Hutchison China MediTech

Interim results

To China and beyond

Pharma & biotech

Hutchison China MediTech (HCM) continues to move swiftly towards its goal of globalization of its innovative oncology assets and building a fully integrated oncology business in China. Regarding the latter, the amended deal terms with Eli Lilly on fruquintinib is a huge positive, which will enable HCM to fully leverage its existing China oncology sales and marketing infrastructure across two assets: Elunate for CRC and surufatinib for NET. The recently reported interim results highlight further progress made since our recent outlook note. HCM is well funded (~$500m in available cash resources includes $119m unused debt facilities) as it accelerates the global development of its unpartnered assets and expands its China and global commercial outreach. Beyond 2024 we expect sustainable profitability and margin expansion. We value HCM at $6.69bn.

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	(162.9)	(0.11)	0.0	N/A	N/A
12/21e	303.9	(152.8)	(0.11)	0.0	N/A	N/A

Note: *Net profit and EPADS are normalized, excluding amortization of acquired intangibles, exceptional items and share-based payments.

Crystallizing further value from Elunate in China

HCM and Eli Lilly (LLY) have announced an amendment to the original 2013 deal on fruquintinib (Elunate). From 1 October, HCM will commercialize Elunate through its 320-strong oncology commercial team for local and regional marketing in China. HCM will be entitled to 70–80% of Elunate sales booked by LLY (through royalties, manufacturing of goods and service fees). This deal crystallizes significant value and sales synergies as it enables HCM to leverage its specialist oncology network, which it has been expanding ahead of surufatinib approval in epNET.

Innovation assets: China & global commercialization

Savolitinib's first NDA was accepted in MET exon 14 skipping NSCLC by the NMPA in China and priority review status was granted in July 2020. Surufatinib's China NDA for pNET has now been filed, with approval in the non-pancreatic NET indication expected by end 2020. In the US, the FDA has granted three fast-track designations (surufatinib in pNET and epNET, fruquintinib in mCRC) and HCM will use a rolling submission from late 2020 into early 2021 for surufatinib (forecast launch end 2021). The registration-enabling FRESCO-2 global Phase III trial for fruquintinib (mCRC) has initiated (first dose expected soon). We note that HCM holds global rights to fruquintinib (amendment made in 2018).

Valuation: $6.69bn ($47.05/ADS)

We value HCM at $6.69bn ($47.05/ADS) vs $6.3bn ($44.49/ADS) previously. The main driver of the uplift is the impact of Elunate deal terms to capture 70–80% of product value vs the prior 15–25% royalties on sales. Our valuation reflects net cash of $254m at end June 2020 plus ~$100m proceeds from the post-period private investment in public equity (PIPE) from General Atlantic. For full details, see our outlook note Eye of the tiger.

10 August 2020

Price	**US$31.52**
Market cap	**US$4,479m**
ADR/Ord conversion ratio	0.2
Net cash ($m) and short-term investments at June 2020 + net proceeds of ~$100m PIPE)	354
ADRs in issue	142.1m
ADR code	HCM
ADR exchange	NASDAQ
Underlying exchange	AIM
Depository	Deutsche Bank

ADR share price performance

52-week high/low	$32.14	$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 US rolling NDA submission	Late 2020
Surufatinib approval and launch in China for epNET	H220
Savolitinib China NDA approval (MET Exon 14 NSCLC)	2021

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Edison profile page

Pipeline update

HCM published interim results on 30 July. We highlight below the progress made since our outlook note Eye of the Tiger published on 6 July 2020, which details HCM's key assets and strategic outlook on a China and international level. Exhibits 1 and 2 highlight the plethora of catalysts ahead in 2020/21.

Elunate Lilly amendment a significant deal

Under the amendment to the Elunate (fruquintinib) deal terms with LLY, from 1 October HCM will be responsible for the development and execution of medical detailing and promotion as well as local/regional marketing activities in China. Both companies will continue to collaborate in the formulation and execution of a national marketing strategy and events in China for Elunate. LLY will retain its principle role and consolidate sales and, subject to meeting pre-agreed sales targets, will pay HCM ~70–80% of Elunate sales in the form of royalties, manufacturing costs and service payments. Importantly, the deal enables HCM to realize synergies in marketing Elunate alongside surufatinib, using its now 320-strong China oncology commercial team (representing a threefold increase in the number of LLY reps detailing the product) covering 1,300 clinical centers. We note there is no upfront payment by either company relating to this amendment.

Notable increase in in-market sales volumes

In-market sales of Elunate as provided by Lilly were $14m in H120 ($11.4m in H119), while actual volumes increased by 174% (as defined by total numbers of treatment cycles: ~18,800 in H120 vs ~6,850 in H119). This reflects inclusion in the National Reimbursement Drug List (NRDL), which has led to increased access (albeit at a 63% reduction to the original list price of $3,260 per cycle). Pricing could come under further downward pressure, although likely modest, at the next NRDL renewal in 2021. HCM believes Elunate has to date attained a market penetration rate of 14% in third/fourth-line metastatic colorectal cancer (mCRC), implying a market opportunity of $200m in the mCRC monotherapy indication. HCM aims to increase the penetration rate to 40% over the next few years. Our forecast peak sales of $202m in China for CRC (unchanged) assume fruquintinib use as monotherapy and in combination with PD-1 inhibitor use once approved. While Elunate's sales evolution in CRC will be a focus point in 2020, other milestones include progressing fruquintinib in other indications in China and launch of a global registration study, FRESCO-2 in mCRC. We note that a Phase Ib expansion study evaluating fruquintinib and Tyvyt combination is underway at the RP2D in China targeting five solid tumor indications.

Fruquintinib could launch in the US in 2023

Elunate's US fast-track designation means fruquintinib could be the third innovation asset to launch in the US in 2023. The FDA has agreed that a New Drug Application (NDA) can be submitted on the basis of two-Phase III trials (FRESCO and FRESCO-2). FRESCO is the China-based Phase III trial that formed the basis of Elunate's approval. The global Phase III registration trial (FRESCO-2) in third- and fourth-line metastatic CRC has now initiated as expected (mid 2020), patient screening is underway and first patient dosing is expected soon. The company aims to recruit over 500 patients across 130 clinical sites in 10 countries globally and the study is targeted to complete recruitment by year-end 2021. HCM retains the full development and commercial rights to fruquintinib outside China.

Surufatinib China and global approval potential 2020–21

HCM has been building its China oncology commercial team ahead of surufatinib launch to 320 personnel (HCM plans to expand the oncology team to 900+ by end-2023 to support future product launches), with the intention of having full coverage of all provinces in mainland China in preparation for launch in late 2020. HCM's long-established commercial platform in China consists of ~2,300 personnel covering prescription drug sales and distribution in 230 cities, highlighting the depth of experience there is in the company's operations in China.

EpNET in China first approval expected end 2020

The China NDA for non-pancreatic NET (epNET) was accepted in November 2019 and was subsequently granted priority review; we anticipate approval and launch in late 2020. HCM estimates that non-pancreatic NET represents ~80% of NET cases in China. At the interim results HCM announced that it has filed the China NDA for pancreatic NET (pNET), we expect approval in this subset in 2021, which means a label encompassing all NETs regardless of origin.

US rolling NDA submission to start end 2020

In the US, the FDA has already granted surufatinib a fast-track designation for both epNET and pNET and an orphan drug designation for pNET, recognizing the need for targeted treatments in this subset. HCM will utilize a rolling submission (enabled by its fast-track designation) from late 2020 into early 2021 that allows completed sections of the NDA to be submitted to the FDA, which the agency will review on an ongoing basis. HCM has provided an update on Europe and is targeting a Marketing Authorisation Application (MAA) submission for NET during 2021. Lifecycle management for surufatinib is focused on PD1 combination approaches; HCM and BeiGene entered into a global PD-1 clinical collaboration in May 2020 to explore the combination of surufatinib with BeiGene's PD-1 antibody, tislelizumab. HCM is exploring surufatinib in other combinations, including with Tuoyi in a Phase II trial in eight indications and in July, Innovent initiated a Phase I combining surufatinib with its China-approved PD-1 monoclonal antibody, Tyvyt. HCM is assessing its US commercial launch strategy for surufatinib in the US for readiness in late 2021; we believe HCM may build a small but focused salesforce or opt for a local partnering deal to co-commercialize the asset as it starts to expand on its US sales and marketing capabilities ahead of further oncology asset launches, starting with fruquintinib in 2023.

Savolitinib collaboration with AstraZeneca is progressing

Partnered with AstraZeneca (AZN), savolitinib is being assessed in lung, kidney and gastric cancers. Its most advanced indication is for non-small cell lung cancer (NSCLC) – in China as monotherapy for MET exon 14 skipping NSCLC (the NDA submission was accepted for review by the China National Medical Products Administration (NMPA) in May 2020), and internationally in combination with AZN's Tagrisso for MET-positive Tagrisso refractory NSCLC (top-line results are expected in 2021). The latter is a blockbuster opportunity being driven increasingly by Tagrisso moving further up the treatment paradigm, and top-line results from SAVANNAH (second-/third-line EGFRm+, Tagrisso refractory, MET-positive NSCLC in combination with Tagrisso), expected in 2021, could be registration-enabling in the US. Key additional 2020/21 milestones for this asset inflection include the start of the global registrational Phase III trial (SAVOIR2) in papillary renal cell carcinoma or PRCC.

Multiple waves of innovation to define longevity

Longevity for R&D-driven biopharmaceutical companies depend on having a pipeline of innovative assets spanning indications and development phases. This is even more imperative for HCM given its global aspirations to become a fully integrated oncology player. HCM has made progress in its

preclinical and early stage R&D pipeline developed from its proprietary world class delivery engine (15-year plus track record in oncology with a fully integrated ~550 in-house scientific team). Importantly, a major shift recently is that future assets will be developed in parallel in China and globally. This will significantly reduce timelines to global launches down the line.

- HMPL-453 (FGFR inhibitor) China Phase II trial in mesothelioma is underway and a phase II trial is planned in cholangiocarcinoma in H220; the latter is a significant unmet need which many FGFR inhibitors are exploring in clinical trials.
- HCM has advanced Phase Ib expansion of both of its Non-Hodgkin Lymphoma (NHL) assets, HMPL-523 (Syk) and HMPL-689 (PI3Kδ) in China. A positive outcome of these studies will inform the decision to start China registrational studies in indolent NHL. In the US and Europe HCM continues to expand the development of HMPL-523 and HMPL-689, with over 20 Phase I sites now enrolling patients.
- HMPL-306 the Phase I in China is underway and HCM expects to initiate Phase I in the US later this year (developing in the US and China in parallel). HMPL-306 is a dual IDH1/2 inhibitor; IDH mutations in tumors are heterogenous for either IDH1, 2 or both. Dual inhibition improves chances of efficacy and stops resistant mechanisms that may come from the upregulation of one of the receptors that is not inhibited.
- We note that HCM has four additional assets currently in preclinical development that are targeting China and global IND by end 2020 and 2021 respectively. HCM retains the worldwide rights for these internally developed assets: HMPL-295 and HMPL-653 for solid tumors, HMPL-A83, HCM's first monoclonal antibody (Mab) for solid tumors and hematological malignancies and HMPL-760 for hematological malignancies.
- Furthermore, HCM is looking at acquiring additional Mabs and the capabilities to develop them to expand its pipeline beyond small molecule therapeutics for the treatment of cancers.

Exhibit 1: China key events 2020–21

CHINA EVENTS: A FULLY INTEGRATED ONCOLOGY BUSINESS IN CHINA	
Fruquintinib	• **Elunate® China commercialization** – Chi-Med to assume medical detailing and marketing activities for Elunate® in all China on October 1, 2020; and • **Enrollment completion of FRUTIGA Phase III** – complete enrollment of China registration study in second-line gastric cancer.
Surufatinib	• **Presentation of SANET-p Phase III data** – pancreatic NET patients study at ESMO[37] 2020 conference; • **Acceptance of NDA in pancreatic NET** – following recent NDA submission based on positive SANET-p Phase III interim analysis; • **Phase II/III interim analysis** – for futility in second-line BTC[38] in China; and • **Potential NDA approval and launch for non-pancreatic NET** – first un-partnered oncology drug launch for Chi-Med in China.
Savolitinib	• **Potential NDA approval and launch for NSCLC** – monotherapy in MET Exon 14 skipping mutation NSCLC. If approved, this will be the first approval worldwide and the first selective c-MET TKI approval in China. Material milestone triggering event.
Early-stage Assets	• **HMPL-689 (PI3Kδ) Phase I/Ib NHL data** – potential presentation of China data at major scientific conference; • **HMPL-689 (PI3Kδ) – Potential registration study start** – in indolent NHL in China; • **HMPL-523 (Syk) – Potential registration study start** – in indolent NHL in China; and • **HMPL-523 (Syk) – completion of dose escalation in ITP[39].**

Source: HCM corporate presentation

Exhibit 2: Global key events 2020–21

GLOBAL EVENTS: REALIZING THE GLOBAL POTENTIAL OF OUR ONCOLOGY ASSETS	
Fruquintinib	• **Global Phase III study (FRESCO-2)** – expansion of registration study in CRC in 10 countries including the U.S., Europe and Japan; and • **Presentation of U.S. Phase Ib data** – preliminary data from study of third and later line CRC patients at ESMO 2020 conference.
Surufatinib	• **U.S. NDA submission for pancreatic- and non-pancreatic NET** – U.S. NDA rolling submission beginning in late 2020 through early 2021.
Savolitinib	• **Internal interim analyses on SAVANNAH** – Complete the review of the first internal interim analysis and conduct further interim analysis to inform regulatory strategy; • **Potential endorsement of global Phase III in kidney cancer** – savolitinib monotherapy in MET-driven PRCC; • **Potential endorsement of global Phase III in NSCLC** – Tagrisso® combination in EGFRm[40] positive, MET positive, NSCLC. Material milestone triggering event; • **Potential endorsement of global registration study in NSCLC** – savolitinib in MET Exon 14 skipping mutation NSCLC; and • **Enrollment completion of SAVANNAH** – AstraZeneca to complete enrollment of Phase II study, with registration potential, of savolitinib/Tagrisso® combination.
Early-stage Assets	• **HMPL-523 (Syk) – Global Phase Ib expansion** – in indolent NHL in the U.S. and Europe; • **HMPL-306 (IDH 1/2) – U.S. IND submission and initiation of Phase I**; and • **HMPL-689 (PI3Kδ) – Global Phase Ib expansion** – in indolent NHL in the U.S. and Europe.

Source: HCM corporate presentation

Valuation

We value HCM at $6.69bn ($47.05/ADS) vs $6.3bn ($44.49/ADS) previously. The main cause of uplift is the impact of the Elunate deal terms to capture 70–80% of value vs our prior assumption that HCM would receive 15–25% royalties on sales. We use a risk-adjusted NPV method to discount future cash flows for the innovation platform (IP) (valuation of $5,238m). We use earnings-based multiples for HCM's commercial platform (subsidiaries and JVs). We apply a 22.6x multiple to our forecast 2020 net attributable profit (equity in earnings of equity investees, net of tax) for the JVs of $42.8m, which yields a valuation of $966.6m. Our valuation reflects net cash of $254m at end June 2020 plus $100m net proceeds from the General Atlantic equity investment in July 2020

(we do not include the $103m of additional cash held at the JV level). Adding in a terminal value of $1,031.8m, offset by an unallocated cost NPV of $904.2m, leads us to our valuation of HCM of $6.69bn. Our sum-of-the-parts valuation does not include HCM's early phase assets HMPL-453 (FGFR inhibitor), HMPL-306 (IDH1/2 inhibitor) or HMPL-309 (WT EGFR inhibitor), the preclinical assets or its discovery platform.

Financials

HCM reported consolidated group revenues of $106.8m in H120 (H119: $102.2m) and a group net loss of $49.7m (H119: $45.4m).Commercial Platform (CP) reported consolidated H120 sales of $99.0m (+4% as reported, +9% CER; H119: $94.9m), driven by the prescription drugs business, which now includes Elunate-related manufacturing sales and royalties. Total consolidated net income from CP increased 14% (+19% CER) to $35.5m (H119: $31.0m). The innovation platform (IP) reported consolidated revenues of $7.8m in H120 (H119: $7.3m) related to service fee payments from AZN and LLY. IP reported a net loss of $73.6m (H119: $67.1m). For FY20, HCM has guided to an adjusted non-GAAP IP segment operating loss of $180–210m and adjusted non-GAAP group net cash flow excluding financing activities of $140–160m.

We maintain forecast R&D expenses of $183.0m in 2020 and $210.0m in 2021 (on a reported GAAP basis), reflecting the substantial need for investment in the burgeoning clinical trial programs across the IP division, including the increased investment in China and global trials plus the initiation of combination strategies across the portfolio. With the likely launch of surufatinib in China by end 2020 and the US in 2022, we expect sales and marketing expenses to accelerate significantly as HCM builds out its global commercial operations. We forecast $20m capex in 2020 and subsequent years as HCM breaks ground this year in a new manufacturing facility in Shanghai. HCM expects the new facility to cost $110–140m over a four-year period financed through a bank loan of 7–10 years' duration. During H120, the CP division contributed strongly to both group profits and cash, HCM received a dividend of $35.3m (H119: $18.2m) from its non-consolidated CP joint ventures, SHPL (Prescription Drugs) and HBYS (Consumer Health).

We now forecast net losses at group level of $162.9m in 2020 and $152.8m in 2021, as we have marginally increased 2021 sales forecasts to $303.9m and now include the land compensation agreement (see below). HCM reported a strong cash position, with available cash resources of $500m (at 30 June 2020) at group level (cash and cash equivalents and short-term investments of $281m, and unutilized bank borrowing facilities of $119.3m minus $27m in debt). Furthermore, post period end in July 2020, HCM received $100m from the equity investment from General Atlantic plus warrants granted for an additional $100m in 18 months (we assume the share price in 2021 will likely be higher than the exercise price of the warrant and thus forecast the additional $100m net proceeds is raised). HCM is well funded and has access to a further $119m in additional unutilized banking facilities and as of 30 June 2020, SHPL and HBYS held $103.3m (31 December 2019: $62.7m) in cash and cash equivalents with no outstanding bank loans.

During H120 HCM announced that HBYS has come to an agreement with the Guangzhou government for the planned return of HBYS's vacant land (HBYS Plot 2, a ~30,000 square meter site). HBYS will receive cash compensation of up to $95m in several stages over the next year as the transaction progresses to completion. We expect that ~40% of the compensation received will make its way to HCM via special dividends, which will be reinvested in the business.

Exhibit 3: Financial summary

US$'000s	2018	2019	2020e	2021e
Year end 31 December	US GAAP	US GAAP	US GAAP	US GAAP
PROFIT & LOSS				
Revenue	214,109	204,890	216,750	303,912
Cost of Sales	(143,944)	(160,152)	(175,919)	(196,866)
Gross Profit	70,165	44,738	40,831	107,046
Research and development	(114,161)	(138,191)	(183,000)	(210,000)
Other overheads	(48,645)	(52,934)	(60,021)	(87,679)
EBITDA	(88,975)	(141,250)	(194,454)	(180,752)
Operating Profit (before amort. and except.)	(92,641)	(146,387)	(202,190)	(190,633)
Intangible Amortization	0	0	0	0
Operating Profit	(92,641)	(146,387)	(202,190)	(190,633)
Net Interest	4,969	3,914	4,805	4,401
Exceptionals	0	0	0	0
Profit Before Tax (norm)	(86,655)	(141,106)	(197,385)	(186,231)
Profit Before Tax (reported)	(86,655)	(141,106)	(197,385)	(186,231)
Tax	(3,964)	(3,274)	(3,300)	(5,000)
Equity investments, after tax	19,333	40,700	42,769	43,418
Profit After Tax (norm)	(71,286)	(103,680)	(157,916)	(147,813)
Profit After Tax (reported)	(71,286)	(103,680)	(157,916)	(147,813)
Minority	(3,519)	(2,345)	(5,000)	(5,000)
Discontinued operations	0	0	0	0
Net profit (norm)	(74,805)	(106,025)	(162,916)	(152,813)
Net profit (reported)	(74,805)	(106,025)	(162,916)	(152,813)
Average Number of Shares Outstanding (m)	664.3	665.7	710.6	718.9
EPS - normalized (c)	(11.3)	(15.9)	(22.9)	(21.3)
EPS - normalized and fully diluted (c)	(11.3)	(15.9)	(22.9)	(21.3)
EPS - (reported) (c)	(11.3)	(15.9)	(22.9)	(21.3)
Average number of ADS outstanding (m)	132.9	133.1	142.1	143.8
Earnings per ADS - normalized ($)	(0.06)	(0.08)	(0.11)	(0.11)
Earnings per ADS ($)	(0.06)	(0.08)	(0.11)	(0.11)
BALANCE SHEET				
Fixed Assets	161,577	148,100	153,133	176,278
Intangible Assets	3,533	3,387	3,000	2,506
Tangible Assets	16,616	20,855	33,506	44,120
Investments	141,428	123,858	116,627	129,653
Current Assets	370,541	317,022	399,837	326,076
Stocks	12,309	16,208	14,459	16,181
Debtors	56,392	59,023	53,445	24,979
Cash	86,036	121,157	307,310	260,294
St investments	214,915	96,011	0	0
Other	889	24,623	24,623	24,623
Current Liabilities	(85,479)	(113,101)	(125,870)	(125,067)
Creditors	(26,180)	(25,789)	(38,558)	(37,755)
Short term borrowings	0	0	0	0
Other	(59,299)	(87,312)	(87,312)	(87,312)
Long Term Liabilities	(34,383)	(39,118)	(39,118)	(39,118)
Long term borrowings	(26,739)	(26,818)	(26,818)	(26,818)
Other long term liabilities	(7,644)	(12,300)	(12,300)	(12,300)
Net Assets	412,256	312,903	387,983	338,170
Minority	(23,259)	(24,891)	(29,891)	(34,891)
Shareholder equity	388,997	288,012	358,092	303,279
CASH FLOW				
Operating Cash Flow	(32,847)	(80,912)	(97,853)	(120,016)
Net Interest	0	0	0	0
Tax	0	0	0	0
Capex	(6,364)	(8,565)	(20,000)	(20,000)
Acquisitions/disposals	0	8,689	0	0
Dividends	(1,282)	(1,282)	(2,000)	(2,000)
Equity financing and capital movements	(2,322)	(95)	210,000	95,000
Other	50,116	118,904	96,006	0
Net Cash Flow	7,301	36,739	186,153	(47,016)
Opening net debt/(cash)	(328,309)	(274,212)	(190,350)	(280,492)
Increase/(decrease) in ST investments	(58,116)	(118,904)	(96,011)	0
Other	(3,282)	(1,697)	0	0
Closing net debt/(cash)	(274,212)	(190,350)	(280,492)	(233,476)

Source: Company accounts, Edison Investment Research

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