Hutchison China MediTech

COVID-19 impact update

Fortune favours the brave

Notwithstanding the COVID-19 pandemic challenges, Hutchison China MediTech (HCM) remains on track for potential approval and launches of two additional assets (surufatinib and savolitinib) in China in 2020/21. HCM is actively engaging with regulators (including the China NMPA and US FDA) with regards to trial initiations and NDA submissions as it continues on its trajectory to a global innovative oncology company. Furthermore, given the broader pipeline progression, it has a high level of visibility on data submission to regulators and international scientific conferences this year, including ASCO, AACR and ESMO. Importantly, with the China COVID-19 experience under its belt, HCM is positioned to capitalize on its experience of conducting business in a COVID-19 environment. We expect 2022/23 to benefit from global drug launches providing continued pipeline progression.

Year end	Revenue ($m)	Net profit ($m)	EPADS ($)	DPADS ($)	P/E (x)	Gross yield (%)
12/18	214.1	(74.8)	(0.06)	0.0	N/A	N/A
12/19	204.9	(106.0)	(0.08)	0.0	N/A	N/A
12/20e	216.8	(161.1)	(0.12)	0.0	N/A	N/A
12/21e	287.9	(165.2)	(0.12)	0.0	N/A	N/A

Note: *PBT and EPS are normalized, excluding amortization of acquired intangibles, exceptional items and share-based payments.

Lessons learned from the China COVID-19 curve

HCM has been dealing with COVID-19 disruptions, which have affected China for months. It has navigated these unchartered waters and is applying lessons learnt to best practice in these challenging times. Its China commercial business and manufacturing operations have not been materially affected so far. China's NMPA has been actively reviewing surufatinib (NDA under review) and HCM expects to file two further NDAs during the year (NDA submission pending for surufatinib in pNET and savolitinib in MET exon 14 deletion NSCLC). We also note that sales of Elunate (third-line CRC) in January/February grew significantly post NRDL inclusion vs FY19 despite deployment of clinical resource to COVID-19, which highlights the continuation of care in severe conditions such as cancer.

Well capitalised to weather the storm

Preparations to initiate global registration studies are expected to complete mid-year for fruquintinib in 3/4L CRC and surufatinib in NET (the US FDA has granted two fast track designations for pNET and epNET). Savolitinib could be the first of HCM's innovation assets to launch globally in 2022 (for MET-positive EGFR refractory NSCLC in combination with Tagrisso, a blockbuster opportunity) through partner AZN. HCM is well funded with available cash resources of >$300m (at 31 December 2019) at group level and the recent capital raise of $110m (net proceeds) provides additional funding flexibility as R&D is set to increase to support global registration studies this year.

Valuation: $5.9bn ($42.57/ADS)

Our valuation is unchanged at $5.9bn ($42.57/share). Our valuation includes net cash of $190m at end December 2019 plus $110m net proceeds from the January 2020 capital raise.

Pharma & biotech

22 April 2020

Price	**US$19.48**
Market cap	**US$2,690m**
	ADR/Ord conversion ratio 0.2
Net cash ($m) and short-term investments at end 2019 + net proceeds of $110m raise	300
ADRs in issue	138.1m
ADR code	HCM
ADR exchange	NASDAQ
Underlying exchange	AIM
Depository	Deutsche Bank

ADR share price performance

52-week high/low	$30.44	$15.19

Business description

Hutchison China MediTech is an innovative China-based biopharmaceutical company targeting the global market for novel, highly selective oral oncology and immunology drugs. Its established commercial platform business continues to expand its outreach.

Next events

Surufatinib China NDA file for pancreatic NET	H120
Surufatinib start global PIII NET trials	H120
Savolitinib China NDA file for NSCLC exon 14 deletion	H120
Fruquintinib start FRESCO2 global PIII CRC trial	2020

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Edison profile page

Learning from COVID-19 impact in China

At its FY19 results, we note that management advised: 'The outbreak is posing some challenges to our operations resulting from restrictions on movement in China. Reduced patient hospital visits for clinical assessment affected the conduct of certain clinical studies and commercial team activities. To-date, none of our manufacturing operations in China have been materially affected. Our teams have adapted quickly and effectively thus far across our businesses, and we will continue to closely monitor what is an evolving situation. At this stage we are unable to assess the long-term effect of the outbreak, if any. We assume at this stage that the financial impact of the recent COVID-19 outbreak will not be material to the Group. Since we cannot predict how the situation will evolve, we will monitor and adjust if new material information emerges.'

Following on from this, our observations are:

- Eli Lilly (LLY) reported Elunate sales of $6.6m in January to February 2020 vs $17.6m in FY19 despite the challenges of COVID-19 (and Chinese New Year), which highlights its inclusion on the National Reimbursement Drug List (NRDL) and the continuation of care for severe conditions such as cancer in the face of healthcare resources deployed to treating COVID-19. Hospital visits are being deferred in some cases, so patients may be receiving prescription drugs in earlier lines of treatment. HCM's China commercial business and manufacturing operations have not been materially affected so far.
- In terms of how HCM has managed disruptions to clinical trial sites, the company has been performing remote follow-ups with patients where possible, clinical protocols have not been compromised. We would anticipate some delays in patient recruitment in the global registration studies, but this will vary from country to country depending on factors such as individual healthcare systems. FDA has given guidance on dealing with the impacts of COVID-19 and maintaining clinical trial data integrity. We note that the company has successfully initiated a Phase II trial of HMPL-453 (pan-FGFR inhibitor) in China in patients with advanced mesothelioma.
- HCM is maintaining active dialogue with China's National Medical Products Administration (NMPA) which has been reviewing the NDA filing for surufatinib (accepted for non-pancreatic neuroendocrine tumors [NET]), and we still expect potential approval and launch in late 2020. HCM is on track for two further China NDA submissions (savolitinib in MET exon 14 deletion NSCLC and surufatinib in pancreatic NET) this year. In the US, the FDA recently (17 April 2020) granted two fast track designations for surufatinib in pNET and epNET, highlighting the unmet need in the treatment of neuroendocrine tumors.
- HCM is in a strong financial position after ADS issuance on 21 January 2020 (the underwriters also exercised an over-allotment option). The recent capital raise of $110m (net proceeds) provides additional funding flexibility as R&D is set to increase to support global registration studies. HCM reported available cash resources of more than $300m (at 31 December 2019) at group level (cash and cash equivalents including short-term investments of $217.2m, and unutilized bank borrowing facilities of $119.3m).

We believe the long-term investment case is underpinned by multiple near-term catalysts that demonstrate HCM's ability to discover and develop drugs, and its success rate as defined by drug approvals and launches. The launch of Elunate in China with partner LLY and subsequent inclusion on China's exclusive NRDL are significant milestones, giving us confidence in HCM's ability to execute on its R&D philosophy of building first- or best-in-class molecules with lower toxicity profiles to enable combination-based strategies for the treatment of cancers. Despite the challenges faced by COVID-19, 2020 is a golden year for HCM: it is scaling up its China oncology commercial presence ahead of surufatinib expected launch in late 2020 and the expected NDA submissions for surufatinib in pancreatic NET and savolitinib in MET exon 14 deletion NSCLC (anticipated 2021

launch). Clinical and regulatory teams are now fully operational in the US and EU. HCM's first global approval (we forecast launch in 2022) in the US/EU could be for a savolitinib combination with AstraZeneca's (AZN) Tagrisso in MET-positive EGFRm NSCLC. Global registration studies planned (no change) to start in 2020 include fruquintinib in 3/4L colorectal cancer (CRC) and surufatinib in NET. For further details, see our note From innovation to oncology commercialisation published in March 2020.

Exhibit 1: Financial summary

US$'000s	2017	2018	2019	2020e	2021e
December	US GAAP	US GAAP	US GAAP	US GAAP	US GAAP
PROFIT & LOSS					
Revenue	241,203	214,109	204,890	216,750	287,863
Cost of Sales	(175,820)	(143,944)	(160,152)	(175,913)	(196,289)
Gross Profit	65,383	70,165	44,738	40,836	91,574
Research and development	(75,523)	(114,161)	(138,191)	(184,000)	(210,500)
Other overheads	(43,277)	(48,645)	(52,934)	(54,521)	(76,679)
EBITDA	(50,692)	(88,975)	(141,250)	(191,948)	(183,546)
Operating Profit (before amort. and except.)	(53,417)	(92,641)	(146,387)	(197,684)	(195,605)
Intangible Amortization	0	0	0	0	0
Operating Profit	(53,417)	(92,641)	(146,387)	(197,684)	(195,605)
Net Interest	(235)	4,969	3,914	2,129	(2,991)
Exceptionals	0	0	0	0	0
Profit Before Tax (norm)	(53,536)	(86,655)	(141,106)	(195,555)	(198,596)
Profit Before Tax (reported)	(53,536)	(86,655)	(141,106)	(195,555)	(198,596)
Tax	(3,080)	(3,964)	(3,274)	(3,300)	(5,000)
Equity investments, after tax	33,653	19,333	40,700	42,769	43,418
Profit After Tax (norm)	(22,963)	(71,286)	(103,680)	(156,086)	(160,178)
Profit After Tax (reported)	(22,963)	(71,286)	(103,680)	(156,086)	(160,178)
Minority	(3,774)	(3,519)	(2,345)	(5,000)	(5,000)
Discontinued operations	0	0	0	0	0
Net profit (norm)	(26,737)	(74,805)	(106,025)	(161,086)	(165,178)
Net profit (reported)	(26,737)	(74,805)	(106,025)	(161,086)	(165,178)
Average Number of Shares Outstanding (m)	617.2	664.3	665.7	690.7	690.7
EPS - normalized (c)	(4.3)	(11.3)	(15.9)	(23.3)	(23.9)
EPS - normalized and fully diluted (c)	(4.3)	(11.3)	(15.9)	(23.3)	(23.9)
EPS - (reported) (c)	(4.3)	(11.3)	(15.9)	(23.3)	(23.9)
Average number of ADS outstanding (m)	123.4	132.9	133.1	138.1	138.1
Earnings per ADS - normalized ($)	(0.02)	(0.06)	(0.08)	(0.12)	(0.12)
Earnings per ADS ($)	(0.02)	(0.06)	(0.08)	(0.12)	(0.12)
BALANCE SHEET					
Fixed Assets	165,737	161,577	148,100	163,759	206,624
Intangible Assets	3,738	3,533	3,387	3,100	2,497
Tangible Assets	14,220	16,616	20,855	23,970	54,412
Investments	147,779	141,428	123,858	136,689	149,714
Current Assets	432,195	370,541	317,022	266,040	270,085
Stocks	11,789	12,309	16,208	14,459	16,133
Debtors	53,566	56,392	59,023	53,445	23,660
Cash	85,265	86,036	121,157	173,513	205,669
St investments	273,031	214,915	96,011	0	0
Other	8,544	889	24,623	24,623	24,623
Current Liabilities	(104,600)	(85,479)	(113,101)	(125,868)	(124,956)
Creditors	(25,344)	(26,180)	(25,789)	(38,556)	(37,644)
Short term borrowings	(29,987)	0	0	0	0
Other	(49,269)	(59,299)	(87,312)	(87,312)	(87,312)
Long Term Liabilities	(8,366)	(34,383)	(39,118)	(39,118)	(249,118)
Long term borrowings	0	(26,739)	(26,818)	(26,818)	(236,818)
Other long term liabilities	(8,366)	(7,644)	(12,300)	(12,300)	(12,300)
Net Assets	484,966	412,256	312,903	264,813	102,635
Minority	(23,233)	(23,259)	(24,891)	(29,891)	(34,891)
Shareholder equity	461,733	388,997	288,012	234,922	67,744
CASH FLOW					
Operating Cash Flow	(8,943)	(32,847)	(80,912)	(143,085)	(133,945)
Net Interest	0	0	0	0	0
Tax	0	0	0	0	0
Capex	(5,019)	(6,364)	(8,565)	(8,565)	(41,898)
Acquisitions/disposals	0	0	8,689	0	0
Dividends	(1,594)	(1,282)	(1,282)	(2,000)	(2,000)
Equity financing and capital movements	291,737	(2,322)	(95)	110,000	0
Other	(255,761)	50,116	118,904	96,006	0
Net Cash Flow	20,420	7,301	36,739	52,356	(177,844)
Opening net debt/(cash)	(56,914)	(328,309)	(274,212)	(190,350)	(146,695)
Increase/(decrease) in ST investments	248,761	(58,116)	(118,904)	(96,011)	0
Other	2,214	(3,282)	(1,697)	0	0
Closing net debt/(cash)	(328,309)	(274,212)	(190,350)	(146,695)	31,149

Source: Company accounts, Edison Investment Research

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