conference). If approved, surufatinib should be launched in 2020, targeting an indication with major unmet medical need and limited treatment options. Surufatinib will be the first self-commercialised product by Chi-Med's growing China Oncology commercial organisation (currently 60-strong but expected to expand to 200+ by end-2020).

First savolitinib filing possible in China in H120…

- **Savolitinib China NDA filing in MET exon 14m/del 1L NSCLC (H120):** The Phase II registration study completed enrolment in July. Initial data was presented at AACR 2019 (see April Update). If the mature data meets an agreed efficacy threshold, the China NDA will be filed in H120. Assuming a successful clinical and regulatory outcome, China would be the first market in which savolitinib would be launched. While AstraZeneca has commercialisation rights, Chi-Med is eligible for royalties of 30% on China sales, plus a potential approval milestone.

....and an interim analysis of SAVANNAH will determine global filing timelines

- **Savolitinib SAVANNAH interim analysis (H120):** SAVANNAH, a Phase II with registration intent, is evaluating savolitinib + osimertinib combination in cMet+ 2L/3L EGFR/T790M refractory NSCLC. Interim analysis in H120 will define whether efficacy data generated by that point would support filing for conditional approval. We note that AstraZeneca and Chi-Med should articulate plans for further lung cancer studies by early-2020.

Exhibit 1: Chi-Med pipeline status

Source: Hutchison China MediTech Notes: [1] in planning/imminent, [2] proof of concept in Australia, [3] SXBX = She Xiang Bao Xin.

Exhibit 2: Hutchison China MediTech news flow to mid-2020

Programme	Timing	Global Innovation	China Oncology
Fruquintinib	H219		Full Phase III FALUCA (3L NSCLC) data at WCLC
	Q419		Possible NRDL inclusion
	H120	Initiation of Phase I for PD-1 combinations	Second interim analysis Phase III FRUTIGA (paclitaxel combination 2L gastric cancer)
		Initiation of Phase II/III trial in 3L/4L CRC	
Savolitinib	H219	Phase II VIKTORY interim data (2L gastric cancer)	
	2019/20	Further Phase II/III studies in NSCLC	
	H120	SAVANNAH interim analysis (osimertinib combination in 2L MET+ EGFRm NSCLC)	China NDA submission for MET exon 14 del 1L NSCLC
		Phase II CALYPSO data (Imfinzi combination in VEGFR-TKI refractory RCC)	
Surufatinib	H219		Full Phase III SANET-ep data (non-panc. NET)
			China NDA submission (non-panc. NET)
	H120	Initiation of Phase I for PD-1 combinations	Interim analysis SANETp Phase III (panc. NET)
		Initiation of Phase II/III (panc. NET)	Phase Ib/II data in 2L BTC at conference
HMPL-306	2019/20		Phase I start
HMPL-523	H219	Initiation Phase I/Ib (indolent NHL)	
	H120		Initiation Phase II China registration study (NHL)
HMPL-689	H219	Initiation Phase I/Ib (indolent NHL)	

Source: Trinity Delta, Hutchison China MediTech Note: WCLC = World Congress on Lung Cancer; NSCLC = non-small cell lung cancer; CRC = colorectal cancer; RCC = renal cell carcinoma; NET = neuroendocrine tumours; BTC = biliary tract cancer; NHL = non-Hodgkin's lymphoma

Financials and valuation

In H119, reported group revenues were flat at $102.2m compared to H118, or grew at 5% at constant exchange rates (CER) due to weakening of the renminbi against the US dollar.

H119 sales growth (+2%; +7% CER) driven by Commercial Platform performance

Underlying sales growth was driven by the continued strong performance of the Commercial Platform, which grew at 2% on a reported basis or 7% at CER to $90.2m. Non-consolidated JVs performed similarly with reported sales increasing by 2% or 8% at CER to $276.9m. Total revenues from the Commercial Platform and non-consolidated JVs on a non-GAAP basis was $367m during the period, generating $28m in net income.

Innovation Platform revenues transitioning to royalty and manufacturing post Elunate launch

The sales contribution from the Innovation Platform, Hutchison Medipharma, fell by $1.6m to $12.0m due to reduced fee-for-service revenues, largely because of the renegotiation of the Eli Lilly fruquintinib collaboration in December 2018. The impact of lower research fees was offset by Elunate royalties of $1.7m and manufacturing revenues of $3.0m, which mark the start of the transition towards higher quality and more predictable sales for the Innovation Platform.

15% growth in H119 R&D spend into a broad and maturing pipeline…

Investment in R&D grew by 15% to $69.3m to support the broadening pipeline. The increase was moderated slightly by the weaker renminbi, and, together with the start of the global registration studies with surufatinib and fruquintinib being delayed from H219 to H120, has led Chi-Med to reduce its guidance for R&D expenses for FY19 to $130m-170m as indicated in Exhibit 3.

… but FY19 guidance benefit from FX and key trials now starting in H120

Overall, group net loss during H119 increased by 39% (48% at CER) to $45.4m, reflecting the increase in R&D. In line with the revised R&D guidance, Chi-Med has also reduced its guidance for group net cash outflows to $90m-120m. The company remains very well-funded with a cash position of $237.3m: in addition to $146.3m in unutilised banking facilities and $64m in cash within the JVs.

A summary of the changes in our estimates is shown in Exhibit 4, and financial forecasts are shown overleaf in Exhibit 6.

Exhibit 3: Chi-Med FY19 guidance (US$m)

	Previous guidance	Current guidance
R&D expenses	(160) - (200)	(130) – (170)
Adj. (non-GAAP) group net cash flows*	(120) – (150)	(90) – (120)

Source: Hutchison China MediTech Note: * excludes potential financing activities

Exhibit 4: Summary of changes to estimates

	Sales ($m)			EBITDA ($m)			Earnings per ADS ($)		
	Old	New	Change	Old	New	Change	Old	New	Change
2019E	168.6	183.1	8.6%	(203.8)	(169.9)	N/A	(1.31)	(1.05)	N/A
2020E	207.6	206.9	(0.3%)	(201.9)	(189.2)	N/A	(1.28)	(1.18)	N/A

Source: Trinity Delta

R&D investment not contingent on proposed HK IPO and primary offering…

Ongoing investment is required to maximise Chi-Med's pipeline opportunities. The proposed Hong Kong IPO and associated global raise is one such mechanism to boost the company's resources. Since the intention to list was announced in April, market conditions have deteriorated which, coupled with an underwriter mandated 90 day lock-in period and a lower share price in connection with CK

Hutchison's discounted secondary placement (see June Lighthouse), means timing is uncertain. Management's view is that market conditions are a critical factor in determining transaction success. We believe that various other options are also available to finance Chi-Med's pipeline.

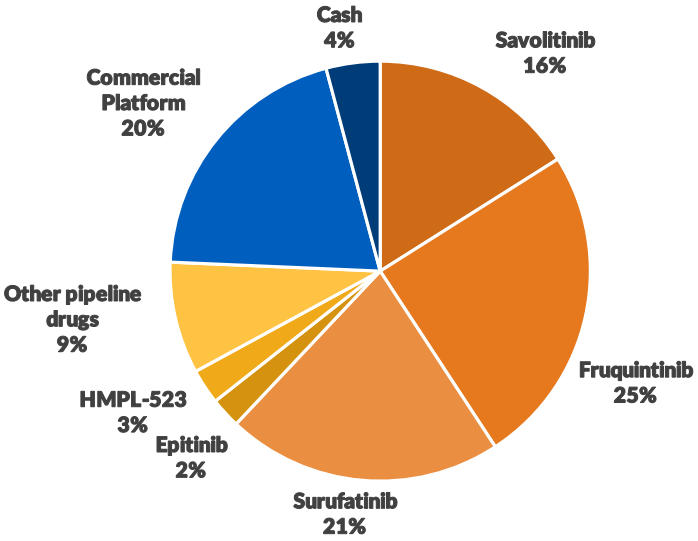
Over time China Oncology profit contributing will increase

Historically, profits from the Commercial Platform provided funding for the drug development activities of the Innovation Platform. In addition to these cash flows, divestment of non-core assets (such as the China OTC business) could generate further cash. Chi-Med is also going through a transition where the Innovation Platform, specifically the China Oncology business is starting to generate revenues. China Oncology will require significant near-term investment in both R&D and expanding its sales capabilities ahead of upcoming launches; however, over time, revenues from Elunate, surufatinib, and savolitinib will become material and increasingly contribute to profits, helping to fund the later-stage development of the Global Innovation pipeline.

$38.55/ADS ($5.14bn) or £5.93/share (£3.95bn) valuation maintained

We maintain our valuation at $38.55/ADS ($5.14bn) or £5.93/share (£3.95bn), which remains a pre-money valuation that does not include any assumed proceeds from the proposed Hong Kong IPO and global placement. Various upcoming catalysts highlighted in this note could prompt us to revisit our assumptions in future. Our valuation methodology is outline in our February 2019 Initiation report, and we provide a summary in Exhibit 5 below.

Exhibit 5: Relative contributions of Chi-Med programmes to valuation



Source: Trinity Delta

Exhibit 6: Summary of financials

Year-end: December 31	$'000s	2015	2016	2017	2018	2019E	2020E
INCOME STATEMENT							
Revenues		**178,203**	**216,080**	**241,203**	**214,109**	**183,099**	**206,935**
Cost of goods sold		(110,777)	(156,328)	(175,820)	(143,944)	(138,989)	(139,554)
Gross Profit		**67,426**	**59,752**	**65,383**	**70,165**	**44,110**	**67,381**
R&D expenses		(47,368)	(66,871)	(75,523)	(114,161)	(166,681)	(206,195)
Selling expenses		(10,209)	(17,998)	(19,322)	(17,736)	(13,802)	(14,194)
G&A expenses		(19,620)	(21,580)	(23,955)	(30,909)	(37,693)	(40,489)
Underlying operating profit		**(9,771)**	**(46,697)**	**(53,417)**	**(92,641)**	**(174,066)**	**(193,496)**
Other revenue/expenses		0	0	0	0	0	0
EBITDA		**(7,756)**	**(44,356)**	**(50,839)**	**(89,051)**	**(169,888)**	**(189,202)**
Operating Profit		**(9,771)**	**(46,697)**	**(53,417)**	**(92,641)**	**(174,066)**	**(193,496)**
Interest income/expense		(953)	(1,129)	(235)	4,969	417	863
Other income/expense		184	470	116	1,017	1,539	1,539
Profit Before Taxes		**(10,540)**	**(47,356)**	**(53,536)**	**(86,655)**	**(172,111)**	**(191,094)**
Adj. PBT		**(10,540)**	**(47,356)**	**(53,536)**	**(86,655)**	**(172,111)**	**(191,094)**
Current tax income		(1,605)	(4,331)	(3,080)	(3,964)	(4,912)	(5,078)
Equity in earnings of equity investees, net of tax		22,572	66,244	33,653	19,333	41,086	42,303
Net Income		**10,427**	**14,557**	**(22,963)**	**(71,286)**	**(135,936)**	**(153,869)**
Minority interests		(2,434)	(2,859)	(3,774)	(3,519)	(2,915)	(3,060)
Net income attributable to equityholders		**7,993**	**11,698**	**(26,737)**	**(74,805)**	**(138,851)**	**(156,930)**
EPS ($)		**0.01**	**0.02**	**(0.04)**	**(0.11)**	**(0.21)**	**(0.24)**
Earnings per ADS ($)		**0.07**	**0.10**	**(0.22)**	**(0.57)**	**(1.05)**	**(1.18)**
DPS ($)		**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**
Average no. of shares (m)		546.6	597.2	617.2	664.3	666.1	666.6
Gross margin		*38%*	*28%*	*27%*	*33%*	*24%*	*33%*
EBITDA margin		*N/A*	*N/A*	*N/A*	*N/A*	*N/A*	*N/A*
Underlying operating margin		*N/A*	*N/A*	*N/A*	*N/A*	*N/A*	*N/A*
BALANCE SHEET							
Current assets		**89,512**	**167,380**	**432,195**	**370,541**	**249,848**	**346,842**
Cash and cash equivalents		31,941	79,431	85,265	86,036	125,330	267,038
Short-term investments		0	24,270	273,031	214,915	53,928	3,928
Accounts receivable		35,215	45,035	42,270	42,958	40,131	45,356
Inventories		9,555	12,822	11,789	12,309	15,232	15,294
Other current assets		12,801	5,822	19,840	14,323	15,227	15,227
Non-current assets		**140,087**	**175,057**	**165,737**	**161,577**	**190,222**	**201,569**
Property, plant & equipment		8,507	9,954	14,220	16,616	20,401	24,886
Intangible assets		3,903	3,606	3,738	3,533	3,526	3,513
Investments in equity investees		119,756	158,506	144,237	138,318	148,755	155,632
Other non-current assets		7,921	2,991	3,542	3,110	17,539	17,539
Current liabilities		**(81,062)**	**(95,119)**	**(104,600)**	**(85,479)**	**(114,918)**	**(365,030)**
Short-term debt		(23,077)	(19,957)	(29,987)	0	0	(250,000)
Accounts payable		(24,086)	(35,538)	(24,365)	(25,625)	(30,463)	(30,587)
Other current liabilities		(33,899)	(39,624)	(50,248)	(59,854)	(84,454)	(84,443)
Non-current liabilities		**(46,260)**	**(43,258)**	**(8,366)**	**(34,384)**	**(38,572)**	**(38,572)**
Long-term debt		(26,768)	(26,830)	0	(26,739)	(27,000)	(27,000)
Other non-current liabilities		(19,492)	(16,428)	(8,366)	(7,645)	(11,572)	(11,572)
Equity		**102,277**	**204,060**	**484,966**	**412,255**	**286,580**	**144,809**
CASH FLOW STATEMENTS							
Operating cash flow		**(9,385)**	**(9,569)**	**(8,943)**	**(32,847)**	**(110,576)**	**(149,528)**
Net income		10,427	14,557	(22,963)	(71,286)	(135,936)	(153,869)
Non-cash adjustments & other operating cash flow		(9,863)	(27,557)	28,525	31,276	4,959	9,504
Change in working capital		(9,949)	3,431	(14,505)	7,163	20,401	(5,162)
Investing cash flow		**8,855**	**(33,597)**	**(260,780)**	**43,752**	**152,640**	**41,235**
CAPEX		(3,324)	(4,327)	(5,019)	(6,364)	(8,347)	(8,765)
Change in short term investments		12,179	(24,270)	(248,761)	58,116	160,987	50,000
Investment in an equity investee		0	(5,000)	(7,000)	(8,000)	0	0
Financing cash flow		**(5,471)**	**92,435**	**273,196**	**(8,231)**	**(2,515)**	**250,000**
Proceeds from equity		(1,733)	97,076	291,737	(2,322)	(1,310)	0
Increase in loans		(3,205)	(4,077)	(16,947)	(4,627)	77	250,000
Other financing cash flow		(533)	(564)	(1,594)	(1,282)	(1,282)	0
Net increase in cash		**(6,001)**	**49,269**	**3,473**	**2,674**	**39,549**	**141,708**
Exchange rate effects		(1,004)	(1,779)	2,361	(1,903)	(255)	0
Cash at start of year		38,946	31,941	79,431	85,265	86,036	125,330
Cash at end of year		**31,941**	**79,431**	**85,265**	**86,036**	**125,330**	**267,038**
Net cash at end of year		**(17,904)**	**56,914**	**328,309**	**274,212**	**152,258**	**(6,034)**

Source: Company, Trinity Delta Note: Adjusted numbers exclude exceptionals. Historic and forecast EPS are adjusted for one-to-ten ordinary share split, with new ADS ratio of 1:5 shares. Our estimate of $250m proceeds from the proposed equity raise are shown as short-term debt in FY20e, until transaction size, structure, and terms are confirmed.

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