Trinity Delta

Hutchison China MediTech

2020 set to be the "breakthrough" year

Update

27 January 2020

Hutchison China MediTech (Chi-Med) has achieved several significant milestones recently, with the early halt for efficacy of surufatinib in the SANET-p study being the latest. Surufatinib will be the first wholly owned asset to be approved and planning for the required commercial infrastructure is well advanced. The other clinical pipeline assets are also progressing well. Notably, savolitinib, partnered with AstraZeneca, is seemingly set to carve out a valuable role in managing Tagrisso's lifecycle. Chi-Med has raised up to c $126m in equity to help advance the multiple clinical opportunities. We have yet to update our estimates and valuation for these recent developments; our existing pre-money valuation is $4.74bn ($35.57/ADS) or £3.65bn (£5.47/share).

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)	(190.5)
Net Income (US$m)	(23.0)	(71.3)	(135.9)	(153.3)
Earnings per ADS (US$)	(0.22)	(0.57)	(1.05)	(1.13)
Cash (US$m)	358.3	301.0	179.3	131.5
Adj. EBITDA (US$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.

- **20-year anniversary set to be "breakthrough" year** Chi-Med's journey since its foundation in 1990 has been impressive. There are eight assets progressing through late-stage clinical development, with over 30 trials currently underway. Elunate (fruquintinib) was launched in China in late-2018 and is now on the NRDL. Savolitinib, the leading compound in the Global Innovation pipeline, is showing encouraging progress. The next wave of programmes is advancing well and efforts to replenish the earlier-stage pipeline appear very promising.

- **Early halt of SANET-p suggests a 12 month gain** The early stop of the SANET-p Phase III trial (see January 2020 Lighthouse) for efficacy expedites timelines for surufatinib in pNET. This follows the similarly early halt of the SANET-ep trial in ep-NET (see October 2019 Update). These outcomes accelerate our forecast timelines for approval and marketing by c 12 months compared to our previous expectations. Surufatinib is wholly owned by Chi-Med and will be marketed through its own China Oncology team and commercial infrastructure.

- **Existing valuation is £5.93/share and $38.55/ADS** The recent equity raise (see January 2020 Lighthouse) will strengthen the available cash resources by c $126m ($110m plus a further $16.5m option). We have yet to factor in the effect of this or the positive surufatinib news in our forecasts or valuation; we aim to do so as soon as practicable. For reference, our existing pre-money valuation is $4.74bn ($35.57/ADS) or £3.65bn (£5.47/share).

Price (US ADS) (UK share)	$23.48 £3.82
Market Cap	$3.13bn £2.26bn
Enterprise Value	$3.24bn £2.64bn
Shares in issue (ADS) (shares)	133.3m 666.6m
12 month range	$16.47-$32.55 261p-487p
Free float	36%
Exchanges	NASDAQ AIM
Sector	Healthcare
Company codes	HCM HCM.L
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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Chi-Med: it is all coming together very nicely

Hutchison China MediTech (Chi-Med) is a success story on so many levels, with a phenomenal journey since its inception twenty years ago. Chi-Med has exploited its early-mover advantage in China to generate a pipeline of innovative oncology programmes and establish a credible domestic presence. The goal is to address both China and global opportunities; initially this was done through partnerships, but increasingly the next wave of clinical assets will be wholly self-developed and commercialised. The recent equity raise has strengthened the balance sheet and removes any foreseeable funding concerns as the pipeline is progressed and the commercial infrastructure established. A raft of news flow is expected over the coming 12 months. Our current pre-money valuation is $35.57 per ADS ($4.74bn) or £5.47 per share (£3.65bn), but this has yet to be updated for the early positive surufatinib SANET-p trial data and the effect of the fund raise.

Positioned for long term growth, in China and globally

Chi-Med has achieved a great deal in the 20 years since its creation. A key aim was to exploit the huge opportunities that existed, and still do, in healthcare in China. Demand was set to explode not only due to economic growth, driven by the rapidly growing middle- and upper-classes, but also by a myriad of supportive Government initiatives to improve access to healthcare. These factors have driven the growth in the domestic market such that it is now the second largest globally. Interestingly, the evolution in clinical demand is well suited to Chi-Med's product portfolio, with specialist oncology products being particularly attractive.

Exhibit 1: Chi-Med portfolio summary

Source: Hutchison China MediTech. Notes: (1) in planning/imminent; (2) SXBX = She Xiang Bao Xin (cardiovascular)

A top-quality drug discovery infrastructure is now in place

The timing was also ideal to exploit the then emergent scientific environment to create a world-class drug discovery company, with cost and time advantages over its US and European counterparts. The result is a genuinely top-quality research platform with over 500 scientists across multiple sites. The impressive success of its discovery programmes has generated a substantial pipeline of highly selective

tyrosine kinase inhibitors (TKIs), purposefully designed to be first- or best-in-class. The clinical, and commercial, relevance of this approach is borne out by the quality of the trial data generated so far. The pipeline has over 30 studies underway worldwide, with eight oncology programmes being developed for the Chinese market (China Oncology) and five programmes being progressed for global markets (Global Innovation).

Pipeline is maturing, with domestic and global assets

The global ambitions should not be underestimated. Chi-Med has always planned to develop products that would initially be self-commercialised in China but, in parallel, the most highly differentiated compounds would also be developed in Western clinical trials for global registrations. The pipeline is well positioned for the emerging immuno-oncology standards in Western markets, where treatment regimes increasingly consist of combination therapies. Chi-Med's highly specific TKIs offer not only advantages in terms of targeted efficacy but, because of limited toxicities, can be readily added to existing treatment regimens. The clinical pipeline, summarised in Exhibit 1, is maturing nicely and should generate several value inflection points over the near- and medium-term.

First launch demonstrates development capabilities

The launch of Elunate (fruquintinib) in September 2018 was an important milestone. It not only marked Chi-Med's maiden approval, but also the first unconditional approval in China of a novel oncology product that was both discovered and developed domestically. Elunate is currently marketed by Eli Lilly, with Chi-Med receiving manufacturing payments and royalties on sales, although renegotiation of the licensing agreement in December 2018 provides Chi-Med with possible future co-promotion rights for 30-40% of China. However, in our view, its importance lies in the establishment of the regulatory, production and distribution infrastructure that will support further wholly self-commercialised oncology products. Additionally, critical market know-how is being gained as exemplified by the fact that Elunate was one of only eight oncology products added to the National Reimbursement Drug List (NRDL) in November 2019.

Savolitinib, the leading global programme, is partnered with AstraZeneca

Savolitinib, a first-in-class c-Met inhibitor, is the leading compound in the Global Innovation programme. It is partnered with AstraZeneca and is being evaluated in fourteen late-stage studies in six cancer indications, covering both monotherapy and combinations in a variety of indications, patient populations, and geographies. It is an important strategic asset for both Chi-Med and AstraZeneca; the latter having licensed global co-development/commercialisation rights in 2011. The major commercial opportunity for savolitinib globally is non-small cell lung cancer (NSCLC); this forms the strategic cornerstone of the collaboration as it could provide a useful life-cycle management opportunity in combination with AstraZeneca's third-generation EGFR TKI Tagrisso (osimertinib).

Surufatinib, the leading unpartnered programme, is progressing well

We view the AstraZeneca collaboration positively as, much as with Eli Lilly and fruquintinib in China, Chi-Med has not only gained valuable credibility and validation of its scientific expertise within the oncology community, it has also gained the necessary experience and expertise required for dealing with European and US regulators. The global infrastructure is being fleshed out, notably with a 30-person strong facility in New Jersey, and will be employed in progressing surufatinib, which appears set to be the first unpartnered drug that Chi-Med will launch. We intend to detail the status of surufatinib and its likely timelines in a forthcoming Update note.

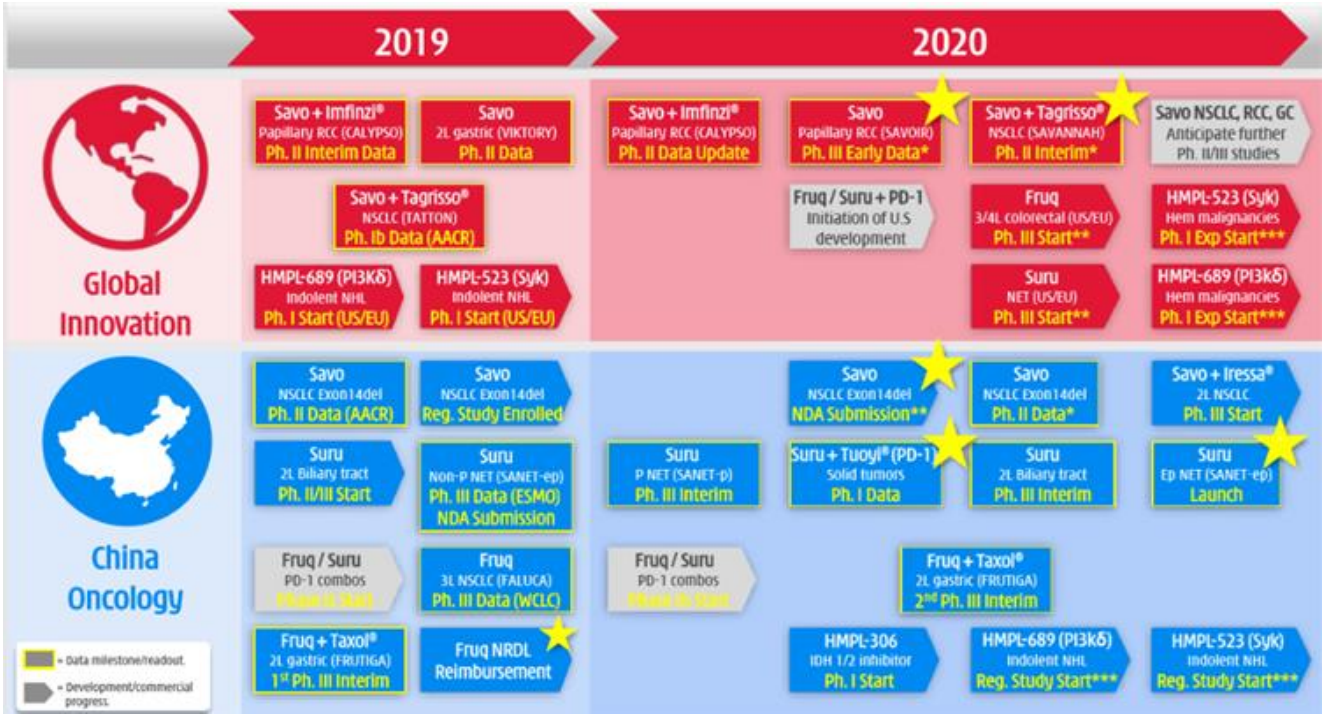
2020 should see a number of important inflection points

Significant news flow expected during the year

We believe we are entering a particularly interesting period as numerous projects are at key points in the development process, where continuing success should result in material value creation. The expected news flow for 2020 is outlined in Exhibit 2. The key events management is guiding to watch out for include:

- **Savolitinib:** interim data from the SAVANNAH global study (with Tagrisso); data from the SAVOIR trial in papillary renal cell cancer; and potential China NDA monotherapy submission for MET Exon 14 deletion NSCLC;
- **Surufatinib:** first NDA (China) of unpartnered programme; possibly first approval and launch; build up of specialist commercial team to 300-350 oncology reps;
- **Fruquintinib:** data to support "best-in-class" claims; sales growth following inclusion of Elunate on NRDL from January 1, 2020;
- **Global:** start of Phase III trial programmes in US and Europe for surufatinib and fruquintinib; initiation of global trials for HMPL-523 (Syk) & HMPL-689 (PI3Kδ);
- **Corporate:** explore role of non-core commercial assets; look to add large molecule development expertise and/or assets.

Exhibit 2: Potential 2020 upcoming events



Source: Hutchison China MediTech. Notes: * submission to scientific conference; ** subject to regulatory interaction; *** subject to supportive data; targets: savolitinib = MET; fruquintinib = VEGFR1/2/3; surufatinib = VEGFR1/2/3 / FGFR1 /CSF-1R; HMPL-523 =Syk; HMPL-689 = PI3Kδ; indications: NHL = non-Hodgkin's lymphoma; NET = neuroendocrine tumours; RCC = renal cell carcinoma; NSCLC = non-small cell lung cancer.

Valuation and financials

Equity raise brings in c $110m, plus prospect of further $16.5m

In January 2020, Chi-Med raised c $110m through the issue of 4.44m American Depositary Shares (ADSs), listed on Nasdaq, at a price of $25.00 per ADS. An additional 660k ADSs, at the same price, have been granted to the underwriters for a 30-day option period, which could raise a further $16.5m.

Following close, 22m new ordinary shares will be issued on AIM (each ADS represents five shares); after which Chi-Med's issued share capital will be 688,906,450 ordinary shares. (137,781,290 ADS equivalent). Chi-Med will receive all the proceeds, net of expenses, and will use the monies to progress its extensive clinical pipeline and build up its commercialisation infrastructure.

CK Hutchison, Chi-Med's largest shareholder (49.85%) through its subsidiary of Hutchison Healthcare Holdings (HHHL), will not take part in the offer and has agreed a 90-day lock up. We estimate that its holding will be 48.3% after the raise is closed.

CK Hutchison share divestment overhang is now history

The original plan outlined in April 2019 for an additional listing in Hong Kong to raise equity finance and sell down CK Hutchison's stake (held through its HHHL subsidiary), to below the strategically important 50%, was one of several future funding options open to Chi-Med. These also included the prospect of enhanced revenues from Elunate following NRDL inclusion and from near-term China approvals/launches, plus possible non-dilutive finance from non-core asset divestment. The subsequent ADS placings by CK Hutchison in June and September 2019 removed a known overhang and allowed Chi-Med to time this offer to suit its needs.

Pre-money valuation currently $35.57 per ADS or £5.47 per share

We have yet to adjust our forecasts for the effect of the raise. Similarly, we have yet to adjust our valuation for both the impact of the raise, and more importantly, the impressive outcome of surufatinib in the SANET-p trial. This could, on our preliminary assessment, result in a probable benefit of c 12 months improvement in approval timelines compared to our existing expectations. We aim to do so as soon as practicable, but in the meantime our current pre-money valuation, based on a rNPV model for the China Oncology and Global Innovation platforms and a multiple-based approach for the existing China commercial business (valuation methodology is detailed in our Initiation note February 2019), is $35.57/ADS ($4.74bn) or £5.47/share (£3.65bn).

Exhibit 3: Summary of financials

Year-end: December 31	$'000s	2015	2016	2017	2018	2019E	2020E
INCOME STATEMENT							
Revenues		**178,203**	**216,080**	**241,203**	**214,109**	**183,099**	**206,935**
Cost of goods sold		(110,777)	(156,328)	(175,820)	(143,944)	(138,989)	(139,554)
Gross Profit		**67,426**	**59,752**	**65,383**	**70,165**	**44,110**	**67,381**
R&D expenses		(47,368)	(66,871)	(75,523)	(114,161)	(166,681)	(206,195)
Selling expenses		(10,209)	(17,998)	(19,322)	(17,736)	(13,802)	(14,194)
G&A expenses		(19,620)	(21,580)	(23,955)	(30,909)	(37,693)	(40,489)
Underlying operating profit		**(9,771)**	**(46,697)**	**(53,417)**	**(92,641)**	**(174,066)**	**(193,496)**
Other revenue/expenses		0	0	0	0	0	0
EBITDA		**(7,756)**	**(44,356)**	**(50,839)**	**(89,051)**	**(169,888)**	**(189,202)**
Operating Profit		**(9,771)**	**(46,697)**	**(53,417)**	**(92,641)**	**(174,066)**	**(193,496)**
Interest income/expense		(953)	(1,129)	(235)	4,969	417	1,413
Other income/expense		184	470	116	1,017	1,539	1,539
Profit Before Taxes		**(10,540)**	**(47,356)**	**(53,536)**	**(86,655)**	**(172,111)**	**(190,544)**
Adj. PBT		**(10,540)**	**(47,356)**	**(53,536)**	**(86,655)**	**(172,111)**	**(190,544)**
Current tax income		(1,605)	(4,331)	(3,080)	(3,964)	(4,912)	(5,078)
Equity in earnings of equity investees, net of tax		22,572	66,244	33,653	19,333	41,086	42,303
Net Income		**10,427**	**14,557**	**(22,963)**	**(71,286)**	**(135,936)**	**(153,319)**
Minority interests		(2,434)	(2,859)	(3,774)	(3,519)	(2,915)	(3,060)
Net income attributable to equityholders		**7,993**	**11,698**	**(26,737)**	**(74,805)**	**(138,851)**	**(156,380)**
EPS ($)		**0.01**	**0.02**	**(0.04)**	**(0.11)**	**(0.21)**	**(0.23)**
Earnings per ADS ($)		**0.07**	**0.10**	**(0.22)**	**(0.57)**	**(1.05)**	**(1.13)**
DPS ($)		**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	688.9
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**	**207,392**
Cash and cash equivalents		31,941	79,431	85,265	86,036	125,330	127,588
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)**	**(115,030)**
Short-term debt		(23,077)	(19,957)	(29,987)	0	0	0
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**	**255,359**
CASH FLOW STATEMENTS							
Operating cash flow		**(9,385)**	**(9,569)**	**(8,943)**	**(32,847)**	**(110,576)**	**(148,978)**
Net income		10,427	14,557	(22,963)	(71,286)	(135,936)	(153,319)
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)**	**110,000**
Proceeds from equity		(1,733)	97,076	291,737	(2,322)	(1,310)	110,000
Increase in loans		(3,205)	(4,077)	(16,947)	(4,627)	77	0
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**	**2,258**
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**	**127,588**
Net cash at end of year		**(17,904)**	**56,914**	**328,309**	**274,212**	**152,258**	**104,516**

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.

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